Monday, 21 February 2022

(10.00 am)

Presentation to the Inquiry about the experiences of people infected and affected through blood transfusions

SIR BRIAN LANGSTAFF: Yes, Ms Burton.

MS BURTON: Good morning, sir.

This morning the Inquiry will hear from a group of clinicians about blood transfusion policy in practice. The purpose of this presentation this morning is to set out the experiences of transfused individuals and their family members. Examples in this presentation are taken from Northern Ireland, Scotland, Wales and England from the late 1950s onwards. This presentation does not seek to be exhaustive, and it does not examine the individual details and the experiences of infected individuals and their families after diagnosis.

What it does seek to do is focus on the medical procedures where transfusions were given, the consenting process for those transfusions, information or sometimes a lack of information given to patient about the risks of blood-borne infection with transfusions, and considers issues of communication of diagnoses.

So there are five key themes when reading the witness statements received by the Inquiry in

relation to individuals who have received transfusions. The first theme is that there are a number of individuals who were unaware that they had even received a transfusion at the time of their surgery. In some circumstances this is because transfusions were given on an emergency basis; ofte individuals were unconscious. But in other circumstances, transfusions were given as part of elective or exploratory procedures.

Now, some witnesses express a concern that there might be individuals out there who are infected and still don't know about it.

The second key theme is about the lack of information given to patients and their families before and after transfusions were given. Almost all witnesses state that they were not informed of any risks of blood-borne infections involved in receiving the transfusion.

The third theme is that there is a wide gap, often measurable in decades, between the date of th transfusion and the date that an individual was informed of their infected status.

The fourth theme, and this is a significant one, sir, is the lack of documentary evidence that exist to say whether a transfusion was given or not given

Many witnesses describe difficulties obtaining thei medical records or the medical records of their loved ones. This is most often in the context of applyin for trusts and schemes.

In many cases, but particularly in cases involving maternity care, those hospitals have long since closed and many of the records have been destroyed. And for a large cohort of patients, receiving a transfusion was part of a one-off interaction with the NHS and therefore they don't have a known clinician that they can approach for information about their treatment.

Where medical records do exist, there are often scenarios where fundamental or important details ar missing from those records, such as the batch numbers of blood that was received. And during the presentation today, we're going to bring up some examples of contemporaneous medical records and particularly consent forms to see if we can show some light in relation to the relevant practices of the time.

The fifth theme, sir, that arises from a review of the witness statements received by the Inquiry i that there's a large cohort of patients who had frequent interactions with the NHS. This is normally

due to long-term health conditions. In particular, individuals with sickle cell anaemia, thalassemia and leukaemia fall into this group.

Now, these people had frequent medical interventions, often over the course of their lives and often at a range of hospitals and treated by lots of different clinicians. Many in this cohort question why, in those circumstances, their infections with blood-borne viruses were not identified earlier, or they were not communicated earlier to them and thei families.

Before we look at those themes in more detail, sir, we're going to look at some of the medical scenarios where transfusions were given. The first relates to maternity. The Inquiry has received a significant number of statements that relate to pregnancy, miscarriage, ectopic pregnancy, labour, and post-partum haemorrhage, but also the Inquiry has received a number of statements that relate to problems nothing to do with having children, so hysterectomies and gynaecological procedures, and we're going to look at some documents now in relation to this category.

So the first example, sir, is a hospital worker, and she was infected with hepatitis C as a result o

a transfusion at St Helier Hospital.

If we could turn up WITN0294002, please, Sully.

What we see here, sir, is an inpatient treatment summary -- you can see that at the top of the page -- and if we go along to the right there's a "Date Admitted" under the word "Speciality" that' 11 September 1975.

Now you might look at the date of discharge and think: is that 1979? But in consideration of the rest of this document and the witness statement is that this relates to care in 1975.

We can see underneath the box "Diagnosis" this is a case of ectopic pregnancy. And if we scroll down, Sully, please, to the bottom of the page, there is a heading that says "Operation", and we can see "Post Operative Course", just above that it says there were 650 units of blood found in the abdominal cavity, and the "Post Operative Course" was a "Transfusion of 3 [units of] blood".

You can take that down. Thank you.

Another example in this category is a woman who received a blood transfusion as part of an emergenc caesarean section in 1984 at the Harrogate General Hospital.

SIR BRIAN LANGSTAFF: Just one moment. Translating the

650ml, which had obviously been lost in the blood cavity, how does that relate in volume to three units of blood?

MS BURTON: Sir, I can't assist with the direct correlation of the matter. It is something we can look at it for you.

SIR BRIAN LANGSTAFF: On the face of it three units of blood would be a rather more --

MS BURTON: It would, sir.

SIR BRIAN LANGSTAFF: -- quite a bit more.

MS BURTON: Yes, that is a theme that we're going to come on to look at, which is the issue of necessity and volume of treatment. That example is just to look at an early example of an operation note.

SIR BRIAN LANGSTAFF: Yes, thank you.

MS BURTON: The second example is that of a woman who, as I said, underwent a C-section in 1984 at the Harrogate General Hospital, and she was diagnosed with hepatitis C in 2003. That hospital has closed down but she has been able to find limited contemporaneous records of her transfusion.

Sully, if we can go to WITN3693002, please, we're going to look at three documents. Just scroll down please. Thank you.

So we can see here, on the left-hand column,

there's a big box at the bottom which says, "Supply [of] 2 units [of] whole blood", and we can see that the treating clinician here has crossed out the other two, and has left a supply of two units of whole blood, and then, on the right-hand side of this document, we've got that the blood is O positive, and those serial numbers.

So this is an example, sir, of somebody that has been able to track down the key information, ie how much blood she received and what those specific serial numbers were.

SIR BRIAN LANGSTAFF: Just as a matter of observation, the coversheet -- I don't want you to go back to it, th coversheet has the surname and the surname is redacted on this sheet here. So can that please be checked by the redactions team?

MS BURTON: Yes. Thank you, sir.

SIR BRIAN LANGSTAFF: If I am right, then either apply a redaction or remove the coversheet.

MS BURTON: Sir, I don't know that's an anonymous witness, I think it's just on this form it's because that's her address and it's just gone over her surname.

SIR BRIAN LANGSTAFF: Thank you.

MS BURTON: So can we go to the next document, please, which is 003, Sully, WITN3693003. We won't go to that

but what it is, sir, I'll just describe it. It's a register of units of blood and it's an undated document but it's a document that's found in her medical records and, on that document, it lists the same blood numbers that we've seen in this document so she's been able to piece those two documents together.

Sully, can we go with the same witness, please, WITN3693006, please. What we see here, sir, is the consent form from the 1984 procedure, and you can see in the middle of the page, where it says "I also consent", that the language of this consent form is:

"I also consent to such further or alternative operative measures as may be found necessary during the course of the above-mentioned operation and to the administration of general, local, or other anaesthetics for any of these purposes."

Pausing there, sir, we can see that, on the face of this 1984 consent form, there is no express reference to a transfusion or any blood or the risk of any blood on the face of this form. Now, this, we say, is important, because it fits with the witness evidence that the Inquiry has received, that lots o individuals were simply unaware that they had, in fact, had transfusions. It doesn't appear to be on the standard wording addressed with patients

pre-operatively.

Another example, please, is WITN0891002. Now, this is another example of an operation -- sorry, a consent form. This relates to a nurse who underw ent a caesarean section in 1995 and was diagnosed with hepatitis C in 2018. So this is a consent form fro a decade and a bit later than the one we've just looked at.

Sully, if you just control down, so we can read what it says, we can see a very similar or almost identical wording that we've just looked at in the 1984 version. So from 1984 to 1995, it suggests th at, again, there's no express reference to an individua receiving blood, or it being formally on the face o a consenting document.

Now, this individual who underwent this caesarean section, her husband has also supplied a witness statement to the Inquiry and we're going to look at some details in it, WITN0840001. This is an anonymous witness, as we can see, but if we look at paragraph 2 of his statement, he says that he's her to speak about his wife's infection with hepatitis C, and it's relevant for our understanding of this witness statement that this man was also a nurse, s some medical experience here.

If we turn to paragraph 10, please, which is on page 3, he describes from his point of view what happened in relation to his wife's caesarean. So h says:

"Very shortly after the C-section was completed, [my wife] was given multiple blood transfusions because she was haemorrhaging. [My wife] began receiving transfusions on the night of the [procedu re] and continued to do so for 2 days.

"11. I was not informed or consulted about these blood transfusions and the only evidence that consent was given is a form apparently signed by my wife at a time when she was under high stress and i extreme pain and discomfort."

Sir, that's obviously the form we've just looked at.

In relation to issues of consent, at paragraph 15, he says this:

"Prior to her transfusions, no information or advice was ever provided to either [my wife] or mys elf regarding the risk of being exposed to any infectio n."

Then in relation to the issue of necessity he says this at paragraph 16:

"I accept that receiving at least one blood transfusion would have been vital for my wife given

the amount of blood she was haemorrhaging; yet I remain unconvinced that all 6 of them were strict ly necessary."

Now, sir, picking up the theme of necessity which you've touched on in your questions to me, a lot of the witness statements query whether transfusion in and of themselves were medically required, but a lso whether the quantity of blood was required. And particularly in relation to maternity issues, lots of the statements refer to doctors speaking to women about topping up their blood levels or aiding their recovery after giving birth. Two examples. The fi rst is a statement from a woman who underwent a forceps delivery in 1985 when she was 16 years old. She wa diagnosed with hepatitis in 2000.

Her statement, please, WITN1910001.

If we can turn on the following page, please, we can see paragraph 6. She describes the location of the transfusion at the Dryburn Hospital in Durham, which has subsequently changed its name.

In paragraph 7 she sets out the issues in relation to the transfusion. So it's recorded in h er medical records that her haemoglobin levels were 9. and she was transfused with two units of blood. On e, as we can see in paragraph 7, on that day, and then ,

if we look at paragraph 8, please, the following da she had a second unit of blood in the evening.

Paragraph 9 refers to this issue of the possible necessity for these transfusions:

"I can remember sitting on the bed after giving birth and I felt really dizzy. I did not have any other symptoms. I do not think I was actually bleeding. I just felt dizzy. At no time, either before or after the transfusion, was any informatio or advice provided to me or my parents about the ri sks of beings exposed to infection."

Now one final example from this category -- we could be here for weeks in relation to the evidence about maternity issues, but one final example, WITN3286001.

Now this is a statement from a widower, and his wife underwent a hysterectomy in 1994.

Could we turn the following page, please, Sully, to paragraph 3.

Paragraph 3 discusses that the operation was a hysterectomy on 9 August 1994 at Saint Margaret's Hospital, and this is confirmed in the medical records, that Maureen was transfused with two units of blood during the surgery.

Paragraph 4, please.

This is an example, sir, of individuals that have been able to track down the specific batch numbers, and we can see them there.

Paragraph 10, please. This is the husband's description of what happened postoperatively.

"Initially all appeared well after the hysterectomy operation and associated blood transfusion. Maureen seemed to be coping well. However, from 15 September 1994 Maureen had become noticeably jaundiced. She also suffered with nausea, vomiting and had diarrhoea. Maureen's urine was also looking very dark."

Then there is reference to a medical record confirming that.

Can we go to paragraph 21, please.

In relation to consent, her husband said this:

"Maureen and I were only made aware of the blood transfusion after Maureen's surgery, when we asked whether the operation went well. It was at this point that the doctors told us that Maureen was given a blood [transfusion][I think it should say], and that Maureen could have possibly managed without having the blood transfusion, but would have taken a little longer to recover."

Sir, the presentation note deals with a wide

range of medical conditions where transfusions were administered, and I'm just going to touch on some of those in this oral presentation. The first aspect relates to stomach and spleen conditions. There's a whole host of conditions in this category. Things like Crohn's disease, colitis, appendicitis, peptic ulcers are all examples where transfusions were given. Often these were emergency scenarios, and we're going to take one example. This is an example of an affected son who describes that his father received a blood transfusion in 1980 or 1981. We don't need to bring this statement up, but just for the transcript it's WITN0525001, the statement of Gary McKelvey.

Now his father developed a stomach ulcer which ruptured. He felt very dizzy and fell over, and he was admitted to the Whiteabbey Hospital in County Antrim for emergency surgery, and in those circumstances he received a blood transfusion.

So that was 1980, 1981.

In 1990, about a decade later, he had a very low platelet count and received a transfusion at the Belfast City Hospital.

He was diagnosed shortly after that procedure with hepatitis C, in March 1991, and the registrar that was treating him told the family that it was the

first transfusion that was likely to have been responsible for the hepatitis C. His father sadly died shortly afterwards, in June 1991, with hepatic failure and viral hepatitis listed I(a), I(b) on the death certificate.

Now, despite repeated and sustained efforts by this family, they've been unable to access any of the medical records and therefore cannot prove that the transfusion took place in 1980 or 1981.

Kidney and liver conditions are another significant area of the witness statements that the Inquiry has received. I'm going to just highlight two examples in relation to kidney treatment. The first is that of Dorothy Anderson.

No need to bring up this statement but, for the transcript, WITN2074001.

In June 1979, she was admitted to the Stirling Royal Infirmary in Scotland in relation to the removal of a kidney stone. This was an elective, not emergency, procedure.

Pre-operatively she had blood taken and was due to undergo surgery the following day. However, she was then told, from an examination of her blood, that her haemoglobin levels were too low and she was not fit enough to be anaesthetised. So what happened then

was she was given a blood transfusion pre-operatively in order to increase her haemoglobin levels. She recalls being given two bags of blood.

She says that the risks of infection were never explained to her and she says this.

"I had absolutely no reason to think that there should be any problems. I did not think about it for years."

Her husband has also provided a statement to the Inquiry, and we're going to look at tab -- sorry, WITN3097001, please.

Sir, just pausing there, the reason that I'm often going to husband's statements, when it's the women that were being treated, is often that they were involved or awake for some of these decisions in relation to consenting processes. So I'm not seeking to remove the voices of anyone infected but it's often the affected members in these circumstances that have detailed evidence to give in relation to consent.

If we look at paragraph 4 of this witness statement, please, her husband says this:

"No doctor spoke about the risk that Dorothy faced by receiving a blood transfusion to either her or I. She was not given the choice, despite the fact it was not life-threatening; it was a case of this was

going to happen and that was the way it was."

Now sir, that expression of "that was the way it was" features in a lot of the statements received b the Inquiry. It is as though the transfusion would have happened in any event, regardless of any patie nt view on it.

SIR BRIAN LANGSTAFF: One of the things that we had emphasised to us by the medical ethicists was that part of the process should involve respectful autonomy, should involve giving a patient choice. At this time, 1979, do you happen to know whether supplementary iron was a treatment readily availabl or not?

MS BURTON: I don't, sir, off the top of my head, I'm afraid.

SIR BRIAN LANGSTAFF: Because I suspect, although I don't know, that later on, rather than give blood, a form of giving iron to increase the ability of the blood to carry oxygen, produced haemoglobin, would have been the preferred option.

MS BURTON: That may well be right, sir, and this week, obviously, we're hearing from a range of clinicians and those are the sorts of questions that can be pu to those individuals.

SIR BRIAN LANGSTAFF: I'm raising it, knowing that that's

the case, and perhaps that can be raised in due cou rse with one or other of those who give evidence.

MS BURTON: Thank you, sir.

So we've just looked at paragraph 4 in relation to the information or lack of information that was given to this couple pre-operatively. The rest of this story is that in about 2002/2003, Dorothy went to her GP because she was feeling constantly tired. H er doctor took her for blood tests and she states that she received a letter from her GP with a single lin saying that she had hepatitis C. The letter did no include any invitation to come and discuss the resu lts or discuss the condition with her and she describes this as "a terrible way in finding out you have got an infection".

She has managed to obtain some of her medical records, however records for this specific transfus ion are missing. Both Dorothy and her husband query wh she wasn't tested or notified prior to 2003 or 2002 This is a theme, sir, that we will come back to in this presentation: the period of delay between transfusion and communication of diagnosis.

The second example is rather striking, in relation to kidney treatment. It was a woman who w as suffering from renal failure and, in May 1984, she was

put on the transplant list. In September of the sa me year, 1984, a matching kidney was found, and she an her husband rushed to a hospital in Manchester for the kidney. Just look at the detail of this, it's WITN2781002.

Sir, this is a rather lengthy letter, which I hope you'll bear with me while I read aloud becau se it summarises the quite striking facts of this example. We can see at the top of the page it's written to some solicitors in September 1992, so so me years after the events.

Sully, if we can just scroll down, starting with that second substantive paragraph:

"[The woman] was admitted under my care as matter of urgency ..."

Sir, for completeness, I should say this is written by a consultant surgeon who was treating th woman:

"... admitted under my care as matter of urgency on the 20th September 1984 for a cadaver renal transplant. She had been in chronic renal failure for approximately 13 years. Her primary disease was pyelonephritis complicated by hypertension. She ha been treated on dialysis for three months prior to admission. She received the right kidney from [I'm

just going to call him 'a man'] aged 23 years who h ad died as a result of a road traffic accident and a h ead injury on the 19th September 1984. Prior to the removal of the kidney [the man] was tested for hepatitis, HIV and cytomegalovirus and found to be negative for all three. The transplant took place on the 20th September. The match was almost perfect w ith only one measured mismatch at A3 on the HLA locus. [The woman] was also tested for hepatitis, cytomegalovirus and HIV and she was negative.

"Post operatively her transplant functioned extremely well. She had two episodes of acute rejection, both of which responded to treatment wit steroids and her progress was complicated by a vira infection with herpes simplex. Subsequently, she m ade excellent progress, was discharged from hospital an followed-up in the Transplant Clinic", with a reference to her treating clinician.

"Approximately 2 years later whilst still under the care of [that treating clinician] she developed an unspecified illness with enlargement of the lymp glands in her neck and tested positive to HIV."

Exact details he refers to the treating clinician.

Bottom of the page, please, Sully:

"Suffice it to say when we went back to look at the donor to see whether or not that was the source of the infection and it transpired that one of the Units of blood given to [the man] during the course of his resuscitation had subsequently been shown to come from an HIV positive donor. This was one Unit of blood in a transfusion of 15 Units of blood, necessitated by his injuries caused in the road traffic accident.

"We then reviewed the other recipients of [the man's] organs and found that the recipient of the other kidney, one of our patients, had also converted to HIV positivity and the recipients of his liver and heart respectively has also converted to positive positivity.

"In conclusion there is absolutely no doubt that [the woman's] HIV infection was transmitted via her kidney transplant from the donor ... and that the origin of the infection was from a positive blood transfusion given to him in resuscitation. During the course of [her] HIV illness she was under the care of Dr Ackrill", and the letter states that further details can be found.

This woman sadly died from AIDS in 1987, aged just 33 years old.

SIR BRIAN LANGSTAFF: We don't, presumably, know what

happened to the other three who were infected as a result of transplants from this individual? What the doctor doesn't say is that the blood in the donation, the donation of blood was tested?

MS BURTON: It doesn't say that, no, sir.

SIR BRIAN LANGSTAFF: Whereas he makes a specific point of saying that both the young man who died and the recipient were.

MS BURTON: Yes, sir.

SIR BRIAN LANGSTAFF: Yes. So the test was done too far down the line.

MS BURTON: Absolutely.

Now, sir, there's a lot of evidence received by the Inquiry in relation to orthopaedic and also traumatic injuries. A large number of statements we have received relate to examples of polytrauma, for example, in the context of a road traffic accident.

There are also examples of physical acts of violence, so stabbings, attacks, football hooliganism but also, at the other end of the spectrum, there are also examples of routine orthopaedic treatments, hip replacements, knee replacements, as well as genetic or inherited conditions. I'm just going to give you one example from this category, there are many more set the out in the written presentation, an example of

a man who was involved in a road traffic in Scotland in 1971 and was diagnosed with hepatitis C in 2018.

We have a copy of the operation note and can we go to WITN0831002, please.

On the first page, we can see there's a heading "In Theatre" -- there we go -- and this is an example of the treatment that was received, and there's a reference to a local anaesthetic, skin grafting. But if we go down the page, please, to the next page, we can see at the top of the page this the road traffic accident, and issues of glass and lacerations of the face, and we can see in the middle of the page the surgeon there explaining the treatment that was given.

Over the page, please, further, Sully, there's a description of the blood that was given. So it says:

"Prior to admission blood loss had been severe. [Blood pressure] on admission about 60. For this reason given plasma on admission followed by 2 pint of blood overnight and in theatre required a further two pints."

Then there's reference to injuries and also an undisplaced fissure fracture of the neck of scapula.

