

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

16 Professor Kerridge -- Professor Farsides.

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

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

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

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

15 **MS RICHARDS:** Professor Farsides?

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

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

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

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

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

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

13 **PROFESSOR FARSIDES:** No, you go ahead, Ian.

14 **PROFESSOR KERRIDGE:** Please follow on from me.

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

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

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

15 **MS RICHARDS:** Professor Cave.

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

21 **SIR BRIAN LANGSTAFF:** If I may just comment, and tell me,  
 22 please, if you think this is wrong, but in the  
 23 scenario which was posed by Ms Richards, in effect,  
 24 the clinician is taking the decision for the patient  
 25 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

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 foetus's health.

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

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

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

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

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

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

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

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

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

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

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

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

24 **PROFESSOR KERRIDGE:** Or others.

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

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

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

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

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

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

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

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

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

25 "Confidentiality and its limits.

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.

17

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.

24

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

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

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?

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

1 I'm not recognising any moral obligations or duties  
 2 that I have to others".  
 3 He says it's reasonable to say to people that's  
 4 actually quite an objectionable argument. It  
 5 certainly runs against social solidarity, it runs  
 6 against reciprocity, it runs against communitarianism  
 7 and it runs against respect for others.

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

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

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

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

10 **MS RICHARDS:** Professor Kerridge.

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

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

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

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

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

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

1 the factual information.

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

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

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

19 **PROFESSOR KERRIDGE:** Bobbie?

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

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,

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

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

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

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

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

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

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

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

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

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

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

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

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

25 **PROFESSOR SAVULESCU:** Well, just two things I said

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

7 **PROFESSOR FARSIDES:** I think this is a very tricky area.  
8 Many years ago, I used to be invited to a European  
9 course which was specifically for receptionists and  
10 medical secretaries to discuss with them the ethical  
11 responsibilities in their work but that was a highly  
12 unusual event and I think there's an added problem in  
13 that the people in question are often members of the  
14 community within which they work. So local knowledge  
15 might mean that they can actually identify patients,  
16 rather than it just being a name or an address on  
17 a letter.

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

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

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

17 **PROFESSOR KERRIDGE:** Sir Brian -- sorry.

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

24 **PROFESSOR KERRIDGE:** No, no. That's -- I mean, I think my  
25 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

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

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

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

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

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

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

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

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

17 **MS RICHARDS:** Professor Cave?

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

1 least, I think that continues to be unproblematic.

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

8 **MS RICHARDS:** Professor Farsides?

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

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

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

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

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

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.

24 (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.

15 **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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1 (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.

17 **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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1 parents' wishes in that case would have been  
 2 overridden.  
 3 So I think Australia's probably midway between  
 4 the UK and the United States in terms of respect for  
 5 autonomy and parental wishes included. So the UK is  
 6 still very much based on a system of best interests  
 7 and doctors' decisions about best interests and courts  
 8 typically siding with doctors in those cases. So, you  
 9 know, I think -- as I said before, I think the UK is  
 10 probably 10 to 20 years behind where a country like  
 11 Australia or New Zealand is.

12 **MS RICHARDS:** Professor Kerridge --

13 **PROFESSOR KERRIDGE:** I think I would agree with that.  
 14 It's interesting. It's often said in relation to  
 15 medical practice in Australia that it's somewhere  
 16 between Europe and North America. In the area that  
 17 I practice in haematology, we often joke that we --  
 18 the protocols that we adopt for treatment of leukaemia  
 19 or bone marrow transplantation borrow from both  
 20 spheres of practice, and we do tend to -- our  
 21 decision-making sort of fits clinically in-between  
 22 those two spheres, and I think the same is true of  
 23 ethics as well. That may reflect in part differences  
 24 in law also where we fit somewhere between the UK and  
 25 the United States as well. So I think there are

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

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

1 interesting differences.

2 **MS RICHARDS:** Thank you.

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

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

1 lives.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 **MS RICHARDS:** Your report emphasises the particular  
25 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

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

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

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

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

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

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

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

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

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1 heading "Human experimentation":  
2 "In 1964 the World Medical Association drew up  
3 a code of ethics on human experimentation. This code  
4 known as the Declaration of Helsinki was revised in  
5 1975 as follows."

