Thursday, 23 June 2011

(9.30 am)

DR VIVIENNE NATHANSON (affirmed)

Questions by MR GARDINER

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Good morning, Dr Nathanson. There is a microphone just in front of you; if you could maybe pull it towards you slightly.

THE CHAIRMAN: Could we just check that Dr Nathanson can be heard so that we don't come to it later.

Could you just say something, please.

A. It's nice to be back in Scotland.

THE CHAIRMAN: Is everyone content that that's been heard?

MR GARDINER: Thank you.

We usually start by looking at an expert witness' CV. So could we have a look at PEN0161163? Perhaps you could start by telling us what your current position is, Dr Nathanson.

A. I'm director of professional activities at the British Medical Association, which means I'm responsible for everything that the BMA does as a professional association, in other words, not the trade union activities. So public health, human rights and a collection of other things.

Q. How long have you been doing that for?
A. 16 years.
Q. If we just have a look at your employment, which is on the first page of the CV, we see that between August 1978 and January 1984 you held various posts in hospital medicine. Could you tell us what that involved, please?
A. My first year was the -- in those days it was the pre-registration house year, so six months of general medicine at Mount Vernon Hospital in London, followed by six months as a house surgeon and then SHO and registrar posts in general internal medicine, finishing with three years in a hospital in North Wales as a specialist registrar in general medicine.
Q. Yes, thank you. We see from the list, under the heading "employment", that in February 1984 you were a management trainee at the British Medical Association, in May 1996 you were head of tax, superannuation and careers advice, and then between April 1987 and December 1989 you were head of ethics and international affairs. Could you explain what that involved?
A. The BMA has had a committee looking at medical ethics for probably around 100 years. It's slightly different depending on the way it's described but certainly around

100 years. I was responsible for that committee and that committee writes advice, advice in the form of books, which go to members or are available to members, guidance notes and leaflets, pamphlets and so on for members, and of course responses to members who ring up with queries. So on a day-to-day basis I and my junior staff were answering questions from doctors on, "What do we do in the following circumstances. Can we talk through the way we should handle particular cases?"

Q. Yes. Thank you.

Then just reading down, January 1990 to December 1994 you were the Scottish secretary (chief executive) of the British Medical Association. What did that involve?

A. I was responsible for everything that the BMA did in Scotland. We have offices in Edinburgh and Glasgow. We also had an office in Aberdeen during that period. So that included the trade union function and the committee function but it also included the professional work, so anything that came in from doctors that they wanted advice on would come to me and either would be answered by myself or by my staff. It included quite a lot of campaigning and advocacy on public health.

Q. Yes. Between 1994 and 2001, we see you were an honorary professor, healthcare management at the department of

management at the University of Stirling. What does that involve?

A. While I was in Scotland, it became clear that doctors were increasingly being asked to be involved in managing healthcare and particularly managing parts of the service, and didn't have the management tools. So we set up, with the University of Stirling, an MBA programme for doctors and dentists and I helped to devise that with the people at Stirling and taught on it. We also bid for and won the contract to train the fast track management trainees or graduate trainees in the NHS in Scotland in management. So it was a classical MBA but everything was related to healthcare and I in particular taught the ethics to both the managers and to the doctors.

Q. Yes. Thank you. We see from 2004 until today -- is that an ongoing commitment for the honorary professor at the University of Durham?

A. It is indeed, yes.

Q. What does that involve?

A. That involved just from time to time going up and teaching but I spend a little more time than I spend teaching actually talking to the dean of the school of medicine -- well actually it's the school of health because although it's a medical school, they also teach

nurses and other professions -- and talking particularly about the integration of ethics into public health teaching.

Q. Yes. Is it the same kind of thing for the University of Strathclyde?

A. The University of Strathclyde; it was just simply a honorary degree in recognition of the work I've done on public health and ethics.

Q. You have told us what your current position is but at the bottom of the page we see that you are chair of the BMA steering group on human rights. Could you tell us a little bit about that, please?

A. Yes, we wrote a report on human rights -- I'm trying to think, it was certainly in the late 1980s and we have done three reports since then. In each of those we were looking at issues, such as medical involvement in protecting human rights, or indeed in some countries in abusing human rights, and in trying to make a difference to the human rights expectation of individuals both in the UK and elsewhere.

So at the moment we have just committed to writing a new report, which we hope to produce by the end of 2012. In between that we do quite a lot of campaigning work and at the moment one of our major areas of activity, for example, is in response to the Bahrain

issues, where doctors who have been treating all patients regardless of their political affiliations have been arrested and told that that's an unacceptable thing.

So we try to defend that and point out the ethical imperative on doctors.

Q. Yes. Thank you.

Could we just go over the page now, please? We see that you teach extensively at Cambridge and Durham on ethics and human rights and that you have contributed chapters to textbooks on ethics and human rights. You have edited three reports on the medical aspects of weapons control issues. What are weapons control issues?

A. This is the impact of international humanitarian law, the laws of war, the Geneva Conventions, and the role of doctors in respect of that; in particular the use of medical knowledge to develop biological or chemical weapons and defences against those, because clearly both weapons are illegal but in developing the defences against them quite often you have to develop some knowledge of how to produce a weapon.

In addition to that there is a particularly interesting area that, as medical knowledge develops, sometimes people will abuse that knowledge and that's

a particular worry in terms of drugs.

Q. Yes. Thank you.

We see that you teach several programmes with the international committee of the Red Cross, for example on ethics for doctors new to ICRC missions and human rights in prison settings, and that you have been an expert witness to select committees of the House of Lords and House of Commons. Could you give us a bit more detail about that?

A. In terms of the Red Cross, it's simply that whenever they have groups of new doctors who are going to be heads of missions or members of the mission, whether that is a permanent mission in a country such as Pakistan or Bangladesh or a doctor going to an emergency where they are going to be setting up hospitals, they want to make sure that they are well-informed about the ethics and the dilemmas they will face around issues such as consent, confidentiality and so on, in particular in conflict situations where the tensions are very great. So they want somebody who can teach both the ethics but who understands the situations. I have worked with them for about ten years now.

In terms of giving evidence to the Houses of Lords and Commons, the nature of my job, because of my responsibility for public health, means that I get

called to give evidence to many different committees. So, for example, I have given evidence, I think, three times now to different committees on healthcare for refugees and asylum seekers, including those who are refused asylum seekers; whether they still have rights, what the ethical issues are, and indeed to a certain extent what the clinical issues are with which they might present. And I'm giving evidence on behalf of the BMA, but of course in these circumstances having to answer questions that fit into the broader ethical and indeed health category.

Q. Yes. I think that you have given evidence to public Inquiries as well before?

A. Only to one. That was to the Baha Mousa Inquiry last year, which I understand is now reporting in September.

Q. What aspect were you giving evidence about?

A. On the duties of physicians to understand the conditions in which prisoners are held, to intervene if they think prisoners are being abused, the ethical duty of a physician who is a military physician, and where that fits or potentially conflicts with their duty as a serving officer; and to comment as well on the advice to serving medical officers by the command structure in the army, whether that was adequate, and including issues such as when prisoners should first be examined

and last examined at different times in their status from arrest or detention until either release or formally going into a very formal prison setting.

Q. Thank you. We can put that away now.

If we could see Dr Nathanson's report, which is [PEN0120330]. The Inquiry asked you to produce a report in connection with certain issues. That's right? Is that the report that you produced there on the computer screen?

A. Yes, this is.

Q. Yes. I think if we go to 0342, we see that's your signature at the end of the report?

A. It is, yes.

Q. Yes, thank you.

So could we go back to the beginning again, 0330? Could you tell us very broadly what material you were given by the Inquiry before you produced your report, always remembering that we are being very careful not to mention the names of specific patients?

A. I had the preliminary report. In addition, I had a number of witness statements by patients and relatives of patients, particularly those who were deceased. I had witness statements from some of the medical staff who were being interviewed by the Inquiry and a number of documents, such as minutes of some meetings of some

of the haemophilia groups and some of the UK Department of Health groups, looking at blood safety and so on.

Q. Yes, thank you. I think you may have seen some of the transcripts of our Inquiry?

A. Indeed, yes. I saw some of the transcripts of a number of witnesses from the Inquiry.

Q. Yes, thank you.

Could we have a look at page 1 of your report? After the introduction, I think you start by giving a history of medical ethics over the last 30 years and perhaps I can just leave it to you, Dr Nathanson, to talk us through that history.

A. Yes. Thank you.

This was a very interesting period in medical ethics. There has been writing on medical ethics, people would say historically, from Hippocrates onwards but that's obviously not the only source of medical ethics advice, but over the centuries there have been a number of ethical statements which people understood and read in different ways.

I would say that in the 1970s, both in relation to doctors looking at the practice of what they were doing and saying, "What is the best way of working with our patients and getting the best result for patients?" and because of external challenges, and in particular the

publication by Ian Kennedy of his Reith lectures in 1979, which were called "The Unmasking of Medicine". And they were very influential and were a particularly useful adjunct to those people who were already beginning to try to change medicine from its historical basis, and that historical basis was really a very paternalistic -- I'm never quite sure whether it really means only men practise medicine; maybe it did. But the basis of medicine in those days was certainly doctors had the knowledge, doctors would tell patients what they thought the patient ought to know and they would tell the patient what they were going to do as doctors to the patient.

We have moved over that period of time from doctors having knowledge and making sure that they share that knowledge with patients and encourage patients to discover for themselves, to use sources of information so that they themselves can question and understand what's going on with themselves, helped of course by the fact that we now have huge amounts of information available, both on paper and electronically.

Today we would see medicine as being about a sharing, that the role of a doctor is not to say "I know everything," but "This is how I would interpret the information you are giving to me and that I'm

learning about you from tests, and this is the sort of things that you might wish to think about when we look at treatment, planning what we are going to do next to help to manage whatever it is that brought you to see me, the symptoms," and so on.

That's really a very radical shift. And during this period there have been many different ways of looking at how you change from an attitude of "Doctor knows everything and will give orders" to "We will share information and my role is to help you make a decision. But not to force you to make the decision, I, as the doctor, will make a decision for you if you don't wish to make a decision", and some patients don't.

So it's actually a more difficult balance today, much easier to order people than it is to help them to make decisions.

Much of the development in that time has been about, "How do we change the way people think and how do we change, even more substantially, the way people behave?" So a great deal, for example, has been about the teaching of medical ethics. I write in -- I think, the third paragraph -- about the surveys that we have done at different times with the Institute of Medical Ethics and on our own on the teaching of medical ethics. It remains an issue that medical ethics teaching in many

medical schools is by clinicians with an interest in ethics and some experience, perhaps some formal training themselves, but in many medical schools, although not all, there is inadequate access to an academic basis of medical ethics, so that the teaching can be patchy and it's inadequately examined. And we know that certainly in medicine, if it's in the exam syllabus, the amount of time that people will spend learning something is probably more limited than it ought to be.

Q. What teaching or instruction would a doctor get in the 1970s about medical ethics?

A. Well, I qualified in 1978 and I don't remember any formal teaching when I was at medical school.

I qualified in medical school in London and there was a thing at the time called the London Medical Group, which is an informal group set up by a number of academics in the University of London, and they went round all the medical schools offering evening lectures on medical ethics and medical law and to a certain extent also a little bit of forensic medicine, and they were highly regarded and very heavily attended because they were such good quality, they were very entertaining as well, and they were very relevant but they were optional.

Q. So in the 1970s it wasn't part of a doctor's formal

training to have instruction in medical ethics?

A. It was unlikely to be part of the formal curriculum.

Q. Yes, thank you.

I think you go on to talk about the development of the BMA and the first booklet that they produced in 1974. Could you tell us a little bit about that, please.

A. Yes. The BMA had always produced information for doctors on medical ethics but the first report that we have ever managed to find, that is actually a formal setting together of all the ethical advice that we had at the time, was printed in 1974 and almost half of that, 50 pages, was actually a set of the rules that existed. So things like the Hippocratic oath were there in full, the Declaration of Geneva, which is the International Code of Medical Ethics, the Declaration of Helsinki, which is the code of ethics for human research, and a number of other things.

I've included a very odd quote that came from actually between the wars, but the fact that it was contained in that booklet and not really criticised demonstrates that at that stage certainly, people were still thinking that, you know, "We all knew what it was to play the game or what the rules were of cricket" and so on, which is a rather odd way of describing that.

And certainly within the next five or six years, that was beginning to be turned round to being very much more specific about what it actually meant, what things like "consent" meant, how you understood that the patient understood enough to give a valid consent.

Q. Yes. I think we can see that quotation. I think we have an extract. If we go to page 2 of [PEN0120416], it is the third paragraph down from "Responsibility". This is from the 1974 booklet. It says there:

"In the relations of the practitioner to his fellows, while certain established customs and even rules are written and must be written, the principal influence to be cultivated is that of good fellowship. Most men know what is meant by 'cricket' and the spirit of the game. Difficulties and differences will arise, but most of them can be successfully met by mutual goodwill and recognition of the other fellow's point of view."

That seems to envisage a practitioner already knowing what to do. Is that right?

A. Yes. Although that particular quote, as I said, does come from between the wars -- it's requoted in 1974 but it is a much earlier quote -- I think it's fair to say that at that time most books that were written about ethical things for doctors tended to say, "You know what

ethics is and you will abide by good ethics". For example, I'm just editing a revision of the International Red Cross' book on ethics for its medical practitioners and it says exactly that. It's an 80-page book and 79 pages are on the law that surrounds them and one page says, "You know what ethics is and that's what you are expected to do". In the new book, 80 pages are on ethics, to explain the complexities of the situations in which they find themselves. And then obviously the same amount on the Geneva Conventions.

I think it's just recognised that ethics is a great deal more complex than just "You know what doing the right thing is", because the right thing is not necessarily always clear.

Q. Yes. You say that there is only one mention of "consent" and what was that in relation to?

A. That was in relation to organ donation. And it's interesting that consent is referred to obliquely in many of the great statements and very specifically in some, such as The Declaration of Helsinki, but it wasn't at that stage put in that 1974 book. But I would say that by 1980 when we produced the first book that I was really aware of, and there were a series then of three very similar ones, they all looked at clinical scenarios and talked about consent in the specific circumstances

of different types of clinical situation.

Q. Yes. This 1974 booklet, you say, had 50 pages. How many pages does the current BMA equivalent --

A. The most recent BMA book, which was published in 2003 -- I should say that the new edition has just gone to the press, in fact last week, but the last one is very far from a pocketbook. It's just under 1,000 pages. It's about 950 -- although you can get it on a CD ROM which makes life a little easier -- and that's partly because what we now do is explain in very great detail -- we don't tell people, "You must do A or B," we explain the way in which you should make judgments, and of course a great deal of it is about the law and about how the law interfaces with medical ethics.

Q. Thank you.

At the bottom of the page you talk about the BMA producing situation-specific advice. Could you explain a bit about that?

A. Yes. It certainly became clear after the 1974 book, if not before, that most of the queries that the BMA was getting were from doctors in particular clinical situations, and quite often you could actually cluster those and say many of them were very similar situations and people were ringing or writing and saying, "In this situation, how do I handle confidentiality or consent?"

So the advice was very much more situation-specific. It would be advice not on the role of doctors. The 1974 book was more about "These are the things that would be unethical and get you struck off," rather than, "In the following situations, this is where consent fits, this is how you regard confidentiality". And consent and confidentiality remain the two biggest issues that we get phone calls about or emails about.

So we were trying to develop a process that would help people to see what the rules were in the clinical situations in which they found themselves.

Q. Yes. If we go over the page to 0331, you say:

"The advice today is far more detailed ... not least because the dilemmas are more complex and nuanced, in part because the relationship between patient and doctor has changed so fundamentally."

Why are the dilemmas more complex and nuanced?

A. I think that if you are living in a world in which both doctor and patient accept that doctor knows everything and can tell the patient what the patient ought to do, there isn't much nuance in that. It's quite a simple relationship of you must tell the patient what you are doing and then you do it, if the patient agrees. But today, when we are working in a situation, quite rightly, where it's about the patient having the power

and the doctor trying to make sure that the patient understands enough to make an informed decision about what they want, what they would prefer, to make choices, where choices are available and there is always at least the choice of saying "yes" or "no", then that actually makes it much more complicated.

In addition to that, over the last 20 or 30 years -- and it continues to accelerate -- the numbers of choices in treatment options in most clinical scenarios have changed significantly. So it isn't just, "This is the only operation that is available" or, "This is the only drug," there may be hundreds of choices and it's trying to balance those. And in particular, because we recognise far more that patients have very different views over what they would find acceptable or important. So for some patients, for example, being pain free may be the most important factor, for others being alert and aware and being able to interact with their families, particularly in the later stages of perhaps a terminal illness, and it's the nuances of getting the balance right between all those different treatment options and what the patient wants.

THE CHAIRMAN: Dr Nathanson, you mentioned this earlier and said that the balance is very much more difficult now than it was, when the approach was to order what

happened. I can see it's very much more difficult for the doctor. Is it not very much more difficult also for the patient?

A. It certainly could be. I think that the key here is whether you are giving the power to the patient to decide whether they want to decide or not or whether you are forcing them to make decisions, and I would say that part of the nuance is offering patients information, helping them to make choices where they want to, but also being prepared where the patient says, "I don't want to make this choice," or "I don't want to know all the things that could go wrong," or whatever it is that they don't want to know; to understanding that, sometimes without the patients having to be completely explicit about the way they say it, to be able to read the patient and test with them that your understanding is correct, so that the patient is not forced into making decisions that they are uncomfortable with.

And I would always give the example that I think that when I see my doctor, I'm reasonably informed and reasonably aware to make decisions but I know that if I go to see my dentist, I don't want to make decisions. If I have a dental abscess, I don't want him saying to me, "There are four ways we can treat this", I just want to say to him, "I don't like pain, do whatever you can

to get rid of the pain as soon as you can." I think that would be the sensitivity. There would be other patients talking about other things being more important.

So part of the nuance and the complexity is protecting the patient as far as you can, but not in a paternalistic manner, from having to take decisions with which they are uncomfortable.

THE CHAIRMAN: But can the dialogue be other than unequal at the end of the day?

A. It's frequently unequal but actually sometimes, interestingly, whereas we used to think that the power and the knowledge were always on the side of the doctor, that's not always the case. If a doctor is dealing with a patient with a particularly rare condition, that patient may have read up enormously and perhaps the specialist may be on a par with the patient but the GP, for example, may only have ever in his or her career seen one patient with that rare condition and that patient may even be better informed than the GP.

The GP brings knowledge of other things that are important to the patient as well. Other medical conditions that might impact on that one. But sometimes the power can be more with the patient than with the doctor, which is fine.

THE CHAIRMAN: Yes.

MR GARDINER: Thank you, sir.

So just looking again at the first paragraph at the top of that page, you are talking about the relationship having changed so fundamentally. I think what you are saying is that the fundamental change is the fact that power has transferred to the patient. Am I right in thinking that?

A. Absolutely, power to the patient but also more openness from the doctor as part of that empowering of patients.

Q. Yes.

THE CHAIRMAN: Has responsibility transferred also?

A. I don't think responsibility has transferred. I think doctors will always expect to have responsibility, and I think that that's an interesting point because the responsibility on a patient is there is a shared responsibility in a sense that you cannot give the best care to a patient if the patient doesn't tell you the truth. And that is the responsibility which we express to patients. It's also one of the fundamental reasons why medical confidentiality is so important because we expect and require of patients that they give sometimes very unpalatable information about themselves and share that with their doctor or other healthcare workers. So we therefore have a responsibility medically to make sure that nobody else inappropriately accesses that

information.

