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

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

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

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."

Then if we go to paragraph 6, please. We will see that he says:

"The period from the 1970s to the early 2000s saw a model of the medical self-regulation which was dominated by the medical profession."

In other words doctors, regulated doctors:

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

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

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

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

in paragraph 14:

"In the 1970s and continuing up until 1980, the GMC's fitness to practise remit extended only to issues of criminal conviction and conduct."

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

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

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

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

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

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

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

and pick it up in paragraph 27. He explains that:

"[The General Medical Council's] procedures for developing and agreeing standards of good practice for doctors were established after 1980 when the GMC was given the legal power to give advice to the medical profession on standards of conduct and performance and medical ethics. Before the 1980s the GMC did not set professional standards, although it did set out a number of general principles arising from the disciplinary cases published in its annual 'Blue Book'."

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

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

And so on.

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

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

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

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

If we look at an example of one of these booklets, Soumik, can we go to GMCO0001697. We can

see this is the first one that we've identified, from 1963, Functions, Procedure and Disciplinary Jurisdiction. If we go to the third page, we'll see what it is under the heading "Introduction":

"This account of the Council's functions, procedure, and disciplinary jurisdiction is intended primarily for the information of doctors who have recently qualified in the British Isles ..."

Then we'll see, if we go down the page, it has a section on medical education, which is talking about the training that doctors go through.

If we go over the page, it has a section on the Medical Register and the requirement for doctors to be registered.

And then if we go on two pages, we can see we get to a heading "Disciplinary Jurisdiction and Procedures". So this the closest we get, as at this point in time, to any kind of guidance to doctors generally on how they should conduct themselves.

You'll see in bold print it said:

"The Council fully realises and appreciates the high standard of professional conduct of the vast majority of doctors in this country who will never find themselves directly concerned with the Council's disciplinary jurisdiction."

Then if we go down the page, a little further, just above the heading in italics -- no, sorry, if we pick up the heading in italics "The Council's Approach to 'Infamous Conduct'; its Duty to Protect the Public" and we see there the phrase "infamous conduct in a professional respect". So that was the standard by which doctors were judged at this point in time by the General Medical Council. What this guidance does, really, is just gives some types of example of infamous conduct in a professional respect.

So if we go to the next page, bottom of the page, the first example that's given is "Convictions". And then if we go over the page, picking it up about six lines down, it says:

"... in the light of the Council's experience over the last hundred years it is possible to indicate, with examples, a number of types of offence or misconduct which raise disciplinary issues."

These are, as it makes clear, intended only to be examples, but they're very limited examples in reality, so we have, by way of examples: illegal abortion, improperly purveying dangerous drugs, adultery with a patient.

Then you'll see a reference there to improperly disclosing information obtained in confidence from

a patient. So when I come to the theme of guidance of issues on confidentiality we'll look and see in more detail at what was said over the years about that, but that is something that has been identified as a key issue: the requirements of confidentiality from an early stage.

Then:

"Gross neglect in diagnosis or treatment.

"'Covering' medical practice by unregistered persons.

And then:

"Convictions arising out of abuse of alcohol."

"Addiction to drugs."

Are examples given.

And if we go two pages on, you'll see at the bottom of the page, very limited information about disregard of personal responsibilities to patients or gross neglect. It simply says:

"In pursuance of its primary duty to protect the public, the Council may feel bound to take cognisance of a case (whether or not it has been investigated under the National Health Service machinery) in which a doctor may appear to have seriously disregarded his personal responsibilities to his patients, or to have been guilty of gross neglect of his professional

duties."

Then we get on to issues such as abuse of alcohol and abuse of drugs and so on.

The longest section, if we go to page 13, Soumik, I think the longest individual section in this guidance and in its consequent iterations for a number of years was actually about advertising and criticising other doctors or -- essentially.

And I think I'm right in recalling correctly from the evidence of the expert group, you may recall the use of the term "etiquette". Quite a lot of the early guidance was really about what could be described as matters of etiquette, how a doctor should describe their practice or how a doctor should or shouldn't interact with other doctors, rather than the patient-focused emphasis that we, as we will see, then begins to emerge over the years.

That's the fairly limited nature of the guidance issued by this booklet by the GMC in 1963.

We won't go to all the various iterations. It doesn't change very significantly but we will perhaps just pick it up in the 1970 version, which is GMCO0001696, please, Soumik.

Oh, that's 1971, sorry.

Sorry, Soumik, 1696_019. My apologies. There

we are.

So this is really to show how little anything changed in terms of the contents of the booklet. If we go to the second page, again, we'll see it follows the same basic structure.

If we turn to page 7, we pick it up under the second paragraph beginning "Under the Act", there's reference to the duty to the public, and if we pick it up six lines down, five lines down:

"Subject, however, to their overriding duty to the public, members of the Committee may and do constantly ask themselves: 'What is in the best interests of the doctor himself?'"

That, I think, wouldn't be the modern approach to regulation, whether by this regulator or any other but that's the approaches at 1970.

Then at the beginning of the next paragraph:

"The Council is as concerned as the doctors themselves to avert wherever possible any need for a formal disciplinary inquiry into a doctor's conduct."

Again, it may give some indication as to the approach to regulation of the profession in 1970 to see those words.

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

under the heading "Statutory Provisions" the last sentence of that section -- sorry, the subparagraph (2), we'll see there the term "serious professional misconduct" appears. So "infamous conduct in a professional respect" has been replaced as a concept by "serious professional misconduct", and if we go over the page, we see the heading "The Meaning of 'Serious Professional Misconduct'" and then there's an explanation that the legislation has substituted that phrase for the phrase "infamous conduct in a professional respect".

If we then go on to page 9, we can see this, again, essentially gives examples of the types of conduct that might result in a doctor at this point in time being called before the disciplinary committee of the General Medical Council. So, again, it's not advice to doctors on the principles by which they should regulate their conduct or their interactions with patients; it's this conduct might result in a finding of serious professional misconduct.

We can see at the bottom of that page, it says this part of the pamphlet sets out certain kinds of offences in professional misconduct which have in the past led to disciplinary proceedings by the Council.

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

examples given of infamous conduct are similar to what we saw from 1963. So, again, it's abortion, drugs, adultery, confidentiality, or breach of confidentiality remains in there. We have added at the bottom:

"Offences discreditable to the doctor and his profession

"False pretences, forgery, fraud, theft, indecent behaviour, assault", and so on.

If we go to the top of the next page we can see a couple more examples: improper attempts to profit at the expense of professional colleagues and then abuse of financial opportunities afforded by medical practice.

Again, there's a little that is patient focused or that captures the kind of ethical principles and norms that the expert group told us about in the course of their evidence.

From 1971, the booklet that was produced by the GMC changed slightly, and so we'll look at that. It's GMCO0001696_002.

So it was still a booklet issued to doctors, it was now called, simply, Professional Discipline and was commonly referred to as the Blue Book.

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

first item, "Disregard of personal responsibilities to patients", although it appears that what's envisaged there is a failure to treat. Again, there's no real content to illuminate what's meant by this, other than the examples of a failure to visit or to provide treatment for a patient.

But that is now the first example given, and then we get some of the familiar examples: "Abuse of alcohol"; if we go over the page, "Abuse of dangerous or scheduled drugs"; "Termination of pregnancy"; "Abuse of professional position ... to further an improper association or commit adultery"; we do then see "Abuse of professional confidence", and again I'll come back to the issue of confidentiality at a later stage; and then "Offences involving dishonesty, indecency or violence".

Over the page, you'll again see the longest section of this document is devoted to advertising and the principles governing relationships between doctors, rather than the principles governing relationships between doctors and patients.

If we go to the last page, just draw attention to the -- oh no, that's not the last page that I have. Sorry, Soumik, if we go to page 15. Can we just go back, I don't know if this is the right document now,

GMCO0001696_002. That's it, thank you. So we can see under the heading "Conclusion":

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

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

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

MS RICHARDS: Yes.

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

MS RICHARDS: Yes.

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

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

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

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

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

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

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

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

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

So if we go to GMCO0001696_011, please, Soumik. This is the Blue Book from April 1985. If we go to the second page, you'll see, under the foreword, it says:

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

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

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

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

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

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

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

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

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

"... [failure] to visit or to provide or arrange treatment for a patient when necessary."

If we pick it up in the next paragraph:

"The public are entitled to expect that a registered medical practitioner will afford and maintain a good standard of medical care. This includes:

"(a) conscientious assessment of the history, symptoms, and signs of a patient's condition;

"(b) sufficiently thorough professional attention, examination and, where necessary, diagnostic investigation;

"(c) competent and considered professional management;

"(d) appropriate and prompt action upon evidence suggesting the existence of a condition requiring urgent medical intervention; and

"(e) readiness, where the circumstances so warrant, to consult appropriate professional colleagues."

And then if we pick it up then in the paragraph beginning "The Council is concerned":

"The Council is concerned with errors in diagnosis or treatment and with the kind of matters which give rise to action in the civil courts for

negligence, only when the doctor's conduct in the case involves such a disregarded of his professional responsibility to patients or such a neglect of his professional duties as to raise a question of serious professional misconduct. A question of serious professional misconduct may also arise from a complaint or information about the conduct of a doctor which suggests that he has endangered the welfare of patients by persisting in unsupervised practice of a branch of medicine in which he does not have the appropriate knowledge and skill and has not acquired the experience which is necessary."

So we have some positive advice. And then, again, the -- "this is what you should not do" there set out.

And that was, as the foreword made clear, new, in terms of the booklets, the Blue Books issued by the General Medical Council.

Now, this guidance was updated over the years that followed, I'm not going to go to all the subsequent versions. Some develop things in a little more detail than others, but it broadly follows a similar format to the 1985 Blue Book.

It wasn't until the early '90s that the GMC Standards Committee started to try to create

a description, a positive description, of what a doctor should do and how a doctor should conduct themselves ... the essential attributes of a good doctor.

What that resulted in is, finally, the publication of something called Good Medical Practice.

That is, or the first version of that we can see at our CGP0000533_005.

