GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL (SERIOUS PROFESSIONAL MISCONDUCT)

Monday 6 July 2009

Regent's Place, 350 Euston Road, London NW1 3JN

Chairman: Mr Andrew Reid, LLB JP

Panel Members: Ms Joy Julien
Mrs Pamela Mansell
Mr William Payne
Dr Roger Smith

Legal Assessor: Mr Francis Chamberlain

CASE OF:

BARTON, Jane Ann

(DAY TWENTY)

MR TOM KARK of counsel and MR BEN FITZGERALD of counsel, instructed by Field Fisher Waterhouse, Solicitors, appeared on behalf of the General Medical Council.

MR TIMOTHY LANGDALE QC and MR ALAN JENKINS of counsel, instructed by the Medical Defence Union, appeared on behalf of Dr Barton, who was present.

(Transcript of the shorthand notes of T A Reed & Co Ltd.
Tel No: 01992 465900)

INDEX

THE CHAIRMAN: Good morning, everybody. Mr Kark, before you call your witness, there are a couple of quick matters of house-keeping I need to raise. The first one, for the record, is that Christine Challis, the Panel Secretary, is unable to be with us at this part of the day and very kindly Lola Babatunde, is standing in for her.

Second, the matter of the drug charts. Clearly there is a great deal of evidence that surrounds the charts. If it is possible the Panel would find it helpful to receive at an early stage a blank copy. I do not know if such a thing is still available, but when we look at the photocopies it appears in some cases that two pages have been put together for the purpose of photocopying. It would assist us greatly if we were able to sort those minor issues out just by reference to a standing blank

MR KARK: We shall see if we can get a blank version but what we do have already, of course, is a file with the original prescription charts. Some of them have come apart; some have not. This is one is Mrs Lake. The only difficulty about trying to find a blank one is discovering whether the same form is being used now as it was at that time and one suspects it might not be. You do, though, have the advantage at least of having a complete folder in three sections for Mrs Lake and for others.

THE CHAIRMAN: At the moment we would only be receiving those when we went into camera at a later stage.

MR KARK: They are available now.

THE CHAIRMAN: If there is no objection. A single one that is complete would be helpful and, frankly, the less that is written on it probably the better. It is not what is written on it that interests us; it is merely the layout.

MR KARK: It is the format.

THE CHAIRMAN: Yes.

MR KARK: Shall I make that available now.

THE CHAIRMAN: Thank you. Shall we give that an exhibit number at this stage?

MR KARK: We were going to exhibit the whole file of them. We can either do them individually or as a file. They contain, I think it is, 15 and contain the original prescription sheets for Patient D onwards. So far as Patients A, B and C are concerned we only, I am afraid, have microfiche. That is why the copies in your bundle are not very good and we have not been able to do much about it. We are very happy at this stage now to exhibit this. It is available to the Panel.

THE CHAIRMAN: I think then, if there are no objections, Mr Langdale, that is how we will do it.

MR LANGDALE: Yes.

THE CHAIRMAN: Then we are not splitting them up. We will receive that in evidence as Exhibit C13. (Bundle marked C13 and distributed) It will be kept with the Panel Secretary

if anybody needs to know where it is at any time.

MR KARK: May I mention one or two other administrative matters. So far as the chronologies are concerned, I think we are very nearly there. We are just missing one, Mrs Stevens, Patient L. Some have been printed up over the week-end and some are waiting to be amended and printed up today. I do not think that is going to cause a particular difficulty because we can produce them patient by patient as we get to them with Professor Ford.

We have the files of Dr Barton's statements available for you, and we can make those available to you now. Perhaps we should do that. That will be C14. That should be marked Dr Barton's statement to the police. (Document marked and distributed)

What I think you are going to be invited to do is, before we turn to each patient, is have a look then at those patients upon whom Dr Barton has commented. You will find that she was not asked about all of the patients that we have, of course, but we have kept in a divider, which may in fact be blank simply for continuity so you can see where she did comment and where she did not through not being questioned about those other patients.

May I mention one other matter? That is this morning at, I think, nine o'clock we received another expert report from the defence which took us by surprise. That expert starts one of his paragraphs by saying that he spent more than 16 months carefully reviewing all of the evidence relating to the twelve cases currently before this Panel. There is extensive criticism of Professor Ford and his report in it.

We have had a short time to show that document to Professor Ford. Mr Langdale, who gave us the report this morning, has indicated to us that he has, in light of the late service which I know he accepts, no objection to us, if necessary, talking to Professor Ford about this report once he has started giving evidence. That is not very attractive and we do not like doing that normally, but I do not particularly want to hold up Professor Ford in his evidence in order to do that. He has already made some comments about it, and it may not be necessary to do more but can I just raise that as a flag, as it were. I have had the opportunity of reading through it once but it may be on a second read-through I will have certain matters I will want to ask Professor Ford about specifically.

THE CHAIRMAN: It is an unfortunate state of affairs. Obviously, if there comes a point when you feel that the best way of dealing with it is for you to have time, I am sure Mr Langdale will not object to that, although I appreciate that in terms of the Professor's own timetable the finding of that time may be very difficult.

MR KARK: Quite. I think the best thing to do is to get on, and if we need to we will ask for time and if we feel the need to Professor Ford about the report, then we will have to ask your permission because he will have started giving evidence.

Finally, could I hand out copies of Professor Ford's curriculum vitae.

THE CHAIRMAN: We will receive those as Exhibit C15.

MR KARK: Can I suggest that those goes behind the next free tab that we have in the Panel Bundle 1 which is, I think, tab 13.

THE CHAIRMAN: In that event we shall not need to give it an exhibit number, so we will put it behind the next free tab in volume 1.

Mr Kark, there is one very small point in relation to the chronologies and any that are yet to come off the press, as it were. I think that the hole punching was not undertaken by your team and we were told that there were some issues with the hole puncher. The issue, as it turns out, is that the hole puncher does not always punch holes in the places were the prongs in our files are located, so if there is to be any hole punching on your side, could we check that the hole puncher matches with the files that are being used. Thank you.

MR KARK: I do not know how it happens, but reprographics here use a different system from the rest of the world but we will cope with that, no doubt.

Can I please call Professor Gary Ford.

GARY ASHLEY FORD, Affirmed

THE CHAIRMAN: Please take a seat, Professor, and make yourself comfortable. I know that you have been in the hearing room while a number of witnesses have been sworn and given their testimony so you will be relieved to hear that I will dispense with the usual orientation speech and hand you straight to Mr Kark.

Examined by MR KARK

Q You are Professor Gary Ashley Ford. Is that correct?
A That is correct.

Q Professor Ford, you are obviously going to be with us giving evidence for some time. I will try and keep an eye on the clock and make sure that you do not have to answer questions for longer than about an hour at a time. Again, the same applies to you. If at any stage you feel the need to take a break, then I am sure the Chairman will allow us to pause and do so.
A Thank you.

Q I want to begin, please, by asking you a bit about your CV. I do not know if you were actually given a copy of your own CV when they came round?
A I have a copy, but I can remember it.

Q Very well. I think you began your medical career back in the early eighties and you became – is it – a Member of the Royal College of Physicians?
A That is correct.

Q In 1985, UK. Then a Fellow of the same Royal College in 1996. In what area of medicine have you specialised since the nineties?
A Following my training in general medicine and geriatric medicine, I was a senior registrar in geriatric medicine and general medicine from 1989 till 1992.

Q And we see that at the bottom of the page?
A Yes.

Q I was appointed as a senior lecturer in clinical pharmacology and geriatric medicine and, as an honorary consultant physician in general medicine and geriatric medicine at what at the time was the Freeman Hospital in Newcastle. My practice at that point was, like many geriatricians, even though I was an academic, quite busy. I did acute medical takes on a one in nine basis, a rota through most of the early 1990s. I was responsible for half of an acute geriatric rehab unit on the Freeman Hospital site and I had responsibilities for what became a rehabilitation ward and a continuing care ward on what was the Walkergate Hospital, which still exists. This, I think, can be described as being very similar to Gosport War Memorial Hospital.

Q When you say you had "responsibility for", what does that mean?
A I was a consultant responsible for patients on two wards. Initially it was more wards but it was a continuing care ward and then what was a continuing care ward and became a rehabilitation ward. One of the early changes that I made was to create ten stroke/rehabilitation beds within the continuing care ward.

Q Just pausing for a moment, is this at the hospital in Newcastle upon Tyne?
A This is Walkergate Hospital, which is one of the hospitals in Newcastle. I had responsibilities in three areas: acute general medicine, acute geriatrics and rehabilitation. I also worked in the day hospital and soon after arriving I became the consultant who is responsible for the geriatric medicine department and I sat on the hospital clinical policy group and oversaw a number of changes in the service over the first six years.

Q How many patients would you have been responsible for, from taking up that post in 1992? You mentioned two wards. How many patients would have been on those wards for whom you had care?
A I had responsibilities for patients on at least four wards; an acute medical unit, where I could have up to 30 patients. It fluctuated, depending if one had been the consultant on take. I had 15 patients on the acute geriatric ward and then I had 22 patients on the rehabilitation unit and initially 20 patients on a continuing care ward. Like many offsite hospital, there was a change in practice where continuing care beds were reduced as patients moved into nursing homes so eventually that ward I was responsible for closed and did not exist, and I was left with the responsibility for the geriatric rehabilitation ward on the Walkergate Hospital site. In terms of the number of patients, it varied a lot, but I do remember at one point having over 120 patients under my care which, again, you would not see now, but it was not uncommon for geriatricians to have very large numbers of patients with different medical needs under their care in the 1990s.

Q Were any of those wards palliative care wards as such?
A No. By definition patients who move into NHS continuing care wards will die on those wards and may need palliative care, but we had no palliative medicine unit on that site and I had no specific palliative medicine training or expertise, except that which obviously geriatricians need to acquire for the end of life management of patients under their care.

Q Because although they were not designated palliative care wards, obviously you were not working in a hospice. Did you have a number of patients who, from time to time, would be on a palliative care regime?
A Yes. And one of the services I did set up was a stroke service and when I took responsibility for stroke, the mortality rate then for stroke patients was around 25 per cent.

A You had a lot of experience of dealing with patients who died.

Q Being a consultant, does it followed you would have had a number of more junior doctors under your control?
A Yes. I had worked as a senior registrar in the same hospital before I became a consultant, so I was familiar with working in that role. Usually there would be a registrar, a senior registrar, working under my supervision. There would be a different senior registrar
B working on acute medicine. I used to have a registrar working for me on the acute geriatric unit and at Walkergate Hospital. Just to talk about the system of care we had at our wards at Walkergate Hospital, again it was slightly different from Gosport War Memorial Hospital. The consultants did, typically, a weekly ward round and then the wards were covered for medical problems by a registrar going down for a session. They went down about five or six times a week. There were around at this point 66 beds on the unit by the mid 1990s, of which two wards were rehabilitation, because it was three wards, then it went to two with a nurse-
C led unit. One was a continuing care ward, and there would be about five or six sessions of medical cover from a registrar.

Q So that we identify any differences or similarities between this setting and that at the GWMH, although these doctors would be doing sessions on the ward, would there still be doctors remaining within the hospital at all times as it were?
A No. Walkergate Hospital at that point did not have a resident doctor. The needs of
D patients were covered within working hours by the consultants if they were there doing a ward round with or without their registrar, and then the registrars when they were down there and if a doctor was not there, there was a registrar who could be called down to see a patient urgently. Out of hours the cover on that unit was provided. It changed over time; there was initially a rota of middle grade geriatric doctors and then it became the on-call physician registrar or SHOs who covered the Walkergate Hospital site.

E Q How different is that scenario from the one we are dealing with in this case?
A I think it was slightly larger, slightly more activity. I cannot give you the exact figures, but it had more beds and it did not have a clinical assistant. It relied on the doctors in training to provide the medical cover.

Q That is an issue I was going to come on to later, but perhaps we can deal with it now. We heard last week from Dr Reid that the post of clinical assistant is not a training post.
F A That is correct. It is a staff appointed post, usually taken by general practitioners part-time.

Q What is the difference, what is the significance between a training post and a staff post?
A In general, training posts are, by their nature, training posts and are meant to, and usually do have, a high level of supervision. Again, that has changed over time. Senior
G registrars, for example, would operate with relatively little supervision at times in the 1990s, whereas now there would be much more involvement of consultants in their actions. A clinical assistant is, again, not a specialist in the area. They can sometimes have acquired some specialist training, but is obviously more experienced in their clinical practice, as a rule, but still work under the supervision of a responsible consultant. The consultant remains responsible for the care of those patients ultimately.

H

Q Moving on in your career, I think that post took you up until 2000 when you became, as we see in your CV, the Jacobson Chair of Clinical Pharmacology, did you change role or not?
A That personal promotion from senior lecturer to Chair did not of itself change my clinical role. What happened was that I became busier and busier developing and running a comprehensive stroke service and the demands of that became more. We appointed other consultant geriatricians and it was appropriate for me to focus my efforts on developing, managing the stroke service. In 1998 I ceased to have responsibility for the Walkergate Hospital wards but continued to do geriatric medicine practice. In around the early 2000s I ceased to do geriatric medicine and continued to do acute medicine and stroke.

Q What was the date you put on that?
A I am trying to remember. I think it was 2000, about 2000, I think. It was around then that I stopped doing acute geriatrics. I then practised acute medicine and stroke with a very heavy clinical workload. In mid-1998 I was the second busiest physician, despite being an academic appointment in the Freeman Hospital. In 2005 when I was appointed to lead and direct the UK stroke/research network, I stopped doing acute medicine because that role took up a third of my time, so since 2005 I have done stroke medicine, mostly acute, and also rehabilitation.

Q Is that necessarily in a geriatric setting or are you dealing with patients of all ages?
A The stroke service is within the elderly care directorate and that is because the majority of stroke patients are elderly, but it is a comprehensive service which takes patients of all ages.

Q If it were suggested to you that you are a mere, forgive me, academic pharmacologist, what would your answer to that be?
A I realise there are academics around, particularly in London and elsewhere, who may have very little clinical practice, but that is not the way I have ever practised as an academic. My academic work has been very based around my clinical practice throughout my working career.

Q We can see, and I am not going to take you through them, you have gained a number of awards – I am looking at page 2 of your CV – mostly, I think perhaps all, in the area of geriatric clinical pharmacology and stroke?
A That is correct.

Q You have either been responsible for, or contributed to, something in the region of 128 publications?
A That is correct.

Q Let us move on to some of the issues with which we have been dealing in this case. I want to start with some the broad areas about which we have been asking witnesses before we look at the individual patients. We are going to go through the individual patients, obviously, one by one in due course. Can we start with the *BNF*, how the *BNF* is regarded in the medical world, what its uses are and what caution has to by applied in using the *BNF*.
A The *BNF* is, I think, probably one of the most used books by any practising doctor. It is a very valuable source of information about drugs, what their indications are, what the potential side effects of drugs are, what the appropriate doses that should be used are and it is

A laid out into sections about different groups of drugs with some general sections on prescribing in certain settings, such as children, the elderly, palliative care and the like.

Q One of the pieces of evidence that this Panel heard, I think it was from a doctor who we will be referring to as Dr X, was guidelines for narrow minded people. First of all, *BNF* is a protocol or a guideline?

A It is certainly not a protocol. It is a source of information which gives you guidance B about the use of drugs. In a way it is not a guideline because guidelines are generally considered to be documents that outline general management of specific conditions. I have during my professional career had quite an involvement in the development of guidelines. I was a member of NICE and the British Hypertension Society Guideline on Hypertension, I have also been on a number of stroke guideline groups at both national and European level, so I am aware of the difficulty in crafting good guidelines. An important principle is that guidelines do not apply to every patient. What they do is they provide a framework of care C based on evidence which should be looked at by doctors as the basis to underpin their practice. Patients do not always neatly follow guidelines for a number of reasons. One, is that they have other comorbidities or there are other issues you have to weigh up, and guidelines do not attempt to cover every clinical setting that a doctor may face. If guidelines could do that, you would not need all the training and experience that it necessary to be a good doctor.

D Q If one is going to prescribe outside the guidelines, what is the basis upon which one can do that? How does one approach going outside the *BNF* guidelines?

A There are two aspects. One is going outside the licence indication for a drug. If you prescribe a drug within its licence indication, you are acting and using that drug in a recognised way and you are highly unlikely to be criticised, or open to criticism, for using the drug if you have prescribed for the correct indication. Generally it is accepted that if a doctor prescribes outside the licence indication for a drug, they should justify the reasons they do so. E There are many occasions when doctors do prescribe outside the licence indication for a drug because the licence indication of a drug is decided by what the manufacturer chooses to apply for it to be used.