6 Then if we go to the next page:

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

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

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

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

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

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

13 **MS RICHARDS:** Dr Kazarian?

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

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

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

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

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

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

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

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1 the interests of science and society.  
 2 "(6) The right of the research subject to  
 3 safeguard his or her integrity must always be  
 4 respected ...  
 5 "(7) Doctors should abstain from engaging in  
 6 research projects involving human subjects unless  
 7 satisfied that the hazards involved are believed to be  
 8 predictable ... should cease any investigation if the  
 9 hazards are found to outweigh the potential benefits."  
 10 (8) is concerned with accuracy of results.  
 11 Then (9), in terms of informed consent:  
 12 "... each potential subject must be adequately  
 13 informed of the aims, methods, anticipated benefits  
 14 and possible potential hazards of the study and  
 15 discomfort it may entail. He or she should be  
 16 informed that he or she is at liberty to abstain from  
 17 participation in the study and that he or she is free  
 18 to withdraw his or her consent to participation at any  
 19 time. The doctor should then obtain the subject's  
 20 freely-given informed consent, preferably in writing."  
 21 Then paragraph (10), if we go over the page,  
 22 talks about the particular difficulties if the  
 23 patient, the "subject", is:  
 24 "... in a dependent relationship to [the  
 25 doctor] or may consent under duress. In that case the

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1 withdraw and that this will have no implications for  
 2 your future care. Because if you think about this  
 3 idea of feeling beholden of having a close  
 4 relationship, the right to refuse may feel somewhat  
 5 perilous, particularly if you feel it's then going to  
 6 have an impact on the care that you receive in the  
 7 future. So we make that very specific now.  
 8 **MS RICHARDS:** Professor Savulescu?  
 9 **PROFESSOR SAVULESCU:** I think it's all generally correct  
 10 except for one major error, which I think has  
 11 subsequently been corrected, but it is quite an  
 12 important error.  
 13 Where it says the interests of the subject  
 14 should always take precedence over the interests of  
 15 society, and the health of the patient must always be  
 16 the primary consideration, that's simply incorrect  
 17 when it comes to research in the following way.  
 18 So when you conduct a randomised control trial,  
 19 as Bobbie said, it's only ethical if you begin with  
 20 what's called equipoise; that is, you have no reason  
 21 to believe that the new intervention is better or  
 22 worse than the existing intervention. So you're  
 23 completely indifferent. But as soon as you start to  
 24 obtain data, equipoise will be disturbed. So after  
 25 100 patients you might have, you know, a belief that

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

4 Then:

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

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

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

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

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

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

24 That's a critical thing in research, that it's  
 25 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

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

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

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

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

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

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

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

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

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

12 **MS RICHARDS:** Professor Farsides?

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

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

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

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

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

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

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

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

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

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

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1 relation to research on children. Professor Farsides?

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

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

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

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

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

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

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

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1 complexity to research involving children.

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

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

20 **PROFESSOR KERRIDGE:** Absolutely.

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

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

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

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

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

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

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

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

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

25 **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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **PROFESSOR CAVE:** It's interesting that in this regard  
12 there's a thing called a Caldicott Guardian, which is  
13 after review of patient identifiable information in  
14 1997, this review, chaired by Dame Fiona Caldicott set  
15 up a government system, whereby there would be  
16 Caldicott guardians in each institution in the NHS,  
17 and they very recently set out a new principle so they  
18 started off with six principles and they have added  
19 two since then, and one of those is the duty to tell  
20 patients how confidential information is shared where  
21 it's going to be shared. So I think this is  
22 a recognition of the fact that things have changed  
23 over time and the methods too will have changed over  
24 time. So now it may well be that websites are used,  
25 previously it might have been that there was more

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

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

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

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

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

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

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

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

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

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

3 **PROFESSOR CAVE:** One reason -- sorry, I beg your pardon.

4 Go ahead Mel, because I've spoken already.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 MS RICHARDS: Professor Cave.

21 PROFESSOR CAVE: There's also some guidance around the  
22 1980s on this. So the Royal College of Physicians in  
23 1984 said that in research it's important to report  
24 any payments to research ethics committees so that  
25 they were aware of them. That's not the same as

1 part of their professional training and  
2 qualifications? Professor Farsides?