So this is the 1995 publication which was the first publication of Good Medical Practice.

If we go to the next page, please, Soumik. And again, if you can zoom in on the top, because it's impossible to read otherwise.

So we can see there set out on the left-hand side:

"The duties of a doctor registered with the General Medical Council

"Patients must be able to trust doctors with their lives and wellbeing. To justify that trust, we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life. In particular as a doctor you must

"- make the care of your patient your first concern;

"- treat every patient politely and

considerately;

"- respect patients' dignity and privacy;

"- listen to patients and respect their views;

"- give patients information in a way they can understand;

"- respect the rights of patients to be fully involved in decisions about their care;

"- keep your professional knowledge and skills up to date;

"- recognise the limits of your professional competence;

"- be honest and trustworthy;

"- respect and protect confidential information;

"- make sure that your personal beliefs do not prejudice your patient's care;

"- act quickly to protect patients from risk if you have good reason to believe that you or a colleague might not be fit to practise;

"- avoid abusing your position as a doctor; and

"- work with colleagues in ways that best serve patients' interests."

And many of those bullet points, sir, will resonate in terms of their relevance to much of the evidence that you have heard, both from those who were patients and from clinicians.

We can see on the right-hand side guidance to doctors:

"Being registered with the General Medical Council gives you rights and privileges. In return, you must meet the standards of competence, care and conduct set by the GMC.

"This booklet sets out the basic principles of good practice. It is guidance. It is not a set of rules, nor is it exhaustive. The GMC publishes more detailed guidance on confidentiality, advertising and the ethical problems surrounding HIV and AIDS."

And we'll look at the latter at a later stage.

It's right to say that although this was new guidance, these were not -- or it may ultimately be a matter for your judgment, sir, but, if we think about the evidence from the expert group, these are not new principles. But they're being articulated here by the GMC for the first time in a publication to doctors.

And if we just go to the next page we see then some of the bullet points that we saw listed on that first page are then explored in greater detail.

So under the heading "Good clinical care", paragraph 2, it talks about the importance of:

"- an adequate assessment of the patient's

condition ...

"- providing or arranging investigations or treatment where necessary;

"- referring the patient to another practitioner ..."

If we look at the bottom of that paragraph 3:

"In providing care you must:

"... keep clear, accurate and contemporaneous patient records which report the relevant clinical findings, the decisions made, information given to patients and any drugs or other treatment prescribed."

If we go to the right-hand column, third bullet point:

"- prescribe only the treatment, drugs or appliances that serve patients' needs."

Then we see the importance of "Keeping up to date", if we can just look at that.

So:

"You must maintain the standard of your performance by keeping your knowledge and skills up to date throughout your working life ... you should take regularly in educational activities which relate to your branch of medicine."

And then if we go to the next page, please, Soumik, and if we can zoom in, under the heading

"Maintaining trust":

"Professional relationships with patients."

So, again, patients really start to come to the forefront in this guidance, in the way in which they weren't in the previous booklets:

"Successful relationships between doctors and patients depend on trust. To establish and maintain that trust, you must:

"- listen to patients and respect their views;

"- treat patients politely and considerately;

"- respect patients' privacy and dignity;

"- give patients the information they ask for or need about their condition, its treatment and prognosis;

"- give information to patients in a way they can understand;

"- respect the right of patients to be fully involved in decisions about their care;

"- respect the rights of the patients to refuse treatment or take part in teaching or research."

Then at the top of the next page:

"- respect the right of patients to a second opinion;

"- ask patients' permission, if possible, before sharing information with their spouses, partners or

relatives."

And if we go to the bottom of that page, paragraph 15, again the importance of trust:

"Because the doctor-patient relationship is based on trust you have a special responsible to make the relationship with your patients work."

Then if we go to the next page, you'll see there there's a section on confidentiality, paragraph 16:

"... right to expect that you will not pass on any personal information which you learn in the course of your professional duties ..."

Again, I'll explore that in more detail later.

Then the next section:

"Abuse of your professional position

"17. You must not abuse your patient's trust. You must not, for example ..."

And if we look at the third, fourth, and fifth bullet points:

"- improperly disclose or misuse confidential information about patients;

"- recommend or subject patients to investigation or treatment which you know is not in their best interests;

"- deliberately withhold appropriate investigation, treatment or referral."

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

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

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

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

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

Then paragraph 46:

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

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

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

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

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

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

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

MS RICHARDS: That's quite possibly the case.

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

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

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

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

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

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

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

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

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

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:

"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."

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

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.

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

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

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

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

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

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

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

"Statement of panel on professional standards

"Introduction

"In April 1970 the Board of Science and Education invited a panel of younger doctors to identify areas of anxiety and conscience in medical practice. Trends in certain spheres of medical practice appeared to challenge the generally accepted principles that the function of the doctor is to maintain respect for human life and the health and welfare of his patients. The Board considered it was an appropriate time for professional standards to be reviewed in the light of current knowledge and thought ..."

Then we can see, if we look a little further

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

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

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

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

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

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

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

confidentiality, for example.

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

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

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

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

"The approach to the subject is completely

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

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

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

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

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

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

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:

"'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

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 with hold 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

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

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

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

MS RICHARDS: Yes, indeed.

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

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

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

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

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

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

MS RICHARDS: Yes.

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

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

"Doctors have rights and responsibilities and

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

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

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

Etc, etc.

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

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

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

I can't find the reference at the moment.

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

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

BMAL0000087.

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

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

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

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

"Because of the special knowledge and the

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

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):

"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

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

quarter to 12. Quarter to 12.
(11.16 am)
(A short break)
(11.45 am)
MS RICHARDS: Sir, I spent some time looking at some of the general materials and the nature and structure of materials produced by the General Medical Council and the British Medical Association because within the period with which the Inquiry is most closely concerned, they were the main sources of guidance to doctors.

I'm just going to now briefly refer to some of the other sources without going into the detail of what they produced, before I turn to some of the key themes.

So, in addition to the British Medical Association we have some materials from the World Medical Association, that was established in part on the initiative of the BMA in 1947, and it's produced on an international plane, Ethical Guidance to Clinicians.

We then have, as a group of organisations, a range of Royal Colleges who have produced material. We referred to some, not every single one of them, in our written note, but sources of relevant guidance

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

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

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

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

Now, they're not regulators, they're bodies that exist to advise and assist doctors in particular facing complaints or facing litigation.

You may recall, sir, the evidence of the Medical Ethics Group, that one of the purposes of these medical defence organisations or societies is to help and protect and prevent doctors from being sued. So there the materials they produce are very much focused upon their being clinician centred rather than patient focused, but nevertheless there is some important material, not least on consent, that emanates in particular from the Medical Defence Union.

Then there is some of the material relating to principles of research emanating from the Medical Research Council. There's some material for the practice of the profession of dentists, emanating from the General Dental Council, so the dental equivalent of the General Medical Council, or from the British Dental Association, which is the dental equivalent of the British Medical Association.

Then a handful of other groups or committees who have produced relevant material over the years which are referred to in our written note and in the chronology the Inquiry has produced.

Then, finally, when we come to look at what will

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

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

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

We can pick that up in 1953, with some material produced by the Medical Defence Union. So one of these medical defence societies acting for doctors. Soumik, if we could have, please, MOJU0000001_013.

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

a prisoner. So not the situation with which we're concerned, but that's the context for the material that we see.

This letter then addressed to the Prison Commission, identifies that issue in the first paragraph. It says:

"... I would not readily concede that your view is correct that consent given by a Governor of a Prison or Borstal Institution is of no legal value with regard to the performance of an operation or the administration of an anaesthetic."

Then reference to what the duties of a governor of a prison might be in terms of responsibility for the wellbeing and care of prisoners.

If we just go over the page and see that the MDU secretary says -- and it's the last -- it's the first paragraph, last sentence:

"I am enclosing herewith for your perusal and retention a document on the giving of consent which I hope you will find interesting and useful."

The purpose of referring to that is it helps give some date to the document I'm going to refer to. So that's at MOJU0000001_014. Actually, no sorry, Soumik, before we go to that can we just go to MOJU0000001_008.

Again, emanating from the MDU in the context we think of the correspondence with the Prison Commission was this document, which goes into more detail about issues relating in particular to questions of consent as they pertain to prisoners.

But I just wanted to refer to the first few lines:

"The general law concerning surgical operations performed without the consent of the patient is but briefly dealt with in the books and there seems to be little authority."

Then there's reference to Halsbury's laws:

"To perform a surgical operation on a person against his will or against the will of the person entitled to consent on his behalf is an assault."

Then this document goes into detail about particular legal issues that might arise in the context of the care of prisoners and the giving of consent. So this is one of the documents that seems to emanate from this exchanges of correspondence in 1953.

Then the second and more directly relevant document is MOJU0000001_014.

It may be that this was the booklet being referred to in the MDU secretary's letter to the

Prison Commissioner -- the Prison Commission. Sir, you'll see it's headed "The Medical Defence Union Limited, Consent for examination and treatment". It says this:

"It is not sufficiently widely known by practitioners that, in law, consent must be given by a patient before an examination can be conducted or treatment administered. Fortunately doctors are not often challenged in the Law Courts on the issue of 'absence of consent' since in the majority of cases consent can be implied from the nature of the relationship of doctor and patient. But the rarity of such an event may lull practitioners into a false sense of security. The following statement is intended to review and clarify the legal position of the practitioner who proposes a professional examination or advocates any treatment."

Then the next paragraph is headed "General considerations":

"Strictly speaking it is illegal for any practitioner to do anything to any patient without consent. If he acts without consent he may be held to have committed assault (for which he may be prosecuted in a Criminal Court), or to have been guilty of trespass (for which he may be sued in a Civil Court).

The person immediately affected may bring an action against the doctor; in some cases a parent, [a] spouse or an employer may also have a right of action.

"It is therefore necessary to consider what is the meaning and scope of consent; how it should be sought and by whom it may be given."