In a case of guidelines, now we have a much clearer system with NICE, the principle is, if you work within the guidelines your practice is defensible and cannot be reasonably criticised, but if you choose to work outside the guidelines, you need to be able to explain and F justify, not necessarily in a defensive way, but in a clear logical way why you have chosen to treat an individual patient under your care outwith established guidelines.

I often practise medicine outside guidelines. I will give you one example. Thrombolitics, for stroke, are licensed to treat people up to the age of 80, but in our unit we often treat people over the age of 80 years, but we are very careful to indicate on the basis of which we do that.

G Q What is the importance in that regard of making notes?

A Again, medical notes are the basis on which doctors record their observations, findings from history and examination, their working diagnosis and then their treatment plan. If one is working outside of accepted guidance or licensed indications, that would be the place to record it. Obviously, the reason to record it is that doctors see very many patients, at least most doctors see many, many patients, and it would be impossible to remember what one's thinking was after the event. There are other reasons why it is important to record it, H because the medical record acts as a document which other doctors refer to and other

members of staff so they can understand the reasoning behind a particular course of action and the findings in that patient at that time.

Q We know that Dr Barton was practising not only as a clinical assistant at the hospital, going in every morning, but also acting as a GP and treating patients, presumably during her daily practice, but she was going into the hospital on an almost daily basis. Does that in any way lessen or increase the necessity to make notes about the patients that she was caring for?

A I cannot see the frequency of contact is the issue. Other doctors were still being involved in the management of patients in the care of Dr Barton and the responsible consultant. I think the other reason to make notes is for your own records. To carry around in your memory when you have a very large number of patients under your care, exactly what you did and why you did it, is very difficult. One often has the experience of looking back over a set of notes of a patient you managed six or twelve months ago and you find it is often not what your memory was. Because we are so busy and see so many patients, the medical records act as the basis of what you did. There is an aphorism that we tell our junior doctors, that if you did not write down what you did, there may be the assumption that you did not do it. It does not mean that you did not do it, but if you did not write it down, it is very difficult to remember exactly what you did do.

Q Can we turn to the *BNF*. You will find it in bundle 1. Could you take out the first file and go to tab 3, and turn to page 2. This is at the very beginning of the book. We can see at the top, it is page 12 of the internal numbering under the heading "Guidance on Prescribing" and then "Prescribing in Palliative Care". Before we go through some of the guidance that is given here, it is important to remember that this is specifically to deal with palliative care. Were all of the patients that this case is concentrating upon, palliative care patients?

A At the time they were admitted to the wards at Gosport War Memorial Hospital, many of the 12 patients were not at that stage admitted for palliative care.

Q When we read this guidance, should we bear in mind that it may not be referable to other patients?

A I think one of the issues is, as I think the Panel will be aware, that there is no strict, agreed definition of palliative care, so one has to be careful when talking about it because people can use it in different ways. Clearly doctors can palliate different symptoms but when the phrase "palliative care" is being used, it often does not mean the palliation of symptoms in people who are expected to recover or have a good life expectancy ahead of them. I think it is interesting and appropriate that the first statement in this section is about providing better treatment and support for patients with terminal illness, so I think this section would be taken by most doctors to be about guidance on the management of patients who have terminal illness.

Q Reading on from where you just stopped:

"The aim is to keep them as comfortable, alert, and free of pain as possible."

A I think everybody would agree with that.

Q Again, unless it is suggested to you that you are in some way biased against the use of opiates, biased against palliative care regimes, do you, yourself, use opiates frequently in your practice?

A I do. I frequently use them where they are required and I am often impatient when I see delays in patients receiving adequate analgesia and pain relief. Relief of pain is one of the primary and most important duties of a doctor.

Q Would you look four paragraphs down on the left-hand side of the page, the heading is "Drug Treatment".

B "The number of drugs should be as few as possible, for even the taking of medicine may be an effort. Oral medication is often satisfactory unless there is severe nausea and vomiting, dysphagia, weakness or coma..."

Dysphagia being difficulty in swallowing?
A That is correct.

C Q "...in which case parenteral medication may be necessary"

– meaning by injection.
A That could be injection into a vein and it might be an intramuscular injection or it could be a subcutaneous injection.

D Q "Analgesics are always more effective in preventing the development of pain than in the relief of established pain".

We will look separately, as a topic, at the concept of anticipatory prescribing. Again, do you have objection – moral, medical or otherwise – to the concept of anticipatory prescribing?
E A Not at all. I think for the provision of mild analgesia, for example, it was common for paracetamol to be routinely prescribed on an "as required" basis to patients, so that patients could be given mild analgesia by a nurse responsible for looking after them rather than any delay in a doctor having to come to the ward to write the patient up. Indeed, there are nurse prescribing protocols in place which allow nurses to provide analgesia at the lower levels.

Q Moving on from paracetamol and the lowest level of analgesia, what about anticipatory
F prescribing with opiates? Professor, is that something you would do in your own practice or have done in your own practice, or not?
A There are two issues. There is the need to prescribe variable doses of morphine to people who require opiate analgesia. So you would put a range of morphine, for example, or another opioid analgesia to be prescribed within, usually, a not-too-wide dose range, and there is the issue of patients who are expected to require opioid analgesia where there may not be a doctor available to write the patient up for that. Clearly, in most acute hospitals, or any
G hospital with a resident doctor, this is not an issue - for example, patients undergoing surgery where the analgesia is written up in advance of them coming out of the surgery, rather than waiting until the patient has pain. The issue of anticipatory prescribing in other settings really depends on the consideration of the risks and benefits, and the problem with anticipatory prescribing for opiates, in terms of in a non-acute hospital setting, is that there would have to be expected deterioration in a patient that was going to require opiate analgesia. It would be in that context. This would typically be somebody who was already
H on moderate analgesia and you might reasonably prescribe PRN as required morphine – that

A would be the standard oral drug to use – in a narrow dose range, but I think I had never come across before anticipatory prescribing of wide ranges of subcutaneously infused drugs. Even in palliative care settings, my understanding, through talking to palliative care specialists, is it is not at all standard practice for palliative care units to have anticipatory prescribing with wide ranges of opiate and sedative drugs.

Q We have heard a lot about the analgesic ladder, and we will have a look, in a moment, at
B the Wessex Protocol. As a basic starting point, as it were, would you expect most doctors to know about the analgesic ladder?
A I think so, in broad terms of the different levels of analgesia, and that in many patients you might go through that ladder but in some patients you would not. If somebody presents with severe chest pain due to myocardial infarction or a major fractured limb, you would immediately go and give opioid analgesia; you would not go through the analgesic ladder.

C Q If somebody comes into the hospital with a broken arm you might not start with paracetamol.
A You certainly would not. That would be considered poor practice.

Q So there are circumstances where you have to take a jump in the analgesic ladder.
A Very much so.

D Q In terms of moving from the oral route to subcutaneous injections in one form or another, if we look at the right-hand side of the page on page 2, towards the bottom, we can see the heading is "Parenteral Route".

> "If the patient becomes unable to swallow, the equivalent intramuscular dose of morphine is half the oral solution dose; in the case of the modified-release tablets it is half the total 24-hour dose ... Diamorphine is preferred for injection because being
E more soluble it can be given in a smaller volume. The equivalent intramuscular (or subcutaneous) dose of diamorphine is only about a quarter to a third of the oral dose of morphine; *subcutaneous infusion via syringe driver* can be useful".

Can we pause on that topic for a moment? We have heard a lot in this case about the shift from oral to syringe driver, and there has been differing evidence as to, ultimately, who could make that decision once the prescription had been written up. First of all, in terms of the
F reasons why that shift has to be made, are there a limited number of reasons?
A There a limited number of reasons and I think they are mostly laid out here. The main reason is when patients are no longer able to swallow, and at that point you have to move from the oral route of administration to a parenteral one. The usual reasons for patients not being able to swallow are they develop swallowing problems or that they become drowsy, and then one can no longer use the oral route. It does not necessarily mean that one moves to continuous infusion of the drug; one can give intermittent injections, and sometimes one will
G see opiate prescriptions written up for either oral or IM or subcutaneous route, to allow flexibility if a patient becomes unable to swallow. In terms of moving to the subcutaneous infusion by syringe driver, the advantages are that where you know the dose of opiate that the patient needs to receive over a set period you then avoid the need for repeated injections which can be uncomfortable in, particularly, frail herpetic older people. There are also, again, some theoretical reasons that you avoid the up and down of drug concentration that one sees with intermittent oral or subcutaneous or intramuscular injections, so you get a
H smoother maintenance of drug concentration in the blood. However, in older people where

A the half-life – the persistence – of opiates, like many drugs, is longer, and the fact you also have active metabolites, this is in real terms probably not a particular advantage in the vast majority of patients.

Q I want to try to avoid becoming too technical, largely for my own purposes but, partly, because I hope it is not going to be necessary. As we will see, there are specific issues that are raised in relation to prescribing opiates for the elderly.

B A Yes.

Q Are you able to give us a simple explanation of why that is so?

A If you give morphine – let us take the standard opiate drug – to young and middle-aged people it has what we call a "half-life". A half-life is relatively straightforward to understand by most people. You give a drug, it is absorbed, you get a peak concentration and the half-life is the time that it takes for the drug concentration to fall to half of its value.

C

Q And then half again.

A And then half again. So by about four half-lives the drug has, essentially, disappeared. For morphine it has got an active metabolite, so the half-life is two hours but the morphine-6-glucuronide, the metabolite that is made by the liver, lasts slightly longer. You get an analgesic effect lasting for about four hours, and then the drug has gone down and you need to give another dose. An important principle is that when you give repeated doses of a drug it

D is about five half-lives before you achieve the steady state. You get accumulation as you give repeated doses of morphine or other drugs. So, in the elderly, the elimination of morphine and its metabolites is less rapid, and that is mainly through the kidney, so the half-life is longer at about three or four hours. So you get more persisting effects and you either need to give a lower dose every four hours or you give the same dose more infrequently. But, in general, we give a lower dose at the same frequency.

E Q Are you saying that, first of all, the effects of the opiate last longer?

A Correct.

Q For any given dose. Are you saying that its potency is greater?

A In general terms, for any given blood level there is some evidence that the elderly may be more sensitive, but it is mostly because they eliminate it less quickly. One point I would like to emphasise is you see large variability in the response to opiates within people and so this is

F why it is necessary to adjust the dose when you first give people opiates so you get to the right level which maximises pain relief and minimises adverse effects. That variability is greater in older people. So, in a sense, you need to monitor more carefully the dose you are going to use in older people.

Q Can we stay on that topic for a moment, and can you give the Panel some assistance as to how, with appropriate and proper prescribing, you are meant to reach that level of analgesia

G so that the patient is no longer in pain but, hopefully, still awake or at least rousable? How do you find the level?

A Typically, you have got a patient who is in pain, you are moving to use opiates, you would give initial dose and that might be, say, 5mg of morphine. Usually, the prescription would say something like: "2.5 to 5" or "2.5 to 10 mg of morphine", and the nursing staff would observe the response to that first dose and if the patient was not pain-free at two hours they would give another amount of the same dose, and then they would observe the response

H two hours later and then probably give double the initial dose that was given. So you just

titrate up gradually and usually you wait at least an hour after one dose, and often two hours, to see whether you have got an adequate response. If you have got somebody in very severe pain that you have to relieve immediately, you would prefer to give the drug intravenously, for example, and that would be in the context of acute myocardial infarction, and you would titrate in small incremental 1mg doses after your initial dose to observe them until they achieve pain relief. If at any point you start to see major adverse effects (the main concern is the development of respiratory depression - there are many other adverse effects) you would have to stop and sometimes if patients are inadvertently given too much opiate drug you would have to give the antidote Naloxone which will reverse the effect. But that is usually not necessary in the context of usual therapeutic dosing of opiates.

Q In dealing with the incremental nature of the increase, in dealing, first of all, with oral opiates, is there any distinction between oral opiates and opiates given via the parenteral route about the incremental increase?
A No, the same principles apply. When you give the drug through the parenteral route – really, through the intravenous route – you get more rapid absorption into the blood. It is immediate in the case of intravenous administration; it is slightly quicker with subcutaneous and intramuscular administration – it is quicker through those routes than it is with oral administration.

Q Can I just ask you about that? At the bottom of the page we see:

> "The equivalent intramuscular (or subcutaneous) dose of diamorphine is only about a quarter to a third of the oral dose of morphine."

Again, looking at it in my very non-medical way, is that because diamorphine is a stronger drug, or is it because it acts more effectively when given subcutaneously?
A No, diamorphine is converted to morphine. It is what we call a pro-drug. The reason is that when you give morphine and diamorphine through the parenteral route you do not get the effect of the liver metabolising a lot of it when it is absorbed, and you also do not absorb all of the drug from the gastrointestinal tract. So the usual, the literature suggests, conversion is a third – up to three.

Q If we go over the page, I am afraid we are going to spend a little bit of time on *BNF*, but it may make our task later, when we are looking at the individual patients, rather quicker. We can see that it deals with transdermal opiate, particularly fentanyl. How does a fentanyl patch compare to either the oral route or the parenteral route?
A It is really very similar to the subcutaneous route. In the case of the fentanyl patch the drug penetrates through the skin and is absorbed through the delivery system in that patch, whereas in the subcutaneous route you are putting it under the skin with a needle. One thing to say about the sustained release preparations and the patches, similar to when you move someone to a continuous infusion at a set rate, is these are appropriate strategies when you know the amount of opiate that a patient needs. So you switch people to sustained release morphine tablets when you dose them initially with ordinary morphine and then you have worked out what their 24-hour requirement is. The problem if you go to using, let us say, sustained release morphine straightaway is you just do not know if you have got the right dose, and the problem with that is you cannot see the effect until after 12 hours, so you cannot increase it until quite sometime after the dose has been given. So you run the risk of either leaving the patient in pain or of them getting unacceptable toxicity. So the patch is similar; if you do not know the dose you are not going to know until it has been on for some

time and has been absorbed, and fentanyl has a longer half-life than morphine, you are not going to be clear till about 12 hours whether you are at the right dose, because that is how long it will take for the drug to accumulate. When you are using patches you have to be aware that the final effect will be fairly delayed with a fentanyl patch, and you need to have some idea of whether that dose is going to be right or you may get toxicity. There were reports when the patches first came out of respiratory depression because they were a quite high dose of equivalent opiates.

Q When did these patches first come out? Do you remember?
A I cannot remember when they first came out. I would have to look that up, but they came out, I think it was, in the early 1990s, if I remember correctly. I would have to look that up. The dose used as shown in the *BNF*, the 15 microgram patch dose is quite a large dose of morphine. It is the equivalent of up to ---

Q If we look at it, it says it is the equivalent to a total dose of up to 135 mg for 24 hours, but that presumably means a total dose taken orally?
A Yes, that is correct. If somebody was controlled on, say, 90 or 100 mg or more, that would be appropriate, but if somebody only needed 40 mg of morphine to control them over a 24-hour period, that would be quite a large dose of opiate equivalent to give them through a fentanyl patch. This issue was eventually recognised in that there is now a 12.5 microgram patch to give a lower dose of equivalent opiates and that, in my understanding, was not available in the 1990s.

Q Can we just seek your assistance, please, of the rapidity of effect of these various routes. You have described how an oral dose would have to be metabolised by the body. It presumably would go through the stomach and would lose some of its effect by the nature of that metabolising process. How long does it take for Oramorph to have an effect ---?
A It takes --- Sorry.

Q --- on an average patient. Not dealing with an elderly patient but just on an average patient?
A The absorption does not differ substantially between younger and older people for most drugs, morphine included, so you have relatively rapid absorption and you have a peak between 30 to 60 minutes. It is not instant but it is relatively quick.

Q If the same drug, diamorphine, say, is injected directly into the body what is the rapidity of the effect of that?
A Intravenously it is essentially immediate. Intramuscularly and subcutaneously it is in between immediate and the oral route, so 15 to 30 minutes. That is to reach a peak. You may get effects, of course, before that at a lower concentration.

Q Let us turn to the issue in this field of the use of syringe drivers. Now a syringe driver is a piece of machinery, effectively. It is a syringe connected to an electrically driven screw, which gradually delivers a dose. We will have a look at one in a moment. First, have you used syringe drivers in your own practice?
A Yes, I have.

Q In terms of the delivery of the opiate, does that differ in any particular way from an immediate injection subcutaneously?

