

Thursday, 17 November 2022

(10.00 am)

(Proceedings delayed)

(10.15 am)

SIR BRIAN LANGSTAFF: Good morning to all of you. Good morning again in your case, Professor Dillon.

PROF DILLON: Morning.

SIR BRIAN LANGSTAFF: Now can you hear me, Dr McClean?

DR McCLEAN: Yes, I can.

SIR BRIAN LANGSTAFF: Good. And you can see me?

DR McCLEAN: Yes, I can. Thank you.

SIR BRIAN LANGSTAFF: Good. Then we are ready to begin.

Let me explain the arrangements so that you all know.

You're not just talking to the audience immediately in front of you but to those who are sitting in a breakout room beyond this room and who are watching on live stream or YouTube. The total figure will be in the region of three figures somewhere, can't say exactly.

To the left there are lawyers who represent various interests in the Inquiry. In the back left there are representatives of the press. So that's your audience, apart from me, of course.

In a moment or two, Ms Fraser Butlin will ask you the questions. But first, Mary will ask each of you in turn to give your respective oaths.

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pharmaceutical companies who sell the drugs for treating hepatitis C also have a contractual obligation to invest in elimination initiatives.

PROF FOSTER: That's correct.

MS FRASER BUTLIN: Can you explain for us what that means, that pharmaceutical companies are -- what are they involved in?

PROF FOSTER: This goes to a large-scale procurement that initiated about five years ago when we recognised that the pharmaceutical companies had skill sets that could be useful to us in an elimination programme. And we realised that if we collaborated with the pharmaceutical industry, we could achieve more than we could in isolation. So we put forward a procurement programme and the programme said the drug companies had to put their best price forward and they had to put forward elimination initiatives and they had to agree to fund those initiatives. All of those were then scored in a very complex legalistic procurement process that led to an awarding of market share. So each of the drug companies is allowed to sell no more than X per cent of their particular product.

So what that means in reality is that instead of a drug representative coming into my clinic and saying, "I want you to use drug X because it's better than

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PROFESSOR GRAHAM RUSSELL FOSTER (affirmed)

PROFESSOR JOHN FRANCIS DILLON (sworn)

DR BRENDAN HEALY (affirmed)

DR JOANNE MCCLEAN (affirmed)

SIR BRIAN LANGSTAFF: Yes.

Questioned by MS FRASER BUTLIN

MS FRASER BUTLIN: Thank you.

Professor Foster, if we can start with you. You are

NHS England's national clinical lead for hepatitis C and national clinical chair for the NHS England's hepatitis C elimination programme.

PROF FOSTER: That's correct.

MS FRASER BUTLIN: Could you tell us what those roles involve?

PROF FOSTER: So I was appointed to the national roles in around 2015. My main focus is providing clinical advice and support to the NHS England hepatitis C elimination team. So that will involve attending the appropriate meetings, providing advice and guidance, recommending strategies, and essentially liaising with clinical colleagues trying to make sure that the clinical opinions are heard at the commissioning level.

MS FRASER BUTLIN: And you discuss in your statement the hepatitis C elimination plan, and you say there that the programme has been funded by NHS England but that the

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drug Y", they come into the clinic and say, "We want to find more patients."

So we have the bizarre situation sometimes where a drug company will recommend a competitor's product so that the patient can get better treatment, because they know if they're treated with a competitor's products there will be a corresponding increase in their performance because the market share is fixed.

I think that's been a great success. It took a year or two to bed in. It was a very difficult working relationship to begin with, but it means that everyone is working on finding people with hepatitis C and getting them on treatment as quickly as we can.

MS FRASER BUTLIN: And in terms of those initiatives, does this mean that pharmaceutical companies themselves are undertaking initiatives to find people (**The witness nodded**) or that they're funding NHS England initiatives?

PROF FOSTER: It's a combination. So there is, for example, direct funding from pharmaceutical companies. They will buy, for example, point of care testing machines and install them in places, they will put them in places where NHS England recommends. There are areas where they clearly can't go. They can't have access to patient information, they can't have access to GP records, et cetera, et cetera, and there they would work

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1 through us.

2 So each initiative is a joint approach with
3 appropriate funding streams, appropriate governance
4 streams, depending on where the particular strengths
5 lie.

6 So, to give you an example of where this is able to
7 expedite performance, is in treating people in injecting
8 drug services, because injecting drug services are not
9 commissioned by NHS England; they're commissioned by
10 local authorities. So NHS England has no authority and
11 so I cannot go into an injection drug service supplier,
12 but a pharmaceutical company can and they can make
13 changes and recommendations.

14 I talked a moment ago about the point of care
15 testing machines. To get a point of care testing
16 machine through the NHS requires a fairly lengthy
17 bureaucratic process, validating and supporting
18 a procurement process. The pharmaceutical company can
19 access those machines very quickly and have them in
20 place within weeks rather than months. So we try to use
21 their skills where appropriate.

22 **MS FRASER BUTLIN:** And when you spoke a moment ago about
23 data that pharmaceutical companies couldn't access so
24 they went through NHS England, just to be clear, I think
25 what you mean is that they would fund somebody in

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1 something else. So if they're testing everybody for
2 hepatitis C, they are going to have to stop testing for
3 diabetes or cardiovascular disease. So, in a fixed
4 resource environment, which is where we work, we try to
5 weigh up where we're going to get maximum advantage, and
6 we need to be very careful that we don't have
7 inappropriate consequences and reduce access to services
8 in other areas.

9 So the first constraint we have is -- in crude
10 terms, how much bang do we get for our buck? Where can
11 we get best advantage? The second constraint is equity,
12 and NHS England does not distinguish by mode of
13 acquisition of disease; we focus on priority and need.
14 We appreciate that individuals may have different views,
15 but our focus is always to try to provide an equitable,
16 equal service, regardless of how people contracted their
17 particular problem.

18 So within those constraints, when we started our
19 programme we had very limited access to drugs, the drugs
20 were very expensive, and there was a cap on the number
21 of treatments that we could give. And to begin with, we
22 didn't know how effective they would be in the real
23 world. So we started our focus on people with
24 decompensated cirrhosis, very advanced liver disease,
25 and then very quickly we moved to an understanding that

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1 NHS England to deal with that data rather than that any
2 of that data would ever go to the pharmaceutical
3 companies?

4 **PROF FOSTER:** Pharmaceutical companies under no
5 circumstances can ever have access to any patient's
6 individual protected data. What they do get are
7 aggregate figures to say, "This month we have treated
8 X hundred patients". So they never get patient level
9 data. Indeed, commissioners at NHS England -- as an NHS
10 commissioner, I'm not allowed to see individual patient
11 data. Commissioning is patient agnostic and anonymised
12 from start to finish.

13 **MS FRASER BUTLIN:** You've talked in your statement about
14 there being three phases to the elimination programme.
15 Phase 1 relating to the provision of oral therapies,
16 phase 2 focused on particular at-risk groups. What can
17 you tell us about what phase 2 involved?

18 **PROF FOSTER:** So if I set the stage perhaps with the
19 constraints that we commission under. The -- our first
20 use is always to look at what resource we are going to
21 deploy on a particular programme. And resource is not
22 just about money; increasingly it's about people and
23 skills. So we're very aware that if, for example, we
24 ask primary care physicians to do a series of tests for
25 hepatitis C, they will not be doing a series of tests in

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1 the treatment was safe, as effective in the real world
2 as it was in the clinical trials. And we started to
3 negotiate a much better deal.

4 So at that stage we set up a "Go" for Hepatitis C
5 Elimination programme. The first thing we did was to
6 institute a sort of facilitatory treatment atmosphere.
7 We did that by dividing the country into networks,
8 operational delivery networks, and each of those
9 networks was given treatment targets, and those were
10 challenging treatment targets. I had a series of emails
11 from people saying, "We really can't find all of these".
12 And if people didn't hit those treatment targets, there
13 was a very significant financial penalty. When I say
14 significant, in the millions of pounds terms for some
15 trusts. So we incentivised people to go out and find
16 patients.

17 We then put a per-treated patient fee. So every
18 patient treated gets a £500 fee from NHS England. So
19 that's an environment that really incentivises and
20 drives people to get as many hepatitis C patients as
21 they possibly can. It has led trusts and organisations
22 to invest in hepatitis C elimination. So that set the
23 soil for the initiatives.

24 We then set up a whole variety of initiatives
25 focusing on different patient populations. I think the

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1 ones that are of main interest to the Inquiry are those
 2 looking for people who might have been infected by
 3 contaminated blood or blood products.

4 The main focus to begin with was looking at people
 5 who were known to have hepatitis C who had a diagnosis,
 6 and we knew there are a lot of people with positive test
 7 results that haven't been offered treatment, haven't
 8 been properly supported. So we wanted to get all of
 9 those patients. We made it a condition of the networks
 10 that they had links to the local virology service, so
 11 they would have access to all the previous tests and,
 12 with our colleagues at Public Health England, we had
 13 a re-engagement exercise and that re-engagement exercise
 14 looked at all of the positive hepatitis C tests. We
 15 cross-referenced to those that we knew had been treated
 16 and removed those and that gave us a list of about
 17 50,000 people who we contacted individually to check
 18 their hepatitis C status and offer treatment.

19 So that re-engagement exercise found, we hope,
 20 a large proportion of the people with hepatitis C.

21 As I mentioned in my statement, we've got a number
 22 of other initiatives that are ongoing and I'm happy to
 23 go into those now or defer as you prefer.

24 **MS FRASER BUTLIN:** If we can just pause on the exercise of
 25 identifying those people who had a previous positive

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1 large number of people, had gone to websites, purchased
 2 treatments, taken it themselves. Quite a lot of people
 3 of Pakistani heritage had gone back to Pakistan and
 4 bought treatment there where it was cheap and,
 5 interestingly, they were keen to engage with us to test
 6 that the treatment had actually worked.

7 So it was a whole different variety of different
 8 reasons for people who hadn't been -- who tested
 9 negative on retesting.

10 **MS FRASER BUTLIN:** Again, this may be something you need to
 11 tell us at a later date, but of that 50,000 roughly how
 12 many of them could you not find? The Inquiry has heard
 13 evidence about previous look-back exercises where there
 14 have been difficulties finding patients.

15 **PROF FOSTER:** I would have to revert to my Public Health
 16 England colleagues and their audit to give you that
 17 detailed data but during the process we had NHS numbers,
 18 GP records and Public Health England were able to give
 19 us an active phone number that was on the GP records, so
 20 we'd already sieved out patients who'd had no obvious
 21 contact point.

22 A proportion clearly weren't contactable and those
 23 that weren't contactable we wrote to the GP and said,
 24 "We have tried to contact this patient. Next time this
 25 patient attends your surgery can you please arrange

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1 test but, for various reasons, hadn't been treated. You
 2 said you ended up with a list of about 50,000. Do you
 3 have any figures -- and you may need to provide them
 4 later -- of how successful that exercise was?

5 **PROF FOSTER:** So, unfortunately, as the programme was being
 6 evaluated and Public Health England had an audit and
 7 assessment of that, the coronavirus pandemic struck, and
 8 that diverted resource. So the audit has not been
 9 completed. The preliminary data that I've seen
 10 suggested about 10 per cent of the people who were on
 11 that list had a positive hepatitis C test and went on to
 12 treatment. So it was about one in ten were caught and
 13 treated, but I don't have a denominator for that, I'm
 14 afraid.

15 **MS FRASER BUTLIN:** Could you help us then what was the
 16 position in relation to the other nine out of ten?

17 **PROF FOSTER:** So a lot of people had false positive tests.
 18 A large proportion of people had been treated. We never
 19 had records of people treated in the interferon era; we
 20 only have records of people treated in the oral
 21 medication era so a lot of people have been treated.
 22 A surprisingly large number of people can access
 23 treatment in other ways and, outside the NHS, there are
 24 ways of purchasing the oral anti-viral therapies and
 25 a significant number of people, quite a surprisingly

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1 a hepatitis C test". So I don't unfortunately have the
 2 data and I suspect that -- because the audit was never
 3 completed I rather suspect that data won't be readily
 4 available.

5 **MS FRASER BUTLIN:** In terms of the other initiatives that
 6 were taken in phase 2, they were primarily focused on
 7 particular risk groups, weren't they?

8 **PROF FOSTER:** So as we moved into an expansion of the
 9 programme, one of our priorities was people who were
 10 transmitting the virus because, clearly, if we're going
 11 to eliminate hepatitis C, we need to stop the virus
 12 transmitting and the people who were transmitting the
 13 virus were people who were disengaged from healthcare
 14 services and treatment provision in needle exchange
 15 centres; people who were injecting drugs were very poor
 16 at that time. So one of our major priorities was to get
 17 treatment into injecting drug services, make sure the
 18 homeless populations, the disadvantaged populations, had
 19 access to therapy so they would not transmit to others.

20 And that was run in parallel with the GP screening,
 21 the awareness raising in primary care and, as I'm sure
 22 we'll come on to in a moment, our GP track and trace
 23 tool.

24 **MS FRASER BUTLIN:** Which we will come to. But, before we
 25 leave phase 2, I think there was also some work done in

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1 relation to patients known to services, to double check
2 their status in relation to patients with haemophilia or
3 who also had HIV infection and to check whether there
4 was co-infection.

5 **PROF FOSTER:** We worked -- the patients who were in
6 haemophilia services -- we have, as you know testing
7 regimes for people in haemophilia services. We
8 incentivise people to go and find those people early on
9 and get from offered treatment as we expanded. It
10 sounds rather facile to say but, in a way, they are
11 probably the easiest patients to find, they are in
12 services, heavily engaged in healthcare and treatment,
13 once we established that it was efficacious and widely
14 available, was very easy to deploy. So I think that we
15 have probably offered anti-viral therapy to all patients
16 in haemophilia services and we work with haemophilia
17 services to confirm that.

18 **MS FRASER BUTLIN:** Then we come on to phase 3. You've
19 described phase 3 as identifying people at risk of
20 infection who haven't been tested and, in your
21 statement, you've identified six measures that are being
22 implemented. If we can take them in turn. First of
23 all, work to encourage testing in primary care. What
24 has that involved?

25 **PROF FOSTER:** So we've written a number of articles to

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1 physician and there's group of people who are worried by
2 stigma of hepatitis C, and all of those three groups are
3 areas that we want to target.

4 So the intention is to set up a website, and we are
5 going through the procurement process now that's been
6 completed, a preferred bidder has been selected, and
7 we're working with them on the design of the website
8 and, hopefully, that will be live before Christmas. So
9 anyone will be able to go into the website, in the
10 website, they will land on an appropriate landing page.
11 So if you've been referred by your primary care
12 physician you will go to a page that says, "Your doctor
13 has recommended, here's what you do". If you've gone to
14 it from an Urdu -- or foreign language, then you'll land
15 on a foreign language site. If you've gone into it as
16 an interested member of the public, you'll be directed
17 to a page that says, "You might need a hep C test if".

18 So the idea is that we will have different landing
19 pages and those are being worked through at the moment
20 and how many end up with and what they'll look like,
21 I couldn't tell you at the moment.

22 But people will then go in, request a test, they'll
23 be sent thorough the post a needle stick lancet and
24 a tube, and put the sample in the tube and post it off.
25 That's worked very successfully in HIV testing and

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1 primary care colleagues, had a number of primary care
2 advisory boards. We have, it's fair to say, found our
3 primary care colleagues distracted by the coronavirus
4 pandemic, and we have not had the engagement that we
5 would have wished. We're just recruiting, as in put out
6 job adverts, for what we call GP Champions and we're
7 going to pilot those in London.

8 So we're going to appoint a small number of general
9 practitioners with a particular interest in hepatitis C
10 who will encourage their colleagues to engage with us.
11 They will also, I hope, undertake some of the basic
12 chores of going through general practice lists,
13 identifying patients at risk. So I hope the GP practice
14 Champion model will work. It worked very well in HIV
15 increasing testing rates, so we'll see if that works in
16 London and, if that is successful, then we'll roll it
17 out nationally.

18 **MS FRASER BUTLIN:** Secondly, you've talked about an online
19 testing portal. Could you tell us what the aim of that
20 portal is?

21 **PROF FOSTER:** There are really several groups of patients
22 that are not accessing proper testing at the moment.
23 There's group of people who have risk factors that they
24 would prefer not to divulge. There's group of people
25 who find it inconvenient to go to their primary care

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1 sexual health, as well as coronavirus testing, so we
2 believe that will be acceptable to people, and we've
3 done some focus group work to see whether people prefer
4 an oral swab or finger-prick swab.

5 When the result is obtained by the laboratory, if
6 it's negative the patient will be contacted directly to
7 say "You are hepatitis C negative". If it's positive,
8 the result will be passed on to the local hepatitis C
9 treating centre who will be contact the patient
10 directly.

11 We don't want patients with a positive test getting
12 a phone call that says, "You've got hepatitis C, you'll
13 have to do something about it". We don't want them
14 getting an email or a text, we want them supported by
15 someone who will say, "You've got hepatitis C, I'm
16 a nurse, who will help you treat it. Here's what you
17 need to do and here's what will happen". So we want to
18 make sure they have counselling and support.

19 I hope that will be live before Christmas, whether
20 it will be live in its entirety or whether it will be
21 a section of it, I can't tell you at the moment but the
22 hope is that that will be up and running in its full
23 form by early next year.

24 **MS FRASER BUTLIN:** You spoke a moment ago about there being
25 foreign language pages as well. When the result is

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1 provided, if it's a positive result, to the local
 2 treatment centre, what provision will there be to deal
 3 with those language or, more significantly sometimes,
 4 the cultural barriers that somebody faces in even
 5 engaging with the treatment centre?

6 **PROF FOSTER:** We're very aware of the high prevalence of
 7 hepatitis C in some of our immigrant communities, I have
 8 particular interest in the Pakistani community and have
 9 done some work out in Pakistan, so we have appropriate
 10 language speakers. We also have peers with lived
 11 experience of hepatitis C from those countries, who can
 12 talk to the individuals in the appropriate language.
 13 The main languages we're looking at are the Eastern
 14 European and Urdu speaking.

15 **MS FRASER BUTLIN:** Your third measure that you deal with is
 16 work being done in introducing testing in emergency
 17 departments. What can you tell us about that?

18 **PROF FOSTER:** This is now live in London and everyone who
 19 goes into an NHS emergency department in London will see
 20 a poster that says "In this department we test everyone
 21 for viral hepatitis and HIV". If they have a blood
 22 sample taken, the treating physician will tick a single
 23 box and that single box will trigger a blood request
 24 form for HIV, hepatitis B, and hepatitis C tests. Those
 25 will be processed in the laboratory and the patients who

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1 across the country we will have a period where everyone
 2 in an emergency department is tested.

3 That will give us a cohort of patients who need
 4 treatment and care and we have strategies to look after
 5 them but it will also give us a very good idea on what
 6 we're missing.

7 As I mentioned at the beginning, we're getting to
 8 a law of diminishing returns. We want to make sure
 9 we're investing our resource, our people, in the right
 10 places, and what I don't know is what I don't know.
 11 Where there are the people I don't know about hiding,
 12 where are there little pockets of hepatitis C infection
 13 that I'm not hitting with our current strategies and
 14 a random testing in people turning up in emergency
 15 departments will help give us that data, and that will
 16 help inform our future strategies.

17 **MS FRASER BUTLIN:** Just to be clear, it's everyone who
 18 attends the accident and emergency and has a blood test.

19 **PROF FOSTER:** And has a blood test, exactly, yes.

20 **MS FRASER BUTLIN:** But there's no requirement for the doctor
 21 to think there's a risk factor here, it's simply a blood
 22 test and it gets ticked?

23 **PROF FOSTER:** If I go to casualty and stick my arm out,
 24 they'll test me.

25 **MS FRASER BUTLIN:** Fourthly, you've mentioned the Liverpool

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1 are positive will be informed, and there are information
 2 leaflets that say, "No news is good news. If we don't
 3 phone you, you do not have any of these infections".

4 So we will contact patients from the centre, and
 5 there's a triage process, whereby patients are contacted
 6 and offered an appointment. If they don't respond to
 7 that they're contacted a second time. If they don't
 8 respond to that, then their GP is informed and their
 9 notes are flagged.

10 We're now running throughout London. I have to say,
 11 that we have found huge numbers of hepatitis B, several
 12 hundred per month, so a very large number of hepatitis B
 13 patients in London that were undiagnosed; relatively few
 14 hepatitis C patients, in the tens of patients per month,
 15 of which a large proportion are already known to
 16 services; and a handful of patients with HIV. In fact,
 17 the HIV and the hepatitis C numbers are roughly similar
 18 at the moment.

19 Now, all of those numbers come with a caveat. These
 20 are very early days, the data streams are not as robust
 21 as they need to be and we haven't yet had the first full
 22 detailed report but that's the trend. It will be rolled
 23 out, we hope, in Brighton and Blackpool very shortly.
 24 We're talking about rolling it out in Manchester and
 25 Birmingham is on the hit list. So the hope is that

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1 surplus blood testing. What does that involve?

2 **PROF FOSTER:** So the proposal here, and we're still working
 3 our way through this unfortunately, is to take 17,000
 4 blood samples that have been tested for other reasons,
 5 so blood samples from GPs, blood samples from hospitals,
 6 surplus samples in the laboratory, run those through
 7 a hepatitis C testing programme.

8 Again, that's looking at a population of patients
 9 that don't have any obvious risk factors and, again, it
 10 will feed into the models we're generating of where are
 11 the missing patients that we're missing. I have to say
 12 it's stumbling along a little bit at the moment, there's
 13 quite a lot of IT issues, quite a lot of laboratory
 14 capacity but I hope we can get that launched. If not,
 15 then we will have to rethink. But I think, using extra
 16 blood samples that would otherwise have been discarded
 17 to do batch runs of hepatitis C tests to give us an
 18 insight into what we're missing, is certainly
 19 a direction we want to go in.

