

Friday, 28 May 2021

(10.00 am)

**SIR BRIAN LANGSTAFF:** Yes, Ms Richards.

Presentation by Counsel to the Inquiry about ethical and professional guidance for clinicians

**MS RICHARDS:** Good morning, sir. Today is about looking at various pieces of guidance issued by a range of organisations. The purpose of today is, in some respects, intended as a companion piece to the expert evidence we heard from the medical ethics group.

So whilst the ethics group explored extremely eloquently and usefully the ethical principles, key ethical principles, that may guide clinical decision making and clinical conduct, what we didn't ask the ethics group to do and what they would not have been in a position to do was to conduct a historical investigation into what, as a matter of fact, was issued by way of ethical guidance to clinicians or other healthcare professionals in earlier decades.

That's work the Inquiry has undertaken, and has near completed, albeit there is still some further work to undertake, some visits, for example, to archives held by some of the Royal Colleges, which was held up because of the events of the last year or so.

Today I will be looking at what, as a matter of

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doctors over the years as to how they should conduct themselves in areas of decision making or action that's relevant to the Inquiry's terms of reference.

So the four themes that I'll be looking at in the course of today are: guidance relevant to issues about consent and informed consent; guidance relevant to issues about confidentiality of medical information; guidance relevant to the conduct of research in an ethically appropriate manner; and then, fourthly, guidance from the 1980s and early 1990s relating to particular ethical issues that arose in the context of the AIDS crisis.

What I'm going to do, however, first of all, is just set out some of the key organisations who have issued guidance. I'm not going to describe all of them that we've set out in the note, but provide a little bit of information about the principal organisations so we can understand the status of the guidance and who might have seen it.

Or, indeed, the limitations of the guidance and part of today's exercise may be to assist you in what wasn't being said to doctors and perhaps could or should have been.

So with that introduction, the first key organisation from whom some guidance has emanated over

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fact, was being said in guidance by clinical organisations, in particular in the 1970s, 1980s and early 1990s.

There are two pieces of material that the Inquiry has produced that effectively accompany this. There is a chronology, which I'm not proposing to go to today, but which has been disclosed to core participants, and then there's a written note, which again has been disclosed to core participants but hopefully will also get placed after today on the Inquiry website, so that those who are not core participants can have the opportunity of reading the material.

What I'm not going to be looking at, sir, is case law. The chronology does identify some of the significant cases on issues, such as consent in the context of clinical negligence over the years, but clearly, sir, you're precluded from making findings about civil or criminal liability, and in any event, as the expert group make clear, ethical principles, the question of what doctors should do, go far wider than the minimum requirements that might exist in order to avoid a successful claim in negligence. So the focus today is not about cases, it's about what the GMC or the BMA or other organisations have said to

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the years is the General Medical Council. The General Medical Council is the professional regulator for doctors. It has other significant roles and responsibilities too, particularly in relation to medical education.

But for present purposes, its guidance largely emanates from its role as the regulator of doctors.

The General Medical Council in some form or another has existed since the middle of the 19th century, and its powers have changed over the years as legislation, primarily legislation, governing its role and responsibilities has been amended.

If we just have a quick look at the witness statement of Mr Massey, Soumik, it's WITN3365001. Mr Massey is the current Chief Executive and Registrar of the General Medical Council and he has provided the Inquiry with a statement which provides some historical background and context in terms of the regulation of doctors.

If we go to the second page, please, Soumik, and we pick it up in paragraph 5, Mr Massey refers to the decades in which the events that the Inquiry's investigating took place and says:

"That period has seen a number of fundamental changes to medical regulation."

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1 Then if we go to paragraph 6, please. We will  
2 see that he says:  
3 "The period from the 1970s to the early 2000s  
4 saw a model of the medical self-regulation which was  
5 dominated by the medical profession."

6 In other words doctors, regulated doctors:  
7 "A broadly equivalent model existed in the other  
8 regulated health professions. The GMC's governing  
9 body, the Council, was made up largely of doctors  
10 elected by their peers with a minority of lay members  
11 appointed by the Privy Council to represent the public  
12 interest."

13 Then he explains how that has, in this century,  
14 changed, in paragraph 7 of his statement, and in  
15 paragraph 8 says:

16 "This shift in the composition of the Council is  
17 reflective of the move away from the late 20th century  
18 model of self-regulation to one of greater partnership  
19 between the profession and the public."

20 Then if we go to the next page, he refers to  
21 some of the documents the GMC has issued over the  
22 years and we'll look at some of those in a moment but,  
23 under the heading "Development of the Fitness to  
24 Practise process", there's a useful summary of the way  
25 in which that has changed over the years. So he says

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1 and pick it up in paragraph 27. He explains that:  
2 "[The General Medical Council's] procedures for  
3 developing and agreeing standards of good practice for  
4 doctors were established after 1980 when the GMC was  
5 given the legal power to give advice to the medical  
6 profession on standards of conduct and performance and  
7 medical ethics. Before the 1980s the GMC did not set  
8 professional standards, although it did set out  
9 a number of general principles arising from the  
10 disciplinary cases published in its annual 'Blue  
11 Book'."

12 We'll look at some examples of that in a moment.  
13 Then he explains in paragraph 29 that with this new  
14 power to give advice from 1980:

15 "... the GMC set up a ... Standards and Ethics  
16 Committee ... with responsibility for considering  
17 questions about standards of good practice and making  
18 recommendations ..."

19 And so on.

20 That's just a quick overview of some of the ways  
21 in which the GMC's role or the way in which it  
22 performs its role has, according to Mr Massey, changed  
23 over the decades, with a different approach now to how  
24 the approach might have been in the decades with which  
25 the Inquiry is particularly concerned.

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1 in paragraph 14:  
2 "In the 1970s and continuing up until 1980, the  
3 GMC's fitness to practise remit extended only to  
4 issues of criminal conviction and conduct."

5 I should say that fitness to practise means the  
6 GMC exercising powers to discipline doctors,  
7 essentially.

8 Then he talks about how that was modified to  
9 bring in performance procedures so that the way in  
10 which doctors were discharging their clinical  
11 responsibilities in more general terms could also be  
12 looked at.

13 You'll note, sir, and in paragraph 16 he says:

14 "... prior to 2002, making a complaint to the  
15 GMC had been a complex procedure for complainants  
16 involving sworn affidavits and very little support or  
17 explanation of our processes. This put off many  
18 patients making complaints to the GMC and thus, the  
19 bulk of our referrals came from employers and other  
20 doctors at this time."

21 Then he contrasts that with what he says the  
22 current position is:

23 "Today, we aim to provide much greater support  
24 for those who wish to make a complaint ..."

25 Then if we go over, Soumik, to page 5, please,

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1 If we then have a look at some of the material  
2 in which the GMC, in terms of its general guidance to  
3 doctors issued in those periods, from 1963 onwards --  
4 sorry, we can take down the statement, thank you,  
5 Soumik.

6 From 1963 onwards, the GMC did issue booklets to  
7 doctors. The booklets were called Functions,  
8 Procedure, and Disciplinary Jurisdiction, and the  
9 first was, we think, published in 1963, and then there  
10 were updated booklets published in a number of years  
11 that followed.

12 We'll see when we look at an example of it, it  
13 gave very limited advice. We are no doubt all  
14 familiar nowadays with the term "professional  
15 misconduct" in relation to professions such as doctors  
16 or, indeed, other health professions, lawyers. The  
17 term that was in play in the sixties and seventies in  
18 the medical world was "infamous conduct in  
19 a professional respect", and the booklets that we'll  
20 look at some examples of essentially did little more  
21 by way of guidance to doctors than give examples of  
22 what might amount to infamous conduct in  
23 a professional respect.

24 If we look at an example of one of these  
25 booklets, Soumik, can we go to GMCO001697. We can

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1 see this is the first one that we've identified, from  
 2 1963, Functions, Procedure and Disciplinary  
 3 Jurisdiction. If we go to the third page, we'll see  
 4 what it is under the heading "Introduction":  
 5 "This account of the Council's functions,  
 6 procedure, and disciplinary jurisdiction is intended  
 7 primarily for the information of doctors who have  
 8 recently qualified in the British Isles ..."  
 9 Then we'll see, if we go down the page, it has  
 10 a section on medical education, which is talking about  
 11 the training that doctors go through.  
 12 If we go over the page, it has a section on the  
 13 Medical Register and the requirement for doctors to be  
 14 registered.  
 15 And then if we go on two pages, we can see we  
 16 get to a heading "Disciplinary Jurisdiction and  
 17 Procedures". So this the closest we get, as at this  
 18 point in time, to any kind of guidance to doctors  
 19 generally on how they should conduct themselves.  
 20 You'll see in bold print it said:  
 21 "The Council fully realises and appreciates the  
 22 high standard of professional conduct of the vast  
 23 majority of doctors in this country who will never  
 24 find themselves directly concerned with the Council's  
 25 disciplinary jurisdiction."

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1 a patient. So when I come to the theme of guidance of  
 2 issues on confidentiality we'll look and see in more  
 3 detail at what was said over the years about that, but  
 4 that is something that has been identified as a key  
 5 issue: the requirements of confidentiality from an  
 6 early stage.  
 7 Then:  
 8 "Gross neglect in diagnosis or treatment.  
 9 "'Covering' medical practice by unregistered  
 10 persons.  
 11 And then:  
 12 "Convictions arising out of abuse of alcohol."  
 13 "Addiction to drugs."  
 14 Are examples given.  
 15 And if we go two pages on, you'll see at the  
 16 bottom of the page, very limited information about  
 17 disregard of personal responsibilities to patients or  
 18 gross neglect. It simply says:  
 19 "In pursuance of its primary duty to protect the  
 20 public, the Council may feel bound to take cognisance  
 21 of a case (whether or not it has been investigated  
 22 under the National Health Service machinery) in which  
 23 a doctor may appear to have seriously disregarded his  
 24 personal responsibilities to his patients, or to have  
 25 been guilty of gross neglect of his professional

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1 Then if we go down the page, a little further,  
 2 just above the heading in italics -- no, sorry, if we  
 3 pick up the heading in italics "The Council's Approach  
 4 to 'Infamous Conduct'; its Duty to Protect the Public"  
 5 and we see there the phrase "infamous conduct in  
 6 a professional respect". So that was the standard by  
 7 which doctors were judged at this point in time by the  
 8 General Medical Council. What this guidance does,  
 9 really, is just gives some types of example of  
 10 infamous conduct in a professional respect.  
 11 So if we go to the next page, bottom of the  
 12 page, the first example that's given is "Convictions".  
 13 And then if we go over the page, picking it up about  
 14 six lines down, it says:  
 15 "... in the light of the Council's experience  
 16 over the last hundred years it is possible to  
 17 indicate, with examples, a number of types of offence  
 18 or misconduct which raise disciplinary issues."  
 19 These are, as it makes clear, intended only to  
 20 be examples, but they're very limited examples in  
 21 reality, so we have, by way of examples: illegal  
 22 abortion, improperly purveying dangerous drugs,  
 23 adultery with a patient.  
 24 Then you'll see a reference there to improperly  
 25 disclosing information obtained in confidence from

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1 duties."  
 2 Then we get on to issues such as abuse of  
 3 alcohol and abuse of drugs and so on.  
 4 The longest section, if we go to page 13,  
 5 Soumik, I think the longest individual section in this  
 6 guidance and in its consequent iterations for a number  
 7 of years was actually about advertising and  
 8 criticising other doctors or -- essentially.  
 9 And I think I'm right in recalling correctly  
 10 from the evidence of the expert group, you may recall  
 11 the use of the term "etiquette". Quite a lot of the  
 12 early guidance was really about what could be  
 13 described as matters of etiquette, how a doctor should  
 14 describe their practice or how a doctor should or  
 15 shouldn't interact with other doctors, rather than the  
 16 patient-focused emphasis that we, as we will see, then  
 17 begins to emerge over the years.  
 18 That's the fairly limited nature of the guidance  
 19 issued by this booklet by the GMC in 1963.  
 20 We won't go to all the various iterations. It  
 21 doesn't change very significantly but we will perhaps  
 22 just pick it up in the 1970 version, which is  
 23 GMCO0001696, please, Soumik.  
 24 Oh, that's 1971, sorry.  
 25 Sorry, Soumik, 1696\_019. My apologies. There

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1 we are.

2 So this is really to show how little anything

3 changed in terms of the contents of the booklet. If

4 we go to the second page, again, we'll see it follows

5 the same basic structure.

6 If we turn to page 7, we pick it up under the

7 second paragraph beginning "Under the Act", there's

8 reference to the duty to the public, and if we pick it

9 up six lines down, five lines down:

10 "Subject, however, to their overriding duty to

11 the public, members of the Committee may and do

12 constantly ask themselves: 'What is in the best

13 interests of the doctor himself?'"

14 That, I think, wouldn't be the modern approach

15 to regulation, whether by this regulator or any other

16 but that's the approaches at 1970.

17 Then at the beginning of the next paragraph:

18 "The Council is as concerned as the doctors

19 themselves to avert wherever possible any need for

20 a formal disciplinary inquiry into a doctor's

21 conduct."

22 Again, it may give some indication as to the

23 approach to regulation of the profession in 1970 to

24 see those words.

25 Then if we go over the page, we can see that the

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1 under the heading "Statutory Provisions" the last

2 sentence of that section -- sorry, the

3 subparagraph (2), we'll see there the term "serious

4 professional misconduct" appears. So "infamous

5 conduct in a professional respect" has been replaced

6 as a concept by "serious professional misconduct", and

7 if we go over the page, we see the heading "The

8 Meaning of 'Serious Professional Misconduct'" and then

9 there's an explanation that the legislation has

10 substituted that phrase for the phrase "infamous

11 conduct in a professional respect".

12 If we then go on to page 9, we can see this,

13 again, essentially gives examples of the types of

14 conduct that might result in a doctor at this point in

15 time being called before the disciplinary committee of

16 the General Medical Council. So, again, it's not

17 advice to doctors on the principles by which they

18 should regulate their conduct or their interactions

19 with patients; it's this conduct might result in

20 a finding of serious professional misconduct.

21 We can see at the bottom of that page, it says

22 this part of the pamphlet sets out certain kinds of

23 offences in professional misconduct which have in the

24 past led to disciplinary proceedings by the Council.

25 If we go over the page, we do now get, as the

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1 examples given of infamous conduct are similar to what

2 we saw from 1963. So, again, it's abortion, drugs,

3 adultery, confidentiality, or breach of

4 confidentiality remains in there. We have added at

5 the bottom:

6 "Offences discreditable to the doctor and his

7 profession

8 "False pretences, forgery, fraud, theft,

9 indecent behaviour, assault", and so on.

10 If we go to the top of the next page we can see

11 a couple more examples: improper attempts to profit at

12 the expense of professional colleagues and then abuse

13 of financial opportunities afforded by medical

14 practice.

15 Again, there's a little that is patient focused

16 or that captures the kind of ethical principles and

17 norms that the expert group told us about in the

18 course of their evidence.

19 From 1971, the booklet that was produced by the

20 GMC changed slightly, and so we'll look at that. It's

21 GMCO0001696\_002.

22 So it was still a booklet issued to doctors, it

23 was now called, simply, Professional Discipline and

24 was commonly referred to as the Blue Book.

25 If we go to the third page, we will see from

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1 first item, "Disregard of personal responsibilities to

2 patients", although it appears that what's envisaged

3 there is a failure to treat. Again, there's no real

4 content to illuminate what's meant by this, other than

5 the examples of a failure to visit or to provide

6 treatment for a patient.

7 But that is now the first example given, and

8 then we get some of the familiar examples: "Abuse of

9 alcohol"; if we go over the page, "Abuse of dangerous

10 or scheduled drugs"; "Termination of pregnancy";

11 "Abuse of professional position ... to further

12 an improper association or commit adultery"; we do

13 then see "Abuse of professional confidence", and again

14 I'll come back to the issue of confidentiality at

15 a later stage; and then "Offences involving

16 dishonesty, indecency or violence".

17 Over the page, you'll again see the longest

18 section of this document is devoted to advertising and

19 the principles governing relationships between

20 doctors, rather than the principles governing

21 relationships between doctors and patients.

22 If we go to the last page, just draw attention

23 to the -- oh no, that's not the last page that I have.

24 Sorry, Soumik, if we go to page 15. Can we just go

25 back, I don't know if this is the right document now,

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(4) Pages 13 - 16



1 GMCO0001696\_002. That's it, thank you. So we can see  
2 under the heading "Conclusion":

3 "It must be emphasised that the categories of  
4 misconduct described above cannot be regarded as  
5 exhaustive, since from time to time with changing  
6 circumstances the Council's attention is drawn to new  
7 forms of professional misconduct. Any abuse by  
8 a doctor of any of the privileges and opportunities  
9 afforded to him, or grave dereliction of professional  
10 duty or serious breach of medical ethics [so we get  
11 that concept at least of medical ethics introduced  
12 here], may give rise to a charge of serious  
13 professional misconduct."

14 There is still a dearth of guidance in these  
15 Blue Book as to what might amount to a breach of  
16 ethics.

17 **SIR BRIAN LANGSTAFF:** So thus far it was telling you what  
18 not to do, rather than what to do?

19 **MS RICHARDS:** Yes.

20 **SIR BRIAN LANGSTAFF:** The sting was in the enforcement, in  
21 that if you did something you ought not to do and it  
22 was proved to what was then the relevant standard, you  
23 could have your registration removed.

24 **MS RICHARDS:** Yes.

25 **SIR BRIAN LANGSTAFF:** It didn't mean you ceased to be

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1 ran the risk, if you did something you shouldn't do,  
2 you could be struck off or disciplined by the General  
3 Medical Council.

4 **SIR BRIAN LANGSTAFF:** So it would have a normative effect  
5 in doctors being very careful not to do what they  
6 shouldn't and, therefore, behaving in a particular --  
7 at least in a particular minimum way.

8 **MS RICHARDS:** Yes, yes. If we then move forward to 1985,  
9 you'll recall from Mr Massey's statement he said that  
10 it was in 1980 the GMC was given certain powers to  
11 issue advice and that changed in the Medical Act 1978,  
12 which led to the establishment, by the GMC, of what  
13 was then called its Standards and Ethics Committee.  
14 We then really have to look at the 1985 Blue Book to  
15 start getting a little more articulation of some  
16 general principles, although it's still relatively  
17 limited.

18 So if we go to GMCO0001696\_011, please, Soumik.  
19 This is the Blue Book from April 1985. If we go to  
20 the second page, you'll see, under the foreword, it  
21 says:

22 "This edition of the Council's blue pamphlet  
23 includes new guidance to the profession which was  
24 approved by the Council in May and November, 1984 and  
25 in February, 1985. In Part II, under the heading,

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1 a doctor; it simply meant you couldn't practice in the  
2 NHS or you wouldn't get an appointment.

3 **MS RICHARDS:** Well, I'd have to check, sir. I'm very  
4 familiar with what the current sanctions that the GMC  
5 can impose are, but what the range of sanctions as at  
6 1970 or in the 1970s, I'd have to check. Currently,  
7 the General Medical Council has a range of sanctions  
8 which would include, as its most serious sanction, the  
9 sanction of erasure or striking someone off the  
10 medical register, which means they cannot practise as  
11 a doctor, whether in the NHS or privately, and then  
12 there are lesser but still serious sanctions,  
13 including --

14 **SIR BRIAN LANGSTAFF:** I think in the documents you've  
15 already shown us, they had -- that system was  
16 operating from early times, erasure, the most serious  
17 penalty, obviously, suspension -- I think this  
18 document, it may be the one before, refers to  
19 suspension for no more than 12 months.

20 **MS RICHARDS:** Yes, and then there has been, for a number  
21 of years, powers to impose conditions on a doctor's  
22 registration but when that began I can't, off the top  
23 of my head, tell you.

24 But you're absolutely right, sir. That was the  
25 approach. This was telling you what not to do and you

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1 'Responsibility for standards of medical care' on  
2 page 10, the Council has defined the features of the  
3 standard of medical care which the public are entitled  
4 to expect from a registered medical practitioner."

5 Then it refers to various other aspects,  
6 including further guidance on professional confidence,  
7 so the issue of confidentiality, and on financial  
8 relationships between doctors and other organisations.

9 If we go to what was really a new feature of  
10 this Blue Book.

11 It should be electronic page 15, I think,  
12 Soumik.

13 Yes, it's internal page 10, "Neglect or  
14 disregard of personal responsibilities to patients for  
15 their care and treatment".

16 Here we have some positive advice to doctors on  
17 what they should do. So, under the heading  
18 "Responsibility for standards of medical care", it  
19 says:

20 "In pursuance of its primary duty to protect the  
21 public the Council may institute disciplinary  
22 proceedings when a doctor appears *seriously* to have  
23 disregarded or neglected his professional duties ..."

24 Then we see the same examples as given in  
25 earlier versions of the booklet.

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(5) Pages 17 - 20

1 "... [failure] to visit or to provide or arrange  
2 treatment for a patient when necessary."  
3 If we pick it up in the next paragraph:  
4 "The public are entitled to expect that  
5 a registered medical practitioner will afford and  
6 maintain a good standard of medical care. This  
7 includes:  
8 "(a) conscientious assessment of the history,  
9 symptoms, and signs of a patient's condition;  
10 "(b) sufficiently thorough professional  
11 attention, examination and, where necessary,  
12 diagnostic investigation;  
13 "(c) competent and considered professional  
14 management;  
15 "(d) appropriate and prompt action upon evidence  
16 suggesting the existence of a condition requiring  
17 urgent medical intervention; and  
18 "(e) readiness, where the circumstances so  
19 warrant, to consult appropriate professional  
20 colleagues."  
21 And then if we pick it up then in the paragraph  
22 beginning "The Council is concerned":  
23 "The Council is concerned with errors in  
24 diagnosis or treatment and with the kind of matters  
25 which give rise to action in the civil courts for

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1 a description, a positive description, of what  
2 a doctor should do and how a doctor should conduct  
3 themselves ... the essential attributes of a good  
4 doctor.  
5 What that resulted in is, finally, the  
6 publication of something called Good Medical Practice.  
7 That is, or the first version of that we can see  
8 at our CGP0000533\_005.  
9 So this is the 1995 publication which was the  
10 first publication of Good Medical Practice.  
11 If we go to the next page, please, Soumik. And  
12 again, if you can zoom in on the top, because it's  
13 impossible to read otherwise.  
14 So we can see there set out on the left-hand  
15 side:  
16 "The duties of a doctor registered with the  
17 General Medical Council  
18 "Patients must be able to trust doctors with  
19 their lives and wellbeing. To justify that trust, we  
20 as a profession have a duty to maintain a good  
21 standard of practice and care and to show respect for  
22 human life. In particular as a doctor you must  
23 "- make the care of your patient your first  
24 concern;  
25 "- treat every patient politely and

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1 negligence, only when the doctor's conduct in the case  
2 involves such a disregard of his professional  
3 responsibility to patients or such a neglect of his  
4 professional duties as to raise a question of serious  
5 professional misconduct. A question of serious  
6 professional misconduct may also arise from  
7 a complaint or information about the conduct of  
8 a doctor which suggests that he has endangered the  
9 welfare of patients by persisting in unsupervised  
10 practice of a branch of medicine in which he does not  
11 have the appropriate knowledge and skill and has not  
12 acquired the experience which is necessary."  
13 So we have some positive advice. And then,  
14 again, the -- "this is what you should not do" there  
15 set out.  
16 And that was, as the foreword made clear, new,  
17 in terms of the booklets, the Blue Books issued by the  
18 General Medical Council.  
19 Now, this guidance was updated over the years  
20 that followed, I'm not going to go to all the  
21 subsequent versions. Some develop things in a little  
22 more detail than others, but it broadly follows  
23 a similar format to the 1985 Blue Book.  
24 It wasn't until the early '90s that the GMC  
25 Standards Committee started to try to create

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1 considerably;  
2 "- respect patients' dignity and privacy;  
3 "- listen to patients and respect their views;  
4 "- give patients information in a way they can  
5 understand;  
6 "- respect the rights of patients to be fully  
7 involved in decisions about their care;  
8 "- keep your professional knowledge and skills  
9 up to date;  
10 "- recognise the limits of your professional  
11 competence;  
12 "- be honest and trustworthy;  
13 "- respect and protect confidential information;  
14 "- make sure that your personal beliefs do not  
15 prejudice your patient's care;  
16 "- act quickly to protect patients from risk if  
17 you have good reason to believe that you or  
18 a colleague might not be fit to practise;  
19 "- avoid abusing your position as a doctor; and  
20 "- work with colleagues in ways that best serve  
21 patients' interests."  
22 And many of those bullet points, sir, will  
23 resonate in terms of their relevance to much of the  
24 evidence that you have heard, both from those who were  
25 patients and from clinicians.

24

(6) Pages 21 - 24

1 We can see on the right-hand side guidance to  
 2 doctors:  
 3 "Being registered with the General Medical  
 4 Council gives you rights and privileges. In return,  
 5 you must meet the standards of competence, care and  
 6 conduct set by the GMC.  
 7 "This booklet sets out the basic principles of  
 8 good practice. It is guidance. It is not a set of  
 9 rules, nor is it exhaustive. The GMC publishes more  
 10 detailed guidance on confidentiality, advertising and  
 11 the ethical problems surrounding HIV and AIDS."  
 12 And we'll look at the latter at a later stage.  
 13 It's right to say that although this was new  
 14 guidance, these were not -- or it may ultimately be  
 15 a matter for your judgment, sir, but, if we think  
 16 about the evidence from the expert group, these are  
 17 not new principles. But they're being articulated  
 18 here by the GMC for the first time in a publication to  
 19 doctors.  
 20 And if we just go to the next page we see then  
 21 some of the bullet points that we saw listed on that  
 22 first page are then explored in greater detail.  
 23 So under the heading "Good clinical care",  
 24 paragraph 2, it talks about the importance of:  
 25 "- an adequate assessment of the patient's

25

1 "Maintaining trust":  
 2 "Professional relationships with patients."  
 3 So, again, patients really start to come to the  
 4 forefront in this guidance, in the way in which they  
 5 weren't in the previous booklets:  
 6 "Successful relationships between doctors and  
 7 patients depend on trust. To establish and maintain  
 8 that trust, you must:  
 9 "- listen to patients and respect their views;  
 10 "- treat patients politely and considerately;  
 11 "- respect patients' privacy and dignity;  
 12 "- give patients the information they ask for or  
 13 need about their condition, its treatment and  
 14 prognosis;  
 15 "- give information to patients in a way they  
 16 can understand;  
 17 "- respect the right of patients to be fully  
 18 involved in decisions about their care;  
 19 "- respect the rights of the patients to refuse  
 20 treatment or take part in teaching or research."  
 21 Then at the top of the next page:  
 22 "- respect the right of patients to a second  
 23 opinion;  
 24 "- ask patients' permission, if possible, before  
 25 sharing information with their spouses, partners or

27

1 condition ...  
 2 "- providing or arranging investigations or  
 3 treatment where necessary;  
 4 "- referring the patient to another  
 5 practitioner ..."  
 6 If we look at the bottom of that paragraph 3:  
 7 "In providing care you must:  
 8 "... keep clear, accurate and contemporaneous  
 9 patient records which report the relevant clinical  
 10 findings, the decisions made, information given to  
 11 patients and any drugs or other treatment prescribed."  
 12 If we go to the right-hand column, third bullet  
 13 point:  
 14 "- prescribe only the treatment, drugs or  
 15 appliances that serve patients' needs."  
 16 Then we see the importance of "Keeping up to  
 17 date", if we can just look at that.  
 18 So:  
 19 "You must maintain the standard of your  
 20 performance by keeping your knowledge and skills up to  
 21 date throughout your working life ... you should take  
 22 regularly in educational activities which relate to  
 23 your branch of medicine."  
 24 And then if we go to the next page, please,  
 25 Soumik, and if we can zoom in, under the heading

26

1 relatives."  
 2 And if we go to the bottom of that page,  
 3 paragraph 15, again the importance of trust:  
 4 "Because the doctor-patient relationship is  
 5 based on trust you have a special responsibility to make  
 6 the relationship with your patients work."  
 7 Then if we go to the next page, you'll see there  
 8 there's a section on confidentiality, paragraph 16:  
 9 "... right to expect that you will not pass on  
 10 any personal information which you learn in the course  
 11 of your professional duties ..."  
 12 Again, I'll explore that in more detail later.  
 13 Then the next section:  
 14 "Abuse of your professional position  
 15 "17. You must not abuse your patient's trust.  
 16 You must not, for example ..."  
 17 And if we look at the third, fourth, and fifth  
 18 bullet points:  
 19 "- improperly disclose or misuse confidential  
 20 information about patients;  
 21 "- recommend or subject patients to  
 22 investigation or treatment which you know is not in  
 23 their best interests;  
 24 "- deliberately withhold appropriate  
 25 investigation, treatment or referral."