So there is some shared responsibility, certainly.

THE CHAIRMAN: I was thinking more of the final decision. I can see that if the patient were to withhold significant information, then there would be consequences from that in itself, but in the situation of open dialogue, where all is known and the patient is presented with the ultimate decision as among -- let's say a few and not the hundreds of options that are open, the patient is being told that "It is your decision" in one sense.

A. Indeed, and it can be extremely uncomfortable for the patient and that's again where this nuancing of not forcing the patient into feeling that they are being given a burden which is unacceptable to them and supporting them, in making that decision. So helping them to come to conclusions that are about a level of decision-making that they are comfortable with.

So, for example, it might be between two or three options which have equal medical merit, which makes it much less uncomfortable for them in making the decision. It would be very uncomfortable -- but there are patients who will say, "I know that that treatment is curative and I know that unless I have that treatment, I might die but I will not have that treatment". And that's

very uncomfortable for the doctor as well because you have a patient with a curable, fatal disease, who is saying that they don't want treatment and you have to accept that.

THE CHAIRMAN: I think the problem just grows in my mind, rather than diminishing, Dr Nathanson.

MR GARDINER: Thank you, sir.

If we return to the history of medical ethics that you were telling us about, in the third paragraph of page 2 of your report you talk about "Medical Ethics Today: it's Philosophy and Practice," which was produced in 1993. I think you have told us a little bit about that but what did that involve exactly?

A. This was the first -- there were actually two earlier editions of the Philosophy and Practice, which again grew in size. It doubled in size over two years. But it was the first time when, rather than saying a clinical situation, such as when you see a patient where there is a doubt about their medical competence, this is how you get consent or who can consent for them, or those sorts of things, when we went into some of the background of the philosophy for the first time -- and that's one of the reasons why the books have grown because we think that rather than just give doctors a set of rules to follow, which in a sense is what the

Hippocratic oath or any of the declarations from the world medical association are, if you give them something about the philosophical or ethical basis, then it helps them when they come across a situation which you haven't detailed, to make a judgment for themselves, and most importantly of all to recognise where the ethical dilemma or issue is.

I guess it also recognised that for years every book that we had produced had had a section, which was growing, that was called the kind of unresolved dilemmas; the dilemmas where, although we would come down on one side, there was still significant arguments on the other side. And these were things that were still in the balance and it was felt there were so many areas where the nuancing of the particular patients' situation was so important that it was much more important to give more information to the doctor to help them to understand how to judge the different things and to recognise as well that ethics is not fundamentally about A is right and B is wrong but it's about balance. It's about balancing different people's rights and responsibilities and duties and so on.

Q. Yes. In the next paragraph you write:

"The development of advice to doctors has gone alongside an increasing dialogue with the public on the

principles of medical ethics."

How has that dialogue developed?

A. This is probably one of the most difficult areas because what we don't have in the United Kingdom is a standing committee on medical ethics that advises government and that involves the public and so on. What we have is a number of organisations who produce ethics advice and probably the BMA has been the one who has been doing it longest. What we did was, instead of having a committee of doctors, we would have a committee that's half doctors and half lay public. When I say "lay public", that includes lawyers, philosophers but it means non-doctors. So they are not coming from a health background.

We also, from time to time, will publish on the public part of our website a series of essays by people with different views on an issue and invite the public, anyone, to comment. We will go out and commission pieces from members of the public, writers of different sorts. We involve them in conferences, if we are looking to develop policy. So on things like organ transplantation and the issues of consent and presumed consent, or indeed on assisted dying, those are particular processes that we have used of going out to the public, both specific groups and anyone who is

interested, to try to get both views. And to try to balance those so that what we don't produce any more is a "This is what doctors think ethics is," it's very much a "This is where we think the balance of what the public expect and doctors expect comes together".

Q. Yes. Thank you.

You say that:

"Medicine was historically paternalistic with doctors feeling that they knew best and limiting the information given to patients or the work undertaken to help patients validly consent to medical investigation or treatment. That position was beginning to break down and be replaced by the concept of patient-centred care and patient/doctor partnership."

Could you explain to us a bit more about patient-centred care. I think you have touched on it already.

A. Patient-centred care is unfortunately becoming a bit of a political phrase and it means different things to different people, but the concept behind it essentially is that it is the patient, the patient's body, the patient's health or illness, so that whatever we do with that individual patient should be something that they are comfortable with, have chosen, have agreed with. Slightly different nuances within that, increasingly

towards the patient choosing from the patient being comfortable with at the beginning. So it has moved from just the patient accepting it, right the way up to the patient deciding this is what they want, although always with the exception that a patient is free to say "You make the choice for me". And centring it around their needs and wants and looking at the patient holistically. And "holistically", in this sense, is the patient as a person, not as a physiological or anatomical or biochemical specimen. The patient as a person within their family, their workplace, their community, their wishes, their beliefs, hopes and so on.

So that there is a great many more different options that need to be looked at from each patient. So you don't have two patients with an identical medical problem necessarily getting the same solution because other things in their lives may make a significant difference, and that's in a sense what we mean by patient centring the care. And that of course means that the responsibility of the doctor is to know as much about the patient as you possibly can. So again, not just their blood test results or their x-rays but who they are as a person and what their wishes would be.

Q. Yes. Thank you.

In the next paragraph you talk about the advisory

book in 1980, which was predominantly a list of things which might give rise to a charge of serious professional misconduct and how now today the GMC produces good medical practice and a series of other guidance on specific areas of clinical practice.

So we are talking about the GMC at this point. Could you explain for us just very briefly what the difference is between the two organisations?

A. Yes, the General Medical Council registers doctors, it maintains the medical register, it says that "This doctor, who is on the list, has passed the exams and is allowed to practise medicine in the United Kingdom". And increasingly now there is a specialist register so somebody, who, for example, is a surgeon would have a certificate of completion of surgical training, specialist training in surgery.

So there is a general register and a specialist register. The GMC will also and has also, since it was set up, had the power to strike people off or suspend them from the register or put limitation on what they can do. In other words, to say if a doctor has practised bad medicine in some way, then they can either be stopped from practising medicine generally or specifically. But when I qualified in 1978, the GMC's advice was still around "There are six reasons for

striking you off". Striking off was still about "gross moral turpitude", a wonderful phrase. I never quite knew what it meant, very non-specific. And the six offences all began with "A" and they were addiction, alcoholism, advertising, abortion, association with unqualified people, and I have forgotten one. But you know, it was very simplistic.

What it didn't do was say to you what is good medicine. It said "These are bad", but it didn't, in any sense really, contribute to the development of the best of medical practice. And certainly when I first went to General Medical Council meetings in the mid-1980s, what was beginning to be discussed was producing more advice that would help doctors be better doctors, be part of this movement to the non-paternalistic medicine and be advice on raising standards. That's what good medical practice started to become and certainly now, with all the supplementary guidance, the detailed guidance on things like consent, it certainly is. It's not as detailed as the BMA's guidance but it is pretty useful information on the kinds of things that are exemplars of what it would see as good practice, as opposed to just a list of bad practice.

Q. Yes, could you maybe describe a bit more the meetings

that you have just mentioned?

A. Yes. When I took over in April 1987 as head of ethics, the chairman of the BMA's ethics committee, then Dr Sandy Macara, now Sir Alexander Macara, was on the General Medical Council's committee on standards and ethics. And we invited the secretary to that committee to attend the BMA committee of ethics and they invited me to attend their meetings. So I used to go to the meetings and hear the debate, which was never about individual cases but it was about the advice they were beginning to put together and how they would structure that.

All the members of the committee other than myself, and I was just an observer, were members of the Council. So members of the council then were predominantly doctors, but there were one or two lay members -- but it was literally one or two. Now, of course, it's just over 50 per cent lay members and a much smaller council.

Q. Yes. You describe in the next paragraph the process, that the GMC advice was written by its committee on standards and ethics. Could you tell us about that?

A. Yes. I think it was my first meeting there. One of the papers was a paper that they had obviously had some discussion of at a previous meeting and it was what became their advice on HIV/AIDS and testing in

particular. The paper had been written probably by the staff based on previous debates and was then debated in the committee, including consideration of the benefits of things like routine testing and particularly of testing without consent.

Testing without consent was actually the most important issue, in my view, that they were discussing. One member of the committee said, for example, that he or she required to be able to test all their patients without consent because they weren't prepared -- this was a doctor in general practice -- to have their staff look after patients who might be HIV positive unless they knew.

They clearly didn't understand the science of HIV at the time, which was partly because we were still in the situation before we could test for the actual virus itself; we were still in the stage of testing for antibodies, and there were things called "windows of infection" between this becoming positive. And after the debate it was agreed that it was unethical to test without consent. And that's what went very firmly into the guidance, which I thought was very important.

I would say that at the same time the BMA did actually pass one year a policy that said doctors should be able to test without consent. It was never put in

place because we did something that has never been done before from our annual meeting, which makes our policy, which was as soon as we came away -- it had been an emergency motion, so we hadn't been able to take advice beforehand, we took legal advice. As we expected, it said this was illegal and we didn't confirm that policy and it was reversed the next year.

Q. Yes.

THE CHAIRMAN: Can we just be clear about the years that you are talking about at this stage?

A. That would be either 1987 or 1988 but I can certainly get back to you with a precise year.

THE CHAIRMAN: I think that's close enough for present purposes.

A. It was late 1980s.

THE CHAIRMAN: Yes.

MR GARDINER: Could you develop a bit more what you said about a misunderstanding of the science?

A. I think it's important to recognise that even by 1986 and 1987, when the committee on standards and ethics was looking at this, the science on AIDS was still at a very early stage and still evolving. The majority of doctors in the United Kingdom had never seen a patient who was HIV positive or who had AIDS. Indeed, today there are probably still very many doctors who have never actually

treated a patient certainly, or seen anyone since they left medical school, because where the cases are is relatively patchy still.

But in those days, with far smaller numbers, most hadn't. We were also at this stage where we had what was originally the HTLV-III test -- became the HIV test. But it was an antibody test and we were still developing knowledge on the window of infection, the period between being infected with the virus and being able to detect the antibodies, as opposed to -- now, of course, we can detect the antigen, the virus itself.

Many doctors who hadn't dealt with patients, they might know all the symptoms -- they knew the theory of if I see the following signs, this is something I should suspect -- but they may not have been completely up-to-date on the nature of the infection and particularly upon this window of infection and what the test meant.

So it was very important to get information out, so much so that one of the first things I did in April 1987 -- when I took over as head of ethics, I was involved with my then boss in developing a series of videos for doctors, which Wellcome actually sponsored, and we got pharmaceutical reps to take it around the country into every GP's surgery: three films

on testing for HIV, including getting consent, upon all the issues around control of blood-borne infections and particularly the kind of advice that they could give to families. We were developing a lot of advice to individuals, but also schools and churches were contacting the BMA for advice on the risks of cross-infection and there was just a lack of good solid, simple consolidated information on the science for the non-experts and the people who might be seeing a case for the first time.

Q. Yes. Am I right in thinking that these discussions at committee eventually resulted in the General Medical Council guidance of 1988?

A. It did indeed, yes.

Q. We can maybe just have a quick look at that. That's [PEN0161165]. That's the first page. If we go over the page, that's a letter dated April 1991, sending out the guidance. Then, if we go over the page again to 1167, we see "HIV infection and AIDS, the ethical considerations." That's the beginning of the guidance and that's the one we are talking about?

A. This is, yes.

Q. Thank you. Could we go back to the report, please? 0331.

THE CHAIRMAN: I think the narrative on the page before said

that that went out in 1988?

MR GARDINER: Yes, that's right.

THE CHAIRMAN: Dr Nathanson, you said that, after the ethics committee meeting, legal advice was taken which said it would have been illegal in effect to give a blanket guidance that you could test without consent.

A. That was after the BMA's meeting, which was a few months later, yes.

THE CHAIRMAN: How far did that go? Could I understand exactly what the process was? I imagine that not every lawyer would necessarily have agreed with that.

A. Indeed. In fact one of our committees had advice from a QC in London that said it would be entirely legitimate to test without consent, and we had conflicting advice from another QC. The advice was that, while one had to balance these issues, given the significance of the test, given that it was not a standard test that people would normally expect to be having because this was not in a group -- this wasn't saying, in patients with particularly high risk factors, "You may take a test," this was about general individuals, it was somebody going into hospital to have their hernia repaired or their varicose veins stripped or whatever.

In those patients this would not be in any sense a standard test and therefore you could not say that

generally the consent given to other blood tests, which were necessary, like a full blood count or whatever, could be said to apply and therefore specific consent was needed.

I would say that it was a difficult case to make to some of our members, who were concerned about the risk to other healthcare workers and indeed to the next patient on the list, as it were. But they were persuaded and authorised us as well to set up a charity simply to get better information out to patients and doctors so that people understood the processes better. We set up that charity, which still exists today, doing exactly that.

THE CHAIRMAN: One should understand that when the legal advice was gathered together, it was not to the same effect and therefore it was the committee that had to decide?

A. In the end it was the BMA's annual meeting, yes, of 600 representative doctors, yes.

THE CHAIRMAN: Thank you.

MR GARDINER: Thank you, sir.

Without going into the detail of the guidance, what was the advice on consent to investigation or treatment? Testing, for example.

A. The GMC's advice on testing was essentially that you

should get consent from the patient, and for the first time that I had seen in anything it talked about counselling the patients so that they understood in more detail the nature of the testing. That's quite important because for most testing that we had been aware of before that, for other conditions, very little counselling was carried out because the tests either indicated a particular condition or they didn't; there weren't other consequences.

I think that that's also one of the important things for the testing for HIV: it wasn't simply the medical consequence of the test, it was also the social, economic and so on consequences which had to be considered and to some extent still do today.

Q. Yes. Again without going into the detail of the guidance at this stage, what was the GMC's guidance on a doctor's duty to inform?

A. The GMC were also clear that doctors should be telling patients the truth. That sounds a very bald statement and again the nuance of that is that really it's not about you must tell the patient the truth, it's that you must offer the patient the information and the truth. That's a subtle but very important difference because the GMC recognised that you have no right to force a patient who doesn't want to know something to know

that, other than in rare and exceptional circumstances.

There are very rare cases -- and it's quite difficult to think of any -- where you might try to push the patient to know more than they want to know. Those cases would be where it would make a significant difference because they are going to have to make a decision and that decision requires them to know something, to know enough, and that decision could quite literary for them be a life or death decision.

Even then you wouldn't necessarily force the patient to know, if the patient said, "I don't want to know, I just want you to do what you think is right." Again you would have to test. But it was the beginning of the GMC trying to iterate that issue of giving the patient the ability to make decisions for themselves. That meant including, of course, the right to know. That in fact was much less contentious because the GMC by then assumed that most patients would be at least offered the truth about a diagnosis.

Q. Yes. Thank you. In the next paragraph you talk about advice from the GMC in the intervening period. Then you talk about its evolution. Could you just tell us a bit about that?

A. Yes, certainly. I mean, the GMC now produces a detailed booklet on consent and on what this looks like in

different clinical situations. So it has evolved into far more detail. They have tried to describe more of the contentious and difficult areas: what do you do with a patient who doesn't want to know; how do you handle that; what is best practice; what do you do when you have a child and particularly a child who is not yet an adult but is clearly competent to make decisions for themselves?

Those are quite complex issues, where you have to try to spell out a mixture of the law and the ethics and how they fit together in those. So the GMC now does that and in a sense the HIV infection document can be withdrawn because what's contained in it is now regarded as good practice in all areas of medicine. So what it says about consent or what it says about confidentiality or so on is now covered as a general in all other cases as well.

Q. Yes. I suppose as well the prognosis for the disease has changed since then?

A. Yes, it's certainly very interesting that in the last 30 years -- the difference in -- so much so that I certainly picked up one heavy-weight magazine last week, I think it was the Economist, that said that we are seeing the end of AIDS as a fatal illness. It might be a little early to say that but it's certainly heading

that way. It's becoming increasingly regarded as another chronic condition. Quite remarkable in terms of the timescale.

But that does make a difference as well. I think the thing that made the biggest difference, however, is the thing that led to that. It's the fact that patients needed to know more early on simply because it began to make a difference in terms of the decisions they could make. They could start making decisions about treatment in particular. That was particularly important. That's a much more important issue for patients. Knowing something when you can't do anything about it is of less importance to many people than knowing something when you then have a series of options which you can take which may make a difference to your future illness or indeed your survival.

Q. Yes. We do have conditions today, other conditions today, that are like that, though. Is that not right?

A. Yes, indeed. There are one or two cancers which we have no effective treatment for, but I think today one of the most interesting issues is the increasing ability to detect some -- a limited number, but some medical conditions because of their genetic link, and I'm thinking in particular of something like Huntington's disease, which is a condition which, if you have the

gene, you are going to get the disease. Sorry, you can be a carrier or you can get the disease, but you can tell that genetically.

If you get the disease, there is nothing that can be done to make a difference to your survival length or the progression of that disease, and what's very interesting is families -- almost every patient who gets this condition knows because it is hereditary. Very, very occasionally you get a mutation, a new case in a family but mostly they have seen this in a parent, grandparents, uncles, aunts and so on, and there is nothing that they can do. The only thing about knowing your result is that if you know your result at 20, say, before you have children, you may choose not to have children because you would pass on the gene.

But only about 10 per cent of people in those families choose to be tested. They prefer not to know because nothing can be done. When you get a condition where you do know that something can be done, most people choose to know because they choose then to know as early as possible, so they can make a difference, including, for example, the gene for breast cancer, where even though the current treatment is pretty radical stuff because it's bilateral mastectomy, which is a horrible procedure, more women choose to know and

then to decide whether to have that or indeed just take the increased risk but to have more frequent examinations because there is something that can be done. So it's a very different situation. HIV at this time, the only thing that you could do, in the very early days, was actually protect others from the transmission of the infection.

Q. So "very early days", we are talking about --

A. In the very early 1980s, until the first of the drugs became available, which would be AZT and then particularly triple therapy in the late 1980s, through into the 1990s.

Q. Yes, thank you.

Just returning to your report, I think the paragraph at the bottom of page 2, you are starting here to sum up what you have been discussing about medical ethics. You write:

"Medical ethics is recognised as a balance between different principles, rights and values. While there are no absolutes, most commentators would agree that concepts of patient autonomy have risen in importance over the last two decades. Against measures of respect for such autonomy are counterbalances such as protecting the public health or the health, safety and well being of others."

You talk a little bit about that balance.

A. Yes. I do give an example here. One of the things that's very interesting in ethics is getting people to understand the balance, because when people first come to look at ethical issues, there is a tendency to say that it's about absolutes, it's about X is right and Y is wrong, and it isn't. It's about a balance and particularly the balance that we see most often is the one between the rights of an individual, the autonomy of an individual, against the rights of society generally, and indeed the duties, not only of that person to society that they are a member of but also the treating doctors, nurses and so on, to the society. They also have duties to society.

It's occasionally the case that some of the rights of self-determination are limited because we will say that puts an unacceptable burden on or risk to others.

So somebody who continues to drive their car when they have epilepsy and are still uncontrolled, still having fits, clearly that's unacceptable and so a doctor may inform the DVLA and have their licence removed or suspended if the patient won't voluntarily stop driving, or themselves tell the DVLA. Those kinds of examples. And those are quite important because if we just look at autonomy and say everything is about the autonomy and

the right of the individual, then it would in fact potentially give people the right to harm others effectively. So that's where we sit the balance.