So sir, that's just an example of blood being given what looks like on arrival and also perioperatively, so during the procedure.

The next collection of conditions, if I can call them that, relate to paediatric conditions and the experiences of children and their parents. And we have lots of examples of individuals who are now adults describing the treatment that they received as children but also their parents looking back and describing their experiences of blood transfusions. A significant number of these, sir, relate to leukaemia, and as you're aware, the treatment for leukaemia obviously involves multiple blood transfusions and sometimes bone marrow transplants.

One example in this category, WITN0267001 -- for the transcript, we don't have to go to it, Sully, but this is a child who was diagnosed with acute lymphoblastic leukaemia as a child. And his family can recall the precise day of the diagnosis with leukaemia, because it was the day after the Pope visited Manchester. He was only three years old but it has gone down in family history or those reasons

Now, between June 1982 and 1984 he received treatment for his leukaemia at a hospital in Manchester, and it was as part of that treatment that

he received a blood transfusion. In 1984, he received the 'all clear' from his leukaemia treatment.

He was then sadly diagnosed with HIV in 1994, when he was just 15 years old. Now, that diagnosis came two years after a period of declining health, weight loss and a lack of growth. We're going to look at a statement by a family member. This is an anonymous witness, so we'll look at a family member's statement, WITN0872001, please.

If we can turn up to paragraph 25, please, Sully. While that document is coming up, sir, just to fill in the factual picture, his family received a lump-sum payment in the mid-1990s from the Department of Health that was paid into court. But the section that I want to look at relates to the experiences of a family member when they were told about their loved one's diagnosis with HIV.

If we can't get there, I'll just read it out, but for the transcript it's paragraph 25 to 27, and the family member says this:

"I remember being at the hospital when they summoned me into a separate room. I do not remember the specific words they said. It was a shock to find out that he had HIV. An explanation was given to me about a treatment process. The first drug was to b

one that started with a Z. I felt numb. My emotions were high. I had such disbelief about the whole situation. It was tough news to take. I remember Dr Wilkins spoke about how people were currently surviving about three years, but they were making great medical progress in finding new ways to treat HIV. News that new drugs were being tested with progress being made was somewhat of a relief. I recall thinking that he may live longer than three years. Always tried to look for the positive and this news gave me some solace. Prior to the test results I did have thoughts, wondering how the infection could have happened. I queried this with the doctors. They said in this case it could have been through a blood transfusion. The only time he had a blood transfusion was during his leukaemia treatment."

Now, considering the facts of this example, sir, one could query why this family didn't receive an HIV diagnosis until 1994, following the transfusion in the period of 1982 to 1984.

Another example in relation to leukaemia is the account given by a woman who contracted hepatitis C as part of her leukaemia treatment. WITN019001, please.

Sir, I think we're having some technical difficulties. May we have five minutes just to hav a look at the --

SIR BRIAN LANGSTAFF: That number is wrong, you're missing two digits, I think. Or one digit.

MS BURTON: That might well be right, sir, but I think the whole system is not working.

SIR BRIAN LANGSTAFF: Right. Well, let's take a short break, shall we?

MS BURTON: Thank you.

SIR BRIAN LANGSTAFF: What do you suggest? Five minutes? Is that going to be long enough, Sully?

MS BURTON: That sounds perfect. Thank you.

SIR BRIAN LANGSTAFF: Five minutes.

(10.42 am)

(A short break)

(10.45 am)

MS BURTON: Thank you, sir, all back up and running now.

We're going to look at an example of from a woman who contracted hepatitis C as part of her leukaemia treatment, and this is the relevant statement here.

If we look at paragraph 2, we can see the description of how this woman was infected, 22 May 1990, as a result of receiving numerous bloo

transfusions and blood products whilst she was in hospital with leukaemia:

"I received several transfusions between September 1989 and June 1990 after I had a bone marrow transplant."

And she explains that she was only 20 months old when she was diagnosed with leukaemia, and two-and-a-half when she was infected with hepatitis C.

Now she was diagnosed in 1995 with hepatitis C as part of a look-back exercise.

And Sully, if we can just go to paragraph 6 on the next page, please.

She says this about the timing of the diagnosis with hepatitis C:

"... just after I had got my big 5 years clear for leukaemia. I had gone into remission, was still having check ups, and had been given the all clear when only a few months later we got the letter about the hepatitis."

And sir, that is a key theme in relation to this cohort of patients, overcoming one significant medical condition and then being faced with having to deal with a second condition.

Malignant haematology is another area where individuals received blood transfusions, and we've got

a statement in relation to a woman who was diagnose with Hodgkin's lymphoma in the late 1980s, early 1990s.

No need to put this up but for the transcript, WITN0938001.

This woman was about 21 years old when she started chemotherapy, and in 1991 she underwent a b one marrow harvest at the Velindre Hospital in Cardiff and she received a platelet transfusion as part of that

In August 1998 -- so the treatment is in 1991, August 1998, she received a letter to say that the blood that had been used as part of her treatment w as positive with hepatitis C. She describes this in h er statement. She felt as though she had been "handed another death sentence" and that she was "ashamed t hat [she] was ill again".

One document in relation to this witness that I want to show you, WITN0938003, please.

We can see this a letter of claim dated 10 July 1997. And if we scroll down, this is a let ter from a consultant haematologist, and it sets out th history that we've just been looking at. So a platelet transfusion in 1991. And then this is said:

"I am not sure how often you are reviewing this

lady, and whether you wish to undertake the necessa ry testing and counselling yourself, or if you would l ike me to see the person. I would be most grateful if you could advise me accordingly. If you undertake the testing yourself it is important that the sample is sent to the University Hospital of Wales for PCR testing and it would assist administrative purposes if the enclosed form could be used."

And some details about the sample, how it should be taken.

Now the witness says that she wasn't ever aware that her blood sample would be sent to the University Hospital of Wales, and she came across t his for the first time when looking at her medical records.

Sir, the next group of patients affected by blood transfusions are those with haemophilia.

Now, prior to the advent of Factor VIII, Factor IX blood products, some haemophiliacs were treated with blood transfusions as an early part of their treatment. However, due to the rather prolif ic use of those blood products, it's often very diffic ult to pinpoint the source of any infection in relation to the cause of a blood-borne infection, but it's righ to acknowledge, and we do so in the presentation, t hat

there are many haemophiliacs who also received bloo transfusions.

The next group of patients are those who suffer from sickle cell anaemia. Now this is an inherited blood condition where red blood cells are sickle shaped, and that means that less oxygen is transpor ted around the body. Sickle cell carriage is found in approximately one out of nine people of African or Caribbean origin, and the sickle cell gene is found in southern Europe, in India and in the Middle East.

Sir, you will know, but just to refer everyone and to refresh people's memories, the Inquiry has produced an expert report on bleeding disorders, an a lot more information about sickle cell and other conditions can be found. The reference for the transcript EXPG0000002.

Now, the Inquiry has only received limited evidence in relation to individuals who were infect ed following transfusions as part of sickle cell anaem ia treatment and the Inquiry continues to welcome and encourage those patients to come forward and give statements to us. It's absolutely not too late for those people to give witness statements.

One example that we have received is from an affected daughter, and she describes that her

mother came to London in the late 1950s from St Luc ia and her mother was diagnosed with sickle cell in around the late 1980s and received three to four transfusions per year. Now, in 2013 her mother was sadly diagnosed with hepatitis B and she died very shortly after that diagnosis, and liver disease is mentioned on the death certificate.

Now, this witness believes that racism has played a part in the treatment of people with sickl cell, and we're just going to look at how she describes that. WITN4729001, please.

If we can turn, please, to paragraph 48 of this statement, right at the end, Sully, paragraph 48, s he says this:

"People who suffer with sickle cell disease tend to be of African heritage and I believe that 'we' h ave been side-lined by the NHS and made to feel as thou gh we are not important. The way the disease was deal with by the health profession was I believe, racist and it was not treated in the same way as other lif limiting health conditions are. The fact that sufferers were also given infected blood is another thing on top of this and checks should have been ma de to ensure the blood was safe."

Now, we've also received a statement from

a mother of a child with sickle cell and she describes, in her view, that there was a stigma within the health profession about treating sickle cell, and we'll look at her words, WITN1823001. Now, this is a statement, sir, we're going to come back to later because it's a fairly remarkable one, but I just want to look at paragraph 42, please, Sully, which is page 11, which addresses this mother's view of a stigma, and she is talking here about treatment in the early 2000s:

"In general, I believe that there was a stigma around having sickle cell in the medical profession at the time of [my daughter's] illness, which may have caused doctors to believe everything wrong with [her] was due to her sickle cell. When she was at Kings College Hospital awaiting a transplant, I felt that doctors kept referring to her sickle cell as the reason why she was deteriorating, or why she couldn't have a transplant. They said things like 'oh, well she is a sickler' when she showed signs of worsenin as if that explained her whole illness."

Sir, another condition that falls squarely within the Inquiry's remit is thalassemia. Now thalassemia, as you know, sir, is an inherited bloo condition, so it causes the body to produce less

haemoglobin, which in turn clauses anaemia and a range of other problems. As with sickle cell disease, we have not received a lot of statements from individuals with thalassemia and we would, again, encourage people to get in touch with us. It's absolutely not too late for those statements.

I'm going to give an example of a statement we have received, and this is WITN0054001 -- 0554001. So this is an individual who suffers from beta thalassemia major. We can see that in paragraph 2. She describes that that diagnosis came when she was just six months old and, over the page, we can see, at the top of page 2 of this statement, that she required transfusions every six weeks, but that the current position is now she needs them every two to three weeks.

This is a woman who was infected with hepatitis C. Now, because of the number of transfusions that she has had over the course of her life, at a range of hospitals, she is unlikely to - unable to pinpoint both the relevant transfusion that infected her but also where that took place. It's simply impossible for her to know.

She thinks that she was told in 1991 about her hepatitis C and thinks that this happened on

a face-to-face basis, although she accepts that it could have been earlier, because she has a vague recollection of family suggestions.

One theme that's apparent from this witness statement, sir, is that she states that the hepatitis C and her subsequent liver problems have adversely impacted on her medical treatment for thalassemia. So, again, we're seeing the interconnection of two different conditions.

The next group of patients relate to those individuals who have been infected by family members, either via spouse or via a child. There are unfortunately several examples of spouse to spouse infections arising from a transfusion but, also, examples of infection passing between parents and their children. A frequently expressed fear of women who receive blood transfusions as part of maternity care is a question of whether their baby has been infected or their subsequent children have been infected and, sadly, there are number of examples where children have been infected by their mothers, so maternal child transmission.

I'm going to bring up a rather unusual example, sir, that could fall within this category but also could fall outside of it. This is the unusual example

of a married couple who both underwent transfusions on the same day in the same hospital without each other knowing.

So for the transcript, this is WITN0286001, WITN0287001. We don't have to bring them up.

Now, the woman received a transfusion due to a post-partum haemorrhage. So this was in 1986 at the Dryburn Hospital in Durham. And she describes an allergic reaction that she experienced post-transfusion. There's some discussion whether it was a penicillin reaction to a component but whilst she was in labour, her husband was admitted for emergency surgery due to a burst stomach ulcer, and he underwent a transfusion at the same hospital.

Now, perhaps unsurprisingly, she was surprised when, postoperatively, she woke to see her husband being wheeled into the room in a wheelchair. But then what happened was a slightly different course. She began to experience hepatitis-like symptoms soon after her transfusion, and in the late 1980s, she had all of the classic signs of hepatitis. Her husband didn't develop any symptoms until 2004.

Now, within the family, they attributed her symptoms to being a mother and being exhausted; the transfusion happened with the birth of their third

child. But it wasn't until, in 2004, she looked at her husband and realised that his eyes were very yellow. He booked a GP appointment and was diagnosed with hepatitis C. It was then recommended that she should undergo testing and she herself was also positive.

So it's unclear, sir, whether this is a spouse-to-spouse infection or whether this is an example of one of them receiving infected blood or both of them receiving infected blood, on the same day, at the same hospital.

The wife received a Skipton payment on the basis of her transfusion, but because her husband self-cleared the virus, he wasn't entitled to any payment.

Sir, I'm going to move on away from those categories to look at the different types of infections that witnesses and their family members have received.

The most common type of infection from a transfusion is a hepatitis infection, predominantly hepatitis C. But there are lots of examples of hepatitis B and also examples of hepatitis A and hepatitis E infections.

Sir, you will recall the oral evidence of

Peter Buckland, whose son Mark contracted vCJD from a blood transfusion in September 1997. So the Inquiry has also received that evidence in relation to vCJD

HIV infections were less common, but unfortunately the evidence received suggests that they absolutely did occur. And there are also examples of people that were co-infected with more than one virus.

Going to look at some examples of HIV infection. The first example is a man with leukaemia who underwent a bone marrow transplant at the Hammersmith Hospital in 1982, and he received platelets as part of that treatment. His health deteriorated and he contracted mumps and was admitted to hospital in June 1983. His wife went to visit him in hospital, and then came home to receive a phone call telling her that he had died.

His wife was told throughout his deterioration that the reason for his death and his ill health ha been due to graft-versus-host syndrome because he did not have leukaemia when he died. So this is 1982, 1983.

Then what happens is that in 1992 she received a letter from the Hammersmith Hospital. We're goin to look at that letter.

WITN0407002, please.

The letter is from a professor of leukaemia biology at the hospital, and it says this:

"You may be a little surprised to hear from the Hammersmith Hospital after the passage of some considerable number of years. Nevertheless, an aspect of her husband's management has recently been drawn to my attention and I would be very grateful if you could make contact with me."

So the woman attended a meeting with this clinician and she was told that, in fact, her husband had received blood infected with HIV and that the cause of his death was not graft-versus-host but wa HIV.

She also found out -- this is 1992 -- that back in March 1987, there had been a published account o her husband's death as part of a research paper.

We're going to look at that document, WITN0407003. So at this meeting she also received a copy of this medical report that was about her husband. If we look on the top right-hand corner, this is a publication in the European Journal of Haematology in 1987, and the clinicians are listed in the middle of the page. If we look on the right-hand column at the bottom of the page, Sully, we can see that it explains the premise here. It says:

"In 1985, 3 patients who had developed [AIDS] between 2 and 5 years after BMT [bone marrow transplant] were reported from France. In each cas the marrow donor was identified as the source of infection. Following this report we investigated a group of patients considered to have been at risk of exposure to HIV for serological evidence of anti-HIV. The group consisted of 28 patients, 25 transplanted since January 1984 and 3 transplanted earlier, who had developed late infectious complications. We report the details of 1 patient found to be seropositive anti-HIV and the events preceding his death 6 month after [the bone marrow transplant]."

Now, it's not a brilliant copy, sir, but you can see the relevant case history set out.

If we turn to the final page, please, Sully, 188 internally -- sorry, penultimate page, 188. We can see the bottom of the left-hand column. It says this:

"Transmission of HIV after [a bone marrow transplant] should be preventible if appropriate steps are taken. We recommend screening not only of bloo product donors but also of the bone marrow donor an recipient and any other person ... asked to donate various [aspects]."

So the conclusion of this study that this woman

received in 1992 was that transmission of HIV in these circumstances should be preventible if appropriate steps are taken.

SIR BRIAN LANGSTAFF: At the time of the transfusion, that was 1982, was it?

MS BURTON: It was -- sorry, sir. 1982. Yes.

SIR BRIAN LANGSTAFF: So there wouldn't have been, at the time, any test for HIV, or HTLV-III?

MS BURTON: Not at the date of the original transfusion, no.

SIR BRIAN LANGSTAFF: So when the article here talks about being preventible, it's looking at the position as is, at the time of the article?

MS BURTON: 1987, yes, sir.

SIR BRIAN LANGSTAFF: Thank you.

MS BURTON: Sir, as part of the Inquiry's consideration of relevant documents, we have seen a lot of documents that relate to the Eileen Trust. Now, this information is not strictly falling into the experiences of infected and affected people that have contacted the Inquiry. Of course, there's some overlap. But what we wanted to do, as part of this presentation, is just draw out some examples of the documentation that we have seen in relation to the Eileen Trust.

Now, these documents haven't yet been disclosed, and they will be in due course. I'm going to give a series of examples but, for reasons of confidentiality and anonymity, some of them are fairly vague in their detail, but it will give you an idea of examples of HIV infections for families and individuals that haven't directly contacted the Inquiry.

The conditions that we can see in the Eileen Trust documentation relate to a broad range of conditions. So gastrointestinal bleeding, replacement of a mitral valve, injuries sustained in a road traffic collision, acute myeloblastic leukaemia, inflammatory bowel disease, during labour, a total hip replacement, extensive burns and an ectopic pregnancy. So, again, a similar range of conditions that we have received directly from witnesses.

They also cover a range, in terms of the temporal period, and some of the examples I'm going to draw out relate to the latter period, in relation to the 1990s.

The first example is a man who received about 22 units of blood for a heart procedure in 1983 in a London hospital. The donors of ten of those units were traced and found to be HIV negative, but

12 units, originating from Hither Green, could not be traced because the documents had been destroyed in a fire. That man sadly died of AIDS in the 1990s.

The second example is a woman who was admitted to hospital in Wales in 1983 following a road traffic accident, and she received multiple blood transfusions as part of her treatment. One of the 11 donors was found to have subsequently tested positive for HIV.

Now, the woman developed AIDS and, at the time of the document in question, her prognosis was note to be poor, but we don't have any more detail about what happened to her.

A third example is one of a late example of infection. So a woman who had leukaemia, who underwent chemotherapy in 1996, she was transfused with 112 units of platelets, and diagnosed with HIV a year later, in 1997. A look-back exercise was undertaken, and the infected donation was collected and transfused in August 1996.

Another example is a woman who sadly died of AIDS in October 1986, and she received a transfusio in February 1982 for a post-partum haemorrhage at a maternity hospital in the north of England. Her child was born a few years later, and he sadly was also infected and died in 1985.

The father of that child was also infected with HIV, and it's not clear from the documents we have -- about his health status.

The fifth example is that of a woman who was transfused in a hospital in the Midlands during treatment for an ectopic pregnancy in 1983. The donation that she received was then found to be positive for HIV and the donor had died of HIV. The woman died in the late 1980s of HIV, aged just 34, leaving behind three children.

And a last example is a woman who was admitted to hospital in the northwest of England in 1996 due to colitis. She underwent a total colectomy and received eight units of blood and four units of FFP, fresh frozen plasma. A look-back investigation in 1997 for another patient, so not the patient we're considering, demonstrated that one of those units of FFP was positive for HIV, so they connected the case back to her by that form of investigation.

SIR BRIAN LANGSTAFF: If you just go back in your notes to the 1996 case, diagnosed 1997, that you told me about it a moment or two ago, where you described how the unit which had been transfused was shown to have been infected, it was a unit that was tested, was it? Do we know?

MS BURTON: Sir, I'll check that specifically in the break. I think it probably was, but I'll go back t the documents and check that.

SIR BRIAN LANGSTAFF: The reason I ask is that it might follow that if the tests had been sufficiently accurate or applied, that that might or should have been detected at the time. But if it's the donor, then it might have happened in a window period.

MS BURTON: Sir, I'll check that in the break and see if we can give any more clarification. Unfortunately, some of these documents are not terribly detailed because they're drawn from applications that people have made to the Eileen Trust, and then what investigations the treating clinicians have done around the side, so it's not always possible to be that exact, but I'll check for you and see if we ca find any more information.

SIR BRIAN LANGSTAFF: Thank you.

MS BURTON: Sir, at this point in the presentation it's probably a convenient moment for a break. I'm just going to move to the second half of the presentatio n.

SIR BRIAN LANGSTAFF: Yes, well, we'll take a break until 11.45.

Just before we break, can I just say one thing. Earlier in your presentation you mentioned the

relative shortage of statements that we have from those who have suffered from sickle cell or suffer from sickle cell and those who suffered from thalassemia. You've also given some disturbing evidence of stigma that might exist or is felt to exist for those who suffered from those conditions, about the way in which they have been dealt with.

Can I just say that we are open to receive any statement from anyone who wishes to tell us. They don't have to, obviously, but if they wish to tell us, we will very happily receive statements from those who have sickle cell and thalassemia, who have or think they may have suffered from the conditions which we are centrally investigating. It has always trouble me that the numbers of those who have suffered infection ought, on an impressionistic view of the overall landscape, to be much higher than the numbers that are reflected in the statements that have come forward.

So it may be that there is a reluctance, for fully understandable reasons, to tell us but we are -- and I want to repeat -- we are open to receive any such statements and hope that those who are listeni ng, if they have been uncertain about it but feel that they might want to make a statement, will do so if

they can. They may help our investigations if they do.