A When you are giving it, or more constantly and continuously as defined, because, let us say, instead of giving 5 mg four-hourly, say, with repeated injections you give 5 mg immediately it is absorbed, and in four hours and 5 mg again it is absorbed, you are giving it much more gradually – the same dose – over a 24-hour period. If we were switching directly, you would give 30 mg in that syringe over 24 hours. So if you were to start somebody who was not already on opiates, it would be quite a time before you had enough drug on board, so you would not, if somebody was just starting opiates, start with a continuous infusion, you B would give what we would call a loading dose to make sure they had some immediate analgesia.

Q That is a bolus dose?
A Yes. It is not necessarily giving an injection under the skin, a subcutaneous injection, or usually more usually what is happening when syringe pumps are being used, patients have been receiving opiates, either orally or by repeated injection, so you know how much they C need and you convert to the appropriate amount to be given through the pump.

Q So once you have found your level, in other words?
A Yes.

Q We have a syringe driver here. I wonder if the witness could be given that. (Handed to the witness) I suspect that in terms of actually setting one of these up and inserting it into D a patient, is that something you would do yourself or leave to your nurses to do?
A Not generally. I have set up syringe pumps with a nurse, usually in the context of delivering thrombolitics for acute stroke where we need to do things very quickly, but I would not have set up a syringe pump to deliver opiates for palliation. that is a nursing task and they have specific training which doctors generally do not. So no, I am not specifically trained or would claim expertise in the practical use of a specific ---

E Q Have you prescribed though?
A Oh yes. Like any doctor, I certainly prescribed it.

Q Can you just hold it up. I am going to ask for it to go round the Panel. Some of the Panel may have seen these before, some may not. We have a syringe in a clear perspex tube at the top, underneath which, I think, it has a little bit of machinery which contains a battery and literally there is a screw, I think, which is attached to the plunger of the syringe.
F A Yes. There is a circular screw which turns around and then that pushes along this piece of plastic here (indicating), which then presses the plunger down the syringe.

Q The end of the syringe, what we would regard as the sharp end of the syringe, would normally be connected to what?
A It is actually blunt, but it is a locking end where you put on, usually, an infusion tube or a butterfly needle, but it would lock on to a thin tube which would then go to a needle G which would be placed in the patient's skin subcutaneously, typically on the abdominal wall or in the thigh.

Q We have heard a bit about butterfly needles.
A Yes.

Q Is there one of those in the box?
H

A There is. It is called a butterfly because the way you hold it to insert it under the skin with a bit of imagination can be seen to look like a butterfly. The orange end here screws into the end of this syringe so you have a system where then the drug in the syringe is injected slowly under the skin through the needle. The same system can be used for intravenous administration. Subcutaneous administration is used because it is easier to maintain and generally more comfortable than having to have intravenous cannulas which generally require medical attention to be replaced.

Q In terms of prescription, first of all you would need to prescribe the drug that is going to go into the syringe driver or the drugs that are going to go into the syringe driver?
A You would.

Q Would you also have to specific that the route is to be by a syringe driver, or is that not necessary?
A You would usually say "continuous infusion" or "via syringe driver," and it would say the amount of drug, usually over a 24-hour period. That would be the standard way of prescribing drugs by continuous subcutaneous infusion.

MR KARK: I wonder if it would be a convenient moment for the Panel to look at what you have been hearing about for the past month. Perhaps we can exhibit this. That would be C15, I think.

THE CHAIRMAN: That is quite right. C15 was earlier withdrawn. We will exhibit the syringe driver as C15, please.

MR KARK: This is a working version. It has a battery with it. If anybody later wants to play with it, as it were, and see it working, then the battery can be inserted. May I just sit down while that goes round? (C15 handed to members of the Panel to inspect) The whole thing should obviously be kept together, together with the leaflet.

THE CHAIRMAN: I think, Mr Kark, a member of the Panel has asked if it is possible to have at a later stage individual photocopies of the booklet?

MR KARK: Yes, certainly. (To the witness) Moving on through the *BNF*, we are going to come, I think, to another drug that we have heard about in this case. If we look at the top of page 3, and look on the right. This is under a heading "Miscellaneous Conditions", and then to the right we see:

> "Excessive Respiratory Secretion. Excessive respiratory excretion (death rattle) may be reduced by subcutaneous injection of hyoscine hydrobromide 400-600 micrograms every 4 to 8 hours; care must however be taken to avoid the discomfort of dry mouth. For the dose by subcutaneous infusion using a syringe driver, see next page."

We have seen hyoscine prescribed, I think in all, but certainly in almost all of the cases that we have been looking at. It is a perfectly acceptable drug to use, presumably for the purposes for which it was used?
A For end of life care where patients are having unpleasant secretions because they cannot swallow, it is a highly appropriate drug to use. It blocks secretions which, of course, is why it can produce a dry mouth but in general end of life dry mouth is not a problem because these patients are near death and often not very alert.

Q Again, I was going to deal with it later on, but perhaps we can deal with the issue of hydration now. Again in this case, we have heard a lot about the issue of hydration. We have heard some nurses who thought that there was subcutaneous hydration available on the wards at GWMH. Others who did not, but can we just deal with the issue generally, firstly dealing with end of life patients?

A The issue of whether to hydrate patients at the end of life is contentious. There is a lack of good evidence to know whether it improves how people feel or whether it makes things worse. I think generally it is considered quite reasonable to provide it or not provide it. We tend to make that decision looking in a broader social cultural view, whether there are strong views expressed by families about hydration. The reason to provide hydration, the arguments go, is that it maintains skin perfusion a bit better and that patients will not feel thirsty if they are awake, but observation suggests that most patients near the end of life, if they are alert, do not complain of thirst even if they have not received fluids. Reasons not to give it are that it is an intervention and it may worsen secretions. So there are arguments both for and against giving hydration. In an individual patient you have to look at what the appropriateness of giving hydration is. But in end of life care there is no strict rule that you should or you should not give hydration.

Q Let us deal with that other category of patients, who may find themselves on a syringe driver, but they are not at the end of their life. They are being treated, cared for, but their symptoms require a syringe driver to control their pain?

A If somebody is not at the end of life, they need hydration because if not they will develop complications from dehydration. Whilst it would be reasonable to wait a day or so, if somebody is not at the end of life it would generally be considered necessary and appropriate to provide hydration. One of the difficulties with hospitals like Gosport War Memorial Hospital and the Walkergate Hospital I worked in is intravenous hydration becomes difficult because doctors are not on hand to immediately put up a drip. In that context those patients, let us say they have a reversible, treatable condition like pneumonia and they are dehydrated and they are not swallowing because they are delirious, you either have to transfer the patient back to the acute hospital to provide it or an alternative, which many units developed and I introduced a protocol in the Walkergate Hospital was to give subcutaneous fluids. You can give a litre or two litres a day. You cannot give more than that, so it is not appropriate if somebody needs a lot of fluid replacement. You can give it again subcutaneously and you administer it under the skin. Typically the fluid would create a bulge and it would be slowly absorbed. You move the needle every 12 hours. This has been shown in most patients to be a reasonable way of providing hydration for a relatively short period of some days.

Q Does that cause the patient any discomfort?

A There is the needle, the small butterfly needle, but most people here will be familiar with having a butterfly needle. It is a sharp stab, but it is not particularly unpleasant.

Q And the bulge you spoke of?

A Patients do not tend to complain. The problem is the fluid. It is absorbed. The problem you can get is local site infection, so you can get – as you can indeed with, of course, a needle into the vein – cellulitis, infection of the needle site.

Q If you put somebody onto a syringe driver and they are no longer swallowing, and you do not provide them with hydration, in your view is that necessarily an end of life procedure and what is going to happen to the patient's body?
A If they are going to remain unable to swallow, I do not think the issue is about syringe drivers. It is they cannot swallow. You have to hydrate somebody and there are various ways to do that. You can put a tube into the stomach, but that is uncomfortable. You can do intravenous or you can do subcutaneous, but if you do not they will become dehydrated and will develop complications of dehydration which are quite substantial and ultimately they will die. That is acceptable where patients are at the end of life. If you think they are swallowing properly, that this is just temporary and they will be swallowing with in 24 to 48 hours, it would be reasonable not to immediately provided fluids, but beyond that one has to make a decision about what you are doing to continue to hydrate this patient if they are not an end of life pathway.

Q And if you are going to hydrate a patient, whether it is by an intravenous method or a subcutaneous method, would that require a doctor's orders or is that something that nurses can do off their own bat?
A I would say it would always require a prescription by a doctor.

Q Why?
A Because fluids can cause problems. You have to get the right sort of fluid. You also have to monitor the salts in the blood every couple of days to check the blood sodium is not too high or to low. It is not equivalent to a nurse offering a patient who can swallow fluids a drink, it is a medical intervention.

Q Would the fluid have to be prescribed by a doctor?
A Yes.

Q As a matter of fact, I do not think we have seen any such fluid prescriptions in the any of the cases that have been dealing with for those on syringe drivers, so unless prescriptions have been lost, can we take it that none of these patients were hydrated once they were put on a syringe driver?
A No, and if these patients were ---

MR LANGDALE: It is not being suggested by the defence that anything ... (microphone off -- inaudible).

THE CHAIRMAN: Thank you, Mr Langdale, that is very helpful.

MR KARK: Can we move on, I think that is accepted by the defence. We can see on the right-hand side of the page, there is a heading "Restlessness and Confusion:

> "Restlessness and confusion may require treatment with haloperidol 1-3mg by mouth every 8 hours. Chlorpromazine 25-50mg by mouth every 8 hours is an alternative but causes more sedation."

Is it methotrimeprazine?
A Methotrimeprazine.

Q

"... is also used occasionally for restlessness."

If we look over the page, staying with that topic, on page 4 looking at the right-hand side of the page, this is under the general heading "Syringe Drivers", which we see on the left:

"Restlessness and Confusion.

Haloperidol has little sedative effect; it is given in a subcutaneous infusion dose of 5-30mg/24 hours."

Then below that we see:

"Midazolam is a sedative and an antiepileptic, and is therefore suitable for a very restless patient. It is given in a subcutaneous infusion dose of 20-100mg/24 hours."

Then underneath the next heading, which is "Convulsions", we see "Pain Control". Before we move on to pain control, restlessness and confusion, have you in your clinical practice dealt with restless and confused patients, elderly patients?

A I think any geriatrician will be familiar with a very large number of acutely confused and chronically confused number of the people we see. Confusion is very much a main part of the care of acutely ill older people and people with cognitive impairment dementia who often have episodes of confusion. The management of confusion in a non end of life setting is something geriatricians deal with all the time. One also sees confusion and restlessness – there is an overlap between the two – in the end of life setting where restlessness is common. I think one of the issues with managing confusion and restlessness in any patient, be they at the end of life or not at the end of life, is looking for what the likely cause is and if there is a treatable cause for that. Typical things one would see are, in a newly acutely confused patient, we look very hard for evidence of infection because you need to treat the infection and not just give a treatment to control confusion. Other problems that can cause confusion are urinary retention, in which case the treatment is to put a catheter in and relieve that.

Q Is that urinary retention?

A Urinary retention where the bladder is distended, constipation. There are very many causes of confusion so it requires a careful assessment of the patient. One of the other key issues in the management of older patients, again both in a usual setting and end of life setting, is whether the confusion or restlessness could be due to any medication that the patient is taking, so you have to also look at that. This is particularly important in the case of patients on opiate drugs, older patients, because one of the major metabolites for morphine is what we call neuroexcitatory. It will produce agitation and confusion, so you always have to look whether opiates are a cause of confusion in older people if that is what they are taking. They may not be, but they may be, so that is an important point to consider.

Q This is an important point, and I think Dr Payne raised this with Dr Reid last week, which is the question of the potential side effects of opiates and the point about whether more opiates cause more side effects. What do you have to say about that?

A The first thing I say is that opiates are not a treatment for restlessness or confusion. The *BNF* says that, the Wessex Protocols will no doubt clearly state that. Opiates are a treatment for pain and may help restlessness where it is the context of pain. They are not a treatment for confusion per se. If you have a patient who has opiate induced confusion or

restlessness, clearly if you give them more opiate that is not going to help the problem, it is, if anything, going to exacerbate it. That is why it is important to recognise that is a potential cause.

Q You may have a patient who is both confused and in pain?
A That is true and often the case.

Q Presumably, in those circumstances, there is no problem about treating the pain with opiates?
A The first strategy would be to treat the pain, control the pain, and then see if the patient was still confused because we are all familiar with the fact that, if we are in pain, most of us are restless and can indeed get confused if it is severe. If after the relief of pain or reasonable treatment with an opiate there was still persisting confusion or agitation, one would use treatments to treat that as well. One of the difficulties and where it is a challenge in looking after older people is working out the relationship between is it the pain that is making them confused or is it something else? It does take careful assessment and you have review whether what you are doing is having the desired effects and be prepared to change the approach and strategy if the treatments you give are not working, or are producing intolerable side effects.

Q What are the strategies, if any, for trying to identify what it is that is causing a patient pain. If you have a patient – a confused, demented patient – presumably they may on occasion not be able to tell you very clearly what it is that is causing their pain?
A Of course. This is why it is much more difficult to care for older people who cannot communicate if they are feeling pain, also true for other patient groups with communication difficulties. This is why, if the patient cannot say, "I have pain in my arm" or "I have pain in my abdomen", you need to conduct a careful examination of the patient to see if there is anything on examination. You might find they have a distended bladder, you might find they are constipated, you might find their leg is twisted and they may have sustained a hip fracture. There are many things one might find. The first thing is to do an assessment of the patient to see if there is a clue on examining them as to the cause of their pain.

Q Taking your example of the distended bladder by way of example, if that assessment, if that careful examination has not taken place and you simply increase the opiates, what effect is that going to have on the patient?
A Since the opiates may well have produced the urinary retention, it is unlikely to have reduced their discomfort. It may temporarily, but it is not dealing with the underlying cause of the pain.

Q You are going to have a confused patient in pain with a lot of opiates?
A Who may become more sedated and drowsy from the increased opiate dose.

Q Can we go to page 4. It is the same topic, but right at the bottom you can see the heading for pain control:

> "Diamorphine is the preferred opioid since its high solubility permits a large dose to be given in a small volume. The table on the next page gives the approximate doses of morphine by mouth (as oral solution or standard tablets or as modified release tablets)."

A That would be the same as MSTs that we have been looking at, would it?
A Yes.

Q Slow release tablets?
A Yes.

Q
B "... equivalent to diamorphine by injection."

Over the page we can see there is a table. It needs quite careful looking at because it is easy to get confused. If we look at the table under the heading "Oral Morphine" and concentrate on the far left column, that is dealing with morphine sulphate oral solution or tablets given every four hours, so if we want to establish what the total dose is over a 24-hour period, do we have to multiply each of those doses by six?
C A We do.

Q Starting on the left-hand side of the page, not trusting my maths I did this over the weekend so that I did not get it wrong in front of the Panel and Mr Jenkins, but if we look at the left-hand side of the page, running down, the first entry is 5 mg, and we need to convert that over a 24-hour period to 30 mgs.
A Yes.
D

Q It may be important to perform this exercise for the first few because I think we will see a pattern. If we look to the far right-hand side of the page, we see the entry for diamorphine hydrochloride by subcutaneous infusion. That column is for a period of 24 hours, and we see – and please tell me if I am getting this wrong – that the conversion from 30 mgs oral dose is therefore halved to 15 mgs?
A That is correct, of those doses.
E

Q If we look at the next dose down, which, on the far left-hand side is 10 mg but we need to convert that to 60 mgs, then we go to the far right-hand side, we can see that when you convert that to subcutaneous infusion, that reduces down to 20 mgs, that is one third of the dose?
A Yes.

F Q If we were to perform that exercise for all the others I think we would find, and we can do it by way of example, 15 mgs converts to 90 mgs over a 24-hour period orally, and on the far right-hand side of the page which, by subcutaneous route, would be 30 mgs so it would be a third. I am not going to perform the exercise, unless anyone wants me to, but if we go all the way down those two columns, after the very first dose, after the very lowest dose, I think we can see that the conversion rate is one third each time?
A Yes, approximately.
G

Q That is in order to provide the equivalent dose to the patient. This is the patient for whom you have identified the appropriate level of pain control by oral solution and then you want to convert it subcutaneous?
A It is, but I would have to emphasise that it is a starting point and the statement at the top of that table, these equivalences, are approximate only and they need to be adjusted according to response, so it would vary for the individual patient.
H

Q It has been underlined with a number of witnesses, and I expect you will agree with this entirely, it is extremely important to look at the state of the patient in front of you when deciding the particular dose?
A Clearly it is important that you are looking at the patient. I think there are two issues. I would say if you have a patient who is adequately controlled without adverse effects, you should switch to the one-third dose. There is a starting point and you may then need to adjust it. It may not, for that particular patient, work out exactly right. If you have somebody who is still in pain, and you are converting them, clearly you would need to increase it. If you have someone who is overly sedated or confused, you would need to reduce it, so it entirely depends on the patient. Very importantly, once you have made the change, you then need to monitor how the patient responds to that change from the oral or other route to a continuous infusion.