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

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

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

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

1 topics that the students learn that are completely  
 2 devoid of the possibility of an ethical complexion.  
 3 Different medical schools have developed  
 4 different curricula. They choose to deliver the  
 5 teaching in different ways. It sometimes depends upon  
 6 the specific interests and specialisms of the  
 7 ethicists involved in the teaching. It may be that  
 8 there's -- in our medical school, we have a lot of  
 9 team-teaching alongside clinicians so that you make  
 10 sure that what you're saying is very much related to  
 11 the clinical experience of the students. And  
 12 alongside this, a community has grown up around the  
 13 discipline with some very active bodies such as the  
 14 institute of medical education which supports and  
 15 promotes ethics in medical schools and encourages  
 16 medical students to think of it as also an  
 17 extracurricular activity with debating contests and  
 18 competitions for writing journal articles, et cetera.  
 19 So it's something that's changed over time.  
 20 You now find -- I can't think of a medical school that  
 21 doesn't have substantive members of staff working in  
 22 this area. It will vary how many. But now I don't  
 23 think you could graduate from a medical degree in  
 24 a British university without being aware that you had  
 25 been taught a substantial amount of medical ethics and

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1 **PROFESSOR FARSIDES:** Yes, that's right.  
 2 **MS RICHARDS:** We touched yesterday, and you touched on it  
 3 in your report, on the limited nature of legal  
 4 remedies. For example, there is no freestanding claim  
 5 for damages for the absence of informed consent.  
 6 Is there any evidence that you are aware of  
 7 that the existence of legal remedies drives up  
 8 standards of care and helps embed ethical standards?  
 9 **PROFESSOR CAVE:** I think we have seen some evidence of  
 10 that in the various documents that you have put up.  
 11 So where there was talk from the Medical Defence  
 12 Union, for example, about consent, it referenced  
 13 assault, and that was -- so the thinking then was how  
 14 can we advise people on how to avoid a claim in  
 15 assault. But then that was from the Medical Defence  
 16 Union, so fairly clear that that was going to be their  
 17 emphasis.  
 18 It's more a symbiotic relationship, I think.  
 19 It's not that one drives the other, it's that both are  
 20 relevant to both. The law can be a lot slower to move  
 21 than ethical guidance but, as we heard over the course  
 22 of yesterday, sometimes codes too can take a while to  
 23 be changed to get consensus, to get agreement. They  
 24 can be fairly slow moving too. So things move at  
 25 different strands at different levels but there

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1 law.  
 2 **PROFESSOR SAVULESCU:** Bobbie is the expert, but I think  
 3 1998 is a sort of key year. The group published  
 4 a core curriculum in the *Journal of Medical Ethics* --  
 5 Bobbie was a part of that group -- and around that  
 6 time, the GMC mandated medical ethics and law teaching  
 7 in medical schools. So it went from this very  
 8 disparate, informal form of teaching to something that  
 9 was really a part of core medical education. And  
 10 around that time, Tony Hope and I wrote our book on  
 11 medical ethics and law textbook for medical schools  
 12 around that core curriculum.  
 13 So I think it's really the late '90s where it  
 14 became, you know, a core part of medical schools.  
 15 But, as Bobbie says, there is still considerable  
 16 freedom and choice around how that's delivered and what  
 17 is actually delivered. So I wouldn't by any means  
 18 want to think that the job is done and that doctors  
 19 are completing their education with a good knowledge  
 20 of medical ethics and law.  
 21 **MS RICHARDS:** The 1998 publication to which you refer,  
 22 that's the consensus statement by teachers of medical  
 23 ethics and law in UK medical schools which is,  
 24 I think, referenced in your report and to which you  
 25 were signatory I think, Professor Farsides?

