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Wednesday, 16 March 2011

(9.30 am)

THE CHAIRMAN: Good morning.

MS DUNLOP: Yes, sir. As indicated yesterday, today we are going to try to get some sort of sense of the size of the problems. We are going to hear from two witnesses, Dr Gillon and Professor Goldberg, in that order.

Our first witness for today is Dr Gillon.

DR JOHN GILLON (affirmed)

MS DUNLOP: Good morning, Dr Gillon.

A. Good morning.

Q. You are John and Jack. Is that right?

A. Yes, that's right.

Q. What do they call you at work?

A. They call me Jack.

Q. So you are Dr Jack Gillon. On your CV you are Dr John Gillon?

A. Indeed.

Q. We are going to start by looking at that. It is WIT0030281.

The first page is giving your basic biographical details and we can see that you studied medicine at Edinburgh University and you have a number of postgraduate qualifications, including an MD and you are a fellow of the Royal College of Physicians. What did

1 you do your MD on?

2 A. The MD was on the intestinal immune response to

3 a gastrointestinal parasite called giardia lamblia.

4 That was because I was training in gastroenterology at

5 the Western General Hospital under Dr, later

6 Professor Anne Ferguson, who was a world expert on GI

7 immunology.

8 Q. I think she has given her name to part of the Western,

9 hasn't she?

10 A. She has indeed. The Anne Ferguson building.

11 Q. Can we look at the next page, please. We see that you

12 worked under Professor Girdwood at Edinburgh

13 Royal Infirmary. He is a name we have come across in

14 the field of blood transfusion?

15 A. Yes, indeed.

16 Q. Who was he exactly?

17 A. He was professor of therapeutics and had a big interest

18 in the use of blood products, among many other things,

19 and was a member of the committee on the safety of

20 medicines and so on. I went to his unit as a general

21 medicine senior registrar. So while I was a lecturer in

22 gastroenterology at the Western, I also, as we all did,

23 to become internal physicians, had to do general

24 medicine as part of that. So I was looking after the

25 generality of patients on that ward at that time.

1 Professor Girdwood, just to add to that, was for
2 many years the chairman of the Blood Donor Association.
3 So he had great interest in blood donors as well as in
4 transfusion as a clinical topic.

5 Q. The Blood Donor Association was a charitable
6 organisation?

7 A. Yes, in a sense I think it goes back to the earliest
8 days of the Scottish Transfusion Service, around the
9 time of the Second World War when it was founded by
10 John Copland. I think it was continuous from that time,
11 and still exists.

12 Q. Right. We see also that you became a senior registrar
13 in Edinburgh and Southeast Scotland Blood Transfusion
14 Service in September 1984. There are basically five
15 regional sections of the Blood Transfusion Service in
16 Scotland. Is that correct?

17 A. That's correct, yes.

18 Q. This is obviously one of them. Then from April 1985,
19 until now indeed, you are a consultant physician in the
20 Edinburgh and Southeast Scotland Blood Transfusion
21 Service and the department of transfusion medicine.
22 Where is the department of transfusion medicine based
23 then?

24 A. Well, basically that is the name that we use for the
25 clinical side of blood transfusion. The term

1 "transfusion medicine" was one that was coined many
2 years ago. We have always been keen on that term,
3 because we are very keen to be involved in the clinical
4 care of the patients who are receiving transfusions, and
5 have been actively in Scotland since that time. Since
6 before the time that I first went there.

7 Q. On page 3 we can see that your current areas of
8 responsibility look to be really 1 and 4. One, you have
9 consultant responsibility for medical care and selection
10 of donors and you are also responsible for the
11 autologous transfusion service. What is autologous
12 transfusion?

13 A. It is actually now defunct to a large extent, in one of
14 the senses in which I was involved. Autologous
15 transfusion refers to a patient donating his or her own
16 blood for use in a planned surgical intervention.
17 That's one form of autologous transfusion. That is one
18 that we set up and was the first in the United Kingdom
19 in 1987. It was popularised in the United States in the
20 years preceding that because of the fear of HIV. There
21 was some demand for it in this country and we felt we
22 should be involved in that and worked with the
23 clinicians to establish a service in the southeast of
24 Scotland, which later was rolled out to the rest of the
25 country. But it never really lived up to its promise.

1 It was something that was useful for some patients but
2 didn't always succeed in avoiding transfusion in the
3 sense that there is a limit to how much blood you can
4 give in the run-up to an operation and if you need blood
5 you are likely to need quite a lot.

6 So worldwide it went out of fashion in the mid 1990s
7 and by early 2001/2002 we had pretty well ceased that
8 completely. Now it is still theoretically available in
9 the Glasgow area but it is very rarely used except for
10 very specific indications.

11 Q. Like many doctors, we see you have a number of
12 administrative roles, responsibilities and you have
13 listed those under the heading "administrative and
14 management contributions". Then on the following page
15 you have listed educational and other academic
16 activities and we can see that these have extended
17 beyond the United Kingdom and you have had some
18 involvement in a WHO project as well in the West Bank.
19 What was involved there?

20 A. That was quite a short course -- I can't remember
21 exactly how long we went for, a week or ten days
22 I think -- to deliver to the hospitals in the West Bank.
23 One was in Bethlehem. I think the other one was in
24 Jerusalem itself. Yes, there were two hospitals. We
25 visited one or two others to do a series of lectures and

1 seminars on transfusion for the doctors and nurses
2 working there.

3 Q. This is the first item on the list: you have also spent
4 three months in a community blood bank in the
5 United States, which has presumably given you first-hand
6 experience of the very different way in which blood
7 collection is organised there?

8 A. Curiously enough, it wasn't all that different. I think
9 the misconception still existed at that time -- probably
10 in some quarters it still does -- that all blood in
11 America is paid for by paid donors, but even then, and
12 in fact for about ten years, since Harvey Alter and his
13 colleagues showed that paid donors were much more likely
14 to carry infectious diseases, transmissible viruses, the
15 whole blood donation in the United States was almost
16 entirely volunteered by that stage.

17 In fact the structure of the blood bank and how it
18 delivered blood to the hospitals and how it interacted
19 with transfusion services in the hospital was remarkably
20 similar, but of course that was not uniform across the
21 United States and I did travel to various other types of
22 centre to see how they did things. It was very
23 interesting and obviously a fairly crucial time in the
24 history of transfusion here.

25 Q. I suppose the clue is in the name "community blood

1 bank"?

2 A. Indeed, and you know, the blood banks in America and the
3 blood collection centres had various different
4 organisations. Most of it was Red Cross but this in
5 fact wasn't a Red Cross blood centre. There was
6 a council of community blood banks, which was another
7 separate organisation from the Red Cross.

8 Q. Lastly, you have a very lengthy list of publications,
9 either in your own name or to which you have
10 contributed. I certainly notice some on Hepatitis C, if
11 we look for example, at 76, which is page 10.

12 You contributed to a workshop on Hepatitis C virus
13 in 1995, and what's that, a paper? "Epidemiology of
14 Hepatitis "C?

15 A. Yes, that was a paper I gave describing our experience
16 and what we found in blood donors once we started
17 testing for Hepatitis C. It largely was similar to work
18 that was published, I think, the year before that, in
19 fact, under the first author of Crawford, which really
20 described the risk factors and other features of blood
21 donors who were found to be positive for Hepatitis C.

22 Q. Number 68. I think we are actually going to look at
23 that, where it crops up in the preliminary report as
24 well, but that's on the page before, the last reference
25 there. Is that the one you are referring to?

1 A. Yes, indeed.

2 Q. Then I also noticed, I suppose because it has a slightly
3 catchy title, number 92. You have written something
4 called "Look-back on HCV look-back" in 1999.

5 A. Yes, Transfusion Today -- this was not a peer-reviewed
6 journal by any means, I think it is the journal of the
7 International Blood Transfusion Society and it was
8 a fairly informal sort of journalistic look at the whole
9 HCV look-back process and some of the issues that
10 surrounded that.

11 Q. Thank you, Dr Gillon. I think now we need to look at
12 your statements. You have provided two statements to
13 the Inquiry, both to assist us in our task of trying to
14 get some numbers together, to get some sort of
15 understanding of how many people may have acquired
16 infection through transfusion properly so-called, or
17 through blood products.

18 In broad terms, is it fair to say that one can
19 either go about the task by trying to count the numbers
20 of people who have been identified and doing that by
21 asking people who may have been in a position to
22 identify those with Hepatitis C, acquired by
23 transfusion, or one can start with known prevalence of
24 Hepatitis C, say among blood donors, and try to do
25 various, more statistical exercises, modelling exercise

1 to try to work out how many people are likely to have
2 become infected?

3 A. Yes, and both are fraught with difficulties, slightly
4 different problems in either approach. What I have been
5 doing in these papers is describing the numbers of
6 people who have been reported to us as individuals, as
7 patients -- well, some of them as donors, presenting to
8 us as donors who had a history of transfusion -- and
9 trying to establish the truth or otherwise of that mode
10 of transmission.

11 So these are really quite restricted numbers. They
12 depend to a large extent on clinicians, who have
13 identified a patient with Hepatitis C thinking about the
14 possibility of transfusion. The patient may mention it
15 spontaneously but may not. Then doing a further leap of
16 logic of saying, "Well, let's see if the Blood
17 Transfusion Service can either verify that or tell us
18 whether or not it is a real issue".

19 The other approach is simply to collect data, as HPS
20 does, and of course it is not simple. Again it depends
21 on having a reporting system. The advantage they have
22 is that they can put in place a systematic reporting
23 system. The first such I think was -- and it is
24 described in Professor Goldberg's statement and I'm sure
25 he will be talking about it later -- when HIV testing

1 was on the horizon, they put in place, through the
2 virus, virology laboratories throughout Scotland,
3 a single unified referral form for the clinicians to use
4 to request the test and HPS -- or SCIEH as it was then
5 called -- automatically received a copy of the referral
6 forms for every positive. So they got to know about
7 every positive HIV identified in Scotland at that time.

8 I am sure Professor Goldberg can elaborate on that,
9 but you can see that that is a much more secure way of
10 getting some feel for the numbers of people out there
11 with a positive test result.

12 We depend much more on a logical deduction from
13 a clinician. Perhaps it is something that needs to be
14 explored further with the transfusion service.

15 Q. There were two points really that arose from that,
16 Dr Gillon. The first was, and I think you have really
17 dealt with this, but as far as the epidemiological
18 modelling and the use of statistics is concerned, we
19 should really ask Professor Goldberg more about that,
20 I think?

21 A. I think that would probably be appropriate. There are
22 a lot of assumptions in any modelling to try and work
23 backwards from those raw numbers that they get and the
24 information that comes with it. Because they do get
25 some information about the patient's risk factors, the

1 age, the sex and so on, and geographical locations.

2 So they have a certain amount of good hard
3 information to go on but to transform that into real
4 numbers in the population is really very difficult. In
5 fact, for any of these viruses it's difficult to get
6 good data on prevalence in the population. I'm sure
7 that is going to be an issue that we will explore.

8 Q. The second point I was just going to confirm with you
9 was that there isn't any obligation on a clinician to
10 report to you as a blood transfusion service that they
11 have come across a patient who may have acquired
12 Hepatitis C via transfusion. Is that correct?

13 A. Historically there was no sort of legal obligation, if
14 you like. It was certainly a recommendation in, for
15 instance, I think, publications like the notes for
16 transfusion that, you know, clinicians should report but
17 not many surgeons would have read that, I wouldn't have
18 imagined.

19 So it has always been informal until fairly
20 recently, and I forgot to mention this in my statement,
21 I think, that that position changed drastically in 2005
22 with the European Directive On Blood Safety, which was
23 transmitted into UK criminal law, as the Blood Safety
24 and Quality Regulations 2005.

25 One of the main focuses of that had come out,

1 I think, largely from what we knew about these
2 transfusion transmissible viruses and the issue of
3 look-back and the difficulty in tracing patients who had
4 had transfusions many years previously and differing
5 standards in, for instance, peripheral hospital blood
6 banks and in transfusion centres and so on.

7 In 2005 BSQR, the safety and quality regulations,
8 stipulated that for the first time the hospital blood
9 banks had to come into the MHRA regulatory framework --
10 that's Medicines and Healthcare Regulatory Authority --
11 whose role was beefed up. They had to take on board
12 inspecting hospital blood banks as well as transfusion
13 centres, which had been inspected through the medicines
14 inspectorate system for many, many years. Largely that
15 was because of this gap in what became known as the
16 traceability of previous donations and therefore the
17 patients who received them.

18 So traceability became entrenched in that and an
19 obligation on clinicians, blood banks and transfusion
20 service, obviously, to report very formally to MHRA when
21 we had a serious adverse event of transfusion, which
22 obviously these cases would be defined as.

23 Q. If we have in front of us [\[PEN0010043\]](#), we can see,
24 I think, from this, as we work through it, an
25 illustration of the type of exercise I was describing

1 earlier about counting the number of people you know
2 about. Indeed, you have described that for us in this
3 statement, grouping people into three categories. Just
4 looking in your preamble, you say that some of the
5 information you have included in a paper on look-back,
6 and you have also obtained information from the national
7 Hepatitis C register, which is at Colindale. That's
8 based in England. That's the Communicable Diseases
9 Surveillance Centre; is that correct?

10 A. That's right. Also known as the Health Protection
11 Agency.

12 Q. So HPA is in England and HPS is in Scotland?

13 A. Yes, that's right.

14 Q. Yes. That HPA, there are data on 103 patients
15 identified through the targeted look-back procedure
16 required by the Department of Health in 1995. Can
17 I just ask you to take us through 1.1. This is
18 people --

19 THE CHAIRMAN: Sorry, before we go there, could I ask about
20 the Colindale data.

21 Is it dependent upon reporting by clinicians as your
22 data was?

23 A. No, this grew out of the formal look-back which is
24 described in 1.1, when, in the run-up to that, it was
25 really our colleagues in the Blood Transfusion Service

1 in England and Wales who had the idea of trying to
2 establish a cohort of these patients who would be
3 followed prospectively and anonymously to get
4 information about the natural history of the disease.

5 The great advantage of these patients for this being
6 that the exact date of the transfusion was known, so
7 that the length of infection was clear.

8 THE CHAIRMAN: At the moment my interest is in knowing
9 whether the data is homogeneous or whether you are now
10 putting together our data from the Colindale type
11 look-back exercise and data of the kind you have
12 described as collected by your department, which
13 depended upon a clinician finding a significant interest
14 in hepatitis and reporting it. Is the data
15 homogeneous --

16 A. It is homogeneous and all derived north and south of the
17 border from patients identified through look-back which
18 starts from a donor with a positive HCV test.

19 THE CHAIRMAN: Thank you.

20 MS DUNLOP: Dr Gillon, the first of your groups of people
21 are those who have come to the attention of the Blood
22 Transfusion Service because they are themselves donors
23 and it has turned out, since the introduction of
24 screening in 1991, that they have been identified as
25 Hepatitis C positive. So that's, if you like, the first

1 way in which a group of people have come to your
2 attention.

3 A. Yes.

4 Q. The number of that group of people -- and you have told
5 us this -- is 59?

6 A. Yes.

7 Q. Is that right? You say that people who have been
8 identified in that way have themselves been investigated
9 to try to establish whether a source donor could be
10 identified, but in only nine of the 59 cases was a date
11 of transfusion given. So that looks like that wasn't
12 a particularly fruitful exercise. Is that correct?

13 A. I think that probably gives too negative a view of it.
14 What I have presented here was what was reported on
15 our routine epidemiology reporting forms back to
16 Dr Brian Dow, who was responsible for liaison with HPS
17 and for collecting the data for SNBTS. It is quite
18 likely that more of those 59 cases in fact, on further
19 investigation, were shown to have been transfused and
20 may in fact have sparked a second round of look-back as
21 a result of finding the donor who was responsible for
22 the donation which led to them being infected with
23 Hepatitis C. So these are just the raw data that were
24 given to Brian Dow quite early on in the process of
25 sorting this out.

1 Because of the numbers and the shortage of time, we
2 simply haven't been able to go back to all of those 59
3 cases to examine them individually and bring that
4 information to the Inquiry.

5 Q. I take it that what's reflected by this number, 59
6 people, is the fact that people who themselves receive
7 a blood transfusion sometimes are motivated to go on and
8 become blood donors. Is that correct?

9 A. Indeed, it is a very powerful motivation and we don't
10 have very good data for the prevalence in the general
11 population of a past history of blood transfusion but,
12 as you can see, the overall 6.8 per cent of these donors
13 is a reasonable percentage. It is very powerful as
14 transfusion in a close relative is also a very powerful
15 motivating factor.

16 Q. In a close relative, did you say?

17 A. Yes.

18 Q. This is really, sir, an issue which has come to the
19 attention of the Inquiry and we are hoping that
20 Dr Gillon will be able to cover it a little more fully
21 when he returns next week because I appreciate it
22 certainly arose in connection with one of the cases we
23 looked at last week.

24 The second of your three groups of people -- and
25 this is on the next page, if we look at 1.2 -- is

1 a group of people who were identified through the
2 targeted look-back procedure required by the Department
3 of Health in 1995. That number is 133 people.

4 I wanted to digress slightly at this point and ask
5 you about look-back exercises in general, in the first
6 place. I gather that "look-back" is a term that was
7 really coined in connection with AIDS. Is that
8 accurate?

9 A. Yes, people had been doing look-back without calling it
10 that, for quite some time. We know that, for instance,
11 when the test for Hepatitis B was introduced in 1970 and
12 they started looking at it in the West of Scotland, they
13 made a recommendation, the very first paper, that there
14 should be an attempt to trace previous recipients of
15 anybody who was found to be positive.

16 So the procedure was already there and I'm not sure
17 to what extent it had been pursued in the case of
18 Hepatitis B. But it was first described as "look-back",
19 as far as I can find, in a paper in 1984 in the
20 United States, which was in relation to HIV.

21 Q. Yes. There are, as I understand it, certain
22 difficulties with any look-back exercise. I wonder if
23 I could try to run some of them past you and obtain your
24 comments, Dr Gillon.

25 First, potential difficulty is how long the

1 infectious agent has been present before a test becomes
2 available. I think it is probably reasonably
3 self-explanatory why that is difficult, why that can be
4 difficult but perhaps you can give us that in your
5 words?

6 A. I can. The contrast between Hepatitis C and HIV is
7 revelatory here because when we started testing for HIV
8 in 1985, the disease, the virus had only been present in
9 the general population, and therefore the donor
10 population, for two or three years really, perhaps
11 slightly longer than that in the United States.
12 Therefore, when the test was introduced, the numbers of
13 previous donations from any individual donor that were
14 dangerous were limited to that two to three-year period.

15 So the donations prior to the virus arriving in the
16 population weren't significant in that sense, whereas in
17 the case of Hepatitis C, we knew then and we know now
18 that it had been present for many years before a test
19 came along, which meant that some donors who had been
20 donating for a long period had in fact been carrying the
21 virus and were therefore capable of transmitting it. So
22 the impact of that on a look-back exercise means that it
23 is hugely more complicated and more difficult and vastly
24 more patients potentially are affected.

25 Q. I suppose, if one were doing look-back in general on the

1 whole of Hepatitis C, you would find secondary and even
2 tertiary levels of infection. If you imagine someone
3 who perhaps acquired it from a blood transfusion and
4 then, as we have said, passes it on through themselves
5 becoming a blood donor; it is almost like a kind of
6 family tree, is it?

7 A. Yes, indeed. There are various methods of spread. They
8 could become an organ donor for instance, or there could
9 be secondary sexual transmission or whatever. So there
10 are ramifications, yes.

11 THE CHAIRMAN: I wonder if I could ask a question at this
12 stage. Doctor, I'm interested in two aspects, I think,
13 of this matter. One is the change over time in the
14 means of transmission, because I assume that people's
15 habits change and the behaviour that can lead to spread
16 will not be the same over history. And perhaps you will
17 see the other aspect is whether one can, in any way,
18 limit retrospectively the point in time at which what we
19 now know as HCV entered the world?