MR KARK: I am going to move on to the topic of prescribing for the elderly. Although we do not seem to have got very far, we have been going for an hour and perhaps it would be a convenient time to take a break.

THE CHAIRMAN: Yes, I think it would. Professor, I think you know the routine. You are on oath, you remain on oath, please do not talk to anyone about the case or allow them to talk to you, other than in so far as has already been agreed. I will not give you that warning again. I will also say this for the first and only time, you should be taken to somewhere where you will be given some refreshment. Please avail yourself of that. We will all return at five to twelve.

MR KARK: Can I raise that issue of where Professor Ford should go. There have been problems so far because I am afraid that we, as a team, have taken one of the rooms which is normally used for witnesses. It is just because of the amount of documentation we have that we needed the room. It has meant in the past that witnesses have gone out to reception where they have been, effectively, surrounded by interested parties and relatives. If Professor could be taken through to the canteen, which is completely separate area. It is only a suggestion, I just hope there is some place he could go.

MR LANGDALE: Whatever is sensible.

THE CHAIRMAN: Thank you Mr Langdale.

MR KARK: Unless there is another room available.

THE CHAIRMAN: I am told there is a room available on the first floor. In terms of timing, does that mean that the Professor will need longer to get there and get back? We are nearly at twenty to twelve now anyway, so we will say we will return for 12 o'clock and see, Professor, whether that gives you adequate time once you have got there to get some refreshment or if you are being rushed back. If you are, we will adjust the dose, as it were. Thank you.

(The Panel adjourned for a short time)

THE CHAIRMAN: Welcome back everyone. Doctor, was that break sufficient for you to get to where you had to get to, get some refreshment and get back comfortably, or not?
A Yes, I was very well looked after, thank you.

THE CHAIRMAN: We will try to keep to 20-minute breaks from now on.

MR KARK: Can I just mention that I have been ticked off because I got the exhibit numbers wrong.

THE CHAIRMAN: It was not just you, Mr Kark, we share equal responsibility. I think the real cause was that the wrong document was facing up at the time.

MR KARK: I, also, was looking at the wrong notebook, but I think our C13 should be 14, and C14 should be 15 and C15 should be 16. So the syringe driver is C16.

THE CHAIRMAN: We will move everything forward one.

MR KARK: Professor, I want to move on, please, still staying with the *BNF*, to page 6. We will find the heading here: "Prescribing for the elderly". I ought to have pointed out at the very beginning of your evidence that the *BNF* that we are referring to is September 1997. I think a new *BNF* is produced every year.
A Or even more frequently, I believe, yes.

Q We have also got 1998 and 1999, but for these purposes I am concentrating on this particular *BNF*. I think, in general terms, the sort of areas that we are looking at, at the moment, do not change hugely between the different editions.
A I think that is true. There was one drug, thioridazine, which was used quite extensively in the management of older people, which has been withdrawn from the market, but otherwise I do not think there have been any major changes in the information or guidance about the drugs under discussion.

Q When was thioridazine taken off the market, approximately? Do you know?
A It was after a colleague of mine did the research showing its toxicity, so this was early - about five or six years.

Q But post these events.
A Post all these events, yes. It was a common drug to use at the time we are discussing.

Q Could we have a look, please, at page 6. I am not going to spend a huge amount of time on this; the Panel have already looked at this on occasion. It is headed "Prescribing for the Elderly". Under the subheading "Polypharmacy":

> "Elderly patients are apt to receive multiple drugs for their multiple diseases. This greatly increases the risk of drug interactions as well as other adverse reactions."

It also deals with the symptoms, which may be relevant in this case, particularly, of sleeplessness, "... which may be associated with social stress, as in widowhood, loneliness and family dispersal." Then, if we go to three-quarters of the way down the page, we have "Susceptibility".

> "The ageing nervous system shows increased susceptibility to many commonly used drugs, such as opioid analgesics, benzodiazepines, and antiparkinsonian drugs, all of which must be used with caution."

Then, on the right-hand side of the page, we see: "Adverse Reactions".

> "Adverse reactions often present in the elderly in a vague and non-specific fashion. *Mental confusion* is often the presenting symptom (caused by almost any of the commonly used drugs)."

Then it deals with other common manifestations. Then "Hypnotics":

> "Many hypnotics with long half-lives have serious hangover effects of drowsiness, unsteady gait and even slurred speech and confusion."

When we talk about hypnotics, is diamorphine a hypnotic or not?
A No, it is not.

Q It is a pure analgesic?
A It has sedative effects but it is not a hypnotic.

Q Have we come across hypnotics in this case – temazepam?
A Yes. Usually, although not exclusively, hypnotics are benzodiazepines, but there are related drugs as well, similar in effect.

Q Of the drugs that we are dealing with in this case, first of all, temazepam, is that a hypnotic?
A It is.

Q Midazolam?
A Midazolam can be used in a number of different settings. It is often used in anaesthesia and sedation on intensive care units. It is not so commonly used as a benzodiazepine for hypnotic use; in fact, I would say it is very uncommonly used for that. As is shown in some of the guidelines, it has been used for terminal restlessness in palliative care.

Q Coming back to that issue, you were dealing with agitation and restlessness earlier. So far as diamorphine is concerned, although it may have the effect, because it is a sedative, of calming a restless patient, is it, in fact, what is called a first line drug for use of agitation or restlessness?
A It is a first line drug for the management of patients who are in pain, and restless due to the pain. It is very commonly used as part of the management of seriously ill patients in an intensive care setting, but in the context of older people who are agitated, opiates would be very far away from your first choice of treatment, so it is not indicated for that.

Q Unless the agitation is the result of pain?
A Severe pain.

Q So the concept being you deal with the severe pain and that should, hopefully, remove the agitation.
A Most agitation in older people is not related to pain; it is related to dementia and other problems; it is not exclusively a problem due to pain.

Q Can I ask you about dementia. That may cause confusion and, presumably, agitation and restlessness.
A You can get confusion in older people and it is more common to get acute confusional states in people with dementia and chronic cognitive impairment.

Q The link between, for instance, Alzheimer's and dementia. Again, can you give us a simple picture?
A I am sorry, Alzheimer's is a form of dementia. Dementia is cognitive impairment in a number of areas leading to, eventually, problems with self-care and functioning.

Q When we see that patients are commented upon as having elements of dementia or "being demented", etc., do demented patients – "patients suffering from dementia", perhaps, is a kinder way to put it – have good days and bad days, or is dementia of a level that continues throughout the rest of the patient's life?
A Dementia is usually progressive – not always – so usually patients get worse over time. Most people are familiar with that. Fluctuation is common – it is not always the case but it does happen - and behavioural disturbances, common in people with dementia, are a major concern for their carers.

Q Coming back to my question: do they have good days and bad days?
A I am sorry; I thought I had covered that with saying they fluctuate. Yes, I am sorry.

Q Can we turn to page 7, please? We see a heading: "Guidelines". This is all under the main heading of "Prescribing for the Elderly".

> "First always question whether a drug is indicated at all. Limit range: It is a sensible policy to prescribe from a limited range of drugs and to be thoroughly familiar with their effects in the elderly."
>
> "Reduce dose. Dosage should generally be substantially lower than for younger patients, and it is common to start with about 50% of the adult dose. Some drugs (e.g. chlorpropamide) should be avoided altogether."

First of all, does this passage relate to diamorphine and opiates as well as to other drugs?
A It certainly relates to opiates because, as we have discussed, the elderly are, in general, more sensitive and show a wider range, also, in their response. So, yes, it would.

Q The concept that one should start with about 50% of the adult dose – how widely known should that be?
A I think that was generally fairly widely known. It is a broad principle. One has to look at the individual patient as to whether that is appropriate to apply, but the other aphorism which is often described is "start low and go slow". Now, that is fine for many chronic conditions in older people, but, clearly, it does not always apply; if you have got somebody in severe pain you may have to go fast, if necessary, in terms of adjusting your drug dose to relieve their pain. The principle of recognising that older people are sensitive to many drugs and, therefore, you should use a reduced dose, I think, is a fairly well-known principle, and 50% is a broad rule of thumb that people have, generally, applied.

Q If we look to the right-hand side of the page we can see:

> "Review repeat prescriptions regularly. It may be possible to stop the drug ... or it may be necessary to reduce the dose to match diminishing renal function."

Is the concept of reviewing your prescriptions regularly one that is relatively well-known in your field?
A Yes. I think, in a way, reviewing the response of patients to their drug treatment is absolutely key, and it becomes even more important in older people with multiple problems, who may have subtle side effects. It is one thing to recognise an adverse problem from a drug in a fit, young or middle-aged person who is being treated for one condition, and they will tell you: "I have a problem", from managing older people who have multiple problems and may have communication difficulties. So a higher level of care and monitoring is needed, and it is why looking after older people is much more challenging and difficult than, frankly, looking after most younger patients.

Q Sometimes they cannot tell you what their problem is?
A And there are multiple issues and problems going on.

Q Speaking of which, we move to the next paragraph: "Simplify regimens".

> "Elderly patients cannot normally cope with more than three different drugs and, ideally, these should not be given more than twice daily."

Is this relevant to the use of opiates?
A I do not think it is relevant to this setting – a hospital inpatient setting with very unwell, frail patients - and I think it would be disputed now, but it was in the context of an outpatient setting where patients were in the community.

Q Can we turn on to page 8, where the *BNF* deals specifically with opioid analgesics? I want to ask you about the issue that is raised in the first paragraph, which is that of "Dependence and tolerance". The authors of the *BNF* write on:

> "... but this is no deterrent in the control of pain in terminal illness."

Can you help us about tolerance to opiates? How quickly is it built up?
A Tolerance, just to explain, is the phenomenon where an individual has less response to a given dose or blood level of drug over time, so you need to increase it to get the same effect. Tolerance occurs over days and weeks; typically, in patients with chronic malignant pain, the dose will need to be increased over a period of weeks and months. It does not occur over a few hours; you are talking somewhat longer than that.

Q It then deals with side-effects:

> "Opioid analgesics share many side-effects though qualitative and quantitative differences exist. The most common include nausea, vomiting, constipation and drowsiness. Larger doses produce respiratory depression and hypotension."

We are going to look, obviously, at the individual patients, but are those side-effects which, in your view, we see in this case?

A Yes. I think the one not mentioned there is confusion and agitation. There are other side-effects as well, but nausea, vomiting, constipation and drowsiness, and the major concern, in terms of severity, respiratory depression, are the key adverse effects of treatment.

Q Hypotension, meaning low blood pressure.
A Correct. But it is generally the respiratory depression which is the more serious adverse effect that one is concerned about, particularly with early dosing. You do get tolerance to respiratory depression as well over time, which is why patients who are taking opiates with malignant disease, for example, for a long time, are at doses that if you gave that dose initially would produce respiratory depression. They do not get that because they have become tolerant to it.

Q When we talk about respiratory depression, obviously, the doctor on the Panel will know what that means, but are we talking about shallow breathing or a very slow rate of breathing, or both?
A Both, but the main thing is the rate of breathing is suppressed, so you get a suppression in the number of breaths a minute – which, typically, will be, say, 16 to 20 – and, ultimately, you can get complete respiratory arrest. When deaths occur in drug users who use drugs illicitly, abuse heroin illicitly, that is the common mode of death.

Q If you are causing respiratory depression in a patient, does that have other effects on the system? Does it lead to hypoxia and problems with the skin, the blood, etc? What does it lead to?
A The main concern is it leads to death.

Q Apart from death.
A You can get a progressive failure or it can be very sudden respiratory depression that occurs.

Q When prescribing and administering opiates, is that something that the medical personnel ought specifically to look out for?
A When you are initially giving opiates or you are making a change in the opiate dose, or you are giving it with other drugs, such as benzodiazepines, that can suppress respiration, it is important to be aware of that as an adverse effect. It would depend on the context, of course. If you are doing this for an elective operation and you are giving opiates, there has to be absolutely close, constant monitoring of respiration. If you are doing it at the end of life, it is less of an issue because the patient is at the end of their life and as long as you are giving an appropriate dose to relieve their symptoms, one is less concerned about the issue of respiratory depression; one accepts that may be a necessary consequence at the end of life for adequate symptom relief.

Q If we look below we see:

> "Morphine remains the most valuable opioid analgesic for severe pain although it frequently causes nausea and vomiting. It is the standard against which other opioid analgesics are compared. In addition to relief of pain, morphine also confers a state of euphoria and mental detachment."

We have heard that being suggested to witnesses. That is your experience?

A A It certainly can do, but it does not occur in everybody. It can actually produce, in older people, confusion and agitation. But it is certainly well-known that there is a sense of mental detachment from the pain. People will say: "I can feel the pain but it doesn't bother me".

Q If we look to the right-hand side of the page, the *BNF* deals specifically with diamorphine.

B "Diamorphine (heroin) is a powerful opioid analgesic. It may cause less nausea and hypotension than morphine."

Pausing there, again, diamorphine is morphine based.
A Essentially, you are achieving the same effect because it is converted to morphine but it is a better preparation to give, if you are giving it subcutaneously.

C Q "In palliative care the greater solubility of diamorphine allows effective doses to be injected in smaller volumes and this is important in the emaciated patient."

Would that be your experience? Obviously dealing with elderly patients do you quite often get elderly patients who are emaciated?
A Yes. You want to minimise – I do not think it is a big issue. It is the preferred drug, D so that is what we use. It is easier to prepare. It is a lesser volume to infuse. I think the volume issue is not in reality a big issue because, as we were talking about with hydrating with subcutaneous fluids, we are giving a litre there, and here we are talking about differences of much less than that. The fact is ---

Q But --- Sorry, go on.
A It is just the standard that is used, and it appropriately so.

E Q Can we turn to page 9 and there is very little I want to ask you about this. Under the heading "Morphine Salts", first of all what is a morphine salt? Are we dealing with morphine salts in this case?
A We talk about morphine, but most drugs come with another molecule attached and that is the salt, but we do not describe exactly which salt it is. I think if you look at the *BNF* now, it would not talk about morphine salts; it would just talk about morphine.

F Q If we look at "Cautions" apart, apparently, from causing hypertension, hypothyroidism, decreased respiratory reserve, then we see:

"... may precipitate coma in hepatic impairment..."

Does hepatic impairment mean ---
G A Meaning usually cirrhosis or other liver disease, but usually cirrhosis.

Q It says:

"(reduce dose or avoid but many such patients tolerate morphine well): reduce dose or avoid in renal impairment...".

H I think we will come back to that certainly with one of our patients.

A Can I comment on this? This guidance: I think it is about carefully monitoring. If you have somebody with significant liver disease who is in severe pain, you are not going to want to deny them opiate analgesia and you would give a lower dose and monitor carefully. It is important to emphasise it is not saying these patients should not receive morphine or other opiates. In renal impairment, the problem is, again, more sensitive and there is this risk, because of the accumulation of metabolites, of a greater likelihood of getting confusion and agitation but I think now their recommendation is to use alternative opiates to morphine in renal impairment. I think however at this time you would still use opiates. You would just use them more carefully.

Q We see at the bottom of that paragraph:

"Palliative care: In the control of pain in terminal illness these cautions should not necessarily be a deterrent to the use of opioid analgesics."

That is exactly what I think you just said?
A Absolutely.

Q

"Contra-indications: avoid in acute respiratory depression, acute alcoholism..."

Pausing there for a moment, what do you do with the alcoholic who is in pain?
A You would look at alternatives, first of all: is there another alternative since opiates are less desirable in this group. In the end, if they had severe pain and they needed opiates, you would give opiates and you would monitor carefully.

Q Does the opiate have a greater effect in those with alcoholic liver disease than it would otherwise have, or is it just a side effect that you are seeking to avoid?
A The effect of renal impairment, to answer your questions directly, is greater than in hepatic impairment on the dose you need to give. The real concern in people with hepatic disease with cirrhosis is there is a risk of precipitating hepatic encephalopathy but in terms of acute alcoholism I am not aware that alcoholics are particularly more sensitive to opiates. I think the concern is, again, if you have somebody who is actually intoxicated with alcohol, you have an increased risk of respiratory depression and other adverse effects.

Q I am not going to go through all the other contra-indications and side effects but can we look at the right hand side of the page:

"Dose: acute pain, by sub injections (not suitable of oedematous patients) or by intramuscular injection, 10 mg every 4 hours...".

