

Wednesday, 27 January 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Ms Richards.

MS RICHARDS: Good morning, sir.

SIR BRIAN LANGSTAFF: We're ready to go. Everyone is in the same places that they were before. I can tell you that yesterday you had just over 200 people watching, so welcome to them if they have as many today, and just to let you on the Panel know the size of the audience that you've got. Ms Richards.

MS RICHARDS: I wanted to ask you first about emergency treatment and the extent to which the requirements for informed consent might be modified in an emergency.

First of all, is this right, that the fact that treatment is required urgently doesn't automatically or necessarily curtail the requirement for informed consent?

PROFESSOR CAVE: Yes, that's correct. If it's possible still to get informed consent then informed consent should be taken.

MS RICHARDS: So if the patient is conscious and the patient is capacitous, although the circumstances in which you're explaining the risks may be less than ideal and time may be limited, it is still incumbent upon the clinician within those parameters to explain,

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rationale for what's being done. So you're urgently and seriously unwell, you need this in order to breathe and then when the person has recovered somewhat, then you can be given more information about what it was, what the risks are, what the benefits are and how it's going to be used, and alternatives into the future.

So the consent still happens it just happens in a particular way.

PROFESSOR SAVULESCU: I would go a little bit further than Ian. So I think one issue is whether you can genuinely imply or there's implicit consent, so in Ian's example you can imply consent to the bronchodilator in somebody who has asthma but, secondly, all of these values, such as informed consent, best interests, have to be weighed against each other. So if a delay was going to compromise the person seriously then, even though the person has capacity and is capable of giving informed consent, you might proceed with treatment. So if you have seconds to make a decision, you aren't going to obtain informed consent in that situation.

So it's a question of: can informed consent be reasonably implied, will obtaining informed consent significantly harm the patient? But, as a general

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in accordance with the principles you articulated yesterday, what the risks are, what alternatives there might be and possible consequences of the different options.

Is that an accurate summary?

PROFESSOR CAVE: Yes.

MS RICHARDS: Professor Kerridge?

PROFESSOR KERRIDGE: Look, I think it's broadly true but, depending on the circumstances and the urgency of the emergency, if you will, that will certainly modify the type of consent that's gained and it certainly won't be fully informed, it will be sufficiently informed or adequately informed. If, for example, somebody comes into an Emergency Department with a severe episode of asthma, struggling to breathe, they have capacity, they can understand how sick they are, they understand the situation they are in, they know they need treatment but they are genuinely struggling to breathe, to spend the time before giving them a medication to open up their airways, explaining the risks and benefits of a bronchodilator would be absurd in the extreme.

So I think it would modify the information that would be given and it may mean that what is simply given in the initial period is a justification or

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rule, it's completely correct that if you can obtain it without harming the patient you should.

MS RICHARDS: The GMC guidance which you have referred to in your report, about the scope of permissible treatment in an emergency, suggests that the treatment should be limited to what's immediately necessary to save life or avoid significant deterioration of health and should be the least restrictive of the patient's future choices.

Does that, in your view, correctly reflect the ethical position?

PROFESSOR KERRIDGE: I think it does. There is a bit of a problem here, of course, for physicians or surgeons because a definition of what is an emergency or what is urgent is extremely vague and, at times, it can be misinterpreted to include things that actually aren't required at the time. Surgery that can be put off for a longer period of time, transfusions that are actually not necessary for a series of hours, as opposed to ones that are necessary immediately.

So I think it is beholden upon the clinician to make an assessment about what actually is required at that particular time and what needs to be urgently administered for that patient's best interests.

MS RICHARDS: If treatment is undertaken without informed

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consent because it is a genuine emergency, where there are only seconds or minutes and there is no means of obtaining informed consent, the patient may be unconscious for example, is there then an ethical obligation, assuming the patient recovers, regains consciousness and is able to engage in dialogue with the clinician, is there then an ethical obligation to ensure that the patient is informed what treatment they have received, blood transfusion, surgery, nature of surgery, and informed at that stage of what the risks are/were, so that even though those risks may already have been run they know to, for example, see whether their health requires to be monitored on an ongoing basis or whether they need to make lifestyle adaptations?

Professor Kerridge -- Professor Farsides.

PROFESSOR FARSIDES: Sorry, I think it's clear that that sort of explanation would be necessary and I'd just add one more potential element to the decision-making in an emergency situation.

Some people have referred in the past to the notion of hypothetical consent, which is bringing a judgment of reasonableness to the measures that you take in an emergency situation, so that you think you are doing something that the patient would reasonably

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the carers who can be involved in that consent process contemporaneously.

Again, that may be truncated in some way but that certainly can continue at the time that emergency treatment is being offered. So taking someone's partner aside and explaining what needs to be done and why it needs to be done urgently and what the options are, that sort of decision can very reasonably take place and invariably does, and that also can then be documented in the record as to who was involved in the decision-making at the time, what were they told, what did they understand. Then when the person who's received that treatment regains capacity then they can be fully informed as to what's actually occurred.

MS RICHARDS: Professor Farsides?

PROFESSOR FARSIDES: That's fine. I was simply affirming what you said earlier.

MS RICHARDS: Then, more broadly -- so this question is not limited to emergency situations -- is it ever ethically acceptable not to tell a capacitous patient about risks or to falsely advise a patient that a treatment is safe for fear that the patient will decline the recommended treatment, a course which the clinician believes is not in their best interests?

DR KAZARIAN: I don't think that would be ethical and,

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accept, then you feel more secure in what you're doing and when you come to the explanation afterwards, hopefully, there is the possibility of someone understanding quite easily why you took those steps and only those steps in the emergency situation.

MS RICHARDS: Is there also an ethical obligation to ensure that treatment received without consent because of a genuine emergency is properly documented and recorded in the patient's records so that there is a clear explanation of what the patient received and why and what possible risks that might lead to?

PROFESSOR KERRIDGE: Absolutely, there is. Sorry, Bobbie.

PROFESSOR FARSIDES: No, you go ahead, Ian.

PROFESSOR KERRIDGE: Please follow on from me.

I think there's absolutely an obligation to record that but, of course, the other part of this scenario that we're missing is that, in emergency settings almost all of the time, certainly in hospital settings, there isn't a single clinician there. There are many people around and it's often in fact the case that there will be a group of health professionals who are administering urgent treatment to the patient and, at the same time, there is invariably someone whose task it is to be speaking with the surrogate decision-makers, the family members, the loved ones,

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like you said yesterday, the patient needs to be informed of the risks, particularly the risks *that are material to them*, *that are* significant to them, so it will be important to inform the patient, even if that might mean that they refuse this particular treatment.

PROFESSOR SAVULESCU: The only circumstance I could imagine where something like that might operate is where treatment of one person is necessary to protect others in a public health emergency. But there I think you would have to invoke a legal instrument to treat the person against their will. So I think it could never be the case that if you have capacity and the treatment is being proposed in your interests that you could fail to give informed consent.

MS RICHARDS: Professor Cave.

PROFESSOR CAVE: Let me just add that a therapeutic exception only applies in the case where there is likely to be serious harm to the patient and the scenario you set out doesn't involve there being serious harm.

SIR BRIAN LANGSTAFF: If I may just comment, and tell me, please, if you think this is wrong, but in the scenario which was posed by Ms Richards, in effect, the clinician is taking the decision for the patient because he knows, or she knows, what the patient

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1 really wants, or at least suspects, what they might
2 really want and is using knowledge as a form of
3 control, denying knowledge in this case, in order to
4 ensure that the patient takes the decision which, had
5 they been fully informed, he thinks they would not
6 have taken.

7 So it's totally objectionable, isn't it?

8 **PROFESSOR SAVULESCU:** Yes.

9 **PROFESSOR FARSIDES:** Absolutely.

10 **PROFESSOR KERRIDGE:** Yes, and certainly none of that would
11 provide a basis for lying to somebody. So deceiving
12 them about the safety or otherwise of the test. The
13 therapeutic privilege doesn't allow you to lie. It
14 may allow you to withhold some information but it
15 certainly doesn't allow you to lie.

16 **PROFESSOR FARSIDES:** But unless you at some point raised
17 the issue of risk and associated that with the
18 treatment that you are assuming the patient wants
19 because of their wishes and the outcome that they hope
20 for, you don't know whether that is actually what they
21 want because they have the right and the ability to
22 weigh up the significance of that risk against their
23 overall goals.

24 **PROFESSOR SAVULESCU:** It's well established that people
25 can refuse even life-saving treatment. So it could

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1 other infection or condition, is available and
2 assuming it's available on the NHS, it's up to
3 a patient to decide whether or not to have that test
4 because of the autonomy principle as articulated by
5 you yesterday; is that correct?

6 **PROFESSOR KERRIDGE:** Yes.

7 **MS RICHARDS:** So you have said in terms in your report
8 it's not ethical to test a person with capacity for
9 such a condition without their consent.

10 Are there any circumstances, for the moment
11 leaving aside public health emergencies -- I will come
12 back to that. Are there any circumstances in which
13 you can consider it could be ethical to test a person
14 with capacity for a condition of that kind without
15 their consent?

16 **PROFESSOR SAVULESCU:** Here, I think you need to
17 distinguish between implicit and explicit consent.
18 Certainly, 30 years ago when I was practising, I saw
19 tests ordered for patients without their explicit
20 consent (for example, syphilis serology was regularly
21 ordered, and ordered on pregnant women without their
22 explicit consent), and the idea was that people come
23 for healthcare, and the doctor is ordering the tests
24 that are necessary for their healthcare or their
25 fetus's health.

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1 have been the case that any kind of benefit to the
2 patient would warrant overriding their consent.

3 **MS RICHARDS:** I want to move --

4 **PROFESSOR KERRIDGE:** The other thing, Sir Brian, you
5 mentioned, you know, a clinician making an assumption
6 about what the patient would want because of how well
7 they know that patient. I mean, Bobbie's an empirical
8 ethicist but there's a huge amount of literature that
9 suggests that clinicians are rubbish at predicting,
10 you know, or knowing full well what patients want by,
11 you know, a genuine and deep knowledge of their
12 values. I mean, I might say other health
13 professionals are also rubbish, sometimes slightly
14 less, but doctors are particularly bad at it. But
15 even patients' loved ones are also particularly bad at
16 knowing full well what someone would want. So all of
17 this provides empirical support for the idea that you
18 have to have that conversation.

19 **MS RICHARDS:** I'm going to ask next about testing, testing
20 for infection. You've dealt with it in some detail in
21 your report and we discussed what I think are the
22 applicable principles yesterday, so I may be able to
23 take this relatively shortly.

24 As I understand your report, if a test for
25 a condition, whether it's hepatitis or HIV or some

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1 Around the 1980s at the time of HIV, that
2 expectation changed, and it no longer became
3 reasonable to imply consent for certain kinds of
4 tests. But, certainly, you know, most tests people
5 don't provide explicit consent for and, in the past,
6 those included controversial tests like syphilis
7 serology. I don't know, Ian, if you agree with that?

8 **PROFESSOR KERRIDGE:** I would agree with that. It's -- and
9 I suppose it goes to the specificity or the extent of
10 consent. When most patients come into contact with
11 a health service, and they -- not in an emergency
12 situation but in sort of less emergent situations,
13 they might have a range of blood tests which might
14 include 50 different indices, testing a whole range of
15 organ system function, and electrolytes, and bone
16 marrow function, immunological function and the like,
17 and it's generally not the case that patients are
18 asked for explicit consent for each of those indices.
19 They are asked for a broad consent, if you want, for
20 health testing in the context of medical treatment;
21 not so much specific testing.

22 **PROFESSOR FARSIDES:** I think that's a really helpful
23 example as well because conducting research around the
24 year 2000 on antenatal screening and testing, there
25 had been this comfortable system where you presented

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as a pregnant woman, and you just accepted the tests that were taken in the understanding that they were to benefit you and the foetus and your subsequent child. And yet syphilis, which would be a very stigmatising condition to reveal and one that could cause family disruption, wasn't commented on. But the emergence of an HIV test in the antenatal setting was thought to be something that did need to then bring in discussion about the extent to which you specified the tests that you agreed to in pregnancy.

So I think, again, going back to one of the questions yesterday, this was a context within which the emergence of HIV did change practice.

PROFESSOR CAVE: Just to follow up on that point, if I may. There are varying ways in which consent can be obtained. So in relation to certain blood-borne viruses, there is in some settings the possibility of an opt-out consent where, for example, in antenatal appointments, in the first appointment consent will be sought from a patient asking if they are willing to be tested for HIV and explaining why, and then it could be that they would agree that in subsequent appointments, without having to go through that again for the duration of pregnancy, then the same sort of tests might occur.

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a qualitative different kind of test. Just as genetic tests are treated differently to other tests -- so HIV and, indeed, I think syphilis would be treated differently than, you know, your liver function tests or your kidney function tests or your, you know, level of anaemia.

PROFESSOR KERRIDGE: I think, just to follow that up, determining what types of test require specific consent and what types of things can be covered by broader consent, if you want, that's certainly changed over time, sometimes for very good reason, like the reasons now that we do get explicit consent for testing for infectious diseases that may be passaged by blood, sometimes just for cultural or historical reasons, because of stigma attached to particular test results, and sometimes just because of changes in science, and things that seemed significant previously become less significant, things believed not so significant become more significant with developments in science.

MS RICHARDS: You have identified in your report in the context of testing for infection the kind of information that should be provided by the clinician, and I'll just -- well, in fact, I will put that on screen because I think it might be useful just for

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My understanding is that the same sort of thing has happened in prisons and part of this is to ensure that there isn't -- that there isn't a problem with missing too many opportunities to treat as early as possible for patients that might be particularly high risk in relation to the prison setting.

MS RICHARDS: I understand from Professor Kerridge's answer that there may be good practical reasons why, if a suite of 50 tests are being performed upon a blood sample, a clinician may not wish to be explaining what each and every test is for and what each and every test entails.

What's the qualitative difference in ethical terms between that and what is the now, as I understand it, generally accepted position, and accepted at least from the 1980s on the basis of your evidence, for treating, testing for HIV, or for syphilis or for hepatitis differently?

PROFESSOR SAVULESCU: The implications of having abnormal, say, liver function are vastly different to the implications of having HIV for your life, for stigmatisation, for employment, for insurance, for a whole range of aspects of your life --

PROFESSOR KERRIDGE: Or others.

PROFESSOR SAVULESCU: And for others. So it is, you know,

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others to follow the text. Soumik, could we have the expert report on the screen, please. The internal pagination is page 63, it will probably be page 67 electronically. It's page 63 if you look at the page numbers at the bottom.

If you go back, it's page 63 using the pagination at bottom, please. Thank you.

So if we look at the list of bullet points there, you've said this:

"In the context of testing for infection, information should be provided about:

"The nature of the test and its implication for well-being, whether experimental/unproven.

"Information relating to both the test and the condition for which it is done. This includes medical indication, utility of the test, risks of the test, the value of the knowledge, alternatives to testing ... cost of the test, who does the testing and who will deal with the information ... implications of testing, for example, for insurance and employment.

"The voluntary nature of the testing and ability to withdraw consent.

"Obligations flowing from test, such as the obligation to inform others.

"Confidentiality and its limits.

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1 "Public health and interest justifications for
2 testing.
3 "Any costs to the patient.
4 "The opportunity to ask questions and time to
5 make a decision."

6 So this would be what we would describe
7 pre-test counselling; is that correct?
8 Professor Kerridge?

9 **PROFESSOR KERRIDGE:** Yes, yes.

10 **MS RICHARDS:** You are addressing here, I think, the
11 current understanding of the kind of processes that
12 would be undertaken. Are you able to assist us with
13 when historically a concept of some form of pre-test
14 counselling, albeit not necessarily encompassing each
15 and every one of these limbs, first became recognised
16 by clinicians or, indeed, by ethicists?

17 **PROFESSOR KERRIDGE:** Goodness. Broadly, I think there's
18 no question that there's been a change in practice
19 over time in terms of the type of information that's
20 given to patients prior to testing. Prior to the
21 1970s/1980s, I think it's fair to say that there would
22 have been very limited information of this kind given
23 to patients prior to testing, whereas at the current
24 time most of these things would be discussed most of
25 the time.

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1 well.

2 **MS RICHARDS:** Professor Cave?

3 **PROFESSOR CAVE:** Just to add to that, I think the
4 conversations that we have had yesterday about
5 informed consent speak to this. It may not have been
6 referred to in the 1980s as counselling, as such, but
7 there was recognition, certainly from 1988, that
8 informed consent was needed for testing for infection
9 and informed consent was about giving the advice
10 needed in order to be able to make a decision. The
11 list that you see there is the information that, in
12 that particular context, was needed in order to be
13 able to make an autonomous decision. It will have had
14 a different name, perhaps, and won't have been spelt
15 out in quite as much detail but that's, I think, what
16 was underlying it.

17 **MS RICHARDS:** The reference to 1988, is that a reference
18 to the decision-making, recommendations and materials
19 that emerged in 1988 in relation to HIV testing?

20 **PROFESSOR CAVE:** That's right. That's the GMC document
21 I'm referring to, which made it clear that for
22 testing, as well as for treatment, informed consent
23 was required.

24 **MS RICHARDS:** Can I then turn to the question of telling
25 the patient the result of a test. Again, I'm not here

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1 There would be some -- and I'd go to, you know,
2 the second bullet point from the bottom, the costs to
3 the patient. There's just been a report released here
4 in Australia regarding financial consent to health,
5 which is predicated around the idea that patients are
6 given very little information about the costs of
7 testing, the costs of treatment, alternatives and out
8 of pocket expenses and so forth, at least in this
9 country. So at this stage already, there's already
10 a number of things here that are not covered.

11 But over the certainly 1980s, 1990s and largely
12 as a consequence of possibly two areas of practice --
13 one was the identification of blood-borne infections,
14 and particularly HIV, and the other was the emergence
15 of and expansion of genetic testing -- the idea of
16 pre-test counselling became much more a part of both
17 ethical and clinical and legal dialogue.

18 **PROFESSOR SAVULESCU:** I think -- I agree with Ian.
19 I think pre-test counselling has been a standard part
20 of genetic testing since very early on. So, I would
21 say, at least from the early 1980s it was a part of
22 genetic counselling and standard for clinical
23 genetics. But, I would say that the late 1980s is
24 when it became standard for HIV and infectious
25 diseases, at least in Australia but I suspect here as

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1 talking about the suite of 50 tests that might have
2 been undertaken to assess the health of different
3 aspects of bodily organs. But if a clinician has
4 a test result for a diagnosable condition, such as HIV
5 or hepatitis C, but it would presumably apply more
6 generally, and assuming the patient is not exercising
7 the right not to know, as they may do, for example, in
8 Huntington's disease or some other scenarios, would it
9 ever have been ethical, is it ethical, not to tell the
10 patient the result of that test, not to tell them
11 their diagnosis.

12 **DR KAZARIAN:** No, I think once a diagnosis is known by the
13 doctor, then the doctor needs to inform the patient
14 because, as we said in our report, without that
15 information the patient cannot actually exercise their
16 autonomous choice about what to do next and what kind
17 of treatment to explore, what kind of options to
18 explore and they will need accurate and transparent
19 information about this particular diagnosis, even if
20 it means doing nothing.

21 **MS RICHARDS:** In the case of an infectious disease --
22 sorry, Professor Savulescu?

23 **PROFESSOR SAVULESCU:** I think that's true but I think that
24 they certainly have to offer to disclose the result to
25 the patient and give the patient the choice whether

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1 they want to know the result. I'm not clear whether
2 ethically it's required for them to tell the patient
3 the result without first inviting the patient to
4 express their preferences about knowing the result of
5 that test. I think patients should know but that,
6 again, is a fringe position and I think the standard
7 position would be patients must be offered the
8 opportunity to have that information if they want.

9 **MS RICHARDS:** Professor Farsides?

10 **PROFESSOR FARSIDES:** Sorry, this really relates to your
11 previous question but I think it now relates to what
12 Julian said. I think a good example of the extent to
13 which we feel a patient should be in control of
14 information around testing for these sorts of
15 conditions is what happens if there has been a needle
16 stick injury in the context of medical treatment.
17 Theoretically, with any patient, that raises the
18 possibility of a healthcare professional or, as we
19 have to often deal with, a medical student being put
20 at a risk of infectious disease. It is still
21 absolutely imperative that the patient is asked
22 whether or not a test can be conducted and also it's
23 discussed with them what to do with the results of
24 that test. If a patient refuses then, in practical
25 terms, it means three months of prophylactic treatment

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1 be some situations where, given the level of
2 paternalism at the time, that there were other factors
3 that might have been brought in to making this
4 decision about when or whether to tell a patient this
5 information.

6 **MS RICHARDS:** If --

7 **PROFESSOR FARSIDES:** Sorry. I wonder if Ian would also
8 agree that sometimes a clinician might come under
9 pressure from family members, in terms of disclosure
10 of all sorts of medical information, and if something
11 is seen as particularly stigmatising or a difficult
12 diagnosis to manage socially, it may well be that the
13 clinician has been directly approached by family
14 members on this issue.

15 **PROFESSOR KERRIDGE:** Yes, thanks, Bobbie. That's actually
16 very common in this part of the world. Not so much,
17 interestingly, in relation to infectious diseases
18 which may be in the West are intensely stigmatising.
19 But in relation to cancer diagnoses in Vietnamese
20 populations, some South East Asian populations and
21 some parts of China, there's a huge family pressure
22 not to disclose cancer diagnoses to older parents but
23 for that information to be retained by their children
24 as a way of sort of managing the hope and expectations
25 and life goals of the parents and allow the family

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1 for the healthcare professional, a lot of uncertainty,
2 but that's an absolute red line in the sand.

3 So, I think, the fact that even when we can see
4 a direct risk to others sitting alongside a decision
5 not to be tested, we still leave that decision with
6 the patient.

7 **MS RICHARDS:** Yes, Professor Cave?

8 **PROFESSOR CAVE:** We've discussed the possibility that,
9 contrary to ethical advice, some patients may not have
10 been aware that they've been tested. If empirically
11 we imagine that situation and then we look at the
12 theoretical possibility that actually there was
13 potentially insufficient certainty about that test and
14 what it means at a particular point, if in theory it
15 was felt at that particular point of time that there
16 was no direct risk to the patient or to others and
17 that there was nothing that a patient could do or
18 anybody else could do, then you could construct
19 a situation whereby a clinician might have thought it
20 wasn't in the best interests of the patient to know
21 a particular result. But we really are building
22 theory on top of theory and fiction on top of fiction
23 there. I think it's very unlikely that you will get
24 a situation where all those things occurred.

25 I just wanted to make the point that there may

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1 unit the autonomous control of that information. That
2 can be a really difficult situation for physicians.

3 The College of Physicians here in Australia has
4 actually just taken this seriously enough that they
5 have produced some guidance and educational resources
6 for junior doctors as to how to deal with that or
7 mediate that type of conflict.

8 **MS RICHARDS:** Presumably in the kind of scenario that you
9 describe, Professor Kerridge, although practically it
10 may be an extremely difficult situation for the
11 clinician to manage, ethically there's really only one
12 answer in light of the principles that you have all
13 been articulating which is: it's the patient's
14 decision, not their child or any other family member.

15 **PROFESSOR KERRIDGE:** No, I disagree. I don't think it is
16 quite so clear. I think there may be very good
17 reasons arising out of cultural respect to actually
18 accept that there may be different ideas about
19 autonomy, and there may be different approaches to
20 giving information. We may still want to give that
21 diagnosis to an aged person, but it may be reasonable
22 under that circumstance to spend days, weeks having
23 conversations about how that information could be
24 given, encouraging people to think through the
25 implications of not giving that information.

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1 So I don't think it's completely clear that you
2 would immediately adapt the idea that that autonomous
3 person must know that information in all
4 circumstances.

5 **PROFESSOR SAVULESCU:** I would disagree with Ian, my
6 colleague, there.

7 **PROFESSOR KERRIDGE:** That's all right.

8 **PROFESSOR SAVULESCU:** I agree with you, you might take
9 some time to understand how to give the information.
10 I completely agree with that, but I do believe that in
11 the end, that person should have the opportunity
12 themselves to make a decision at least about whether
13 to receive that information or not. So we have
14 a disagreement, and I think it's a reasonable
15 disagreement.

16 **SIR BRIAN LANGSTAFF:** May I ask a question here?
17 The hypothesis that a clinician may, as it
18 were, hide the test result from a patient, which
19 Professor Cave mentioned, means that the patient won't
20 be told there is a result. If the patient's going to
21 exercise autonomy properly, don't they need to know if
22 there is a result before they are asked, in effect,
23 whether they want to know it or not? And is perhaps
24 the answer to the cultural question, in certain
25 communities where there may be different cultures,

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1 is undertaken, and then further work around the
2 sharing and interpretation of the results.

3 **MS RICHARDS:** Professor Cave.

4 **PROFESSOR CAVE:** I just wanted to add that the point
5 I made very briefly was explanatory rather than
6 justificatory. We have stated very clearly that we
7 think there should be openness about the fact that
8 there was a test and about the test results.