Now, pausing there, the focus of this is not on ethical principles but on legal rights and obligations. But nonetheless it is the earliest document we found issued to or potentially issued to or available to doctors looking specifically at this issue.

Then we see the heading "The Significance of Consent":

"Consent means that the individual patient concerned either by himself or with or through another has indicated by implication or specifically (preferably in writing) that he is willing to submit himself for examination and for treatment."

Then there's discussion of how consent can be oral or as preferably written.

"The question of consent [so this is the next paragraph] is not often raised since the parties concerned could be shown by their conduct to have mutually understood the position, to have implied

consent on the one hand and the acceptance of professional responsibility on the other, and to have dealt with one another accordingly."

And then if we go to the bottom of this page, and this is really where we get the concept of informed consent in this document:

"The request for consent" is the heading:

"To obtain consent it is necessary for the practitioner to explain carefully to the patient in non-technical language the need for an examination to arrive at a diagnosis or decide on the line of treatment. The character and the likely results of the treatment should be outlined to the patient in such terms that he can appreciate fully what is proposed and what may ensue. A practitioner, aware of the uncertainties of treatment, should avoid sweeping promises; and should not minimise the risks that may be inherent in the procedure he proposes."

And then, the paragraph continues:

"If the patient is one with whom it would be undesirable for psychological or other reasons to discuss these matters, a different procedure may justifiably be adopted in which the information is placed before some near relative who by himself (or preferably in conjunction with the patient) gives

consent to the treatment.

"The consent obtained must be genuine consent; not merely an apathetic acquiescence but a real expressed willingness by the patient to undergo the treatment after he has had its nature, its risks, and its objectives clearly explained."

Then the document goes on to deal with certain specific cases, including the unconscious patient or the patient who lacks capacity, or children, with which I don't think I need to take up your time, sir.

But we can see here, in 1953, the Medical Defence Union, so the body involved in trying to, as it were, represent the interests of doctors, here articulating the need for the risks involved in treatment to be spelt out to the patient.

There's a further document produced by the MDU in 1962.

It's at DHSC0100081, please, Soumik.

You'll see from the title "Consent to operative treatment" that it's concerned essentially with surgery.

But nonetheless, the underlying principles are of some importance.

Sir, if we go to the third page, and if we could zoom in on the right-hand side, "Consent to Operative

Treatment" it says this:

"A person suffering from disease or injury is not normally bound to submit himself to medical treatment or even to consult a doctor if he does not wish to do so. It follows, therefore, that an operation carried out without the consent of the person concerned, subject to certain exceptions to which reference will be made in due course, amounts to an actionable assault. Such an assault may lead to an action for damages under the civil law and it follows, therefore, that if a surgeon performs an unauthorised operation he or his employing authority, or both, may be confronted with an action for assault for which damages may be recoverable."

So, again, the focus is protecting the doctor from litigation. But there, again, the importance of consent being emphasised.

And then we see the heading "Consent May be Expressed or Implied", and that's discussed in the first paragraph, and it's said all these forms of consent may be equally efficacious.

But if we pick it up in the second paragraph under that heading:

"To be an effective answer to a claim for assault the consent must be fully and freely given.

The patient should be given a fair and reasonable explanation, in non-technical language, of the effect and nature of the operation. This should be given only by a person who is competent and qualified to give it, preferably by a medical practitioner. If an inadequate or misleading explanation is given there is the danger that the apparent consent obtained will be held to be ineffective. If the operation contemplated carries special risks, which are probably unknown to the patient, he should, as a general rule, be informed of these risks."

And then, and this perhaps may reflect the paternalism of the era, it continues:

"The surgeon may, of course, on occasion be justified in not revealing or in minimising the risk involved if he thinks it necessary to do so in the interests of the patient."

And there's reference to what has now been regarded as the somewhat surprising decision of the courts in --

SIR BRIAN LANGSTAFF: It's interesting that, in one respect, the 1953 advice is wider than this, because it talks about "and what may follow", being advised of not only what's inherent in the procedure and its risks, but what may follow, what the consequences are.

It is not mentioned here.

MS RICHARDS: No, that's right. That may be explicable by reason of that this is very much focused on the question of surgery, so it's the application of the broader principles to the particular context of surgery where the focus may be on the risks inherent in the surgical operation.

SIR BRIAN LANGSTAFF: Yes.

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

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

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

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

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

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

If we go to DHSC0103246, please, Soumik.

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

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

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

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

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

"A person suffering from disease or injury is

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

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

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

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

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

"To be an effective answer to a claim for

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

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

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

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

This is MDUN0000064, please, Soumik.

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

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

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

material risks ... of the proposed procedure. The patient must be capable of understanding the explanation given ..."

And then there's a reference to the position of the patient who lacks capacity. Again, we're not concerned with that particular situation.

"Where the patient has been given insufficient information, the doctor may be found to have been in breach of his duty and liable to the patient if damage results."

Then we see a discussion of types of consent: implied consent, express consent, oral consent -- if we go over the page -- written consent.

And then if we look at the heading halfway down the left-hand side, "Obtaining consent":

"1. Explanation by knowledgeable doctor.

"Consent should be obtained by a medical practitioner who should be familiar with the details and risks of the proposed operation or investigation."

Then if we go to the next page, you'll see here, sir, if we look at the bottom of the left-hand side, under the heading "Material risks", reference to what are, in legal terms, the fairly well known authority of Sidaway v Bethlem Royal Hospital. So, again, the focus here is on the minimum that the doctor must do

in order to act in accordance with the law. And we have there set out what was said by the House of Lords in that case.

So that's the 1986 guidance. And if we then look at I think it's the 1993 version just see again how the emphasis shifts over the year.

MDUN0000065, please, Soumik.

This is the document -- the same booklet essentially, Consent to Treatment, but produced in 1993.

Here we can see now, on the front page of it, we have the definition of consent set out:

"... express willingness, give permission, agree, voluntary agreement permission, compliance."

Then if we go to page 2, under the heading "Consent to treatment" on the left-hand side, what we see now is the language of patient rights.

So top of the left-hand side:

"Every patient has the right to make his or her own decision regarding medical treatment and care and, in order to make that decision, is entitled to have full information about the material risks. The clinician's duty is to supply the information in sufficient detail to enable the patient to make that decision."

And then further guidance is then given, and reference again to various legal principles, and cases and legislative provisions.

But what we see here, missing from the earlier versions, is the recognition here of the patient's right.

I won't go to it, but when we look -- if we were to look at the 1996 version of this, we then see the concept of autonomy being introduced as well.

So that's the material produced by the Medical Defence Union on the issue of consent over some of the earlier decades.

If we can then look at some of the material produced by the British Medical Association on the issue of consent, and go back to a document I looked at briefly before the break.

So this is the BMA's 1980 publication, BMAL0000086, please, Soumik.

If we go to page 10, we see at the bottom of the page, the heading "Consent":

"The patient's trust that his consent to treatment will not be misused is an essential part of his relationship with his doctor but for a doctor to touch a patient without consent is an assault. Consent is valid when freely given if the patient

understands the nature and consequences of what is proposed. Assumed consent or consent obtained by undue influence is valueless."

And then paragraph 1.9 at the bottom of the page:

"The necessary degree of understanding of what is proposed depends on the patient's education and intelligence, the seriousness and urgency of the condition being investigated or treated, and other relevant factors."

And then this:

"The onus is always on the doctor carrying out the procedure to see that an adequate explanation is given."

And then there's a section on consent of minors, and incapacity to consent.

So not much in this, but it is, at least for the first time in terms of the BMA materials, an articulation of the principle of consent in any event.

And that was 1980.

The World Medical Association in 1981, adopted something called the Declaration of Lisbon.

That is at RLIT0001509.

We can see it's headed:

"The World Medical Association ...

"World Medication Association Declaration of Lisbon on the Rights of the Patients"

So, again, it uses the language about patient rights.

"Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981

"Recognising that there may be practical, ethical or legal difficulties, a physician should always act according to his/her conscience and always in the best interests of the patient. The following Declaration represents some of the principal rights which the medical profession seeks to provide to patients.

"Whenever legislation or government action denies these rights of the patient, physicians should seek by appropriate means to assure or restore them."

Then, for the present purposes, looking at the question of consent, it is (c) that's important.

"The patient has the right to accept or to refuse treatment after receiving adequate information."

So that's, again, the concept of patient rights and informed consent.

Now that's obviously expressed in fairly short and succinct terms.

This declaration was amended in 1995, so some years later.

If we go to RLIT0001508.

We can see this is September 1995: "World Medical Association Declaration of Lisbon on the Rights of the Patient".

And we can see "Amended by the 47th General Assembly, Bali, Indonesia, September 1995".

And then there is a preamble which is perhaps worth looking at because it introduces some of the ethical norms that the expert group have told us about:

"The relationship between physicians, their patients and broader society has undergone significant changes in recent times. While a physician should always act according to his/her conscience and always in the best interests of the patient, equal effort must be made to guarantee patient autonomy and justice. The following Declaration represents some of the principal rights of the patient which the medical profession endorses and promotes. Physicians and other persons or bodies involved in the provision of healthcare have a joint responsibility to recognise and uphold these rights."

And if we look at the principles then, towards

the bottom of the page, you'll see the first principle is the "Right to medical care of good quality".

And 1(c):

"The patient shall always be treated in accordance with his/her best interests."

Then if we go over the page, we can see at paragraph 3, or principle 3, the "Right to self-determination":

"The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions.

"A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent.

"The patient has the right to refuse to participate in research or the teaching of medicine."

Then if we just go to the next page, I'll come back to confidentiality later but principle 7 is the "Right to information":

"The patient has the right to receive information about himself/herself recorded in any of his/her medical records, and to be fully informed about his/her health status including the medical facts about his/her condition ... confidential information in the patient's records about a third party should not be given to the patient without the consent of that third party.

"Exceptionally, information may be withheld from the patient when there is good reason to believe that this information would create a serious hazard to his/her life or health."

Then various other matters about the patient's rights.

So a more detailed exposition here in this amended version of the Declaration of Lisbon of patient rights based clearly upon the principle of autonomy.