I am not going to go through all of that.

"By slow intravenous injection, quarter to half corresponding intramuscular dose."

A Yes. That relates to the conversion table that we read.

Q We just read that?
A Yes.

Q Then, can we go down to:

> "Chronic pain, by mouth or by subcutaneous injection (not suitable for oedematous patients) or by intramuscular injection .... dose may be increased according to needs; oral dose should be approximately double corresponding intramuscular dose and triple to quadruple corresponding intramuscular diamorphine dose...".

So it is in fact saying, one has to read it quite carefully. In effect it is saying the same thing.
A The reverse way, yes.

Q Oramorph is dealt with on the next page. I am not going to spend very long on that. We can see the doses set out:

> "Dose: severe pain uncontrolled by weaker opioids, 30 mg every 12 hours, increased to 60 mg every 12 hours when required, then further increments of 25-50% if necessary. For lower initial doses in patients who have not received other opioids."

Dealing with the opiate naïve patient, first of all can we identify what is "opiate naïve"? If a patient has been in hospital and he has been on codeine – and we have seen some patients, I think, who have been on codeine phosphate, or one patient in particular – and then came to Gosport War Memorial Hospital and eventually was put onto Oramorph, is that patient in general terms regarded as opiate naïve or not opiate naive?
A Strictly speaking, because codeine is a mild opioid, they are not opioid naïve but in practical terms, one would consider those patients opioid naïve.

Q Why?
A Because the codeine would not produce sufficient tolerance to make you adjust or alter your initial dose approach.

Q Let us go to page 11, please. The heading is "Diamorphine Hydrochloride". Is that any different to diamorphine?
A No.

Q We can see towards the bottom of the page:

> "Chronic pain, by mouth or by subcutaneous intramuscular injection, 5-10 mg regularly every 4 hours; dose may be increased according to needs; intramuscular dose should be approximately half corresponding oral dose...".

We have seen that, I think and I will not read it through again. Then on the following page we have fentanyl. There is just one aspect of this that I want to ask you about. Let us look at the top right hand side of the page:

> "Administration: see under preparation, below"

and then these words:

> "Long duration of action. In view of the long duration of action, patients who have experienced severe side-effects should be monitored for up to 24 hours after patch removal."

You have assisted us already about fentanyl and the way that it works on the body and the rapidity of its effect. I do not think you have assisted us as to what the effect of the removal of the patch is? How quickly would the removal take effect?

A Because it has a longer half life, because it is cleared less quickly from the blood than morphine, diamorphine, the effect is more sustained and the half life is at least six hours in older people, so you are going to have an effect – and it can be longer – that is going to last much longer. One of the issues is, although it is giving the drug incrementally, it is not an academic point. It is important for people who use it to realise that once you take the patch off, you still have significant drug there which is going to take some time before it disappears from the circulation. That is why that comment is there, particularly.

Q Right at the bottom, under the heading "Durogesic" – I have taken that to be a form of fentanyl?

A It is the trade name for the fentanyl, yes.

Q We can look right at the very bottom, the four lines in brackets:

> "(important: it may take 17 hours or longer for the plasma-fentanyl concentration to decrease by 50%, therefore replacement opioid therapy should be initiated at a low dose, increasing gradually)."

Do those words have any significance to this case?

A I think they do in some of the patients that will be discussed because this is the key point. Once the fentanyl patch is removed one still has significant effects from that. I said six or more hours, and it is saying you have to be even more cautious than that. You may not be down to half of the concentration of fentanyl till 17 hours. That means, if you are moving from fentanyl to another opiate drug you have to adjust, being aware that you have the fentanyl slowly going down and the drug you are introducing. You cannot just replace the fentanyl with a subcutaneous infusion of diamorphine. If you were just hoping to achieve exactly the same, you would have to give a lower dose of diamorphine for a day or two, and then get up to the equivalent dose, otherwise ---?

Q The fentanyl is still ---

A Because the fentanyl is still there. You would be giving much more than you were intending by the subcutaneous infusion alone.

Q Again, it is in the *BNF*, but is that something you would expect a doctor prescribing this sort of medication to know?

A I suspect unfortunately that there were doctors who might not have been aware of this, but as a prescriber you are required to know the important aspects and so it is something one should know if one is starting opiates in somebody who has been on a fentanyl patch. The information is there in the *British National Formulary* for that reason.

Q You may not be able to answer this but fentanyl presumably comes in some sort of box?

A The packets come in a box and you take off the cover and you apply it to the skin.

Q Nowadays we get a lot of information with medicines. There is almost always a leaflet with everything, but going back to the mid- to late-nineties, do you know how much information would have come with the fentanyl, and whether it would have ---?
A It would have had... Gosh – I would have to check, but it would have at least the minimum information here, and more. I am not talking about a patient information leaflet. We are talking about the information that comes with the drug for the prescribers and nurses who administer it, and it would be more information than here.

Q Could you go on to page 15, please. I can deal with this quite quickly. We have already looked at hyoscine. We have looked at what it is used for, but can we just look at the cautions and side-effects.

> "See under Atropine Sulphate; may slow heart; avoid in the elderly (see notes above);"

Hyoscine may not be avoidable in the elderly if you are trying to dry somebody's secretions?
A I think, again, one has to differentiate between using it at the end of life where most people are elderly, and you would not avoid it from using it in another context. The reason it says "in a non-end of life setting" is the high risk of causing confusion and other adverse effects in older people. But no, it does not mean it should not be used in older people at the end of life.

Q The following page, page 16, we can see on the right-hand side midazolam.

> "Indications: sedation with amnesia, and in conjunction with local anaesthesia, premedication induction.
>
> Cautions: Contra-indications; Side-effects: see under Diazepam. ... Important: profound sedation with erythromycin and possibly other drugs;"

Help us, please, a little bit about the effects of midazolam, what it can properly be used for?
A Yes. I think this can be quite confusion. Midazolam is generally used as an intravenous bolus to induce sedation and as part of a premedication drug in patients undergoing procedures or surgery. It has a very rapid effect there because it is taken up into the brain and then it redistributes and the effect does not last very long. But in the context of using it by continuous infusion the effect is more sustained; the half life is two or three hours in that context. It does not just switch off when you stop the midazolam.

Q If you are using it in conjunction with diamorphine, will it increase the sedatory effect?
A Very much so, but more importantly it would increase the risk of respiratory depression. That is why the combination of diamorphine and midazolam was first used in intensive care settings, where there is very close monitoring of patients. It was then applied to end of life settings, to deal with terminal restlessness and the use of midazolam there. In that context, the risk of respiratory depression, as long as the drug was used appropriately, would be accepted to be a reasonable risk. But you would not, for example, use diamorphine and midazolam infusions on a patient on a general medical ward who was acutely confused and in some pain, but you are expecting a full recovery.

Q Because you may ---
A Because you just could not. The risk would be too high and you would not have appropriate numbers of staff for monitoring. Used in a very high dependency setting, where you have one-to-one nursing staff, and then used in an end of life setting, there the risks are acceptable.

Q We are going to turn to the Wessex Protocol in a moment, but it may be suggested to you, as it is sometimes in cases with other experts, that you are setting an extremely high standard and that you are looking at this with the retrospectoscope, et cetera. I want to look for a moment with you at *Good Medical Practice*, which I think you comment on in your generic report. I am going to ask for the 1995 version of *Good Medical Practice* to be handed up. It is the one that was in force, as it were, between 1995 and July 1998, so it is relevant to our first three patients at least.

THE CHAIRMAN: It should be behind tab 2, I think, of the Panellists' small bundles.

MR KARK: Is this the version you have (displaying a copy)?

THE CHAIRMAN: Tab 2.

MR KARK: Oh, that bundle. I am sorry. We have one available to you, if you want one, that you can mark up and slip in to the file.

THE CHAIRMAN: It would be helpful as we are not supposed to mark these up.

MR KARK: It is very difficult now to find copies that are not marked up.

MR LANGDALE: I am sorry to interrupt. I just want to be clear. Is this the document I received earlier on? *Good Medical Practice* 1996?

MR KARK: Yes.

MR LANGDALE: Thank you very much.

MR KARK: Can I suggest that this gets popped in after the CV, into tab 14, so we do not have to give it a new exhibit number?

THE CHAIRMAN: It will go into volume 1, ladies and gentlemen. It will be the latest available tab.

MR KARK: *Good Medical Practice* is a document which we, who regularly appear at these Panels, are very, very familiar with. How commonly known is it or used in practice? What would you expect the average GP to know of *Good Medical Practice*?
A I am not sure I am qualified to comment on that. I am not a general practitioner. I can speak as a hospital physician. What I would say is, I think very few people in 1995 could recite from memory *Good Medical Practice*, but they would certainly be aware of it. I would find it very difficult if any doctor was not aware of it, and would be aware of the basic principles within it. I think it would be unusual, certainly for a senior qualified doctor not in training not to be aware of *Good Medical Practice*. It was sent out to all doctors and I think there was increasing awareness over time.

Q Can we turn, please, to page 2. We have stayed, I can see, with the internal numbering . I do not think that will cause a problem. "Good clinical care" is the heading.

> "You must take suitable and prompt action when action when necessary. This must include:
>
> • an adequate assessment of the patient's medical condition, based on the history and clinical signs including, where necessary, an appropriate examination."

Pause there for a moment. When a patient comes in as a new admission into a hospital, such as the Gosport War Memorial Hospital, in one of the wards that Dr Barton was looking after, in your view how important is an adequate assessment of that patient's condition on arrival or shortly after arrival. How important is that?

A I think it is very important. I will tell you how important it is. I remember we had problems – for example staffing, with registrars, our hospital – at some point on a Friday afternoon temporarily, and I decided, as the consultant in charge of that service, that we would not accept patients onto the ward on a Friday because they could not be clerked and assessed by the registrar. That did not go down too well with my physician colleagues at the time, but that is because we considered, as a group of clinicians, that it was important that patients were adequately assessed when they were transferred.

One would not expect a full clerking as you would do with a patient who is acutely ill, which would be a full history and examination, but it is important to document, first of all to the team coming in, familiarise themselves (the medical team) with that patient and to document what the main problems are, that, as I think is an issue in some of the patients that are being discussed here, there has been no major change in their condition since the agreement to transfer the patient has come across. So, what we would we expect? I would expect, and certainly when I was in this position, that one would go and see the patient, one would read the notes, see what the background was, one would ask the patient how they were, if they could tell you, you would perform a relevant examination depending on what their problems were and, certainly if there were any new problems you would want to examine the patient. You would summarise what their main problems were, what the plan for their admission to that hospital ward was and check that their drug therapy was appropriate because that has to be prescribed anyway. That process would take, it depends on the patient and it depends on the experience of the doctor involved, but 20 to 30 minutes would be a reasonable amount of time for most patients. Clearly, if the patient was not straight forward, it would take longer than that.

Q Two issues you raised in passing. The first issue was the notes coming with the patient. We have heard a number of different accounts in this case from Mr Beed. I think you said it was only in 1 in 10 or 1 in 20 cases that the notes were late or missing. We have heard other evidence that it was much more common than that. Let us imagine for the moment that there are a number of occasions that the notes do not come with the patient. What is the importance then?

A This is a situation I and many geriatricians have seen many times. It is extremely frustrating because you do not have a record of what has gone on. It means you have to do a lot more work which is why we do not like it, because you have to assess the patient completely and fully yourself because you do not have the relevant information. It is the same as when the patients turn up in the outpatient clinic and you do not have their records.

You have to go back to scratch to find out exactly what is going on, but that is what you have to do because otherwise you do not know what is happening with the patient. When that happens, we would get back on to the unit and you have policies to try and stop this happening. There was a problem that some units would think it was more important that they kept the notes to do their discharge summary or whatever they needed to do. I think now that it is an absolute principle recognised that the relevant patient notes always need to transfer with the patient. If you do not have that, you have no alternative, but really, if you are going to safely manage the patient, to go through the history yourself, ring up the unit, find out what was going on and you have to do a lot more.

Q What about making a note about it?
A I think the situation where you have a patient transferred with no notes and no summary of what is wrong with them is extremely problematic and hazardous. That is not a safe situation. I am not saying this is academic, and looking at this it is not good clinical practice, I am saying it as a consultant who has responsibility for patients and I would be very concerned if I had patients under my care in that situation.

Q We have also heard it being suggested on numerous occasions, and it being accepted on numerous occasions, that the transfer itself can cause a deterioration in the condition of the patient. First of all, is that something that you have come across in your own practice?
A Certainly, I think there are two issues round that. I think, first of all, transferring frail, older, vulnerable patients to a new environment often produces confusion and upset and the transfer itself, if it is a long journey, may not be well tolerated. Usually you would expect the patient to be back, to have settled in, within a day or two. I think that has to be differentiated from a major deterioration due to another event happening, such as they have developed another medical problem that has led to their deterioration. Any deterioration needs an assessment as to what the cause is. Deterioration certainly occurs, we are all aware of this. One of the problems is, when you are responsible for units like Walkergate Hospital or Gosport War Memorial Hospital, if patients deteriorate, you have to accept sometimes that it is necessary to transfer them back, or you may even find that the patient arrives and it was not appropriate that they were transferred over at the time they were. There is a problem that the base units, particularly if they are non medical wards, once a decision to transfer is made, there is not always a close documentation of any deterioration that should have occurred. That should not happen, but sometimes it does and you have to be able to deal with that if you have a ward and you are responsible for it.

Q If you receive a patient and they have deteriorated and it does not appear to be a significant event. Let us take our case and take Gladys Richards out of the picture for the moment, because it is obvious in that case that something happened on, probably, two occasions where the transfer caused a significant event in that patient's care. If there is a deterioration in the patient simply because of the journey itself, is it your experience that that deterioration persists or can that deterioration resolve itself and the patient recover after a few days?
A It can persist. You have a problem. You are dealing with a population of older, frail people who can deteriorate anyway, so the deterioration may be coincidental or it may be reversible or irreversible. Let me give you an example. An ambulance transfer, in and of itself, you would not expect to make a patient move from being able to mobilise to not being able to mobilise at all. It depends on the nature of the deterioration.

Q If you recognise there is a significant change in the patient's condition between the first hospital and your hospital, what do you do about it?
A If there is a deterioration, what you are trying to do is to find out, is there anything treatable? It is to assess the patient and find out whether they have developed a new infection, was there something overlooked which was evolving at the previous hospital. It is the issue of the reason to assess the deterioration, is there maybe something one can do about it? If the conclusion, once you have assessed the patient, is that you cannot find anything new, then you watch and wait and you carry on with your usual or revised treatment plan.

Q I think that probably takes us to the next bullet point which is:

"• providing or arranging treatment where necessary;

• referring the patient to another practitioner where indicated."

I think in essence you have dealt with those, the need to assess and then upon the basis of that assessment to arrange treatment.
A Yes. Can I make a comment. You made a comment that others have been critical about my holding someone to a standard which is not reasonable in clinical practice. I am well aware of the challenges of providing high quality care in older people services and the battles one has to get adequate funding and staffing and the difficulties staff in those units are challenged with. *Good Medical Practice* is *Good Medical Practice*, I did not define this. I am interpreting it in as reasonable a way as I can and in the context of what I am used to in practice. I have deliberately not looked at this as an academic exercise, but it can be very challenging sometimes if one is very over pressed to consistently deliver all aspects of *Good Medical Practice* in every patient. We can discuss what the appropriate response is to doctors who find themselves in that position, but I do recognise that issue.

Q Under heading 3:

"In providing care you must:

...

• be competent when making diagnoses and when giving or arranging treatment;

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

Pausing there, I expect we are going to hear, and it has been suggested on numerous occasions to witnesses, that Dr Barton simply did not have the time. It was a case of either looking after the patient and not making a note about it, or making copious notes but not actually looking after the patient. Have you been in this sort of position or have you dealt with people in this position before?
A I have managed a service and trained in older people's services and had to keep contemporaneous notes. I have seen juniors and other staff working with me how they have kept notes. With any important clinical contact where there is a major change of patient status or a major change in treatment, I think it is difficult to say one is too busy to write a three, four, five-line summary of what has happened. It only takes a short time to write a

brief summary. I think it is a matter of what is a prioritisation if one is very busy. My understanding was that Dr Barton had three and a half sessions a week which is, if I have it correct, 14 hours of contracted time to see and assess patients at the Gosport War Memorial Hospital in 44 beds. I may have the numbers slightly wrong. Many of those patients, because they were in continuing care, would, for the most part, be stable and that was my experience. One of the problems with NHS continuing care was that there often was not as much medical input as there ought to be. That has gradually changed in most units and consultants did more systematic ward rounds. There were, on average, around, as far as I can work out, four admissions a week. I have indicated each of those should reasonably take about, maybe, 30 minutes.