20 I have seen reference to HCV not being known before
21 a certain period. Does that bear on where it may have
22 come from in time? Has it always been here?

23 A. It is certainly a very ancient virus, an ancient group
24 of viruses. In broad terms, we think of it as having
25 been an issue since the Second World War but that's

1 partly, I think, because transfusion has really only
2 existed since the Second World War.

3 Professor Peter Simmonds, who worked with us on
4 Hepatitis C and is now a world expert on Hepatitis C as
5 a virological problem -- he is an expert in the genetics
6 of Hepatitis C or the virus itself -- they have
7 developed methods of looking at the subtypes of virus
8 and how they have diverged and effectively constructing
9 an evolutionary tree for the virus. I think it is
10 thought to be quite an ancient virus that has been
11 around for a long time.

12 Having said that, the impact on the human population
13 is fairly recent, I think, and the data that we have --
14 and again Professor Goldberg might be the best person to
15 speak to this -- studies from America and modelling
16 studies from France, some data from the HPA, suggest
17 that the incidence -- in Western countries, certainly --
18 ramped up through the 70s and 80s and peaked around
19 about the mid 1980s. Largely that was to do with
20 intravenous drug use.

21 THE CHAIRMAN: Thank you very much.

22 That was the sort of distinction that I was
23 interested in. We have something of indeterminate age
24 that affects the population from time to time in ways
25 that will vary according to factors such as the

1 introduction of intravenous drug abuse or perhaps other
2 forms of conduct, and certainly because of the way the
3 transfusion services themselves may have operated from
4 time to time.

5 A. Yes.

6 THE CHAIRMAN: Thank you.

7 MS DUNLOP: Doctor, I was asking you about some of the
8 factors that can make look-back either more
9 straightforward or more difficult, and another one I was
10 going to put to you was the virulence of the agent.

11 A. Yes. I think the truth is that if you have a very
12 virulent agent, by the time you do a look-back, if
13 a long time has elapsed before you manage to get a test
14 to identify the people who had been carrying it, if it
15 is a very virulent agent, a large proportion of them may
16 be dead as a result of that.

17 We find in any look-back, depending on the length of
18 time before you start doing it, that, of course,
19 a significant proportion of patients will have died from
20 the presenting disease or indeed from some other
21 disease.

22 Q. Yes. Perhaps the point you are making is summed up by
23 the propositions that I have had from you before today,
24 that the number of patients traced and found to be alive
25 in a look-back exercise is inversely proportional to the

1 time elapsed between transfusion and the discovery of
2 the patient via the look-back, which may sound a bit
3 indigestible but I think is probably common sense?

4 THE CHAIRMAN: Perhaps if we take it again --

5 MS DUNLOP: I think Dr Gillon can express it more simply
6 today; I think he already has.

7 A. Well, I think the simple fact is that the longer time
8 that has elapsed between the putative transmission event
9 and the point at which that is identified, the more
10 likely it is that that person will have died, probably
11 of some other cause but possibly of the infection itself
12 in the meantime.

13 Q. Yes.

14 THE CHAIRMAN: Only survivors can be candidates for
15 examination.

16 A. Indeed.

17 MS DUNLOP: And the number of those candidates that one will
18 be able to find is inversely proportional to the time
19 which has gone past or the time which has elapsed
20 between the transfusion event and the person being
21 identified.

22 Another difficulty, I think, with look-back
23 exercises and one which I think may be present here, is
24 that records from the early 1980s -- that is blood
25 transfusion records, bloods bank records in hospitals

1 and so on -- and before tend to be in paper form. Is
2 that a problem?

3 A. I think the past tense is more a problem. They tended
4 to be in paper form and many of them were lost or
5 destroyed or discarded and it also depended on how paper
6 records were kept, how easy it was to relate back to an
7 event that had happened a long time ago.

8 For instance, let's say in Edinburgh, Edinburgh
9 Royal Infirmary or whatever, in 1979 a patient had been
10 transfused. We didn't get to know about it until the
11 1990s. We would be entirely dependent, first of all on
12 the hospital records still being in existence. That
13 would be necessary to give us the unique donation
14 numbers that could link that unit of blood to a given
15 donor; but secondly, also to our own record-keeping
16 system. Even with a donation number, at that distance
17 in time it would be virtually impossible for us to link
18 the donation number to the donor because it was a simple
19 card system that we had for the donors in the 1970s,
20 which were not stored alphabetically, were not
21 searchable in the modern sense of, you know, putting
22 a donation number into a computer and linking it to the
23 donor who gave that. Different transfusion centres had
24 different systems for how they kept the donor records,
25 whether it was a card system or -- well, they were all

1 by definition card systems in those days.

2 Q. This is really the pre-computer era, you are describing?

3 A. It is the pre-computer era. The first computerisation
4 was in 1983, which was one of the first in the world, if
5 not the first in the world to link that specific
6 donation number to the identity of a donor and to the
7 identity of the patient who got it. Since then we have
8 been able to do that.

9 THE CHAIRMAN: Doctor, I think I have seen reference to
10 a system operating in the Glasgow and South Western area
11 very early on that used computer tape, what was then
12 called computer tape. It was really a form of machine
13 accounting. Do you remember that?

14 A. I do.

15 THE CHAIRMAN: How long back did that go?

16 A. I am afraid I can't answer that but that was largely
17 a laboratory-based method. So that was about the
18 donation and the tests on the donation. What was
19 different in what we developed in Edinburgh in 1983 was
20 the link to the patient.

21 THE CHAIRMAN: I see. Since I remember these systems
22 operating in the late 1950s, when I was an auditor
23 assistant in a firm of chartered accountants, they go
24 back an awful lot longer than the period you are talking
25 about.

1 Ms Dunlop, I wanted to interrupt. There is quite
2 a bit of interference coming through from time to time
3 which must be due either, I'm told, to someone having
4 left their mobile phone on for text messages and emails
5 coming into laptops. If it is the latter, I don't know
6 that there is anything that can be done about it but
7 I would like people to make sure that they don't have
8 their phones on. It is quite annoying getting the
9 feedback and if anyone can switch off their inbox,
10 I don't know whether they can, that's going to help too.

11 So ladies and gentlemen, if you would just make sure
12 you are not the cause of the interference, I would be
13 obliged.

14 MS DUNLOP: I think, Dr Gillon, we can imagine the problem
15 you are describing because we have seen, even from the
16 1970s, that people's medical records may very faithfully
17 document a batch number of a pack of blood that was
18 transfused to them, but the question of whether one can
19 do what is really the reverse exercise, and go to some
20 sort of record, see that batch number or that pack
21 number and work out where it went, is really the problem
22 that you are describing, I think, is it?

23 A. Well, it can go either way. It can be difficult in
24 either direction.

25 Q. So it can be very difficult to discover to whom

1 a component was transfused and then I expect there are
2 the additional human difficulties when one tries to
3 track patients, that people move and become lost or even
4 emigrate -- women marry, change their names, all of
5 these -- which make people difficult to trace.

6 A. That's correct, we could have quite a clear track back
7 to identify an individual patient but then find it quite
8 impossible to trace where that patient now was or who --
9 you know, people move, they may not register with a new
10 GP.

11 One of the ways we used to track patients is through
12 the GP tracking system, which in those days wasn't
13 particularly good. Nowadays, it is really relatively
14 easy to find people almost anywhere in the UK quite
15 quickly, provided they have registered with a GP.

16 Q. I wanted to ask you still in connection with the notion
17 of look-back, if you could look at another document,
18 [\[PEN0020803\]](#). This is a report to the health committee
19 in the Scottish Parliament and the interesting feature
20 of it is that it contains within it a little more
21 information about the numbers traced by the look-back
22 exercise.

23 We need to look at page 2. This is a report for
24 which the then health secretary, Andy Kerr, was,
25 I think, responsible. It was submitted to the health

1 committee on 31 January 2006. If we look at page 2, you
2 see there that the results of the look-back for Scotland
3 have been tabulated. I think the number we need to look
4 at to link into your statement is the 133, which we see
5 a little more than half way down. If we look at the
6 table, it is basically a sequential progression through
7 the different steps; is that right, doctor?

8 A. Yes, that's correct.

9 Q. Once screening of donated blood comes in in 1991, it is
10 possible to identify blood donors using that test and if
11 they have given before 1991, you can work out how many
12 donations they have contributed. That would be the
13 1,658 number?

14 A. Yes.

15 Q. Then that 1,658 has become 2,026 components. What do we
16 mean by "components"?

17 A. That refers to the process whereby a whole blood
18 donation is separated by centrifugation into its
19 cellular components, which are red cells primarily.
20 That's what we think of as a blood transfusion, red
21 cells, and tiny cells called platelets which form
22 a separate layer in centrifugation. They can be
23 separated out and used as a concentrate for patients at
24 risk of bleeding because of a low platelet count.

25 These are cells which are crucial in the coagulation

1 process and the supernatant, the clear fluid, which is
2 the plasma, which until 1998 was used for fractionation
3 into further blood products such as Factor IX,
4 immunoglobulins and so on, or can be used as fresh
5 frozen plasma and given to an individual patient.

6 Q. Yes. But when you are talking about the number of
7 components, the 2026, which breaks down into 1,356,
8 which were traced in the 60s and 70s, which were not
9 traced, that presumably doesn't include the blood
10 product concentrates made for people with haemophilia?

11 A. No, that's correct. When we talk about components, we
12 are usually referring to the fresh blood components,
13 which would be red cells, platelet concentrate and fresh
14 frozen plasma.

15 Q. Then we go further down the sequence of events. Of the
16 1,356 components that were traced, it was possible to
17 identify 880 recipients, and the number of people
18 potentially eligible for counselling and testing perhaps
19 at first sight looks a small fraction but there is some
20 explanation of that, if we look in the box below, where
21 536 people are described as being deceased?

22 A. That's right, it is slightly out of sequence there, yes.

23 Q. So the point that his Lordship made earlier, that
24 obviously, to be eligible for counselling and testing,
25 you have to be alive.

1 A. Yes.

2 Q. It is true, is it, doctor, that a number of those who
3 receive a blood transfusion don't survive more than,
4 what, one or two years after the transfusion?

5 A. Yes, there are various studies from various parts of the
6 world, and I think it has improved with time in the
7 sense that the medical care for the primary condition
8 that the patient has has improved, but when this started
9 to be looked at in the late 80s and early 90s, the
10 survival of patients who had had a transfusion was
11 really surprisingly poor. That was not to do with the
12 transfusion or viruses but with the severity of the
13 illness that led to the transfusion. Within a few years
14 you could expect to find 50 per cent of people had died.

15 Q. Out of the 266 people, exactly half in fact had been
16 counselled and tested positive. 133. Then 70 of them
17 had been counselled and had tested negative. The other
18 group of 63 people, there are some different
19 explanations for that group: people who didn't want to
20 be tested or where the results for whatever reason
21 haven't made their way back to the Blood Transfusion
22 Service, or a group of people described as not
23 appropriate for testing. What might that cover?

24 A. That would be a small group of patients usually very
25 elderly, maybe in a care home, perhaps with dementia,

1 with a low life expectancy who were not able to consent
2 appropriately to being tested. It was usually the GP's
3 decision that they didn't want to inform the patient.

4 Q. Finally, there were 78 recipients who were just not
5 traceable and that perhaps reflects the points we made
6 earlier about the human factors.

7 A. Yes.

8 Q. People moving away or moving abroad even, and other
9 circumstances like that. So that's where the second of
10 your three numbers comes from, the 133 people who were
11 identified through the look-back. I wanted actually
12 just before we leave the topic of look-back, to look at
13 what is said in the preliminary report about this. If
14 I could ask that Dr Gillon has in front of him page 321
15 of the preliminary report, please. It is chapter 9 and
16 it is paragraph 9.295.

17 It's probably slightly slower, sir, because each
18 page doesn't have its own identifier. We have chapter
19 9. It is a long chapter, I am afraid. It does have its
20 own number. I just didn't know it, sorry.

21 Mr Mackenzie's suggestion is that you should go to the
22 back because it is quite near the end of the chapter.
23 So that might be quicker. Here we are, 321, thank you.

24 Here you are, Dr Gillon, in the preliminary report
25 in paragraph 9.295, and this is actually a description

1 of an earlier, I suppose, look-back, that you had done
2 within Scotland. Is that right?

3 A. That's correct. We started doing look-back as soon as
4 we started Hepatitis C testing. In fact this became our
5 contribution to the look-back. So our patients
6 identified through that are part of that 133.

7 Q. Right. That, I think, we can see from the footnote,
8 which is 344, I think. It is actually from the previous
9 paragraph but the footnote, 344, is the reference to the
10 paper that we found in your CV. I think it was number
11 68. Is that right?

12 A. Yes.

13 Q. Crawford and others?

14 A. Yes. That doesn't refer to the look-back as such.
15 That's just the characteristics of the donors. The
16 look-back is described in a following reference, Ayob et
17 al.

18 Q. Yes, thank you. I did want to look also at the extract
19 from your paper, the Ayob report, which is quoted on the
20 following page, 322. We find there, Dr Gillon, really a
21 summation of the views of the authors as to the,
22 I suppose, ethical reasons for undertaking the exercise.
23 Is that what's being described?

24 A. Yes. I felt very strongly that the look-back was
25 ethically -- well, more than desirable. I felt it was

1 a responsibility that we should take on board.

2 Q. You felt an overwhelming responsibility to the
3 individual patient?

4 A. Yes.

5 Q. Thank you. The third and final group in your group of
6 three different categories of individuals is back to
7 your report and back to your statement at PEN0010044.
8 This is the group of people who have been reported to
9 SNBTS by clinicians. So for the most part
10 hepatologists, gastroenterologists who have come across
11 a patient who has Hepatitis C and they think that the
12 likely mode of infection has been transfusion. Is that
13 right?

14 A. That's correct, yes.

15 Q. You give us a breakdown for the five Scottish areas of
16 that group of patients who total 28.

17 Then you provide a slight reservation. You say:

18 "It is not always possible to establish the
19 diagnosis of transfusion transmitted Hepatitis C with
20 certainty as frozen sample archives mostly date back
21 only as far as 1986 and it is often not possible to
22 trace the implicated donors for testing."

23 That's frozen sample archives of blood?

24 A. Well, of plasma really, and in some cases serum, taken
25 from the original donation and frozen at the time.

1 Q. Right. Plainly, if a person is mentioned as a likely
2 case of transfusion transmitted infection and you can go
3 to a sample and test it and find that the sample did
4 contain antibodies to the virus, then you would, as it
5 were, have found the reason for the infection?

6 A. Yes.

7 Q. But where that's not possible, you draw conclusions, as
8 you say, from circumstantial evidence. You say that can
9 be because no other risk factor was declared. I think
10 you are saying that this figure reflects the fact that
11 some people have not been included, if there was,
12 I suppose, no evidence. You instance documentary
13 evidence of transfusion, absence of blood bank or donor
14 records. Would it be enough if you had one of these?
15 Would it be enough support for transfusion as the mode
16 of infection if you had documentary evidence of
17 transfusion, say?

18 A. We haven't really tried to define this. I should say
19 that this statistical exercise is entirely retrospective
20 and generated purely to answer the question from the
21 Inquiry. In other words, these were individual records
22 of individual investigations and we have tried to find
23 out such records in the five Scottish centres that still
24 exist.

25 Since 1998, which coincides with the so-called

1 completion of the look-back -- and obviously we still
2 look back if we find any reason to do so -- for the
3 statistical purpose, the counting of the look-back
4 ceased in 1998. But that coincided with the UK
5 transfusion services setting up an informal system of
6 reporting adverse events, called the SHOT system,
7 Serious Hazards of Transfusion. That was a voluntary
8 service to which we contributed and since then
9 Dr Brian Dow has collated all look-back cases and
10 reports from Scotland to forward them on to the SHOT
11 system and we therefore do have a database of this
12 information from 1998. Prior to 1998 we are dependent
13 on finding individual case records in the transfusion
14 centres and that's an amalgam. The pre-1998 stuff and
15 the post-1998 stuff is included in that 28. But
16 including cases, particularly these older ones, but some
17 of the more recent ones as well, the information is open
18 to interpretation. It can be difficult to know whether
19 to say, "Well, we accept this as a case of transfusion
20 transmission. This one probably is but we really don't
21 have enough documentary evidence to say with certainty".

22 On a number of occasions we can rule it out. We can
23 say the blood that this person received was tested, all
24 the donations were negative, all of the donors have come
25 back and tested negative subsequently. We can be

1 confident that transfusion did not transmit that
2 infection. In fact, what the data post-1998
3 demonstrates very nicely is that the majority of reports
4 that we received turned out not to be transfusion
5 transmitted infections. I have looked at Brian Dow's
6 data and in fact, since 1998 we have had 58 cases
7 reported to us. 11 of them have resulted in a concrete
8 diagnosis of transfusion transmission. In other words,
9 we have identified a donor who was positive.

10 Sorry, I think an extra 12 come into this
11 interpretable category of: we know they have had
12 a transfusion but we can't identify a donor, either
13 because there is no archive samples or there is a piece
14 of information missing somewhere but we are confident
15 the patient does have another risk factor and it looks
16 as if that might have been a transfusion transmission.

17 Interestingly, the case that illustrates that very
18 well is Mrs O'Hara because we do not have confirmation
19 that that's a transfusion transmission. So we can never
20 be 100 per cent certain.

21 Then there is the other category of patients, the
22 majority, where we can rule it out. So out of 58 we had
23 23, I think, that we would accept either categorically
24 transfusion transmission or possible transfusion
25 transmission. I think Mrs O'Hara would fit into that

1 second category.

2 There are some cases where you can feel that the
3 information that we have is a bit skimpy and therefore
4 you would hesitate to say that this is likely to be
5 a transfusion transmission. Some, like Mrs O'Hara, you
6 would be fairly confident to say, "This is probably
7 a transfusion transmission". But we know there are
8 other ways of picking up transmissible viruses in
9 hospital environments, as we will see in some of the
10 data from the renal units, for instance. Therefore,
11 unless we can identify a donor and establish that link
12 with certainty, there is always a bit of interpretation
13 that's necessary here.

14 As I think I have said, I have tried to be inclusive
15 here. In other words, not to wish to minimise the
16 figures in any way, but there is this caveat that, we
17 can never be certain unless we make the link.

18 Q. Dr Gillon, you were asked some further queries by the
19 Inquiry team after you produced this statement and you
20 provided a further written response.

21 THE CHAIRMAN: Ms Dunlop, before you go on, could I go back
22 to the first page of the document that's on the screen,
23 please, just for a moment?

24 I would just like to understand the figure of 867
25 and the 59 a little bit better, Dr Gillon. You say that

1 the number of patients treated and known to have
2 contracted Hepatitis C includes, 867 blood donors that
3 were HCV positive to the end of 2009. That's a fairly
4 precise figure, 867. That's just the accumulation of
5 data from records, is it?

6 A. Yes, these are realtime accumulating data on the numbers
7 of blood donors identified through our routine testing
8 system to have antibodies to Hepatitis C.

9 THE CHAIRMAN: Those 6.8 per cent, 59 people, have been
10 identified by what one might now call a conventional
11 testing mechanism.

12 A. No. Those are people who on counselling, usually by
13 a transfusion service doctor but sometimes by their GP
14 or the clinician who was responsible for the initial
15 transfusion, have said that they think they got it from
16 blood transfusion.

17 THE CHAIRMAN: I see. So there is not an objective
18 verification of that. It depends upon the reporting by
19 the individual?

20 A. Yes, entirely.

21 THE CHAIRMAN: I see. If we go back to the following page,
22 please, just to get a clearer picture of the nature of
23 the data. The second class, I think you have identified
24 fairly clearly as the people who are identified
25 positively by the look-back.