9 **PROFESSOR SAVULESCU:** We talked yesterday about moral
10 relativism, and I think this is a good case where
11 cultural relativism comes up against what has been
12 called in the report moral objectivism, and that's
13 just a fundamental philosophical disagreement. And
14 I think there are some values, and that's the movement
15 of universal human rights, and in particular respect
16 for people's autonomy that cross cultures, and I think
17 this is a very good example where you have to go on
18 one side of the fence.

19 **PROFESSOR KERRIDGE:** Maybe just to clarify, I actually
20 agree with Julian. I wasn't necessarily arguing for
21 non-disclosure, but just arguing against the idea of
22 simplicity and suggesting there might be a long and
23 involved conversation. But I do think it is the
24 individual's right to have that information.
25 But I think it's -- and it's -- just to take up

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1 that if the patient is aware there is a result, he may
2 say, "Well, don't tell me. Tell my children?"

3 **PROFESSOR SAVULESCU:** Yes.

4 **PROFESSOR KERRIDGE:** Yes.

5 **PROFESSOR SAVULESCU:** And if people receive information
6 they don't want, they have many psychological
7 mechanisms of dealing with it and putting it to the
8 side as well, but you're exactly right. They can make
9 a choice about who has that information. So I have to
10 disagree with Ian on this. I think that it's
11 a person's right to know about their life to the
12 extent that they want to.

13 **PROFESSOR FARSIDES:** I think Sir Brian's point is
14 a helpful one because if you stage the discussion and
15 start with the introduction of the idea of a test, you
16 can put the brake on there in terms of discussing what
17 will be done as a result of the test. If you haven't
18 been open about the fact that you are testing for X or
19 Y, then you have to do all the subtle cultural
20 negotiation that Ian sets out at the time of the
21 result already being held.

22 So I think one of the features of genetic
23 counselling, which has been referred to, is that there
24 is a lot of preparatory work to be done to introduce
25 people to the idea of what is entailed before the test

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1 moral relativism, I think it's possible to respect
2 cultural differences and cultural norms while at the
3 same time not completely acceding to them. So
4 cultural respect means that we could listen to
5 a different cultural viewpoint about the types of
6 information people would like to be given to their
7 parents and so forth, and that can be respected and
8 listened to and engaged with over a long period of
9 time. But respecting that cultural norm doesn't mean
10 necessarily being a slave to it, and I think that's
11 sometimes confused.

12 **PROFESSOR SAVULESCU:** I agree.

13 **MS RICHARDS:** In your report you identify, in terms of the
14 ethical obligation to tell a patient the result of
15 a test, not only the autonomy principle but in the
16 context of infectious diseases also the potential risk
17 to others and the rights of others.

18 Can I ask for your assistance with this in that
19 context, so infectious diseases where others might be
20 at risk and the right not to know. If you have
21 a patient who you know has been tested for and
22 diagnosed with a highly infectious disease which they
23 are at risk of passing on to others, and that patient
24 exercises the right not to know, what are the
25 obligations both ethically and practically of the

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1 clinician in that regard? Dr Kazarian?

2 **DR KAZARIAN:** So, as you said, in that context the

3 information to the patient is important because there

4 is a risk that this particular patient might infect

5 others and, therefore, information is actually

6 protecting not only the patient but also their loved

7 ones. So it is important to inform the patient.

8 However, if the patient refuses that information, it

9 will be for the clinician to decide what to do and to

10 explain to the patient that actually non-disclosure

11 will be dangerous to their loved ones as well.

12 So it might be a matter of giving time and

13 space to the patient in order to process that

14 information to understand what's at stake, and maybe

15 ask the patient if they would like to see some other

16 members of the team to explain things further, to have

17 a bit more support. So there's a whole process that

18 needs to be put in place in order to help the patient

19 understand what could happen if they are not informed.

20 So, at the end of the day, if it is a matter of

21 protecting third parties, other people, then, yes, the

22 doctor will need to make a choice as to whether or not

23 they need to inform that patient.

24 **MS RICHARDS:** Ethically, is there an answer to the

25 question of what the clinician should do at that

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1 **PROFESSOR CAVE:** Well, it will depend in part on the

2 relationship between the doctor and the partner, or

3 partners, as may be. If the partner is also a patient

4 of the doctor then the doctor owes a duty of care to

5 that patient too, in which case there may be some

6 circumstances where it's acceptable to breach a duty

7 of confidentiality in the public interest, in order to

8 protect another. But doctors aren't detectives. They

9 are not able to know, they won't necessarily know, who

10 else is at risk or to be able to track them down and

11 give them that information. So unless, as Julian

12 said, there's a legal mechanism, then the primary duty

13 is to persuade because there are practical impediments

14 to doing much more in some situations.

15 **MS RICHARDS:** Professor Kerridge?

16 **PROFESSOR KERRIDGE:** If I could add to that, I think

17 ethics is really helpful in these kind of situations

18 because it does provide the basis for disclosing test

19 results without the consent of the individual who's

20 been tested but, at the same time, it says that to do

21 that is a very significant act. So, therefore, you

22 have to go through a series of steps. So you can't

23 just go straight to that end point. You'd have to

24 start by having a proper process of pre-test

25 counselling. Once you have the test result, the test

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1 stage? If one assumes the clinician has made every

2 effort to engage with the patient potentially over

3 a reasonably significant period of time, to persuade

4 them of the importance of them being given information

5 about their diagnosis and its implications, to no

6 avail because the patient continues to exercise the

7 right not to know, does ethics provide an answer to

8 the clinician then? Are they entitled to go to the

9 patient's partner and say "Your husband has HIV"?

10 **PROFESSOR SAVULESCU:** I mentioned yesterday the concept of

11 moral responsibility, which is a function of the

12 avoidability of harm and the foreseeability. So this

13 is a case where, if the doctor can avoid the harm to

14 a third party and can foresee it, if they don't act

15 they are morally responsible for the harm that occurs.

16 So here they have to weigh the magnitude of the harm

17 and how likely it is against the failure to respect

18 the patient's autonomy. So if the risk of harm is

19 non-trivial and the harm is great, it seems to me

20 there's a clear moral responsibility to act, and if

21 there's a legal mechanism of enabling them to act,

22 they should act, unless the likelihood of harm is very

23 small.

24 **MS RICHARDS:** Professor Cave, do you have any reflections

25 from the legal perspective?

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1 result has to be explained to the patient and

2 information given to them about what it means and also

3 what the implications are for others. You then give

4 them time to understand that and then you can again

5 say, look, this has implications for others, and you

6 might then move to strong persuasion if you want,

7 saying, look, we would really ask you to do this

8 because we think that you have a moral obligation to

9 do so and we have a moral obligation to take into

10 account the risks to others.

11 Finally, then you might get to a point of

12 actually going to someone who's recognisable, who's

13 close and who has a definable risk of not knowing that

14 information and then disclosing that information to

15 them.

16 The other concept that I think is helpful here

17 is one that Grant Gillett, a New Zealand philosopher,

18 came up with, which is the concept of moral

19 free-loading, which I love in this context. So this

20 is the idea that it's quite objectionable for

21 a patient to say "You have to respect my moral right

22 not to know this information but I'm not going to

23 respect the moral right of others to be protected from

24 harm and I'm not going to recognise your moral

25 responsibility, so everybody has to recognise mine but

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I'm not recognising any moral obligations or duties that I have to others".

He says it's reasonable to say to people that's actually quite an objectionable argument. It certainly runs against social solidarity, it runs against reciprocity, it runs against communitarianism and it runs against respect for others.

PROFESSOR SAVULESCU: I would, again, just slightly qualify what Ian has said. I think there are significant harms to the person of that information being released and they may have very valid reasons to say I don't want to know and I think you have to acknowledge that, that you are going to harm that person to benefit another and, unfortunately, that's what ethics deals with and justice deals with, distributing harms and benefits amongst different people and, in this case, the doctor does have a moral responsibility to others besides his or her patient.

But I think, you know, saying it's moral free-loading, I think, is diminishing the harm that is done to the person who doesn't want to know this information and may be significantly harmed by it.

MS RICHARDS: From an ethical perspective -- what does ethics have to assist us with understanding how information about a diagnosis should be communicated

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So I think, even before you go into the discussion, if you're working in a field where you know that you're going to be probably repeatedly put in a position of giving people information that they really rather would not have, you need to understand at a sort of sociological, cultural level what that means and, at that point, I hand over to my clinician colleagues to say something more specific about the actual encounter that might follow.

MS RICHARDS: Professor Kerridge.

PROFESSOR KERRIDGE: I am happy to offer a little bit here Julian, if you want.

PROFESSOR SAVULESCU: No, no. You are the clinician.

PROFESSOR KERRIDGE: I think this is one of the areas where law, ethics and professional practice are almost in complete alignment, you know, because there's now -- most of the colleges or medical associations give very explicit advice about the kinds of information that needs to be given about diagnosis, including its classification, its stage, its prognosis its aetiology, its treatments, its risks and benefits, its expected outcomes, the costs, the processes, who's involved, et cetera, et cetera. So it's a huge amount of information, I think, that follows from a diagnosis rather than just the diagnosis. But that's just all

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to a patient? So a diagnosis of a serious condition such as HIV or hepatitis C or, indeed, some of the conditions that you referred to in your evidence elsewhere, cancer, how ethically should the clinician go about providing that diagnosis and information to the patient? Professor Farsides?

PROFESSOR FARSIDES: Yes, one of the ethical responsibilities that precedes any conversation with a particular patient is to be well aware of what a social psychologist might call the social representations of the particular disease or condition in question, so that the clinician understands the sensitivities, understands what, in other contexts, might seem a very unusual wish not to know about this thing or not to share information with others.

Going to back to our discussion yesterday of keeping up with your education, there's a sense in which, if you're working in a particular field, you want to understand what we sometimes call the ethical landscape, what matters to people, what people are scared of, what the implications of knowledge are for people and what the implications of not knowing are, the extent to which it is a purely personal decision with only personal repercussions and the extent to which it will necessarily have an impact on others.

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the factual information.

It also goes to -- you know, the type of thing that Bobbie's talking about is that it needs to be given in a way that it's meaningful for the person involved, and that involves according to the style of delivery that they will want. Some people might like more or less detailed information. Some might like diagrams. Others might like quantitative or more qualitative information and the like. It may need to be given in a whole series of different genres, and it may need to be given over a long period of time.

So I think this is an area where we've got, I think, quite strong agreement of the necessity to give this information, to give it appropriately, to give it sensitively, and to give it over repeated periods of time and with lots of opportunity for clarification.

MS RICHARDS: What's the role of candour and honesty in that process?

PROFESSOR KERRIDGE: Bobbie?

PROFESSOR FARSIDES: Well, some philosophers have chosen to substitute those terms with the term "truthfulness". So it's a sense of judging the amount of information someone can deal with at any time. So the whole truth is not necessarily to be put on the table right at the beginning of coming to terms with

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1 a particular diagnosis, but there is a basic level of
2 information without which someone will simply not
3 understand where they are at the moment and what
4 the implications of this diagnosis are.

5 So, you know, there are many examples of bad
6 communication that is not about withholding but about
7 dumping all the difficult information on a patient
8 because, as we discussed yesterday, it's not easy to
9 give people difficult bad news. You want to give
10 people hope, you want to give them a sense that you
11 are going to make things better, and that's not always
12 possible.

13 So I think it's very much bespoke, as Ian said.
14 It's reading the signs from the patient that you are
15 dealing with about what they may already be thinking
16 and worrying about, what you may need to dispel in
17 terms of false understandings or fears. But a gentle
18 process that is, again, going back to the term that
19 the GMC want us to think about in terms of any medical
20 decision-making, based on meaningful communication
21 and meaningful dialogue between the doctor and the
22 patient.

23 **DR KAZARIAN:** That would be particularly relevant,
24 especially if the infection was caused by a particular
25 product that was given to the patient, and so,

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1 I agree too, truth telling is a central ethical duty,
2 but just to add that its conspicuous in its absence
3 from certain professional guidelines and from the law
4 until fairly recently. So it's only recently become
5 a statutory requirement as the duty of candour and
6 I think that's quite telling that it's taken so long
7 for that to happen.

8 **PROFESSOR KERRIDGE:** I think it's had a much longer
9 history in ethical codes in some ways. Sometimes the
10 Beauchamp and Childress principles were referred to as
11 four, sometimes the six principles, and I think the
12 fifth principle is veracity or truth telling or honest
13 disclosure. So certainly within bioethics it's got
14 a longer scholarship and within professional codes
15 there's at least some suggestion of truthful
16 disclosure in some of the more ancient codes as well.
17 **PROFESSOR SAVULESCU:** From an ethical perspective, the
18 goal is that the patient understands the situation and
19 is able to navigate their life and the options that
20 are available to them. So if you are not fully candid
21 and including not telling the origin of the infection,
22 you will close off options, such as the ability to
23 seek rectification, the ability to exercise their
24 legal rights and various other options that they are
25 entitled to, even though the pursuit of those options

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1 therefore, the doctor, the clinician, has a duty to be
2 frank and honest with the patients, to explain what
3 happened and to explain that there might be
4 uncertainties about what has happened and the type of
5 options that the patient now has after the information
6 was given to them.

7 **MS RICHARDS:** I think it probably follows from discussions
8 that we were having yesterday that, if the cause of
9 the infection is the treatment which the patient has
10 been receiving, there is an ethical obligation for
11 that information to be shared with patient, albeit
12 there may be issues depending on the patient's
13 presentation, state, degree of shock, et cetera, there
14 may be issues of timing as to how and when you provide
15 that information, but patients should be told
16 ethically if it's the medical treatment that's
17 infected them; is that right?

18 **PROFESSOR KERRIDGE:** Absolutely.

19 **DR KAZARIAN:** The clinician shouldn't be concerning about
20 protecting their own interests because it's the
21 patient's life that matters first.

22 **PROFESSOR FARSIDES:** Yes, there has to be openness and
23 transparency. I think we all agreed on that
24 yesterday.

25 **PROFESSOR CAVE:** Just to add -- we are all agreed, and

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1 will go against the interests of the doctor or the
2 health system. But those are genuine options the
3 patient has and the decision not to enable the patient
4 to pursue them is a violation of their autonomy.

5 **MS RICHARDS:** Then --

6 **PROFESSOR KERRIDGE:** Sorry, I just think in that sense
7 truth-telling is not just about consent, of course.
8 I mean, it's a mark of a health professional-patient
9 relationship and it's an expected virtue of health
10 professionals as well. I mean, we expect it in
11 relationships we have at home with our loved ones and
12 we certainly would expect it as a virtue in
13 a healthcare setting, and it's a fundamental plank of
14 the doctor-patient relationship.

15 **MS RICHARDS:** We've discussed this morning the ethical
16 considerations that come into play in terms of
17 potentially telling a partner in the absence of the
18 patient's consent about the patient's infection. More
19 broadly, to what other third parties could it be
20 ethical to provide information about a patient's
21 infection in the absence of their consent, assuming
22 capacity? Professor Cave?

23 **PROFESSOR CAVE:** In our report we looked at two other
24 possibilities in particular. One is that the
25 information might be given to other healthcare

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professionals and the other is that in some situations it might be passed on to the child's school. We noted that there was a report from the Council of Europe which recommended respecting confidentiality, insofar as information should only ever be given to a child's school either with consent or where it was very clear that it was in the best interests of the child in order to do that.

Similarly, with regards to healthcare professionals. The preferred approach was to persuade rather than to force and to only go ahead with telling another healthcare professional if not doing so would put that healthcare professional at serious risk.

MS RICHARDS: I think it would follow from that that it must be unethical to tell a third party of a patient's diagnosis, without having actually even asked the patient for consent in the first place.

PROFESSOR CAVE: Yes, I think that would be right.

MS RICHARDS: Then just to ask you a little about --

SIR BRIAN LANGSTAFF: May I just ask what I think is probably a very simple question. Doctors, whether in hospital or in the surgery, a GP surgery, will generally act, communicate, with the help of secretaries or receptionists. Is it a breach of the duty which they owe the patient that the typist, the

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stigmatising cause of death written on it. You would want to be assured, again, that there would be confidentiality within the community but this is probably something that people haven't previously had to think about.

So I have to say I think you ask a very interesting and difficult question and one where we might remain with some disquiet because we have not gone to great lengths to offer direct and very specific training or guidance to people in that position. One only has to hope that, for example, in the GP setting, senior partners would see it as very much their responsibility to induct staff into questions and talk to them about confidentiality. Patients are sensitive to this.

There was a drive a couple of years ago to ask GP receptionists to request people to sign up on to the organ donation register when they came for an appointment, and that policy was dropped quite quickly because people felt they didn't want that person to know whether they had or had not done this thing. It was personal to them.

So I don't have an answer, but I recognise a problem there.

PROFESSOR SAVULESCU: Well, just two things I said

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secretary, may be typing up a letter which describes a condition about which if he or she had not been typing up they would not have known, or the receptionist knows, in order to make an appointment, of a condition which they would not have known about had they not been informed for that purpose.

PROFESSOR FARSIDES: I think this is a very tricky area.

Many years ago, I used to be invited to a European course which was specifically for receptionists and medical secretaries to discuss with them the ethical responsibilities in their work but that was a highly unusual event and I think there's an added problem in that the people in question are often members of the community within which they work. So local knowledge might mean that they can actually identify patients, rather than it just being a name or an address on a letter.

So I think, certainly, there were discussions in the early days around HIV of how you could impart upon people who came in touch with this information, who didn't have the same sort of grounding and education in their specifically ethical responsibilities to deal with it responsibly. For example, taking a death certificate to a building society that has a sensitive or potentially

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yesterday I think are applicable. In an ideal world, receptionists and typists wouldn't be involved in these confidential matters but, as I said yesterday, "ought" implies "can". And there are extraordinary limitations on the NHS, and whether it would be reasonable to expect that level of confidentiality to be achieved with the resources available, I just don't know the answer to that.

But we've made voluminous recommendations in our report, or made many, many claims. How far those are achievable within the constraints, the resource limitations of the NHS is, I think, a major question and I do think we at some point need to address those sorts of constraints of what can be reasonably achieved. But, yes, in an ideal world, they wouldn't be involved.

PROFESSOR KERRIDGE: Sir Brian -- sorry.

PROFESSOR CAVE: I just wanted to add just a very brief legal point that they would, I think, be under a legal duty to protect the patient's confidentiality, but they wouldn't be bound by the professional codes that apply to doctors. That was the point I wanted to make. Go ahead, Ian.

PROFESSOR KERRIDGE: No, no. That's -- I mean, I think my point adds to this.

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1 I mean, Sir Brian, 30 years ago there was
2 a very famous paper published in the New England
3 Journal of Medicine by Mark Siegler called
4 "Confidentiality in medicine: a decrepit concept" in
5 which he pointed out that a promise given to a patient
6 to keep one piece of information -- say their
7 diagnosis, whether it was HIV or a cancer diagnosis or
8 a stigmatising disease -- the promise to keep that
9 confidential is very hard to sustain because in any
10 one day a patient -- an in-patient in a hospital will
11 have contact with somewhere between 30 and 60 health
12 professionals let alone other people, whether they are
13 receptionists or ward clerks or what have you. So an
14 enormous number of people who may have varying degrees
15 of awareness of their ethical responsibilities and
16 varying relationships with the person whose knowledge
17 is being kept confidential.

18 So Julian's point about what's genuinely
19 achievable and what promise should be offered to
20 somebody, in terms of the degree to which
21 confidentiality can be respected, I think that's
22 a really important conversation that needs to be had.

23 **PROFESSOR FARSIDES:** But do you not think it could be
24 a basic component of the induction to working in any
25 healthcare setting, to put it glibly: what happens in

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1 to do with someone, the idea that they should have
2 access but a nurse who has a lot to do with someone
3 shouldn't have access is a bit odd.

4 So I think there's a whole range of ways that
5 confidentiality can be protected, but I just don't
6 know that they give us the surety of saying it doesn't
7 go further than an individual.

8 **MS RICHARDS:** And then ethically, do the principles
9 governing respect for patients' confidentiality,
10 non-disclosure of information save in certain
11 circumstances, do they alter following the patient's
12 death, and if so how?

13 **DR KAZARIAN:** The doctor has a duty of confidentiality
14 after the patient's death. One reason for this is
15 because if confidentiality didn't survive death, then
16 the trust between a doctor and a patient would be
17 breached and patients would not want to actually tell
18 the doctor a lot of different things about themselves
19 if they knew that this would be disclosed after their
20 death. So it's a very important principle that
21 confidentiality survives the death of the patient and
22 also to respect the patient's information and to not
23 disclose it to other parties.

24 **PROFESSOR CAVE:** That's Absolutely right. The GMC does
25 recognise that there are times when information can be

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1 the hospital stays in the hospital. What happens in
2 the GP practice stays in the GP practice. And if you
3 don't bother to underline that and reiterate it and
4 make sure that people do the best they possibly can,
5 then the fact that you have a legal obligation and
6 your staff have a legal obligation, it becomes quite
7 worrying that you haven't made those very basic
8 efforts.

9 **PROFESSOR KERRIDGE:** No, I think all of that needs to be
10 done. I don't know necessarily that it removes the
11 complexity, but I think, you know, it's made very
12 clear to all health employees when they come in to
13 work in a hospital, whether it's in the NHS or an
14 incredibly well resourced hospital in some far off
15 land, the ethical responsibilities they have to
16 maintain confidentiality.

17 Hospital records systems have been adjusted to
18 accommodate this already. Many hospitals, if there
19 are certain diagnoses, HIV being one, that's only
20 acceptable to -- or only accessible, rather, to
21 certain access codes, and so that might be the
22 patient's primary clinician, or in many hospitals,
23 it's actually medical staff but not nursing staff
24 which is sort of an interesting distinction in a way
25 because it's not -- you know, a doctor who has nothing

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1 passed on, though. So it recommends in its guidance
2 on confidentiality, that first there is consideration
3 of what the patient wanted and if there's no evidence
4 of that, then look to possible distress to the family
5 of releasing certain information, and it's recognised
6 that that will often diminish over time. Another
7 thing to look at is whether it's already public
8 knowledge and whether the information in question can
9 be anonymised and what the purposes are for
10 disclosure.

11 So it's not a sort of hard and fast rule that
12 information can never be passed on but Melinee is
13 absolutely right that the duty of confidentiality,
14 ethically and potentially legally as well, goes beyond
15 death.

16 **MS RICHARDS:** I wanted to ask you, finally on this topic
17 and before we break, about storage of blood samples
18 without patient knowledge or consent. To what extent
19 has it ever been or is it now ethical for there to be
20 stored samples of a patient's blood kept for possible
21 future testing without the patient knowing about it or
22 having consented to that?

23 **PROFESSOR KERRIDGE:** It's -- I think there are some
24 circumstances where it's ethically relatively
25 unproblematic for blood to be retained and used

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without somebody's consent. That certainly has been in the past and continues that way and there's probably two that are relatively unproblematic.

The first is for legal reasons. So blood-alcohol testing in the context of car accidents, for example, whether a patient consents to their blood being taken and stored for subsequent testing is generally irrelevant and the law overrides a patient's consent, and there's other situations where that's the case legally as well.

The other is, though, in the healthcare setting is for quality assurance in laboratory processing. So it's been the case for many, many decades that when people donate blood to a blood service that a certain percentage of that blood is used to maintain a quality control of instruments in the laboratories and in the blood service, and that type of quality assurance and laboratory management is an incredibly important part of making sure that the blood service produces safe and high-quality and high-utility products. That's often -- or generally it's been done without people's consent. There isn't any harm that arises to the patient. There's no risk, there's no retention, there's no further testing. So I think that's been relatively unproblematic previously and, to me at

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if I gave a specimen for a diagnosis of a cancer, I would expect that if there were improvements in the future in the diagnosis of that cancer or maybe better specification of the types of cancer that was relevant to my ongoing care, that my specimen would be retested and I would be informed of the results of that.

However, as Ian said, if I wasn't told that a specimen would be used for research purposes and it was, that would be something that would be a violation of my autonomy. So you know it really depends on what the person is understanding that they are doing and I think it's a reasonable expectation that our, you know, specimens will be reused in various ways for testing, as Ian said, for quality assurance. But it really depends on what the future use or the purpose of the storage and the future use is.

MS RICHARDS: Professor Cave?

PROFESSOR CAVE: In terms of context, databases are hugely important. Without them, it's often impossible to spot safety concerns or to undertake research. The Cumberlege review, for example, has made clear that all sorts of problems with medicine and devices that we didn't manage to spot, we perhaps would have done if there had been good databases. So there is a very strong public interest in having these databases.

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least, I think that continues to be unproblematic.

Increasingly though, it's regarded that retention of bio-tissues or blood samples for other reasons that are going to be tested or the subject of research without consent, at some time and at some point and in some form, rather, that's increasingly regarded as being unethical.

MS RICHARDS: Professor Farsides?

PROFESSOR FARSIDES: I just wondered whether it's also worth talking about whether or not those samples immediately become de-identified and detached from a patient's clinical notes and history. So you might think differently about, as Ian's put it, a spare amount of blood going to a very good practical purpose, without that being in any way associated back to the patient who provided that blood. If, however, as Ian again said you store it and you keep it very much identified with that particular patient and subsequently conduct tests that reveal information relevant to that patient, you find yourself in a terribly difficult ethical position when the results come back.