20 **MS FRASER BUTLIN:** Then we come to the development of the
 21 case finding search tool. How will this tool operate?

22 **PROF FOSTER:** So this is a tool that we've developed in
 23 co-ordination with MSD. Again, this is one of the
 24 advantages of the pharma collaboration. They've done
 25 quite a lot of work with GP search tools looking for

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1 patients with risk factors. We've developed a tool that
 2 allows a general practitioner to screen their patient
 3 notes and identify risk factors for hepatitis C. The
 4 plan is that we will run the tool on a GP practice,
 5 identify people at risk and then test all of those
 6 people. We want to stratify the risks and stratify the
 7 testing. So for people with a very high risk, and that
 8 will probably include people with a known blood
 9 transfusion in the at-risk periods, people with a known
 10 positive test, people with active injection drug use,
 11 et cetera, those will be contacted directly for a test
 12 by a phone call.

13 The people with an intermediate risk, the idea is
 14 that we will navigate them to the website and we will
 15 also, at the same time, flag the general practitioner
 16 notes, so that when they come in for an incidental
 17 event, and the third group will be people at lower risk
 18 who we will simply refer to the website.

19 We'd hoped that it would be up and running by now
 20 but it has been slow to implement, and what we've been
 21 working on is trying to define what are those risk
 22 categories. If we were to test a large group of people
 23 with risk factors A, B and C how many would be positive?
 24 Whilst we know from our preliminary studies that 6 to
 25 7 per cent of GP practices, patients, flag up positive

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1 studies that we're doing, the casualty studies, the
 2 look-back studies.

3 **MS FRASER BUTLIN:** You said there that one of the risk
 4 factors that would put someone into the high-risk
 5 category would be a transfusion in the relevant period.

6 **PROF FOSTER:** That's right but we're very aware that,
 7 because of the paper records at that time and the
 8 electronic transfer, that transfer may be incomplete,
 9 which is why we're looking at other markers, abnormal
 10 liver function tests and other risk factors.

11 It's difficult to know where to look until we've
 12 done the preliminary screens that would give us more
 13 information on the risk factors but identifying a high
 14 risk cohort is an absolute priority for us.

15 **MS FRASER BUTLIN:** You've pre-empted my question, which
 16 related to the difficulties of a lack of evidence in
 17 medical records. So, in terms of that, are you building
 18 into the risk factors at this stage anything that
 19 suggests if there's been major trauma, even though
 20 there's not a transfusion noted, that would count or
 21 perhaps evidence of the a woman having given birth in
 22 a particular time frame?

23 **PROF FOSTER:** We do -- it's a very good question and, at the
 24 moment, we don't include major trauma and we don't
 25 include previous pregnancy. Clearly, if that were to

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1 on the algorithm -- so that would mean huge numbers of
 2 tests -- we don't want to go out and test all of those
 3 patients just for hepatitis C, a lot of them have -- the
 4 risk factor is abnormal liver function tests, so they
 5 may have other causes of liver disease and it seems
 6 silly to go and test people today for hepatitis C, go
 7 back next week when we're doing a hep B, we want to do
 8 them once. So we're looking at ways we can automate
 9 that and link into a more general liver screen.

10 I think we are probably going to go, if we can, to
 11 a national overview of this. Our attempts to persuade
 12 our primary care colleagues to run the tool and work
 13 with it have been disappointing, they've got a lot of
 14 pressures on at the moment. So we're working with
 15 NHS Digital and the idea is we will do this across the
 16 country. So at central office we'll go through every
 17 patient's record throughout the country, flag up those
 18 with risk factors for hepatitis C and then those will be
 19 contacted electronically or whatever.

20 The governance, the information rules about handling
 21 data in that way, are extraordinarily complex, and we
 22 haven't yet solved it. I think it's fair to say that we
 23 have an absolute commitment to screen GP records and
 24 pull out those patients who are at risk and, obviously,
 25 what risk factors we find will be informed by the other

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1 come up as a potential flag then we would incorporate
 2 it, and I'm sure we will come on to in a moment the
 3 100,000-patient study that again we hope will inform.

4 So the challenge we're trying to face is not
 5 overburdening primary care colleagues but not missing
 6 anyone and that is the tension that we're constantly
 7 running.

8 It's also important to bear in mind that people very
 9 quickly get fatigued if they're doing tests and not
 10 getting positive results. So we did a large scale study
 11 looking at hepatitis C in people of Pakistani heritage,
 12 and it was a research project, but very quickly GPs were
 13 saying "We've tested 100 and found nothing, this is
 14 a waste of our time", and of course that is a problem if
 15 you are looking for an uncommon condition and doing
 16 a lot of tests that come back negative.

17 Healthcare professionals disengage and realise that
 18 it's a waste of their time. So we need to be very
 19 careful into how we manage this, how we sell this to our
 20 primary care colleagues that it is worthwhile if they're
 21 testing a lot of people and finding very few.

22 So there's constant tension between investing time
 23 and resource and mission fatigue, and finding numbers of
 24 patients, and we have to try to find a way round that,
 25 and our policy at the moment is to get the data that

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1 will allow us to have a very strategic approach to this,
2 getting the maximum in return on our testing approach.

3 **MS FRASER BUTLIN:** I've just had a message from our
4 stenographers asking if we could both speak a little
5 more slowly because they are trying to take a full note
6 of our conversation. I think we've both got so engaged
7 with it we've forgotten about the stenographers!

8 **PROF FOSTER:** My apologies for my pace.

9 **MS FRASER BUTLIN:** In terms of engaging with your primary
10 care colleagues, perhaps this is something we'll confirm
11 back as a full panel, if we may, but in relation to one
12 particular aspect, do you agree that, to some extent,
13 the flagging approach will only work if the significance
14 of that flag is fully understood by the GPs?

15 **PROF FOSTER:** I -- very much so. We have to work with our
16 primary care colleagues. Primary care colleagues quite
17 rightly say that if the 'while you're there' testing
18 were to take place on every patient, they would spend
19 the entire consultation going the 'while you've got the
20 patient', do their blood pressure, their diabetes,
21 mention the cervical screen -- sorry, I'm speeding --
22 but GPs are being asked to do large amounts of primary
23 prevention and every extra test means that something
24 else has to be reduced, and you're quite right that we
25 have to work in partnership and we have to be sure that

25

1 70-80 primary care practices, going through randomly
2 picking patients over the age of 40 and sending them
3 through the post an oral swab. So you wipe the inside
4 of your mouth, send it back, and that will give
5 a hepatitis C test result. The patient will then be
6 contacted if they're infected, obviously, and offered
7 treatment, and we will then look at how many of those
8 patients would have been identified by the MSD search
9 tool, how many would have been identified by other flags
10 on their notes and how many would have been missed.

11 So the idea is to look at the unknown unknowns.
12 We're hoping from the 100,000 that we will get at least
13 10,000 to 15,000 returns. We know that there's a poor
14 return rate. I can tell you that the last meeting
15 I had, which was a few weeks ago, we had over 10,000
16 samples returned. At that stage the first few thousand
17 had been tested and a single antibody positive case had
18 been identified and was working through. I haven't
19 heard of any more positive cases in the remaining 5,000,
20 so at the moment we're looking at a rate of about one
21 per 5,000, one per 10,000 people who have no obvious
22 risk factors. So the hope is, again, that combining
23 that data with the emergency department data with the
24 Liverpool 17,000 surplus samples data will give us an
25 idea of what we're missing, because my challenge, as

27

1 we're making good use of their skills.

2 **MS FRASER BUTLIN:** What work has been done and is planned to
3 be done to ensure that primary care colleagues are
4 equipped to deal with patients and have that
5 understanding of hepatitis C?

6 **PROF FOSTER:** We've had a number of focus groups with
7 primary care colleagues, we've had a number of education
8 sessions, we've had a number of lecture sessions -- not
9 all of which, I have to say, have been very well
10 attended. So our strategy going forward is to use the
11 GP Champion model. And the reason for doing that is
12 it's been very successful in HIV. So using GPs who
13 believe in the value of hepatitis C testing persuade
14 their colleagues is, we think, more likely to be
15 successful than having myself or one of my many esteemed
16 colleagues banging our particular drum. So we think we
17 will subvert from within.

18 **MS FRASER BUTLIN:** The final measure you've noted is
19 research to identify prevalence in those who wouldn't be
20 identified by the case findings search tool. Can you
21 tell us about that?

22 **PROF FOSTER:** So this is a programme of work we've
23 commissioned from the University of Bristol, in
24 Matt Hickman's group, who have done a lot of work in
25 primary care. We will be going out to some

26

1 I said right at the beginning, is how do I deploy the
2 resource in the most effective way? Who am I going to
3 miss?

4 I really don't want to stop the hepatitis C
5 programme until we've got everyone who wants to be
6 found. And we all accept there are people who do not
7 wish to be tested and they're perfectly free to do so,
8 and there will be people who will test positive who do
9 not want treatment, and they're perfectly free to do so.
10 So we need to strike the balance between pestering
11 people and informing them. I don't want to stop too
12 early but equally, in a very resource-stretched service,
13 I don't want to take money away from testing for
14 hepatitis B, where we have huge numbers of people to
15 find, and waste my time looking for people who aren't
16 there. So it's finding the sweet spot between an
17 appropriate delivery of treatment and appropriate
18 testing strategy that uses the resources widely.

19 As I say, it's not -- it really isn't, for once,
20 about the money; it's about the time and the
21 opportunities to primary care, and everything that we do
22 for hepatitis C has an opportunity cost for something
23 else. So we're trying to get the data to allow us to
24 make an informed decision.

25 **MS FRASER BUTLIN:** And you've said in your -- sorry, before

28

1 we get there, once that research is complete,
2 particularly the Bristol research and the case study --
3 case search tool, what do you anticipate the next steps
4 would then be?

5 **PROF FOSTER:** I think there are three possibilities. The
6 first is that the rate is very low, in which case we
7 congratulate ourselves, celebrate, and think about where
8 are the tiny pockets left. I don't think England
9 universally has been -- is close to elimination, I think
10 there are parts that are very close to elimination. So
11 it may be that there is very little left to be done, and
12 that would be very good news.

13 It may be there's a very large number in
14 a particular group. And clearly if, for example, we
15 find that, to take your pregnancy-associated transfusion
16 group, if we find that women who gave birth 30-40 years
17 ago have a surprisingly high risk of hepatitis C, then
18 we could organise a targeted case-finding initiative,
19 perhaps with a targeted publicity campaign that would
20 pool in that particular risk group.

21 The third possibility is that we will find very
22 large numbers across the board, that we're further away
23 from elimination than we think. And if that's the case
24 then we will need to think again about some form of near
25 global testing. My personal view would be that that

29

1 be the view of my colleagues. So we're not seeing many
2 people coming forward. I'm very much aware that
3 Rachel Halford from the Hepatitis C Trust tells me they
4 have a regular stream of phone calls, which is clearly
5 a matter of concern. But if we look at the numbers --
6 the Inquiry, as you know, produced a detailed review of
7 the likely numbers, and, if I quote, the mean number was
8 2,700 people chronically infected were still alive. In
9 the English treatment database, we have 3,498 people
10 treated --

11 **MS FRASER BUTLIN:** Could you just pause there to allow us
12 just to put the table up from the statistics report so
13 that people can follow the numbers.

14 The reference is EXPG0000049, and it's page 54 which
15 is the table, I think, Professor Foster, you're
16 referring to.

17 It's page 50 of the physical copy if anyone is using
18 the physical book, 54 on the electronic version.

19 Thank you.

20 If we can just zoom in to the table so we can see
21 it. There we go.

22 Professor Foster, you were saying?

23 **PROF FOSTER:** Um ... I'm not sure --

24 **MS FRASER BUTLIN:** You were looking at the column which is
25 "Chronically infected, survived to end of 2019",

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1 global testing would be best delivered as part of
2 a liver health screen. I don't really want to go and
3 test people for hepatitis C and then go back next year
4 and do their diabetes and their other tests of liver
5 disease. I'd rather do a liver health screen once and
6 make sure the patients are properly reassured.

7 So those are the three possible outcomes and we'll
8 make decisions, obviously, as the data comes through.

9 All the data, important to say, of course, will be
10 published. This will all be public domain data. It
11 will be published in peer review journals. NHS England
12 will make it available as press releases. So this will
13 be a public consultation and, clearly, if there's a very
14 strong feeling from the general public that we should be
15 doing less or more, then we'd take that into account.

16 **MS FRASER BUTLIN:** In your statement you've expressed a view
17 that there are probably not many more individuals who
18 have been infected with hepatitis C by blood or blood
19 products who have not yet been identified. Can you
20 explain why that is your view?

21 **PROF FOSTER:** So several reasons underlying that. The first
22 is I run a big clinical practice in the northeast of
23 London and I haven't seen a patient who has been
24 infected by blood or blood products who hasn't been
25 diagnosed for many, many years now. And that tends to

30

1 I think, which, at the bottom, "Total UK" gives a figure
2 of 2,700.

3 **PROF FOSTER:** I have it. Yes, so, as you correctly say,
4 thank you, 2,700 is the total UK estimate.

5 **MS FRASER BUTLIN:** With a range of 3,910-2,050?

6 **PROF FOSTER:** Exactly.

7 So there are clearly a lot of assumptions and
8 estimates in this that the author has made very clear.
9 What we know from the NHS England treatment registry, we
10 ask people to record all the treatments that they
11 administer, and there are financial penalties if they
12 don't. So they are asked to record a risk factor of
13 'infected by receipt of contaminated blood or blood
14 products'. What we don't do is distinguish whether that
15 was administered in the UK or abroad. So there may be
16 some increase. We also have it as patient thoughts. So
17 it may be that patients believe they might have had
18 a transfusion and report that as their risk factor when
19 in fact it's different. So the data we have comes with
20 caveats to it. But even allowing for the caveats, in
21 England I can tell you 3,498 people, when I last looked
22 at the registry download, which was a few months ago,
23 had been infected in that way. So the total number of
24 patients that we have treated in England is
25 significantly greater than the total number estimated to

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1 be alive within the United Kingdom.
 2 So that gives me some degree of confidence that we
 3 are close to finding and treating all of those patients
 4 infected in that way. But as I hope I have made clear,
 5 we're not sufficiently arrogant to say we've got them
 6 all because there will always be people we miss.
 7 I think we have a reasonable strategy to try to fill the
 8 gaps, and I think all of the different studies that
 9 we've unveiled will give us confidence to say whether we
 10 are close to finding everybody or not.
 11 **MS FRASER BUTLIN:** And as you've said, there's -- and the
 12 Inquiry has heard evidence from the Hepatitis C Trust in
 13 relation to, as you described, a fairly steady stream of
 14 people --
 15 **PROF FOSTER:** Yes.
 16 **MS FRASER BUTLIN:** -- who have recently been diagnosed with
 17 hepatitis C, and indicate that their risk factor is
 18 blood or blood products?
 19 **PROF FOSTER:** I'm absolutely sure there are people out
 20 there. I'm -- tragically, we will never manage to find
 21 everybody, no matter how hard we try. The question is:
 22 how many are we missing and what is the opportunity cost
 23 of finding those people? If I put all my resources on
 24 testing everyone for hepatitis C, then other tests will
 25 not be done. And that is the challenge that we're tying

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1 similar questions, there are a couple of matters that
 2 arose in your statement, on different points, that I've
 3 been asked to ask you about.
 4 In terms of the phase 1 of the strategy and the
 5 direct active anti-virals, was any consideration given
 6 to early access to those drugs for the infected blood
 7 cohort?
 8 **PROF FOSTER:** We discussed this at great length and
 9 the decision we reached was that it would be
 10 inappropriate to treat patients with milder disease
 11 because of the mode of acquisition rather than patients
 12 with a more severe disease.
 13 At that time we had very limited access to the
 14 treatments. There was a fixed number of treatments. We
 15 had a large number of people with advanced liver disease
 16 who were likely to die and our initial priority was to
 17 treat people who were likely to die within the next
 18 12 months. We then extended to people who were at
 19 significant risk of harm, patients with cirrhosis,
 20 patients with significant mental health problems from
 21 hepatitis C, and we recognised at the beginning that
 22 some people with hepatitis C have their lives ruined by
 23 the mere presence of the infection and they will not be
 24 able to move on with their lives until they've cleared
 25 the infection. And we recognised that that was a reason

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1 to face. How do we make best use of the human resources
 2 that we have to minimise the harm to people at large?
 3 And I'm very cognisant of our obligation to do all that
 4 we possibly can to find everyone who has been infected,
 5 whatever the mode of infection. We want them found and
 6 we want them treated.
 7 **MS FRASER BUTLIN:** Is it right, then, that the search
 8 finding tool and the research by Bristol will also
 9 assist you in assessing whether there is a cohort that
 10 are being missed in terms of those infected by blood or
 11 blood products?
 12 **PROF FOSTER:** Absolutely. One of the driving factors behind
 13 the Bristol study was to answer exactly that question.
 14 There are two cohorts I worry about: people who dabble
 15 with illegal drugs and have moved on in their lives and
 16 don't want to declare it, and people who are infected by
 17 blood or blood products who don't have records or indeed
 18 a memory of it. And I'm very aware that people will be
 19 infected by blood transfusions during operations when
 20 they didn't realise they'd had a transfusion. So those
 21 are the two big unknown unknowns at the moment, and
 22 we're putting a lot of effort into finding out how many
 23 fit into those different categories.
 24 **MS FRASER BUTLIN:** Thank you. That table can come down.
 25 Before I move to the others on the panel and discuss

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1 for prioritising patients. We recognised that mothers
 2 who were wanting to get pregnant may well want to be
 3 clear of the virus, so we allowed that to be a priority.
 4 So we tried to cover all possibilities. We were
 5 specifically asked whether or not we would consider
 6 prioritising patients by mode of acquisition and we
 7 decided that, given the National Health Service has
 8 never prioritised any treatment by mode of acquisition,
 9 given that it would be inappropriate to treat people
 10 with mild disease, whilst people at risk of dying were
 11 left untreated, we felt that was inappropriate. So we
 12 chose not to do so and that was our very strong clinical
 13 recommendation from the panel that was operational at
 14 the time, and that was a universal decision.
 15 **MS FRASER BUTLIN:** Slightly different topic. You said in
 16 your statement that there should be universally
 17 available FibroScan technology as part of the
 18 operational delivery networks. In oral evidence, the
 19 Hepatitis Expert Group decided access to FibroScan
 20 technology as "patchy". What's your understanding of
 21 the situation?
 22 **PROF FOSTER:** When we started the networks, we made
 23 available to every network funding for a FibroScan so
 24 every network had a FibroScan provided. The demand and
 25 supply has increased dramatically. I think the supply

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1 of FibroScans as a tool is, as you quite rightly say,
2 "patchy", but I believe there are sufficient
3 alternatives to FibroScan that are now available. So,
4 for example, there are blood tests there's a simple APRI
5 scoring system that gives a very good indication of
6 whether patients have cirrhosis, there is an enhanced
7 liver function test, an ELF test that can be tested, so
8 there are blood tests that can be used to exclude
9 cirrhosis.

10 So whilst I agree that FibroScanning is not as
11 widely available as perhaps I would like, I think there
12 are sufficient modalities of investigation to exclude
13 cirrhosis in patients and I think those are sufficiently
14 widespread.

15 I think it would be very unusual for a patient not
16 to have an opportunity to have some form of liver
17 fibrosis assessment.

18 **MS FRASER BUTLIN:** Now this is a question you may not be
19 able to assist us with but I've been asked to ask you.
20 In terms of further research, do you think there is
21 a need for further work to be undertaken on the needs of
22 those infected by blood and blood products, particularly
23 in terms of the longer term impacts of treatments
24 they've received in the past?

25 **PROF FOSTER:** I've a longstanding concern about the

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1 **MS FRASER BUTLIN:** You're attending today on behalf of the
2 Scottish Health Boards.

3 **PROF DILLON:** I am.

4 **MS FRASER BUTLIN:** What can you tell us about your
5 involvement in the hepatitis C work in Scotland?

6 **PROF DILLON:** So since 2009, Scotland -- each Health Board
7 has been mandated by the Scottish Government to have
8 a clinical lead for hepatitis and I've been NHS
9 Tayside's clinical lead. The clinical leads for those
10 health boards meet together two or three times a year to
11 discuss strategic policy across hepatitis C, and to
12 respond to whatever diktats we receive from the
13 Department of Health in Scotland as to what we should be
14 doing, so that process and that structure has continued
15 since then.

16 **MS FRASER BUTLIN:** In 2006, the hepatitis C action plan
17 phase 1 in Scotland was implemented (**The witness nodded**)
18 and in 2008 phase 2 was implemented.

19 (**The witness nodded**)

20 Could we just turn to WITN4062002, please. This is
21 the proposal approved by the Scottish Government in
22 July 2019, the Action Plan: Achievements ... and
23 Proposals. If we turn to page 3, please, Lawrence. We
24 see in 2008, just at the bottom of the page, there's
25 a timeline, and in 2008 it indicates that there was

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1 long-term impact of interferon-based treatments on
2 individuals, published some research looking at its
3 impact on psychological health. So I think I have to
4 answer that, yes, there is a need to look at the long
5 term impact of interferon on the other treatments. We
6 know some of the first generation oral anti-virals,
7 telaprevir and simeprevir were particularly toxic drugs,
8 so I would certainly agree there is a need for evidence
9 to assess the long-term impact of those.