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1 certainly are cases where changes in law have driven  
 2 changes to guidance. *Montgomery* is an example of  
 3 that.  
 4 It's strange in a way because *Montgomery* came  
 5 about, in part recognised the GMC had recognised for  
 6 many years a standard of informed consent that hadn't  
 7 been fully adopted by the courts. Yet the GMC then  
 8 went on to revise their guidance in order to take  
 9 account of some of the nuanced aspects of the  
 10 judgment, such as the reference to the therapeutic  
 11 exception, which we've talked about, and reference to  
 12 dialogue and the importance of dialogue, and to really  
 13 draw that out, to operationalise some of the legal  
 14 aspects that *Montgomery* had set into law.  
 15 **MS RICHARDS:** Moving to a different issue now, what  
 16 ethical principles guide how clinicians should guard  
 17 against stigma or conscious or unconscious bias in  
 18 their practice? Professor Farsides?  
 19 **PROFESSOR FARSIDES:** Again, I think you would not have  
 20 heard this term "unconscious bias" mentioned within  
 21 the medical curriculum until very recently, probably,  
 22 but certainly the GMC has been very aware of the  
 23 impact of unconscious bias when considering how the  
 24 Fitness to Practise processes operate, and the ways in  
 25 which people's judgments of what happened might be

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

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

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

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

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

4 **MS RICHARDS:** Professor Cave?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

15 Professor Farsides?

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

1 not having enough time to engage in a difficult  
2 discussion and not wanting to because it's difficult  
3 and you'd rather do something else.  
4 I don't know of any systematic research on this  
5 but my strong suspicion is there's a mixture of all  
6 three in practice and just how much of it is vicious  
7 and how much of it is the result of very flawed system  
8 is difficult to say.

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

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

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

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

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

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

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

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

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

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

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

13 **MS RICHARDS:** Professor Farsides?

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

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

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

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1 perhaps moral and ethical rights.

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

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

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

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

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

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

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

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

4 **MS RICHARDS:** Yes, I think so.

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

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

18 So it was paternalism, but it was a certain  
 19 kind of paternalism where there was a genuine belief  
 20 that this is what patients want. And I think that  
 21 that has begun to crumble in the last 30 or 40 years.  
 22 But it wasn't straightforward "we're just going to do  
 23 what we believe is best for you". I think there was  
 24 a belief that -- and in many cases, it was true that  
 25 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

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

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

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

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

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

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

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

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

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

25 **MS RICHARDS:** Dr Kazarian?

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1 consent themselves, necessarily.

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

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

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

15 **MS RICHARDS:** Yes. Sorry --

16 **PROFESSOR SAVULESCU:** -- how I understand the question.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 One of the most wonderful PhDs I've supervised  
 2 in recent years was where Dr Jane Peake spoke to 37  
 3 people who had suffered from Parkinson's Disease over  
 4 a period of between three months post-diagnosis to  
 5 30 years, and some of the things that she uncovered in  
 6 that were invaluable in challenging dominant medical  
 7 perceptions of what a diagnosis of that type can mean.

8 **MS RICHARDS:** Professor Cave?

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

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

25 One of the systems we have at the moment is a

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

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

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

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

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

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

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

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

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

6 **MS RICHARDS:** Does anyone have a different view?

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

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

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

19 So it was expressed before by Emma that the  
 20 Shropshire problem was a failure to respect women's  
 21 autonomy, and that's certainly correct. It's been  
 22 a legitimate option for women for over 20 years to  
 23 elect caesarean section, but it's been an option that  
 24 has been rejected by many medical professionals on  
 25 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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1 the standards that we as ethicists would like them to  
2 meet because of the way in which a system has been  
3 denuded of finances or where attention hasn't been  
4 paid to organisational problems, systemic issues.

5 Whilst I think we're doing our best in terms of  
6 medical education to try and support individual  
7 doctors in being the best they can, and also by things  
8 like widening participation, correcting the profound  
9 gender imbalance that existed at the time some of the  
10 documents we've looked at existed, we're trying our  
11 best to train good doctors but, with all the will in  
12 the world, if they then emerge into a system that  
13 makes demands upon them that is completely  
14 unreasonable, then the patient remains at risk.

15 **PROFESSOR SAVULESCU:** To echo what Bobbie said, I think  
16 there are some of the best doctors and health  
17 professionals in the world in the UK, and I've  
18 certainly benefited from their care. So I think  
19 that's the starting point. But they are operating in  
20 a system that isn't fit for purpose. The UK has one  
21 of the worst cancer survival rates in Europe, and  
22 that's not because, you know, of the quality of the  
23 doctors. That's because the system needs to be  
24 revised and I think you're just seeing Inquiry after  
25 Inquiry, and I think it's time to move into the 21st

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1 a journal article nowadays that this has received  
2 ethics committee approval. So journals have tried to  
3 and editors have tried to exercise some quality  
4 control in that way.