28

(7) Pages 25 - 28

1 Then if we go to page 8, please, Soumik. Zoom  
2 in.

3 On the right-hand side you'll see the heading  
4 "Research". Again, I'll be exploring the guidance in  
5 relation to research in more detail, but so as to  
6 avoid the need to come back to this document you'll  
7 see it says, under the heading "Research", 43:

8 "If you are taking part in clinical trials of  
9 drugs or other research involving patients you must  
10 make sure that the research is not contrary to the  
11 patients' interests. Check that the research protocol  
12 has been approved by a properly constituted research  
13 ethics committee.

14 "44. You must keep to all aspects of the  
15 research protocol and may accept only those payments  
16 approved by a research ethics committee. Your conduct  
17 in the research must not be influenced by payment or  
18 gifts.

19 "45. You must always record your research  
20 results truthfully and maintain adequate records."

21 Then paragraph 46:

22 "You should read the guidance on confidentiality  
23 in research ..."

24 So that's good medical practice that -- the  
25 first version of which was produced in 1995, and

29

1 **SIR BRIAN LANGSTAFF:** It may be that the doctor most in  
2 mind of those who drafted this would have been the  
3 general practitioner, who, if he were a sole  
4 practitioner or she were a sole practitioner, might be  
5 expected to go on seeing the same patient over and  
6 over again, which is not necessarily the model today.

7 **MS RICHARDS:** That's quite possibly the case.

8 **SIR BRIAN LANGSTAFF:** And it wouldn't necessarily apply in  
9 the same way to hospitals, where the keeping of  
10 records tends to be a shared responsibility.

11 **MS RICHARDS:** Yes. And it is obviously an important  
12 matter that we will be looking into further. But  
13 there's no further guidance in this material as to --  
14 in relation to records.

15 Mr Massey's witness statement tells us that the  
16 publication of this document was regarded as  
17 a fundamental shift in -- by the GMC in its approach  
18 to meeting its regulatory responsibilities, and we can  
19 see why when we look at it and compare it to the  
20 earlier versions of the booklet.

21 That's some of the general material emanating  
22 from the GMC. The next body, which was a prolific  
23 source of information in the decades with which we are  
24 in particular concerned, was the British Medical  
25 Association, the BMA.

31

1 a form of good medical practice has since then formed  
2 the bedrock of the GMC's guidance to doctors. It's  
3 been -- it's changed over the years, it's been  
4 expanded, but it remains at the heart of the advice  
5 that the GMC now promulgates to doctors.

6 **SIR BRIAN LANGSTAFF:** Just one question which arises out  
7 of it. The word -- and it may just be reading too  
8 much into one word, but the obligation is to keep  
9 medical records. The word used is "keep", not "make".  
10 The guidance envisages the handing over of records if  
11 the doctor and patient lose trust in each other and  
12 the patient moves on to another doctor. And the words  
13 used here in "Research" is "maintain adequate  
14 records".

15 Is there any guidance at all as to for how long  
16 and in what circumstances they are to be "kept"?

17 **MS RICHARDS:** Not in the materials we are looking at  
18 today. There are other materials relating to  
19 practices in terms of medical records, guidance that's  
20 been issued over the years, different practices in  
21 different local areas, impact of data protection  
22 legislation and so on. We'll be exploring those,  
23 I think probably at a rather later stage of the  
24 Inquiry's hearings, when we look at issues about  
25 candour, transparency, cover-up.

30

1 The BMA is not a regulatory body, so doesn't  
2 have the same function as the General Medical Council.  
3 It's a professional association and trade union for  
4 doctors. Like the GMC it was founded in the  
5 19th Century, in 1832. The BMA has had an Ethics  
6 Committee in some form or another since the middle of  
7 the 19th Century, first established I think in 1849,  
8 and it's produced, over the years, guidance, notes,  
9 and had a role in providing advice to individual  
10 doctors. But it's also a source of important  
11 publications over the years.

12 If we go to -- just a moment while I get the  
13 reference -- the GMC's publication -- sorry, the BMA's  
14 publication from 1949 on ethics. It is RCPH0000226.  
15 So we'll see it's entitled "Ethics and members of the  
16 medical profession". We can see from the bottom of  
17 the page it's published by the BMA in 1949.

18 If we go to the third page, we can see the  
19 preface:

20 "A high standard of ethics is expected from  
21 members of the medical profession. This standard has  
22 on occasion proved difficult to maintain in recent  
23 years on account of the upheaval caused by the war.

24 "This booklet has been prepared by the British  
25 Medical Association primarily for the information of

32

(8) Pages 29 - 32



practitioners who have qualified during the last ten years, and an attempt has been made in the following pages to set out, in a form easy for reference, the salient points of medical ethics.

"It is hoped that practitioners will find guidance on the numerous problems relating to professional conduct with which they are likely to be confronted."

Then, if we go over the page, we can see there's some very general observations under the heading "Ethics and members of the medical profession":

"The medical profession occupies a position of privilege in society because of the understanding that a doctor's calling is to serve humanity under all conditions and because in the past members of the profession have built up a tradition of placing the needs of the patient before all else.

"On admission to the brotherhood of medicine, every new member not only succeeds to the benefit of its special place in society, but also takes upon himself the duty of maintaining this high position. The justification for the freedom of medicine lies in the hands of those who practise it."

Then reference is made to the Hippocratic oath.

Then if we go to the bottom of the page, it says:

33

Then it says:

"When in doubt a practitioner will be wise to seek advice from one of the professional organisations or from a colleague of experience".

It sounds as though what is going to follow is then a detailed articulation of what doctors should do. In fact, it is perhaps more notable for what isn't in the guidance.

So if we go to the next page, I'll just pick it up on the headings that are in bold print. So the first section is about "Setting up in Practice", and how it's regarded as unethical to set up in practice in an area where you've already been in partnership and it's broken down. So it's about respecting the right of your fellow doctors to practise in a particular geographical area.

Next bold topic is "Premises and Doorplate". If we go to the next page, "Relationship with Other Practitioners". If we go over the page "Relationship with Dentists". If we go to the next page, "Association with Clergy". Following page "Association with Chemists and opticians", "Commercial Enterprises and Patenting"; and bottom of the page "Insurance Agents". Next page, "Lectures, Broadcasting and Television", "Publications", if we go

35

"To-day these general rules still hold good as part of a code of standards of professional behaviour which must be observed if the honour and dignity of the profession are to endure. To command the respect of his patients and the public should be the aim of every doctor. The strict observance of basic ethical principles will enable the doctor to attain this end, which is necessary to good practice and to successful treatment."

There's then a section on the General Medical Council. If we go on to page 9, we see the heading "Code of professional conduct", and the guidance says this:

"In addition to the requirements of the General Medical Council, and in elaboration of them, there are customs and ethical rules which are observed by the profession as a code of conduct. The endless number of situations that might, and do, arise in the course of professional life cannot all be covered specifically in any set of rules. The following rulings are accepted as covering the major and more common features of professional life and will serve to illustrate the principles of behaviour. These principles can be, and should be, applied to other problems and situations that may arise."

34

towards the bottom of that page, "Change of Address or Conditions of Practice".

Over the page, "Telephone Directories". Then we get to something which is patient focused, only at the bottom of this page, "Professional Secrecy", so that here introduces confidentiality into this document. So:

"A practitioner should not disclose voluntarily, without the consent of the patient, preferably written, information which he has obtained in the course of his professional relationship with the patient."

Then the rest of that page is concerned with the circumstances in which confidential information might be disclosed.

Then over the page, "Termination of Pregnancy", "Nursing Homes" and "Dichotomy" are the headings there.

So, in terms of the issues with which we're concerned and the kind of ethical principles which our expert group articulated to us, this document doesn't really address any of those matters, with the exception of the section on confidentiality. So perhaps more significant for what it doesn't cover than for what it does.

36

We really need to go to 1970, so to move on from 1949 to 1970, to see the first substantive publication on the kind of areas that we might have expected to see covered in the BMA's Medical Ethics document, which we'll find at BMAL0000085. You'll see, sir, again this published by the British Medical Association, it is entitled "Medical ethics", and we see the date in the bottom right-hand corner, 1970.

If we go over the third page, please, Soumik, "Medical Ethics", and you'll note, sir, or at least I noted on reading this, the masculine pronoun throughout to denote a doctor but, in any event, "The Brotherhood of Medicine":

"The entrant to the profession of medicine joins a fraternity dedicated to the service of humanity. He will be expected to subordinate his personal interests to the welfare of his patients, and, together with his brother practitioners, to seek to raise the standard of health in the community among which he practises. He inherits traditions of professional behaviour on which he must base his own conduct, and which he must pass on untarnished to his successors."

Then we see reference to the Hippocratic Oath, and we see this:

"When the methods and details of medical

37

consecrate my life to the service of humanity ..."

That's the first promise. The third is:

"I will practise my profession with conscience and dignity ..."

Then this:

"The health of my patient will be my first consideration ..."

Then:

"I will respect the secrets which are confided to me ..."

So that's the Declaration of Geneva. Then, bottom of the page, we see the English text of the International Code of Medical Ethics:

"Duties of Doctors in General.

A doctor must always maintain the highest standards of professional conduct."

Then if we go to the next page, I'll just pick up on the right-hand column:

"A doctor owes to his patient complete loyalty and all the resources of his science."

Then:

"A doctor shall preserve absolute secrecy on all he knows about his patient because of the confidence entrusted in him."

Then if we go back to the page we can see the

39

practice change with the passage of time and the advance of knowledge, the fundamental principles of professional behaviour have remained unaltered through the recorded history of medicine. From time to time attempts have been made to codify the standard of conduct expected of the doctor in the practice of his profession, the most celebrated being that attributed to Hippocrates in the 5th Century BC."

Then you'll see there set out an English translation of the Hippocratic Oath. Then if we go over the page, we can then see, and we'll look at some of these materials in more detail in a little while, but we'll see there concepts of ethical principles are here articulated in contrast to the 1949 document. And we see reference to an International Code of Medical Ethics and to the Declaration of Geneva. I'm going to come back to that.

We looked at some of this material with the expert group in their evidence earlier this year. But we can see there the Declaration of Geneva intended to constitute some form of international code of medical ethics. In fact whilst we're here we might as well look at it. We can see the text there:

"At the time of being admitted as a Member of the Medical Profession I solemnly pledge myself to

38

heading "Human Experimentation", reference there to the Declaration of Helsinki. I'll come back to that when I look at documentation in relation to research but what we can see is here the BMA, in its publication to doctors in 1970, is telling doctors about these international instruments.

Then, if we go to page 11, you'll see there's a section on "Professional Confidence". I'll come back to that when I look at issues of confidentiality but there's a more detailed set of advice to doctors on professional confidence in this document.

But what we then have, if we go over the page -- sorry, if we go to page 13. My apologies, Soumik. We then start to see some of the more familiar items that we saw in some of the earlier guidance. So it then goes back to issues such as setting up in practice, advertising, interrelationship with other doctors, and so on.

So the 1970 document starts to identify these ethical principles but still doesn't flesh them out to the extent that we'll see in later materials.

This publication, beginning in 1970, was updated on a fairly -- well, not on an annual basis, I think it was next updated in 1974 and then 1980, 1981 and 1982. By 1980 it's become something called the

40

1 Handbook of Medical Ethics and we may look at that at  
2 a later stage.

3 Also, in the 1970s, or in 1972, the BMA  
4 published a document call Professional Standards, "A  
5 Statement prepared ... by the Board of Science and  
6 Education of the British Medical Association", and  
7 that is at ... if you just give me a moment.  
8 BMAL0000082. You'll see it's just entitled  
9 "Professional Standards".

10 If we go to the second page, we'll see the date  
11 March 1972. Then if we go to page 4, we can see:

12 "Statement of panel on professional standards  
13 "Introduction  
14 "In April 1970 the Board of Science and  
15 Education invited a panel of younger doctors to  
16 identify areas of anxiety and conscience in medical  
17 practice. Trends in certain spheres of medical  
18 practice appeared to challenge the generally accepted  
19 principles that the function of the doctor is to  
20 maintain respect for human life and the health and  
21 welfare of his patients. The Board considered it was  
22 an appropriate time for professional standards to be  
23 reviewed in the light of current knowledge and thought  
24 ..."

25 Then we can see, if we look a little further

41

1 confidentiality, for example.

2 But we can see again, it's an attempt to  
3 identify and draw to doctors' attention some of the  
4 fundamental overarching principles of medical ethics  
5 and putting the health and welfare of patients as the  
6 priority.

7 What we then get to through the various  
8 different versions of the BMA guidance, some of which  
9 I'm going to come on to when we look at issues of  
10 consent. We then get to 1988 and its publication  
11 "Philosophy and Practice of Medical Ethics", and  
12 that's at BMAL0000080, and if we go to page 5, in the  
13 preface, we'll see this:

14 "Originally, the words 'Ethics' and 'Morals'  
15 were Greek and Latin expressions with the same idea --  
16 the code of conduct acceptable and normal within  
17 a particular society. In the modern world they have  
18 come to mean very different things, and it is  
19 necessary to stress that these is a handbook of  
20 Ethics, not of Morals. The authors believe medical  
21 ethics to represent the accepted code of behaviour  
22 within a particular group -- for our purposes the  
23 medical profession ..."

24 Then if we go to the fourth paragraph, it says:

25 "The approach to the subject is completely

43

1 down the page, we can see reference in paragraph 2 to  
2 some of the codes, so the Hippocratic Oath, the  
3 Nuremberg Code -- I'll come on to that when we come to  
4 look at research -- the Declaration of Geneva, that  
5 we've looked at in passing already, and the  
6 International Code of Medical Ethics and the  
7 Declarations of Helsinki, and so on.

8 Then if we go to the next page, we'll see in  
9 paragraph 4 at the top of the page:

10 "The understanding of and adherence to the  
11 principles of medical ethics are of the utmost  
12 importance to the profession."

13 Then if we look at the next paragraph we can see  
14 a heading "Teaching of Ethics":

15 "The teaching of medical ethics should be  
16 undertaken in the light of current knowledge and  
17 foreseeable advances. Ethics of medicine should form  
18 part of the medical curriculum."

19 At some point, sir, we'll seek to establish the  
20 point in time at which the teaching of medical ethics  
21 did become part of the medical curriculum but you'll  
22 see that here being advised by the BMA.

23 There aren't, I think, any other particular  
24 passages I'm proposing to refer you to in relation to  
25 this, but we can see that there is a section on

42

1 different from that in all previous editions. We have  
2 sought to set out the arguments and counterarguments  
3 which lead either to universally accepted ethical  
4 principles of practice or consensus views. There are  
5 some situations in which there is no professional or  
6 public consensus and which by their nature do not  
7 permit a consensus view.

8 "This edition of the Handbook of Medical Ethics  
9 represents our first major redraft since the 1980  
10 edition was published."

11 You'll see that this book published in 1980, or  
12 this guide published in 1980, was intended to take  
13 a different course from the materials that the BMA had  
14 produced previously and to set out for the first time  
15 in more detail underlying principles, arguments and  
16 counterarguments.

17 We can see that again, I'm not going to go  
18 through it in great detail, but if we go to page 9, we  
19 can see under the heading "Background", there's  
20 a chapter on the philosophical and religious  
21 influences on the development of medical ethics and in  
22 the first paragraph:

23 "Doctors use technical skills and expertise  
24 which the untrained person does not possess.  
25 Possessing these skills gives him great power over his

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(11) Pages 41 - 44

patients who by the very fact of being patients are dependent, ill and vulnerable. In caring for his patients, a doctor makes a series of judgments and decisions which patients have the right to expect are made fairly in the light of the doctor's knowledge and experience. Most people will agree with these statements."

If we look at the next paragraph:

"The argument is about what influences the individual doctor in making judgments and decisions. Professor Ian Kennedy has asserted that the judgements are based not on the doctor's technical skill and training but rather that 'Doctors make decisions as to what ought to be done'."

Then it goes on to again quote from Professor Kennedy about ethics and his own view that:

"... medical ethics are not separate from but part of the general, moral and ethical order by which we live."

That's a quotation from Professor Kennedy's Reith Lectures, which were referred to in our expert group's report.

So we have this chapter on "Philosophical and religious influences on the development of medical ethics", and if we go to page 13 of this document, so

45

"'Truth telling' is another principle by which people address medical ethics ... the doctor and the patient are bound by an unspoken, unwritten agreement which is based on the patient's ability to trust his doctor. Truthfulness is therefore seen as important because it is a moral imperative in itself and on utilitarian grounds produces a good social relationship."

Then if we go to page 15, we can see there's a chapter on discussing further concepts of autonomy and paternalism. I'm not going to go through the detail of it, but it is perhaps important to read in full.

If we move on to within this chapter to page 19, we can see towards the bottom of the page, the heading "The Importance of Communication":

"Good communication between doctor and patient is the foundation of a good relationship which will ensure optimal use of the doctor's professional knowledge and skills and also the patient's understanding and co-operation."

It talks about how vital it is to explain information to patients.

And then, if we move to page 26, and I'll come back to this when I look at confidentiality in more

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still within the chapter, halfway down the page, we can see this:

"It is universally agreed that a doctor should at least do no harm. This concept is enshrined in the Hippocratic Oath ..."

Then we see in the last sentence of that paragraph the issue of paternalism being raised:

"... the assumption that the doctor knows better than anyone, including the patient, what is best for that patient.

"Paternalism is in direct conflict with the principle of autonomy."

So, again, we see the underlying principles, and issues such as paternalism and issues such as autonomy here being articulated in some detail by the BMA in contrast to a number of the earlier publications.

"Broadly speaking autonomy means the individuals should have personal liberty to decide their own actions or their own destiny. Although the concept of autonomy is not new it is now becoming a central influence on the expectations of patients. In the past, many patients would accept without question decisions made by their doctor. Today, patients are more critical."

Then at the bottom of that page:

46

detail, but we'll see there's a whole chapter in this guidance on confidentiality.

And then, if we go to page 35, we'll see there "Consent to Treatment", so there's a whole chapter on consent to treatment:

"The basis of any discussion about consent is that a patient gives consent before any investigation and treatment proposed by the doctor. Doctors offer advice but the patient decides whether to accept it.

"Before a patient can consent, the options have to be presented in such a fashion as to allow a decision to be made. Consent must involve the ability to choose. One of the patient's options is not to be troubled with having to make a [choice]. Doctors sometimes argue that patients do not want to be told all the facts. In an increasingly articulate society doctors are moving away from this paternalistic approach and any doctor who decides to withhold information should examine stringently the reasons for doing so. Society is moving away from paternalism towards partnership ..."

And then, picking it up last few lines of that paragraph:

"Even though a few patients 'don't want to be told', there is now little justification for

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1 withholding information - unless 'to tell all' would  
2 be clearly detrimental to the individual. It is  
3 therefore only when the patient specifically delegates  
4 responsibility for the decision to the doctor that  
5 it's ethically right for the doctor not to disclose  
6 all of the relevant facts."

7 Again, I'll come back to this part of the  
8 guidance in a little while.

9 **SIR BRIAN LANGSTAFF:** Quite interesting that it talks  
10 about society moving away from paternalism towards  
11 partnership. And what's interesting about it is that,  
12 in the earlier 1970 edition which you showed us, one  
13 of the first principles was mutual respect, which --  
14 it's difficult to have mutual respect if one person is  
15 telling the other what to do.

16 **MS RICHARDS:** Yes, indeed.

17 **SIR BRIAN LANGSTAFF:** Mutual respect isn't spelled out in  
18 terms, but in one sense it could be regarded as  
19 a summary of everything that is said here.

20 **MS RICHARDS:** Yes, absolutely. And, indeed, that's why we  
21 were looking at the GMC's guidance produced in 1995.  
22 I made the observation that the guidance might be the  
23 new, the guidance might change, but that doesn't mean  
24 the principles which underpin it are new.

25 And, sir, you're absolutely right. What we see

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1 duties and powers which require them to do or not to  
2 do certain things in certain circumstances."

3 Then there's reference to codes, to legislation,  
4 and then:

5 "Rights and Responsibilities provides  
6 a practical guide to the law as it affects doctors.  
7 It aims to cover the main areas that are of interest  
8 and concern to most doctors. Designed as a handbook  
9 ..."

10 Etc, etc.

11 So this was designed essentially as a handbook  
12 to be used by doctors. And I'm not going to go to the  
13 detailed content of it, and this is the 1992 version,  
14 I think, in any event, but if we go to page 4, we can  
15 just see from the table of contents that the very  
16 first chapter is about consent.

17 And then if we go to the following page we'll  
18 see that chapter 3 is about confidentiality. And  
19 indeed, chapter 4, medical records. I don't think  
20 we've got that -- necessarily have that chapter in  
21 what I have here, but I can certainly look and see if  
22 there is any answer there, sir, to the questions which  
23 you identified.

24 And there's also a chapter on research, if we go  
25 to page ... there is a chapter on research here.

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1 increasingly in the guidance as it changes over the  
2 years is a much more detailed exposition, and here we  
3 see an actual discussion of some of the underlying  
4 philosophical and other arguments.

5 But whether there's actually been a change in  
6 the core underlying ideas and principles, well, will  
7 be a matter for you to determine, sir.

8 **SIR BRIAN LANGSTAFF:** Well, I think the view of our  
9 ethical experts will be that there hasn't been, and  
10 certainly, if I'm right in the observations I've just  
11 made about mutual respect, what has changed is not the  
12 principle but the articulation of it, or the degree of  
13 articulation of it.

14 **MS RICHARDS:** Yes.

15 The same year as the publication we've just been  
16 looking at, and as I say, I may come back to it  
17 a little bit more in this particular chapter, but in  
18 that same year, 1988, the BMA also published  
19 a document called Rights and Responsibilities of  
20 Doctors, and if we go to RLIT0000397, we can see that  
21 there set out.

22 And if we look, on the left-hand side, what is  
23 actually the back page of the book there, pick it up  
24 in -- well, actually, we pick it up at the top:

25 "Doctors have rights and responsibilities and

50

1 I can't find the reference at the moment.

2 But in any event, those are the two twin  
3 publications that emanate from the BMA in 1988.

4 Just before I then turn to a handful of the  
5 other organisations that have produced materials of  
6 relevance, I should perhaps have gone to the 1980 BMA  
7 handbook.

8 BMAL0000087.

9 I showed you, sir, previously the 1970 guidance  
10 medical ethics, and then we saw a few minutes ago the  
11 1988 publication Philosophy and Practice of Medical  
12 Ethics. As I say, various situations over the years.  
13 But the 1981 was perhaps -- contained some more  
14 substantive articulation of principles than the 1970  
15 or 1974 versions. So I'll just draw attention to some  
16 of the contents of the 1980 guidance.

17 So if we go to page 4, first of all. We'll see  
18 there the date at the top of the page, this the 1980  
19 publication. If we go to the next page, we can see  
20 there set out under the heading "Foreword":

21 "In this Handbook we set out the broad framework  
22 of ethics within which the medical profession works."

23 If we go to page 7, we can see, just picking it  
24 up in the first paragraph:

25 "Because of the special knowledge and the

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(13) Pages 49 - 52

vulnerability of their patients, members of the medical profession have traditionally been regarded as particularly trustworthy and responsible by the public. From the profession, therefore, society expects high standards, not only of scientific education and clinical skill, but also of professional and humane conduct."

And then if we go to page 9, you'll see under the heading "Therapeutic Doctor-Patient Relationships", so paragraph 1.2, it talks about how the first form of contact may be a person consulting a doctor as a patient.

Then this:

"The doctor then acts in the interests of the patient and is responsible to the patient for his actions."

So, again, an articulation there of some fairly basic principles.

There is then, over the page, and I'll come back to this after the break when I look at consent in more detail, but you'll see there's a section on consent.

If we go then to page 15, there's then a more general section on trust. And if we pick it up in paragraph 2.6:

"The relationship between patient and doctor is

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"He shall respect human life and studiously avoid doing it injury."

Paragraph (5):

"He shall respect the confidence of his patient as he would his own."

Then we can see, if we go back to that page, the Canadian Medical Association code of conduct, there's a code of ethics there:

"(1) Consider first the well-being of the patient.

"(2) Honour your profession and its traditions."

Then if we go to the next page, and this is all part still of the Canadian Code, bottom of the page, "Responsibilities to the Patient", we see there the concept of the "Ethical Physician", and at the bottom of that page the concept of "Patient's Rights". In particular point (5), so this is what the ethical physician will do:

"[He] will recognise that the patient has the right to accept or reject any physician and any medical care recommended to him."

And then if we go over the page, again, still in this section of what the ethical physician under the Canadian Code will do, paragraph 8, for example:

"will recommend only those diagnostic procedures

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based on trust."

Then there's a section on research. Again, I'll come back to that.

If we go to page 66 -- in fact I'll pick it up -- sorry, Soumik -- page 53.