That's all that I wanted to say. 11.45.

(11.16 am)

(A short break)

(11.46 am)

MS BURTON: Sir, two matters that arose before the break that I have had an opportunity to look at.

You will recall right at the beginning of this oral presentation I gave an example of a woman who received blood following having 650 millilitres of blood in her abdominal cavity, and you asked me about measurements. I'm grateful for those behind who ha ve said that one unit is 500 millilitres, so the fact that she was given three units of blood would amount to 1,500 millilitres in the context where the blood loss on that operation note says 650 millilitres.

SIR BRIAN LANGSTAFF: Yes.

MS BURTON: So the point you were making absolutely stands.

SIR BRIAN LANGSTAFF: Well, I don't think I made a point; I asked a question. But it was certainly at the ba ck of my mind that there was a potential overcompensation.

MS BURTON: Yes.

Now the second question you asked just before we broke was about a little more detail for a woman in relation to the Eileen Trust documentation. Just reminding everybody, this was a woman who had leukaemia who underwent chemotherapy in 1996. She was transfused with 112 units of platelets and diagnose with HIV in 1997.

I've found this extract, which we're not able to put up but I'll just read it to you, sir, and as pa rt of the investigation, a consultant haematologist wr ote this:

"The donor had completed medical screening satisfactorily, and completed the usual declaration of good health and absence of risk activities. During the course of the investigation, archived samples f rom the donors contributing to the 112 units given to X during her treatment were re-tested, and all were negative on repeat HIV antibody screening. A donat ion was identified using a PCR technique which demonstrated HIV viral DNA, and this donation [and then the donation number is given] was also HIV P24 antigen positive. This case therefore represents a window period transmission. No other risk factor were identified."

So, sir, not a complete answer to the specific

question you asked about testing but I think that gives a broader position of the information.

SIR BRIAN LANGSTAFF: Well, I wondered if there had been proper testing or, as it were, one that got through the net, or whether there was a window period example, and that is -- appears, from what you've just said, to have been -- the latter appears to have been the case.

MS BURTON: Yes, sir.

SIR BRIAN LANGSTAFF: Yes.

MS BURTON: Now the latter point of this presentation examines the nature of information and issues of consent in relation to procedures, and specifically the period before and after a transfusion was given The available evidence suggests that almost all patients were not informed that there was a risk of blood-borne infection prior to or after receiving a transfusion.

In the vast majority of cases received by the Inquiry, there was no discussion about the risk of transfusions, even for patients who received frequent transfusions and were regularly seen in hospital.

So the evidence we've seen, sir, does not suggest, for example, that those with sickle cell o thalassemia or leukaemia had the risks explained to them in detail.

Many witnesses in their evidence make the point that they did not connect their poor health following a transfusion to any infection, but had attributed it to their underlying condition, or that the symptoms of their underlying condition masked the symptoms of blood-borne infection.

And so that's important, because they therefore didn't go to the GP or seek medical attention in relation to an infection.

A significant area of the evidence relates to examples of transfusions where there was no consent given, or even an express statement that an individual did not want to receive blood. I'm going to take you to an example of that.

This is a statement from a mother of a child who received a blood transfusion when she was 5 years old, in 1990, at the Charing Cross Hospital. Now, this little girl was admitted as part of a sickle cell crisis, and she was treated with oxygen and monitored for several days. The treating clinicians then asked the mother whether the child could have a blood transfusion. And the witness spoke to her family members and, crucially, her sister, who was a Jehovah's Witness. Therefore, after this discussion, the mother decided that the outcome of the

consideration was that no transfusion should be given, and therefore the mother communicated that to the treating clinicians.

If we just look at this witness statement, WITN1823001. If you can turn to paragraph 11, please. Next page.

So what she says is that:

"At no point was I ever informed of the potential risks of having a blood transfusion. It was mentioned to me as possible treatment for [my daughter] to help her improve faster, at which poin I specifically told the doctors that I did not consent to her having one, and it was then done behind my back."

So the woman describes in this statement being at work and then coming to the hospital and finding out that her daughter had received a blood transfusion against her wishes.

Now in the daughter's medical records, there is reference to an additional transfusion that took place in June 1991. The mother does not recall the details of that specific transfusion, but accepts in her statement that if it's in the records then it's likely that there was a second transfusion that took place.

When the daughter was around 14 years old, she

started to develop yellowing of her eyes. And in June 2002, she collapsed and was admitted to Homerton Hospital, and it was at that stage that sh received a diagnosis of hepatitis C. She was then referred to the Royal Free Hospital due to the fact that she developed ascites and chronic liver disease. The daughter sadly died in 2003, aged 17, and the cause of death was concluded to be liver failure.

The statements received by the Inquiry also draw on the communication of diagnoses and, sir, this is a theme you've heard in oral evidence and written evidence to date. Within the presentation we set out a number of examples of poor communication about diagnoses. Some witnesses are critical of the fact that they received their diagnoses in writing rathe than on a face-to-face basis, and there are multipl examples of witnesses who only found out that they were infected because they had themselves donated blood. And there's a frequently expressed sentimen that they donated blood because they had benefited from receiving blood.

So it's common for some blood-borne infections to be flagged as part of a blood donation and, in those circumstances, it's common for that notification to be in writing.

Some witnesses highlight the potential difficulties of that approach, particularly people receiving a letter completely out of the blue with no preparation or warning. Some of the examples in th witness statements relate to opening a letter at a time of day when the phone lines in that letter are closed, so feeling like they've got no one to turn to for any access or support. Other individuals, opening a letter at home when they're alone with no family members, or after a really difficult day at work. So there are various criticisms made in relation to th written approach.

The Inquiry, to date, has heard a lot of evidence orally of examples of poor communication techniques, involving individuals when counselled face-to-face, and the witnesses that have received transfusions describe insensitively put questioning about their sex life, about tattoos, about alcohol use, about drug use, and many witnesses describe th at as a very negative process.

Other individuals describe being told of their infections in busy wards by busy doctors without an proper confidentiality. Others describe being told by doctors where it's clear that the doctor thought th at the patient already knew. So passing references, "Oh

says this:

"After my Mum's funeral, my Dad went to visit the North East for a few days, where he and Mum spe nt time together before they married, to feel close to her again. It was during this time, five days afte Mum's funeral, that it was disclosed to my sister a nd I that Mum had received blood infected with HIV. T his devastating news was given to us by Mum's GP ..."

And other clinicians.

Paragraph 13, please:

"We were told it had been discovered that two other patients had become HIV positive through receiving blood transfusions from the same donor th at my Mum had. We were told that the lab still had samples of my Mum's blood after her death (I am uns ure why this would be so, or if this was indeed true) a nd this blood ... had been tested, and it was confirme that Mum was HIV positive. It was at this point, i my Dad's home that he had shared with my Mum, that Dr Martlew acknowledged that 'the person who was giving the blood at Liverpool had not been screened properly by staff and would have been high risk'. No further information was given to us. Neither docto provided any information about the effect of the vi rus on my Mum's illness and death."

that's because of your hepatitis", for example, whe the individual is unaware that he or she was infect ed in the first place.

There are also a number of examples where individuals were infected and not aware during the course of their lifetime. Two examples in this category, sir.

WITN3323001, please.

So this is a witness statement from an affected daughter and in paragraph 3 she sets out her variou medical experience, and that's important context fo something she says later in the statement. If we c an go to paragraph 5, please, Sully.

She describes that her mum was in hospital having been recently diagnosed with multiple myelom and having -- receiving treatment for it. She required a blood transfusion due to her low haemoglobin levels and then there's a discussion ab out how long she was likely to live for.

Can you look at paragraph 6, please:

"This conversation took place in September 1996, around the time Mum received the infected blood transfusion, yet she died only 8 months later ... [in] 1997."

Can you look at paragraph 12, please, Sully. It

Thank you, you can take that down.

Another example of communication of diagnosis after death is WITN1417001. This is another family who found out about an infection after their father , in this case, had died. Just turn to paragraph 4 f or the outline details. The father had been involved in a motorcycle accident 1978 and was given a blood transfusion at the Frenchay Hospital in Bristol and he was infected with hepatitis C as a result.

Paragraph 5, please:

"We only found out that my father had [hepatitis C] after he died and after my father's p ost mortem. I learned that my father had [hepatitis C] when I contacted the Coroner by telephone to find o ut why our local funeral directors were treating my father as an infection risk. My father never knew that he was infected with [hepatitis C]."

Sir, another theme that's been clear, I hope, throughout some of the statements we've looked at, is this temporal gap between the date of the transfusi on and the timing of a communication of diagnosis. It 's very common to have sometimes periods that are deca des long, and I'll just give you one example, which is a woman who experienced a period of 33 years of del ay. She had a transfusion at the Victoria Hospital in

Blackpool in 1984. She went for a health check-up with her husband in 2017, and she was told that she was hepatitis C positive in February 1998.

She queries why it took such a long time. That example is not unique or unrepresentative, rather the opposite; it's representative of lots of people's experience.

If we can turn up WITN0394002, please.

WITN039001. No, okay.

SIR BRIAN LANGSTAFF: That must be 394001, surely?

MS BURTON: Yes, sorry. 0394001. Thank you, sir, I'm grateful.

This is the witness statement of the individual I've just been describing. If we turn to paragraph 7, please, on page 2, her statement there that:

"I received no information or advice before having the blood transfusion about the risk of bein exposed to infection."

Then she was infected with hepatitis C as we can see. Then if we turn up to paragraph 32, penultimate page, please, Sully. This is an expression that many statements repeat, and I'm just going to read it aloud:

"I want to know why no one ever tried to come and find me, and others like me, to tell me what ha

happened and offer help. I have lived at the same house and had the same GP and the same local hospital for 33 years, and I have had [hepatitis C] all that time."

Sir, of course we've got multiple examples of individuals who were contacted through the look-bac exercise, and you've heard lots of evidence to date about the look-back processes. But there are other like this witness who only found out about their infections because of their own actions, ie going t the doctor, having a check-up because they were feeling unwell.

The last theme I want to address, sir, relates to testing. You have heard a lot of evidence to date about testing for blood-borne infections, and the evidence for those who have received transfusions and their infected family members is very similar to a lot of the oral evidence we have already heard. But on statement, I think, is a good example, WITN3324001. This is the affected husband of a woman who receive a blood transfusion when she was very young.

If we can turn up paragraph 6, please, Sully on page 2, there's a description here in relation to how her infection was communicated:

"She was suffering with abdominal pain in 2018

and was having tests to investigate this. She received some results and was told it wasn't cancer which was a great relief as that had been her main concern. However, the Advanced Nurse Practitioner asked to see her, so we thought it was some sort of follow-up appointment. It was for this reason that we didn't think it necessary for me to attend the appointment with her, so she attended alone."

Next paragraph, please:

"I was at work at the time of her appointment and she called me in the afternoon. She told me that she had been diagnosed with [hepatitis C] and sounded very shocked."

Paragraph 8:

"My wife and I usually see the same [Advanced Nurse Practitioner] and he is very, very good. I understand that he would not have wanted to scare her, however, I was disappointed that he didn't tel [my wife] he was testing her for [hepatitis C]. This meant that she had no opportunity to prepare for such a diagnosis. I would also have liked to have been present at the appointment with her, rather than he having been alone to receive this diagnosis."

So, sir, just one example, but it fits with a vast majority of statements who -- with witnesses

who say they were totally unprepared when they received their diagnosis.

Sir, that's the conclusion of this presentation in relation to the experiences of infected individuals and their family members about transfusions.

We've got another presentation to follow which relates to the guidance available to clinicians in relation to transfusions.

Just looking at the time and whether we should be taking early --

SIR BRIAN LANGSTAFF: Just before you do, you said at the start that this wasn't comprehensive. It didn't se out to be. It set out to produce exemplars, I think, of the themes that you identified.

Is there possibly a sixth theme -- you identified five at the start -- which is that of those who indicated at the time that they did not want a transfusion, nonetheless having a transfusion given to them against their will or against their wishes or their wishes being, as they have put it in statements, in some way -- they're treated as reluctants and overcome i that way?

I have in mind in particular two testimonies which we've had orally, there are probably others, but this is just from the back of my memory. That of Lesley Mc Evoy,

in Leeds, who gave a very description of how she wa deceived, if she is right -- and there is no eviden ce to the contrary at the moment -- into receiving two un its of blood on the basis that the blood had been heat treated, which we know it could not have been.

And the second is that of Gill Fyfe, who gave evidence in Edinburgh, I think, and who said that s he had declined to have a blood transfusion and nonetheless was given the transfusion. And, indeed , that forms, I think, the centrepiece of part of a b ook which she told me she wrote about her experiences thereafter as a result.

Now, they're not the only examples, because I've read a lot of the witness statements, some of which describe a very similar happening to them. So is there possibly a sixth theme? I don't know if your researchers allow you to say.

MS BURTON: Yes, sir, and what I would say about that is it's obviously a much smaller group of people that have had the experience that you've just outlined, because it requires --

SIR BRIAN LANGSTAFF: Or a similar one.

MS BURTON: Yes, because it requires knowledge about the risks posed in transfusions. So some of the examples in the written presentation relate to

an individual who asks, in the early 1990s, "That blood doesn't have AIDS in it, does it?", when they 're receiving a transfusion. So it requires a base lev el of knowledge about the risk of transfusions. And t hat needs to be contextualised, as we've heard within t he evidence, of people not being informed by their treating clinicians about those risks. So, absolutely, I remember both of those witnesses who you have raised vividly, and I agree that they would ac as their own theme.

The problem is that there is so much evidence in front of us that you could probably have a seventh, eighth and ninth theme, but I agree with you that t hat certainly is apparent on the evidence.

SIR BRIAN LANGSTAFF: Yes, so if not a theme, at any rate, something to be borne in mind.

MS BURTON: Yes, sir.

SIR BRIAN LANGSTAFF: It follows also, those two examples, that this is a presentation which indicates the lie of the land, rather than every detail of the topograph y.

MS BURTON: Absolutely, sir. We simply don't have the time to lay out all of the witness evidence that we 've received.

SIR BRIAN LANGSTAFF: Yes, well, thank you very much.

Now, do we want a break before we start with the

next --

MS BURTON: I am seeing some nodding from Ms Fraser Butlin. So, yes, that would be helpful.

SIR BRIAN LANGSTAFF: I see Ms Fraser Butlin, who is going to present it, I think, is nodding. So shall we ha ve a short break? What would you suggest, five minute or ten minutes?

MS BURTON: Five minutes to check some documents, sir.

SIR BRIAN LANGSTAFF: Very well, five minutes it is. We'll come back, then, at 12.17.

(12.11 pm)

(A short break)

(12.17 pm)

Presentation to the Inquiry about the guidance avai lable to clinicians about the use of blood transfusions

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Good afternoon. This afternoon and continuing into tomorrow, I'm going to be giving a presentation on the UK guidelines that were available to clinicians in relation to the use of blood transfusion.

Once again it can't be exhaustive, but it will hopefully give a broad overview of the material available to clinicians from 1949 until the 2000s.

I'll be going through general guidance that was

available as well as guidance specific to certain specialities. Again, inevitably, I can't cover the guidance for every medical and surgical scenario, a nd so this presentation will focus on those specialiti es in relation to which those who were infected by infected blood were treated.

The overarching theme of the presentation is that the guidance was initially relatively limited. More recently, extensive general guidance and specialty specific guidance has been produced. The reasons for the change over time is a theme that I anticipate we will return to on a number of occasio ns over the next few weeks as the Inquiry hears oral evidence from various clinicians, but in this presentation I'll address some of the more recent guidance to provide what I hope will be a useful counterpoint to the position during the earlier tim frame.

The extent and nature of compliance with that guidance, and what was understood about compliance, is another theme that we will touch on -- I will touch on in this presentation, and again, certainly somethin we will be exploring with the oral witnesses as we carry on this week and next.

So we start with a document called the *Notes on*

Transfusion for House Officers, issued by the Minister for Health in 1949.

And Sully is ahead of me but for the purposes of the transcript the reference is DHSC0200152. If we turn it to page 3, please.

So we can see at the start that it's *Notes on Transfusion for House Officers* issued by the Ministry of Health for the National Blood Transfusion Servic in March 1949. And if we turn the page, it starts in this way:

"Transfusion therapy should be undertaken only after careful assessment of the patient's clinical condition to determine the nature and quantity of fluid to be transfused, and the rate of administration. The patient may require whole bloo d, concentrated red cells, or plasma."

Then under the heading of "Choice of Fluid":

"Whole blood is used to restore blood volume or the oxygen-carrying capacity of the blood, or to replace one or more missing elements of the blood."

Then just below that, in italics:

"*Blood is commonly indicated for*:

"(i) Haemorrhage -- acute or chronic.

"(ii) Anaemia -- acute or chronic.

"(iii) Oligaemic shock.

"(iv) Blood deficiency states ..."

Then:

"Concentrated red cells are ideal for the treatment of anaemic states in which it is desired to raise the haemoglobin level, and in which blood volume restoration is not required."

That may be read, sir, to suggest that red cells concentrates at that time were to be used in a situation where there was not acute haemorrhaging

Then at the bottom of the page, in relation to plasma, we see in bold text:

"Plasma or serum should not be given unless the advantages to be gained by its transfusion outweigh the risk of transmitting homologous serum jaundice.

And it asks us to turn to another section.

If we go to that section -- it picks up on page 14 of the document, please -- we can see the heading of this section, section VII, "Complication and Dangers of Transfusion".

And we carry on to page 16, please, Sully.

And the seventh complication and danger that's noted is homologous serum jaundice, and the section says this:

"This complication appears 40 to 120 days in up to 10 per cent of persons receiving transfusions of

'large pool' plasma, and in 2-3 per cent of persons receiving 'small pool' plasma, and should be report ed immediately to the Regional Transfusion Officer. The jaundice is due to hepatitis thought to be caused b a virus, and may be fatal. *Plasma should not, therefore, be used unless the benefits to be gained by the transfusion outweigh the risk of transmitting homologous serum jaundice.* This complication may very occasionally follow the transfusion of whole blood.

So, sir, you will have noted that the bold text at the beginning of the handbook relates to plasma and, here, in relation to jaundice, it's only mentioned that whole blood may vary occasionally, g ive rise to jaundice.

SIR BRIAN LANGSTAFF: At this stage, do we know what "small" meant in relation to "small pool"? Because my general understanding had been that it meant not ve ry much more than single transfusions somewhere betwee nought and ten.

MS FRASER BUTLIN: Yes, sir. I recall reading the pool size. Let me see if I have flagged it, and if not I will need to look at it over the break. I can't immediately locate it in this document.

SIR BRIAN LANGSTAFF: The question arises in my mind because, if the risk is very similar to the risk of

single donor donation, and it is here singled out for special mention, why should it be only very occasionally that the complication would follow the transfusion of whole blood?

MS FRASER BUTLIN: Indeed, that's certainly something you would need to consider. The logic doesn't entirely flow.

SIR BRIAN LANGSTAFF: It depends, really, what "small" is in "small pool".

MS FRASER BUTLIN: It does. And my apologies, sir, I can't instantly place it, but I will look over th break.

SIR BRIAN LANGSTAFF: Thank you.

MS FRASER BUTLIN: That's the specific section on jaundice, but I want to track back in the document in relation to the use of transfusion. So could we tu rn back to page 6, please. We see the heading "Volume and Rate of Transfusion", and if we pick up the number (1), which addresses severe injury or acute blood loss, it says:

"In the presence of severe injury or acute blood loss, the rapid and adequate restoration of the blo od volume is the immediate aim, and sufficient blood (or where sufficient blood is not available, plasma and blood in ratio 1:2), to raise the blood pressure to at

least 100 mm Hg should be given. *In the previously healthy* patient, a rate of 100 ml/minute will usually be tolerated ..."

And then it goes on to the matter of the speed of the transfusion.

Then if we turn the page, we see a heading in relation to treating anaemia, and it addresses primarily the rate of transfusion. But then we see this in the final paragraph of the section:

"*Ideally, no major surgical procedure should be carried out unless the haemoglobin is within normal limit*s. Pre-operative transfusions for anaemia should be given an adequate time before operation to allow the full benefit of the transfusion to develop and to avoid the possibility of a reaction during operation."

And it's the phrasing there, sir, that I would want to highlight, that surgery is indicated -- it should not be carried out "unless the haemoglobin i within normal limits". That's a theme we will pick up through the documents: the level of haemoglobin tha is required before surgery or, indeed, that post-labour, in the obstetric context, transfusions are required.