Q. Yes. You mention informing sexual contacts as well, as another example.

A. That's a very much more difficult one. In that case what happens in practice is that sexual contacts will be told that they have had contact with somebody who has disease X. They will not be told the name of the person. Now, depending upon that individual's own sexual history, it may be quite clear to them that it can only be one person but it could be that there are a number of other people. And here this is about -- you do everything you can to protect the confidentiality of the indexed patient, but given that there are two problems, one is that there is a public health risk of somebody with a transmittible disease and transmitting it potentially to others and then not being treated, and the fact that these are all essentially treatable diseases today, it is very important that they know and know early so that they can be treated and hopefully treated effectively, but it is done in a way to minimise the risk of a breach of confidentiality of the first person.

Q. Yes. I think you say here that the process involves,

first of all, encouraging and attempting to persuade the patient to allow the information to be passed to the third party?

A. Yes.

Q. Yes.

A. Yes, and that recognises that for many patients they will know immediately the person who has contacted the second contact, who the person is who you are talking about. So you have to try to persuade them to volunteer that. The other issue is that, of course, if the patient doesn't volunteer, how do you know who to contact. So again, you need the cooperation of the patient and there is great skill at the GU medicine clinics in persuading people about how this will be handled to try to minimise the breach of their own confidentiality but also to reduce the risk to others. And it's exceptionally rare for people not to want to co-operate because they don't want other people to go through what they have gone through.

Q. Today, in a situation where a patient like that does not want to co-operate, is it legitimate for a doctor to eventually disclose the information to the third party?

A. The answer is, yes, it is, provided you have gone through all the attempts to persuade them to co-operate and that you limit the disclosure as much as you can.

The difficulty, of course, is that in most cases you won't know who the sexual contacts are but you will know, of course, about a husband/wife partner in that sense but you won't know about others, and that's why so much goes into persuading them to help you with the contacting.

Q. Yes. Thank you.

The final paragraph in your introduction talks about the period in question, and I think most of our questions were about the period between 1984 and 1990. Is that the period that you are referring to there?

A. Yes.

Q. You say that it represents a period of significant change. Is that for all the reasons that we have discussed already?

A. Indeed, and particularly going back to Kennedy and 1979 and the wash-up of that, which really started, I suppose, in the early 1980s, of the movement to change in medicine gathering pace. So it was at the beginning of this. And certainly people who had qualified 20 or 30 years earlier would have been established in patterns of practice that were in the paternalistic phase and people who were just qualifying were beginning to see the newer attitudes and it was the conflicts between those or the development of new methods.

Q. Yes. Thank you.

Sir, I'm going to move away from the introduction and on to the questions.

THE CHAIRMAN: We will have a break at that stage.

At some stage you might help me by seeing some of these issues in the context of an approach to practice at the time, that accommodated the idea that individual clinicians were completely independent in their practice and not particularly open to the advice of others.

A. Indeed.

(10.58 am)

(Short break)

(11.27 am)

MR GARDINER: Could we have a look at the third page of your report, Dr Nathanson, and we see half way down, the first question, which the Inquiry asked you to consider:

"What is the current approach to consent to treatment? In particular what information should a clinician provide to his/her patients about the risk of a particular kind of treatment? Is there a difference between drug treatment and invasive treatment such as surgery? What is the current GMC guidance on this point?"

Perhaps I could just ask you to answer that in your own way.

A. Yes, certainly.

There is often a mistaken thought that in the UK we go down the line of fully informed consent and we don't. That's actually largely a North American construct. But consent has to be what we would normally say is sufficiently informed for consent to be real or valid. And "sufficiently informed" means that the patient must have enough information, within the patient's own framework of wants and beliefs, to make a decision, to make a choice. So that means that you can't prescribe exactly how much information must be given; you must find out from the patient what is important to them, but there are clearly, obviously, things that you would normally offer. So information about what, say, the diagnosis is, what it is you are seeking to treat, what the options are, the principal options, and some of the major side effects.

It's an interesting one because having to understand what the patient wants, you can't say specifically there are things that you must or don't need to give. A patient who says, "I want to know everything that could, for example, go wrong," you have to do your best to give all of that information, and it's again complicated by the fact that the second thing you have to do is to test, to a certain extent, that the patient

has understood it, and that means in a sense asking them to echo back to you what they have taken from what you have said so that they at least, as far as you can ascertain, have understood the principal things that they ought to know. And nothing can be done to a patient without that consent.

But having said that about giving the information, it is, of course, entirely in keeping with that for an individual patient to say, "I don't want to know anything. Please just do what you think is best." It's not ideal because the more the patient understands about what's happening to them, the better they are able to cope with it. For example, if you give a lot of information to patients before an operation about post-operative pain, they actually need less pain control because they are not frightened by the pain, which is interesting. And we know that the more a patient knows about their medical condition, the better they tend to do with that. But nevertheless people have the right to opt out of knowing anything and that's something that you also have to figure in.

The biggest issue is, if you are going to do an operation, for example -- it is always easiest to describe in surgery -- where the chances of dying on the table are 50 per cent, the chances of dying if you don't

have the operation are 100 per cent or close to 100 per cent, it's very difficult to do that operation without indicating to the patient, however much they don't want to know, just how dangerous this could be. But nevertheless you know, you are trying not to force information on patients who really don't want it and it is entirely legitimate for people to give a valid consent, a real consent, but without knowing really even the basics about what's happening.

Q. Yes. We see that you say that the requirement to have the necessary information is something referred to in documents from the 18th Century?

A. Yes.

Q. There is a reference there to 1767, and I think this is a quotation from the case of Slater v Baker and Stapleton from 1767. Is that right?

A. Indeed, yes.

Q. That says that it is:

"Reasonable that a patient should be told what is about to be done to him, that he may take courage and put himself in such a situation as to enable him to undergo the operation."

That's in the context of anaesthesia?

A. Yes.

Q. Yes. Then you go on to discuss an excerpt from the 1993

publication. How did that develop from the previous position?

A. In previous documents we talked about consent very much more in a -- how you must give patients information because that made the consent valid. We were describing things in a rather different way by 1993, by trying to reflect that this actually was about the principles of things like autonomy, of the patient making choices for him or herself and that, as part of that process of enabling people to make treatment choices or to understand the options, you obviously need to give people information to make sure they have that information. Today we would also say it in the way that if you were thinking of a drug treatment in particular, you need to make sure that the patient has accurate information, because if people have read a great deal on the Internet, you do not know whether they have read from a good site or a site that's full of pretty spurious information. So you are again trying to test that they have understood the facts as far as you reflect on them and have made their choice on that basis.

Q. In the paragraph at the bottom of the page you talk about how the skilled practitioner will work with the patient to find out what the patient would consider

important, and to form a relationship which helps the patient to see that this individual discussion is part of a process. How is that done, Dr Nathanson?

A. It's really done predominantly by spending as much time as you can with the patient, but very often by simply saying, "This isn't a once and for all decision. This is something that you can change your mind about at any time."

Clearly, if you are having an operation, it's very difficult if you say, "Yes, I want the operation" and then 30 seconds before you have the anaesthetic you can change your mind. But you still have the right to do that. The point being that doctors will now say repeatedly that, "You can ask me more questions at any stage. You can revisit the decision." And of course making the point that in most medical conditions today you do not make a single decision and that's your treatment plan set forever. Your treatment plan will evolve as you respond in different ways to the treatment because no two people respond in exactly the same way. And making it clear that throughout the whole of this process and the relationship that you have, you will be deciding what option next, whether you continue on the original treatment plan, whether you want to vary it, and within that trying to explore what matters most to

you.

The people who do this best are probably in two groups, I would say, and that's because of the nature of their relationship. One is the palliative care physicians who, because we can't cure someone, would say, "Let's find out what it is that matters particularly to you so we can make a treatment plan that gives you the things that you value: pain-freeness or more awareness or less awareness," whatever it is. And of course, the others would be the general medical practitioners, the GP, who spend often a lifetime looking after the same patient and who get to know them well and know literally their family and workplace and all of those things, so they are able to find out this is a patient who has always been rather phobic about needles. So when I'm offering treatment, if I can manage it without injections, it is important, or they don't mind that but they admit to being very disorganised and can never remember to take their tablets on time.

It's all of these things become small and subtle but actually can be very important to the patient in the treatment working for them, and that's what I mean. The skilled practitioner then, if you are seeing somebody effectively for the first time, try to get some of this

information about the patient in discussion with them. And that's about trying to get that patient to feel that they can express their views and recognising that however non-paternalistic doctors would like to think they are, patients are often very frightened. They can be intimidated by the doctor but they are even more likely to be intimidated by their medical condition and by fear about what's going on with them.

Q. Yes. If we go over to the top of page 4, in the first paragraph at the top of the page you talk about patients who opt not to know, and you have touched on that. Could you explain to us what doctors should do with patients who opt not to know?

A. I think the first thing is not to force people to know, to start with, and then to try to find out why the patient does not want to know. Is it fear about what they are going to hear? Is it fear about certain words? Is it about their experience, or you know, people they have known with some diagnosis which they think might be similar to their own? What is it that makes them reluctant to know? Many of those things can be dealt with, can be helped.

For example, we know that for many patients the word "cancer" is a very frightening one and very often in some circumstances there are many cancers which are

close to 100 per cent curable, or certainly where the outcome of treatment is very positive.

So again, it's trying to put things into a context that you can encourage the patient to know more, to give them the confidence to feel able to know more, but there will always be a small number who choose not to know and that's something that you have to respect. The only question then is: do you respect that if it means that they can't make a decision about a treatment, when it's particularly important? And it is very uncomfortable often for a doctor, if they are asked by the patient, "Don't tell me what it is, don't give me any choices, just say, 'This is what we are going to do'," when in the doctor's mind there are two equally valid treatments but they are very different and they require an understanding of the patient and the patient's wishes that is different, and then it's trying to get the patient to understand enough without forcing information on them, so that at least it helps you to make the judgment on which of those options would be the one that would fit in most with the patient's feeling. But it's a very difficult process.

It's also one of the reasons why consent today is increasingly done by the most senior doctors in the team, simply because of their experience and their

ability to actually draw out some of these quite subtle messages.

Q. So it's a process of trying to find out what the patient wants?

A. Absolutely, even if the patient finds it difficult to express that. And always underneath that trying to give the patient the confidence to express his or her views.

Q. Yes. Thank you.

Then I think on that page you go on to discuss the situation where a patient is unconscious or whether there is an emergency. Perhaps you can just briefly explain that.

A. Yes. It's just the simple fact that clearly, if somebody is unconscious, they can't consent to a treatment and rather than say you can't do anything, you are allowed to give treatment in those circumstances, and that treatment is meant to be limited to that which is necessary to sustain life and health. How that's described is quite difficult. I mean, clearly, you know, if somebody comes in unconscious having been knocked down by a bus in the street and they need emergency surgery, that's what you would carry out but you wouldn't necessarily go on and, say, do something else that might be potentially helpful but isn't essential at that time, and you would wait until

they were able to consent and give that treatment at that point.

In doing that, where possible you will find out more about the patient, because if they are accompanied by friends and relatives -- because again, even in emergencies, there is sometimes a choice between two or three options, and the more you know about the patient and what others think they would have said, helps you in making a choice and a decision. And again, as far as the patient is able to give information to you, it's to talk through with them what has been done and why.

Q. Yes.

THE CHAIRMAN: Could I just ask about that. I'm slightly concerned that it might be a very absolute situation, that one shouldn't go beyond what is essential. I would have thought it possible that there would be occasions in which the opportunity arose to do something in the course of a surgical procedure which wasn't strictly necessary at that point but which could only be dealt with later by another significant surgical procedure.

A. Yes.

THE CHAIRMAN: Which must, in the nature of things, carry new and different risks. So is the rule absolute or does one have to be prepared to modify the approach to circumstances?

A. In theory the rule is absolute. In practice, and certainly with a critically ill patient, if there is something that is clearly going to need to be done probably in the near future with somebody who is already critically ill, then you would do it but with the one exception that you wouldn't do it, even if it would need a second operation for example, if the amount of time on the table, which is also associated with risk, was likely to be so significantly extended it would raise a new risk. But if it raises no new risks, then yes.

MR GARDINER: On the bottom half of the page you have set out the basic model of consent from the booklet, "Consent: Patients and Doctors Making Decisions Together". Is that the most up-to-date version of it?

A. This is from the most up-to-date the version of Good Medical Practice, yes.

Q. Thank you. If we go over the page, to the second paragraph, I think you are addressing the question about whether there is any difference, depending on the types of treatment. Could you just talk about the differences, please?

A. Yes. Generally speaking, it's regarded that any medical treatment requires the same level of consent. There are just a couple of exceptions, where you would be rather more formal about getting that consent. Particularly,

the common one would be sterilisation because by its nature, it is regarded as irreversible. We know that in a small number of patients sterilisations can be successfully reversed but generally they can't. Because it is of that nature, because of emotive issues associated with it, you would be very, very formal about documenting, and usually in those patients there are several relatively formal interviews with information given and people testing the understanding of that just to make sure that people understand it's an irreversible one.

Psychosurgery, in this example, is regarded in the same way. And this is a neurosurgery that's done to change behaviour. So people who have psychosurgery, so perhaps they are seriously depressed, and there are still a few people who might have neurosurgery in an attempt to reverse that. Again, because of the nature of that, and that we can't take the brain back to what it was, then it's very important to get very detailed consent and to be very, very careful about that.

It's a very rare circumstance in which that happens but certainly with drug treatment. The difficulty, of course, that most of us who have been to see our GP would feel that we don't necessarily feel that we

consent to the drug treatment but in practice we do because you are handed the drugs, you take them home and you then decide whether to take them or not, and we know a lot of people actually then choose not to take them. Interestingly, many of them then go back and get a repeat prescription, get it filled and still don't take them. But that's freedom. That's part of the autonomy of choosing not to take the tablets.

Q. You note that drugs like the ones you have been discussing often have medical information sheets with them?

A. Yes. Every drug now that you get, just about, from the pharmacy will come usually in the manufacturer's pack with an information sheet. That has been a big development. And that's actually very important because there is key information there to reinforce not only what the GP will have told you about why you are having those drugs but about some of the side effects. And because very often it's very important to pick up issues such as the contra-indications and the interactions with other things. Many patients take herbal medicines, for example, and don't necessarily tell their doctors that they are taking a herbal medicine which they can buy over the counter but which may have a very powerful interaction. So that's the reason these have been

written, but also so that they are very understandable by patients and they answer a lot of the common questions which patients might have forgotten to ask us, their doctor, or indeed have forgotten the answer when they did ask the doctor.

THE CHAIRMAN: Dr Nathanson, some people might form the impression that the haystack was so large that the needle of relevant information was impossible to discover. Are these sheets really thought to be helpful?

A. I think many patients do find them helpful, but they can be scary. The problem with them is of course, they are obliged to have all the side effects and contra-indications and it's very difficult to find one that doesn't tell you you might get a rash, for example.

Now, you know, a little bit of occasional spot or a bit of a rash, a bit of redness doesn't matter. There are occasional rashes which are very significant, which you definitely need to see somebody immediately about, but the problem for the pharmaceutical companies is that they are required to put that information. And you are absolutely right, it is pulling out the bit that matters that is very difficult and some of us would like to see them much simpler so that you actually only really record significant interactions, but unfortunately

I think it can be difficult. They do try very hard to say, "This type of rash, for example, is important and is something you should see a doctor about". But that's a problem.

MR GARDINER: Could we just move on to the next question, which is also about consent? Question 2:

"What was the equivalent approach to consent to treatment between 1974 and 1990? In particular what information would a clinician have been expected to provide to his/her patients about the risk of a particular kind of treatment? What was the GMC guidances during this period and how did it evolve?"

You start the answer in your report by mentioning the Nuremberg Code, and perhaps I could just ask you to talk about that, please?

A. Certainly. The Nuremberg Code was written after the Nuremberg trials, which were essentially into the abuse of medicine -- well, the one's which I'm considering here -- medical experimentation on people, clearly not in the interest of those individuals and clearly without any consideration of their humanity or anything else. There is a problem with the Nuremberg Codes, which is that most doctors have never looked at them or read them. So one of the things that was done immediately after Nuremberg was to try to put those into language

which would make sense to doctors around the world and that would produce the same outcome of the highest standards of consent.

That led to a variety of codes, particularly from the World Medical Association, which in fact was established after the Nuremberg trials, and as a response to the need to have an international global standard.

Key within that was consent, particularly consent around experimentation, but not only experimentation and research, consent generally. And it just developed all the time, throughout the thread of everything that has followed Nuremberg: the right of individuals to make a choice, to say "yes" or "no".

What has been evolving and can be tracked from Nuremberg, I think, is the way that is described from the paternalistic of, "Will you agree to have this operation, which I think is the right one for you," to, "These are the treatment options including the operations and let's discuss which option you prefer". And there has been a move in that period from one to the other. And I would say that in the 1970s, it was still very much more in that paternalistic model of the doctor saying, "This is the treatment I recommend, do you agree to have it?" And then depending on the patient, far

fewer patients than today would then interrogate the doctor, would ask the doctor questions. They would be much more likely to say, "If you think it's the right one, then, yes, I will agree."

Q. Yes. Just moving down to the bottom of the page, you talk about BMA advice to doctors, reflected in the evolution of the language. Could you just talk a little bit about that?

A. Yes. When we were writing in 1980, we were clearly also saying that consent to treatment wouldn't be misused, but by 1988 we were talking about the amount of information that needed to be given and shared and really empowerment. That reflected, from the late 1970s when we were writing the 1980 advice, through the 1980s, this evolution from paternalism of, "This is what I think you ought to have, will you agree to it?" reflected in the 1980 words of, "They would consent to treatment but they wouldn't misuse that consent," through to the basis of the discussion about consent and the idea that consent would follow a discussion indeed, as opposed to a process of, "Here is a form, please sign it" -- was the evolution into sharing information and giving patients the information to make choices for themselves.

Q. Yes. A little bit further down the page you talk about

what Lord Scarman said in the Sidaway case. Could you talk about that as well, please?

A. Yes. Certainly. This is certainly the case that I think most doctors in England would recognise as being about the duty to inform patients about risks inherent to illness. And of course, one of the problems in the concept of consent, real and valid consent, which I discussed before, is this issue of what is the information that is so important that you cannot omit giving it to a patient.

There really isn't anywhere a specific that says, "If the risk is a certain percentage or a certain seriousness" -- although the Sidaway judgment gives you a little bit more about that.

But the key at the beginning in that quote is that the patient is making his own decision about whether he will or will not undergo treatment. And I think that the words there helped us to understand and to put together information about the fact that consent is a process in which doctors are offering information to patients, information about choices that they can make and then helping that patient to exercise that choice. Because exercising that choice, operation or drug prescription or whatever, is something that a doctor has to do for the patient and to the patient but it is the

patient's choice to make that option. So quite apart from the amount of information which Sidaway was fundamentally about, it is this issue of options and sharing of information which definitely came out of that. So I think that we would say that the law and the development of medical ethics were there absolutely hand in hand.

Q. Yes. If we think about the period in the early 1980s, what steps would you be expecting doctors to be taking to draw patients' attention to risks in treatment?

A. This was a very difficult one because one of the things that doctors were struggling with was how to identify which were the key risks and particularly, for many of the risks that patients were exposed to in different treatments, you may not know the frequency with which that risk was likely to happen or the severity; but to try to put that into language that the patient would understand and insofar as your own experience went with patients.