PROFESSOR SAVULESCU: I think it depends on what the patient's expectations were and what they understood at the time they gave the specimen. So, for example,

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As we've already discussed, anonymisation certainly reduces the ethical implications. It doesn't take them away entirely, there's still matters of trust and autonomy, but it does take away a significant number of issues and it's broadly recognised that data, so long as it's anonymised, can be stored. If it's used for research it may require ethics committee approval but it can potentially be stored without explicit consent. Even when it isn't anonymised, although explicit consent is optimal from an ethical point of view, there are legal exceptions to the requirements to get explicit consent, even today.

So, for example, in the coronavirus crisis there have been regulations under section 251 of the NHS Act requiring that confidential information is passed on so that they have the relevant information in order to be able to fight and respond and to react to the coronavirus crisis. Okay, so that's the basic point I wanted to make.

MS RICHARDS: Picking up on Professor Savulescu's points, if a patient has never been told that blood taken from them is going to be stored in their name (so not de-identified, not anonymised), and has never been told that that blood may be tested for blood-borne

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1 infections or for other purposes at some future stage,
 2 it sounds to me from your answers as though that would
 3 be ethically problematic.
 4 **PROFESSOR KERRIDGE:** Yes, hugely problematic. I mean,
 5 it's then -- obviously, there's examples from many
 6 countries around the world where this absolute thing
 7 has taken place. It's then beholden upon the Health
 8 Service or the university or the museum or the
 9 laboratory to develop processes by which the people
 10 whose tissue has been retained or their relatives are
 11 then informed that this is the case and provided with
 12 the opportunity to make an autonomous decision about
 13 the management of that tissue at that point, even
 14 though consent hadn't been gained originally, and that
 15 would be done in different ways, depending on what the
 16 tissue is, who's retained it and what type of sort of
 17 consent process is desirable.
 18 **PROFESSOR FARSIDES:** Going to back to what Emma said about
 19 the value of biobanks and repositories and registers,
 20 it's a terrible lost opportunity if you don't have
 21 good ethical values at the outset that mean that the
 22 people whose samples are included have, in some real
 23 sense, donated and become part of that enterprise. In
 24 fact, I think some people get comfort ultimately from
 25 the fact that they were able to donate part of

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1 actually require consent to be gained for every single
 2 test at every single point into the future. It may be
 3 possible to respect autonomy by designing different
 4 consent processes upfront, but that does require that
 5 people are informed that their tissue's being
 6 retained. They're given not just the opportunity;
 7 they have complete control over whether that occurs,
 8 and they can say at that point what they consent to.
 9 And it may be that they could say, "Look, I consent to
 10 all future testing of my tissue relative to my
 11 particular disease but not necessarily for other
 12 diseases, as long as that research project and that
 13 test has gone through an approved scientific and
 14 ethical review process". And there are concepts like
 15 broad consent and dynamic consent that have changed
 16 the type of consent to still make it ethically and
 17 legally robust but also more scientific and civil
 18 utility.
 19 **MS RICHARDS:** Thank you. Sir, given the time, and I am
 20 going to move on to the issue of research, is this
 21 a convenient moment to take a break?
 22 **SIR BRIAN LANGSTAFF:** Yes, it is. We will take a break
 23 until 10 to 12.

(11.25 am)

(A short adjournment)

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1 a cancer tumour or blood and research has proceeded on
 2 the basis of that.
 3 Even in the darkest moments of the retained
 4 organ scandal in this country, many parents said had
 5 they been asked in a sensitive way to donate their
 6 child's heart or other tissue samples, and been given
 7 a reason for that, being told the potential benefits
 8 that could follow from that, then actually, far from
 9 being something that they would have resented or found
 10 unbearable, it's something that might have helped them
 11 give some meaning to the terrible tragedy in their
 12 life. So I think, again, you have to be careful not
 13 to make assumptions about what will happen round
 14 an issue like this.

MS RICHARDS: Sir, I note the time --

16 **PROFESSOR KERRIDGE:** Just to take that a little bit
 17 further because, I mean, Julian gave the example of
 18 his own tissue being -- cancer tissue being retained
 19 and tested at multiple points in the future, and
 20 Bobbie's also talked about and Emma's talked about the
 21 value of these biorepositories. There's a really
 22 important issue in relation to consent there because
 23 there may be a process because science develops over
 24 time and tests change over time and tissue can be
 25 retained over a long period of time that we don't

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(11.50 am)

2 **MS RICHARDS:** Before I turn to the question of research,
 3 there's one question I have been asked to ask
 4 Professor Kerridge before you disappear at lunchtime,
 5 which is this: what are or have been the principle
 6 differences between the approach and adherence to
 7 medical ethics between the UK and Australia, in
 8 particular with regard to the prominence given to
 9 patient autonomy?

10 **PROFESSOR KERRIDGE:** Well, in fact, Professor Savulescu's
 11 probably a better person to answer that question than
 12 I am, I think, because Julian's been working in the
 13 field for longer than I have and has had more
 14 experience in the UK. So I might hand that over to
 15 Julian to start with and then see if I can think of
 16 something to say.

MS RICHARDS: Certainly. Professor Savulescu?

18 **PROFESSOR SAVULESCU:** I think Australia has had a greater
 19 focus on respect for autonomy and also parental
 20 autonomy. So in the recent Charlie Gard case where
 21 the court decided that it was in the best interests of
 22 Charlie Gard to die, despite his parents wanting to
 23 take him to the United States for experimental
 24 treatment at a world-class institution, that wouldn't
 25 have happened in Australia. I can't see that the

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parents' wishes in that case would have been overridden.

So I think Australia's probably midway between the UK and the United States in terms of respect for autonomy and parental wishes included. So the UK is still very much based on a system of best interests and doctors' decisions about best interests and courts typically siding with doctors in those cases. So, you know, I think -- as I said before, I think the UK is probably 10 to 20 years behind where a country like Australia or New Zealand is.

MS RICHARDS: Professor Kerridge --

PROFESSOR KERRIDGE: I think I would agree with that.

It's interesting. It's often said in relation to medical practice in Australia that it's somewhere between Europe and North America. In the area that I practice in haematology, we often joke that we -- the protocols that we adopt for treatment of leukaemia or bone marrow transplantation borrow from both spheres of practice, and we do tend to -- our decision-making sort of fits clinically in-between those two spheres, and I think the same is true of ethics as well. That may reflect in part differences in law also where we fit somewhere between the UK and the United States as well. So I think there are

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children and their bodies and their situation.

So I think what we're saying is we're behind the research agenda. We see the benefits that follow, both individually and for society as a whole, and the challenge is to find ways methodologically, scientifically, and ethically to do that in the best way possible. Part of that project is moving away from the idea that you do research on people to an idea of conducting research with people so that your participants have influence on the research agenda, advise on the development of protocols, and actually feel as if they're part of a societally beneficial enterprise rather than, to use the very pejorative term that has been used in the past human, guinea pigs.

PROFESSOR SAVULESCU: I think there's a moral obligation to take part in research because we all stand on the shoulders of people who have contributed to or made sacrifices through past research. That doesn't mean that unreasonably risky research should go ahead or people should be forced to take part in research without their consent. But there is a general obligation to contribute to ongoing benefit, just as we've benefited from the enormous amounts of research that have enabled us to have generally unparalleled

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interesting differences.

MS RICHARDS: Thank you.

I want to come on then to the question of research. You've emphasised in your report the importance of medical research and say that one's moral responsibilities in this area would not be served by being research-averse, and I wondered if I could invite one of you to expand upon that a little.

PROFESSOR FARSIDES: I think the point that we were making is that although it has long been appreciated that this is an area where the potential for ethical wrongs is very real, we wouldn't want that to undermine our attempts to ensure that as broad a range of the population as possible benefits from scientifically sound evidence-based medical practice. And what has happened in the past is sometimes are concerns about the vulnerabilities of particular groups (be that children, or people with psychiatric complaints, people with learning disabilities) has meant that we haven't found ways of doing scientifically and ethically robust research. We sometimes, in relation to children, use the term "therapeutic orphans" because much of what we do has not been tested in a context where it would specifically relate to

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lives.

PROFESSOR KERRIDGE: I think these are important points, and they might seem a little trite in some ways, but it's important for us as a group of people working in ethics and law to say that we think research is a good because ethics, you know, for a number of decades has worked to actually make things worse and to exclude some groups of participants from research. I don't mean make things worse generally, but this particular problem of being so concerned with the vulnerability of particular populations or the potential harms of research that ethically it seemed that the right thing to do was exclude that population or sub-population from research entirely.

So as Bobbie mentioned, you know, children, people at the end of life, people in acute emergencies, people in intensive care units, people with dementia, people with end stage neurological disorders, pregnant women, foetuses. There's enormous number of populations who have been neglected from the benefits of research and advances in medical progress because of an ethical concern about their vulnerability and the possibility of harm. So it's important for us to say research is a good, and there's an ethically robust reason to support research

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1 and to come up with ways that encourage participation.
 2 **MS RICHARDS:** Is it fair to say that the importance, the
 3 value of research to society is enhanced rather than
 4 undermined by undertaking research in an ethical and
 5 moral way?

6 **PROFESSOR SAVULESCU:** Yes.

7 **PROFESSOR KERRIDGE:** Yes.

8 **PROFESSOR FARSIDES:** Absolutely.

9 **MS RICHARDS:** You have identified in your report two basic
 10 ethical principles to protect participants in
 11 research: the idea of reasonable risk, and then
 12 informed consent and I wanted to ask you about each of
 13 those in turn, starting with the issue in relation to
 14 reasonable risk. I don't know who would like to
 15 assist our understanding.

16 **PROFESSOR SAVULESCU:** I think I've introduced that term,
 17 so maybe I should say what I mean by that.

18 Protections for research grew out of the Nazi
 19 experiments and the holocaust and the Nuremberg Code,
 20 and the idea was that participants should not be
 21 harmed by taking part in research. But most research,
 22 particularly clinical research, involves risks, and
 23 you can't say for sure that somebody won't be harmed.
 24 What you expect is that, first of all, the risks are
 25 as small as possible given the goals, that they are

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1 issue before I ask about informed consent in the
 2 context of research?

3 **PROFESSOR KERRIDGE:** No, I think that's really well
 4 articulated.

5 **PROFESSOR FARSIDES:** Likewise, yes.

6 **MS RICHARDS:** So can I ask you next then about the second
 7 prominent factor ethically in relation to
 8 participation in research, which is informed consent,
 9 and ask you just to -- we've obviously talked through
 10 the principles of informed consent in general terms
 11 and in relation to treatment. If I could ask you to
 12 tell us about informed consent in the context of
 13 participation in research and what that entails.

14 **PROFESSOR FARSIDES:** Could I just ask: are you asking that
 15 as a sort of legally-focused question or more
 16 ethically-focused question?

17 **MS RICHARDS:** At this stage ethically, I'm going to ask
 18 you to look at the Declaration of Helsinki in a few
 19 minutes but just in terms of the general ethical
 20 approach.

21 **PROFESSOR SAVULESCU:** Again, if you want me to start, it's
 22 fairly straightforward. As with any consent, people
 23 need to know what the alternatives are to
 24 participation and what the risks and benefits of
 25 participation and non-participation are and what their

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1 minimised, that you have done enough preparatory work,
 2 for example in animal models or through computer
 3 modelling or epidemiological research, before you move
 4 to exposing human beings to risks, and then the risks
 5 proportionate to the benefits, either to that
 6 individual, if it's a therapeutic trial, or to other
 7 people in society. So there's a proportionality
 8 between the benefits and risks.

9 The idea is that ethics committees need to --
 10 and ethics review needs to ensure that certain
 11 features of the risks are taken into account. So
 12 sometimes you'll hear that the risks of research
 13 shouldn't be greater than ordinary life. That may
 14 apply to so-called non-therapeutic research, research
 15 with no possible benefit to the patient, but it
 16 doesn't apply in, for example, in Ian's field where
 17 people are, you know, dying of leukaemia or of other
 18 blood cancers where you can entertain much higher
 19 risks given that the alternative is death.

20 So it requires a nuanced ethical assessment of
 21 risk and then, secondly, the presentation of that risk
 22 to the patient so they can make their decision about
 23 whether to take on those risks for either the benefit
 24 to themselves or to other people.

25 **MS RICHARDS:** Is there any further reflection on that

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1 probabilities are. So they need to be able to
 2 understand what will happen to them or what is likely
 3 to happen to them or what could happen to them, both
 4 in terms of the risks and benefits, both of taking
 5 part and not taking part.

6 They also will need to be informed of the
 7 broader context of the research. So, for example,
 8 what might be the implications for other people in
 9 society, what's the financial structure of the
 10 research, how will it be commercialised. Those
 11 features people might have particular values about.
 12 But, in general, the same principles that apply in
 13 terms of respect for autonomy in clinical care apply
 14 in research. People need to understand what it is
 15 that they are doing, what their options are and what
 16 the risks and benefits of those options are.

17 **PROFESSOR KERRIDGE:** There are some important
 18 qualifications though, and I'd agree with Julian that
 19 the basic principles of consent are the same, whether
 20 it's in clinical practice or in this research setting,
 21 but there are things that need to be emphasised in
 22 that consent process in the research setting. The
 23 first one, obviously, is that this is research and
 24 it's not clinical practice. It's not care. So the
 25 primary purpose here is the generation of new

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knowledge or scientific knowledge. The purpose is not to benefit the research participant or the patient, if they are both.

We know that that's important because there's a thing called therapeutic misconception, which is where people participate in research studies in clinical studies, at least, believing that they will benefit from this piece of research and, furthermore, that they won't be harmed. Others may be harmed and others may not get benefit but they won't be, they will get benefit and they will not be harmed. That's a genuinely difficult problem in the research setting and a difficult problem for consent.

The second is the notion of scientific merit. So there's an emphasis here on what the research question is and what the research purpose is.

The third is the notion of uncertainty because uncertainty is unquestionably higher in the research setting and, indeed, if there was no uncertainty there shouldn't be that research taking place. It starts to look like audit or starts to look like unnecessary duplication of effort.

The fourth, I think, then is the role and the skills and the integrity of the researchers themselves, and this is something that was

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hope is an established beneficial treatment; the other the new agent), it is not probably in the control of the clinician to decide which treatment will be given to their patient in the same way as it ordinarily would be.

Similarly, to avoid bias, it might be the case that a clinician themselves is unaware of exactly what is being administered to their patient. It will be one of two things but they don't know which.

So I think one of the things one has to explain to patients is how there will be that slight shift in the emphasis of the activities of the treating clinician, who will always keep their basic interests at heart and would, hopefully, never sign up to be part of a clinical trial that they didn't feel ethically confident in, but they have slightly different responsibilities when wearing their researcher's hat.

PROFESSOR SAVULESCU: There is one other thing that I think that follows on from what Ian was saying and yesterday, some people will enter clinical trials in order to access a new intervention, particularly when they have a serious condition. It's a part of informed consent, both in clinical care and research trials, to tell people all of their options and,

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acknowledged in Nuremberg and, subsequently, in Helsinki, and so forth, is that do these people know what they are doing? Have they done research before? Can they give some type of guarantee that the process of research will be followed through to its end point? So I think there are things in research or in consent for research that are emphasised more than they are in clinical practice.

PROFESSOR FARSIDES: I would agree and, on that final point of the role of the researcher, I think it's particularly important for patients who become involved in research run by their own clinicians to understand that that individual or that team will now be wearing too slightly different hats and, whilst the first will be very much focused on the best interest of the patient and that thought isn't abandoned when they become engaged in a research process, there might well be things that the clinician can no longer do because of the constraints of the scientific protocol, and the scientific protocol is designed to get the best possible results from the research, rather than to necessarily fit with the needs of a particular patient.

So, for example, if a trial entails randomisation between two treatments (one of which we

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indeed, whether that intervention can be accessed through some other route, which he discussed yesterday, either paying for themselves or through compassionate release.

So it wouldn't be enough just to describe the options of participation in this trial or not getting the treatment, it would be necessary also to discuss what other options are available if the person is really to give informed consent to take part in that sort of trial.

PROFESSOR FARSIDES: One of the other responsibilities we sometimes discuss is to explain the position of equipoise to the patient, because there is this attraction with the new but the very fact that it is subject to research is because we don't, as yet, know everything about this new treatment and things might emerge that show that it isn't as promising and it might have greater side effects, it might not have as good effects. So a clinician also needs, to some extent, to counter the rush to the new until we have a building evidence base to suggest that it is, in fact, a sound alternative to the standard treatment that is currently offered.

MS RICHARDS: Your report emphasises the particular importance of voluntariness, the patient voluntarily

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1 participating in research and the particular problems
2 that can arise in the context of an existing
3 clinician-patient relationship, where there is the
4 risk of coercion or a sense that the patient might
5 feel that they owe it to the clinician or participate
6 through a sense of gratitude.

7 How best are those ethical problems addressed?

8 **PROFESSOR KERRIDGE:** Well, I suppose the first thing to
9 say is voluntariness is a problem. I mean, it's
10 a feature of consent legally and ethically and it's
11 an issue in clinical practice and it's also an issue
12 in research. I think a better way to think of it is
13 sufficiently voluntary or sufficiently free, rather
14 than completely voluntary and completely free because
15 I would suggest that when someone is unwell, when they
16 are in hospital, when they are in a whole series of
17 relationships where power is not equally shared and
18 when they are in desperate need, is they won't be
19 completely free and they won't be uncoerced by things
20 that are a part of normal life, whether they are
21 relationships or a need to obtain assistance from
22 people.

23 The ways that we deal with that are through the
24 consent process particularly, through time, through
25 giving the opportunity to withdraw, and through doing

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1 I think there are specific things you can do to take
2 account of this but creating as much of
3 an arm's-length relationship in the research part of
4 the relationship would minimise the potential effects
5 of pressure or influence or even coercion.

6 **MS RICHARDS:** I'm going to ask you to look at the
7 Declaration of Helsinki with me. It was, I think,
8 first promulgated in 1964 and then revised in 1975.
9 I am not going to ask you to go through the various
10 iterations of it, but for the purposes of asking you
11 to comment on it, I'm going to go to the 1975 text as
12 set out in the BMA's ethics handbook in 1980.

13 So if we could have on screen, please, Soumik,
14 BMAL0000087. I'm going to ask you to look first at
15 the text of the handbook. Soumik, it's numbered
16 page 24. It may correspond to the electronic page.
17 I'm not sure at the moment. If we go back two pages,
18 please. If we look at the bottom of the page, we see
19 the heading "Research in human subjects":

20 "The third form of contact with doctors occurs
21 in the field of research. The law lays down a minimum
22 code in matters of professional negligence and the
23 doctrine of assault, but this is not enough. Most
24 patients trust their doctors and will consent to any
25 proposal. Experimental procedures are nearly always

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1 the kinds of things that Julian and Bobbie are talking
2 about, which is explaining very clearly to people the
3 alternatives to participation in research.

4 Finally, I think it's the promise, particularly
5 if, as Bobbie mentioned, it's the clinician who is
6 also a researcher, the promise which can be made very
7 explicitly that their best interests will always be
8 paramount and so, if the clinician believes that at
9 any time the right thing to do is to withdraw from the
10 study, then they should also be saying, "Okay,
11 I really think you should not be in this study at this
12 point" or "Pursuing this study is working against your
13 best interests, I would suggest that you withdraw from
14 it". They are the kinds of things that I think
15 protect against coercion.

16 **PROFESSOR SAVULESCU:** I would add a couple of things to
17 that. I used to chair the department of human
18 services ethics committee in Victoria. So if
19 a proposal like this came in to me, what I would want
20 to make sure is there are structures in place to
21 ensure that care wasn't affected. I would also want
22 somebody other than the clinician, the caring
23 clinician, to be obtaining consent and possibly
24 assigning a patient advocate to partner with the
25 patient to ensure that there wasn't any coercion. So

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1 too technical for patients or non-experts to
2 understand. For practical purposes, therefore, the
3 doctor concerned carries a moral responsibility for
4 the investigations that are or are not proposed to his
5 patient or volunteer.

6 "Medical advances have always depended upon the
7 public's confidence in those who carry out
8 investigations on human subjects. This confidence
9 will be maintained only if the public believes that
10 such investigations are submitted to rigorous ethical
11 scrutiny and self-discipline. It is unethical to
12 conduct research which is badly planned or poorly
13 executed.

14 "Codes, regulations and laws help to keep
15 standards of ethical behaviour high, but volunteers
16 and patients are best protected by ethical conduct.
17 The subjects' interests must come first."

18 Then there's a discussion about controlled
19 clinical trials in paragraph 4.4. This is the fourth
20 line:

21 "Consent must always be obtained from the
22 individual subjects."

23 And 4.5:

24 "Because of the ethical problems which may
25 arise, controlled clinical trials should always be

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approved and supervised by a properly constituted ethical committee. Any doctor must remain free to remove a patient from under his care from such a trial or give additional treatment at any time if he feels it to be in the patient's best interest. Any patient must also remain free to withdraw from such a trial."

Then it goes on to talk about research on children which I will come back to.

Just before we look then at the text of the Declaration of Helsinki which is set out in this handbook, are there any observations or comments that you have on those passages of the handbook?

PROFESSOR KERRIDGE: I would agree with almost everything that's said there, except for the sentence that says that patients and non-experts can't understand experimental procedures. I think they can, and I think it just takes time and effort and proper communication process to make sure that they can understand it. The rest, I think, is ethically very appropriate and broadly accepted.

PROFESSOR FARSIDES: I think another empirical assumption that's outdated is that everyone will agree to participate in research if suggested to them by their doctor. If you look at the challenges that some incredibly well designed important clinical trials

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heading "Human experimentation":
"In 1964 the World Medical Association drew up a code of ethics on human experimentation. This code known as the Declaration of Helsinki was revised in 1975 as follows."

Then if we go to the next page:

"It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

"The Declaration of Geneva of the World Medical Association binds the doctor with the words, 'The health of my patient will be my first consideration', and the International Code of Medical Ethics declares that 'Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest'.

"The purpose of biochemical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease [et cetera].

"In current medical practice most ... procedures involve hazards. This applies *a fortiori* to biomedical research.

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face in terms of recruitment these days, there are many reasons why people might choose not to be part of a clinical trial or of some form of medical research.

PROFESSOR CAVE: Another thing to point out is that the guide refers to research subjects, and there's a preference today to term it "participants" because the idea is that they are consenting individuals that agreed to participate in something, rather than have something done to them. This flows from the principles that I think Ian in particular was talking about yesterday, of treating people as an end in themselves rather than as a means to an end.

MS RICHARDS: Dr Kazarian?

DR KAZARIAN: I agree. I think I would agree with everything that's said in this text, apart from the fact that participants were called subjects at that time and now there's -- the model is more participatory and more collaborative with people, and that's an important point, but I think we can explore that further later.

MS RICHARDS: Then if we go then to the text of the Declaration of Helsinki as revised in 1975, Soumik, it's page 59 of the numbered pagination. It may be 57 electronically. If you go back one page, thank you. We can pick it up at the bottom of the page under the

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"Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects."

Then this, which I'm going to ask you to comment on in a moment:

"In the field of biochemical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research."

Then we see some principles then set out, starting at the bottom of the page, but if we could go over to the next page. So we see paragraph (2) is about the need for a protocol and an independent committee. Paragraph (3) is about research being conducted only by scientifically qualified persons under the supervision of a clinically competent medical person. Then (4) is the proportionality of objective and risk. (5), the need for a prior:

"... careful assessment of predictable risks in comparison with foreseeable benefits ... Concern for the interests of the subject must always prevail over

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the interests of science and society.

"(6) The right of the research subject to safeguard his or her integrity must always be respected ...

"(7) Doctors should abstain from engaging in research projects involving human subjects unless satisfied that the hazards involved are believed to be predictable ... should cease any investigation if the hazards are found to outweigh the potential benefits."

(8) is concerned with accuracy of results.

Then (9), in terms of informed consent:

"... each potential subject must be adequately informed of the aims, methods, anticipated benefits and possible potential hazards of the study and discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing."

Then paragraph (10), if we go over the page, talks about the particular difficulties if the patient, the "subject", is:

"... in a dependent relationship to [the doctor] or may consent under duress. In that case the

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withdraw and that this will have no implications for your future care. Because if you think about this idea of feeling beholden of having a close relationship, the right to refuse may feel somewhat perilous, particularly if you feel it's then going to have an impact on the care that you receive in the future. So we make that very specific now.

MS RICHARDS: Professor Savulescu?

PROFESSOR SAVULESCU: I think it's all generally correct except for one major error, which I think has subsequently been corrected, but it is quite an important error.

Where it says the interests of the subject should always take precedence over the interests of society, and the health of the patient must always be the primary consideration, that's simply incorrect when it comes to research in the following way.

So when you conduct a randomised control trial, as Bobbie said, it's only ethical if you begin with what's called equipoise; that is, you have no reason to believe that the new intervention is better or worse than the existing intervention. So you're completely indifferent. But as soon as you start to obtain data, equipoise will be disturbed. So after 100 patients you might have, you know, a belief that

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informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship."

Then:

"(11) In the case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation ...

"(12) The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with."

Then, before we go on to look at the distinction between clinical research and non-clinical, biomedical research in the following paragraphs, can I ask for any observations or comments you have upon this code.