SIR BRIAN LANGSTAFF: Yes, but the way in which autonomy was explained by the ethical experts included the right to make a choice, a choice between no treatment and treatment but also a choice between the treatment options available, and none of the statements you've taken me to so far have made any explicit reference to a right to choose alternative therapies if they might

be available.
MS RICHARDS: They don't. No, that's absolutely right.
SIR BRIAN LANGSTAFF: Nor does it say that information explicitly doesn't say -- sorry, doesn't say explicitly, that information should be given about options, which is the basic -- a basic principle which the ethical experts were articulating.
MS RICHARDS: No, you're absolutely right, sir, and of course one of the objectives in showing this material, this guidance, is not only for what it does say, but also to see what it does not say. And what was absent from the materials that were being disseminated to clinicians at the relevant time.
SIR BRIAN LANGSTAFF: I mean, with modern eyes, one could say the principle of mutual respect going back to 1953, has within it the right to know of what the options are, where there are options.
MS RICHARDS: Yes.
SIR BRIAN LANGSTAFF: But that's reading in with modern eyes what was not expressly there in the text at the time.
MS RICHARDS: Yes, and I'll check as we go through it, but I don't think in the materials we're looking at from the 1970s, 1980s or early 1990s, we'll see anything that articulates that right to make a choice in quite

the way that you have done, sir, or the way in which the expert group did, and that may be one of the deficiencies of the material that was promulgated.
SIR BRIAN LANGSTAFF: Right.
MS RICHARDS: Sir, that's the Declaration of Lisbon in its various -- in its amended form.

If we then, turning to the publications of the BMA, we looked at -- I've looked at the 1980 guidance but it's really the 1988 guidance where we see a more detailed examination of the principles of consent. That's at BMAL0000080. We looked at this before the break, in terms of seeing what kind of general steer was being given by the British Medical Association. If we go to the section that is specifically on consent, if I can find chapter 4, page 35, Soumik.

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

So this, I think, is probably the first reference in the materials to the point you articulated, sir.

Then there's the discussion about the position of the patient who doesn't want to be told, which is articulated in the remainder of that paragraph.

Then picking it up in the next paragraph:

"Normally, the patient will wish to decide. The doctor should remember that his specialised training and knowledge puts him in a powerful position compared with the patient who will usually lack the detailed knowledge to grasp the essential facts immediately. The lack of this knowledge does not mean that the patient is unable to understand. Consent without understanding is invalid and it is the doctor's moral, professional and legal duty to help the patient reach this understanding. In so doing, the doctor should follow the patient's lead and present as many of the risks and benefits as the patient needs to know. Naturally a doctor can only discuss matters in relation to the accepted state of medical knowledge at the time.

"One of the problems about consent is that it must follow the disclosure of information and thus understanding of the medical condition."

Then there's reference to UK case law, and the Sidaway case but, very importantly, the last two sentences of this first paragraph, after referring to the case law:

"It is important to remember that a doctor's legal obligations are much less than his moral obligations. The legal minimum is not necessarily ethical."

Then there is a discussion of certain exceptions including the patient who lacks capacity and the statutory provisions that enable compulsory treatment in certain circumstances of psychiatric patients.

If we go to page 39, I think, Soumik. Bottom of the page, under the heading "Obtaining consent", it says this:

"At times consent is implied, as in attendance for an inoculation which implies that the patient expects the inoculation. This does not, however, absolve the doctor from explaining any risks. Equally there are times when oral consent is not sufficient and written consent essential. It is important that consent should be free of any form of pressure or coercion ..."

Then if we go over the page, we can just see, after the extract from what the GMC has said about the

relationship between doctors and patients, the point about trust:

"The doctor/patient relationship is based on trust."

So that's the 1988 guidance from the BMA in relation to consent. If we then move to 1990 for the next material publication. That's a publication, I think, by the Department of Health. NHBT0007444_001, please, Soumik.

It's an NHS publication, I should say. It's called "A guide to consent for examination or treatment", and you'll see it's published by the NHS Management Executive. Let's just see if we've got a date recorded on the document. Our understanding is that this is from August 1990, in any event.

If we go to the second page, because I'm not going to go through each chapter, you'll see there what the chapters cover: "A patient's rights in accepting treatment"; "Health Professional's role in advising the patient ..."; reference to a specific statutory provision; "Examples of treatment which have raised concern"; "Consent by patients suffering from mental disorder"; and then "The Sidaway Case".

Just go to the next page, what you'll see is that this very much focused on legal rights and

responsibilities, rather than ethical ones, and we see that from paragraph 1:

"A patient has the right under common law to give or withhold consent prior to examination or treatment ... This one of the basic principles of health care."

Then paragraph 2:

"Patients are entitled to receive sufficient information in a way they can understand about the proposed treatments, the possible alternatives [so there again we get the concept of options and choice emerging] and any substantial risks, so they can make a balanced judgement. Patients must be allowed to decide whether they will agree to treatment, and they may refuse treatment or withdraw consent to treatment at any time.

"3. Care should be taken to respect the patient's wishes."

Then if we go to the next page, under the heading "Advising the patient", paragraph 1:

"Where a choice of treatment might reasonably be offered the health professional may always advise the patient of his/her recommendations together with reasons for selecting a particular course of action. Enough information must normally be given to ensure

that they understand the nature, consequences and any substantial risks of the treatment proposed so that they are able to take a decision based on that information."

Then if we go to paragraph 4, further down the page, again, this is very much from the perspective of what the minimum legal requirements were:

"A doctor will have to exercise his or her professional skill and judgement in deciding what risks the patient should be warned of and the terms in which the warning should be given. However, a doctor has a duty to warn patients of substantial or unusual risk inherent in any proposed treatment. This is especially so with surgery that may apply to other procedures including drug therapy and radiation treatment."

Then reference again to the Sidaway case.

Then the next page, please, Soumik. If we look at paragraph 9, just over halfway down the page:

"Consent given for one procedure or episode of treatment does not give any automatic right to undertake any other procedure."

Then I should just refer to page 13, in which attention is drawn to the Sidaway case. So, again, this is very much based on explaining what was

required in terms of legal responsibility or to avoid an action against a doctor.

There's similar guidance from Scotland. I'm not going to go to the detail of it because there aren't material differences, but we can just see that from PRSE0000713.

"Scottish Office

"National Health Service Scotland Management Executive

"Dear colleague

"A guide to consent to examination, investigation, treatment or operation."

We can see:

"The Department of Health issued in August 1990 its Guide to Consent for Examination or Treatment [the document we just looked at]. Ministers agreed that it was necessary to produce a similar guide for the use of health professionals in Scotland to maintain consistency throughout the UK in the area of patient consent."

Then the guide followed but, as I say, it's in materially similar form.

Then, now, in the 1990s, we see more detailed guidance on consent from the British Medical Association. So if we go to BMAL0000089, this is the

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

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

"The aims of the book

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

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

Then the next paragraph:

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

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

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

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

If we look at the last sentence of that paragraph:

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

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

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

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

Next paragraph tells us:

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

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

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

Next paragraph:

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

reflect the evolving nature of treatment."

Then we look at the bottom of the page:

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

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

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

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

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

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

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

Then picking that up in the second paragraph:

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

relationship.

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

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

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

Then the BMA expresses concern that:

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

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

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

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

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

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

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

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

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

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

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

So that's the 1995 --

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

back to page 30, which I noticed as we slipped past it --

MS RICHARDS: Is that electronic page 30?

SIR BRIAN LANGSTAFF: Electronic page 30. There's a heading, a paragraph which is headed "The autonomy of doctors". Now there's no similar paragraph in respect of patients, because, I suspect, the autonomy of a patient is demonstrated throughout the text.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And it's maybe thought quite interesting that it is, as it were, necessary to spell out what autonomy a doctor has when, in the early fifties and sixties, it might be said that the debate was about whether a patient had any.

MS RICHARDS: Yes. Yes, indeed.

So that was the 1993. There's then -- let's just look at in passing -- a publication from 1995 by the Royal College of Physicians, which is at RCPH0000404.

So 0000404_003, please, Soumik.

This is specifically looking at the position of consent for patients undergoing treatment for cancer but, nonetheless, may be illuminating in terms of understanding some of the wider principles in play.

So we can see there is -- it says:

"There is an increasing demand for patients with cancer to receive better information about their disease and its treatment than has been customary in the past, and this is coupled with the issue of informed consent for treatment."

Then there's specific reference to a declaration of the rights of people with cancer.

And if we just go down a few lines, that includes the right "to be informed fully about treatment options and to have explained to me the benefits, side effects and risks of any treatment".

If we go over the page, just picking up the first line and a half:

"Consent for treatment can no longer be assumed or implied by the patient presenting themselves for treatment ..."

Then if we go to the next page, under the heading "Current situation", it says:

"There can be no doubt that expectations regarding consent are changing and that in the light of this the legal position on consent is likely to reflect an increasing onus upon doctors to ensure that patients receive full information regarding treatment and its side effects before giving informed consent."

Then if we go a little further down, we see:

"The delivery of information to patients can be regarded in three main areas:

"(a) A discussion of the proposed treatment, alternative treatments and realistic expectations from treatment;

"(b) The process of treatment.

"(c) The possible toxicity of treatment."

And then if we go to the next page, not going to go through this in detail, but there are "Proposals for future practice" as to how to make the delivery of information really a more valuable and useful exercise. So little paragraph (a) talks about the consultation taking place in appropriate surroundings, (b) talks about the ideal of the initial consultation being distant from the arrangements for treatment so the patient feels that a true choice is being offered rather than a fait accompli. Paragraph (c) talks about the provision of:

"... supporting written information in the form of patient information leaflets, which would cover not only the process of treatment, but also realistic expectations from treatment, and both acute and late toxicities."

And if we go to the next page, we see (d), it's about patients being:

"... given the opportunity to ask for information beyond that which is volunteered by the clinician ...

"(e) All patients should have access to clarification and further information following the initial discussion."

And (f):

"It is important that there is full documentation of all advice given and of any written information leaflets or other back-up material taken by the patient."