So you would expect doctors to tell patients of the major risks and certainly, for example, you know, a risk of death from something or if you have a drug, a risk of the most serious side effects, both life-threatening and in terms of discomfort, and almost to start in a semi-hierarchical way with the most serious and not

necessarily always with the commonest but often going on to the commonest -- so back to my drugs causing a rash, saying, "Almost everyone who has this drug gets a minor rash. It's just a little bit of redness. It might be a bit itchy for a day or two. Don't worry, it goes away." If that was the case, obviously it has to be accurate and honest as well, but the point being that you would start off with the most serious things because those are the things that you think should most influence the patient's choice, the things that they should be thinking about, and if you know enough about the patient, you would always try to pull out the things that they would likely be most concerned about.

So, for example, some patients are particularly worried about scars after surgery. You might talk about the nature of the scar. People who are very worried about pain, you would talk about the nature of the pain, how severe it would be, how you could treat it and how long it would last for. So it's that sort of thing, of trying to give the major risks and trying to contextualise them for that patient.

Q. Yes. In the early 1980s -- I'm talking about 1983/1984 -- would you expect a clinician to mention a risk of death from taking a particular treatment or drug?

A. A great deal depends on how much they knew about the risks of death, whether it was associated with that, and how common it was. Certainly death is such a serious risk, it's not a risk you would ever dismiss. And again we are back to that you would highlight the most serious risks. The difficulty is that if you have a risk that's one in a million of somebody dying, would you tell somebody? Probably not, certainly in those days. If the risk is 1 in 100, you probably would tell them. But it's not nailed down. It was always about the doctor's judgment.

Increasingly, the judgment is more to give all information or to offer all information, but again to contextualise it because again, when you talk about something like the risk of death, the risk of death doesn't come out of the blue, it is usually associated with a particular side effect or complication. So it would be contextualised. "In the following circumstances there is a risk of ... this is what we can do to reduce those circumstances and to make them less likely". And that's important because again that's also part of helping the patient to understand why it's important that they tell you whether they are following the treatment regimen appropriately because sometimes that's a part of the prevention protection.

I think it's important to say that in the early 1980s the amount of information offered was certainly less than it would be today and different doctors would give different amounts of information, partly associated with their own experience, their own knowledge, but also partly because those from a more paternalistic background would traditionally offer less. They would say, "This is what I advise," whereas those with a different background of a more open exchange of information would be the early offerers of information, up front, rather than waiting for the patient to ask.

Q. Yes.

THE CHAIRMAN: This is approaching, of course, the point I suggested I might raise with you just before the break. I have in mind the particular context in which we have clinicians of various generations, as it were, confronting a new disease, confronting it at about the same time but approaching it from very different backgrounds. If one thinks of the haemophilia clinicians becoming a specialist group but perhaps in the 70s, in fact coming from very different backgrounds, the general advice you are talking about, the general development of ethical standards seems to me possibly to be difficult to communicate to these people. Is there anything you can help me with in understanding the

nature and the degree of the problem in the 1970s, first of all, and then the 1980s?

A. You certainly identified one of the major issues here, which is how, as advice and practice change, do you encourage everyone, regardless of when they qualified, to embrace that change. And in fact, even if you were ignoring ethics at the moment and thinking of a clinical issue, it is absolutely one of the key issues that we see: how do we make sure that new knowledge changes people's practice, if it ought to change people's practice. And that would be the same whether it was ethical practice or prescribing and it's extremely difficult. It has to be done in many different ways.

Firstly, you have to persuade people that this is the best way to do things, whether, if it is a clinical practice because it gives you better results or in ethical practice because it gives you a better relationship with patients, which is better for them and therefore better results, and to try to get that information to people, to make sure that everyone understands it, that it is not just about, you know, the tick list of if you avoid all these things on the tick list, you won't be struck off by the GMC, to this is a set of examples of the ways in which you behave optimally to empower your patients. Sorry about the

word "empower" but it's a good way of actually encapsulating what we were trying to do.

The way that we did that was really by huge numbers of meetings, going to every postgraduate meeting of doctors' training group that you possibly could to talk to doctors -- which was very good because it was intergenerational. You would have everyone from the senior consultant down to the most junior house officer, and if there were medical students there, those would be there as well, and the local GPs -- and using that and making sure that we provided information, that others provided information for academics and others at every local hospital so that somebody would generate a debate: how do we do this? How do we make change? But it is always a difficult issue because it's hard.

The relationship between a doctor and patient is one-to-one and very often not observed by somebody else when they are talking, which means you don't know whether things have changed and it's difficult to test. You can test prescribing practice because you can look at the prescriptions, you can't test communication practice.

Today no medical student can graduate without really quite a lot of training on communication skills, which is actually the heart of this. A lot of those older

doctors were not taught how to communicate and particularly how to communicate with patients who were frightened, who were going to be given bad news potentially, and that's a very difficult thing to acquire.

But it's a matter of just keeping and trying and doing it repeatedly in every method that you can. Today increasingly, it is actually assessed because, for example, we ask patients what their experience was.

THE CHAIRMAN: In the nature of things, that's a problem that's incapable of being solved instantly.

A. Oh, indeed.

THE CHAIRMAN: It can only be progressively over time.

A. Indeed, and that is exactly why, as I have said, the nature of the change from -- let's say the start of this was the Kennedy Reith lectures in 1979. And the change took time to make sure that everybody became not only comfortable with this new concept, with the way you communicated and worked with patients, but skilled at doing it because some people want to embrace it but didn't have the skills and that's even worse. If they try to communicate in a different way and actually are unable to do it successfully.

THE CHAIRMAN: Yes, thank you very much.

MR GARDINER: So just to try and be clear, in the mid 1980s

you wouldn't necessarily be critical of a clinician who simply didn't mention a risk of death from treatment to their patient?

A. It wouldn't be best practice but we wouldn't necessarily criticise it, and particularly if the alternative of no treatment or of another treatment had a higher risk. So somebody who was nevertheless going to die without a treatment and where the treatment itself had risks, you would accept that. It wouldn't be the best practice. We would be encouraging people to be more open but we would recognise that it still happened, probably in too many places.

Q. Just to try to flesh that out a bit, we are interested in the risks that come from taking factor concentrates. And of course, in the mid 1980s, 1983, there is emerging knowledge about the risk. By mid-1983 we have heard that there is a possibility that there is a virus which is being transmitted by blood products and that some people, if this is a virus, who have the virus have died. That's a little bit imprecise but given that background, could you maybe talk about what a clinician should be doing?

A. I mean, the difficulty here -- and if we limit it just to thinking about AIDS, about HIV, at the moment -- is that the level of knowledge at this time about firstly,

what was the cause of this illness and secondly, what happened if you were exposed to it, if it was an infectious agent, and thirdly, what did having antibodies in your blood mean, all of those were highly uncertain and I have seen lots of different estimates in the historical data of how likely it was that somebody exposed to the agent and it getting into their blood may be producing an antibody response, how likely it was that they would go on to become clinically ill, and if they did become clinically ill, whether they would die and that took some time to develop, as it does with every new illness.

In an illness like HIV, where the time period between infection and clinical illness can be extremely prolonged today -- and probably even in the early days was pretty long for some patients -- it's extremely difficult to actually say, "This is the likelihood of you becoming ill, and this is the likelihood, if you become ill, of that becoming a lethal illness". All of those uncertainties make it very difficult to say to someone, "There is a risk associated with this," because how do you then categorise the level of that risk?

I recognise that sometimes people didn't want to categorise it because they found it difficult to, but I think it genuinely was difficult. People just didn't

know. Do you tell people that maybe one in 1,000 people exposed to this virus or agent or whatever it was -- it turned out to be a virus -- are going to become ill and may die from it, which seemed to be one of the estimates? Or do you say everyone? And there is a period in which it became clear that it was far more than the 1 in 1,000. It became commoner. And that's actually quite an important issue. It was very difficult for people to know all of that, to have all the latest information and to know.

As the information became more available and more certain, then you increase the expectation that that will be told to the patients.

Q. Yes.

A. But against that there is also the other side of it. We have not talked at all about the benefits.

Q. Yes.

A. And again, as with anything, there are two sides. The benefits of the treatment that you are stopping or might be stopping or might be questioning also need to be understood. So when you are saying to the patient, "There is a risk in this," you are counteracting that by saying, "The benefits of this are X and the alternatives to that are something which is less good in other ways but doesn't potentially have this risk".

Q. I'm talking about a scenario where the risk is not discussed at all by the clinician. I'm just wondering if you are saying that the uncertainty about HIV, as we now call it, at this stage put it in the category of such an uncertain risk that it was legitimate for clinicians to simply not mention it to patients?
A. At the very beginning of this period, yes, but decreasingly so during the period.
Q. Yes.
A. It becomes, as you know more about it, as you understand the risks more and indeed, sadly, as it became clear that the risks were higher than had originally been thought, less acceptable to not warn the patients.
Q. Yes.
THE CHAIRMAN: Would you like to go back to your example of death and see whether emerging knowledge that people were dying made a difference?
MR GARDINER: Yes.
A. Indeed. The problem with knowledge that people are dying is that individual deaths don't unfortunately give you the statistic of the mortality, and it's actually understanding the rate. Yes, you do need to know that some people die but if I can give you a different example. Two years ago, when we had pandemic flu, we had a very major response to that because the evidence

from Mexico was that 50 per cent of the people with flu died. Of course, what we now know is that only 1 in 1,000 of the people who actually had flu were diagnosed with flu. So actually 1 in 2,000 were dying and probably even less than that. This is the problem. The fact that the numbers of deaths that you have, unless you are actually really understand the natural history of the illness, and whether there are people who are equally infected but not actually ill or dying, then you can't actually say how high the risk is.

I suppose that now -- and it may well be as a response to HIV -- we, in a sense, overreact, we are over cautious, which is expensive but good in the sense that it means that we are able to intervene, provided we have something that we can do. But it is actually the other side of the argument. We now over emphasise the risks of particular illnesses so that we can try to get people in treatment. We get equally criticised for that but I suppose the advantage is that people aren't dying because of errors.

THE CHAIRMAN: I think a particular example might be, as I understand it, this: certainly around about 1983, there were still differing views as to what was causing the immune deficiency in certain groups of patients. One view, promoted by the CDC in particular, was that it was

an infective agent and they were very firmly of that view. Another was that immune deficiencies were acquired in a whole variety of ways, cytomegalovirus, Epstein-Barr, lots of other viruses could do it, and there was a fairly well accepted view among certain people that simply the accumulated effect of injection of foreign proteins could lead to immune deficiency.

I think the very particular question is: whichever mechanism, once one had haemophilia patients dying of PCP or matters of that kind, perhaps the mechanism became less important and the fact of death from serious and progressive immune deficiencies should have triggered a change of attitude and practice. Is that a way it can be put?

MR GARDINER: Thank you, sir.

A. Yes, I think that's entirely legitimate and I agree with you that the modality of becoming immune-deficient was irrelevant provided that you linked it in some way to the regular injections and assuming -- because all of the models did link it to the factor, the problem was still you didn't know the numbers and therefore the level of risk. And if the risk had been much, much lower than it turned out to be -- one in 1 million, one in 100,000, one in 1,000 -- then the question is: when do you trigger the fact that it becomes so important

that you tell the patients? Or do you tell the patient regardless of the likelihood because the risk is so big? And I think that certainly in the 1980s, if the risk was a very serious one, such as death, but the likelihood was thought to be very low, you didn't always tell the patient and as it became clear that the frequency was much higher. So it's the frequency issue which became a little bit later the case. So it didn't matter whether it was a virus or an accumulation of viruses or something else, but it's that factor --

THE CHAIRMAN: I think it's very important that I should understand just exactly what would tip the balance. I can see that the prevalence of a condition resulting in death must be a factor at some point, and I understand that what you are saying is that the absolute fact of a death related to this would not be sufficient to tip the balance, that it would require an accumulation of knowledge of growing severity of the risk, actual deaths beginning to emerge and so on, that would lead to it, but I don't at the moment have any feel whatsoever for what sort of statistical data or projected frequency would be required before one could say generally that circumstances had changed.

A. No, absolutely, and this, in a sense, goes back to Sidaway and it's exactly that. In that case they were

looking at paralysis after an operation. I think it's extremely difficult. Our advice has always been, certainly all the time I have been advising on ethics, that if there is a risk of death, it should always be mentioned however rare, and you might then say, "Look, there is this risk but it is extremely rare". Others differed from me, certainly in the early 1980s. Today I think very few people, if any, would differ from my saying that but the question would be -- certainly in the early 1980s, people were looking at this issue of the statistical level of risk and I think it's very difficult, because I think when you start putting the statistics in there, you end up saying how many people have to die before it becomes sufficiently common for me to tell others about it. I think it's a much easier one to tell people always that there is that risk and then to say, "So far as we know today, that risk is pretty low", or, "So far as we know today, I am afraid that risk is very high".

So you give the information and you then contextualise it. I think that's better. But that was not the case in the early 1980s and this is exactly, I think, the difficulty people got into because they were waiting until they were clearer on the statistics, and indeed they were over-reliant upon statistics that

were sadly very optimistic, as we know, in retrospect.

THE CHAIRMAN: But I suppose, looking at things in retrospect, there would be a stage at which the population was not well enough defined even to begin to assess the risk for those who were in the affected group.

A. Absolutely, it can be very difficult. I mean, we have become better at statistics on these since then but partly because we have been dealing with conditions that were very much easier. Since HIV our ability to identify viruses, to understand what's going on, has increased absolutely enormously. So now, when we see a rare condition like SARS or a common condition like flu, say, new innovative viruses, we can see much more quickly exactly what's happening to individuals, but this particular case, this is a particularly awful virus because of its nature, of its hiding in cells for so long, of it not exposing people to illness, it was extremely difficult to work out in that early period exactly what number of people were infected, who was at risk and therefore what the risk was to others as well and what the natural history was of the illness. We learned very quickly, once we were able to, to do antigen as opposed to antibody testing, we learned a great deal more about the natural history of the illness

and that actually helped us. The tragedy in these cases is that these were people who were infected early and who therefore didn't get exposure to the effective treatments when they became available for most of them.

MR GARDINER: Thank you, sir.

If we take the story a little bit further forward in Scotland, by December 1984 it was known that some Scottish patients with haemophilia had become infected by using Scottish blood products. Although at that stage it wasn't necessarily clear what that meant, would you expect a clinician, after December 1984, to draw his patient's attention to the risk of continuing with a treatment that had the risk of becoming infected in that way?

A. Again, it is back to the evolving information and given the evolution of information at that time, yes, by that time, I would have expected that clinicians would be explaining to the patients the risks associated with this particular treatment and the level of certainty and uncertain about the statistics.

Q. Yes. What level of risk today triggers a clinician advising a patient about the risk of a particular treatment?

A. There is no lower limit to the level of risk. It's being open to explain to patients all risks. Again, you

would do that in a hierarchical way. You would talk about the most significant risks first, which are both the common risks and the most serious risks. So two different types of significance. But there would be nothing that you would hide from a patient. But nor would you force the patient to hear that risk. You would tell the patient about any risk. That, of course, is another reason why it is the most senior doctors which get consent from patients because the most junior doctors may not know all those risks, and again it's trying to contextualise them to that patient and say "the risk of no treatment", "the risk of this treatment", "the risk of an alternative treatment," so that the patient can balance what is an acceptable risk to them, and it can be very frightening to be a patient when you get some of this information.

THE CHAIRMAN: Mr Gardiner put the question in terms of being infected with the virus. I think perhaps the situation might have been at that stage that antibodies had been found that indicated they had been exposed to the virus. Would that make any difference to the answer you have just given?

A. I think that the antibody test -- the problem with it would have had to be explained as well. So it's contextualising it. Again, it's telling the patient the

result of the test or what the test was looking for if you were seeking permission to do a test, and explaining what you didn't know about the results of that test, because early on we didn't know how many patients who tested positive were going to go on to get the condition and then as it became clearer that the majority would, we didn't know the timescale, and we certainly couldn't assess it for an individual patient early on. That came from CD4 and CD8 tracking over some years.

So again, you would have to contextualise it. And part of the context, of course, is also, "What can we do about this? We can watch you for infections so that you can get early treatment if you get a chest infection, in case it's developing into pneumocystis carinii or something."

THE CHAIRMAN: It may be my age, doctor, but I'm suddenly getting to the point at which the patient might have been so submerged in all of this information that it might have been losing impact.

A. This is a danger. And this is the danger of giving patients all the information. In fact, I have certainly written that fully informed consent is a way of the doctor giving all the responsibility to the patient and taking it away from the doctor. At least with valid consent, what you are trying to do is contextualise it

and to say, "This is a risk which is significant and you should be considering. These are risks which, you know, I'm happy to talk through but they are unimportant in your context". And that, I think, actually helps the patient to not be submerged under so much information that you can't actually find your needle in the haystack.

THE CHAIRMAN: Yes, thank you.

MR GARDINER: Perhaps we could move on to the next question, which is question 3. That question is:

"What is the current approach to testing for diseases such as HIV and Hepatitis C? In particular, what information should a clinician provide to his/her patients about the diseases which they are being tested for and the implications of a positive diagnosis? What is the current GMC guidance on this point?"

Could you just answer that in your own way, Dr Nathanson?

A. Certainly. The General Medical Council's advice is that consent requires that the patient understands what you are doing, why you are doing it and what the consequences are and what you will do about it. It's a counsel of perfection. How much we all, as individual patients, remember about what we are told is always variable and arguable, but certainly all that

information should be made available and should be offered to the patient and there should be no limit. There shouldn't be anything which you say, "I will not be prepared to tell the patient". You should be prepared to tell the patient everything. Most patients in fact only want to know a limited amount about individual tests and particularly if you are thinking of tests which are either a part of a continuing treatment or part of a diagnosis. You have gone to the doctor with a pain somewhere or a lump and they are doing a series of tests. Do you go through all of the individual -- some patients what to know what are all the tests and why. Others will say, "No, no, so long as at the end of this you tell me what it is that you have found", and they may want to discuss early on what are the most likely diagnoses that you think you are looking for. But patients are very variable.

It's the offering of information and answering the questions of the patient, but in a sense asking the patients to tell you what they want to know rather than just waiting blindly for them to maybe be brave enough to ask you a question.

Q. Yes. What you have described there, would that be termed "pre-test counselling"?

A. Pre-test counselling is a little different. When you

are testing for some conditions, what you would then do is say, "In this one area of testing there are some very specific things which you need to understand about the limits of the test or the implications of the test." with HIV we really started to discuss pre-test counselling in a very formal basis, not necessarily because of the diagnosis clinically but predominantly because of the social and economic consequences. So the inability, for example, to get life insurance, mortgages, those sorts of things, for patients. And particularly early on, when we didn't know whether people would survive or not, and indeed, when early triple therapy came in and it became increasingly likely that people would live long lives and still couldn't get life insurance and so on.

It's equally true for genetic testing today, which would be the similar one. If you were having genetic screening, there are some diagnoses which might make it very difficult for you to get life insurance. It probably won't be the same social stigma that so sadly affected patients, particularly in the early days of HIV disease. But pre-test counselling would talk through all of those things so that the patient understood the consequences and the only patients who should have had HIV testing without pre-test counselling were those

giving blood as blood donors.

Q. Yes.

A. And even then it became subject to you got it; written information about it.

Q. Yes. Do you remember when triple therapy was introduced?

A. Late 1980s/early 1990s, as all the different medicines came on stream, but established therapy changes, I think it's about 1996, I think.

Q. Yes.

A. Yes, 1996.

Q. Were there any particular implications of triple therapy?

A. I think the major implication of the better therapy was simply that this became a disease which became a chronic illness rather than a death sentence. And of course, it's one of these odd things that if you are going to live a long time with something, it's particularly important that the social consequences, and particularly things like getting a job or life insurance, are not things that you are excluded from. If you are going to die in three months, it doesn't matter very much if you can't get a mortgage because you probably wouldn't get a mortgage anyway for other reasons.