So here, in 1949, it's indicated as needing to be within normal limits.

If we then carry on to page 13, we pick up the heading "Transfusion Records":

"A record of every transfusion should be made, preferably in the patient's case notes AND on the special card or form (NBTS 11) attached to the bott le.

"Such records should show:

"*Serial numbers of bottles of blood and plasma.* The recording of these numbers must never be omitte d, since they may be the only means of tracing and checking a donor's blood if there is any question o incompatible transfusion, or homologous serum jaundice. The latter occurs 40-120 days after transfusion of plasma or serum or, rarely, of blood and ..."

And again, sir, it's that reference to "rarely, of blood".

"... and it is not only important to be able to trace the donor bearing the infective agent, but al so to be able to trace and withdraw other bottles of t he same icterogenic batches of plasma or serum. Only by the careful and invariable recording of serial numb ers on bottles of transfusion fluid can this be accomplished. All cases of homologous serum jaundice should be reported immediately to the Regional Transfusion Officer. The necessity of accurate

recording is not yet fully appreciated."

Then we pick up at the bottom of this page:

"Every hospital should keep a record book showing the following details of blood transfusion and plasma. Whenever possible the hospital transfusion officer should keep this record; in hospitals havin no transfusion officer it should be the duty of a responsible person.

"The book should show:

"(i) Date of transfusion.

"(ii) Full name of recipient."

And then in (vi):

"The serial number of each bottle of plasma or serum transfused."

So that was the guidance produced in 1949 for all -- or seemingly given to all house officers, th most junior qualified doctors at that time.

What is not present in this booklet is any reference to matters of consent from or information to be provided to a patient. Given the date of the booklet, that may be unsurprising, and its absence may chime with other evidence the Inquiry has heard abo ut the nature of the doctor-patient relationship at th at time.

We then have the 1954 edition of the *Notes on*

Transfusion. I'm not going to go to it, but for the transcript the reference is DHSC0200153.

In that edition, the guidance on pre-operative transfusions has been amended and it's noted there that surgery should not take place unless a patient's haemoglobin is at least 10.4 grams, rather than the phrase "normal limits".

The 1954 edition retains the requirements to record transfusions that are given but the bold tex warning of the risk of jaundice and advising that plasma should not be used unless the benefits outwe igh the risks does not appear in the 1954 edition.

The discussion on jaundice is also shortened and simply highlights the need to report cases of homologous serum jaundice, together with the serial numbers, to the Regional Transfusion Director.

I want to then pick up and look at a book written by Mollison called *Blood Transfusion in Clinical Medicine*. We're going to return to various editions of this book to consider what was written. It's the Inquiry's understanding that this was one of the core texts of the time dealing with transfusion in clinical medicine.

The reference is RLIT0001567, please. If we can turn to page 10, please. Hopefully it will turn,

there we go. We're the right way up.

This the preface of the book. It doesn't specifically address transfusion transmitted infection at this point in the preface but it perhaps gives some insight into how blood transfusion was viewed by clinicians. The preface says this:

"Blood was once regarded as a fluid of infinite complexity, the very essence of life. The blood of each person seemed to carry in it the secrets of individuality."

Then in the next paragraph --

SIR BRIAN LANGSTAFF: I think you should follow on, just for the sake of it, "As recently as".

MS FRASER BUTLIN: "As recently as 1666", which doesn't seem terribly recent compared to 1951:

"As recently as 1666 it was natural for Mr Boyle, in writing to Dr Lower, to speculate in the following terms about the possible effects of cross-transfusion: '... as whether the blood of a mastiff, being frequently transfused into a bloodhound, or a spaniel, will not prejudice them in the point of scent'."

Sir, the point I was actually going to pick up was the next paragraph:

"If each person's blood were as individual as

this, transfusion would indeed be complex and would deserve to rank as the most refined branch of medicine. However this early view of the subtlety of transfusion was eclipsed at the beginning of this century by the discovery that the blood of all huma beings could be divided into four groups. It seeme that, provided blood of the same group was transfused, one person's blood was indistinguishable from another's. Indeed, it came to be believed that people who belonged to the common group O could give their blood to anyone whatsoever. This point of view reached its widest acceptance in the early 1940s, when hundreds of thousands of bottles of group O blood were given as a general panacea for the injuries of war, with remarkably satisfactory effects. As a result of this experience, a generation of medical men has grown up believing that blood transfusion is one of the simplest forms of therapy.

"And yet, this view of the interchangeability of blood has to be reconciled with the growing knowledge of its immense complexity."

Then if we turn the page, there's then an explanation of the book's purpose and we pick it up in the second paragraph -- sorry, the next page, second paragraph, my apologies:

"This book is thus composed mainly of an account of blood groups from a clinical point of view and o descriptions of the effects of transfusion on the circulation and of the survival of transfused red cells; it also contains chapters designed to fill i the remaining background of knowledge about the results of transfusion in man."

Sir, I just wanted to highlight that view from the preface and the linkages between the understanding in relation to blood, linked to the effect in the war of having substantial quantities of group O., and the suggestion here that there was a generation of medical men, as it puts it, believing that this was a simpl form of therapy at that time.

If we then carry on into the book, page 48, please. We see the heading "Transfusion and Anaemia". Bearing in mind the date of this book is 1951, we see this:

"As a general rule, transfusion should be used as a method of treating anaemia only when the anaemia cannot be cured by the administration of iron, live or other haematinics."

The separate question -- acute haemorrhage is dealt with separately:

"It must never be forgotten that transfusion

carries risks which are large compared with those o conservative treatment."

So, as early as 1951, in relation to the treatment of anaemia, Mollison's text is indicating that great care should be taken.

Later in the book, I won't take you to it, sir, unless you'd like to see it, there is a discussion of the risk of homologous serum jaundice and that risk is noted.

In the second edition of Mollison's textbook, published in August 1956, the same warning is given against using transfusion to correct anaemia, as is the warning given of the risk of homologous serum jaundice.

An additional note is provided in relation to the appropriate treatment of acute haemorrhage and I'd like to turn to that. The document is RCPE0002067, please, page 52, please. We can see from the top right of the page that we're in a chapter headed "Haemorrhage and Transfusion", and it's the other half of the page, please, Sully.

Under the heading "Restoration of Blood Volume by Transfusion", this is what's written:

"Blood volume can be rapidly restored by giving blood, serum, plasma, albumin or some other plasma

substitute."

Then it addresses the use of transfused red cells and, at the bottom of this half of the page, it says this -- there's a discussion about the studies which have dealt with the bleeding of dogs to establish the relative relationship between blood volume and restoring blood volume. Then it says this:

"However there can be little doubt that it is a disadvantage to allow the circulating red cell volume to fall below a certain level. In acute experiments in dogs Case, Berglund and Sarnoff (1955) found that when the packed cell volume was lowered from 49 to 32 there was no depression of ventricula function but that when the packed cell volume was lowered to between 24 and 31, there was a definite depression, probably because at this level coronary vasodilatation was already maximal. Clinical impressions suggest that haemoglobin concentration should not be allowed to fall below 9 [grams per] 100ml, (Grant and Reeve, 1951). Evidently this is a minimum. The ideal should be to replace approximately as much whole blood as the patient ha lost.

"A further reason for using blood rather than plasma in patients who have been traumatised is tha

the patient is less likely to develop a severe degree of anaemia subsequently."

It's a little unclear, sir, how a patient would develop a severe degree of anaemia subsequently or whether they would simply have a degree of severe anaemia, which hadn't been corrected.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: But the point here is this reference to haemoglobin concentrations shouldn't be allowed to fall below 9 but the aim was to replace the full blood volume lost. We then return to the *Notes on Transfusion* document, and the 1958 edition, WACAS00000008, please -- 0000008, apologies. Thank you.

We see, sir, it's very much the same format:

"Issued by the Ministry of Health in Association with the Department of Health for Scotland for [both] the National Blood Transfusion Service and the Scottish Blood Transfusion Service."

Then if we turn to page 3 please. We have the left-hand page:

"This edition of *'Notes on Transfusion'*, like the two previous editions, has been prepared by the Committee of Regional Transfusion Directors of the Ministry of Health. The booklet is intended primarily

for use by medical staff of hospitals and its purpose is to describe briefly some of the principles of th practice of transfusion and to suggest procedures; it is not intended that the booklet should supersede already established local practice and procedures without the agreement of those concerned."

So two points arise, sir. Firstly, that the booklet is now not only, it seems, for house officers, but for medical staff more broadly and, secondly, the suggestion that it shouldn't supersede established local practice, unless everyone agrees to do so.

Then we turn to the second half of the page:

"Transfusion therapy should be undertaken only after careful assessment of the patient's clinical condition to determine the nature and quantity of fluid to be transfused and the rate of administration. The patient may require whole blood, concentrated red cells, or plasma. A transfusion should never be given without a definite indication; not only is this in the patient's interest but supplies of blood are not unlimited and with the ever-growing demand for bloo it is imperative that it is not used unnecessarily.

Then if we turn to page 6, in the italics halfway down the page:

"Preferably, no major surgical procedure should

be carried out unless the haemoglobin is at least 10.4g per cent (70 per cent Haldane).

"If the haemoglobin level cannot be restored by appropriate medical treatment, pre-operative transfusions may have to be given."

And that is the recommendation that's retained from the 1954 edition.

Then if we turn on to page 9, "Transfusion Records", we see the same first sentence as the previous edition:

"A recording of every transfusion should be made in the ... case notes AND, if issued, on the specia card ..."

And then this addition -- sorry:

"It is not always appreciated that the main reason for accurate recording is the protection of the patient."

We'll come back to a textbook from 1960 but whilst we're thinking about these *Notes on Transfusion*, it's worth noting that in the 1963 update to the *Notes on Transfusion*, an addition was made to that first paragraph that careful assessment was required before a transfusion should be given, and it states this:

"The use of transfusion to correct moderate or

slight degrees of anaemia that could be overcome as effectively, if more slowly, by other means seems unjustifiable, unless some cogent reason for speed of recovery exists. In some instances, failure to institute simpler and safer but equally effective treatment earlier leads to the quite unnecessary us of blood transfusions."

Just for the purposes of the transcript, the reference for the 1963 edition is JPAC0000162_021.

Sir, at the moment the written presentation that's been disclosed doesn't include that reference. It was missed. We will correct it and re-upload th written presentation to make sure that that referen ce is available for anyone who wants to look at that further.

If we then turn to the -- sorry, in fact, we're not going to turn it up, I'm simply going to read something from it -- Dr Discombe's textbook, *Blood Transfusion: A guide to the practice of blood transfusion within hospitals*. We have the second edition from 1960. We are seeking, sir, to obtain the first edition to identify if there is anything significant but for various reasons we have not managed to get hold of the first edition yet.

The second edition is 1960. Dr Discombe

emphasises that hepatitis is a very important dange and must never be forgotten when assessing the need for transfusion. He also addresses the use of bloo to correct pre-operative anaemia, and he states:

"There is one very common use of transfusion which, to my mind, is inexcusable: the use of transfusion to raise the haemoglobin of a patient just before operation when, in fact, the anaemia is due to chronic blood loss and could have been corrected by pre-medication with iron. This is very common in gynaecological work, especially in the management o patients with menorrhagia caused by fibroids. In m opinion, every woman placed on a surgical waiting list should be treated with small doses of iron."

For the transcript, that textbook is at RCSE0000002.

I want to move on then to an article published by Dr Jean Grant, director of the Oxford Regional Transfusion Centre, published in The Practitioner i August 1965.

Could we have PRSE0003897, please, Sully.

It's an article headed "Complications of Blood Transfusion", and in her first paragraph, if we can just go down a bit, it says this:

"We have learnt how to avoid or minimise most of

the unpleasant ..."

Oh, we'll just give that a moment.

I don't think we're going to manage to get any closer to it, so I hope people can read it on the screen. I'll try again.

"We have learnt how to avoid or minimise most of the unpleasant general and local effects but it can not too often be reiterated that the safety of transfus ion can be maintained only so long as there is a strict organisation of blood-banking technique and unceasing watchfulness on the part of all who have a hand in the preparation of apparatus, and the collection, storage, recording, labelling, matching, transporting and giving of the blood."

The article then addresses a variety of complications of transfusions and the possibility o infection with hepatitis.

And then in her conclusions -- page 8, please, Sully -- Dr Grant says this, in her "Conclusion":

"The practitioner should satisfy himself that it is really necessary to give blood and that no other treatment would be equally efficacious even though it might take a little longer to achieve results. He might even benefit his patients by occasionally having the strength of mind to make the unfashionable

decision not to transfuse. The hitherto healthy patient can well afford a one-pint (0.5 litre) haemorrhage without replacement -- after all, as pointed out by Chassar Moir, the blood donor himsel lost a pint without anybody feeling that he ought therefore to receive a transfusion."

We return then to Mollison's *Blood Transfusion*, this time we go to the fourth edition published in 1967. We won't go to the book because the key poin ts I want to highlight are spread throughout the book but, for the transcript, the reference is RLIT0001570. There are four points to highlight from the textboo k.

Firstly, Mollison indicates that patients with severe anaemia, as a result of recurrent haemorrhag e, have to be transfused, unless it's reasonably certa in that there will be no further haemorrhage.

Where patients have had haematemesis and whose haemoglobin falls to 7 to 8 grams per 100 millilitres, transfusion is recommended. So that's in the conte xt of recurrent haemorrhage.

Secondly, he indicates in pre-operative situations, it's said that haemoglobin should be raised above 10 grams per 100 millilitres and, ideally, to within normal range, which would be 12.5 grams per 100 millilitres for women and

13.5 grams per 100 millilitres for men. But the book also emphasises that many pre-operative transfusion could be avoided if it were a routine practice to determine a person's haemoglobin concentration at the time when operation is first considered, as there would then, more often, be time to treat the anaemi with iron, et cetera.

Thirdly:

"In situations of haemorrhage the recommendation is that clinical impression suggests that in injure patients the haemoglobin should not be allowed to fall below 9 grams per 100 millilitres. Evidently, this is a minimum, the ideal should be to replace approximately as much whole blood as the patient ha lost."

We've seen that recommendation before, in earlier editions. Fourthly:

"Serum hepatitis is noted as one of the unfavourable effects of transfusion. It's noted to be a virus with a long incubation period, and a wide spectrum of clinical effect."

We will, though, then turn up the fifth edition of Mollison's book, RLIT0001573. It was published in 1972. If we can turn, please, to page 30, we see the heading "Indications for the Transfusion of Red

Cells", and the subheading "Relatively acute situations":

"*Anaemia produced by a form of haemorrhage likely to recur*

"Patients who have developed severe anaemia as a result of recurrent haemorrhage have to be transfused ..."

So that's very much the same as the 1967 edition.

"... unless it is reasonably certain that there will be no further haemorrhage. It is most undesirable to allow such patients to become severely anaemic and for this reason patients who have recently had haematemeses and whose haemoglobin is as low as 7-8 [grams per] 100ml should be transfused."

Then, under the heading "Pre-operative transfusion":

"There is evidence that when the PCV falls below about 30%, corresponding to a haemoglobin concentration of about 10 [grams per] 100ml, there is some interference with cardiac function. Therefore before surgery is undertaken the haemoglobin should raised above this level, even if only trivial haemorrhage is expected.

We have then the same recommendation as I noted

from the earlier edition that pre-operative transfusions could be avoided if it was routine to check haemoglobin well in advance.

If we then go on to page 82, please, we are picking up in the chapter on transfusion in oligaemia. "Restoration of Blood Volume by Transfusions or Infusions", it starts in this way, it's just below that:

"In the treatment of haemorrhage it is evident that a point must be reached where the number of re cells remaining in the body is so small that only whole blood can restore the patient. Nevertheless, in treating lesser degrees of haemorrhage restoration of circulating blood volume alone is highly effective.

Then, over the page, we pick up on the top left corner "Minimum acceptable haemoglobin level". We have the same words as before in relation to the coronary vasodilatation, and the clinical impressions of haemoglobin not being allowed to fall below 9 grams per 100ml. Then this addition:

"Similarly, it has been concluded that losses equivalent to 20-30% of the blood volume, (ie 1-1.5 litres in a normal male adult) can be replaced effectively with erythocyte-free fluids such as dextran."

That is the guidance or the textbook indications from 1972. We then turn to the *Notes on Transfusion* again, and the 1973 and 1975 editions. The written presentation erroneously states that these notes were produced by the DHSS and Welsh Office, and not the Scottish Home and Health Department. In fact, both editions were published by the DHSS, the Welsh Office, and the Scottish Home and Health Department and a correction will be made to the written presentation in due course.

If we can have a look at those, if we pick up HCDO0000861, please. We're picking up the 1973 edition, and if we turn to page 3, we see the same introductory note that was on earlier editions.

Then if we turn to page 4, we see at the start of the booklet the same recommendation to take a cautious approach, and the same warning in bold, that there needs to be a definite indication for a transfusion, and that the use of transfusion to correct moderate or slight degrees of anaemia, that could be dealt with more slowly, would not be justifiable.

Then if we move forwards to page 11, towards the bottom of the page in italics we have the same recommendation in relation to surgery, the need for

a haemoglobin of at least 10.4.

Then if we turn to page ... sorry, my notes are illegible -- page 18, sorry, we see the amendments that are made in this edition. Under the heading "Transfusion Records", we have the same wording:

"A record of every transfusion should be made in the patient's case notes in addition to the details recorded in the transfusion laboratory."

But in this version -- in this edition, I should say, this text is in bold. Whereas before it wasn't. Perhaps suggesting that this recommendation had not been consistently followed and they were trying to draw this to people's attention even more.

If we then carry on to page 23, we see a more substantial treatment of serum hepatitis, and obviously a change in what is said about it. If I might just read that:

"Although the rejection of blood donations giving positive tests for the presence of Australia antigen or its antibody diminishes the risk of transmitting hepatitis, the methods of screening at present applicable do not detect antigen or antibod in every instance. Until more sensitive methods ca be used routinely, the transmission of hepatitis will therefore continue to be a risk associated with the

use of blood, concentrated red cells, platelets, fresh frozen plasma, cryoprecipitate, dried plasma, human antihaemophilic globulin, Factor IX concentrate, fibrinogen and thrombin."

Then at the bottom of the page --

SIR BRIAN LANGSTAFF: Just go on for a moment. Go back.

MS FRASER BUTLIN: "Human plasma protein fraction and human albumin are rendered non-icterogenic by heating at 60ºC for 10 hours; human immunoglobulin prepared by ethanol fractionation is not icterogenic."

SIR BRIAN LANGSTAFF: Thank you.

MS FRASER BUTLIN: Then at the bottom of the page:

"Cases of serial hepatitis, together with the serial numbers of the containers of blood and blood products involved must, as already recommended, be reported immediately to the Regional Transfusion Director so that donors can be investigated and any unused materials of the same batch may be withdrawn."

Once again, sir, you can see that it is in bold, to draw -- perhaps to draw attention to the requirement to report cases of jaundice.

I see the time, sir. There's just one more edition of Mollison that if I might take you to, sir, before we take a break --

SIR BRIAN LANGSTAFF: Yes, we can do that.

MS FRASER BUTLIN: -- simply because then it's a rather tidier place to pause.

Could we have RLIT0001569, please.

We're now in the sixth edition of Mollison, in 1979, and if we can turn to page 43, please. Apologies, I think I might have the -- sorry, it's not 43, it's 34.

We see, on the left-hand side of the screen that we're in, the part of the book dealing with indications for the transfusion of red cells. And if we pick up the next half of the page, we see the heading "Pre-operative transfusion", and there is this:

"There is evidence, from experiments on animals ..."

We've read this before, it's the same as earlier editions about the coronary vasodilatation.

"... that ... there is some depression of ventricular function ..."

Then it says:

"On the other hand, [oxygen] extraction, central venous PO2 and coronary sinus PO2 remain unchanged until the PCV is down to about 20%."

SIR BRIAN LANGSTAFF: Now, the "PCV", that stands for "packed cell volume", does it not?

MS FRASER BUTLIN: It does, sir, apologies. I should have made that clear, packed cell volume:

"It has been suggested that a [packed cell volume] of 20% or more is acceptable in patients undergoing surgery in civilian practice provided that cardiac, pulmonary, hepatic and renal function are normal and that there is a normal blood supply to the brain.

"Although most clinicians seem likely to continue to demand that their patients shall have a PCV of at least 30% before undergoing major surgery, it does seem that in healthy young adults, there is little need to insist on a higher figure."

So that's the change to Mollison in 1979.