So that's, as I say, from the Royal College of Physicians specifically in the context of cancer care.

And then two final documents to note on the topic of consent in 1990s.

There's the GMC's 1995 publication "Good Medical Practice". We looked at that this morning. I'm not proposing to go back to it but that talked about the rights of patients to be fully involved in decisions about their care and the right to refuse treatment.

And then, and this document I do want to look at, is the GMC's first specific guidance on consent.

That's at PRSE0003177, please, Soumik.

We can see this is being issued by the GMC in November 1998, "Seeking patient's consent: The ethical

considerations". And as I say, it's our understanding it's the first specific piece of guidance issued by the General Medical Council on the question of consent.

If we go to the second page, second paragraph:

"This booklet sets out the principles of good practice which all registered doctors are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research."

I should say, sir, this is a later version. So although November 1998 appears on the first page, we can see, from references here -- the 2006 version of Good Medical Practice has been inserted. The Inquiry doesn't currently have the original version so we're not quite clear at the moment the extent to which there were amendments.

But, again, much of this is by way of what the ethicists told us are well established, longstanding principles. We see under the heading "Introduction" again the reference to trust:

"To establish that trust you must respect patients' autonomy -- their right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death. Patients must be given sufficient

information in a way they can understand to enable them to exercise their right to make informed decisions about their care."

Paragraph 3, first sentence explains that:

"Effective communication is the key to enabling patients to make informed decisions."

Then if we go further down the page, we'll see the heading "Consent to investigation and treatment, Providing sufficient information", and then if we just pick it up perhaps at paragraph 5, at the bottom of the page:

"The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

"details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;

"uncertainties about the diagnosis including options for further investigation prior to treatment;

"options for treatment or management of the condition, including the option not to treat ..."

Then at the top of the next page:

"the purpose of a proposed investigation or treatment; details of the procedures or therapies involved ..."

Then the next bullet point:

"for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment;

"advice about whether a proposed treatment is experimental ..."

And so on.

And then, I'm not going to go through the detail of the remainder of it but if we go to the next page, we can just see some of the headings. So "Responding to questions" talks about the importance of responding honestly to any questions the patient raises.

"Withholding information.

"You should not withhold information necessary for decision making unless you judge that disclosure of some relevant information would cause the patient serious harm."

And importantly this:

"In this context serious harm does not mean the patient would become upset, or decide to refuse treatment."

So a doctor is not entitled to decline to provide information because he or she thinks that that

will lead to the patient refusing treatment the doctor thinks the patient should have. And again, that resonates very much in the context of some of the evidence that the Inquiry has heard.

So that's, again, it's a document that merits reading in full; it also has a section on consent to research.

But that's the GMC's position in relation to consent.

There's also, I think, perhaps finally on the topic of consent, a publication by the British Medical Association specifically in relation to children.

That is at GMCO0000679, I think. Yes.

You'll see here it says "Confidential" and "Strictly Confidential", but there are also references in the course of the document to it being available to patients and so on. So we have seen that at some point it became a published report.

Again, I'm not going to go through it in any detail. I think I'll just show you, sir, the contents list so we can see the kind of issues that were being covered in this particular document. So if we go to page 2, we see chapter 1 is:

"An ethical approach to treating children and young people."

So placing ethical principles really at the forefront of this report.

Chapter 2 then looks at "The Legal Framework".

And then if we go to the next page, we see at the bottom half of the page there is a whole chapter, chapter 5, on non-treatment and refusal of treatment.

So it's, again, a detailed discussion of the principles of consent in the particular context here, of providing messages to or offering treatment to children.

So, sir, those are the principal materials that the Inquiry has obtained that bear on the question of consent, in terms of the guidance given to clinicians.

The next topic I'm proposing to turn to is the issue of confidentiality and I'm happy start now or take lunch early, whatever is easiest for you, sir.

SIR BRIAN LANGSTAFF: Well, it's probably sensible to have it in one go, isn't it?

MS RICHARDS: Yes, certainly.

SIR BRIAN LANGSTAFF: So let's take a break now until ten to two.

MS RICHARDS: Thank you, sir.

(12.50 pm)

(The Luncheon Adjournment)

(1.50 pm)

MS RICHARDS: Sir, I turn next to guidance and other material relevant to the issue of confidentiality and the duty of confidence owed by doctors to patients.

We can pick this up at RLIT0001510, please, Soumik.

Taking these in chronological order, if we look at the bottom of the page, we'll see the Declaration of Geneva 1948, we've looked at this in more general terms previously, bottom of the left-hand column, "I will respect the secrets which are confided in me" is how the requirement of confidentiality was embodied in the 1948 declaration of Geneva.

If we look at the top of the page, this the World Medical Association's International Code of Medical Ethics adopted by its third General Assembly in London in 1949, and if we look in the right-hand column under the heading "Duties of doctors to the Sick" a third item is:

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

Then if we go to RLIT0001504, please, if we look at the bottom of the page, we can see here a modification, an amendment made by the World Medical Association in 1968, left-hand column, last three

lines:

"I will respect the secrets which are confided in me, even after the patient has died."

So that was to make clear that the duty extended beyond the lifetime of patient.

In terms of what we can then see in the professional guidance, if we go back briefly to a couple of documents we looked at this morning, first of all, GMCO0001697_001, please, Soumik. This was the original 1963 publication by the GMC functions procedure and disciplinary jurisdiction, and if we go to page 8, we see there, I referred to it briefly earlier, the examples given of what might have been infamous conduct in a professional respect and one of those is "Improperly disclosing information obtained in confidence from a patient", although no further guidance given in relation to that in this particular publication.

Then if we go to RCPH0000226, this is was the 1949 BMA publication page 16, please, Soumik, bottom of the page, again we see what was then termed "Professional secrecy":

"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 there was some specific example -- a handful of circumstances identified in which it might be legitimate to do that in terms of whether there were risks to others. But we can look at that in more detail in other documents.

Then if we look at the GMC's Blue Book from 1977, GMCO0001696_006. If we go to page 19, we see under the heading "Professional confidence" the GMC referring here, in fact, to guidance issued or contained within the BMA's Medical Ethics Booklet from 1974, but then here promulgated by the GMC's Blue Booklet:

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

"'It is a doctor's duty (except as below) strictly to observe the rule of professional secrecy by refraining from disclosing voluntarily to any third party information which he has learned 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.

"'There are some exceptions to this principle:

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

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 spelt 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

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):

"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

practice or organisation is structured.

SIR BRIAN LANGSTAFF: Presumably there would be, I suppose, no difficulty with it if the patient, upon coming to the surgery for the first time, were to give a general consent, but that might have to be revisited depending upon the condition which the patient was later found to suffer?

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

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

SIR BRIAN LANGSTAFF: Yes.

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

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

And then (6) says that:

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

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

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

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

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

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

doctor/patient relationship. It was contained in early codes such as the Hippocratic Oath ...

"Patients attend their doctor in the belief that the information they supply to the doctor or which the doctor finds out about them in the course of investigation or treatment will be kept secret. This encourages them to speak frankly and thus provide the doctor with clues or information which can be essential to diagnosis or treatment."

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

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

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

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

a healthcare professional.

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

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

Sorry, bottom of the previous page, my apologies.

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

Next page:

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

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

necessary to prevent a serious risk to public health; in certain circumstances, for the purposes of medical research.

And then, just picking up the bottom of the page, under the heading "Consent to disclosure":

"The information that a doctor obtains about a patient remains the property of the patient. However, the patient may, in certain circumstances, authorise the doctor to share it."

And then further discussion in relation to that.

Then the remainder of this chapter deals with the -- what are said to be the exceptions to the principle. Just note at page 33 the heading "Security of storage and access", and the guidance that:

"The doctor must ensure, as far as he can, that all medical information is kept in a secure place."

That's the BMA's 1988 guidance.

There is then, I won't turn to it, but the patient's charter or the first version of the patient's charter was published by the NHS in October 1991, and that talks about the obligation on NHS staff to keep medical records confidential.

Then we have some specific guidance from the GMC on professional confidence in the early 1990s.

So that's BMAL0000102.

Sir, we can see it's guidance for doctors on professional confidence, revised edition, published November 1991. And if we go to the next page, we can see at the very top of the left-hand side:

"This text replaces paragraph 76 to 85 in the GMC's publication Professional Conduct and Discipline: Fitness to Practise."

So this essentially extracted from the more general Blue Book type guidance and published in the form of a specific keys of guidance on confidentiality, a similar text.

Paragraph 1, under the heading "Principles":

"Patients are entitled to expect that the information about themselves or others which a doctor learns during the course of a medical consultation, investigation or treatment, will remain confidential. Doctors therefore have a duty not to disclose to any third party information about an individual that they have learned in their professional capacity, directly from a patient or indirectly, except in the cases discussed ... below."

And then we can see paragraph 3 talks about doctors carrying "prime responsibility for the protection of information", and must "take steps to ensure, as far as lies in their control, that the

records ... which they keep or to which they have access, are protected by effective security systems".

And then we can see various examples in terms of exceptions on the right-hand side, so "Disclosure in relation to the clinical management of a patient":

"In exceptional circumstances [paragraph 7] a doctor may consider it undesirable, for medical reasons, to seek a patient's consent to the disclosure of confidential information."

And further guidance there given out.

But stress that that's exceptional.

Then we see some of the other examples: disclosure required by statute.

Paragraph 11:

"Rarely cases may arise in which disclosure in the public interest may be justified, for example a situation in which the failure to disclose appropriate information would expose the patient, or someone else, to risk of death or serious harm."

Then if we go over the page, we see at paragraph 16, "Disclosure after a patient's death":

"The fact of a patient's death does not of itself release a doctor from the obligation to maintain confidentiality."

So that's the GMC's 1991 guidance.

I won't go to it, because really these all largely say the same thing, but invite you to note that the BMA in its 1993 publication, which we've looked at this morning, has a section on confidentiality.