Q. Yes, I understand. Perhaps we can move on to the next

question, also about testing. The question is:

"What was the approach to testing for HIV between 1984 and 1990? In particular, what information should a clinician have provided to his/her patients about the disease and the implications of a positive diagnosis? What was the GMC guidance on this point and how did it evolve? Were there any circumstances in which a named sample from a patient could appropriately have been tested without the patient's consent?"

I think you start your answer by talking about necessarily implied consent. Could you just explain that, please?

A. Yes. Necessarily implied consent really means that the patient is doing something which makes it clear that nobody would argue that they are doing anything other than consenting to that test. The interesting issue around this, was, for example, if you go in to see a doctor and the doctor says, "I want to take some blood tests" and you roll up your sleeve and hold your arm out to have blood taken, then you are clearly necessarily implying, to having a needle stuck in your arm and some blood taken. The question is: does that mean that anything that the doctor wants to test that blood for, you have given necessarily implied consent for? And I would say that in the mid 1980s that was the issue

about which people were discussing, and I think we really came to the conclusions that you might say that there were certain tests that were so routine, that are so often done, that you were necessarily consenting to them without being given the details.

So, for example, if you go in to see your GP and you are just not well, something indeterminate, the GP says, "We need to look and see what this is, there are lots of different things, so I'm going to test your kidney function, your liver function" and so on. Then you might say that a blood count and liver function test and so on, you have given necessarily implied consent when you rolled up your sleeve. But it was felt that a test for HIV was sufficiently different because of the clinical uncertainty, what did a result mean, and because of the social consequences, that you needed to get a specific consent to say that.

Now, it's interesting because, you know, liver function tests could also show you something which was significant and might make it impossible for you to get life insurance or difficult to get a job or whatever, but nevertheless it wasn't felt to be quite as unusual.

So, in a sense, certain of the blood tests, certain blood tests became almost divided into two groups, where one you had to be very, very specific and certain that

the patient understood in detail what the likely consequences of the test could be and others which were sufficiently routine that you didn't necessarily -- although good practice would be, of course, to offer patients information.

Q. The question is between 1984 and 1990 -- so that's quite a broad span. I think you just said that, "We came to the conclusion ..." When would you have come to the conclusion during that period?

A. Well, certainly the GMC advice published in 1988, so written 1987 to 1988, would certainly be absolutely evidence of that conclusion.

Q. Yes.

A. The BMA advice came out a little earlier than that. Which is what I was reflecting in the GMC meeting, but we were faced with many people who felt that explicit consent, even to testing for HTLV-III and then for HIV, was not required, certainly until the GMC advice, as it were, nailed it and said, "This is absolutely something that requires specific consent". So certainly through the 1980s, until, I would say, probably until the GMC advice came out in 1988, that period of questioning existed.

Q. Yes. So you wouldn't necessarily be critical of clinicians who hadn't conducted their practices in the

same way that the guidance suggested they should in the period leading up to 1988?

A. No, I wouldn't be because I think a lot of that advice on consent was understood to be more about consent to treatment than it was about consent to testing. And I should have said that one of the issues that was discussed a great deal in the run-up to this advice from the GMC was whether treatment, testing, and so on were all covered by the same concepts of consent. The eventual conclusion was that, yes, everything was, but there were many people who would have said that again, necessarily implied consent, you have agreed to have a blood test or you have come to the doctor and said "I'm not well, can you find out what it is and see what needs to be done" was necessarily implied consent to whatever tests were felt to be necessary.

Again, until the GMC made it clear that actually, no, there were some tests that were not and that actually good practice was to be as specific as you could be about all testing.

Q. Yes. The Inquiry has heard evidence about clinicians testing stored samples of blood in about 1984 and these are stored samples which have been given by patients without the patients knowing that they will be tested in the future, and also without the patient's consent to

testing at the time of testing and from what you are saying, doctor, you wouldn't necessarily be critical of those clinicians?

A. No. Not least because it depends upon what those samples were taken for. Did patients know that samples were being stored? As I understand it, they did. Did they know that these would be used to look for the viruses which were known to be around? Particularly there was this issue of non-A non-B hepatitis, although there was no test for Hepatitis C, as it later became, and because tracking was done, including retrospectively, as I understand it, to what was happening to many different elements of the patient's biochemistry, and that retrospectively -- and that is still done today, although we would now be very much more explicit in taking it, but this is the kind of testing that we follow up on and we would probably limit that. But certainly in the early 1980s, you would probably say, "It is a routine to just keep looking and making sure that we are testing the accuracy of our testing", and it may well have been seen as part of that and again as part of, you know, the consent that you necessarily implied consent, in a sense.

But again, during that period, the move to being more explicit. And at the same time, interestingly, to

saying, if this is about research, then actually trying to put some teeth into the requirement to get research ethics approval. And that research ethics approval required explicitly to know what the patient has consented to and that what you are doing is not any more than the patient consented to. So you can't get consent to test for A and then six years later decide to test for B on stored samples because the consent wouldn't be valid. You would have to go back to the patients. That's today, of course.

Q. Yes. It seems that an important part of the need for pre-test counselling was the social implications of having the test. So that cannot have arisen, that implication cannot have arisen until later on in this period. Is that right?

A. Yes, indeed, and I think pre-test counselling particularly, started to be discussed as the social implications began to arise. So 1984, 1985, 1986. But certainly in the very early days of the testing, of HTLV-III testing, because of the uncertainty, nobody knew what the positive test result meant in the very early days, that would be the thing that you would be counselling about if you were doing pre-test counselling. You might say, "There is this new test, what looks like a new virus, we don't quite know what

a positive test means," and that's actually quite a difficult one because the patients quite rightly say, "Why are you testing for it, if you don't know what it means?" It seemed odd.

Q. But I think you are saying that until we get to 1988 you would not be critical of clinicians for not doing that --

A. No, I wouldn't regard it as best practice but I would regard it as something that's quite common.

Q. Yes.

Sir, I propose to pass on to the next question unless you have any questions?

THE CHAIRMAN: No, I'm content.

MR GARDINER: Thank you. Could we go to page 0337 now, which is on page 8, and question 5:

"What is the approach to communicating the results of a test for a disease such as HIV or results which suggest that a patient has a terminal disease? What is the current GMC guidance on this point?"

I think I'll just let you answer that in your own way, Dr Nathanson.

A. Thank you. Patients have an absolute right to know everything and anything about them that the doctor is aware of. That doesn't mean that the patient must be forced to know what the doctor knows about them from

test results. What it does mean is that the doctor is obliged to offer the patient information. This is actually quite a complex process. This means sitting down with a patient, giving them time, trying to explain what you are doing and trying to contextualise the information that you want to give them, particularly if that information is essentially saying, "You have a terminal illness."

It is extremely difficult. It's certainly clear that if you are saying to patients, "There is something we know from tests," or examinations, or whatever, "that we need to tell you," it's very difficult for a patient to say, "I don't want to know," without actually already knowing, at least in part, but it recognises that for many patients, even though they may know or think they know about the bad news you are going to tell them -- and they are very few patients that don't want to know good news -- actually they may not know the facts and they may just be afraid of a particular word or a particular phrase.

So again it is back to the skill. It's the skill of the doctor, in interviewing the patient and talking to them, to try to find out what it is that the patient does not want to hear and why they don't want to hear it: Do they have a particular experience in life,

a friend, a family member or whoever, who something has happened to them that is making them afraid of hearing a particular piece of news? That may not be a reflection of current treatment or current expectations or likelihood.

It's trying to find out that. But it's not ever forcing patients to hear bad news or indeed to hear any news. The difficulty here is always where the patient needs to know something because they need to make a decision and where, without understanding something, that decision can't be made.

It's that delicate balance of trying to give the patient enough information, sometimes just without using particular words that people are particularly phobic about. The word "cancer", for example, is one that many of us are very scared of, and it's trying to get enough information to the patients so they can help to take part in making a plan or at least saying to the doctor what they would want their treatment plan based upon, what their wishes were, and to try to give them that information.

Within all of this, of course, there is the difficulty of families always wanting to know what's going on. Families actually have no rights to know; it is up to the patient to decide whether the family can be

told. So the key issue again very often for doctors is to talk to the patient and say, "Would you like me to talk to your relatives? If so, which relatives would you like me to talk to? Would you like to have some or all relatives --" probably not all but a number of relatives "-- with you when I talk to you?" It is again trying to give the patient the control over who delivers the message, how the message is delivered and to whom.

It is always difficult if patients are given a very serious diagnosis or piece of information and they don't want their family to know. Doctors would work very hard to try to persuade patients, gently but persuasively, that their family should know because that's where most people get their support from. When I say "family", I mean their nearest and dearest, not necessarily actually relatives, but if we take it as meaning their nearest and dearest in this case. Most people get a lot of support throughout their illness from somebody or some other individuals and it's helpful if they can also be aware and know what the patients knows. There are occasions when patients say, "I don't want anybody in my family to know." That is very difficult but that is absolutely the patient's right.

Q. Yes. Just at the end of the first paragraph there you mention the difficult position that doctors were in in

the early days of testing for HIV. Can you just talk about that a little bit?

A. Yes, in the very early days, when the first HTLV-III tests were done, firstly we didn't know how many patients -- we didn't know what it meant, we didn't know if that was somebody who was now immune or going to get the illness. It became clear in a relatively short period of time that these were patients who were likely to become ill and that that illness, once it started, once we got through, as it were, the pre-clinical phase, would be relatively short and relatively nasty and almost everybody would die fairly quickly. So very, very difficult because of a period, first, of uncertainty and then of very bad news: more certainty but about bad news.

Again in the period where we really didn't know what a test meant, extremely difficult to communicate that to people sensitively and to actually try to explain to them because the one thing patients find very difficult is uncertainty, not surprisingly. We all find uncertainty difficult but it's very difficult to be told, "We have done this test, we think it's important but we don't know how important to you yet." People get quite angry about that, very understandably. Not helped by the fact that, when we did know more about it, it was

to say, "We now know more and it's actually bad news."

It is now much easier to explain some of these tests to patients, partly because we tell in advance, before we test, routinely, but also partly because we have got used to trying to explain relative risks and what uncertainty means and what we can do about uncertainty, and, frankly, the periods of uncertainty in new illnesses are now often much shorter simply because of better diagnostic testing.

Q. Yes. There must also be non-clinical reasons that a patient might not want to know the full details of their results.

A. Very often I think patients don't want to know their results because they simply say, "Will the result change anything in my life?" If there is no treatment, patients may say, "Why would I want to know this? What can I do with that information? It may make me depressed. It may be difficult for me. It may be something I will have to declare to people." That's more often a reason for not being tested rather than not knowing the result.

But there may be no benefit in knowing and for some patients there are real benefits in knowing, even if there is no treatment that you can give specifically. Genetic testing, where there is no treatment to be

given, patients may make reproductive decisions, may choose not to have children and so on. But not everybody wants information, for that reason.

They may also not know how to tell other people, they may find that very difficult. I notice in a number of the witness statements people not saying that they or somebody had HIV disease but saying they had, say, leukaemia or something else because it was not an issue which people discriminated against. People were sympathetic to it, as opposed to HIV disease, which, sadly, people were very unsympathetic about.

Q. From your own personal experience, doctor, in practice have there been any occasions when patients, for non-clinical reasons, have asked you not to give them the full results of investigations?

A. I can give you an example of when I was a pre-registration house officer. I was a house surgeon in general surgery, so my boss did general entero-abdominal surgery, and on this particular day two men, both in their early 60s, both thought to have cancer of the stomach, gastric cancer, and one of them was thought to be possibly inoperable but just possibly operable, just enough of a possibility to make it worth doing the operation, the other was thought almost 100 per cent to be operable, and at operation neither

was operable, both had spread everywhere. At the end of the operation the consultant I worked for said, "Of course, we don't tell patients the diagnosis." I said I don't think that's right and he said, "In that case you can tell them."

I went and talked to both the patients a couple of days later, when they were out of the anaesthetic fully, and I said, "I would like to tell you what we found at operation. Would you like me to talk to you on your own or with a family member?" One of the patients said, "I don't want to know the diagnosis, I just want your reassurance that, when I need further care, there will always be a bed for me if I'm in pain." So he was telling me he knew the diagnosis, without actually wanting to hear the word, but, "Would you tell my sister, with whom I live and who looks after me?" So we did that.

The other patient said, "I want to know exactly what's going on. Will you tell me with my wife?" And we did that and he was very grateful because he only had one daughter, who was living in Australia, and it meant that as soon as he was over the operation, he was able to plan to go to Australia to see his new grandchild, whom he hadn't yet seen, rather than wait until he was better.

So both of them got exactly what they wanted; they got the information they wanted. Their decisions were made for reasons that were nothing to do with the diagnosis, they were about planning their lives and who they trusted and who they wanted to hear.

I always thought that one of the best things that I knew was that by the time I left that unit, it was routine to offer the information to every patient. This was in 1979. I think that that was the beginning of that movement. What I thought was very interesting was very senior consultants willing to learn that this was a different way of handling it and to learn, what's more, from the patients' experience. The thing that convinced them was not what I said, it was what the patients said to them about their experience of being told information that in the way that they needed to hear it.

Q. Yes. What you did with the patients, passing on the information and finding out what they wanted, is that the modern approach to dealing with patients?

A. Yes, it is.

Q. Yes. Could we go to page 0338? I think you set out there the current guidance on consent, which states:

"You must give patients the information they want or need about:

"(a) the diagnosis and prognosis ..."

And so on. At the bottom of that extract you say:

"In terms of communicating information of particular sensitivity or which might be especially distressing, it is clear that doctors are expected to do this carefully, empathetically and openly."

How is that done properly?

A. Firstly throughout medical education communication skills are now regarded as essential and they are taught throughout pre-clinical and clinical courses for medical undergraduates and then they are reinforced very often in postgraduate training. I think all the medical royal colleges expect this to happen. It's a mixture of a formal approach, in terms of people are taught what they should think about, how they should plan what they should say, right the way through to videoing it. In fact often for medical undergraduates it is done with actors coming in. It's a very good way of learning without actually distressing anyone.

They watch this on video, they watch back and learn to self-criticise. Learning by sitting in with others doing it who are experienced. Learning to do it -- and I suppose there are lots of different rules within it. Perhaps the most important are privacy and time, finding a place where you can sit with the patient where there

is not a thousand people passing, as there are in, say, a busy hospital ward, trying to find somewhere quiet and trying to make it clear to the patient that your time is theirs, this is not something that you have got 30 seconds for and you are going off to do something else. Putting those two things in place and being as sympathetic as you can.

It is very difficult. If you are a surgeon, the last thing your patient wants is you to be too empathetic in the middle of an operation. They want you to be quite removed, quite distant in a sense, but they also want you to be empathetic when you sit and talk to them, and it can be quite difficult to have the two different skill sets. There are, without doubt, people who are better at it than others but everybody is trained and tested to see that they are doing it reasonably well today.

Q. Clinicians who had trained in the 1970s and 1980s, I imagine they wouldn't have any training in that kind of thing?

A. None. There would be none at all. They would learn, if they were lucky, by sitting in on more senior clinicians doing these interviews, but given that fewer senior clinicians were experienced in communicating bad news, they may not have had good practice or good role models

to learn from.

Q. Yes. Could we just go down to the next paragraph, which starts, "It is well-known ..." I think what you describe here is a phenomenon about what happens when individuals are told difficult or bad news, and this may be relevant to what we are looking at. Could you just explain?

A. Yes, there has been a lot of work, some of it led by the Royal College of General Practitioners, who do quite a lot of videoing of patient interactions, partly as their summative assessment of whether a doctor is fit to become a member of the College. One of the things that became quite clear is that when you video an interview, a normal interview, between a doctor and a patient, with complicated information, not necessarily only bad news -- it can be complex news as well -- even though the patient has asked questions and those questions have been answered and even though in the best practices doctors have done the reflective thing of asking the patient what they have understood about what they have said -- "So what do you think I have told you?" as it were -- if you then talk to the patient an hour later and you say to them, "What did the doctor tell you?" they may deny that they were ever told some of the key things which the doctor has told them. If you then play them the video, they will be astonished and they will

have absolutely no memory of the discussion that they had.

That's hugely important because what it means is you have to actually develop things that are not just a skill at that one interview because you think you have done all the right things of reflecting back on what the patient is asking you and getting them to reflect on what you have said, but you have to continue to follow it up. You have to support it with information sheets perhaps, you have to raise it again at the next meeting with the patient to make sure that they have continued to remember the things that are important because otherwise people will not remember.

This is isn't about patients being fools or anything else; this is about the psychology of the way we are able, as people, to deny information that we don't want to hear, and also just the fact that we are emotionally fraught. Even if it's not necessarily a very bad news interview, the fact that it's difficult, complicated stuff, we can actually forget. We are so busy being tense and scared and not sure what to say or do that we somehow don't absorb the information.

Understanding that means that we now practise far more in terms of trying to repeat that information, but it's still quite often difficult. Some patients find it

very difficult to ever remember the things that are said because they are so tense at the time of the interview.

Q. Yes. How is the information repeated to the patient in that situation?

A. Sometimes simply by repeating it every time but most often by accompanying it now with information sheets, very simple ones that just would highlight the key facts, so that you are helping to jog the memory repeatedly. It is also part of this process that we would always describe as -- processes of things like consent are not one-off events. The whole relationship with patients is about a continuing relationship, about always being open to more questions and trying to encourage patients to feel that asking questions is not seen by the doctor as threatening or unacceptable; it is seen as a part of the mature relationship that the patient and doctor have.

Q. Yes. Thank you. Sir, I propose to move on to the next question.

THE CHAIRMAN: I think we should break at that stage. It's not really a surprise to a judge to hear that what people remember of what they were told, or what they saw even, is often very partial simply because of the way the mind works at the time. Observation is usually partial and then recollection is never complete and, of

course, the mind operates on primary information that is remembered. All these factors tend to happen in your practice too?

A. Absolutely. All of those factors happen and that, I think, is why, increasingly, one of the things that many doctors use for things that they see not necessarily commonly but frequently enough is to try to have basic information sheets to hand out immediately as things to help jog the memory. Increasingly, one of things that we are encouraging is people are trying to add to that details of websites, which will give good information, so that if people go off and search the web, which many people do, the help to be directed to, say, the website by a disease society, which tends to usually be extremely well informed --

THE CHAIRMAN: Rather than taking Wikipedia as the --

A. Indeed, although sometimes Wikipedia can be right, but sometimes it is wrong, and the difficulty is, if a piece of information, if a diagnosis, is completely new to you as a patient, you can't judge between the good sites and the bad sites, and that's where people really do come a cropper because they can read something which can make them feel I can't co-operate with that treatment, when actually every legitimate site would tell you that's the absolute gold standard of treatment.

THE CHAIRMAN: I think we have now come right up to date.
MR GARDINER: I think there is a plan to start a little bit earlier.
THE CHAIRMAN: I'm quite happy to start whenever people are ready.
MR GARDINER: If we start at maybe ten to two.
(1.00 pm)
(The short adjournment)
(1.50 pm)
THE CHAIRMAN: Yes, Mr Gardiner?
MR GARDINER: Thank you, sir.

Dr Nathanson, before lunch I think we had got to question 6, which is on page 0338, so at the bottom of page 9. The question is:

"What was the correct approach to communicating the results of a diagnosis of HIV between 1984 and 1990? What was the GMC guidance on this point? How did that guidance evolve?"

Just over the page, at the top, you start by referring to the 1988 guidance. So I think we should have that on the screen, and it's page2 of [PEN0161165]. If we look at that first.