So there's a section of this 1980 book which then looks at a range of different ethical codes, from the Hippocratic Oath, if we go over the page, to material produced by the World Medical Association. Again, I'll come back to some of these as necessary.

If go over two pages, to page 56, we see a reference to motions on discrimination in medicine. Then we see reference at the bottom of the page to the Declaration of Helsinki. And that's set out -- the text is set out in the Declaration of Helsinki. There are a number of other international documents, conventions, guidelines, set out.

Then if we go then to page 66, you'll see that the BMA also then set out and drew to the attention of doctors various national codes. So we've got the code of -- the Ethical Code of the Commonwealth Medical Association:

"... doctor's primary loyalty is to his patient."

Is paragraph (1) of that. At paragraph (3):

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which he believes necessary to assist him in the care of the patient, and therapy which he believes necessary for the well-being of the patient."

Then you'll see if you go to the next page, there's a section on clinical research, and then if we go to page 72, you'll see there a heading "Ethical decisions of annual representative meetings". These are forms of decision making by the BMA's representative body. You'll see on the next page, one of those decisions taken by the BMA was about confidentiality of medical records.

Again, I'm not going to go through the detail of that, but what you'll see from the structure of this, is that, as well as the specific sections of the Handbook of Medical Ethics, we'll look at issues such as consent and confidentiality, the doctor's decision is -- sorry, the doctor's attention is here being drawn to these various multiple international and national codes and ethical standards.

Sir, I note the time. It might be a sensible point at which to take a break because I'm going to move on from the BMA to just look at a handful of other organisations before I then look at the specific guidance on consent.

**SIR BRIAN LANGSTAFF:** Well, let's then have a break until

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1 quarter to 12. Quarter to 12.  
 2 (11.16 am)  
 3 (A short break)  
 4 (11.45 am)  
 5 **MS RICHARDS:** Sir, I spent some time looking at some of  
 6 the general materials and the nature and structure of  
 7 materials produced by the General Medical Council and  
 8 the British Medical Association because within the  
 9 period with which the Inquiry is most closely  
 10 concerned, they were the main sources of guidance to  
 11 doctors.  
 12 I'm just going to now briefly refer to some of  
 13 the other sources without going into the detail of  
 14 what they produced, before I turn to some of the key  
 15 themes.  
 16 So, in addition to the British Medical  
 17 Association we have some materials from the World  
 18 Medical Association, that was established in part on  
 19 the initiative of the BMA in 1947, and it's produced  
 20 on an international plane, Ethical Guidance to  
 21 Clinicians.  
 22 We then have, as a group of organisations,  
 23 a range of Royal Colleges who have produced material.  
 24 We referred to some, not every single one of them, in  
 25 our written note, but sources of relevant guidance

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1 Now, they're not regulators, they're bodies that  
 2 exist to advise and assist doctors in particular  
 3 facing complaints or facing litigation.  
 4 You may recall, sir, the evidence of the Medical  
 5 Ethics Group, that one of the purposes of these  
 6 medical defence organisations or societies is to help  
 7 and protect and prevent doctors from being sued. So  
 8 there the materials they produce are very much focused  
 9 upon their being clinician centred rather than patient  
 10 focused, but nevertheless there is some important  
 11 material, not least on consent, that emanates in  
 12 particular from the Medical Defence Union.  
 13 Then there is some of the material relating to  
 14 principles of research emanating from the Medical  
 15 Research Council. There's some material for the  
 16 practice of the profession of dentists, emanating from  
 17 the General Dental Council, so the dental equivalent  
 18 of the General Medical Council, or from the British  
 19 Dental Association, which is the dental equivalent of  
 20 the British Medical Association.  
 21 Then a handful of other groups or committees who  
 22 have produced relevant material over the years which  
 23 are referred to in our written note and in the  
 24 chronology the Inquiry has produced.  
 25 Then, finally, when we come to look at what will

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1 include the Royal College of Physicians, the Royal  
 2 College of Surgeons the Royal College of General  
 3 Practitioners, and so on. We will look at some of the  
 4 relevant bits and pieces as I go through some of the  
 5 substantive guidance.

6 We then have some guidance emanating from those  
 7 concerned with the world of nursing. So the Royal  
 8 College of Nursing, which essentially performs  
 9 a similar function to the BMA but for nurses. So it's  
 10 a membership organisation and trade union, and it's  
 11 produced guidance to nurses, much of which is also  
 12 relevant to the issues which the Inquiry is exploring.

13 Then we have the Nursing and Midwifery Council,  
 14 previously called the United Kingdom Central Council  
 15 for Nursing, Midwifery and Health, that's the nursing  
 16 equivalent of the General Medical Council and, again,  
 17 it's produced some relevant guidance that we'll look  
 18 at.

19 The next category of organisations that have  
 20 produced relevant materials are the medical defence  
 21 organisations. So there are several such  
 22 organisations in the United Kingdom, the principal  
 23 ones, for our purposes for the Medical Defence Union,  
 24 the Medical Protection Society and the Medical and  
 25 Dental Defence Union of Scotland.

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1 be the last topic I explore today, this afternoon,  
 2 which is some of the guidance about relationships  
 3 between clinicians and pharmaceutical companies,  
 4 there's material produced by the Association of the  
 5 British Pharmaceutical Industry.

6 So those are the sources, or the principal  
 7 sources, of the material we've been looking at.

8 Having identified those organisations, what  
 9 I now want to do is to look in a little more detail at  
 10 the guidance that has been produced over the earlier  
 11 decades with which the Inquiry is concerned, on the  
 12 issue of consent and consent to treatment and informed  
 13 consent.

14 We can pick that up in 1953, with some material  
 15 produced by the Medical Defence Union. So one of  
 16 these medical defence societies acting for doctors.  
 17 Soumik, if we could have, please, MOJU0000001\_013.

18 This was a letter written by the secretary of  
 19 the Medical Defence Union in April 1953, to Dr Snell  
 20 of the Prison Commission, and the particular issue  
 21 with which it was concerned was consent to the  
 22 performance of medical procedures on prisoners and, in  
 23 particular, whether the governor of a prisoner or of  
 24 a borstal institution, as Young Offender Institutions  
 25 were then known, could give consent on behalf of

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1 a prisoner. So not the situation with which we're  
 2 concerned, but that's the context for the material  
 3 that we see.  
 4 This letter then addressed to the Prison  
 5 Commission, identifies that issue in the first  
 6 paragraph. It says:  
 7 "... I would not readily concede that your view  
 8 is correct that consent given by a Governor of a  
 9 Prison or Borstal Institution is of no legal value  
 10 with regard to the performance of an operation or the  
 11 administration of an anaesthetic."  
 12 Then reference to what the duties of a governor  
 13 of a prison might be in terms of responsibility for  
 14 the wellbeing and care of prisoners.  
 15 If we just go over the page and see that the MDU  
 16 secretary says -- and it's the last -- it's the first  
 17 paragraph, last sentence:  
 18 "I am enclosing herewith for your perusal and  
 19 retention a document on the giving of consent which  
 20 I hope you will find interesting and useful."  
 21 The purpose of referring to that is it helps  
 22 give some date to the document I'm going to refer to.  
 23 So that's at MOJU0000001\_014. Actually, no sorry,  
 24 Soumik, before we go to that can we just go to  
 25 MOJU0000001\_008.

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1 Prison Commissioner -- the Prison Commission. Sir,  
 2 you'll see it's headed "The Medical Defence Union  
 3 Limited, Consent for examination and treatment". It  
 4 says this:  
 5 "It is not sufficiently widely known by  
 6 practitioners that, in law, consent must be given by  
 7 a patient before an examination can be conducted or  
 8 treatment administered. Fortunately doctors are not  
 9 often challenged in the Law Courts on the issue of  
 10 'absence of consent' since in the majority of cases  
 11 consent can be implied from the nature of the  
 12 relationship of doctor and patient. But the rarity of  
 13 such an event may lull practitioners into a false  
 14 sense of security. The following statement is  
 15 intended to review and clarify the legal position of  
 16 the practitioner who proposes a professional  
 17 examination or advocates any treatment."  
 18 Then the next paragraph is headed "General  
 19 considerations":  
 20 "Strictly speaking it is illegal for any  
 21 practitioner to do anything to any patient without  
 22 consent. If he acts without consent he may be held to  
 23 have committed assault (for which he may be prosecuted  
 24 in a Criminal Court), or to have been guilty of  
 25 trespass (for which he may be sued in a Civil Court).

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1 Again, emanating from the MDU in the context we  
 2 think of the correspondence with the Prison Commission  
 3 was this document, which goes into more detail about  
 4 issues relating in particular to questions of consent  
 5 as they pertain to prisoners.  
 6 But I just wanted to refer to the first few  
 7 lines:  
 8 "The general law concerning surgical operations  
 9 performed without the consent of the patient is but  
 10 briefly dealt with in the books and there seems to be  
 11 little authority."  
 12 Then there's reference to Halsbury's laws:  
 13 "To perform a surgical operation on a person  
 14 against his will or against the will of the person  
 15 entitled to consent on his behalf is an assault."  
 16 Then this document goes into detail about  
 17 particular legal issues that might arise in the  
 18 context of the care of prisoners and the giving of  
 19 consent. So this is one of the documents that seems  
 20 to emanate from this exchanges of correspondence in  
 21 1953.  
 22 Then the second and more directly relevant  
 23 document is MOJU0000001\_014.  
 24 It may be that this was the booklet being  
 25 referred to in the MDU secretary's letter to the

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1 The person immediately affected may bring an action  
 2 against the doctor; in some cases a parent, [a] spouse  
 3 or an employer may also have a right of action.  
 4 "It is therefore necessary to consider what is  
 5 the meaning and scope of consent; how it should be  
 6 sought and by whom it may be given."  
 7 Now, pausing there, the focus of this is not on  
 8 ethical principles but on legal rights and  
 9 obligations. But nonetheless it is the earliest  
 10 document we found issued to or potentially issued to  
 11 or available to doctors looking specifically at this  
 12 issue.  
 13 Then we see the heading "The Significance of  
 14 Consent":  
 15 "Consent means that the individual patient  
 16 concerned either by himself or with or through another  
 17 has indicated by implication or specifically  
 18 (preferably in writing) that he is willing to submit  
 19 himself for examination and for treatment."  
 20 Then there's discussion of how consent can be  
 21 oral or as preferably written.  
 22 "The question of consent [so this is the next  
 23 paragraph] is not often raised since the parties  
 24 concerned could be shown by their conduct to have  
 25 mutually understood the position, to have implied

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(16) Pages 61 - 64



1 consent on the one hand and the acceptance of  
 2 professional responsibility on the other, and to have  
 3 dealt with one another accordingly."  
 4 And then if we go to the bottom of this page,  
 5 and this is really where we get the concept of  
 6 informed consent in this document:  
 7 "The request for consent" is the heading:  
 8 "To obtain consent it is necessary for the  
 9 practitioner to explain carefully to the patient in  
 10 non-technical language the need for an examination to  
 11 arrive at a diagnosis or decide on the line of  
 12 treatment. The character and the likely results of  
 13 the treatment should be outlined to the patient in  
 14 such terms that he can appreciate fully what is  
 15 proposed and what may ensue. A practitioner, aware of  
 16 the uncertainties of treatment, should avoid sweeping  
 17 promises; and should not minimise the risks that may  
 18 be inherent in the procedure he proposes."  
 19 And then, the paragraph continues:  
 20 "If the patient is one with whom it would be  
 21 undesirable for psychological or other reasons to  
 22 discuss these matters, a different procedure may  
 23 justifiably be adopted in which the information is  
 24 placed before some near relative who by himself (or  
 25 preferably in conjunction with the patient) gives

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1 Treatment" it says this:  
 2 "A person suffering from disease or injury is  
 3 not normally bound to submit himself to medical  
 4 treatment or even to consult a doctor if he does not  
 5 wish to do so. It follows, therefore, that an  
 6 operation carried out without the consent of the  
 7 person concerned, subject to certain exceptions to  
 8 which reference will be made in due course, amounts to  
 9 an actionable assault. Such an assault may lead to an  
 10 action for damages under the civil law and it follows,  
 11 therefore, that if a surgeon performs an unauthorised  
 12 operation he or his employing authority, or both, may  
 13 be confronted with an action for assault for which  
 14 damages may be recoverable."  
 15 So, again, the focus is protecting the doctor  
 16 from litigation. But there, again, the importance of  
 17 consent being emphasised.  
 18 And then we see the heading "Consent May be  
 19 Expressed or Implied", and that's discussed in the  
 20 first paragraph, and it's said all these forms of  
 21 consent may be equally efficacious.  
 22 But if we pick it up in the second paragraph  
 23 under that heading:  
 24 "To be an effective answer to a claim for  
 25 assault the consent must be fully and freely given.

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1 consent to the treatment.  
 2 "The consent obtained must be genuine consent;  
 3 not merely an apathetic acquiescence but a real  
 4 expressed willingness by the patient to undergo the  
 5 treatment after he has had its nature, its risks, and  
 6 its objectives clearly explained."  
 7 Then the document goes on to deal with certain  
 8 specific cases, including the unconscious patient or  
 9 the patient who lacks capacity, or children, with  
 10 which I don't think I need to take up your time, sir.  
 11 But we can see here, in 1953, the Medical  
 12 Defence Union, so the body involved in trying to, as  
 13 it were, represent the interests of doctors, here  
 14 articulating the need for the risks involved in  
 15 treatment to be spelt out to the patient.  
 16 There's a further document produced by the MDU  
 17 in 1962.  
 18 It's at DHSC0100081, please, Soumik.  
 19 You'll see from the title "Consent to operative  
 20 treatment" that it's concerned essentially with  
 21 surgery.  
 22 But nonetheless, the underlying principles are  
 23 of some importance.  
 24 Sir, if we go to the third page, and if we could  
 25 zoom in on the right-hand side, "Consent to Operative

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1 The patient should be given a fair and reasonable  
 2 explanation, in non-technical language, of the effect  
 3 and nature of the operation. This should be given  
 4 only by a person who is competent and qualified to  
 5 give it, preferably by a medical practitioner. If an  
 6 inadequate or misleading explanation is given there is  
 7 the danger that the apparent consent obtained will be  
 8 held to be ineffective. If the operation contemplated  
 9 carries special risks, which are probably unknown to  
 10 the patient, he should, as a general rule, be informed  
 11 of these risks."  
 12 And then, and this perhaps may reflect the  
 13 paternalism of the era, it continues:  
 14 "The surgeon may, of course, on occasion be  
 15 justified in not revealing or in minimising the risk  
 16 involved if he thinks it necessary to do so in the  
 17 interests of the patient."  
 18 And there's reference to what has now been  
 19 regarded as the somewhat surprising decision of the  
 20 courts in --  
 21 **SIR BRIAN LANGSTAFF:** It's interesting that, in one  
 22 respect, the 1953 advice is wider than this, because  
 23 it talks about "and what may follow", being advised of  
 24 not only what's inherent in the procedure and its  
 25 risks, but what may follow, what the consequences are.

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(17) Pages 65 - 68

1 It is not mentioned here.  
 2 **MS RICHARDS:** No, that's right. That may be explicable by  
 3 reason of that this is very much focused on the  
 4 question of surgery, so it's the application of the  
 5 broader principles to the particular context of  
 6 surgery where the focus may be on the risks inherent  
 7 in the surgical operation.

8 **SIR BRIAN LANGSTAFF:** Yes.

9 **MS RICHARDS:** If we just go over the page, again, in the  
 10 first paragraph on the left-hand side, again, it's in  
 11 the context of surgery, but a statement of broader  
 12 application.

13 "A surgeon should not contravene the express  
 14 instructions of a patient and if he goes outside the  
 15 scope of the authority which has been conferred upon  
 16 him he may be liable to the patient for an assault.  
 17 The fact that he was acting as he thought in the best  
 18 interests of the patient, that the operation was  
 19 carefully and skilfully performed and that it was  
 20 successful will not afford him any defence if he is  
 21 sued for assault."

22 Then the quote from the case of  
 23 *Bennan v Parsonnet*, and then this:

24 "No amount of professional skill can substitute  
 25 the will of the surgeon for that of his patient."

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1 not normally bound to submit himself to medical  
 2 treatment or even to consult a doctor if he does not  
 3 wish to do so. It follows that treatment carried out  
 4 without the consent of the person concerned, subject  
 5 to certain exceptions to which reference will be made,  
 6 can amount to an assault which may lead to action for  
 7 damages."

8 An example is given of a surgeon. And then it  
 9 continues:

10 "This memorandum considers principally the  
 11 position of the surgeon but the advice given applies  
 12 to all forms of treatment which involve physical  
 13 contact with the patient's body."

14 Again, the focus here is on the doctor not being  
 15 sued, so it's looking at the concept of assault. But  
 16 the underlying principles, as we learnt from the  
 17 expert medical group, are of much wider application  
 18 and aren't limited simply to interactions that involve  
 19 physical contact between the healthcare practitioner  
 20 and the patient.

21 And then if we look at the heading "Consent May  
 22 be Express or Implied", if we look at the last  
 23 paragraph on this page, we can see in similar form to  
 24 the 1962 guidance:

25 "To be an effective answer to a claim for

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1 That's perhaps a pithy but useful summary,  
 2 succinct summary, of one of the core underlying  
 3 principles.

4 So that's the 1962 publication on consent to  
 5 operative treatment. We can see a further booklet,  
 6 still emanating from the Medical Defence Union, in  
 7 1966.

8 If we go to DHSC0103246, please, Soumik.

9 This is consent to treatment, not limited here  
 10 to surgical treatment, operative treatment.

11 If we go to the second page, we'll see the date  
 12 at the bottom of the page, September 1966.

13 If we go to the third page, we'll see, as it  
 14 were, elevated to an important status, at the  
 15 forefront of this document, the extract from the case  
 16 that I just referred to, that famous quote:

17 "No amount of professional skill can justify the  
 18 substitution of the will of the surgeon for that of  
 19 his patient."

20 Then if we go to the next page, we see the  
 21 heading "Consent to Treatment". So this is in similar  
 22 terms to the 1962 document, but, as I say, now dealing  
 23 more broadly with treatment generally rather than  
 24 solely surgery.

25 "A person suffering from disease or injury is

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1 assault [again that's the focus here] the consent must  
 2 have been fully and freely given. The patient should  
 3 therefore be told, in non-technical language, of the  
 4 nature and effect of the operation."

5 Then, again, reference to "special risks"  
 6 unknown to the patient should be -- the patient should  
 7 be informed of those risks.

8 This booklet, produced by the MDU, the consent  
 9 to treatment booklet, was then updated on a number of  
 10 occasions over the years. I'm not going to go through  
 11 all the different versions. We've given the dates in  
 12 our note of the various occasions on which it was  
 13 updated.

14 I want to go, however, to the 1986 version of  
 15 this, so we can see how the way in which the guidance  
 16 is expressed has changed.

17 This is MDUN0000064, please, Soumik.

18 So we can see it's Consent to Treatment. It's  
 19 produced by the Medical Defence Union.

20 Let me go to the third page. We see, bottom of  
 21 the left-hand side, it's 1986. And then, on the  
 22 right-hand side, we see the concept of informed  
 23 consent, there set out.

24 "A doctor has a duty to explain to the patient  
 25 in non-technical language the nature, purpose and

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1 material risks ... of the proposed procedure. The  
 2 patient must be capable of understanding the  
 3 explanation given ..."  
 4 And then there's a reference to the position of  
 5 the patient who lacks capacity. Again, we're not  
 6 concerned with that particular situation.  
 7 "Where the patient has been given insufficient  
 8 information, the doctor may be found to have been in  
 9 breach of his duty and liable to the patient if damage  
 10 results."  
 11 Then we see a discussion of types of consent:  
 12 implied consent, express consent, oral consent -- if  
 13 we go over the page -- written consent.  
 14 And then if we look at the heading halfway down  
 15 the left-hand side, "Obtaining consent":  
 16 "1. Explanation by knowledgeable doctor.  
 17 "Consent should be obtained by a medical  
 18 practitioner who should be familiar with the details  
 19 and risks of the proposed operation or investigation."  
 20 Then if we go to the next page, you'll see here,  
 21 sir, if we look at the bottom of the left-hand side,  
 22 under the heading "Material risks", reference to what  
 23 are, in legal terms, the fairly well known authority  
 24 of Sidaway v Bethlem Royal Hospital. So, again, the  
 25 focus here is on the minimum that the doctor must do

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1 And then further guidance is then given, and  
 2 reference again to various legal principles, and cases  
 3 and legislative provisions.  
 4 But what we see here, missing from the earlier  
 5 versions, is the recognition here of the patient's  
 6 right.  
 7 I won't go to it, but when we look -- if we were  
 8 to look at the 1996 version of this, we then see the  
 9 concept of autonomy being introduced as well.  
 10 So that's the material produced by the Medical  
 11 Defence Union on the issue of consent over some of the  
 12 earlier decades.  
 13 If we can then look at some of the material  
 14 produced by the British Medical Association on the  
 15 issue of consent, and go back to a document I looked  
 16 at briefly before the break.  
 17 So this is the BMA's 1980 publication,  
 18 BMAL0000086, please, Soumik.  
 19 If we go to page 10, we see at the bottom of the  
 20 page, the heading "Consent":  
 21 "The patient's trust that his consent to  
 22 treatment will not be misused is an essential part of  
 23 his relationship with his doctor but for a doctor to  
 24 touch a patient without consent is an assault.  
 25 Consent is valid when freely given if the patient

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1 in order to act in accordance with the law. And we  
 2 have there set out what was said by the House of Lords  
 3 in that case.  
 4 So that's the 1986 guidance. And if we then  
 5 look at I think it's the 1993 version just see again  
 6 how the emphasis shifts over the year.  
 7 MDUN0000065, please, Soumik.  
 8 This is the document -- the same booklet  
 9 essentially, Consent to Treatment, but produced in  
 10 1993.  
 11 Here we can see now, on the front page of it, we  
 12 have the definition of consent set out:  
 13 "... express willingness, give permission,  
 14 agree, voluntary agreement permission, compliance."  
 15 Then if we go to page 2, under the heading  
 16 "Consent to treatment" on the left-hand side, what we  
 17 see now is the language of patient rights.  
 18 So top of the left-hand side:  
 19 "Every patient has the right to make his or her  
 20 own decision regarding medical treatment and care and,  
 21 in order to make that decision, is entitled to have  
 22 full information about the material risks. The  
 23 clinician's duty is to supply the information in  
 24 sufficient detail to enable the patient to make that  
 25 decision."

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1 understands the nature and consequences of what is  
 2 proposed. Assumed consent or consent obtained by  
 3 undue influence is valueless."  
 4 And then paragraph 1.9 at the bottom of the  
 5 page:  
 6 "The necessary degree of understanding of what  
 7 is proposed depends on the patient's education and  
 8 intelligence, the seriousness and urgency of the  
 9 condition being investigated or treated, and other  
 10 relevant factors."  
 11 And then this:  
 12 "The onus is always on the doctor carrying out  
 13 the procedure to see that an adequate explanation is  
 14 given."  
 15 And then there's a section on consent of minors,  
 16 and incapacity to consent.  
 17 So not much in this, but it is, at least for the  
 18 first time in terms of the BMA materials, an  
 19 articulation of the principle of consent in any event.  
 20 And that was 1980.  
 21 The World Medical Association in 1981, adopted  
 22 something called the Declaration of Lisbon.  
 23 That is at RLIT0001509.  
 24 We can see it's headed:  
 25 "The World Medical Association ...

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1 "World Medication Association Declaration of  
 2 Lisbon on the Rights of the Patients"  
 3 So, again, it uses the language about patient  
 4 rights.  
 5 "Adopted by the 34th World Medical Assembly,  
 6 Lisbon, Portugal, September/October 1981  
 7 "Recognising that there may be practical,  
 8 ethical or legal difficulties, a physician should  
 9 always act according to his/her conscience and always  
 10 in the best interests of the patient. The following  
 11 Declaration represents some of the principal rights  
 12 which the medical profession seeks to provide to  
 13 patients.  
 14 "Whenever legislation or government action  
 15 denies these rights of the patient, physicians should  
 16 seek by appropriate means to assure or restore them."  
 17 Then, for the present purposes, looking at the  
 18 question of consent, it is (c) that's important.  
 19 "The patient has the right to accept or to  
 20 refuse treatment after receiving adequate  
 21 information."  
 22 So that's, again, the concept of patient rights  
 23 and informed consent.  
 24 Now that's obviously expressed in fairly short  
 25 and succinct terms.

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1 the bottom of the page, you'll see the first principle  
 2 is the "Right to medical care of good quality".  
 3 And 1(c):  
 4 "The patient shall always be treated in  
 5 accordance with his/her best interests."  
 6 Then if we go over the page, we can see at  
 7 paragraph 3, or principle 3, the "Right to  
 8 self-determination":  
 9 "The patient has the right to  
 10 self-determination, to make free decisions regarding  
 11 himself/herself. The physician will inform the  
 12 patient of the consequences of his/her decisions.  
 13 "A mentally competent adult patient has the  
 14 right to give or withhold consent to any diagnostic  
 15 procedure or therapy. The patient has the right to  
 16 the information necessary to make his/her decisions.  
 17 The patient should understand clearly what is the  
 18 purpose of any test or treatment, what the results  
 19 would imply, and what would be the implications of  
 20 withholding consent.  
 21 "The patient has the right to refuse to  
 22 participate in research or the teaching of medicine."  
 23 Then if we just go to the next page, I'll come  
 24 back to confidentiality later but principle 7 is the  
 25 "Right to information":

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1 This declaration was amended in 1995, so some  
 2 years later.  
 3 If we go to RLIT0001508.  
 4 We can see this is September 1995: "World  
 5 Medical Association Declaration of Lisbon on the  
 6 Rights of the Patient".  
 7 And we can see "Amended by the 47th General  
 8 Assembly, Bali, Indonesia, September 1995".  
 9 And then there is a preamble which is perhaps  
 10 worth looking at because it introduces some of the  
 11 ethical norms that the expert group have told us  
 12 about:  
 13 "The relationship between physicians, their  
 14 patients and broader society has undergone significant  
 15 changes in recent times. While a physician should  
 16 always act according to his/her conscience and always  
 17 in the best interests of the patient, equal effort  
 18 must be made to guarantee patient autonomy and  
 19 justice. The following Declaration represents some of  
 20 the principal rights of the patient which the medical  
 21 profession endorses and promotes. Physicians and  
 22 other persons or bodies involved in the provision of  
 23 healthcare have a joint responsibility to recognise  
 24 and uphold these rights."  
 25 And if we look at the principles then, towards

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1 "The patient has the right to receive  
 2 information about himself/herself recorded in any of  
 3 his/her medical records, and to be fully informed  
 4 about his/her health status including the medical  
 5 facts about his/her condition ... confidential  
 6 information in the patient's records about a third  
 7 party should not be given to the patient without the  
 8 consent of that third party.  
 9 "Exceptionally, information may be withheld from  
 10 the patient when there is good reason to believe that  
 11 this information would create a serious hazard to  
 12 his/her life or health."  
 13 Then various other matters about the patient's  
 14 rights.  
 15 So a more detailed exposition here in this  
 16 amended version of the Declaration of Lisbon of  
 17 patient rights based clearly upon the principle of  
 18 autonomy.  
 19 **SIR BRIAN LANGSTAFF:** Yes, but the way in which autonomy  
 20 was explained by the ethical experts included the  
 21 right to make a choice, a choice between no treatment  
 22 and treatment but also a choice between the treatment  
 23 options available, and none of the statements you've  
 24 taken me to so far have made any explicit reference to  
 25 a right to choose alternative therapies if they might

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(20) Pages 77 - 80



1 be available.