PROFESSOR FARSIDES: It's just a very quick one. It is very recognisable to us, and much of the information that they set out as important would now be offered to patients by the form of a participant information sheet, so it would be very clearly stated and carefully written. But I do note that one of the very standard phrases that you could probably never escape putting on such a form is that you have the right to

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the difference could only be -- have arisen with a 5 per cent chance. After 10,000 patients, you might be much more confident that the new intervention is better, and there's only a 1 in 10,000 chance that it arose by chance. So the more patients you accrue, the higher your level of confidence that there really is a difference.

But from the patients' perspective, after 50 patients, there's going to be information about whether there's a difference and once -- and trials never finish. Large clinical trials never finish with what's called a P value of 5 per cent, or 1 in 20. They continue to have a confidence of 1 in 10,000 that there's no error because we want to maximise the benefits to other people in society. We want to minimise the chance that a new intervention is put on the market with side effects. But from the patients' perspective, trials would be better ending much earlier. And that's why I said you can't have this principle of no harm. You have to say that the risk is reasonable. In this case, the risk is reasonable not because it's good for the patient, but because it's good for others in society and future patients.

That's a critical thing in research, that it's simply not true that in large clinical trials the

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1 interest of your patient is paramount. It's the
2 interest of other people that is paramount and that
3 can be reasonable, provided that the patient isn't
4 exposed to too great a risk or that the benefits to
5 other people are significantly large enough. But that
6 is an important error in this declaration that
7 persisted for decades.

8 **PROFESSOR FARSIDES:** I absolutely agree with your
9 challenge, but historically you can see why there was
10 that emphasis because it goes back to your point
11 yesterday about not using people merely as means to
12 ends. And perhaps what should have been made more
13 explicit is you have to keep in mind the best
14 interests of your patients and, as was previously
15 said, withdraw them from the trial at the point at
16 which you feel that it is very significantly counter
17 to those best interests. So you're not simply going
18 to stick with your patient being part of research,
19 irrespective of the impact on them. You are going to
20 be minded to keep that in your head.

21 But I agree with you absolutely. Whilst they
22 remain in the trial, the priority is doing those
23 things that add to the benefit of the trial being
24 completed in a scientifically robust manner. But it
25 may well be that there are patients for whom the

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1 trial started, meta-analysis showed that streptokinase
2 was superior to placebo.

3 There are cases where patients are recruited
4 when it's not in their interests and I think you need
5 to be honest with people about what the research is,
6 what the levels of certainty are at the beginning of
7 it, and what their options are.

8 **MS RICHARDS:** Professor Kerridge.

9 **PROFESSOR KERRIDGE:** Just on that, I mean, the point of
10 certainty about whether something works or does not
11 work and the point of certainty about whether
12 a particular adverse effect occurs or does not occur,
13 I point that out that they are two different outcome
14 measures and they won't necessarily always map on at
15 the same time. That will differ depending upon the
16 context, and it will differ depending upon the
17 availability of other treatment alternatives, and it
18 will differ depending upon the severity of illness and
19 the severity of adverse events from the new
20 intervention.

21 So if, for example, we are testing a statin, so
22 a cholesterol-lowering drug, we already have 20 other
23 cholesterol-lowering drugs on the market, all of which
24 have relatively predictable side effects. The level
25 of certainty that we will want to show that that is

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1 deprivations or the burdens of a particular trial or
2 experiment clearly run counter to their best interests
3 and if you were their clinician, would you not
4 consider the issue of withdrawing them from the trial.

5 **PROFESSOR SAVULESCU:** To give an example, in one of the
6 most famous trials in the 1980s, the ISIS-2 trial on
7 streptokinase, the UK recruited roughly 10,000
8 patients to that trial. After 1,000 or so patients,
9 Richard Doll from the data monitoring committee said
10 they had already reached their statistical end point
11 for significance, but they were going to continue to
12 recruit patients. They couldn't recruit patients in
13 the US to this trial because US doctors just didn't
14 believe giving a placebo was justified, given the
15 evidence.

16 Those patients -- and I calculated that
17 something like 230 patients extra died after the data
18 monitoring committee itself had said they reached
19 their statistical end point. And that was an example
20 of using patients to achieve greater levels of
21 certainty. The argument was: we need to convince
22 clinicians to change their practice; we need very high
23 levels of certainty. And that simply didn't operate
24 in the US where they said, "It's not in my patient's
25 interest to get a placebo". In fact, even before the

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1 better than all of the alternatives and is deserving
2 of market access, for example, will be enormously
3 high. So we will want to test many, many, many
4 thousands of people before we actually bring that
5 trial to a conclusion.

6 If, on the other hand, we're faced with
7 something like a global pandemic, we'll accept
8 significantly lower levels of evidence before we
9 actually draw a trial to a conclusion, we cease the
10 trial, we produce the drug or the vaccine and make it
11 accessible. We saw that with swine flu. We're seeing
12 it now with Covid-19.

13 In situations where there's a disease that
14 affects children where there's no alternative agents,
15 again, we will actually accept much lower levels of
16 certainty, much less than 5 per cent in fact, before
17 we actually draw a trial to a conclusion and make it
18 available. What we do now, though, is that we
19 continue to gain evidence through what's called
20 real-world data collection, or phase 5 data analysis,
21 where we look at data after a product is available, or
22 after a product is on the market, and we continue to
23 get information about it. Sufficient information that
24 sometimes we may then, at some point in the future,
25 choose to withdraw that drug or withdraw that vaccine

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1 or cease subsidisation of it. So we can actually
 2 adjust it depending upon the circumstances.
 3 **MS RICHARDS:** Professor Cave?
 4 **PROFESSOR CAVE:** Just two additional points: one, that the
 5 BMA is incorporating the Helsinki guidance within its
 6 wider guidance I think is noteworthy (it shows that it
 7 recognises the broad relevance and the importance of
 8 ensuring that doctors are aware of the declaration);
 9 and, secondly, the focus, for the first time I think,
 10 on disclosing risks and benefits is also noteworthy.
 11 So we've seen that it took far longer for the same
 12 principle to be recognised in law and guidance in
 13 relation to clinical treatment.
 14 **MS RICHARDS:** Dr Kazarian?
 15 **DR KAZARIAN:** Maybe just a quick comment about ensuring
 16 informed consent and the points that we made earlier.
 17 I think what's important to note from this text
 18 is also that if there is an issue with duress or the
 19 participant feels that there is a dependent
 20 relationship with a clinician, then the informed
 21 consent should be obtained by an independent person,
 22 and I think that's an important feature of that
 23 declaration as well.
 24 **MS RICHARDS:** If we could look at the next two sections of
 25 the document --

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1 beyond the point of your withdrawal, so you may still
 2 be harmed. But the important thing is that that
 3 person is able still to access the type of care that
 4 they need for their condition but also for the adverse
 5 event suffered as a consequence of the trial and that
 6 they are not prejudiced in terms of the healthcare
 7 they receive by withdrawal.
 8 **PROFESSOR SAVULESCU:** I think Sir Brian's point is: could
 9 they access the product, the superior product, outside
 10 of the clinical trial? There is a concept now which
 11 is only very recent of post-trial access to people for
 12 medical care that is not standardly available but that
 13 they received during the trial, that they have a right
 14 to continue to receive not just ordinary care but best
 15 possible care, given their contribution to research.
 16 Is that your question, whether they should
 17 continue to be able to access outside of the trial
 18 that which they received in the trial?
 19 **SIR BRIAN LANGSTAFF:** Indeed, yes.
 20 **PROFESSOR SAVULESCU:** That was not standardly a part of
 21 research. You reverted to whatever the best clinical
 22 care was at the time. But since probably the 1990s
 23 and early 2000s, where trials of AZT were done in
 24 Africa and people were then stopped from receiving
 25 that treatment once the trial finished, there arose

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1 **SIR BRIAN LANGSTAFF:** May I just ask a question here?
 2 This is about the freedom to withdraw without, you
 3 tell me, without having any prejudice to the future
 4 treatment of the individual.
 5 Suppose you have a trial which involves
 6 administering a drug on one hand, which is something
 7 like benzodiazepine, or that in tobacco which is
 8 chemically addicted compared to the placebo. It might
 9 be very difficult, mightn't it, in practical terms to
 10 actually stop? And the example could be perhaps
 11 multiplied to cases where blood products sourced from
 12 humans are used. Part of the idea may be to limit
 13 risk and to improve products, but it might be said
 14 that shifting from one to another, going back to the
 15 old treatment, may come with increased risk of health
 16 to the subject. How does that actually affect the
 17 concept of freedom to withdraw?
 18 **PROFESSOR KERRIDGE:** Sir Brian, I mean, the way I think
 19 about freedom to withdraw is the freedom to continue
 20 to access healthcare. Because you are right, if you
 21 withdraw after you've received a product that, let's
 22 say, has got a half-life of weeks or an impact on the
 23 immune system of six months or a year or 18 months or
 24 so forth, withdrawing after you have received that
 25 product will still give you the adverse events well

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1 a view that people should continue to receive that
 2 level of care, even if it wasn't standardly available
 3 in that place at that time.
 4 So I think best practice would say -- best
 5 ethical standards would say: yes, you should be able
 6 to receive that higher level of care, but that wasn't
 7 available for many decades.
 8 **PROFESSOR FARSIDES:** I think I heard Sir Brian's question
 9 slightly differently, which was a question around the
 10 practicalities of withdrawing from the trial and what
 11 might be entailed in terms of side effects or risks of
 12 prematurely ending the procedures that are involved in
 13 the trial.
 14 I think if there were any risk of that, it
 15 would have to be included in the information provided,
 16 that withdrawal from the trial would need to be
 17 carefully managed and would be managed by the team
 18 involved in the research to ensure that the patient
 19 came to no harm.
 20 On the question of post-trial benefits, I think
 21 it's a huge issue globally, and I suppose there's the
 22 issue of reciprocity. It's usually framed that one
 23 would receive those benefits, having been
 24 a participant in the whole trial and after the trial
 25 has collected the results it needs. Are you saying

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1 that you can withdraw from the trial and still benefit
2 from receiving the treatment you would not otherwise
3 be able to access?

4 **MS RICHARDS:** I'm going to ask you to look at the two
5 types of research that are then described in the text
6 of the declaration. So we see, first of all, "Medical
7 Research Combined with Professional Care", which is
8 termed here "Clinical Research":

9 "... the doctor must be free to use a new
10 diagnostic and therapeutic measure, if in his or her
11 judgment it offers hope of saving life,
12 re-establishing health or alleviating suffering.

13 "The potential benefits, hazards and discomfort
14 of a new method should be weighed against the
15 advantages of the best current diagnostic and
16 therapeutic methods.

17 "In any medical study, every patient ... should
18 be assured of the best proven diagnostic and
19 therapeutic method.

20 "The refusal of the patient to participate in
21 a study must never interfere with the doctor-patient
22 relationship.

23 "If the doctor considers it essential not to
24 obtain informed consent, the specific reasons for this
25 proposal should be stated in the experimental protocol

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1 clinical research, medical research combined with
2 professional care? What was that allowing the
3 clinician to do and how? Professor Cave?

4 **PROFESSOR CAVE:** So today it's much clearer that
5 innovation, with respect to an individual patient,
6 might be possible. So tweaking a treatment, doing
7 something that has the best interests of that patient
8 in mind, even if it isn't something that is standard,
9 might be acceptable, and that research is any
10 investigation in man or woman designed to develop
11 knowledge. But that distinction was previously much
12 less clear and we see that in the 1970 -- in this
13 particular -- the 1975-version of the Declaration of
14 Helsinki where if the research also combined medical
15 treatment, then it was seen as something else, as not
16 necessarily to be viewed as research, and this was
17 something that continued really for some time.

18 I can give you an example from
19 Margaret Brazier's *Medicine, Patients and the Law*, her
20 textbook from 1987. She talks about the case of
21 Mrs Wigley, and Mrs Wigley died when a trial drug was
22 given to her without her knowledge and without her
23 consent, but having been approved by 11 separate local
24 research ethics committees. They proceeded on the
25 basis that consent to the surgery that she'd given

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1 for transmission to the independent committee.

2 "The doctor can combine medical research with
3 professional care, the objective being the acquisition
4 of new medical knowledge, only to the extent that
5 medical research is justified by its potential
6 diagnostic or therapeutic value for the patient."

7 I will come back to that in a moment but we can
8 see it is contrasted with "Non-Therapeutic Biomedical
9 Research Involving Human Subjects", and if we just go
10 over the page we can see briefly what's set out at the
11 top of the page in relation to that:

12 "... duty of the doctor to remain the protector
13 of the life and health of that person on whom
14 biomedical research is being carried out.

15 "The subjects should be volunteers -- either
16 healthy persons or patients for whom the experimental
17 design is not related to the patient's illness.

18 "The investigator ... should discontinue ... if
19 ... it may ... be harmful to the individual.

20 "... the interest of science and society should
21 never take precedence over considerations related to
22 the wellbeing of the subject."

23 Can we go back to the previous page, please,
24 Soumik. Can I ask you to assist in understanding what
25 the declaration is telling us about what it terms

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1 also included consent to some of the drugs after
2 surgery, including one that was experimental.

3 This, in turn, flowed from a lack of clarity in
4 the Declaration of Helsinki and other guidance which
5 distinguished between therapeutic and non-therapeutic
6 trials, and said that consent wasn't necessarily
7 essential in therapeutic research so long as the
8 research ethics committee had approved it. This was
9 one of the cases that, sort of, led to a challenge to
10 that distinction, and it's one that we don't tend to
11 use today, we don't tend to see this distinction
12 between therapeutic and non-therapeutic research.

13 **PROFESSOR SAVULESCU:** I think the critical clause is
14 number (3), that says "every patient -- including
15 those of the control group ... -- should be assured of
16 the best proven diagnostic and therapeutic method".
17 So the idea of this section is that when it comes to
18 clinical research, clinical care should not in any way
19 be compromised or shortcuted in order to allow
20 research to occur. So the problem here is placebo
21 controls where a patient may be taken off or not
22 offered something that would benefit them, in order
23 for a placebo-controlled trial to occur.

24 What this is saying is you can't do that. You
25 have to ensure that people receive the best medical

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care, in addition to taking part in research. Research can never compromise clinical care but, in fact, that happened and I've written on that well into the 1990s, where people were placed on placebo-controlled trials for antibiotics for, say, caesarean section, where it had been proven that antibiotics were effective, so half of those patients were denied a proven therapeutic method.

So I think the important point here is that you should not receive anything other than best standard clinical care if you're part of a research project.

MS RICHARDS: Professor Farsides?

PROFESSOR FARSIDES: I think you have to acknowledge, though, that the constraints of a study may mean that you cannot avail of all the possible supportive measures that might be in place. This is particularly true of people in end-of-life care where additional visits to hospital might deprive them of the possibility of spending time at home or in a hospice being cared for there. There's a sense in which participation brings hope for benefit but it can, at times, be burdensome in ways that you've agreed to and understood and in ways that have been minimised, but they do mean that the way in which you're cared for necessarily has to be adjusted in order to accommodate

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that would be one case where it's essential not to obtain informed consent because it's an urgent clinical trial, for example. Tranexamic acid and stroke would be an example of that sort of research.

PROFESSOR KERRIDGE: As Julian mentions, the classical one from the last few years was urgent neurosurgical interventions where there was delays in getting research participants into surgery or getting them into neurosurgical interventions, specifically because of delays around informed consent. So there may be situations where that's done but a key part here, though, is the second part of the sentence, which is that if there's a decision to not get informed consent that has to be absolutely clearly specified and justified, it can't be assumed by the researchers.

PROFESSOR FARSIDES: There will have been a lot of prior work ahead of that decision both in the research and clinical teams involved and the ethics committees who have approved the study, because it will be seen as a significant departure from normal practice that is justified because of the urgent requirement to move forward.

MS RICHARDS: Can I then ask -- you can take that down for now, Soumik -- can I ask about any particular ethical dimensions or issues or problems that arise in

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the trial. So, for example, if there were a counter-indication between a drug that you might be offered for pain relief and the drug that you are being given in the context of the trial, that could be problematic and challenging to ensure that you get the best possible care, whilst also remaining true to the commitment that has been made to the trial.

MS RICHARDS: Can I ask you just to look at paragraph (5) of this:

"If the doctor considers it essential not to obtain informed consent ..."

One reading of that may be that the normal expectation would be in relation to the clinical research being described here that, for all the reasons we've discussed, the informed consent should be obtained. What could be the circumstances in which a doctor could ethically conclude it was essential not to obtain informed consent?

PROFESSOR SAVULESCU: Well, the standard example is emergency medicine research, where a person comes in needing urgent medical treatment and, you know, there have been studies where application of the intervention has been delayed by several hours while consent has been sought from family members or third parties, and that's led to harm to the patient. So

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relation to research on children. Professor Farsides?

PROFESSOR FARSIDES: I feel I should come in here, having chaired the Nuffield Council on Bioethics working group on research involving children, and you will probably have to stop me talking for too long.

We've already alluded to the moral imperative I think we have to increase our knowledge and our evidence base, pertaining to the medical treatment of children, and some of the advances that we have seen in the last century, particularly in paediatric oncology, have been precisely because old clinicians found ways to work with children and their families to combine rigorous research and therapeutic treatments.

We know that we can safely conduct research in paediatric settings but we also know that it is challenging, that we have to be particularly mindful of the ways in which children and their parents can be made to feel very vulnerable, first of all, by the onset of an illness, or by the birth of a child who has multiple medical problems, but also by the nature of entering into a medical environment, the urgency that's often entailed in getting treatment started; the challenges are significant.

Then we combine with that some of the issues we discussed yesterday about capacity and the ability to

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consent and what to do in those situations where we have to say that someone does not have the ability to consent, how are we going to proceed ethically in doing something to them, which will almost inevitably be the case, without their consent? Are we going to feel satisfied by involving them as best we can and maybe looking for children's assent? What weight do we give to parents' consent?

So there are many, many issues and we've talked about the need to ensure a child's open future. That has an impact on how we think about any of the risks associated with participation in research but, of course, it would also speak to the risks of not being involved in research and care in relation to their particular condition not thereby advancing.

So my sort of mantra is that we have to do research but we wish to conduct -- as I said earlier this morning, we wish to conduct research with children not on children and we increasingly got incredible examples of the extent to which very young people, children, can contribute to our understanding of what, in our report, we discussed will be seen as a fair offer, something that we can put to children and their families as a proposition to be involved in research at a time that is already incredibly

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complexity to research involving children.

The other issue with children, of course, and Bobbie talked about this in relation to relational autonomy yesterday, is that children are not -- they are not independent agents, they are part of families, they have siblings, they have relationships with their parents, the disease that one child gets inevitably has impacts upon the family unit, and taking all of those things into account when trying to make a best interests determination for a single child can be particularly challenging. So all of these things can be dealt with but they do make it complex.

PROFESSOR FARSIDES: Absolutely, and I think the thing to say is that when we look at that complexity, and we must never forget that it's there, and where we look at the potential for vulnerability, we see it as an amber light, it's a warning light. It's not a red light, it's not a stop light, because we have got to improve.

PROFESSOR KERRIDGE: Absolutely.

MS RICHARDS: Your report has drawn attention to guidance from the BMA in 1981. I won't put it on screen but you have identified three points from that 1981 guidance, in relation to research on children. Is this a project that can only be carried out with the

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stressful, incredible difficult, and at a time when they are burdened with information about diagnostics, therapeutics. But it can be done and I think we have a very strong commitment to do it.

MS RICHARDS: I think you told us in your report --

PROFESSOR KERRIDGE: Just if I could add to that, research involving children is difficult, in part because children don't stay children forever. They grow up, they gain capacity, they gain the capacity including to provide consent for research, and this is particularly an issue for longitudinal studies and longitudinal, particularly large epidemiological studies are enormously important in the study of chronic diseases, including infectious diseases, including those from blood malignancy in a range of conditions where studies may start with children, where their decisions are made for them for their parents. They then will become, you know, adolescents and young adults, they will move through periods of being mature minors, to the point where they are adults themselves and their goals and values may change during the course of that development.

Reassuringly, during that same time, of course, their parents are losing capacity, which is sad but true. So this undoubtedly adds an additional issue of

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use of children? Requirements for informed consent should be particularly stringent in relation to children under the age of 10, and then a requirement that local ethical committee approval should be obtained.

Those observations reflect more generally the ethical concerns that have always been held about research on children.

PROFESSOR FARSIDES: I think there's some of the concerns and to some extent they persist. We now have a very well-supported research ethics committee structure in the UK, but one of the findings and subsequent recommendations of our report was that there should be more expertise embedded within those committees, specifically about paediatric medicine. So you can have a committee that does not include anybody, either with lived experience of, you know, going through trials as a child, or any specialists nurses or doctors who have cared for those individuals.

So having a structure of ethics committees we think is a very good start but you then have to look at what is the relevant expertise to properly judge the risks and benefits when talking about research involving children.

MS RICHARDS: You have referred in your report to some

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1 1984 guidance from the Royal College of Physicians of
2 London on the practice of ethics committees,
3 September 1984. I can put it up on screen if required
4 but I really want to ask you more general questions
5 about ethics committees.

6 In broad terms, what is the function of
7 an ethics committee and how does it operate, and has
8 that changed significantly from the late 1970s or
9 1980s to the present day?

10 **PROFESSOR CAVE:** So the function is broadly to subject the
11 research protocols to independent scrutiny. So the
12 group of people -- the constitution of ethics
13 committees has changed over time but, generally, there
14 must be lay people on it, as well as researchers that
15 will understand the science and people who will
16 understand the ethics. The idea is to scrutinise it
17 to see whether it should be given approval. But
18 things have changed vastly over time. We now have
19 an organised supported system. That's been relatively
20 recent occurrence.

21 The Royal College of Physicians has called for
22 research ethics committees to be set up from the 1960s
23 but they were few and far between and, even when it
24 was recommended that local research ethics committees
25 were formed, so that there was one in every district

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1 know, as Emma has pointed out that, increasingly,
2 there have been very specific guidelines and
3 instructions for how ethics committees should operate
4 and the consideration that they should take into
5 account. But, broadly, you know, their job is to
6 ensure that the participants are exposed to reasonable
7 risks and they are protected, and secondly that they
8 understand and give valid consent to take part; that
9 that's basically their job.

10 Increasingly, they have also taken on their
11 shoulders assessing the scientific validity of the
12 research, and in my view, that's a mistake. But it's
13 important to recognise that although these are called
14 ethics committees, they are really public acceptance
15 committees. They apply ethical guidelines that are
16 prescribed to them and really are a part of -- there
17 is rarely anyone with formal training in academic
18 ethics on such a committee, and there are a broad
19 range of people -- theologians, a lawyer, a clinician,
20 a lay person -- and they use guidelines that have
21 specified the sorts of things they need to attend to.

22 So while they have become more professional,
23 they started off as a group of friends in an
24 institution who would approve projects within their
25 institution, but they now have moved to being much

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1 health authority from about the mid-1970s, they were
2 inconsistent in terms of their form and their
3 constitution and what it is that they were supposed to
4 do. So that if there was research conducted across
5 a number of different district health authorities, you
6 might get three very different answers from the
7 research ethics committees.

8 It was only really when training was
9 established and set out from about the year 2000 and
10 when multi-centre research ethics committees were
11 introduced and ethics guidance starting in 1991 but
12 then some additional guidance in 1997 that we got
13 a smoother operating system that was -- had greater
14 consistency with regards to what they did, their
15 constitution, their form.

16 Interestingly, we're seeing a fairly similar
17 thing happen with regards to clinical ethics
18 committees today. So we've had guidance from the GMC
19 saying they should be set up, and even with regards to
20 Covid, recommendations that things go before them, but
21 very little information about how they should be
22 supported or structured or who should be on them. So,
23 yes, it's something that has improved very much over
24 time.

25 **PROFESSOR SAVULESCU:** I think it's worth saying that, you

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1 more tightly regulated and specified, but they operate
2 really in a bureaucratic way to ensure that the
3 research conforms to various guidelines and
4 specifications.

5 **PROFESSOR FARSIDES:** I would want to differ with Julian on
6 the issue of the scientific merit. I actually served
7 on the first ethics committee. I served on in the
8 late '80s and, at that point, there was a separate
9 scientific merit committee that looked at any research
10 prior to it coming to the ethics committee. So one
11 had a confidence that someone had looked -- someone
12 with expertise had looked at this project.

13 That system seems to not be followed as
14 rigorously anymore, and particularly in a university
15 setting where some quite invasive research can
16 sometimes take place if you have a medical school
17 within the university. And if one has genuine doubts
18 about the ability of a methodology to offer some sort
19 of viable results, I think you have an ethical duty to
20 investigate that, challenge it, and possibly withhold
21 your approval until you are reassured that that's the
22 case.

23 Now, you don't want people overstepping their
24 brief or their expertise, but, as you say, the makeup
25 of ethics committees is often people who have an

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interest in ethics but are also themselves very experienced researchers, be that qualitative or quantitative in a social scientific way, or medical researchers. I would say that the very first step towards ensuring that some research is ethical is to ensure that it's not wasting time or resources and that you will have the real possibility of finding something out as a result of doing it, and if you don't look at methodology, or you are not reassured that someone has carefully looked at methodology, then you have a problem.

PROFESSOR SAVULESCU: I do agree that the scientific methodology of research ought to be scrutinised. It's just that ethics committees are not set up and don't have the sufficient expertise to evaluate that, and I completely agree with you. Expert committees are a very valuable thing.