This is the letter. We had a quick look at this this morning, but this is the letter dated April 1991 from Sir Robert Kilpatrick, president, and Donald Irvin,

the Chairman of Standards Committee, which says:

"Dear colleague, in August 1988 the attached statement was sent to all doctors on the principal list of the register and to those holding limited registration. It contains important material offering guidance to doctors in approaching a number of ethical questions which arise in relation to the management and control of HIV infection and the diseases associated with it. These questions are both sensitive and difficult and warrant the careful attention of every doctor. The statement stands as an expression of the Council's view in four main areas where ethical difficulties can arise: the doctor's duty towards patients; duties of doctors infected with the virus; consent to investigation or treatment; confidentiality."

If we go to the next page, 1167, we see that the heading is "HIV infection and AIDS: the ethical considerations", and the guidance goes through the different issues that were mentioned. We have "the doctor/patient relationship", "the doctor's duty towards patients". Over the page, "duties of doctors infected with the virus", paragraph 12, "consent to investigation or treatment"; then if we go to the next page, paragraph 13, we have "testing for HIV infection: the need to obtain consent". Further down the page we have,

"confidentiality". I think it's the bottom of that paragraph that you refer to in your report. Perhaps I could just let you answer the question?

A. Thank you.

Yes. At the bottom of the paragraph on confidentiality, the GMC states that:

"The Council takes the view that any doctor who discovers that a patient is HIV positive or suffering from AIDS has a duty to discuss these matters fully with the patient."

I think that that's the first time that the GMC was as explicit as this and I'm not aware in any of their earlier publications that they had been as explicit, in any condition, about informing the patient. It had been implicit in a great deal of what they have said but not explicit. So certainly at that time, in 1988, it would have been clear to all doctors on the basis that GMC advice goes literally to all doctors on the register.

It didn't go into any more detail about it but I think that the duty to discuss these matters fully is pretty explicit and would make it clear that you had to discuss all the relevant matters.

Even then, 1988, they were advising doctors, many of whom had never seen a case of HIV/AIDS, and weren't sure whether they ever would -- nobody knew at that stage how

the epidemic would expand, whether it would spread more generally into the population or not, and certainly there were a limited number of doctors who were seeing a number of cases, case clusters, but this was explicit to everyone. The implication, of course is not just about HIV; I think the implication is for all conditions but it was absolutely explicit about HIV/AIDS and it recognised, of course, that that hadn't been the case in the past. If all doctors had always told all patients the full details, fully informed, fully discussed, then they wouldn't have needed to make the statement or the statement would have been made something like, "As with all other conditions," or something of this form.

The fact that they felt it necessary showed that they recognised that doctors didn't always tell patients everything or fully discuss and that this was essential. And certainly in the late 1970s, it would have been extremely rare to tell patients everything but this was part of this evolution towards patient-centred care that I described earlier, that this was becoming a commoner practice anyway.

I think it's also important to recognise that much of the discussion that went on about how you talked to patients and how you told them everything, given that at the time the GMC was writing this advice, there was

still considerable uncertainty in terms of HIV/AIDS about the outcomes and whether the new treatments that were being started were likely to be very successful, the length of lifespan you could expect and so on, and nobody deals well with uncertainty.

So those questions were being asked. But it was also felt to be important not only that, as a matter of principle, patients had the opportunity to understand everything but also because for some patients this would also give them opportunities to make decisions, plans, particularly in the case of HIV/AIDS, to protect others, particularly in terms of sexual contact but also, of course, in blood contact.

Q. Yes. If we read on in the guidance at page 5 of [PEN0161165], at paragraph 16, it covers informing other healthcare professionals, and if we go over the page, that continues with advising other healthcare professionals, down to paragraph 19, which talks about informing the patient's spouse or other sexual partner. What it says there is:

"Questions of conflicting obligations also arise when a doctor is faced with the decision whether that fact that a patient is HIV positive or suffering from AIDS should be disclosed to a third party, other than another healthcare professional, without the consent of

the patient. The Council has reached the view that there are grounds for such a disclosure only where there is serious and identifiable risk to a specific individual who, if not so informed, would be exposed to infection. Therefore, when a person is found to be infected in this way, the doctor must discuss with the patient the question of informing a spouse or other sexual partner. The Council believes that most such patients will agree to disclosure in these circumstances, but where such consent is withheld the doctor may consider it a duty to seek to ensure that any sexual partner is informed, in order to safeguard such persons from a possibly fatal infection."

Of course, both of these bits of guidance about a doctor's duty to fully inform patients and informing the patient's spouse are in a guidance dated 1988. So, Dr Nathanson, what was the position up until this guidance was communicated to the doctors?

A. Until it was produced, the guidance for doctors would be the GMC guidance more generally, which was very much more limited. I think I indicated before that up until around this time, the GMC guidance was more a list of the things that will get you struck off, rather than "This is good practice", and this is really one of the first times in which they attempted to detail good

practice, so not just the things that you must not do but the things that you ought to do, the things that amounted to good practice, and I think in many ways was one of the things that led to the publication of not only the current Good Medical Practice but all the subsequent appendices to that, the detailed documents that now come out on issues such as consent and research and so on.

Because it was well received, because it was found to be valuable, and I think that doctors before then had been seeking advice from many different people, or indeed not seeking advice and just working according to previous practice, which would be very variable because it would depend upon where they qualified, when they qualified and what their clinical experience had been. So there would have been very different practices, in particular around informing the patient of the diagnosis, probably rather less variation in terms of the confidentiality in relation to spouses, sexual partners, because confidentiality had been regarded as something that people had understood rather better and where practice was at a rather higher order generally, and generally doctors didn't -- I mean, the interesting thing here is it's one of the first references by the GMC to "confidentiality isn't absolute", and you may

breach an individual's confidentiality for the sake of others, and that was actually extremely helpful and is something that's now very widely understood.

Q. Between, let's say, 1984 and this guidance, would you be critical of a doctor who didn't fully discuss HIV status with his patient or inform the sexual partners of such a patient?

A. Certainly, in terms of not fully informing the patient, I would say it wasn't best practice but it was understandable and widespread and something that was becoming less understandable and less widespread, if you like, diminishing.

In terms of sexual partners, I would be very much more surprised because my understanding was that in most cases the debate was had with the patient and the partners were told, predominantly because it was established practice in genito-urinary medicine, and GUM specialists tended to help people who were not in GUM but were seeing patients with a condition that can be sexually transmitted and therefore explaining how they did spousal information.

Q. I suppose if a doctor is not having a full discussion with his patient about his HIV status, then he wouldn't be able to discuss the question of informing sexual partners?

A. Indeed. If you do not tell the patient everything, then not only can you not protect others, you can't actually, of course, alert the patient to things that they should think about doing for themselves to protect themselves from other illnesses or indeed about early spotting of other serious problems. There are many reasons which are practical, as well as ethical ones, for being honest and open with the patients.

Q. Yes. But notwithstanding that risk to third parties, you would say that not fully discussing that with a patient was understandable and widespread in that time period, 1984 to 1988?

A. It was understandable and widespread but diminishing during that period. It was part of this move to more openness.

Q. What about the other approach, which might be fully discussing the matters with a patient without regard to their wishes as to whether or not they want to have the results communicated to them?

A. Because this is still a time at which communication with the patient was being developed and from really quite a poor base in some areas, there would be some doctors who might tell the patient who didn't want to know and who would tell them in a way which was less considerate to their feelings and their wishes than is perfect. But

clearly we are dealing with people who were not used to the communication of difficult news or bad news.

It would probably be done on the basis of, "This will help you to protect others," which is not an excuse for it but is actually one of the very difficult tensions here, because given that with HIV -- and particularly if you have a sexually active patient -- if you don't tell them, then they are putting their partner or partners at risk. It is very difficult to, in a sense, allow the patient, who wishes to be ignorant of the diagnosis to continue to be ignorant. You can try it by saying, "You are in a group of patients some of whom have this condition". Whether or not you know that you are or not a risk to others, you would be best to act as if you are a risk to others and therefore to take the following precautions, and that might work for some patients but it's a difficulty and I think it's better if you can persuade the patient to know the information. That helps. And particularly because if you say to the individual, "This will help you, not just for yourself but to actually protect others," and particularly as you are talking about others that that person usually cares deeply about, then most patients would say, "Yes, I want to know", in the same way that contact tracing has never been a major issue because most patients want their

contacts to know and to be helped if they need help.

Q. Yes. There is a separate question, which I asked you to have a think about earlier this morning, and I would just like to ask you it. I'm going to put a scenario to you and ask for your comment. In 1984, if a clinician had results that indicated that his patient was antibody positive and if, after discussion, the clinician believed that the patient did not want to know his results, what should the clinician do?

A. This is a very difficult scenario and I think that it probably happened to some extent quite a lot in the early days. The answer is that the clinician has to try and find out why the patient doesn't want to know. Is there a particular issue that the individual is afraid of, that you can reassure them about or is it simply that, as quite understandably, somebody doesn't want to know because they know it's bad news and they just don't want to be confronted by it?

Then the question is, if that individual is putting somebody else at risk, do you have the right to force them to know or can you say to them, which I think is what most would have done in this situation, "I won't force you to know the results but given that we know that a percentage of people are positive and given that you will want to protect those you love, these are the

things that you need to do to protect them; you need, in other words, to act as if you are positive, whether or not you are," and say that you are saying that to everyone regardless of their results.

In fact, for doctors it was easier if you didn't know the results in an individual patient at the time you told them this because then you could genuinely say "I don't know the results but the safest thing you can do to protect your family is to act as if you are positive."

In fact doctors did that. If we had patients who were regarded as being at high risk, regardless of their blood results, which may be negative, they were treated as though they were positive in terms of putting them at the end of operating lists to protect other patients and to allow better cleaning of the theatre and so on.

Once you explain that to people, that it is not that you are being refused treatment or being treated differently, you are being treated differently only insofar as it protects you as a patient and others. People accept that.

Q. So that approach of telling patients that they should, without actually knowing their status, proceed on the basis that they are positive, you would say that that was an acceptable way for a doctor to deal with the

problem that I'm setting out in this question?
A. Certainly in 1984. As time moved on, things began to change.
Q. Yes.
A. And that particularly was because it wasn't simply about protecting others; it was about our increasing knowledge of what we could do to help that patient. So two things: firstly, the development of the first antiretrovirals but, in addition to that, our knowledge that patients who were HIV positive presented with particular types of infections which needed to be treated very quickly and quite intensively with antibiotics, rather differently to the average patient, if you like, and that made a significant difference to their likelihood of surviving that acute infective episode.

So given that, that was another factor that you would tell the patient to try to persuade the patient to agree to be told the information. And there would be a point at which you might even consider forcing the patient to know, simply because of the value to them of getting different treatment, if they became ill with something else.
Q. Yes. So what period are we talking about?
A. Well, certainly in the very end of the 1980s, with the

beginnings of reasonable antiretroviral issues and certainly by the mid-1990s with established triple therapy, it would be unacceptable to not know, but at that time of course, we were in the much better situation that no patient would have been tested without explicit consent. So all of this would have been gone through in advance.

It would be exceptionally rare for you to know -- so rare that I can't think of a circumstance where you might do a test and know today that this patient is HIV positive and not have actually already gone through with them the reasons why you would do a test. And in fact it's one of the factors that you would include in your counselling, that "These are the downsides of knowing, that having had a test you may still find certain things difficult, even if you test negative, but the positive is that we can offer you these treatments which may make a significant difference to your survival and to your quality of life."

Q. The point at which a doctor should force his patient to know the results would be the point at which the patient would benefit from treatment?

A. Effectively, yes, and particularly where that treatment is a significant benefit, although I don't like the word "force". I think it's just that the amount of weight

that you put into persuading the patient about the benefits to them, and I think most clinicians in this circumstance find that patients don't ever say they don't want to know something when you are telling them that there is a benefit to them in knowing.

Q. One of the things that has troubled us is how a doctor would approach the question of, "Do you want to know your results?" without signalling to a patient that they have some bad news to impart.

A. It's an extraordinarily difficult thing to do. I mean, the easiest thing is where, if tests have been done and you actually know there are results but you don't know them on that particular patient. For example, that might come out of some research that a patient has been involved in where the doctor doesn't know that sample whatever relates to a particular patient and then it's later found that that result of that test is significant. That would be the situation today that could occur. You may be able to break the code and link it to a patient, but in those circumstances you would at least have the advantage of saying, "I don't know what the result is in your case. I don't know whether in your case you are, as it were, negative or positive" and patients may or may not want the results.

We are talking about a situation here in which

patients had results who hadn't been warned in advance that the test was being done in the early 1980s, and particularly in the early 1980s, where the result itself was of uncertain consequence.

So the difficulty then for the doctor is approaching several things: firstly, saying, "We have been testing for something new which we haven't discussed with you in detail before. We have a result. We don't know what that result means in detail. Do you want to know that?"

It became easier, I think, with time, in the sense that I think most the patients, who were a very well-informed group, realised, because they saw the literature as well, exactly what was happening and that this was becoming something that more and more of their number were being found to be positive. But that still left the doctors -- and it is in fact, of course, one of the practical reasons why you shouldn't do tests without the patient's consent, because you never get yourself into this position, because the patient always knows and they know that that test may come up with something that is unpleasant as well as something that is reassuring. So all you can do is try to say, "We have some information, do you want that information?" and I think it puts you in a very difficult position to do it sensitively.

Q. I imagine that it is important for the doctor to let the patient know that he has the information?
A. Yes. It's essential that the patient knows and I think it is a duty on the doctor -- I think this is again what the GMC were saying -- that the doctor's duty is to make sure that the patient is aware that the information is there for them. How much you press the patient to know is a separate issue but you can't leave it for a patient to say, "You haven't by any chance put me into a group that has been tested for something?" You have to say to them, "We have done some tests. Do you want the results?"
Q. Yes. In 1984 would you be critical of a doctor who didn't clearly let a patient know that they had the information?
A. I think I would be critical of a doctor who, even in 1984, wasn't telling the patient that, "We have important information that you don't know". Caveats around that. Clearly you have to say to the patient, "We don't quite know what it means", but I think you must offer to the patient -- you must say, "We have information. Do you want to know it?" and particularly, at a stage where the benefit of that knowledge to the individual patient is relatively limited.
Q. Yes. Just bear with me a second. (Pause)

In terms of a doctor letting a patient know that he has this information in 1984, what mode should that have been?

A. I think that really depends upon how often you see the patient and what the relationship is with the patient. That would be equally true today in the sense of communicating results. The clear issue is of course to make sure that the patient knows, or is given the availability of that knowledge, as early as possible.

In 1984 that would almost certainly have meant writing to patients and saying, "We have information available, please make an appointment to come and see me if you want to know that information." If you have patients that have routine appointments within the next few weeks, you could probably not write to that group but you must make sure that they are seen, and if by any chance they don't come to those appointments, then make sure they get an offer of another appointment quickly.

Today, of course, we would probably email everybody but it's exactly the same principle; it's what is the fastest and simplest way to get to patients in a way that is not too scary, because remember that this would be information coming out of the blue. So you have to again make sure that it's written in terms that are supportive or as supportive as you possibly can.

Q. Presumably the message is, "We have information about you"?

A. Yes, but it could equally be -- it's a difficult one. You would have to be very careful about how you worded it. You could try and say:

"We have been doing some tests on all patients that we see at these clinics. Would you like to see information that we may have about you?"

You certainly can't lie in that and leave it and say, "We have information about some patients" and just leave it to patients to say, "Does that include me?" There must have been at least an implication somewhere that that would include information about them as an individual; otherwise I think you are not informing a patient that there is something that they may wish to see.

MR GARDINER: Sir, I propose to move on to the next question, unless you have any questions of Dr Nathanson?

THE CHAIRMAN: I'll allow you to go forward at this stage.

MR GARDINER: Thank you, sir.

Could we just move on to question 7, please, which is at the bottom of page 10? The question is:

"What is the current ethical position in relation to the use of patient information in medical studies and reports in medical journals? Does a doctor require to

obtain a patient's consent before including a patient's medical data in a study?"

Dr Nathanson, you start by mentioning The Declaration of Helsinki.

A. Yes, I mean, The Declaration of Helsinki was written by the World Medical Association. I said earlier, I think, that the World Medical Association was set up after 1948, after the Nuremberg trials, to look in particular at the standards of medical ethics, and human experimentation was one of the most important areas. The Declaration of Helsinki, which is actually reflected in national law in many countries around the world now as the sort of overarching body of ethical advice on human experimentation, has been looked at and amended many times since then. The most major amendments in 2000 being to turn the language round completely. It says much the same things but in language that actually works rather better today.

But the key issues within it are that no experiments should be carried out without the understanding and knowledge of the individual and their free agreement to be part of that experiment and research, and that that includes -- and we would be absolutely explicit about this today -- what's going to happen to that information. Is it going to be published and in what

form?

So give patients the guarantee and the understanding that in almost all publications that information would be aggregated or presented in such a way that they couldn't be identified from it, that being the major issue that most patients worry about in terms of research publications.

And again, it is back to and it fits in very well with the informed consent, or at least the valid consent model and the patient-centred, that they have the choice of either being in the research or not. You also need to make sure that the patients understand that refusal to be part of the research will not change their access to healthcare. That's another key component of research ethics.

Q. Yes. If we just go over the page there, please. You talk about anonymisation. Could you say a bit about that?

A. Yes. Anonymisation and the horrible word "pseudonymisation", which is also used in this phrase, really means you may or may not start with identifiable patient information, that is actual files about individual patients, but whatever is done with that information is treated in such a way that all identifiers are removed.

Pseudonimisation. The only difference is that you will have a coding so that you could, in theory, if you have the code, get back to the named patient and that's quite important in certain circumstances, again with particular permissions. But the point about anonymisation is that the information has to be -- you have to be very careful that you are not presenting information which, even though you have removed the patient's name, date of birth and so on, doesn't have sufficient detail to mean that you could potentially identify the patient, simply because the circumstances that you are describing are sufficient to identify because such a small number of people would have those identifiers.

That's one of the things that we look at very carefully when we are looking at anonymisation. The biggest research studies are all fully anonymised data, rather differently, which is aggregated data, where you might look at information extracted from, you know, the 5 million population of Scotland to look at -- I think there was something on the news last night about looking at DNA evidence in Scotland and the likelihood of different diseases. That's aggregated data. You couldn't identify an individual from the information that the researcher has. And that has somewhat

different constraints upon it to patient's data that started with named and is looking at small groups.

Q. Yes. On the same page you say:

"There is a separate point about the use of material obtained for one purpose, the clinical care of the patient, and then being used for research. And the ethics advice on this is explicit, that this is unacceptable."

You have a quotation, which I think is from the GMC --

A. The BMA booklet.

Q. BMA, "Medical Ethics Today". Could you just explain about that separate point, please?

A. Yes. Any research that's carried out on human subjects needs to have research ethics approval. This is in the medical field. And that ethics approval will look at the information that the patient has given and be assured that the patients have consented, that they have been free to consent or refuse. It will also look at what the samples are being taken for and in what way and what they are going used for. And the approval to the use of that, indeed the patient's approval for the extraction of that sample, is about its use in that specific context. So to use it for something different is unacceptable because you have no consent. This

happens very often, that stored samples would be useful, and there is a well worked-through -- well, today there is a well worked-through process in which you would go back to the patients and get their permission to use these historical samples that were gathered for another reason.

That's actually often very valuable because some of these historic banks of tissue -- although there are far fewer of them today since the Human Tissue Act and Alder Hey and various other scandals, but they are very valuable where we have them because sometimes they can give you a historic timeline, but you still need the individual's consent and that has been an important element.