And then the next piece of specific GMC guidance was issued in April 1999. That's at RCGP0000520_107. You'll see there it's entitled "Confidentiality: Providing and Protecting Information", April 1999.

If we go to page 3, second paragraph:

"Doctors hold information about patients which is private and sensitive. This information must not be given to others unless the patient consents or you can justify the disclosure. Guidance on when disclosures may be justified are discussed in this booklet."

Then if we go over the page, we can see the principles, again, reasonably well established by this time. So the right to confidentiality articulated in paragraph 1. And then various exceptions in which confidential information may be disclosed set out in the followed paragraphs, so where there's consent.

If we go to page 7, we can see under the heading "Sharing information with others providing care", then

this talks about sharing of information amongst colleagues or where care is provided by a team of doctors and other healthcare workers. That's paragraph 13.

Then we do get a reference to, for example, a secretary in paragraph 14:

"Where patients have consented to treatment, their explicit content to disclosure is not always needed before relevant information is shared within a team in order to allow that treatment to be provided. For example, explicit consent would not be needed for a general practitioner may disclose relevant information to a medical secretary who will type a referral letter, or physician may make relevant information available to a radiologist when requesting an X-ray, unless the patient objects."

So that's the GMC's suggested approach in 1999. Whether that's an accurate reflection of the principles in relation to confidentiality may be another matter. And, of course, may depend upon the context.

I don't think there's anything else in this document which deals with the specific example, sir, that you raised. Ah, note, there's a reference to disclosure for administrative purposes, but in fact

it's not dealing with the issue which you raised, sir.

Then if we go to page 14, we can then see some guidance in relation to disclosures without patient consent, but again, it's the fairly well established examples where there are -- there's a legal requirement so to do, direction of the court. And then the next page, paragraph 38:

"Disclosures may be justified where a failure to disclose information may expose the patient or others to a risk of death or serious harm."

So, fairly exceptional circumstances articulated there.

Those are the principal pieces of guidance from the seventies, eighties and nineties, and indeed to some extent in the earlier materials, in relation to confidentiality.

There is some specific guidance in relation to the confidentiality of medical information relating to children and, again, there making it clear it's essentially the same principles but that medical information may be shared with parents or guardians.

SIR BRIAN LANGSTAFF: Now just one query. You may not be able to answer this without looking further, but there is a reference in one of the earlier documents which you have just shown me to medical records being made

available to subsequent clinicians who are treating you. And the suggestion there is that, in the case of an ongoing condition, it should be available, to a subsequent clinician.

It might be thought to follow that if there is a congenital condition, then that would require, if it were to be honoured, those records of all treatment, from the date of birth onwards, to be kept and retained for that purpose.

It wasn't addressing retention directly, it was looking at the question of confidentiality. But the words would suggest that that is the principle being put forward.

Have we got anything else on that?

MS RICHARDS: Not in the material that we're looking at today, no. Again, we are looking more broadly at issues relating to retention of records, so we can pick up on the point that you've made, sir, and see whether there is any guidance on the retention of records which looks as it from that perspective. So the passing on of care to other clinicians.

But there's nothing I can think of at the moment, sir.

The next topic, then, that guidance relates to is the question of medical research. If I can start

with the 1947 Nuremberg Code, that is at RLIT0000372. We can see just below the heading "The Nuremberg Code (1947)", it says this:

"The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects."

Then we see set out those basic principles, which are said to be observed in order to satisfy moral, ethical and legal concepts. 1 is, for present purposes, the most important, although I will go through all of them. 1 is:

"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him

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.

"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

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

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.

"If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation."

Then:

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

So that, as it were, is research in the context of actually providing therapeutic care to the patient and that scenario, again, recognises the importance of the patient receiving the full explanation.

Then we have "Non-therapeutic clinical research", paragraph 2:

"The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

"3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed ...

"3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

"3c. Consent should, as a rule, be obtained in writing."

Then:

"4a. The investigator must respect the right of each individual to safeguard his personal integrity ...

"4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for the research to be continued."

Then:

"The investigator or the investigating team should discontinue the research if in his or their judgement, it may, if continued, be harmful to the individual."

That's the 1964 text for the Declaration of Helsinki. It is, as our expert group explained, a document that has been amended over the years and I'm not going to go through all the various iterations but that's it in its original form.

Perhaps the only variation or amendment I will show you is the 1975 amendment, which we have at RLIT0001506. Sir, we'll see this took the text to the Declaration of Helsinki and revised it in the 29th World Medical Assembly in October 1975. We can see the heading "Basic principles" at the bottom of this

page and, if we go over and look at paragraph 9, so again this is part of the basic principles:

"In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time."

Then if we go to the next page, we can see the distinction retained between medical research combined with professional care, sometimes called clinical research, and then non-therapeutic biomedical research involving human subjects, sometimes called non-clinical research. And then just looking at the clinical research, paragraph 5, we see there, contemplating the possibility of not obtaining informed consent, but it says:

"If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee."

There's a later amendment in relation to research on children, but I'm not going to go to that

now.

If we then look at RLIT0001349, please, Soumik. We can see here a publication or statement by the Medical Research Council in 1964, "Responsibility in Investigations on Human Subjects. If we pick it up, left-hand column, fourth paragraph down, we can see again this distinction being drawn between the two types of research:

"A distinction may legitimately be drawn between procedures undertaken as part of patient-care which are intended to contribute to the benefit of the individual patient, by treatment, prevention, or assessment, and those procedures which are undertaken either on patients or on healthy subjects solely for the purpose of contributing to medical knowledge and are not themselves designed to benefit the particular individual on whom they are performed. The former fall within the ambit of patient-care and are governed by the ordinary rules of professional conduct in medicine; the latter fall within the ambit of investigations on volunteers."

And then if we look at the heading "Procedures Contributing to the Benefit of the Individual", so this first category, what we see there set out wouldn't necessarily accord with what we've seen

elsewhere in relation to consent, so if we pick it up six lines down:

"Provided ... that the medical attendant is satisfied that there are reasonable grounds for believing that a particular new procedure will contribute to the benefit of that particular patient, either by treatment, prevention, or increased understanding of his case, he may assume the patient's consent to the same extent as he would were the procedure entirely established practice."

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

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

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

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

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

Not precisely clear what's meant by that.

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

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

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

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

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

And then we see the reference to adequate explanation.

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

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

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

MS RICHARDS: Yes.

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

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

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

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

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

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

I'm not proposing to go to those.

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

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

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

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

matters of clinical research investigation."

Then, if we go to the next page, we can see the heading "Explanations to subjects or patients who may participate in clinical research investigations".

Paragraph (a):

"Patients. Wherever the research investigation is not expected or is not intended to benefit the individual, a full explanation of the proposed procedure should be given and the patient must feel completely free to decline to participate or to withdraw at any stage."

So that's the category with no clinical benefit to the individual.

We then look at the third paragraph:

"Where the research is intended to benefit the patient, although consent should ordinarily be sought, there are sometimes circumstances in which it is inappropriate or even inhumane to explain the details and seek consent. Ethical committees should examine such cases with particular care."

This might be thought to be a minor advance on the 1964 document that we looked at, because it suggests that, in relation to research intended to benefit the patient, so the clinical research, consent should ordinarily be sought, so it at least gives it

as the starting point, although we then have here articulated, in very broad terms, a potential exception. Difficult to think of examples in the real world where it might be thought "inhumane" to explain the details.

SIR BRIAN LANGSTAFF: Well, it looks as though it is suggesting that the basic approach should be: number one, get the consent of your patient, fully informed; number two, if you don't think that's appropriate or if you think it might be inhumane, you must go to the Ethics Committee.

MS RICHARDS: Exactly.

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

MS RICHARDS: Yes, precisely. A safeguard.

So that was the RCP Committee's 1973 publication.

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

Helsinki.

Then, if we look at the last paragraph on this page, it says:

"Two broad groups of subjects [subjects as in participants in research] have been recognised. The first group consists of both patient and non-patient volunteers for whom the procedure is not of direct therapeutic benefit; the second comprises patients who may be anticipated to derive direct benefit."

So the same distinction there being drawn:

"Most of the initial studies with a substance are performed on subjects in the first group. The nature of the trial, its objectives and likely adverse effects should be explained to each volunteer [who is asked to freely give their consent]."

Then it says:

"In patients of the second group [so where there's an anticipated direct benefit to the patient] the validity of the results of certain types of investigation may be reduced by full disclosure to patients ... and a certain latitude in explanation may be exercised. The information given to the patient is at the discretion of the clinician in charge of the trial."

Go over the next page:

"But unless there are any real medical contraindications, it is wise to obtain consent after describing the study to the individual."

So again, we see a range of different shades of meaning in these publications, in terms of what information should or shouldn't be given to the participant in a study in which it's the doctor's judgment that they may derive some benefit.

Then we can go next to the BMA's Handbook of Medical Ethics from 1980. which is at BMAL0000087. If we go to page 22, we can see the heading at the bottom of the page "Research in human subjects". Then if we go to the next page, there's discussion -- well, actually, we'll just pick it up at the top of the page. It says:

"Most patients trust their doctors and will consent to any proposal. Experimental procedures are nearly always too technical for patients or non-experts to understand. For practical purposes, therefore, the doctor concerned carries a moral responsibility for the investigations that are, or are not, proposed to his patient or volunteer."

Quite what's meant by "moral responsibility" in that context is not clear.

Then 4.3, it talks, in the second line:

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

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

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

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

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

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

"These guidance presume that four premises are accepted.

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

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

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

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

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

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

But it's an editorial which talks about a range

of moral problems associated with research on children.

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

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

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

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

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

SIR BRIAN LANGSTAFF: Absolutely.

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

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

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

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

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

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

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 ..."

That may be comprehensible. Then we get:

"... acute grave illness, inability to comprehend. In all cases an Ethics Committee will give very close consideration to any proposal to proceed without consent and will satisfy itself that the decision not to seek consent from an individual is ethically acceptable."

Then at the bottom of the page we see:

"use of patient records presents real ethical issues. Care should be taken to ensure that such use is in accordance with current codes of practice ..."