10 I think we still do not genuinely know the lifetime
11 impact of hepatitis C infection because, fortunately,
12 not too many people have died from it, and there may
13 well be other consequences that will manifest in the
14 distant future, as a result of those treatments that we
15 deployed, so I think it's certainly a reasonable
16 research proposal.

17 I don't, I have to say, have any evidence at the
18 moment that we are seeing any long term effects of
19 interferon, telaprevir and simeprevir but it would be
20 perfectly reasonable to look into it.

21 **MS FRASER BUTLIN:** Thank you.

22 Professor Dillon, you're a consultant hepatologist
23 and gastroenterologist with NHS Tayside and also the
24 clinical lead for hepatitis C for them.

25 **PROF DILLON:** Yes.

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1 serious investment, approximately £15 million per year
2 of additional dedicated funding for education, awareness
3 raising, prevention, diagnosis, treatment/care services
4 and for co-ordination, monitoring and research and the
5 introduction of hepatitis C treatment targets.

6 What can you tell us about that block of funding
7 that was started in 2008?

8 **PROF DILLON:** So that was distributed to each health board
9 to fund additional staff and resources and treatment
10 costs to start to increase the numbers of patients being
11 treated for hepatitis C using interferon based regimes.
12 So each health board made its own decisions as to what
13 it should do. It was mandated to have an executive lead
14 on the board responsible for hepatitis C and a clinical
15 lead and it led to the funding of several nursing posts
16 in each health board to allow and facilitate treatment
17 for hepatitis C and pay for those treatment costs. And
18 FibroScan machines, as Professor Foster has alluded to
19 already became part of that development as well in terms
20 of being able to stage patients in terms of, in those
21 days, treating patients with cirrhosis, with interferon
22 based therapies was somewhat risky.

23 So rather than prioritising patients for treatment
24 we were finding the patients we couldn't treat with
25 those investments. So that was that money. Some of it

40

1 was recurring and has become part of the each health
 2 board's infrastructure.

3 **MS FRASER BUTLIN:** In terms of identifying those who were at
 4 risk of being infected with hepatitis C, finding the
 5 patients, what work took place at that point?

6 **PROF DILLON:** At that point, there was rolling out of dried
 7 blood spot testing to make testing easier, so instead of
 8 having to take venipuncture blood, a drop of blood from
 9 a finger spot could be used to make the diagnosis of
 10 hepatitis C, it was sent to the lab and processed in the
 11 usual way. But it meant people were much closer to
 12 a test in terms of, rather than having to find someone
 13 who could do venipuncture, we trained large numbers of
 14 people who could do dry blood spot testing in the
 15 environment where the person who was at risk was
 16 located.

17 There were a series of look-back exercises conducted
 18 at that stage around blood transfusion, awareness
 19 raising amongst general practice, sign guidelines were
 20 developed recommending who should be tested and listing
 21 the risk factors at that stage, and those were
 22 promulgated through joint meetings with general
 23 practitioner colleagues, other general medical
 24 colleagues and generally trying to raise awareness
 25 around hepatitis C and use that opportunistic testing.

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1 "A 45% reduction in the number of people living with
 2 chronic hepatitis C from an estimated 38,000 to 21,000.

3 "A 55% reduction in the number of people unaware of
 4 their infection from 23,500 to 10,500", and then
 5 a figure in relation to those who have cleared their
 6 virus.

7 Then, in the context of the era of the direct acting
 8 anti-viral therapies available since 2014:

9 "New presentations of hepatitis C related
 10 decompensated cirrhosis (liver failure) declining 67%
 11 from a peak of 141 in 2013 to 47 in 2018.

12 "New presentations of hepatitis C related
 13 hepatocellular carcinoma declining 69% from a peak of
 14 58 in 2016 to 18 in 2018.

15 "Hepatitis C related deaths declining 49% from
 16 a peak of 67 in 2015 to 34 in 2018."

17 There is then the strategy proposed that's dealt
 18 with --

19 Sorry, sir, it's just been indicated to me that the
 20 Northern Irish link appears to have just gone down.
 21 We've lost Dr McClean.

22 **SIR BRIAN LANGSTAFF:** Yes, I don't know if that's got
 23 anything to do with putting the document up on screen,
 24 but --

25 **MS FRASER BUTLIN:** I wonder if we should just pause for

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1 It also -- the action plan also took over the
 2 previously research-based database across Scotland for
 3 hepatitis C, which gave us everyone who'd ever had
 4 a positive diagnosis of hepatitis C in Scotland, and so
 5 their healthcare records could be followed and the
 6 health boards were then aware of who was in their
 7 territory and who they had to be responsible for.

8 We've never had the overarching strategies of
 9 England, each health board has made its own decisions,
 10 we don't have an NHS England equivalent in Scotland, and
 11 so each health board makes its decisions. Now, clearly
 12 we have a geographical issue in Scotland, we have 14
 13 health boards, four of them are large urban-based
 14 territories, three are medium size with some significant
 15 conurbations in them but lots of rural things, and seven
 16 are very rural with a very, very different complexion.
 17 So hepatitis C poses different challenges in each of
 18 those environments.

19 **MS FRASER BUTLIN:** If we turn the page and continue the
 20 timeline, we can see there the questions of the Penrose
 21 Report and its recommendations and then, in 2019, the
 22 Scottish Government launches its Hepatitis C Elimination
 23 Strategy. If we turn the page, we have some data.
 24 Achievements include:
 25 "Between 2006 and 2018:

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1 a moment and establish whether Dr McClean can hear us at
 2 least.

3 **SIR BRIAN LANGSTAFF:** We're pretty close to when we would
 4 normally have a break.

5 **MS FRASER BUTLIN:** We are.

6 **SIR BRIAN LANGSTAFF:** So perhaps this would be -- albeit
 7 forced upon us -- an earlier break.

8 **MS FRASER BUTLIN:** Absolutely, sir. Was going to deal with
 9 the document and then suggest a break but perhaps we can
 10 take a break now instead.

11 **SIR BRIAN LANGSTAFF:** Let's do that and then come back to
 12 the document. So we'll take a break now until 11.40 and
 13 hope that when we come back we will have full function
 14 from Northern Ireland restored.

15 **(11.11 am)**
 16 **(A short break)**

17 **(11.40 am)**

18 **SIR BRIAN LANGSTAFF:** Yes.

19 **MS FRASER BUTLIN:** Thank you, sir.

20 We were looking, Professor Dillon, at the 2019
 21 Action Plan: Achievables and Proposals, and we had just
 22 looked at the achievements between 2006 and 2018, and
 23 then since 2014.

24 We can see then the heading "The Following Strategy
 25 is Proposed", with a "Vision" and a "Why".

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1 Then if we turn the page, we pick up "How":
 2 "NHS Boards, together with local authorities and
 3 third sector organisations, and supported by Health
 4 Protection Scotland, should:
 5 "- Treat a minimum of 2,500 people during 2019-20
 6 and 3,000 each year thereafter; it is predicted that
 7 this strategy will achieve elimination by 2024.
 8 "- Guided by the recommendations by the SLWG on
 9 Hepatitis C Case Finding and Access to Care, intensify
 10 efforts to identify those people undiagnosed, and to
 11 re-engage diagnosed people not in contact with
 12 hepatitis C services. An eclectic model of hepatitis C
 13 care -- ie, the provision of services in both hospital
 14 and community settings, tailored to the needs of the
 15 patient -- should be adopted."
 16 Then there's a point about those who inject drugs.
 17 You said earlier, Professor Dillon, that it's
 18 a matter for local health boards to deal with this
 19 strategy.

20 **PROF DILLON:** Indeed, so each health board has its
 21 proportion. Up until 2019, the proportion of the
 22 treatment target was by population, and so each health
 23 board in proportion to population had to contribute to
 24 that total target. So the 2019/2020 target of 2,500 was
 25 achieved, but there were some health boards that did

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1 various risk groups were identified, and each health
 2 board could then take what it needed to allow it to
 3 achieve its targets. Clearly the bigger urban health
 4 boards had a different set of risk factors in terms of
 5 injecting drug use being a much more dominant risk
 6 factor than in other parts of the country. And so that
 7 was the -- that's why the word "eclectic" was used.
 8 **MS FRASER BUTLIN:** Can you give us a flavour of the sorts of
 9 measures that local health boards have taken in order to
 10 identify people?
 11 **PROF DILLON:** Okay. So, in terms of diagnosis, we've -- so
 12 in all addiction centres that are NHS provided, which is
 13 the majority model in Scotland, it was a requirement
 14 that everyone who was on opiate substitution therapy was
 15 tested every year for hepatitis C. Treatment pathways
 16 and diagnostic pathways were rolled out into needle
 17 exchange facilities and so using dry blood spot testing
 18 to ensure that patients could provide, could get easy
 19 access to testing.

20 There was ongoing awareness raising amongst general
 21 practices around what the risk factors were. There was
 22 automated testing of abnormal liver function tests.
 23 This was for all liver diseases but included hepatitis C
 24 and hepatitis B testing. This is now standard practice
 25 across NHS Tayside and NHS Fife, which accounts for

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1 better than others, and so Greater Glasgow and Clyde and
 2 Tayside were particularly overdelivering in terms of
 3 therapy.

4 We don't have the same pharma arrangements as
 5 NHS England does but we did have a capped deal so that
 6 as we reached a certain number of patients treated, the
 7 drug effectively became free beyond that; so if you
 8 over-treated in any one year there wasn't a financial
 9 penalty. We didn't get financial rewards for treating
 10 more patients but it didn't cost us any more. So there
 11 was an incentive to try to reach that treatment target
 12 so you could then treat patients that you wouldn't have
 13 to treat in future years.

14 So the 2,500 was achieved, and then we all know what
 15 happened in 2020.

16 The Short Life Working Group did meet and did
 17 convene and did finish its recommendations, and so that
 18 produced a series of -- a review of the world literature
 19 as to what was the best pathways of care to be used. It
 20 highlighted the work done in various parts of Scotland,
 21 so what was being done -- what was excellent in parts of
 22 Scotland were shared. We looked at our English and
 23 Welsh colleagues as well to see what they had and we
 24 shamelessly borrowed ideas from them.

25 So that potpourri of ideas, of ways of reaching the

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1 800,000 people of our 5,100,000 population.

2 NHS Glasgow and NHS Lothian, which are 1.5 million
 3 and 800,000 respectively, are about to roll this out.
 4 It has been Government policy but clearly the last
 5 two years have rather held back some of these sorts of
 6 developments.

7 **MS FRASER BUTLIN:** And have there been any general awareness
 8 campaigns about hepatitis C, run by local health boards?

9 **PROF DILLON:** So there have been over the years since the
 10 action plan started. There have been none since the
 11 elimination plan was decided. The individualised
 12 treatment targets for each health board based on -- as
 13 well as on their population -- on their previous
 14 performance, were being developed for roll-out in the
 15 2020/2021 financial year. All of the staff that were
 16 involved in that disease modelling had another disease
 17 to model instead, and they have only just come back to
 18 hepatitis C work about six weeks ago.

19 I'm promised in two weeks' time at a meeting that
 20 the first tranche of those new numbers will be available
 21 to us so and so we will have some more data at that
 22 stage.

23 **MS FRASER BUTLIN:** At this point the elimination programme
 24 doesn't have any specific measures addressing the
 25 identification of people with hepatitis C infected

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1 through blood and blood products; is that right?

2 **PROF DILLON:** It doesn't, no.

3 **MS FRASER BUTLIN:** Can you explain for us why that is?

4 **PROF DILLON:** So we looked back through our previous efforts

5 to see if there were any gaps, anything that we couldn't

6 do, that we could do anew in terms of reviewing GP

7 records, in terms of looking up blood transfusion

8 records, in terms of look-back procedures, et cetera.

9 All of those have -- where they are feasible, have been

10 done already. We looked at our database in terms of --

11 because of Scotland's its record linkage abilities,

12 we've captured everyone that's ever had a hepatitis C

13 diagnosis in Scotland. And as of the end of 2020, which

14 is -- I think the numbers are for your statistics, we

15 have diagnosed and treated 460 people, who are still

16 resident and alive in Scotland, which is in excess of

17 the proportion of patients from the UK estimates that

18 you would expect. So, rather like Professor Foster has

19 alluded to already, we seem to have found more people

20 than the estimates would suggest that have blood

21 products or blood transfusions as a risk factor, which

22 gives us some confidence that the numbers of patients

23 who could be missed will be relatively small.

24 **MS FRASER BUTLIN:** What do you see as the barriers in

25 Scotland to identifying any remaining people who have

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1 days of old would have been in the old Lloyd George

2 envelopes that occupy -- you know, took up lots of space

3 in GPs surgeries, those were summarised in preparation

4 for digitisation in the mid-1990s and so, if we had

5 a discharge summary of three pages summarising

6 a complicated gallbladder operation to remove the

7 gallbladder that went wrong and had multiple blood

8 transfusions, if the patient came out the other side of

9 that, that large discharge summary would be summarised

10 as cholecystectomy, which is a surgical term for

11 gallbladder removal, and any other details about blood

12 transfusion, et cetera, will have been lost in that

13 digitisation. So that's one of the problems.

14 More recently, we have been -- so there has been

15 national guidance that any blood transfusion carried out

16 in hospital should appear in discharge summaries. We've

17 audited that across Scotland and, at the moment, we get

18 about 50 per cent of blood transfusions recorded in

19 a discharge summary. So, in terms of trying to find

20 those patients, you can see that we sort of

21 progressively miss people.

22 Assuming there are relatively few left, the

23 transfusion booklets are no use to us. The discharge

24 summaries have been lost from hospital records back in

25 that period of time because they've been culled, unless

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1 been infected by blood and blood products?

2 **PROF DILLON:** So if we go back through the record, so

3 clearly the patients who have had haemophilia or

4 an inherited bleeding disorder are likely to be under

5 ongoing follow-up and will have been in contact with

6 their haemophilia centres or bleeding centres and will

7 have been tested. Those that had random blood

8 transfusions are the more challenging group to find. If

9 we -- we've looked back at the transfusion books that go

10 back into the 1970s and '60s and these are old-fashioned

11 large ledgers. Most of them contain a date, a name with

12 no date of birth, and a ward on which the patient might

13 have been on at the time that the blood transfusion was

14 requested.

15 We know that the blood left the transfusion

16 laboratory with that patient's name on it. We have no

17 idea if the blood was ever transfused or not, and

18 clearly, with, you know, some common surnames, et cetera

19 it's difficult to identify who that patient may have

20 been.

21 The hospital records, going back and doing name

22 searches for someone who might have been in hospital at

23 that time, have been destroyed, by and large, so that's

24 a problem.

25 In terms of hospital discharge summaries that in

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1 the patients have ongoing contact with the hospitals, in

2 which case they're very likely to have been tested. The

3 GP records are lost to us now and we don't have that

4 option, and, you know, if the rate of recording of that

5 data in the GP records or in the discharge summary is

6 not very good now, when it's mandated, we can only

7 assume it was worse in the past.

8 **MS FRASER BUTLIN:** In terms of the elimination strategy

9 going forward, what measures do you understand local

10 health boards to be taking to identify people who were

11 infected with hepatitis C generally, that might also

12 pick up those who have been infected by blood or blood

13 products?

14 **PROF DILLON:** So the risk factors that are identified will

15 still be there and are still operating since 2009 and

16 those are being -- that message is being re-emphasised.

17 There is a move across Scotland for the earlier

18 diagnosis of liver disease in general, and we are, as

19 the -- the process of -- a device called "intelligent

20 Liver Function Testing", where, if blood is sent to the

21 lab for liver function tests, if they are abnormal,

22 a whole gamut of tests are performed to arrive at

23 a diagnosis for the liver disease and amongst those

24 tests are hepatitis C and hepatitis B.

25 That's now Government policy, clearly the rollout

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1 has been held back by Covid. It is active in the two
2 health boards, which I think I mentioned before, and
3 it's being rolled out across the country. So that would
4 help detect those patients who have -- their risk factor
5 for hepatitis C is lost in the past and are of advancing
6 years, and you can find patients that way.

7 In Tayside we've now put 21,000 patients through
8 that process in the years that the service has been
9 running and we've found 142 hepatitis C positive
10 antibodies. To my recollection, none of them are
11 transfusion related and all of them have other risk
12 factors or are idiopathic.

13 **MS FRASER BUTLIN:** As I did with Professor Foster, there is
14 one other matter in your statement I've been asked to
15 address with you. You address in your statement
16 palliative care and say that the viral hepatitis
17 contribution to the group of patients requiring
18 palliative care is very small. Can you explain for us
19 what you meant by that?

20 **PROF DILLON:** Okay, palliative care in liver disease is
21 an emerging need. Hepatologists have been rather
22 focused on saving everybody and resurrecting everybody
23 from their lived failure because that's our background.
24 We are now becoming increasingly aware of a group of
25 patients in whom we can't achieve cure and survival and

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1 transplanted for hepatitis C, which has, from -- in 2011
2 and 2012, we were predicting that our entire transplant
3 programme in Scotland and the UK would be overwhelmed by
4 hepatitis C and we would be transplanting nothing but
5 hepatitis C, and I think most transplant units can't
6 remember the last time they transplanted someone for
7 hepatitis C induced liver failure.

8 There is still an ongoing need for hepatocellular
9 carcinoma transplantation, there is still a need for
10 palliative care around those long term hepatocellular
11 carcinomas but there is emerging evidence that the risk
12 of hepatocellular carcinoma falls over time after cure.
13 It probably never goes back to population normal but the
14 risk isn't as high as when you have active infection.
15 And that's my reason for saying that the driving force
16 for palliative care is not viral hepatitis alone; it's
17 the generality of liver disease.

18 **MS FRASER BUTLIN:** The Inquiry has heard evidence from the
19 palliative care panel that, from their experience, it
20 wasn't a historical thing. One of the experts
21 indicated:

22 "This is seeing patients within the last few weeks
23 of my practice who are presenting with advantage liver
24 disease from blood transfusions years ago. It's still
25 an active issue and these issues are still very live."

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1 they are not suitable for transplantation and so we need
2 to be more focused on their symptomatology.

3 Palliative care medicine is also changing and is
4 moving away from patients who will inevitably die of
5 cancer to looking at symptom control in a broader group
6 of patients, and liver disease is one of those areas
7 where there's a high mortality and lots of symptoms that
8 can be controlled.

9 That's need around liver disease as a whole and
10 that's a growing area of need. There are emerging
11 professional consensuses as to what should be done, at
12 the moment there's no Government funding to support
13 that. Within that group of patients, it depends on the
14 etiology of the liver disease, if you can't change the
15 projection or trajectory of the liver disease because
16 you can't change the underlying cause then the patients
17 will inevitably get worse.

18 In viral hepatitis, both hepatitis C and
19 hepatitis B, treatment will change that trajectory for
20 most patients and so their liver will recover and
21 regenerate. So, if we were making the case for
22 palliative care and the needs for it, the hepatitis C
23 group of patients contributes less to that overall need
24 because they have the option for cure, as we've seen,
25 for instance in the numbers of patients being

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1 Does that then not accurate with your experience?

2 **PROF DILLON:** So if you'd come to my ward five years ago,
3 six years ago, half my liver patients would have had
4 hepatitis C. The only patients we have in who have had
5 previous hepatitis C are now in because of
6 hepatocellular carcinoma, and that's a small number. So
7 there has been a dramatic change in the complexion of
8 the people that we're seeing in liver failure on the
9 wards.

10 And I think it's important to differentiate those
11 patients who have active viraemia and those who had
12 hepatitis C and have an additional risk factor that's
13 driving their liver disease, be it non-alcoholic fatty
14 liver disease or alcohol-related liver disease, that the
15 two together are acting synergistically to drive things
16 forward. So the previous damage from the hepatitis C
17 has fertilised the field, if you like, and then the
18 addition of another liver disease drives them through
19 faster.

20 **MS FRASER BUTLIN:** So you are seeing that element where
21 there's a synergy between the previous hepatitis C, even
22 though they're now in sustainable virological response
23 but the synergy of that previous issue and something
24 else --

25 **PROF DILLON:** Yes.

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1 **MS FRASER BUTLIN:** -- does drive the liver disease more
 2 rapidly?
 3 **PROF DILLON:** Yes.
 4 **MS FRASER BUTLIN:** Thank you.
 5 Dr Healy, you are the blood-borne virus clinical
 6 lead for Wales; is that right?
 7 **DR HEALY:** Correct yes.
 8 **MS FRASER BUTLIN:** Can you tell us what that role involves?
 9 **DR HEALY:** Yeah, so, similar to my colleagues, it's my
 10 responsibility to look at the clinical side of
 11 hepatitis C management and hepatitis B management and
 12 elimination. So I help with strategy around testing and
 13 treatment across the health boards in Wales. I lead
 14 a network of clinicians across Wales, similarly to try
 15 to drive towards elimination. Yeah, and I'm charged,
 16 I suppose, on a clinical basis, to try to find as many
 17 patients and deliver treatment and a cure to as many
 18 patients as possible.
 19 **MS FRASER BUTLIN:** Could we turn to RLIT0001821, please.
 20 This is a Welsh Health Circular from October 2017.
 21 We can see it's title "Attaining the WHO targets for
 22 eliminating hepatitis (B and C) as a significant threat
 23 to public health". If we go towards the bottom of the
 24 page we can see it's been sent by the Chief Medical
 25 Officer for Wales.