1 A. Yes.

2 Q. The third class of people who have been fully examined,
3 fully followed up, as it were, and overall we have got
4 a number that comes to 220 people.

5 A. Yes.

6 THE CHAIRMAN: Would it be right to look on the
7 candidates -- just among those numbers, and forgetting
8 the background -- as really coming to about 1,000? The
9 867 plus the other two categories. Or is the class much
10 wider than that?

11 A. No, the 867 are the seropositive blood donors identified
12 on routine screening. If you take 59 away from that,
13 the rest are the other blood donors who had a risk
14 factor such as drug use or some other means of
15 transmission. A substantial proportion, 20 to
16 30 per cent -- and every transfusion finds this --
17 report no risk activity whatever.

18 THE CHAIRMAN: But again, that depends on the subjective
19 material provided by the individual being studied?

20 Yes. Is there any sense of underreporting by people
21 who are asked questions or is it just a case that the
22 individual may not know?

23 A. There is a sense of underreporting. Certainly in my own
24 experience, I have encountered donors who on meeting
25 them for the second or third time -- and we sometimes

1 follow them up, depending on how much support they
2 need -- will say, "Well, I didn't tell you this the
3 first time I saw you but I used drugs once at a party in
4 1978" or something like that.

5 THE CHAIRMAN: Quite apart from drugs there would be those
6 who had piercings in their youth and may have forgotten?

7 A. Well, one of the things that people don't realise is how
8 dangerous homemade tattoos were. There was a bit of
9 a fashion for that in the 70s and 80s.

10 THE CHAIRMAN: I suppose something like that will almost
11 certainly not have had any symptomatic signs at the
12 time.

13 A. No, the vast majority of non-A non-B hepatitis as it
14 then was, Hepatitis C, have no symptoms whatever.

15 THE CHAIRMAN: So we are dealing with people who may not
16 have attributed any significance at all to this event in
17 their past.

18 A. That's correct.

19 THE CHAIRMAN: It may not necessarily be wilful withholding
20 of information in some cases.

21 A. Yes. I think at times there is denial going on about
22 behaviour in the past.

23 THE CHAIRMAN: Well, there is a natural explanation of
24 denial, isn't there?

25 A. Yes.

1 MS DUNLOP: Just another short point, Dr Gillon, and then

2 I think it is probably time for a break.

3 You were posed some further queries by the Inquiry
4 team.

5 Sorry, but this is one occasion where I would like
6 to juxtapose the two documents, if I could, please. The
7 follow-up queries of [\[PEN0131557\]](#). We need to go to the
8 second page, please, to PEN0131558. Thank you.

9 Just in case people are wondering what the question
10 was, firstly you were asked: could there be any overlap
11 between those three groups? You have answered that
12 there. I think in short you are saying: well, you can't
13 rule it out but you don't think it is very likely.

14 A. Yes, I think that's exactly right.

15 Q. Can we go down that answer a little bit, please.

16 You go on to say what you have really just said in
17 your evidence. You have explained a little bit more of
18 the detail, particularly of the third group; how you
19 went about deciding whether or not to include
20 a particular individual in your third group of people.
21 We find that set out there. Is that correct?

22 A. Yes, that's right. I think there is no doubt that a
23 total of 28 is way off what is the reservoir of such
24 cases in the population. We don't know by how much, of
25 course.

1 Q. Yes, because -- and we really come full circle here but
2 we are right back to what you said at the beginning
3 about clinicians -- it is really dependent on the
4 clinician having the thought and reporting somebody to
5 you as a possible case of transfusion transmitted
6 Hepatitis C.

7 A. Yes.

8 MS DUNLOP: I think, sir, that would be quite a good moment
9 to stop for a short break and then we can take the rest
10 of the Dr Gillon's evidence.

11 THE CHAIRMAN: Yes, I should ask one question about that
12 last category which is interesting me. Where one is
13 dependent on a clinician making a report, is it likely
14 that the clinician will report only where he sees some
15 significance in the context of his operations for the
16 factor or feature, or do people report just casually if
17 they come across it?

18 A. No, I think the first is the correct interpretation,
19 which is that we would tend to see reports historically
20 from, for instance, haematologists, who are dealing with
21 patients all the time, who are requiring multiple
22 transfusions. We have fairly close and constant
23 interaction with them. So the link is there.
24 Similarly, in units who use a lot of blood, like cardiac
25 surgery -- and again we have a lot of clinical links --

1 introduction of testing. The reason they were
2 interested in this and monitoring it was that it was
3 well-known that hepatitis transmission in renal units.

4 THE CHAIRMAN: Ms Dunlop, I have to interrupt. There is
5 something wrong with the sound system. No one is
6 hearing what's being said.

7 (Pause)

8 Can we start again.

9 A. Is that better?

10 MS DUNLOP: Yes. I think you are going to have to start
11 again, Dr Gillon, with your explanation of where the 18
12 people come from.

13 A. Right. Well these were patients who were reported by
14 the renal units in the West of Scotland as having been
15 identified to have Hepatitis C when they started routine
16 testing for that after the test became available, and
17 who might have been infected as a result of
18 a transfusion.

19 Hepatitis of all sorts really -- it started with
20 Hepatitis B-- does have a high prevalence in patients
21 on chronic dialysis. That had been known for many
22 years. The reasons for that weren't entirely clear even
23 to this day. Some of it was transmitted by the process
24 itself, by the difficulty in sterilising dialysis
25 machines, particularly the earlier ones. It's not

1 a problem now. But there were probably other routes of
2 spread within dialysis units as well.

3 On top of that, patients with chronic renal failure
4 have sometimes quite severe anaemia as part of their
5 condition and require regular transfusions. So many of
6 these patients will have had many, many transfusions and
7 most of those would probably have gone back beyond the
8 time when the sample archive was started, which in the
9 West of Scotland, was 1986, I think.

10 So I don't know who made the decision but at some
11 point it was decided that these cases should not be
12 investigated or could not be investigated further to try
13 to identify a source. But they were there. They were
14 known as potential transfusion transmissions and that's
15 as much as I know about it.

16 Q. Right. You have explained to us about the renal
17 dialysis unit. Is that the second paragraph? The
18 paragraph beginning "A small number ..."? You talk
19 about the risk of nosocomial infection, which goes with
20 dialysis.

21 A. Yes. That's what I was talking about, either through
22 the equipment itself, through, conceivably, reuse of
23 other types of equipment which shouldn't have happened,
24 like, you know, reuse of needles. It just shouldn't
25 have happened, that kind of thing. There is still some

1 doubt about exactly how the prevalence in some units got
2 to be as high as, in some places, 20 per cent of
3 patients.

4 Q. We did, I think, ask you about this too in our follow-up
5 document, Dr Gillon. If we could again see that beside
6 Dr Gillon's statement, please. The document is
7 [\[PEN0131557\]](#).

8 If we could go to the next page, please and the page
9 after that too. There is a paragraph with the number 4,
10 where you say the high prevalence of parenterally
11 transmitted virus infections. Parenterally infections
12 are those which are essentially blood to blood or wider
13 than that, bodily fluids?

14 A. Bodily fluids yes.

15 Q. Rather than enterally which would be things you eat and
16 drink?

17 A. Yes.

18 Q. Yes?

19 A. Can I apologise for the typo, which a colleague
20 gleefully pointed out to me, of "incompletely
21 misunderstood".

22 Q. I was just about to take you to that, yes. There is an
23 extra "mis" in there. We will take that out. I think
24 that's the explanation you have just given us. I'm also
25 interested in the word "nosocomial" which we have seen

1 before. That probably has classical etymology but could
2 we just say hospital-acquired infection?

3 A. Yes. I am afraid I can't enlighten you about the
4 derivation of the term.

5 Q. I think the other people I was interested in were the
6 bone marrow transplant recipients. They number 18,
7 I think. Are those people with leukaemia and other --

8 A. Yes, they would be people with primarily leukaemia who
9 had had multiple transfusions over many years, resulting
10 in bone marrow transplantation.

11 Q. They have been added in but as I understand it, you are
12 saying identification of the donations which infected
13 them was considered impossible because of the number of
14 transfusions involved. So they have had a lot of
15 transfusions and you presumably do not have test results
16 which would enable you to pinpoint any one transfusion
17 in relation to an individual.

18 A. I imagine that was the case. In such a case, really the
19 only way you can find if there is a donor who
20 transmitted would be to have archive samples which you
21 can go back and test. We have certainly in Edinburgh
22 done occasional look-backs where we have tested between
23 100 and 200 samples, which is a very big exercise.
24 Occasionally it does provide results. But some of these
25 patients will have had hundreds of individual units of

1 transfusion and many of them will have had these
2 transfusions before the archive samples started, which
3 would make it impossible.

4 Q. I see. You were also asked, if you could, to address
5 the date of transfusion -- and this is back to your
6 report -- which resulted in each patient -- I think it
7 is probably contracting Hepatitis C. You have told us,
8 first in relation to the second of your three groups --
9 that is the look-back people, if we can call them that
10 for shorthand --

11 A. Yes.

12 Q. You have set out in your report, beginning at the bottom
13 of page 3, the numbers identified for each year. The
14 subset is in fact 103 of the 133. I think you were
15 asked, "Well, why is it only 103 of the 133?" And
16 that's in the further queries at the side. You have
17 dealt with that too. Paragraph 5. The goal was to
18 include all 133 but for various reasons 30 of them
19 dropped off the survey really.

20 A. Yes.

21 Q. You say you have discussed this with Dr Helen Harris,
22 who is the coordinator of the register from CDSC or HPA
23 at Colindale. She made a number of visits to the
24 transfusion centres and she included all the patients
25 whose details she could get. You say:

1 "The reasons why some patient records were not
2 available ..."

3 This is looking at your paragraph 5:

4 "... are not clear. It is likely work was ongoing
5 in certain cases, ongoing correspondence ..."

6 But you say:

7 "The 103 patients can be taken as unselected and
8 therefore representative of the 133."

9 So you think they are a reasonable spread?

10 A. I'm sure they are representative having spoken to
11 Helen Harris. There was no selection for entry into the
12 study, other than that the records should be available.
13 She, like me, cannot explain why on the day she got some
14 records and not others. But she certainly got most of
15 them. The only real entry criterion was that it should
16 be transfusion transmitted -- which it was by
17 definition -- and a known date of transfusion.

18 Q. In appendix 1 to your report, page 50, PEN0010050. There
19 is a tiny typo here, Dr Gillon. If we look at the
20 right-hand column and count four from the bottom, that
21 should obviously be 1985?

22 A. Oh, yes, I do apologise.

23 Q. Just so we know. You have actually produced the same
24 data in the body of your statement, showing us the
25 numbers in each particular year. So if we go back to

1 page 45. It is PEN0010045 on the left.

2 It looks actually, give or take one or two years,
3 a pretty steady rise to 1991. I wondered if that was
4 just because in the nature of the exercise you are
5 looking at blood donors who have been picked up after
6 screening in 1991 and you are more likely to find
7 donations that they have given that have been transfused
8 in the years closer to 1991 than if you were to go
9 further back. Is it as simple as that?

10 A. Probably not quite as simple. It will also illustrate
11 the point that we made earlier that, the further back
12 you go, the more likely it is that the patient will have
13 died of some other problem or indeed that it will be
14 harder to trace the person -- well, no, obviously these
15 are people who have been traced.

16 Q. Thank you.

17 A. I think your point is valid.

18 THE CHAIRMAN: If we treat the 103 as truly representative
19 of the whole group, then one would expect the spread to
20 be similar for the unknowns as it is in the 103? Or
21 not?

22 A. I'm sorry, the "unknowns"?

23 THE CHAIRMAN: You have indicated that Dr Harris' study
24 identified 103 of the 133.

25 A. Yes.

1 THE CHAIRMAN: Whose data could be analysed and you and she
2 agree that they are representative of the class as
3 a whole.

4 A. The 133, yes.

5 THE CHAIRMAN: Yes. So if we take 103 from 133, we get an
6 answer that so far doesn't have a date of transmission
7 attributed particularly.

8 A. Well, no, I don't think she excluded them on that basis.
9 I think for some reason the records were not there when
10 she --

11 THE CHAIRMAN: I appreciate that. I'm just wondering
12 whether the chronological spread can be taken to follow
13 the same curve --

14 A. I would expect so.

15 THE CHAIRMAN: -- as the 103.

16 A. I would expect so.

17 THE CHAIRMAN: So one would have again a concentration in
18 the second half of the overall period.

19 A. Yes.

20 MS DUNLOP: Then the same exercise, Dr Gillon, for the
21 people who have come by the clinician reporting route.
22 This is paragraph 2.2.

23 You say that those transmissions -- transfusions
24 ranged between 1979 and March 1991 and that's in
25 appendix 2, which should be page 52.

1 One of the things that struck me about this,
2 Dr Gillon, was that if you, perhaps slightly
3 laboriously, go through and list the period between the
4 date of transfusion -- so column 3, and column 2, the
5 date when this person's infection was reported to
6 SNBTS -- you produce quite a spread but the shortest
7 seems to be number 9, who has a transfusion on
8 23 October 1987 and is then reported to SNBTS as
9 a possible case of transfusion transmitted infection
10 in March 1988. Do you think it might be somebody who
11 has been acutely ill with hepatitis? Might that be ...?

12 A. I think it must have been. I don't recall the
13 individual case. It's certainly a short period of time.
14 And the occasional patient who is infected with
15 Hepatitis C will develop jaundice in the early part of
16 acute hepatitis. That is relatively rare but it does
17 happen. I think that must have been the case. But then
18 we have gone back to that when testing became available.

19 THE CHAIRMAN: I'm a bit worried about 1988. If one looks
20 at all the dates of reporting down that column, it
21 stands out as being very, very early.

22 A. It does.

23 THE CHAIRMAN: Could it be 1998?

24 A. It could be 1998. It could be another typo. I would
25 have to look into that. I think that's the most likely

1 explanation actually.

2 MS DUNLOP: If you could, perhaps, Dr Gillon, and let us
3 know.

4 At the other extreme there is number 15. Patient
5 number 15 appears to have had a transfusion in 1980 and
6 is then reported to SNBTS in 2007. So 27 years have
7 passed. I think, apart from people who have received
8 multiple transfusions, these seem to be the opposite
9 ends of the spectrum.

10 A. Indeed, and again, I don't remember the individual case
11 and I would guess that we certainly wouldn't have had an
12 archive. It is unlikely that we would have been able to
13 trace that donor or test them.

14 Q. I think if we were to take out the six-month person, the
15 next shortest would be two years, which would be the
16 second patient. Had a transfusion in 1990 and is
17 reported as under two years in May 1992. Anyway.

18 A. Indeed.

19 Q. Largely speculative to study this for too long,
20 I suspect.

21 A. I could identify that patient. I think that's almost
22 certainly Mr Laing.

23 Q. Oh. Would it help us to know why?

24 A. Sorry, why ...?

25 Q. Why you think that's misleading?

1 A. It can't have been, no, I beg your pardon.

2 Q. Sorry, my ears are going. It is the wrong date, I am
3 afraid.

4 A. It's the wrong date.

5 Q. It was 7 August 1990?

6 A. And it's the wrong category of patient, I do apologise.

7 Q. Going back to the body of your statement, you have also
8 given, for the 103 patients -- and this is paragraph 3,
9 I think on page 46 -- the Blood Transfusion Service
10 region in which the blood for each transfusion was
11 collected. The breakdown really accords with the
12 population spread, does it, more or less?

13 A. Yes. Relatively speaking, Aberdeen seems low there.
14 Whether that means that there were more records
15 unavailable on the day in Aberdeen or what, I'm not
16 sure. But otherwise it does seem to represent
17 populations.

18 Q. If we can look over to the next page, please, that of
19 the 103. You are able to tell us that only 49 of them
20 were known to be alive at January 2011. I suppose,
21 obviously, more of them may be alive; it is just that
22 the data that's held by HPA is only able to tell you
23 definitely in relation to 49 people. Is that right?

24 A. Well, no, they know for sure that 53 -- sorry --

25 Q. Yes, sorry, I'm forgetting. Of course, you are coming

1 on to that.

2 A. They have a report of the death and a copy of the death
3 certificate.

4 Q. Yes. In fact, most of the reports in this area that one
5 reads seem to deal with patients known to have died
6 rather than patients known to be alive.

7 A. Yes.

8 Q. That's presumably a slightly safer measurement with
9 which to work, is it?

10 A. It is, yes. I think they enquire into the status
11 through the register office annually, I think -- maybe
12 six monthly. So they are getting very regular updates
13 on these patients.

14 Q. In relation to the patients known to have died, the 54
15 patients in the next paragraph, you mention that one of
16 those was a consular notification for which no cause of
17 death was known but you have a spreadsheet. I'm not
18 sure how easy this is going to be to display.

19 THE CHAIRMAN: CinemaScope.

20 MS DUNLOP: Yes. Your appendix 3. I think we were hoping
21 to display those by alternative means.

22 I'm sorry, it is only available in hard copy but
23 perhaps I can allow everyone else to have a look at the
24 hard copy when we stop for lunch and let people see that
25 if one goes through the spreadsheet with the 53 people

1 on it, there seem to be 14 deaths which mention
2 Hepatitis C at some point in the death certificate.
3 I don't know if you have a copy with you, doctor.

4 A. I don't have a copy but I do remember that. I think the
5 surprising thing is that only 14 mention Hepatitis C,
6 when they all had Hepatitis C in fact.

7 Q. Yes. Then you yourself examined the 53, and you say
8 your interpretation is that Hepatitis C was the cause of
9 death or contributed materially to the cause of death in
10 eight of the 53 patients for whom the causes of death
11 are known. So in very general terms I take it that
12 where somebody had, for example, died of a myocardial
13 infarction but was known as also having Hepatitis C, you
14 didn't count them --

15 A. Yes, I think that would be correct.

16 Q. -- as people for whom Hepatitis C was the cause of death
17 or a material contribution.

18 THE CHAIRMAN: Ms Dunlop, I'm anxious that there should be
19 some record of methodology so that, quite apart from the
20 examination of the document over lunch, there is
21 something in the transcript that tells us what Dr Gillon
22 has done. Might it help if he had it and just gave
23 a brief description --

24 MS DUNLOP: Yes, certainly. I'll pass it over. I have
25 highlighted all the Hepatitis Cs, Dr Gillon. (Handed)

1 A. Thank you.

2 THE CHAIRMAN: I think, doctor, if you could identify the
3 data, describe the methodology and explain the
4 selections, first of all, then we might get a basis for
5 going forward.

6 A. This, in a sense, is the essence of the study that was
7 set up, in that -- well, this is the Scottish
8 contribution to the data. Of course, there is a much
9 bigger number which includes data from England and Wales
10 too, but by knowing the date of transfusion they then
11 planned to follow the outcome in these patients, not
12 only by looking at the register of deaths but also by
13 regular reports from these patients' clinicians. The
14 clinicians were asked to sign up to this at the
15 beginning and give access to the hospital records so
16 that clinical data could be obtained right from the
17 start and then regularly throughout.

18 THE CHAIRMAN: Does that mean that the death certificates
19 are not the exclusive source of information in this
20 case?

21 A. They are not the exclusive source but they are in
22 a sense. This is the hardest end point, which is about
23 mortality. I should also add that these data are so far
24 not analysed by HPA and haven't been published. So this
25 was kindly made available to us by Dr Helen Harris for

1 the purposes of the Inquiry. The interpretation which
2 I have given is a personal interpretation, and may not
3 reflect what they finally decide when they analyse these
4 things formally through HPA and publish the data.

5 THE CHAIRMAN: It is the exercise of your judgment for the
6 time being.

7 A. As counsel said, I really categorised people into those
8 who had clear evidence that their final demise was
9 fairly directly attributable to hepatic disease. In
10 other words they have liver failure or a complication
11 such as sepsis, or they had hepatocellular carcinoma.
12 Again, there may be a primary cause of death such as
13 bronchial pneumonia, but hepatocellular carcinoma,
14 Hepatitis C. That is clearly attributable to the
15 Hepatitis C.