Q You have had a look at the admissions books, I think?
A No, I have not looked at the admission books. I saw the finished consultant episode figures from the charge report. Then, obviously, a number of patients would deteriorate. I think it would be a reasonable expectation that any major issues would be documented by the doctor responsible for day-to-day care. I think it would not be possible to document every patient contact or every conversation with relatives and, indeed, one would not usually do that. There would be a note, for example, in the nursing notes that a doctor has met and discussed things with the relatives. It is an issue that, even when you are very busy, one needs to, within that time, focus on documenting the main changes in a patient's status. That may mean one does not have time to do other things, like talking to relatives for example. It is weighing up what are the most important things to do.

Q I would like to move on to another topic before we break for lunch. Page 8, we can see at the bottom at paragraph 28:

> "You may delegate medical care to nurses and other health care staff who are not registered medical practitioners if you believe it is best for the patient. But you must be sure that the person to whom you delegate is competent to undertake the procedure or therapy involved. When delegating care or treatment, you must always pass on enough information about the patient and the treatment needed. You will still be responsible for managing the patient's care."

Can we ask for your assistance about the issue of delegating to nurses. We have heard a huge amount about the nurses, various descriptions of their excellence and their experience, about Sister Hamblin, how well she ran the ward. Do you delegate to nurses certain aspects of the medical care of your patients?
A I suppose there is the issue about what one defines as medical care, but clearly the answer would be "Yes". Currently, there is a much clearer framework for this. There are competences and you sign people off and there was not for many aspects of this in the mid-1990s, so it was less well defined. There are some tasks you cannot delegate legally. You cannot delegate the prescribing of drugs, for example. I would emphasise the responsible consultant also does take some responsibility for what is going on with delegation of care for patients under their care.

Q Can we stay with the issue of delegating the prescription of drugs. It is obvious that it is always the doctor who actually has to write out the prescription.
A It is and the doctor carries legal responsibility for that prescription.

Q Whether there is a consultant who is more senior to that doctor or not, legally whose responsibility is the prescribing itself?
A The doctor undertakes that prescription.

Q If a doctor writes out a PRN prescription, is it legitimate in appropriate circumstances to allow nurses to decide when that PRN prescription should be administered?
A Very much so and that is standard practice. That is how many most PRN prescriptions are interpreted.

Q If that is going to happen, what are the safeguards in place to ensure that it is not inappropriately used, what does the doctor have to do?
A It so much depends on the nature of the drug. If it is a laxative or a mild analgesia, one would generally not have a protocol for that, one would leave that to the discretion of nurses to identify a patient who has constipation or mild pain and you would need to do no more. That would also apply for patients who have angina, for GTN, who have asthma for nebulisers. Once you get on to more potent drugs, you need a clearer framework. You would not – for example, I am not aware of it being common practice for doctors to delegate the prescription of antibiotics to nursing staff because that is quite an important decision and generally requires a medical assessment. We have already talked about the fact that nurses need discretion to adjust the dose of opiates when you are giving morphine. The issue is well accepted that nursing staff had discretion about the use of opiate drugs. That is a principle you would find throughout most practice in the NHS. However, the issue around delegating the decision to commence subcutaneous infused potent drugs, such as morphine and midazolam, I think is very different. Most people would not think it desirable to delegate that in the first instance. If one was going to, one would need a clear protocol that it was absolutely clear that nurses understood when they should move to giving subcutaneous drugs and what doses they should use if you have a dose range.

MR KARK: I am going to pause there because I do not think we will finish this particular topic, which is an important one, in the next few minutes. So I wonder if that would be a good time to break.

THE CHAIRMAN: Yes, it would, thank you, Mr Kark. We will break now and return at 2pm, please.

(Luncheon adjournment)

THE CHAIRMAN: Yes, Mr Kark.

MR KARK: We were dealing with the issue of delegating medical care to nurses and, in particular, the issue of the use of opiates.
A Yes.

Q I want to ask you for your assistance. You have heard a lot of evidence in this case (I think you have been seen the transcripts which you have been looking at), and, again, there has been a difference of opinion, it would appear, between the nurses as to what level of responsibility they actually had in relation both to starting syringe drivers and, secondly, increasing medication. Can I ask you about the first issue first? So far as the decision as to when to start a syringe driver in relation to a patient who may require it, whose decision in your view should that be, in terms of the timing of the commencement?

A I would say that should be a medical decision by the responsible doctor. My comment is it depends on a broader issue of what the significance of moving to the subcutaneous therapy is, and so I am slightly wary in my comments to you. If there was a clear protocol in place, let us say, which said: "This patient is at the end of their life; they are on oral morphine and when they are unable to swallow it is appropriate to switch them to an equivalent subcutaneous infusion of opiates and an equivalent infusion of a sedative, if they are on a sedative, and they were stable on that", I can see that that could be seen to be reasonable, if everybody understood their roles and there was a clear understanding by both the medical staff who were delegating that and the nursing staff to make that switch. But if it is in the context of a change in a patient's status, that becomes more complicated because then the patient needs evaluation to see what the appropriate response is, and that response might be appropriate to switch to a syringe driver but it might not; there might be other aspects of the treatment which need changing.

Q When you talk about the change in the patient's status, do you mean switching from a curative or rehabilitative regime to a palliative, end of life, regime?
A I think that is a major change in status. I think, from my understanding of what I have heard and read from the transcripts, once a patient was receiving subcutaneous therapy with diamorphine and midazolam, they were (to use a current phrase we would use) on an end-of-life pathway. The concern one might have would be if the decision to put the patient on the end-of-life care pathway was being delegated. That, I think, would not be deemed to be appropriate by most medical practitioners.

Q What if the suggestion is: "Well, we had to leave that decision on occasions open – the decision to start the syringe driver – because the patient might suddenly find themselves in pain and they would need immediate relief, and Dr Barton might not be there over a weekend", or something of that nature? Does a syringe driver necessarily deal with that situation?
A To me that is not a very strong or sound argument because, as I indicated earlier, when you give a syringe driver, you are giving a continuous infusion and it takes a while before the effect of that has come to what we call a steady state, because it takes a while for it to build up, if you made a change in the equivalent dose. I can see the situation of somebody at a stage due a dose of oral morphine, they now can no longer swallow and you can see they are not going to have any opiates, that it would be appropriate to give some opiate to ensure they remained pain-free. I think we would all recognise the importance of that. But that opiate could be a single subcutaneous injection, which would last for four hours, and I think, from my understanding of the cover at the Gosport War Memorial Hospital, it would not be unreasonable to expect a doctor, at any time of the day or night, to be able to respond within four hours. So I do not see the very strong logic for needing to move to subcutaneous infusions as opposed to giving drugs by a subcutaneous route.

Q We will have a look at the Wessex guidelines, in a moment, but what about the issue of nurses being able to increase the dose? First of all, is that a fairly accepted regime within the medical community? If there is a PRN dose a nurse can, within limits, increase it?
A Adjust either up or down?

Q Yes.
A So it might go both ways. Yes, I think it is recognising the importance of some adjustment within clearly defined limits of nursing staff to optimise pain relief or to reduce, if there are adverse effects becoming apparent.

Q You talk about clearly defined limits. How do you, as the doctor, define those limits?
A I think if you have a patient where you are reasonably clear about what dose of opiate they need, within a two-fold dose range – so like the standard PRN dose, 5-10mg – would seem, I think, reasonable. From talking to palliative care specialists they operate within a two to three-fold dose range, typically, in hospices, but all those changes are always discussed by the nursing staff (at least, in our local area) with the available medical consultant. So one can set up arrangements like that where there is adjustment; it does not require a doctor to come into hospital but there is discussion and confirmation. The method used locally, I understand, is there is an email or a text message sent. Clearly, that was not a mechanism one could use in the NHS in the mid-1990s, but some similar check. I do not think most practitioners in this area, because palliative care units, for example, have very experienced staff dealing with this all the time, would be expecting nurses to be making significant adjustments without some reference to medical staff.

Q Let us have a look then, please, at the Wessex Protocol, or the Palliative Care Handbook. It is at our tab 4. I am not going to spend a great deal of time on this but simply to go through some of the broader principles with you. First of all, this is a booklet that you have looked at, I think, in the preparation of your reports. Can we take it, because you were not working in the Portsmouth area, that you were not applying this specific document in your own Trust?
A Yes. Before I was asked to look at this I was unaware of this document.

Q Do the principles within it broadly reflect wider medical practice across the country?
A I believe they do, and I asked a palliative care colleague was this document representative and they commented it was a very good document that reflected the principles of practice at that time.

Q Was it the sort of principle of practice that you yourself would have been applying in prescribing for your patients, if necessary?
A Yes. There is a level of detail in here which I would not have been familiar with. There is information in here and drugs that I would not have used in my own practice.

Q We will see if we come across those, but if we go to page 4, I just want to see, if I may, with you, what would have broadly known principles in any event, even if you did not know about this book, and what would have been outside the norm. If we look under the heading "General principles of symptom management", it talks about accurate and full assessment. We have seen that already in *Good Medical Practice*. Then this, halfway down the page:

"Be careful that drug side-effects do not become worse than the original problem".

Is that a known principle in geriatric medicine?
A I think geriatricians – and I am saying this as a geriatrician, trying to put my clinical pharmacology hat to one side – in general, as a group, are very aware of the issues of adverse drug effects in older people, and I think most geriatricians would be very aware of that principle and be monitoring patients for any side-effects of therapy. That is because older people are more likely to get adverse effects from drugs and they take more drugs, so it is an issue geriatricians have to deal with much more than groups of doctors who look after younger people.

Q And is an issue you have already dealt with of some relevance to using opiates.

A Yes, because these are drugs that are known to have significant adverse effects, and some are very predictable and need careful monitoring for.

Q If we look to the right-hand side of the page:

> "Pain is a common although not inevitable symptom in cancer. A successful treatment requires an accurate diagnosis of the cause and a rational approach to therapy."

Again, I think that reflects the evidence you have already given, that the first thing to do if a patient is in pain is to try to identify the source of the pain.
A This is a key principle because if the pain is not nociceptive, if it is neuropathic, due to nerve problems, or if it is due to somatisation, psychological in onset, opiates are not going to be a helpful treatment.

Q Somatisation. Can you help us please?
A This is a description of psychological distress manifesting itself as physical symptoms. I think most people are familiar with this: young children, for example, when they are upset will say they have got abdominal pain, but there is nothing wrong with the inside of their abdomen, it is just the way children manifest when they are upset. There are similar examples throughout a lot of adult medical practice.

Q So far as the patient is concerned the pain can be very real.
A Pain is real; pain is what the patient says it is. There is no dispute about that.

Q Page 5. Again, I am not going to spend any time on this. We can see the World Health Organisation Analgesic Ladder is set out. Again, you may not have had this particular book, but would the broad principles of this be well-known to you?
A Yes, I think most people were aware of that principle of starting with milder and going up through moderate to more potent analgesics.

Q Can we go to page 6, please, and paragraph 2, under the heading: "Use of Morphine".

> "Start by using an immediate release morphine (liquid or tablet) for dose titration giving it every 4 hours. The eventual effective dose may range from 2.5mg to more than 200mg but only a minority of patients will need more than 30mg 4 hourly."

Pausing for a moment, this handbook, we have to bear in mind throughout, is a palliative care handbook.
A Yes, and mostly framed around the management of patients with cancer, although not exclusively so.

Q It goes on:

> "Give a double dose at bedtime to avoid waking at 2-3am but ensure that at least 5 doses are given per 24 hours. Start with a low dose and increase by 30 – 50% increments each day until pain is controlled or side effects prevent further increase. Doses can be rounded up or down"

and then it gives a common dose sequence. That concept of 30 to 50% increments each day: again, we have heard a number of nurses talking about some knowledge of that. Is that a principle that you have applied in your own hospital?
A Yes, I think most non-palliative care specialists would use a principle of around 50%.

Q Five-zero?
A Five-zero, yes. Interestingly, palliative care physicians are probably more conservative in the way they increase opiates, I suspect, than many generalists. I think Dr Reid, if I quote him correctly, initially had a protocol which doubled opiates. So best practice for most people would have been increasing by 50% but some practitioners, normally in the specialist palliative care setting, would have doubled if a patient was in persisting, severe pain. Obviously, when you do that there is more of a risk of getting adverse effects.

Q Doubling over what period? Or increasing by 50% over what period?
A Generally, we are talking about every 24 hours unless you are absolutely clear, and you are adjusting it four-hourly, that the patient still remains in pain. As I indicated earlier, if you are starting opiates it is going to be a while before you see the full effect of the dose you have given because it is going to be five half-lives, so that is about 20/24 hours, in older people, before you have got to the steady state effect. Again, it depends on the setting one is in and it depends upon the extent of pain that the patient has. When you are starting off you may need to escalate quite rapidly every two hours or so, as I was indicating, to obtain analgesia.

Q If we look at paragraph 5 we read:

> "Use continuing pain as an indication to increase the dose and persisting side-effects, e.g. drowsiness, vomiting, confusion, particularly in association with constricted pupils, as an indication to reduce the dose. If both pain and side effects are present, consider other approaches."

Are there circumstances where if you have a patient who is exhibiting side-effects but continues to be in pain you have to continue using opiates and increasing it?
A It depends on the severity of the side-effects. What that is saying is you cannot just keep prescribing opiates if there are major adverse effects which are unacceptable. Respiratory depression is unacceptable; severe restlessness and agitation are unacceptable if it is drug-induced. So one should pull back and think about – it is really saying "Go back to the beginning and just check have you understood what the cause of the pain is? Are there other approaches to relieving pain than giving opiates which are going to relieve this patient's pain?" We have been through all that already so I will not reiterate that, but there might be other drugs that one might use as well.

Q Paragraph 7:

> "When oral administration is not possible" (and we have looked at this) "consider changing to diamorphine by subcutaneous infusion using a syringe driver. The conversion from oral morphine to subcutaneous diamorphine ... varies between one-third and one-half allowing some flexibility depending on the requirement for increased or decreased opioid effect."

That, obviously, seems, on the face of it, to go beyond the *BNF*.

A I think what it is saying (I would interpret this – and this is just my interpretation) is that if one needs increased opioid effect go to a half and if one needs the same or slightly less go to a third, in the first instance.

Q Then it has got a table on the right of the opioid equivalents. Although it deals with syringe drivers I am not going to go into that. It is page 14, because I think you have covered it in your general evidence. You have dealt with nurses' responsibilities and you have dealt with the importance of making notes where there is a change in the patient's condition. I want to deal with the decision about switching a patient to a palliative care route and the process that one should go through and what notes should be made about it. You understand the broad area of the topic. It is the point at which somebody, either a nurse or a doctor, decides that this patient is now to a palliative care regime by which I mean end of life. Who should be taking that decision? How should it be taken? Who needs to be consulted and what notes should be made about it?

A I will preface my comments by saying this is a very challenging area of practice. I think there is a recognition that end of life care was often suboptimal in medical practice. This led to the development of guidelines and protocols like the Liverpool Care Pathway, which is now used quite widely. It specifically gives an approach and system for checking that the issues at end of life are met. That is the first thing to say. This was an area where practice in general was often not as good as it would now be seen it ought to be. Again, I think we have to say that the culture has changed in the last ten to fifteen years. Now there would in general be a much more explicit open process of that decision being made, with discussion with either the patient or, if they lacked capacity, a discussion with their relatives, not for them to consent but to give a context and information to ensure a decision was being made in the patient's best interest.

Q Just pausing for a second, you made a very specific point – not for them to consent.

A I am in front of lawyers, so I hesitate to comment on what is a legal area, but my understanding is that relatives do not consent for adults. They should be part of the decision-making process, because relatives may not always – not always – have the best interests or perceive what may be the best interests of the patient.

Q If a patient needs pain relief in your view, in your – the doctor's – view, and the patient is not in a state either to say yes or no, ultimately whose decision is it to give that pain relief?

A You would not seek consent to give analgesia to an incapacitated adult who was in pain. You would give the analgesia and you would explain for information and good practice to the relative, carers and family what was happening with the management of the patient. In terms of making the decision, because it is clearly such an important decision to put somebody on an end of life terminal care pathway, that decision in my experience was always made or discussed with the senior doctor responsible for that patient's care. There might be exceptions to that if a patient with advanced cancer or dementia came in on an acute medical take, who was clearly very ill. The senior registrar, possibly registrar, might initiate palliative treatment without waking up – in the nineties – the on-call consultant for that patient. But in general, in a patient where this had not been considered before, you would expect that to at least have been discussed with the responsible consultant – at least I would have, or the consultant responsible for the care of that patient.