2 **MS RICHARDS:** They don't. No, that's absolutely right.

3 **SIR BRIAN LANGSTAFF:** Nor does it say that information

4 explicitly doesn't say -- sorry, doesn't say

5 explicitly, that information should be given about

6 options, which is the basic -- a basic principle which

7 the ethical experts were articulating.

8 **MS RICHARDS:** No, you're absolutely right, sir, and of

9 course one of the objectives in showing this material,

10 this guidance, is not only for what it does say, but

11 also to see what it does not say. And what was absent

12 from the materials that were being disseminated to

13 clinicians at the relevant time.

14 **SIR BRIAN LANGSTAFF:** I mean, with modern eyes, one could

15 say the principle of mutual respect going back to

16 1953, has within it the right to know of what the

17 options are, where there are options.

18 **MS RICHARDS:** Yes.

19 **SIR BRIAN LANGSTAFF:** But that's reading in with modern

20 eyes what was not expressly there in the text at the

21 time.

22 **MS RICHARDS:** Yes, and I'll check as we go through it, but

23 I don't think in the materials we're looking at from

24 the 1970s, 1980s or early 1990s, we'll see anything

25 that articulates that right to make a choice in quite

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1 So this, I think, is probably the first

2 reference in the materials to the point you

3 articulated, sir.

4 Then there's the discussion about the position

5 of the patient who doesn't want to be told, which is

6 articulated in the remainder of that paragraph.

7 Then picking it up in the next paragraph:

8 "Normally, the patient will wish to decide. The

9 doctor should remember that his specialised training

10 and knowledge puts him in a powerful position compared

11 with the patient who will usually lack the detailed

12 knowledge to grasp the essential facts immediately.

13 The lack of this knowledge does not mean that the

14 patient is unable to understand. Consent without

15 understanding is invalid and it is the doctor's moral,

16 professional and legal duty to help the patient reach

17 this understanding. In so doing, the doctor should

18 follow the patient's lead and present as many of the

19 risks and benefits as the patient needs to know.

20 Naturally a doctor can only discuss matters in

21 relation to the accepted state of medical knowledge at

22 the time.

23 "One of the problems about consent is that it

24 must follow the disclosure of information and thus

25 understanding of the medical condition."

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1 the way that you have done, sir, or the way in which

2 the expert group did, and that may be one of the

3 deficiencies of the material that was promulgated.

4 **SIR BRIAN LANGSTAFF:** Right.

5 **MS RICHARDS:** Sir, that's the Declaration of Lisbon in its

6 various -- in its amended form.

7 If we then, turning to the publications of the

8 BMA, we looked at -- I've looked at the 1980 guidance

9 but it's really the 1988 guidance where we see a more

10 detailed examination of the principles of consent.

11 That's at BMAL0000080. We looked at this before the

12 break, in terms of seeing what kind of general steer

13 was being given by the British Medical Association.

14 If we go to the section that is specifically on

15 consent, if I can find chapter 4, page 35, Soumik.

16 We do here have reference to options, sir. So

17 "Consent to Treatment":

18 "The basis of any discussion about consent is

19 that a patient gives consent before any investigation

20 and treatment proposed by the doctor. Doctors offer

21 advice, but the patient decides whether to accept it.

22 "Before a patient can consent, the options have

23 to be presented in such a fashion as to allow

24 a decision to be made. Consent must involve the

25 ability to choose."

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1 Then there's reference to UK case law, and the

2 Sidaway case but, very importantly, the last two

3 sentences of this first paragraph, after referring to

4 the case law:

5 "It is important to remember that a doctor's

6 legal obligations are much less than his moral

7 obligations. The legal minimum is not necessarily

8 ethical."

9 Then there is a discussion of certain exceptions

10 including the patient who lacks capacity and the

11 statutory provisions that enable compulsory treatment

12 in certain circumstances of psychiatric patients.

13 If we go to page 39, I think, Soumik. Bottom of

14 the page, under the heading "Obtaining consent", it

15 says this:

16 "At times consent is implied, as in attendance

17 for an inoculation which implies that the patient

18 expects the inoculation. This does not, however,

19 absolve the doctor from explaining any risks. Equally

20 there are times when oral consent is not sufficient

21 and written consent essential. It is important that

22 consent should be free of any form of pressure or

23 coercion ..."

24 Then if we go over the page, we can just see,

25 after the extract from what the GMC has said about the

84

(21) Pages 81 - 84

1 relationship between doctors and patients, the point  
 2 about trust:  
 3 "The doctor/patient relationship is based on  
 4 trust."  
 5 So that's the 1988 guidance from the BMA in  
 6 relation to consent. If we then move to 1990 for the  
 7 next material publication. That's a publication,  
 8 I think, by the Department of Health.  
 9 NHBT0007444\_001, please, Soumik.  
 10 It's an NHS publication, I should say. It's  
 11 called "A guide to consent for examination or  
 12 treatment", and you'll see it's published by the NHS  
 13 Management Executive. Let's just see if we've got  
 14 a date recorded on the document. Our understanding is  
 15 that this is from August 1990, in any event.  
 16 If we go to the second page, because I'm not  
 17 going to go through each chapter, you'll see there  
 18 what the chapters cover: "A patient's rights in  
 19 accepting treatment"; "Health Professional's role in  
 20 advising the patient ..."; reference to a specific  
 21 statutory provision; "Examples of treatment which have  
 22 raised concern"; "Consent by patients suffering from  
 23 mental disorder"; and then "The Sidaway Case".  
 24 Just go to the next page, what you'll see is  
 25 that this very much focused on legal rights and

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1 that they understand the nature, consequences and any  
 2 substantial risks of the treatment proposed so that  
 3 they are able to take a decision based on that  
 4 information."  
 5 Then if we go to paragraph 4, further down the  
 6 page, again, this is very much from the perspective of  
 7 what the minimum legal requirements were:  
 8 "A doctor will have to exercise his or her  
 9 professional skill and judgement in deciding what  
 10 risks the patient should be warned of and the terms in  
 11 which the warning should be given. However, a doctor  
 12 has a duty to warn patients of substantial or unusual  
 13 risk inherent in any proposed treatment. This is  
 14 especially so with surgery that may apply to other  
 15 procedures including drug therapy and radiation  
 16 treatment."  
 17 Then reference again to the Sidaway case.  
 18 Then the next page, please, Soumik. If we look  
 19 at paragraph 9, just over halfway down the page:  
 20 "Consent given for one procedure or episode of  
 21 treatment does not give any automatic right to  
 22 undertake any other procedure."  
 23 Then I should just refer to page 13, in which  
 24 attention is drawn to the Sidaway case. So, again,  
 25 this is very much based on explaining what was

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1 responsibilities, rather than ethical ones, and we see  
 2 that from paragraph 1:  
 3 "A patient has the right under common law to  
 4 give or withhold consent prior to examination or  
 5 treatment ... This one of the basic principles of  
 6 health care."  
 7 Then paragraph 2:  
 8 "Patients are entitled to receive sufficient  
 9 information in a way they can understand about the  
 10 proposed treatments, the possible alternatives [so  
 11 there again we get the concept of options and choice  
 12 emerging] and any substantial risks, so they can make  
 13 a balanced judgement. Patients must be allowed to  
 14 decide whether they will agree to treatment, and they  
 15 may refuse treatment or withdraw consent to treatment  
 16 at any time.  
 17 "3. Care should be taken to respect the  
 18 patient's wishes."  
 19 Then if we go to the next page, under the  
 20 heading "Advising the patient", paragraph 1:  
 21 "Where a choice of treatment might reasonably be  
 22 offered the health professional may always advise the  
 23 patient of his/her recommendations together with  
 24 reasons for selecting a particular course of action.  
 25 Enough information must normally be given to ensure

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1 required in terms of legal responsibility or to avoid  
 2 an action against a doctor.  
 3 There's similar guidance from Scotland. I'm not  
 4 going to go to the detail of it because there aren't  
 5 material differences, but we can just see that from  
 6 PRSE0000713.  
 7 "Scottish Office  
 8 "National Health Service Scotland Management  
 9 Executive  
 10 "Dear colleague  
 11 "A guide to consent to examination,  
 12 investigation, treatment or operation."  
 13 We can see:  
 14 "The Department of Health issued in August 1990  
 15 its Guide to Consent for Examination or Treatment [the  
 16 document we just looked at]. Ministers agreed that it  
 17 was necessary to produce a similar guide for the use  
 18 of health professionals in Scotland to maintain  
 19 consistency throughout the UK in the area of patient  
 20 consent."  
 21 Then the guide followed but, as I say, it's in  
 22 materially similar form.  
 23 Then, now, in the 1990s, we see more detailed  
 24 guidance on consent from the British Medical  
 25 Association. So if we go to BMAL0000089, this is the

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1 BMA's 1993 publication Medical Ethics Today, Its  
2 Practice and Philosophy, and if we go in this document  
3 to page 7, you'll see from the contents that the first  
4 chapter is about consent and refusal.

5 Then if we go to page 27, please, Soumik --  
6 sorry, actually could we just pick it up page 22 in  
7 the introduction, just so we can see the purpose of  
8 this document:

9 "The aims of the book

10 "This book is intended to be a practical guide  
11 which reflects contemporaneous ethical thinking. It  
12 is written primarily for doctors but we hope that  
13 other people will find it useful. Its approach is  
14 patient-centred."

15 So now we have the patient at the centre of the  
16 guidance rather than the clinician.

17 Then the next paragraph:

18 "The fundamental principles observed by the  
19 medical profession remain constant but their  
20 application to newly evolving situations requires  
21 debate. Each of these chapters centres on ethical  
22 questions which doctors raise with the BMA and  
23 attempts to show briefly how moral theories can be  
24 applied to these common dilemmas."

25 Then if we go to page 27, please, Soumik we can

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1 guidance as to the optimal course of action but must  
2 also recognise that patients' responses will not be  
3 formed solely on the basis of clinical data but by  
4 their circumstances, needs, rational conclusions and  
5 irrational emotions. Individuals have varied  
6 information requirements ... Thus, a doctor who seeks  
7 guidance about the amount or type of information which  
8 should be made available must first listen to the  
9 patient and consider, among other things, what it is  
10 that the patient wants to know."

11 Next paragraph tells us:

12 "Patient consent must be voluntary, free from  
13 pressure and arise from a competence to decide."

14 Then if we look at the third paragraph, it  
15 looks, as it were, at the intertwining of law and  
16 ethics:

17 "In many aspects of medicine, the legal and  
18 ethical requirements are separate and ethical guidance  
19 need make no reference to the law. Consent, however,  
20 is an issue which binds the two ..."

21 Next paragraph:

22 "It would be wrong to assume that consent is  
23 only relevant when initiating an examination or  
24 treatment. Consent is a process and not an event and  
25 it is important that there be continuing discussion to

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1 see the chapter on consent. So we have here a much  
2 more detailed discussion about the principles. So  
3 under the heading "Introduction, the doctor-patient  
4 relationship":

5 "The relationship between doctor and patient is  
6 based on the concept of partnership and collaborative  
7 effort. Ideally, decisions are made through frank  
8 discussion, in which the doctor's clinical expertise  
9 and the patient's individual needs and preferences are  
10 shared, to select the best treatment option. The  
11 patient's consent to be examined and to receive  
12 treatment is the trigger which allows the interchange  
13 to take place."

14 If we look at the last sentence of that  
15 paragraph:

16 "Regardless of how it is expressed, the basic  
17 premise is that treatment is undertaken as a result of  
18 patients being actively involved in deciding what is  
19 to be done to them."

20 Then if we go to page 29, Soumik, under the  
21 heading "The therapeutic relationship":

22 "As a prerequisite to choosing treatment,  
23 patients have the right to receive information from  
24 doctors and to discuss the benefits and risks of  
25 appropriate treatment options. Doctors give medical

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1 reflect the evolving nature of treatment."

2 Then we look at the bottom of the page:

3 "Clearly, the opportunity to consent to  
4 treatment is counterbalanced by a right to refuse it."

5 Then there's a further discussion in relation to  
6 that.

7 Then if we go to page 33, bottom half of the  
8 page, under the heading "Seeking consent", we can pick  
9 it up in the bottom paragraph:

10 "Some people see the purpose of consent as  
11 chiefly being the provision of a defence for doctors  
12 against legal liabilities which come up for discussion  
13 when patients allege that their apparent agreement to  
14 treatment has been rendered invalid by the doctor's  
15 failure to give enough information for specific  
16 consent. In the BMA's view, respect for others and  
17 their rights [so there's that principle you referred  
18 to, sir, in the earlier documents] lies at the heart  
19 of the issue of consent. A feature of our present  
20 society is the emphasis on the value and dignity of  
21 the individual. It is said that principles of  
22 inherent natural rights dictate that each person who  
23 is competent to do so should decide what happens to  
24 his or her own body. The patient exercises this  
25 autonomy by deciding which treatment option to accept.

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(23) Pages 89 - 92

1 The decision is based on information given by the  
2 clinician. For consent to be valid, the patient must  
3 know what options are available and have the ability  
4 to choose."

5 Then if we go over the page, that guidance  
6 continues:

7 "In addition to the moral and symbolic  
8 importance of promoting patient self-determination,  
9 patient co-operation is a very practical requirement."

10 Then picking that up in the second paragraph:

11 "This perhaps foreshadows current thinking that  
12 most people fare best when they have a clear view of  
13 what is being proposed and its implications. In the  
14 past, concern to avoid worrying patients has been seen  
15 as a reason for in order telling them the full  
16 implications of either their condition or different  
17 options for treatment. Sometimes only their relatives  
18 were given information of the likely outcome. Even  
19 nowadays, doctors are often reluctant to mention  
20 medicine's ubiquitous uncertainties and arguments are  
21 made for restricting information in certain  
22 circumstances on the grounds that autonomy is not the  
23 only ethical imperative. It is sometimes argued that  
24 an exaggerated regard for this single principle puts  
25 at risk the whole concept of the doctor-patient

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1 Then the BMA expresses concern that:

2 "... although ... schools [so that's medical  
3 schools] provide some form of communication-skills  
4 training for medical students, relatively few are  
5 committed to formal instruction and students are not  
6 bound to achieve any particular standards."

7 Then if I can go to page 36, please, Soumik, we  
8 can see a section headed "Provision of information".  
9 Reference is made to the Declaration of Lisbon, which  
10 we've already looked at. Then I can pick it up four  
11 lines down:

12 "... how much or how little is considered to be  
13 adequate [in terms of the provision of information]  
14 will vary with each patient. It must also be a matter  
15 of clinical judgement and the standards set by other  
16 doctors. From an ethical viewpoint, the criteria  
17 should be as much information as the patient needs or  
18 desires."

19 Then in the next paragraph again, we see the  
20 distinction between good practice and legal minimums.

21 Then if we go to the next page, top half of the  
22 page, there's a citation, again from the House of  
23 Lords in Sidaway, and then it says this:

24 "Thus ideally, the doctor should inform the  
25 patient about any risks inherent in the treatment

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1 relationship.

2 "Here, we take the opportunity to reaffirm that  
3 it is not the doctor's role just to provide a list of  
4 alternatives from which patients select options,  
5 according to their need and desires. Doctors must,  
6 indeed, bear in mind other ethical principles, such as  
7 the duty of acting in the patient's best interest by  
8 attempting to recognise what the patient wants. In  
9 most cases, patients can choose better for themselves  
10 than doctors can choose for them, but occasionally the  
11 patient's final choice is to let the doctors choose.  
12 This not an abnegation of choice and the patient who  
13 makes such a decision with regard to one aspect of  
14 treatment should not be seen as relinquishing choice  
15 on other issues. Nevertheless, whilst information and  
16 uncertainties should not be forced upon patients at  
17 a time when they are particularly vulnerable and  
18 clearly unready, most people do deal with very  
19 difficult choices despite their anxieties if given the  
20 support to do so."

21 Then the bottom of the page picks up on the  
22 issue of communication:

23 "Information is only useful if it is provided in  
24 a manner intelligible to the hearer and at a pace at  
25 which the recipient can digest it."

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1 which might be particularly important to that patient  
2 as well as explaining the risks and benefits of  
3 alternatives and of non-treatment.

4 "Information allows the patient to make  
5 a rational decision, but decision-making is not solely  
6 a rational activity. It involves intuition, personal  
7 values, preferences, and emotion."

8 Then, again, there's a more detailed discussion  
9 about the exchange of information between doctor and  
10 patient. Then if we just look at the bottom half of  
11 this page, under the heading "The duration of  
12 consent":

13 "Doctors often query the length of time for  
14 which patient consent can be considered valid. In  
15 usual practice, this is not a question since consent  
16 is an evolving matter and not a once-and-for-all  
17 decision."

18 So that's -- the chapter then goes on to look at  
19 the particular scenarios in which a patient cannot  
20 consent, so again, the unconscious patient and  
21 emergencies, children and parental rights to consent  
22 and impaired capacity, and I don't think we need to  
23 look at any of those materials.

24 So that's the 1995 --

25 **SIR BRIAN LANGSTAFF:** Just a comment on this. If one goes

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(24) Pages 93 - 96



1 back to page 30, which I noticed as we slipped past  
 2 it --  
 3 **MS RICHARDS:** Is that electronic page 30?  
 4 **SIR BRIAN LANGSTAFF:** Electronic page 30. There's  
 5 a heading, a paragraph which is headed "The autonomy  
 6 of doctors". Now there's no similar paragraph in  
 7 respect of patients, because, I suspect, the autonomy  
 8 of a patient is demonstrated throughout the text.  
 9 **MS RICHARDS:** Yes.  
 10 **SIR BRIAN LANGSTAFF:** And it's maybe thought quite  
 11 interesting that it is, as it were, necessary to spell  
 12 out what autonomy a doctor has when, in the early  
 13 fifties and sixties, it might be said that the debate  
 14 was about whether a patient had any.  
 15 **MS RICHARDS:** Yes. Yes, indeed.  
 16 So that was the 1993. There's then -- let's  
 17 just look at in passing -- a publication from 1995 by  
 18 the Royal College of Physicians, which is at  
 19 RCPH0000404.  
 20 So 0000404\_003, please, Soumik.  
 21 This is specifically looking at the position of  
 22 consent for patients undergoing treatment for cancer  
 23 but, nonetheless, may be illuminating in terms of  
 24 understanding some of the wider principles in play.  
 25 So we can see there is -- it says:

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1 "The delivery of information to patients can be  
 2 regarded in three main areas:  
 3 "(a) A discussion of the proposed treatment,  
 4 alternative treatments and realistic expectations from  
 5 treatment;  
 6 "(b) The process of treatment.  
 7 "(c) The possible toxicity of treatment."  
 8 And then if we go to the next page, not going to  
 9 go through this in detail, but there are "Proposals  
 10 for future practice" as to how to make the delivery of  
 11 information really a more valuable and useful  
 12 exercise. So little paragraph (a) talks about the  
 13 consultation taking place in appropriate surroundings,  
 14 (b) talks about the ideal of the initial consultation  
 15 being distant from the arrangements for treatment so  
 16 the patient feels that a true choice is being offered  
 17 rather than a fait accompli. Paragraph (c) talks  
 18 about the provision of:  
 19 "... supporting written information in the form  
 20 of patient information leaflets, which would cover not  
 21 only the process of treatment, but also realistic  
 22 expectations from treatment, and both acute and late  
 23 toxicities."  
 24 And if we go to the next page, we see (d), it's  
 25 about patients being:

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1 "There is an increasing demand for patients with  
 2 cancer to receive better information about their  
 3 disease and its treatment than has been customary in  
 4 the past, and this is coupled with the issue of  
 5 informed consent for treatment."  
 6 Then there's specific reference to a declaration  
 7 of the rights of people with cancer.  
 8 And if we just go down a few lines, that  
 9 includes the right "to be informed fully about  
 10 treatment options and to have explained to me the  
 11 benefits, side effects and risks of any treatment".  
 12 If we go over the page, just picking up the  
 13 first line and a half.  
 14 "Consent for treatment can no longer be assumed  
 15 or implied by the patient presenting themselves for  
 16 treatment ..."  
 17 Then if we go to the next page, under the  
 18 heading "Current situation", it says:  
 19 "There can be no doubt that expectations  
 20 regarding consent are changing and that in the light  
 21 of this the legal position on consent is likely to  
 22 reflect an increasing onus upon doctors to ensure that  
 23 patients receive full information regarding treatment  
 24 and its side effects before giving informed consent."  
 25 Then if we go a little further down, we see:

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1 "... given the opportunity to ask for  
 2 information beyond that which is volunteered by the  
 3 clinician ...  
 4 "(e) All patients should have access to  
 5 clarification and further information following the  
 6 initial discussion."  
 7 And (f):  
 8 "It is important that there is full  
 9 documentation of all advice given and of any written  
 10 information leaflets or other back-up material taken  
 11 by the patient."  
 12 So that's, as I say, from the Royal College of  
 13 Physicians specifically in the context of cancer care.  
 14 And then two final documents to note on the  
 15 topic of consent in 1990s.  
 16 There's the GMC's 1995 publication "Good Medical  
 17 Practice". We looked at that this morning. I'm not  
 18 proposing to go back to it but that talked about the  
 19 rights of patients to be fully involved in decisions  
 20 about their care and the right to refuse treatment.  
 21 And then, and this document I do want to look  
 22 at, is the GMC's first specific guidance on consent.  
 23 That's at PRSE0003177, please, Soumik.  
 24 We can see this is being issued by the GMC in  
 25 November 1998, "Seeking patient's consent: The ethical

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(25) Pages 97 - 100

1 considerations". And as I say, it's our understanding  
 2 it's the first specific piece of guidance issued by  
 3 the General Medical Council on the question of  
 4 consent.  
 5 If we go to the second page, second paragraph:  
 6 "This booklet sets out the principles of good  
 7 practice which all registered doctors are expected to  
 8 follow when seeking patients' informed consent to  
 9 investigations, treatment, screening or research."  
 10 I should say, sir, this is a later version. So  
 11 although November 1998 appears on the first page, we  
 12 can see, from references here -- the 2006 version of  
 13 Good Medical Practice has been inserted. The Inquiry  
 14 doesn't currently have the original version so we're  
 15 not quite clear at the moment the extent to which  
 16 there were amendments.  
 17 But, again, much of this is by way of what the  
 18 ethicists told us are well established, longstanding  
 19 principles. We see under the heading "Introduction"  
 20 again the reference to trust:  
 21 "To establish that trust you must respect  
 22 patients' autonomy -- their right to decide whether or  
 23 not to undergo any medical intervention even where  
 24 a refusal may result in harm to themselves or in their  
 25 own death. Patients must be given sufficient

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1 Then the next bullet point:  
 2 "for each option, explanations of the likely  
 3 benefits and the probabilities of success; and  
 4 discussion of any serious or frequently occurring  
 5 risks, and of any lifestyle changes which may be  
 6 caused by, or necessitated by, the treatment;  
 7 "advice about whether a proposed treatment is  
 8 experimental ..."  
 9 And so on.  
 10 And then, I'm not going to go through the detail  
 11 of the remainder of it but if we go to the next page,  
 12 we can just see some of the headings. So "Responding  
 13 to questions" talks about the importance of responding  
 14 honestly to any questions the patient raises.  
 15 "Withholding information.  
 16 "You should not withhold information necessary  
 17 for decision making unless you judge that disclosure  
 18 of some relevant information would cause the patient  
 19 serious harm."  
 20 And importantly this:  
 21 "In this context serious harm does not mean the  
 22 patient would become upset, or decide to refuse  
 23 treatment."  
 24 So a doctor is not entitled to decline to  
 25 provide information because he or she thinks that that

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1 information in a way they can understand to enable  
 2 them to exercise their right to make informed  
 3 decisions about their care."  
 4 Paragraph 3, first sentence explains that:  
 5 "Effective communication is the key to enabling  
 6 patients to make informed decisions."  
 7 Then if we go further down the page, we'll see  
 8 the heading "Consent to investigation and treatment,  
 9 Providing sufficient information", and then if we just  
 10 pick it up perhaps at paragraph 5, at the bottom of  
 11 the page:  
 12 "The information which patients want or ought to  
 13 know, before deciding whether to consent to treatment  
 14 or an investigation, may include:  
 15 "details of the diagnosis, and prognosis, and  
 16 the likely prognosis if the condition is left  
 17 untreated;  
 18 "uncertainties about the diagnosis including  
 19 options for further investigation prior to treatment;  
 20 "options for treatment or management of the  
 21 condition, including the option not to treat ..."  
 22 Then at the top of the next page:  
 23 "the purpose of a proposed investigation or  
 24 treatment; details of the procedures or therapies  
 25 involved ..."

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1 will lead to the patient refusing treatment the doctor  
 2 thinks the patient should have. And again, that  
 3 resonates very much in the context of some of the  
 4 evidence that the Inquiry has heard.  
 5 So that's, again, it's a document that merits  
 6 reading in full; it also has a section on consent to  
 7 research.  
 8 But that's the GMC's position in relation to  
 9 consent.  
 10 There's also, I think, perhaps finally on the  
 11 topic of consent, a publication by the British Medical  
 12 Association specifically in relation to children.  
 13 That is at GMCO0000679, I think. Yes.  
 14 You'll see here it says "Confidential" and  
 15 "Strictly Confidential", but there are also references  
 16 in the course of the document to it being available to  
 17 patients and so on. So we have seen that at some  
 18 point it became a published report.  
 19 Again, I'm not going to go through it in any  
 20 detail. I think I'll just show you, sir, the contents  
 21 list so we can see the kind of issues that were being  
 22 covered in this particular document. So if we go to  
 23 page 2, we see chapter 1 is:  
 24 "An ethical approach to treating children and  
 25 young people."