Interestingly, there is a group called the Committee On Publication Ethics, which is essentially the editors of the main medical and science journals and they also won't accept any research paper where there is no evidence of ethical approval, even where it is anonymised and even looking at non-research case histories and so on, and this is all a tightening up which continues to this day, including at the moment they are beginning to look at saying, "Maybe we should actually know more about the research ethics approval, rather than just that it was got, to make sure that it

really was being fulfilled so that we can interrogate the data ourselves".

Q. Thank you.

Can we move on to question 8, which is also about the same topic. Question 8 is:

"What was the ethical position in relation to the use of patient information in medical studies and reports in medical journals in the period between 1984 and 1990? Did a doctor require to obtain a patient's consent before including medical data about them in a study."

What's the answer to that, Dr Nathanson?

A. Again, I come back to the Declaration of Helsinki, which was, as I said, first published in 1964, and indeed was included in full in every ethics text that we have ever produced, including the 1974 one, which makes it clear that you require the patient's consent to taking part in ethical studies and that must include what happens with those results, including reports into medical journals.

I think it's fair to say that, certainly in the early 1970s, medical journals may well have accepted -- certainly would have accepted, I think -- studies where they had no evidence of ethical approval, but they shouldn't have -- and I don't believe they did generally -- accept studies which didn't protect patient

anonymity, although our view on anonymity has hardened in the sense of we would apply a higher test today about what is truly anonymous than perhaps we did in the 1970s, partly in response to the fact that we see that people are rather better at tracing people from what we think of as very scanty information.

Q. Yes. If we go to the next page, please, 0341, the third paragraph that starts "although", I think you say that the use of stored blood or tissue samples was contrary to the spirit of The Declaration of Helsinki. I wonder if you could just expand on that?

A. I believe that the use of stored samples is contrary to the spirit in the sense that if it was being done as a research protocol, then clearly it didn't have consent and was clearly therefore in breach of the Declaration of Helsinki. The difficulty comes if people believe that in using those samples, they were just extending what they did by using them as a reference bank of saying, "Were our liver function tests accurate in those days compared to today?" or whatever else they were using stored samples for, say. That's the difficulty.

People might have seen this not as a piece of research but as a piece of the continuing monitoring of the quality of the care that the patient was getting. And that's a very fine line between the two.

The spirit of Helsinki, I think, is clear, that where in doubt, err on the side of think of this as a research protocol and go through the right processes. But that is probably a more modern construct of the way people look at the Declaration of Helsinki.

Certainly, I think, people would argue against it, as I said, by saying that this was part of continuing care. I don't think that's what The Declaration of Helsinki, the writers of it, would regard that as. I have been involved in the rewriting of it for the last 15 years, unfortunately. On an annual basis we rewrite bits.

Q. If we go on a bit further down the page, we see that the paragraph that begins "given", you say that in essence, although doing this without permission might be contrary to the spirit of the declaration, in practice it did occur at that time. Is that the case?

A. Indeed. Indeed. And again, I think because people didn't see this as research, it didn't go through research ethics approval. People were not asked because it was seen as almost a check and balance on whether the quality of care and diagnostics and so on was accurate, and I think that that was fairly widespread, not just in the UK but internationally.

Q. Yes. So although it's contrary to the spirit of the

declaration, you wouldn't necessarily be critical of clinicians that are doing this in the 1980s?

A. I would be critical but recognising that it was commonly the case. I would say it was again, not the gold standard but it was a common fault and it was commonly done.

Q. Thank you.

Can we move on to question 9, which is the second last question and that is:

"What is the duty of a treating doctor with regard to keeping a record of a patient's medical condition and treatment? In particular, what information about treatment and diagnosis should be kept on a record by a treating clinician? Are there any circumstances in which a doctor can legitimately fail to record that a patient has been diagnosed with an infectious disease such as HIV?"

A. Keeping records is a very interesting issue because there is very little anywhere written about what needs to be in a medical record, other than they have to be fit for purpose. That's interesting because different people would say you need different things. But clearly, any information that is important to the future diagnosis, management, care, support and so on of a patient that you have, should be recorded in the

records.

That often includes negatives as well as positives. In other words, it's as important sometimes to say that a patient does not have X or a test has shown a negative result, as it is to show a positive result, not least to show that you have at least thought of that and perhaps excluded something.

In terms of not putting something in the record, I think there is never an excuse for not recording it; the question is whether there are ways in which you can separate the records out into two parts, because that was quite commonly done and particularly at this time, and particularly because of the social stigma that was associated with HIV, and in particular the way some patients were treated by neighbours, friends, in the workplace, schools and so on, that it was felt that the fewer people who knew, other than those that the patient chose to tell, the better, and that one way to do that was to make sure that there was nothing obvious in their notes, given that the NHS is the biggest employer in the United Kingdom, third biggest in the world or something, so we are told, and that means there is an awful lot of people who may have access to some part of records.

So if you can have a confidential part, that is still not so separated -- and this is where it becomes

difficult -- you cannot have that so separated from the main record that when the patient becomes acutely ill you don't have it available, and that is the difficulty. Today, with electronic records, we are talking about things called "sealed envelopes", so the patient can say, "This piece of information should only be available in emergencies when I'm acutely ill or only to certain people" but generally speaking, doctors who were doing the ongoing care of patients with HIV very commonly kept much of the information about their HIV status in a separate set of records which they were able to access as soon as they saw the patient, but they recognised in doing it, it wasn't perfect, and in the best centres they would discuss with the patients, the potential risks of this.

Again, we are back to: if you are knocked down by a bus in the street and we don't know certain key factors, that may act against your interests. So that was something that the patient would make a judgment on with the doctor.

Q. Yes. If we look at question 10, which is over the page, that was:

"What was a treating clinician's duty with regards keeping a record of a patient's medical condition and treatment between 1984 and 1990? At that time, were

there any circumstances in which a doctor could legitimately fail to record that a patient had been diagnosed with HIV?"

I think you have just given us an answer in that area. I think you are suggesting that it would be legitimate to keep a separate record to avoid stigma as long as it's not so separated that it affects the clinical care? Is that right?

A. Absolutely, and then trying to find ways of making sure that both records are available as they are needed.

Q. Yes. In the previous question you mention "sealed envelopes" within the electronic record. Could you give us a example of when a sealed envelope might be used nowadays?

A. If we ever get to the stage where the NHS in England has a working IT system -- and that's a very big "if" -- we will then have sealed envelopes. We don't currently but the concept here would be that a patient would say to their doctor -- and this is again also back to having a complete clinical medical record, not just a summary record, but to be able to say, "There is this information about me, which I have given to you, which I do not want to be generally available to all clinicians who have legitimate access to my records," and different patients have different things that they would want in

a sealed envelope, but the commonest two examples that we are given are actually a history of mental health problems and a history of terminations of pregnancy. Those are the two usual ones and that would be in a sealed envelope. But there are other people who are sensitive about other issues. I remember a barrister in England telling me that he would be sensitive that anyone even knew he had gone to see his GP, because he might have been going for a travel vaccination but the solicitor might think, "You are not well and I therefore I won't offer you the next case". So people have different things that they would want to keep in that sealed envelope.

The risk and the thing that is quite clear in the advice that's ready to go, if we get to the stage where sealed envelopes are feasible, is the patient would have to know absolutely explicitly if there were risks with that information not being available.

It's very difficult in most of the circumstances of the kind of information patients would want there to think of it being a risk that it wasn't available in an emergency, but there might be people who wanted something hidden that could be really important. So again, there have to be protocols for opening the sealed envelope in certain genuine, life-threatening

circumstances.

So the patient who is unconscious for unknown cause and so critically ill that you really don't know what's going on, would you then be able to open the sealed envelope just to see if there was anything in it that could be important?

Q. Yes.

A. And those are really quite important issues. The difficulty for some patients is that of course simply knowing what their prescription is means you immediately know their diagnosis. If you are on triple antiretroviral therapy, we know the diagnosis. And the same thing for a triple therapy or quadruple therapy for TB and many other things.

Q. I see. Just to return to question 10, you told us that it would have been legitimate to keep separate records to avoid stigma, records of HIV status. I'm just wondering to what extent would a doctor in that situation have to make sure that other people would know where these records were in the event that he was knocked down by a bus?

A. Well absolutely. I mean, those records have to be something which are secure and separate but which can be used because it should be about -- and the agreement with the patient would be quite clear, that, "We will

keep the information about your HIV status separate but that element of your notes would be available for whoever runs this clinic and the person who is operating this clinic. So it might be me today but it might be a colleague of mine in six months' time" and so on, and that's the agreement that was reached with patients.

Q. Yes.

A. In GPs' practices, some GPs actually physically had a separate small, locked cabinet in which elements of notes were not in the general reception area with all other notes, and all the partners had access to it and would know that this was a patient with an extra file that only they could access.

Q. So during the period of 1984 to 1990 would you be critical of a doctor who is keeping a separate file for these reasons, stigma reasons, but who is not sharing with medical colleagues where the file is, so that, in the event that something happens to him, the patient's records can be recovered?

A. I would certainly be critical if they weren't telling others that the records could be recovered. That would be unusual because most doctors were very cautious about that. They were very concerned that if they weren't available, the records were available and, of course, wherever they could, they tried to persuade the patient

to not have a separate record because of the potential risks of it and partly also to try to persuade the patient that this could be one of the things that would help them to destigmatise the condition. But they recognised the reality was it was very difficult for the patients.

Q. Just bear with me. (Pause)

I don't have any more questions, sir.

Thank you very much, Dr Nathanson.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Dr Nathanson, I wonder if I can deal first of all with the testing for the HTLV-III virus in autumn 1984. I think your evidence today has been that -- and correct me if I am wrong -- a problem is going to arise if one carries out that test on a named-patient basis without that patient's knowledge. That's going to give rise to a problem. Is it reasonable to say that?

A. Yes, it is.

Q. Would you have expected a doctor, an experienced clinician, at that time to have applied his or her mind to the problem that would arise?

A. They may or may not. I think one of the things that's interesting here is that the early tests for HTLV-III -- there were two or three things that were unusual. The

first was that you got a result but you didn't actually know what it meant in terms of the clinical condition of the patient, certainly in the early days and certainly at that time.

Secondly, I think that far more patients in this group were testing positive than anyone had expected. Also, it was such a new condition and such a new scenario that I don't think anybody had up until then had a test that they might start to use for a previously unknown condition. So they mightn't in fact have worked out in advance what do I do when I get the test results. They should have done but they may not have done because it was such an unusual cluster of circumstances.

Q. We are dealing here not with just, I suppose -- necessarily at least -- with any clinician, we are dealing with clinicians who were involved in a particular field, who would have knowledge about the -- they would have knowledge, obviously, of haemophilia, they would have knowledge of the fact that AIDS was, potentially at least -- or they knew by this stage it was a blood-borne virus and that they would know that the condition would be fatal in haemophiliacs. They would also know that the condition was sexually transmissible by autumn of 1984?

A. By the end of 1984 they would know that it was sexually

transmissible, they would know that some haemophiliacs would die from it but they wouldn't know how devastating it would be yet. The information was just beginning to emerge, but not yet. Within the next year, or two years certainly, they would know that, but I think at the very beginning of that period they wouldn't necessarily have all of that information.

Q. They would know that haemophiliacs had died?

A. They would know that some had died, yes, but we are back to this issue of what percentage and I think that that's the difficulty that they would face. There would be a lot of uncertainties around what they were doing. I'm quite clear that it's not the best practice; I think I understand why it could happen and I think that people testing without consent did so because they hoped that the information would be helpful for them in helping their patients and they hadn't thought through fully the consequences of having information that the patients didn't expect them to have.

Q. Can I just stop you there then? Can I just deal with that? Once certain results had come back and those gave a positive result, would that not then cause the clinician to pause before carrying out tests on other patients, on the basis that at that stage it would be known that the results were not necessarily at least --

it's clear now that the results were not going to be helpful?

A. My understanding is that a lot of these were historical samples sent off collectively, in groups, so they got the results back at one time on a lot of patients, in which case, to a certain extent -- it would certainly mean that, for future patients coming in, you would not want to do testing without actually talking it through with them because you would be beginning to know the consequences were likely to be -- or seemed to be higher than you had previously thought to be positive and therefore something that the patient should be aware of. But certainly I think at the time when all the mass samples, the historical samples, were sent off, you wouldn't have known.

In fact, if they had wanted to do it perfectly, what they should have done was send off aggregated past samples with no names attached. So they would have got back, "Of your 50 patients, X number were positive," at which point they could have then gone to patients and said, "Look, we have got a higher than expected. We have no idea whether it is you or not and we would like to find out. Do you agree? And these are the reasons why we want to do it."

That's the benefit of hindsight, finding that. But

my belief is that they probably expected in the initial tranches of samples sent to get a much lower positive rate.

Q. Just dealing with the specific scenario that I'm putting to you then, it's that you have a clinician who has a group of patients, he sends so many of them off for a test, positive results come back. Again he then sends off another set. Now, the second set -- presumably, what you seem to be telling me is that in that situation that would certainly give cause for concern, if someone was doing that, given that they know at that stage that there is a much greater possibility that they are going to get a positive result with the second batch, and they haven't got the consent for the patients at that stage. Is that reasonable?

A. Yes, if we assume that the two sets were random. If they had selected a particular group in your first set who were different in some way from the average, then they may feel that this was an atypical group, but assuming that these were what you might call random sample, then I would have expected, before the second group was sent, there would be an alert. People would have been thinking, "What am I going to do with all of these results and what would that mean? Does that mean something different in the way I send for

testing?"

Q. What is your understanding -- and I'm dealing with Edinburgh in 1984 --

THE CHAIRMAN: Just a moment. I want to ask a question before you particularise it in that way, Mr Di Rollo.

MR DI ROLLO: Of course.

THE CHAIRMAN: At page 145, line 18, you started your answer by saying:

"My understanding is that ..."

And you described a practice of lots of samples being sent off. I think it's important that I at least know the context in which you are saying that, Dr Nathanson. Where did this understanding come from?

A. My understanding from reading some of the witness statements is that groups of 10, 11 or 12 of -- sorry, a significant proportion of a centre's --

THE CHAIRMAN: Does it relate to Scotland only? Is it the witness statements relating to Scotland only that you are relying on or is there a wider context? I think that's what I want to know.

A. No, one of the witness statements is a clinician in England. So it may be his samples as well.

THE CHAIRMAN: But is it all from material that has been adduced before this Inquiry?

A. Absolutely, yes.

THE CHAIRMAN: Sorry, Mr Di Rollo, that's what I wanted to make sure. I think it's appropriate now to particularise it. But I think it's also fair to Dr Nathanson to make sure that she knows particularly what body of evidence it is that you are referring to.

MR DI ROLLO: I'm obliged, sir. What I wanted to ask you in slightly more specific terms was in relation to your understanding of what had occurred in Edinburgh in the autumn of 1984. Really, the question I want to ask you was what is your understanding as to the purpose of carrying out the test for the HTLV-III virus at that time.

A. In none of the statements that I have read does anyone say a specific purpose that I can recall for doing the testing, other than to know what the percentage status was, and the implication from what they were saying that I took was they were doing this to see what percentage of patients were who had been -- well, who were positive to this test, given that there seemed, in the very early days, to be some link with this new disease, even though they weren't completely clear what a positive antibody test meant in terms of the likelihood of the disease, and whether that would then have an implication for the future treatment of their haemophilia, as opposed to future treatment for HIV disease, at that stage; in

other words, whether there was something that should be done differently in their haemophilia treatment to reduce their exposure to this putative agent.

Q. Are you surmising the purpose then from what you have seen, rather than a specific purpose being articulated in the material that has been shown to you?

A. Yes, because the only purpose I have seen articulated in the materials is, "We wanted to know what the percentage of patients were who were positive to this new test".

Q. Right.

A. And one has to assume that that was done for a reason.

Q. One possible reason could be a need to know as to whether or not the blood supply in Scotland was infected. That could be a reason.

A. That could be a reason. I'm sure there are many reasons that you could postulate.

Q. Yes. At that stage, presumably, one wouldn't have necessarily at least in the forefront of one's mind the individual patients concerned at that particular point?

A. No, I think you always have the particular patient in the forefront of your mind because, as a clinician you are treating individual patients. They may be a group of patients but they are still all individuals. So you always have the individuals in mind as well as the group.

Q. In which case can you see of any reason why one would not obtain the consent of the individual patient to carry out test?
A. I can't speculate why individuals didn't go back to the individual patients and ask for their consent.
Q. Does that mean that you can't give us a reason as to why that didn't --
A. No, other than the reasons that I have already given, that this was a time at which getting full and open consent to everything was not always the case. It was part of practice. It was a diminishingly acceptable part of practice but it was part of clinical practice and that's the only reason that I can speculate that it happened in this group of patients.
Q. A practice may be widespread but not acceptable. Just because it's widespread doesn't make it acceptable in this area. Is that fair?
A. It's not the gold standard, as I said. This was a period of change and this was a period where the common standard was being changed. It was in the process of moving towards what it is today. So it was common, it was something that people were moving away from and certainly in today's light, it would be far from ideal but in the light of that day it was something that was common and was regarded by many people as

acceptable but, as I said, I wouldn't have regarded it as the gold standard even then.

Q. Right. Once the results come back and they are positive, the clinician then has a problem and one of the reasons the clinician has a problem is because consent hasn't been obtained for the test in the first place. That is the case, as you have already indicated, that that puts the clinician into difficulty. There are parallels from other areas of medical practice at the time -- and I think you have mentioned genitourinary medicine as being one of them -- where, before tests were carried out, you would expect to get the patient's consent and there is a reasonable parallel to be drawn from that field. Is that reasonable?

A. Yes, and indeed in much of medicine -- well, can I go back? Throughout medicine, consent was obtained for most things that are done. The question was always about whether a test was something that was so much inherently part of the treatment, including the diagnosis, of that patient that it was covered by necessarily implied consent or whether it was something that was less common, less usual, less standard, and therefore needed to be explicitly taken out of that and to be absolutely explicitly the subject of consent. We were in the process of moving towards being as explicit

as possible about everything that is done and that included the HIV test, and many people who were content with the concept of necessarily implied consent for many other tests were not content for it on HIV, for example, because of other reasons, not necessarily purely medical ones but because of the consequences of the test result.

Q. And I think that at that stage the obligation on the clinician, I think you have indicated, is that the patient has an absolute right to know but there is not an obligation to be told, as it were. I think you put it something along those lines earlier in your evidence?

A. Yes, there is a right to know but there is not an obligation to know.

Q. Yes.

A. I think that's the key. It's incredibly rare to force a patient to have information that the patient doesn't want. But that is never to be seen as the doctor not being very encouraging to the patient to know. It should never be taken as an, "Ah, well, they didn't ask so therefore I didn't tell them," it's about, "I have tried to offer them this information and they have told me, subtly or explicitly or both, that they don't want to know it". In that case you don't have to force them to know.

Q. I think it may be the case that having obtained certain

results in relation to certain patients, those patients not having given their consent, those patients were not informed that a test had been carried out on them specifically and those patients were not informed that they were positive for some time, and it may be at least until at the end of 1986 or the beginning of 1987. Can you give a view as to whether that state of affairs -- and there are two elements to it. There is the fact that they have not been informed that a test had been carried out and the second element is they had been informed they are positive. Can you give a view as to the appropriateness of that state of affairs?