16 So my reading is that eight of these 53 had a final
17 illness where Hepatitis C was the significant factor.

18 THE CHAIRMAN: So that in the balance of 45, Hepatitis C is
19 certainly an aspect of their general medical history.

20 A. Indeed.

21 THE CHAIRMAN: But in your view, looking at the totality of
22 the information available, it was not a significant
23 contributor to death.

24 A. Yes. I think that by and large at this sort of length
25 of follow-up, which is 20 years plus now, that's broadly

1 in line with what's in the published literature.

2 THE CHAIRMAN: Ms Dunlop, I don't know if it is necessary to
3 go beyond that.

4 MS DUNLOP: No, I don't think so, sir. It gives us
5 an impression. Perhaps an interesting feature is the
6 feature Dr Gillon has highlighted, that all 53 of these
7 people had Hepatitis C and it has only been recorded in
8 relation to 14 of them. Then the next stage is, as your
9 Lordship put it, the exercise of judgment that Dr Gillon
10 carried out. He thought that it featured prominently,
11 if one can put it that way, in eight of the individuals.

12 Dr Gillon, that really concludes the information
13 that you included for us in this first statement. You,
14 I think, really refer us to Health Protection Scotland
15 for some of the other data and obviously we have got
16 Professor Goldberg coming to help us with that.

17 But you also provided a statement in relation to
18 transfusion transmitted HIV, which is [\[PEN0010038\]](#), and
19 I don't want us to lose the further queries either,
20 please, if you could hang on to them for the moment.

21 You tell us that 18 patients are known to SNBTS and
22 HPS to have contracted HIV as a result of a blood
23 transfusion in Scotland. Ten of these patients were
24 identified through the targeted look-back by SNBTS. Am
25 I right to think that that was in 1985?

1 A. Well, 1995 was --

2 Q. Sorry, this was the HIV look-back.

3 A. I'm sorry.

4 Q. There was an HIV look-back in 1985?

5 A. Look-back was instituted as online as soon as we started
6 HIV testing in 1985 and that was a UK Transfusion
7 Service's policy decision.

8 Q. Through that mechanism you identified ten people and
9 then another eight patients were reported, presumably to
10 you, to the Blood Transfusion Service?

11 A. Yes.

12 Q. By their doctors as possible transfusion transmitted
13 infections.

14 A. Well, actually, only 17 of those were reported to us.
15 There was one patient whose data was on the HPS
16 database, about whom we knew nothing.

17 Q. That's patient 9. We are coming on to patient 9, sorry.
18 You say in four cases it was possible to identify
19 a blood donor as the probable source of the infection,
20 whereas in three of the remaining four, the evidence for
21 transfusion transmission was circumstantial. You
22 explain that, that you couldn't get actual evidence
23 because transfusion had occurred before testing for HIV
24 and there was no archive sample that you could go back
25 and test. I think you have already said to us that the

1 systematic storage of archive samples began in 1986?

2 A. Yes, a little earlier in Edinburgh.

3 Q. Sorry. When was it in Edinburgh?

4 A. It was mid 1984.

5 Q. Then the remaining case, you say, was reported to

6 Health Protection Scotland by clinical staff in The

7 Western Infirmary, Glasgow, but is not known to SNBTS.

8 Then you were asked some questions about that person.

9 If we could go to the further enquiries document. Look

10 at the first page. You were asked some questions about

11 this patient: whether you accepted that this patient did

12 acquire HIV from transfusion, which number in the table

13 the patient was and how the patient had been missed

14 really. You have explained this. You have said:

15 "The patient was patient 9 in the table."

16 We will look at the table in a minute:

17 "...of Dates of transfusion. The patient was

18 reported to Health Protection Scotland which was then

19 ..."

20 Do you pronounce it SCIEH?

21 A. Yes, SCIEH is what people tend to say.

22 Q. SCIEH. That stood for?

23 A. The Scottish Centre for Infection and Environmental

24 Health.

25 Q. Thank you:

1 "... by the consultant virologist at the Western
2 Infirmary, Glasgow, in 1986."

3 The only additional information you had was that the
4 patient had sickle cell anaemia. Can you explain sickle
5 cell anaemia, please?

6 A. Before that, it may be worth saying that this was
7 through the mechanism I identified earlier, of automatic
8 reporting of the referral form back to SCIEH when
9 a positive was found. As far as I or anybody now
10 working at HPS knows, that is the only information that
11 was obtained about this patient. So what was on the
12 referral form.

13 Sickle cell anaemia is an inherited disorder of red
14 cells, which is commonest in black African and black
15 American/Caribbean populations and is a major source of
16 serious disease which can result in what's called
17 a sickle cell crisis. The red cells have a structural
18 defect which in certain circumstances can cause them to
19 be distorted and to effectively clog up the smaller
20 arterials and capillaries. It is a very serious and
21 very painful disorder. To prevent that they receive
22 frequent top-up transfusions of normal red cells. So
23 you have to keep a proportion of normal red cells in the
24 blood to prevent this.

25 Of course, transfusion is one of the treatments of

1 a sickle cell crisis.

2 So from an early age people with severe sickle cell
3 anaemia are heavily transfusion-dependent.

4 Q. I see. You say in relation to that patient -- and I'm
5 reading from the follow-up queries:

6 "It is not known whether these transfusions were
7 given in Scotland or elsewhere."

8 The only reservation I had about that was that you
9 go on in your statement to list for all 18 individuals,
10 transfusions in various different parts of Scotland. So
11 we can take it that this person had had at least one
12 transfusion in Scotland. Is that right?

13 A. I think it is an assumption but, yes, the patient was
14 being treated at the Western Infirmary in Glasgow. So
15 we have to assume that transfusions took place there
16 then.

17 Q. Right. Then --

18 A. And in fact there is the date of, I think it was,
19 May 1984, which is also on the HPS database and that's
20 what was on the database.

21 Q. In your follow-up queries, you have explained what
22 I think you have just alluded to, which is the reporting
23 mechanism, that sometimes it was possible to get further
24 information but the basic information that came from the
25 virology laboratory was just whatever had been on the

1 test request form. Just sticking with the response to
2 the further enquiry, you say it suggests that the
3 clinician involved did not report the case to
4 Health Protection Scotland nor to the SNBTS.

5 So didn't report the case. Whoever was looking
6 after, the consultant who was looking after the patient
7 did not reported the case to Health Protection Scotland,
8 it just came from the lab.

9 A. I think that's what happened. At this distance in time
10 and given that HPS is an anonymised database, I don't
11 think there is any way of investigating that further.

12 Q. I think where you say why you included this case, you
13 say that the circumstances were compatible with the
14 relatively high risk of exposure through -- I think that
15 should probably be transfusion, should it, rather than
16 "transmission"? That's the end of the third paragraph,
17 on the right-hand side.

18 A. Yes, of course; yes. Apologies.

19 Q. Not at all. Then you say:

20 "There has never been an agreed policy nor a legal
21 requirement for clinicians to report possible
22 transfusion transmitted infection to [you], although you
23 have sought to encourage that."

24 A. Yes. In fact HIV was not a reportable disease. So in
25 that sense there was no legal obligation on the

1 clinician to report to HPS either.

2 Q. Going back to your main statement on this topic,
3 Dr Gillon, you then cover the date of the transfusion
4 which resulted in each patient contracting HIV, saying
5 no date can be established for three patients. In fact,
6 we can see from the follow-up query that the three you
7 have in mind when you say this are 2, 9 and 12. So if
8 we look at the table, which is on PEN0010042, you
9 regarded it as not possible to establish a date of
10 transfusion for three patients. Just to look again at
11 the table, that's 2, 9 and 12.

12 But for the remaining 15, appendix 1 has shown the
13 most accurate available information. And we can do this
14 exercise ourselves but you say the earliest was
15 in August 1983. So out of the remaining 15, the
16 earliest was August 1983, the latest in August 1986 and
17 for the years between, it would be three for 1983, nine
18 for 1984, one for 1985 and two for 1986.

19 Right. Can we go back to the body of the report,
20 page 44, it will be. 38 I think it was or 39.
21 PEN0010039. You were also asked how many patients were
22 under 16 when the transfusion took place. You have said
23 four, with one possible extra in the group who had no
24 confirmed date of transfusion. 4 and 5. In 4 you tell
25 us where the transfusions took place and these are

1 health board areas.

2 A. Yes.

3 Q. So eight in Lothian, six in Greater Glasgow, three in
4 Tayside and one in Lanarkshire. Then for question 5 or
5 paragraph 5, you have given us geographical data but
6 related to the blood transfusion areas, which are
7 different, and that's the five regions that we spoke
8 about earlier.

9 So you have the sources of the infective donations
10 for all 18 being Edinburgh and the south-east, eight,
11 Glasgow, seven, and Dundee, which is the east of
12 Scotland area, three. So your five regions, also
13 including the Highlands and Grampian, we have none for
14 either of those areas.

15 A. That's correct, yes.

16 Q. Then if we turn on to the next page, please,
17 paragraph 6, you are asked about how many patients in
18 this group had died of HIV/AIDS. You say you don't know
19 about the cause of death for these people but you do
20 know that 15 of them -- that's 15 out of the 18 -- were
21 known to have died as at the end of last year.

22 A. Yes.

23 Q. I suppose, though, we should bear in mind the piece of
24 information you gave us earlier about the number of
25 people who may die quite shortly after a transfusion

1 anyway because of the illness or concern that led to
2 them needing a transfusion in the first place?

3 A. Yes. HPS does have some clinical information on some of
4 these patients and many of the comments really are
5 AIDS-defining illnesses. So many of these patients will
6 have died of AIDS.

7 Q. Then in conclusion, you were asked the number of
8 partners who contracted HIV, and you weren't able to
9 answer that because you don't collect that information.
10 In view of that you weren't able to answer question 8
11 either.

12 Allow me a moment, sir. (Pause)

13 Yes, there was one other document I wanted to put to
14 you, Dr Gillon. It is [\[PEN0010053\]](#).

15 We can actually see Dr Dow's name on this, if we
16 look at the second page. This is just to tell us about
17 the two viruses in relation to the question of how many
18 infected donations have been detected since testing came
19 in.

20 First of all, we can see that it's a tabular summary
21 of data submitted to the SNBTS NMRU?

22 A. National Microbiology Reference Unit.

23 Q. It is, funnily enough, on the front as well, sorry.
24 Infection surveillance system by 12 July 2010 about
25 positive donations. If we look at the first table,

1 table 3 tells us that since screening for antibodies to
2 Hepatitis C began in relation to blood donation on
3 1 September 1991, 867 donations have been collected,
4 which have been positive, and that in fact takes us
5 right back to the beginning of your earlier statement,
6 where you had that 867 figure. The detection of
7 positive donations is also shown for us in a graph at
8 the bottom. Very crudely put, we can see that the
9 trend, both in relation to new donors and repeat donors,
10 has been one of diminution and that's what you would
11 expect, is it?

12 A. Yes, it is certainly what we would expect to see in
13 repeat donors. The drop in prevalence of new donors,
14 can reflect two things broadly speaking. It can reflect
15 a change in the population prevalence, which may well be
16 happening. It could also represent better donor
17 selection, to put it broadly. It is impossible to
18 separate out the two really, I think.

19 Q. If we turn the page, we can see the same sort of table
20 but in relation to HIV. We can see, if we look in the
21 same place on that table -- that is the bottom right --
22 that since testing began on 1 October 1985, a total of
23 95 positive donations have been detected. That one,
24 from the graph, is bouncing around quite a bit more,
25 isn't it, Dr Gillon?

1 A. Yes, the one in new donors. It is really very low
2 numbers, though. That reflects the left-hand column in
3 the table and as you can see, you are dealing with tiny
4 numbers: 1, 0, 2, per annum.

5 Q. In fact a number are none.

6 A. In some years none. I'm sure there is no statistical
7 significance there.

8 Q. There is, presumably, quite a lot of resource which goes
9 into the screening programme?

10 A. There is indeed, yes.

11 Q. Yes. Do you have any --

12 A. I assume by resource, you mean pounds, shillings and
13 pence.

14 Q. Yes, I do. I just wondered if by any chance you had any
15 sense of a figure?

16 A. Yes, I looked at this and in crude terms, just in terms
17 of the cost of tests itself, we are currently expending
18 roughly three quarters of a million pounds on our first
19 line screening and what's called NAT testing, nucleic
20 acid testing, which is also known as PCR, for these
21 viruses. It is a little difficult to separate out the
22 individual components because the machines which do this
23 use combination tests now. But as far as we can
24 separate it out, it is costing us about £750,000 a year
25 for HIV testing.

1 THE CHAIRMAN: Who are "we" in this context, Dr Gillon? Is
2 it the whole of Scotland or --

3 A. The whole of Scotland, SNBTS, yes. So that's for
4 250,000 donations a year, approximately. The actual HIV
5 component of the screening process is only 57 pence.
6 The nucleic acid testing, which is the testing directly
7 for the virus genome, costs around £2.20 per HIV test.

8 THE CHAIRMAN: £3 a cycle, is it?

9 A. It is about that. Then there are repeats that you have
10 to do and follow-up samples and so on. Overall the
11 laboratory manager's best estimate is three quarters of
12 a million for that.

13 MS DUNLOP: The only reason for asking, Dr Gillon, is that
14 in a book which a number of us have looked at,
15 Douglas Starr's book on blood, there is a quote for how
16 much the testing programme is costing in the
17 United States and over a period of years it seems to be
18 in the region of several hundred million dollars but
19 perhaps they are doing more extensive testing than we
20 are doing here.

21 A. No, they certainly aren't. That would be hundreds of
22 millions of dollars over years for the American
23 population.

24 Q. So it is just a reflection of the different --

25 A. It is just the different scale of population.

1 Q. Right, thank you. Thank you very much.

2 THE CHAIRMAN: Mr Di Rollo?

3 MR DI ROLLO: Mr Dawson has one or two questions.

4 MR DAWSON: I think my voice is being picked up.

5 THE CHAIRMAN: Your voice is very quiet here.

6 QUESTIONS BY MR DAWSON

7 MR DAWSON: I'll speak up.

8 Dr Gillon, perhaps we could have Dr Gillon's
9 statement, which is number [\[PEN0010043\]](#) on the screen.
10 This is your statement to the Inquiry, Dr Gillon, which
11 relates to transfusion transmitted hepatitis.

12 You work for SNBTS. Is that correct?

13 A. That's correct.

14 Q. As I understand it from the first paragraph that one
15 sees under "preamble", in providing information to the
16 Inquiry, you have collated information from a number of
17 different sources on this topic. Is that correct?

18 A. The collation refers to an attempt -- not an attempt.
19 We did sit down with HPS, with Professor Goldberg and
20 others, to make sure that we each knew about the data
21 that the other held.

22 Basically, all of this information is from patients
23 who have either been identified by SNBTS or reported to
24 SNBTS from clinical sources.

25 Q. I'm interested to know what the relative

1 responsibilities of the various bodies that you identify
2 in the preamble are with regard to the compilation of
3 statistical information such as that you have provided
4 to the Inquiry. Can you help me?

5 A. Well, as I say, this is all primary SNBTS-derived data.
6 So when we talk about HPA data, this refers to the study
7 which was set up by HPA in combination with the
8 transfusion service in England and Wales to which
9 Scotland agreed to contribute after a lot of
10 deliberation and discussion to make sure that we were
11 satisfied that (a), the data were going to be
12 sufficiently well anonymised, that no patient could be
13 identified through that, and (b), that those data would
14 remain available both to SNBTS, to clinicians throughout
15 the United Kingdom for further research.

16 In other words, it wasn't going to be put in a box
17 and never made accessible to other researchers. Those
18 criteria have been fulfilled. In fact, I know that
19 Scottish clinicians have applied to and been granted
20 access to the data for follow-up information.

21 Q. Are there any other bodies, other than those you have
22 mentioned in that preamble paragraph, who would have
23 statistical information that might be useful to the
24 Inquiry on the issue of the number of people who may be
25 infected with Hepatitis C as a result of blood

1 transfusions?

2 A. Other than the data on haemophilia patients, which would
3 be treated separately in the Inquiry, I'm not aware of
4 anything else.

5 Q. I'm obliged.

6 Could I just ask you briefly about paragraph 1.1,
7 which appears in the bottom half of that page that we
8 are looking at. As I understand it, what you are
9 recording here is, first of all, the number of
10 HCV-positive blood donors that SNBTS had on its records.
11 That's 867. You are then identifying a percentage of
12 those, 6.8 per cent, who are a cohort of that larger
13 number, who have identified blood transfusions as their
14 only risk factor for contracting HCV. Is that correct?

15 A. That's correct.

16 Q. Could I ask you whether the greater figure that is
17 produced there represents the number of people who have
18 been diagnosed as having Hepatitis C in Scotland or
19 whether it represents the number of people who have
20 received blood transfusions in Scotland, who have been
21 so diagnosed?

22 A. The figure of 867 refers to blood donors who have
23 presented themselves as blood donors and undergone
24 testing of that blood donation. They are the ones who
25 have been found to be positive for HCV antibodies,

1 presenting as blood donors, not presenting as patients
2 with clinical illness.

3 Q. So these patients appear on your list because they have
4 been tested as HCV positives in Scotland?

5 A. By the SNBTS, yes.

6 Q. Do you know, in deriving the 59 figure from that,
7 whether or not the 59 received blood transfusions in
8 Scotland?

9 A. We know that they declared that as a risk factor. We
10 will have investigated them individually. As
11 I explained earlier, for the purposes of presenting
12 these data, we have not been able to go through these
13 individually. Some may have been transfused outside
14 this country, some, as we found with the
15 clinician-reported cases of HCV, could be excluded on
16 the basis of investigation. They may never have had
17 a transfusion.

18 Q. So the position is that these are people who have tested
19 positive in Scotland, who have identified blood
20 transfusion as the only risk factor but they have not
21 indicated blood transfusion in Scotland as the only risk
22 factor?

23 A. Not specifically, necessarily.

24 Q. I think you have accepted that that might mean, if one
25 were to investigate it more thoroughly, that some of the

1 59 may have received their blood transfusions outside
2 Scotland?

3 A. That's entirely possible.

4 Q. Is the converse also true, that there may be people who
5 perhaps are identified outwith Scotland because that's
6 where they were tested as blood donors, who received
7 transfusions in Scotland? Would those people be
8 identified by this process?

9 A. Not by the process that we went through to do this, no.
10 It is entirely possible. I'm sure there have been cases
11 who have presented in England, for instance.

12 Q. That's precisely what I was thinking of, Dr Gillon. It
13 may be that, on the assumption that a similar process
14 has been gone through in England, there may be people
15 who, because they are currently in England or gave their
16 donations in England, are identified as English
17 positives, if you like, but they may have received their
18 transfusions which give rise to that in Scotland.

19 A. That's entirely possible.

20 Q. Thank you. If I might ask you, could we go over to the
21 next page? I have a brief question on the issue of the
22 look-back exercise, which is the second of the
23 categories you have taken into consideration. I think
24 you have identified in your evidence already that the
25 look-back exercise which was undertaken has some

1 limitations on it, insofar as it might be taken to be
2 a representation of the total number of people who are
3 transfusion-transmitted HCV patients.

4 You have mentioned, I think, that it is dependent on
5 good record-keeping and you have mentioned that there
6 are a number of people who, for various reasons, are not
7 able to be tested, be it because they were deceased or
8 were simply unavailable for some other reason.

9 Could you explain how it is that people come to be
10 traced by the look-back procedure and could you confirm
11 my understanding that it is only on the basis of repeat
12 donations that one identifies what I think counsel for
13 the Inquiry has called the "infection families"?