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1 [hepatitis C] who are actively engaged in behaviours
 2 likely to lead to further transmission."
 3 Then if we turn the page, please, we see a heading,
 4 "Identify individuals who are infected with
 5 [hepatitis C] including those who have acquired
 6 [hepatitis C] outside the UK and are now resident":
 7 "2.1 Individuals infected with hepatitis C who were
 8 not linked to care.
 9 "There are a number of individuals who have been
 10 diagnosed with hepatitis C but who, for a variety of
 11 different reasons, have never been linked to care or who
 12 have never received follow up investigation or treatment
 13 (for example, if they were diagnosed before there was
 14 any treatment available) who now can be identified
 15 through searches of the laboratory data system ...
 16 "By the end of December 2017 Public Health Wales
 17 will have sufficient information collated from
 18 laboratory systems to identify these individuals and
 19 will notify general practitioners of affected patients
 20 registered with their practice."
 21 Just pausing there, what can you tell us about that
 22 process of identifying individuals who had a positive
 23 hepatitis C test but hadn't engaged with treatment?
 24 **DR HEALY:** Yes, so that programme of work is ongoing. It
 25 was separated out into two phases. The patients

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1 If we just turn the page, Dr Healy, I'm just going
 2 to take us through the document and then ask you about
 3 it:
 4 "The WHO has announced a global sector strategy on
 5 viral hepatitis which sets out to eliminate hepatitis B
 6 and hepatitis C as significant public health threats by
 7 2030. The WHO target is a 90% reduction in incidence
 8 and 65% reduction in mortality due to hepatitis B & C by
 9 2030. Wales is signed up to this strategy.
 10 "The Minister for Social Services and Public Health
 11 has been advised by The Welsh Viral Hepatitis Subgroup
 12 of the Liver Disease Implementation Group on what is
 13 required from the NHS and partners for Wales to achieve
 14 this target."
 15 Then if we could go down to the second half of the
 16 page:
 17 "I am writing to you to request that measures are
 18 put in place to:
 19 "Reduce and ultimately prevent ongoing transmission
 20 of [hepatitis C] within Wales;
 21 "Identify individuals who are currently infected
 22 with [hepatitis C] including those who have acquired
 23 [hepatitis C] outside the UK and are now resident in
 24 Wales; and
 25 "Test and treat individuals currently infected with

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1 identified -- it's 5,000 there but I think it was 8,000
 2 in total with the final figure -- vary in their risk, in
 3 terms of having ongoing hepatitis C. So this is been
 4 established by a trawl through our testing databases,
 5 our lab databases.
 6 So sometimes we can establish someone has active
 7 infection and hasn't been treated. Sometimes we can
 8 only establish that someone has been tested and it's not
 9 clear whether they've been treated or not. So they're
 10 in different categories of risk.
 11 In the first phase, 1,650 individuals were written
 12 to alert them of their potential risk. So that's the
 13 highest risk group in terms of having ongoing infection.
 14 We had 140 individuals, about 10 per cent of
 15 individuals, who responded to that and 62 who have
 16 completed treatment as a consequence.
 17 Phase 2 was interrupted by the Covid pandemic and
 18 we're now just in the process of starting phase 2.
 19 Of those remaining 90 per cent that didn't respond
 20 to a letter, their details, along with details of other
 21 patients on that list, will be passed to the blood-borne
 22 virus teams across Wales, and it will be the responsibility
 23 of those teams to cross-check against patients that have
 24 been treated. So some of these individuals will have
 25 actually been successfully treated and they're just not

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1 linked up on the database, to actively try to contact
 2 them to bring them back to service, but also to flag
 3 them, so that if they make contact with services for
 4 other reasons, that the issue of hepatitis C can be
 5 picked up.
 6 When we wrote to the GPs to alert them of the
 7 patients involved, we also asked for them to be flagged
 8 on the system for that reason as well, so that they
 9 could be picked up in that way.
 10 **MS FRASER BUTLIN:** Again, this may be something you can't
 11 assist us with but do you have any sense of the numbers
 12 of those patients who simply couldn't be tracked because
 13 records aren't there, their address is wrong, someone
 14 has changed their name, those sorts of issues?
 15 **DR HEALY:** I could get figures on that. But of the 1,650
 16 that we wrote to, they will have been matched across
 17 the -- I think it's called the Welsh Demographic
 18 Service, so they have been matched and they have
 19 addresses that could be written to. So those 1,650 are
 20 the ones we know we can contact. But there will be some
 21 that aren't contactable, for sure.
 22 **MS FRASER BUTLIN:** And in terms of those who are not the
 23 1,650, what's happening for those other individuals?
 24 **DR HEALY:** Yes, so that's part of phase 2, where we're
 25 trying to match them up with local teams to see if some

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1 last decade to improve the coverage of testing,
 2 diagnostic rates remain low and many individuals who are
 3 hepatitis C positive are unaware of their status."
 4 "- Testing needs to be increased in all of the above
 5 settings and health boards will want to consider whether
 6 there is merit in adopting opt-out testing in substance
 7 misuse services. As a minimum, commissioners of these
 8 services should include a requirement to adhere to the
 9 existing annual testing offer for those accessing these
 10 services."
 11 There's then discussion in relation to other --
 12 services in relation to high prevalence populations.
 13 And then:
 14 "- All health boards should consider which
 15 populations are most at risk in their area and work with
 16 substance misuse Area Planning Boards ... and services,
 17 third sector agencies, [blood-borne virus] leads and
 18 blood-borne virus nurses to implement effective testing
 19 strategies.
 20 "The Welsh Viral Hepatitis Subgroup of the Liver
 21 Disease Implementation Group is currently undertaking
 22 a number of pilots in different community settings and
 23 will share strategies which are effective."
 24 In terms of those broader measures of identifying
 25 those who don't know that they're infected, first of

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1 have been contacted.
 2 They don't always contain the full dataset for
 3 example. So if they don't have an NHS number or they
 4 don't have a full demographic, sometimes there might be
 5 spelling mistakes within the system, et cetera,
 6 et cetera, and they can only really be overcome by
 7 individuals looking at them and sort of intelligently
 8 working them through.
 9 **MS FRASER BUTLIN:** And that will be the responsibility of
 10 the blood-borne virus teams --
 11 **DR HEALY:** Yes.
 12 **MS FRASER BUTLIN:** -- within the region you think the person
 13 is to then try to actually track down the correct
 14 individual?
 15 **DR HEALY:** Yes, exactly.
 16 **MS FRASER BUTLIN:** If we continue reading the document we
 17 see 2.2:
 18 "Identifying individuals who are infected with
 19 hepatitis C, who have never been tested and are unaware
 20 of their infection.
 21 "[Hepatitis C] testing on the basis of risk exposure
 22 rather than clinical diagnosis of symptomatic
 23 presentation is currently available via substance misuse
 24 services, GUM services, prisons and in some primary care
 25 settings throughout Wales. Despite efforts over the

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1 all, who has responsibility for implementing these
 2 measures in Wales?
 3 **DR HEALY:** It's the health boards and the area planning
 4 boards.
 5 **MS FRASER BUTLIN:** So where does the funding come from to
 6 address any initiatives that they might want to pursue?
 7 **DR HEALY:** That has to come from the individual health
 8 boards and the area planning boards.
 9 **MS FRASER BUTLIN:** So is it right that there's no central
 10 ringfenced funding for elimination?
 11 **DR HEALY:** That's correct, yeah.
 12 **MS FRASER BUTLIN:** In your statement you've talked about two
 13 other locations that funding can be obtained from.
 14 Firstly, the Liver Disease Implementation Group. What
 15 can you tell us about the funding that that group can
 16 provide -- has access to?
 17 **DR HEALY:** Yeah, so the Liver Disease Implementation Group
 18 has a budget of 1 million per year. It's only ever been
 19 available on a yearly basis, so it's never been clear
 20 whether there would be another programme the following
 21 year, which means any money that was available had to be
 22 spent within that financial year. And from that money
 23 we have funded a number of posts, which are in the
 24 report, to help with elimination. So I receive one
 25 session as blood-borne virus lead. We have a national

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1 pharmacy post, a national project lead.

2 **MS FRASER BUTLIN:** So, just to be clear, you have one

3 session a week as the clinical lead on this?

4 **DR HEALY:** Correct.

5 **MS FRASER BUTLIN:** And one session is just half a day?

6 **DR HEALY:** Half a day, correct, yeah.

7 **MS FRASER BUTLIN:** And in terms of the funding only being

8 available a year at a time, what impact does that have

9 on the strategies that you could hope to pursue?

10 **DR HEALY:** Um, it significantly limits what you're able to

11 achieve, because in general you'd find out that funding

12 is available around about the beginning of the financial

13 year, so any strategies that you have that you might

14 want to implement, they then require being worked up

15 into a business case, so you lose a lot of the time just

16 in the preparation. So, in reality, you're only able to

17 fund things that might run for six months, maybe even

18 shorter, and it's very difficult to plan over the longer

19 term.

20 **MS FRASER BUTLIN:** Would that also have an impact on the

21 staff who you could employ, because their posts would

22 only be secure for a year?

23 **DR HEALY:** Yeah. Yeah, so staffing you have to -- you tend

24 to employ on a secondment basis. Although I should

25 point out that, as we discussed at the beginning, the

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1 watching are aware of it.

2 RLIT0001822.

3 We have a:

4 "Written response by the Welsh Government to the

5 report ... on progress towards achieving Hepatitis C

6 elimination in Wales."

7 And if we turn the page, we see:

8 "Recommendation 1. We recommend [so that's the

9 committee recommendation] that the Welsh Government

10 produces a comprehensive national elimination strategy

11 for hepatitis C, with clear ambitious targets, and

12 workforce planning built in, and provides sustainable

13 funding until elimination is achieved. This must be

14 done as a matter of urgency, given that the current plan

15 will end in that year, and funding for dedicated posts

16 is only confirmed until 2021."

17 And we see that the response is "Accept in

18 principle", but then if we go down to the bottom of the

19 page we see in bold:

20 "Financial implications: None. Delivering the

21 local actions required to achieve elimination of

22 hepatitis B and C as a public health threat will be

23 absorbed from within existing programme budgets and NHS

24 allocations."

25 So is that right? There was a proposal that there

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1 responsibility lies with the health board and the area

2 planning board, so longer-term appointments could be

3 applied for through those routes.

4 **MS FRASER BUTLIN:** You've also indicated that some funding

5 is available through the Public Health Wales

6 Communicable Disease Surveillance Centre, or at least

7 they can assist with the strategy. **(The witness nodded)**

8 What's their role in the elimination strategy?

9 **DR HEALY:** It's the latter, they support through programmes

10 of work and -- within their budget. So, similar to the

11 health board being responsible for delivering

12 elimination locally, Public Health Wales assist through

13 their programmes of work.

14 **MS FRASER BUTLIN:** And I think you've indicated that that's

15 primarily through epidemiological support or data

16 analysis and co-ordination support?

17 **DR HEALY:** Correct.

18 **MS FRASER BUTLIN:** A strategy based on long-term central

19 funding was proposed in 2015/2016 by the Health, Social

20 Care and Sport Committee of the Welsh Government.

21 **(The witness nodded)**

22 The Welsh Government report in response did not

23 pursue that; is that right?

24 **DR HEALY:** That's correct, yeah.

25 **MS FRASER BUTLIN:** Could we just turn to that so those

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1 would be sustainable central funding and the response

2 was it would be dealt with locally?

3 **DR HEALY:** Yeah, I think that's correct. So I think their

4 position was that they didn't have central funding for

5 other disease targets, you know, cancer, et cetera, and

6 that it was devolved to health boards, and they were

7 taking a consistent approach, I suppose.

8 **MS FRASER BUTLIN:** And we see a similar point in

9 recommendation 2, over the page, the recommendation was

10 for:

11 "The strategy must include a targeted awareness

12 raising campaign to reach out to at risk communities and

13 also provide for education and training for health

14 professionals.

15 "... Accept in principle."

16 But then, in relation to "Financial Implications":

17 "None. Delivering the local actions required to

18 achieve elimination ... will be absorbed from within

19 existing programme budgets and NHS allocations".

20 In terms of the strategies taken by local health

21 boards, what can you tell us about what has been done by

22 local health boards?

23 **DR HEALY:** Yeah, so similar to what's happened in England

24 when Professor Foster was talking at the beginning,

25 right back in the beginning when the DAAs became

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1 available -- sorry, the directly acting anti-viral
 2 agents became available -- we had a number of people in
 3 care who needed treatment, and the treatment was
 4 allocated to those individuals on the basis of clinical
 5 need, and that backlog was cleared within 2 years. So
 6 I think -- was it -- 2014 was year 1, so by 2016 we had
 7 cleared the backlog of patients that needed treatment.

8 There were some anxieties, as you pointed out
 9 earlier, about people having to wait, but the wait for
 10 individuals who had mild liver disease was much shorter
 11 than anticipated and we didn't see that really as
 12 a significant clinical problem. And we worked as
 13 a network to ensure that there was equitable and
 14 transparent access to care across the country. So there
 15 was no postcode prescribing; everybody was treated at
 16 the same rate at the same time.

17 We worked with our haematology and consultants and
 18 teams looking after haemophilia patients to make sure
 19 that they were reviewed so that any were referred -- any
 20 that wanted to be referred were referred to care, and
 21 the new treatment options were discussed with them.

22 Subsequent to that, in phase 2 we have focused a lot
 23 on the -- our population where there's ongoing risk of
 24 active transmission and where we have our highest
 25 prevalence, so through substance misuse services, people

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1 **DR HEALY:** Identifying a very large number of individuals
 2 many of whom weren't at risk, and then not getting very
 3 much in terms of pull-through from primary care in
 4 relation to those number of patients identified.

5 **MS FRASER BUTLIN:** So when you say "pull-through from
 6 primary care", what do you mean by that?

7 **DR HEALY:** So we might identify a large list of people who
 8 might have a risk factor -- difficult, then, to know
 9 exactly what that risk factor is -- and then not many of
 10 them accessing testing and then not many of them ending
 11 up in treatment.

12 **MS FRASER BUTLIN:** You talked a moment ago about doing some
 13 sort of awareness raising with primary care colleagues
 14 about the new treatments. What can you tell us of what
 15 that involved?

16 **DR HEALY:** So that will have been done locally in each
 17 health board. I'm also the lead for hepatitis in
 18 Cardiff, so all primary care physicians have to go to
 19 training days and they're split so that the practices
 20 are still active. Yeah. So, in order to cover all of
 21 the primary care practitioners in Cardiff, you have to
 22 do two events. So we've done that on two separate
 23 occasions to raise the issue of hepatitis specifically
 24 with -- with our primary care colleagues.

25 **MS FRASER BUTLIN:** Have there been any measures taken

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1 who inject drugs, we've developed key performance
 2 indicators for those services, which were due to start
 3 in 2019, again have been disrupted by the pandemic. So
 4 the target for this year is the same as 2019's target,
 5 which is 50 per cent, with an anticipation increase to
 6 90 per cent from next year.

7 Treatment is freely available. Clinicians are free
 8 to choose whichever medication they feel is most
 9 appropriate for the patient that they're seeing, and
 10 we've done educational events across the country to
 11 inform primary care -- other services about the change
 12 in treatment that's available to encourage referral
 13 through to service.

14 We have done a number of different projects. So
 15 Professor Foster was talking about the GP programme
 16 which can pick out people with risk factors for
 17 hepatitis C., so we did trial that in North Wales some
 18 time ago. We didn't find it as successful as we might
 19 have hoped. We're watching very carefully what's
 20 happening in England, and we have been talking recently
 21 about whether that is something that we might try again,
 22 because I understand it's been quite refined since we
 23 first used it.

24 **MS FRASER BUTLIN:** Just pausing there, can you tell us what
 25 the problem was when you first used the tool?

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1 specifically to try to identify those who have been
 2 infected through blood or blood products?

3 **DR HEALY:** Not outwith those two programmes that
 4 I mentioned. So we anticipate that a significant number
 5 of people who would have been infected through blood or
 6 blood products will have been diagnosed previously. So
 7 the programme of work trying to find people who have
 8 been diagnosed but not linked to care will capture them.
 9 The primary care looking for people with liver disease,
 10 was an attempt to try and capture those individuals
 11 suffering from the same problems that we've heard from
 12 my two colleagues, in terms of what data is held in
 13 primary care and records dating back that far in
 14 relation to blood transfusion.

15 So that was an attempt to do that but, like I say,
 16 because of its lack of success, we've paused on that.

17 **MS FRASER BUTLIN:** You talk in your statement about a number
 18 of places that testing is available in the community.
 19 You've highlighted it being available through substance
 20 misuse services, criminal justice services, prisons and
 21 homeless services, as well as primary and secondary
 22 care, and you have said that testing in pharmacies is
 23 under development. What can you tell us about that?

24 **DR HEALY:** So because we have a rural community, we know
 25 that a significant number of our at-risk population,

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1 people who inject drugs, only access needle exchange and
2 opiate substitution therapy through pharmacy. So it's
3 a key part of our strategy that testing is available in
4 those settings.

5 We have found it difficult to get traction in terms
6 of numbers of individuals being tested, so we're
7 continuing to work on that. We're not giving up on that
8 strategy because it's such a key element of delivering
9 elimination because of the rural nature of Wales and the
10 fact that such a significant proportion of people only
11 access care that way.

12 **MS FRASER BUTLIN:** I've been asked to ask do you think that
13 having to attend somewhere like a substance misuse
14 centre might put people off attending for testing,
15 particularly if they think they've been infected through
16 blood or blood products and what do you then see as the
17 benefits of the pharmacy provision?

18 **DR HEALY:** Yeah, so pharmacy provision is specifically
19 targeting that group. We wouldn't expect to capture
20 people who have been infected through other routes
21 through that programme of work. Testing is widely
22 available, primary care, anyone should be able to access
23 testing in Wales in a relatively straightforward
24 fashion.

25 We have also been looking at the programme of work

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1 that role, I've responsibility for ensuring that the
2 agency discharges it's -- all statutory public health
3 functions, so those related to infectious diseases are
4 one area, and I'm also responsible for public health
5 input to service development to screening and to wider
6 health improvement activity.

7 **MS FRASER BUTLIN:** The hepatitis C elimination plan phase 1
8 was published in January 2021 (**the witness nodded**), so
9 before you became director.

10 **DR McCLEAN:** Yes.

11 **MS FRASER BUTLIN:** What can you tell us of the focus of that
12 plan? What has the focus been?

13 **DR McCLEAN:** As you say, it was published in January 2021
14 and it's very much focused on people who have acquired
15 hepatitis C through injecting drugs. That is, by some
16 distance, our biggest group of new infections, and it's
17 a particularly challenging group to target and to engage
18 with services to ensure we -- that people receive
19 treatment. So, for that reason, because it is our
20 biggest epidemiological group, the focus has been on
21 that group to date.

22 **MS FRASER BUTLIN:** If we turn to RLIT0001696, please,
23 Lawrence.

24 We see the Elimination Plan and if we turn to
25 page 8, we see the heading "Priority populations" and

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1 that was going on in England around postal testing and
2 that's something we're also keen to develop. We want to
3 make testing as freely available and as tailored to the
4 individual as we possibly can, but that work is also in
5 its infancy.

6 **MS FRASER BUTLIN:** So just to be clear the pharmacy testing
7 is connected with needle exchange.

8 (**The witness nodded**)

9 It's not a general provision where somebody could
10 think that they wanted to be tested and go in and be
11 tested?

12 **DR HEALY:** Correct, yeah.

13 **MS FRASER BUTLIN:** So somebody who thought they might have
14 been infected through blood and blood products would
15 have to go to their GP to access testing?

16 **DR HEALY:** Yeah.

17 **MS FRASER BUTLIN:** Thank you.

18 Dr McClean. Can you see and hear me?

19 **DR McCLEAN:** Yes, I can. Thank you, Sarah.

20 **MS FRASER BUTLIN:** You are the Director of Public Health in
21 the Public Health Agency in Northern Ireland; is that
22 right?

23 **DR McCLEAN:** That's correct. I've been the Director of
24 Public Health in the Public Health Agency since the
25 1 September this year, so relatively new in post, and in

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1 it's the second paragraph:

2 "Over two thirds of those treated for hepatitis C
3 infection in Northern Ireland have a history of
4 injecting drug use ..."

5 Then it continues:

6 "This population is a priority in terms of the clear
7 burden of experiencing hepatitis C infection. Within
8 this population, priority risk factors include
9 homelessness, addictions, and admission to prison."

10 Then it says:

11 "Other populations include: people who were infected
12 with blood/blood products, healthcare staff with needle
13 stick injuries", et cetera.

14 **DR McCLEAN:** Yeah.

15 **MS FRASER BUTLIN:** You've indicated in your statement that
16 there are no specific actions relating to those who were
17 infected with blood and blood products within the
18 elimination plan. Can you help us with why that is?

19 **DR McCLEAN:** So I think it is because the focus in this
20 plan, which is very much the first phase of the
21 elimination plan, was to focus on that larger group, and
22 also to focus on this group, which are challenged to
23 engage with services. So quite often it can be hard to
24 reach this group to get them to go for testing and to
25 get them to engage with treatment services. So I think

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1 it was felt that particular effort was required around
2 that group.
3 Having said that, another of the actions in the
4 elimination plan was that hepatitis C was made
5 a notifiable disease in Northern Ireland and that
6 happened in summer of last year. So that's a relatively
7 new thing. The important thing from a public health
8 point of view about that is that every time someone is
9 now diagnosed with hepatitis C, it's mandatory that the
10 laboratory tells us in public health, and that then
11 allows us to work with the clinicians involved and to
12 work with people looking after the patients and the
13 patients themselves to identify their risk factors, do
14 contract tracing and really find out more about where
15 they have acquired their hepatitis C.
16 Now, my understanding is that since the elimination
17 plan has been published, the information that we have
18 received is that we have not had a new diagnosis of
19 hepatitis C associated with historic use of blood
20 transfusion and blood products in Northern Ireland but
21 the introduction of hepatitis C as a notifiable disease
22 does allow us to systematically start to gather
23 information about that in a way which we couldn't in the
24 past.