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

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

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

SBTS0000005_006, please, Soumik.

So this is the "APBI Report on Good Clinical

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

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

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

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

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

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

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

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

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

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

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

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

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

Pausing there, that would suggest that it would

bring with it all the normal requirements of good practice.

Then 2.3:

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

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

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

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

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,

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.

"... 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.

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

research, the first is the BMA's 1993 publication on medical ethics.

So we've looked at this for other purposes already.

Soumik, it's BMAL0000089. And if you could go, please, to page 221, I think.

So there's a fairly detailed chapter in this 1993 guidance from the BMA on research. If we go to page 223, under the heading "Definitions", bottom of the page, it talks about how:

"Confusion sometimes arises from the wide range of procedures covered by the term, 'research'."

Then bottom of the page talks about the division into therapeutic and non-therapeutic research.

If we go over the page, we can see reference to the Declaration of Helsinki, and the distinction between therapeutic or non-therapeutic research.

Then in the last four lines of that first section -- sorry, can we just go up a page, Soumik.

So in paragraph 8.2.1 the BMA says this:

"Despite the implication in the Declaration of Helsinki, the distinction between therapeutic and non-therapeutic research is often not at all clear, with a consequent blurring of the moral focus."

And then we see 8.2.2 talks about

non-therapeutic research and talks about how that must be subject to full ethical review by local ethics committees. And the subject's consent must be based upon adequate information.

There's then a reference to innovative treatments, and the BMA says:

"It is often unclear how new treatments and techniques fit into the framework of ethical review. At present they are sometimes seen as an extension of the usual treatment, even though such treatments may expose the patient to more than a minimal risk of harm. However, they are often classified as research."

Then if we go to the -- still under this heading but the bottom of the next page. I think this may be of some importance, sir, when you're assessing some of the evidence you've heard from the clinicians about their involvement in research:

"It is clear that where the clinician's intention is to acquire new knowledge rather than solely to care for the patient, the constraints applicable to the conduct of research should apply."

Then it continues:

"Thus, in cases where a doctor proposes, for an individual patient, a course of action which

diverges substantially from normal medical practice, with the intention of gaining information which might help future patients, the activity must be subject to review by a local research ethics committee ..."

Then over the next page, under the heading "Areas of overlap", the BMA says this:

"As has already been mentioned, some projects overlap from one category into the other but where the focus of attention is not solely the best interests of the individual patient, treatment must be subject to the rigorous standards required for research projects."

So it could perhaps be summed up in a rather simplistic way as this: if in doubt, assume that this is something which requires the full panoply of safeguards, in terms of Ethics Committee approval, and so on.

There's then a more detailed discussion of consent in the context of research from page 229 onwards. Bottom of the page:

"Research brings the risk of causing harm, in the practical sense of possibly damaging or disadvantaging a patient, and of doing wrong, in the moral sense of ignoring the autonomy of that individual. People are wronged if they are deprived

of choice or their values are transgressed on the assumption that the best clinical outcome is necessarily what is best for them. The possibility of harm cannot be entirely eliminated from research but by insisting that patients have adequate information and choice about participation, we minimise the possibility of wronging them."

There's then a discussion about the Nuremberg Code. If we go to the next page, under the heading "General principles", there's then a discussion of the broad fundamental principles of consent, and it says:

"[It can be] seen the BMA generally lays great emphasis on valid patient consent ..."

If we pick it up five lines down:

"The researcher should inform the subject about potential benefits and risks of the procedure, why it's proposed and the significance in terms of advancing knowledge and the researcher's own stake (if any) in proposing the procedure. Where patients are offered choices, they need information about the alternatives to the treatment recommended by their doctor. When a clinical study is proposed patients need to know about the advantages and shortcomings of conventional treatments as well as the options in the trial. In any situation, the more risky or invasive

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

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

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 often blood products in order to reconstitute them ready for administration."

Then it talks about the making available of

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 (Veneral Diseases) Regulations and then adds this:

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

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

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

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

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,

anaesthetists and dentists dealing with patients infected with HTLV-III. And if we just go to page 8, and I'm focusing only on those parts of the materials that give rise to essentially broader ethical questions but in the context of HIV:

"Confidentiality of health care data

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

There's then reference to the same regulations. Then it says:

"For all HTLV-III positive patients the normal rules of medical confidentiality apply and unless the patient has given his consent, personal health data relating to him must not be disclosed to anyone for any purpose other than the health care of that patient, except where disclosure is necessary to prevent the spread of infection."

And then we see the bit in square brackets at the end of that paragraph:

"Normally it is inappropriate to test a patient for HTLV-III antibodies without their consent unless it is part of a clinical investigation of signs and symptoms."

There appears to be a suggestion there that it

can be appropriate to test the patient without their consent, and we'll see how that debate develops over the next couple of years.

"If a patient refuses to be tested then they should be treated on the assumption that they're positive if they're deemed to be in a high risk group."

Then, without going into the detail of it, if we look at the next paragraph, you'll note that this booklet then talks about isolation techniques and the circumstances in which HTLV-III positive patients should be nursed and the facilities which they can and can't access in hospital.

So that's the autumn of '85. There's then some European guidelines issued in January of '86, at SHTM00002515. SHTM00002515.

We see there guidelines on AIDS in Europe produced by the World Health Organisation. If we go to page 12, if we could zoom in on the right-hand side, so bottom right-hand side:

"Preventing the spread of infection from those known to be positive to anti-LAV/HTLV-III.

"Testing of healthy individuals for anti-LAV/HTLV-III should be done only after informed consent has been obtained. Individuals who have been

tested ... on their own initiative and found positive should be offered individual counselling and psychosocial support."

Then it sets out information they should be provided with:

"They should be informed that they are infectious through sexual contact and through their blood and semen. They should be encouraged to inform their sexual partner(s) about the risk ... urged to refrain from donating blood, plasma," etc, etc.

But there, the first sentence really, the importance of informed consent is there stressed.

So that's what the World Heath Organisation had to say.

Then you can see the next publication by the BMA at BMAL0000031_024. So "Statement on AIDS", if we go to the next page we'll see the date, May 1986. It's a state from the BMA's Board of Science and Education, so not, in fact, from its Ethics Committee. But if we go to page 12, we can see, first of all, the issue of confidentiality. Paragraph 1:

"It is vital to maintain the confidence of those in high risk groups to ensure that by coming forward for testing or counselling there will be no breach in confidentiality."

Then it refers to a specific set of regulations, which I don't think is necessarily particularly relevant for present purposes. If we go to the next page, go to the top of the next page, we can see there again the particular protection given to those who go for blood tests at a sexually transmitted diseases clinic, because of the NHS Venereal Diseases Act, and they had to be treated under terms of strict confidentiality.

If we go to paragraph 5 on the same page:

"The strictest confidentiality must be maintained for affected individuals ..."

Then it refers to the Department of Health guidance. Then if we go down to paragraphs 6 and 7:

"Individuals with a confirmed sero-positive test should inform doctors and dentists who are treating them that they are antibody positive ... so that the appropriate precautions can be implemented.

"It is anticipated that the vast majority of HTLV III antibody positive individuals will give consent for their own doctor to be informed of the test results. Similarly, it is very seldom founding in practice that a patient will persistently refuse to tell a spouse of his/her antibody position or who refuses permission for the doctor to contact his/her

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

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

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

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

SIR BRIAN LANGSTAFF: In practice, it might be quite

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

MS RICHARDS: Absolutely.

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

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

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

at the bottom of the page under the heading "Counselling, confidentiality and informed consent":

"Individuals must give informed consent before being tested for anti-HIV. Informed consent implies that the reasons why the test is advised are carefully explained to the individual and equally, that the results will be carefully discussed. In individuals who have positive tests, counselling will be necessary. If counselling is not available, testing should not be done. The results of anti-HIV tests must be strictly confidential. A positive result may have enormous psychological implications and may adversely affect the individual's employment, marriage and other relationships. It may also preclude an application for life insurance ... Under no circumstances must the results of anti-HIV testing be casualty communicated to other health care workers, unless they are providing direct patient care."

So there's an exception contemplated there.

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

So the nursing guidance, you might think,

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

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

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

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

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

consistently'.

"Currently HIV infection and AIDS remain very emotive topics. However, the social implications for the patients are immense."

Then the last sentence:

"Nurse to nurse communication must be confidential."

We can then --

SIR BRIAN LANGSTAFF: Do the relevant personnel include hospital porters?

MS RICHARDS: I'm not sure I can answer that, sir. I can't think of any obvious reason why they should.

SIR BRIAN LANGSTAFF: No. I mean, it's the ambiguity in the sense of "relevant personnel".

MS RICHARDS: Yes, the question of who is relevant. It is difficult to see why a hospital porter would need to know, either for the discharge of their responsibilities or to safeguard their own healthcare, that a patient is HIV positive. I'm fairly confident there's nothing in the materials that we've seen that deals with that expressly.

SIR BRIAN LANGSTAFF: Yes, it does arise in the evidence.

MS RICHARDS: Oh, it does. Absolutely.

Then BMAL0000031_023, this is the BMA's Third Statement on AIDS. This is 1987 now. If we go to

page 16, we can see the heading "Consent".

So it's paragraph 3.14.1:

"People should only be tested for HIV antibodies if they have freely consented to this, and fully understand the possible implications, because of the considerable disadvantages to the individual in being found to have antibodies. Consent means the ability to choose, free of duress and with the benefit of relevant information, what course of action to take. Moves to test people against their will or without their knowledge might encourage them to conceal behaviour that could place them at risk ... and to avoid seeking medical attention for problems that may be wholly unrelated to AIDS. It is essential that the medical profession commands the confidence of patients and prospective patients; if patients perceive the actions of doctors as contrary to their interests this will deter them from seeking necessary advice or treatment to the detriment of their health, and will undermine the effectiveness of measures aimed at controlling the spread of infection."

So there a statement in pretty clear terms about the need for informed consent and not to test patients for HIV antibodies without their knowledge.