14 A. That's a new term to me. I'm not sure what's meant by
15 "infection families". But, yes, the look-back, as
16 a starting point, takes those donors who are now known
17 to have Hepatitis C, who have donated in the period
18 prior to the introduction of testing in 1991. When such
19 a donor is identified, the process that we go through
20 is, of course, initially the informing and counselling
21 of the donor, which is done through the clinician
22 responsible for the transfusion, or the GP and the
23 SNBTS. Any of those three might undertake the
24 counselling and that is where the information about the
25 donor history and donor exposure is obtained.

1 In terms of tracing the recipients, the next step is
2 to identify what happened to each previous donation; in
3 other words, what components were made from it, where
4 were they sent to, what do we know about the fate of
5 those individual components. Some of them will have
6 been time-expired without being transfused, some will
7 have gone off to quality control, most will have been
8 shipped to hospitals.

9 You then, through formal routes, contact those
10 hospitals, informing of this and asking them for details
11 of the fate of that individual component; in other
12 words, where it did it go, was it time-expired, did
13 a patient get it and, if so, can we identify the
14 patient.

15 Q. Am I correct in saying that the donors who were
16 identified in the look-back exercise were repeat donors
17 who were tested between 1991 and 1997?

18 A. Yes.

19 Q. 1997 being the date when the look-back exercise came to
20 an end?

21 A. 1998 really but, as I mentioned earlier, that is
22 ongoing. We would still, if we identified a donor now
23 who had donated, and indeed I think Lord Penrose pointed
24 out one who had donated in 2007.

25 Q. If that were to happen, would those numbers be included

1 within the figures you produced here?

2 A. Yes.

3 Q. Thank you.

4 There are, of course, a number of epidemiological

5 studies which would suggest that there are considerably

6 higher numbers of people who have been infected with HCV

7 as a result of blood transfusions in Scotland, and

8 I understand we will be going to those with different

9 witnesses later, but no doubt you will be aware that

10 such studies exist?

11 A. Yes.

12 Q. And they use different methods to arrive at their

13 conclusions than your methods. Is that correct?

14 A. Yes, entirely different.

15 Q. Would it be fair to say that, given the way in which you

16 have compiled your data, your final number, which

17 I think is either 220 or 238, could be categorised as

18 probably a minimum number of infections in Scotland

19 through this route?

20 A. Yes.

21 Q. Thank you. I have one further question for you, which

22 straddles over the two areas on which you have provided

23 reports. You have provided information relating to

24 transfusions in general, but both Hepatitis C and HIV.

25 Do you have information about co-infection rates, ie

1 people who have been infected through this route with
2 both types of infection?

3 A. I'm not aware of such a case.

4 Q. Would it be possible to compile such data?

5 A. It would be possible. I'm not sure exactly how
6 difficult or otherwise it would be. I simply can't
7 remember any such case myself. It is possible that
8 other witnesses could help with that, specifically
9 Dr Brian Dow.

10 Q. On the basis of the material you have looked at, you are
11 not aware --

12 A. I'm not aware of it, yes.

13 Q. Thank you very much, Dr Gillon. Thank you.

14 THE CHAIRMAN: I take it that cases of co-infection must
15 have happened, Dr Gillon.

16 A. It is quite likely but, as we have seen, the number of
17 HIV cases from transfusion transmission is small and
18 they occurred in an era when there was no Hepatitis C
19 testing.

20 THE CHAIRMAN: Whether you could, from collected sources,
21 identify these might depend on whether the data was
22 anonymised before being passed on to a central agency.
23 Do you know whether Health Protection Scotland data is
24 anonymised or not?

25 A. It is anonymised.

1 THE CHAIRMAN: And what about your data? Is it anonymised?
2 A. Well, no, our data -- the data that we hold within SNBTS
3 is all patient-specific or donor-specific.
4 THE CHAIRMAN: Mr Dawson, that might lead to question as to
5 whether, on SNBTS data, there is any example of
6 co-infection. I don't know whether you want to ask that
7 or not.
8 MR DAWSON: Well, my understanding of the evidence that has
9 been given is that, on the basis of the data to which
10 Dr Gillon has access, he is not aware of any. It may be
11 that other people have access to different data which
12 would give different (inaudible).
13 THE CHAIRMAN: Speculation won't help at this point.
14 MR DAWSON: Absolutely.
15 THE CHAIRMAN: Mr Anderson?
16 Questions by MR ANDERSON
17 MR ANDERSON: I'm obliged, sir.
18 Can I ask you about a matter to which you alluded
19 earlier this morning but which has not been ventilated;
20 that is to say, the prevalence of Hepatitis C in the
21 general population.
22 A. Yes.
23 Q. I ask you this, Dr Gillon, because of what might be
24 thought to be a slightly mixed message coming out of
25 a passage between one of the experts we have heard from

1 previously, a Dr Colvin, and the chairman. I don't know
2 if you have seen this. Have you seen this discussion,
3 which took place on 9 March?

4 A. I haven't read the transcript of that, no.

5 Q. All right.

6 Sir, for your information and for others, it may be
7 helpful. It was within the evidence of Dr Colvin and it
8 can be found on the transcript of 9 March at pages 111
9 and 112?

10 THE CHAIRMAN: 9 March is which day?

11 MR ANDERSON: Wednesday.

12 THE CHAIRMAN: It helps me to know the day of the Inquiry
13 since that's the way I've noted it.

14 MR ANDERSON: Sorry, day 2.

15 THE CHAIRMAN: Day 2.

16 MR ANDERSON: Can I just take you through this, Dr Gillon?

17 Dr Colvin, in his evidence-in-chief, suggested that
18 the prevalence of Hepatitis C in the general population
19 was 0.1 per cent. All right? Now, if we just pause
20 there, I think I'm right in saying that 0.1 per cent is
21 one tenth of 1 per cent. Is that right?

22 A. That's correct, which translates to one in 1,000.

23 Q. All right. The chairman then asked Dr Colvin -- what he
24 said was this:

25 "I can understand that the prevalence in the

1 population is 0.01."

2 Which is a different matter, isn't it?

3 A. Yes, that would be one in 10,000.

4 Q. All right. Dr Colvin replies to this and appears,
5 I think, to seek to correct matters by saying:
6 "With respect ..."
7 But he then, rather strangely, goes on to say,
8 "I think it is 0.01," which is indeed precisely what the
9 chairman says. But he then says:
10 "I think it is a tenth of 1 per cent."
11 Just to clear up this confusion -- and it may be as
12 a result of the transcription, we don't know -- what is
13 your understanding? Is it a tenth of 1 per cent or not?

14 A. I think even that is too low a figure, to be honest, but
15 certainly 0.01 per cent is far too low for the
16 prevalence, as I understand it, in the British
17 population.

18 Q. Where do you get this understanding from? What is the
19 basis of the understanding?

20 A. I think I mentioned in passing earlier that good
21 population data -- in other words, data which you derive
22 from taking a representative cohort of the population in
23 terms of demographic age, sex and so on and get them to
24 agree to testing is very difficult to do and to my
25 knowledge hasn't been done in the UK. The only

1 population data as such that I know of in the UK was a
2 paper by Balogun et al from HPA in 2002. I'm sorry,
3 I don't have the reference but I'm sure that this paper
4 is known to the Inquiry.

5 They based this on taking the results of samples
6 referred to the public health laboratories in England
7 and Wales and came up with a prevalence figure of
8 0.7 per cent in the British population. That's probably
9 too high because these were, by definition, clinical
10 samples of some sort.

11 If you look at population data, some of which is
12 based on speculation, I suppose, to put it broadly, in
13 terms of trying to extrapolate from clinical data, some
14 of which is very good, from the United States, where
15 they have a rolling programme called the "NHANES":
16 National Health and Environmental Nutrition and
17 Environmental Studies" -- they do massive surveys
18 I think it is roughly every seven years. In one fairly
19 recent study, I think around about 2001/2002, they
20 managed to get over 20,000 people, representative of the
21 population across the United States, with one or two
22 exceptions -- with the exception of people living in
23 hostels and people in prison, I think -- I think
24 everybody else was tested -- and they acquired vast
25 amounts of information about these people, as well as

1 getting them to agree to give blood tests, and their
2 information in the United States suggests that the
3 population prevalence is something like 1.6 per cent.

4 In France they estimate it is 1.1 per cent. I have
5 seen figures for other north European countries of
6 around 0.6 to 1 or 2 per cent, with high prevalence in
7 certain areas, like south Italy. American and northern
8 Europe is considered low prevalence. In other words,
9 anything under 2 per cent is considered a low prevalence
10 area, but I think 0.1 per cent is too low for the
11 United Kingdom and 0.01 per cent is unrealistically low.

12 Q. It is perhaps a rather rough and ready approach but
13 would it be reasonable to suggest that it is somewhere
14 between 0.1 per cent -- that is to say a tenth of
15 1 per cent; and 0.7 -- that is to say seven tenths of
16 1 per cent?

17 A. I think so, yes.

18 Q. You have mentioned the United Kingdom. Would I be right
19 in thinking that that would apply to Scotland as well?

20 A. Yes, I think there is pretty good evidence that Scotland
21 has a higher overall prevalence than England.

22 Q. I think you will see that the paper by Balogun and
23 others has helpfully been put up on the screen and we
24 see, for the purposes of the transcript, that it is
25 [\[PEN0020822\]](#). Is that correct?

1 A. That's correct, yes.

2 Q. I'm much obliged to you, doctor, thank you.

3 PROFESSOR JAMES: Lord Penrose, can I interpose one brief
4 thing? Would you mind?

5 THE CHAIRMAN: Of course.

6 PROFESSOR JAMES: I believe that Dr Colvin was quoting as
7 a prevalence in the United Kingdom the prevalence of HCV
8 in the general population to Lord Penrose. Actually,
9 the figure, which he got from the blood donor
10 population, was very, very close to the figure that
11 Dr Gillon had found from his original HCV blood donor
12 population study, which we have already heard about this
13 morning. So I think this difference between the
14 0.1 per cent, quoted by Dr Colvin, and the 1 per cent,
15 seen in the Balogun paper that we have had on the
16 screen, is due to a misapprehension by Dr Colvin, rather
17 than a sort of mysterious difference.

18 THE CHAIRMAN: Well, I have no doubt that we are going to
19 get lots of mysterious differences but if you are
20 looking at the transcript on page 112, Mr Anderson,
21 there is actually a word missing. What I was putting to
22 Dr Colvin wasn't really concerned with a figure but with
23 something else and it should be:

24 "I can understand that if the prevalence is 0.01 --
25 and that doesn't much matter -- then a single treatment

1 from a single donor will reflect that prevalence."

2 We then go on to the person with multiple
3 transfusions. That was my interest, not in getting
4 an actual figure.

5 MR ANDERSON: Sir, I think it would be remarkable if there
6 wasn't the odd glitch in the transcript, I have to say.
7 But perhaps I should explain. The reason is I think
8 certain parties outwith this room have misunderstood and
9 misinterpreted that passage, and I was simply --

10 THE CHAIRMAN: That will happen also.

11 MR ANDERSON: Indeed. I was simply anxious to clear up what
12 appeared to be a misunderstanding.

13 THE CHAIRMAN: You can take it that I will not find myself
14 bound by anything I said at that stage in arriving at
15 the prevalence in the UK as a whole.

16 I think that we have actually seen a number of
17 different figures. I seem to remember a figure of 0.088
18 as a prevalence in Scotland at one stage.

19 A. I think that would be a population prevalence based on
20 blood donor prevalence. Blood donors are not a good way
21 to assess population prevalence.

22 THE CHAIRMAN: I think I would like to follow that just
23 a little. If one carries out a full epidemiological
24 study, it would require a random selection from the
25 population generally.

1 A. Yes.

2 THE CHAIRMAN: Is that right?

3 A. Analogous to what the Americans have done.

4 THE CHAIRMAN: Analogous to --

5 A. Yes.

6 THE CHAIRMAN: And that on any view would be an extremely
7 difficult exercise even in a place the size of Scotland.

8 A. Yes.

9 THE CHAIRMAN: Partly because of the probability of
10 different prevalences across different parts of the
11 country.

12 A. And that apparently is the case. In the Balogun paper,
13 for instance, London has a much higher prevalence than
14 the rest of England and Wales, as judged from those
15 public health laboratories.

16 THE CHAIRMAN: Once one introduces an element of
17 self-selection into the definition of any statistical
18 population, what happens?

19 A. You get a skewed result.

20 THE CHAIRMAN: And the probability of a good fit between the
21 data obtained from the self-selected population and the
22 general population reduces very considerably?

23 A. Yes.

24 THE CHAIRMAN: So if one looks at the blood donor
25 population, one starts, by definition, with

1 a self-selected population?

2 A. Yes, and then we add the selection process which we
3 impose.

4 THE CHAIRMAN: And some of the selection criteria relate to
5 age, general fitness, medical history and so on?

6 A. Yes.

7 THE CHAIRMAN: All of which restrict even further the
8 general applicability of the data obtained from the
9 exercise?

10 A. Yes.

11 THE CHAIRMAN: Is that a correct understanding of the
12 problem?

13 A. That is correct, yes, and also blood donors
14 demographically do not represent the general population,
15 by definition, because of age restrictions, and new
16 blood donors tend to be in the younger age group of
17 eligibility for blood donation, whereas regular donors
18 tend to be in the older age groups. So there are all
19 sorts of subtleties in there.

20 THE CHAIRMAN: If one then ends up with a data set that is
21 skewed, is there anything one can do with it in the way
22 of general application, by the application of judgment,
23 or does it just represent what you find?

24 A. I think it is what you find. Given these subtleties
25 about demographics, I don't see that it is valid to

1 extrapolate from blood donor prevalence data to the
2 general population.

3 THE CHAIRMAN: Mr Anderson, I don't know if you have any
4 follow-on on that?

5 MR ANDERSON: No, sir.

6 THE CHAIRMAN: Mr Sheldon?

7 MR SHELDON: No questions, sir, thank you.

8 THE CHAIRMAN: Ms Dunlop, does anything arise out of this
9 that is of interest to you at this point? Sorry, in the
10 sense of provoking additional questions.

11 MS DUNLOP: It's all of interest, but, no, I don't need to
12 ask any more questions, thank you, sir.

13 THE CHAIRMAN: Thank you very much.

14 A. Thank you.

15 (12.51 pm)

16 (The short adjournment)

17 (2.08 pm)

18 MS DUNLOP: We have Professor David Goldberg this afternoon.

19 PROFESSOR DAVID GOLDBERG (sworn)

20 Questions by MS DUNLOP

21 MS DUNLOP: Good afternoon, professor.

22 A. Good afternoon.

23 Q. I'm going to ask you first of all one or two questions
24 from your CV, which we have. That is PEN0020646.

25 In fact this is a short form. I have a much longer

1 CV and I realise that I'm not sure I have the number for
2 the much longer CV. It is obviously not going to come
3 after this page because this is only 1 of 1. Perhaps
4 I can just ask one or two questions anyway.

5 We can see from this that you are a consultant in
6 public health medicine at Health Protection Scotland and
7 we heard the HPS. You are a honorary professor of
8 public health at Glasgow University.

9 Thank you very much. I'm obliged to Mr Dawson for
10 giving me the right number.

11 You are administrative head of the group for
12 blood-borne viruses, sexually transmitted infections...

13 Could I get that back for a second until we have
14 finished looking at the short one. PEN0020646.

15 You obviously have a group within
16 Health Protection Scotland, which deals with blood-borne
17 viruses, sexually transmitted infections, vaccine
18 preventable diseases, respiratory infections. So they
19 are all organised together from a statistical or
20 epidemiological point of view. Is that the case? And
21 then you are the lead on Hepatitis C and HIV programmes
22 of work.

23 A. Correct. Yes, that's right.

24 Q. We see you serve on several United Kingdom and Scottish
25 committees, are involved in academic supervision, author

1 of many peer reviewed articles and the holder of many
2 grants. You have a team which secured a £43 million
3 investment for Scotland's Hepatitis C action plan. You
4 are chair of the action plan governance board.

5 If we go to your longer curriculum vitae, which is
6 PEN0020671, to the second page, you tell us about your
7 education and your medical qualifications. We can see
8 you are a fellow of all three of the colleges of
9 physicians, Glasgow, Edinburgh and London, and you take
10 us through your medical career and your move into
11 epidemiology. You started in the area, I suppose, when
12 you were a registrar in infectious diseases at Ruchill;
13 that right?

14 A. That's correct, yes.

15 Q. And rather developed your interest from there on. Then
16 if we turn to the next page, we see your honorary
17 appointments, and then you list the public service, that
18 is within Health Protection Scotland. Is that right?
19 Were you there when it was called SCIEH?

20 A. Yes, and before that CDSU. Communicable Diseases
21 Scotland Unit.

22 Q. Right. We also see from the next page -- and this is
23 about the middle of the page -- that over the last
24 12 years, much of your work has focused on leading
25 a team and describing the epidemiology of the

1 Hepatitis C epidemic in Scotland and developing
2 prevention, diagnosis and treatment services for
3 Scottish people. Then you talk about the action plan on
4 Hepatitis C, phase 1. What was involved in phase 1?

5 A. Phase 1 was essentially generating the evidence and from
6 the evidence identifying proposed actions and costing
7 these actions out. Effectively a business case for
8 phase 2. Phase 2 was about the actual implementation of
9 the action plan to improve services in all the areas
10 that I have described. So phase 1 is this sort of
11 business case development period between 2006 and 2008,
12 involving evidence generation and the actions
13 themselves.

14 THE CHAIRMAN: Ms Dunlop, I seem to be hearing the professor
15 naturally and not through the transmission of rather
16 peculiar sound.

17 A. I'm -- that's because I'm --

18 THE CHAIRMAN: It is more likely to be the machinery.

19 A. I was too far back.

20 MS DUNLOP: Phase 1 of the plan was really evidence
21 gathering and phase 2 is presumably about implementation
22 of the plan you had drawn up.

23 A. That's right. In phase 1 there was also a, I suppose,
24 co-ordination component, getting some co-ordinating
25 infrastructure into place. We had an action plan

1 co-ordinating group and in terms of the relevance to
2 this Inquiry, we did have a patient representative for
3 haemophiliacs with HCV and HIV.

4 Q. Yes, because, as you have told us, you have a great deal
5 of experience as an epidemiologist in both Hepatitis C
6 and HIV.

7 A. Yes. I mean, it is HIV which really, from a clinical
8 perspective, inspired me in the mid 1980s when I was at
9 Ruchill Hospital doing infectious diseases. That's why
10 I moved into the epidemiology of HIV at that time and
11 then that moved on to Hepatitis C.

12 Q. I think we have covered this already. From page 6, you
13 talk about being head of that particular group within
14 Health Protection Scotland, but I noticed from page 7
15 that you still perform on-call duties and this is really
16 as a public health doctor.

17 A. That's right, yes.

18 Q. You make a contribution on a one in five consultant
19 basis?

20 A. That's right, yes.

21 Q. What are the sorts of things that crop up?

22 A. Oh, just anything. I mean, what we tend to deal with
23 are problems that health boards find difficult to deal
24 with. So it is a hub and spoke mechanism. We have at
25 the centre Health Protection Scotland. That's the hub.

1 Then there are spokes out into each of the health boards
2 which have their own health protection units. So they
3 are very much more reactive than we are and they deal
4 with the day-to-day sort of issues, gastrointestinal
5 infection outbreaks, respiratory infections, meningitis,
6 that sort of thing. They tend to deal with it without
7 our support. But if a problem is complex or involves
8 more than one health board, we are brought in to advise.

9 I mean, recently, for example, we were involved in
10 an incident -- and I led this -- involving two
11 haemodialysis patients in the West of Scotland, who'd
12 gone to Mallorca. They were Hepatitis C antibody
13 negative before they went and they came back Hepatitis C
14 antibody positive on screening. You know, they get
15 screened every three months. We investigated that
16 incident along with individuals in Spain and we
17 identified that they did indeed become infected. They
18 became infected through haemodialysis in Mallorca. So
19 I can just give you that as an example but it also, of
20 course, is relevant to Hepatitis C.