I'm about to move on to some specific Scottish guidance from 1970s, so that probably makes it a good place to pause until we have lunch.

SIR BRIAN LANGSTAFF: Yes, well, we'll come back to that, shall we, at 2.05.

MS FRASER BUTLIN: Thank you, sir.

SIR BRIAN LANGSTAFF: So 2.05.

(1.05 pm)

(The Luncheon Adjournment)

(2.04 pm)

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Sir, you asked me a question about the 1949 *Notes on Transfusion* and the small pool plasma size. I knew I'd read it somewhere, I had. It's in the 1951 Mollison book, and if we can put that on the screen and just address that point straight away.

RLIT -- you're already there. Wonderful. Page 179. We pick it up under the heading "Homologous Serum Jaundice". The first part of it is familiar to us. Then the second paragraph and over the page:

"The transmission of the virus of hepatitis by the transfusion of pooled plasma at one time threatened to prevent altogether the use of plasma. When it is recalled that in one of the first series to be studied, (Morgan and Williamson, 1943) nine out of fifty patients receiving a plasma transfusion later developed an illness lasting three to twelve weeks, the seriousness of the problem can be realised. At first it was not clear that the pooling of large numbers of plasma samples played an important role in the incidence of the disease. Later, when this was realised, small pools were prepared and the incidence of hepatitis was greatly reduced. Lehane and others, (1949) have reported the following figures for the incidence of homologous serum jaundice: after whole

blood, 0.8%; after transfusion of small-pool plasma, (derived from not more than ten donors), 1.3%; afte large-pool plasma (derived from not less than 300 donors), 11.9%. The use of large-pool plasma has, of course, now been abandoned. In the series of Lehan and others the incidence of jaundice after the transfusion of small-pool plasma was not significantly greater than that following the transfusion of whol blood."

SIR BRIAN LANGSTAFF: Presumably by "significantly" there, it means scientifically --

MS FRASER BUTLIN: Indeed, sir, indeed.

SIR BRIAN LANGSTAFF: -- significant? So it was isoclinally *(unclear)* significant. So the actual figure is potentially greater but we don't know really by how much, with accuracy.

MS FRASER BUTLIN: Not with accuracy. The figures are from 0.8 per cent up to 1.3 per cent and then not more than ten donors, so we can't say more than that.

SIR BRIAN LANGSTAFF: But it leaves it rather -- the justification for saying "rarely" or "occasionally" in the case of whole blood and yet regarding small-pool plasma as a real risk, is not entirely clear, given that material.

MS FRASER BUTLIN: It doesn't appear to be consistent at

all, sir. And the other thing I double checked was that the Lehane and others study is indeed a Britis study, rather than anything else.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: And it is; it's a study published in the British Medical Journal.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: I can locate a reference, sir, if you --

SIR BRIAN LANGSTAFF: There was a reference made to that in the course of the recent evidence we've heard.

MS FRASER BUTLIN: There was, exactly. But this is where we have the figures from small pool plasma, and in the Lehane and others paper it makes it clear that the numbers of donors within a small pool plasma pool are derived from the Ministry of Health, so they're not just randomly drawn; they are specific figures.

SIR BRIAN LANGSTAFF: Yes, thank you.

MS FRASER BUTLIN: In which case, sir, I'll pick up where we left off just before lunch, which is to look at some specific Scottish guidance in the 1970s.

In 1971, 1972, Dr John Cash, at that time deputy director of the Edinburgh and South East Scotland Blood Transfusion Service, wrote in the proceedings of the Royal Society in Edinburgh about the principles of

effective and safe transfusion.

The reference, just for the transcript, is PRSE0002637.

He noted that 80 per cent of all donations used in Scotland during 1971 had been given in the form of whole blood. He suggested that the Blood Transfusion Service had seen no clear necessity to conserve the plasma that would otherwise have been available fro the same donations, that most regional centres, he said:

"... are so isolated from the bedside, it has been difficult to encourage effectively the use of cell concentrates and, of much less significance, our clinical colleagues have on occasion been somewhat reluctant to use this product."

Having addressed the risks of hepatitis, Dr Cash suggested that a much more conservative approach to blood transfusion by clinicians could make a significant impact on the incidence of post-transfusion hepatitis.

The themes in the paper published by Dr Cash then appeared in a document called A Scottish New Blood Transfusion Policy, drafted in 1975, which we'll turn to. SBTS0003061_001.

If we turn across to page 2, the introduction

reads as follows:

"With the commissioning of the new Scottish National Protein Fractionation Centre here in Edinburgh our clinical colleagues in Scotland will, for the first time, have access to a whole range of therapeutic products hitherto largely unavailable. It is now apparent that the rate limiting factor which will prevent the realisation of this goal is the serious shortage of raw material -- plasma. In response to this challenge we have already set in train plans to increase the number of donations we will collect by a factor of 10,000 per annum (a difficult task for an already fully stretched region). At the same time we introduced a new transfusion policy designed to collect increasing amounts of plasma from our existing input -- the policy is one of a dramatic increase in the use of red cell concentrates rather than whole blood."

If we turn the page, we see that policy.

"For patients not bleeding acutely.

"We believe it is in the individual patient's interest (see notes) that he or she should always receive red cell concentrates rather than whole blood."

"2. For intra-operative or acutely bleeding

patients.

"The first two units of blood issued for all requests will AUTOMATICALLY [and there's a star] be red cell concentrates [then there's a circle]. Further requests for the same patient in the succeeding 24 hours AUTOMATICALLY be met by whole blood."

We see there three points that are then dealt with below:

"This ruling can be over-ridden by any member of the clinical staff provided instructions are received by telephone. The occasions when this is likely to be desirable will be very rare.

"It is suggested that those patients in whom the clinician is concerned to 'make good' the volume deficit of 2 units of red cell concentrates (less approximately a total of 350ml of plasma) can best be managed by running in 600ml of Ringer's Lactate Solution."

The point about it being automatically whole blood that's provided in succeeding 24 hours, the note is this:

"This will be automatic and thus be the responsibility of the Blood Bank staff."

Then if we go over the page to page 5, please.

We see at the bottom of the page a note on the advantages of red cell concentrates:

"Greater oxygen carrying capacity ...

"Reduced exposure to sodium, potassium ammonia and hydrogen ions ...

"Reduced exposure to foreign plasma proteins, platelets and leukocytes ...

"Reduced exposure to isoantibodies ..."

Over the, page number 5:

"Reduced incidence of post-transfusion hepatitis."

Then, under the heading "Attention", on the same page:

"Please remember that attempts to 'make-up' the 2 units of red cell concentrates with reconstituted pooled dried plasma rather than Ringer's lactate (o any other appropriate crystalloid) will not only defeat the purpose of our policy, but expose the patient to a hepatitis risk as much as 30 times tha of a single donation."

A similar approach can be seen in the paper by Major General HC Jeffrey, National Medical Director of the Scottish Blood Transfusion Service, titled "Modern Transfusion Practice". For the transcript, that's DHSC0003738_045.

He emphasised that the:

"... modern approach to transfusion must be to give the patient only those components of blood which he lacks, thus eliminating to a very considerable extent sources of reaction, infection and sensitisation and enabling optimal use of the blood collected."

That's where we complete the story up until the end of the 1970s. As I said to beginning, sir, perhaps one of the most striking features of that period is the very limited amount of guidance that was available through those years, especially as we now move forwards and see rather more.

If we pick up in the 1980s, in 1982, in the Department of Health's Health Services Division 1, HS1, tasked the Central Management Services to stud the existing controls on the movement of blood. We have a report of the CMS, that's at DHSC0002221_011 please.

If we can then turn to page 5, please, Sully, we have the heading "Origin of the study" giving us th context:

"Recent enquiries and investigations into the use of blood and blood products highlighted the inadequacy of records kept to control the movement of

blood from collection to transfusion or disposal. As a result Health Services Division 1 (HS1) asked Central Management Services to study the existing controls and recommend suitable procedures so that they might issue revised guidance to Health Authorities.

"Some doubt was raised about the ability to trace a donation from collection to transfusion or disposal and for the following reasons the Department wished to rectify the situation:

"Medical -- a trace between donor and patient is needed to inform either party should any previously undetected illness emerge;

"Accountability -- blood and its components, in particular plasma protein fraction (PPF) and Factor VIII, constitute a valuable resource and an adequate stock control is required;

"Level of unused whole blood (time-expired) -- although blood products are produced from time-expired blood, the return rates of such blood run at an average of 13% and Ministers have expressed concern about this continuing high level."

If we turn to page 8, please, we see under the heading "Findings", the extent of the survey:

"Findings in the report are confined to the

5 Regional Centres and associated hospital blood banks of which 16 were NHS units and 3 privately run. In addition 2 private hospitals which used the Regiona Centre as a blood bank for supplies and all cross-matching are included."

If we go on to page 12, please, we see the results of the survey at a hospital level, paragraph 40 and 41:

"Twenty one hospitals featured in the survey and of these 5 were privately run 2 of which did not hold a supply of blood. Eight contained haemophiliac wards or clinics. Appendix M shows the hospitals visited [et cetera]. In all the hospitals the Consultant Haematologist (or Pathologist) was considered accountable and responsible for the activity in blood banks, but of the MLSOs interviewed more than half stated that responsibility for managing the stocks, supplies and issues of blood and its products was delegated or left to them.

"Twenty one variations on stock control and record keeping were identified. Considered in broa terms each hospital was offering the same service, achieving differing degrees of success, but their systems had developed over the years and were used by many different people. Most systems had not been

subjected to scrutiny prior to this study and to change them would cause widespread confusion which could not be justified provided the essential minimum controls are present."

If we turn on to page 14, under the heading "Control of stock, Blood":

"The day to day management of stock required flexible practices by the MLSOs who found it easier with experience and knowledge of how the medical staff used the supply. It was said that greatest demand for blood originated from surgical and maternity units where blood was ordered to cover emergencies but no necessarily used. In contrast, medical patients' needs were more predictable and most of the blood requested was actually used."

If we pick up paragraph 51:

"Most people accepted that the stock control and wastage rates in the use of blood were partly, if not largely, influenced by the policies of the medical staff, particularly surgeons, using the blood. It is a clinical decision whether and what to transfuse. Everyone respects this fact yet they readily agreed that there were economic considerations which could be bought to bear on the use of blood and its products without endangering the patient. Some hospitals

visited had gone a long way towards setting up a dialogue with the medical staff which encouraged economical ordering of goods, supported very positively with the back up facility to provide the in cases of emergency. In the hospitals achieving success in this field the Consultant Haematologist was a key figure. He, supported by the necessary statistical information from the blood bank, had th authority to ask his medical colleagues to reconsider their clinical practice."

That role of the consultant haematologist with statistics is something that crops up in later documents as well, and we'll see that as a subtheme through this.

If we can then carry on to page --

SIR BRIAN LANGSTAFF: Well, thus far, just -- I was fascinated by the fact that 21 hospitals are looked at, and each of them appears to have a different system.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: 21 hospitals, 21 systems.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: So no one system would cover all and you couldn't -- what general lessons were learned?

MS FRASER BUTLIN: In terms of?

SIR BRIAN LANGSTAFF: The overall view as to what were guiding principles, if there were any, as to stock control and use of blood?

MS FRASER BUTLIN: There's more of the document I want to take you to, sir, so perhaps I can do that and then if I still haven't answered your question, then I can look again.

If we could turn on to page 18. Some very specific recommendations were made at the end of this report but before we get to them I want to just set a few things up. Page 18, record keeping, paragraph 70s and 71.

"The guidance issued by the Department in 1964 and 1975 suggested that hospital blood banks keep a register to record the issue and fate [not just the issue of the blood but also the fate of it] of unit of blood and appropriate books have been made available from Centres."

Paragraph 71:

"The majority of blood banks first registered their supply of blood at the cross-matching stage when the unique number was recorded against the patient' name. Most MLSOs stated that control of blood by a register of units received on arrival in the bank and using the unique number and recording the fate of

each, would be too onerous and time-consuming to operate with current staffing levels. To trace individual units, it was considered less time-consuming overall to go through the records held mainly for other purposes, when a request arose, than to constantly record the destination of every unit from arrival to disposal. In practice requests from the Centre to trace a unit of blood occurred once or twice per year on average."

Then if we go over the page, paragraph 74:

"Underlying the recording systems at all blood banks was the assumption that a unit of blood had been transfused if it had been cross-matched for a patient and, either in a register or on a request or card, someone (in an official capacity) had signed for that unit of blood. What happened after the blood had left the fridge was considered to be out of the control of the blood bank staff and therefore someone else's responsibility to use or return."

Then in relation to blood returns, if we turn the page, paragraph 77:

"It was established that little information was kept at hospital level about returns to Centres ... and few records were found which recorded the disposal of unusable units or units which had been passed

elsewhere for testing or research purposes."

Then if we turn on to page 24, please -- sorry, page 22, apologies. The heading is "The recording of unique numbers and batch numbers in patients' notes":

"86. At the end of the chain in blood transfusion, the patient receives the blood and/or a component and in case there should be any transfusion reaction, or at a later stage if some defect is found in the items transfused, the recording of the issue of individual units or a batch product to recipients has great importance.

"87. In 19 of the 21 hospitals visited the unique numbers of transfused units of blood were recorded in patients' notes and were found either on the top copy of the request form, on which a signature or a tick indicated that a particular unit had been transfused, or on the intravenous treatment charts or the fluid balance charts. In one hospital a special stamp had been designed to imprint on the medical notes a series of boxes in which the numbers of transfused units could be entered. Records of the individual units of blood being transfused in those hospitals were therefore available in the patients' notes for the period those notes were kept."

Before I read the paragraph 88, just a note

there, sir, that 19 out of 21 had the records, but they were in locations like the intravenous treatment charts, so they weren't necessarily in the core clinical records of the patients; they were in extra parts of the medical records. And we know the Inquiry has heard evidence, sir, of struggles to find those documents, and it may be that that's explained some of it, that while there's a set of core clinical records available to somebody now seeking their medical records, they may not have the intravenous treatment charts where the blood transfusion would be recorded, when someone is going back to try and obtain their notes.

SIR BRIAN LANGSTAFF: And they might not think to look on the fluid balance charts.

MS FRASER BUTLIN: Well, indeed. Fluid balance charts either might not exist or somebody wouldn't think to look at them.

What this isn't telling us is that they're in the core medical records.

Then if we pick up, if I may, paragraph 88 on the same page.

"In most hospitals the nurses stated that during their training they had been instructed about the importance of the handling of blood and blood products

and nursing procedures seen at several hospitals were quite specific in instructing the nurses to record unique and batch numbers at transfusion. In theatre cases it was often the anaesthetists who transfused the blood and they were responsible for recording the issue and the unique numbers of the appropriate units."

We then go on to pick up the conclusions and recommendations which, sir, I hope will answer your questions to me earlier.

Page 24. We pick up under the heading "Regional Centres":

"99. The methods adopted at each Centre for supplying hospitals with blood and components varied. As a result systems at hospital blood banks showed a wider variation; they were based on the Centre's systems and had developed from that base."

"100. The different procedures and processes found amongst hospitals within the same Region showed that the Centres had little influence over methods of blood banking, issues, and supplies. Although the hierarchy in both are not related, and no accountability is strictly placed on the Centres for the management of supplies in hospital blood banks, the blood bank staff in each hospital could benefit

from an exchange of ideas through a central body. Should computerised record-keeping develop in hospital blood banks the need for co-ordination by Centres and for information to be exchanged becomes acute.

"101. It is recommended that Centres consider as part of their role a formal process to enable the exchange of ideas and good practice at operational level for hospitals to whom they supply substantial quantities of blood and blood products."

Then if we turn to the next page, the heading is "Record keeping".

"109. Recording at Centres where the fractionation of red cells and plasma produces several products was found to be comprehensive, complicated and possibly prone to transcription errors because of the length of the identifying numbers and the numerous records in which their entry was required. The computer systems seen, although not without their own problems, offered much in terms of accurate records easy tracing and regular statistics. Savings in staff time were not obvious but more immediate management information and easier compilation of them appeared to be benefits worth pursuing."

There's then a recommendation around duplicate delivery notes.

If we turn the page:

"113. Returns of blood received at Centres were recorded either by unit number and/or in volume per group. To aid the dialogue between hospitals and Centres in the event of tracing a particular unit, it would be helpful if all Centres could record, against records held for each hospital returning the blood, the unique numbers of the units received. (This would also serve as a security check if compared with records of returns kept at blood banks.)

"It is recommended that Centres record returns by unique number as well as volume per group for individual hospitals."

Then over the page, for the hospital level recommendations:

"123. In most places stocking the blood bank appeared to be governed more by experience than quantified managerial information. Although it is recognised that demand for blood and its products is very difficult to predict, information about past and future use was more readily accessible at this level. In some places a management information system combined with flexible ordering arrangements by those using blood and blood products had reduced the requirements at hospital blood bank level."

Then, further down the page, 127 and to the end of the page:

"127. The haematologists in charge of the blood banks were considered to be responsible for the services offered. Some were actively concerned with good management practice, most were not. They are best placed to influence usage of blood and blood products and should be encouraged to pay more attention to the economical management of the stock

"128. It is recommended that haematologists are reminded of their full responsibilities in the management of blood."

Then under the heading "Stock control: Blood":

"129. It is accepted that the stock control and wastage rates for blood are largely influenced by the policies adopted by the medical staff, particularly surgeons, using the blood. If efficiency is to be improved each bank must reconsider, with the users, its cross-matching policies and stock inventory levels."

Again, we see:

"The haematologist in charge of the bank therefore must feature in discussion about economie if it is to bear fruit."

Because they'll be more influential.

Then if we just turn over the page, we see a final recommendation I want to draw to your attention, paragraph 134, in relation to record keeping:

"134. It is recommended that to facilitate the tracing of units of blood, a chronological file of details showing patients' name, unique number of th units cross-matched and a signature for the removal of a unit from the blood bank should be kept. The decision whether this takes the form of a register to or a file of back copies of request forms should be left for the hospital blood bank to decide in light of their well established practice and evaluation ..."

In February 1983, the SNBTS directors published a proposal for modifications, and they recommended that Regional Transfusion Centres accept a formal responsibility for encouraging good practice in those hospital blood banks for which they're responsible for supplying blood and blood products, and that this should involve meeting at least annually to discuss transfusion practices in the hospitals, and that that meeting should be attended by representatives of th medical staff of the RTC, the Regional Transfusion Centre, haematologists, and consultants representin divisions of surgery, anaesthetics, paediatrics,

medicine, and obstetrics and gynaecology.

Sorry, sir, I've just lost a reference. If I can just have a moment.

The next reference I want to take you to, sir, is CBLA0001819.

We saw at the beginning of the CMS report that the purpose of it was to possibly then produce a health circular, and this document is what we've identified as the health circular that followed fro the CMS report. It's dated March 1984, and we can see its summary as:

"This Circular asks health authorities to review arrangements for the supply of blood and blood products, and to review concurrently record-keeping and stock control arrangements in Regional Transfusion Centres (RTCs) and hospital blood banks. Its contents have been endorsed by the Advisory Committee on the National Blood Transfusion Service."

Then if we see paragraph 2, please.

"To facilitate a Regional review of policies, it is suggested that RMOs [regional medical officers] should convene regular meetings between their Regional Transfusion Directors (RTDs) and the consultants responsible for the hospital blood banks in their Regions to consider matters such as current and future

requirements for blood, the scope for economies in blood usage, the proportion of plasma-reduced blood to be supplied, the use of ad hoc deliveries and the amount of stock which becomes time-expired in blood banks. Consideration should also be given to inviting the Central Blood Laboratories Authority (CBLA) to send representatives to these meetings so that thei requirements for plasma are fully taken into accoun in determining requirements. The meetings should also provide the forum for the exchange of ideas as to what constitutes 'good practice' in the Region with regard to blood supplies."

If we go over the page, paragraph 7:

"For medical reasons and from the point of view of accountability for a valuable resource, records kept at RTCs, hospital blood banks and at ward leve *must permit the tracing of any unit of blood from collection to transfusion or disposal*. Health authorities are asked to ensure that the systems employed at Transfusion Centres and hospital blood banks do so."

So we see the Health Service circular addressing the points raised in the previous report we looked at, or some of them.

We then return, sir, to Mollison, 1983 edition.

It's RLIT0001571. This edition retained its previous recommendation of transfusion for patients with recurrent haemorrhages and a haemoglobin of 7 to 8 grams per decilitre, and for pre-operative transfusion, where haemoglobin is lower than 10 grams per decilitre.