When I was the chair of the DHS ethics committee, I would outsource any kind of scientific evaluation to experts. I wouldn't ask our committee to try to evaluate it, but that's not what's happened with these committees. They have taken it on their own shoulders to evaluate often very complex methodology. But I agree with you, it needs to be evaluated. It's a question of where and by whom.

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standard view, that if you are going to publish, if you are going to systematically study this, it constitutes research and needs the approval of a research ethics committee.

MS RICHARDS: Would it be fair to infer from everything else that you said yesterday and today that the patient or patients who are being treated and studied in that way should be made aware of that fact?

PROFESSOR FARSIDES: I think there can be differences between research and audit and service evaluation, and one of the differences is the proximity to the direct experience of the patient.

So if, for example, what we're looking at is a survey of notes every so many months and a collation of information that is then anonymised, that feels somewhat different to a research intervention that is very much going to become part of that person's life.

The problem, as Julian I think has alluded, is that it's a fuzzy boundary, and there may well be occasions on which we would want to think carefully about the ethical implications of audit or service evaluation. And when we do, there's nowhere to go because the ethics committees have been set up to look at research, and they are often overburdened, and if they feel that something is described as audit, they

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MS RICHARDS: Then moving away from ethics committees and just before we break for lunch, can I ask you about one further matter.

If you have a clinician who is providing treatment to a patient which is the treatment that they think is the appropriate treatment for that patient but they want to study the consequences, the side effects, the efficacy of how that treatment is working on a group of their patients, potentially for the purposes of analysing that information and publishing their thoughts, what are the ethical requirements in relation to that kind of undertaking?

PROFESSOR SAVULESCU: This is a particularly tricky problem that Professor Sir Iain Chalmers, who established the Cochrane Collaboration, described as the double standard that if you claim that, you know, you've got a new intervention that's going to be better, you can just introduce it without any real constraints. But if you want to measure whether it's working and compare it to what you've been doing, that becomes research and requires the approval of a research ethics committee.

So his argument was: you're essentially auditing what you're doing, and you shouldn't require ethics approval for that. That, however, is not the

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at least have the option of saying: that's not our business.

So audit, I think, is another very valuable tool in medical -- in terms of medical progress. It's about judging whether something one has adopted remains fit for purpose, whether there might be a need for research to start developing a bit further or even replacing it fully. We want to know by following up and auditing what happens once something that has been subject to research becomes part of standard clinical practice and, for the most part, that won't raise as acute or complex ethical issues as a piece of research.

But I think it's important not to be complacent. Where it raises issues about confidentiality or privacy, these sorts of things that are in common with our concerns, both in the clinical setting and the research setting, then where does a clinician go for advice on how best to, and appropriately, conduct their audit?

PROFESSOR SAVULESCU: I think today, in relation to your question about consent from the patient, if something looks like research, it ought to go to a research ethics committee, and if you don't want to get the patient's consent, that should be approved by the

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1 research ethics committee would be my position on that
2 issue. If it looks vaguely like research, you need at
3 least the approval of the ethics committee, and if you
4 are not going to get consent, they need to have
5 approved that.

6 **PROFESSOR KERRIDGE:** The corollary of that is that if
7 something is very clearly part of, sort of, total
8 quality management or a quality management process,
9 then there doesn't necessarily need to be consent but
10 there still needs to be information. So patients can
11 be told upfront, "During the process of your treatment
12 your information will be collected, data about
13 outcomes will be collected, it will be reported to the
14 following database", or in the situation that I work
15 in "it will be reported to the following national and
16 international registries". This is an important part
17 of gaining information about the future. It continues
18 *ad nauseam*.

19 So there's no one particular research question
20 but it is gaining knowledge and it's creating the
21 basis for further research, as Bobbie says. So it's
22 suggested at the very least there's broad acceptance
23 now there aren't clear lines between research and
24 audit, and there has to be, you know, upfront thinking
25 about is there a research question here, does this --

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1 which you are falling over yourself, as it were, to
2 ask Professor Kerridge because, of course, you will
3 lose him?

4 **MS RICHARDS:** No, I think the one specific question I had
5 for Professor Kerridge has been answered.

6 **SIR BRIAN LANGSTAFF:** Very well.

7 **PROFESSOR KERRIDGE:** I am delighted to hear that.

8 **SIR BRIAN LANGSTAFF:** You never know. If there is
9 a question, we won't let you escape quite that easily.
10 It will have to come to you for answering probably in
11 writing.

12 **PROFESSOR KERRIDGE:** I am very happy to.

13 **SIR BRIAN LANGSTAFF:** Can I just thank you enormously for
14 your contribution to this. Those of us who are not
15 normally used to going to work between 9.00 at night
16 and midnight will fully appreciate and understand what
17 you have done for us, particularly [as] I think you've
18 just started coming back off a break. So thank you
19 for giving us your time. Thank you for your
20 contribution, which has been refreshing. As with
21 everyone else, you haven't been at all hesitant in
22 saying where your views might differ, although broadly
23 they probably don't, and can I thank you for that.

24 **PROFESSOR KERRIDGE:** Thank you, Sir Brian, and thanks
25 Julian, Bobbie, Emma and Melinee, and good luck for

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1 as Julian says, does this look like a piece of
2 research and if it does, well, then it needs to be
3 turned into a proper piece of research and done
4 properly.

5 **PROFESSOR CAVE:** I think the underlying point here is that
6 the definition of research isn't uncontested. There's
7 a grey area between research and audit, between
8 research and compassionate care, between research and
9 compassionate use. So I made the point previously,
10 a few minutes ago, that there was this grey area
11 between research and medical care that was potentially
12 exacerbated by the earlier versions of the Declaration
13 of Helsinki and other guidelines. We have moved to
14 a view now that where the aim is in part a research
15 aim, that the patient should be aware of that fact and
16 that that really wasn't so clear in guidance
17 previously.

18 **MS RICHARDS:** Sir, I note the time. I have a few further
19 questions but also need to afford Core Participants
20 the opportunity to suggest further questions. Can
21 I invite you to take the lunch break now and to make
22 it an hour and a quarter, because I am anticipating
23 that there may be quite a few questions from Core
24 Participants that I will need to look at over lunch.

25 **SIR BRIAN LANGSTAFF:** There will be -- is there nothing

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1 the rest of the day.

2 **MS RICHARDS:** Thank you.

3 **SIR BRIAN LANGSTAFF:** Let's then say, shall we, 2.30.

4 **MS RICHARDS:** Thank you, sir.

5 (1.12 pm)

(Luncheon Adjournment)

7 (2.30 pm)

8 **MS RICHARDS:** Sir, the majority of the questions which
9 follow are questions which I have been invited to ask
10 you by Core Participants, and they are going to,
11 therefore, dart around somewhat from topic to topic.
12 But the first set are on the subject of research which
13 we were discussing prior to lunch.

14 What kind of information about a patient,
15 gleaned either from research or from clinical
16 treatment, can be used by a clinician and put into the
17 public domain by a clinician ethically without the
18 patient's consent?

19 **PROFESSOR SAVULESCU:** Well, having just finishing editing
20 the Journal of Medical Ethics, I can say none at the
21 moment. So we -- the British Medical Journal group
22 require patients to consent, even if all identifying
23 details have been removed from the description of
24 their case. So at least within that publishing group,
25 it's not possible to even put de-identified case

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1 histories, anonymised photographs, any details in the
2 public domain without the consent of the patient.

3 **MS RICHARDS:** Thank you. Any other observations?
4 Professor Farsides.

5 **PROFESSOR FARSIDES:** I would agree with that. I can only
6 speak from the perspective of conducting qualitative
7 research, so that is research that's actually trying
8 to get a patient's views and life experience, so, of
9 course, it's very easy to see that as potentially
10 identifying somebody. And not only do we pay
11 attention to the possibility of that happening and it
12 being an issue, but, of course, the important other
13 people in that person's life might be identified by
14 the stories they tell or the associations that are
15 alluded to.

16 So I think certainly when we're talking about
17 information that's gained through what we see as
18 increasingly important research that touches upon the
19 experience of people who have had particular diseases
20 or undergone particular treatments, we want to be
21 absolutely sure that they understand the implications
22 of how we will use that data, to what extent there is
23 an intention, for example, to directly quote people;
24 how they might be described. Even if we give people
25 pseudonyms and slightly change the description, we

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1 research they participated in has been completed and
2 what the results were. But I believe that, ethically,
3 they ought to be.

4 **PROFESSOR FARSIDES:** I agree, and you can take different
5 approaches to doing that. For example, you could
6 provide people with a web link from when they start
7 participating in the research and undertake to update
8 that regularly so that they know about the progress of
9 the research. Unfortunately, some people never get to
10 learn the research wasn't concluded that they had been
11 a part of.

12 Interestingly, when we spoke to children and
13 young people about this matter, it was one of the ones
14 on which they had the strongest view. They were
15 absolutely outraged at the thought that they could
16 participate in research and never learn what happened
17 and what benefits followed from it.

18 **PROFESSOR CAVE:** What Julian and Bobbie have said is
19 something that's also seen within the Declaration of
20 Helsinki. So paragraph 26 requires that participants
21 are given the option of being informed about the
22 general results of the study.

23 **MS RICHARDS:** What about audit or something that might be
24 in that grey area between audit and research? Do the
25 same considerations apply?

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1 would want everybody to feel absolutely comfortable
2 with how data was presented. And certainly in my own
3 case, if I was relying heavily on reported data,
4 I would share drafts of publishable material with my
5 participants.

6 **PROFESSOR SAVULESCU:** It's important to qualify both --
7 what we both said. In the past, that was not the
8 norm. In the past, photographs with eyes blacked out
9 or de-identified case histories could be published or
10 were published without consent.

11 **PROFESSOR FARSIDES:** And, sadly, not in the distant past
12 either. I mean, there have been relatively recent
13 cases of people challenging journal editors or
14 becoming very upset when monographs are published that
15 allege to have presented anonymised patient accounts
16 that are, nonetheless, very recognisable to the people
17 involved.

18 **MS RICHARDS:** Should patients be informed of the outcome
19 of research that they have been part of and also
20 informed when it's been published?

21 **PROFESSOR SAVULESCU:** Ethically, I think they should, and
22 I think that they should be provided with an
23 intelligible report of the research that they have
24 participated in. Again, that has not been the
25 standard, that people have been notified, that the

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1 **PROFESSOR SAVULESCU:** Historically, patients have not been
2 informed of the results of audit. They have been used
3 internally for improving quality of service delivery.
4 But as I think Emma has said before, the boundary
5 between research and audit has been blurred, and there
6 is an argument now where the results of an audit would
7 be relevant to patients, they ought to be informed of
8 that result.

9 **PROFESSOR CAVE:** That's right. It depends on what that
10 audit reveals. But it's important to recognise that
11 even though with audit there isn't a requirement for
12 a review from an ethics committee, there is still
13 a requirement of ethical oversight. It doesn't mean
14 that audit doesn't contain or doesn't have any ethical
15 issues or require any oversight.

16 **MS RICHARDS:** Is the reason or a reason for there being
17 different ethical requirements relating to clinical
18 and nonclinical research that in the former case it's
19 assumed that proper informed consent to the treatment
20 being administered has already been undertaken?

21 **PROFESSOR FARSIDES:** I don't think you would make anything
22 rest on that assumption because consent to treatment
23 doesn't necessarily entail consent to what will be
24 undertaken during the course of the research.

25 If you felt that -- you know, if you felt as

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a patient that consent had always been very well managed in your clinical experience, that might give you some confidence to expect the same in a research setting, but I don't think you can assume that just because things have gone well around consent to treatment that that relieves you of a very explicit obligation to get consent to anything that falls under the heading of research.

PROFESSOR SAVULESCU: It's also important to recognise that research is extremely broad, and non-therapeutic research can refer to many different kinds of research which might include observational research. And I think people in the past have thought that because you weren't doing anything to somebody in some kinds of non-therapeutic research that you didn't need to get consent. That, however, has changed in recent decades.

MS RICHARDS: Given the difficulties that you've referred to that there can be between -- in distinguishing between research and audit, to what extent is there an obligation ethically to seek advice on whether a proposed course of action is one which requires ethical approval before embarking upon it?

DR KAZARIAN: I think when the boundary becomes blurred between audit and research, and sometimes in big

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this isn't research" might have taken a long time, and so that's one of the factors that might have been relevant when people were trying to make that decision.

MS RICHARDS: You talked before lunch about something -- a project might look like research, and can I ask you about whether the two hypothetical examples and how they should be treated.

A course of action, a study, where the publication of the results has always been likely, is that something which should be treated as research rather than audit?

PROFESSOR SAVULESCU: Yes. In general, if you're thinking of publishing the results, it's usually considered to be research.

PROFESSOR FARSIDES: As Julian suggested, journal editors have actually been quite influential on this matter of not allowing too easy a distinction between research and audit and therefore requiring that when submitting publications to a journal. It's clear that, as Emma put it, there's been sufficient and appropriate ethical oversight, whether it's research or audit.

PROFESSOR SAVULESCU: And the reason for that is, if it's been published in a journal, it's original knowledge. It's not really just internal improvement of service.

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projects there are aspects and elements of both, in that situation, that particular situation, then this would probably require formal ethical approval because otherwise there might be ethical issues that need to be resolved.

PROFESSOR SAVULESCU: I think there is some default positions that we should adopt in these debates. So when in doubt, talk to the patient. When in doubt, seek the feedback of an ethics committee about whether it needs to be consulted. So, in general, there should be a default position of protecting the interest of the patient or the participant or of getting consent or involving others, you know, in the oversight of that project.

So, you know, I think we need to start with ethical defaults, not unethical defaults.

MS RICHARDS: You talked before lunch about -- sorry, Professor Cave?

PROFESSOR CAVE: Just a minor point that it's relatively easy now to work this sort of thing out. There are tools that can be used that you can follow on the HRA website to help you work out whether it's something that requires ethical approval, but there was more of a blurry line in the past. And to apply to the ethics committee just to get a response saying "actually,

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So that's why it got into a journal, because it's creating new knowledge that needs to be shared within the academic community.

MS RICHARDS: I think this may follow from the answers you've already given this afternoon, but would that also be the case where the subject of the study is an identifiable group of patients for whom anonymisation may be much harder to achieve. Haemophiliacs within a certain geographical location within a certain period of time, for example?

PROFESSOR FARSIDES: I think one of the strongest moral obligations upon researchers who work with small and identifiable populations is ensuring that, as far as possible, their confidentiality and privacy is protected and, therefore, if you feel you need advice on that, it's possibly too late to wait until you've got something to publish. It might be right back at the beginning of what you intend to do that you need advice on how to code your participants, how to describe without being misleading in a scientific or social scientific way who and where they are in order to preserve their anonymity as far as possible.

PROFESSOR CAVE: It's also worth pointing out that anonymisation isn't always a panacea. One of the things that a research ethics committee would want to

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1 look at is how effective anonymisation might be in
 2 a particular case because taking away somebody's name
 3 doesn't necessarily mean that you can't piece together
 4 who something is about. So that's something that
 5 great care needs to be taken over.

6 **MS RICHARDS:** Then how does an ethics committee ensure, or
 7 what other mechanisms exist to ensure, that
 8 undertakings that have been given about proposed
 9 research or conditions attached to research have been
 10 adhered to? How, for example, does the ethics
 11 committee satisfy itself that informed patient consent
 12 was actually taken?

13 **PROFESSOR FARSIDES:** It's interesting that some of the
 14 historical documents that we've looked at over the
 15 past few days, that you have shared with us, say, oh,
 16 it can't possibly be done, you know, once the research
 17 is approved then it's quite difficult to see what
 18 happens next. I think it did take quite a long time
 19 for ethics committees to think very constructively
 20 about how you might monitor the actual progress of
 21 a piece of research that you have given approval to.
 22 Certainly on a very specialised research ethics
 23 committee that I chair, for as long as the research is
 24 ongoing there is quite a detailed form that is sent
 25 out to researchers that would hopefully capture

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1 **PROFESSOR CAVE:** I can't be exact but in the '90s I was
 2 involved in a paper writing about the idea that there
 3 ought to be monitoring and there wasn't at that point.
 4 So I would imagine, sort of, late '90s but I can't be
 5 exact on that. My apologies.

6 **PROFESSOR SAVULESCU:** I haven't followed the developments
 7 in the UK but I know in 1999 the Australian Health
 8 Ethics Committee constructed what is called the
 9 National Statement on Conduct in Research and that
 10 placed monitoring responsibilities on ethics
 11 committees to continue to monitor the conduct along
 12 the lines Bobbie suggested, but also including site
 13 visits. So it was -- I think it was 1999 exactly when
 14 that became a responsibility of ethics committees in
 15 Australia.

16 Now, again, I don't know if that's been made
 17 the case in the UK but it certainly illustrates that
 18 around that time there was an expectation that it
 19 wouldn't be just you approved the project but that you
 20 ensure that deviations are reported, adverse events
 21 are reported and that you monitor the conduct of the
 22 research.

23 **PROFESSOR FARSIDES:** I think other parties have become
 24 interested in monitoring the ethical conduct of
 25 research, for example funding bodies. I mean, my

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1 anything that was not going as it should have been,
 2 given the terms upon which the original approval was
 3 given.

4 So I think ethics committees are more alert to
 5 this but, if the work involved in that is quite
 6 substantial, and if you were working in an NHS
 7 committee with a much larger flow-through of research
 8 than the one I'm referring to, it might only be that
 9 you could sample a small number of projects a year and
 10 follow them through. But there is a recognition that
 11 your responsibility formally ends when you give
 12 approval but your ethical interest in what happens
 13 next should remain live and, if you have a way of
 14 practically monitoring that, then it's certainly
 15 something that one would want to happen.

16 **PROFESSOR CAVE:** It's a fairly recent thing. So the idea
 17 of monitoring decisions to make sure that researchers
 18 are doing as they promise to do is fairly recent. For
 19 many years it wasn't done. There was no capacity to
 20 do it and I think still in some institutions it's not
 21 done as effectively as it might or perhaps there's
 22 a lot of variation in how it's done, perhaps across
 23 university, for example.

24 **MS RICHARDS:** When you say "fairly recently", are you able
 25 to give us an idea of how recently?

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1 first meeting tomorrow morning is in a role as
 2 a member an independent ethical advisory group for
 3 a very large and complex clinical trial, and it was
 4 the requirement of the funders that such a body be
 5 established and keep a quite close eye over the
 6 conduct of the trial, not looking at the science but
 7 specifically looking at the ethical issues that might
 8 arise and giving support, advice but also finally
 9 maybe giving comment on whether or not it was thought
 10 that the study was sticking to the terms of the
 11 permissions given by the ethics committees.

12 **PROFESSOR CAVE:** The paper I wrote was in the year 2000,
 13 so it seems we were behind Australia again, sadly.

14 **MS RICHARDS:** Dr Kazarian?

15 **DR KAZARIAN:** I think the work of research ethics
 16 committees is an ongoing process and it's important
 17 that -- they are important to preserve ethics and the
 18 ethics of research projects, not just at the stage of
 19 the ethics approval but if there are changes during
 20 the study and there are amendments made, then they
 21 have a role as well and that's why, more recently, as
 22 has been said, this monitoring role has become more
 23 and more important.

24 **MS RICHARDS:** You have said in your report that there may
 25 be large cohort studies that could be approved,

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whereby anonymised data is provided over a period of time to inform scientific knowledge, et cetera, and particular patients might be unaware of their involvement in that but that there should be a general public awareness of the existence of the study.

The question I wanted to ask arising out of that is what kinds of steps should either clinicians providing data or those controlling the data take to ensure public awareness of such studies, particularly amongst relevant patient cohorts?

PROFESSOR CAVE: It's interesting that in this regard there's a thing called a Caldicott Guardian, which is after review of patient identifiable information in 1997, this review, chaired by Dame Fiona Caldicott set up a government system, whereby there would be Caldicott guardians in each institution in the NHS, and they very recently set out a new principle so they started off with six principles and they have added two since then, and one of those is the duty to tell patients how confidential information is shared where it's going to be shared. So I think this is a recognition of the fact that things have changed over time and the methods too will have changed over time. So now it may well be that websites are used, previously it might have been that there was more

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subject registries in a way that, if people are interested, they can find out whether their information is going into those registries.

So, for example, there was a large scandal recently when the NHS provided data to Google DeepMind, and that's an example where I think people should have been made aware of the nature of that project, its value, the protections in place, the financial arrangements, and better public information disclosed in an accessible way.

There's been a greater movement towards disclosure, for example, registries of clinical trials in the past there was no requirement to make public that you would perform a clinical trial and now it's been acknowledged that that's important to find out what is going on and how many trials are not publishing their results, or their results are not being published. Because that's another public problem in research, where negative results are not published, trials are repeated when it has already been shown that some intervention is ineffective or harmful and, generally, knowledge is not advanced.

So things have moved on a lot but I wouldn't know whether -- I would have to know more about the precise nature of the situation to say whether it's

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focus on leaflets in the right places, in places where people were more likely to come across them.

MS RICHARDS: If, for example, there's a National Register for a particular condition on which a patient's details are entered, would you expect, ethically, that patient to be notified that their details are going to be entered into the registry?

PROFESSOR CAVE: It's not quite so straightforward, I suppose, because it depends what we're going to do with that registry. If it's for research purposes, for example, then the ethical requirements might be different.

The optimal situation will be that there is explicit consent to that but there are exceptions to that which we discussed before the break. So there are situations where the law allows, subject to application, registries to collate data without getting informed consent in each instance.

PROFESSOR SAVULESCU: So, for example, there are cancer registries where cancer information is submitted. I think, ideally, as Emma says, there would be -- people give exclusive consent. Next best would be that they are informed that this information is available and the next best option would be that there's public disclosure and information about

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ethically important to or ethically mandatory to directly inform patients of a particular registry.

PROFESSOR CAVE: One reason -- sorry, I beg your pardon. Go ahead Mel, because I've spoken already.

DR KAZARIAN: Just following up on that particular point, the Caldicott Report recognised that, actually, the duty to share information is as important as the duty to protect confidentiality, and it might be sometimes in the patient's best interest to share that particular information.

But the purposes of the sharing of information must be justified, so that's another important requirement from the report.

PROFESSOR CAVE: The law on data protection has become clearer over time. Until the Data Protection Act 1998 it really was very unclear, and even after 1998 there was a lack of clarity as to the sort of consent, whether it should be express or whether it could sometimes be implied as to what would suffice, and the same really can be said about the law of confidentiality.

So we have a law saying that you must keep information secret under certain circumstances but there are a great number of exceptions to that and the clarity with regards to those exceptions wasn't great.

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PROFESSOR FARSIDES: I think another thing to think about is alongside the growth of our recognition of the value of medical data and the sharing of, and I think it's really helpful that Mel's reminded us of that element of the Caldicott recommendations.

Alongside that, we've got a growing amount of evidence of what the general public think on these matters. There's been quite substantial research conducted. There's been across the nation citizens' juries. If you look at establishments of projects such as the 100,000 Genomes Project which was going to be responsible for storing a huge amount of sensitive data, one of the first committees established as part of that process was the participant panel so that people who themselves were going to be part of the project could have a say and advise and comment on the arrangements around the sharing and storage and use of data.

So if we were wanting to feel a bit more positive about the direction things are going, I think that's where to look. The idea that this is no longer an area where decisions are made by doctors or even information technologists and specialists, it's an area for public debate, public engagement and involvement, and very specifically in areas where, you

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reporting them to the patients, of course, but at least it's requiring that there's an openness.

The GMC around the same time said that it was improper to accept payments unless they are approved by a research ethics committee, same as the RCP, but also said that the same applied to treatments where clinicians were asked to report adverse events or incidents per capita which they saw as a quasi form of research.

More recently, we have the Cumberlege Reports, which I know I've alluded to a number of times, but it made very important recommendations with regards to mandatory reporting for pharmaceutical payments to hospitals and research institutions and also to individuals. And the GMC has agreed that it would be a useful thing to set up a list of financial and non-pecuniary interests for all doctors. So that's -- I suppose it shows that this is something that has been ongoing -- an ongoing problem that we haven't quite worked out the solution to, but hopefully one is just around the corner.

MS RICHARDS: I wanted next to ask you about training in medical ethics for doctors.

To what extent since 1970 or thereabouts has there been training in medical ethics for doctors as

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know, patient communities feel that they have particular concerns or interests, the involvement of those with lived experience.

MS RICHARDS: Is there an expectation ethically that a clinician who is involved in medical research in relation to developing products or has an involvement with a particular pharmaceutical company will tell their patient that if they're proposing to treat their patient with that product or with a product manufactured and supplied by that pharmaceutical company?

DR KAZARIAN: I would say yes that now -- I think it wasn't clear before in the past, but now if there is a particular or possible conflict of interest, for instance, then that needs to be disclosed to the patient or the research participants. Sources of funding as well is something that needs to be disclosed to the patient, and I think that's made clear in the Declaration of Helsinki as well.

MS RICHARDS: Professor Cave.

PROFESSOR CAVE: There's also some guidance around the 1980s on this. So the Royal College of Physicians in 1984 said that in research it's important to report any payments to research ethics committees so that they were aware of them. That's not the same as

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part of their professional training and qualifications? Professor Farsides?