25 **MS FRASER BUTLIN:** So in terms of making hepatitis C

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1 the priority population that you think would still
2 impact on identifying and engaging with those infected
3 through blood and blood products?
4 **DR McCLEAN:** So we have, and for number of years have,
5 highlighted -- or run -- run information things around
6 hepatitis awareness. So, for example, on World
7 Hepatitis Day, the Public Health Agency would
8 disseminate particularly social media posts and videos
9 and information, and they will remind people or inform
10 people about the risk factors for hepatitis B and C more
11 generally. And one of those risk factors that the media
12 content includes is highlighting people who have
13 received blood products and blood transfusions in the
14 time primarily before 1981 (*sic*) and '86.

15 **MS FRASER BUTLIN:** Could I turn you then to WITN7311004,
16 please.

17 Sorry, Dr McClean, I've just seen on the transcript
18 that you referred to blood transfusions primarily being
19 "before 1981", did you mean 1991?

20 **DR McCLEAN:** Yes, before 1991, apologies.

21 **MS FRASER BUTLIN:** I'm not sure if it was a transmission
22 issue or an error but we just want to make sure that the
23 transcript is correct.

24 WITN7311004, thank you, Lawrence.

25 This the Northern Irish Regional Hepatitis B & C

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1 a notifiable disease, you've indicated it allows the
2 tracking of how many people are being diagnosed --
3 **DR McCLEAN:** Yeah.
4 **MS FRASER BUTLIN:** -- whose risk factor relates to blood and
5 blood products.
6 **DR McCLEAN:** That's correct, yes.
7 **MS FRASER BUTLIN:** Dr McClean, would it also allow for any
8 tracing backwards if someone has also been a blood
9 donor?
10 **DR McCLEAN:** So I think that would be something that the
11 clinical team and the Northern Ireland Blood Transfusion
12 Service would be better able to answer. I can find more
13 information about that and provide you with further
14 detail on that but, if someone has been a blood donor,
15 that will be a question for those services to
16 investigate, but I can provide more information.
17 **MS FRASER BUTLIN:** I think what I was asking you,
18 Dr McClean, is whether you were aware of any linking up
19 between the notification of the disease and the
20 Transfusion Service?
21 **DR McCLEAN:** So at the minute I'm not.
22 **MS FRASER BUTLIN:** The notifiable disease point is one
23 aspect of the actions that have been taken in relation
24 to what you've termed the "priority population". Are
25 there any other actions that have been taken relating to

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1 Managed Clinical Network Annual Report 2020. Before we
2 look at the content of it, could you tell us first of
3 all what the network is, and what its purpose is?

4 **DR McCLEAN:** So the network is a collaboration of clinicians
5 and -- from across Northern Ireland, those working in
6 the regional hepatology centre who will be responsible
7 for treating all our patients with hepatitis B and C,
8 along with people in local trusts, and people who work
9 in other areas, for example prisons, drug services,
10 things like that. So it's bringing everyone together,
11 along with service commissioners and the Public Health
12 Agency to try to put in place the best possible
13 treatments for patients with hepatitis B and C.

14 **MS FRASER BUTLIN:** If we turn to page 10, there is a table
15 setting out the route of hepatitis C transmission
16 recorded by patients presenting for treatment in
17 Northern Ireland 2000 to 2020.

18 **DR McCLEAN:** Yes.

19 **MS FRASER BUTLIN:** We can see that, in relation to blood and
20 blood products, the number is 128, out of a total
21 of 1,696. So a percentage of about 7.55 per cent.

22 Would it be fair, then, that from this table it
23 seems that there are still a reasonable number of people
24 being identified as infected with hepatitis C from blood
25 and blood products?

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1 **DR McCLEAN:** That table relates to people who were diagnosed
2 over the past 20 years, so the bulk of the people who
3 are in that group for the blood and blood products group
4 I imagine will have been diagnosed at the earlier part
5 of the time frame, so in the early 2000s rather than in
6 more recent years, and I think that number, whenever you
7 look at it compared to the numbers in the statistical
8 report, makes me think that we have identified certainly
9 a large proportion of people in Northern Ireland who
10 were identified -- or who were infected through blood
11 and blood products.

12 **MS FRASER BUTLIN:** Then if we turn the page, we see
13 the heading "Hepatitis C patient re-engagement", and I'm
14 just going to read it out for those listening, and then
15 ask you about it, Dr McClean.

16 "The Liver clinic has an extensive database of
17 patients known to have HCV infection and in February
18 2019 it started using the database to try to reconnect
19 with those with whom we had lost contact. A 'call back'
20 process was started to trace and treat patients who were
21 previously diagnosed as having a chronic active
22 infection and referred, but who never attended clinic.
23 Several of these patients were identified, contacted and
24 offered testing to confirm whether they still had an
25 active infection and then invited to clinic to be

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1 potentially have not yet been identified, you said in
2 your statement that you anticipate that actions will be
3 set in relation to that group in phase 2 of the plan.
4 Do you have any understanding of what those actions are
5 likely to be?

6 **DR McCLEAN:** So I think that we are open to constantly
7 reviewing our plan and our actions, and I've listened
8 with interest and read the statements, particularly from
9 England, around the efforts that they have made to
10 further reach out to this group of patients, and I think
11 it would be very helpful for us to take the learning
12 from the various projects under way in England to see is
13 there a way that we can refine testing, refine targeting
14 of patients, to try to identify any remaining patients
15 who may be undiagnosed in the population.

16 **MS FRASER BUTLIN:** I want to then move to some more general
17 questions to all of you as a panel. First of all, if
18 I can start with thinking about the English case finding
19 search tool and the Bristol study. In terms of,
20 Dr McClean, Professor Dillon, Dr Healy, what are your
21 perspectives on whether a similar exercise would be
22 helpful in Scotland, Wales or Northern Ireland?

23 **DR HEALY:** I think our intention is to wait and see what
24 happens from the England perspective and the report on
25 it. Separate to that, we are working on some

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1 assessed for the newer more effective treatments.

2 "Of those identified and contactable, only 7% came
3 forward for specialist assessment and treatment and have
4 since cleared the virus. The rest of those individuals
5 identified were either uncontactable, refusing to
6 engage, no longer living in Northern Ireland or had
7 died.

8 "All those who were uncontactable or who did not
9 attend appointments during the 'CALL BACK' process will
10 be sent follow up letters and the outcomes of this will
11 be reported on at a later stage during 2020."

12 In terms of the database of patients who were being
13 reconnected with, would this include those who had
14 contracted hepatitis C through blood and blood products,
15 and had a previous positive test but who'd then not
16 engaged with treatment, or not felt able to carry on?

17 **DR McCLEAN:** So the database is held by the clinical
18 service, so it's held in the Belfast trust by the
19 hepatology unit, so it will be anyone who they have
20 engaged with in the past who have had a positive
21 treatment and they've had contact with, irrespective of
22 how they contracted their hepatitis C.

23 **MS FRASER BUTLIN:** In terms of the -- apologies.

24 In terms of the specific group of people who have
25 been infected with blood and blood products who

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1 epidemiology work to try to better identify what the
2 prevalence is within Wales, and an epidemiology
3 colleague is looking at carrying out -- I forget the
4 term, actually, but it's looking at all different risk
5 groups, essentially, and trying to get testing carried
6 out in various risk groups, pooling that together,
7 multiplying it up to get an overall idea of prevalence
8 which would capture some of what you're trying to
9 ascertain. And I think that project hasn't been
10 definitely funded but we're working on that and, if
11 that's funded, we'd put that together with what they
12 gather in England and then devise a strategy on the back
13 of that.

14 **PROF DILLON:** From a Scottish perspective, we'll see what
15 our English counterparts come up with. We have
16 an ongoing project, again working with Professor
17 Hickman's group in Bristol, looking at the epidemiology
18 and the changing epidemiology of hep C infection in
19 Scotland, and that is due to report in another two
20 years' time. So we'll have more data from that in terms
21 of the ongoing risk of transmission and whether that's
22 falling.

23 The early cuts to that data suggest that the rate is
24 falling and there are not hidden pools of transmission
25 and some things are coming to an end, and we're not

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1 seeing, with our record linkage, a huge surge of
 2 patients presenting late with liver disease, related to
 3 hepatitis C that was transfusion related.

4 **MS FRASER BUTLIN:** Dr McClean, do you want to add anything
 5 from a Northern Irish perspective?

6 **DR McCLEAN:** Just to say we'll also wait and see what the
 7 English work shows us and if there's any learning for
 8 us.

9 **MS FRASER BUTLIN:** All four of you have mentioned the impact
 10 of Covid on the ability to address and progress the
 11 elimination strategies. Post Covid, do you have any
 12 concerns about whether hepatitis C will be given
 13 priority in terms of resources and focus?

14 **PROF FOSTER:** I'll start with the English perspective. With
 15 no suggestion that the pace within the elimination
 16 programme will falter, we're looking ahead to the next
 17 year at similar levels of funding, the procurement
 18 contract with pharma finishes in 12 months time and
 19 we're already starting discussions about extending into
 20 a slightly different model.

21 So certainly in England there's no suggestion that
 22 we're taking our foot off the gas. A lot of it will be
 23 driven by the data that comes forward, how much left to
 24 do, but there's very much a commitment from a very high
 25 level to finish the job we started.

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1 **PROF DILLON:** I think there is concern about that, where
 2 lots of people have been redeployed and haven't come
 3 back. The teams in Scotland weren't people who are
 4 focused solely on hepatitis C. They continued a number
 5 of other functions through needle exchanges, community
 6 pharmacies, et cetera. The way addiction services have
 7 been organised has changed dramatically during Covid
 8 and, whether they will return to the pathways that we
 9 had before, I think that's unlikely.

10 They will be different and so we'll need to start
 11 building those relationships all over again to encourage
 12 people who are involved with the populations who are
 13 injecting or have injected drugs in the past, and
 14 getting them back in sync with the hepatitis C
 15 elimination programme will be a new challenge to go
 16 forward with.

17 **MS FRASER BUTLIN:** Dr McClean?

18 **DR McCLEAN:** I think that our elimination plan being
 19 published when it was was a big challenge because it was
 20 right in the middle of Covid. It is only now that we're
 21 starting to bring our teams back and get key staff in
 22 post to be able to deliver this. So I do think that
 23 whilst it's been challenging at least we are now in
 24 a position where we're able to move forward and we have
 25 resources for key posts related to this.

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1 **PROF DILLON:** I think the decision is yet to be made in
 2 Scotland. We got stopped as we were starting, the teams
 3 were largely broken up and redistributed to Covid. Very
 4 few of us were still doing any hepatitis C work during
 5 that time. The epidemiological data is due to appear,
 6 as I said, later this month and the civil servants that
 7 are part of the committees that will be reviewing that
 8 will be reporting to ministers.

9 It would need a new pharma contract, it would need
 10 ongoing commitment to very a substantial increase, you
 11 know, having lost two and a half years of progress, it's
 12 now looking at delivering 6,000 or 7,000 patients into
 13 treatment a year, as opposed to 3,000 patients a year to
 14 achieve elimination, which is a very tall order. So
 15 I suspect that a delay to the elimination date might be
 16 the most likely outcome, but we'll see what's happened
 17 to the epidemiological data over the years of Covid.
 18 Whether there has been ongoing transmission or whether
 19 transmission has fallen during the lockdown is one of
 20 the unknowns at the moment. We're looking forward to
 21 seeing that date.

22 **MS FRASER BUTLIN:** You obviously have concerns about whether
 23 you'd reach your elimination target but, in terms of
 24 funding and staffing, is there any concern about
 25 returning to pre-Covid levels of your teams?

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1 **MS FRASER BUTLIN:** Dr Healy?

2 **DR HEALY:** On Tuesday I attended the first meeting of the
 3 elimination oversight group, which has a number of key
 4 individuals that -- key posts in Welsh Government and
 5 health boards. So there's definitely an appetite to
 6 move forward with elimination. However, at the same
 7 time, I'm very conscious that we're pitching for funding
 8 in a very resource-limited area and so I think -- I'm
 9 hopeful but I'm also realistic, and time will tell
 10 a little bit, in terms of where we get to.

11 **MS FRASER BUTLIN:** In terms of those sort of structural and
 12 co-ordination elements you've talked about, the issue of
 13 engaging with primary care colleagues has been raised by
 14 all of you. Why do you think it's difficult to engage
 15 with primary care colleagues? What are the challenges
 16 that you're facing?

17 **(The witnesses laughed)**

18 **PROF DILLON:** The GP workforce has fallen in terms of
 19 doctors, the demand has gone up, and it's another straw
 20 on the camel's back and I expect them to deliver more
 21 from a diminishing resources struggle. So that's part
 22 of -- and I don't see an imminent solution to that, in
 23 terms of recruitment into general practice, training new
 24 general practitioners, et cetera.

25 It's an aging workforce, large numbers of them have

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1 retired in the last year or are on the verge of retiring
2 and that makes it an increasingly difficult group to
3 deal with. I think they've equally had, you know --
4 Covid has been difficult for everybody. But I think the
5 general practitioners probably had a disproportionate
6 impact on the workload and less resilience, and that has
7 added to the problems and I think the general appetite
8 amongst them for taking on something new and different
9 is pretty low at the moment.

10 **MS FRASER BUTLIN:** Do others have any thoughts that they
11 want to add to that?

12 **PROF FOSTER:** I strongly agree with John. It's
13 an increasing demand on a fragile, limited and reducing
14 workforce. So it would be difficult with -- public
15 expectations of primary care seem to have risen
16 dramatically and -- at the same time when the capacity
17 to deliver those has been reduced. So it will be
18 a significant challenge.

19 **MS FRASER BUTLIN:** The English idea of GP Champions was
20 raised. Do any of you have any views of what could be
21 done to improve engagement with primary care colleagues?

22 **PROF DILLON:** To be honest, we've probably moved away from
23 using general practice as the major delivery workforce
24 for this and we'll be looking to third sector partners
25 and nurse-led and peer-led initiatives to deliver the

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1 what could be done to assist GPs to be more aware of
2 hepatitis C and the need to test?

3 **PROF DILLON:** So I think from the -- from presenting with
4 symptoms of tiredness, fatigue and abnormal liver
5 function tests, decision support tools such as
6 intelligent Liver Function Testing, which is now part of
7 the clinical diagnostic centres' policy in England and
8 is also policy in Scotland, will help, because then the
9 testing becomes automated so that they -- it doesn't
10 require a specific thought about hepatitis C, it's part
11 of -- the whole panel is tested on those abnormal test
12 patients. And using the appropriate normal ranges for
13 ALT will find those patients that had previously been
14 missed by using ALT strategies before which were at
15 a normal range that was too high. And so we will find
16 those patients. But, as we've seen from the statistical
17 estimates of how many people there are, we are dealing
18 with a small number of patients, unless those
19 statistical estimates are wildly inaccurate, which, with
20 the thoroughness they've been done, seems unlikely.

21 **MS FRASER BUTLIN:** Do any of the rest of the panel want to
22 add anything?

23 **PROF FOSTER:** No.

24 **MS FRASER BUTLIN:** No. In terms of other steps that might
25 be taken to identify individuals, do you think a public

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1 majority of treatment, and decentralising prescription
2 away from medics into other partners in healthcare is
3 the direction of travel in Scotland. And so I -- we
4 don't anticipate general practice playing a -- having to
5 play a large role in delivering elimination in Scotland.

6 **DR HEALY:** Yeah, I agree with that. We've decentralised,
7 we're using different models of care to try to engage.
8 I suppose central to the question you're asking is: how
9 do we engage primary care in trying to ensure that there
10 are no missed individuals from -- who may have received
11 blood products in the past? They definitely need help
12 in that regard and, hopefully, the program of work that
13 they're doing in England in terms of identifying at-risk
14 people will help.

15 How we then encourage those individuals to get
16 tested is a challenge, isn't it, I think. Yeah.

17 **MS FRASER BUTLIN:** Dr McClean do you have anything you want
18 to add to that?

19 **DR McCLEAN:** I concur, that for general practice it's such
20 a huge workload.

21 **MS FRASER BUTLIN:** Professor Dillon, you've indicated you're
22 sort of moving away from using GPs too much but, in
23 terms of that awareness and education element, so that
24 if a patient presents saying, "I think I've been
25 infected" or with a raised ALT and testing is needed,

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1 awareness campaign should be commissioned about the
2 risks of hepatitis C from blood and blood products?

3 **PROF FOSTER:** From the English perspective we've looked at
4 this very carefully, considered it, and at this stage we
5 don't think we have enough information to guide us
6 there. I think at some point a public information
7 campaign for hepatitis C and blood-borne viruses might
8 be very useful but I'm not sure where I would target
9 that at the moment. Are we targeting people who used
10 drugs 20, 30 years ago? Are we targeting immigrant
11 communities? Are we targeting people who gave birth
12 in -- 20, 30 years ago? So I think until we have
13 information about where we would want to target that,
14 I wouldn't want to advocate it. Essentially, you get
15 one shot at a public health campaign so you've really
16 got to get the targeting right and I'm not sure we have.
17 And I think we'd want to look at a public health
18 campaign for blood and blood product recipients in
19 a very targeted fashion.

20 It may be better to say, "If you have a 20-year old
21 child, you need to be tested for hepatitis", and we
22 might be able to do that by a more effective way than
23 a public awareness campaign. So I'm not yet convinced
24 but I think we would certainly be attuned to the idea if
25 it was shown to be valuable.

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DR HEALY: I'm not best placed to answer that question because that's not my expertise, but we have discussed it within Wales over the years, and people who know a lot more about this than I do have pointed out that people tend to remember the very successful public health campaigns but they don't remember the unsuccessful public health campaigns, and there is a degree of anxiety around launching an unsuccessful public health campaign with all -- which is costly, and money that might have been better spent elsewhere. So I'd agree with Professor Foster in terms of, if we are going to launch one, then we need to make sure we get it right, because you only get one chance.

PROF DILLON: In Scotland we did it a decade ago. It wasn't terribly successful, there was no appreciable increase in the number of patients diagnosed, it was focused across the whole spectrum of possible risk factors and encouraged people to access testing. There was a corresponding awareness-raising campaign amongst primary care colleagues, so they were ready to expect it, and we didn't notice an impact from it at all, despite spending I think upwards of £7.5 million on it.

MS FRASER BUTLIN: Dr McClean, you're nodding. Is there anything you want to add?

DR McCLEAN: I think it's really important that we remember

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advocating an abnormal LFT pathway rather than a hep C pathway, but we'd be very sensitive to data and will change if necessary.

PROF DILLON: I would agree with Professor Foster. It's always nice when he takes one of my ideas but in terms of the health economic arguments, if we were to set up a screening programme or a case-finding programme, it would be more cost effective to look at the broader health implications of liver disease in general rather than hepatitis C specifically and that would be an easier argument to win in terms of the allocation of resources, because it wouldn't cost much more to look across the whole spectrum of liver disease, rather than just focusing on viral hepatitis.

MS FRASER BUTLIN: And I think you think you'd get better buy-in from GPs?

PROF DILLON: Yes. Absolutely. It comes back to Professor Foster's earlier comment that, if you have people doing lots of tests and never finding it positive, people lose faith in any form of screening programme and so, if we were to broaden it across liver disease, you would find liver disease -- it's about 3 to 4 per cent have significant occult liver disease that requires some form of intervention and so, amongst that, it will be the hepatitis Cs and hepatitis Bs.

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that public health information campaigns cost a lot of money and we need to make sure that they're targeted appropriately and that we know what we want to get out of them, so would echo what others have said.

MS FRASER BUTLIN: And what are your views of whether a wide-scale hepatitis C screening programme of the public should be undertaken, perhaps for those over a certain age or perhaps for women who have got -- or who have given birth at a particular time frame? What are your views of something like that?

PROF FOSTER: I think, again, almost refer to: let's see what the data shows. If the data shows that that would be helpful and if people over the age of 50 -- between 50 and 70 are coming up in all of our testing, then that would be a good thing do. But I tend, I'm afraid, to follow John's approach in Scotland, which is that we should be focusing on liver health, and hepatitis C is part of that.

Hepatitis C is a minority cause of abnormal liver function tests nowadays. If we go for abnormal liver function tests we may get better buy-in from primary care physicians. We'll certainly get a lot bigger hit, we'll find a lot of people with manageable disease, and in so doing will also pick up any remaining hepatitis C. So I would at the moment, with the data we have, be

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DR HEALY: Just one thing to add, whenever you are doing any screening programme, you have to consider the potential harms that might come from a screening programme. So I think people tend to think relatively simplistically in so much as "If we screen, we'll find people with infection and we'll treat them", but you have to take account of the fact that some false positive tests will occur and any screening programme around liver disease you'll get false positive tests around whatever test you employ.

So they do have to be carefully considered. It's not quite as simple as it at first sounds.

MS FRASER BUTLIN: Does anyone want to add anything else to the discussion?

DR McCLEAN: I think I would add that, for any population screening campaign, we'd want it carefully considered by the National Screening Committee. We have a range of population screening programmes in the UK, all of which are considered carefully by that committee because, as others have said, there are harms, and as well as that, if we headed out and identified lots of people with -- who might have a condition, we then have to have of the services in place to actually assess and diagnosis them. So it's really important that any decisions are taken through of the National Screening Committee on this.

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1 **MS FRASER BUTLIN:** As a different thought in terms of
2 identifying people, in Wales there's obviously the
3 pharmacy testing but only in relation to needle
4 exchange. What are your views of whether extensive
5 provision of hepatitis C testing should be available at
6 that community level for anybody attending a community
7 pharmacy?