If we then turn to page 72, please, Sully, it's the right-hand side of the page. We see this under the heading "Post-operative transfusion":

"The practice of giving 'topping-up' transfusions post-operatively with the idea of bringing the patient's [haemoglobin] concentration up to an acceptable level is widespread but there are very variable opinions as to what constitutes an acceptable level. In healthy young adults it is difficult to justify transfusion at levels above 8 [grams per decilitre] since, when the anaemia is due solely to previous blood loss, the administration o ions in adequate amounts will result in the cure of the anaemia in a matter of weeks. On the other hand, with patients who have impaired cardiac for pulmonary function there may be a case for giving transfusion at lower levels of [haemoglobin], eg 10 [grams per decilitre].

"It has been shown that following operations

associated with marked post-operative haemorrhage a higher percentage of women than men are transfused, and it has been suggested that this is because there is a tendency to use the same level of haematocrit (or [haemoglobin]) in women as in men in deciding whether transfusion is required. There would be a substantial saving in blood if the normal difference in haematocrit between men and women were taken into account in deciding the need for transfusion."

The other aspect to note in this volume of Mollison is that there is no reference, that I've been able to identify, to HTLV-III or AIDS. That's a 1983 edition of Mollison.

We see the same point in the 1984 edition of the *Notes on Transfusion*, for the transcript it's PRSE0004766. We don't need to bring it up.

In the 1984 edition of the *Notes*, under the heading of "Complications and Dangers of Transfusion", reference is made to post-transfusion hepatitis and addresses the risk of both hepatitis B and non-A, non-B hepatitis. But, again, I've been unable to identify any reference to AIDS or HTLV-III.

SIR BRIAN LANGSTAFF: Do we know when in 1984 it was published?

MS FRASER BUTLIN: If you just give me one moment, sir,

I can double check. Sorry, sir, the text is rather small, which is why you can see me peering at my notes. It simply says, "Revised 1984". I can certainly go back and check whether we have a more specific date. But certainly, on the front of it, it simply says, "Revised 1984".

In 1984, the British Committee for Standardisation in Haematology of the British Society for Haematology published a report "Guidelines on Hospital Blood Bank Documentation and Procedures". That is NHBT0111389_001. If we turn to page 3, please:

"This document had been prepared by the Blood Group and Transfusion Task Force under the auspices of the British Committee for Standards in Haematology. Its purpose is to define minimum requirements for documentation in relation to blood transfusion. No attempt is made to prescribe the format in which the information is stored as experience has shown a very wide variety of record keeping systems in use in this Country. The principles on which the Task Force has based its recommendations are as follows.

"The patient identification must be unique.

"There must be a clear link between each stage of the procedure from the collection of the sample to

the connection of the unit of the unit for transfusion.

"That it be possible to trace every stage, the time at which it occurred and the individuals who were involved.

"The Task Force strongly recommends that, where nursing staff are involved in blood transfusion arrangements, a joint working party established to talk through and agree procedures so that there is total agreement of all staff involved in direct patient care."

If we turn the page, under the heading "Supply of Blood from the Transfusion Centre":

"Blood either whole or in component form is received in batches from the Transfusion Centre having been selected, grouped and screened ...

"It is essential that a record is available which shows the details of the units of blood received and the eventual fate of each unit. This may be kept as a register which is also used as a recording of the blood issued. Alternatively the information about each unit may be kept on a card relating to that unit."

So very much the same as the health circular.

Then if we turn on to page 8, please, in the

middle of the page:

"As stated above each unit of blood transfused should be recorded in the patient's notes on a special intravenous administration form."

It then goes through what should be recorded. Then:

"This document should form a permanent part of the patient record."

Then we pick up, in 1988, a document called the *Handbook of Transfusion Medicine.* It was produced by the NBTS and the SNBTS as a successor to the *Notes on Transfusion* that we started this presentation with.

NHBT0099310_002, please. If we could turn to page 3, please.

I'm very aware in this presentation that some of it feels rather repetitive, and that is because the documents themselves repeat very many of the same messages, and so we see -- in the preface to this handbook, we see:

"This handbook has been produced at the request of the Directors of the UK Transfusion Services, as a successor to the publication *'Notes on Transfusion*'. It is intended for use by medical and other health care personnel, as a source of information about blood component therapy and the clinical use of plasma

fractions."

Then on the other half of the page, please, Sully.

"WHO THIS BOOK IS FOR

"This book is for staff who are responsible for prescribing or administering blood products. It aims to give practical information about the composition and use of these products. A small number of problems account for most of the difficulties and dangers associated with transfusion, for example; delay in obtaining of compatible blood when the patient need it urgently, transfusion of blood which was intende for someone else, over-transfusion leading to heart failure, and viral infection from transfused products.

"This book is intended to help clinicians to avoid the avoidable risks and to explain those whic are unavoidable, so they can be taken into account when clinical decisions are made about transfusion for individual patients."

Then we move to look at some more specific guidance in this handbook. Page 19, please. Under the heading "Massive Blood Loss":

"This section refers to situations where urgent administration of blood is necessary for the patient's survival. The objectives are:

"i. intensive early treatment to restore circulating volume and avoid hypoperfusion. This i the key to avoiding late severe complications of shock.

"ii. control of bleeding and maintenance of adequate blood oxygen transporting capacity.

"Treat haemorrhagic hypertension promptly ..."

It then goes through the insertion of a cannula. It says:

"... infuse saline or a mixture of saline and a colloid volume expander as rapidly as possible unti an acceptable blood pressure is reached. After about 40% of the estimated blood volume has been in fused (30-35 ml/kilogram), 5% albumin can be introduced t comprise 50% of the total infusion volume."

At the end of this paragraph:

"Red cell concentrate or whole blood should be infused as soon as available.

"Hypovolaemia with low blood pressure and poor tissue perfusion is the patient's greatest enemy. The priority is to give any intravenous fluid quickly, and enough to maintain normal circulation. The restoration of haemoglobin level and the maintenanc of colloid osmotic pressure are normally of secondary importance."

If we turn the page, under the heading "Blood component replacement" we see at the end of that paragraph:

"As an alternative to stored whole blood, red cell concentrate together with fresh frozen plasma may be used but this exposes the patient to a greater number of donors, increasing the risk of virus transmission."

Then if we move on to page 21, we pick up the perioperative transfusion:

"Surgical and anaesthetic practice has tended to be guided by the belief that a haemoglobin level below 10g/dl (haematocrit below 30%) indicates a need for perioperative red cell transfusion. There is littl or no firm evidence supporting this belief and experience in recent years suggests that patients with severe anaemia may tolerate anesthesia and operatio without major morbidity or mortality resulting from the anaemia itself. Evidence from clinical and physiological studies does not support the necessit for the '10g/30% rule'."

Then the next paragraph, please.

SIR BRIAN LANGSTAFF: If you just go on, actually.

MS FRASER BUTLIN: Oh, apologies.

"Experimental evidence indicates that in healthy

humans cardiac output does not increase dramaticall until the haemoglobin falls below 7g and healthy anaesthetised primates survive a haematocrit down t 5% when breathing oxygen.

"The decision to transfuse red cells to an individual patient should take account of the duration of anaemia, the procedure to be carried out, the extent of likely blood loss, and the presence of co-existing conditions such as myocardial ischaemia, pulmonary disease, and cerebral vascular disease.

"As a guide, patients who are otherwise healthy with a haemoglobin of 10g/dl or greater, rarely require perioperative transfusion. Acute anaemia with a haemoglobin below 7g will generally require red cell transfusion. Some patients with chronic anaemia, such as those with chronic renal failure tolerate haemoglobin values below 7g and withstand anesthesi and surgery at this level. The decision to transfuse red cells will depend on clinical assessment and ma require laboratory data such as arterial oxygenation, oxygen extraction ratio and blood volume."

Then if we turn on to page 25, we pick up the situation of "Transfusion for patients with bone marrow failure":

"Treatment of leukaemia and other malignant

conditions may lead to periods of profound suppression of the bone marrow during which there is a fall in production of platelets, red cells, and white cells

"Because episodes of marrow failure may be repeated or prolonged there are special problems in providing transfusion support.

"Thrombocytopenia and platelet replacement: Bleeding in the presence of a platelet count below 50 x 10 [to the 9 per litre] will require platelet replacement. High doses (6 units twice daily or more) may be needed, particularly if there is concurrent sepsis or DIC."

DIC is disseminated intravascular coagulation, so it's a coagulation difficulty.

"To prevent bleeding, platelets are often given prophylactically to patients with marrow failure whose platelet counts fall below a predetermined level. This level may be set at 20 x 10 [to the 9 per litre] although some authorities advise a lower threshold (10 x 10 [to the 9 per litre]) for prophylactic use of platelets when the patient is not febrile."

Inevitably, sir, I've only picked out some of the specific scenarios that are addressed in the *Handbook*, and I've tried to do it on the basis of the broad spread of evidence the Inquiry has heard from

those who have been infected, so that the core -- the areas in which we know many people were infected are addressed but others who are interested might want to go back to that handbook and look at other scenarios that are picked up by the handbook.

The 1989 *Handbook of Transfusion Medicine* added a note that details of all blood components infused, including the donation numbers, must be entered into the patient's case record, together with the compatibility report provided by the transfusion laboratory.

In 1988, so at about the same time as the *Handbook* edition we've just looked at in some detail, *Guidelines for Transfusion for Massive Blood Loss* were published by the British Society for Haematology. It's NHBT0000037_013, please. We see in the introduction, this note:

"These guidelines have been prepared in an attempt to summarise current opinions regarding the management of massive transfusions and also to identify those areas where unjustified therapy should be curtailed. In this regard it should be borne in mind that many of the currently established transfusion practices are based more on benefits that are hoped for than those that have been proven. These

notes make no attempt to resolve the numerous highly contentious issues surrounding aspects of transfusion therapy in this situation."

Then if we turn on to page 6, please. Under the heading "Haematological Monitoring":

"Whenever possible, the investigations shown in Table 1 should be performed during massive transfusions. Both the absolute values and the direction of change of results must be considered as a guide to replacement therapy."

If we go over the page, please, we'll find table 1. We see the note of investigation and the target value. Haemoglobin, haematocrit, we see is 10 grams per decilitre or 0.32, for the haematocrit; platelet count greater than 50, times 10 to the 9; prothrombin time, less than 1.5 times control; and the same figure is given for the partial thromboplastin time; and then fibrinogen at greater than 0.8 grams per litre.

If we then look under the heading "Platelet concentrates", it tells us that:

"Platelet concentrates (1 pack [per] 10kg) are indicated for continuous (non-surgical) bleeding when platelet counts are below [50 times 10 to the 9] or are falling towards that value."

Then fresh frozen plasma, if we can go down to

that.

"Frozen plasma ... provides broad spectrum replacement for correction of coagulation abnormalities. Abnormal prothrombin and partial thromboplastin times ... should in theory provide the indications for treatment but in practice these tests correlate poorly with bleeding manifestations. It must also be accepted that although the use of FFP is widely advocated in this context there is still a paucity of objective clinical evidence that it is of any benefit."

If we go over the page, "Red cells (concentrates and optimal additive suspensions)":

"These will be adequate during the initial resuscitation phase but once the need for massive replacement is recognised it is more economical to provide whole blood."

Then under "Fresh whole blood":

"The place of fresh whole blood, (eg blood donated up to 24 [hours] previously but still fully tested) in modern transfusion practice is still vigorously contested ...

"There is no particular advantage to be gained by transfusing fresh whole blood in these circumstances unless the appropriate components are

not readily available."

Then we have the heading, just under this, "When to Give Components":

"For massive uncontrolled traumatic haemorrhage, maintenance of full haemostatic competence by means of component therapy may be unrealistic. In this situation the priority is for major vessel bleeding to be stemmed surgically. Combinations of stored whol blood, red cell concentrates, colloids and crystalloids should be used to maintain blood volum or pressure and haemoglobin or haematocrit values a [greater than] 7.0 or 0.25 [grams per decilitre] respectively. It is preferable to upon serve use o limited supplies of fresh blood, plasma or platelet until the haemorrhage shows signs of control."

Then in 1989 the British Society for Haematology produced *Guidelines on Hospital Blood Bank Documentation and Procedures*. For the transcript, the reference is AHCH0000053. The guidelines state tha the procedures for the administration of blood products should be agreed between medical and nursing staff, and should be implemented as part of a nursing Code of Practice. The recommended procedure included the requirement that each unit of blood transfused must be recorded in the patient's notes on a specia

intravenous administration form and in the continuation notes. This is important for medical audit, and it said:

"This document must form a permanent part of the patient record."

In 1989 a booklet was produced by the Clinical Resource Efficiency Support Team, Crest, of Norther Ireland, entitled "Use and supply of blood products in Northern Ireland".

It aimed to provide helpful practical advice to clinicians and boards. The booklet recorded specific recommendations, including that each clinician should review their prescribing policy for blood products in light of constraints on supply, that each acute hospital should establish a hospital transfusion committee to monitor and audit the use of blood products, and also promote good clinical practice b consultants and junior doctors.

Each health and Social Services board should establish a committee to monitor and audit the use of blood products by hospitals in their area, and the NIBTS should work together with representatives of clinical specialities to draw up regional guidance on the use of blood products in their particular area of expertise.

I want to move, then, on to some specific guidance for particular specialities during the 1980s.

Firstly, surgery. In 1984 the *Textbook on Surgery* was published and, for the transcript, the reference is NHBT0000114_042. In that text, it's noted that blood transfusion carries some risk and alternative methods should be chosen whenever possible. Anaemia is often better corrected before operation by prescribing oral or parenteral iron. The textbook notes that the most serious problem in relation to infection is that of serum hepatitis and, once again, I've been unable to identify any reference to AIDS or HTLV-III.

In another textbook in 1985, *Principles and Practice of Surgery,* the transmission of disease was noted. If we could turn to that, please. NHBT0000114_105, please. If we can turn to page 8, please. We see under the heading "Transmission of disease":

"Transmission of viral hepatitis remains the most serious and frequent complication of the administration of blood and blood products."

Then further down:

"The best preventative measure is to avoid unnecessary transfusions."

Then, at the bottom of the section that we have on the screen:

"Recent studies have indicated that blood donations and some blood products may rarely transmit an infectious agent which gives rise to the development of severe (often fatal) acquired immune deficiency (AIDS) in recipients."

Just turn the page.

"This problem is currently under intense investigation."

Then if we turn to page 10, please. We see the guidance given in relation to blood products and their clinical uses, "Blood Replacement":

"In acute haemorrhage, an average healthy adult can lose 500ml of blood rapidly without ill effect.

Then turn to the next page:

"Provided circulatory volume is maintained, with crystalloids and/or colloids, the loss of 1-2 litre of blood will not lead to irreversible hypertension

...

"The assessment of blood loss is difficult, particularly following acute haemorrhage. Measurements of blood volume are time-consuming and often inaccurate, particularly in anaemic and/or debilitated patients. Estimates of haemoglobin and

haematocrit are notoriously misleading when plasma and red cells are lost in the same proportion. Serial clinical observations of increasing pulse-rate, falling blood pressure, irritability, sweating, col extremities, intolerance to exertion, and frequent changing of posture are the best indications for blood transfusion in haemorrhage. Hasty action from a single clinical observation should be avoided unless additional information such as evidence of major internal haemorrhage into muscle or abdomen is available."

So it might be suggested that there is something of a changed tone in there is textbook, emphasising a little more the need for clinical observations, o it may simply be a different writer with a differen style.

Then if we look on to chronic anaemia:

"The risks associated with blood transfusion contraindicate its routine use for the use of chronic anaemia. Blood transfusion should only be considered when haematinics have failed."

A little bit further down:

"Although successful major surgery can be performed on patients with haemoglobin levels of less than 5g/dl with appropriate pre-operative transfusion,

many surgeons and anaesthetists still prefer an initial haemoglobin of 10g/dl before commencing an elective major operation. Provided surgical haemorrhage and pre-operative transfusions can be controlled and the pre-existing anaemia is asymptomatic a lower figure, eg 7g/dl, can be accepted."

In relation to malignant haematology, the British Society for Haematology published guideline on the care of adult patients with leukaemia and lymphoma and other disorders associated with severe borne marrow failure in 1986.

In relation to category 1 patients, those severely immune compromised, a high standard of supportive care was required, as almost half of patient deaths during induction treatment -- that's substantial chemotherapy treatment -- they were due to infection or bleeding. Therefore, the guidelines said:

"... because it is common practice either to transfusion six units of platelet concentrate each day to patients who are bleeding, or to give prophylactic platelet transfusions to patients with platelet counts below 20 x10 [to the 9], a plentiful supply of platelets should be available at all times, including

weekends and holiday periods. This supply should b held at the hospital blood bank, which should receive regular deliveries from the Blood Transfusion Service to replace platelets that have been used. The decision to use platelet transfusion for clinical bleeding or for prophylaxis will depend on local practice."

Sir, I'm about to move on to the 1990s. It's a little before our normal break but I wonder if it's a good time to pause.

SIR BRIAN LANGSTAFF: Yes, it probably is. So let's come back then, shall we, at 3.40. So 3.40.

(3.12 pm)

(A short break)

(3.39 pm)

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Thank you, sir.

We pick up in 1990. November 1990, Dr Napier prepared a second set of recommendations for the Institute of Audit within the NBTS. For reference, it's BCUH0000060 but we won't go to it. He indicated th at hospital transfusion committees was to have a range of disciplines on it, and was to focus on educational matters, audit and review, policy development, safety of transfusion, and review of proficiency assessment

performance.

The educational function of those hospital transfusion committees included an awareness of national guidelines for the promotion of good transfusion practice, development of local hospital guidelines, transfusion policy induction procedures for new staff, review of nursing procedures for the administration of blood products, promotion of important new information regarding transfusion matters, and ensuring that patients are adequately informed of matters that may concern them.

It was noted in his recommendations that hospital transfusion committees could have an overview function with regard to many of the above items, encouraging particular clinical departments to review and question the appropriateness of their own transfusion practices by a peer group pressure mechanism. He said:

"There is good evidence to suppose that, at least for certain blood products, a substantial proportion of usage does not accord with well founded clinical guidelines, making inroads into such areas of dubious use would contribute greatly to safety and economy."

In November 1991 the British Committee for

Standards in Haematology produced guidelines for th use of fresh frozen plasma. The introduction to th ose guidelines states that:

"Studies of the use of fresh frozen plasma have shown that it is often misused. This is largely du to the misconceptions regarding its haemostatic effectiveness and inadequate knowledge of the situations in which its use is inappropriate. In t he UK the number of units of FFP transfused during the past 15 years has increased greater than tenfold. Although FFP has been used in an increasingly wide range of clinical situations, in many instances, th ere is no rational basis for its administration."

The guidelines note that there are few well documented and universally accepted indication for the use of FFP. Those indications were limited to the treatment of bleeding episodes or preparation f or surgery in patients with factor deficiencies where the specific factor concentrates are unavailable.

Following a concern that was raised by the Chief Medical Officer about the use of single unit blood transfusions, in November 1991, Dr Williams, direct or of the medical care research unit of the University of Sheffield, produced a review for the Department of Health titled "The use of single unit blood

transfusion practice in this country is incomplete and not accurately ascertainable using existing routine information systems.

"The National Blood Transfusion Service Directorate's Management Information System receive its datasets from Regional Blood Transfusion Servic es. These in turn, describe only the nature and volumes of products donated, processed and distributed to hospital blood banks. No routine data exist at regional level on transfusion practice in the institutions served which would allow the incidence of single-unit transfusions to be measured."

If we turn to page 7:

"A final comment on the present state of knowledge is that transfusion strategy appears to b based almost entirely on clinical consensus based o wide experience over many years. Reports of clinic al trials, systematically organised with random allocation of patients to different types of transfusion intervention or non-intervention, are rare. There are ethical issues involved in mountin such trials, particularly issues of safety, with possible attendant risks of transfusion or non transfusion. If systematic auditing of the tariffs and schedules recommended for transfusion

transfusion".

Could we have that on screen please, Sully; DHSC0025270.

If we turn straight to page 4, please. We see the heading "The arguments":

"Single unit transfusions of red cells are generally thought to be unwarranted in as much as t he oxygen-carrying enhancement they represent is marginal, except in certain circumstances such as small-volume recipients and for the augmentation of an autologous transfusion; or where the quantity neede to produce a desired result is less than anticipate d; or where the patient dies while the transfusion is progressing.

"In practice, where otherwise they do occur they are assumed to be due to questionable clinical judgment about the need for 'top-up' enhancements during or after surgery, particularly for the elder ly, or about the need in obstetric cases. The extent o their use for non-surgical cases is not so well kno wn but, again, it is commonly thought to be associated with the 'top-up' philosophy."