21 Q. Thank you. On the following page you have a list for us
22 of the different pieces of work in which you
23 participated for the Scottish Executive. We can see
24 really quite a number which are relevant to the viruses
25 that we are considering. Perhaps we can highlight the

1 AIDS co-ordinating group and the expert advisory group
2 on HIV/AIDS treatment, the chief medical officer's
3 committee on Hepatitis C and then all the ones which
4 relate to the action plan that you described.

5 A. Yes.

6 Q. Then you are also, beyond the Executive, you are
7 involved in -- or you were involved in -- the Scottish
8 hepatitis working group. I think we have actually
9 already heard about that. Is that now defunct?

10 A. Yes, that's defunct.

11 Q. Then looking at the next page, you are involved in the
12 SIGN group on Hepatitis C infection. Then you have
13 a list of United Kingdom committees as well and then
14 international representation of SCIEH. Then a number of
15 guest lectures, many of them obviously on Hepatitis C.
16 The supervision you carry out of postgraduate work and
17 the grants you have received for research. Finally
18 a long list of publications of various different types,
19 in which again, a great deal of the matters in which the
20 Inquiry is interested feature, and even a list of book
21 chapters as well.

22 A. Hm-mm.

23 Q. So you come here today from Health Protection Scotland
24 to contribute to our attempt to get some feel for the
25 size of the problems and to do that by looking at

1 epidemiological data.

2 You have prepared two different statements and
3 I would like to start with [\[PEN0130014\]](#). You have
4 helpfully repeated, as question 1, that you were asked
5 about the number of patients treated by the NHS in
6 Scotland known to have contracted Hepatitis C as
7 a result of a blood transfusion. Before we look at your
8 answer, professor, I wanted to ask generally as an
9 exercise in epidemiology, is this quite difficult?

10 A. This is an extremely difficult question because not only
11 are you asking if an individual has Hepatitis C, you are
12 asking if they have had a blood transfusion, and then
13 you are also asking if there is an association between
14 the blood transfusion and the infection. So effectively
15 I didn't answer that question.

16 Q. Right.

17 A. Because the question is "known to have contracted".
18 I think initially, in discussion with my colleagues at
19 SNBTS, we felt that it would be best to concentrate on
20 the look-back data, which are far more accurate in this
21 respect. Of course, Jack has spoken to you this
22 morning. Then I was asked to also just provide data
23 that HPS holds in relationship to blood transfusion and
24 Hepatitis C and I have done that. But the word "may" is
25 in there:

1 "... may have resulted in the acquisition of
2 Hepatitis C infection."

3 As you can see.

4 Q. Yes.

5 A. So I think that applies essentially to all the questions
6 being asked.

7 Q. I suppose some of the reasons why this is a difficult
8 exercise would be that the problem appears to have been
9 occurring over a long period of time and there may be
10 quite an interval between somebody having a transfusion
11 which may have caused them to become infected and that
12 infection coming to light. Am I on the right lines?

13 A. Yes. Obviously pre-1991 is the issue and Hepatitis C
14 has been around for a long, long -- probably going back
15 into certainly the middle of the last century. To what
16 extent we are not sure but I think it would be
17 reasonable to assume that it was around. Discovered of
18 course in 1989, the test available in 1991. So
19 I suppose the factors which influence matters is the
20 prevalence of Hepatitis C in the general population and
21 then that influences the prevalence of Hepatitis C in
22 the blood donor population. Okay?

23 So you have got the blood donor population, and
24 because you don't know for sure what the prevalence of
25 Hepatitis C in the general population was pre-1991, you

1 wouldn't know for sure what the prevalence was in the
2 donor population.

3 Then, of course, there is the issue of
4 epidemiological screening that took place in the early
5 1980s and beyond. Screened out people at high risk,
6 principally for HIV, at that time. So I think there is
7 a huge amount of uncertainty here and we can estimate
8 the size of the problem. I believe you have asked us to
9 do that and we will generate some estimates of the
10 number of people infected through blood transfusion
11 during 1970 to 1991.

12 Q. Yes. You are hoping that that work will be available
13 for the Inquiry towards the end of April. Is that
14 right?

15 A. That's right.

16 Q. Thank you. You referred in your answer, professor, to
17 epidemiological screening. I take it that what you are
18 talking about is that in the early 1980s, there was
19 quite an intensive focus on perhaps not accepting blood
20 from particular groups of donors?

21 A. That's right.

22 Q. Even though it was directed towards AIDS, may as a side
23 effect have also withdrawn from the pool people who had
24 hepatitis?

25 A. That's right.

1 Q. But then on the other hand it might be -- I suspect
2 possibly is the case -- that the actual prevalence among
3 a group of people, maybe those using drugs, injecting
4 drugs, might have been increasing. That would affect an
5 assumption that you might choose to make as well. So
6 these are, I suppose, the imponderables of the
7 situation, are they?

8 A. So, on the one hand you have measures that were being
9 introduced to make blood supply more safe, the
10 epidemiological screening, culminating in the testing.

11 Q. Yes.

12 A. But on the other hand you have an increase in the
13 prevalence of infection. Our work at HPS indicates that
14 there really was quite a dramatic increase in that
15 prevalence towards the end of the 1970s and beginning of
16 the 1980s, contemporaneous, of course, with the increase
17 in injecting drug use that we saw.

18 Q. You say in your answer that:

19 "Health Protection Scotland is aware of 304
20 individuals known to be antibody positive in Scotland
21 for whom information indicated that a blood transfusion
22 ..."

23 And I take your point. You say:

24 "... may have resulted in the acquisition of
25 Hepatitis C infection."

1 You are excluding people who looked to have received
2 a transfusion outside Scotland and also other
3 individuals who are also known to have injected drugs.
4 Then you say:

5 "Transfusion should only be regarded as a possible
6 and not a definite or confirmed route of acquisition for
7 these cases."

8 I think we will come to look at the notes which were
9 attached to the statements that you provided. But two
10 questions I wanted to ask you. I wanted to ask you both
11 the how and the why of a report coming to you -- perhaps
12 we could take the why first: why does a report come to
13 Health Protection Scotland if someone is identified as
14 having Hepatitis C? Is it just -- well I don't want to
15 say "record-keeping". That sounds pejorative. But
16 there must be more to it than that.

17 A. Yes. I mean, we established our Hepatitis C diagnosis
18 database in 1996 and we acquire data from Hepatitis C
19 testing laboratories in Scotland. They hold information
20 that has been obtained through the test request form
21 that accompanies the blood sample to the lab. In the
22 instance of Hepatitis C, clinicians were and still are
23 using a general request form. It varies actually in
24 different parts of the country, the type of form that's
25 used. It is not uniform in this respect. Of course, on

1 that form the clinicians document demographic
2 information, identifying information. But also on that
3 form is an additional information or clinical
4 information space and sometimes they provide the
5 laboratory with relevant information. It is by
6 interrogating those forms at the laboratory that we are
7 able to access the information that we need for our
8 surveillance, epidemiological purposes.

9 Q. You are both monitoring what is happening and also --
10 and this links back to your description of the action
11 plan -- trying to draw up the most suitable services for
12 the population, based on the information you have about
13 the extent of the problem?

14 A. Absolutely. This is just one source of information that
15 we use. So we use this information in association with
16 other pieces of information that we obtain through
17 surveys of various population groups and also clinical
18 information that we get through a national clinical
19 database. So a whole number of information sources. We
20 use all this information to answer some very key
21 questions about this infection.

22 Q. Yes. I don't want to lose site of the statements; this
23 is another occasion, if we can, for putting documents
24 side by side. I wanted to ask you about a paper, which
25 is [\[PEN0120066\]](#). I'm hoping that the other parties also

1 have a hard copy of this. It is a paper about
2 notifiable diseases.

3 Professor, I just want to ask you about this
4 mechanism first before I ask you about its efficacy.
5 This is a summary of the legal position that has been
6 prepared by a member of the Inquiry team. It sets out,
7 sir, the legislative provisions governing the position
8 insofar as notifiable diseases are concerned. I think
9 we can see that the legislative regime has quite
10 recently changed in form of the public health et cetera
11 Scotland Act 2008, but of course it is the position
12 a little further back in which we are mainly interested.

13 You see that viral hepatitis -- the inclusive name
14 for various types of hepatitis, including Hepatitis C --
15 became a notifiable disease under the 1975 regulations
16 which came into force on 2 April 1975. I should say,
17 sir, that we have looked at the position from 1975
18 onwards because that is the period of time in which the
19 Inquiry is interested.

20 That, obviously, corresponds reasonably well with
21 the time when the Inquiry is really beginning its
22 examination. We can see viral hepatitis listed in the
23 left-hand column. So that's something that certainly
24 was in the 1975 regulations, and was also in the 1988
25 regulations which replaced the 1975 ones.

1 THE CHAIRMAN: I have seen the background correspondence in
2 the files that show how this came about and what was
3 understood by viral hepatitis at the time.

4 MS DUNLOP: Yes. Well, I think --

5 THE CHAIRMAN: If necessary --

6 MS DUNLOP: -- the professor has certain views about the
7 efficacy of all this. But just looking at what the
8 mechanism is, we can see from the next page that there
9 is an obligation, or there was an obligation on a
10 registered medical practitioner to notify, in this case
11 viral hepatitis, if they had a reasonable suspicion that
12 a patient whom they are treating has the disease:

13 "The disease is reported to the health board who in
14 turn notify Health Protection Scotland."

15 Then there was a style form and a copy of that is
16 there, shown on the next page.

17 This is scrolling on to the next page as well,
18 please. We are told that:

19 "Health Protection Scotland have been in charge of
20 retaining this information since 2007 and notifications
21 are recorded in weekly and annual databases."

22 I think those of us who have gone on to your
23 website, professor, are aware that you publish a lot of
24 weekly reports of information. The paper also notes
25 that HIV is a notifiable disease in some countries but

1 has never been a notifiable disease in the UK. And then
2 there is a copy of a form which actually, I think, comes
3 from the haemophilia centre doctors' organisation for
4 their own system of reporting of a case of AIDS or HIV.

5 You were explaining to me before lunch, professor,
6 that the system in the 2008 Act has changed slightly in
7 that hepatitis is now not a reportable disease but
8 a reportable organism. Is that right?

9 A. Hm-mm.

10 Q. What's the distinction that's being made there?

11 A. I think prior to the recent Act, as you can see, it was
12 viral hepatitis that was the notifiable condition and it
13 is not specific. There are different types of viral
14 hepatitis. There is A, B, C, D, E, and there are other
15 infections, viral infections, associated with hepatitis,
16 such as Epstein-Barr virus, the virus that causes
17 glandular fever, that can be associated with hepatitis,
18 cytomegalovirus, that can be associated with hepatitis.

19 So you can see the difficulty here. It is not
20 specific in any way and in reality, clinicians rarely
21 reported the clinical entity, viral hepatitis, to health
22 boards. So as far as we were concerned, the data that
23 were ultimately collated by the information and
24 statistics division of NSS, we ignored that information
25 because we got better information by going direct to the

1 hepatitis testing laboratories. You cannot be diagnosed
2 with, for example, Hepatitis C, unless you have
3 a positive test for Hepatitis C.

4 So by going direct to the laboratories, using this
5 voluntary approach, reporting approach, we managed to
6 get the information that we actually needed.

7 That's for national epidemiological purposes.
8 I think for local purposes the importance of this, in
9 terms of the new 2008 Act, is that the laboratory is now
10 being required to report the information to the health
11 boards on individuals testing positive for these
12 viruses, the hepatitis viruses. Certainly for
13 Hepatitis B and Hepatitis A, it is important because
14 there is a vaccine available for these infections and it
15 means that you can go out and identify close contacts
16 and vaccinate them. That's why it is important that
17 these two infections are notifiable in this respect.

18 For Hepatitis C, I'm not so sure because there is no
19 vaccine available. Certainly from my own knowledge of
20 what happens at a health board level, the close contacts
21 of individuals who are Hepatitis C infected generally
22 speaking are not contacted; simply because I think there
23 is no vaccine intervention available that can be
24 implemented.

25 Q. Might that also be something to do with the relative

1 ease or difficulty of transmission of the virus just
2 from person to person in ordinary contact?

3 A. I suppose that's a reasonable point. It is more
4 difficult to transmit Hepatitis C in that way but
5 I suppose, if the individual identifies as an injecting
6 drug user, then the chances of the individual's partner
7 being an injecting drug user might be quite high. But
8 there is no vaccine anyway. So there is not much you
9 can do in that respect.

10 Q. Just looking back at your statement, your figure, we can
11 see, for the number of individuals about whom you have
12 information is 304.

13 A. That's right, yes.

14 Q. But when you are asked if you can supply information
15 about dates of transfusion, you tell us in answer number
16 2, that's not something that you hold.

17 A. No.

18 Q. Indeed, we have heard some evidence from Dr Gillon about
19 that and he is no doubt in a better position to provide
20 that information.

21 THE CHAIRMAN: Could I ask a question at this stage about
22 language?

23 In your answer to question 1 you say that in the
24 cases involved blood transfusion should only be regarded
25 as a possible and not a definite or confirmed route of

1 acquisition. I'm a bit concerned about the extremes
2 since I would have thought that a possibility was
3 a hypothesis that couldn't be excluded. At the other
4 end you have got something from which all alternatives
5 have been excluded. Are we talking about possibilities
6 here or probabilities?

7 A. Sir, are you talking about greater than 50 per cent in
8 this respect? Probability being greater than a
9 50 per cent chance?

10 THE CHAIRMAN: Yes. Take that as a test.

11 A. I really don't know.

12 THE CHAIRMAN: Possibility was not much good to anyone since
13 it simply means that it is the hypothesis that you can't
14 exclude.

15 A. Do you know, I think that, because there is so much
16 uncertainty about these cases, I mean, what we are doing
17 here is just taking some information that has been
18 recorded on a request form. We did not seek additional
19 information. We didn't clarify whether indeed that
20 information provided was accurate. So that was why the
21 word "possible" was provided here.

22 If I had to put money on it, I would say that less
23 than 50 per cent of the 304 contracted their HCV through
24 blood transfusion.

25 THE CHAIRMAN: That's perhaps a much more valuable approach

1 for me because that means I take it that looking at the
2 totality of the information available, you are in
3 a position to offer a judgment as to the prevalence
4 among this group.

5 A. Partly based on additional information that we have
6 about these individuals, their age at the time of
7 diagnosis, for example. But it is a difficult area and,
8 as I say, I would put money on it. I don't know how
9 much money I would put on it.

10 THE CHAIRMAN: We don't have the mechanism to test the odds
11 on that approach. The other thing that I would like to
12 ask, just before we leave the material that you have
13 been dealing with, is just exactly what is meant over
14 time by "viral hepatitis". Because I think that there
15 may have been a period at the beginning of the reference
16 period when, in the minds of many clinicians, viral
17 hepatitis and jaundice were not seriously distinguished.

18 A. I think it's a fair point because I remember even at the
19 time in Ruchill Hospital we had admissions in the
20 mid-1980s of individuals with jaundice and abdominal
21 pain. They clearly clinically had hepatitis. They were
22 then tested for Hepatitis A, negative, Hepatitis B
23 negative; and in the case notes it was recorded as non-A
24 non-B hepatitis. I think the other thing to point out
25 was that other possible causes of hepatitis were

1 excluded in this respect.

2 THE CHAIRMAN: Cytomegalovirus and Epstein-Barr or others?

3 A. I think sometimes -- whether they had a full viral
4 screen is difficult to remember, but there were no other
5 clinical indications that they had these viruses. There
6 was no indication that the hepatitis could be caused by
7 a drug, a medication, which is often a common cause of
8 hepatitis. There were no other causes of hepatitis
9 which might have explained the condition.

10 So you were left with hepatitis from unknown causes
11 but having said that, the individual probably had
12 injected drugs and that information, coupled with the
13 fact that there was no other explanation, led to
14 a diagnosis of non-A non-B hepatitis, which was probably
15 correct in most instances.

16 THE CHAIRMAN: My problem at the end of the day, professor,
17 will be to decide what inferences I can draw from the
18 totality of the information I get and perhaps the more
19 one undermines the foundations, the less likely it
20 becomes that there will be much reliable information
21 that can be used. Where do I stand with your 304
22 individuals?

23 A. I think as I said to you, to colleagues in CLO,
24 I couldn't answer this particular question in the first
25 place. You asked how many were known to have contracted

1 Hepatitis C as a result of blood transfusion and as
2 I say, all we can do is provide you with what we have.
3 You have asked me to estimate what proportion of the 304
4 I think actually acquired their infection through blood
5 transfusion. I really don't know the answer to that
6 question but when pressed, I would say in my judgment,
7 from looking at other information available to me, that
8 we are in the less than 50 per cent category.

9 THE CHAIRMAN: Thank you.

10 MS DUNLOP: Sir, it is probably only fair to put up at this
11 point the notes to which Professor Goldberg refers -- at
12 least I think they are the right notes -- which appear
13 at the end of the other statement. Again, if we could
14 have these side by side. If we go to PEN0010212 at the
15 end of the statement ... (Pause)

16 THE CHAIRMAN: I think while this is being looked for,
17 Ms Dunlop, it occurs to me that it might be a great
18 advantage to me, and perhaps to others, to have hard
19 copies of some of this material because looking from
20 page to page on screen is fine when the pages are there
21 but they tend to escape. If there is anyone else who
22 would benefit from having a hard copy, if they would let
23 us know now, we can perhaps get them all at once.

24 MS DUNLOP: Yes, by all means, sir.

25 It was just, professor, that I think this paragraph

1 really should be read along with your answer to question
2 1. That's really a summary of the reservations that you
3 have expressed in your evidence, I think, isn't it?
4 A. Indeed, yes.
5 Q. So you tell us in short, in the middle of that
6 paragraph, that:
7 "The lack of confirmation associated with blood
8 transfusion is a weakness in the system. However, it is
9 not much better in other places."
10 A. Yes. I mean, I'm pretty confident that the information
11 that Scotland has on Hepatitis C is as good as, if not
12 better than anywhere else in the world.
13 Q. Thank you.
14 THE CHAIRMAN: I'm tempted to say that if all the apples in
15 the barrel are bad, it doesn't help one to find good
16 fruit.
17 A. I think, that comment -- I wasn't being in any way
18 flippant there. I would hold by that statement. I think
19 there are weaknesses in our information base with
20 respect to blood transfusion and blood factor, but in
21 general our information about Hepatitis C is pretty
22 good. If you want to compare our diagnostic
23 information, ie numbers of people known to be infected,
24 with the information available in England, then we are
25 in a far superior position in terms of the completeness

1 of our data and indeed its accuracy. That probably
2 doesn't help matters.

3 THE CHAIRMAN: No. I look forward to the April elucidation
4 of all of this.

5 MS DUNLOP: I think the April exercise will be the other
6 kind of exercise, as I understand it. It will be
7 a modelling exercise rather than an attempt to count
8 heads, as it were.

9 A. It will be a modelling exercise and it will be done in
10 the context of the time that we have available to do it.

11 Q. Yes. We will come on to that kind of exercise in
12 a minute. Just now we are still at the counting of
13 heads.

14 A. Indeed.

15 Q. I mean, perhaps one can say that the fact that there are
16 difficulties in other countries may reflect the inherent
17 difficulties in the issue.

18 A. I think there is also one other point to make and that
19 is that much of the data that we collect, it's about
20 preventing future infection and disease. So when we
21 started this exercise in 1996, ie the creation of the
22 diagnosis database, I think it was felt that, as far as
23 blood transfusion is concerned -- and indeed blood
24 factor is concerned -- these were not serious issues in
25 relationship to preventing further transmissions. But

1 there were other areas which were very much more
2 important and indeed are still very important.