8 **PROF FOSTER:** In England we found it very difficult to
9 engage with pharmacies and we're very envious of the
10 success that our Scottish colleagues have had, and a lot
11 of that is related to the workload in pharmacies,
12 they're busy. The yield in terms of hepatitis C test
13 positives has been relatively low, so they haven't been
14 terribly well reimbursed. There is a fear, I think,
15 perhaps an overblown fear, that if we were to say to
16 pharmacists "We'll pay you £15 for testing anyone who
17 might have hepatitis C", a smart community pharmacist
18 would put a very junior individual at the door and test
19 thousands of people a day to very little gain.

20 So I think we would want to look very carefully at
21 what the added value would be of community testing in
22 pharmacy. We do want more testing but it does need to
23 be appropriate testing, and I think it's striking that
24 balance between spending a lot of money testing a lot of
25 people. And I think the comments from Dr Healy were

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1 I think it would be a risk because I think the
2 population prevalence outside those with an overt risk
3 is very low. Now, someone who is particularly concerned
4 and who is going in to ask for a test, they probably
5 think they have a risk factor and therefore the pick-up
6 rate would be justified for that. So I think it would
7 be that assessment of the risk factor before randomly --
8 because of the stigma associated with hepatitis C and
9 a more anonymous testing route for those people who
10 aren't still engaged in opiate therapy or injecting
11 behaviours, then that facility might be a more neutral
12 ground. Although the online options that
13 Professor Foster has described earlier on might be
14 a good option for that.

15 **DR HEALY:** Similarly, very keen to see barriers to testing
16 lowered in appropriate populations. As colleagues have
17 alluded to, you protect against the harm of screening by
18 making sure you're targeting an appropriate population
19 with at least a decent prevalence to protect against the
20 risk of false positives. So yes to reducing barriers,
21 but we have to do it intelligently.

22 **MS FRASER BUTLIN:** So perhaps -- I think I'm hearing from
23 Scotland and Wales, and perhaps also Northern Ireland
24 can indicate the -- Dr McClean, your views -- of the
25 postal and the online portal giving access to postal

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1 entirely apposite, that testing everyone does yield
2 false positives and they become very distressing to all
3 involved.

4 We're just dealing with -- we've done a 10,000
5 patient survey in addiction services. I have two false
6 positive HIV tests and those people are very distressed
7 by that. So there is a cost to a test and no matter how
8 good the test, when you test a large number of people
9 you will find some, and that will cause harm.

10 **MS FRASER BUTLIN:** Any other views?

11 **PROF DILLON:** In Scotland -- in Tayside, my part of
12 Scotland, we've had good success using community
13 pharmacies with testing focused on needle exchange and
14 opiate substitution therapy recipients. We're in the
15 process of negotiating a national pharmacy contract
16 around doing that for the whole of Scotland. It's
17 become part of a more generalised contract, which has
18 been bogged down a little recently, and so those
19 negotiations are ongoing.

20 **MS FRASER BUTLIN:** But what would your view be of extending
21 that to perhaps a particular age group who would be able
22 to walk into a community pharmacy and request testing?

23 **PROF DILLON:** I think for the general population, if they
24 don't have a particular risk factor we would find more
25 false positives than we'd find true positives, so

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1 testing might be more appropriate than wide-scale
2 community pharmacy testing; would that be your views?

3 **PROF DILLON:** I think it overcomes the barriers of stigma,
4 et cetera. It allows -- it makes it easier for people
5 to make that choice that they wish to pursue a test, and
6 I think that's a lot of attractions to it, rather than
7 having to go and explain yourself to someone in
8 a pharmacy as to why you want a test, which I think
9 would be daunting for some people. So I think the
10 online tests with, you know, supportive advice, from
11 what I've seen of the portal, in terms of appropriate
12 testing might be the better way forward.

13 **MS FRASER BUTLIN:** Dr McClean, do you any views on the
14 online portal?

15 **DR McCLEAN:** I'd agree with that as long as it provides
16 information and is targeted in some way, so that it
17 doesn't become like a backdoor random kind of testing
18 process.

19 **DR HEALY:** Yeah, it's the targeting, I think, which is key.

20 **MS FRASER BUTLIN:** Final issue. When considering how to
21 avoid something like this happening again, in terms of
22 the infected blood situation, and in terms of the
23 challenges that have been faced in tracing people who
24 have received blood and blood products, it might be
25 suggested that record keeping is important and it might

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1 be suggested that there are matters in that regard that
2 need to be addressed.
3 Professor Dillon, you explain in your statement that
4 compliance is suboptimal with the guidelines that
5 recommend that transfusions are included in the
6 discharge communications with GPs. Can I ask the panel
7 broadly what your views are on that issue of
8 communication from a hospital setting to a GP, and
9 record keeping that indicates someone has received
10 a transfusion?

11 **PROF DILLON:** So I think that has now moved away from the
12 ancient clerk books of times gone by, and blood
13 transfusion services now have extensive records of who
14 has received which unit of blood from whom. And indeed
15 all of the blood products, I think, in terms of if
16 the -- if we were going -- if there is, you know, a new
17 infection or a new complication from blood transfusion
18 that we need to think about going forward, for the last
19 decade, two decades, we now have very sophisticated
20 records that would allow us to identify exactly who
21 received what, and what their risk factors were. And so
22 I think that's changed. And so we're not going to be
23 going through GP records and old hospital records -- was
24 always the second best option, which we've had to use
25 because there wasn't a best option in terms of we didn't

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1 **DR HEALY:** I'm not aware of any risks but that question
2 would be better directed towards the Welsh Blood
3 Transfusion Service. I also agree with Professor Foster
4 that the risk in the future may not be related to blood
5 transfusion; it's a much broader topic around record
6 keeping in general and records being available, and
7 there's definitely a lot more work that needs to be done
8 within the NHS in relation to that, as a whole.

9 **MS FRASER BUTLIN:** Dr McClean, I don't know if you have any
10 views you want to add?

11 **DR McCLEAN:** No, just to concur and say that, as we move
12 towards electronic records that patients have access to
13 as well, I think that will better inform patients about
14 their own treatments as well.

15 **MS FRASER BUTLIN:** Sir, those are the questions I have for
16 the panel. We obviously now need a break to allow
17 recognised legal representatives to provide me with any
18 further questions they would like me to ask the panel.

19 **SIR BRIAN LANGSTAFF:** Well, you've timed it very nicely to
20 coincide with our usual break time for lunch.

21 **MS FRASER BUTLIN:** It was entirely intentional, sir.

22 **SIR BRIAN LANGSTAFF:** Very well, let's say not before 2.00.

23 I imagine the hour will give plenty of time for
24 Ms Fraser Butlin to field any questions that Core
25 Participants may have for you, which they will direct

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1 have sophisticated records for blood transfusion, which
2 we now do. I mean, the Health Service had less
3 sophisticated records previously. They are now better
4 and I think, in terms of blood transfusion, we'd be able
5 to trace those patients very effectively.

6 **MS FRASER BUTLIN:** I've been asked to ask the panel whether
7 any of you have any residual concerns about the current
8 system of record keeping that would allow that tracing
9 to take place? It may be that you can't assist us on
10 this question because it's not really your area.

11 **PROF FOSTER:** I agree with John. I think the system is so
12 much better. I'm not an expert on data transfer and
13 data linkage but we do seem to have an awful lot of
14 systems which talk very poorly to each other and we have
15 a lot of systematic barriers to data transfer. Data
16 protection in the Health Service is something we treat
17 very carefully and perhaps too carefully, in that GP
18 records often aren't available for treating doctors in
19 hospitals and vice versa.

20 So I think there is certainly work to be done
21 linking up the data systems and having a more grown-up
22 conversation about what data can be shared with which
23 healthcare professional, and I think those conversations
24 are beginning. But I think the systems are much, much
25 better but not perfect.

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1 through their own lawyers to Ms Fraser Butlin. But just
2 in case there are more or, for that matter,
3 late-coming-in questions, we'll say not before 2.00.
4 You'll be told if it's any later. I can't tell you
5 quite how long you'll be detained after that but it will
6 be, I would hope, in plenty of time for your travel
7 arrangements this evening.

8 **MS FRASER BUTLIN:** Thank you.

9 **SIR BRIAN LANGSTAFF:** 2.00, not before 2.00.

10 (1.03 pm)

(The Luncheon Adjournment)

12 (1.58 pm)

13 **MS FRASER BUTLIN:** Thank you. I just have a couple of
14 questions I've been asked to ask you.

15 First of all, Professor Foster, in your evidence you
16 said that you never had records from the interferon era.
17 Can you help us at all with why that was?

18 **PROF FOSTER:** So the interferon treatment was administered
19 locally by individual hospitals. There was no central
20 registry of treatments administered. And we go back to
21 the problem we have with notes that are missing, old
22 handwritten notes going back to the 1990s. So
23 unfortunately we don't have a central registry.

24 **MS FRASER BUTLIN:** A number of you described using the
25 record of a blood transfusion within the relevant period

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1 as a risk factor for hepatitis C, and 1991 being the end
2 stop for that. I'm asked to ask that after the Inquiry
3 report is published, will any findings that may be made
4 relating to the end stop date be taken into account when
5 publishing anything about the hepatitis C relevant
6 period?

7 **PROF FOSTER:** I'm sure if there was a different conclusion
8 reached we'd want to act on it and want to respond
9 appropriately.

10 **MS FRASER BUTLIN:** And is that the situation across the
11 nations?

12 **PROF DILLON:** Absolutely.

13 **DR McCLEAN:** Yes.

14 **MS FRASER BUTLIN:** Again, Professor Foster, a question for
15 you. Dealing with the use of blood samples that have
16 been taken for other reasons being tested for
17 hepatitis C, can you tell us what the position is in
18 relation to consent for testing?

19 **PROF FOSTER:** We are currently working through that process
20 with the local teams in Liverpool, who are doing it as
21 a research project. There is an issue as to whether it
22 will be anonymised or whether patients will be
23 pre-consented, but nothing will take place outside the
24 jurisdiction of an appropriately constituted ethical
25 review board.

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1 **DR HEALY:** Yes, a similar response. It would be additional
2 to other mechanisms for being tested. And if we became
3 aware of a particular group that needed testing in
4 a particular way, we would be very open to developing
5 whatever is required in that regard, as evidenced by how
6 we're expanding testing in so many different ways.

7 **MS FRASER BUTLIN:** Dr McClean, is there anything you would
8 like to add?

9 **DR McCLEAN:** Similarly, we would want to make it accessible
10 for all populations.

11 **MS FRASER BUTLIN:** Sir, those are the questions I've been
12 asked to ask. I don't think there is anything further.
13 Is there anything you would like to raise?

14 **SIR BRIAN LANGSTAFF:** I have no additional questions of my
15 own.

16 **MS FRASER BUTLIN:** Professor Foster, is there anything else
17 you would like to add before we finish?

18 **PROF FOSTER:** No, I think we've covered things very clearly,
19 thank you.

20 **MS FRASER BUTLIN:** Professor Dillon.

21 **PROF DILLON:** I have nothing to add.

22 **MS FRASER BUTLIN:** Professor Healy?

23 **DR HEALY:** The only thing I'd add is I think you asked me
24 earlier about looking back and I was talking about in
25 the recent past. I didn't allude to the earlier

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1 **MS FRASER BUTLIN:** Finally, you've all talked about the
2 utility of online portals for patients to access
3 testing. What arrangements are being made or would you
4 anticipate being made to ensure that those with less
5 access to the Internet can still access that
6 information? Perhaps if we start with what is being
7 considered and then others, if you have a view of what
8 might be considered.

9 **PROF FOSTER:** We see the web portal as giving us insights
10 into populations that we're missing, and we would hope,
11 and anticipate, that there would be a fairly broad
12 spectrum of people that will access it. I think the
13 idea that the elderly don't use the Internet is very
14 much a myth, but that will identify populations at risk
15 who can then be selectively targeted. So if, for
16 example, we find a cohort of over eighties have
17 unexpected hepatitis C, then we would start to think
18 about ways we could implement. So we'll use it as the
19 learning. It's another plank in our evidence base to
20 what else we need to do, rather than a final game point.

21 **MS FRASER BUTLIN:** Do any of you want to add to that?

22 **PROF DILLON:** I don't think -- there isn't
23 a one-size-fits-all solution and so I think having lots
24 of options so people can choose according to their
25 abilities and preferences.

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1 look-back in 1995 but I took that as for granted, yeah.

2 **MS FRASER BUTLIN:** Thank you.

3 Dr McClean, is there anything else you would like to
4 add?

5 **DR McCLEAN:** Nothing to add. Thank you.

6 **SIR BRIAN LANGSTAFF:** Can I, for my part, thank each of you.
7 I know that this is, in some respects, an imposition
8 upon busy practitioners, particularly after what you've
9 said about the stresses on the system following Covid
10 and the backlog that there may be after that. So it is
11 particularly valuable to have you here and what you have
12 told us, particularly given the approaches in England
13 and Scotland, has been most informative and instructive,
14 and very helpful. So thank you.

15 **MS FRASER BUTLIN:** Sir, we obviously just need a short break
16 to allow the panel to go and our next witness to attend.
17 I know that's a little bit awkward having just had the
18 lunch break, but perhaps we can just have ten minutes.

19 **SIR BRIAN LANGSTAFF:** Yes, so not before 2.15.

20 **MS FRASER BUTLIN:** Thank you.

21 (2.03 pm)

(A short break)

23 (2.14 pm)

24 **SIR BRIAN LANGSTAFF:** Dr Mulholland, let me explain the
25 arrangements. You're talking to an audience here which

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1 consists of those who were infected and affected,
2 participants and Core Participants. To the left you
3 have lawyers who represent various different interests
4 in the Inquiry. And at the back left there are those
5 who may, from time to time, include representatives of
6 the press.

7 But beyond this room there is a wider audience, both
8 here, in Aldwych House, and watching on YouTube or live
9 stream. I can't tell you quite how many it will be but
10 it will be probably in three figures and may be
11 substantially so.

12 Ms Fraser Butlin will be asking you the questions
13 but, first, Mary has to invite you to affirm.

14 Mary.

15 **DR MICHAEL NIAL CONNOR MULHOLLAND (affirmed)**

16 **Questioned by MS FRASER BUTLIN**

17 **MS FRASER BUTLIN:** Dr Mulholland, you're a practising GP and
18 also the honorary secretary of the Royal College of
19 General Practitioners; is that right?

20 **A.** That's correct.

21 **Q.** Can you tell us, in layman's terms, what the royal
22 college's role and remit is?

23 **A.** The Royal College of GPs -- is to foster and maintain
24 the highest standards of general practice and encourage
25 that as we move forwards with new generations of GPs.

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1 your Certificate of Completion of Training, and that
2 then is looked at by the GMC as the marker that you can
3 then practice as a GP specialist in the UK.

4 **Q.** In terms of training on communication skills, can you
5 explain for us what's required by the royal college
6 before someone is signed off, licensed as a GP?

7 **A.** So communication skills come into the whole of the exam,
8 and the tri-pass. We have a three-part exam, which
9 includes clinical skills assessment, communication
10 skills assessment. We've got workplace-based
11 assessments and a knowledge test as well. Within each
12 part of that, our curriculum has parts that will be
13 tested in each stage. The most obvious one, looking at
14 it, is the clinical skills testing, where communication
15 is observed either in the workplace by the GP trainer or
16 by assessors during the examination, and that's a core
17 part that a trainee must part -- pass both the WPBA, the
18 workplace -- and the communication skills.

19 **Q.** Just broadly, when you're assessing communication
20 skills, what must a trainee demonstrate before they are
21 passed? What is the college requiring of trainees?

22 **A.** So our communication skills, in the assessment, has been
23 looking at particularly that they must have a knowledge,
24 they must know what they're doing, and pay the right
25 clinical management of a patient. They look at the

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1 **Q.** As honorary secretary, what are your responsibilities?

2 **A.** My responsibilities are mostly around governance of the
3 college and governance to the Trustee Board, and within
4 that I have roles in supporting the membership team.
5 I look at the clinical -- I oversee the clinical policy
6 on behalf of the officer team as well.

7 **Q.** I want to address my next set of questions about the
8 training of GPs, just so we can understand how GPs are
9 trained and what role the college has. So, in terms of
10 initial training to become a GP, what role does the
11 college have within that?

12 **A.** So all doctors that want to become a GP enter GP
13 training schemes, and the role of the college within
14 that is to -- we set the curriculum for general practice
15 training. We obviously oversee the exam at the end of
16 general practice training. And to become a GP they then
17 go through three areas of GP training that's overseen by
18 the statutory education bodies around the four nations
19 of the UK, but we bookend that training process with
20 curriculum and assessment.

21 **Q.** In terms of those exams at the end, by passing those
22 exams, then a GP is effectively allowed to practice in
23 the UK as a GP?

24 **A.** Yeah, passing the MRCGP exam, the Member of the Royal
25 College of GPs exam, is also used as a marker to get

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1 interpersonal skills. And the third one escaped my mind
2 but it's generally to look at how well they communicate
3 their ideas to the patient and understand where the
4 patient's ideas are as well and take them into
5 consideration as they have a whole assessment of their
6 care.

7 **Q.** I think you also talk about the attitudes, feelings and
8 biases?

9 **A.** Yes.

10 **Q.** Is that part of it?

11 **A.** Yes, that's part of it, and that we test it not only in
12 those clinical skills, videos or simulated situations
13 they're in, but also during case-based discussion work
14 they do during workplace-based assessment. A trainer is
15 then able to explore a case that they have gone through
16 and then ask them specifically about how they have
17 managed those cases and what their attitudes were during
18 it and make an assessment based on that.

19 **Q.** In terms of Wales, Scotland and Northern Ireland, what's
20 the position in those three nations? Is there
21 a difference?

22 **A.** There isn't a difference in terms of the assessments.
23 It's a four-nation exam that we run.

24 **Q.** You described the royal college bookending the initial
25 training, but the training itself being done -- I don't

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1 think you used the word when you were giving your oral
2 evidence but in your statement you used the word
3 "deaneries" doing the actual training?

4 **A.** Yes.

5 **Q.** First of all, can you explain what a deanery is?

6 **A.** A deanery -- within the UK there are four statutory
7 education bodies, one for each nation, in England it's
8 Health Education England. They then divide into
9 regional bases of deaneries and they're -- I think
10 there's 14 of them in the UK, across it, and the deanery
11 then looks after a proportion of trainees that are
12 closely related to the practices in that area.

13 **Q.** How much interaction then is there between the royal
14 college and the local deaneries as to what should or
15 shouldn't be included in the training that's given?

16 **A.** So the curriculum is there that the deaneries are
17 training to. What we then get involved in is not
18 actually what's being trained in, but how the
19 assessments are quality assured. So we don't get
20 involved in that training part. That is left to the
21 education bodies for themselves.

22 **Q.** Then, once somebody has qualified as a GP, what role
23 does the college have in relation to continuing
24 professional development?

25 **A.** So, as a college, we, in common with the other medical

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1 CPD presentations and courses that you can go on online
2 from it.

3 **Q.** How are new CPD resources provided or new topics chosen?
4 What's the process that is followed?

5 **A.** So the college has a CPD strategy group that sits
6 underneath the vice chair of professional development
7 and standards, and they work through where they're
8 hearing both the needs of new things that came up -- so
9 obviously when Covid came up there was an immediate need
10 that we needed to swap all of our CPD resource to Covid
11 for several years. But also we then have experts or
12 specialists or experts around the country that will feed
13 in: "These are the new things that are happening in
14 women's health", or infectious disease or whatever that
15 comes up that's topical and new that we will -- they
16 will try to put in. And so the strategy group put that
17 in through the courses and through the conferences.

18 **Q.** The Inquiry has heard evidence from a number of female
19 witnesses related to their hepatitis C being undiagnosed
20 by GPs for a period of time, and their symptoms being
21 put down to motherhood or perimenopause or menopause and
22 then old age. Does the college's CPD material deal with
23 anything around inequalities and discrimination?

24 **A.** Yes. I think in everything that we've done we've looked
25 at where equality sits, and -- whether it's in the

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1 royal colleges, we provide education materials that GPs
2 may turn to, or our members can turn to. Sometimes we
3 provide materials for everybody, that can access freely,
4 other times it's specifically for our members. But we
5 do not say what anyone should be learning in that year
6 because it relates very much to where a GP is practising
7 where their knowledge gaps are, what they need to know
8 more of, and that will be determined between the GP --
9 often at their appraisal they will discuss it with their
10 appraiser, what they might be doing next. So we provide
11 the resource but we don't have any say over what people
12 do and who uses it.

13 **Q.** In terms of the resources you're providing, what sort of
14 material is provided? What sort of topics does the
15 college provide material on?

16 **A.** As a generalist college we provide material on almost
17 everything that can be covered across medicine or the
18 wide spread of it, and we provide it in different
19 formats. Sometimes we do webinars, and they have become
20 very popular during the pandemic, as we all turned to
21 electronic means of communicating, but we do have
22 face-to-face courses. We also have what we call our
23 Essential Knowledge Updates, which are providing
24 up-to-date knowledge on a quarterly basis that people
25 can work through courses. And then there's a range of

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1 curriculum, where we teach all the way through the
2 importance of looking at biases that can come into
3 thinking and in decision making, not just about the
4 clinical diagnosis but about the people that are in
5 front of you, whether you have unconscious bias there,
6 but also, then, in our materials, the teams are
7 conscious of what they're doing and how they fit them to
8 make sure it is not discriminatory, that it does include
9 everybody, and that any biases that might be present are
10 addressed during the CPD learning.