Then if we turn to page 5, "Present state of knowledge":

"Our present state of knowledge of blood product

practice among our hospitals were to show moderate or wide degrees of variation, there might be scope for mounting comparative trials of similar but not identical transfusion practice (2 units against 3 etc), the outcomes being measured both in technical terms (haematocrit, etc) and in terms of impact on overall health and well-being (health status profil es, etc).

"Next steps

"Neither the overall pattern of transfusion practice in this country nor any variations in it a re at all well known. The issues of safety, effectiveness and resource conservation which are involved, along with the more stringent requirement imposed by recent legislation imply that there may now be a 'need to know'."

The report then recommends further research on what the practice was in relation to transfusions i various specialities.

During this time, a major study was ongoing involving Dr Brian McClelland called The Sanguis Study. This was a study being undertaken across Europe to produce a database of current surgical transfusion behaviour. The interim report noted th at 60 to 80 per cent of blood components were used in

surgical procedures. Six classes of procedure had been selected for audit across teaching hospitals i ten countries, and the data showed a wide variation in use of red cells between the different hospitals in Great Britain for total hip replacement surgery as well as a wide variation across Europe.

In June 1992 we have another set of guidelines from the British Committee for Standards in Haematology, this time in relation to platelet transfusions.

Could we turn to BSHA0000031, please.

We see at the start the indication:

"The use of platelet transfusions has risen considerably in recent years, mainly as a consequence of the increasingly intensive treatment of patients with haematological malignancies."

Then under the heading "Indications for platelet transfusions":

"Platelet transfusions are indicated for the prevention and treatment of haemorrhage in patients with thrombocytopenia or platelet function defects. Clinically, this may involve one or more transfusions for the treatment of a single incident or repeated transfusions over a period of time."

Then under the heading "Bone marrow failure":

"1. Platelet transfusions for patients who are bleeding. Platelet transfusions are established as effective treatment for patients with thrombocytopenic bleeding associated with bone marrow failure caused by disease, cytotoxic therapy or irradiation. Serious spontaneous haemorrhage due to thrombocytopenia alone is unlikely to occur at platelet counts above 10-20 x 10 [to the 9]/l ... Minor bleeding such as purpura and epistaxis may occur at platelet counts below 50 x 10 [to the nine]/l.

"2. Prophylactic platelet transfusions. Prophylactic platelet transfusions have been shown to decrease morbidity, although not mortality, in patients with thrombocytopenia due to bone marrow failure ..."

If we continue down:

"The use of platelet transfusions to keep the platelet count above 10 x 10 [to the nine]/l reduce the risk of haemorrhage as effectively as keeping i above any higher level ... A recent study showed that a further reduction in the threshold for prophylactic platelet transfusions may be possible ... However, if factors associated with bleeding in thrombocytopeni patients are present, such as fever and infection, concurrent coagulopathy, a rapid fall in platelet

count, or if there are potential bleeding sites as result of surgery, the use of prophylactic platelet transfusions might be considered to keep the platelet count above 20 x 10 [to the 9]/l. An optimal polic for prophylactic platelet transfusions has not been defined ... and the threshold platelet count should be based on an audit of local clinical practice."

In relation to massive blood transfusion, the guidelines cross refer to the guidelines for massiv blood loss.

In 1994, the second edition of the Red Book, *Guidelines for the Blood Transfusion Services* were published. It contains no guidance on when a blood transfusion should be given but it does contain a note that there should be an audit trail allowing traceability of the blood product from the patient to the donor. It notes that the key to traceability i the donation number.

Can we then turn to DHSC0004486_097, please. We pick up here a meeting of the British Committee for Standards in Haematology, dated 13 July 1994. At the bottom of this page, we see a note, "Consent for Transfusion". It's the blood transfusion Task Force:

"The Task Force discussed the proposal at length. Written comments from the profession were

considered. The following conclusions were reached;

"1. The risks associated with blood transfusion were not of such magnitude that there should be a legal requirement for informed consent to transfusion.

2. There is a clear ethical duty upon doctors to inform patient what is to be done to them and this includes blood transfusion. The problem of transfusion given to patients under anaesthesia for elective conditions without their knowledge was particularly highlighted.

"3. The information leaflet was considered to be valuable and should be made available to patient upon request. The members of the Task Force felt that this was not an area where they could publish a guideline. It was felt that the information leaflet could be incorporated in to the Transfusion Handboo where it would provide a valuable data source for junior doctors. The question of incorporating consent for transfusion in to the consent for operation in some way was felt to be a problem which this Task Force could not address and which referred to good medical practice in surgical specialities which should be addressed through either the respective Royal Colleges or perhaps by the Department of Health. The

Task Force concluded that the information data should be incorporated into the Transfusion Handbook, but that no further action could be taken by this group in regard to the question of consent for transfusion."

Then if we go on to NHBT0059394, please.

SIR BRIAN LANGSTAFF: Just go back to the page and up to the page we were on before.

MS FRASER BUTLIN: Of course. DHSC0004486_097, please.

SIR BRIAN LANGSTAFF: Turn over the page. I'm just trying to understand how 1 and 2 fit together. Let's just starts with 2 "clear ethical duty upon doctors to inform patient what is to be done to them". But 1, "the risks ... were not of such magnitude that ther should be a legal requirement for informed consent to transfusion".

If the question here is negligence, clinical negligence, the general standard would be the standard which a doctor acting properly would adopt. If a doctor acting properly has clear ethical duty, that's the standard, isn't it?

MS FRASER BUTLIN: Sir, I think the distinction may be the difference between informing the patient of what's to be done and obtaining consent for what is to be done.

SIR BRIAN LANGSTAFF: So you can inform him that you're going to give him a transfusion and not ask him to

consent to it?

MS FRASER BUTLIN: That appears to be what the document is suggesting.

SIR BRIAN LANGSTAFF: Which, legally, would mean, effectively, doing something to a patient which involves breaking the skin --

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: -- putting a substance into him, that's an assault, unless there's consent, technically, isn't it?

MS FRASER BUTLIN: Indeed. It is a very strange document, which is why I felt it was important that it was provided today.

SIR BRIAN LANGSTAFF: It just struck me, just as you were passing from the document, that there was a tension between the first two paragraphs.

MS FRASER BUTLIN: There is a very clear tension between information and consent in this, these meeting minutes, and also, that the information leaflet, if we just look at 3, the information leaflet is valuable but only available to patients upon request.

SIR BRIAN LANGSTAFF: Yes, and this was a task force of whom?

MS FRASER BUTLIN: It's the Blood Transfusion Task Force for the British Committee for Standards in Haematology

of the British Society of Haematology. All the guidelines that we've looked at from the British Society of Haematology have arisen from this Committee for Standards.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: So they've produced a large number of guidelines, which is why the minutes of this particular task force are of particular relevance.

SIR BRIAN LANGSTAFF: Yes. Thank you.

MS FRASER BUTLIN: If we can then pick up the 1995 edition of the *Handbook of Transfusion Medicine*, NHBT0059394. Because, sir, you'll recall that the meeting minute indicated that the information leaflet would go int this handbook. So if we turn to page 25, please, w see the heading "Procedures, Information for patients":

"Explain the proposed transfusion treatment to the patient or relatives, and record in the case notes that you have done so!

"Patients or their relatives may be worried about the risks of transfusion. Some may wish to know more about the risks, about the need for transfusio and about alternatives such as autologous transfusion or drugs such as erythropoietin. Patients of the Jehovah Witness faith are strictly banned by their

religious beliefs from receiving blood components, but may be prepared to accept plasma fractions or alternative treatments.

"Research has shown that patients often have no recollection of being informed about treatment options, or feel that they have not had answers to questions that worry them. The balance of legal opinion is that a written record that the patient has been given information and that his or her question have been answered is more valuable in a medico-legal case than the patient's signature on a consent form

"Answers to most patient's questions should be found in this book. We have also included an outline of an information sheet for patients on page [and it's not there]. You should check if your hospital has a leaflet of this type and that your patients receive it."

This appears to be the implementation of that decision in the task force meeting. It might appea from this that there is clear guidance in relation to the information to be provided to patients but no reference to expressly seeking consent.

SIR BRIAN LANGSTAFF: Although it's implicit that, if you happen to know that your patient is a Jehovah's Witness, that the Jehovah's Witness may

have something to say about it.
MS FRASER BUTLIN: Indeed.
SIR BRIAN LANGSTAFF: Indeed, the suggestion implies, at any rate, that there is a discussion --
MS FRASER BUTLIN: Indeed.
SIR BRIAN LANGSTAFF: -- on the basis that there is a right to say "No, thanks".
MS FRASER BUTLIN: Indeed but it's not explicit here that consent must be obtained.
SIR BRIAN LANGSTAFF: No.
MS FRASER BUTLIN: To give some indication of the practice on the ground, the Inquiry has identified a Royal College of Physicians report in January 1998. Thei "National Audit of the Clinical Blood Transfusion Process". NHBT0042247, please. If we turn to page 3 please, "Background".

"Assessment of the quality assurance of blood transfusion pays little attention to the clinical interface. The British Committee for Standards in Haematology makes recommendations for good transfus ion practice through its Blood Transfusion Task Force a nd laboratory performance is monitored by the National External Quality Assurance Scheme for Blood Group Serology."

Then there's discussion of there having been

regular review is carried out."

If we turn to page 6, please. We see, under Q5:

"*Informed consent*. No hospitals required informed consent for blood transfusion."

Then if we look at the bottom of the page:

"*Transfusion date and two signatures for each unit transfused*. The transfusion date and two signatures were recorded for only 85% and 79% respectively of all units transfused."

Which, of course, goes to the question of traceability.

Moving on to speciality-specific guidance in the 1990s, I want to turn first, as I did last time, to surgery.

And if we go to NHBT0000104_027, please.

We're picking up the Royal College of Surgeons course material in clinical surgery in general in 1993. If we turn the page, we are in chapter 17, dealing with the "Correction of preoperative, perioperative and postoperative anaemia". And it starts in this way:

"The administration of blood and blood products represents substitution therapy and can correct alm ost immediately and invariably the existing anaemia, thrombocytopenia, coagulopathy or hypoproteinaemia in

a workshop in 1992, to try to establish the process and the audit that was taking place. If we can tur to page 4, we see under the heading "Audit" that:

"53 haematologists initially expressed interest in the audit and 50 hospitals eventually took part. Most areas of England were represented and there we re participants from Scotland, Wales and Northern Ireland."

Then against Q1b:

"*Policies for the transfusion of blood on the wards* existed in 89% of hospitals. These hospitals also had written policies for the administration of blood on the ward and most included guidance on monitoring transfusion and advice about what to do if a transfusion reaction occurs. In 93% of hospitals copies of the policy were available on all wards."

Then in relation to "Hospital transfusion committees":

"In 79% of hospitals there is a transfusion committee and in 65% of these audits of transfusion practice had been carried out; in all but one of these, recommendations on transfusion practice had been made based on results of the audits.

"*Maximum surgical blood order schedule.* This existed in 87% of hospitals and in 71% of these

the patient. However, the administration of blood and blood products is not without risk and should be carried out where the indications are clearly established, ie where the benefits to the patient outweigh the risks of transfusion."

If we then pick up at the bottom of this page, ready to go over the page:

"The main objective in the management of anaemia encountered in surgical practice is to ensure adequ ate oxygenation of tissues and particularly of the hear and the brain. Experience accumulated over the las few years has shown that that objective is achieved when the haemoglobin concentration is above 8.0 [gr ams per decilitre]. That level of haemoglobin, at whic a decision to transfuse the patient is usually made , is generally known as the 'transfusion trigger'. While the transfusion trigger can be useful as a pointer for action, it should never be used as an immutable value, as for example, a young patient wi th haemoglobin concentration substantially lower than 8.0 ... may tolerate the operation much better than an old patient with a higher haemoglobin level but with a failing heart or compromised cerebral circulation."

Just a little bit further down:

"Although it is well documented that the level

of haemoglobin and postoperative survival are inversely correlated, neither clinical observations nor laboratory experiments have been able to define the lowest 'safe' haemoglobin concentration. Therefore, it is mandatory to assess each patient individually and to consider the type and probable duration of anaesthesia and of operation before a decision to administer blood is made."

Then on the same page, under the heading "Pre-operative Anaemia":

"The determination of haemoglobin concentration -- part of the pre-operative assessment of the patient ... will reveal the presence of anaemia [then the figures are given]. Faced with the anaemic patient awaiting surgery, the surgeon should first ensure that the correct diagnosis of anaemia is made or at least that the samples required for the diagnosis have been collected. Second, he should decide whether to proceed with or defer the operation. Finally, he should decide whether the patient requires transfusion of blood. The decision to transfuse the patient should be based on the type and degree of anaemia and the urgency for surgery. Elective surgery should be delayed until haemoglobin concentration is raised to the level considered safe for the patient."

So that approach in the guide on surgery could be compared with the 1980s approach, which was perhaps more ready to transfuse rather than delay the surgery.

With regard to haemoglobinopathies, the Secretary of State for Health invited the standing Medical Advisory Committee to consider the care of patients with haemoglobinopathies and to report. The report was published in 1993 and recognised that the care of patients with haemoglobinopathies was not always of the highest quality even where these disorders are frequently seen.

Recommendations were made in relation to improving that care.

Interestingly, there is no reference throughout the report to patients having been infected with hepatitis C or HIV by infected blood, and consequently nor are there any recommendations in relation to their subsequent care and treatment.

Guidelines for the administration of blood products in infants and neonates were published by the British Committee for Standards in Haematology in 1994. Although the guidelines acknowledge the difficulties of haemoglobin measurement, especially in any case associated with gestational age and prematurity changes, the guidelines recommend red cell

transfusions should be considered for any symptomatic neonate whose haemoglobin concentration is less than 10.5.

Neonates requiring supplemental oxygen should be maintained at a higher level. Prophylactic platelet transfusion is stated to be probably justified at platelet counts below 30 x 10 to the 9, or, in the case of very sick and premature neonates, when counts fall below 50 x 10 to the 9, because thrombocytopenia is believed to be more hazardous in neonates.

We move now to the 2000s. First of all, in my other file, NHBT0009569, please.

We have another guideline from the British committee, "Guidelines for the clinical use of red cell transfusions".

We pick up the second paragraph:

"There is evidence of very significant variation in the use of red cell transfusions, for example as provided by the Sanguis study, indicating that currently available guidelines have little impact o clinical practice (The Sanguis Study Group 1994). This variation does not correlate with patient characteristics, appearing to be more dependent on the individual clinician ordering the transfusion, strongly suggesting that inappropriate use is

widespread. Several recent events in relation to blood transfusion in the UK support the view that renewed efforts should be made to encourage better use of red cell transfusions ..."

And that includes renewed concerns about the safety of transfusion in light of some SHOT reports the Serious Hazards of Transfusion initiative reports, and the "theoretical risk of transmission of varian [CJD]", is how they describe it, and new safety requirements, such as leukocyte depletion and nucleic acid testing, increasing the cost.

The guidelines then go on to consider parameters that are to be used to indicate the need for red cell transfusions. Picking up at the bottom of the column:

"Acute anaemia. Acute anaemia is usually caused by blood loss, where the effects of anaemia should be separated of those of hypovolaemia. Clinical experience has shown that losses of up to 30-40% ca be treated with crystalloids ..."

If we move to page 3, please.

"... alone in young healthy patients. Acute isovolaemic anaemia to a haemoglobin concentration of around 5g/dl in a study of volunteers and patients produced no evidence of inadequate oxygenation ... Recent studies have thrown that a threshold for red

cell transfusion of 8g/dl was as safe as one of 9g/dl in patients undergoing coronary artery bypass surgery ... and a threshold of 7g/dl was a safe and possibl superior to a threshold of 10g/dl in critically ill patients ..."

And then on the other column:

"For many years, it was traditional to use a trigger of a haemoglobin concentration of 10g/dl for peri-operative red cell transfusion and for transfusions to medical patients. However, there i evidence that renal transplant patients and Jehovah's Witnesses undergo surgery successfully with lower haemoglobin concentrations ..."

If we turn over the page, in the middle of the column, "Conclusions":

"There are no reliable parameters to guide the need for red cell transfusion. The decision to transfuse red cells is a complex one and depends on factors such as the cause of the anaemia, its severity and chronicity, the patient's ability to compensate for anaemia, the likelihood of further blood loss and the need to provide some reserve before the onset o tissue hypoxia. The risks of transfusion also need to be balanced against the perceived benefits. Although guidelines for red cell transfusion often specify

a given concentration of haemoglobin, in order to b pragmatic, consideration of the patient's clinical condition is an essential part of the decision to transfuse red cells or not and is a matter for clinical judgment."

Sir, you'll recall that earlier this afternoon I dealt with a document from CREST in Northern Ireland, and I'd like to move to the 2001 document from them.

DHNI0000013_065, please.

We see this is January 2001, and if we turn to page 5, please, we read this as the introduction.

"Ten years ago CREST issued guidance on the use and supply of blood products in Northern Ireland. Since then, there has been an increasing awareness of the need to use blood only when it is essential. I view of this changing environment, CREST decided to revisit its guidelines and a small group of physicians, haematologists and transfusion medicine specialists was established to take this forward ..."

In other words, between the guidance we looked at earlier in the afternoon, in 1989, this appears -- and from our searches, we can't find anything else -- this appears to be the next guidance provided in Northern Ireland, in relation to blood

transfusion.

The guidance that is then provided is largely mirroring that in England and Scotland.

In Scotland in 2002, the SNBTS published a leaflet for doctors and nurses about red cell transfusions. It reminds clinicians to consider whether each transfusion is truly necessary before ordering it. It gives guidance that red cell transfusion is rarely indicated in perioperative, postoperative and intensive care use when haemoglobin is above 8, and almost never when it is at greater than 10. It states that:

"... with bone marrow failure, haemoglobin should be maintained at greater than 8, or if platelet support is needed and bleeding is a problem, then a greater than 10."

Red cell transfusion is noted as only rarely necessary to treat iron and other haematinic deficiency. The need to keep clear records, including the reason for transfusion and what was given, is noted, as is the need to provide understandable basic information to patients about the transfusion.

In 2003 the British Committee for Haematology provided guidelines about platelet transfusions, updated guidance. The lack of consensus with regar

to prophylactic use of platelet transfusions was noted and thresholds were identified for patients with bone marrow failure, chronic thrombocytopenia, and in massive transfusion.

It's worth then noting that on 31 March 2004, an EU Directive was enacted, coming into force in February 2005, requiring Member States to ensure the traceability of blood from donor to the recipient, and vice versa. Data required for full traceabilit was to be retained for a minimum of 30 years after clinical use.

If we can then turn to another edition of the Handbook of Transfusion Medicine, RLIT0000812, please, and we'll turn straight to page 18. What we have here are what's called the transfusion "ten commandments". And its number 1 is noted as:

"Transfusion should only be used when the benefits outweigh the risks and there are no appropriate alternatives.

"2. Results of laboratory tests are not the sole deciding factor for transfusion.

"3. Transfusion decisions should be based on clinical assessment underpinned by evidence-based clinical guidelines.

"4. Not all anaemic patients need transfusion

(there is no universal 'transfusion trigger').

"5. Discuss the risks, benefits and alternatives to transfusion with the patient and gain their consent.

"6. The reason for transfusion should be documented ..."

Then there are further matters of identification --

SIR BRIAN LANGSTAFF: What date is this?

MS FRASER BUTLIN: This is -- apologies, I had it noted -- 2013. So relatively recent.

SIR BRIAN LANGSTAFF: 2013. So 2013 there's an express reference to getting consent?

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: Is there an earlier one?

MS FRASER BUTLIN: Sir, I feared you were going to ask me that and, at this point in the afternoon, I think there was. I would need to just go back to the written presentation to confirm it. But it's certainly wasn't until the 2000s because we saw the documents in the 1990s --

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: -- that addressed no consent. I can certainly identify that for you.

If we can turn on to page 4 of the handbook, we

see, in "Essentials":

"Avoid unnecessary and inappropriate transfusions."

Then the fifth bullet point:

"At every stage of the blood administration process the key elements are positive patient identification, excellent communication and good documentation. These can be enhanced by the use of electronic transfusion management systems and barcode technology."

Then the next bullet point:

"Hospitals should develop local transfusion policies based on national guidelines and ensure all staff involved in the clinical transfusion process are appropriately trained and competency assessed."