PROFESSOR FARSIDES: I don't think you would go as far back as 1970s. There may have been, you know, a lecture, but I think it might have been very much in the terms of the etiquette model that we keep coming across in the documents of that time.

I myself have been involved in medical ethics since the mid-1980s. That was relatively early, and the education initially was more likely to be post-graduate education, I think, for interested professionals who wished to develop skills in that area.

From the mid-1980s, Professor Raanan Gillon, whose name came up yesterday, established a very thorough, respectable, intensive course at Imperial College that still runs to this day and attracts people from around the world.

But in terms of medical schools, it took longer, but once it happened, it happened. The GMC decided, as I think I said yesterday, that ethics should be a continuous strand through medical education because there's a sense in which you can't unpick where it is and isn't relevant. There's the potential for relevance throughout. There's very few

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topics that the students learn that are completely devoid of the possibility of an ethical complexion. Different medical schools have developed different curricula. They choose to deliver the teaching in different ways. It sometimes depends upon the specific interests and specialisms of the ethicists involved in the teaching. It may be that there's -- in our medical school, we have a lot of team-teaching alongside clinicians so that you make sure that what you're saying is very much related to the clinical experience of the students. And alongside this, a community has grown up around the discipline with some very active bodies such as the institute of medical education which supports and promotes ethics in medical schools and encourages medical students to think of it as also an extracurricular activity with debating contests and competitions for writing journal articles, et cetera.

So it's something that's changed over time. You now find -- I can't think of a medical school that doesn't have substantive members of staff working in this area. It will vary how many. But now I don't think you could graduate from a medical degree in a British university without being aware that you had been taught a substantial amount of medical ethics and

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PROFESSOR FARSIDES: Yes, that's right.

MS RICHARDS: We touched yesterday, and you touched on it in your report, on the limited nature of legal remedies. For example, there is no freestanding claim for damages for the absence of informed consent.

Is there any evidence that you are aware of that the existence of legal remedies drives up standards of care and helps embed ethical standards?

PROFESSOR CAVE: I think we have seen some evidence of that in the various documents that you have put up. So where there was talk from the Medical Defence Union, for example, about consent, it referenced assault, and that was -- so the thinking then was how can we advise people on how to avoid a claim in assault. But then that was from the Medical Defence Union, so fairly clear that that was going to be their emphasis.

It's more a symbiotic relationship, I think. It's not that one drives the other, it's that both are relevant to both. The law can be a lot slower to move than ethical guidance but, as we heard over the course of yesterday, sometimes codes too can take a while to be changed to get consensus, to get agreement. They can be fairly slow moving too. So things move at different strands at different levels but there

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law.

PROFESSOR SAVULESCU: Bobbie is the expert, but I think 1998 is a sort of key year. The group published a core curriculum in the Journal of Medical Ethics -- Bobbie was a part of that group -- and around that time, the GMC mandated medical ethics and law teaching in medical schools. So it went from this very disparate, informal form of teaching to something that was really a part of core medical education. And around that time, Tony Hope and I wrote our book on medical ethics and law textbook for medical schools around that core curriculum.

So I think it's really the late '90s where it became, you know, a core part of medical schools. But, as Bobbie says, there is still considerable freedom and choice around how that's delivered and what is actually delivered. So I wouldn't by any means want to think that the job is done and that doctors are completing their education with a good knowledge of medical ethics and law.

MS RICHARDS: The 1998 publication to which you refer, that's the consensus statement by teachers of medical ethics and law in UK medical schools which is, I think, referenced in your report and to which you were signatory I think, Professor Farsides?

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certainly are cases where changes in law have driven changes to guidance. *Montgomery* is an example of that.

It's strange in a way because *Montgomery* came about, in part recognised the GMC had recognised for many years a standard of informed consent that hadn't been fully adopted by the courts. Yet the GMC then went on to revise their guidance in order to take account of some of the nuanced aspects of the judgment, such as the reference to the therapeutic exception, which we've talked about, and reference to dialogue and the importance of dialogue, and to really draw that out, to operationalise some of the legal aspects that *Montgomery* had set into law.

MS RICHARDS: Moving to a different issue now, what ethical principles guide how clinicians should guard against stigma or conscious or unconscious bias in their practice? Professor Farsides?

PROFESSOR FARSIDES: Again, I think you would not have heard this term "unconscious bias" mentioned within the medical curriculum until very recently, probably, but certainly the GMC has been very aware of the impact of unconscious bias when considering how the Fitness to Practise processes operate, and the ways in which people's judgments of what happened might be

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skewed somewhat by biases they simply do not know that they hold or operate.

Stigma is, again, I think, something that for many years was not well understood and could too easily be overlooked, even by the most dedicated clinician. It's since medicine has become more open to working in partnership with disciplines such as anthropology, sociology, ethics, that we've worked together to define, understand and then move on to try and find ways of minimising experiences of stigma.

But it's a huge challenge and it requires a lot of careful work and the work doesn't stop in terms of what you manage to achieve as an individual doctor and patient. Stigma is a societal problem and what we sometimes need is the expertise of all those who have come to recognise the existence of stigma to be applied to sharing their knowledge and understanding more widely, so that we try to tackle it as a societal problem.

MS RICHARDS: The next question is again on a different topic. The process of death certification -- I know the panel doesn't claim any particular experience of or expertise in relation to that process -- but, ethically, what are the implications of omitting or obscuring a cause of death on a death certificate for

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So it denies people the opportunity for legal redress if the death certificate is misleading or inaccurate.

MS RICHARDS: Professor Cave?

PROFESSOR CAVE: The GMC says that death certificates must be completed honestly and fully and to the best of the clinician's knowledge and belief. But I think it's also true to say that it isn't an exact science, that it isn't always clear what a main cause is and what an underlying or a cumulative cause is, and so there is an element of subjectivity. But that comes within the broad ethical requirement that the completion of the certificate should be honest and full and to the best of the person's belief.

PROFESSOR FARSIDES: I agree with all of that but it's interesting, isn't it, that it goes against Mel's point earlier about retaining privacy in death because there may be information then provided in a very public way about the manner and cause of somebody's death, which I absolutely agree needs to be publicly known but may, nonetheless, be problematic in confidentiality terms.

I also remember in the very early days of HIV and AIDS discussions about the possibility of almost having two versions of a death certificate, such was

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what may be well-motivated reasons of avoiding stress or preserving confidentiality?

PROFESSOR SAVULESCU: Well, I mean, first of all, it has implications for a health system and for other patients if death is not accurately recorded and we can't understand what's happening with patterns of death or with perhaps adverse events in hospitals or around clinical care.

So, first of all, it's essential that death certificates are accurate for medicine to advance. Secondly, it can deny the family appropriate understanding of the circumstances of death, and perhaps even their risks or matters to do with their own future well-being, and also to do with many future redress.

So, for example, you know, to take one personal example my father had died, when he was in hospital for the investigation of jaundice, and during a radiological examination a needle pierced an artery in his liver and because he was 87 he was essentially allowed to bleed to death, and the death certificate recorded a heart attack, which I didn't challenge but which was inaccurate and if I had wanted to pursue a legal case would have made pursuing that legal case more difficult.

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the fear of stigma and the wish of families not to be exposed, as they felt they would be, by local knowledge of the cause of death. So you would record a death and how -- you know, it was incredibly important in order to understand the epidemiology and the prevalence, et cetera, but that you could have a document that would be somewhat more euphemistic and we all know that very common euphemisms arose in that context to be used by the family in public spaces.

So I think whilst it is crucially important and sometimes important to the family that they have an openness and transparency to relate to, it's not unproblematic because of the impact of certain diagnoses and causes of death.

MS RICHARDS: We spoke yesterday about team decisions, team working. You may to some extent have answered this question already but the question is this: does an individual clinician bear ethical responsibility for a multidisciplinary team decision that is ethically wrong?

PROFESSOR SAVULESCU: Typically, as we were saying yesterday, there is a senior treating doctor who is responsible for the oversight or management of the patient and that doctor, unfortunately, like the Prime Minister, has to take responsibility for the decisions

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1 that, you know, that they ultimately make, even if
2 it's the result of a team decision. So, normally,
3 there is a doctor who will be the primary person who
4 is responsible for that care, and the patient will be
5 under that bed card, under that consultant, and that
6 person is responsible for getting whatever input,
7 including team consultation, that they require but it
8 is ultimately an individual decision, not
9 a Parliamentary vote.

10 **PROFESSOR FARSIDES:** I agree that there has to be somebody
11 ultimately who holds responsibility for a team's
12 decision because that person has also, to some extent,
13 got responsibility for the proper functioning of that
14 team. So if you are the chief consultant and your
15 team is not working in a way that upholds the best
16 interests of patients or doesn't show due regard to
17 keeping up-to-date with research, or any of the things
18 that we've discussed so far, you've got a systemic
19 problem before that translates into an individual
20 problem, and it might be that we go back to look at
21 the actual functioning of the team, as well as the
22 particular decision that was made, because sometimes,
23 for example, if junior doctors are not well supported
24 and senior colleagues do not make themselves
25 adequately available to advise or support, that might

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1 extent of whether you want to escalate the case.

2 **PROFESSOR CAVE:** To follow on from Julian's point, it can
3 be escalated, of course, outside institutions. Julian
4 mentioned court, the GMC also has a role which means
5 that clinicians can report issues to the GMC which
6 will then act upon that. It's also interesting that
7 the recent reports into the actions of breast surgeon
8 Ian Paterson, the James Report, that reported not just
9 the wrongful actions of one individual but the wilful
10 blindness to those actions by those around him.

11 I think there has been, for some time,
12 a problem with regards to whistle-blowing, with
13 regards to the protection of whistle-blowers in the
14 NHS, and there have been various statutes and
15 guidelines that have tried to resolve that but, in the
16 past, that was even more of a problem than it is
17 today.

18 **SIR BRIAN LANGSTAFF:** May I just ask a question. We're
19 talking here on and off in this last question and
20 answer about responsibility and team working and
21 a clinician, the lead clinician having responsibility
22 for the team. What if we take this example: suppose
23 that part of what is identified in somebody who is
24 being treated by a lead clinician, who is
25 a haemophilia doctor, is that the individual suffers

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1 be at the root of the problem and it is, as I say,
2 a problem, a systemic problem that would then need to
3 be addressed to ensure that future incidents of the
4 same type did not occur.

5 **PROFESSOR SAVULESCU:** So where there's a controversial
6 case or disagreement between, say, the team and the
7 lead consultant or amongst the team, there are various
8 ways of escalating the responsibilities. So, for
9 example, I was peripherally involved in
10 a controversial case in Australia of a late
11 termination of a 32-week pregnancy for dwarfism, and
12 that involved at least five different specialists who
13 all were in agreement, but because of unclarity in the
14 law contacted the hospital medical administrator who
15 involved medical administration in the decision. You
16 can also involve the hospital lawyers, in terms of
17 seeking an opinion from them about legality of any
18 proposed course of action or seek the view of
19 an ethics committee in terms of advice on the case.

20 So when there are different views, it can go in
21 an escalating way and, ultimately, it can go to court
22 for a court decision about which course of action is
23 in the best interests of the patient.

24 So it will depend on how controversial it is
25 and what the nature of the disagreement is and the

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1 from a liver condition for which he is referred to
2 a hepatologist. Both are, in one sense, part of the
3 same team because they are both administering care to
4 the same patient. Who takes responsibility? Someone
5 overall, or just each for what? Because in some cases
6 that we've heard about in the Inquiry, it may have
7 been the case that the haematology doctor would keep,
8 as it were, the patient as his patient and the
9 hepatologist would visit. In others, it would be that
10 the hepatologist would have a separate clinic. Who
11 has responsibility and for what? How do we decide?

12 **PROFESSOR SAVULESCU:** Well, I think it's a shame we don't
13 have Ian here to answer that question, and maybe we
14 want to pose that to him in writing.

15 My understanding is that it depends on which is
16 the dominant problem. So, for example, to give you an
17 analogy, often patients will end up in intensive care
18 with an intensive care specialist as their main
19 doctor, but they will have a neurosurgeon involved,
20 maybe a cardiac surgeon, a neurologist, and in that
21 case the neurosurgeon will be responsible for the
22 neurosurgical aspects of the care, but the intensive
23 care consultant will be in charge of the overall
24 management and co-ordination of these different
25 specialties.

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1 Then the patient may in the end be discharged
2 out of intensive care to neurology, and that
3 consultant then becomes the primary consultant. So it
4 would depend on whether the main problem was
5 haematological or whether it was hepatological, and
6 that person would be, if you like, the main
7 co-ordinating clinician, and the other one would be
8 secondary, and that may shift according to the way in
9 which the problem evolves.

10 That's my understanding of the distribution of
11 responsibility in medicine, but it's been a long time
12 since I've been actively involved in it.

13 **DR KAZARIAN:** I think I would agree with that, and I think
14 there is a difference between moral responsibility and
15 ethical responsibility and legal responsibility. And
16 often in healthcare failing cases, as Bobbie has
17 mentioned and Emma has mentioned, there are a lot of
18 systemic issues which come to play, and that has an
19 impact on how care is delivered to the patient.

20 In these cases, it is often very complex to
21 attribute responsibility to one particular person.
22 Ethically, I think that if a doctor, a clinician, has
23 a patient to whom they are delivering care, then
24 ethically they are responsible towards that patient
25 for their well-being. Legally, it's more complicated.

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1 for ongoing management and co-ordination.

2 **MS RICHARDS:** Returning to the issue of informed consent,
3 and this question would relate both to consent to
4 treatment and consent to participation in research,
5 how does one guard against the dangers of a clinician
6 effectively sugar-coating the message by emphasising
7 the positives and benefits of the treatment or the
8 proposed participation and downplaying the potential
9 adverse consequences and risks?

10 **PROFESSOR SAVULESCU:** Well, that's not informed consent.
11 It's not -- a person needs to understand accurately
12 what the risks and benefits are, not have
13 a mis-perception.

14 And, of course, I mean, it can be -- we talked
15 about subconscious bias. Another thing in the last
16 30 years is an acknowledgement of the heuristics that
17 we operate under; psychological framings. So whether
18 you simply frame something in one way in terms of
19 gains instead of losses will tend to push people into
20 choosing the option. So you can present exactly the
21 same information but framed in a different way and
22 will influence patient choice. That is a big obstacle
23 to enabling fully informed and autonomous choice. So
24 ideally, the information should be presented in
25 a number of different ways to not hijack these biases

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1 And it could be argued that sometimes responsibility
2 must be shared and distributed, but sometimes it might
3 be a case of actually that's a systemic issue, and,
4 therefore, it is very difficult to attribute
5 responsibility to one particular person.

6 **PROFESSOR SAVULESCU:** And there is a problem, Sir Brian,
7 with patients falling between the cracks there where
8 nobody knows who's taking responsibility. My
9 memory -- and, again, Ian, I think, we should ask, but
10 my memory in haemophilia was that the clinics were, at
11 least in Australia, very protective of the patients
12 and tended to maintain primary responsibility,
13 regardless of the other problems and retain that
14 responsibility for co-ordination of care because there
15 was, if you like, a community around that group of
16 patients. But it is a complicated area where people
17 can easily fall through the cracks.

18 **SIR BRIAN LANGSTAFF:** Presumably, the patient needs to
19 know who is really going to take responsibility for
20 their care.

21 **PROFESSOR SAVULESCU:** Yes. I think the most important
22 thing is that that's decided and it's clear to the
23 patient. You know, in some ways, it really will
24 depend on the circumstance, but it needs to be clear
25 who is going to take over the overall responsibility

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1 or heuristics that we all operate under.

2 **PROFESSOR FARSIDES:** I know I'm beginning to sound like
3 a broken record, but I think, again, this topic tells
4 us of the experience of learning from people who maybe
5 have gone through these treatments before because it's
6 not only the case sometimes that a clinician
7 unconsciously or otherwise could sugar-coat the risks.
8 But there was some interesting research conducted by
9 Morris Slevin many years ago around the risks
10 associated with chemotherapy. And he conducted some
11 scenario-based research with patients, nurses and
12 doctors asking: what sort of risk would you be
13 prepared to accept in order to acquire this type of
14 benefit? And what his research revealed was that the
15 doctors and nurses were far more conservative around
16 risk than the patients.

17 So there is also the possibility, on occasion,
18 that without understanding patient experience, your
19 presentation of risk could err too much on the side of
20 caution. We worry much more about those who
21 sugar-coat or misrepresent risks in a way that makes
22 them unexpected or completely obscures them for the
23 patient, but I think we should also think that if we
24 continue to make decisions without any reference to
25 those who had direct experience, we have a risk of

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1 going in the other direction as well.
 2 **PROFESSOR SAVULESCU:** Just to illustrate that point with
 3 this issue of framing. Say you have a patient with
 4 a life-threatening condition, and you say to the
 5 patient, "We can do an operation, but there's
 6 a 20 per cent chance that you'll die," people will
 7 tend not to take the operation. If you say, you know,
 8 "There's an 80 per cent chance you'll survive the
 9 operation and be cured of the condition," they will
 10 tend to take the operation. So that's what framing
 11 effect is.

12 So what's important is you present them with
 13 both information, both framings, and enable them to
 14 make their own decision about whether to take on the
 15 risk or not. And that's really something that hasn't
 16 permeated entirely medical practice now, and I think
 17 that's going to be a challenge for the future. Sorry,
 18 Emma.

19 **PROFESSOR CAVE:** No, not at all. I quite agree with what
 20 you said and what Bobbie said as well.

21 I just wanted to add the proviso that in some
 22 cases patients will ask the doctor, "What would you
 23 do?" And in those cases, it's acceptable for the
 24 doctor to say, "This is what I'd prefer to do."
 25 That's an entirely different thing to sugar-coating

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1 are you aware of any cases, civil or criminal, where
 2 testing without informed consent has led to litigation
 3 and resulted in a concluded or reported case?
 4 **PROFESSOR CAVE:** There was a case called *Re C* involving
 5 consent of a child -- consent of parents in relation
 6 to HIV testing of a child which is interesting because
 7 in 1988, the GMC recommended that it wouldn't
 8 necessarily be the case that you would need to get
 9 consent of parents in order to test a child, and
 10 I think that was highly controversial, given that
 11 we've discussed over the last couple of days the
 12 importance of having a valid consent to avoid the
 13 possibility of an assault.

14 So in this particular case, what happened was
 15 that there was a question about whether the child
 16 should be tested for HIV. The parents objected, said
 17 they didn't want that to happen, and the court decided
 18 that in this particular case it would be in the best
 19 interests of the child to be tested so that any
 20 treatment that the child might need could be
 21 delivered. So that's one particular case.

22 There's also the case of *S and S*, which is
 23 a 1972 case where the House of Lords said that taking
 24 blood from an adult against his will is contrary to
 25 the law because it interferes with his personal

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1 and not giving the information properly, but I think
 2 it's important to recognise that does sometimes
 3 happen.

4 **PROFESSOR FARSIDES:** Although, in some areas of medicine,
 5 and particularly in nursing -- and often, I think we
 6 mustn't forget that the nurse is the person someone
 7 turns to and asks that question because they're
 8 sometimes more accessible, the person might have got
 9 to know them better and feel more relaxed with them.

10 There's a long-standing tradition of what we
 11 call non-directive counselling, and the idea that
 12 actually particularly where the decisions that
 13 somebody makes have an ethical complexion to them,
 14 such as whether or not to terminate a pregnancy due to
 15 a foetal anomaly or suchlike, that question is often
 16 batted back to the patient as something that can't be
 17 answered because that would be directive. And then
 18 you need to support the clinicians in having sort of
 19 communication skills level 1B such that, actually, you
 20 can still enter a meaningful dialogue with the patient
 21 around the concern that they are raising and not just
 22 say, "I can't answer that question."

23 **MS RICHARDS:** The next question is for Dr Kazarian and
 24 Professor Cave, and it may be one that you can't
 25 answer but would be able to in writing. It's this:

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1 liberty. That's a slightly different situation
 2 because that was -- the actual physical act was
 3 against the person's will, rather than the issue of
 4 whether the individual was aware as to what was being
 5 consented to.

6 So they're two cases. I'm not sure that that's
 7 comprehensive. There may be others, but they are two
 8 I am aware of. Do you know or any others, Mel, that
 9 might be --

10 **DR KAZARIAN:** Those are the two I am aware of as well.
 11 I can have a further look and maybe respond in
 12 writing --

13 **MS RICHARDS:** Thank you.

14 **DR KAZARIAN:** -- if that would be helpful.

15 **MS RICHARDS:** The next question picks up upon
 16 a discussion, I think, led by Professor Savulescu
 17 yesterday about hard and soft paternalism. I think it
 18 may be that this question has already effectively been
 19 answered by your evidence yesterday but I am asked to
 20 ask it.

21 Does a failure to provide a capacitous patient
 22 with information known to the clinician in order for
 23 them to make an informed decision amount to hard
 24 paternalism?

25 **PROFESSOR SAVULESCU:** Yes, unless there is some deficiency

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with the decision-making capacity but if, as you stipulate, the person is fully competent, rational, thinking clearly, yes, that's a case of hard paternalism and that's generally taken to be unjustifiable.

MS RICHARDS: Then, again, in terms of clinicians failing to obtain or provide an opportunity for patients to give informed consent, we've explored the role of paternalism. Is there any research or understanding as to the extent to which that type of behaviour by clinicians may have occurred, not because it's paternalistic but because it's easier, it's lazy doctoring? Is there any research or work along those lines?

Professor Farsides?

PROFESSOR FARSIDES: I wonder if the question has emerged because of the emphasis we placed on the beneficent motivations of some paternalists and it's trying to make a distinction between those who chose to take that route, genuinely because they felt they had reasons to protect and go against what we might think was the best interest of the patient and those who simply either had a habit of behaviour or felt that this was the way that things were done, or more, as the question poses, realised it would be much more

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not having enough time to engage in a difficult discussion and not wanting to because it's difficult and you'd rather do something else.

I don't know of any systematic research on this but my strong suspicion is there's a mixture of all three in practice and just how much of it is vicious and how much of it is the result of very flawed system is difficult to say.

PROFESSOR FARSIDES: I think that's hugely helpful, Julian, and I think it also helps us to understand how people might look back and reflect upon what happened in some cases with personal regret, with some acknowledging belatedly that the system had not allowed them to do what they would wish to do. So I think that trio of examples is really helpful.

PROFESSOR CAVE: It's not research, as such, but in relation to lazy practices, and also practices where doctors may have been operating as best as they can, we've seen a number of examples in recent public inquiries. I've mentioned already the Paterson Review, where there was a complete failure to get consent in some cases and professionals, sort of, protecting their own. I've also mentioned a couple of times the Cumberlege Review where there was avoidable harm to patients because they weren't listened to, and

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difficult to follow the other path and maybe time should be spent on more important matters -- I don't know.

But I don't know about specific research that reveals the extent to which either of those patterns of behaviour existed. But what I would say is I think it's a useful distinction because, however much we would prefer that things had moved away from a paternalistic model, we can at least allow some sense of it being attached to beneficent intentions, whereas if we go for the sort of example that I think is behind the question then we can't be so generous initially.

PROFESSOR SAVULESCU: Can I add just something to what Bobbie said. I think it is a useful distinction but I think you need a tripartite distinction. You need to distinguish between beneficent paternalism, even if it's misplaced, you need to identify lazy or other -- what is sometimes called vicious practices, practices which just represent a flaw in the physician, and the third category which I've alluded to is people operating as best they can within a system which just doesn't allow them to do the right thing and I think that many or some of the problems may be the result of systemic problems. So there's a difference between

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consent is a theme that runs through that report as well. Then we very recently have the interim report from the Ockenden Review and that's a review about caesarean section rates and trying to keep those as low as possible and failing to listen to women who actually wanted another course of treatment and the result has been deaths and injury to babies and to women.

So we do see examples of the three categories that Julian was referring to in some of these public inquiries.

DR KAZARIAN: Following on from that point as well, and I think Julian is completely right about these three categories of practices. I think there is -- there are common themes to different healthcare failing episodes that we've seen in different inquiries. Like Emma said, the lack of information given to patients, the lack of transparency, the lack of openness, the failure to actually listen to patients and listen to their concerns, that's something that has come back in almost all inquiries that have addressed a particular failure, a particular episode, in particular the Francis Report, for instance, as well.

This is why now the duty of candour is a legal requirement. That's just one example but it is -- so

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1 we see that there are -- there is an issue of not
2 knowing what is actually good practice, and maybe in
3 the past there wasn't so much clarity between what was
4 good information to patients and what wasn't. There
5 is a difference with incompetence and not actually
6 giving the patient the right information just because
7 we're not actually doing our job properly.

8 There is a higher degree of deliberate and
9 a deliberate lack of information because -- that might
10 be because there is a systemic issue behind it but it
11 might also be because there is a culture within that
12 particular institution of hiding things from patients.

13 So there are different degrees of, I would say,
14 bad practices but I wouldn't call bad practices the
15 first example, so it's difficult to clarify it.

16 **MS RICHARDS:** Just following on from that, to what extent
17 do organisations which employ clinicians, so hospital
18 trusts or health boards, or organisations such as
19 professional organisations of which clinicians are
20 a member, to what extent do they have an obligation to
21 ensure that those who work under them or within them
22 adhere to their ethical obligations?