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(26) Pages 101 - 104

1 So placing ethical principles really at the  
2 forefront of this report.  
3 Chapter 2 then looks at "The Legal Framework".  
4 And then if we go to the next page, we see at  
5 the bottom half of the page there is a whole chapter,  
6 chapter 5, on non-treatment and refusal of treatment.  
7 So it's, again, a detailed discussion of the  
8 principles of consent in the particular context here,  
9 of providing messages to or offering treatment to  
10 children.  
11 So, sir, those are the principal materials that  
12 the Inquiry has obtained that bear on the question of  
13 consent, in terms of the guidance given to clinicians.  
14 The next topic I'm proposing to turn to is the  
15 issue of confidentiality and I'm happy start now or  
16 take lunch early, whatever is easiest for you, sir.  
17 **SIR BRIAN LANGSTAFF:** Well, it's probably sensible to have  
18 it in one go, isn't it?  
19 **MS RICHARDS:** Yes, certainly.  
20 **SIR BRIAN LANGSTAFF:** So let's take a break now until ten  
21 to two.  
22 **MS RICHARDS:** Thank you, sir.  
23 **(12.50 pm)**  
24 **(The Luncheon Adjournment)**  
25 **(1.50 pm)**

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1 lines:  
2 "I will respect the secrets which are confided  
3 in me, even after the patient has died."  
4 So that was to make clear that the duty extended  
5 beyond the lifetime of patient.  
6 In terms of what we can then see in the  
7 professional guidance, if we go back briefly to a  
8 couple of documents we looked at this morning, first  
9 of all, GMCO0001697\_001, please, Soumik. This was the  
10 original 1963 publication by the GMC functions  
11 procedure and disciplinary jurisdiction, and if we go  
12 to page 8, we see there, I referred to it briefly  
13 earlier, the examples given of what might have been  
14 infamous conduct in a professional respect and one of  
15 those is "Improperly disclosing information obtained  
16 in confidence from a patient", although no further  
17 guidance given in relation to that in this particular  
18 publication.  
19 Then if we go to RCPH0000226, this is was the  
20 1949 BMA publication page 16, please, Soumik, bottom  
21 of the page, again we see what was then termed  
22 "Professional secrecy":  
23 "A practitioner should not disclose voluntarily,  
24 without the consent of the patient, preferably  
25 written, information which he has obtained in the

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1 **MS RICHARDS:** Sir, I turn next to guidance and other  
2 material relevant to the issue of confidentiality and  
3 the duty of confidence owed by doctors to patients.  
4 We can pick this up at RLIT0001510, please,  
5 Soumik.  
6 Taking these in chronological order, if we look  
7 at the bottom of the page, we'll see the Declaration  
8 of Geneva 1948, we've looked at this in more general  
9 terms previously, bottom of the left-hand column,  
10 "I will respect the secrets which are confided in me"  
11 is how the requirement of confidentiality was embodied  
12 in the 1948 declaration of Geneva.  
13 If we look at the top of the page, this the  
14 World Medical Association's International Code of  
15 Medical Ethics adopted by its third General Assembly  
16 in London in 1949, and if we look in the right-hand  
17 column under the heading "Duties of doctors to the  
18 Sick" a third item is:  
19 "A doctor shall preserve absolute secrecy on all  
20 he knows about his patient because of the confidence  
21 entrusted in him."  
22 Then if we go to RLIT0001504, please, if we look  
23 at the bottom of the page, we can see here  
24 a modification, an amendment made by the World Medical  
25 Association in 1968, left-hand column, last three

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1 course of his professional relationship with the  
2 patient."  
3 Then there was some specific example --  
4 a handful of circumstances identified in which it  
5 might be legitimate to do that in terms of whether  
6 there were risks to others. But we can look at that  
7 in more detail in other documents.  
8 Then if we look at the GMC's Blue Book from  
9 1977, GMCO0001696\_006. If we go to page 19, we see  
10 under the heading "Professional confidence" the GMC  
11 referring here, in fact, to guidance issued or  
12 contained within the BMA's Medical Ethics Booklet from  
13 1974, but then here promulgated by the GMC's Blue  
14 Booklet:  
15 "The following guidance has been given the on  
16 the principles which should govern the confidentiality  
17 of information relating to patients:  
18 "It is a doctor's duty (except as below)  
19 strictly to observe the rule of professional secrecy  
20 by refraining from disclosing voluntarily to any third  
21 party information which he has learned directly or  
22 indirectly in his professional relationship with the  
23 patient. The death of the patient does not absolve  
24 the doctor from the obligation to maintain secrecy.  
25 "There are some exceptions to this principle:

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if the doctor is in doubt before making any such exception in disclosing information he should seek advice ... The exceptions to the general principle are: (a) the patient or his legal adviser gives valid consent; (b) the information is required by law; (c) the information regarding a patient's health is given in confidence to a relative or other appropriate person, in circumstances where the doctor believes it undesirable on medical grounds to seek the patient's consent; (d) rarely, the public interest may persuade the doctor that his duty to the community may override his duty to maintain his patient's confidence; (e) information may be disclosed for the purposes of a medical research project ...' In such a case the project should have been approved by a recognised Ethical Committee appointed for such a purpose."

Then over the page:

"If, in the doctor's opinion, disclosure of confidential information to a third party is in the best interests of the patient, it is the doctor's duty to make every reasonable effort to persuade the patient to allow the information to be so given. If the patient still refuses, then only very exceptionally will the doctor feel entitled to overrule that refusal. Again if in doubt, he should

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with other medical practitioners, effectively as part and parcel of a team caring for of the patient. We see from the last sentence of (b):

"It is the doctor's responsibility to ensure that such individuals appreciate that the information is being imparted in strict professional confidence."

(c) is:

"If in particular circumstances the doctor believes it is undesirable on medical grounds to seek the patient's consent [in those circumstances, information] may sometimes be given in confidence to a close relative or person in similar relationship to the patient."

(d) then repeats what we saw in the earlier guidance, if the doctor considers disclosure of information is in the interests -- to someone else is in the interests of the patient, the doctor should try and persuade the patient to allow that to be given but only in exceptional cases could the doctor feel entitled to disregard the patient's refusal.

(e) is where there's a specific statutory requirement to disclose information, such as the notification of an infectious disease.

(f) is direction of court.

Over the page, (g):

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seek advice.

"A doctor should be prepared to justify his action in disclosing confidential information."

So that's the material published by the GMC and BMA in the course of the 1970s. If we then go to the 1983 Blue Book, GMCO0001696\_010, please, Soumik. So this is, if we go to page 22, we can see at the bottom of the page a little more detail here spelled out, "Professional confidence":

"The following guidance given is on the principles which should govern the confidentiality of information relating to patients:

"[While] It is a doctor's duty to his patient (except in the cases mentioned below) strictly to observe the rule of professional secrecy by refraining from disclosing voluntarily to any third party information which he has learnt directly or indirectly in his professional relationship with the patient. The death of the patient does not absolve the doctor from the obligation to maintain secrecy."

Then we have number of possible exceptions set out. (a) is consent from the patient or, it says, his "legal adviser", I'm not quite clear what the scope of that was intended to be.

(b) was the sharing of confidential information

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"Rarely, disclosure may be justified on the ground that it is in the public interest, which, in certain circumstances such as, for example, investigation by the police of a grave or very serious crime, might overwrite the doctor's duty to maintain is patient's confidence."

Then (h) is:

"Information may also be disclosed if necessary for the purpose of a medical research project which has been approved by a recognised ethical committee."

Then the guidance continues --

**SIR BRIAN LANGSTAFF:** Can we just go back to (b) for a moment? (b) sets out an exception, in the second sentence, does a receptionist or person working in the reception area, in the doctor's surgery, come within the description of a healthcare professional?

**MS RICHARDS:** No, there is reference in some of the guidance. I can't, I'm afraid, off the top of my head remember which and it may be I'll have to find it notify it to you, sir, at a later stage, but one of the documents, at least, does deal with that particular scenario, the secretary or the receptionist and suggests that it may be permissible for such information to be shared with individuals from those kind of responsibilities, depending upon how the

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1 practice or organisation is structured.  
 2 **SIR BRIAN LANGSTAFF:** Presumably there would be,  
 3 I suppose, no difficulty with it if the patient, upon  
 4 coming to the surgery for the first time, were to give  
 5 a general consent, but that might have to be revisited  
 6 depending upon the condition which the patient was  
 7 later found to suffer?

8 **MS RICHARDS:** Absolutely. Because a general consent to  
 9 knowing that your GP records recording that you've had  
 10 a flu vaccination might be something which is accessed  
 11 by a secretary is very different in nature from  
 12 knowing that a secretary or receptionist might be able  
 13 to discover your HIV status.

14 But there is certainly something in one of the  
 15 documents, but I don't have a note of it off the top  
 16 of my head, which alludes to the position of  
 17 receptionist or secretary but this would not appear to  
 18 capture that because this is talking about registered  
 19 medical practitioners, nurses, and other healthcare  
 20 professionals.

21 **SIR BRIAN LANGSTAFF:** Yes.

22 **MS RICHARDS:** Then if you go to the next page, we can see  
 23 (3) is the requirement that the doctor must be able to  
 24 justify any decision to disclose confidential  
 25 information, and a recommendation of seeking advice.

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1 doctor/patient relationship. It was contained in  
 2 early codes such as the Hippocratic Oath ...  
 3 "Patients attend their doctor in the belief that  
 4 the information they supply to the doctor or which the  
 5 doctor finds out about them in the course of  
 6 investigation or treatment will be kept secret. This  
 7 encourages them to speak frankly and thus provide the  
 8 doctor with clues or information which can be  
 9 essential to diagnosis or treatment."

10 Et cetera. And then it talks about how that is  
 11 desirable for society as a whole.

12 Then if we go to the next page, the third  
 13 paragraph talks about how the doctor may have reasons  
 14 for wishing to preserve confidentiality, but the  
 15 followed paragraph says:

16 "Despite the doctor's interests in maintaining  
 17 confidentiality it must be agreed that the crucial  
 18 reasons for maintaining it relate entirely to the  
 19 patient's interests, not those of the doctor."

20 And then the next paragraph deals again with  
 21 sharing of information with medically qualified  
 22 colleagues, or in multi-disciplinary teams, and refers  
 23 to difficulties in that regard. Again, doesn't  
 24 expressly deal with the person who may not be a member  
 25 of the multi-disciplinary team and may not be

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1 (5) deals with particular scenarios such as  
 2 occupational health, which I don't think we need to  
 3 concern ourselves with.

4 And then (6) says that:

5 "The ... guidance on confidentiality applies  
 6 equally to medical information which a doctor has  
 7 received in the course of administrative or  
 8 non-clinical duties."

9 But it doesn't deal with the situation of people  
 10 who are not doctors who are performing administrative  
 11 or non-clinical duties.

12 So that's the 1983 GMC Blue Book guidance. And  
 13 similar provision is made in later versions of the  
 14 Blue Book. I won't go through all the various  
 15 iterations.

16 The next piece of guidance which deals in  
 17 substance with confidentiality is the BMA's 1988  
 18 publication, philosophy and practice of medical  
 19 ethics, which is at about BMAL0000080.

20 We looked before lunch at the chapter on  
 21 consent. If we look now at the chapter on  
 22 confidentiality, it's page 26. And we can see it  
 23 says:

24 "The principle of confidentiality is basic to  
 25 the practice of medicine and fundamental to the

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1 a healthcare professional.

2 And then there's some basic guidance, bottom of  
 3 the page:

4 "The doctor is responsible to the patient with  
 5 whom ..."

6 Sorry, bottom of the previous page, my  
 7 apologies.

8 "The doctor is responsible to the patient with  
 9 whom he is in a professional relationship for the  
 10 confidentiality and security of any information which  
 11 he obtains."

12 Next page:

13 "A doctor must preserve secrecy on all he knows.  
 14 The fundamental principle is that he must not use or  
 15 disclose any confidential information which he obtains  
 16 in the course of his professional work for any purpose  
 17 other than the clinical care of the patient to whom it  
 18 relates."

19 Then it sets out what are said to be the only  
 20 exceptions to this principle: patient's consent;  
 21 patient's interest to disclose the information but  
 22 impossible or medically undesirable to seek the  
 23 patient's consent; the law requires disclosure;  
 24 there's an overriding duty to society; disclosure  
 25 necessary to safeguard national security; disclosure

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1 necessary to prevent a serious risk to public health;  
 2 in certain circumstances, for the purposes of medical  
 3 research.  
 4 And then, just picking up the bottom of the  
 5 page, under the heading "Consent to disclosure":  
 6 "The information that a doctor obtains about  
 7 a patient remains the property of the patient.  
 8 However, the patient may, in certain circumstances,  
 9 authorise the doctor to share it."  
 10 And then further discussion in relation to that.  
 11 Then the remainder of this chapter deals with  
 12 the -- what are said to be the exceptions to the  
 13 principle. Just note at page 33 the heading "Security  
 14 of storage and access", and the guidance that:  
 15 "The doctor must ensure, as far as he can, that  
 16 all medical information is kept in a secure place."  
 17 That's the BMA's 1988 guidance.  
 18 There is then, I won't turn to it, but the  
 19 patient's charter or the first version of the  
 20 patient's charter was published by the NHS in  
 21 October 1991, and that talks about the obligation on  
 22 NHS staff to keep medical records confidential.  
 23 Then we have some specific guidance from the GMC  
 24 on professional confidence in the early 1990s.  
 25 So that's BMAL0000102.

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1 records ... which they keep or to which they have  
 2 access, are protected by effective security systems".  
 3 And then we can see various examples in terms of  
 4 exceptions on the right-hand side, so "Disclosure in  
 5 relation to the clinical management of a patient":  
 6 "In exceptional circumstances [paragraph 7]  
 7 a doctor may consider it undesirable, for medical  
 8 reasons, to seek a patient's consent to the disclosure  
 9 of confidential information."  
 10 And further guidance there given out.  
 11 But stress that that's exceptional.  
 12 Then we see some of the other examples:  
 13 disclosure required by statute.  
 14 Paragraph 11:  
 15 "Rarely cases may arise in which disclosure in  
 16 the public interest may be justified, for example  
 17 a situation in which the failure to disclose  
 18 appropriate information would expose the patient, or  
 19 someone else, to risk of death or serious harm."  
 20 Then if we go over the page, we see at  
 21 paragraph 16, "Disclosure after a patient's death":  
 22 "The fact of a patient's death does not of  
 23 itself release a doctor from the obligation to  
 24 maintain confidentiality."  
 25 So that's the GMC's 1991 guidance.

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1 Sir, we can see it's guidance for doctors on  
 2 professional confidence, revised edition, published  
 3 November 1991. And if we go to the next page, we can  
 4 see at the very top of the left-hand side:  
 5 "This text replaces paragraph 76 to 85 in the  
 6 GMC's publication Professional Conduct and Discipline:  
 7 Fitness to Practise."  
 8 So this essentially extracted from the more  
 9 general Blue Book type guidance and published in the  
 10 form of a specific keys of guidance on  
 11 confidentiality, a similar text.  
 12 Paragraph 1, under the heading "Principles":  
 13 "Patients are entitled to expect that the  
 14 information about themselves or others which a doctor  
 15 learns during the course of a medical consultation,  
 16 investigation or treatment, will remain confidential.  
 17 Doctors therefore have a duty not to disclose to any  
 18 third party information about an individual that they  
 19 have learned in their professional capacity, directly  
 20 from a patient or indirectly, except in the cases  
 21 discussed ... below."  
 22 And then we can see paragraph 3 talks about  
 23 doctors carrying "prime responsibility for the  
 24 protection of information", and must "take steps to  
 25 ensure, as far as lies in their control, that the

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1 I won't go to it, because really these all  
 2 largely say the same thing, but invite you to note  
 3 that the BMA in its 1993 publication, which we've  
 4 looked at this morning, has a section on  
 5 confidentiality.  
 6 And then the next piece of specific GMC guidance  
 7 was issued in April 1999. That's at RCGP0000520\_107.  
 8 You'll see there it's entitled  
 9 "Confidentiality: Providing and Protecting  
 10 Information", April 1999.  
 11 If we go to page 3, second paragraph:  
 12 "Doctors hold information about patients which  
 13 is private and sensitive. This information must not  
 14 be given to others unless the patient consents or you  
 15 can justify the disclosure. Guidance on when  
 16 disclosures may be justified are discussed in this  
 17 booklet."  
 18 Then if we go over the page, we can see the  
 19 principles, again, reasonably well established by this  
 20 time. So the right to confidentiality articulated in  
 21 paragraph 1. And then various exceptions in which  
 22 confidential information may be disclosed set out in  
 23 the followed paragraphs, so where there's consent.  
 24 If we go to page 7, we can see under the heading  
 25 "Sharing information with others providing care", then

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1 this talks about sharing of information amongst  
 2 colleagues or where care is provided by a team of  
 3 doctors and other healthcare workers. That's  
 4 paragraph 13.  
 5 Then we do get a reference to, for example,  
 6 a secretary in paragraph 14:  
 7 "Where patients have consented to treatment,  
 8 their explicit content to disclosure is not always  
 9 needed before relevant information is shared within  
 10 a team in order to allow that treatment to be  
 11 provided. For example, explicit consent would not be  
 12 needed for a general practitioner may disclose  
 13 relevant information to a medical secretary who will  
 14 type a referral letter, or physician may make relevant  
 15 information available to a radiologist when requesting  
 16 an X-ray, unless the patient objects."  
 17 So that's the GMC's suggested approach in 1999.  
 18 Whether that's an accurate reflection of the  
 19 principles in relation to confidentiality may be  
 20 another matter. And, of course, may depend upon the  
 21 context.  
 22 I don't think there's anything else in this  
 23 document which deals with the specific example, sir,  
 24 that you raised. Ah, note, there's a reference to  
 25 disclosure for administrative purposes, but in fact

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1 available to subsequent clinicians who are treating  
 2 you. And the suggestion there is that, in the case of  
 3 an ongoing condition, it should be available, to  
 4 a subsequent clinician.  
 5 It might be thought to follow that if there is  
 6 a congenital condition, then that would require, if it  
 7 were to be honoured, those records of all treatment,  
 8 from the date of birth onwards, to be kept and  
 9 retained for that purpose.  
 10 It wasn't addressing retention directly, it was  
 11 looking at the question of confidentiality. But the  
 12 words would suggest that that is the principle being  
 13 put forward.  
 14 Have we got anything else on that?  
 15 **MS RICHARDS:** Not in the material that we're looking at  
 16 today, no. Again, we are looking more broadly at  
 17 issues relating to retention of records, so we can  
 18 pick up on the point that you've made, sir, and see  
 19 whether there is any guidance on the retention of  
 20 records which looks as it from that perspective. So  
 21 the passing on of care to other clinicians.  
 22 But there's nothing I can think of at the  
 23 moment, sir.  
 24 The next topic, then, that guidance relates to  
 25 is the question of medical research. If I can start

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1 it's not dealing with the issue which you raised, sir.  
 2 Then if we go to page 14, we can then see some  
 3 guidance in relation to disclosures without patient  
 4 consent, but again, it's the fairly well established  
 5 examples where there are -- there's a legal  
 6 requirement so to do, direction of the court. And  
 7 then the next page, paragraph 38:  
 8 "Disclosures may be justified where a failure to  
 9 disclose information may expose the patient or others  
 10 to a risk of death or serious harm."  
 11 So, fairly exceptional circumstances articulated  
 12 there.  
 13 Those are the principal pieces of guidance from  
 14 the seventies, eighties and nineties, and indeed to  
 15 some extent in the earlier materials, in relation to  
 16 confidentiality.  
 17 There is some specific guidance in relation to  
 18 the confidentiality of medical information relating to  
 19 children and, again, there making it clear it's  
 20 essentially the same principles but that medical  
 21 information may be shared with parents or guardians.  
 22 **SIR BRIAN LANGSTAFF:** Now just one query. You may not be  
 23 able to answer this without looking further, but there  
 24 is a reference in one of the earlier documents which  
 25 you have just shown me to medical records being made

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1 with the 1947 Nuremberg Code, that is at RLIT0000372.  
 2 We can see just below the heading "The Nuremberg Code  
 3 (1947)", it says this:  
 4 "The judgment by the war crimes tribunal at  
 5 Nuremberg laid down 10 standards to which physicians  
 6 must conform when carrying out experiments on human  
 7 subjects."  
 8 Then we see set out those basic principles,  
 9 which are said to be observed in order to satisfy  
 10 moral, ethical and legal concepts. 1 is, for present  
 11 purposes, the most important, although I will go  
 12 through all of them. 1 is:  
 13 "The voluntary consent of the human subject is  
 14 absolutely essential. This means that the person  
 15 involved should have legal capacity to give consent;  
 16 should be so situated as to be able to exercise free  
 17 power of choice, without the intervention of any  
 18 element of force, fraud, deceit, duress, overreaching,  
 19 or other ulterior form of constraint or coercion; and  
 20 should have sufficient knowledge and comprehension of  
 21 the elements of the subject matter involved as to  
 22 enable him to make an understanding and enlightened  
 23 decision. This latter element requires that before  
 24 the acceptance of an affirmative decision by the  
 25 experimental subject there should be made known to him

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the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."

Then, whilst we're on this document, I'll just read through the further principles.

"2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by methods or means of study, and not random and unnecessary in nature.

"3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history or the disease of other problem under study that the anticipated results justify the performance of the experiment.

"4. The experiment should be conducted so as to avoid all unnecessary physical and mental suffering and injury.

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believe, in the exercise of good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject."

Those, sir, are the Nuremberg principles. We then come in 1964 to the Declaration of Helsinki, RLIT0001505. We can see it was adopted by the 18th World Medical Assembly in June 1964.

We see reference in the second paragraph to the Declaration of Geneva and the health of the patient being the first consideration, and then the fourth paragraph above the heading "Basic principles":

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

We'll see that distinction drawn in a lot of the guidance in relation to research, sir, although with a recognition in some pieces of guidance that it's an easy enough distinction to draw in practice -- to describe in principle, but not so easy to determine in

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"5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

"6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment."

Then over the page:

"7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

"8. The experiment should be conducted only by scientifically qualified persons."

Then reference to the highest degree of skill and care:

"9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where the continuation of the experiment seems to him to be impossible.

"10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to

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practice.

Then basic principles:

"Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts."

Then I won't read them all out:

"3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

"4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or others."

Then if we go over the page, so those were the basic principles, and we then see II deals with the "Clinical research combined with professional care", and III with "Non-therapeutic clinical research".

So "Clinical research combined with professional care", at the top of the page, says this:

"In the treatment of the sick person the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

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1 "If at all possible, consistent with patient  
2 psychology, the doctor should obtain the patient's  
3 freely given consent after the patient has been given  
4 a full explanation."  
5 Then:  
6 "2. The doctor can combine clinical research  
7 with professional care, the objective being the  
8 acquisition of new medical knowledge, only to the  
9 extent that clinical research is justified by its  
10 therapeutic value for the patient."  
11 So that, as it were, is research in the context  
12 of actually providing therapeutic care to the patient  
13 and that scenario, again, recognises the importance of  
14 the patient receiving the full explanation.  
15 Then we have "Non-therapeutic clinical  
16 research", paragraph 2:  
17 "The nature, the purpose and the risk of  
18 clinical research must be explained to the subject by  
19 the doctor.  
20 "3a. Clinical research on a human being cannot  
21 be undertaken without his free consent after he has  
22 been informed ...  
23 "3b. The subject of clinical research should be  
24 in such a mental, physical and legal state as to be  
25 able to exercise fully his power of choice.

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1 page and, if we go over and look at paragraph 9, so  
2 again this is part of the basic principles:  
3 "In any research on human beings, each potential  
4 subject must be adequately informed of the aims,  
5 methods, anticipated benefits and potential hazards of  
6 the study and the discomfort it may entail. He or she  
7 should be informed that he or she is at liberty to  
8 abstain from participation in the study and that he or  
9 she is free to withdraw his or her consent to  
10 participation at any time."  
11 Then if we go to the next page, we can see the  
12 distinction retained between medical research combined  
13 with professional care, sometimes called clinical  
14 research, and then non-therapeutic biomedical research  
15 involving human subjects, sometimes called  
16 non-clinical research. And then just looking at the  
17 clinical research, paragraph 5, we see there,  
18 contemplating the possibility of not obtaining  
19 informed consent, but it says:  
20 "If the doctor considers it essential not to  
21 obtain informed consent, the specific reasons for this  
22 proposal should be stated in the experimental protocol  
23 for transmission to the independent committee."  
24 There's a later amendment in relation to  
25 research on children, but I'm not going to go to that

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1 "3c. Consent should, as a rule, be obtained in  
2 writing."  
3 Then:  
4 "4a. The investigator must respect the right of  
5 each individual to safeguard his personal integrity  
6 ...  
7 "4b. At any time during the course of clinical  
8 research the subject or his guardian should be free to  
9 withdraw permission for the research to be continued."  
10 Then:  
11 "The investigator or the investigating team  
12 should discontinue the research if in his or their  
13 judgement, it may, if continued, be harmful to the  
14 individual."  
15 That's the 1964 text for the Declaration of  
16 Helsinki. It is, as our expert group explained,  
17 a document that has been amended over the years and  
18 I'm not going to go through all the various iterations  
19 but that's it in its original form.  
20 Perhaps the only variation or amendment I will  
21 show you is the 1975 amendment, which we have at  
22 RLIT0001506. Sir, we'll see this took the text to the  
23 Declaration of Helsinki and revised it in the 29th  
24 World Medical Assembly in October 1975. We can see  
25 the heading "Basic principles" at the bottom of this

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1 now.  
2 If we then look at RLIT0001349, please, Soumik.  
3 We can see here a publication or statement by the  
4 Medical Research Council in 1964, "Responsibility in  
5 Investigations on Human Subjects. If we pick it up,  
6 left-hand column, fourth paragraph down, we can see  
7 again this distinction being drawn between the two  
8 types of research:  
9 "A distinction may legitimately be drawn between  
10 procedures undertaken as part of patient-care which  
11 are intended to contribute to the benefit of the  
12 individual patient, by treatment, prevention, or  
13 assessment, and those procedures which are undertaken  
14 either on patients or on healthy subjects solely for  
15 the purpose of contributing to medical knowledge and  
16 are not themselves designed to benefit the particular  
17 individual on whom they are performed. The former  
18 fall within the ambit of patient-care and are governed  
19 by the ordinary rules of professional conduct in  
20 medicine; the latter fall within the ambit of  
21 investigations on volunteers."  
22 And then if we look at the heading "Procedures  
23 Contributing to the Benefit of the Individual", so  
24 this first category, what we see there set out  
25 wouldn't necessarily accord with what we've seen

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1 elsewhere in relation to consent, so if we pick it up  
2 six lines down:  
3 "Provided ... that the medical attendant is  
4 satisfied that there are reasonable grounds for  
5 believing that a particular new procedure will  
6 contribute to the benefit of that particular patient,  
7 either by treatment, prevention, or increased  
8 understanding of his case, he may assume the patient's  
9 consent to the same extent as he would were the  
10 procedure entirely established practice."