11 **Q.** I'm asked to ask whether any of your materials cover
12 listening to female voices, particularly in relation to
13 their symptoms and when they're experiencing pain and
14 how a woman's experience of illness is understood?

15 **A.** I don't know specifically on that, I'm sorry.

16 **Q.** Do you have any materials in relation to race
17 discrimination as well?

18 **A.** Yes, there are.

19 **Q.** Can you tell us a little bit more about what work the
20 college has done in relation to that?

21 **A.** So it's become a significant part of our college's work
22 on how we address race discrimination. Over the past
23 few years the college has been working on both the
24 college diversity and inclusion of our membership, as
25 well as our patient groups, as well. So there's been

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1 a task group led by our Chair and COO who have led this
 2 through the college. There are materials being put out
 3 our CPD, I know, has got a new module recently on
 4 unconscious bias, our curriculum is being reviewed
 5 completely to make sure there are no biases within that
 6 and it has gone on in every area of the college that we
 7 have.

8 **Q.** We've obviously discussed the provision of materials by
 9 the college, but there are also commercial organisations
 10 who may also provide CPD materials --

11 **A.** Yeah.

12 **Q.** -- is that right?

13 **A.** That's correct, yeah. And many GPs will go to
 14 commercial organisations as well. We have 54,000
 15 members as a college, there are many more GPs than that,
 16 and some people will exclusively use commercial
 17 providers as their CPD resource.

18 **Q.** Does the college have any involvement or oversight of
 19 those CPD resources that are provided commercially?

20 **A.** No.

21 **Q.** How is the continuing professional development of GPs
 22 monitored? You spoke a moment ago about appraisal.
 23 What's the system involved there?

24 **A.** So, annually, each GP has an appraisal with an external
 25 appraiser who has been appointed in England by

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1 may not have and those would come into the appraisal and
 2 to your CPD at that point.

3 **Q.** Given that flexibility of GPs of essentially trying to
 4 work out what they themselves need to be trained on, is
 5 there a risk that some GPs may not receive the training
 6 that objectively they do require?

7 **A.** Yeah, I think that's fair. We never know all our
 8 unknowns and they come up, and what we try to train
 9 people to do is to understand that that's -- to make
 10 that a smaller and smaller part of their knowledge, that
 11 with the feedback that we get, and patient feedback very
 12 directly in practices, when you're working in teams you
 13 become aware of what others think your gaps may be and
 14 then you spend the time doing your work on that.

15 But yes, there is also a risk that as GPs we don't
 16 know everything and we try to cover as much as possible
 17 and are aware of the curriculum but there is a risk.

18 **Q.** In relation to communication skills, how is that
 19 addressed within the appraisal process?

20 **A.** That probably mostly comes in the -- from the
 21 multi-source feedback and the patient feedback that we
 22 get on a five-yearly cycle as part of revalidation. The
 23 patients are asked specific questions about your
 24 communication and how much they understood, how much you
 25 communicated, and how they felt about the consultation.

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1 NHS England, who reviews with you your practice. It's
 2 usually a several-hour discussion. Before the pandemic,
 3 it relied on you providing an awful lot of evidence to
 4 show what you had done. That is less so during the
 5 pandemic, they have changed the model during that time,
 6 but your appraiser is there to check the areas of your
 7 working, that you're actually doing CPD that you're
 8 covering the areas of concern. If you've had any
 9 complaints or health issues or anything else those would
 10 be discussed during your appraisal as well.

11 **Q.** So, in terms of identifying a need for CPD that there is
 12 an area that perhaps the GP needs some input on or some
 13 training on, how is that identified?

14 **A.** Often we identify through self-reflection and the way
 15 they work. You obviously recognise that you have
 16 patients with problems that you've not been able to
 17 identify for yourself and that's all part of the GP
 18 training that we encourage people to be very mindful of
 19 what they do and don't know and reflect on each patient
 20 and the gaps in the knowledge there. But during your
 21 appraisal it's often a time -- we've also got, every
 22 five years, patient feedback and colleague feedback to
 23 arranged into that and, from that, you may find there
 24 are other issues that have come up, sometimes around not
 25 so much clinical issues but other skills that you may or

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1 Did they get the information required? And that's
 2 probably where it's assessed most objectively on
 3 a five-yearly basis.

4 **Q.** That would then be discussed with the appraiser?

5 **A.** The appraiser then discusses that with you afterwards.

6 **Q.** If there was a concern that a GP perhaps had entrenched
 7 attitudes or an unwillingness to adapt familiar
 8 practices, rather than needing new knowledge, if I can
 9 put it that way, how does CPD address that sort of
 10 issue?

11 **A.** At that point, if the appraiser was picking that up
 12 they'd probably guide you in your professional
 13 development plan for the following year, to focus on
 14 that area. Because we have appraisers often in many
 15 areas for two or three years they would be often coming
 16 back to it the following year to check had it been done,
 17 what had been done, had you got new evidence? And
 18 sometimes appraisers will ask for new evidence that
 19 an area has been covered, if they felt there was
 20 a significant weakness in that.

21 **Q.** What resources or training programmes are available to
 22 somebody faced who is with an appraiser saying
 23 "Actually, there are issues here that need to be
 24 addressed" that aren't a knowledge question, it's
 25 an attitude question?

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1 A. There are some courses available for that from
 2 commercial providers or from the college on other
 3 skills, whether it is bias training or that sort of
 4 thing. It can be -- there are courses there that
 5 doctors can access.

6 Q. Carrying on, on the same issue, if the appraiser has
 7 recommended something and the GP has not then engaged
 8 with that issue, what is the process then?

9 A. It's probably beyond my knowledge. I believe it goes
 10 towards the responsible officer for the area who then
 11 can address it.

12 Q. So it would be escalated?

13 A. Escalated.

14 Q. The Inquiry has heard about a number of guidelines that
 15 have been introduced over time and that there are
 16 a substantial number of guidelines coming in all the
 17 time. Starting off in England, how are GPs in England
 18 kept up to date with new guidelines?

19 A. With -- GPs face so many new guidelines coming often
 20 from specialist colleagues that it's very hard to keep
 21 up to date with that. There are many publications that
 22 will summarise guidelines and receive them in the post.
 23 The college tries very carefully in our CPD approach to
 24 inform GPs of new important things, our clinical policy
 25 team works on that as well as the CPD teams.

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1 hepatitis C, what can you tell us about the work that
 2 the Royal College has undertaken to increase the
 3 awareness of GPs about hepatitis C?

4 A. Since 2006 or 7, I believe, the college has been
 5 actively producing guidelines and information for GPs to
 6 update them. From when hepatitis C was a newer disease
 7 and not known as much, the college took a leading role
 8 in developing that and has updated guidance ever since
 9 to try to keep GPs to the forefront. Hepatitis B and C
 10 we have modules on and learning CPD resources, and those
 11 have been provided and updated to -- 2021, I think, was
 12 the latest review we've done of them.

13 Q. If we could turn to the guidance that the college
 14 produced in relation to the "prevention, testing
 15 treatment and management of hepatitis C in primary
 16 care", WITN7294006 -- I'm sorry 7249006. Apologies,
 17 I've got my numbers wrapped the wrong way.

18 We can see it's the Royal College of General
 19 Practitioners' guidance and if we turn to page 3, we can
 20 see the contents page setting out broadly what the
 21 guidance covers, including information about what
 22 hepatitis C is, the natural history of it, making the
 23 diagnosis, testing in general practice, referral and
 24 then over the page, treatment.

If we can then carry on to page 11, please. We can

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1 The organisations like NICE, the Institute of
 2 Clinical Health and Excellence, do send out emails
 3 regularly to tell us new guidelines are coming, so
 4 there's a wealth of places they come from. Choosing
 5 which ones you need to see is the harder part because
 6 there's so many, to know whether they relate to your
 7 primary care experience is difficult.

8 Q. How does it work in Scotland; are you able to assist
 9 with Scotland, Wales and Northern Ireland at all?

10 A. Probably no more than in my witness statement.

11 Q. Very well. For those listening, the witness statement
 12 reference is WITN7249001 and there is material there.

13 In relation to how best practice is embedded into
 14 GPs practice to ensure that day-to-day best practice is
 15 followed, how does that work for GPs?

16 A. Each practice will have their own systems and ways of
 17 doing that. As a college we encourage quality
 18 improvement activity and have seen that going into our
 19 QOF assessments, as well as for training, and so quality
 20 improvement activity also falls into our appraisals and
 21 each year quality improvement is something that GPs try
 22 to show that they've done. So that would be how we try
 23 and embed new things into practice to audit, review and
 24 improve the care.

25 Q. Moving out to being more specific in relation to

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1 see the heading "Transmission of hepatitis C", and
 2 further down we have the subheading "Blood transfusions
 3 and blood products":

4 "Prior to the introduction of screening of all blood
 5 donations in 1991, there was a risk to recipients of
 6 blood. A heat treatment process to protect blood
 7 clotting factors (used in the treatment of haemophilia)
 8 against hepatitis C and other viruses was introduced in
 9 the mid-1980s (treated Factor IX available in 1985 and
 10 Factor VIII in 1987). There is a high prevalence of
 11 hepatitis C in people with haemophilia who received
 12 untreated clotting factors before these dates. However,
 13 [hepatitis C] should still be considered in patients
 14 from overseas or who have travelled abroad, who have had
 15 blood transfusions or surgery."

16 This paragraph might be read as having a particular
 17 focus on those with haemophilia and those receiving
 18 treatment abroad, with only a relatively brief mention
 19 of those who have received blood transfusions in the UK,
 20 prior to 1991. Could you help us with why that emphasis
 21 might be there?

22 A. I think this was the 2006/7 guidance and I wasn't part
 23 of it at that stage. Whether it was that was the extent
 24 of the knowledge, I know that in the more recent
 25 documents that we've published, in the learning modules

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1 that there are, it focuses much more on blood
2 transfusions as well.
3 **SIR BRIAN LANGSTAFF:** I note in passing that in the middle
4 of the second-last sentence on the page it says:

5 "There is a high prevalence of hepatitis C in people
6 with haemophilia who received untreated clotting factors
7 before these dates."

8 In other words, before 1985 and 1987, so far as
9 Factor IX and Factor VIII were concerned.

10 I wonder whether that is strictly accurate,
11 Ms Fraser Butlin, because the evidence which the Inquiry
12 has is certainly there was a product in England produced
13 by BPL which was effective in respect of eliminating
14 hepatitis C non-A, non-B, as it was called at the time,
15 but that didn't mean that commercial products, which
16 formed around about half, if not more, of the products
17 supplied had the same protection, and it ought not to be
18 thought, I think, ought it, Ms Fraser Butlin, in
19 accordance with the evidence that we've heard, that
20 commercial product was free of hepatitis for some time
21 after that?

22 **MS FRASER BUTLIN:** Absolutely, sir. You've pre-empted
23 a further question I was going to raise of why those
24 dates had been used and --

25 **SIR BRIAN LANGSTAFF:** What does the footnote say?
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1 of hepatitis C, rather than a significant awareness of
2 those who have received blood transfusions in other
3 circumstances, in terms of obstetric care or trauma or
4 something like that?

5 **A.** I think today people are much more aware of a blood
6 transfusion having been somewhere that patients received
7 the blood and it was infected at the time. So I think
8 the knowledge now would be greater than it was whenever
9 that was 16 years ago, 15 years ago, that it's much more
10 widespread in UK centres, and it's an issue for GPs to
11 be aware of.

12 **Q.** But even as relatively recent as 2007, would it be fair
13 that perhaps the emphasis wasn't on those who had
14 received transfusions in the UK?

15 **A.** It would appear so from this.

16 **Q.** Could we then turn to page 15 of this document and we
17 see the heading "Who should be tested", and it says
18 this:

19 "The following people should be offered
20 a [hepatitis C] antibody test. It is good practice to
21 offer HIV, [hepatitis A] and [hepatitis B] testing along
22 with [hepatitis C] after the appropriate discussion."

23 Then at number 4 we see:

24 "Recipients of blood (before 1991) or blood products
25 (before 1986 in UK) and/or organ transplants (before
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1 **MS FRASER BUTLIN:** If I can just take a moment, footnote 41.
2 It refers to The Lancet study of 1997 by Derby, Ewart,
3 Giangrande and others in relation to the Haemophilia
4 Centre Directors Organisation "Mortality from liver
5 disease in haemophilic men and boys in the UK".

6 **SIR BRIAN LANGSTAFF:** Yes.

7 **MS FRASER BUTLIN:** So it just takes you to a reference but
8 it doesn't deal with that issue you have raised, sir, as
9 to whether that is actually an appropriate date.

10 **SIR BRIAN LANGSTAFF:** Yes, thank you. Well, I don't know if
11 that's been corrected in recent editions or is this the
12 most recent edition?

13 **A.** No, that's 2007, which is the first information that the
14 college had produced on hepatitis C at that stage. So
15 I'm sure in more recent editions it's been corrected but
16 I'll look to make sure --

17 **SIR BRIAN LANGSTAFF:** Well, you're sure?

18 **A.** I will make sure it is.

19 **SIR BRIAN LANGSTAFF:** You well make sure it is. Thank you.

20 **MS FRASER BUTLIN:** Just staying with that paragraph and that
21 emphasis on transmission in relation to those with
22 haemophilia and transmission where blood has been
23 received abroad, do you think that that is the
24 understanding of many GPs, that that's the primary issue
25 of blood transfusion and blood products and transmission
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1 1992)."

2 So the same issue about the dates arise.

3 Then number 12:

4 "Consider any patient with abnormal liver function
5 tests (LFT), especially elevated alanine
6 aminotransferase (ALT)."

7 In terms of the recipients of blood or blood
8 products, it might be suggested that this would assume
9 someone knew they had received blood. Was there any
10 recognition then, is there any recognition now, in
11 relation to the problems with medical records showing
12 someone's had blood and indeed the knowledge of
13 a patient who might have been unconscious, whether
14 they've had blood?

15 **A.** I think there's an awareness now that blood was given in
16 a different way in the 1970s and '80s than it is now,
17 without the very strict tracking of where blood has come
18 from and who it has gone to and I think we'll be aware
19 that in our older patients they may not have knowledge
20 of having blood during surgery or other procedures at
21 the time, nor would GPs have been aware that that
22 necessarily was being transferred to us through records.

23 **Q.** In terms of the point 12, of considering any patient
24 with abnormal liver function tests, when, as a GP, would
25 you consider testing or is the Royal College guidance on
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1 testing a patient when they have abnormal liver function
2 tests?

3 **A.** Yeah, I think we would now look at the NICE Guidance,
4 that's quite clear on when you should be testing and
5 when you should look at an abnormal ALT and the tests
6 that should be following it, one of which is hepatitis
7 screening, but also ultrasounds and tests. The more
8 common things that would produce this in patient groups
9 include fatty livers and alcohol-related disease. So we
10 would have those in that screen as well, as well as
11 ultrasounds and hepatitis screening.

12 **Q.** Then if we turn on to page 28, please. We see the
13 heading "Ongoing care", and we see a subheading -- if
14 you just go down to the bottom of the page, please,
15 Lawrence.

16 You see the heading "Ongoing care" and then
17 a subheading "Ongoing care during treatment, usually in
18 hospital", so there's a discussion there of blood tests,
19 ongoing advice regarding injecting medication, ongoing
20 support.

21 Then the next column, please, "Ongoing review/care
22 after treatment", with the relevant PCR testing.

23 Then the next heading "In general practice", there
24 are a series of points dealing with support of a patient
25 during their treatment for hepatitis C, provision of

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1 everything else that we do as part of a GP service. But
2 the disease itself would now be managed in secondary
3 care.

4 **Q.** So you've indicated there's up-to-date guidance which,
5 sir, I will ask those in the team to identify and ensure
6 that they are available on Relativity as soon as we can.
7 You've discussed some of the education materials that
8 have been produced. Have there been any other measures
9 taken to increase awareness of hepatitis C?

10 **A.** I think in each of the countries around the UK the RCGP
11 has done different things. Within Scotland, where they
12 have a high IV drug use population, where hepatitis C is
13 more common, they have done specific Scotland-related
14 initiatives. Beyond that, I'm afraid I don't know.

15 **Q.** Has there been anything else in England that you're
16 aware of?

17 **A.** Not that I'm aware of.

18 **SIR BRIAN LANGSTAFF:** Could we just go back to the very
19 first page of this document, because something caught my
20 eye in passing which I may want to ask a question about.

21 **MS FRASER BUTLIN:** Of course. Sir, did you mean page 1?

22 **SIR BRIAN LANGSTAFF:** I do.

23 **MS FRASER BUTLIN:** Do you mean the page we looked at --

24 **SIR BRIAN LANGSTAFF:** The cover page, yes.

25 **MS FRASER BUTLIN:** The cover page.

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1 ongoing general medical services to support the patient
2 through the treatment process, supporting patients on
3 therapy, giving practical advice to them on managing
4 side effects, ongoing support, ongoing harm reduction
5 information, et cetera, and some points about referrals.

6 It appears from this guidance that the ongoing care
7 in general practice in relation to hepatitis C comes to
8 an end when someone achieves a sustained virological
9 response. Is that fair, of what the guidance suggests,
10 or is there guidelines about what happens to the patient
11 after they've achieved sustained virological response?

12 **A.** I think treatment for hepatitis C has changed so much in
13 that time that our awareness in the hepatology units,
14 the secondary care colleagues, we would refer very
15 quickly. The management of that disease tends to sit
16 with our secondary care colleagues until they have
17 reached an endpoint which, I think these days, would not
18 just be on viral clearance. We would then get
19 information back as to what follow-up was required in
20 primary care or in secondary care, as well.

21 The main bit that stays with us and has always been
22 there is the holistic, ongoing care of the patient, who
23 has ongoing health needs. So that stays with general
24 practice and often that involves the support in managing
25 day-to-day living, as well as psychological and

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1 **SIR BRIAN LANGSTAFF:** I don't have the question, I think,
2 any more. Let me tell you what it arose out of. The
3 prevention, the drug -- the document is prepared by the
4 bodies set out there, and the first one caught my eye,
5 which was the RCGP Substance Misuse Unit, and then the
6 Sex, Drugs & HIV Task Group, which -- obviously someone
7 has got to write it -- but it might suggest,
8 particularly given your reference to unconscious biases,
9 that someone -- not yourself, I suggest -- but someone
10 reading this, might think "Oh, this is about this sort
11 of area", whereas, at this time in 2006, it wouldn't
12 have been really, would it?

13 **A.** It --

14 **SIR BRIAN LANGSTAFF:** It might have been more by way of
15 intravenous drug use but certainly there will be quite
16 a large component from those who have been infected by
17 blood or blood products?

18 **A.** I think at that time -- I was talking to our president
19 Professor Dame Clare Gerada yesterday about this paper
20 that she was one of those that was involved in the Drug
21 Misuse Unit at the time, but that was where the focus
22 was. It was in the IV drug use population where
23 hepatitis C had just become a real issue for them at
24 that stage, and we were understanding that this was the
25 first time that GPs were being given information around

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1 that, so it did focus on this area.

2 I think, at that stage, the awareness of it being
3 a blood transfusion as being a major contributor to
4 hepatitis C wasn't there as much at the time, amongst
5 the general practice side anyway.

6 **SIR BRIAN LANGSTAFF:** One of the side effects of that would
7 be that when patients came in to see a GP, they might be
8 faced with, "Well, what drugs have you had? What
9 alcohol have you been taking?" That sort of approach,
10 rather than asking questions about transfusion.

11 **A.** Absolutely.

12 **MS FRASER BUTLIN:** The next series of questions I want to
13 ask you relates to what might be said in submissions to
14 this Inquiry, that there remains a considerable
15 knowledge gap for many GPs about hepatitis C, and there
16 are a series of scenarios I want to discuss with you.
17 One issue that's been raised is that sometimes someone
18 might present to a GP over a period of time with
19 non-specific symptoms and mildly deranged liver function
20 tests, but hepatitis C testing doesn't follow for some
21 time.

22 What could be done to improve the knowledge and
23 awareness of GPs about the need for testing for
24 hepatitis C? Or do you think that issue has now been
25 addressed?

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1 look-back exercises that had already taken place.

2 The Inquiry has also heard evidence about the
3 limitations of those look-back exercises. What could be
4 done there, again, to improve the knowledge and
5 awareness of GPs about the issues surrounding infected
6 blood and the limitations of previous look-back
7 exercises?

8 **A.** I think doctors in general now are much more aware of
9 the risks of infected blood, not just for patients, but,
10 as we've run through hospitals during this time, of
11 needlestick injuries, everyone is very aware that the
12 screening for that includes hepatitis as well as HIV and
13 other diseases. So I think we're aware of blood-borne
14 disease as a real concept when maybe 15, 20 years ago it
15 wasn't in people's minds as much.

16 The look-back exercises, general practice records
17 are very good but only very good with the information
18 that general practice receives. And so if -- blood
19 transfusion will not be given in primary care except for
20 very specific military circumstances, I'm told, but --
21 so what we rely on is the information coming to us and
22 coding it. One suggestion I was given this week is that
23 on the electronic platforms that we do our consultations
24 on could have, as part of the onboarding for a new
25 patient and the new patient screens, not just what your

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1 **A.** I think the awareness will be greater now, that people
2 are aware that hepatitis C is a disease that's been
3 transferred in blood transfusions as well as through
4 intravenous drug use.

5 There are always -- a need to increase the knowledge
6 of specific diseases, of which, as a college, we hear
7 many, all the time, of things that where GPs have taken
8 time -- time to recognise disease. But I think it's
9 something, as a college, we're aware of, particularly me
10 attending today, has focused our mind on where we sit in
11 that blood -- in making GPs aware, again, of
12 hepatitis C.