5 **SIR BRIAN LANGSTAFF:** That would itself create the  
6 expectation that anything which might be published  
7 should have ethical approval?

8 **PROFESSOR SAVULESCU:** That's the first thing I tell my  
9 students, at least, that if we want to publish this we  
10 have to get ethics committee approval. So that's --  
11 that was -- that's a relatively recently phenomenon.  
12 That certainly, you know, wasn't the case last  
13 century, that journals required ethics committee  
14 approval before they published the paper.

15 **SIR BRIAN LANGSTAFF:** When roughly did it change in this  
16 millennium?

17 **PROFESSOR SAVULESCU:** I'm thinking around the turn of the  
18 millennium, journals started to require that. So  
19 that's my guess. I don't know if the others have  
20 a more accurate memory of that but, you know, I think,  
21 you know, in the '80s and '90s that wouldn't have been  
22 standard practice at all.

23 **PROFESSOR FARSIDES:** I still think there's a sort of  
24 intermediate position and it's certainly something  
25 that I have provided to people as the chair of

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1 century.

2 **MS RICHARDS:** My final question was going to be to offer  
3 Professor Savulescu the opportunity to raise the issue  
4 of NHS funding but I think through the last question  
5 you have been able to do that, I hope.

6 So, sir, over to you.

7 **SIR BRIAN LANGSTAFF:** Yes. Just one issue, if I may. It  
8 goes back to what was said by you,  
9 Professor Savulescu, earlier. You were speaking about  
10 the question of research and if it was published, if  
11 any document was published it was likely to be  
12 research, and it led me to wonder whether one of the  
13 controls on whether there should be proper ethical  
14 approval on a paper which might be published, is that  
15 a journal might require there to be evidence of such  
16 approval before publishing. It may be a common  
17 practice. Is it common practice that journals seek  
18 a proper assurance that there has been ethical  
19 approval for that which they are to publish --

20 **PROFESSOR SAVULESCU:** Yes, it is now and now journals, as  
21 far as I know all, but certainly typically in the  
22 major journals all require evidence of ethics  
23 committee approval and, as I mentioned, typically when  
24 patient data or information is published, that the  
25 patient has consented. But you always see now on

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1 an ethics committee, which is where something is very  
2 clearly audit or health services evaluation but there  
3 is an intention to publish, we will look at -- we will  
4 ask them to fill in the same form as if it were  
5 a research protocol, we'll look at it but the letter  
6 that we provide will state very clearly that it has  
7 been presented to us as audit or health services  
8 evaluation, because I think there is a merit to  
9 keeping that distinction clear if you're being  
10 straightforward and accurate in the way that you use  
11 it.

12 **SIR BRIAN LANGSTAFF:** Thank you, Ms Richards. That's all  
13 that I have to ask.

14 **MS RICHARDS:** Is there anything further which any member  
15 of the panel would wish to add that we haven't  
16 covered?

17 **PROFESSOR FARSIDES:** Could I just say something which  
18 I would have liked to have said at the beginning but  
19 my internet system let me down.

20 We've spent two days discussing complex  
21 principles and theories and documents but I think  
22 we're all very minded of the fact that these are of  
23 great interest to people listening today whose lives  
24 have been touched in a very profound and real way by  
25 the issues to which we are applying these somewhat

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1 abstract ways of thinking. I would just like to say  
2 that, personally, and I know that people will speak  
3 for themselves, but I know we share this, that we've  
4 been very moved by the testimony that we've heard from  
5 Core Participants and, whilst we haven't touched upon  
6 their direct experience and their stories, they  
7 haven't been far from our minds when we have been  
8 speaking with you over the last two days.

9 **PROFESSOR CAVE:** I would like to echo that. It's been  
10 a huge privilege to be of some assistance to the  
11 Inquiry and it was an honour to attend some of the  
12 hearings. I was lucky enough to go to Leeds and to  
13 Edinburgh and to hear firsthand the accounts of the  
14 infected and affected, and also to meet some of them  
15 in the breaks at lunchtime. So thank you very much  
16 for that.