11 So, sir, you may wish to consider no doubt at  
12 some stage the extent to which that statement sits  
13 with the broader ethical principles and norms that  
14 we've had articulated elsewhere, not least by the  
15 expert group.

16 Then if we go to the next page, we see however  
17 at the top of the next -- I'm sorry, Soumik it's  
18 actually the previous page, top of the right-hand  
19 column, my apologies.

20 So we do see, however, in the second in line of  
21 the top of the page:

22 "That it is both considerate and prudent to  
23 obtain the patient's agreement before using a novel  
24 procedure is no more than a requirement of good  
25 medical practice."

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1 instruments we've looked at, still less with the  
2 exposition of principles we've heard, seems to draw  
3 a distinction between these two categories of  
4 research. And that distinction is well established  
5 but seems to be saying that the consent of the  
6 participant is not really required and can be assumed  
7 for the purposes of the clinical research and that  
8 it's all a judgment for the -- a decision for the  
9 judgment of the doctor.

10 **SIR BRIAN LANGSTAFF:** Yes, it leaves it as a matter of  
11 "good medical practice" as opposed to ethical  
12 obligation.

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** And it doesn't have any sense of the  
15 importance of partnership or autonomy and choices, and  
16 so on.

17 **MS RICHARDS:** It does not. Of course, it's dated  
18 July 1964, but we have seen earlier references than  
19 that to principles of consent, not least for the  
20 Medical Defence Union material from the 1950s.

21 And, indeed, the legal requirements, as a bare  
22 minimum.

23 The latter part of the 1960s -- we can take that  
24 document down, thank you, Soumik.

25 The latter part of the 1960s saw a call for the

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1 So seems to be suggesting here, I mean in the  
2 context of this type of research, having said that  
3 previously you can assume the patient's consent, that  
4 if it's something novel, it may be good medical  
5 practice to obtain the patient's agreement.

6 Not precisely clear what's meant by that.

7 If we go now to the next page we then see the  
8 heading "Procedures not of Direct Benefit to the  
9 Individual", and here requirements in relation to  
10 consent are more clearly set out.

11 So if we look at the third paragraph under that  
12 heading, you can see a reference there to "true  
13 consent":

14 "By true consent is meant consent freely given  
15 with proper understanding of the nature and  
16 consequences of what is proposed."

17 And then if we go to the right-hand column on  
18 the same page, top half of the page, third paragraph:

19 "Investigations that are of no direct benefit to  
20 the individual require, therefore, that his true  
21 consent to them shall be explicitly obtained."

22 And then we see the reference to adequate  
23 explanation.

24 So, as at 1964 the Medical Research Council, not  
25 necessarily consistent with the international

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1 establishment of an ethical review process, and we put  
2 a reference in the notes to a number of documents that  
3 deal with the establishment of ethics committees.

4 I'm not proposing to go to those.

5 If we come, then, to 1970, again, I'm not going  
6 to go back to this but we looked at the BMA's medical  
7 ethics publication from 1970 this morning, and that  
8 includes -- without any particular comment, but it  
9 includes the Declaration of Helsinki, which, as we  
10 saw, talked about the need for consent before  
11 conducting research on patients.

12 We then come, in the early part of the 1970s, to  
13 RCPH0000545. This is a publication by the Royal  
14 College of Physicians in July of 1973. It's a  
15 committee on the supervision of ethics of clinical  
16 research investigations in institutions.

17 If we go to the third page, please, Soumik, it  
18 refers to an earlier report. Again I think we've  
19 given the references to this in our note. And then  
20 this talks a little more about the role of ethics  
21 committees in broad terms, so under the heading  
22 "Introduction" it tells us that:

23 "The objective of ethical committees is to  
24 safeguard patients, healthy volunteers and the  
25 reputation of the profession and its institutions in

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1 matters of clinical research investigation."  
 2 Then, if we go to the next page, we can see the  
 3 heading "Explanations to subjects or patients who may  
 4 participate in clinical research investigations".  
 5 Paragraph (a):  
 6 "Patients. Wherever the research investigation  
 7 is not expected or is not intended to benefit the  
 8 individual, a full explanation of the proposed  
 9 procedure should be given and the patient must feel  
 10 completely free to decline to participate or to  
 11 withdraw at any stage."  
 12 So that's the category with no clinical benefit  
 13 to the individual.  
 14 We then look at the third paragraph:  
 15 "Where the research is intended to benefit the  
 16 patient, although consent should ordinarily be sought,  
 17 there are sometimes circumstances in which it is  
 18 inappropriate or even inhumane to explain the details  
 19 and seek consent. Ethical committees should examine  
 20 such cases with particular care."  
 21 This might be thought to be a minor advance on  
 22 the 1964 document that we looked at, because it  
 23 suggests that, in relation to research intended to  
 24 benefit the patient, so the clinical research, consent  
 25 should ordinarily be sought, so it at least gives it

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1 Helsinki.  
 2 Then, if we look at the last paragraph on this  
 3 page, it says:  
 4 "Two broad groups of subjects [subjects as in  
 5 participants in research] have been recognised. The  
 6 first group consists of both patient and non-patient  
 7 volunteers for whom the procedure is not of direct  
 8 therapeutic benefit; the second comprises patients who  
 9 may be anticipated to derive direct benefit."  
 10 So the same distinction there being drawn:  
 11 "Most of the initial studies with a substance  
 12 are performed on subjects in the first group. The  
 13 nature of the trial, its objectives and likely adverse  
 14 effects should be explained to each volunteer [who is  
 15 asked to freely give their consent]."  
 16 Then it says:  
 17 "In patients of the second group [so where  
 18 there's an anticipated direct benefit to the patient]  
 19 the validity of the results of certain types of  
 20 investigation may be reduced by full disclosure to  
 21 patients ... and a certain latitude in explanation may  
 22 be exercised. The information given to the patient is  
 23 at the discretion of the clinician in charge of the  
 24 trial."  
 25 Go over the next page:

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1 as the starting point, although we then have here  
 2 articulated, in very broad terms, a potential  
 3 exception. Difficult to think of examples in the real  
 4 world where it might be thought "inhumane" to explain  
 5 the details.  
 6 **SIR BRIAN LANGSTAFF:** Well, it looks as though it is  
 7 suggesting that the basic approach should be:  
 8 number one, get the consent of your patient, fully  
 9 informed; number two, if you don't think that's  
 10 appropriate or if you think it might be inhumane, you  
 11 must go to the Ethics Committee.

12 **MS RICHARDS:** Exactly.

13 **SIR BRIAN LANGSTAFF:** So either way, there's a check.

14 **MS RICHARDS:** Yes, precisely. A safeguard.

15 So that was the RCP Committee's 1973  
 16 publication.

17 If we just briefly look at RSME0000025, please,  
 18 Soumik. This is a 1977 publication by the Association  
 19 of the British Pharmaceutical Industry. The date is  
 20 on page 3. It's largely focusing on matters such as  
 21 the design of clinical trials and so on. But it's  
 22 right to note, if we go to page 11, under the heading  
 23 "Ethical considerations" you'll see that the  
 24 recommendation of the ABPI was that the principles  
 25 adopted should accord with the Declaration of

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1 "But unless there are any real medical  
 2 contraindications, it is wise to obtain consent after  
 3 describing the study to the individual."  
 4 So again, we see a range of different shades of  
 5 meaning in these publications, in terms of what  
 6 information should or shouldn't be given to the  
 7 participant in a study in which it's the doctor's  
 8 judgment that they may derive some benefit.  
 9 Then we can go next to the BMA's Handbook of  
 10 Medical Ethics from 1980, which is at BMAL0000087. If  
 11 we go to page 22, we can see the heading at the bottom  
 12 of the page "Research in human subjects". Then if we  
 13 go to the next page, there's discussion -- well,  
 14 actually, we'll just pick it up at the top of the  
 15 page. It says:  
 16 "Most patients trust their doctors and will  
 17 consent to any proposal. Experimental procedures are  
 18 nearly always too technical for patients or  
 19 non-experts to understand. For practical purposes,  
 20 therefore, the doctor concerned carries a moral  
 21 responsibility for the investigations that are, or are  
 22 not, proposed to his patient or volunteer."  
 23 Quite what's meant by "moral responsibility" in  
 24 that context is not clear.  
 25 Then 4.3, it talks, in the second line:

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1 "... volunteers and patients are best protected  
2 by ethical conduct. The subjects' interests must come  
3 first."

4 Then we have reference to controlled clinical  
5 trials, 4.4, where at line 4:

6 "Consent must be obtained from the individual  
7 subjects ..."

8 There's then reference to research on children  
9 and the processes for clinical trials of new drugs.  
10 So it's not, at this stage for the BMA, the fullest or  
11 the greatest of respect, the clearest exposition of  
12 the underlying ethical principles.

13 Again, in 1980, there was a specific publication  
14 relating to research involving children. This is at  
15 RLIT0000658 please, Soumik. We can see it's entitled  
16 "Guidelines to aid ethical committees considering  
17 research involving children".

18 It's been produced by a Working Party of the  
19 British Paediatric Association, and then we see this:

20 "These guidance presume that four premises are  
21 accepted.

22 "[1] That research involving children is  
23 important for the benefit of all children and should  
24 be supported and encouraged, and conducted in an  
25 ethical manner.

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1 of moral problems associated with research on  
2 children.

3 On the second page -- in fact, it's the bottom  
4 of the first page and then the second page --  
5 particularly picks upon the British Paediatric  
6 Association document. If we just look at the bottom  
7 half of this page, please, Soumik, left-hand side. We  
8 can see in the last seven or eight lines of that long  
9 paragraph a number of questions being posed in this  
10 editorial about the moral acceptability of taking  
11 degrees of risk in relation to children.

12 As I say, sir, really one needs to read the full  
13 two documents, I think, to understand the nuances but  
14 it's an articulation of concern about the state of the  
15 guidance in relation to the ethics of conducting  
16 research on children.

17 **SIR BRIAN LANGSTAFF:** Well, on the left-hand side it  
18 focuses upon the definition which we looked at, which  
19 had me thinking, as you've been speaking, which  
20 describes the negligible risk as a risk less than one  
21 would have in normal life, which is a bit odd because  
22 one has to assume the subject remains alive during the  
23 research, and so there will be a normal life, and the  
24 only question is what effect the research has. If it  
25 has no additional effect, then I don't see how one can

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1 "[2] That research should never be done on  
2 children if the same investigation could be done on  
3 adults.

4 "[3] That research which involves a child and is  
5 of no benefit to that child (non-therapeutic  
6 research), is not necessarily either unethical or  
7 illegal.

8 "[4] That the degree of benefit resulting from  
9 a research should be assessed in relation to the risk  
10 of disturbance, discomfort, or pain -- the  
11 'Risk/Benefit ratio'."

12 Then there is -- and I'm not going to take time  
13 going through the detail of it because it really has  
14 to be read really carefully in full to follow what's  
15 being set out, but there is then guidance as to what's  
16 meant by risk, what's meant by benefit and how the  
17 risk/benefit principle could be applied.

18 It's perhaps relevant to note that there's some  
19 criticism of the position in relation to guidance on  
20 research involving children. A couple of years later  
21 in the Journal of Medical Ethics, if we go to  
22 RLIT0001381, please, Soumik. Again, I'm not, sir,  
23 going to go through the detail of this, it needs to be  
24 read in full.

25 But it's an editorial which talks about a range

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1 say there's any risk at all, let alone negligible  
2 risk. But it's a curious definition.

3 **MS RICHARDS:** It is curious. The extent to which the  
4 previous guidance, the British Paediatric Association  
5 guidance, influenced research in practice, in the  
6 early part of the 1980s is not, I have to say, very  
7 clear. There's much more recent guidance in relation  
8 to the ethics of conducting and the parameters of  
9 conducting research on children, which our expert  
10 group referred to, which is very clear in terms of the  
11 circumstances in which research on children is  
12 permissible.

13 **SIR BRIAN LANGSTAFF:** Absolutely.

14 **MS RICHARDS:** But the position in, certainly the early  
15 part of the 1980s, the materials that we found are not  
16 clear.

17 **SIR BRIAN LANGSTAFF:** Well, it certainly is just a debate  
18 which may end up going nowhere in that paragraph all  
19 about what on earth is meant by negligible risk and  
20 what it is.

21 **MS RICHARDS:** Then, again, there are -- and I'm not going  
22 to go to the various versions, but the position in  
23 relation to research is expanded from time to time in  
24 the various handbooks published by the British Medical  
25 Association. The next document of substance, however,

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really is some guidelines published by the Royal College of Physicians in 1984 and that is RCPH0000014. So we can see it's Guidelines on the Practice of Ethics Committees in Medical Research, and date below is September 1984.

If we go to page 11, so this is talking about giving guidance to ethics committees rather than directly to clinicians but it helps to understand what's said to be the ethical principles that should underpin research. So we can see:

"The objectives of Ethics Committees. The objectives are to facilitate medical research in the interests of society, to protect subjects of research from possible harms, to preserve their rights, and to provide reassurance to the public that this is being done."

Then there are a number of points set out. If we just pick it up at the bottom of the page:

"-- every effort will be made to inform prospective subjects of the objectives and consequences of their involvement, and particularly of identifiable risks and inconvenience."

Then if we go to the top of the next page:

"-- any arrangement to delegate consent has adequate justification and appropriate safeguards will

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large but sometimes very small and both should be subject to review ..."

Then if we look at the next -- so that's a division into non-experimental and experimental, and then we see the more familiar distinction in the next paragraph:

"Research may also be classed as (a) research which may benefit the individual participant (therapeutic research) and (b) research that will not or is unlikely to benefit the individual participant (non-therapeutic research). Ethics Committees will naturally give close attention to non-therapeutic research."

Then the rest of this deals largely with matters of constitution of the committee and modes of working.

If we go to page 22 we then pick up consent as a topic. So paragraph 8:

"Obtaining true (or informed or understanding) consent is central to the ethical conduct of clinical investigation. The terms 'true' and 'informed' imply that the subject has all the information, in a form that is comprehensible, to enable him or her to make a proper judgment. The obvious impracticability of this in many cases has led to the saying 'there is no such things as informed consent', which is less than

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be instituted to ensure that the rights of the subjects will in no way be abused."

Again, not entirely clear what's envisaged by that, but at least contemplated some form of safeguard.

Then, if we go to the next page, under the heading "Definition of a research project", it says:

"Definition of a research project that should be put before an Ethics Committee continues to present difficulties. Any investigation in man designed to develop or contribute to knowledge raises ethical issues, though these may sometimes be quite small. Since any such study may involve subordination of at least the immediate interest of the individual participant to the objective of the advancement of knowledge, all should be subject to ethical review."

Then we see the distinction drawn between the two major classes of research, that which involves -- defined here in slightly different ways from how we've seen it previously:

"... that which involves making observations without any interference with the subject (non-experimental), eg use of case records, and investigations that involve interference (experimental). Both raise ethical issues, sometimes

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fair."

Then it talks about different ways of obtaining consent:

"Modes of consent include ..."

Then we see a distinction between trivial or minimum procedures where verbal consent may be sufficient, and more substantial procedures, where it is suggested there should be an explanatory document.

Then if we go to the next page, if we pick it up at (h):

"The question remains whether there are some undoubted research activities that can be carried out without consent of the patient, eg

"(i) minor procedures that entail no, or negligible, discomfort to a patient and where to ask for consent would be more likely to cause distress than to proceed without it. In such cases the criterion has been proposed that the procedure should not cause appreciably more discomfort than would be experienced by a patient undergoing routine diagnostic procedures for patient care ..."

Then the next category that's discussed is:

"major procedures where to attempt to obtain 'informed' consent can be impossible or devastating, eg unconscious patients ..."

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1 That may be comprehensible. Then we get:  
2 "... acute grave illness, inability to  
3 comprehend. In all cases an Ethics Committee will  
4 give very close consideration to any proposal to  
5 proceed without consent and will satisfy itself that  
6 the decision not to seek consent from an individual is  
7 ethically acceptable."

8 Then at the bottom of the page we see:  
9 "use of patient records presents real ethical  
10 issues. Care should be taken to ensure that such use  
11 is in accordance with current codes of practice ..."

12 There's then a discussion on research involving  
13 children, and there's a suggestion that the parent or  
14 guardian can consent. And that's further explained.

15 Again, it doesn't really provide an enormous  
16 amount of additional practical assistance in  
17 understanding the approach, other than the subtext  
18 appears to be, or the basic principle appears to be  
19 that, save in certain identifiable circumstances,  
20 consent should be obtained.

21 Then I think perhaps the other -- or, the next  
22 document that's worth looking at is a further document  
23 produced by the APBI in 1986.

24 SBTS0000005\_006, please, Soumik.

25 So this is the "APBI Report on Good Clinical

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1 the comparator drugs (including placebo), benefits and  
2 risks and where appropriate, an explanation of  
3 alternative standard recognised medical therapy has  
4 been given."

5 And I'm not going to go through the detail  
6 of it, but if we go to the next page, there's then  
7 a more detailed exposition of the elements of informed  
8 consent.

9 Then I think the remainder of the document deals  
10 with other matters relating to the conduct of clinical  
11 trials, which are not particularly material for the  
12 Inquiry's purposes.

13 Then the next document which may be of  
14 assistance is a further report of the Royal College of  
15 Physicians. RCPH0000232.

16 This is published January 1990, it's entitled  
17 "Research involving patients". And then, if we go to  
18 page 9, under the heading "Definitions" we see  
19 a discussion of different types of research. So 2.2:

20 "When an activity is undertaken solely with the  
21 intention of benefiting an individual patient and  
22 where there is a reasonable chance of success, the  
23 activity may be considered to be part of 'medical  
24 practice'."

25 Pausing there, that would suggest that it would

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1 Research Practice", and we see the date, July '86.

2 If we turn to page 8, bottom of the page talks  
3 about "Ethics Committees", and their objectives:

4 "The objectives of ethics committees are to  
5 protect subjects of research, to preserve their rights  
6 and to provide public reassurance. They are also  
7 protective of investigators and institutions."

8 Then if we go to the next page, we see an  
9 endorsement of, amongst other matters, the Declaration  
10 of Helsinki. And then we get the topic informed  
11 consent:

12 "The purpose of informed consent is to ensure  
13 that the person who is the subject of human  
14 experimentation in any form is made fully aware of  
15 that experimentation of his/her own rights and  
16 responsibilities within that experiment. Properly  
17 given informed consent protects the subject,  
18 investigator and the institution. Subjects should  
19 have free opportunity for information and be able to  
20 volunteer without pressure to participate. Equally  
21 they should be free to change their minds."

22 Then there's a discussion about how consent to  
23 be obtained. Picking it up fourth line down:

24 "Written or verbal consent should be obtained  
25 only after a full explanation of the study, its aims,

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1 bring with it all the normal requirements of good  
2 practice.

3 Then 2.3:

4 "In contrast, where an activity involving  
5 a patient is undertaken with the prime purpose of  
6 testing a hypothesis and permitting conclusions to be  
7 drawn in the hope of contributing to general  
8 knowledge, this is 'research'. The fact that some  
9 benefit, expected or unexpected, may result from the  
10 activity does not alter its status as research."

11 So a slightly different definition here of the  
12 two forms of -- two principal forms of research.

13 Then if we look at the next paragraph, there's  
14 a recommendation -- sorry, a recognition that it's not  
15 always easy to distinguish between the two.

16 "The distinction between 'medical practice' and  
17 'research' is often less clear than is suggested above  
18 because both are practiced simultaneously. A doctor  
19 who makes careful records of the outcome of treatment,  
20 the effectiveness of a diagnostic investigation, or  
21 the use of some resource in the course of his ordinary  
22 work may be considered to be engaging in quality  
23 control -- now often referred to as 'medical audit' --  
24 rather than in research. In general, however, where  
25 an effort is made to formalise the acquisition of

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information gained in the course of medical practice this may be considered to be at least a component of research. A retrospective review of case records is usually to be regarded as research, particularly where this is undertaken systematically according to a formal protocol or when an individual other than the person who constructed the records undertakes the analysis. Any activity which affects the patient in any way which is additional to ordinary medical practice is to be regarded as research."

There's then a discussion about innovative treatment.

Then if we go to -- where's the discussion of consent? Yes, if we see, if we go to page 22.

Sorry, if we go back, first of all, to pages 16 to 17, Soumik. My apologies.

I'm not again going to go through the detail of this but I'm just going to flag up what we have here.

You'll see, sir, the heading on the left side "Risk/benefit analysis", and there's then quite a detailed discussion about how someone proposing research should approach the question of risk/benefit analysis.

And that continues for the rest of this page and over the next page. I don't want to read it all out,

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"... which is totally without risk or intrusiveness; (2) innocuous research into comprehension; (3) examination of anonymous specimens; (4) research based on medical records; and (5) research into the management of unexpected overwhelming emergencies."

So those are said to be the types of scenario in which those important rules may not apply. And then 7.8 again talks in now familiar terms about consent:

"For consent to be valid it is self-evident that it must be offered voluntarily and based on adequate understanding."

Four lines down:

"Some research is complex but we believe it must be possible for researchers to achieve adequate understanding on the part of patients of the reason for the research and the nature of what is intended, including any benefits and hazards, before consent can be sought and the patient enrolled."

Then, again, there's more guidance as to methods of obtaining consent, provision of information sheets, giving patients time to reflect, and so on.

And then, I'm not going to go to it but I invite you to note at page 26, sir, there's then a section on consent in children.

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but again, it merits careful consideration.

Then if we go to page 18, we can see in paragraph 5.23, the third paragraph, it talks about the role of the research ethics committee, it needs to do more than a mere risk/benefit analysis. So an analysis of probable benefits, comfort and safety of the participant and so on.

And then the issue of consent is then addressed on page 22. There's reference -- if you just look at the top of the page, first of all, there's reference to the Nuremberg Code.

And then, Soumik, exactly where you were before, bottom of the page. Under the heading "Consent", paragraph 7.6, there are two important rules for research involving patients: patients should know they are taking part in research; research involving a patient should only be carried out with the patient's consent.

So those are what are said to be the two important rules.

Then, perhaps inevitably, identified what's said to be special exceptions to these rules, which apply to:

"(1) observational research ..."

Top of the next page.

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So that's January 1990.

There was also then, further on the topic of research and children, a publication by the MRC, Medical Research Council, in January 1991 on The Ethical Conduct of Research on Children. I'll just put it briefly on screen so we can see it, but I'm not going to go to it in detail.

Soumik, it's MRCO0000585.

We've given the date of it in our note as January 1991. I think in fact it may have been December 1991, looking at this.

If we go to page 8, Soumik, there's a section on the right-hand side on the ethical case for including children in research. And there's a discussion there about consent at 6.1.3.

So 6.1.2 talks about the need for strict safeguards, and then 6.1.3 talks about the consent to be sought where a child has sufficient understanding to consent. And then reference to seeking -- also parental consent. And there's then a more detailed discussion of some statutory provisions, in particular under the Family Law Reform Act 1969, which I don't think is going to be particularly useful to you, sir.

I think probably the last document -- the last two documents that I'll refer you to on the issue of

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1 research, the first is the BMA's 1993 publication on  
 2 medical ethics.  
 3 So we've looked at this for other purposes  
 4 already.  
 5 Soumik, it's BMAL0000089. And if you could go,  
 6 please, to page 221, I think.  
 7 So there's a fairly detailed chapter in this  
 8 1993 guidance from the BMA on research. If we go to  
 9 page 223, under the heading "Definitions", bottom of  
 10 the page, it talks about how:  
 11 "Confusion sometimes arises from the wide range  
 12 of procedures covered by the term, 'research'.  
 13 Then bottom of the page talks about the division  
 14 into therapeutic and non-therapeutic research.  
 15 If we go over the page, we can see reference to  
 16 the Declaration of Helsinki, and the distinction  
 17 between therapeutic or non-therapeutic research.  
 18 Then in the last four lines of that first  
 19 section -- sorry, can we just go up a page, Soumik.  
 20 So in paragraph 8.2.1 the BMA says this:  
 21 "Despite the implication in the Declaration of  
 22 Helsinki, the distinction between therapeutic and  
 23 non-therapeutic research is often not at all clear,  
 24 with a consequent blurring of the moral focus."  
 25 And then we see 8.2.2 talks about

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1 diverges substantially from normal medical practice,  
 2 with the intention of gaining information which might  
 3 help future patients, the activity must be subject to  
 4 review by a local research ethics committee ..."  
 5 Then over the next page, under the heading  
 6 "Areas of overlap", the BMA says this:  
 7 "As has already been mentioned, some projects  
 8 overlap from one category into the other but where the  
 9 focus of attention is not solely the best interests of  
 10 the individual patient, treatment must be subject to  
 11 the rigorous standards required for research  
 12 projects."  
 13 So it could perhaps be summed up in a rather  
 14 simplistic way as this: if in doubt, assume that this  
 15 is something which requires the full panoply of  
 16 safeguards, in terms of Ethics Committee approval, and  
 17 so on.  
 18 There's then a more detailed discussion of  
 19 consent in the context of research from page 229  
 20 onwards. Bottom of the page:  
 21 "Research brings the risk of causing harm, in  
 22 the practical sense of possibly damaging or  
 23 disadvantaging a patient, and of doing wrong, in the  
 24 moral sense of ignoring the autonomy of that  
 25 individual. People are wronged if they are deprived

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1 non-therapeutic research and talks about how that must  
 2 be subject to full ethical review by local ethics  
 3 committees. And the subject's consent must be based  
 4 upon adequate information.  
 5 There's then a reference to innovative  
 6 treatments, and the BMA says:  
 7 "It is often unclear how new treatments and  
 8 techniques fit into the framework of ethical review.  
 9 At present they are sometimes seen as an extension of  
 10 the usual treatment, even though such treatments may  
 11 expose the patient to more than a minimal risk of  
 12 harm. However, they are often classified as  
 13 research."  
 14 Then if we go to the -- still under this heading  
 15 but the bottom of the next page. I think this may be  
 16 of some importance, sir, when you're assessing some of  
 17 the evidence you've heard from the clinicians about  
 18 their involvement in research:  
 19 "It is clear that where the clinician's  
 20 intention is to acquire new knowledge rather than  
 21 solely to care for the patient, the constraints  
 22 applicable to the conduct of research should apply."  
 23 Then it continues:  
 24 "Thus, in cases where a doctor proposes, for  
 25 an individual patient, a course of action which

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1 of choice or their values are transgressed on the  
 2 assumption that the best clinical outcome is  
 3 necessarily what is best for them. The possibility of  
 4 harm cannot be entirely eliminated from research but  
 5 by insisting that patients have adequate information  
 6 and choice about participation, we minimise the  
 7 possibility of wronging them."  
 8 There's then a discussion about the Nuremberg  
 9 Code. If we go to the next page, under the heading  
 10 "General principles", there's then a discussion of the  
 11 broad fundamental principles of consent, and it says:  
 12 "[It can be] seen the BMA generally lays great  
 13 emphasis on valid patient consent ..."  
 14 If we pick it up five lines down:  
 15 "The researcher should inform the subject about  
 16 potential benefits and risks of the procedure, why  
 17 it's proposed and the significance in terms of  
 18 advancing knowledge and the researcher's own stake (if  
 19 any) in proposing the procedure. Where patients are  
 20 offered choices, they need information about the  
 21 alternatives to the treatment recommended by their  
 22 doctor. When a clinical study is proposed patients  
 23 need to know about the advantages and shortcomings of  
 24 conventional treatments as well as the options in the  
 25 trial. In any situation, the more risky or invasive

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the procedure, the greater attention must be paid to the patient's understanding of it and consent to it."