Q And making any notes about it, we have seen on occasion notes such as "For TLC, keep comfortable, not for 555"? Not for 555, I think is accepted to be in a separate category?

A I think as other people have commented it is important to recognise the decision about resuscitation is completely different from that of the level of care. Many people are not on an end of life care pathway or not for resuscitation because it is their wish, or it is generally considered it would be inappropriate for a number of reasons to attempt resuscitation in the event of a sudden cardiac or respiratory arrest. But you would expect to see documentation in the notes that a patient was on end of life care. As you say, now we are much more clear and explicit about how we write these down. A number of phrases would be used: "tender loving care" was one; "keep comfortable" was another and TLC was probably the most commonly used phrase for patients entering end of life care.

Q Would you just give me one moment, please.
A Can I just add another comment to that?

Q Yes.
A Now we are much more explicit in this decision-making end of life, of deciding what the limits of care are. Even for patients not at the end of life we might decide somebody is not for resuscitation but for antibiotics and other active treatment, but not for admission to intensive care. In the 1990s there was not such an explicit consideration and usual description in the notes of these issues of the level of care, so practice has changed since the 1990s.

Q The last document that I wanted to look at – and I hope this is already in the bundle, but I have to confess although it is in mine I am not sure if it has been given out – is behind tab 8. There should be a document headed "Pain Relief - P. Crome". Do you have that?
A I do.

Q Do the Panel? I understand now that you do, so we all have it. Can you just tell us what this book is please?
A This is a chapter from a book that Peter Crome, the author of this chapter, and I were editors of "*Drugs in Older People*".

Q I am trying to see when this was published.
A It is on my CV. I would have to look at my CV. I think it was 1998. Perhaps we could just check that.

Q I just wanted to draw your attention to one aspect and first of all for you to identify this. Is this regarded, without being overly modest, as authoritative or what lawyers might call "authoritative text" in your field? How would you describe it?
A There are two or three textbooks about drug therapy in older people I would not like to say whether it was more authoritative than any others.

Q I do not think it is paginated. Could we look at page 585 within the internal numbering.

THE CHAIRMAN: The numbers are at the top right-hand side.

MR KARK: Exactly. I am not going to spend any time on this, but I do not think it says much more than you have already told us about the broad principle, the basic principles, of dealing with acute pain.

A This chapter is written by a geriatrician with some interest in clinical pharmacology like myself. I think it summarises, again, the broad principles which we have seen in the *BNF* and also in the Wessex guidance.

Q I will not take any time. We can see the words that you used earlier in the middle of that paragraph "Start low, go slow", and is that referable to elderly patients and pain relief?
A Yes, with the qualifier in the following sentence, that to avoid patients remaining in pain, you may not need to go slow; you may need to go fast.

MR KARK: Very well. I think we are going to move on, please, to deal with individual patients. There will no doubt be other topics which arise as we begin to look at individual patients but we are going to start with Patient A. I think the Panel indicated that at this point in the evidence the Panel, first of all, would like time to remind themselves of the new chronology and also the opportunity to read Dr Barton's comments about each patient. I do not know if that is how you want to do it?

THE CHAIRMAN: I think it is very sensible, Mr Kark. Do you have a sense of the sort of time that we are likely to need?

MR KARK: I would have thought you would need at least 20 minutes and possibly longer. Mr Langdale is saying half an hour. Can I suggest we start with 20 minutes and then you send a message?

THE CHAIRMAN: Yes. We will send a message before the 20 minutes is up to avoid you --
-

MR KARK: I only say that because if we say 30 minutes now, we have twelve patients to get to. If it becomes 30 minutes for each of those patients, we may not need that long for all of them.

THE CHAIRMAN: Very well. We shall start with twenty minutes and after fifteen we shall let you know if we are on track.

MR KARK: In the meantime, can Professor Ford be given – I think he already has them but can we just speak to him? It is merely about the administration and making sure he has the up to date chronologies.

THE CHAIRMAN: Yes, indeed you may.

MR KARK: Thank you.

MR LANGDALE: Do the Panel have the new detailed chronology?

THE CHAIRMAN: The new detailed chronology for Mr Pittock? I think they have.

(The Panel adjourned for a short time)

THE CHAIRMAN: Welcome back, everyone. Mr Kark, it seems that on the first run with Patient A, at least, we needed nearer the half hour than the twenty minutes.

I note, Professor, you have been hard at work in one way or another since we started the afternoon session. Perhaps we can bear that in mind, Mr Kark, and perhaps be aiming for a break for the Professor at around 3.30. Are you fit to continue now?

THE WITNESS: I am quite happy to continue, yes.

MR KARK: May I also mention a matter in relation to the chronology – I think I have the right one. If you go to page 11 of the chronology you will see there is a note on 9 January at the moment by Nurse Barrett from the "Significant events" in the nursing notes. Over the page, there is another nursing note. In fact what we are missing there, and I have asked Mr Fitzgerald to amend it so I am afraid you will be given another page, is actually a note by Dr Barton that is in the original medical records at page 196. It is for 9 January 1996. That should definitely be in there, unless I am missing something, apologies for that. I am afraid I have only just noticed that.

THE CHAIRMAN: Very well. We will insert that when it comes to hand.

MR KARK: I refer to it specifically because Dr Barton, in her own statement, makes a comment about it and I am surprised not to see it in the chronology. That, I am afraid, is bound to happen with the best work and will in the world. I can only apologise and we will try and get it right in due course.

THE CHAIRMAN: Not at all.

MR KARK: Professor Ford, I am going to ask you to have your report open and available to you and it is the report in relation to Patient A . I going to try and not have too many documents open at the same time. I suspect, although we have the chronology, the Panel may still at least want to turn up or have available to them the clinical note made by Dr Barton. That they will find in Mr Pittock's note at page 196, and the drugs charts they will find beginning at page 199. Because we have the chronology, I am going to try and avoid going to more documents than that, if at all possible. (To the witness) This gentleman had chronic, long term depression?

A Yes.

Q And you have had the opportunity of reviewing all of his notes. He was admitted to Mulberry Ward under Dr Banks first of all in September 1995 and then he was returned to the Hazeldene rest home, and then he was re-admitted to Mulberry Ward in December 1995. He then had sacral sores which were noted and then, so far as your report is concerned, I am on page 3, where you very helpfully set out in chronological sequence the events. There is a nursing assessment on the 5 January. We will look at Dr Barton's note in a moment. It records that Mr Pittock had a

> "...poor physical condition with broken pressure areas to his buttocks and hips, and broken skin on his scrotum. He was weight bearing to a very minimal degree, was low in mood but settled in behaviour. His fluid and diet intake was noticed to be poor but that he was drinking supplement drinks."

Then we have Dr Barton's note. Again, I am not going to read all the way through these, but we can see that his current problems were immobility, depression and broken sacrum, meaning the skin on the sacrum. Then long-standing depression for which he was on lithium.

I think in your report you record his marked deterioration, in already poor condition as reflected in the nursing notes on the 19 January. Could we then go, please, to concentrate on the drugs. For these purposes we can concentrate on our chronology. Can we go to page 12 of the chronology first of all. He is on a drug, as we can see on page 12, called Arthrotec. Was that to deal with pain from arthritis?

A Yes. It is a non-steroidal anti-inflammatory drug, so it was appropriate to prescribe that and see if that improved his pain, which was thought to be due to arthritis.

Q We can see Dr Barton has made a note on 9 January:

"Painful right hand. Held" - I think it is – "in flexion.
Try Arthrotec.
Also increasing anxiety and agitation.
? sufficient diazepam
? Needs opiates."

Then the next entry is by Dr Tandy, which reads:

"Depression. Catheterised. Superficial ulcers. Barthel 0. Will eat and drink. For TLC."

Plainly that is an important note in relation to this patient?

A Yes.

Q And it reflects, does it, your understanding, as you told us earlier, "TLC" would mean that this patient was now on a palliative care regime?

A Yes, I think so. The picture one obtains from the notes is a very frail, older man with severe depression who is deteriorating, has bedsores. I think nearly everybody who saw him as a geriatrician would recognise this man was nearing the end of his life.

Q We can see at the bottom of the chronology that on that date, 10 January, there was a note from Nurse Hamblin, that the patient was seen by Dr Tandy and Dr Barton.

"To commence on Oramorph 4 hrly this evening."

Then, over the page, Arthrotec was discontinued and then Oramorph was prescribed by Dr Barton at 5 mg to be given five times daily. I am going to look at the drugs globally first and come back to the comments you have about them. Underneath that in the drug charts at page 200, we have the following prescriptions from Dr Barton. Diamorphine, for variable dose between 40-80mgs over 24 hours; hyoscine between 200-400 mcg over 24 hours; and midazolam between 20-40 mgs via subcutaneous infusion. All of those were intended to be given by syringe driver?

A Yes.

Q On the next page of the chronology we can see that Oramorph was administered. I think 5 mgs had been administered the night before, but now on 11 January began a regime for this patient of Oramorph and the patient was receiving, I think, 30 mgs of Oramorph daily, 5 mgs at 6 o'clock in the morning and at 10, 2 pm, 6 pm and 10 mgs administered at 8 o'clock at night?

A Yes.

Q Just dealing with that on this one occasion, that idea of giving a patient a higher dose in the evening, is that, in your view, acceptable medical practice if the patient requires opiates?
A I think it is generally considered good practice because it saves waking the patient up every four hours in the middle of the night if they are sleeping, so it is quite common to give a double dose of morphine as the night time dose. It sounds good practice.

MR KARK: So far as the prescriptions for 5 mgs of Oramorph four hourly, you comment in your report at paragraph 10:

> "Despite the limited medical documentation the decision of Dr Barton to prescribe 5 mgs of Oramorph 4 hourly on 10 January was in my view reasonable given that Patient A was likely to be in significant discomfort and pain from his pressure sores. It would be difficult to determine whether the restlessness and agitation in Patient A were due to pain or his depression. The decision had been made that day that Patient A was for 'TLC". This indicates that Dr Tandy considered Patient A was likely to die within days or weeks and the focus of treatment at this stage was to towards palliating any symptoms he might have rather than the initiation of other interventions to treat or prevent active ongoing problems."

MR LANGDALE: Sir, may I interrupt. I appreciate Professor Ford is an expert witness, and I appreciate he has a lot of material to get through. I have no objection to my learned friend leading where appropriate but I do rather question what appears to be emerging – it may be this is the only time it will be done – simply reading out a chunk from his report in this way. I wonder if my friend would, and I am not going over the ground that has already been covered, be careful to take the evidence from the witness rather than simply reading out a chunk from his report. Sometimes I appreciate a sentence may be perfectly sensible to put it in context, but I think we may run into difficulties if we are reading out passages like that.

MR KARK: I take my friend's point, but all I was going to ask the Professor was whether, having heard all the evidence he has, do you still stand by what you have written in your report?
A Yes. I believe the decision to start opiates, from the information present in the medical and nursing notes, was entirely appropriate.

MR KARK: I did it on this occasion because it is favourable to Dr Barton rather than a criticism of Dr Barton.

MR LANGDALE: If I give a wry smile, I am not laughing at that in another sense. I appreciate my friend, as we all do in his position, would be dealing with points which are favourable to a defendant by way of leading, but I wonder if he could bear it in mind. I am not going to criticise him every time he does it.

THE CHAIRMAN: I think Mr Kark has the point.

MR KARK: I was then going to turn to your views – and I am looking at paragraph 12 of your report, to guide you as to where you dealt with it – as to the prescription written out by Dr Barton that we can see set out in our chronology. First, diamorphine prescribed at

between 80-120 mgs PRN by subcutaneous infusion. Can we stop for a moment there. This patient is on 30 mgs of oral morphine.
A Yes.

Q Daily, every 24 hours?
A Yes, correct.

Q Having looked at the various conversion tables that we have in the guidance that is given, and I am going to ask for your mathematics rather than mine, although I think it is a simple sum, what would the normal subcutaneous dose have been if the same level of analgesia was required?
A If we use the third conversion, 30 mgs of oral morphine over 24 hours is equivalent to 10 mgs of diamorphine over 24 hours by subcutaneous infusion. If one were to accept half conversion, that would be 15 mgs.

Q That would be a small increase or an incremental increase?
A Yes, the general conversion, as we have discussed, is accepted to be a third.

Q What is your view on the appropriateness or otherwise of prescribing between a variable dose between 80 and 120 mgs of diamorphine?
A If this prescription was written in the event that Mr Pittock, Patient A, could not swallow, a replacement dose would have been 10 or 15 mgs over 24 hours, so that is what one would expect the prescription to be for if that was the purpose of the prescription, to provide an equivalent dose of diamorphine to the oral morphine. As we discussed before, allowing for some increased need and the flexibility of nurses, if it was considered appropriate one could then say a two or three-fold increase at an appropriate range to give some leeway to increase would have been, say, to go to 20 mgs, maybe 30 mgs, of diamorphine a day. You could say, in case he was getting adverse effects, you might have had the range slightly lower in case there was a need to reduce it. I cannot, from the information I have seen in the notes, understand why there was such a large increase in the equivalent opiate prescribed for Patient A, which is, using the word one-third conversion it is an 8-fold increase, at the lower dose of the range, 12-fold, if you use 50 mgs it is 5-fold, to 8 or 9-fold increase, which is not consistent with any guidance either in the BNF or the Wessex Protocols as we have discussed.

Q Is it consistent with any medical practice you have come across?
A No, not a magnitude of this increase.

Q Does it give rise to any particular danger or hazard?
A As discussed, when one increases a dose of opiates, there is the risk of developing significant adverse effects, most notably respiratory depression and decreased conscious level. That is the concern, particularly in the context of the potential administration of other drugs, notably midazolam, which will also potentially have major effects on respiratory drive and conscious level.

Q I will come on to midazolam. Even if the diamorphine were being prescribed on its own without the midazolam, consistent in your view, or inconsistent, with *Good Medical Practice*?
A I cannot see how it is consistent with *Good Medical Practice*. I cannot see how it was in the patient's interest to have such a large increase in opioid prescribed.

Q Midazolam was also prescribed as part of this prescription between 40-80 mgs. Midazolam does what?
A We discussed it is a potent benzodiazepine that is used in the management of terminal restlessness in patients at the end of life. Again, the difficulty I have is that the medical notes are not clear in explaining, and do not explain, the rationale for these drugs so that, assuming that was what the indication for it was, to manage restlessness and agitation at the end of life, that certainly is an appropriate drug to consider. There are other drugs that could have been given, such as the usual one you would use, antipsychotic drugs for the management of agitation as were subsequently used in Mr Pittock, but the starting dose is very high. The recommended starting dose in the elderly would be 5 or 10 mgs over 24 hours and a starting dose of 40 mgs over 24 hours – a benzodiazepine in a naive patient – is extremely high and likely to produce adverse effects.

Q I am looking at paragraph 14, when we look at the joint prescription of diamorphine with the lowest dose of 80 mgs and midazolam with the lowest dose of 40 mgs and then with a range above that, what, if any, are the dangers that are carried with that sort of prescribing practice?
A The problems are, first, it is unlikely he will remain alert. He is going to have a very depressed conscious level, as happened. Secondly, you will bring about respiratory depression and death at an earlier point. This man is dying, I think everybody recognises that. I think there is little disagreement by any of the experts about that or the clinicians involved, but the treatment he is receiving as a dying man should still be appropriate to his needs. The use of sedation therapy is an area of potential concerns in other countries. Sedation therapy, it has been commented, is open to misuse. I am not saying it was misused, but the problem is, because they are so powerful at producing respiratory depression, one systematic review of sedation in end of life care comments that it can ostensibly be used to relieve distress but with the manifest intent of hastening death. I am not saying that was the intent here, I am saying that is the concern about why one needs to document very carefully the use of sedation in an end of life setting, that it is used appropriately to control patients' symptoms.

Q If we look at the documentation we have, which is in relation to the specific prescription by Dr Barton, the note is limited. We have 9 January, which we have looked at, we have Dr Tandy's note of 10 January, and then the next note we have from Dr Barton, I think, is on 18 January. Is there anything in these notes that appears to justify such a prescription?
A There is a note that the patient has anxiety and agitation. Clearly, there was a good indication recorded for the use of an antipsychotic or a benzodiazepine and both were used at different times. There is some information there, it is not related immediately to the prescription, but I think one can assume this was a man with anxiety and agitation. That may have been due to the opiates, but it is not clear from the notes whether they thought the staff thought he would gain benefit from the morphine he started in terms of his pain.