17 **PROFESSOR SAVULESCU:** Well, I mean, maybe I should declare  
18 a slight conflict of interest at the very end here  
19 because I think I graduated from medicine in 1988 and  
20 I looked after patients with haemophilia. I was in  
21 a hospital which was a major haemophilia treatment  
22 centre and also a major HIV treatment centre, and  
23 I looked after patients who died of AIDS and who had  
24 HIV from blood products. You know, I know firsthand  
25 that, at that time, I think in our hospital, patients

1 been a privilege to give evidence for the Inquiry or  
2 to be involved in it. Actually, it's our privilege to  
3 have had you. You have, over the last two days, given  
4 us a really valuable understanding of how ethics may  
5 fit in. Those who have been watching, who perhaps  
6 wondered why there have been less direct questions  
7 about particular instances of a failure, as they would  
8 see it, of the treatment they may have had, whether as  
9 people with haemophilia or people who simply had  
10 a transfusion for some other issue, why they haven't  
11 had the ethics of that particular situation explored  
12 and explained, but that would be to focus upon the  
13 individual and we have been focusing upon the general,  
14 the lie of the land.

15 What you have done, is you've given the Inquiry  
16 and those who participate in it the tools, the ethical  
17 tools, to help to understand and dissect some of the  
18 evidence we've had to understand where they may have  
19 been ethical failings, inappropriate action,  
20 shortcomings, as we now see them and, of course, we  
21 are judging necessarily from a perspective of  
22 2020/2021, maybe 2022, what may have happened in the  
23 past. You have shown us, I think, really how complex,  
24 how sophisticated, how nuanced -- those are the words  
25 that you, Professor Farsides, used -- ethics can be,

1 got the best possible care but many people, many  
2 clinicians, including myself, often were embarrassed  
3 or ashamed and we viewed patients with haemophilia as  
4 a failure of medicine.

5 We had promised miracles and given them HIV and  
6 for that, you know, as a part of the medical  
7 profession I would like to apologise. I can't say  
8 anything about the decisions of Sir Brian but I do  
9 hope that you get the justice and compensation that  
10 you deserve and I hope that we can move forward into  
11 the future and identify the ethical failings and do  
12 better in the future.

13 So I look forward to Sir Brian's report and  
14 I hope to write about this in the future.

15 **DR KAZARIAN:** I would like to echo that as well. I think  
16 it has been a long time coming and I feel very  
17 grateful for being part of this panel because,  
18 finally, we were hoping that the victims and their  
19 families and many patients will have the justice that  
20 they need.

21 **SIR BRIAN LANGSTAFF:** You have spoken about the privilege  
22 of seeing some of the hearings -- you,  
23 Professor Farsides, and you, Professor Cave. You have  
24 spoken about your experiences, Professor Savulescu,  
25 when you were a young doctor, and you said that it's

1 but the value of it in considering, exploring the  
2 issues and looking for other possibilities and a much  
3 clearer appreciation, I think, of how those nuances,  
4 those complexities, actually play out in practice, and  
5 I really do want to thank you, as I thanked  
6 Professor Kerridge earlier, for your time, for your  
7 effort and what, for my mind, is a very good,  
8 well-written, very helpful report. I look forward to  
9 meeting you further when circumstances permit but  
10 thank you all, one and all.

11 I do have something to say now to those who are  
12 watching online. By all means, sign off if you would  
13 rather. Otherwise, you may have to be detained for  
14 another five minutes. That's, I hope, not going to be  
15 ten.

16 But it is this: if I can address the wider  
17 audience who are watching. The eagle-eyed amongst you  
18 will not have missed that Dr Jones, Dr Peter Jones,  
19 was earlier timetabled to give oral evidence next  
20 week, but there are now no plans to call him to  
21 testify. I promised that this Inquiry would be as  
22 transparent as the law permitted. And to make good on  
23 that principle, you are entitled to know why Dr Jones  
24 will not be giving evidence orally. It's because  
25 after considering both submissions on his behalf under

1 section 21(4) of the Inquiries Act 2005, supported by  
2 evidence, as well as the public interest in hearing  
3 orally what he may have to say, I have determined that  
4 it would not be reasonable in all the circumstances to  
5 require him to do so.