Then there's a discussion about some particular issues that can arise in relation to randomised trials, and then reference, towards the bottom of the page, to the BMA's support for the general tenants of the Helsinki declaration. Then a discussion about information and information sheets in the context of research.

So there you'll see from the BMA's perspective in this 1993 publication, a clear emphasis being placed upon the importance of the fundamental principles of consent in the context of research, really, however that research might be classified.

Then we have detailed various other pieces of guidance in our note which touch on ethical principles governing the undertaking of research. I'm not going to go to any of the further documents, save to just draw to your attention, sir, a report by the GMC published in November 1998, which is talking about seeking patient's consent, the ethical considerations, and talks about the particular importance of obtaining consent from patients participating in research programmes.

Sir, that brings me to the last main topic for

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Nursing in the course of 1983. It talks about the term AIDS, it identifies the presenting symptoms, it refers -- if we just go a little further down the page -- to the syndrome having been reported mainly in male homosexuals having a large number of sexual partners, and a small number of haemophiliacs and intravenous drug abusers.

It then goes on to talk about certain precautions that could be taken in relation to protecting staff. If we look over the page, under the heading "Precautions to be taken", it refers to the hepatitis B precautions and says:

"The same precautions should be taken when dealing with a patient suffering from suspected AIDS, and should include avoiding contamination of the skin and mucous membranes with blood, blood products, secretions and excretions of AIDS sufferers or suspected sufferers."

Then various precautions then set out. Then the next paragraph:

"Nurses who are handling blood or blood products should be aware that risk is greater during the mixing of blood products in order to reconstitute them ready for administration."

Then it talks about the making available of

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today, which is looking at some of the specific guidance in the context of the ethical issues arising in the AIDS crisis in the 1980s. Perhaps we could take a short break as then pick that up afterwards.

**SIR BRIAN LANGSTAFF:** Let's have a break for some 20 minutes and come back 25 to 4.

(3.13 pm)

(A short break)

(3.35 pm)

**MS RICHARDS:** Sir, I'm going to look next at some documents and guidance, publications produced in the course of the 1980s, looking at what was said to be some specific ethical issues arising in the context of the AIDS crisis. The first document I'm going to go to doesn't really touch on the ethical issue, it's perhaps more relevant to matters relating to knowledge of risk of AIDS, but it's not a document I think we've previously looked at in an Inquiry hearing and therefore just worth drawing attention to more broadly.

It's HCDO0000019\_001. It's a document issued by the Royal College of Nursing, headed "Acquired Immune Deficiency Syndrome", and it's dated September 1983, so it's interesting to note that the first publication along these lines comes from the Royal College of

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facilities in the event of accidental contamination.

So not specifically an ethical guideline, but a publication recognising clearly there the association between blood, blood products and the transmission of AIDS.

I'm then going to -- I should note there are some similar publications about precautions to protect healthcare staff published by the Department of Health in the course of 1984. I'm not, however, proposing to go to those.

In terms of ethical issues, if we pick matters up with a publication from the BMA in 1985, BMAL0000010\_021. This is a BMA statement, second paragraph:

"The BMA Central Ethical committee recognises that the rapid spread of AIDS has raised problems of confidentiality in the minds of some doctors."

Then there's a reference to where someone is tested and is thought to have HIV, HTLV-III as a result of sexual transmission, there's a specific obligation of confidentiality under the terms of the National Health Service (Venereal Diseases) Regulations and then adds this:

"Unless the patient has given his consent, personal health data relating to him must not be

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disclosed to anyone for any purpose other than the health care of that patient, except where the disclosure is necessary to prevent the spread of infection.

"Accordingly, we have always accepted, that for the purpose only of preventing the spread of infection (and for no other reason) a doctor may in exceptional circumstances disclose relevant information with the consent of the patient. This is entirely in accordance with advice given by the Chief Medical Officer. Furthermore, our own discussions with experts treating AIDS cases, have shown that it is extremely rare for disclosures to be made without the consent of the patient."

That's a statement, in any event, published by the BMA in the course of 1985. That document itself is not dated, but we've got a press statement that appears to accompany it that's dated 13 December 1985.

**SIR BRIAN LANGSTAFF:** Is it intending to say "without the consent of the patient" in the third line there of the last paragraph?

**MS RICHARDS:** I'm just looking at the two versions we have. I am not sure, sir. I think it must be.

**SIR BRIAN LANGSTAFF:** Because if the patient has consented, there might -- and the consent is a proper

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booklets in total that were issued.

If we go to the next page, we can see the context is that this is a "Dear Doctor" letter from the Chief Medical Officer, it's dated 1st October 1985. And what had precipitated it was the introduction of the test for HTLV-III antibodies for screening purposes at regional transfusion centres. If we look at the bottom of this page, we can see the Chief Medical Officer saying:

"It is essential that all individuals who are found to have positive antibody tests receive counselling both in order that they may understand the meaning of results and to advise them how to avoid transmitting the infection to others."

Then, top of the next page, reference to potential availability of counselling services. And then the third paragraph, it says:

"The antibody test is an important tool, in the control of the spread of HTLV-III infection. If it is to be used effectively, very strict confidentiality must be maintained in respect of positive results ..."

So that's the accompanying "Dear Doctor" letter from the CMO. If we go to the next page we see the booklet itself. And if we go to page 7, again, there's emphasis there on the importance of

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consent, there might be thought to be no problem.

**MS RICHARDS:** Yes. Actually, if we look at the press comment, which is BMAL -- or press statement -- BMAL0000010\_020, sir, we can see there it's a slightly pithier statement but in similar terms and it's headed "Press Comment".

**SIR BRIAN LANGSTAFF:** Yes.

**MS RICHARDS:** There we say -- we see:

"We have always accepted, in accordance with legislation, that for the purpose only of preventing the spread of infection (and for no other reason) a doctor may in exceptional circumstances disclose relevant information without the consent of the patient."

So yes, I think it is intended to say that.

That was a BMA publication on AIDS and confidentiality in 1985.

If we then go to DHSC0000177, please, Soumik.

This is AIDS Booklet 2, produced by the DHSS:

"Information for doctors concerning the introduction of the HTLV-III antibody test."

We haven't got booklet 1 here, but that was general background information in relation to AIDS, as I recall. The date of this, we see from the bottom of the page, October 1985. And there are, I think, three

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counselling for seropositive individuals. And then if we go over the page we see the heading

"Confidentiality":

"The strictest confidentiality must be maintained when an HTLV-III antibody positive individual is identified."

Then we can see reference to the -- again what we saw from the BMA statement, the terms of the NHS (Venereal Diseases) Regulations.

"Unless the patient has given consent, personal health data relating to him must not be disclosed to anyone for any purpose other than for the health care of that patient, except where the disclosure is necessary to prevent the spread of infection. Disclosure of this information for purposes other than medical or public health reasons could lead to serious consequences for the informant. Adequate safeguards to protect individuals against unauthorised disclosure must be adopted."

So that's the Department of Health talking about confidentiality.

Then we can see, if we go to DHSC0003713\_013, please, Soumik.

This is booklet number 3. This is also autumn of '85, and this is guidance for surgeons,

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1 anaesthetists and dentists dealing with patients  
 2 infected with HTLV-III. And if we just go to page 8,  
 3 and I'm focusing only on those parts of the materials  
 4 that give rise to essentially broader ethical  
 5 questions but in the context of HIV:  
 6 "Confidentiality of health care data  
 7 "The strictest confidentiality must be  
 8 maintained when an HTLV-III antibody individual is  
 9 identified."  
 10 There's then reference to the same regulations.  
 11 Then it says:  
 12 "For all HTLV-III positive patients the normal  
 13 rules of medical confidentiality apply and unless the  
 14 patient has given his consent, personal health data  
 15 relating to him must not be disclosed to anyone for  
 16 any purpose other than the health care of that  
 17 patient, except where disclosure is necessary to  
 18 prevent the spread of infection."  
 19 And then we see the bit in square brackets at  
 20 the end of that paragraph:  
 21 "Normally it is inappropriate to test a patient  
 22 for HTLV-III antibodies without their consent unless  
 23 it is part of a clinical investigation of signs and  
 24 symptoms."  
 25 There appears to be a suggestion there that it

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1 tested ... on their own initiative and found positive  
 2 should be offered individual counselling and  
 3 psychosocial support."  
 4 Then it sets out information they should be  
 5 provided with:  
 6 "They should be informed that they are  
 7 infectious through sexual contact and through their  
 8 blood and semen. They should be encouraged to inform  
 9 their sexual partner(s) about the risk ... urged to  
 10 refrain from donating blood, plasma," etc, etc.  
 11 But there, the first sentence really, the  
 12 importance of informed consent is there stressed.  
 13 So that's what the World Health Organisation had  
 14 to say.  
 15 Then you can see the next publication by the BMA  
 16 at BMAL0000031\_024. So "Statement on AIDS", if we go  
 17 to the next page we'll see the date, May 1986. It's  
 18 a state from the BMA's Board of Science and Education,  
 19 so not, in fact, from its Ethics Committee. But if we  
 20 go to page 12, we can see, first of all, the issue of  
 21 confidentiality. Paragraph 1:  
 22 "It is vital to maintain the confidence of those  
 23 in high risk groups to ensure that by coming forward  
 24 for testing or counselling there will be no breach in  
 25 confidentiality."

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1 can be appropriate to test the patient without their  
 2 consent, and we'll see how that debate develops over  
 3 the next couple of years.  
 4 "If a patient refuses to be tested then they  
 5 should be treated on the assumption that they're  
 6 positive if they're deemed to be in a high risk  
 7 group."  
 8 Then, without going into the detail of it, if we  
 9 look at the next paragraph, you'll note that this  
 10 booklet then talks about isolation techniques and the  
 11 circumstances in which HTLV-III positive patients  
 12 should be nursed and the facilities which they can and  
 13 can't access in hospital.  
 14 So that's the autumn of '85. There's then some  
 15 European guidelines issued in January of '86, at  
 16 SHTM00002515. SHTM00002515.  
 17 We see there guidelines on AIDS in Europe  
 18 produced by the World Health Organisation. If we go  
 19 to page 12, if we could zoom in on the right-hand  
 20 side, so bottom right-hand side:  
 21 "Preventing the spread of infection from those  
 22 known to be positive to anti-LAV/HTLV-III.  
 23 "Testing of healthy individuals for  
 24 anti-LAV/HTLV-III should be done only after informed  
 25 consent has been obtained. Individuals who have been

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1 Then it refers to a specific set of regulations,  
 2 which I don't think is necessarily particularly  
 3 relevant for present purposes. If we go to the next  
 4 page, go to the top of the next page, we can see there  
 5 again the particular protection given to those who go  
 6 for blood tests at a sexually transmitted diseases  
 7 clinic, because of the NHS Venereal Diseases Act, and  
 8 they had to be treated under terms of strict  
 9 confidentiality.  
 10 If we go to paragraph 5 on the same page:  
 11 "The strictest confidentiality must be  
 12 maintained for affected individuals ..."  
 13 Then it refers to the Department of Health  
 14 guidance. Then if we go down to paragraphs 6 and 7:  
 15 "Individuals with a confirmed sero-positive test  
 16 should inform doctors and dentists who are treating  
 17 them that they are antibody positive ... so that the  
 18 appropriate precautions can be implemented.  
 19 "It is anticipated that the vast majority of  
 20 HTLV III antibody positive individuals will give  
 21 consent for their own doctor to be informed of the  
 22 test results. Similarly, it is very seldom founding  
 23 in practice that a patient will persistently refuse to  
 24 tell a spouse of his/her antibody position or who  
 25 refuses permission for the doctor to contact his/her

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1 partner. In the very few cases where permission for  
2 disclosure is denied by the patient then it is open to  
3 the doctor to contact the doctor of the partner at  
4 risk and with this doctor's co-operation to ensure  
5 that steps are taken to safeguarding the interests of  
6 both parties."

7 Then it refers again to the position of patients  
8 attending sexually transmitted diseases clinics, doing  
9 so on the basis they'll be dealt with in  
10 a confidential manner. So perhaps a degree of tension  
11 there between the position of those who have the  
12 protection conferred by the NHS Venereal Diseases Act,  
13 or Regulations, and then what's said -- what's  
14 contemplated here is that there would be circumstances  
15 in which one doctor can contact another doctor to pass  
16 on an HTLV-III positive result and so as to inform  
17 a partner.

18 Again, this issue is picked up in later  
19 materials, but this is what was being said by the BMA  
20 in 1986.

21 We can then see the heading "Counselling of  
22 patients after the HTLV III antibody test", and it  
23 talks about the difficulty of receiving that news,  
24 "careful counselling will be required".

25 **SIR BRIAN LANGSTAFF:** In practice, it might be quite

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1 at the bottom of the page under the heading  
2 "Counselling, confidentiality and informed consent":  
3 "Individuals must give informed consent before  
4 being tested for anti-HIV. Informed consent implies  
5 that the reasons why the test is advised are carefully  
6 explained to the individual and equally, that the  
7 results will be carefully discussed. In individuals  
8 who have positive tests, counselling will be  
9 necessary. If counselling is not available, testing  
10 should not be done. The results of anti-HIV tests  
11 must be strictly confidential. A positive result may  
12 have enormous psychological implications and may  
13 adversely affect the individual's employment, marriage  
14 and other relationships. It may also preclude an  
15 application for life insurance ... Under no  
16 circumstances must the results of anti-HIV testing be  
17 casually communicated to other health care workers,  
18 unless they are providing direct patient care."

19 So there's an exception contemplated there.

20 "To do so would not only be illegal but also  
21 a grave breach of professional ethics and a violation  
22 of the Code of Professional Conduct of the [UKCC]  
23 United Kingdom Central Council for Nursing, Midwifery  
24 and Health Visiting."

25 So the nursing guidance, you might think,

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1 difficult to know precisely who the doctor of the  
2 partner is --

3 **MS RICHARDS:** Absolutely.

4 **SIR BRIAN LANGSTAFF:** -- and if one were to make any  
5 enquiries about that, you'd be in danger of breaking  
6 confidentiality anyway, so it doesn't look a very  
7 practical system.

8 **MS RICHARDS:** It doesn't. I mean one might be able to  
9 contemplate if you're talking about a general  
10 practitioner, it's possible, but by no means certain,  
11 that a partner would be registered at the same  
12 practice, and the doctor would ultimately potentially  
13 be telling himself of the position in order to then  
14 pass on the information to the partner. But if one  
15 thinks then of the kind of context that arises in many  
16 of the cases with which this Inquiry is concerned, the  
17 information about diagnosis is not coming from the GP  
18 but from the haemophilia clinician. So yes, the steps  
19 that would be involved in the haemophilia director  
20 then himself trying to locate and inform the doctor,  
21 presumably the GP, of the spouse or partner, could be  
22 problematic.

23 We then, I think, can look, still in 1986, at  
24 a publication by the Royal College of Nursing. It's  
25 NHBT0057138. We can go, I think, straight to page 12,

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1 expressed in rather more straightforward clear,  
2 unequivocal terms, than some of the material  
3 disseminated either by the Department or by the  
4 organisations concerned with doctors.

5 In the same document if we go to page 16. We  
6 see the heading "Confidentiality", and there's  
7 a reference there to booklet number 2, issued by the  
8 Department of Health. Then it looks, below that first  
9 long paragraph, beginning "The strictest  
10 confidentiality", it then looks at some of the  
11 practical ways in which confidentiality can or can't  
12 be safeguarded within the care team in hospital. So  
13 it says:

14 "For nurses the main objective must be to  
15 protect the patient's identity from inappropriate  
16 disclosure both inside and outside the hospital.

17 "Access to medical records in the clinical  
18 setting should be restricted to relevant personnel,  
19 the medical records should be kept in a safe location  
20 where access can be monitored.

21 "Before discussing the patient's condition with  
22 lovers, family and friends, it is essential that staff  
23 ascertain exactly what the patient has told this  
24 important group about his/her illness and lifestyle,  
25 to ensure that enquiries are answered accordingly and

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1 consistently'.  
 2 "Currently HIV infection and AIDS remain very  
 3 emotive topics. However, the social implications for  
 4 the patients are immense."  
 5 Then the last sentence:  
 6 "Nurse to nurse communication must be  
 7 confidential."  
 8 We can then --  
 9 **SIR BRIAN LANGSTAFF:** Do the relevant personnel include  
 10 hospital porters?  
 11 **MS RICHARDS:** I'm not sure I can answer that, sir.  
 12 I can't think of any obvious reason why they should.  
 13 **SIR BRIAN LANGSTAFF:** No. I mean, it's the ambiguity in  
 14 the sense of "relevant personnel".  
 15 **MS RICHARDS:** Yes, the question of who is relevant. It is  
 16 difficult to see why a hospital porter would need to  
 17 know, either for the discharge of their  
 18 responsibilities or to safeguard their own healthcare,  
 19 that a patient is HIV positive. I'm fairly confident  
 20 there's nothing in the materials that we've seen that  
 21 deals with that expressly.  
 22 **SIR BRIAN LANGSTAFF:** Yes, it does arise in the evidence.  
 23 **MS RICHARDS:** Oh, it does. Absolutely.  
 24 Then BMAL0000031\_023, this is the BMA's Third  
 25 Statement on AIDS. This is 1987 now. If we go to

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1 page. So the first paragraph:  
 2 "The traditional confidentiality of the  
 3 doctor-patient relationship must be upheld in the case  
 4 of patients suffering from AIDS and HIV seropositive  
 5 individuals. According to DHSS guidelines, unless the  
 6 patient has given consent personal health data should  
 7 not be disclosed to anyone for any purpose other than  
 8 the healthcare of that patient, except where  
 9 disclosure is necessary to prevent the spread of  
 10 infection. As HIV is not spread through casual  
 11 non-sexual contact there could be very few  
 12 circumstances in which disclosure would be justified."  
 13 Then, again, there's a reference to the NHS  
 14 (Venereal Diseases) Regulations. Then the next  
 15 paragraph, says:  
 16 "With counselling, the majority of infected  
 17 individuals can be persuaded voluntarily to inform  
 18 their general practitioner, dentist and sexual  
 19 partner(s) of their infected status."  
 20 Then in the third paragraph:  
 21 "It is the duty of the general practitioner to  
 22 ensure that information is kept strictly confidential,  
 23 unless the patient consents to disclosure. Patients  
 24 should be strongly encouraged to permit disclosure  
 25 when there are firm medical reasons for this, such as

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1 page 16, we can see the heading "Consent".  
 2 So it's paragraph 3.14.1:  
 3 "People should only be tested for HIV antibodies  
 4 if they have freely consented to this, and fully  
 5 understand the possible implications, because of the  
 6 considerable disadvantages to the individual in being  
 7 found to have antibodies. Consent means the ability  
 8 to choose, free of duress and with the benefit of  
 9 relevant information, what course of action to take.  
 10 Moves to test people against their will or without  
 11 their knowledge might encourage them to conceal  
 12 behaviour that could place them at risk ... and to  
 13 avoid seeking medical attention for problems that may  
 14 be wholly unrelated to AIDS. It is essential that the  
 15 medical profession commands the confidence of patients  
 16 and prospective patients; if patients perceive the  
 17 actions of doctors as contrary to their interests this  
 18 will deter them from seeking necessary advice or  
 19 treatment to the detriment of their health, and will  
 20 undermine the effectiveness of measures aimed at  
 21 controlling the spread of infection."  
 22 So there a statement in pretty clear terms about  
 23 the need for informed consent and not to test patients  
 24 for HIV antibodies without their knowledge.  
 25 Then confidentiality is dealt with on the next

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1 when undergoing surgery. In general however, the  
 2 fewer people know of a person's antibody status the  
 3 more people in high risk groups will come forward  
 4 voluntarily for testing or treatment. Much of the  
 5 pressure for disclosure of patients' antibody status  
 6 has resulted from misconceptions about levels of risk,  
 7 which still remain common among doctors and other  
 8 health service professionals. This indicates the  
 9 importance of clear education for these groups."  
 10 Then the next paragraph talks about insurance  
 11 companies:  
 12 "Insurance companies sometimes ask [GPs] to  
 13 provide information about patients who are seeking  
 14 insurance. GPs should complete insurance company  
 15 forms truthfully to the best of their knowledge, but  
 16 should make clear to the patient what information is  
 17 being disclosed, and what the possible implications  
 18 may be. It is then up to the patient to decide  
 19 whether the form should be sent."  
 20 And then some further narrative in relation to  
 21 that.  
 22 So that's the BMA's third statement. We've seen  
 23 all the iterations of that statement, in the course of  
 24 1985, 1986 and 1987.  
 25 Yes, I think the third statement, it was perhaps

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1 printed December 1986 but it's not clear whether it  
2 was copyright 1987, so it's not clear the exact month  
3 in which it was published.

4 There's then a GMC publication in May 1987.  
5 DHSC0003701\_028.

6 If we zoom in a little closer:

7 "21st May, 1987

8 "AIDS: The doctor's duty towards patients

9 "The Standards Committee of the [GMC] are  
10 engaged in considering the ethical implications of the  
11 control and management of AIDS. In particular, they  
12 are considering in detail the problems which arise in  
13 this context in connection with confidentiality. The  
14 Committee have meanwhile drawn to the Council's  
15 attention their concern at recent reports that a few  
16 doctors may have been refusing to accept for treatment  
17 patients who are HIV positive or are suffering from  
18 AIDS."

19 Then we see the GMC setting out its view.

20 "The Council is seriously concerned at recent  
21 reports that, in a small number of cases, doctors have  
22 refused to provide patients who are HIV positive, or  
23 are suffering from AIDS, with necessary care and  
24 treatment. The Council expects that the profession  
25 will extend to such patients the same high standard of

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1 June 1987. It is headed "Trust and liability of GPs  
2 in question", and it touches on the issue of  
3 confidentiality:

4 "The emergence of AIDS has forced family doctors  
5 to reconsider long held conventions on patient  
6 confidentiality following conflicting pronouncements  
7 by legal experts.

8 "Worries about confidentiality have severely  
9 dented the trust that some patients have in their  
10 doctors, and perhaps more damaging still the  
11 professional image of the medical profession has been  
12 called into question with some GPs reacting with what  
13 the [BMA] has described as 'hysteria'.

14 "In April Professor Ian Kennedy, head of the  
15 Centre of Medical Law and Ethics at King's College,  
16 London told the House of Commons social services  
17 committee that GPs may be sued if they do not note in  
18 their medical records that a patient has AIDS.

19 "Professor Kennedy warned that a doctor would be  
20 liable if his partners did not know of the condition  
21 and therefore were not aware of the danger posed to  
22 others and then they advised the patient that there  
23 was no need to change his behaviour.

24 "He further explained that if a GP or a locum  
25 subsequently treated an AIDS patient without complete

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1 medical care and support which they would offer to any  
2 other patient."

3 Then there's a reference to in general terms,  
4 the propriety of doctors with conscientious objections  
5 to undertaking a particular course of treatment or who  
6 don't have the appropriate knowledge, skills or  
7 facilities in referring patients elsewhere rather than  
8 treating them themselves.

9 But then says:

10 "... it is unethical for a registered medical  
11 practitioner to refuse treatment, or investigation for  
12 which there are appropriate facilities, on the ground  
13 that the patient suffers, or may suffer, from  
14 a condition which could expose the doctor to personal  
15 risk. It is equally unethical for a doctor to  
16 withhold treatment from any patient on the basis of  
17 a moral judgment that the patient's activities or  
18 lifestyle might have contributed to the condition for  
19 which treatment was being sought. Unethical behaviour  
20 of this kind may raise a question of serious  
21 professional misconduct."

22 So we have that in May 1987. We then have  
23 a publication in June 1987 from the Royal Society of  
24 Medicine, HSOC0001488. This a publication called The  
25 AIDS Letter, and we can see it's volume 1, number 1,

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1 medical notes and part of that consultation involved  
2 a third party (ie lover, partner or friend) then the  
3 doctor responsible for the absence of notes would be  
4 liable."

5 This is the bottom of the same page:

6 "He also said that GPs could be sued if they did  
7 not advise the partners of AIDS victims that they are  
8 at risk. This amounts to a warning that family  
9 doctors must sometimes disregard an AIDS patient's  
10 confidentiality for the sake of people who may be at  
11 risk."

12 Then there's a contrary legal view, said to be  
13 put forward by a barrister:

14 "... in the doctor's newspaper, *General*  
15 *Practitioner*, [pointing] out that although  
16 confidentiality is not legally absolute, it is  
17 ethically accepted that a doctor is duty-bound to keep  
18 a patient's medical affairs confidential. Any breach  
19 of that confidentiality which results in financial  
20 loss to the patient could lead to a claim against the  
21 doctor for compensation."

22 Then I knew there was a reference to  
23 receptionist somewhere in the material, sir:

24 "This particular liability also includes surgery  
25 staff employed by a GP, and there have already been

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cases where receptionists, for example, have breached patient confidentiality following the diagnosis of AIDS.

"... this is dangerous ground for GPs. Due to ignorance, prejudice and simple fear, AIDS sufferers than lose, along with everything else, their jobs."

Then it suggests that the question of confidentiality for AIDS patients will remain controversial until settled by the courts.

So that's the Royal Society of Medicine's publication.

What we then get to, in the middle of 1987, is a debate within the British Medical Association about testing patients for HIV without their consent. And we can pick it up I think probably in a letter -- or a letter written to the British Medical Journal in July '87 at BMAL0000031\_027.

We see in the bottom right-hand corner, under the heading "Aids: a faltering step":

"Last week the annual representative meeting of the BMA passed by 183 to 140 votes a motion saying that doctors should be allowed to test a patient for antibodies to ... (HIV) without first gaining consent. The debate was largely concerned with what the proposer called 'occasional circumstances' but the

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tested may experience substantial psychological and social consequences. And who will tell the patient? Certainly anybody who considers testing a patient should be prepared to counsel the patient fully when a result proves positive. A recommendation to see an AIDS counsellor as quickly as possible is not enough on its own. The doctor who has done the test without consent is also likely to have destroyed his relationship with that patient."