3 We still estimate that around about 1,000 to 1,500
4 people are becoming infected every year with Hepatitis C
5 in Scotland. So a great bulk of our energies are
6 focused on the behaviours associated with transmission
7 of HCV in that respect.

8 Q. Yes. By far the most common means of acquiring
9 Hepatitis C, as I understand it, is by injecting drug
10 use.

11 A. Absolutely.

12 Q. That has been so really for as long as the virus has
13 been identified?

14 A. In this country but not in every country.

15 Q. Right. Let's stick to Scotland just now.

16 A. Sure.

17 Q. That statement we should just look at. You have said
18 that in relation to those 304 people -- that is answer
19 4:

20 "219 of them are not known to be dead as
21 at December 2009."

22 Then if you turn the page, again at that point, 85
23 of the 304 cases were known to have died.

24 A. Yes.

25 Q. "Of these, 18 had a primary liver-related cause of death

1 on the death certificate and 13 had a secondary
2 liver-related cause of death. It is not possible to
3 conclude from this information alone if Hepatitis C
4 materially contributed to death in these instances."

5 Professor, we looked this morning at a different
6 cohort of people. 53 people who have all died and who
7 are all known to have had Hepatitis C. It was
8 interesting to see that hepatitis was only recorded on
9 the death certificates of 14 of them. So in very broad
10 outline, this seems to be a similar sort of picture but
11 I think you are not yourself enthusiastic about using
12 death certificates as a reliable guide. Is that fair?

13 A. That is fair. It's not a reliable guide and that's one
14 of the reasons why we use the Hepatitis C diagnosis
15 database in association with the death register, to
16 identify individuals with Hepatitis C who have died,
17 rather than going straight to the death certification
18 register and just relying on that source of information.
19 It just is completely unreliable in that respect.

20 Q. Certainly I think this is a vivid illustration of the
21 degree of underreporting we would have encountered if we
22 had simply tried to count the number of people who had
23 it on their death certificate. That looks from these
24 two exercises as though that would have been really
25 quite unreliable.

1 Can I ask you to look at the --

2 THE CHAIRMAN: I don't think you got an answer.

3 MS DUNLOP: I think there was a nod.

4 THE CHAIRMAN: I think the point is that simply if the death

5 certificates were the only sort of information, the sum

6 total produced would be a gross underestimate.

7 A. It would be a gross underestimate and that's why having

8 the diagnosis database is so important in this respect.

9 Very few other countries in the world have a diagnosis

10 database and even if they do have one, it is very

11 difficult for them to do this type of linkage exercise.

12 We are able to do that and therefore are able to

13 identify the number of individuals known to be infected

14 with Hepatitis C and who have also died, but not

15 necessarily as a result of Hepatitis C. That's where we

16 get into difficulties. What is the actual cause of

17 death in those individuals can be difficult.

18 MS DUNLOP: Yes. I suppose, in theory, there is the

19 possibility of error in the other direction, but that

20 perhaps is more theoretical than anything else, that

21 somebody could have Hepatitis C on their death

22 certificate but for whatever reason they have never been

23 reported to you in their life as having hepatitis. But

24 that's presumably a very small number.

25 A. It's a very small number and indeed we don't collect

1 data on individuals who are diagnosed in the private
2 sector. It is a small number of individuals who will be
3 diagnosed with Hepatitis C in the private sector. We
4 think it is a small number. So these individuals would
5 not be included on our database.

6 Q. We should look at your tables which follow on on the
7 next page. I'm hoping we will have hard copies.
8 I think it must be [\[PEN0130016\]](#) that is the tables.
9 Possibly not actually, because I can see it says "2 of
10 2". [\[PEN0130016\]](#) might be it. No?

11 THE CHAIRMAN: Which tables are these?

12 MS DUNLOP: There are three tables. [\[PEN0130024\]](#). This
13 actually goes with your statement, I think, professor,
14 doesn't it?

15 THE CHAIRMAN: This is not ...

16 MS DUNLOP: No, well, it is just a breakdown of the 304
17 really, isn't it?

18 THE CHAIRMAN: All right. It is on one page and we do have
19 the hard copies of the other materials so we can
20 cross-refer.

21 MS DUNLOP: Just to look very quickly at it, professor.
22 Perhaps unsurprisingly the greater number of people are
23 on the Greater Glasgow and Clyde Health Board area,
24 followed by the Lothian Health Board area. Then
25 Grampian, Grampian Highland, Lanarkshire and Tayside all

1 quite similar and then a big drop. Then you have given
2 the deaths, the 219 and the 85, then the figure that you
3 have also included in the text about the causes of
4 death. Then I was completely thrown by the column at
5 the bottom that says "cumulative per cent", but you have
6 told me that I can completely ignore that.

7 A. Yes.

8 Q. It seems to have got on by some mechanism that we are
9 not very sure about. I'm glad to learn I don't have to
10 try to understand it.

11 The other statement is [\[PEN0010206\]](#). This is your
12 statement in relation to the number of haemophilia
13 patients infected with Hepatitis C. We can see that
14 initially you were asked to do this by
15 Haemophilia Centre, which you were not able to do, but
16 you could do it according to NHS board of residence or
17 the board of the source of the original specimen. You
18 are aware of a total of 351 individuals who have
19 received blood factor and have been diagnosed as
20 Hepatitis C antibody positive. For all those 351
21 people, there was no information to indicate that the
22 blood factor was received outside Scotland.

23 I'm hoping that the table is the next page, which
24 will be PEN0010207. Yes, it is.

25 There is a slight difference, professor, from the

1 figure that was on your website for the period to
2 30 September 2010. There seems to have been some
3 adjustment of the figure since then. Is that something
4 you know about? Presumably the refinement of the
5 accuracy of certain figures.

6 A. Yes, the figure you are making reference to was --
7 I don't have that in front of me.

8 Q. Right. It was just that, for example, the table up to
9 last September, the figure for Lothian was 77 not 71.
10 I mean, it is quite a small changes but I just wondered
11 if you had been doing some work on the figures in recent
12 months.

13 A. What I have in front of me -- Laura, are you saying that
14 the figure that I provided in the witness statement is
15 different from another figure?

16 Q. Well, it was just that on the Health Protection Scotland
17 website, as it happened, there had been a slightly
18 higher figure and it was 361 a few months ago. That was
19 all. It just made me wonder if there had perhaps been
20 some further investigation.

21 A. I see. I think again it is going back to the original
22 question. I mean, we have excluded individuals for whom
23 information indicated that treatment, ie blood factor
24 treatment, was received outside of Scotland. So that
25 will explain the differential between the 361 and the

1 351.

2 THE CHAIRMAN: I wonder if I can help. Professor James
3 suggests that we look at the reference date, that what
4 appears in this table is correct as at December 2009.

5 PROFESSOR JAMES: What Ms Dunlop referred to was a website
6 dated towards the end of 2010.

7 MS DUNLOP: Yes, I'm obliged.

8 A. The 351 is up-to-date. The December 2009 date relates
9 to dead. The 351 is up-to-date and applies to
10 individuals for whom there is no information to indicate
11 that they received blood factor outside Scotland. The
12 361 includes ten individuals, okay, for whom that
13 applies. That's my reading of the situation.

14 THE CHAIRMAN: It is not that some people have died and
15 disappeared off the list.

16 A. No, the deaths are a separate entity.

17 THE CHAIRMAN: A separate entity.

18 MS DUNLOP: Right. And you have also broken down the
19 information according to the different reported blood
20 disorder that each individual had. Then 3, the year of
21 the earliest specimen positive for Hep C antibody. We
22 can see, completely unsurprisingly, that there is a big
23 group in 1991 in association with, obviously, the
24 availability of a test.

25 Then the information is shown in the same manner in

1 these tables as in the previous statement about the
2 number of people who are known to be dead and then the
3 causes of death. You have also repeated that in the
4 text, of the 351 people, 78 of them were known to have
5 died by December 2009; then in relation to those, 15 had
6 a primary cause of death which was liver-related, 15 had
7 an secondary cause which was liver-related and the rest,
8 at least on the face of it, didn't. You referred to the
9 ICD9 and ICD10 codes. That's the international
10 classification of diseases, is it?

11 A. That's correct.

12 Q. Right. Where does the international classification of
13 diseases come from? Is that an American publication or
14 is it truly international?

15 A. I think it is World Health Organisation.

16 Q. Thank you. I was trying to remember. I think there is
17 one system which is an American one and one which is
18 WHO.

19 A. I can't be absolutely certain about what I have just
20 said there but certainly WHO are involved in the whole
21 process.

22 Q. I also wanted to ask you about the work that was carried
23 out by Kate Soldan and others. Dr Soldan, I think, is
24 an epidemiologist based at CDSC in London. Is that
25 correct?

1 A. That is correct, yes.

2 Q. Right. Just in a nutshell: she researched the number of
3 transfusion transmitted Hepatitis C infections in
4 England and then she was asked to do a similar sort of
5 modelling exercise for Scotland. I think she was asked
6 by Dr Brian McClelland. Is that right?

7 A. That's right. I mean, I'm looking at a letter from
8 2002.

9 Q. We should have that. That's [\[SGH0057201\]](#). Is that the
10 letter you are meaning?

11 A. Yes.

12 Q. The one that says:
13 "Dear Bob ..."?

14 A. Yes, that's right.

15 Q. And this was all done in connection with Lord Ross's
16 enquiry into the extent of the problem in Scotland.

17 A. Hm-mm.

18 Q. There was an attempt made to gather some data and that's
19 the context in which Dr Soldan was approached. Sorry,
20 did you want to draw our attention to the letter?

21 A. I was just making that comment because I think that's
22 the only reference to Kate Soldan I actually have in my
23 notes.

24 Q. Actually the work relating to Scotland is appended to
25 that letter and we see it at [\[SGH0057203\]](#). Her name is

1 on SGH0057204. I didn't want not to go to the main
2 publication, professor, so even though it is late in the
3 day I would ask you to look at her principal article and
4 she refers to it on [\[SGH0057203\]](#). Do you see at the top
5 she says:

6 "Estimates of the contribution of transfusion to HCV
7 infection in England have been made and are in press
8 [with Epidemiology and Infection]."

9 That article was duly published. It is entitled
10 "The contribution of transfusion to HCV infection in
11 England". We have that at [\[PEN0131580\]](#). There are some
12 hard copies of it as well, sir. I don't know if you
13 would want to have one. Would that help? We have some
14 extra ones. (Handed)

15 THE CHAIRMAN: If it's a pre-condition that I'm convinced it
16 will help. I'm not sure that I shouldn't resist. I
17 will have a look. I have seen it before.

18 MS DUNLOP: I just thought it was easier to understand the
19 Scottish exercise if you looked at and even, on a good
20 day, understood the English exercise as well. I mean,
21 I think as we said when we were discussing this before
22 lunch, if we look at the chart, just two pages on,
23 I certainly find the middle column perhaps the least
24 difficult. The right-hand column is slightly more
25 difficult and the one on the left is really quite hard

1 to follow, but if we can just look at it and hopefully
2 not spend too long on it.

3 Dr Soldan appears to have been the coordinator of
4 quite a large group of people conducting this exercise
5 and she tells us in the text that a large number of
6 people from different blood centres in England supplied
7 data. She was able to get data for eight blood centres
8 which had handled 80 per cent of all blood components
9 which had entered the look-back programme in England.
10 So she had information from them and then in fact she
11 had information on all tested recipients as well.

12 This is, I guess, the way an epidemiologist works,
13 is it, this kind of chart? Not all the time. It is one
14 of the things an epidemiologist can do. Is that
15 accurate?

16 A. I suppose so, yes. It is a fairly standard, I think,
17 approach to try and make things as easy as possible to
18 understand. A flow diagram.

19 Q. Yes. The word "path" is used a lot in the article.
20 I suppose "path" is slightly confusing because if you
21 are on a path you can both join it and leave it whereas
22 you have used the word "flow". I wonder if it is better
23 to try and think of this as a flow, because certainly
24 people do leave the flow but nobody joins the flow.

25 I suppose there is one group of people who join the

1 flow but generally you do not join the flow half way
2 down. But just look at it, if we start in the middle at
3 the top, "The observed path of components that entered
4 the look-back programme and resulted in known
5 Hepatitis C status of recipients," she tells us firstly
6 that there were 9,222 components which entered the
7 look-back programme. We have already heard about the
8 look-back programme. It was UK-wide but this is in
9 relation to England. Components are the different parts
10 that can be used from a donation of blood.

11 Then the first group which leave the flow, the
12 2,119, these are components whose fate is not traced.
13 Of the remaining components, 4,586 were transfused,
14 but -- and again, some are leaving the flow to the
15 right -- 154 of the components which were transfused
16 didn't have an identified recipient. 2,711 of the
17 recipients had died and then there is another group of
18 people who were eight, who were known to have been
19 infected. I take it from the way it is written that
20 they are dead as well.

21 So that reduces the number quite a bit. There were
22 1,713, if we go back to the middle of the flow, 1,713
23 identified recipients, assumed to be alive. Of that
24 number 1,062 were tested, 651 weren't. I should say
25 that every so often she has to scale up her number

1 because she only had 80 per cent of the components, data
2 for 80 per cent of the components. So she scales it up
3 to 100 per cent to give her a more accurate number,
4 a more complete number.

5 Then, of those who were tested -- and at this point
6 271, who come from the other 20 per cent of the
7 components -- 271 tested recipients join in. They are
8 in italics and the total number found to be infected was
9 677.

10 A. Hm-mm.

11 Q. So 677 infections were identified during the look-back.
12 Then if we look on the right-hand side, she has charted
13 all the components which dropped out of the flow for
14 whatever reason and worked out a number for the likely
15 infections from those. Then finally the exercise on the
16 left-hand side, as I understand it, is that she had to
17 come up with a figure for the HCV-positive components
18 which would have entered the system, as it were, between
19 1980 and 1991 but which had not come to light in the
20 look-back exercise.

21 A. Hm-mm.

22 Q. So she works out -- and this is really pretty
23 complicated, and I find it difficult, so we will not
24 bother going into it -- a figure of 19,525 for the
25 additional components entering the system. Then she

1 applies the same percentages that she has established
2 from the middle column to that figure as well.

3 A. Hm-mm.

4 THE CHAIRMAN: 19,000 -- you have lost me at that point. Up
5 there, I see, yes.

6 MS DUNLOP: Yes. It is at the top on the left-hand side.

7 THE CHAIRMAN: Let me see whether I do understand this. I'm
8 not sure that the persons and the figures are always
9 necessarily presented in the same way but if we look at
10 the top of the middle column, 9,222 is an absolute
11 number, which represents 80 per cent of the total
12 components entering the look-back. Is that right?

13 A. Hm-mm.

14 THE CHAIRMAN: Then 2,119 components had a fate that wasn't
15 traced.

16 A. Hm-mm.

17 THE CHAIRMAN: If we look below that and find that 7,103 is
18 the difference between 9,222 and 2,119, so that at that
19 point she has not grossed up to 100 per cent. I'm not
20 quite sure why. We then get to the next stage,
21 65 per cent of the 7,103 -- one full figure and one not
22 grossed up -- is carried down to the next line, where
23 there are two alternative blocks to the right, and
24 where, regrettably, I can't get the arithmetic work.
25 Because if I take 7,103 and subtract 2,649, the

1 grossed-up figure, I get to 4,454 and not 4,424. Which
2 is the figure she has used. Then it goes down.

3 I regret, at that at the moment, I can't quite
4 follow in detail the logic of the presentation. It may
5 be me simply not getting it right, professor. Can you
6 help me understand?

7 A. Certainly. I have been put on the spot here because
8 I knew of the existence of this paper and I was given
9 a copy about just over an hour ago. So what I would
10 have to do is go through it, preferably with Kate,
11 because I'm seeing Kate next week. The reason I'm
12 seeing Kate next week is to help me generate the
13 Scottish estimates that you want for the period 1970 to
14 1991, and of course this period that we are talking
15 about just now is 1980 to 1991.

16 So, sir, if you would like me to spend some time
17 sort of adding things up just now and also sort of going
18 back to the text, I can do that, but I'm sorry, I'm not
19 in a position to --

20 THE CHAIRMAN: I can assure you I don't want you to do the
21 arithmetic. It happens to be something I tend to do and
22 play with the arithmetic. I'm much more interested in
23 the process. It looks to me as if she starts with
24 a gross number of people and then adjusts that number
25 down for a series or sequence of factors that she can

1 identify as affecting the general development of her
2 thesis. Some components' fate was not traced. Exactly
3 what the arithmetic is is less important than knowing
4 that that's why she discounts the figure for that. Then
5 we have unidentified recipients and she discounts her
6 exercise for that. Then there are people who are not
7 tested and they are taken out of the loop, and finally
8 we get down to 677 infections identified, of whom
9 1 per cent are known to be dead.

10 What interests me is that if one has once done that
11 and progressively reduced the relevant focus for enquiry
12 into a relatively small number of people, what's the
13 next step? And how do you get up to a much larger
14 figure, for example at the top of the left-hand column?
15 What's the significance of the reduced figure in the
16 overall picture, when it has been reduced by so many
17 factors to such an extent? Sorry, that's rather
18 a complex point, I suppose. But what can one make of
19 this?

20 A. I mean, what she has done here is she has got some
21 pretty solid data on the 9,222 and then she has
22 extrapolated the findings to those components for which
23 she doesn't have solid data, and I think that's
24 a reasonable thing to do.

25 I'm not convinced this is the only way to estimate

1 the size of the infected population. I think there are
2 other ways of doing it. As I explained just before
3 coming in here, if you use a combination of approaches,
4 then you do reduce uncertainty. But that all takes time
5 and much, of course, is dependent on the information
6 that's available to you. So for Scotland we have
7 information generated through the look-back, but we also
8 have other information about the size of the infected
9 population, ie Scottish population, during the 1980s but
10 also during the 1970s as well. So I would expect to use
11 these data.

12 I have probably not answered your question properly
13 but I hope what I have just provided you with is of
14 relevance.

15 THE CHAIRMAN: Perhaps I can put it quite briefly. We start
16 off with 9,222 pieces of hard information, pieces of
17 hard data. By the end of the exercise, 73 per cent of
18 those cases have disappeared because of a number of
19 factors which mean that they can no longer be taken into
20 account.

21 What is the confidence one can have in inferences
22 drawn from the 27 per cent that are left?

23 A. I'm just looking through this chart just now to try and
24 answer that question. I mean, I think the information
25 is pretty solid in that -- for example, you have

1 infected components but not all of these have been
2 transfused. You have to eliminate, obviously,
3 individuals who have died. You then test the 1,713
4 living individuals who received components, so you test
5 two thirds of those individuals.

6 The question is: is there bias here? Are the 651
7 individuals who were not tested more likely or less
8 likely to be infected?

9 THE CHAIRMAN: That involves a stage beyond what I would
10 want to pause at. If one reaches the stage at which 677
11 effective tests are available, and 651 persons who would
12 qualify for testing have not been tested, you are
13 getting down pretty well to 50 per cent of the relevant
14 population at that stage. Indeed, if we gross the 651
15 up to the full 100 per cent, more than 50 per cent of
16 those who would have qualified, as it were, who would
17 have been within the class for testing, have not been
18 tested.

19 I don't know, I'm not a statistician. I don't know
20 what the statistical validity of a percentage of this
21 kind might be, but I think it is legitimate for me to
22 ask you what confidence one can have in extrapolations
23 based on this about the general population.

24 A. For me it is the 651 recipients who were not tested. So
25 they were alive and they were not tested. The other

1 factor, of course, is the 2,711, those who had died
2 further up, were they more likely to be infected. After
3 all they had died and so Hepatitis C may have been
4 a contributing factor in those instances.

5 I know what you are driving at: the potential bias,
6 all the way through here. I think there clearly must
7 have been reasons why, for example, of the individuals
8 who were alive, 651 were not tested. What were the
9 reasons for them not being tested? I presume in most
10 instances it was just failure to get access to them.
11 One possibility is refusal. Why would somebody refuse?
12 Would that make them more likely to be infected or less
13 likely to be infected? I don't know if you can make any
14 assumption, other than there is potential bias in the
15 system.