6 This is a good point at which to explain why  
7 certain potential witnesses are not giving oral  
8 evidence. A consequence of the time it took before  
9 a statutory UK-wide inquiry was decided on is that  
10 many of the matters we are investigating date back  
11 many years. Some potential witnesses have developed  
12 health conditions that mean that they cannot now give  
13 evidence as once they would have done. Some witnesses  
14 have been able, with difficulty in some cases, to give  
15 a written statement but not to give it orally. Some  
16 are able to give neither. In each case, I start from  
17 the basis that if it is desirable to have evidence  
18 from a witness, the Inquiry should get it. I have  
19 powers to compel it which I am quite prepared to use.  
20 It is necessary to have compelling material to  
21 persuade me either that they cannot do so or that it  
22 would be unreasonable, taking everything into account,  
23 that they should.

24 The Inquiry's statement of approach entitled  
25 "Information for witnesses" is published on the

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1 I hope that helps those of you who may have  
2 been wondering about when we might hear from those  
3 witnesses.

4 Turning back then to next week, Ms Richards, we  
5 resume on Tuesday, do we not, starting at ten o'clock  
6 with a presentation on the first Cardiff AIDS patient,  
7 Kevin Slater. That's something which you promised,  
8 I think, during the evidence at the time we were  
9 listening to Professor Ludlam. To be followed by a  
10 rather longer one on the Newcastle Haemophilia Centre.

11 **MS RICHARDS:** Sir --

12 **SIR BRIAN LANGSTAFF:** Is there anything else next week,  
13 Ms Richards?

14 **MS RICHARDS:** No, that's all. And I should say in  
15 relation to the presentation on the first Cardiff AIDS  
16 patient, we have previously not named him, for obvious  
17 reasons. We now do so with the knowledge and consent  
18 and agreement of his family, to whom we are very  
19 grateful for the assistance they have provided in  
20 furnishing us with information about him. So we will  
21 be looking at his case in terms of what it tells us  
22 about the knowledge of risk in the course, in  
23 particular, of 1983 and there is a presentation that  
24 has been, or shortly will be, provided to Core  
25 Participants. And then we will then for most of the

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1 website. It sets out the process so that anyone can  
2 read it. Paragraphs 18 to 20, in particular, are  
3 applicable. Each case requires separate often  
4 painstaking examination. Each is different because  
5 the particular situation of each witness is different.  
6 I have to make a judgment, too, about the public  
7 interest in hearing from that particular clinician.  
8 It is only after consideration, careful consideration,  
9 of their individual circumstances that I've come to  
10 the conclusion that some of the clinicians who were  
11 directors of haemophilia centres and attended UKHCDO  
12 meetings in the 1980s are not in a position to give  
13 evidence.

14 What this means is that the Inquiry will not be  
15 taking oral evidence from the following haemophilia  
16 clinicians whom it would otherwise have wished to  
17 call: Peter Jones of the Newcastle haemophilia centre,  
18 Charles Rizza of the Oxford Haemophilia Centre,  
19 Richard Wensley from Manchester, Frank Hill from the  
20 Children's and the Queen Elizabeth hospitals in  
21 Birmingham, Elizabeth Mayne from the Royal Victoria  
22 Hospital in Belfast, Morag Chisholm from the  
23 Southampton centre, Layinka Swinburne from the Leeds  
24 centre. Some have been unable to give written  
25 statements.

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1 rest of the Tuesday and Wednesday be looking at  
2 Newcastle.

3 **SIR BRIAN LANGSTAFF:** So Tuesday and Wednesday next week  
4 starting at 10.00 on Tuesday.

5 **MS RICHARDS:** Yes.

6 **SIR BRIAN LANGSTAFF:** Thank you very much. Thank you all  
7 and good night.

8 (4.55 pm)

9 (Adjourned until 10.00 am on Tuesday, 2 February)

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<p><b>DR KAZARIAN: [20]</b> 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><b>MS RICHARDS: [141]</b> 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><b>PROFESSOR CAVE:</b> <b>[51]</b> 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><b>PROFESSOR FARSIDES: [68]</b> 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><b>PROFESSOR KERRIDGE: [47]</b> 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 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(70) onset - Paterson