13 I know my Scottish colleagues have done more
14 recently because with drug use in Scotland it has been
15 more of a problem, that they've needed to inform their
16 members because it was something they were all seeing
17 all the time.

18 How we do that, I'm not sure at this moment, but
19 certainly something we can consider as we move forward.

20 **Q.** Another scenario might be where someone has gone to
21 their GP and asked for a test for hepatitis C. The
22 Inquiry has heard evidence that, in some circumstances,
23 some GPs have either said it was unnecessary or said
24 that if the person had received an infected blood
25 transfusion then they would have been identified in the

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1 weight and alcohol is but have you ever had a blood
2 transfusion? So some of those might improve that.

3 **Q.** I want to come back to that thought in a moment. My
4 question was slightly different, in that how could --
5 what could be done to improve the knowledge and
6 awareness that look-backs weren't perfect in the past,
7 there were limitations, and so perhaps to address the
8 issue of where a GP might say to somebody, "Don't worry,
9 if you received an infected blood transfusion you'd know
10 about it"? What could be done to address that scenario?

11 **A.** I think that's probably an issue beyond general
12 practice, that is information to the public at large,
13 not just doctors, that look-back wasn't as effective as
14 we might have perceived it to be. And being aware of
15 those limitations to it, that's something that could
16 come to doctors, to be aware that your look-back
17 exercises weren't quite right or could come to the
18 public the other way round. So we're all aware of it
19 together. But I think that's not knowledge GPs would
20 necessarily have without somebody informing us that the
21 look-back hadn't been as accurate.

22 **Q.** Thirdly, in terms of evidence of people who have had
23 treatment for hepatitis C, they've achieved a sustained
24 virological response but they continue to suffer
25 ill health, the Inquiry has heard some evidence where

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1 GPs have then dismissed those concerns because they've
2 reached a sustained virological response. Again, what
3 could be done to improve the knowledge and awareness of
4 GPs about the ongoing health issues that arise from
5 chronic hepatitis C, even after having sustained the
6 virological response?

7 **A.** I think some of those are dealt with in the newer CPD
8 modules that I've looked at recently. I think that
9 awareness of hepatitis C as being a disease that is
10 there with long-term sequelae to it is something that we
11 could work out through the CPD side.

12 I was just thinking about the first question you
13 asked me about the person coming with non-specific
14 symptoms, and there are so many non-specific symptoms
15 that present to general practice every day that the
16 diagnostic process is based on step-by-step working
17 through them, and it is that awareness that when we get
18 the abnormal result, it is time to do the next step.
19 And hopefully in our more modern publications we do have
20 that, that raised ALT goes ahead to the hepatitis
21 screen.

22 **Q.** There's obviously a wide range of resources that the
23 Royal College is providing in terms of CPD. It might be
24 submitted, in light of the ongoing difficulties -- the
25 evidence of ongoing difficulties in terms of GPs having

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1 a blood transfusion, would it be fair, then, that
2 because in their region there weren't so many people who
3 were infected with hepatitis C through other means,
4 intravenous drug use, their GP might not perceive there
5 to be a need for that training?

6 **A.** I think with the current awareness, and I suspect from
7 the college as we put it out again, that I've been here
8 and will be informing members of that, that hepatitis C
9 will rise up and the importance of checking through or
10 reviewing patients that have had a transfusion in the
11 past when you've got it on the records, or with patients
12 if they tell you about it, that hepatitis C is one of
13 the risks and will have been coming through that and we
14 should be checking them.

15 **Q.** From your perspective, how effective are financial
16 incentives such as quality and outcomes, framework
17 payments, at changing approaches in general practice?

18 **A.** I think that's probably one for our policy team rather
19 than for myself. The QOF payments are -- they're --
20 I don't think there's any good evidence on how effective
21 they are for any GP to achieve change. People strive to
22 provide quality, and in fact when we had quality
23 improvement modules as part of the QOF, the college
24 supported them as a way to move them forward but,
25 actually, looking at specific areas rather than just

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1 that awareness, it might be suggested that this is
2 a cultural issue rather than a question of more
3 education. What can be done to change the culture of
4 how GPs operate?

5 **A.** Can you be more specific on the "cultural" issue?

6 **Q.** That although resources are being provided, change isn't
7 necessarily happening on the ground. I think it is
8 a general question of, how does one translate CPD and
9 knowledge into change on the ground?

10 **A.** I think, because of the nature of general practice, each
11 GP will probably have a different set of learning needs
12 each year. What we can -- to mandate that every GP in
13 the country would do hepatitis C training each year, or
14 even once in the next five years, may mean that many GPs
15 that don't see hepatitis C as part of their workload,
16 because their patient population is different, don't do
17 the training, and the others that really need it maybe
18 miss out for three or four years. So we tend not to
19 mandate anything specific except resuscitation training
20 and safeguarding training as the two things that we do
21 every year or every few years as part of a requirement.
22 But everything else is, hopefully through the appraisal
23 process and the GP's reflective behaviour, picked up and
24 done that way.

25 **Q.** But in terms of those who may have been infected through

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1 getting points for numbers.

2 **Q.** Could you see a case for incorporating hepatitis C
3 testing or hepatitis C-related outcomes into a framework
4 such as the QOF framework?

5 **A.** I think that's probably beyond the college's remit.

6 **Q.** Can you see a justification for assessing or spot
7 checking GPs for having undertaken hepatitis C CPD?

8 **A.** No, I think is probably the answer. I think if we were
9 specifically focusing on one disease, it will mean that
10 the GP's doing something different and may miss other
11 real learning gaps they have for that time. And it's
12 hard to know where that process would stop. Would we
13 spot check on every disease and see had we covered it?
14 We'd hope through the appraisal process, again, that
15 that would be picked up if there were gaps that were
16 significant.

17 **Q.** Finally, in terms of -- obviously today we've been
18 talking a lot about identifying individuals who have
19 been infected with hepatitis C by infected blood and
20 blood products but who haven't yet been identified.
21 Practically, what would the issues be, both positive and
22 negative, of having a mandatory requirement that
23 patients over a certain age are asked if they have had
24 or suspect they may have had a blood transfusion in the
25 past to then enable them to be tested?

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1 **A.** I think the biggest issue that springs to mind is
 2 resource, and how that would fit in to what's an
 3 overstretched, under-resourced -- the workload that
 4 would come with that, I think that would require an
 5 additional service as well as -- in addition to general
 6 practice, to actually have the resource to be able to do
 7 all these tests and follow up appropriately. Because
 8 inevitably I would feel we'd pick up patients who have
 9 positive hepatitis C that didn't know about it who would
 10 need the time and the expertise of someone to go through
 11 that with them rather than just being told, "You have
 12 a result that we've picked up in a test." It's not the
 13 same as -- the screening programmes that do go on have
 14 all been approved by the National Screening Committee,
 15 and they have the resources behind it to support the
 16 patients that have positive diagnoses. And I think if
 17 it was just as a mandatory requirement for general
 18 practice there would be no guarantee of that support and
 19 the systems were -- there alongside it, if we had -- if
 20 it came along.

21 **MS FRASER BUTLIN:** Those are the questions I have for
 22 Dr Mulholland. I obviously just need a short break to
 23 ascertain whether there are any further questions from
 24 the Recognised Legal Representatives.

25 **SIR BRIAN LANGSTAFF:** How long do you think you might need?
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1 questions, and they address various different things
 2 from our earlier discussion.

3 This morning, with the panel who gave evidence, it
 4 was discussed whether there should be requirement on GPs
 5 to test people for hepatitis C on a 'while you're there'
 6 basis, so much like blood pressure and diabetes.

7 **A.** Mm-hm.

8 **Q.** What would be the issues in terms of funding and
 9 staffing that would arise were such a requirement
 10 imposed?

11 **A.** I think the staffing is the biggest challenge. GPs run
 12 as independent businesses. We have a staff ratio that
 13 allows us to do the work that we know that we have.
 14 Anything we add in in addition to that means that the
 15 same people are doing an additional job rather than
 16 anything else, so probably reducing the work they're
 17 doing in some other area. So I think who would do this
 18 work if there's an additional -- if there's additional
 19 blood tests. Because it won't be while you're there, it
 20 would be at another appointment that you get your blood
 21 taken, usually by the phlebotomy team. So it really is
 22 around the workforce and how that would be fitted into
 23 whatever is the overstretched workflow problem we have
 24 in general practice already.

25 **Q.** Do you think it would be valuable for GPs to have
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1 **MS FRASER BUTLIN:** I think probably just ten minutes or call
 2 it 15.

3 **SIR BRIAN LANGSTAFF:** Well, we're getting close to the first
 4 afternoon break, so let's roll the two together, shall
 5 we?

6 **MS FRASER BUTLIN:** Yes, of course.

7 **SIR BRIAN LANGSTAFF:** -- and allow people to have a cup of
 8 tea, if they want.

9 Let me explain, Dr Mulholland. Those who are
 10 Core Participants and are represented have a right,
 11 through those legal representatives, to have questions
 12 put to you by counsel after hearing your evidence.
 13 Plainly, they haven't heard it all -- or haven't had
 14 a chance to reflect upon everything you've said just
 15 yet. They will, in the next 20 minutes or so. I can't
 16 say how many there will be. There may be a number of
 17 questions, there may be very few, but we will say not
 18 before 3.20 we'll come back. If it's any later than
 19 that, it'll be because there's a late question coming in,
 20 and you'll be told. But otherwise, not before 3.20.

21 **(3.01 pm)**
 22 **(A short break)**
 23 **(3.19 pm)**
 24 **SIR BRIAN LANGSTAFF:** Yes?
 25 **MS FRASER BUTLIN:** Dr Mulholland, I've just got three
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1 specific training on the issue of infected blood?

2 **A.** That's a difficult question because every disease it
 3 would be good for us all to have specific training on,
 4 and, as part of the professional process of CPD, it's
 5 self-driven. Knowing everything about everything is
 6 impossible, and there will always be diseases that a GP
 7 or many GPs will not know everything about. So specific
 8 training, it's probably very hard to work out who needs
 9 it, how to deliver it, where it would go to and what
 10 benefit it would actually make to the patients.

11 I think general training -- or general information
 12 and information sharing, both to doctors and to the
 13 public, that, "You may have had a transfusion in the
 14 past; if you've not discussed this with your doctor,
 15 please discuss it with them at some point" is probably
 16 a more useful way of that people who are affected by it
 17 to come forward. Because while you're -- a patient
 18 coming to see a GP about a specific problem may only
 19 still deal with that specific problem while they're
 20 there, because that's the priority at that moment.

21 How you would then -- what the extra training would
 22 achieve may not be as useful as having more information
 23 generally that infected blood was the source of HCV.

24 **Q.** Finally, do you think there's a risk that because
 25 previously GPs might have thought that everyone infected
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1 through infected blood would be identified in the
 2 look-back, then even now that might result in barriers
 3 to identifying people with hepatitis C who haven't yet
 4 been diagnosed?

5 **A.** I think identifying people that haven't been diagnosed
 6 is always challenging, both -- patients will need to
 7 know that they've had a transfusion and come forward
 8 from that side. Just GPs being aware -- I think these
 9 days people are more aware, certainly with the Inquiry
 10 being on the news and hearing so much about it over the
 11 past years, that we know there are patients still coming
 12 forward who are being diagnosed now -- I saw on some of
 13 the footage of the Inquiry -- 30 years later, for the
 14 first time this year. And I think (unclear) GPs are
 15 aware of that, and doctors are increasingly aware there
 16 could be more information shared that the look-back
 17 wasn't as effective as might have been imagined.

18 **MS FRASER BUTLIN:** Sir, I have no further questions. Do you
 19 have anything you would like to add?

20 **SIR BRIAN LANGSTAFF:** Yes, I do.
 21 Very early on in your evidence, you were talking
 22 about CPD, and you told us that a lot of GPs may choose
 23 to go to an independent provider, and that the college
 24 had no control over the independent provider. You will
 25 know as we all do, I think, that if you go onto the
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1 and scientists are looking for evidence-based courses
 2 and evidence-based information, but as a college we
 3 haven't tried to get involved in the quality of other
 4 people's work.

5 **SIR BRIAN LANGSTAFF:** The reason I ask in particular is that
 6 in certain professions, and I'm thinking of the Bar in
 7 this, amongst others, which I obviously have had
 8 experience of, my understanding is that the CPD courses
 9 or courses which are offered by the person who takes
 10 them as part of their CPD are actually approved as
 11 having so many hours CPD by the -- in this case, the
 12 Council of the Bar. That's the case, is it not?

13 **MS FRASER BUTLIN:** Not anymore, sir.

14 **SIR BRIAN LANGSTAFF:** Not anymore? Right. Well, it used to
 15 be the case.

16 **MS FRASER BUTLIN:** It did.

17 **A.** We do provide -- if provider wants a course accredited
 18 by us, we do offer that as a service from the college,
 19 and that would then be a stamp from the college,
 20 a Kite Mark, effectively, to say: this is RCGP
 21 recognised standard of information you're about to get.
 22 But that's very much a choice for the provider to make,
 23 not that we go looking for it or insist on it.

24 **SIR BRIAN LANGSTAFF:** Yes. Thank you.
 25 The second is this: again, it's relating to
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1 Internet and look at something which is related to
 2 healthcare, you will get -- how can I put this -- you
 3 will get a number of websites which are more reliable
 4 than others, which are certainly less reliable. And
 5 some of the less reliable ones may be thought to have
 6 more commercial influence than others.

7 **A.** Yeah.

8 **SIR BRIAN LANGSTAFF:** You're nodding. Is there any process
 9 or have you thought of any process by which the CP
 10 course offered by -- CPD course offered by an external
 11 provider is validated or approved, at least as to the
 12 curriculum and content, generally speaking, by the
 13 college?

14 **A.** The college hasn't been involved in that because we work
 15 at providing that curriculum and content for our own
 16 CPD. I know that other CPD companies take it as
 17 seriously as we do in their own way, and probably within
 18 general practice, although there are many things on the
 19 web that you could go to look at, there are a number of
 20 companies that run very effective courses and -- up to
 21 date, based on NICE guidance, and I think increasingly
 22 NICE guidance is used as the standard we all hold our
 23 CPD to. So if someone who is teaching outside what NICE
 24 or SIGN, in Scotland, are saying, people would question
 25 where the evidence is coming from. So I think doctors
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1 education. What we've heard a lot of, we've heard quite
 2 a bit of it today, and you yourself have been frank
 3 about the demands upon a GP's time, being a GP in these
 4 days, we were told in very clear terms by this morning's
 5 panel, involves a certain amount of stress, if you like,
 6 which has led to the general profile of the profession
 7 aging, people being less inclined to do it. And two
 8 things arise out of this. First is, is there any
 9 particular training available, whether it's CPD or
 10 general, for the GP themselves? They're one party to
 11 a conversation, after all, with the patient, in terms of
 12 their own resilience and their own -- how to deal with
 13 the stresses which they may experience in practice,
 14 particularly given the unpredictable demands that it may
 15 bring?

16 **A.** Increasingly with the workload and workforce pressures
 17 in general practice, and we know that the number of GPs
 18 full time equivalence is falling over the past years,
 19 whilst the population and the demands have risen, and we
 20 have 1.3 million consultations per day in general
 21 practice now, compared to about 1 million before the
 22 pandemic, that GPs are really struggling to maintain
 23 their resilience, as you say.

24 So many -- both the college and other CPD providers
 25 and local networks are working very hard to maintain GP
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1 wellbeing and health and resilience within that with
 2 courses with support. Unfortunately, what we see is GPs
 3 do do the job, they work 12-hour days very often but
 4 they do fewer of them to maintain the space in their
 5 lives and work-life balance to allow them to be able to
 6 do the full amount of work on the days when they're in.
 7 So we're seeing a knock-on in the profession that the GP
 8 numbers fall because the workforce or the demands of the
 9 workload are so high on the days they work.

10 So very often people are concentrating -- and we do
 11 it within the faculty structure in the college --
 12 provide courses on wellbeing and support and resilience
 13 for the GPs, so they can actually learn skills as well
 14 as support to get through it.

15 **SIR BRIAN LANGSTAFF:** May I ask, the job you do is
 16 voluntary, is it?

17 **A.** I'm paid a small amount for the sessions I do. So
 18 I work for the college as an officer. So in that role
 19 I'm paid.

20 **SIR BRIAN LANGSTAFF:** So in that role, you have time which
 21 is remunerated?

22 **A.** Yes.

23 **SIR BRIAN LANGSTAFF:** Is that true of those to who sit on
 24 the council of the college?

25 **A.** No, as a council member people do it voluntarily. So
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1 week, even if it's as a volunteer, it helps to stimulate
 2 the brain, it keeps them interested in the work, rather
 3 than just having to constantly go through large numbers
 4 of -- or large amounts of work on a day in practice.

5 **SIR BRIAN LANGSTAFF:** Thank you. The next question again
 6 arises really out of this morning's exchanges in
 7 evidence. We were told that, even though in Scotland
 8 it's now mandated that the discharge letter should refer
 9 to a blood transfusion, in about 50 per cent of cases it
 10 doesn't. Looking at the discharge letters you will have
 11 seen and those in your practice will have seen, so far
 12 as you are aware, is it the case that it is probably
 13 50 per cent or less of those letters will refer to
 14 a transfusion which, so far as -- again, depends on the
 15 information you've got about it -- so far as you know
 16 has or has most probably been given?

17 **A.** I think the number of discharge letters with blood
 18 transfusion on them is probably quite small, so most of
 19 my patients in the elderly population are going in with
 20 medical problems that don't need transfusion. Sometimes
 21 they do. But the numbers that we're receiving are quite
 22 small numbers saying transfusion on them.

23 **SIR BRIAN LANGSTAFF:** So the probability is that they're not
 24 recording all of them?

25 **A.** I don't know about the recording in hospital.
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1 I was a council member for some years before I was
 2 an officer and that's a voluntary role.

3 **SIR BRIAN LANGSTAFF:** So they will be giving their time,
 4 which they can ill afford to give, given the demands of
 5 practice, in order to deal with the general interests of
 6 the profession. This is maybe a difficult question for
 7 you to answer but does that risk the quality of
 8 leadership being less strong than it used to be?

9 **A.** As a GP leader, it's a difficult question to answer,
 10 but --

11 **SIR BRIAN LANGSTAFF:** Well, the word is "risk". I'm not
 12 asking you to say, "Yes, that's the case", unless you
 13 think that is.

14 **A.** No, I think the quality of leadership we're seeing
 15 coming through, particularly from our younger members as
 16 well in the college, is as strong as it always has been
 17 but people are now seeing that as part of their career
 18 and factoring the time required in their workload but as
 19 a voluntary role. So we have volunteers working in our
 20 faculties, we have volunteers working on various
 21 projects through the college on the assessment of
 22 evidence and other parts and these people will see it as
 23 they -- it helps balance some of the resilience from
 24 practice.

25 If they're doing a different job for part of the
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1 I wouldn't want to guess what they record.

2 **SIR BRIAN LANGSTAFF:** You can't know without that --

3 **A.** No, we can't know without --

4 **SIR BRIAN LANGSTAFF:** -- but if, as a matter of general
 5 practice, you might expect a certain proportion of
 6 patients who have been in hospital for various
 7 conditions to have had transfusions and if you're
 8 getting actually very few letters which say "Yes, so and
 9 so had a transfusion of whatever", then chances are that
 10 some are not being recorded.

11 **A.** Possibly, yes.

12 **SIR BRIAN LANGSTAFF:** Thank you. That's all I ask.

13 **MS FRASER BUTLIN:** Dr Mulholland, is there anything else you
 14 would like to add?

15 **A.** May I make a statement?

16 **MS FRASER BUTLIN:** Please do.

17 **A.** Good afternoon, thank you. I'm Michael Mulholland, a GP
 18 in Buckinghamshire and honorary secretary of the Royal
 19 College of GPs. The RCGP is the largest medical royal
 20 college and it represents over 54,000 family doctors in
 21 the UK. Our mission since we were founded 70 years ago
 22 has always been to raise the standards of patient care
 23 I've been asked by my college in coming here today to
 24 add to my evidence that we send our sympathy to everyone
 25 whose life has been impacted and to their families.
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1 Lessons must be learnt from the experience and the
 2 college will play our part in preventing anything
 3 similar happening in the future.
 4 **SIR BRIAN LANGSTAFF:** Thank you for that, and thank you for
 5 your evidence, particularly given what we've just been
 6 saying about the busyness of a GP's practice and role.
 7 **THE WITNESS:** Thank you.
 8 **MS FRASER BUTLIN:** Sir, that concludes the evidence for
 9 today.
 10 Tomorrow we will be hearing from Professor Sir
 11 Jonathan Van-Tam.
 12 **SIR BRIAN LANGSTAFF:** Yes, Professor Sir Jonathan Van-Tam
 13 tomorrow, 10.00.
 14 **(3.34 pm)**
 15 **(The hearing adjourned until 10.00 am the following day)**
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1	I N D E X	
2		
3	PROFESSOR GRAHAM RUSSELL FOSTER	2
4	(affirmed)	
5		
6	PROFESSOR JOHN FRANCIS DILLON	2
7	(sworn)	
8		
9	DR BRENDAN HEALY (affirmed)	2
10		
11	DR JOANNE MCCLEAN (affirmed)	2
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13	Questioned by MS FRASER BUTLIN	2
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15	DR MICHAEL NIAL CONNOR MULHOLLAND	109
16	(affirmed)	
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18	Questioned by MS FRASER BUTLIN	109
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