16 THE CHAIRMAN: I think I could almost forecast that a point
17 Mr Dawson will want to ask you about is the net result
18 of this, that this is a minimum number.

19 A. The 651?

20 THE CHAIRMAN: Not the 651, the 677 that one ends up with.

21 A. Absolutely. It is a minimum number and that's why the
22 overall estimated number is 13,500. But the thing is
23 that the extrapolations appear to be based on the middle
24 column and the question is: can you extrapolate?
25 Because there may well be biases in the system which

1 mean that the numbers infected, or the expected numbers
2 infected may be an underestimate or an overestimate.

3 I don't know if this is discussed by Kate in the
4 paper but I would be surprised if it wasn't.

5 MS DUNLOP: I don't know if it helps, sir, to note that she
6 says:

7 "We may have underestimated or overestimated the
8 infections --

9 THE CHAIRMAN: I noticed that. I'm not sure it helps at
10 all.

11 MS DUNLOP: It certainly shows she is frank.

12 THE CHAIRMAN: Mea culpa, mea culpa, mea maxima culpa is
13 frank. It doesn't necessarily enlighten one.

14 I don't want to play this down at all. It looks
15 like a serious exercise carried out in a very difficult
16 area in the absence of hard data, but somehow or other,
17 professor, I have to try to get a measure of numbers.
18 There is a great danger in taking a figure that may be
19 fundamentally flawed. From my point of view it may be
20 that one just has to have a general estimate and perhaps
21 you can help us as best you can for Scotland, but not go
22 beyond that. I don't know.

23 MS DUNLOP: The main problem perhaps, professor, is that out
24 of the limited group she did have, the people who made
25 it to the end of the flow, certain results have been

1 obtained and then, no doubt because there isn't any
2 better way, after that the team applied the findings
3 from the group of people who made it to the end to the
4 people who dropped out. As you have said, that may not
5 be valid because of the people who dropped out, there
6 may have been more Hepatitis C in those groups or,
7 I suppose, less Hepatitis C for particular reasons.

8 So you are starting with a disadvantage because you
9 are assuming that, as his Lordship would say, the people
10 are really homogeneous. So if you were able to get the
11 people who dropped out, they would produce the same kind
12 of results if you tested them and so on, and that may
13 not be right. Then the problem is no doubt magnified
14 when you try to work out the much bigger number, which
15 is the components that didn't get into the look-back
16 exercise in the first place --

17 A. Hm-mm.

18 Q. -- and apply the same assumptions to them because there
19 might again be all sorts of reasons why these
20 assumptions are not very accurate. But perhaps there
21 isn't really any other data that the team could have
22 used.

23 A. I think that's why I was saying that, you know, if you
24 just use one method, you are opening yourself up
25 a little. I mean, you know, this is actually a very

1 good piece of work undertaken by Kate, who probably
2 knows more about this field than anybody else in the UK.
3 But it does have its limitations and I think we just
4 have to acknowledge these limitations.

5 Q. Yes.

6 A. By and large, when you are doing this sort of work, if
7 you use maybe two or three methods -- but much depends
8 of course on the information you have available to
9 you -- I think your confidence in your final outcome is
10 very much greater because if you have considerable
11 differences in your results, you can get an average or
12 you can take what's regarded as the best or whatever.
13 That, I think, would help you, sir, in feeling confident
14 that one actually had the best estimate possible.

15 THE CHAIRMAN: I just introduce a word of caution at that.

16 I understand that. If there is variation in the basic
17 data that is used, but if the basic data happens to be
18 common to all three methods and particular numbers are
19 dominant, then it may be that simply having different
20 approaches to analysis should not give one greater
21 confidence.

22 A. I think that's right. But it may be that, you know, you
23 are using different data sources. So in this instance
24 we are just using look-back data but there are
25 potentially other sources of information that one might

1 use.

2 PROFESSOR JAMES: Lord Penrose, can I point one other thing
3 out? Would you mind?

4 THE CHAIRMAN: No, anything that helps.

5 PROFESSOR JAMES: Professor Goldberg, of all the 13,500, the
6 big, big number at the bottom, the biggest number comes
7 from the left-hand column, the 9,455 infections due to
8 components not entering the look-back. That is based on
9 the assumption that the observed prevalence of anti-HCV
10 during the first four months of donor testing, in
11 England 0.066 per cent existed from 1980 through to
12 1991; in other words, for every year. Then they have
13 extrapolated against the number of units of blood
14 transfused over that decade, 25 million donations,
15 et cetera, et cetera, and made some extrapolations. So
16 that's just another set of assumptions --

17 A. Absolutely.

18 PROFESSOR JAMES: -- to add to the mix and it does actually
19 produce the biggest number, if you see what I mean. No
20 doubt you will be examining that number, particularly
21 since the Inquiry has asked you to look at 1970 to 1980,
22 which is even further away from being able or justified
23 to make an assumption on a prevalence made in 1991, but
24 you will be looking at that with various caveats in
25 order to help the Inquiry as best you can.

1 A. We will certainly do our best. What you can do is you
2 can do what's called a sensitivity analysis, which means
3 that you can vary various assumptions to see what impact
4 that variation actually has.

5 So you might generate a range of estimates. As
6 I say, this has not been done in this particular
7 instance. I mean, I suppose as far as Scotland is
8 concerned, if we are going to do this work, these things
9 do take time and my understanding is that you want
10 something as soon as possible, clearly, and so the
11 complexity of the work that we undertake has to be
12 considered in the context of the time available to do
13 the work.

14 THE CHAIRMAN: Professor, I think you should take it that
15 you have made one important point today, as far as I'm
16 concerned, and that is that your primary focus is on
17 those who are infected now and how matters can best be
18 adjusted to protect people in the future.

19 You may take it that I don't want to see this
20 becoming a massive statistical exercise that may end up
21 with less confidence in it than your own judgment can
22 provide. I think that one is entitled to look to
23 a practitioner in the field, like yourself, and ask for
24 your best estimate, making use of such data as you have
25 and such methods as you think are right. For my part,

1 although others may have a different view, I will not be
2 disappointed if I get your best judgment.

3 A. Thank you. Thank you, sir.

4 MS DUNLOP: Professor Goldberg, I just wanted to go back to
5 [\[SGH0057203\]](#). We looked at this before. This is
6 Dr Soldan's short paper on the exercise she did for
7 Scotland. If we look at that table in the middle. We
8 can see that she did the same thing. She had the middle
9 column and that's the 106 people. So she started --

10 THE CHAIRMAN: Sorry, Ms Dunlop, before you get into it,
11 I understand that we really must give the stenographer
12 a break. We should stop at that point briefly. I
13 should also say that I have a commitment at half past
14 four, which is not inelastic but I wouldn't want to stay
15 too much beyond that.

16 MS DUNLOP: Thank you.

17 (3.46 pm)

18 (Short break)

19 (4.01 pm)

20 MS DUNLOP: Can we just have [\[SGH0057203\]](#) again, please?

21 This is Dr Soldan's exercise for Scotland. Just to
22 look at the table, if we might, for a moment. In short
23 she did the same exercise but with Scottish data. So
24 the top row in the table -- that is the row that's
25 described as identified by the HCV look-back programme

1 in Scotland -- that would be the middle column in
2 Dr Soldan's paper.

3 So that's all the people who made it to the end, as
4 I said a short time ago. Then the next row is people
5 who received components that entered the look-back but
6 did not receive testing in that programme. That's the
7 column on the right-hand side of her chart. So the
8 components that dropped out of the flow along the way,
9 for whatever reason.

10 Then the last row, those who received components
11 issued between 1980 and 1991 is the column on the
12 left-hand side. So the estimate that one has to prepare
13 for the components that didn't enter the look-back
14 programme. In other words, from donors who were
15 positive but who were not picked up via look-back. The
16 figures that Dr Soldan was able to use were the actual
17 figures that had been ascertained in the Scottish
18 look-back. So, for example, the unidentified
19 recipients, the people who were dead, the people who had
20 declined testing, the people whose test results were
21 insufficient and so on. They could be used for Scotland
22 and they didn't have to use the English figures.

23 The only thing that was different, or the figure
24 that was different for Scotland, which she used, was the
25 prevalence in the donors. We should just go back to

1 remind ourselves that the prevalence among donors in the
2 first four months of testing in Scotland was not
3 0.066 per cent, as it was in England and as Dr Soldan
4 used, but 0.088 per cent. We find that in the
5 preliminary report, if we can go back to chapter 9,
6 please.

7 If we can go to chapter 9 -- are you better with the
8 paragraph number or the page number? Again starting at
9 the back, we are going to page 318.

10 Paragraph 9.285. This is Dr Crawford reporting that
11 in the first six months of testing in Scotland -- so
12 between September 1991 and February 1992 -- donors were
13 tested and the prevalence rate amongst Scottish blood
14 donors was 0.088 per cent. The reference for that is
15 given in footnote 332.

16 So we have looked at all of that material, really,
17 professor, just to try to get in very broad terms an
18 understanding of the sort of exercise that Kate Soldan
19 did for Scotland and how she produced the figure she
20 produced. We can see the conclusion of her table. She
21 got, in round terms, 3,500 for the total number of
22 infections, and she says again in the note at the bottom
23 of -- sorry, this is going back to [\[SGH0057203\]](#):

24 "Many assumptions were used, some of uncertain
25 validity."

1 Do you see that?

2 A. Hm-mm.

3 Q. There has been another figure mentioned recently,
4 professor. You may know nothing about this and that is
5 no reflection on you, certainly, but in the recent
6 review conducted on the instructions of the Department
7 of Health, the review of the support available for
8 individuals infected with Hepatitis C and/or HIV,
9 a figure is given for the whole of the United Kingdom
10 for the period 1970 to 1991 of 28,043 infections.

11 The thing about that is that from the Soldan paper
12 she had 13,500 for the 1980 to 1991 period. I'm not
13 going to go back to it but she added on 10,000 for the
14 decade of the 1970s. So that paper would be 23,500, and
15 that in the Department of Health paper it says that the
16 28,000 figure has been arrived at by "correcting
17 Dr Soldan's paper for the UK." But there is no
18 explanation of how they got their additional figure. In
19 fact, if it is only the addition of 4,500-odd for Wales,
20 Scotland and Northern Ireland, that looks quite low.

21 A. Certainly in the context of that 3,498 for Scotland for
22 the 11-year period.

23 Q. You haven't been involved in any work leading to the
24 Department of Health's figure then?

25 A. No, nor was I or any colleague in HPS involved in this

1 piece of work, the 7203 work that Kate Soldan did.
2 That's one of the reasons why I'm seeing her on Tuesday.

3 Q. Yes. Perhaps she might be able to enlighten you as to
4 how this most recent figure, which purports to be
5 a figure for the whole United Kingdom, was obtained as
6 far as Scotland is concerned because that's a bit of
7 a poser when you read that report?

8 A. Absolutely. I think your calculation is a very
9 reasonable one. There really is some inconsistency
10 there.

11 Q. Yes.

12 A. Certainly the prevalence of 0.088 versus the English
13 prevalence of, was it, 0.066 is consistent with our
14 estimates for HCV in the general population in Scotland
15 versus England. I mean, in Scotland it is estimated
16 there are probably about 30 to 50 per cent more infected
17 individuals per head of population, ie the prevalence is
18 about 30 to 50 per cent greater, and that is, as I say,
19 consistent with that difference that you observe for
20 prevalence among blood donors.

21 Q. Yes. We know, sir, that you yourself have looked at
22 this report and it just seemed another possible source
23 of statistics, but the only reference which is given for
24 that 28,000 figure for the whole UK is the 2002 Soldan
25 article, at which we have just been looking, which is

1 described as having been corrected to the UK but there
2 is no explanation of how.

3 THE CHAIRMAN: I have a strong suspicion that "corrected"
4 should be expressed as "adjusted" and it may be no more
5 than a crude accumulation of estimates but one can't
6 tell.

7 MS DUNLOP: It is just another figure, sir, at the end of
8 the day. Another figure which the Inquiry has obtained
9 is that there have been 636 payments from the Skipton
10 fund to people in Scotland and that's obviously not
11 inconsistent with the lower range of figures that have
12 been described at points today.

13 THE CHAIRMAN: I'm suggesting to Professor James that if one
14 tried to do a stochastic projection of the range of
15 values here, the vector would be nearer to that of
16 a blunderbuss than a shotgun, professor, really, the
17 variables are become becoming so wide.

18 A. I think that's fair comment.

19 MS DUNLOP: I don't have any more questions for
20 Professor Goldberg. Thank you, professor.

21 THE CHAIRMAN: Mr Dawson, are you asking again?

22 MR DAWSON: Yes.

23 Questions by MR DAWSON

24 MR DAWSON: Thank you, sir. I have a few questions.

25 Professor, as I had you noted in connection with the

1 issue of notifiable disease legislation, your position,
2 as I understand it, was that under certain provisions of
3 that legislation information would be communicated to
4 Health Protection Scotland but that you considered that
5 information to be broadly unreliable. Is that your
6 position and if it is your position, could you explain
7 why that source of information is unreliable?

8 A. Yes, I mean imported directly to
9 Health Protection Scotland from 2007 onwards but prior
10 to that it was ISD. Unreliable for two reasons. One
11 was that the numbers of individuals with viral
12 hepatitis, unspecified, pretty meaningless to us, and
13 then the number of individuals actually being reported
14 by clinicians bore no relationship to the actual data we
15 were getting from the laboratories. I'm not saying our
16 laboratory data are 100 per cent complete but certainly
17 over 90 per cent complete and so our feeling was that we
18 weren't being just dismissive, recklessly dismissive, in
19 this respect, we were basically saying, "Look, the
20 information we are getting from the laboratories is
21 fairly accurate," and the information that we would have
22 got from the notification system would not have helped
23 in any way at all; it would have actually hindered us in
24 our understanding of the epidemiology of this infection.

25 Q. Thank you. In your paper on transfusion-transmitted

1 Hepatitis C you give a figure, which you have discussed
2 in detail, of 304 individuals. That number comes from
3 a number of people in connection with whom reports have
4 been made to Health Protection Scotland.

5 A. That's right.

6 Q. And the reason why reports are made to
7 Health Protection Scotland in respect of these 304
8 people is because they have tested positive for
9 Hepatitis C in Scotland. Is that right?

10 A. That is correct.

11 Q. And the way in which one connects that positive test
12 with a possible blood transfusion is that blood
13 transfusion is included in the data with which you are
14 provided and it is the only risk factor. Is that
15 correct?

16 A. It is certainly a risk factor. We did exclude from that
17 figure 51 individuals for whom injecting drug use was
18 also recorded on the request form because what we were
19 trying to do was get as near to answering the question
20 as possible, ie contracted Hepatitis C as a result of
21 blood transfusion. So our view was that if you had on
22 your request form, "Blood transfusion and injecting drug
23 use," it is much more likely that you would have been
24 infected through injecting drug use behaviour because we
25 knew, certainly in the 1980s, that in most centres

1 between 80 and 90 per cent of injectors were infected
2 with Hepatitis C. It was a very, very high percentage.
3 But that 304, I suppose, could be increased to 355 if
4 you include those individuals who also have the risk
5 factor injecting drug use as well.

6 Q. In compiling this statistic, was information available
7 to you as to where these individuals had received their
8 potentially infecting blood transfusions?

9 A. Our position is that if information indicated that they
10 had received their blood transfusion outside of
11 Scotland, then we excluded them from this particular
12 figure. So often you would find on the request form
13 a person from, I don't know, Zambia, blood transfusion
14 from Zambia. We would exclude that individual from that
15 figure. In total we have 49 individuals for whom there
16 is information indicating, strongly indicating, that the
17 transfusion was received outside Scotland. Of course,
18 that doesn't mean to say that for the 304 individuals
19 they definitely received their transfusion within
20 Scotland; there just was no information indicating
21 otherwise.

22 Q. So it is an assumption you made --

23 A. It is really just an assumption because a clinician
24 would only tend to include information if they thought
25 it was relevant, if it was unusual. So, for example, if

1 they put on the request form, "Blood transfusion," and
2 the person had the blood transfusion in Scotland, they
3 wouldn't say, "In Scotland", they would just say, "Blood
4 transfusion." It would be probably assumed by the
5 clinician that that had taken place inside the country.
6 So I think the problem here is that the absence of
7 information, of course, doesn't mean that in this
8 instance blood transfusion didn't occur outside
9 Scotland.

10 Q. As I understood your evidence, you expressed the view
11 that you thought that perhaps less than 50 per cent of
12 the 304 actually did get their infections through the
13 transfusion. What was the reason for you expressing
14 that view?

15 A. I think I answered the question originally by saying
16 that I just didn't know.

17 Q. Is it to do with the unreliability of the information
18 which --

19 A. I think it is to do with that, the unreliability of that
20 information. I think the age distribution is a bit
21 lower than I thought it would be for a blood transfusion
22 recipient group. Having said that, individuals, older
23 individuals, who received blood and were infected
24 through blood transfusion, many of these would have not
25 been diagnosed with Hepatitis C simply because they

1 would have succumbed to other things.

2 So that in some ways influences matters as well.
3 But, you know, I was asked a question and I said, "Well,
4 if I was putting money on it, I would lean towards
5 possibility as opposed to probability, less than
6 50 per cent than to over 50 per cent, but that's just
7 a personal sort of judgment.

8 You have asked me on what basis. I don't think
9 I have looked at this in enough depth to make a proper
10 judgment in this respect but I'm not sure if in fact we
11 have sufficient data to actually make a judgment, and so
12 my actual answer of, "I don't know," I think is probably
13 the correct one.

14 Q. At the end of your first report, more accurately
15 described as the document at [\[PEN0010206\]](#), the front
16 page PEN0010210, you explain the methodologies that are
17 applied to the compilation of data, first of all in
18 connection with HIV, which I don't think you have been
19 asked to give any information about, but, secondly,
20 perhaps more relevantly for the matters upon which you
21 have given your views on Hepatitis C from the following
22 page.

23 I just wanted to ask you: my understanding in
24 relation to HIV is that the information with which
25 Health Protection Scotland is provided is likely to be

1 more comprehensive than the information with which
2 Health Protection Scotland might be provided on the
3 issue of Hepatitis C. I understand that that's
4 principally because of the fact that there is a specific
5 form which asks specific questions about HIV, whereas no
6 such specific form exists in relation to Hepatitis C.
7 Is that an accurate understanding?

8 A. I think that's fair. We introduced the HIV dedicated
9 HIV test request form in 1989 and so this is really just
10 a prompt list for clinicians requesting a test. So you
11 are absolutely right that the information obtained for
12 HIV is likely to be more reliable than that for
13 Hepatitis C. We did make some attempts to try and get
14 a dedicated Hepatitis C request form but there were
15 obstacles and we didn't manage to achieve that.

16 Q. Thank you very much, professor, thank you, sir, I have
17 no more questions.

18 THE CHAIRMAN: Mr Anderson?

19 MR ANDERSON: I have no questions.

20 THE CHAIRMAN: Mr Sheldon?

21 MR SHELDON: Nor I, thank you.

22 THE CHAIRMAN: Thank you very much indeed for your help. We
23 look forward to hearing from you again.

24 A. Thank you.

25 MS DUNLOP: Tomorrow we are going to hear from

1 Professor Turner and Dr Norfolk, who are going to talk
2 really about transfusion from -- if this isn't too
3 crude -- a sort of seller and purchaser point of view,
4 the people who collect the blood and how they do that
5 and the systems that they use, and then the various uses
6 to which the blood is put in the therapeutic context.

7 So that is what we have planned for tomorrow, as
8 much to give us general background which should be
9 useful throughout the whole of the rest of the Inquiry
10 as anything else.

11 (4.27

12 (The Inquiry adjourned until 9.30 am the following day)

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