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(80) vary - whether

<b>W</b>	<b>whilst</b> [8] 66/14 81/21 94/6 140/10 159/2 185/18 193/5 197/5 <b>whistle</b> [5] 143/12 143/13 190/13 191/24 191/25 <b>whistle-blowers</b> [4] 143/13 190/13 191/24 191/25 <b>whistle-blowing</b> [1] 143/12 <b>who</b> [87] 3/14 6/21 7/1 7/10 16/18 16/19 26/9 28/21 31/9 32/13 33/21 42/20 42/21 45/14 46/25 47/2 50/16 59/18 60/20 61/14 66/11 67/13 70/5 72/7 78/1 78/2 95/18 96/19 100/19 101/15 102/22 103/24 104/25 106/4 106/14 107/7 111/14 113/19 120/12 120/21 121/4 129/15 130/5 132/12 137/15 140/22 141/3 141/3 141/11 142/12 142/14 143/23 143/24 144/4 144/10 146/19 146/25 148/4 148/20 148/25 153/19 153/22 156/5 157/21 158/12 176/18 176/20 177/2 178/8 183/23 184/5 184/18 185/3 187/5 189/13 191/18 192/10 197/23 197/23 199/5 199/5 199/9 199/16 200/11 200/17 202/10 203/1 <b>who's</b> [7] 7/12 31/19 32/12 32/12 35/22 53/16 146/8 <b>whole</b> [10] 12/14 14/23 29/17 36/10 36/24 47/4 59/4 69/16 88/24 190/4 <b>whom</b> [9] 81/25 90/13 90/16 105/25 120/7 145/23 176/22 202/16 203/18 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<p><b>Y</b></p> <p><b>years... [11]</b> 147/16 148/9 158/23 164/21 169/1 169/5 174/14 185/2 185/5 188/22 201/11</p> <p><b>yellow [1]</b> 186/1</p> <p><b>yes [47]</b> 1/18 2/6 9/8 9/10 11/6 17/9 17/9 22/7 23/15 26/3 26/4 29/21 34/7 38/22 41/18 44/15 53/4 55/22 61/6 61/7 63/5 87/19 88/5 102/23 119/13 130/12 135/1 146/21 152/25 153/3 161/14 162/21 163/15 164/4 173/10 173/13 173/20 176/10 176/13 178/15 180/1 181/21 188/4 191/7 194/7 194/20 204/5</p> <p><b>yesterday [34]</b> 1/7 2/2 8/1 10/22 11/5 13/12 19/4 27/9 30/10 34/16 37/8 38/8 38/24 44/1 44/3 67/21 68/3 74/11 81/11 96/25 99/4 107/6 132/15 132/21 135/2 135/22 140/15 140/22 152/17 152/19 162/5 164/10 169/9 190/9</p> <p><b>yet [3]</b> 13/4 68/15 136/7</p> <p><b>you [484]</b></p> <p><b>you'd [2]</b> 31/23 155/3</p> <p><b>you'll [3]</b> 62/12 149/6 149/8</p> <p><b>you're [17]</b> 1/23 3/1 6/1 26/8 34/18 35/2 35/3 79/22 81/17 93/11 93/24 106/23 106/24 119/13 133/10 193/24 196/9</p> <p><b>you've [17]</b> 1/10 10/20 16/9 58/4 86/21 93/22 106/17 106/20 111/17 117/18 120/5 120/16 141/18 167/3 167/14 173/3 199/15</p> <p><b>young [5]</b> 97/20 98/19 115/13 170/9 198/25</p> <p><b>your [72]</b> 4/4 4/10 8/13 10/21 10/24 11/7 13/3 14/16 14/21 14/23 15/4 15/5 15/5 15/21 21/10 28/13 28/18 30/9 32/24 34/3 34/17 46/6 53/2 58/4 59/9 61/9 68/24 70/12</p>	<p>79/2 80/6 81/1 81/8 81/10 81/14 81/18 81/20 87/1 87/16 98/5 99/21 100/25 104/21 108/21 109/11 109/12 111/14 111/19 111/19 111/22 117/2 120/19 122/11 122/12 124/24 128/3 134/24 135/3 141/14 148/18 152/19 159/5 162/7 162/21 166/14 167/2 175/17 183/8 188/15 189/23 198/24 200/6 200/6</p> <p><b>yourself [3]</b> 50/20 111/1 174/8</p> <hr/> <p><b>Z</b></p> <p><b>Zealand [2]</b> 32/17 57/11</p>				
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