Q Pausing there. He started on the Oramorph on 10 January?
A Yes. As I said in my report, it would be difficult to dissect out the cause of his agitation and it could have been due to a number of different causes.

Q If we look – and I am staying with the chronology to save time – at the entry for 13 January, there is a note made by Nurse Ring:

"Catheter bypassing. Mr Pittock looks distressed."

If we go over the page, there is a further comment:

"Catheter bypassing +++ so catheter removed. Tip of catheter very mucky. Pad and pants in situ."

On 15 January we can see that the diamorphine was started at the lowest rate of 80 mgs. Why is this catheter bypassing, from what you are able to tell from the notes, what are the possible causes for that happening and what is the remedy?
A One possibility is that the catheter has become blocked and debris accumulates in catheters placed in patients, particularly if they have them long term. The other possibility is that a larger catheter is needed. The relevant point in terms of assessing the patient would be to establish whether they had a distended bladder and whether that was a possible cause of their distress. There is no particular information about that I could find in the medical nursing notes, so I cannot comment whether that was or was not a cause of his distress.

Q The note that we have is that the patient is agitated, and it is in the same note, that the catheter is bypassing but we do not know if the two are linked or may be?
A That could have been a factor that was contributing to his agitation, as could the morphine, as could his agitated depression. There are a number of factors that could be contributing in this man.

Q There is no specific reference to pain.
A I think there was earlier on, I think there are records that he was in pain and, certainly, prior to the commencement of oral morphine there was.

Q The patient we know had very sore areas around his genitals.
A Yes. I think the prescription of opiates was appropriate in this man to see if that improved his level of comfort. I think it was reasonable to carry on continuing a dose of opiates that was not obviously causing him problems.

Q Is there any indication that you have seen as to why a syringe driver was started as opposed to oral opiates?
A I did not find any clear information in the notes which indicated the rationale from switching from the oral route to the subcutaneous route. I am trying to recollect whether there was an entry in the notes as to whether he was taking food and drink at the time or if he stopped eating and drinking. His intake was definitely poor.

Q If we look at the chronology, page 15, I am not sure this is going to help you?
A We certainly know that after the infusion was commenced he was unable to swallow. What I cannot tell from the notes is whether he was unable to swallow before the infusion was commenced.

Q Once the syringe driver has started we can see, if we look at the bottom of page 15: "Seen by Dr Barton, has commenced syringe driver" and then it sets out the amounts. "Daughter informed of father's deterioration during the afternoon". I think we must amend that as well; it is not "no unresponsive" it is "now unresponsive. Unable to take fluids and

diet." If this syringe driver started at 8.25 in the morning, to what effect is it going to be having an effect upon him by 7.00 at night?
A By that time he has received almost 30mg of midazolam and 40mg of diamorphine ----

Q Because it is almost 12 hours.
A Twelve hours. I think it would be highly unlikely he was not significantly sedated with that dose of midazolam and, also, he is receiving diamorphine by that time. It does not surprise me he is "now unresponsive". However, whether his level of responsiveness and whether he was able to take fluid and diet before that was commenced, I was not able to establish from review of the notes.

Q Can we go to the following day, please, 16 January? We can see that the diamorphine remains the same, I think, as does the midazolam. The haloperidol is now prescribed, and indeed administered. Haloperidol will have what effect?
A It is an antipsychotic drug, primarily used to control agitation.

Q If we look at the note underneath where the drug chart is set out on the chronology: "Condition remains very poor. Some agitation was noticed when being attended to. Seen by Dr Barton. Haloperidol at 5-10mg to be added to driver. Night condition remains poorly. All care be continued." Haloperidol can be used, I think, for agitation or to assist with agitation.
A Yes, it can.

Q Does it have a sedative effect?
A It does have some sedative effect, yes.

Q Does it follow from that the sedation will be on top of the sedation already provided by the diamorphine and midazolam?
A Yes, it would. I think there is not a clear note made by Dr Barton which indicates the rationale of using haloperidol but the nursing notes suggest that it was because he was showing signs of agitation. In that sense, haloperidol, to treat agitation, is a high starting dose; the recommended dose is start with 2.5 over 24 hours, but I think it is not unreasonable to start with 5. There, perhaps, should have been a consideration – he is on a very high dose of midazolam and is still agitated, he is on a very high dose of opiates, and could they, in fact, be contributing to it, particularly the opiates, at this point? So we have got very high doses of diamorphine and midazolam still continuing with, now, an antipsychotic added in as well.

Q Can we pause for a moment and just look at the prescribing itself and the way that it is written out, and whether that, in itself, carries with it any problems. Could you turn up the patient notes. I am trying to avoid doing this as much as possible. Could you go to page 200?
A Yes, I have that.

Q I think you commented on this in your report at page 20, if that helps you. We can see, at the top of the page, the prescription for Oramorph, and then, underneath that, a prescription for diamorphine for between 40 and 80mg, which does not appear ever to have been administered.
A Yes.

A Q Underneath that, hyoscine, 200-400micrograms; underneath that midazolam for, I think, 20-40mg – none of which appear to have been administered.
A Yes, which I found surprising since this is in the regular medication section, if this is a correct copy.

Q Before asking you to comment I just want you to look at the next page, page 201. We have then got the prescription that we have just been looking at: the diamorphine of 80-120;
B the hyoscine 200-400micrograms, plus midazolam 40-80mg, and a further prescription under that for midazolam (I think it is) at 80mg on 16 January – the first three being on 11 January. Just looking at 11 January, and the prescription the day before, those prescriptions all appear, certainly at some stage, to be live.
A Yes, I think there was a problem that there seemed to be two open prescriptions for diamorphine and midazolam on the same drug chart, unless they were different drug charts,
C and the risk then is that they could both be administered. It would be usual to cross an old prescription off. They were not administered, but it is not good prescribing practice. The only alternative explanation I can think is that they are from separate prescription charts, but I assume that is not the case.

Q Unfortunately, we do not have the original sheet, and we are all on microfiche for these. If they are on a separate sheet, what is the appropriate practice if you are writing out a new prescription because you think the old prescription was either wrong or ineffective or not
D enough? What are you meant to do?
A You put a line through the old prescription and you sign and date, usually, the date of discontinuation.

Q And then that is clear.
A And then that is clear that that prescription is no longer active. Sometimes, if you have got a new prescription chart, the usual practice is to put lines through all of the front of it, to
E make clear the whole chart is inactive, so that was why I was saying if it was a new chart, but I think there is an overlap of the dates, certainly for some of these, which led me to believe it was – one cannot tell, actually, on this one.

Q Can we go on through page 16, please? We can see the diamorphine at 80mg and midazolam at 60mg and hyoscine at 400mg was administered, together with haloperidol 5mg. There is a nursing note that the patient's condition remained very poor and agitation was
F noted when being attended to. Then we can see that a bed-bath was given; that his right ear was very blistered and swollen and all pressure areas were marking easily. Then can we go to 17 January, please, the following page. Also page 18. It may be useful to look at page 18 first. This is a note made by Nurse Douglas at 9 o'clock in the morning.

> "Seen by Dr Barton. Medication increased, 8.25, as patient remains tense and
> G agitated. Chest very bubbly, suction required frequently, bed-bathed, hourly turning; remains distressed on turning. 14.30 seen by Dr Barton. Medication reviewed and altered. Syringe driver renewed." Then Sister Hamblin makes a note: "Further deterioration in already poor condition."

Can we then look at the prescriptions. Diamorphine was increased to 120mg, and that was started at 8.30 in the morning on 17 January, or it appears to have been. Hyoscine was delivered at 600mg, midazolam was increased to 60mg, and then to 80mg, which was also
H administered, it would appear from the drug chart, on 17 January. Haloperidol was also

increased to 20mg and put into the syringe driver in the afternoon at 15.35. These sorts of increases – have you seen anything that, in your view, appears to justify them?
A I think increasing any one of them would have been a reasonable and appropriate approach.

Q Depending on what? I am sorry.
A In terms of the patient is, at this point, agitated and so you have to make a judgment, from seeing the patient, is it because they are in pain? He does not seem to have responded well to opiates so far, from what one can tell, but ----

Q Does or does not?
A Does not seem to respond particularly well to opiates, from what one can tell from the notes. But it is difficult because the information and records are limited. If it is thought not to be due primarily to pain but terminal restlessness, or agitation, I think either increasing the midazolam, if he is not unduly sedated by it, or increasing the antipsychotic drug dose of haloperidol is appropriate. I think increasing all three at once – there is a four-fold increase in haloperidol and a 33% increase in midazolam and a 50% increase in diamorphine, I think, is excessive.

Q If we then go to the following day, we can see there is a review by Dr Barton. This is at the bottom of the chronology at page 18: "Further deterioration". Pause there for a moment. We see "deterioration" all the way through these notes. What does the deterioration describe?
A Obviously, in the absence of any other information, one cannot tell. If there were more detailed nursing records one could cross-reference to those but I was not able to ascertain what the deterioration was.

Q This patient, on the basis that he is now unresponsive and on a syringe driver, I think we can take it, from everything we have heard, was not being hydrated.
A Yes, and I would suspect he had a very depressed conscious level. Again, there is no formal record so it is difficult to be certain.

Q He has got a depressed conscious level. He is not being hydrated. Will that of itself cause what could be described as deterioration, or would that be described as something different?
A Yes, I am trying to work out when he stopped eating and drinking. It was back on ----

Q We have got 11th.
A We are seven days on, are we not? So I think one would expect deterioration from dehydration itself, at that point.

Q How would that manifest itself?
A Patients move less, their skin colour looks worse, they are becoming less and less responsive and alert.

Q Their skin colour looks worse because that is related to?
A Poor perfusion. These are soft but clear signs that staff can recognise when they are managing patients. I think, obviously, the difficulty one has with Mr Pittock is interpreting what is due to drug therapy, at this stage, and what is due to him approaching end of life from natural causes.

Q Bottom of page 18:

"Difficulty controlling symptoms", writes Dr Barton, "Tried Nozinan"

Nozinan does what?
A That is a sedating, antipsychotic drug. I think that if he had agitation that was related to his depression and general condition, that was not an unreasonable drug to switch to from the haloperidol, if the haloperidol was not controlling his symptoms, but it was given, I believe, initially, from what I can tell, in addition to the haloperidol. It is not recommended one uses two different antipsychotic drugs at the same time.

Q Just to be sure that we understand you; when you just said if he is agitated because of his depression, at this stage, when you refer to his "depression" you are not talking about ----
A His general state. The other problem was if he was opiate-intoxicated he could be having myoclonic jerks which might be misinterpreted as agitation. It is very difficult to tell.

Q That is something we have not heard about. What are those?
A This is where the muscles jerk involuntarily, which you can get with opiate intoxication.

Q When you talk about "opiate" – did you say "intoxication"?
A Yes. When you have got very high levels.

Q Toxicity.
A Yes.

Q Is that something that happens naturally, or is that a sign of over-sedation?
A It is a consequence of having high – it is an adverse effect of having high levels of morphine and the metabolite, particularly in the metabolites; they accumulate.

Q If we go to page 20, we can see that the diamorphine was continued at 120, the hyoscine was – I think that is an increase to 1200micrograms – the midazolam continues at 80mg, haloperidol is now being administered at 20mg, and now we have got Nozinan added at 50mg. Do each of those drugs have a sedating effect?
A Yes. Not the hyoscine – it does not have major sedating effects.

Q I thought you told us it had some sedative effects but it is not ----
A Some, but I think the major drugs causing sedation here, at this point, would have been midazolam and the Nozinan. To a lesser extent the diamorphine and haloperidol.

Q Then we can see, on 19 January, the same drugs are administered. If we go to 20 January, please, there are comments, at the top of page 21 of the chronology:

"Marked deterioration in already poorly condition. All nursing care continued. Breathing very intermittent. Colour poor."

You have dealt with that.
A I think he is clearly dying at this point.

Q On 20 January, the diamorphine remains the same, as does the midazolam. We know that Dr Briggs discontinued the haloperidol but increased the Nozinan. What sort of effect is that going to have on the patient?
A Well, more sedation. From the notes Dr Briggs was contacted by the nursing staff because they thought he was still exhibiting signs of agitation.

Q Then, on 21 January, we can see that that mixture of drugs continued, and on 22 January and 23 January - the haloperidol, of course, has now gone – and the patient died in the early hours of the morning of 24 January. Before we take a break, first of all, I want to ask you about the assessment so far as the notes that we have got here are concerned. In your view, did Dr Barton appear, at least, to provide an adequate assessment of the patient's condition on his admission, or shortly thereafter?
A I think the initial description summarised the problems and there was a documentation of agitation which was there. However, there really was not a documentation of more detailed assessment as to the possible causes of his agitation and a justification for the prescriptions that were written, particularly the initial subcutaneous infusions of midazolam and diamorphine.

Q In terms, again, going back to the initial prescription, of the diamorphine and midazolam in relation to the lowest doses of those two drugs - in your view, acceptable or not?
A I cannot justify an eight-fold increase in the change from oral morphine to diamorphine and, in addition, the prescription of a very high starting dose of midazolam.

Q Perhaps it goes without saying that in terms of the width of the prescription - is that acceptable in your view or not?
A The width is within the two-fold I said might be desirable, but the problem here is the starting dose for both drugs is excessively high and was likely to produce significant adverse effects, and appeared to do so in terms of his rapid deterioration, in terms of his conscious level, and then within 12 hours of commencing the infusions.

Q There is a specific charge relating to the prescription on the 18 January, adding 50 mg of Nozinan to the other drugs already prescribed. The suggestion is that that was excessive. In your view, was that an acceptable prescription, to add the Nozinan at that stage in combination with the other drugs or not?
A It goes against guidance. You should not give two antipsychotic drugs at the same time. I think it was reasonable to switch from haloperidol to Nozinan if haloperidol was not controlling symptoms, but not to give it in addition, particularly with the other drugs. I think this was a difficult area. This was a man who was dying and we are talking about what level of attention and care to adjusting his drug treatment for palliation are we expecting to see consistent with *Good Medical Practice*. That is the issue and I have laid out the areas where I think it was not consistent with *Good Medical Practice*.

Q The last question I want to ask you and it may be particularly relevant to this patient, so I will ask it now. Then perhaps we can take a break. It is the principle of double effect. Can you just tell the Panel something about double effect?
A The principle of double effect is that one may need to palliate symptoms, and that the treatment one needs to give to palliate symptoms may lead to a shortening of life through adverse effects. That is well accepted as being a reasonable and appropriate aspect that may happen when one adequately palliates symptoms. One has to give drugs and doses that are reasonable and appropriate to palliate symptoms. Then, with certain groups of drugs like

A sedatives the issue is giving excessively high doses which have an effect which go beyond what the patient needed to palliate their symptoms.

MR KARK: That is all I am going to ask you about Patient A at this stage. I wonder if that would be a good time for a break. We are moving on to Patient B. I would like, if it is possible, to get started on Patient B if the Panel have the energy to carry on, but it will take twenty minutes to half an hour of reading first. I am therefore in your hands. Alternatively,
B we could start slightly earlier tomorrow morning. I am just aware of how much there is to get through.

THE CHAIRMAN: I am just thinking of when the Panel started to because although we were flagged for a ten o'clock start, in fact all the Panel were working at nine on pre-reading. They have put in a fair bit already.

C What you are proposing is a break now, and the time that they would need to prepare for Patient B, and then to start Patient B?

MR KARK: I can see that is not getting a huge amount of positive support.

THE CHAIRMAN: There does not appear to be, no.

D MR KARK: I am totally in your hands, but perhaps the reading could at least be started this evening so we get a fresh start tomorrow morning.

THE CHAIRMAN: I think we will say that we will start tomorrow at the usual time of 9.30, but by that time the Panel will have pre-read the Patient B elements, both in terms of the new chronology, if we have it, and certainly Dr B's statement, so it will be a clean start from everybody else's point of view.

E

MR KARK: May I hand up the new chronology?

THE CHAIRMAN: Yes, please. We are going to receive that now, ladies and gentlemen, and in the usual way simply place it in the appropriate Panel bundle so it does not require an exhibit number. (Document distributed)

F MR KARK: Professor Ford understands that even though he is an expert, I am not now allowed to talk to him. At the moment I do not intend to, in relation to the new expert report that we were given.

MR LANGDALE: Sir, may I make it clear. If the need arises, I have absolutely no objection to Mr Kark talking to his expert.

G THE CHAIRMAN: That is very helpful. Thank you very much indeed, Mr Langdale and Mr Kark. Professor Ford, you have noted that.

Ladies and gentlemen, we will formally break now until 9.30 tomorrow morning please. Thank you very much.

(The Panel adjourned until Tuesday 7 July 2009 at 9.30 a.m.)

H