A. I believe that all patients should be told that they have been tested and the results of that test, or at least offered that information. I think that that should be done positively. I think that should be done as quickly as possible. I find it difficult to think of any reason for delaying that and I think that during that period -- so that's about a two-year period that you are describing, I think, from some of the initial testing through to some of these patients being told -- there was clear evidence emerging through there of some benefits to those patients in having that information, particularly the early use of antibiotics and aggressive treatment with infections, and that makes it even more

important that they are told the results so that they know to seek medical advice when they get what might otherwise appear to be a trivial illness. I think there is a secondary benefit, which is their ability to protect others from the virus that they are carrying.

Q. Presumably another element to those two very important ones you have just mentioned would also be the fact that some of them at least would want to have the opportunity of knowing where they are one way or another. Is that not part of it?

A. That's absolutely implicit in everything I'm saying. It's the patient's body and therefore the patient's right to know what's going on with it.

Q. At that time it became clear that if one did develop the condition in its full-blown form, if you like, it could be a fairly quick demise and therefore one would want to put one's affairs into order, and one way of doing that would be to know in advance that there was a possibility of that happening. Is that not fair?

A. Yes, it is. It's always a difficult issue, this issue of putting your affairs in order, because you have a particular diagnosis when you are not actually acutely ill with that. Certainly at the time people became ill they wanted to be able to make decisions but if you are carrying a virus which nobody yet knows exactly when you

are going to become ill, it is very difficult and quite dangerous, and certainly doctors today would advise patients very strongly against making too many decisions about financial and other decisions, putting their affairs in order, because sometimes people sell their house and think I'm going to be dead in six months and they are not. There are as many doctors out there that they have been accused by patients of telling them they are going to die and then they have survived and instead of saying, "Thank you, I have survived" -- and it's actually a more important issue, which is the point about individuals having the right to have access to information is not only is it their right as individuals but what it does is help people to decide what more information they want and who to ask and how to plan.

So doctors would say, "No, don't make immediate plans, don't decide this is the end of everything," but it does give you the opportunity to think, "I need to think about what's important to me", and perhaps more than putting their affairs in order is to actually think through what it is that you want to do with whatever time you have left, and to start to explore what options you have. And that, I think, is another reason -- it is not the principal reason for giving patients the information. The principal reason is really a simple

ethical one. It's their information.

THE CHAIRMAN: Mr Di Rollo. I think that before we pursue selling the family silver any further, we have to find out whether there is a need for a break and how much longer we are going to keep Dr Nathanson. Is it time to have a break? Yes.

(3.09 pm)

(Short break)

(3.33 pm)

THE CHAIRMAN: Yes, Mr Di Rollo?

MR DI ROLLO: Thank you, sir.

Can I just take up one point that you mentioned in answer to question 8 in the statement? It concerned the Committee on Publication Ethics. Can you just tell us when that group began its work? When was it formed?

A. I'm not sure of the exact date but it was in the 1990s.

Q. Right.

A. I think the very end of the 1990s what's more, but I could certainly, if it would be helpful --

Q. Obviously it's relatively recently?

A. Indeed.

Q. The period that we are particularly interested in, it wasn't in operation at that particular point, is that right?

A. That's right.

Q. I want to ask you about the issue of consent to research and you mentioned that a distinction might be drawn between research on the one hand and monitoring patients on the other. I think you used the phrase that it's a "fine line" between one and the other. I take it that in certain situations it should be possible to tell whether it's research on the one hand and monitoring on the other, and that sometimes the two would meet and it might be difficult to tell. What are the hallmarks of research? Could you tell us that?

A. I would say that the hallmarks of research are where you have a question to answer and that that question is something about -- that you are testing a theory, if you like, about a causation or a result of a treatment and so on. But you can see exactly where the fine line comes. And in fact, if you read the old version of the Declaration of Helsinki, you will note that it talks about therapeutic and non-therapeutic research. And therapeutic research is exactly this fine line. It's not a phrase we would use today but it certainly was at that time. And that's this point that there are times when what you are doing is not part of established therapy -- and established therapy, of course, includes established protocols in terms of continuing testing or routine tests -- but is something which is part of the

way in which you are treating that patient and you are seeking a better way or more information and it sometimes verges into research and sometimes doesn't, and it has always been an area where it is difficult to say, "This is research and this is treatment", because some of these areas do straddle that line; they fit on both sides of it.

Q. From the point of view of the patient, the patient may think that it is research and from the patient's point of view it wouldn't really matter whether the doctor thinks it's monitoring. If the patient thinks it is research, then the patient might think they would like at least to have given consent to the activity that has been carried out. Do you see what I mean?

A. I do see what you mean. I don't think it has ever been described in that way, in the medical and ethical literature. In fact sometimes patients think that a very well established treatment that the doctor is carrying out is research and you can get some confusion, and a lot of times doctors would be explaining to patients that although this treatment may seem to them to be research, it isn't, it is, in fact, established, it's in all the literature, it's something that everybody with the same patient would follow almost exactly. And very often the reason patients get

confused about this is because you are continuing to test and assess. But that's the nature of medicine, that at its best you are always assessing what the impact has been on that patient, and that group of patients, to make sure that it continues to provide the benefits that you have expected.

So this is where you can get some very great confusions as to what is research and what is continuing treatment.

Q. Well, we do know that in Edinburgh, between 1983 and 1985, a detailed study was carried out on the immune function of certain haemophilia patients in Edinburgh, and I take it you have certain information to that effect from the material that you have seen?

A. Indeed, yes.

Q. From what you have seen, how would you characterise that activity? Would you characterise that as research or would you characterise it as monitoring?

A. I would characterise that as being exactly on this borderline but I would have -- if people had asked me at the time, I would have encouraged them to consider it as research and to go through the protocols for research, simply because of the benefits that that brings.

Q. I mean, the fact that the results are published, does that alter the position or not?

A. It makes very little difference. The point about publication is that publication requires consent if there is any likelihood of individuals being identified. And if you are carrying out a research protocol today, but not in the 1980s, you would very explicitly put in your research protocol how you would expect to publish -- what you would expect to publish, so that the people giving approval would actually understand how you would guarantee the non-identification of individuals and so on.

Q. I think further studies, detailed studies, were carried out after 1983/1984 on the cohort of haemophilia patients in Edinburgh and some of those patients were unaware that such studies were taking place, and I don't think there can be any -- there may or may not be but it doesn't appear that there is any dispute that the further work that has been carried out looks very much like research, and I take it that it would be your position that patients ought to have given consent to that activity?

A. Absolutely. They should have been asked for consent. Sadly, at that time, it was all too common for patients not to be asked for consent. But again, we are back to this was not the gold standard. The gold standard was that you always got consent for research protocols in

full. Even where it didn't require any specific separate intervention on the patient, you would still get consent.

Q. You talk about the gold standard at that time. I mean, one of the problems we have is that until relatively recently, guidance is not written down; it's not articulated in written form and there is an attitude, I suppose, getting back to your original cricket-type quotation, which is that we ought to know what the right thing to do is, and it doesn't need to be written down. We have moved from a process of that kind. But even in those days what matters is to have at the forefront of your mind how the patient will feel about something. Even though it may not be written down, that's a very important consideration. Is that fair?

A. That is absolutely an important consideration and indeed is outlined in the declaration of Helsinki, even in the earliest editions of it, which were 1964.

Q. It does appear that we have a situation that certain patients were unaware that studies were being undertaken. They were unaware specifically that they had been tested for HTLV-III virus. The same patients were unaware that they were positive. They were not informed of the results and they were also unaware that follow-up research on them was being published in the

Lancet.

Then they subsequently are informed of all of these things. Is it any surprise, looking at it from a patient point of view, that they are a bit upset about that?

A. There is no surprise at all that they are upset about it and it's exactly why the advice has been for a long time now to fully inform and involve the patients so that they make free and informed choices for themselves. It avoids you upsetting the patient unexpectedly. The fact that it was common for people to do these things without the patient's agreement is not something that we can look at with any satisfaction or happiness but it was common, I am afraid, at that time.

Q. No further question, sir.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: Thank you, sir.

On this question of research and monitoring, Dr Nathanson, my friend specifically drew your attention to the study carried out between 1983 and 1985 in Edinburgh and he said, "Well, that's exactly on the borderline". Would it be fair to suggest that something might start out as long-term safety monitoring of patients and metamorphose into what might objectively be

regarded as research?

A. I think that's absolutely the case. I think this is clearly the issue when you start off with work that is on this borderline, that you start off intending to simply monitor that you are getting the treatment right, that the patient's blood tests are going in the right direction or you are not seeing anything unexpected. You find something unexpected and it morphs into something that is different, and that's a very great difficulty and it's particularly difficult to then stop what you are doing and to redesign the whole thing and to say, "We will now make this into a formal research protocol". And I think that that's why, in times when the ethics approval for research was rather less rigid than it is today, that much of this happened. It didn't start off with malign intention, it just metamorphosed in exactly that way.

Q. I'm obliged to you.

Can we discuss now briefly, please, the dissemination of results? If you will forgive me, I'm going to set the scene just to make sure that we both have the same understanding.

THE CHAIRMAN: Mr Anderson means he is going to define the hypothesis.

MR ANDERSON: A lot of my friend's questions were, I think,

centred upon the Edinburgh experience, all right? We know that in Edinburgh, when severe haemophiliacs were at their appointments, blood would be drawn from them and that blood would be used for various examinations of platelet count, white cell count, haemoglobin levels, whatever. Then that same blood would be tested for lymphocyte counts, all right? It was observed that there was something strange happening with the immune system, which was not thought to be attributable to AIDS -- correctly, as it turned out. But tests became available and in the autumn of 1984 certain samples were sent down to England for testing. The results were obtained on 26 October 1984. Do you know all that?

A. Yes.

Q. I'm obliged to you. I think, to the surprise of the clinicians concerned, because those individuals had almost exclusively, but not exclusively, received Scottish product rather than commercial concentrate, the results turned out to be positive. So confirmatory testing was requested and the results were obtained in about a week to ten days or so. There then occurred a meeting of the UK haemophilia directors, I think, in England on 10 December, and as far as Scotland was concerned, there was then a public meeting to which all the haemophiliacs were invited. I think prompted by the

fear that the incidence of the virus in Scottish blood, the result was going to be put in a newspaper, basically. So there is that meeting. There were then, within about a week or a fortnight after that, AIDS information sheets given out and invitations made to contact the haemophilia director to find out the individual's position. Are we at one so far?

A. Yes, indeed.

Q. I'm obliged to you.

When someone goes to see their haemophilia director in those circumstances and is told, "Right, we have results. Do you want to know them or not?" and at the same time there is some encouragement to know the results, can the clinician be criticised for that approach?

A. No, that's exactly the right approach because it's an invitation, fairly promptly, to get the results and then an invitation -- with support, one hopes -- well, certainly on a one-to-one basis -- to know your own results.

Q. We know that during 1985, those that had tested positive remained asymptomatic to all intents and purposes. We also know that there was no treatment available to all intents and purposes, and we also know that everybody, whether they had tested positive or negative, was being

told to assume that they were infected and therefore to take precautions. Do I take it that in those circumstances, then the doctor could not be criticised for insisting on giving the result to the patient?

A. Sorry, you are asking me if a doctor could be criticised for insisting on giving the results --

Q. Sorry. In such circumstances, would you criticise a doctor for not insisting on telling the result?

A. I think in those circumstances you wouldn't criticise for not insisting, as long as the offer had been made. The difficulty is when do you get to a stage where the benefits to the individual of knowing are so substantial that you push harder for them to know the result? While there were no antiretrovirals, there was the beginning of some understanding on the management of things like pneumocystis carinii pneumonia and so on, about early treatment. So it was beginning, certainly by the end of 1985, to get to the stage where you would probably push harder for individuals to know.

Q. I think you said earlier you didn't like the word "force"?

A. No.

Q. But if a clinician took the view that there was treatment available that in the case of a particular patient might very well be of benefit to him, would that

be a circumstance in which it would be justifiable, however strongly the patient had said "I don't want to know the result," to -- using the word you do not like -- force him to know?

A. It's a very difficult issue to force somebody to have information they don't want, and I'm reluctant to say that it's ever justified to really force somebody. But it certainly ups the ante significantly the more that you can do to benefit the patient if they know into persuading them to know. One of the things that became very interesting during this period, exactly this period, is that the people with great experience in dealing with patients with very serious diseases, particularly lethal diseases of this sort, were very skilled at persuading people to become comfortable with knowing, and that was a skill that people needed. And I would certainly have said to individuals contacting us at the time, "Are there other people who might be able to also talk to the patient and to find out why they don't want to know?" Because the fact is that if somebody is saying repeatedly to you "I don't want to know", they already know the answer. It is just that the words haven't been spoken. And they know the answer because they also know that you wouldn't, in a sense, be repeatedly saying to them, "We ought to tell you" if

there isn't something there that's significant. It is one of these rather odd logic loops. And that's where it becomes very difficult.

I'm very reluctant ever to force people to know but you do get situations sometimes where the risk to that individual of not knowing is so substantial that you may effectively force them to know with as much support as you possibly can give.

Q. Of course, we are dealing at the moment with a situation where the doctor will probably know his patient very well and will have known them for not just years but probably decades, not only know him but know other members of his familiar, because other members of his family are likely to be treated for haemophilia, for example. Therefore, in relation to needing to know why the patient doesn't want to know, the clinic may very well know the answer to that. Is that not so?

A. Indeed.

Q. I'm obliged. Thank you very much.

THE CHAIRMAN: Lawyers love playing with words, Dr Nathanson, but I do find it very difficult to envisage a situation in which one could reach the point of saying to a patient, "You have persistently refused to ask the question but I can now tell you that I have got a treatment that will help a person who suffers from

this condition. Do you want to know?" That's not really short of putting the person in the position of appreciating that both parties know. What would happen then?

A. I think, if there was genuinely a treatment, you would actually have to say to the patient, "I have to tell you that we have done this test," and what the results are and then to say, "and the reason I'm telling you is because there is this exciting new treatment that really makes a significant difference and this is good news," because patients, when they have refused the answer to tests or refused to be tested, very often it's because they are terrified that they have that condition, quite understandably so, and they assume that it's invariably lethal or untreatable. Actually, the reasons that you would persuade people to know is usually because there is something that you can really do about it now, so it's not as bad as the patient had suspected. So it's getting that skill again of trying to communicate that to the individual.

THE CHAIRMAN: Mr Johnson, are you going to break your duck?

MR JOHNSTON: Thank you, sir, no, only in the sense that I have no questions for Dr Nathanson.

Further questions by MR GARDINER

MR GARDINER: Sir, I have one clarification, if I might.

Dr Nathanson, I would like you to clarify or further comment in light of a response that you gave to my learned friend Mr Di Rollo. It's in the same area as what you have just been discussing with Mr Anderson but at page -- we can't get this up, so I will have to read it out to you, but page 153 of the transcript, today's transcript, at line 18. You were asked a question by Mr Di Rollo about testing and advising of results between the period of 1984 and the beginning of 1987, if you remember that, and your answer was:

"Answer: I believe that all patients should be told that they have been tested and the results of that test or at least offer that information. I think that that should be done positively. I think that should be done as quickly as possible. I find it difficult to think of any reason for delaying that. I think that during that period ... "

So that's a two-year period that you are describing:

" ... from some of the initial testing through to some of these patients being told, there was clear evidence emerging of benefits to those patients in having that information, particularly the early use of antibiotics and aggressive treatment with infections, and that makes it even more important that they are told the results so that they know to seek medical advice

1 when they get what otherwise might appear to be
2 a trivial illness."
3 Just to clarify, I think I know the answer to this
4 but you appeared to be critical of a doctor who is not
5 passing over results in that period, 1984 to the
6 beginning of 1987, because a patient could miss out on
7 treatment for an AIDS-related condition. My
8 first clarification is, is that even if the doctor
9 believed that his patient did not want to know his
10 results?
11 A. No, I hope I was clear in saying that the offer of the
12 information must be made to the patient. Again I don't
13 believe that, certainly in the beginning of that period
14 and probably even at the end of that period, the
15 benefits to the patient were so substantial that you
16 would get into the situation of forcing them to know
17 that the offer should be made.
18 THE CHAIRMAN: Does that include an appreciation of the
19 benefit of prophylactic treatment for PCP?
20 A. Yes, because I think that in that period the benefits of
21 prophylactic treatment were emerging but not until late
22 in the period were they really clear. Certainly I would
23 say that by 1987/1988 it became increasingly important,
24 but probably not before that.
25 THE CHAIRMAN: It is helpful to get these transitional dates

well established, Mr Gardiner.

MR GARDINER: Yes, indeed. The other clarification, which I think I have just got, is that the treatment that you are referring to in your answer there would be something like pentamidine for PCP?

A. Indeed, yes.

MR GARDINER: Just to put another scenario to you for your comment, if a doctor says that, because of his knowledge of his patients at that time -- and I mean there the date of infection and his knowledge of the progression of the disease at that time -- he knows that his patient will not develop an AIDS-related condition during that period, like PCP, would you be critical of him for not, I think you put it, pushing hard to pass over the results? I'm talking about that period between 1984 and the beginning of 1987.

A. Provided that the offer of information has been made, because that's the key factor here, that the offer of information is made to the patient. How hard you push depends upon the clinical situation of the individual patient: what you know about the patient, what the other offers are, why they don't want to know. Clearly, people who are looking after patients for long periods know quite a lot about that and the benefits of the treatments that might be available.

Medicine is a very inexact science so we don't usually know for sure that somebody is going to or not going to get a particular condition but you would judge the evidence that you have so far about the condition generally and about that patient, and that would be part of this matrix that you put together to decide on how far and how hard you push.

But it's about offering and it's about making it clear that that offer was not a once and for all offer. Provided the offer is made, I think that you have done the right thing to help the patient.

Q. Yes, and I think you said that you make the offer but as treatment comes along and the necessity for treatment comes along, a doctor would be expected to push harder. I'm just wondering if you would agree that, with the scenario I have put to you, where a doctor says that he thinks he knows that his patient will not develop a condition which will require that treatment, that excuses him from pushing harder to pass over the information?

A. That is part of the matrix that you make on how hard you are going to push, and the more confident you are that this patient is not going to have that condition within that period, then, of course, you don't need to push as hard.

Q. Yes. It goes back to what you said in your report about there not being a metric for every patient. You have to deal with the individual patient. Is that right?

A. Exactly. Every patient has to be treated as an individual and reviewed as an individual, just in the same way as you do for all other clinical elements of care.

Q. Yes, thank you very much.

THE CHAIRMAN: One would have to be very confident about the natural history of a particular condition before being convinced that the patient wasn't going to develop it in a given timeframe.

A. Indeed, and particularly at that time because it was very uncertain how patients would respond. Indeed, it still is today. You can't look at any two patients who are diagnosed new today and know which ones are going to become ill and in what timescale. You can have a little more certainty, that's what 30 years of tracking patients around the world has given us, but it's still not certain. The human being is an organism and not a mechanical being. We are not actually that good at predicting, even with mechanical things, what will go wrong; we are certainly not good with humans. But people know their patients well and sometimes you can have a fairly well informed feeling about this patient,

that they are not somebody who is deteriorating.

I think the other issue is these were patients who were being followed up regularly. So it is not again a once and for all, "I'm not going to tell you." It is, "At this moment it seems to me that you are not in this group that I'm going to push very hard on," as long as that is a decision that is reassessed every time you see the patient, that allows you to say, "Now is the time when, even though you are not ill yet, I am beginning to think" -- perhaps your CD4 count is going down -- "now is the time that I really do have to press you to know."

THE CHAIRMAN: Dr Nathanson, thank you very much indeed. It's very helpful.

A. Thank you.

MR GARDINER: Friday's witness is Dr Perrie.

(4.03 pm)

(The Inquiry adjourned until 9.30 am the following day)

I N D E X