23 **PROFESSOR CAVE:** So we've talked about various strands of
24 regulation. On the one hand, there's individual
25 regulation, and we've mentioned the GMC and the fact

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1 understand the ethical challenges of their work. So
2 whilst we've concentrated to some degree on problems
3 and issues, at the same time there is a growing sense
4 of recognition and commitment to this being something
5 you continue to think of through your career, albeit
6 a minority of individuals involved as actively as
7 that, but they do have a voice and can sometimes very
8 directly advise or suggest to their peers in a way
9 that a more distant organisation might not have such
10 an impact.

11 **PROFESSOR SAVULESCU:** I think historically institutions or
12 employers have had a clear obligation to ensure that
13 their employees are behaving legally and there's been
14 recourse to hospital lawyers and advice in that
15 regard. But in terms of ethical oversight of
16 practice, it's been left historically for peers and
17 the profession themselves to monitor, rather than
18 employers or institutions.

19 I think that's probably changed now to some
20 degree. Institutions would see they are not only
21 responsible for their employees to behave legally but
22 also ethically, but that led to self-regulation in the
23 past, rather than being set as an institutional
24 responsibility, is my take on it.

25 **MS RICHARDS:** The next question is for

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1 that it used to be quite responsive and reactive to
2 problems that had been brought before it but now
3 exercises revalidation to try and make sure that
4 doctors have the right sort of skills. So there's
5 individual, there's professional, there's also
6 institutional, and so there are -- the Care Quality
7 Commission, for example, will both respond to
8 complaints but also inspect institutions to make sure
9 that they are following standards and that includes
10 standards in relation to informed consent.

11 **PROFESSOR FARSIDES:** I think also, as we've got a growing
12 number of doctors who have emerged from medical school
13 with an interest in or commitment to ethics, we've
14 seen the Royal Colleges establish very active -- not
15 only active committees but groups, we have
16 associations around particular areas of medicine that
17 seek to ensure that people understand their shared
18 ethical responsibilities and debate very openly and
19 transparently issues that might be of particular
20 importance within their specialty.

21 Certainly, for example, in the area of genetics
22 and genomics there are very lively multidisciplinary
23 groups that have been going for many years, where
24 people in their own time and of their own volition
25 come together to discuss and hopefully better

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1 Professor Savulescu. I don't know whether you will be
2 able to answer it but, in terms of the Journal of
3 Medical Ethics, do you have a sense of what its
4 prominence was, particularly historically but also
5 now, in terms of the extent to which it was read or
6 issues raised by it might have become known to
7 clinicians and not just ethicists and academics.

8 **PROFESSOR SAVULESCU:** I would invite Bobbie also to
9 comment on this because she has been in the UK longer
10 than me and I took over from Raanan Gillon, I think,
11 in 2001. To be honest with you, I think that ethics
12 is still seen by the profession as a peripheral issue.
13 I don't believe that the Journal of Medical Ethics is
14 hot on many clinicians' desks and I think its
15 penetration is and always has been minimal within the
16 profession.

17 There is an extraordinary amount of self-belief
18 within the profession that they are ethical experts
19 and, to give you one striking example which I think
20 illustrates the state of medical ethics in the medical
21 profession, I mentioned the case of Charlie Gard.
22 When I was the editor of the Journal of Medical
23 Ethics, I saw this case when it was first reported
24 before it became international news and thought this
25 raises very interesting ethical issues, and proposed

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to the British Medical Journal that Dominic Wilkinson and I, our professor of medical ethics and editor, write a piece about the article, and their response was there is nothing new or interesting about this case, and this was their response to two professors of medical ethics and editors of the Journal of Medical Ethics.

It went on to be world news that Donald Trump and the Pope became involved in, The Lancet immediately picked up that pair of articles, but that illustrates the degree of self-belief that traditional doctors have in their intrinsic knowledge of ethics.

MS RICHARDS: Professor Farsides?

PROFESSOR FARSIDES: Yes, I agree that can be problematic.

I think also there is a growing opportunity for ethicists to publish within the medical literature, so one does get invited from time to time to write for the BMJ, The Lancet or one might put a paper in to an anaesthetics journal, et cetera. But sometimes the way in which the editors want you to reduce down and simplify what you have to say and, God forbid, put it in charts, makes it difficult for you to convey the complexity that we keep going back to time after time.

So I think when we really want to think a subject through, we tend to stick to our own

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perhaps moral and ethical rights.

MS RICHARDS: Then, Professor Cave, when we were looking at the guidance, the 1970 BMA guidance, you made the observation that this was BMA guidance and not GMC guidance and, therefore, didn't attract the sanctions that non-compliance with GMC requirements might, in terms of GMC processes.

To what extent do you think a lack of sanction has affected adherence to fundamental principles of medical ethics? Sorry, we can't hear you, professor.

PROFESSOR CAVE: The point I was making was that things have changed over time with regard to the link between the GMC's ethical guidance and the possibility that they might be held to account in terms of Fitness to Practise. That's been a gradual change. So, yes, that link has become stronger over time. So still guidance is just guidance; it's not law. And there may be a reasonable excuse for not following guidance, and that would be something that the GMC would be interested in.

But perhaps it would explain a closer following and a closer allegiance to professional guidance if there is a possibility that there may be questions as to Fitness to Practise if they don't follow that. And that's strengthened even further, perhaps, if there's

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journals and hope that we can then, on the basis of that, produce something that might be read more widely in either the medical press or in specialist journals. But that's not without its challenges.

MS RICHARDS: Then, given the references yesterday, I think, to the discussion of Kantian philosophy and the reference in your report, I think, to 18th century cases on informed consent, the answer to this may be clear but I want to ask it as I've been requested to, in any event. Over the period of time with which this Inquiry is concerned -- so the second half of the 20th century to date -- would it be right to say that patients have always had the right to be provided with information, such as to be able to give informed consent to treatment, leaving aside of course the exceptions that you have already discussed. But, in principle, the right and the importance of informed consent has always been recognised with different degrees of emphasis, perhaps, during that period? Professor Cave?

PROFESSOR CAVE: Yes, subject to your proviso at the end "with different degrees of emphasis". If we're talking about rights, we have to work out what sort of rights we're talking about. If we are talking about legal rights, that's developed more slowly than

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a possibility that they might breach the law in relation to criminal law or medical negligence. Does that answer the question?

MS RICHARDS: Yes, I think so.

Next question I've been asked to ask again goes back to the issue of paternalism, and it's this: was paternalism a form of coercion?

PROFESSOR SAVULESCU: Well, I think it's -- in reality, it was, but the generous interpretation, I think as I said yesterday, is that I think doctors believed that patients were coming for the treatment and prevention of their disease, and that's what they wanted. So what -- they implied consent to whatever was necessary that they believed necessary as medical experts to achieve that. So it was a belief that there was implied consent that may not have been the case.

So it was paternalism, but it was a certain kind of paternalism where there was a genuine belief that this is what patients want. And I think that that has begun to crumble in the last 30 or 40 years. But it wasn't straightforward "we're just going to do what we believe is best for you". I think there was a belief that -- and in many cases, it was true that this is what patients also wanted. Would others

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1 disagree with that?

2 **PROFESSOR CAVE:** No, I wouldn't disagree, but I wouldn't

3 go as far as to say it was coercion in law at least.

4 Because there was a legal distinction between valid

5 consent and informed consent and still is that legal

6 distinction. So for consent to be valid, it must be

7 voluntary, it must be capacitous, and it must be

8 minimally informed. So not giving that additional

9 information wouldn't be seen as invalidating consent;

10 it would be seen as not giving sufficient information

11 which would then invoke the possibility of

12 a negligence claim.

13 So it's a complex legal issue, and you could

14 argue there's a moral case for a degree of coercion,

15 but in law that wouldn't be the case, I don't think.

16 **PROFESSOR SAVULESCU:** It's also important to realise that

17 society -- it's hard to imagine people now going to

18 fight in the First World War. I think people's

19 expectations and social norms and co-ordination has

20 changed over the decades. And I think the 1980s was

21 a period of quite significant change in terms of

22 people's aspirations and expectations for their own

23 lives, their deference to authority, and that

24 continues today.

25 So one of the benefits of the guidelines that

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1 essentially inform you of the important aspects of

2 your care and for whatever reason that doesn't happen,

3 it does feel as if you've been disadvantaged.

4 **MS RICHARDS:** The next question relates to the therapeutic

5 privilege. Would imposing a treatment on a capacitous

6 patient in the absence of informed consent because the

7 clinician thinks it has medium- to long-term benefits

8 in terms of morbidity or mortality ever have been

9 ethically justified on the basis of the therapeutic

10 privilege?

11 **PROFESSOR CAVE:** The therapeutic privilege applies, today

12 at least, when it's felt that disclosing a particular

13 risk will cause serious harm. And it's not clear from

14 what you've just stated where that serious harm would

15 be, in which case the therapeutic exception, as it

16 applies now, wouldn't be relevant.

17 I have discussed the fact that it was broader

18 in the past, that it was more akin to the idea that

19 doctors should tell a patient what was reasonable, but

20 it still wouldn't necessarily follow that it was

21 reasonable to exclude information about risks and

22 benefits in the situation that you set out.

23 **MS RICHARDS:** The harm, I think, underpinning the question

24 or the notion of harm would be if the patient was

25 given full information, they might elect to go for

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1 the GMC and the BMA put out is they set out a set of

2 expectations at a period of time, but those were

3 always changing. And, you know, as I said, I think

4 that the doctor-patient relationship in the 1940s

5 would have had quite different expectations and

6 experiences for the doctor-patient relationship today.

7 **PROFESSOR FARSIDES:** I think the particularly unfortunate

8 characteristic of the examples we're thinking about

9 and discussing is: there were very few other places to

10 go to get the information that was being withheld. So

11 one's voluntariness was very substantially undermined

12 because the person that you trusted to tell you what

13 was important, what you needed to know had decided for

14 themselves that you didn't need to know or that your

15 knowing would be too damaging, and, therefore,

16 balancing considerations, they chose not to tell

17 you -- all the examples we discussed earlier.

18 Nowadays, we have so many places to turn for

19 information, for opinions, sometimes dangerously so

20 because we can't trust all of it, and we still need

21 our clinicians to help us filter out the erroneous

22 information, to understand the relevance of sometimes

23 mountains of information that you can access. But at

24 least there were those other possibilities. If one is

25 reliant upon an individual or a particular team to

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1 a form of treatment which is less -- which the

2 clinician thought would be less advantageous in the

3 medium- to long-term in terms of morbidity or

4 mortality.

5 **PROFESSOR CAVE:** I think it's clear that it wouldn't be

6 ethical on that basis because it's effectively trying

7 to push them into a decision that isn't a free

8 decision.

9 **PROFESSOR SAVULESCU:** And it's important to stress again

10 that people have the right to choose an inferior

11 course of action or no action. That's entirely their

12 prerogative. And I think that that's something that

13 doctors have had great difficulty accepting, that

14 somebody would choose a course of action that doesn't

15 maximally or promote their health in their view. But

16 that has been established since 1910 -- the

17 *Schloendorff* case -- or longer. So I think that, you

18 know, even if they choose to have no treatment

19 whatsoever, that's their right.

20 **MS RICHARDS:** Do the ethical --

21 **PROFESSOR SAVULESCU:** Sorry, go ahead.

22 **MS RICHARDS:** Do the ethical requirements for informed

23 consent differ at all in the case of chronic patients

24 where the clinician has been responsible for the care

25 of the patients, and will continue to be over many

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1 years, and there is a no alternative to the care being
 2 provided by that individual doctor?

3 **PROFESSOR FARSIDES:** There are advantages to the model of
 4 care offered to people with chronic illness in that
 5 there might be a continuity over the years that is
 6 very reassuring. It means that information is held;
 7 history is shared. However, that cannot become a form
 8 of complacency.

9 We said early on yesterday about remaining
 10 alert to when patients are giving messages that they
 11 wish to change their mind on something, perhaps, or
 12 their priorities have shifted, or the things that are
 13 preoccupying them have changed. And I think that the
 14 great privilege of caring for someone over a long
 15 amount of time, as an individual or a team, is that
 16 you can get to know them and understand them, but that
 17 doesn't allow you to make presumptions about what they
 18 would or would not consent to in the future. You
 19 still have to check, particularly in very important
 20 and new interventions, that their consent is valid.

21 **MS RICHARDS:** Then the next question is for
 22 Professor Farsides. In relation to children, and it
 23 may, I think, have been in the context of the evidence
 24 that you were giving about research and children, you
 25 used the phrase "assent". Is there any difference

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1 this morning and the discussion this morning about the
 2 failure to obtain patient consent for specific blood
 3 testing for infectious disease. There was
 4 a discussion about this being recognised around the
 5 time of the HIV epidemic.

6 Although it may have been that that was the
 7 time when this issue came into particular prominence
 8 and was the subject of discussion by the BMA and
 9 guidance from the GMC, was it not always contrary to
 10 patient autonomy to test a patient for a specific
 11 infectious disease without their knowledge and
 12 consent? I'm talking here ethically rather than
 13 legally.

14 **PROFESSOR FARSIDES:** There is a very famous case from the
 15 United States which I slightly hesitate to mention
 16 because I think it's very triggering for members of
 17 the black American community to even be reminded of
 18 this. But in this case, which came to be known as the
 19 *Tuskegee* case, a cohort of black men were tested for
 20 syphilis, and then a proportion of those men were left
 21 untreated with the express intention of charting the
 22 natural progression of the disease. This is something
 23 that we can barely countenance now.

24 But it really made us think that -- this is
 25 a hard case in the same way as the Nazi

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1 between "assent" and "consent", and if so, what is it
 2 and why does it apply to children?

3 **PROFESSOR FARSIDES:** Sometimes the term "assent" is used
 4 to suggest something a little bit more than agreement
 5 or acquiescence but something that doesn't have the
 6 legal force of "consent" in the context within which
 7 we might use the term.

8 So an ambition sometimes with particularly very
 9 young children is that you should reach a point where
 10 you feel that they understand sufficiently what's
 11 going on in order to agree and not resist what is
 12 being done to them and maybe, on occasion, go a little
 13 bit further than that and express an opinion that if
 14 they had age on their side or if they were fully
 15 capacitous would be seen as consent.

16 So it's a sense of respecting that children,
 17 particularly children living with life-long
 18 conditions, become invested in and knowledgeable about
 19 and able to participate in their care and research
 20 before they might have the legal right to consent.

21 I'd love to see if Emma is happy with that
 22 explanation because she's very much an expert in this
 23 area.

24 **PROFESSOR CAVE:** Brilliant, Bobbie.

25 **MS RICHARDS:** The next question picks up on the evidence

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1 experimentation is a hard case, but at the core of it
 2 is that lack of knowledge, that lack of understanding
 3 of what was being done to those people, and the lack
 4 of ability they had to walk away or object or even,
 5 for a very long time, get any form of just recompense
 6 for what had happened.

7 So I think we are acutely aware of what -- how
 8 we wrong people when we do things to them without
 9 their knowledge that had and could have profound
 10 consequences.

11 **MS RICHARDS:** Any other observations?

12 **PROFESSOR SAVULESCU:** Well, I think I mentioned this
 13 morning that it was routine to do syphilis serology on
 14 patients presenting with neurological conditions to
 15 exclude that differential diagnosis, and people were
 16 not explicitly consenting to do syphilis serology. As
 17 I have explained, I think the basis for that was that
 18 consent was implied to identify the cause of the
 19 illness.

20 So while the question is correct that
 21 technically it is a violation of the person's autonomy
 22 not to explicitly consent to that, that was
 23 a widespread practice, and, again, a failure to
 24 appreciate the significance of such testing and the
 25 importance of people's autonomy.

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1 **MS RICHARDS:** Is there any relevant difference, picking up
 2 on what you just said, between testing for a range of
 3 conditions that you've no reason to believe the
 4 patient suffers from, but because you are excluding
 5 a range of conditions in order to arrive at
 6 a particular separate diagnosis or understanding of
 7 the patient's condition and the situation where you
 8 are specifically testing someone because you have
 9 reason to suspect that they may have that condition?

10 **PROFESSOR SAVULESCU:** Yes, that is a very good point, that
 11 if you have a reason to believe, you should be
 12 discussing that reason with the patient. That is
 13 a relevant difference. Yes, you are correct.

14 **MS RICHARDS:** Where the testing is being undertaken to
 15 investigate the possible adverse effects and
 16 consequences of the treatment given by the clinician,
 17 is there then, as it were, an enhanced obligation to
 18 ensure the patient's aware that that testing is being
 19 undertaken.

20 **PROFESSOR SAVULESCU:** Yes.

21 **MS RICHARDS:** Then picking up, again, on the right not to
 22 know, Professor Savulescu, how does a clinician
 23 ethically satisfy themselves that a patient really
 24 does not want to know the result of a test or
 25 a diagnosis?

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1 opinion of the person you were speaking to. Only
 2 subsequently would you have the ability to engage
 3 perhaps with a broader community or look on the
 4 internet and, therefore, it goes back to something we
 5 talked about again, about having sufficient time to
 6 make a decision and part of that decision is do I want
 7 to proceed at all with this test, given what I now
 8 understand about the implications of getting a result.

9 **MS RICHARDS:** Sir, I think I have about another
 10 20 minutes, half an hour of questions possibly,
 11 questions and answers. I raise it so that you can
 12 decide whether you would like to take a break or
 13 whether I press on.

14 **SIR BRIAN LANGSTAFF:** That's a question I think
 15 essentially for me but I am going to do what you do,
 16 or what you did, and ask our panel. We will only go
 17 on with your informed consent. Part of the
 18 information you need to know is there is always a risk
 19 when counsel poses a time the time will actually be
 20 longer. It is very rarely shorter but I think if we
 21 take -- if we were to take, let us say, 20 minutes
 22 now, the chances are we might be finished my 5.15; is
 23 that fair, do you think, Ms Richards?

24 **MS RICHARDS:** Fair but, of course, it may make no
 25 allowance for questions you have, sir.

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1 **PROFESSOR SAVULESCU:** I have no idea, apart from
 2 discussing the possibility with them. So I think this
 3 is why the right not to know is fraught with danger
 4 and I think some broad discussion of the issue is
 5 necessary to, at least, get a direction about what the
 6 patient's preferences are. We cannot assume a right
 7 not to know or guess it.

8 **PROFESSOR FARSIDES:** I think you yourself mentioned the
 9 issue of Huntington's disease and a relatively low
 10 take-up amongst families affected by Huntington's
 11 disease, particularly in, sort of, early adulthood.
 12 I think that is a very -- having worked with the
 13 Huntington's Disease Association a couple of times
 14 over the years, I'm very struck by the thoughtfulness
 15 that goes into the decision by a particular individual
 16 whether or not to be tested and, therefore, whether or
 17 not to acquire the information. But I think that
 18 again speaks to the value of being part of a community
 19 in which these issues are recognised and the
 20 importance of giving thought to undertaking a test is
 21 understood.

22 That's not always going to be the case. One
 23 could turn up *de novo* in a medical situation and
 24 a test be taken that had significant consequences for
 25 you, and you would only then in the room have the

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1 **SIR BRIAN LANGSTAFF:** No, at the moment I have one, but
 2 there we are. So the question is: do you want to go
 3 on or do you feel in need of a break or not? If
 4 anyone wants a break we will take a break.

5 **PROFESSOR FARSIDES:** I am completely open to either
 6 option.

7 **PROFESSOR CAVE:** Me too.

8 **PROFESSOR SAVULESCU:** I am happy to go with the flow.

9 **SIR BRIAN LANGSTAFF:** Dr Kazarian?

10 **DR KAZARIAN:** Me too, sorry. Yes, I'm fine with that.

11 **SIR BRIAN LANGSTAFF:** Are you content to go on,
 12 Ms Richards?

13 **MS RICHARDS:** Certainly, yes.

14 **SIR BRIAN LANGSTAFF:** Well, so am I.

15 **MS RICHARDS:** The next question is one I don't know the
 16 extent to which you will be able to assist but I want
 17 to ask it anyway, and it concerns the position of
 18 doctors who would be involved in the collection of
 19 blood within blood services but not then involved
 20 directly with patients who are the end users of the
 21 blood or the products derived from blood. Do you have
 22 a sense, ethically, of to whom doctors in that
 23 position owe ethical obligations?

24 **PROFESSOR FARSIDES:** Again, I think we're all missing lan
 25 with this question but I wouldn't have perceived blood

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being collected in quite that way, although of course, interestingly, the blood with antibodies -- people who have suffered Covid is a very recent example that I don't know the details of, but might be collected in the hospital. I do not know.

What I am aware of is the very strong ethical responsibilities now felt by the Blood Transfusion Service as an organisation, that it has national responsibility for collecting blood for medical use and producing blood plasma, et cetera and, I would say that my observations of their approach in both working alongside them both in the vCJD incidents panel, and in relation to the organ donation task-force, is that there are very clear standards of ethics in relation to their donors and, sadly, informed by the events and issues that we're here to reflect on and think about and discuss to recipients.

PROFESSOR SAVULESCU: I might just add, my understanding is that anyone putting a needle into a patient needs to ensure that informed or valid consent has been given. So a more common situation is where a patient comes to surgery and the anaesthetist must put in a line prior to surgery. Now, the anaesthetist needs to ensure that the patient has given properly informed consent but they don't need to obtain fully informed

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which is something that limits their autonomy and takes away from them the possibility of doing something they probably value greatly but they understand that if there's any risk of their blood contaminating the blood supply that that is a choice that might have to be taken.

So I think -- I can only speak from my experience of working with professionals in that area, that they are, to some degree, haunted by the possibility of a contaminated blood supply and many ethical issues follow on from that, including very difficult discussions around what to do if the first time someone's blood has been tested is because they presented themselves as a donor and had maybe no reason to believe that they were carrying a transmissible disease. Some had suggested, well, all you need to do on that occasion is dispense of the blood and you no longer have a dangerous situation for the end user, as you put it, but actually, what about the responsibility to the donor to inform them of something that is very relevant to their health?

So that's the level to which I have personally observed discussions taking place within the blood service.

MS RICHARDS: Dr Kazarian?

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consent themselves, necessarily.

So I would have thought in the situation you describe that the person taking the blood needs to be sure that, in some way, the person has given valid consent or obtained that themselves.

MS RICHARDS: Forgive me, my question was insufficiently clear and that's my fault. I was talking about those clinicians who work within transfusion centres or the Transfusion Service, to what extent do they have ethical obligations to the end users of the blood that's being collected and may be used for transfusion or used for the manufacture of blood products?

PROFESSOR SAVULESCU: Oh, that's passed on to another party?

MS RICHARDS: Yes. Sorry --

PROFESSOR SAVULESCU: -- how I understand the question.

MS RICHARDS: I don't know whether you can assist or whether it's too specific a context.

PROFESSOR FARSIDES: There are clear obligations to screen, as far as is possible, the blood and ensure that it is a safe product. Unfortunately, we know that that has not always been possible and, certainly, those discussions became very live again around the issue of vCJD and one of the steps that is sometimes taken is to limit the eligibility of people to donate,

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DR KAZARIAN: So, I would say that, yes, it is important for the end users to know what's in the actual product and that would also be a legal requirement to inform them of the potential risks there might be if they used that particular product, and that also applies to blood products.

MS RICHARDS: The next question is about ethical guidelines. We've looked at various guidance, we've looked at the Declaration of Helsinki, BMA and GMC guidance. To what extent do you think there should be, in a national healthcare system such as the NHS, a single national ethics code or a body with national standing able to issue ethical guidance, that isn't a regulatory body or doctors' union? Professor Cave?

PROFESSOR CAVE: Well, this is a very complex issue and I will turn to Bobbie immediately afterwards because she may be able to say more about this than I will.

We don't have a national ethics committee but we have something which comes very close, which is the Nuffield Council of Bioethics, which does really marvellous work in relation to discussing these issues and making sure there's public engagement about issues, et cetera.

But we don't and haven't had a national bioethics committee and some countries do and they can

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be very useful, but won't necessarily produce something that's definitive and which has absolute consensus, as we've seen recently in the Covid crisis.

So what has tended to happen is that, as Royal Colleges have developed specialties, they can speak to those particular specialties in a way that resonates with that particular profession and responds to particular issues that that particular aspect of that profession might face.

This is a good thing, in many ways, but it is also problematic if you end up with lots and lots of different guidelines that perhaps conflict slightly and, again, we've seen that in the recent Covid-19 crisis, lots and lots and lots of guidance, some of which may conflict.

So I can see why it would be advantageous to have a single ethical code but also I think highly unlikely that it would be specific enough and relevant enough to the different specialties.

MS RICHARDS: Professor Farsides?

PROFESSOR FARSIDES: Yes, I think we could probably go on far too long about this. It's a very live issue at the moment and, personally, I'm not rushing to get a national ethics body and I too have huge respect for the Nuffield Council on bioethics, and if you speak to

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licensing of a product. Is there anything that ethics can tell us about the gathering of information, about subjective matters, such as pain, or information from patients about their experience of new products? Professor Farsides?

PROFESSOR FARSIDES: I'm sorry, I lost you slightly for a moment so please forgive me if I don't fully address your concerns.