Then confidentiality is dealt with on the next

page. So the first paragraph:

"The traditional confidentiality of the doctor-patient relationship must be upheld in the case of patients suffering from AIDS and HIV seropositive individuals. According to DHSS guidelines, unless the patient has given consent personal health data should not be disclosed to anyone for any purpose other than the healthcare of that patient, except where disclosure is necessary to prevent the spread of infection. As HIV is not spread through casual non-sexual contact there could be very few circumstances in which disclosure would be justified."

Then, again, there's a reference to the NHS (Venereal Diseases) Regulations. Then the next paragraph, says:

"With counselling, the majority of infected individuals can be persuaded voluntarily to inform their general practitioner, dentist and sexual partner(s) of their infected status."

Then in the third paragraph:

"It is the duty of the general practitioner to ensure that information is kept strictly confidential, unless the patient consents to disclosure. Patients should be strongly encouraged to permit disclosure when there are firm medical reasons for this, such as

when undergoing surgery. In general however, the fewer people know of a person's antibody status the more people in high risk groups will come forward voluntarily for testing or treatment. Much of the pressure for disclosure of patients' antibody status has resulted from misconceptions about levels of risk, which still remain common among doctors and other health service professionals. This indicates the importance of clear eduction for these groups."

Then the next paragraph talks about insurance companies:

"Insurance companies sometimes ask [GPs] to provide information about patients who are seeking insurance. GPs should complete insurance company forms truthfully to the best of their knowledge, but should make clear to the patient what information is being disclosed, and what the possible implications may be. It is then up to the patient to decide whether the form should be sent."

And then some further narrative in relation to that.

So that's the BMA's third statement. We've seen all the iterations of that statement, in the course of 1985, 1986 and 1987.

Yes, I think the third statement, it was perhaps

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

There's then a GMC publication in May 1987. DHSC0003701_028.

If we zoom in a little closer:

"21st May, 1987

"AIDS: The doctor's duty towards patients

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

Then we see the GMC setting out its view.

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

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

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

But then says:

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

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

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

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

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

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

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

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

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

This is the bottom of the same page:

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

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

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

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

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

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

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

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,

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

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

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:

"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

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

profession about the passing of the motion, the BMA sought medical -- sorry, sought legal advice from Michael Sherrard QC. We have his advice at BMAL0000013_033.

Now, obviously he is talking about the legal position; Dr Chisholm was talking about both the legal and ethical position. But in terms of the legal position, Mr Sherrard's advice is pretty unequivocal. He says in 1:

"It must be appreciated that such effect as the resolution may have is limited to the domestic policy of the BMA (and, possibly disciplinary proceedings before the [GMC]). It does not, affect the law of the land."

Then he talks about:

"[The] fundamental principle of the English common law that every adult human being of sound mind has a right to determine what shall be done with his own body ..."

He talks about torture, battery and assault.

Then:

"3. It will be apparent, therefore, that any medical treatment which involves physical contact with the patient's body is a potential battery ... It is the existence of the patient's consent to the touching

which renders the touching legally unobjectionable. We shall use the term 'treatment' to include 'testing' in this context."

Then there's a discussion of consent:

"As a general rule, the consent of the patient is an essential prerequisite to medical treatment of any kind, even that of a relatively minor nature."

Then there's a discussion over the page of various cases. At the bottom of the page, under the heading "Implied consent", we pick it up in the end of the third line:

"In our opinion the doctrine of implied consent is not at all likely to be held to cover testing for HIV antibody. The taking and testing of a sample, though it may commonly be carried out, would not, in our opinion, be considered 'routine' by the courts. Given the far-reaching implications of a positive result it cannot reasonably be contented that an HIV test can be covered by the notion of implied consent ..."

Then that paragraph ends with:

"Accordingly, a medical practitioner is under a duty to ensure that the patient's explicit consent to the testing is obtained."

There's then a discussion about the legal

requirements for informed consent. If we go over the page, there's then a heading of some further practical considerations and then we go to conclusions, at the bottom of the next page:

"The implementation of the resolution under discussion has the potential for placing medical practitioners in an extremely difficult position. As the law stands at present, the consent of patient is essential if the act of taking a sample for testing is not to constitute an assault or expose the practitioner to a claim in negligence for failing to inform the patient of the nature of the test and possible consequences of a positive result. This leaves aside any questions of professional misconduct which may arise."

Then at paragraph 13:

"It is clear that the courts will strive to uphold the individual's bodily integrity ..."

Paragraph 14:

"We are of the opinion that, where, in essence, a medical practitioner has, without the genuine consent of the patient, obtained a blood sample for the pre-dominant purpose of testing for HIV antibody, the Courts are likely, in the end, to accept the formulation expressed by Lord Scarman in the course of

his speech in the Sidaway case ..."

Then bottom of the page:

"In the final analysis, it is our opinion that the Courts will continue ... to hold that the right to decide rests with the patient and not with his medical adviser. It would be unwise for practitioners to adopt a course which pre-empts possible legislation and exposes them to both criminal and civil proceedings."

That's the conclusion, and the date of the advice, September 1987.

The advice was effectively accepted by the BMA and promulgated by the BMA, and we can see that at BMAL0000031_067. I won't go through it. It is essentially the text of the advice that was published by the BMA, and subsequent publications by the BMA made clear that they did not stand by the Motion 363 that had been passed.

Just in terms of publications then emanating from others, and I take this fairly shortly, but again, it's instructive to see what the UKCC -- so what the Nursing Council were saying, BMAL0000029_13. "AIDS -- Testing, Treatment and Care". So we can see this refers in the first paragraph to the BMA's decision at its annual representative meeting, and

then says:

"On the specific issue of the taking of blood for testing without consent, the Council [so that is the Nursing Council] has advised nurses, midwives and health visitors on its professional register who have approached it, and now advises all its practitioners that they expose themselves to the possibility of civil action for damages or criminal damages of assault if they personally take the blood specimens, and of aiding and abetting such an assault if they knowingly collude with a doctor in obtaining such specimens. Additionally these actions, like that of being party to any statements aimed at leading patients to believe that blood specimens taken for AIDS testing were for some other purpose, expose nurses, midwives and health visitors to the possibility of complaints to their registration body alleging misconduct which would put their registration status and right to practise at risk."

So in no uncertain terms, the Nursing Council rejecting the BMA position.

There were later and more detailed statements issued by the UKCC, which reiterate, again, that position in no uncertain terms.

Then I think probably the final document that we

can look at is a GMC publication in May of 1988, at NHBT0010410.

This is the GMC's document "HIV infection and AIDS: The ethical considerations". And again, this was updated over the course of the following years.

And if we look at page 2, under the heading "The doctor/patient relationship", paragraph 2:

"The doctor/patient relationship is founded on mutual trust, which can be fostered only when information is freely exchanged between doctor and patient on the basis of honesty, openness and understanding. Acceptance of that principle is, in the view of the Council, fundamental to the resolution of the questions which have been identified in relation to AIDS."

Then if we go to the bottom of the next page there's an articulation in paragraph 12 of the general principles that a doctor should treat a patient only on the basis of the patient's informed consent.

"Doctors are expected in all normal circumstances to be sure that their patients consent to the carrying out of investigative procedures involving the removing of samples or invasive techniques, whether those investigations are performed for the purposes of routine screening ... or for the

more specific purpose of differential diagnosis."

There's a recognition that there can be circumstances of -- where a patient might agree to provide a specimen of blood for multiple analysis.

Then, over the page, the Council, the General Medical Council, then applies that principle to testing for HIV, and says this:

"The Council believes the above principle should apply generally, but that it is particularly important in the case of testing for HIV infection, not because the condition is different in kind from other infections but because of the possible serious social and financial consequences which may ensue for the patient from the mere fact of having been tested for the condition."

And then there is a further discussion emphasising that point.

Should just note the last sentence of that paragraph:

"Only in the most exceptional circumstances, where a test is imperative in order to secure the safety of persons other than the patient, and where it is not possible for the prior consent of the patient to be obtained, can testing without explicit consent be justified."

And again, it may be difficult to think of circumstances other than the unconscious patient, where the nature of the surgery or investigation that's required is such that people will be placed at great risk if the status of the patient is not known, but that's probably about the only thing that might come within that very limited exception there given.

And then there's a reference to confidentiality, two paragraphs further down.

So these publications in the BMA and the GMC and so on were then reissued over the following years in broadly the same terms with respect to issues of consent and confidentiality.

I should just draw attention -- though I'm not going to go to the documents, not least in view of the late hour -- to the fact that there was -- in 1990 and then I think in '91, '92, there was an exchange of statements or various statements being published contemplating that there might be cases in which surgeons should be allowed to test patients without their consent for HIV so that the surgeons would not be placed at risk. So the Royal College of Surgeons in Edinburgh published a statement in March of 1990 which identified circumstances in which it was said it might be appropriate to test patients without their

consent.

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

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

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

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

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

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

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

MS RICHARDS: I'm not sure without checking, sir. I certainly don't think there's anything which says in positive terms that that's an ethically acceptable course of events. The extent to which there is -- there are -- publications say in positive terms it is unethical is what I would need to check.

Sir, those are the documents that related

specifically to some of the broader ethical issues as applied to the emerging AIDS crisis in the 1980s.

The very last topic in our note -- I'm not going to go to any documents now because I think we can probably usefully pick it up at a later hearing -- was about the relationship between doctors and pharmaceutical companies and the circumstances in which doctors can or cannot accept hospitality and the gifts and the like from pharmaceutical companies, but it may be that -- only a handful of documents that we would need to look at in that regard -- but it may be that when we have our autumn hearings on pharmaceutical companies, we can look at those materials then.

SIR BRIAN LANGSTAFF: Yes.

Yes, thank you very much.

So we are not involved in hearings next week.

MS RICHARDS: That's correct.

SIR BRIAN LANGSTAFF: And the week after?

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

SIR BRIAN LANGSTAFF: It is the 8th.

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

some are giving evidence remotely.

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

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

MS RICHARDS: Thank you, sir.

(4.38 pm)

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

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