Then if we turn to page 47, we see the heading "Documentation":

"The documentation required at each stage of the transfusion process should be kept to an essential minimum and, whether hard copy or electronic, be 'user-friendly' to encourage compliance by busy clinical teams. Combined transfusion prescription and monitoring charts or care pathways can be used to record the information and provide a clear audit trail. The development of standardised transfusion

documentation in the UK has the potential to reduce errors by clinical staff moving between hospitals. All transfusion documentation should include the minimum patient identifiers."

Then we see in "Pre-transfusion", the requirements:

"The reason for transfusion ...

"The risks, benefits and alternatives to transfusion that have been discussed with the patient and documentation of consent.

"The components to be transfused ..."

Then "During transfusion", the third bullet point:

"Donation number of the blood component."

Then if we turn the page, we have the heading "Patient consent":

"The Advisory Committee on the Safety of Blood Tissues and Organs recommends that 'valid consent' for blood transfusion should be obtained and documented in the clinical record ..."

Sir, I suspect it's that set of minutes that I will provide to you to make sure we have the correct date.

In November 2015, NICE published a guideline on blood transfusion which recommended the use of red

cell transfusions when haemoglobin was 7 grams per decilitre -- sometimes it's written as 70 grams per litre but it's 7 -- and to use single unit red blood cell transfusions for adults without active bleeding. So we see a shift in the mid-2000s towards single unit transfusions rather than the previous practice of avoiding them.

That's something that, sir, I think we'll pick up with some of the witnesses later this week.

"Platelet transfusions are recommended prophylactically for patients with platelet counts below [10 times 10 to the 9], who are not bleeding or having invasive procedures or surgery, excluding those with chronic bone marrow failure, autoimmune thrombocytopenia, heparin induced thrombocytopenia and thrombotic thrombocytopenia purpura."

Then when we come to specialty specific guidance, there was a plethora of guidance produced during the 2000s and, in a sense, the existence and the extent of that guidance may itself be of interest. Inevitably, I have selected a very small number, just to give a broad overview of the position in the 2000s.

In relation to anaesthesia, in 2001 the Association of Anaesthetists of Great Britain and Ireland produced the document *Blood Transfusion and*

the Anaesthetist: Red Cell Transfusion, recommending that anaesthetists should play a lead role in pre-operative assessment and preparation and that the decision to transfuse should be on an individual patient basis, not to achieve a normal haemoglobin concentration.

A permanent record of the administration of each unit of red blood cells should be kept. The use of blood ordering schedules and having an anaesthetic representative on the hospital transfusion committe is also recommended.

As to surgery, in October 2001, the Scottish Intercollegiate Guidelines Network produced a national clinical guideline on perioperative blood transfusion for elective surgery:

"The guidelines recommend that the provision of clear verbal and written information about the risk and benefits of allogenic blood transfusion is emphasised as good, clinical practice. Whenever possible, alternatives to transfusion should be discussed with the patient in advance of need, to allow arrangements for their delivery to be put in place.

"The guidelines note a wide variation of transfusion practice which may be due to many factors,

including differing opinions on the threshold level of haemoglobin for transfusion.

"Differences in surgical and anaesthetic techniques, and differences in case mix. The guidelines recommendations include that pre-operative anaemia should be corrected by, for example, iron therapy, prior to major surgery, to reduce exposure to allergenic transfusions.

"Intraoperatively, when there is ongoing surgical blood loss, haemoglobin measurements shoul be interpreted in the context of a multifaceted clinical assessment.

"Postoperatively, transfusion is unjustified at haemoglobin levels greater than 10 and is required at levels of less than 7, although for patients with cardiovascular disease or those expected to have covert cardiovascular disease", then it's noted tha those patients are likely to benefit from transfusion when their haemoglobin level falls below 9.

In obstetrics the first edition of a guideline from the Royal College of Obstetricians and Gynaecologists on blood transfusion in obstetrics was published in February 2007. Sir, the fact of that date for a first guideline from the Royal College i relation to blood transfusion is perhaps in itself

significant. There were certainly guidelines in relation to obstetric transfusion from the haematologists but, in terms of the Royal College o Obstetricians, this is the first guideline that's been identified.

SIR BRIAN LANGSTAFF: Yes, and obstetrics is really where modern practice of transfusion began, isn't it?

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: I think in 1818, with Blundell.

MS FRASER BUTLIN: I bow to your superior knowledge on that, sir. I'm afraid I can't claim to know about that, but obstetrics certainly has been the guiding force, particularly in relation to massive blood loss and significant haemorrhage.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: So it's somewhat surprising, perhaps, that the first guideline on blood transfusion and obstetrics is published so late in the piece.

The guidelines recommend that where major haemorrhage occurs, there are no firm criteria for initiating red cell transfusion, and the decision t do so should be made on clinical grounds. It says, nevertheless, that transfusion is rarely indicated in a stable patient when haemoglobin is greater than 9 and is almost always indicated when less than 4 to 5.

Postnatally, where haemoglobin is between 7 and 10, and there is no ongoing or threat of bleeding, the decision to transfuse:

"... should be made on an informed, individual basis. In fit, healthy, asymptomatic patients ther is little evidence of the benefit of blood transfusion."

In relation to haematology the British Society produced guidelines on the management of acute myeloid leukaemia in adults in 2006, which included the recommendation that there was no good evidence to support a particular red cell transfusion policy in AML, whereas platelet transfusions were recommended to support thrombocytopenia, with a transfusion threshold of 10 times 10 to the 9, unless there were additional risk factors, such as sepsis or concurrent use of antibiotics.

With regard to sickle cell disease, guidelines on red cell transfusion in sickle cell disease were produced by the British Society in 2016. If I coul turn them up, RLIT0000806, please.

We can see that it says:

"Red cell transfusion has an important role in the management of sickle cell disease in both emergency and elective settings ... The present

guideline examines current available evidence on indications for transfusion in [SCD]. This may not be appropriate for all clinical scenarios and clinical decisions must be based on individual patient considerations.

"In both guidelines, the term sickle cell disease refers to all genotypes of the disease, and sickle cell anaemia to the homozygous state (SS)."

Then under the heading "Key recommendations" in the right-hand column:

"Consideration of sickle cell patients for transfusion, particularly long-term regimens, shoul weigh up the potential benefits against potential risks.

"*Cerebrovascular disease*. Regular transfusion to maintain HbS [sickle haemoglobin of less than] 30% should be offered as initial treatment to children with SS or [SB] thalassemia aged 2-16 judged to be at high risk for a first stroke on the basis of Transcranial Doppler ultrasonography."

If we turn the page, we see on the left-hand column:

"Long-term transfusion to maintain HbS [less than] 30% is recommended for the prevention of recurrent ischaemic stroke due to sickle cell disease

in both children and adults".

Then further down, under the heading of "Surgery":

"Preoperative transfusion is recommended for SS patients undergoing medium-risk surgery ..."

SIR BRIAN LANGSTAFF: (inaudible). Yes?

MS FRASER BUTLIN: Sorry, sir, indeed.

"Preoperative transfusion is recommended for SS patients undergoing medium-risk surgery (eg abdominal, tonsillectomy, orthopaedic).

"Preoperative transfusion is recommended for SC patients undergoing medium-risk surgery ...

"Transfusion is recommended for sickle cell patients of all genotypes requiring high-risk surgery (eg cardiovascular, brain)."

Then further down:

"For patients requiring emergency surgery" --

Sorry, Sully, we were just there.

"For patients requiring emergency surgery, the urgency and complexity of the procedure should be taken into account in the timing of perioperative transfusion. Simple transfusion should be given preoperatively if [haemoglobin is less than 90 at 9], provided this will not result in undue delay to surgery. If transfusion is likely to cause an

unacceptable delay to surgery, it is reasonable to proceed to surgery while arranging to transfuse the patient intra or post-operatively if necessary.

"*Acutely ill patients*. Transfusion is recommended and may be life-saving in acute sickle complications such as splenic sequestration, hepati sequestration, aplastic crisis and severe acute chest syndrome.

"Transfusion should be considered in the unwell patient with acute multi-organ failure, mesenteric syndrome and patients with severe sepsis."

Discussion should be had with the specialist haemoglobinopathy team.

In 2006, the British Society for Haematology produced updated guidelines in relation to massive blood loss, and that's something, sir, I anticipate addressing with one of the witnesses later in the week, so I'll simply note that it's there and we'll discuss the details of it with a witness.

Sir, I have one final part of this presentation. I'm very aware that we were due to be sitting tomorrow as well, but it's not a very significant section so if I may, I'll continue for perhaps another --

SIR BRIAN LANGSTAFF: Roughly how long do you think it will take?

MS FRASER BUTLIN: I think about 20 minutes.

SIR BRIAN LANGSTAFF: Shall we simply go ahead?

MS FRASER BUTLIN: That was my instinct, sir. Thank you, I will.

SIR BRIAN LANGSTAFF: It's better to do that than come back tomorrow for 20 minutes.

MS FRASER BUTLIN: Absolutely. I just wanted to flag that we are on the final part and I don't expect to be very much longer than 20 minutes.

So the final part of the presentation is to address the UK Chief Medical Officer's National Blood Transfusion Committee. On 6 July 1998, a symposium was held called the UK Chief Medical Officer's Symposium on Evidence-Based Blood Transfusion. This laid the foundation for many of the subsequent guidelines that followed from 1998. As we've highlighted in the presentation, the late 1990s and through the 2000s, there was a significant increase in guidance, and many of those can be pinned to the Chief Medical Officer's initiative of the National Blood Transfusion Committee.

It might be suggested that the initiative led to very significant changes in both attitudes and practices in relation to blood transfusion. So although it's rather late in the piece, it may give

some insight into what is possible when a UK-wide approach is taken.

Following the symposium, an interim National Blood Transfusion Committee was established with th aim of establishing a structure throughout the UK o hospital, regional and then the national transfusio committee, and for that to be done by September 200 1.

Also, following the symposium, a Health Service circular on Better Blood Transfusion, dated 11 December 1998 was published. Could we put that on the screen please, Sully. It's NHBT0083701_002, please. We can see the date at the top. If we jus go down slightly, we can see that it's "For action by", and it's the Health Authorities of England and the Chief Executives, the Directors of Public Healt h, and the Finance Directors, and then the NHS Trusts, the Medical Schools, and the Post Graduate deans.

If we turn the page, please, we see under the heading "Summary":

"Attention has focused on blood transfusion practice recently for several reasons:

"greatly increased demand for blood compared with the increase in donations

"the likely additional demand for blood associated with the waiting list initiative

"the rise in the cost of blood with leucodepletion and nucleic acid testing

"the recommendations from the Serious Hazards of Transfusion (SHOT) enquiry on how the safety of patients receiving blood could be improved

"the theoretical risk of new variant [CJD]

"the implications of clinical governance for blood transfusion practice.

"This circular details the action required of NHS trusts and clinicians to improve transfusion practice."

Then if we go to the next page, please. We have the heading "Hospital Transfusion Committees":

"Every NHS Trust where blood is transfused should have an adequately resourced multi-disciplinary hospital transfusion committee. Some NHS Trusts ma share a committee, whilst others may need more than one. Given its key role in resource and risk management, the HTC should be an integral part of local arrangements for clinical governance, with corresponding lines of accountability to the Chief executive. The structure and organisation of an HT should be informed by the best practice of existing HTCs and it should be in close contact with local a nd national blood user groups. About 65% of NHS trust

already have an HTC and there is a wealth of knowle dge about what works best. The National Blood Users' Group is an excellent information resource.

"As a minimum, an HTC should:

"promote best practice through reference guidelines.

"lead multi-professional audit of the use of blood components within the NHS Trust, focusing on specialities where demand is high, eg haemato-oncol ogy and certain surgical specialities

"maintain a database that allows feedback on performance to all hospital staff involved in blood transfusion

"promote the education and training of all clinical and support staff involved in blood transfusion

"have the authority to modify existing blood transfusion protocols and to introduce appropriate changes to practice

"report regularly to local, and through them to national, blood user groups

"consult with local patient representative groups where appropriate

"contribute to the development of clinical governance."

Then we see, under the heading "Transfusion guidance and protocols":

"The use by clinicians in the NHS of red cells, platelets and fresh frozen plasma for the same procedures is highly variable. This suggests that some of these scarce resources are being used unnecessarily and could be better managed. This al so has implications for patient safety. In general, a nd in the field of blood transfusion, evidence-based clinical guidelines have been shown to improve clinical practice. Currently however, most guideli nes on blood transfusion practice come from expert committee reports and opinion and, although soundly based, may lack the rigour of well controlled clini cal trials. Therefore, whilst existing guidelines from the British Blood Transfusion Society and British Committee for Standards in Haematology and protocol based on them, need to be encouraged and implemente d, the development of evidence-based practice must be supported.

"Agreed hospital blood transfusion protocols should be on induction programmes for all clinical staff, be available in summary form in hospital handbooks, and on the wards. Their implementation will require the support of the senior clinical nurse.

Where there are gaps in knowledge, further systematic review of current work and research into transfusio practice are required."

In Scotland a management executive letter was circulated, and that is SCGV0000039_177.

The letter was circulated on 2 February 1999, and if we turn the page, we can see the action that was required:

"From March 1999, all NHS Trusts where blood is transfused should:

"ensure that hospital transfusion committees are in place to oversee all aspects of blood transfusion; [and should]

"participate in the annual SHOT enquiry.

"By March 2000, all NHS Trusts where blood is transfused should:

"have agreed and disseminated local protocols for blood transfusion, based on guidelines and best national practice, and supported by in house training, [and]

"have explored the feasibility of autologous blood transfusion and ensured that where appropriate, patients are aware of this option; in particular they should have considered the introduction of perioperative cell salvage ..."

A second CMO -- a second Chief Medical Officer conference was held on 29 October 2001. Prior to the conference, the purpose of the conference was established with the four UK CMOs, and it was this:

"Despite work over the last three years, local audits still suggest that the use of blood components remains highly variable between clinicians and hospitals, and needed to be explored as a marker of surgical/clinical practice. Most importantly, and in the aftermath of the recent HCV ruling, the risk of blood transfusion would need to be recognised upfront and put in clear perspective for the public, patients and clinicians. The main issue, therefore, was about risk: scoping the risk of receiving blood components against effectiveness, communicating thi to patients and the service in the context of the benefits, and reducing the risk through best clinical practice.

"This approach would require a full and honest partnership between the blood services and the public. It would need to be based on an agreed recognition of the risks, a policy that did not promote blood transfusion as safe, and fully governed by informed consent."

It's said that the plain message was to be that

"We've come a long way since 1998."

At that second conference, it was noted that an audit of the implementation of the 1998 circular showed that most hospitals had established hospital transfusion committees, had participated in the SHO scheme, and had protocols for the administration of blood.

"However, there was also evidence of poor provision of training for clinical staff and patien information, few protocols for the appropriate use of blood, few audits of transfusion practice, and limited use of autologous transfusion.

"At the seminar, the establishment of the CMO's National Blood Transfusion Committee was also highlighted. It was hoped that the flow of information between hospital transfusion committees and regional transfusion committees and the CMO's National Blood Transfusion Committee should encourage good local blood transfusion practice and the implementation of national transfusion guidelines.

"One of the first initiatives of the National Blood Transfusion Committee was to undertake a national comparative audit in blood transfusion, one of the purposes of which was to enable comparative data between trusts to be used for the improvement of

practice involving education and the development of achievable benchmarks."

A further health service circular was published on 4 July 2002. It was focused on ensuring that Better Blood Transfusion was an integral part of NHS care. Once again, it emphasised the need to have a hospital transfusion committee which would implement good transfusion practice, regular, documented training for staff, the provision of timely written information about blood transfusion and its alternatives for patients and, having agreed and disseminated protocols for safe and effective transfusion practice, adopting national guidelines for the appropriate use of blood.

In terms of progress that was made, I want to turn now to the second annual report of the Nationa Blood Transfusion Committee from September 2004.

RLIT0000852, please.

We see towards the bottom of the page the heading "Progress in the implementation of the [200 circular]":

"A questionnaire was issued to haematologists in charge of blood banks in April 2003. There was an overall response rate of only 47% of NHS hospitals.

"Progress since 2001 on the implementation of

Better Blood Transfusion in the NHS hospitals who responded to the questionnaire included:

"Greater participation in the SHOT scheme to 100%

"An increase in Hospital Transfusion Committees to 98%

"An increase in hospital blood banks with accreditation to 86%

"An increase in the number of hospitals with transfusion practitioners to 51%."

Now, of course one must recall that the response rate was only 47 per cent, and those percentages ar therefore of that 47 per cent.

Sir, I'm sure you recall the evidence that we heard about the SHOT scheme earlier, maybe a month ago, in terms of how it was set up, and the challen ges that were faced in the early days of getting hospit als to actually engage with it.

This report does note, however, the lack of progress in the following areas: training of staff, the development of protocols for the appropriate us of blood, and the provision of information to patients:

"There was evidence of regional variation in the development of Hospital Transfusion Teams."

Then if we go over the page to page 3, please, "National comparative audit":

"The national audit of transfusion practice in collaboration with the Royal College of Physicians, Clinical Evaluation and Effectiveness Unit revealed deficits in the practice of blood transfusion ..."

Then it's the third bullet point:

"Record keeping was often poor, making it difficult to demonstrate that optimal care was give n, and demonstrates lack of preparedness for the 'Vein to vein' approach to documenting blood transfusion practice as required in the EU Directive."

So even as in 2003, 2004, there are ongoing difficulties noted about the traceability of blood transfusions.

In September 2006, NHS Scotland published clinical standards on blood transfusion. These standards flowed from the UK CMO's conference. The include that the NHS board must have a system in pl ace to ensure that every unit of blood component receiv ed into the hospital transfusion laboratory can be unmistakably traced to its recipient, or to its fin al fate, if not transfused. The decision to transfuse is made following consideration of the potential risks and benefits of and the alternatives to transfusion

Where possible, this is discussed between the clinician and patient (or their legal guardian) in advance of transfusion. And procedures are in plac to optimise blood use and minimise wastage.

In 2006 a review of the progress of the Better Blood Transfusion initiative was produced covering the period 1998 to 2006. It considered what was requir ed to "refocus and energise it". The report noted the progress and remaining gaps. It recorded that medi cal use was by then a significant user of red cells, whereas surgical use had reduced.

There had also been little effect on the use of fresh frozen plasma and platelets. Audits, it said , indicate considerable inappropriate usage of these products, which should also become a focus for reduction.

The report noted some of the underlying reasons for the slower than ideal implementation, namely th lack of an effective means of enforcement by the CM O's National Blood Transfusion Committee, that appropri ate use of blood was not high enough up on the hospital priority and risk management agendas, the lack of resourcing for hospital transfusion teams, and insufficient awareness/education within hospitals regarding the potential impact of blood shortages o

patient safety.

And those areas became the focus for the work of the National Blood Transfusion Committee.

There were further health service circulars in 2007 and 2010, and the National Blood Transfusion Committee continued to operate, coming under the leadership of Dr Wallis in October 2014.

Later this week, the Inquiry will be hearing evidence from Dr Wallis and from Dr Murphy, both of whom have been heavily involved in the Better Blood Transfusion Initiative, and it's anticipated that t he ongoing work and the current position will be addressed with them rather than through this presentation.

Sir, that draws this presentation to a close. I think within my 20 minutes, perhaps. Unless ther e's anything you'd like me to address further?

SIR BRIAN LANGSTAFF: No, except I think you may have answered the question about the first reference to consent that is traceable, because you did tell me, I think, that in the -- in 2001, in the -- there wa a requirement or suggestion that there should be consent for transfusion.

MS FRASER BUTLIN: Thank you, yes.

SIR BRIAN LANGSTAFF: There may have been an earlier one

but at least it goes back in one of the official documents to 2001.

MS FRASER BUTLIN: I will double check again that there's nothing earlier, but yes, I think it certainly appears in the 2001 CMO documentation.

SIR BRIAN LANGSTAFF: But yes, so that concludes this presentation.

MS FRASER BUTLIN: It does.

SIR BRIAN LANGSTAFF: This presentation had originally been planned to go on tomorrow, as you may know. Obviously it won't now, because we've finished it. So tomorrow we will not be sitting, but we begin again on Wednesday.

MS FRASER BUTLIN: We will be hearing from Professor Philip Steer and Dr David Bogod. Professor Steer is an obstetrician and Dr Bogod is an obstetric anaesthetist.

SIR BRIAN LANGSTAFF: So we hear them at 10.00 on Wednesday. So until 10.00 on Wednesday, thank you.

(4.52 pm)

(Adjourned until Wednesday, 23 February 2022 at 10. 00 am)

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