But I took you to be asking whether there's any way of capturing more subjective accounts of medical experience, particularly around issues such as pain?

MS RICHARDS: That's part of it. Or capturing patients' experiences of new products, side effects that they may be experiencing, how can that information post-licensing be gathered and captured and then shared with future patients?

PROFESSOR FARSIDES: That's a very good question. Well, I think funding bodies such as the Wellcome Trust, the European Commission, the MRC, have become increasingly interested in understanding what the experience is of patients, either in innovative fields of medicine, in very established fields of medicine, where there are still unresolved issues, or those who have been part of complex clinical trials or longitudinal studies, and what tends to happen is that you then get social

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the people that work there, they say one of their great strengths is their independence and their ability to challenge and to offer reports that are sophisticated, nuanced, complex, and don't necessarily give politicians and policy makers an absolutely straight line to follow.

I think that anybody that's listened for the last two days will see that that's where we feel the value of ethics lies, in revealing and exploring complexity and difficulty in offering alternative perspectives. My worry is that a national ethics committee could become too close to politics. It could be beholden to -- I think one of Trump's early acts was to disband the national ethics body in the States, the President's Commission, and we don't want high quality advice to be in any way dependent upon political support or patronage. So it's not to say that some national bodies haven't done very good work on particular issues but I think a degree of independence is to be valued.

MS RICHARDS: The next questions, in a sense, emerge out of what one learns from reports such as those referred to by Professor Cave and, in particular, the Cumberlege Review, and it's really about what systems there are to capture patient experiences post the

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scientists, ethicists, working to look at the experience of patients in those fields.

So, for example, the medical sociologist Anne Kerr has just published an excellent study of the experience of cancer patients who have been offered the possibility of personalised treatment through the increased knowledge around genetics and genomics as it relates to cancer. So her interest all along has been what were the expectations of these patients? Were they met? What did she observe in the consultations between them and their consultants and other healthcare professionals to suggest whether they understood fully or were being told fully what the tests or results that were being dealt with actually meant to them?

So I think there's more of a multidisciplinary interest in these questions of the experience of people who are undergoing testing treatment. I myself have done work in relation to antenatal screening and testing. Many you know very good scholars have made their careers by focusing on making more public the experience of patients and sharing that knowledge not just with other patients but finding ways to feed that knowledge back to clinicians so that they can understand better.

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One of the most wonderful PhDs I've supervised in recent years was where Dr Jane Peake spoke to 37 people who had suffered from Parkinson's Disease over a period of between three months post-diagnosis to 30 years, and some of the things that she uncovered in that were invaluable in challenging dominant medical perceptions of what a diagnosis of that type can mean.

MS RICHARDS: Professor Cave?

PROFESSOR CAVE: It's clear from the Cumberlege report that the system that we have at present is inadequate; it doesn't do enough. And there are various methods of post-market surveillance. And in a way, we're all research participants when it comes to novel drugs. Novel drugs that have been licensed; they've gone through a process; they have gone through clinical trials; they are recognised as safe, but then there is a period of time, and that period of time may go on for a very long time whilst there is post-market surveillance.

We know that innovation is dangerous without proper post-market surveillance, and we know also that doctors and patients can't understand the risks properly if they are not given the full information, and, therefore, they can't make informed decisions.

One of the systems we have at the moment is a

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rethinking the way in which we gather data about drugs and devices and other interventions.

PROFESSOR FARSIDES: I think Julian makes a really important point, and it's particularly relevant to families with rare disease who may have thought that until now they were the only people in the world literally to be dealing with the situation, instead of which, through the power of the internet, the creation of the rare disease community has grown. And the alliance between pockets of that community and particular scientists -- not even clinicians; basic scientists -- is one of the most exciting things to emerge so that people don't feel that they are therapeutic orphans in the way that you can again be with a rare disease because suddenly there are people, albeit on the other side of the world, where data can be pooled, scientific interest can be encouraged, and work with clinicians interested in the field can proceed because they have a pool of potential participants when they are able to offer research.

And if you attend a rare disease conference these days, I think that's one of the most exciting things that is presented to you, this sense of an alliance growing that is global and allows science, medicine and patient experience to come together.

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yellow card scheme where doctors and patients are able to upload onto a website experiences of any adverse reactions they have had. But we don't really know how accurate those reports are, and we don't know how often they are made. There may be many instances where there are adverse reactions where nobody makes such a report. So there are real gaps in the system.

One of the things that is proposed from the Cumberlege report is there should be a new patient safety commissioner, and that has been taken forward in the Bill at present.

PROFESSOR SAVULESCU: So this is not really my area, but one thing I'm aware of are patients or patient groups organising themselves. So, for example, motor neurone disease patients are connecting through the internet, social media, sharing experiences or sharing information. So another way, I think, in the future would be to connect patients to enable them to share experiences and drive the research agenda from the ground up with democratisation of this kind of surveillance.

Another issue is that, you know, with big data, we have enormous capacities for greater evaluation of these sorts of events, but that will require dealing with privacy and confidentiality concerns and

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MS RICHARDS: Do any of the panel have views on the merits of the Cumberlege recommendation for a patient safety commissioner? Professor Cave?

PROFESSOR CAVE: Yes, I think it's absolutely marvellous and necessary.

MS RICHARDS: Does anyone have a different view?

The penultimate area of questioning really again picks up upon what Professor Cave has referred to in terms of Cumberlege and Mid Staffs and the Ockenden report and others.

It would appear from those reports that there remains in 2021 a problem of doctors still not placing patients first. What do the panel think are the cultural or institutional blocks to this happening, and from your perspective, how can fundamental change be effected to address that problem?

PROFESSOR SAVULESCU: I may as well start because I do have a kind of position on this.

So it was expressed before by Emma that the Shropshire problem was a failure to respect women's autonomy, and that's certainly correct. It's been a legitimate option for women for over 20 years to elect caesarean section, but it's been an option that has been rejected by many medical professionals on their beliefs about the interests of the woman or the

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1 fetus.

2 And so I think one issue is really education
3 around the importance of autonomy but also about
4 rethinking how we conceive of risks and benefits and
5 what really is best for people because this has -- the
6 *Montgomery*, the *Ockenden*, all of these reports refer
7 to women being denied a very reasonable option. And
8 this idea that there can be multiple options of care
9 that have different risks and benefits that are within
10 a tolerable range and that people's autonomy is
11 important to respect are both elements, I think, of
12 medical ethics education that need to be -- we need to
13 produce a better group of clinicians who can think
14 more broadly about what is benefit and also take
15 account of people's autonomy more.

16 So I think having more commissioners and more
17 regulation may help, but I think the problem is deeper
18 than that. It's about people enforcing their own
19 ideology or their own faith in what they believe is
20 best for people, which is not either properly
21 evidence-based, or not properly ethically-based on
22 a broader conception of well-being and autonomy.

23 **PROFESSOR CAVE:** You talked in your question about the
24 problem of doctors not placing patients first, and
25 I think it's true that there are examples of that, but

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1 been a healthcare system run on a shoestring, and, you
2 know, you get what you pay for, really.

3 These are really deep problems that, you
4 know -- I feel somewhat affronted when I'm told to
5 stay home and save the NHS. I mean, the NHS should
6 have been saved over decades through proper
7 investment. And, yes, all we can do now is stay home,
8 but there is radical underinvestment in the NHS, and
9 that is certainly a significant part of the problem.
10 It's not the only contributor to the problem, but
11 I think this is a time where I hope that you will take
12 a courageous step and encourage politicians to invest
13 properly in their healthcare system.

14 **MS RICHARDS:** Professor Farsides? Sorry, Dr Kazarian.

15 **DR KAZARIAN:** It is a complex question, and it is
16 a question that we could talk about for a long time.
17 But I think what Emma's pointed out is important.

18 It's only some doctors who do not put their
19 patients' best interests first. I think from what we
20 see from the different inquiries that have come out on
21 different episodes, there was a problem and there is
22 still a problem of ineffective regulation of medical
23 practice and also of the lack of transparency and the
24 issue of whistle-blowers, as Emma's pointed out. The
25 fact that whistle-blowers were not given voice, were

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1 I think we also need to be clear that it's some
2 doctors -- in fact, it's some healthcare
3 professionals. And there's also problems with the
4 system as a whole that leads to some of these issues.
5 I think Julian was quite right that education is key
6 here.

7 There are other problems as well, and we could
8 talk about them for hours and hours. Just to name
9 a couple of them, I've already mentioned yesterday the
10 clinical negligence system that we have which is
11 fault-based which gives an incentive to keep quiet
12 about certain things, which is problematic. I've also
13 mentioned failure to protect whistle-blowers in some
14 instances, which is hugely problematic. I think
15 perhaps one obvious the biggest issues is that of
16 funding, that the lack of time, the lack of resources
17 is hugely problematic in the NHS. And it's trite to
18 say that this is what it comes down to sometimes, but
19 I think we do need to at least acknowledge that
20 factor.

21 **PROFESSOR SAVULESCU:** I think it's -- I have wanted to
22 bring this up. I don't know exactly the figure, but
23 the UK spends about 8.5 per cent GDP on healthcare.
24 Most other advanced European countries spend 11 or
25 12 per cent. And at the end of the day, it's just

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1 not respected, and things were not being fully
2 explained to patients. So that's been a problem in
3 the NHS, and it's still a problem to an extent. And
4 I think regulation will be very important in order to
5 adjust that as well.

6 **MS RICHARDS:** Professor Farsides?

7 **PROFESSOR FARSIDES:** Well, I would want to endorse what's
8 been said. I agree with Emma that we mustn't lose
9 sight of the many healthcare professionals,
10 particularly at the moment, who are very much putting
11 patients first, often at personal risk and personal
12 risk that has been exacerbated by a lack of
13 appropriate support financially and organisationally,
14 and I think we have to think seriously about what it
15 takes to offer an ethically robust health system.

16 Back in the 1950s, the political philosopher
17 Plamenatz put forward an account of what it meant in
18 terms of consent if you voted in an election, and he
19 said at the end of it "If you think that what I'm
20 saying is" -- "the definition of consent that I've
21 given is impractical because that's just not the way
22 things work, it's not necessarily the case that I have
23 to change my definition; it might be that we have to
24 change the system". I think sometimes when you see
25 things go wrong, it's because people simply can't meet

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the standards that we as ethicists would like them to meet because of the way in which a system has been denuded of finances or where attention hasn't been paid to organisational problems, systemic issues.

Whilst I think we're doing our best in terms of medical education to try and support individual doctors in being the best they can, and also by things like widening participation, correcting the profound gender imbalance that existed at the time some of the documents we've looked at existed, we're trying our best to train good doctors but, with all the will in the world, if they then emerge into a system that makes demands upon them that is completely unreasonable, then the patient remains at risk.

PROFESSOR SAVULESCU: To echo what Bobbie said, I think there are some of the best doctors and health professionals in the world in the UK, and I've certainly benefited from their care. So I think that's the starting point. But they are operating in a system that isn't fit for purpose. The UK has one of the worst cancer survival rates in Europe, and that's not because, you know, of the quality of the doctors. That's because the system needs to be revised and I think you're just seeing Inquiry after Inquiry, and I think it's time to move into the 21st

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a journal article nowadays that this has received ethics committee approval. So journals have tried to and editors have tried to exercise some quality control in that way.

SIR BRIAN LANGSTAFF: That would itself create the expectation that anything which might be published should have ethical approval?

PROFESSOR SAVULESCU: That's the first thing I tell my students, at least, that if we want to publish this we have to get ethics committee approval. So that's -- that was -- that's a relatively recently phenomenon. That certainly, you know, wasn't the case last century, that journals required ethics committee approval before they published the paper.

SIR BRIAN LANGSTAFF: When roughly did it change in this millennium?

PROFESSOR SAVULESCU: I'm thinking around the turn of the millennium, journals started to require that. So that's my guess. I don't know if the others have a more accurate memory of that but, you know, I think, you know, in the '80s and '90s that wouldn't have been standard practice at all.

PROFESSOR FARSIDES: I still think there's a sort of intermediate position and it's certainly something that I have provided to people as the chair of

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century.

MS RICHARDS: My final question was going to be to offer Professor Savulescu the opportunity to raise the issue of NHS funding but I think through the last question you have been able to do that, I hope.

So, sir, over to you.

SIR BRIAN LANGSTAFF: Yes. Just one issue, if I may. It goes back to what was said by you, Professor Savulescu, earlier. You were speaking about the question of research and if it was published, if any document was published it was likely to be research, and it led me to wonder whether one of the controls on whether there should be proper ethical approval on a paper which might be published, is that a journal might require there to be evidence of such approval before publishing. It may be a common practice. Is it common practice that journals seek a proper assurance that there has been ethical approval for that which they are to publish --

PROFESSOR SAVULESCU: Yes, it is now and now journals, as far as I know all, but certainly typically in the major journals all require evidence of ethics committee approval and, as I mentioned, typically when patient data or information is published, that the patient has consented. But you always see now on

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an ethics committee, which is where something is very clearly audit or health services evaluation but there is an intention to publish, we will look at -- we will ask them to fill in the same form as if it were a research protocol, we'll look at it but the letter that we provide will state very clearly that it has been presented to us as audit or health services evaluation, because I think there is a merit to keeping that distinction clear if you're being straightforward and accurate in the way that you use it.

SIR BRIAN LANGSTAFF: Thank you, Ms Richards. That's all that I have to ask.

MS RICHARDS: Is there anything further which any member of the panel would wish to add that we haven't covered?

PROFESSOR FARSIDES: Could I just say something which I would have liked to have said at the beginning but my internet system let me down.

We've spent two days discussing complex principles and theories and documents but I think we're all very minded of the fact that these are of great interest to people listening today whose lives have been touched in a very profound and real way by the issues to which we are applying these somewhat

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abstract ways of thinking. I would just like to say that, personally, and I know that people will speak for themselves, but I know we share this, that we've been very moved by the testimony that we've heard from Core Participants and, whilst we haven't touched upon their direct experience and their stories, they haven't been far from our minds when we have been speaking with you over the last two days.

PROFESSOR CAVE: I would like to echo that. It's been a huge privilege to be of some assistance to the Inquiry and it was an honour to attend some of the hearings. I was lucky enough to go to Leeds and to Edinburgh and to hear firsthand the accounts of the infected and affected, and also to meet some of them in the breaks at lunchtime. So thank you very much for that.

PROFESSOR SAVULESCU: Well, I mean, maybe I should declare a slight conflict of interest at the very end here because I think I graduated from medicine in 1988 and I looked after patients with haemophilia. I was in a hospital which was a major haemophilia treatment centre and also a major HIV treatment centre, and I looked after patients who died of AIDS and who had HIV from blood products. You know, I know firsthand that, at that time, I think in our hospital, patients

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been a privilege to give evidence for the Inquiry or to be involved in it. Actually, it's our privilege to have had you. You have, over the last two days, given us a really valuable understanding of how ethics may fit in. Those who have been watching, who perhaps wondered why there have been less direct questions about particular instances of a failure, as they would see it, of the treatment they may have had, whether as people with haemophilia or people who simply had a transfusion for some other issue, why they haven't had the ethics of that particular situation explored and explained, but that would be to focus upon the individual and we have been focusing upon the general, the lie of the land.

What you have done, is you've given the Inquiry and those who participate in it the tools, the ethical tools, to help to understand and dissect some of the evidence we've had to understand where they may have been ethical failings, inappropriate action, shortcomings, as we now see them and, of course, we are judging necessarily from a perspective of 2020/2021, maybe 2022, what may have happened in the past. You have shown us, I think, really how complex, how sophisticated, how nuanced -- those are the words that you, Professor Farsides, used -- ethics can be,

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got the best possible care but many people, many clinicians, including myself, often were embarrassed or ashamed and we viewed patients with haemophilia as a failure of medicine.

We had promised miracles and given them HIV and for that, you know, as a part of the medical profession I would like to apologise. I can't say anything about the decisions of Sir Brian but I do hope that you get the justice and compensation that you deserve and I hope that we can move forward into the future and identify the ethical failings and do better in the future.

So I look forward to Sir Brian's report and I hope to write about this in the future.

DR KAZARIAN: I would like to echo that as well. I think it has been a long time coming and I feel very grateful for being part of this panel because, finally, we were hoping that the victims and their families and many patients will have the justice that they need.

SIR BRIAN LANGSTAFF: You have spoken about the privilege of seeing some of the hearings -- you, Professor Farsides, and you, Professor Cave. You have spoken about your experiences, Professor Savulescu, when you were a young doctor, and you said that it's

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but the value of it in considering, exploring the issues and looking for other possibilities and a much clearer appreciation, I think, of how those nuances, those complexities, actually play out in practice, and I really do want to thank you, as I thanked Professor Kerridge earlier, for your time, for your effort and what, for my mind, is a very good, well-written, very helpful report. I look forward to meeting you further when circumstances permit but thank you all, one and all.

I do have something to say now to those who are watching online. By all means, sign off if you would rather. Otherwise, you may have to be detained for another five minutes. That's, I hope, not going to be ten.

But it is this: if I can address the wider audience who are watching. The eagle-eyed amongst you will not have missed that Dr Jones, Dr Peter Jones, was earlier timetabled to give oral evidence next week, but there are now no plans to call him to testify. I promised that this Inquiry would be as transparent as the law permitted. And to make good on that principle, you are entitled to know why Dr Jones will not be giving evidence orally. It's because after considering both submissions on his behalf under

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section 21(4) of the Inquiries Act 2005, supported by evidence, as well as the public interest in hearing orally what he may have to say, I have determined that it would not be reasonable in all the circumstances to require him to do so.

This is a good point at which to explain why certain potential witnesses are not giving oral evidence. A consequence of the time it took before a statutory UK-wide inquiry was decided on is that many of the matters we are investigating date back many years. Some potential witnesses have developed health conditions that mean that they cannot now give evidence as once they would have done. Some witnesses have been able, with difficulty in some cases, to give a written statement but not to give it orally. Some are able to give neither. In each case, I start from the basis that if it is desirable to have evidence from a witness, the Inquiry should get it. I have powers to compel it which I am quite prepared to use. It is necessary to have compelling material to persuade me either that they cannot do so or that it would be unreasonable, taking everything into account, that they should.

The Inquiry's statement of approach entitled "Information for witnesses" is published on the

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I hope that helps those of you who may have been wondering about when we might hear from those witnesses.

Turning back then to next week, Ms Richards, we resume on Tuesday, do we not, starting at ten o'clock with a presentation on the first Cardiff AIDS patient, Kevin Slater. That's something which you promised, I think, during the evidence at the time we were listening to Professor Ludlam. To be followed by a rather longer one on the Newcastle Haemophilia Centre.

MS RICHARDS: Sir --

SIR BRIAN LANGSTAFF: Is there anything else next week, Ms Richards?

MS RICHARDS: No, that's all. And I should say in relation to the presentation on the first Cardiff AIDS patient, we have previously not named him, for obvious reasons. We now do so with the knowledge and consent and agreement of his family, to whom we are very grateful for the assistance they have provided in furnishing us with information about him. So we will be looking at his case in terms of what it tells us about the knowledge of risk in the course, in particular, of 1983 and there is a presentation that has been, or shortly will be, provided to Core Participants. And then we will then for most of the

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website. It sets out the process so that anyone can read it. Paragraphs 18 to 20, in particular, are applicable. Each case requires separate often painstaking examination. Each is different because the particular situation of each witness is different. I have to make a judgment, too, about the public interest in hearing from that particular clinician. It is only after consideration, careful consideration, of their individual circumstances that I've come to the conclusion that some of the clinicians who were directors of haemophilia centres and attended UKHCDO meetings in the 1980s are not in a position to give evidence.

What this means is that the Inquiry will not be taking oral evidence from the following haemophilia clinicians whom it would otherwise have wished to call: Peter Jones of the Newcastle haemophilia centre, Charles Rizza of the Oxford Haemophilia Centre, Richard Wensley from Manchester, Frank Hill from the Children's and the Queen Elizabeth hospitals in Birmingham, Elizabeth Mayne from the Royal Victoria Hospital in Belfast, Morag Chisholm from the Southampton centre, Layinka Swinburne from the Leeds centre. Some have been unable to give written statements.

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rest of the Tuesday and Wednesday be looking at Newcastle.

SIR BRIAN LANGSTAFF: So Tuesday and Wednesday next week starting at 10.00 on Tuesday.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Thank you very much. Thank you all and good night.

(4.55 pm)

(Adjourned until 10.00 am on Tuesday, 2 February)

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<p>DR KAZARIAN: [20] 7/25 20/12 29/2 37/23 38/19 47/13 74/14 85/15 117/24 124/15 128/5 130/12 145/13 152/10 152/14 156/12 176/10 180/1 191/15 198/15</p> <p>MS RICHARDS: [141] 1/4 1/11 1/21 2/7 4/3 4/25 6/6 7/15 7/18 8/15 10/3 10/19 11/7 14/7 15/21 17/10 19/2 19/17 19/24 20/21 21/9 22/7 23/6 24/8 27/3 28/13 29/24 30/24 31/15 33/23 35/10 36/17 38/7 40/5 40/15 41/14 41/19 47/8 48/16 50/8 51/17 52/21 54/15 55/19 56/2 56/17 57/12 58/2 61/2 61/9 62/25 63/6 63/17 68/24 71/6 74/13 74/21 79/8 83/8 85/3 85/14 85/24 89/4 93/12 94/8 95/23 98/5 99/21 100/25 106/1 107/5 110/18 111/4 112/2 112/4 112/8 113/3 114/18 115/23 116/16 117/18 118/17 119/5 120/4 121/6 122/24 124/14 124/24 126/3 130/4 130/20 131/22 134/21 135/2 136/15 137/20 139/4 140/15 147/2 150/23 152/13 152/15 153/6 157/16 159/25 161/13 162/5 163/2 164/4 167/4 167/23 168/20 168/22 169/21 170/25 172/11 173/1 173/14 173/21 175/9 175/24 176/13 176/15 178/6 178/15 178/17 179/25 180/7 181/20 182/21 183/12 185/8 188/1 188/6 191/14 192/6 194/2 196/14 203/11 203/14 204/5</p> <p>PROFESSOR CAVE: [51] 1/18 2/6 8/16 13/14 19/3 19/20 22/8 27/4 31/1 38/25 40/23 41/18 44/18 47/24 51/18 74/4 85/4 91/4 101/10 110/5 115/18 116/9 118/19 120/23</p>	<p>122/16 123/1 124/12 125/11 126/8 128/3 128/14 130/21 135/9 139/5 143/2 149/19 151/4 155/16 157/23 162/21 163/11 165/2 167/11 168/5 170/24 176/7 180/15 185/9 188/4 189/23 197/9</p> <p>PROFESSOR FARSIDES: [68] 5/17 6/13 7/16 9/9 9/16 12/22 21/10 23/7 26/13 34/7 36/20 38/22 42/7 45/23 50/9 53/18 58/10 61/8 63/5 63/14 66/9 68/11 73/21 78/18 81/8 88/8 93/13 95/16 96/2 99/13 100/9 104/5 107/9 113/5 114/11 115/4 116/21 119/16 120/11 121/13 123/23 129/1 132/3 135/1 136/19 139/15 141/10 148/2 150/4 153/16 155/9 158/11 161/14 166/7 169/3 170/3 171/14 174/8 176/5 176/24 178/19 181/21 183/6 183/17 187/3 192/7 195/23 196/17</p> <p>PROFESSOR KERRIDGE: [47] 2/8 4/12 6/12 6/14 9/10 10/4 11/6 12/8 14/24 15/7 17/9 17/17 23/15 24/15 25/7 26/4 27/19 31/16 35/11 35/14 36/19 38/18 39/8 40/6 44/17 44/24 46/9 48/23 53/4 54/16 56/10 57/13 60/2 61/7 63/3 64/17 69/8 73/13 83/9 86/18 95/5 98/6 99/20 109/6 111/7 111/12 111/24</p> <p>PROFESSOR SAVULESCU: [81] 3/10 8/6 9/8 9/24 11/16 14/19 14/25 18/18 20/23 25/5 25/8 26/3 26/5 27/9 28/12 30/10 33/8 35/13 39/17 43/25 50/23 56/18 59/16 61/6 61/16 63/21 67/19 70/16 79/9 82/5 87/8 87/20 92/13 94/19 102/25 105/12 106/13 108/21 112/19 114/6 114/21 116/1 117/9</p>	<p>118/6 119/13 119/23 123/6 126/19 134/2 138/3 140/21 142/5 144/12 146/6 146/21 147/10 149/2 152/25 154/14 159/11 160/8 164/8 165/16 168/9 168/21 172/12 173/10 173/20 174/1 176/8 177/18 178/13 178/16 186/12 188/17 190/21 193/15 194/20 195/8 195/17 197/17</p> <p>SIR BRIAN LANGSTAFF: [28] 1/3 1/5 8/21 25/16 41/20 55/22 86/1 87/19 110/25 111/6 111/8 111/13 112/3 143/18 146/18 175/14 176/1 176/9 176/11 176/14 194/7 195/5 195/15 196/12 198/21 203/12 204/3 204/6</p> <p>.</p> <p>'80s [2] 104/8 195/21 '90s [4] 123/1 123/4 134/13 195/21 'Any [1] 75/15 'The [1] 75/12</p> <p>.</p> <p>... 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(81) whether... - years

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