Then there's then some background and context to the BMA debate and then if we go to the right-hand column, second paragraph:

"Most important of all -- and here we enter the ethical arguments -- when doctors say that it is acceptable to test patients without consent they are likely to destroy the trust that those at risk of HIV infection ... have in doctors. We have no chance of defeating the AIDS epidemic if we do not have that trust."

Then skipping a few lines:

"It is a basic tenet of medical ethics that we do not treat patients without their consent, and we have to have very good reasons for breaking that doctrine, as the BMA's Handbook of Medical Ethics emphasises. In this case we do not have such reasons,

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motion did not contain that phrase and nor did most of the reports in the media. The BMA thus appears to have departed from the advice given by both the World Health Organisation and the Department of Health and Social Security, and, in our view, the decision might do serious damage to Britain's attempt to contain the epidemic of ... (AIDS)."

If we go over the page, left-hand column, first main paragraph.

"The clinical, ethical, and possibly legal reasons why last week's decision is wrong are worth repeating."

Then the first refers to the risk to healthcare workers and says the risk of healthcare workers becoming infected is "very small".

Then we go to the next paragraph:

"The second clinical argument against the decision is that testing without consent will do little if anything to reduce the chances of becoming infected."

Then if we go to the next paragraph:

"The clinical arguments for testing without consent are thus marginal, but those against are considerable. Patients who are told that they are infected when they never even knew they were being

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although we might have some justification in rare circumstances."

A particular example is given about an unconscious patient being assessed for intracranial disease.

Then if we look at the last paragraph, the authors of this letter say:

"We hope very much that a way can be found to ameliorate the possible effects of the decision [The BMA's motion] to test without consent ..."

If we then look at BMAL0000031\_035. We have what's described as a "Summary of debate on motion 363: testing for AIDS", and I'm not going to go through all the arguments, but we can just see the fourth paragraph refers to:

"Chisholm (opposing) said that the doctor is the servant and not the master of the patient. The patient must consent to testing and must understand the implications. If patients cannot trust their doctors they will not consult or conceal behaviour which could put them at risk."

So that's a view being expressed, in opposition to the motion, by Dr John Chisholm, who subsequently became a member of the BMA Ethics Committee and is currently the chair of the BMA Ethics Committee, and

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he has kindly provided a statement to the Inquiry, giving his perspective on the debate that the BMA held.

If we can just look at that it's WITN5507001. If we go to page 5, please. We can see the heading there:

"Annual Representative Meeting Resolution of 1987

"I am asked to describe my involvement in the 1987 Annual Representative Meeting ... of the BMA ... and in particular my recollection of the discussions relating to and conclusions reached about the resolution 'that testing for HIV antibody should be at the discretion of the patient's doctor, and should not necessarily require the consent of the patient' ..."

Then if we go to the next page, he describes various other debates taking place about HIV, and a motion -- this is at the top of the page -- that had proposed that if someone was found to have HIV antibodies then, irrespective of consent, their GP, other medical practitioners and other healthcare professionals might be told of the result.

Then he says this:

"I was not, to my recollection, called to speak in that debate. However, it was very apparent to me

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"The ARM Resolution was passed against the clear and correctly ethical wishes of the Chair of the Council of the BMA ... To my mind the debates had given a poor impression of the ethics and attitudes of some of those contributing, in the presence of journalists from national print and broadcast media."

Then if we go to the next page, paragraph 10, Dr Chisholm describes how he was asked to go on TV and be interviewed with the BBC early evening news to try and:

"... ameliorate the damage done to the BMA's reputation caused by the ... Resolution and the wider debate on AIDS, which had included speeches in support of the breaching of patient's confidentiality in order to protect doctors."

Then last sentence of that paragraph:

"It was very clear to me that the policy not to seek patients' consent and the threats to breach patients' confidentiality were ethically indefensible and that the policy would have to be revisited."

Then if we go to the top of the next page, picking it up in the second line:

"It was my view at the time, as I expressed in the debate, and remains my view, that testing without consent, let alone 'routine or indiscriminate testing

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while it was taking place, and during the other debates in the session, that significant numbers of speakers and of those present were in favour of circumventing normal consent procedures and breaching patient confidentiality through the taking of blood without consent in order to test for AIDS, despite this being unlawful. Some contributors to the debates were seemingly more concerned about protecting healthcare staff from the risk of infection than about the rights of patients. My own position was that the normal principles of consent and confidentiality should be applied, and that all healthcare professionals undertaking exposure-prone procedures should take precautions with all patients to avoid or minimise needlestick injuries and the risks of cross-infection."

If we go to the next paragraph:

"The BMJ report is accurate in its reporting of the tone and nature of the debates. My recollection of the session on AIDS is that it was undoubtedly the most dysfunctional, confused, unruly and, at times, heated, session I have seen in more than 40 years attending [Annual Representative Meetings]."

He refers then to someone losing control of the meeting, and then he says:

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for HIV without the patient's consent', was not just inappropriate but wholly unethical."

So he sets out views in no uncertain terms.

Sir, the reason, in part, for drawing attention to that is not just out of, as it were, historical interest but because you'll recall that some clinicians, certainly in written, and I think probably oral evidence, have referred to the BMA debate that took place and the passing of the motion to suggest that there was a degree of support for a practice of testing without the patient's consent. Therefore, it's interesting to see the view of Dr Chisholm, and indeed what we're told was the position of the chair of the Council of the BMA about the nature and inappropriateness of that decision.

**SIR BRIAN LANGSTAFF:** Well, there's another side to it as well. This raises the profile of the question of consent for testing, and it means that those doctors who were party to the decision one way or the other would have a view on it, and the profession were pretty well bound to be aware that there was a big issue, and the policy changed shortly after that, didn't it?

**MS RICHARDS:** It did, precisely so. So following widespread, I think, expression of concern within the

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1 profession about the passing of the motion, the BMA  
 2 sought medical -- sorry, sought legal advice from  
 3 Michael Sherrard QC. We have his advice at  
 4 BMAL0000013\_033.  
 5 Now, obviously he is talking about the legal  
 6 position; Dr Chisholm was talking about both the legal  
 7 and ethical position. But in terms of the legal  
 8 position, Mr Sherrard's advice is pretty unequivocal.  
 9 He says in 1:  
 10 "It must be appreciated that such effect as the  
 11 resolution may have is limited to the domestic policy  
 12 of the BMA (and, possibly disciplinary proceedings  
 13 before the [GMC]). It does not, affect the law of the  
 14 land."  
 15 Then he talks about:  
 16 "[The] fundamental principle of the English  
 17 common law that every adult human being of sound mind  
 18 has a right to determine what shall be done with his  
 19 own body ..."  
 20 He talks about torture, battery and assault.  
 21 Then:  
 22 "3. It will be apparent, therefore, that any  
 23 medical treatment which involves physical contact with  
 24 the patient's body is a potential battery ... It is  
 25 the existence of the patient's consent to the touching

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1 requirements for informed consent. If we go over the  
 2 page, there's then a heading of some further practical  
 3 considerations and then we go to conclusions, at the  
 4 bottom of the next page:  
 5 "The implementation of the resolution under  
 6 discussion has the potential for placing medical  
 7 practitioners in an extremely difficult position. As  
 8 the law stands at present, the consent of patient is  
 9 essential if the act of taking a sample for testing is  
 10 not to constitute an assault or expose the  
 11 practitioner to a claim in negligence for failing to  
 12 inform the patient of the nature of the test and  
 13 possible consequences of a positive result. This  
 14 leaves aside any questions of professional misconduct  
 15 which may arise."  
 16 Then at paragraph 13:  
 17 "It is clear that the courts will strive to  
 18 uphold the individual's bodily integrity ..."  
 19 Paragraph 14:  
 20 "We are of the opinion that, where, in essence,  
 21 a medical practitioner has, without the genuine  
 22 consent of the patient, obtained a blood sample for  
 23 the pre-dominant purpose of testing for HIV antibody,  
 24 the Courts are likely, in the end, to accept the  
 25 formulation expressed by Lord Scarman in the course of

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1 which renders the touching legally unobjectionable.  
 2 We shall use the term 'treatment' to include 'testing'  
 3 in this context."  
 4 Then there's a discussion of consent:  
 5 "As a general rule, the consent of the patient  
 6 is an essential prerequisite to medical treatment of  
 7 any kind, even that of a relatively minor nature."  
 8 Then there's a discussion over the page of  
 9 various cases. At the bottom of the page, under the  
 10 heading "Implied consent", we pick it up in the end of  
 11 the third line:  
 12 "In our opinion the doctrine of implied consent  
 13 is not at all likely to be held to cover testing for  
 14 HIV antibody. The taking and testing of a sample,  
 15 though it may commonly be carried out, would not, in  
 16 our opinion, be considered 'routine' by the courts.  
 17 Given the far-reaching implications of a positive  
 18 result it cannot reasonably be contented that an HIV  
 19 test can be covered by the notion of implied consent  
 20 ..."  
 21 Then that paragraph ends with:  
 22 "Accordingly, a medical practitioner is under a  
 23 duty to ensure that the patient's explicit consent to  
 24 the testing is obtained."  
 25 There's then a discussion about the legal

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1 his speech in the Sidaway case ..."  
 2 Then bottom of the page:  
 3 "In the final analysis, it is our opinion that  
 4 the Courts will continue ... to hold that the right to  
 5 decide rests with the patient and not with his medical  
 6 adviser. It would be unwise for practitioners to  
 7 adopt a course which pre-empts possible legislation  
 8 and exposes them to both criminal and civil  
 9 proceedings."  
 10 That's the conclusion, and the date of the  
 11 advice, September 1987.  
 12 The advice was effectively accepted by the BMA  
 13 and promulgated by the BMA, and we can see that at  
 14 BMAL0000031\_067. I won't go through it. It is  
 15 essentially the text of the advice that was published  
 16 by the BMA, and subsequent publications by the BMA  
 17 made clear that they did not stand by the Motion 363  
 18 that had been passed.  
 19 Just in terms of publications then emanating  
 20 from others, and I take this fairly shortly, but  
 21 again, it's instructive to see what the UKCC -- so  
 22 what the Nursing Council were saying, BMAL0000029\_13.  
 23 "AIDS -- Testing, Treatment and Care". So we can see  
 24 this refers in the first paragraph to the BMA's  
 25 decision at its annual representative meeting, and

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1 then says:  
 2 "On the specific issue of the taking of blood  
 3 for testing without consent, the Council [so that is  
 4 the Nursing Council] has advised nurses, midwives and  
 5 health visitors on its professional register who have  
 6 approached it, and now advises all its practitioners  
 7 that they expose themselves to the possibility of  
 8 civil action for damages or criminal damages of  
 9 assault if they personally take the blood specimens,  
 10 and of aiding and abetting such an assault if they  
 11 knowingly collude with a doctor in obtaining such  
 12 specimens. Additionally these actions, like that of  
 13 being party to any statements aimed at leading  
 14 patients to believe that blood specimens taken for  
 15 AIDS testing were for some other purpose, expose  
 16 nurses, midwives and health visitors to the  
 17 possibility of complaints to their registration body  
 18 alleging misconduct which would put their registration  
 19 status and right to practise at risk."  
 20 So in no uncertain terms, the Nursing Council  
 21 rejecting the BMA position.  
 22 There were later and more detailed statements  
 23 issued by the UKCC, which reiterate, again, that  
 24 position in no uncertain terms.  
 25 Then I think probably the final document that we

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1 more specific purpose of differential diagnosis."  
 2 There's a recognition that there can be  
 3 circumstances of -- where a patient might agree to  
 4 provide a specimen of blood for multiple analysis.  
 5 Then, over the page, the Council, the General  
 6 Medical Council, then applies that principle to  
 7 testing for HIV, and says this:  
 8 "The Council believes the above principle should  
 9 apply generally, but that it is particularly important  
 10 in the case of testing for HIV infection, not because  
 11 the condition is different in kind from other  
 12 infections but because of the possible serious social  
 13 and financial consequences which may ensue for the  
 14 patient from the mere fact of having been tested for  
 15 the condition."  
 16 And then there is a further discussion  
 17 emphasising that point.  
 18 Should just note the last sentence of that  
 19 paragraph:  
 20 "Only in the most exceptional circumstances,  
 21 where a test is imperative in order to secure the  
 22 safety of persons other than the patient, and where it  
 23 is not possible for the prior consent of the patient  
 24 to be obtained, can testing without explicit consent  
 25 be justified."

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1 can look at is a GMC publication in May of 1988,  
 2 at NHBT0010410.  
 3 This is the GMC's document "HIV infection and  
 4 AIDS: The ethical considerations". And again, this  
 5 was updated over the course of the following years.  
 6 And if we look at page 2, under the heading "The  
 7 doctor/patient relationship", paragraph 2:  
 8 "The doctor/patient relationship is founded on  
 9 mutual trust, which can be fostered only when  
 10 information is freely exchanged between doctor and  
 11 patient on the basis of honesty, openness and  
 12 understanding. Acceptance of that principle is, in  
 13 the view of the Council, fundamental to the resolution  
 14 of the questions which have been identified in  
 15 relation to AIDS."  
 16 Then if we go to the bottom of the next page  
 17 there's an articulation in paragraph 12 of the general  
 18 principles that a doctor should treat a patient only  
 19 on the basis of the patient's informed consent.  
 20 "Doctors are expected in all normal  
 21 circumstances to be sure that their patients consent  
 22 to the carrying out of investigative procedures  
 23 involving the removing of samples or invasive  
 24 techniques, whether those investigations are performed  
 25 for the purposes of routine screening ... or for the

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1 And again, it may be difficult to think of  
 2 circumstances other than the unconscious patient,  
 3 where the nature of the surgery or investigation  
 4 that's required is such that people will be placed at  
 5 great risk if the status of the patient is not known,  
 6 but that's probably about the only thing that might  
 7 come within that very limited exception there given.  
 8 And then there's a reference to confidentiality,  
 9 two paragraphs further down.  
 10 So these publications in the BMA and the GMC and  
 11 so on were then reissued over the following years in  
 12 broadly the same terms with respect to issues of  
 13 consent and confidentiality.  
 14 I should just draw attention -- though I'm not  
 15 going to go to the documents, not least in view of the  
 16 late hour -- to the fact that there was -- in 1990 and  
 17 then I think in '91, '92, there was an exchange of  
 18 statements or various statements being published  
 19 contemplating that there might be cases in which  
 20 surgeons should be allowed to test patients without  
 21 their consent for HIV so that the surgeons would not  
 22 be placed at risk. So the Royal College of Surgeons  
 23 in Edinburgh published a statement in March of 1990  
 24 which identified circumstances in which it was said it  
 25 might be appropriate to test patients without their

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1 consent.  
2 There was a responsive statement from the GMC  
3 saying that could really only be in the most  
4 exceptional circumstances. And then a further  
5 statement from the Royal College of Surgeons in  
6 England in January 1991 touching on the same issue.  
7 And in March 1992, a further statement. There,  
8 apparently limiting what was said to be the  
9 circumstances in which testing without consent could  
10 be undertaken to the following scenario: if the  
11 surgeon or other member of the operating team receive  
12 a serious injury during treatment of or operation on  
13 a high-risk patient in whom serological status is not  
14 known, it was their view that the surgeon had the  
15 right to test the patient for HIV whether or not the  
16 patient had previously given consent for testing. And  
17 that then, after the operation, the patient should be  
18 told that.

19 Whether that's a scenario that ever, in the real  
20 world, occurred, is not something that the documents  
21 themselves tell us.

22 So finally on this issue, and without needing to  
23 go to the documents, 1993 then saw the BMA in its  
24 medical ethics practice and philosophy document --  
25 we've looked at that, the long sections on consent and

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1 specifically to some of the broader ethical issues as  
2 applied to the emerging AIDS crisis in the 1980s.  
3 The very last topic in our note -- I'm not going  
4 to go to any documents now because I think we can  
5 probably usefully pick it up at a later hearing -- was  
6 about the relationship between doctors and  
7 pharmaceutical companies and the circumstances in  
8 which doctors can or cannot accept hospitality and the  
9 gifts and the like from pharmaceutical companies, but  
10 it may be that -- only a handful of documents that we  
11 would need to look at in that regard -- but it may be  
12 that when we have our autumn hearings on  
13 pharmaceutical companies, we can look at those  
14 materials then.

15 **SIR BRIAN LANGSTAFF:** Yes.

16 Yes, thank you very much.

17 So we are not involved in hearings next week.

18 **MS RICHARDS:** That's correct.

19 **SIR BRIAN LANGSTAFF:** And the week after?

20 **MS RICHARDS:** The week after we begin our hearings on the  
21 Tuesday, which is I think 8 June.

22 **SIR BRIAN LANGSTAFF:** It is the 8th.

23 **MS RICHARDS:** And we hear Tuesday, Wednesday, Thursday,  
24 Friday of that week from a number of campaigners, most  
25 of whom will be giving evidence in person. Not all;

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1 confidentiality -- had a specific section on testing  
2 without consent for HIV and, strongly opposed to that,  
3 made clear its view that HIV testing without consent  
4 should not take place.

5 And the GMC updated its guidance on the ethical  
6 considerations in relation to HIV and AIDS in 1993.  
7 Again, emphasising that HIV testing required patient  
8 consent, even where blood samples had already been  
9 taken for another purpose.

10 **SIR BRIAN LANGSTAFF:** Ah. It was that last matter which  
11 I wanted to ask you specifically about.

12 Is that the only reference that there is which  
13 might touch upon the question of whether blood samples  
14 taken for one purpose or for a generality of purposes,  
15 none of which, on the information known to patient or  
16 doctor at the time, might have involved testing for  
17 HIV, should and could, ethically, subsequently be  
18 tested for HIV without the patient knowing?

19 **MS RICHARDS:** I'm not sure without checking, sir.

20 I certainly don't think there's anything which says in  
21 positive terms that that's an ethically acceptable  
22 course of events. The extent to which there is --  
23 there are -- publications say in positive terms it is  
24 unethical is what I would need to check.

25 Sir, those are the documents that related

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1 some are giving evidence remotely.

2 And then the following week we conclude that,  
3 and then we return to the topic of Haemophilia Centres  
4 with a presentation looking at a number of the smaller  
5 Haemophilia Centres or non-Reference Centres that we  
6 haven't explored in the oral evidence so far.

7 **SIR BRIAN LANGSTAFF:** So that's what the next three weeks  
8 has in store, the first week being a break. And  
9 I hope everyone has the opportunity to enjoy the Bank  
10 Holiday weekend and next week's break -- we would have  
11 it as a break -- as best they can.

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

13 (4.38 pm)

14 (The hearing adjourned until 10.00 am on Tuesday,  
15 8 June 2021)

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(79) unconscious - welfare



<b>W</b>	153/18 154/19 155/17 160/3 162/12 167/5 168/7 171/13 173/19 176/23 178/9 180/16 180/17 183/12 185/12 185/24 192/13 193/18 196/21 196/22 201/8 202/24 204/7 <b>what's [15]</b> 16/2 16/4 49/11 68/24 134/6 140/23 142/14 142/15 142/16 145/9 146/3 154/21 173/13 173/13 188/12 <b>whatever [1]</b> 105/16 <b>when [46]</b> 7/4 8/12 11/1 18/22 20/22 21/2 22/1 30/24 31/19 35/2 37/25 40/3 40/9 42/3 43/9 47/25 49/3 53/20 59/25 75/7 75/25 80/10 84/20 91/23 92/13 93/12 94/17 97/12 101/8 120/15 121/15 124/6 151/20 153/6 158/16 160/22 163/13 168/5 169/8 179/25 180/1 186/25 187/4 187/14 198/9 203/12 <b>Whenever [1]</b> 77/14 <b>where [55]</b> 21/11 21/18 26/3 31/9 35/13 65/5 69/6 73/7 81/17 82/9 86/21 101/23 109/8 111/21 120/23 121/2 121/7 122/5 122/8 126/1 126/4 126/21 137/15 138/4 139/17 141/5 148/6 148/7 148/15 148/23 151/2 151/22 152/4 152/24 153/4 154/12 156/18 158/19 158/24 159/8 160/19 164/18 165/2 168/13 169/17 173/1 176/20 179/8 185/1 195/20 199/3 199/21 199/22 200/3 202/8 <b>where's [1]</b> 153/13 <b>wherever [2]</b> 13/19 137/6 <b>whether [22]</b> 11/21 13/15 18/11 48/9 50/5 60/23 82/21 86/14 97/14 101/22 102/13 103/7 108/5 121/18 123/19 148/11 180/19 181/1 198/24 201/15 201/19 202/13 <b>which [252]</b>	<b>while [6]</b> 32/12 38/12 49/8 78/15 110/13 190/1 <b>whilst [4]</b> 1/11 38/22 94/15 125/12 <b>who [61]</b> 2/11 3/14 3/19 6/24 9/7 9/23 24/24 31/2 31/3 33/1 33/23 45/1 48/18 57/23 59/21 63/16 65/24 66/9 68/4 73/5 73/18 83/5 83/11 84/10 91/6 92/22 94/12 114/10 114/10 115/24 121/13 123/1 125/8 137/3 139/8 139/14 150/13 152/19 153/7 163/21 167/10 170/25 172/5 172/16 172/24 173/11 174/1 175/8 177/15 180/13 181/17 181/22 182/5 184/10 186/24 187/2 187/3 187/7 188/23 192/19 197/5 <b>whole [5]</b> 48/1 48/4 93/25 105/5 115/11 <b>wholly [2]</b> 178/14 192/2 <b>whom [10]</b> 3/25 64/6 65/20 116/5 116/9 116/17 132/17 139/7 201/13 203/25 <b>why [7]</b> 31/19 49/20 160/16 175/5 177/12 177/16 186/11 <b>wide [1]</b> 157/11 <b>widely [1]</b> 63/5 <b>wider [5]</b> 2/21 68/22 71/17 97/24 191/12 <b>widespread [1]</b> 192/25 <b>will [87]</b> 1/25 2/10 5/1 9/23 12/16 12/21 14/25 21/5 24/22 28/9 31/12 33/5 34/7 34/22 35/2 37/16 39/3 39/6 39/9 45/6 47/18 50/6 50/9 55/18 55/19 55/24 55/25 58/3 59/25 61/20 62/14 62/14 67/8 68/7 69/20 69/25 70/18 71/5 75/22 79/11 83/8 83/11 86/14 87/8 89/13 91/2 95/14 104/1 106/10 107/2 109/24 115/6 118/16 121/13 124/11 126/3 130/20 133/5 140/16 143/23 145/19 145/25 146/2 147/9 147/11	149/3 149/5 171/24 172/20 172/23 173/24 175/7 175/8 178/10 178/18 178/19 180/3 181/25 185/8 186/18 187/2 188/20 193/22 195/17 196/4 200/4 203/25 <b>willing [1]</b> 64/18 <b>willingness [2]</b> 66/4 74/13 <b>wise [2]</b> 35/2 140/2 <b>wish [5]</b> 6/24 67/5 71/3 83/8 133/11 <b>wishes [2]</b> 86/18 191/2 <b>wishing [1]</b> 115/14 <b>with [172]</b> 3/24 4/17 5/10 6/21 7/13 7/16 7/23 7/24 8/14 9/24 10/17 10/23 12/15 15/19 17/5 18/4 21/23 21/24 23/16 23/18 24/20 25/3 27/2 27/25 28/6 31/23 33/7 35/18 35/20 35/21 35/22 36/11 36/13 36/19 36/22 37/17 38/1 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77/1 77/5 78/4 106/14 106/24 127/9 130/24 138/4 170/18 171/13 186/3 201/20 <b>Worries [1]</b> 183/8 <b>worrying [1]</b> 93/14 <b>worth [4]</b> 78/10 149/22 162/19 186/11 <b>would [47]</b> 1/15 18/8 19/4 31/2 46/22 49/1 55/5 61/7 65/20 79/19 79/19 80/11 91/22 99/20 103/18 103/22 113/2 113/17 119/18 121/11 123/6 123/12 133/9 143/21 148/16 148/19 151/25 151/25 173/14 174/11 174/12 174/19 175/20 177/16 179/12 182/1 183/19 184/3 191/20 192/20 194/15 196/6 197/18 200/21 202/24 203/11 204/10 <b>wouldn't [4]</b> 13/14 18/2 31/8 132/25 <b>writing [2]</b> 64/18 130/2 <b>written [15]</b> 2/8 36/10 57/25 59/23 60/18 64/21 73/13 84/21 89/12 99/19 100/9 107/25 150/24 185/16 192/7 <b>wrong [3]</b> 91/22 159/23 186/11 <b>wronged [1]</b> 159/25 <b>wronging [1]</b> 160/7
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(80) well - yes

F:



<b>Y</b> <b>yes... [22]</b> 80/19 81/18 81/22 97/9 97/15 97/15 104/13 105/19 113/21 135/10 135/13 138/14 153/14 166/2 166/7 166/15 174/18 177/15 177/22 180/25 203/15 203/16 <b>yield [1]</b> 125/14 <b>you [86]</b> 3/21 8/4 12/10 17/1 17/17 17/21 17/21 17/22 17/25 18/1 18/2 18/23 18/25 18/25 19/1 19/1 19/2 22/14 23/12 23/22 24/17 24/17 24/24 25/4 25/5 26/7 26/19 26/21 27/8 28/5 28/9 28/10 28/15 28/16 28/22 29/8 29/9 29/14 29/19 29/22 41/7 42/24 49/12 50/7 51/23 52/9 56/4 59/4 61/20 82/1 83/2 92/17 101/21 103/16 103/17 104/20 105/16 105/22 112/20 113/22 120/2 120/14 121/24 122/1 122/22 122/25 123/2 130/21 133/11 134/3 134/12 135/24 138/9 138/10 138/10 154/9 154/12 155/24 156/23 156/25 157/5 171/15 175/25 202/11 203/16 204/12 <b>you'd [1]</b> 174/5 <b>you'll [39]</b> 6/13 9/20 10/24 11/15 16/17 19/9 19/20 28/7 29/3 29/6 37/5 37/10 38/9 40/7 41/8 42/21 44/11 53/8 53/21 54/18 56/4 56/6 56/9 56/13 63/2 66/19 73/20 79/1 85/12 85/17 85/24 89/3 104/14 120/8 138/23 153/19 161/10 170/9 192/6 <b>you're [6]</b> 2/18 18/24 49/25 81/8 158/16 174/9 <b>you've [7]</b> 18/14 35/13 80/23 113/9 123/18 143/19 158/17 <b>young [2]</b> 60/24 104/25 <b>younger [1]</b> 41/15 <b>your [28]</b> 17/23 23/23 23/23 24/8 24/10	24/14 24/15 24/19 25/15 26/19 26/20 26/21 26/23 28/6 28/11 28/14 28/15 29/16 29/19 35/15 55/11 61/7 61/18 66/10 113/9 113/13 138/8 161/19 <b>Z</b> <b>zoom [6]</b> 23/12 26/25 29/1 66/25 170/19 181/6				
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(81) yes... - zoom

F: