GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL (SERIOUS PROFESSIONAL MISCONDUCT)

Wednesday 29 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 THIRTY-FOUR)

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.
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THE CHAIRMAN: Good morning everybody. Mr Jenkins?

MR JENKINS: I know that a problem has arisen with the Panel secretary. We had anticipated there might be a slight delay but, obviously, things go seamlessly as always; I should have known better. I am going to ask for 10 or 15 minutes. I am hoping to call a witness first thing this morning. I have raised certain matters with Mr Kark and, indeed, with your Legal Assessor. We were having a discussion about certain legal matters which we had not quite concluded when the Panel came in. I am going to ask for 10 or 15 minutes so we can finish that discussion. It may be things can move on smoothly after we have had that time.

THE CHAIRMAN: I am wondering how firm that time is likely to be. In other words, whether the Panel should remain in or should we wait to be called in.

MR JENKINS: I would take your ease as they say. You will have made your own judgment yesterday about my time estimates and the reliability of them.

THE CHAIRMAN: They are no worse than mine!

MR JENKINS: Mr Kark is laughing. When I said to you I would be 15 minutes with a witness, Mr Kark says I was half an hour, so when I say it will be 10 or 15 minutes it may be better for the Panel ---

THE CHAIRMAN: Very well, we will rise now and we will return when we are told that you are ready for us.

(The Panel adjourned for a short time)

MR JENKINS: We have had some discussions. I am not going to pursue matters with that witness now. It may be there will be legal argument about that witness at a later stage. We have asked the lady to go home.

MR LANGDALE: The next witness to be called is Dr Sikora. He is sitting at the back of the room and I will call him forward now.

PROFESSOR KAROL SIKORA, Sworn

(Following introductions by the Chairman)

Examined by MR LANGDALE

MR LANGDALE: I announced you as Dr Sikora, but I think it is Professor Sikora. Is that correct?

A Correct.

Q Your first name is Karol – K A R O L?

A Correct.

Q I would like you to tell the Panel your qualifications, medical and otherwise.
A I qualified in 1972. I pursued a career in oncology, cancer medicine. My longest job was Professor of cancer medicine at Hammersmith Hospital where I have been for 23 years. I am now Medical Director of a joint venture between the NHS and the private sector, Cancer Partners UK.

Q Forgive me for interrupting, would you, first, just give your qualifications and then I will go through the history in a moment.
A My qualifications are BA from Cambridge; MBBCh Cambridge, having done that at Middlesex Hospital; MRCP which became FRCP; FRCR which is Fellow of the Royal College of Radiologists to learn radiotherapy; I am also a Fellow of the Faculty of Pharmaceutical Medicine at the College of Physicians.

Q Medical Director currently of Cancer Partners UK?
A Correct.

Q What are Cancer Partners UK?
A It is an interesting joint venture between the private and public sector to improve capacity in cancer services around the UK, both radiotherapy and chemotherapy.

Q Is it right that you were Professor and Chairman of the Department of Cancer Medicine at Imperial College School of Medicine?
A That is correct.

Q I think you are still a consultant oncologist at Hammersmith?
A I am. I spend one day a week running clinics at Hammersmith.

Q Is it also right that you run a Chair of Scientific Advisory Board of Source BioScience Plc, which is one of this country's leading diagnostic companies?
A That is correct.

Q I think you have said something about this already in your evidence – are you Dean and Professor of Medicine at what is this country's first independent medical school at the University of Buckingham?
A That is correct.

Q Also a Fellow of Corpus Christi, Cambridge?
A Yes.

Q I think you have indicated that you studied medical science and biochemistry at Cambridge, then after clinical training where was your first post at a hospital?
A My first consultant post was at Cambridge Addenbrooke's Hospital, where I was a consultant oncologist for five years.

Q After your training had you been, initially, a house physician at the Middlesex?
A Yes.

Q And then a registrar in oncology at St Bartholomew's?
A Yes.

Q You were then a research student at the MRC Laboratory of Molecular Biology in Cambridge?
A Yes.

Q You then obtained your PhD and became a clinical Fellow at Stanford University in California before returning to this country to direct the Ludwig Institute in Cambridge, so back in Cambridge again.
A Exactly.

Q As you indicated, you were a Clinical Director for cancer services at Hammersmith for 12 years. Is that right?
A Correct.

Q Involved in the setting up of a cancer research laboratory. Is that right?
A Correct.

Q Also chairing Help Hammer Cancer, an appeal, which raised a certain of amount of money, in terms of millions, towards the construction of a new cancer centre at Hammersmith?
A That is correct.

Q Just dealing with remaining matters, Deputy Director of Clinical Research of the ICRF?
A Correct.

Q From 1997 to 1999, Chief of World Health Organisation, WHO, cancer programme?
A Correct.

Q From 1999 to 2002 Vice President of Global Clinical Research Oncology at the Pharmacia Corporation?
A Correct.

Q I am not going to ask you all the detail, but I think you have published a number of papers and written or edited a number of books?
A Correct.

Q Are you also a member of the UK Health Department's Expert Advisory Group on cancer?
A Yes.

Q The Committee on Safety of Medicines?
A Yes.

Q Do you remain an adviser to the World Health Organisation?
A Correct.

Q I think, Professor Sikora, you prepared a report in connection with issues in this case?
A I have.

Q I am going to ask you, first, about the material that you have had the opportunity of seeing, in the sense of it being provided to you one way or another. I think you have reviewed the notice of inquiry, that is Fitness to Practise Panel hearing notice of inquiry setting out the allegations against Dr Barton?
A I have.

Q You also had the opportunity, although I am not going to ask you about it, but you saw the Commission for Health Improvement or CHI report material?
A I did.

Q Which was back in 2002. You had the opportunity of reading the reports of Professor Ford?
A I did.

Q Have you also had the opportunity of reading transcripts of the evidence he has given to this Panel?
A I have.

Q You have also had provided to you the general police statement, as we have called it, of Dr Barton herself and you have also seen the statements she made with regard to twelve patients?
A I have.

Q It follows that you have seen statements that she made with regard to all twelve, nine of which I think were police statements prepared for the assistance of the police. May I also ask you, in terms of material that you have seen, you have seen transcripts of her evidence?
A I have.

Q Sir, I am going to ask a number of questions in leading form, simply to establish what it was this witness understood the position to be. It is all factual, it is not asking his opinion. I am trying to take you through certain matters of which you became aware with regard to the history of this case. On the information you have been able to gather from what you have seen and so on in terms of Dr Barton, you understood, you cannot give direct evidence for this, that she had been contracted as a clinical assistant for four to five sessions a week at the Gosport War Memorial Hospital?
A Correct.

Q We are familiar with the dates, 1988 to 2000. The hours, as you understood it, were flexible to allow her and her general practice to provide 24 hour cover to the patients at the hospital?
A Yes.

Q A total of 40 plus beds, I think it may have a total of 48 all together, designed for the long term care of elderly patients?
A Yes.

Q As you understand it on the information you have been given, the nature of the clinical case mix changed during the 1990s to include patients transferred from the acute sector for rehabilitation?
A That is my understanding.

Q As you understand it, no increase in medical or nursing time and no enhancement of social services, physiotherapy, occupational therapy or support staff to help to meet that new function?
A That is correct.

Q Is it your understanding that Dr Barton worked as a part-time GP locally with a personal list of something like 1500 patients?
A That is correct.

Q Furthermore, I am going to ask you more about what your understanding of the matter was because it will assist the Panel in terms of understanding the basis of your opinion about certain matters. Was it your understanding that Dr Barton had no specific training or postgraduate qualifications in internal medicine, care of the elderly or rehabilitation?
A That is correct.

Q In your experience is that normally the case with clinical assistant posts?
A That is the purpose of a clinical assistant.

Q Work, as you understand it, was supervised by two consultants initially, Doctors Lord and Tandy, with Dr Reid replacing Dr Tandy at some point in 1999?
A That is correct.

Q On your understanding those consultants all have major clinical responsibilities elsewhere and their contribution to the care of the Gosport patients was apparently limited to a weekly ward round which did not always take place?
A Correct.

Q Again, the Panel will have heard evidence about this but that is your understanding about the position. You were also informed about Dr Tandy being away on maternity leave from some point in the late 1990s, I think in April 1998, and the Trust made the decision not to provide any full-time locum cover for her until she returned in February 1999?
A That is correct.

Q We have heard evidence from Dr Tandy about it. You were also given information about Dr Barton's habitual work pattern – I am not going through it – the morning visit, returning not necessarily every day but around about lunch time to deal with the new admissions, clerking in and so on and then an evening visit depending on the needs of relatives and so on?
A Correct.

Q You were given the history about that?
A Yes.

Q You were aware of the evidence that Dr Barton raised the problem, or the difficulties, with increasing work load with more than one person, but no changes were implemented?
A That is correct.

Q Was it also your understanding, and the Panel have heard the evidence, that at no time during her twelve years at Gosport were any changes suggested to Dr Barton in relation to her mode of work, prescription habits or her abbreviated style of note keeping?
A Correct.

Q You have read the evidence that there has been in relation to her rapport with the nursing staff, which appears, so far as you can judge it, to have been excellent?
A It does.

Q What is your view in terms of the material you have seen as to whether it was effective or not in terms of the way her unit dealt with a pretty large patient volume with the staff that were available. What was your impression?
A My view, based on my experience as a clinical manager at Hammersmith including palliative care, is that the work load changed, the pattern of patients changed over a decade and although the staffing may have been suitable at the beginning of the decade, by the end of the decade the patient flows had changed, the dependency on nursing care had changed, but the staff had not changed in numbers.

Q In terms of criticisms of Dr Barton's work, is it right that you have summarised the common themes in the allegations against her as being – in relation to the fitness to practice allegations themselves, they can be summarised as being – that the lowest doses in the sliding scale of her prescriptions for diamorphine and midazolam were too high?
A Correct.

Q That the dose range was too wide?
A Correct.

Q Are you aware of the fact that Dr Barton has accepted, not in every case but in a number of cases, the dose range in the 20 to 200 mg range was too wide?
A Correct.

Q That the prescription created a situation whereby drugs could be administered but were excessive to the patient's needs, adequate assessment of patients was not made and properly recorded and, again, are you aware of the fact that Dr Barton has accepted that her recording, her note keeping and other recording, was not as it should have been?
A I do.

Q Also an allegation that advice from a senior colleague was not obtained when patients deteriorated?
A Yes.

Q In terms of Professor Ford's report, which you have considered and you have read transcripts of his evidence, you are aware of the fact that he looked at the generic issues around the use of pain control medication?
A Yes.

Q What is your view as to the only way to judge accurately a patient's needs for analgesics?
A The only way is to be with the patient and see what happens after a given dose of an analgesic that is given. The teaching in the World Health Organisation when I started ten

years ago is very much doing things by the drugs; in other words where in the ladder of analgesics, strength of analgesics, you start; by the route, whether it is by mouth to start with or subcutaneous injection by infusion; by the clock, to avoid periods when the patient is in pain because the level of analgesic has dropped, and by the patient. The teaching is very much "by the patient" is the most important thing. So without seeing the patient, without looking at detailed notes, which are often not recorded in people that are terminally ill, it is impossible to make a judgment unless you were there.

Q Just going back over that, that sequence you have just dealt with in terms of the World Health Organisation approach, number one the drug?
A Correct.

Q What are we thinking of there?
A There are several drugs, increasing in strength, to get rid of pain. The WHO twenty years ago constructed what is called the WHO pain control ladder that is widely used round the world, especially in countries where there really is not much active treatment because of costs. The ladder is to begin with a mild analgesic – paracetamol, aspirin; to go to a middle analgesic, dihydrocodeine, for example, and then to go to an opiate such as morphine and diamorphine. That ladder is a way of getting the right drug in a sequence that is logical, to teach doctors and nurses to give a logical sequence for pain control.

Q Would you look please at a file marked "1", in the collection of files to your left, in those boxes. Would you look, please, in file 1 at tab 4. In tab 4 we can see it contains a photocopy of something called the *Palliative Care Handbook*, which was something that was available at Gosport and other places as well known, I think also, as the Wessex Procedure. Look, please, at page 5 in tab 4. We can see there mention of the WHO analgesic ladder?
A Yes.

Q Without troubling about the detail, is that the same thing, in effect, as what we were just talking about?
A The same one.

Q Thank you. That was the drug. We dealt with that. Then the route was the next thing itemised.
A The route – the most convenient route – for most patients is oral but some patients cannot swallow and sometimes the oral route is not adequate because they start vomiting because of the side effects of the drug. The next way to do it would be parenteral injection, which means injecting something under the skin. That could be subcutaneous, it could be intramuscular. Over the last twenty years the availability of subcutaneous pumps, relative cheaply, has meant that one can give 24-hour infusions, which give a much better pharmacological distribution of pain-killer drug, and therefore better pain control, over a longer period of time.

Q Does that bring us onto the clock, which was the next in the sequence you were citing?
A By the clock is the idea that you do not wait for the patient to complain. In every healthcare environment all over the world there will be a delay, even if the patient has one-to-one nursing, which is a great luxury. In most environments, patients do not have that, and therefore giving drugs by the clock means that you do not allow the analgesic level in the blood to drop to a level where the pain comes back and the patient is suffering, maybe for an

hour or two hours, but intermittently. It is not just one or two hours. It is every few hours the level drops, and they start suffering. So "by the clock" is a way of teaching healthcare workers to avoid that trough in level, and therefore the pain.

Q Then you said "the patient".
A That is the most important. A patient's pain is judged by what they say it is. No one else can judge pain. Obviously if someone is completely well and they say they are in severe pain you want to work out why, but if a diagnosis has been made of the cause of that pain or distress – and it can be caused by multiple factors, especially in the elderly – then you want to make sure that the patient has enough drug by the right route to get rid of that pain.

Q We may have to come back to it later, but may I just ask you in the context of what you just said about material in relation to which the Panel have heard quite a lot of evidence. As you are aware, no doubt, from read the transcripts, reference has been made to the BNF?
A Yes.

Q Principally the *Palliative Care Handbook*, and so on, all of which set out particular matters with regard to, and we are focusing here obviously on analgesics.
A Yes.

Q They set out dose ranges, what the drugs can and cannot do?
A Yes.

Q What are possible adverse side effects and so on. You will obviously be familiar with all this?
A I am.

Q But in relation to patients who are reaching, or who are on, what has been described in the context of this hearing as a terminal care pathway is anything set out in any documentary material of which you are aware as to how much? In other words what sort of dosage and at what rate the patient should receive when they are on a terminal care pathway?
A There is no literature or guidelines on the actual doses because it is so patient sensitive. It is the individual patient who has to be judged there and then. There is no other way of doing it, so certainly in the WHO teaching literature, there is nothing about the absolute level at which to do things.

Q As you know, in relation to Professor Ford's report and his evidence, he was examining issues with regard to wide dose ranges, use of PRN prescriptions, drug combinations and the use of subcutaneous infusions and the use of anticipatory prescribing?
A That is correct.

Q We will come back to those, in some respects, later. Obviously everybody is proceeding on this basis and I think you are proceeding on this basis. The responsibility of Dr Barton as the physician responsible for Gosport War Memorial Hospital on a day to day basis, her responsibility lay in relation o all of those issues?
A Yes.

Q They are matters for her to deal with?
A Yes.

Q But as you are aware, and Dr Barton was only one member of a team?
A That is correct.

Q We will come back to that in due course.
A Did you find in relation to Professor Ford's report and evidence on these wider issues, that he had really addressed the question as to whether there was any practical solution for the circumstances that Dr Barton found herself in in that period?
A I could not find the practical solution. I think Dr Barton was using various recipes because it was the only practical solution to the situation she found herself in.

Q Again, we can come back to that in some more detail. What was your view as to what degree Professor Ford addressed the wide, individual variation between patients with regard to opiate needs?
A You must not base that on the actual patient data because there was no patient data presented to consider. Therefore "by the patient" was not being considered in that. I think also the dose ranges presented were from 20 to 200 mg per 24 hours in the pump, but of the 12 patients only one got above 100 mg.

Q I think it was broken down for you, and you set it out in your report, that the ranges were 120 in terms of the twelve the Panel are considering – that is in one instance, Patient A, and then the variation was 100, 90, 80, 60, 40, 30 and 20, in terms of the maximum amount of diamorphine that was being received by the patient at the time of their death?
A That is correct.

Q In relation to those – we have heard these figures before – in two the maximum was 20; in one the maximum was 30; two, maximum 40; two, maximum 60; two, maximum 80; one at 90 and one at 100, in addition to the 120 we referred to?
A Correct.

Q Would you help, please, with regard to this question in individual variation between patients to opiate need in your experience?
A It is very complex. There are multiple factors. First of all, psychosocial factors – people that are disturbed in unfamiliar environments feel more pain than if they are in a more relaxed environment – the availability of skilled nursing care and close relatives able to help reduces the need for analgesics. Then there are pharmacological factors: the fact that the patient may be metabolising the drug in different ways, partly because they have other disease problems, such as liver and renal problems, and also because there are different kinetics in how each of us as individuals disposes of morphine-like drugs. So there are many, many factors that play, and that is why the teaching is "Look at the patient and see what happens," rather than use any pre-conceived dosage or formula.

Q In terms of care for patients, we have heard evidence about this to some degree already. Does one have to look at the question of how is a patient best cared for by considering different aspects of care. We have heard about – and you have indeed just referred to, as it were – psychological support?
A Correct.

Q The importance of good nursing care?
A Yes.

Q And obviously drug therapy to relieve anxiety, distress, pain, whatever it might be?
A Correct.

Q Where does the balance lie? Is it impossible to say where the balance lies between those aspects of patient care in relation to the type of patient we are considering in this hearing?
A It is very difficult, and certainly in elderly patients it is much more difficult because they may not be able to communicate exactly what the problem is in the way a younger patient may be able to.

MR LANGDALE: I am going to ask, with some hesitation, that the Panel receive a document. My learned friend Mr Kark has seen it. It is not a document prepared by Professor Sikora himself. He has seen it. It has been prepared by those instructing me and it is an attempt to show by way of a chart that the level of morphine which a patient will receive if it is administered subcutaneously. It is not absolutely mathematically precise, and the Panel will see that it has been divided into two charts. One shows the picture if the half life of the morphine is two hours; the other shows the picture if the half life of the morphine is four hours. The Panel have heard a certain amount of evidence, in particular from Professor Ford, about the sort of level you would expect the morphine seemed to have peaked at, and so on, in the course of the evidence you have already heard. I am putting this in with the agreement – and I am grateful for it – of counsel for the GMC, simply to assist the Panel to get an idea. It is not set in stone, and I am going to ask Professor Sikora to deal with it in very general terms. I wonder, sir, if those documents could be put in.

THE CHAIRMAN: They will be D7.

MR LANGDALE: Thank you very much. That is D7. D7a will be the two hour one, and D7b for the four hour one, perhaps.

THE CHAIRMAN: By all means.

MR LANGDALE: Perhaps Professor Sikora could also have a copy. (Document marked and circulated) Sir, I stress, this is not his document. (To the witness) Professor Sikora, I am going to invite you to look at this with us and ask you some very general questions about it.
A Of course.

Q We are looking at subcutaneous infusion of diamorphine. Both of these charts are headed "Diamorphine Blood Levels" on the assumption that it is a dose of 20 mg subcutaneously over 24 hours. First of all 7a, with a two hour half life; secondly, 7b, a four hour half life. Looking first at 7a, the way in which this document has been set out shows on the left hand column the hours. In other words, after hour one – at the top on the left – 0.83 mg has (in my words) gone into the patient?
A Correct.

Q So at the end of an hour, it is 0.83, assuming a two hour half life. The rest of the plan sets out the figure you reach after each one of the hours up to and including hour eleven after administration?
A Correct.

Q If it is a two hour half life we can see how the amount of morphine in the patient, allowing for the fact that at each stage you have to take into account the remaining morphine from the previous infusion and how it declines. On the right hand side you have the amount, so after two hours, 1.46 and so on. Then, after eleven hours it reaches the peak that at any one time would be in the patient's body, 2.86?
A Correct.

B Q I am told Mr Barker has rounded up these figures to avoid any kind of misleading impression. Looking at the position with regard to the four hour half life, 7b, the same method has been used, and we can see that in relation to the first hour the same amount has been received by the patient, but as you go on, if you assume a four hour half life, the amount in the patient's body is in general terms higher?
A Yes.

C Q Because the morphine is there (again in my words) for longer?
A Correct.

Q On this particular exercise, again staying with the 20 mg over 24 hours, after 21 hours the peak has been reached of 5.32?
A Correct.

D Q This is just an exercise to try and demonstrate a general picture. It is not meant to be, as I say, a certain standard, but in general terms without your having checked the figures – they are not yours – is that the sort of view or understanding we should have with regard to the way the morphine gets into the patient, stays there and eventually declines?
A Yes. It is a good teaching exercise on the value of a subcutaneous pump rather than intermittent injection, where you would have peaks and troughs. Peaks may have an overdose of morphine or diamorphine, and a trough where you get breakthrough pain. With a
E subcutaneous pump you reach a plateau and you can see with the two hours you reach the plateau actually at about the fifth or sixth hour. There is very little rise from 2.41 up to 2.86. With the four hour half life patient, you see you reached the plateau when you get to about 13 hours. It really goes up very little from then.

Q So in the case of the four hour half life plateau it is reached more or less after thirteen?
F A Correct, yes.

Q And the lower figure for the two hour half life. Thank you for dealing with that. I am going to ask you a little bit more about your area of expertise, and about your experience with regard to palliative care generally. As you set out in your report, your area of expertise is cancer medicine?
A Correct.

G Q And you have been a consultant in that discipline for getting on for 30 years.
A I have.

Q Does that experience of yours include the palliative care of elderly patients suffering from cancer?
A It does. The majority of patients with cancer are elderly and palliative care is,
H unfortunately, necessary for many patients.

Q As you have already indicated you have worked as a consultant at two teaching hospitals, Addenbrookes and also the Hammersmith Hospital.
A I have.

Q You have obviously had appropriate support from more junior colleagues.
A I have.

Q It is also right to point out that you yourself have never had to practise in an isolated clinical environment.
A That is the case.

Q So you have never been in the same sort of situation as Dr Barton for instance.
A No.

Q When you were clinical director for cancer services between 1986 and 1998 at the Hammersmith Hospitals NHS Trust did that include the management of the palliative care services?
A It does. We created a palliative care position among the consultants and, with the local hospice, we developed palliative care as a separate sub-specialty within our department.

Q It may be that one will have to draw some distinction between the palliative care of cancer patients and patients who are not suffering from cancer. We can come on to that later and it may be an issue which will be explored with you, but I just want to ask you about this: in terms of the whole concept of palliative care – and your experience in this particular field obviously embraces the period of time that the Panel are concerned with in this hearing, the 1990s – can you give us a thumbnail sketch as to how you saw it in terms of palliative care either originating in hospices or whatever it might be; a little picture of how things have developed?
A When I began in cancer medicine as a registrar there was really no palliative care. It developed in London at St Christopher's Hospice and migrated around the UK, both in hospitals and in community settings, together with charitable support from the Macmillan Fund, which was one of the major drivers of the palliative care movement. Today it has changed beyond all recognition. Initially it was just for cancer patients, now the protocols and the way in which the teaching is given applies to all situations including a common pathway of terminal decline which happens in all diseases, so the lessons from cancer have been applied right across the board. Currently there are major forces trying to get palliative care more into the community; the current Government has an initiative to allow people to choose where they wish to die, and that is a very challenging effort, whether they wish to die at home or in a hospice or indeed in a hospital. It is difficult to implement because obviously it costs money – it is not about drugs necessarily, it is about staffing to make sure that people can die in the home, for example, which is much more consuming of staff time.

Q May I ask you this, again in general terms: is there any significant difference between the approach to be adopted in palliating symptoms of pain, distress, agitation and so on – again, my words because we have heard different labels such as terminal restlessness and so on – in patients who are suffering from some form of cancer and patients who are suffering as a result of some other problem such as illness, comorbidity, whatever words we use?
A I personally do not think there is and I think it has been very tragic that it has taken our profession so long to recognise that. The lessons from cancer, where palliative care has

really been developed, are now being applied across the board to all terminal phases of illness and, indeed, hospices are opening their doors now to non-cancer patients for the first time. I suspect the origin of this is that cancer is thought of as an incurable illness; many other diseases are not thought to be incurable and that was the reason for that distinction. A terminal pathway is a terminal pathway by definition.

Q We have heard evidence that certainly for a period in the early 1990s a nurse or two or three nurses at Gosport War Memorial Hospital were concerned about subcutaneous analgesia, in particular diamorphine, being administered to patients who were not cancer patients. There was a concern of that kind or at least a thinking process of a similar kind elsewhere was there?
A There was.

Q We heard evidence from Professor Ford who said in relation to Patient C – Eva Page, the lady who was suffering from the carcinoma of the bronchus – that in his view it was acceptable and appropriate to prescribe and administer opiates to relieve anxiety and distress, whereas he certainly seemed to be indicating at other parts of his evidence, as you may have read, that in his view opiates such as diamorphine should be administered simply for the relief of pain. What do you say about that?
A The only way to decide is to judge it by the patient. Diamorphine is a valid drug for people in severe distress and various other indications, not just for pain, but it has to be a clinical decision, done on the spot.

Q It is right to say that he accepted that there was a body of opinion which might hold the same view as you just expressed in the country at large. In looking at your consideration of the position Dr Barton was in, did you go on the basis that when she took on the job in the first place it was on the basis that she understood it would be a commitment which could initially be managed within the time constraints of her comparatively limited sessions?
A That is what I assumed.

Q And as you have already indicated you proceeded on the basis – I do not think there is any dispute about this – that the nature of the clinical workload at Gosport changed very significantly as the 1990s moved on.
A It did.

Q In terms of what you have seen of the evidential picture in this case, what do you say about the adequacy of clinical consultant support provided to her?
A Dr Barton was, however competent, untrained in any specialty other than general primary care, general practice, and the patients were managed by a named consultant. There would have been on the notes, maybe even above the bed, the name of that consultant. That is normal practice throughout the world. The consultant was responsible for patient care. My understanding is that the consultant ward round was once a week, sometimes once every two weeks, and for a period when there was maternity leave not at all – for nine months presumably. Clearly there was a system problem in terms of consultant monitoring of patient care. It may be acceptable if it really is a nursing home type of atmosphere with just long term admissions with no changes, but certainly towards the end of the nineties that was not the case. These people were being discharged from neighbouring acute hospitals with serious medical problems and it would imply there should be consultant cover almost on a two or three day a week basis.

Q Similarly with regard to the evidential picture presented to you, did the staffing model at Gosport continue on the basis of low dependency care of elderly patients or did it in any way change as a result of the change in the patient mix?
A I only changed after the various investigations; until then there was no change and there was no change in the back-up professionals such as occupational therapy, physiotherapy, radiology and so on.

B Q If that is the right evidential picture I would just like to ask you about the situation that is created as a result for those concerned with trying to care for patients of this rather different kind. It is a truism perhaps for us to state, but perhaps one would make it clear with you, that obviously drugs form an important part of good palliative care. There is no dispute about that.
A Yes.

C Q In the context within which we are operating in this hearing there are drugs to control pain, anxiety and distress – I will use those three labels as being convenient shorthand ways of describing it. What about the importance of good nursing care, what would you say about that?
A Good nursing care is vital in this situation and obviously it allows not only psychological care for the patient but also the monitoring on a regular basis of what is happening and therefore there is an inter-relationship between drug therapy and its
D monitoring and the availability of staff.

Q What is the consequence, therefore, in terms of the practicalities as to what is to be done with any particular patient or patients within a particular category. What are the practical consequences if nurses are trying to provide good care, the clinical assistant is trying to provide good care, but the ratios and the resources are as you understand them to be? What is the practical consequence?
E A If we take the relationship between nursing care and drug therapy there is no doubt in my mind that if the availability of nursing care is low and there are few nurses for many patients, then in doing the prescribing you are going to have to start at a higher dose and have a sliding scale to allow decisions to be made quickly. There also was not medical cover as far as I can see, the medical cover was inadequate, and therefore the idea that you could call a doctor and get action within a three or four-hour time period was unrealistic in the set-up as described in the various documents, so the nursing, medical and drugs all are intertwined.
F

Q You say the impact in terms of what the doctor is going to prescribe and have administered in terms of drugs is going to be affecting the doses. How do you square that with what is in the patient's best interest?
A The idea is to write out a prescription that can be delivered with freedom to the clinical observer at the time; in other words it does not require someone to be called from the other side of Portsmouth to come and make the decision, the people on the spot – who
G inevitably were the nursing staff – could make a decision about what to do. That is the attraction of having a sliding scale and a subcutaneous pump, it allows the person on the spot to take the clinical decision, looking at the clinical parameters and make their own decision. Of course, different people, different staff, will come to different conclusions, but at least they can do what they think is the best for the patient.

Q Are you aware of the evidence from the nursing staff – although their evidence varied
H to some degree – about the practice of seeking approval or consent or authorisation (whatever

the right word is) from Dr Barton, in default of her from an on-call doctor, in relation to decisions of that kind?
A I am, and that seemed an eminently sensible way to approach it. If Dr Barton was there she knew all the patients so she could guide the decision. If she could not be contacted someone in the practice who was on call could be contacted, but they would not know the patient so inevitably – and certainly in my experience – you would go with whatever the nurse was asking for, unless there was some special reason not to. The third way is that the nurses make the decision on their own if they could not get hold of anybody.

Q Just looking at it as a matter of practicality, if you had got full resources – say in a teaching hospital – in terms of the administration of analgesia of the kind we are talking about, what is the best picture? Assuming you have got the resources what do you try to do with regard to administering opiates?
A If you have got a patient who is in distress what you really need is to assign much more nursing time – maybe not one to one but getting towards that level. In a teaching hospital there may not be a resident doctor but there will be someone on call 24 hours a day who could come and change the prescription if necessary, so the combination of being able to change the prescription 24 hours a day, to have a doctor there 24 hours a day if necessary and to have good nursing care available, very frequently making observations, is a luxury that was not available, from what I have read, at Gosport.

Q If the luxury is available does that have an impact on whether it is appropriate to titrate doses up? Just give us the picture with regard to what you would do if you had all those resources available.
A If you have all the resources available and you are able to titrate things in real time you do not need to leave a blanket prescription, you can just change it as you go. If the resources are not there you have to leave a wider range to allow whoever is there to adapt to the circumstances the patient finds themselves in.

Q If you have not got the resources to titrate up in steps, say after every four hours checking and so on and so forth, what is appropriate in terms of the initial dose if your objective is to prevent pain or to control pain?
A In terms of diamorphine I would say at least 20 mg to start with.

Q I will come on to that in a moment; so that may be affected by the practical situation you are in.
A Absolutely.

Q Apart from relieving the distress of patients, if you are operating in the sort of circumstances that Dr Barton was operating in, what about the distress of their relatives or close family?
A That can be very distressing. It is part of therapy – one treats the patient but one is treating the whole carer group as well and to see an older person who may be severely demented, suffering because of some physical illness as well, and disturbing the family is profoundly unpleasant. Doing something about that is part of good practice.

Q You have seen the general picture – I am not asking you about individual patients – with regard to opiates being prescribed with quite wide dose ranges and with, as I think you described it, an effective minimal dose.
A Correct.

Q We have covered the picture with regard to what discretion the nursing staff had in relation to the administration of these drugs but in terms of your experience of doctors involved in palliative care teams, do they all share one philosophy in relation to the actual level of the starting dose of diamorphine?
A Absolutely not. In cancer medication the drugs for cancer are rigidly adhered to around the country. If you have 100 oncologists they will be using the same drug dose. If you go to palliative care it is much more subjective how you do palliative care and there is much greater variation between different palliative care physicians about the starting dose and the scales that they use.

Q Can I come back to something you mentioned a moment or two ago in relation to a starting dose with diamorphine. I appreciate different patients and different situations but in general a starting dose of diamorphine of, say, 10 to 20 – or 20 as we have commonly come across in this case – what do you say about that generally speaking, bearing in mind it is subcutaneous delivery by means of a syringe driver over 24 hours?
A To me 20 mg seems a reasonable starting dose.

Q I would like to ask you about plasma levels of active drug achieved over a 24 hour period. What do you say about that in terms of the level?
A The plasma level – one is trying to achieve a level where one can get rid of pain over a smooth curve of 24 hours and the levels with 20 mg depend on how quickly the drug is metabolised, how quickly it is destroyed by the body. That is a variable and we have seen the two charts, the two hours and the four hours, which show that in both cases you inevitably reach a plateau.

Q In relation to the sort of plateaus, appreciating it varies from patient to patient and so on, but just looking at the broad brush picture, with those sorts of levels of morphine in the body would they be such as to be likely to lead to dangerous side effects? Just taking our 20 mg administration.
A Over a 23 hour period, even in an opiate naïve patient – someone that has not received opiates before – it would not lead to serious consequences in most patients.

Q Again, there is no dispute in the evidence in this case that whether a patient has been on some form of opiate before subcutaneous administration may affect, first of all, when you start subcutaneous analgesia and the amount that it is appropriate to administer.
A That is correct.

Q That, I think is a given in this case. It is also the case, as you will see from the pattern of the prescriptions, that the analgesia administered in the form of diamorphine, also on many instances had the addition of a sedative or tranquilising drug, midazolam?
A It did.

Q First, in general terms, anything unusual with patients falling into this sort of category in the administration of diamorphine and midazolam together?
A No, and indeed the BNF is quite clear. There are a series of drugs tabled there that can be given in the same syringe driver at the same time.

Q In terms of any other drugs that had been administered in the syringe driver in this case, haloperidol is one we have seen from time to time and also hyoscine?

A That is correct.

Q Looking at those.
A They can be mixed and the are used for different indications; haloperidol for people who are severely distressed and agitated depression, and hyoscine especially if the terminal event involves a lot of fluid gathering in the lung which is very distressing both for the patients and for relatives. Hyoscine essentially dries up the membranes of the lung.

Q In terms of the dose, the dose needed of an analgesic and an anxiolitic in relation to the dose, the amount, when considering the need to allay symptoms in the individual patient in general, is that affected by the increase that patients experience as a result of fear, isolation, unfamiliar environment and so on. Does that affect the dose that you think it is appropriate to administer?
A I believe it does and, basically, pain has multiple components and anxiety, distress and lack of familiarity increase fear. That fear means to get the same analgesic effect you have to give more drug. That is why cocktails of drugs, midazolam with diamorphine, are effective because one takes away some of the fear allowing the analgesic, where there is pain, to have a better effect.

Q So one has to be looking at the combined effect and the combined situation?
A Exactly, and the art of good palliative care is to make the decision as to what the key problem is to vary the doses appropriately.

Q In terms of patients who are on the terminal path, an expression that has been used in this case more than once – I am looking at your report on page 6, the third paragraph down – you deal with what you describe as dying patients. I would like you to deal with the question of the size of the dose that may be appropriate because, obviously, a given in this case, you do not have to worry about drug dependency with regard to a patient in that situation?
A One of the fears in giving opiates to any patient is that they will become dependent on the drug and you will have to wean the patient off the drug just like an addict. That does not apply to people who are dying, whatever the cause of that death. The only way to sort out the correct dose is to make individual patient assessments. Physicians who are not in palliative care, or indeed in oncology, tend to be very sparing on opiates and one of the problems in many general wards for surgery and medicine is that there are patients in serious pain even still, and palliative care education is one of the ways to try and deal with that.

Q You have already covered the point, and we have already heard it from other witnesses in this case, that pain and distress are enormously variable from patient to patient. We have heard about what the severity of the pain may depend on and you have covered that in your evidence. In terms of the causes of deterioration – you will have seen from the transcripts you have read that patients are described as deteriorating and so on – I am not asking about individual patients in this case but, in general terms with elderly patients with multiple sometimes comorbidities, what is the practicality in terms of the clinician endeavouring to establish the cause of the deterioration?
A In most of the situations where patients are deteriorating, especially if they are doing so rapidly, there is absolutely no point doing more investigations. At Gosport it would not have been possible to get urgent investigations, x-rays or blood tests and unnecessary to do so. Only good clinical decision making can really contribute and a clinical assessment on the spot by a doctor or nurse and a decision how to vary the drugs appropriately.

Q If I could ask you to deal with this issue in general terms. In terms of the doctor concerned, in this case obviously the clinical assistant Dr Barton, trying to determine what is the product or what is the contribution of the medication you are providing to control symptoms as to where the balance lies, how can you check whether you are right?
A The only way is to go back an hour, two hours, later and see what has happened. It is a continuous circle of monitoring and then varying the dose appropriately, changing the composition of the drugs in the syringe driver appropriately.

Q What do you say about the stopping of subcutaneous analgesia, first stopping it to check whether the patient is suffering more from their condition or more from the sedating effect of the drug or the respiratory depressive side of the other drug that has been administered?
A I think it would be very difficult to do that. It is very rarely done in any clinical situation when one knows the patient is on the terminal pathway. It would almost, to me, be unethical to make the patient suffer unnecessary pain in the last few hours or last few days of life by doing that experiment.

Q What about reducing to see if the pain breaks through again. What is the appropriate approach there?
A That is certainly possible, but on the whole a good clinical assessment would mean that it is unlikely that you get to a point in a dying patient where you start reducing the dose.

Q The reasons for that being unlikely with a patient who is on a terminal pathway?
A Because, inevitably, if you reduce the dose enough, you will get symptoms coming back and why would you want to see that?

Q In your report you dealt with the issue of, what I always mispronounce, parenteral fluids. I do not think it is an issue that the Panel is any more concerned with in terms of allegations in this case because it is clear that at Gosport they did not have the facilities to hydrate patients in that way and we have heard about the different views as to the propriety of trying to hydrate in these sort of circumstances. If anyone wants to raise the issue with you, no doubt you can deal with those questions but I am not going to ask you about it.

THE CHAIRMAN: Mr Langdale, the witness has been up for a little over an hour. Would that be a convenient moment?

MR LANGDALE: Yes, I do not have a great deal more, but it is more than five minutes.

THE CHAIRMAN: We will have a break now. You will be taken somewhere you can get some refreshment and some rest before you come back for further questions. I am going to say 15 minutes, 11.20am.

(The Panel adjourned for a short time)

THE CHAIRMAN: Professor, you of course remain on oath. Mr Langdale?

MR LANGDALE: Professor Sikora, I am dealing with matters which are contained on page 7 of your report. I have covered issues with you with regard to the combination of anxiolitics, such as midazolam and haloperidol with diamorphine and so on and I am not going to go over that material with you again. I would like to ask you about the practical

position. In a hospital with full resources, if a doctor is able, with the aid of nursing staff and so on, to give a much more closely monitored assessment of the condition of a patient than if the resources are rather more limited because of the practical consequences of lesser resources, if it is the case that a doctor with less resources, with the sort of resources that we are talking about at Gosport War Memorial Hospital, is aiming to control pain and distress symptoms to prevent the patient suffering from pain and distress and with any one possible dose range – just take a dose – at which to start the administration of subcutaneous analgesia or indeed the level to which it is to be increased, if there is no absolute set rule as to precisely how much should be prescribed, there is a variation, in terms of a doctor tending to go higher rather than lower within the possible or permissible range, what do you say about where the choices really lie?

A I would believe the choices lie between increased suffering if the dose is not enough, or increased suffering is the delay in which you can get someone to rectify the low dose to convert it to a high dose, or starting at a higher dose. If there is one to one observation, if there is a doctor on call who can change the prescription, it is a very different situation to what was happening in Gosport.

Q You have covered the position with regard to anticipatory prescribing which you touch upon in relation to the third paragraph of this particular page of your report, and I am not going over the procedure, you have already indicated what your understanding of it was. What effect does the reduction of staff levels proportionate to the increased and different patient mix, what effect does that reduction of staff levels in terms of the availability of numbers and time have on the choices available to a doctor in Dr Barton's position with regard to the pharmacological route?

A It means that there is not going to be the level of observation that would, perhaps, be optimal on an individual patient in distress and pain. Therefore, using the pharmacological route at a higher dose, starting dose and a higher upper limit, would seem a reasonable proposition under those circumstances.

Q Did you take on board the fact that so far as you could judge it – it is for the Panel to decide, not you, but as far as you could judge it – what Dr Barton was doing had the approval, certainly did not have the dissent, of the consultants, nursing staff and pharmacist?

A Absolutely, and there was no formal appraisal in those days and clinical assistants were exempt from appraisal until relatively recently so there was no mechanism of feed back, but there was tacit acceptance. The charts were written up and if a consultant does not look at the chart that is his responsibility in my mind.

Q Looking at the situation in general terms with regard to the general practice and the general procedure adopted by Dr Barton, taking into account the position that she was in – we have looked at the different aspects – what is your view as to what the alternatives were in terms of being available to her?

A She could live in the place 24 hours a day, that would be one alternative, or otherwise what she did seems to me perfectly reasonable. As I say in the report, it is a very vulnerable end of health care all over the world. It is a forgotten area, it is an area which not much is invested in; nothing to do with the NHS, it is throughout all health care systems.

Q Would you enlarge on that. You say "a vulnerable area" and isolated as it were, what do you mean by that?

A Isolated because geographically it was isolated from mainstream medicine. Junior doctors were not available to Dr Barton or the whole of Gosport War Memorial Hospital.

The patients had multiple comorbidities. Once they went into the terminal phase they were outside mainstream medicine. That is quite fair, they needed to be given symptom control in an environment which is not luxurious in terms of staffing.

Q You say this is a world wide problem. In relation to palliative care generally, do you mean?
A Britain has exported some of the finest palliative care regimens outside to the rest of the world, I think we have driven that. There is no doubt that palliative care all over the place is under resourced and terminal care particularly so.

Q Considering the position again, broad bush, what were the practicalities, apart from walking away from the job, for any doctor in terms of doing anything different to what Dr Barton did?
A Developing systems internally to try and cope with the problem, which I think she did; trying to lobby for more staff which, from reading the various bits of evidence, she did. One of the problems is that it was an outpost of the main Hospital Trust and, therefore, the management control did not seem to be clear how the place was being managed from the centre. How would you actually go about getting better resources and whose responsibility was it? I would say it was not the responsibility of a five session clinical assistant to have to do that.

MR LANGDALE: Professor Sikora, that is all I am going to ask you because were you not asked to look at the individual twelve patients and check all their records, and so on and so forth. Obviously you have seen material relating to them in your reading of the transcripts, but I am not asking you to go into individual cases. That is all from me at this stage. Would you wait there because you will be asked some more questions.

THE CHAIRMAN: Thank you, Mr Langdale. Yes, Mr Kark.

<u>Cross-examined by MR KARK</u>

Q Professor Sikora, I was going to start where Mr Langdale left off. That was to just examine with you what you have not reported on, as it were. So far as the material that you were given, I do not think you were given any of our patient notes, were you?
A That is correct.

Q So you have not actually examined the individual cases of those patients?
A That is correct.

Q In terms of what the Panel have looked at but you perhaps did not – and this is not criticism of you whatever – although you had Dr Barton's statements, the notice of inquiry, Professor Ford's reports, and you have read his evidence and her evidence – I do not think you were given the patients' relatives' statements?
A No, I was not.

Q The nurses' or the consultants'?
A I have seen the transcripts.

Q You have seen the transcripts – of whom?
A The consultants.

Q And the nurses?
A Some of them.

Q And the actual prescriptions that were written by Dr Barton. I know, obviously, you have seen the reports about them. You have seen what people said about them. Have you examined the prescriptions yourself?
A I have not examined the original prescriptions.

Q For that reason, quite properly, you have not sought in your report or your verbal evidence now to comment on the treatment of any of the patients?
A That is correct.

Q So far as your own practice is concerned, you are a cancer specialist?
A I am.

Q You are, if I may say so, a very well known cancer specialist. You would not class yourself as a geriatrician?
A No.

Q And obviously you deal frequently with people who are in the terminal stages of illness, do you?
A I do.

Q And have to be treated with palliative care or by palliative care?
A I do.

Q As you are probably aware, I think only one of our patients in fact had a carcinoma of the bronchus?
A That is correct.

Q Just thinking about the position at the Gosport War Memorial Hospital obviously you have not practised anywhere similar to that community hospital, or the like?
A I have been responsible for palliative care in a community hospital.

Q In a consultant role?
A No. In a management role.

Q As I think you commented in your report, there are various things one can say about the Gosport War Memorial Hospital. First of all, there seems to have been a lack of supervision over what Dr Barton was doing?
A That is correct.

Q It may well be that the consultants whom you have spoken about were not as available or indeed as active as perhaps they should have been?
A It is difficult to judge.

Q And you have also spoken about the changes in the nature of the patients in the latter half of the nineties. Just looking at that for a moment, that was a nationwide problem, I think. That is not restricted to the Gosport Peninsular, is it?
A No. It is ubiquitous.

Q That was happening, fortunately or quite possibly unfortunately, in community hospitals up and down the country?
A Correct.

Q And so people in Dr Barton's role – and her role, again, was not unique, was it?
A No.

Q The role of clinical assistant where a doctor would be visiting a community hospital and not there on a full time basis is – was – a very well known position?
A Correct.

Q And so people in Dr Barton's role would be having to deal with that sort of change nationwide in community hospitals, up and down the country?
A There would be local variation on the severity of the issue.

Q Absolutely. I absolutely take you point, and we all understand, that when a doctor is prescribing for a patient, and you have very much highlighted this, it is important obviously to observe the signs and symptoms of a patient?
A Correct.

Q And I think in your report you commented on the difficulty of going back through sparse, sometimes sparse, notes and then forming an opinion about the management of the patient?
A Correct.

Q I expect that you accept that there are circumstances where a prescription can be so obviously wrong, or a plan of treatment or lack of treatment can be so obviously wrong, that an expert is entitled to comment?
A Yes.

Q Because that, of course, is the nature of expert evidence?
A Absolutely.

Q So far as the issue of note-making is concerned, you have not commented on it particularly but, again, the vast majority of doctors working in a hospital environment, particularly one suspects in the NHS, would describe themselves accurately as very busy?
A Yes.

Q And quite possibly overworked?
A Possibly.

Q And perhaps particularly geriatricians?
A The numbers of patients involved are large.

Q And although we know that doctors are taught to make notes about everything that they do, it is not always possible?
A No.

Q Some notes, I expect you would agree, are rather more important than others?
A They are.

B Q I am going to run through it, if I may. A note of an assessment when a patient first arrives at a hospital can be fairly critical to give the doctors and nurses a starting baseline?
A It can.

Q Such a note can be critical for the future care of the patient, because without it you do not know where you started from?
A It can.

C

Q You would expect, would you not, in general terms for major changes in the condition of the patient, or deterioration of a patient, to be made?
A Yes.

Q You would expect in general terms for major changes in the management of a patient to be noted?
D A Yes.

Q And when there is a major change in the drug regime, and by way of example, starting opiates where a patient has not been on opiates before, you would expect a careful note to be made about that decision?
A Yes.

E Q And the decision to enter into non-curative palliative care is a particularly important decision in a patient's life, is it not?
A It is.

Q And is that something which in your own practice you would either note down yourself, or I expect now you may be too lofty to do so, but you would certainly ensure that doctors under your management would note it?
F A Yes.

Q You have spoken about starting doses. I think in your report you say this:

"A range of starting doses between 10 mg to 20 mg"

– and you are referring, I think, to diamorphine?
G A I am.

Q

"A range of starting doses between 10 mg to 20 mg subcutaneously delivered by a syringe driver over 24 hours would in my opinion be reasonable."

A Correct.

H

Q In what circumstances?
A When someone has chronic pain. When someone is chronically agitated and is going into a terminal phase of their illness.

Q Plainly you would not write out such a range unless you felt there was good reason either for believing that the patient was at that time in chronic pain, although perhaps that is a misnomer. Chronic pain means long term pain, does it not?
A Correct.

Q Or very soon to be visited by serious pain?
A Yes.

Q In general terms, and you have been dealing with this sort of patient for a long time, a range of the starting dose between 10 and 20 mg – is that something that you yourself have written in the past?
A Yes, yes.

Q And it is the sort of prescription that you would expect to see among those practising under you?
A Yes.

Q What matters, of course, is the patient, as you said, in front of you?
A Correct.

Q And an attitude of "one size fits all" would be wholly inappropriate, would it not?
A It would.

Q You also said in the course of your evidence, and this was not quite consistent with your report, I think you said, "A starting dose of 20 mg seems a reasonable dose". I did not quite understand in what circumstances you intended that to be read?
A I think in a unit where the doctor cannot return within an hour, and where the staff ratios are relatively low. There it would be reasonable to start at 20 mg rather than 10 mg, for example.

Q But for what sort of patient? What are you referring to?
A For a patient who is either in pain or severe distress, or likely to be in pain.

Q Over what time period? Presumably before the doctor can get back?
A Yes. Twenty-four hours, I would assume in this case.

Q I do not know if you are aware of this, but in relation to this particular hospital, we have heard a number of things about the cover that was available there.
A Right.

Q We have in fact heard that there was effectively – that horrible expression – 24/7, but there was in fact round the clock on-call cover. Were you aware of that?
A I was, but it was clear from some of the statements that that cover was very variable in terms of its actual delivery.

Q So far as the starting dose is concerned, you have spoken about the WHO, the analgesic ladder. I just want to ask you a little bit about that. Do you still have that binder near you? You have been an adviser to the WHO, although in a different capacity of course, and I do not think you took any role in the devising of these particular guidelines. Indeed, the analgesic ladder, I expect, has been around as long as you have, Professor Sikora?
A Yes. It was there twenty years before I arrived.

B Q It is a very well known basic medical principle, really. Does it go hand in hand with the titration of doses?
A It does. It does, and the ladder itself is about the type of drug, so by the drug, by the route, by the clock and by the patient. These are the four bits in the WHO, but the ladder is specifically about moving from mild pain control to severe pain. One of the problems right across the world is the unwillingness of systems to actually move patients through to the severe pain when it is indicated.

C Q And these guidelines and, indeed, the guidelines in the BNF that you have not looked at, but these guidelines are devised to deal with people potentially in chronic pain?
A That is the case.

Q People dying of cancer and other serious illnesses?
A The guidelines were made for cancer but, as I think I said earlier, the palliative care
D movement across the world is adapting very similar guidelines to other areas of terminal care outside the oncology world.

Q And the guidelines, can we assume, were devised by people on the basis of knowledge built up from dealing with patients in chronic pain?
A And it applies also to acute pain that is not caused by something ---

E Q You are quite right. You are quite right to correct me. I keep using "chronic pain". I mean both chronic and acute pain.
A Yes.

Q So it is to guide those who are dealing with patients at the patient's bedside, perhaps, who are in serious pain?
A Correct.

F Q This is not a purely academic exercise, is it?
A This is not an academic exercise.

Q You do not have the BNF or the *Palliative Care Handbook* in your pocket, as it were, and then you throw them out of the window as soon as you are confronted with a patient?
A Exactly.

G Q These are there to help you prescribe for the patient in front of you in chronic or acute pain?
A They are also there to help health workers, whatever their rank, to give benefit to patients.

Q We have heard quite a lot about the effects of these drugs on the elderly. Again, I do
H not want to spend very much time with you on this issue, but I do not think you have been

asked to deal with it specifically. Again, we have looked at the BNF. We have looked at the palliative care guidelines. It is a well known principle, is it not, and fact that the elderly are more susceptible, more sensitive, to the use of opiates?
A That is the case.

Q And just by way of example, the sort of half lives that we are looking at in these two documents, that the defence have produced, D7a and b, if one is dealing with an elderly patient, possibly with renal impairment, you would not be looking at a two hour half life, would you?
A No. It would be nearer four.

Q Four or above?
A Could be above.

Q Let us put 7a away, and let us look at 7b. What I think you said was that it demonstrates that there is a plateau at 13 hours and the effectiveness of the drugs goes up a small margin, as it were, beyond 13 hours, but it reaches its effective point – is that fair – at the 13 hour point?
A It probably reaches it in some patients a bit before that, but then it plateaus off slowly.

Q Just looking at the column on the right hand side, and I am focusing on 7b because it is much more relevant to elderly patients, is it not than others?
A It is.

Q We can see that after five hours you in fact only reach 2.71 mg?
A I think it is 3.13.

Q I am sorry. Thank you. It is the one below – 3.13. And so 3.13 mg; if you had a patient who had what I think is described as breakthrough pain ---
A Yes.

Q --- and you wanted to give them an immediate relief from pain, you might give them – what – a 2.5 mg dose or a 5 mg dose by injection?
A That would be possible, so you get an immediate spurt of plasma level.

Q And you would hope, would you, that that sort of dose would deal with breakthrough pain?
A It could deal with the breakthrough pain, but then you would have to do it again in four hours.

Q I understand that.
A It may not be possible.

Q I entirely understand that. That is the peaks and troughs problem?
A Correct.

Q What this does demonstrate is that a syringe driver is not actually very well equipped to deal with a patient who is suddenly in pain?

A Not a patient that is suddenly in pain, but that is usually not the case. The patients develop pain slowly and the attraction of the syringe driver, once it is there it goes on smoothly for 24 hours a day.

Q In terms of setting your starting dose with a syringe driver, and we have talked about the analgesic ladder and titration, it is important if at all possible to have titrated to the dose which you want to start the syringe driver at. That is very bad English, but does it make sense?

A That would be the ideal situation to go for, to have either oral morphine or long-acting morphine or, in four-hour injections, work out over a two or three day period what the dose is, set that and then give the subcutaneous morphine.

Q Because unless you do that there is a serious danger that you are either going to start too low or too high.

A That is the case.

Q With your syringe driver.

A Exactly.

Q I have dealt with the *Palliative Care Handbook* and the WHO guidelines but the principle of titration does not go out of the window because you are dealing with a patient in pain; it is very relevant, is it not, for a patient in pain?

A It is. One of the reasons the subcutaneous drivers are not mentioned in any WHO book is because they are from low resource environments where you do not have the luxury of them, but they are recognised as a superior form of long term pain control.

Q The principle of titration does not mean, does it, that you need to have a nurse sitting watching the patient for a 24-hour period at the bedside, it means fairly regular review and occasional notice, is that fair?

A It does, but it also means variable prescription and, if necessary, injections every four hours.

Q Certainly, but if you were trying to titrate the dose to get to a point where you knew you could control the patient's pain, presumably you would have your nurses observe the patient every hour or two – sorry, you are nodding.

A Yes, that would be the case.

Q And then make a note of it every four hours perhaps.

A Yes.

Q I think that actually is the guidance given by the Liverpool Care Pathway, is it not?

A It is.

Q You spoke about the use of opiates and I think you were talking about for a dying patient.

A Yes.

Q Who is very fearful and agitated.

A Yes.

Q Do you yourself use opiates in those circumstances?
A Yes, I have done.

Q You have done.
A I have done.

Q Can you just tell us something about the circumstances in which that occurred?
A Death is very difficult to deal with for all of us, however experienced you are at seeing it, and the specialty of palliative medicine has made it much easier for the broader community of physicians and other health professionals. Sudden declines are very common within a 24-hour period – a patient goes from being relatively stable into a decline – and with older people it is very difficult to work out what the cause of that decline is. If patients are in pain or distressed then some form of medication is necessary, and that can be done in a variety of routes. Ideally one begins with the oral route but often patients cannot take it – they have sickness, they vomit up the drug that is given, and therefore converting to a parenteral route is the next step. The advent of subcutaneous pumps about 20 years ago through palliative medicine really changed the way in which the terminal pathway can be implemented in patients that are estimated to be within three or four days of death. One of the problems is that it is very difficult to make that estimate, it is very difficult to know the true situation, and I have certainly seen that in my patients – that patients have died much more rapidly than I would ever predict and, conversely, people have hung on for weeks.

Q It follows from that that if you take the decision that your patient is on a terminal care pathway too early you may get it wrong.
A You might.

Q What I was asking about in fact was the use of opiates in the agitated and distressed dying patient who is not in pain, and I was asking about the circumstances in which you yourself have used opiates in those circumstances.
A Can you just repeat that – the patient in pain or not in pain?

Q Not in pain.
A Okay.

Q Do you use opiates in those circumstances or do you use sedatives?
A No, I use opiates and sedatives.

Q Can you just tell us about the circumstances?
A The most vivid memory is a patient who was in severe distress, a relatively young man, not an old patient, and we just could not get rid of the pain – sorry, we could not get rid of his distress. He was not in any pain.

Q What was his distress arising from?
A A fear of death. He was extremely agitated and it could not be allayed by his family; the nursing care was superb, we were well-staffed. We decided to put a subcutaneous pump in and give diamorphine.

Q That was to give the patient a sense of euphoria and calmness.
A A sense of euphoria and a smooth passage.

Q Right. Was that a relatively unusual event?
A Unusual in a young person, not so unusual I do not think in older people.

Q You have spoken quite a bit about diamorphine, but of course in this case I think it was invariably used in conjunction with midazolam.
A Correct.

Q You can confirm, can you not, that midazolam itself has a powerful sedating effect?
A It does.

Q One therefore has to be doubly cautious when using the two together.
A Yes.

Q I am sorry to keep coming back to it, but it is relevant to what you just said, if a patient is on a terminal care pathway we can take it that that does not avoid the necessity of using the analgesic ladder or the guidelines so as to ensure you are not over-sedating.
A Correct.

Q Because the danger is otherwise that you can end up with an unconscious patient who does not need to be.
A That is correct.

Q Or a dead patient who does not need to be.
A Correct.

Q You spoke about the possibility of stopping a syringe driver completely perhaps in the circumstances we have heard in this case, if a relative wanted that to happen. There would be no difficulty, would there, if there were strong reasons for doing so, good reasons for doing so, in reducing the amount of opiate to see if you could find yourself in the position of having a conscious patient but a patient without pain.
A There is a fine balance and it can only be done on an individual patient basis. People do not die from at one moment being completely well and pain-free and not distressed and then at another moment they keel over and that is it. That is not the sort of patients that were at Gosport in any case.

Q I entirely understand that but if you have a patient who one day has been talking and eating, let us say, and the next day is unrousable and a relative wants to be able to speak to that patient to find out if that is the state in which they wish to be, you would consider, would you not, reducing the dose if you felt it appropriate so that the patient could be roused to speak to?
A It would depend totally on why they had been started on that but just to do it for the relative's wish to speak to them is not reasonable I would have thought.

Q It depends on the level that was needed in the first place.
A It depends on the whole clinical circumstance.

Q You spoke about the possibility of having to start at a higher dose than you would otherwise want to if you have inadequate staffing levels, and I just want to ask you a little bit about that. Was it your understanding and the basis for that comment that the nursing levels at this hospital were inadequate?

A They seemed to be inadequate from many of the documents I have read towards the end of the period, in the late nineties, not so much the beginning of the nineties.

Q Can I just read a comment. We have heard from a lot of nurses and I am just taking the words of a nurse that we heard from just yesterday, a sister, who was asked this:

> "Did the nursing notes suffer in any way as a result of the increasing workload?
> A No. I must point out I had an excellent team of nurses. I am afraid I am a bit old school and I like to think my standards were quite high and my nursing staff knew of this, and if there had been any backlash from this, they would have either come to me or gone to management and it would have been discussed, but I never found that the extra workload affected my nurses' care in any way at all."

That was Sister Joines. If the position was in general terms that the nursing care on these two wards that we have been dealing with has been described as either very good or excellent, yes? You are nodding and it will not appear on the transcript.
A Yes.

Q Although Dr Barton's time was plainly limited, as we have heard, we have heard from a number of nurses that although the patient type changed and they had to account for that, the patients did not suffer as a result.
A Right.

Q You are not saying, are you, that in the circumstances in which Dr Barton found herself at this hospital she was entitled to ignore either the *Palliative Care Handbook* or the *BNF* when writing out her prescriptions?
A Well, did she ignore it?

Q Apparently, yes, she said so.
A Okay.

MR LANGDALE: I am sorry, that is not what her evidence was. She was not saying "I ignored ..." She was well aware of what was in the *Palliative Care Handbook* and the *BNF* and she took her decisions for reasons which she explained to the Panel. She was not ignoring it in the sense that my learned friend is suggesting.

MR KARK: We will have to check the transcript. My recollection is – perhaps it does not matter what my recollection is but certainly Dr Barton accepted that she was not following the principles in either the *BNF* or the *Palliative Care Handbook.* I do not know if that is challenged as well.

MR LANGDALE: You say "the principles" – she gave the reasons why she prescribed as she did and the reasons for them not being according to specific guidelines set out in the *BNF* and the *Palliative Care Handbook.*

THE CHAIRMAN: Can we work on an agreed basis that she made a conscious decision not to adhere to the guidelines. Would that be a reasonable way of proceeding?

MR LANGDALE: Speaking for myself I think that covers it.

MR KARK: We have a measure of agreement. Can I just ask you this: are there circumstances in which you yourself have taken the decision not to adhere to the guidelines?
A Yes.

Q What have those circumstances been?
A Relevant to this to give much higher doses of analgesics in certain circumstances.

B Q Can I ask you what those circumstances were, please?
A They are all related to cancer and they are all in patients with really severe pain and in one case distress and agitation that was really very distressing for the family.

Q Were you there on the spot?
A I was there on the spot. I was called by the senior registrar who was not able to deal with the situation. It is very unusual but it does happen, even in a very well-staffed C environment.

MR KARK: That is all that I ask, thank you very much.

Re-examined by MR LANGDALE

Q Professor Sikora, two matters arising out of the questions you have just been asked by D Mr Kark. May I take up the last matter you were asked about when you said what you yourself had done. In terms of the *BNF* is there any guidance in the *BNF* as to the dose that is appropriate in patients who are on a terminal pathway?
A That is avoided in all literature because there is no written dose that is standard, it has to be decided on the spot.

Q Something that you said earlier on when Mr Kark was asking you about the analgesic E ladder and so on and asked you to look at the particular passage in the *Palliative Care Handbook*, you said if I have noted it correctly that there was a reluctance – I think you said worldwide – to move to the higher strength or stronger opiates. I may not have got your words down precisely but in broad brush terms is that what that was saying?
A That is correct.

Q Could you just enlarge on that?
F A In many countries it is not the availability of the opiates, it is the willingness to use them. Often on cancer wards the patients gain because people are used to it but on non-cancer wards there is much more hesitation. That is changing but it is there. There are also professional differences, so nurses may be much more reticent to use opiates compared to physicians and I guess it is to do with the recognition that the patient really is terminal. Nurses that are there caring for the patient all the time may not wish to acknowledge that inside and therefore are much more hesitant before committing a patient to that, and that may G be one of the reasons for the difference.

Q There has been some evidence – I do not know whether you will have picked it up in the transcripts that you yourself have had the opportunity of reading or not – that in the hospitals, the common hospitals that we have been encountering in these cases – the Haslar and also the Queen Alexandra Hospital, the two main local hospitals – there was some evidence to the effect that in the hospitals for patients who had received some kind or surgical H

intervention or some kind of acute treatment as it were there was a tendency to tolerate higher levels of pain in patients than you would find, perhaps, elsewhere.
A Absolutely, that is a common phenomenon in all hospitals. When I had my appendectomy I made sure I got my own private bottle of analgesics.

MR LANGDALE: We will not go into that. That is all I need to ask you about that. Sir, that is the last of the questions I need to ask in re-examination. Thank you.

THE CHAIRMAN: Thank you Mr Langdale. Professor, we have reached the point when it is for the Panel to consider whether they have other questions for you. I am afraid we operate in a somewhat lower gear to learned counsel and we are unlikely to be in a position to launch straight into questions. What I suggest, Mr Langdale, Mr Kark, is that we go into camera now for the Panel to consider such questions as they may have and say at this stage not before two. After the luncheon break hopefully we will be in a position to proceed.

Professor, we will rise now. You remain on oath so please do not discuss the case with anybody during this period. You are very free to leave the building and you can have, as a consequence, a somewhat longer lunch than might otherwise have been the case, but please be back here for two, at which time I hope, but cannot guarantee, that the Panel will be in a position to go forward. Thank you very much indeed, ladies and gentlemen.

STRANGERS THEN, BY DIRECTION FROM THE CHAIR, WITHDREW AND THE PANEL DELIBERATED IN CAMERA

(Luncheon adjournment).

STRANGERS HAVING BEEN READMITTED

THE CHAIRMAN: Welcome back everyone. I am sorry we lost an additional half-hour but it just goes to show I was correct when I consoled Mr Jenkins with the observation that my time estimates are no better than his.

Professor, I remind you that you remain on oath. What will happen now is that individual members of the Panel will put their questions to you. When we have done that, there is a final hurdle, which is that counsel themselves have an opportunity to ask you any questions that might arise out of any of the questions that we have asked. Is that clear?

THE WITNESS: Thank you, yes.

Questioned by THE PANEL

THE CHAIRMAN: Mrs Pamela Mansell is a lay member of the Panel.

MRS MANSELL: Professor Sikora, much of the evidence you have been giving us is related to terminal care and patients who are on a terminal care pathway. I understand you to say that when moving on to a terminal care pathway, there is an expectation, there is a clearly defined diagnosis, that we have patients for whom there is no further cure for their medical conditions.
A Right.

Q Part of those medical conditions is really around extreme pain so the management of that pain takes the priority. When we are considering the patients we are considering through this hearing, we have patients who have been admitted to the hospital for continuing care and for rehabilitation. They have then speedily moved, seemingly speedily moved, on to a terminal care pathway. What standards would you expect there to be in place as we move into a different pathway?

A In an ideal world, you would want to compare this unit with another unit. You would want to be able to audit. Audit really came in acute NHS facilities around the time of this incident, during the 1990s, but, even to this day, has not come to the chronic long term care environment in the way one would like. What one would really like to see is, using information technology, was there something different going on during different time points and you cannot do that because there is no comparator. You are quite right, it is difficult to know retrospectively. One assumes that patients are going there for chronic rehabilitation and that was something that changed with time, and a certain percentage of those patients will suddenly deteriorate over a week or so and go into a terminal phase. I do not know from the evidence I have seen what the denominator – we know there are 12 patients being considered here – I do not know what that was out of. Was it out of 20 patients in which case it would be a little alarming, or was out of several thousands of patients which would make it not alarming?

Q I accept what you are saying, but I would like to direct your attention not to any particular patient, but if we are thinking around any standard relating to any particular patient as you are moving from one to another, so protecting the patients' interests and all those sorts of processes, what are the sort of standards that you would expect around processes for individual people to protect their interests?

A One would like to see a multidisciplinary team discuss the patient before doing it. However, that, certainly with the staffing structure as alluded in the evidence, would not be possible. I do not believe there was a conventional multidisciplinary team meeting to do just that, certainly not one that can be convened quickly to deal with a patient who is deteriorating over a 24 hour period, for example. To my knowledge there are no written standards of that sort of thing around, certainly in the 80s and 90s. Now people are much more careful about starting a terminal care pathway and document it much more thoroughly, but 10 to 15 years ago this was not the case.

Q Although there was not a disciplinary team, there were consultants around that Dr Barton could consult with, who perhaps were the people who were responsible for those patients when admitted. What would have been your expectations round that?

A My expectation would be that Dr Barton and the nursing team would make the decisions and the consultants would ratify it when they came round. I would not have thought they would come especially to see a patient out of hours. That would be unusual and really not possible. It is clear that the consultant's attendance was not on a regular basis for some of the time, it was not even weekly some of the time, therefore you could not get that ratification, so I think Dr Barton and the team of nurses are acting on their own in many ways with the sort of decision. They would not be able to get advice as to whether to go or not go on a terminal care pathway, they would have to make the decision themselves.

Q You are saying that in a multidisciplinary team meeting everyone would have had to have seen the patient to have made that decision?

A Not usually, but some of the staff would have seen the patient but they would sit around, discuss the patient, those who had seen would contribute and then an agreed decision would be made, but that takes time.

Q It does, but it is a far cry from it then becoming Dr Barton's decision and the nurses' decision?
A I understand.

Q What would have been an intermediate step – phoning the consultant, discussing?
A It would be difficult for the consultant to contribute down the phone. I think he or she would have to come and visit if they were going to make a meaningful contribution. They could be contributing to policy but not to an individual case.

Q Let us look at another standard about the choice for patients. What about patients' involvement? If a patient is suffering from dementia and is not articulate and cannot contribute, that is one set of circumstances, but when patients are actually articulate, what about their actual involvement in the choice about whether it is going to be terminal care or perhaps more invasive surgery?
A I think it is very rare surgery versus terminal care, it would be very unusual for that to happen. Involving patients is something that, again, there has been a huge change of patient empowerment over the last 15 years. My clinics with new cancer patients take a lot longer and my colleagues in cardiology say the same thing. All the options are gone through and the patient is then involved in choosing the decision-making. That certainly was not the mode of operation in the 1990s – the challenge in these particular circumstances, the very age of the patients in many cases and the fact that they had multiple comorbidities. Many of the cases, I am sure, reading the evidence would not have been able to take part in the decision-making in a meaningful way. Their families would but they would not.

Q I will bear in mind within that that you do not actually know the individual patients because you have not looked at their circumstances.
A Exactly.

Q I move on to a slightly different point, because all the time we have to look at how we protect the interests of patients. You said that in terminal care it is open to the discretion of the clinician, the doctor, as to the dosage of opiates that actually may be used. What safeguards should there be in place to prevent that patient being over dosed?
A Audit and monitoring: in other words, the pharmacy; there should be monitoring in what is going on in real time with good information technology, which was available – local computer programmes were available but not in place; consultants checking protocols and checking that policy is adhered to; nurses who were also involved in this should be the same; and management, who are ultimately responsible for day to day operation and strategic development, should also be involved in the process. There should be checks. The difficulty is the change in era. Today there are checks everywhere and people are very conscious of this aspect. In the 1990s there was not anywhere.

Q Clinical governance was in place, was it not, in the early 1990s?
A I suspect Gosport was the sort of place where governance reached last because of the nature of it.

Q From the perspective of the personal accountability of the doctor, how would you see the standards being managed? You talked about the audit and you have talked about management and overseeing the doctor, from the personal accountability of the doctor when making such critical decisions when to move someone into terminal care, how would you see that doctor making sure that their standards were very transparent and overt?
A I imagine the best way in those days was discussion with the consultant ultimately responsible for that patient – named consultant, named patient – and Dr Barton; obviously, if it cannot be done immediately at the next available opportunity. The problem, again, from the evidence is that the consultants were busy, mainly elsewhere. It is not that they were not working, it was just that were tied up in clinics and ward rounds elsewhere within the Portsmouth system. To them it is relatively low priority.

Q Is that sufficient justification for the doctor not to make that a priority?
A Dr Barton or the consultant?

Q We have heard that the consultants could be available. If Dr Barton wanted the consultants to be available, they could be available. You are saying that a good standard would be for the doctor to discuss the patient's condition with the consultant and then to jointly form a decision, or at least discuss it the next time that the consultants are on the ward. I am looking at the standard for that and you are saying they were busy people, but that cannot overcome what is actually in the interests of the patient, can it?
A Absolutely not, but I would imagine that the patients were discussed with the consultant at the next available visit but, unfortunately, that visit may not be for two weeks after a decision had been made and that is one of the issues. The ideal situation is to have a daily meeting of some form where every patient is discussed, but that would not have been possible for Dr Barton with her plan, or her self constructed job plan, because there was no formal job plan for her.

Q What accountability does the doctor have to make sure that there are certain standards put in place?
A To me it would be the responsibility of the consultants to make sure that they have a system in place that allows their patients to be protected. It was not up to Dr Barton to construct that, she was the part-time clinical assistant who was implementing policy that was the responsibility of the consultants.

Q A final question from me. I understood you to say when you looked at it that you saw that the Gosport had no easy access to x-ray equipment or to acute services, but what you are not saying is that moving to a terminal pathway can be justified because you do not have access to those services?
A No.

Q Have I understood you correctly, or were you saying you might move to a terminal pathway because you do not have those sorts of services?
A No. The only option if you are going to have x-rays and other investigations done, was to transfer the patient over 20 miles. If a patient is near death, that would seem almost cruel to me because the chances are that whatever is causing the symptoms is going to get worse if you start transferring patients. Also acute services, certainly on the south coast during the 1990s, were very over stretched, so you would be moving patients around on a regular basis which would be difficult.

MRS MANSELL: Thank you.

THE CHAIRMAN: Ms Joy Julien is a lay member of the Panel.

MS JULIEN: Good afternoon. Some of my questions slightly overlap so, unfortunately, I may need you to go over some ground you have already gone over, but from a different perspective. My first question is in relation to the range of the doses of what you described as a cocktail of opiates, the wide range of the cocktail. I think you had said that the wide range allowed the nurses freedom and flexibility, I do not know your exact words. My question is that, in a situation where there are fewer resources, the nurses using that wide range would be going in straight at the higher rate than they would possibly in another situation. What I am concerned about is, if there is not titration from the beginning, how do you think, under that sort of regime, the risks to the patients could be managed?

A The only way to manage the risk is closer observation. The reassuring factor, looking at the data, is that there was only one patient given at the higher end, at 120 mgs, of the diamorphine. The majority of patients were actually under 80 mgs, so it looks as though, from that evidence, there has been a titration process in place and the nurses were following it. I have not seen the patients, but one assumes the 120 mg patient was had severe problems and that is why the dose was given at that level.

Q The range allowed them to be in a position that they could have gone higher?

A They could have gone to 200 mg, yes.

Q It may be that they did not, but they could have.

A Exactly.

Q That is really my point. In that sort of situation, how would the risk be managed, particularly in terms of adverse effects?

A The way to manage it would be to have the pharmacy monitoring it, producing weekly, monthly reports so you can see any trends in the patters of diamorphine, midazolam and other drug usage.

Q It is the pharmacist who has to manage the risk?

A There was a ward pharmacist, the clinical pharmacist and it would be they who were responsible for patterns of drug use that were changing with time.

Q Would that be sufficient to prevent over sedation of the patient?

A Together with observation by the nursing and medical staff, that should be.

Q If it is a weekend or late at night and it is just the nurses and they are working within that regime, the pharmacist is not necessarily going to be around at that sort of time. Is that sufficient to manage the risk?

A I think all one can do is observation by the staff. What one does retrospectively is to have the pharmacy audit to see if there is a pattern change which happened. That would ring the alarm bells if there was.

Q Would that sort of system be in place at that time in your experience?

A I have seen no evidence that it was in place.

Q You have seen no evidence that that was in place, so the nurses were working under a system where they had quite a lot of discretion?
A They had discretion. The fact that they did not go to the top end immediately and there was a distribution of doses, suggests that they were using that discretion appropriately, although, as you know, I have not seen the individual cases so I cannot comment on that.

Q You accept that there could have been a situation where they may not have done that, it was left open?
A Indeed.

Q Going back to the terminal pathway situation, I think you said that once a patient gets to the point where they are on the terminal pathway, that would not be the time to conduct or to initiate any sort of investigations. I think you said it was a time for good decision making?
A Exactly.

Q What about before you get to that point, would a doctor need to be sure that they had carried out all the investigations before they got to that point?
A I think these patients in many cases had been actively treated not at Gosport but another hospital, and transferred there, so the whole purpose of Gosport was to try and free up space in the acute hospitals, and also to provide a more gentle environment for the management of a patient. If a patient started deteriorating for whatever reason, if there was thought to be a medical problem that could be elucidated, they could be sent for further investigation. On the other hand, if they were beyond that, if they were deteriorating rapidly, there would be no point and a decision would be made just not to further investigate the patient. That would be the normal practice.

Q The doctor would have to be sure in herself that she had carried out all the investigations, because you are saying there would be no point once they were on the terminal pathway?
A It would be based on the history. It would be based on the medical details of that individual patient. Over the last few months, why have they come to that point? If there are factors that are essentially irredeemable – renal failure, cardiac problems, chest problems and so on – you make the decision there is no active treatment that can be done. In cancer it is slightly easier because you have good ways of monitoring the cancer. In general medicine, it is a bit more difficult. In post-surgical procedures such as hip surgery, and so on, it is a bit more difficult, and in patients that cannot give you a history, it is doubly difficult but I think you can come to a point where you say, "No more active treatment. Tender loving care only," and you put the patient into that pathway. You deal with the symptoms as they arise.

Q And that pathway can take quite a lot time to get to the end of?
A It is extremely variable. It can be 24 hours or it can be 24 days.

Q Let us suppose in the event that it is 24 days, under no circumstances would you consider it would be appropriate to conduct any sort of investigation or another opinion?
A Unless the investigation was going to lead to a change in treatment, and that seemed very unlikely in this group of patients, even a simple chest X-ray – what would it do? Would you really start patients like this on antibiotics, for example? So why do the chest X-ray? We always teach students that diagnosis is only a guide to treatment.

Q Possibly you could consider it. You may not actually carry it out but it does not mean you close the door and you do not consider it?
A You could consider it. I am sure there were patients transferred back to the acute sector over the years from Gosport.

Q Just moving on to the syringe drivers in general, there was a point where you were talking about the possibility of reducing, or taking someone completely off a syringe driver, I think you said that it could be seen as unethical to do so. My question is this: in a situation where a patient could be taken off and a level of consciousness could come up to a level but they have not actually started to experience pain – maybe just before that pain threshold if you understand what I am talking about?
A Yes, I do.

Q Surely that would not be unethical at that stage, would it?
A It would require close monitoring because otherwise the patient could be in pain for several hours before anything is done about it. It is possible to do that.

Q The hospital could do it. And if they were experiencing some pain but not intense pain, but some pain that they could communicate?
A If they could communicate, you could then increase the dose again. They go back to a higher dose.

Q And it would not be unethical to do that, but I think to stop everything would be unethical, which is really the only way to find out what is going on – to stop all medication and see what happens to the patient.

Q So stopping would, but a reduction would not?
A The problem with a reduction is, you would have to do it stepwise and monitor the whole thing. It may take several days before you knew what was going on. There are circumstances in medicine where we do stop everything where we are not sure if it is the drugs that are actually contributing to the medical problem. We stop everything and see, but in a very controlled and monitored environment.

Q And that could be seen to be in the best interests of the patient, would you say?
A It the environment is properly monitored it can be, but it depends on the type of patient. I would have thought with this group of patients, to me, it does not seem likely that you are really going to get any benefit. The idea is to make these people comfortable.

Q Does the reason for not stopping its impact and reducing, whether you think it would be ethical or not, the reason for doing it? I am thinking of, let us suppose, the next of kin want to speak to the patient, or want to make necessary arrangements, what would be your take on that?
A I think that would be difficult. I think if the patient had had severe symptoms, I would try and persuade the relative that it would be unkind to do that sort of thing if they wanted to. Patients do surprising things in the terminal phase. Sometimes people suddenly wake up and suddenly have a lucid moment. They talk for ten or fifteen minutes, and they express their wishes – and this does happen – but on the whole the terminal event tends to be a progressive downward spiral as the organs shut down. So it is really unkind to suddenly stop everything and try to get the patient to... We have ways of counteracting diamorphine with drugs. If someone takes an overdose we have an antidote that we can give, and is given

across the road but it would be unethical, I would have thought unethical, to do this in this group of patients where the illness trajectory is definitely downhill.

Q So in those particular circumstances unethical, but you are not saying it is a blanket situation?
A No. There are circumstances where we do do it, and it would not be unethical.

B Q My other question is about the options available to Dr Barton. You had said at one point that you considered the various options or alternatives would have been available to her once she found herself in that particular situation. I think you had started to talk about her resigning being an option, but you were not able to pursue that. I just wanted you to elaborate on that?
A One option for her is walk away from the whole issue – just say, "This is no good. I cannot stand it." The other option would be to discuss the issues with the consultants, which
C ---

Q Yes. I think you did talk about that. I was specifically interested in her resigning.
A Right.

Q Just what your view is about that.
A I think morally it would be difficult to do. She would be leaving. The next person
D would come along to the same circumstances, so changing the system would seem better than just walking away from the system, to get the whole thing better. I think the difficulty is, there was no clear leadership amongst management, both general management and medical management, that she could go to so far as I can see from reading the evidence.

Q We do know that after Dr Barton resigned there was an improvement in terms of resources.
E A Right.

Q Do you have any different take on the matter, knowing that?
A I think the public outcry at the time was great and the health authority had to do something. They funded a full time position permanently based at the hospital, not offsite at all, afterwards.

F Q And my last question relates to note-taking. You would accept that keeping clear and accurate records. It is part of good clinical practice?
A Yes.

Q It is part and parcel of clinical practice in general?
A Yes.

G Q Would you say it is an integral part?
A It is an integral part.

Q Would you say it has equal weighting to actually providing treatment and care?
A I think if you had to chose or the other, you would choose the care first and the notes afterwards. There is no doubt that is the way. The other thing is doctors in different specialties and different levels of experience tend to write less and less as they get older.
H Certainly comparing my notes in outpatient clinic to the registrar's notes – the registrar fills a

page and I put two lines down. I like to think that there is enough information in those two lines. And the medical student fills three pages, and that has always been the case in my experience.

Q In principle they have the same weighting though? The treatment and the ---
A To me the treatment and care are more important than the note-taking, but the note-taking is important because it decides future treatment.

Q But according to *Good Medical Practice*, when you look at it, there is not a hierarchy. It has equal status?
A I did not write *Good Medical Practice* but I would have thought, if you had the choice, if you were lying on the street and you had a man with a notebook or a man with a stethoscope, you would choose the man with a stethoscope.

Q But you do accept that it is an integral part of clinical practice?
A I accept fully it is an integral part.

Q And do you accept that if a doctor does not give sufficient weight to note-taking, that he or she does that at her peril?
A I think, again, it is difficult for an individual. My notes last week, because I was in a hurry for a variety of reasons, were brief. No one has told me that my notes were too brief. I had no feedback. I had the feeling from the papers I read that Dr Barton had no feedback about this.

MS JULIEN: Thank you very much.

THE CHAIRMAN: Thank you. Mr William Payne is a lay member of the Panel.

MR PAYNE: I am going to take you back right to the first part of your evidence that you gave because I want to be refreshed. I do not expect you for one minute to be critical of any colleagues, but I want to discuss the input that you said that you first made when you were first asked questions by Mr Langdale with regard to the consultants that were looking after the ward. I think you said – and you have also just said it to my colleague – there was insufficient leadership, no clear guidance and you did not say "insufficient input" but you went on to be very kind, and say they were obviously very busy people, but there was not a lot of input from the consultants above. Can you tell me how you came to that conclusion, to start with?
A A combination of reading the papers before and then the transcripts of this, and listening to them talking. There is no doubt that management in hospitals and health care facilities is best if there is one person that is clearly responsible, a single person that is clearly the place where things get solved. That one person has to be available and approachable and willing to be approached, not just by his medical colleagues but also nursing colleagues, even the cleaning ladies if there is some problem. There has to be that in good management. That was clearly not the case here, and that was the impression I got from the transcripts and the notes.

Q I think you said that the name above the patient's bed was the person who was in charge, and that was the consultant?
A Yes. That is the tradition in British hospital. It is the consultant's name, not the patient's name.

Q Thank you. I believe that you also said that Dr Barton had had inadequate training for the role that she was expected to do as the nature of the work changed. Am I correct in that?
A She was a GP, and she was trained as a GP. She had done no specialist training in internal medicine or palliative medicine or, indeed, care of the elderly as far as I know.

Q Right, thank you.
A She was competent, I would have thought, from her training to be a clinical assistant but by its title "clinical assistant" implies there is someone that is not the assistant who is looking after her.

Q Right. If you have someone in that situation that you identified as not necessarily having the adequate training, and you have a consultant who obviously had the adequate training, who should be responsible for making the decision to put someone on a terminal pathway or an end of life pathway?
A Ultimately it is the consultant's responsibility, definitely, but having said that they can delegate that to people on the spot, and they did delegate it to people on the spot.

Q How did you come to that conclusion, that they had delegated it?
A They were not there. Without seeing the patient, it would be difficult. Even if they knew the patient, and the patient had changed, and they did not come to see the patient, and they were not running the place on that basis – they were not available to come on a Tuesday afternoon, for example, suddenly to see one patient, it would disrupt their normal clinical patterns of work, then they would have to delegate, and that is what they did.

Q You went on to speak about the best way to assess the needs and requirements of a patient is to be by the bedside and see them?
A Correct.

Q And if you were going to have to make a decision with regards to, say, pain relief, then the best decision would be after you had seen the patient?
A Yes.

QBut would you agree with me that it is also – I have to use the word – "guesswork", but there has to be some form of working it out, and a stab in the dark to start with perhaps. Would you agree with that?
A I would, and that is the purpose of the sliding scale; that you start off at one end and you can go higher if necessary, so getting started is a stab in the dark.

Q Would that be more difficult if you have not had adequate training for the specific area that you are working in?
A It is a difficult question because a lot of my generation of doctors were trained by observation in the work place, and no formal training programmes. I do not mean in cancer medicine, but in things like palliative care. I had to do palliative care as a registrar without any training whatsoever. We did it. The consultants were not interested in talking about it and that sometimes happens.

Q Can I just take that slightly further with you? We have listened to your C.V., and you are very eminent in your field, you are a leader of your field probably, but if you were being

taken out of that scenario and placed into a different field, you would not feel too comfortable about making the decisions for someone else, would you?
A No. I thought long and hard what I would do if I had been in Dr Barton's shoes in Gosport. I cannot see any other way out as to what happened. She was delegated. The consultants were there. They knew they were responsible. They could not get more hours at Gosport. Whatever they did there was no way they could spend more time there. The ward seemed to run well and the system worked as far as I could see.

Q But if you were in that situation, Professor, and you were having to make a decision, and you are not adequately trained and you are having to use opiates, for instance, would you not rely to some degree on the use of knowledge that is available to you, like the BNF or the Wessex Protocol, for guidance with regard to the size and the width of the drugs you are going to prescribe?
A Unfortunately the BNF does not have that. It recommends 10 to 20 mg as a start dose, but it does not have an upper limit of the range in it. It does not have a range, in fact, so I think that will be very difficult. A competent GP is trained to give opiates, is trained to give palliative care in patients' homes. This is an extension of that primary care role.

Q Correct me if I am wrong, but the BNF does give a guide to the conversion from, say for instance, Oramorph onto diamorphine?
A It does.

Q By subcutaneous ---
A Exactly.

Q Would it be for someone who, as you have described it, has not had the adequate training to use that as a guide to move forward, initially at least?
A The conversions at two-thirds of the dose of oral morphine – that is presumably what you are alluding to – a patient on 60 mg of morphine ---

Q A third to a half.
A A third to a half, morphine to diamorphine, continuous over 24 hours, that is at two-thirds of the dose to diamorphine. The evidence I have looked at – I agree I have not looked at all the notes – suggest that that was adhered to essentially when the patients had been on opiates before.

Q So you would not be aware that perhaps those doses were maybe twice and three times higher than the recommendations from the BNF?
A The reason for starting the subcutaneous pump was that some event had happened to require a change in the management from oral dose. It may be that the patient was being sick, but in most cases it was because, as far as I can see from Dr Barton's statements, there had been a deterioration in the patient requiring more analgesic and therefore the conversion may not be quite correct. It may not be exactly the same. It would be at a higher level basically.

Q Can I just press you a little more on that? If someone comes to you, let us say, who has been on step one – paracetamol perhaps – would it be appropriate then to write out, even as an anticipatory prescription, a prescription for diamorphine that is three times higher than, say, the minimum start?

A It depends on the clinical circumstances. If that patient is in severe pain we may go to a very high level and then maybe come back. Lots of things depend completely on the clinical situation.

Q What would be the situation where you would come back?
A If the pain disappeared or if the symptom, whatever the symptom of the distress or anxiety, also disappeared.

Q If a patient is heavily sedated with, say, midazolam, if you have introduced that as well which leads to heavy sedation, how will you know that you have over-prescribed the diamorphine?
A It is an educated guess, as I think you said earlier, and clinical skill that you realise that the symptoms have now gone and the patient is comfortable. That is the level at which you continue.

Q You think that the system was working acceptably here.
A I think for that decade it was working in an acceptable way. I could find no evidence of huge, inappropriate doses being given of any of the drugs in the syringes.

MR PAYNE: Thank you very much indeed for answering my questions.

THE CHAIRMAN: *Dr Roger Smith is a medical member of the Panel.*

DR SMITH: Good afternoon, Professor. Let us go back to the terminal pathway. The terminal care pathway is predicated on knowledge that the patient is in the terminal stage. In your world of cancer that is pretty well defined, is it not, it is a chronic process that is pretty much predictable.
A Yes.

Q Apart from one patient in our bundle, 12, there is not a patient with cancer, so I want to ask you this really. First of all, if you are dealing with pain does the object have to be to render the patient pain-free or is it a reasonable alternative to get the patient to a position where they are in a degree of pain that is acceptable to them?
A I would prefer to be pain-free and usually it is achievable, to get pain-free without troubles from the side effects of the medication including over-sedation side effects by judicious use of the drugs in most patients. I would certainly rather be pain-free.

Q I think you suggested that in the terminal phase it is reasonable to have a patient drowsy or even unconscious if you know what the course of their illness has been.
A Yes.

Q That is fine for chronic pain.
A Yes.

Q And you have said that it would be unethical perhaps to withdraw some or all of the treatment to see what they are like, except in exceptional circumstances.
A Yes.

Q What if the pain, as part of a chronic decline in an old person, with many comorbidities, was an acute pain and because of the acute pain a syringe driver was started

with the full knowledge and intention that it would not be stopped, that the terminal pathway had now been entered?
A I think the implication in that question is that the syringe driver was the termination event, and I do not think that was the case. I do not think anyone would consider that in this country. The syringe driver was there ---

Q Explain to me what you mean by that, nobody would consider that.
A You are suggesting that the syringe driver was used to bring about a terminal event.

Q I did not suggest that.
A I am sorry, I misunderstood. Basically if a patient is in acute pain and one agrees that the patient has no way of coming back to a normal existence the symptoms are treated in the most appropriate way. In some patients a syringe driver is the most appropriate way.

Q If he was in acute pain how do you know if the pain has gone? It is a silly question.
A Death is a mysterious business, as you know, and the events that put a patient into the decline and the timing of the physiological events are really completely unknown and under-researched – for obvious reasons it is a very difficult area to research. To me a doctor's duty is to get rid of symptoms. Sure, if a patient has no other disease and they are in some short term problem – say acute post-operative recovery – things may be different. But that was not this class of patients here; these patients had chronic disease, long term illnesses, that were gradually going down, and some of them exhibited a sudden deterioration which involved symptoms, so getting rid of those symptoms when the patients are deteriorating in the most appropriate way seems reasonable.

Q But would you still apply the adjective "unethical" in that situation if you were to pull back on the dose to see?
A Unethical only in the sense that patients are suffering and have suffered. You have got them out of suffering with the medication and now you are going to make them suffer again to satisfy the curiosity of seeing the effects of the drug versus the effects of the disease.

Q What if that change of tack and that treatment were applied in a situation where there was not pain?
A That is more tricky but distress and anxiety are well-known pre-terminal events and seeing a patient is distressed, often shouting, often very disturbed and very disturbing to families, sometimes with death rattles and so on, is a very disturbing experience for everybody including the patient, so stopping the drugs under those circumstances would not make much sense.

Q With your expertise would you be prepared to answer a question about a patient with very advanced dementia who did not have cancer?
A If they have got symptoms – whatever they are, not symptoms of dementia but symptoms of anxiety, distress or pain – they should be treated like anybody else. The difficulty of course is getting the response.

Q Are you happy to answer a question if I put it to you about such a patient?
A Yes.

Q Do you have experience of looking after elderly demented patients who do not have cancer?

A Only as a registrar in medicine.

Q I will ask it because it is pertinent to our inquiry. Would you agree, from that experience as a registrar, that elderly demented patients in hospital, because of inter-current illnesses or events, can become extremely agitated?
A Yes.

B Q As an acute event.
A Yes.

Q And that such episodes can be well-defined episodes – that is to say they occur and they resolve.
A Yes.

C Q So then if such an event occurred and to that patient was applied a terminal pathway because of that event, what would you expect to be the justification for such a decision?
A Starting a patient on terminal pathway would require more than just having dementia, there would have to be some other underlying problem that was going on that was basically pointing out the fact that this patient was coming to the end phase of their life, so that would trigger the terminal pathway, not the dementia as such.

D Q Such a treatment renders the patient unconscious. This is not pain: would it be unethical to pull back on the treatment or stop the treatment to see if the agitation had gone away?
A It is possible to do that but, as you know, it would require adequate monitoring to do that sort of procedure.

Q Just in relation to old people you drew attention to the distress of a fear of dying, and I
E think you talked about a young man with cancer. You may not be able to answer this but you may through your experience. Is the fear of dying a prominent problem in the elderly or the very old or does it tend to wane with age?
A I certainly do not know of any information on that or any data that it does that. One would like to think it wanes and older people have a much more realistic approach about death generally when you talk to them, even people that have not got serious, life-threatening illnesses, but it depends completely on the circumstances around the terminal event whether
F people get frightened or not.

Q Thank you. You said that titration is the ideal but what if I put it to you that it is the norm?
A I would say that it may be the norm under certain circumstances but not everywhere.

Q I am not into semantics so I will not go further than that. This is a side issue because
G you said in a certain context that the consultant cannot make the decision – it was a decision about terminal care over the telephone. I wonder how different that is to you being phoned by a registrar in the night when you are on call and given the full details of a patient's situation and then being able to make a decision that helps that registrar.
A There is a similarity but then we have 24/7 cover by registrars, 24/7 cover by SHOs or foundation year doctors, which was not present in Gosport. Occasionally even now I do get phoned up by the registrar to say do you want to resuscitate the patient, for example; if I
H know the patient it is usually quite easy, if I do not know the patient – and these consultants

in Portsmouth had a lot of patients under their overall care and they could not possibly remember the details of all the patients I would have thought – it would be very difficult to know what to do.

Q Even with a very experienced clinical assistant who had been there for ten years or 20 years.
A Exactly.

Q Right. Can we turn to guidelines? You have said that you stepped out of guidelines.
A Yes.

Q I am sure we all have. When you step out of guidelines what do you do?
A You write it down.

Q Why?
A So you do not come to the GMC I guess. No, so that people can understand, so that other staff members understand the rationale for you diverting from guidelines.

Q To justify it.
A Justify it, yes.

Q Would you expect to do that on an individual patient basis every time you do it?
A I do not do it every time, it depends how unusual the event I am doing and how far I am going from the guidelines.

Q Some doctors – indeed quite a lot of doctors – when you mention the word "guidelines" groan.
A They do.

Q We have even heard one doctor here say that they are tramlines, but guidelines are there for a purpose are they not? They are there to guide us as to what to do. Dr Barton has made, in her evidence, a number of references to not taking account of or ignoring guidelines in the form of either the little green book, the *Palliative Care Handbook* or the *BNF* when writing prescriptions for syringe drivers. She cites as her justification her long experience, and indeed Mr Kark on one of those occasions asked her about writing such a prescription that was called anticipatory, some days before it was started. He asked her what the justification was for making that decision about that level in anticipation that something would happen and she said that it was based on "knowledge of the patient, having seen him the previous week, and long experience of starting doses of subcutaneous analgesia when needed, faced with a particular patient." I wonder if you would find that an acceptable thing if that was applied to one or two patients.
A Yes.

Q If it was applied to a large number of patients is that acceptable?
A The number of patients flowing through Gosport during Dr Barton's period working there must have been several thousand so one would imagine that a handful of patients where she had experience, she knew the patient, she could predict what was likely to happen seems reasonable in an experienced GP.

Q Does it become reasonable that the norm is rejecting guidelines on the basis of your own experience?
A I think we all do it, all doctors do it.

Q You said in certain circumstances.
A Yes, in certain circumstances where one's experience is that this patient is going to suffer if we do not do something then we go away from guidelines.

Q What if you have had no training?
A One of the difficulties now is we are comparing practice 15 years ago with practice today. Why tramlines comes out is that guidelines are a relatively recent invention and certainly in the 1990s there were very few guidelines.

Q The *BNF* has been around for 300 years or more.
A Okay, but the guidelines in the *BNF* are about analgesics mainly – and other drugs obviously – they are not about patient management. Now there are guidelines everywhere for every aspect of patient management as you know and we do frequently divert from them.

Q You alluded to the fact that, like me, you were not trained, you got experience, but if your experience is gained in a place where there are no checks and balances how valid is that experience?
A The checks and balances are relatively recent additions to modern medicine. Certainly when I trained as a medical student and then as a registrar there were really no checks on what I was doing, it is just that things have changed.

Q Do you think you got there by luck?
A No, I think I did not have any disasters by luck but I did not get there by luck.

Q Just one other question. You said that it was perfectly reasonable to start at 20 mg of diamorphine in a syringe driver and you have gone through a number of discussions about that. But if I tell you that the *BNF* cautions that the elderly should receive one-third of the dose of an adult then would you agree that that 20 mg becomes 60 mg equivalent?
A I am not sure it does say that but it tells you to be careful of the doses in elderly patients; I do not think it had any specific – I could look it up for you.

Q We will, just to be sure that I am on the right track. It is in bundle 1 again, I have in mind half to a third. If you look at page 7, this is from September 1997. This is "Prescribing for the Elderly" and it says "Guidelines" on the left. It starts "First always question"?

A No, I am looking at the wrong --

Q It is behind tab 3, page 7.
A Fifty per cent of the adult, not a third of the adult.

Q Let us take that. That becomes the equivalent of 40 mgs in an adult, otherwise called an adult.
A Right.

Q Is 40 mgs, as a norm, in anticipation that pain may occur, a reasonable starting dose?

A It might be depending on the clinical circumstance.

Q I did not ask about that, I asked about the norm in anticipation in case something happened.
A I reply again that it totally depends on the clinical circumstances, not just the patient but what the clinical background is that is leading to the clinical situation and how reversible it is, or non reversible it is, and the speed of deterioration. A lot of this is like watching a ballet where what you are seeing is a series of still shots, you are not seeing the movements and, therefore, you cannot predict what is going to happen. You have to do it looking at the stills.

Q Is that not the point?
A If you need that sort of evidence, if you need to see the ballet, you will not relieve the symptoms, you will be watching what is happening all the time and not actually taking effective action.

Q You are describing something of an unpredictability in these patients.
A Death and life is unpredictable and these patients are unpredictable.

DR SMITH: Thank you.

THE CHAIRMAN: You are down to me. I am a lay member, as I am sure will become very apparent. I would like to pick up very quickly on one of the points raised by Ms Julien when she was talking about note-taking. Note-taking is an integral part of clinical care, is it not?
A It is.

Q Any suggestion that, on the one hand you will take care of the patient and then you will do the notes, is by definition inappropriate?
A Yes.

Q You talked earlier about the delegation of some fairly important functions. One of them is the whole issue of when that decision that the change over is occurring and that the patient is now moving from general care or general palliative care into that terminal pathway. Who do you perceive the delegation extended to in the making of the decision as to when you move from one to the other?
A To me, the consultant is responsible and the delegation was to Dr Barton to make the decision. In an ideal world that decision would be reviewed at some point in the future but not at the time. It was not necessary at the time.

Q You would be quite happy that Dr Barton was more than competent to make such a decision?
A Yes.

Q What about the nursing staff?
A They were not making the decision to start a terminal pathway, they were involved in the decision about the dose escalation.

Q With respect, not just that. You have talked about anticipatory prescribing and I think you have dealt, very specifically, with instances where there would be an absence of consultation with Dr Barton because she was not available and an absence of consultation

with any other doctor because they were not available. One of the consequences of anticipatory prescribing of a syringe driver where there is no start date on it, inevitably is that there is at least the risk that nursing staff, of their own volition, will make that judgment, no doubt with the best of intentions, but that is a risk, is it not?
A It is.

Q Is that in your view an acceptable risk?
A I think for the period of time and the location in terms of the structure, it was an acceptable risk. I cannot see any other way of getting appropriate symptom control. These are not well patients, the ones who are being written up for the syringe driver. They are not people who are ever likely to go out of hospital, so the decision is made to give them the best palliative care as quickly as possible if they do develop symptoms and the person on the spot, in this case the nurses, make the final decision and then it is reviewed the next day by the doctor.

Q They do that in the presence of an open ended prescription which takes the patient directly on to what you describe as the cocktail of opiates and the syringe driver. You also discussed with Mr Kark, and indeed with Dr Smith, what you had indicated was the ideal approach, which was, I think you said, to spend up to a couple of days defining, through titration, the appropriate dose for the patient to start on the syringe driver?
A Yes.

Q The reason why in the ideal world you would want to do that rather than go directly on to the syringe driver, or the reasons, is what?
A So that you give an accurate dose, no more than is needed and no less than is needed, and the patient's comfort is assured for the next few days.

Q No more than is needed; what are some of the effects of that, of not over sedating?
A All drugs have side effects and, therefore, one wants to avoid those side effects, including sedation.

Q I will come to the side effects, but just the sedation itself to be less obscure about it. Is it that, if you do not over sedate, you are going to have an alert patient?
A An alert patient that has no symptoms is great, but, sadly, that cannot often be achieved. You have to get a certain level of sedation to get rid of certain symptoms.

Q Absolutely right and I think you said to us a few moments ago that usually it is possible to get pain free without side effects and over sedation by judicious use of the opiates?
A Yes.

Q What I am suggesting is that when you said, "In the ideal world what we would do is titration over a period of up to two days", that would indeed be a judicious use of opiates?
A It would.

Q Its consequence, if it was done properly, would be that a patient would be able to remain pain free whilst at the same time sufficiently alert to spend his or her last hours or last days, at least part of the time, in the company of their family in a meaningful way.
A I think death is, what one reads about it, from the practicality there is a great difference. It is very difficult. When you actually have patients dying, the vagaries of the

process are tremendous. The only way to ensure comfort in any environment, even when you have doctors on call all the time and so on, is to make sure that the patient's symptoms are treated, and that was the reason for the WHO Guidelines on Pain Control, but it also applies to other symptoms than pain.

Q I am sure we have all taken on board very clearly that in the terminal situation a patient can, for perfectly natural reasons, become drowsy, become unrousable and so on. What I am concerned about is your phrase, "judicious use of opiates to best effect". It seemed to me that what you were saying was that, if one were to have this judicious use of opiates through a period of titration, it would reduce the risk of a patient being treated for what appeared to be symptoms, such as agitation and restlessness, as a result of the terminal process, but which were actually created as a consequence, as a side effect, of the over use of the opiate. By titrating you make that much less likely to happen. Was that your point?
A Yes, but the titration is far more labour intensive than just putting up the syringe driver.

Q You said that to us and you said one of the reasons for not going down that particular route was that a doctor would have to keep coming back every four hours or so. I did not quite understand that because the system that Dr Barton had developed of anticipatory prescribing with a range of doses, surely would allow for that. If, before one reached a prescription for the syringe driver one had a prescription, in effect for this up to 48 hour period of titration whereby the nurses themselves are able to monitor the patient, and indeed they are there to do just that, then they will go and administer because they have a prescription for it an increased individual dose if there is a need for it, but if there is not, then they would not do it. As a consequence, the patient could not become over sedated and, as a consequence, there would be less likelihood of the patient exhibiting symptoms as a result of the overdose of opiates that might be mistaken for end of life restlessness or agitation?
A I think if the patient was titrated orally with oral morphine, either slow release morphine or soluble morphine which acts quickly, one could get the 24-hour need. The difficulty is that if you start giving it intramuscularly or subcutaneously by bolus injection and you want to change that dose, that requires much closer monitoring to get the 24-hour level. It also allows variable prescriptions. I have never seen a practice where people, other than oral morphine, write variable prescriptions of intramuscular morphine in advance, whereas with the subcutaneous pump it is common practice to have a range of doses.

Q Aside from breaking a new path, because I do not think that is something that this doctor has been accused of not doing, you say that there would be a need for a greater degree of – I forget your words exactly – supervision and monitoring.
A Exactly.

Q How would that be more so than every four hours going to see how the patient is, making a determination as to whether you were (a) going to give any further sedation of opiate or diamorphine intramuscularly at all; or whether you were going to give the same as the previous dose; or whether you were going to give more?
A Intramuscular prescriptions are one at a time. It would be difficult to see how you would give a variable dose and know what was going on because you could have a different person every four hours – it has to be given every four hours – coming along and drawing up a different size of injection and then the kinetics would be all over the place. With subcutaneous pump the kinetics are smooth, with the oral medication the kinetics are smoothing out because of the time taken to absorb the dose.

Q Your clear evidence is that it would be in impractical to adapt that course?
A It would be.

Q The risk of not taking that difficult course, of course, is that you are going to therefore go straight to the syringe driver. Is that right?
A Yes.

Q That, without titration, carries with it the risk that you get the dose wrong and over sedate the patient.
A You begin at a low dose and work up with the syringe driver.

Q There has been a considerable discussion about whether a dose is low or not, but the risk would be in the abstract that, whatever dose you chose, you would run the risk of over sedating the patient?
A That is always the case with any form of analgesic.

Q The particular danger when that analgesic is an opiate is what?
A Respiratory depression, sedation.

Q Both of which lead ultimately to?
A To death.

Q What we are looking at here, it appears, is a regime where the single, most important element is to keep a patient pain free at all times?
A Yes.

Q You have discussed the potential for discussing with the patient, prior to putting them on to a syringe driver, whether that is a course that they would want to take and you rightly point out that in many cases that would not be something that elderly patients, with the sort of comorbidities we have been looking at, might be able to participate in?
A That is right.

Q In the cases where – and there may only be a few – they would be able to do that, would you regard that as an essential prerequisite before putting them on to that particular path?
A I would certainly try and explain what was going on and get their views on it, but that may not be possible in this group of patients.

Q I am specifically referring to those for whom it might be possible.
A In my experience it is pretty rare because people who are either in severe pain or very distressed just want the distress and the pain to end, they do not want to enter into an intellectual discussion about it or, indeed, have the existentialist thought about death with you.

Q Even in those very rare circumstances, do you think it should be for you to decide whether or not the patient wants to enter into that discussion, or would you feel it appropriate to at least give them the opportunity to do so?
A It may be that this group of patients could not get involved in the discussion.

Q If they could not, what would have been lost?
A Their consent to it, but I would go ahead.

Q If they could not consent, then you would not have lost the consent. You have only lost the consent, have you not, when they could have given it and you did not ask them?
A Yes, that is the case.

Q The whole business of keeping the patient pain free, is not automatically achieved by placing them on to a syringe driver with this combination of opiates, is it?
A Absolutely not.

Q Because breakthrough pain, at some stage there is the potential they are going to require more opiates?
A Yes.

Q The only way to be absolutely sure that your patient never again experiences pain is to keep increasing the dosage on a daily basis?
A That is the case, or not, to reduce it, to keep it steady and make sure they are still pain free or symptom free.

Q If you are doing either, but particularly if you are increasing it every day, the end result is obvious, is it not?
A Not having studied the patient, I am not sure it was increased every day.

Q I am talking in the abstract?
A In the abstract yes.

THE CHAIRMAN: Thank you, that completes my questions and, therefore, all the questions from the Panel. I am conscious that you have been grilled by us since 2.30. We normally reckon an hour is about enough. You have had coming up to an hour and a half. We will take a break now, because I am sure counsel will have more than one or two questions for you. Am I right in that, I think so, yes.

MR LANGDALE: I think I saw Mr Kark nodding, so I will be guided by him.

THE CHAIRMAN: We will return at ten past four.

(The Panel adjourned for a short time).

THE CHAIRMAN: Welcome back everyone. I hope you have had a chance to refresh yourself a little, Professor Sikora. I am going to pass you now to Mr Kark.

Further cross-examined by MR KARK

Q Professor Sikora, I am going to work backwards, as it were, from the Chairman's questions round. I just want to deal with the topic that you were dealing with shortly before the break. That is the issue of titration. I want to make sure that I understand it. First of all, is it right that it is easier to titrate before you start a syringe driver?
A Both are possible, and it depends on the clinical circumstances. If things are very slowly changing, then normally what happens, you begin at a low dose of an oral analgesic,

often a mild one, and go up the ladder, get to the opiate, titrate the opiate and then convert to a syringe driver. That is if there is a slow progress of the symptoms. If the progress is more rapid, which does occur, you may decide to just go straight into the subcutaneous pump.

Q If you are trying to deal with pain immediately, I think we have already established that a syringe driver is not actually the way to do it. To deal with acute immediate pain, you do not start the syringe driver, do you?

B A Very few patients get the sudden onset – one minute they are pain-free, the next minute they get sudden onset severe pain. It is usually a build-up that comes.

Q But the best way of titrating, as you said, I think, is you start with oral doses. You find out what the level is that will deal with the patient's pain and then, if necessary, you can convert to a syringe driver?

A Correct.

C

Q I just want to understand how titration works with a syringe driver. Have you still got this schedule that was produce, D7b?

A Yes.

Q From what you told us, the patient is not going to get to the plateau that you have described until about 13 hours into the medication?

D A Pretty close to the plateau, much sooner than that, but I agree they do not get into the final end of the plateau till then.

Q So it might take ten hours, not thirteen hours, but it takes a good while?

A It does.

Q You may then find that you need to increase the dose because the patient is still in

E pain, and you are going to increase it incrementally. Just using this table for a moment, let us imagine that we do not follow the guidelines and we double up, and you add another 20 mg to the syringe driver. If we go to hour 13, just to see if I can follow this, what will be in the patient's system before the new dose is put in is around, is it, 4.88?

A Yes.

Q And then, when the second dose of 20 mg is put in, so the patient is now receiving 40,

F they are going to still be receiving 4.88 but additionally to that, in the first hour, another 0.83?

A Correct.

Q That increased dose itself, of course, takes a long time to work up to the system?

A It does.

G Q If you are trying to deal with immediate pain, I suppose there is a danger that you increase the syringe driver by too much in order to deal with that immediate pain, but in hour 12-13 you are going to hit a problem, are you not?

A There is. The aim of the syringe driver is to reach a steady state over a 24 hour period, and just keep repeating that. Now, what one does if one doubles from 20 to 40, one has the plateau for 20, and if at any time you add another 20, you gradually go up to a new plateau.

H

Q Yes.
A Within 12 hours.

Q And there is a danger, is there not, if you do that too quickly that you are not just dealing with a patient's pain, but you are going to over-sedate them in ten hours' time?
A Certainly these drugs have side effects and, as you mentioned, that is one of the side effects. When you add an incremental dose to a syringe driver, you have to be thinking forward, as it were, to what that is going to peak to in ten or eleven hours' time?
A Yes.

Q That is very helpful. And so does it follow from that, that your responsibility for monitoring the patient is obviously that much greater?
A It is.

Q You told the Chairman when he was asking you questions about delegation, that nurses were not taking the decision to move to palliative care, and that may or may not be wrong. I just want to know on what basis you said that. Is that because you have taken that from Dr Barton's statements? Where have you got that from?
A Because only a doctor can write these drugs up, and therefore the doctor has to be involved in the decision. The nurses cannot write them up.

Q No, I am sorry. Okay. I might have misunderstood you. When we have an anticipatory prescription, we have a prescription sitting on the sheet - yes?
A Yes.

Q For a syringe driver to be started?
A Yes.

Q That can be started by nurses, can it not?
A Indeed, that can, but the doctor has made that decision that if the pain gets to a certain level, as judged by the nursing staff, they are empowered to start it.

Q Of course, it is difficult for the doctor to make that decision if the patient does not have any pain at that time – at the time she or he writes a prescription?
A But if they know the patient, and they can assess the progress of the disease, rather like ballet, they get the moving picture, then it may reasonable to do that.

Q I understand that. If they had known the patient for a good period of time, and they see how things progress ---
A Yes.

Q --- is that what you are talking about?
A Exactly so.

Q You spoke on a number of occasions about "this group of patients", and you said, for instance, "These patients have chronic diseases and long-term illnesses". You said earlier, "I cannot see the benefit of reducing the drugs to this group of patients". How are you grouping this?
A I was reading ---

Q They are twelve individuals.
A After the denominator that is unknown to me or presumably to us here, simply by reading the statements from Dr Barton on these patients, which I have read.

Q I am not criticising you for this, but which you accepted?
A Yes.

B

Q Because, of course, it is dangerous, is it not, to look at this as a group of patients because these are twelve individuals?
A Yes.

Q Some had hip fractures, one had a broken arm, some had sacral sores, some had dementia. It is dangerous if you start grouping ---
A It is. All had distress in common, and most had pain in common.

C

Q On the basis of Dr Barton's statements?
A Yes.

Q I see. Dealing with Dr Barton, you were being asked questions by Mr Payne about the issue of training, and I think your view. We have heard a bit of evidence about some training that Dr Barton had, but your view was that Dr Barton did not have specific training
D in palliative care, and obviously she was not a geriatrician, as it were, although she dealt with old patients?
A Yes.

Q For a doctor in that position, the guidelines, the Wessex protocol, which I expect you have heard of ---
A I have.

E

Q --- and the BNF take on an even greater significance, do they not?
A Yes.

Q The guidelines are there to guide the average doctor?
A Yes.

F

Q Is that fair?
A That is the case.

Q And of course there are circumstances, as you have told us, where a doctor can step outside the guidelines, but they have to exercise considerable caution when doing so?
A Yes.

G

Q And note it?
A Yes.

Q You said in your answers to Ms Julien that the fact that the nurses did not go to the top end demonstrates that the nurses were using their discretion appropriately. That is my précis; that is not by any means an exact note of your comments, but does that properly reflect an observation that you made?
H A The twelve doses and the twelve patients was a wide range, the top dose given.

Q Yes.
A *Which would imply that there is some form of titration going on.*

Q I just want to examine how you feel able to say that, not having seen the notes?
A Simply that if all patients had been put onto 100 mg, for example, every one of the twelve patients, that would imply that that is what they are using as standard, and they are not really using a sliding scale. The fact they vary from 20 to 120, with the average between 60 and 80, that suggests the sliding scale is being used appropriately.

Q It certainly suggests that a scale is being used, does it not?
A Yes.

Q Whether or not it is being used appropriately depends entirely on what the nurses were actually reacting to when they either started the syringe driver, or when they increased it, does it not?
A That is correct.

Q If it was inappropriate at the start, or that the increases were inappropriate, then the fact they did not get up to 100 mg does not matter ---?
A No.

Q --- at all, does it?
A Absolutely.

Q You were asked by Mrs Mansell about checks and balances, and Dr Barton was in a particular position at this hospital. She had the check, as it were, of the consultants?
A Yes.

Q But they were coming in less frequently than perhaps one might hope. They came in apparently on a weekly or fortnightly basis?
A Yes.

Q And she was not working in a hospital environment – an acute hospital environment – when she was surrounded by other doctors doing a similar sort of thing. But she did have, as we understand it, those consultants on the end of a telephone, did she not?
A Right.

Q Of course, for a doctor in Dr Barton's position, it takes a certain insight, I suppose, to say to yourself as the doctor, "I think I had better pick up the phone and speak to a consultant about whether I am going to start a terminal path with this patient." That requires the doctor to think about what she or he is doing?
A Yes, but I assume she did that on ward rounds. Patients were discussed on ward rounds.

Q With whom?
A With the consultant, when the consultant came round.

Q I think you said it was the responsibility of the consultants to adopt the role, to take the role of checking?

A Yes.

Q But again, there is a personal responsibility, is there not, on the doctor who writes the prescription, to ensure that their practice is appropriate?
A Yes.

Q Just finally this on the issue of notes – again, you were asked about this by Mrs Mansell, and I think you said, now, before a patient is started on a terminal pathway or even a palliative pathway, you would expect there to be a multi-disciplinary team decision. Yes?
A Yes.

Q And you said that that should be noted, and the reasons should be noted now, but were you saying that was not the case ten or fifteen years ago? Are you saying that even ten or fifteen years ago a doctor should not have made a note that a patient was being put on a terminal pathway?
A In a sense, the prescription could serve as the indication that that has started – the very prescription is a note. But in an ideal world certainly you would expect to see at least a one line note saying this has happened, and maybe an annotation of the reasons.

Q It is not just an ideal world, is it, the cake with frosting on the top? It is pretty basic, is it not, ten or fifteen years ago to make a note that you are entering a patient on a terminal pathway?
A I have not seen the notes, so I do not know what notes were made.

Q But that would be a pretty basic note to make?
A Some sort of annotation would be optimal.

MR KARK: Thank you.

THE CHAIRMAN: Mr Langdale.

Further re-examined by MR LANGDALE

Q Professor Sikora, I am only going to take about half a dozen matters arising out of questions you were asked by the Panel. I am going to take them more or less in the order in which the Panel members dealt with them. The question of – my words – Dr Barton consulting the consultant before concluding that a patient's condition was such that they were in a state of terminal decline – again, my words. Did you realise that the evidence from the consultants was that they did not expect Dr Barton to consult them about that? Did you realise that that was the evidence?
A I did not realise.

Q So in relation to a clinical assistant in the position of Dr Barton, with the consultants not expecting her to consult with them, and not expecting her to consult with them about whether a syringe driver should be started or not, what do you say about the clinical assistant's position?
A She or he has to do the best they can within their capacity, within the system and the constraints of it, and I have done the same. When I was first a consultant, I consulted on many patients by telephone with a senior colleague at another hospital before making a

clinical decision. In the end he told me politely not to bother him. "You are now on your own. Just do it. You make the decision," and I suspect that may have happened here.

Q In relation to the question of nurses, as it was put to you, the risk of nurses going in at a higher rate, I am not going to trouble you with the detail that we have heard in this case about whether nurses started at the bottom of the range prescribed, or did not, but just so we can consider this in relation to the case of the patient who, when he died, was receiving 120 mg of diamorphine in 24 hours, I think you indicated it would depend on how it was built up.
A Yes.

Q This particular patient had been on Oramorph for something like four or five days before diamorphine at 80 mg was started. He was on that for two days, and then the dose had 50 per cent added to it, so it became 120, and he was being treated with medication in terms of the diamorphine at 120 mg per day for six days. Is that something which would appear to you to be a consistent kind of build-up, or not?
A Yes, yes.

Q In terms of Dr Barton as clinical assistant, matters were raised with you about her training. It is not suggested in this case, and has never been suggested by the GMC, that she was not properly, adequately trained to be a clinical assistant.
A Absolutely not.

Q And I think it follows from what you have told us that that was the view you had formed?
A Yes.

Q In relation to a clinical assistant being somebody who was a competent and experienced GP, would there be anything to cause anyone concern in relation to such a person being entitled to make a decision as to what was an appropriate amount of opiate to prescribe to a patient in this elderly type of patient group?
A I would imagine that is perfectly within the capability of an experienced GP.

Q Similarly, in relation to whether it was appropriate to commence the administration of opiates by means of a syringe driver?
A Yes, again, within the capability of a GP.

Q We have heard evidence about GPs being responsible, not only in general, but also in Dr Barton's case, for people who are on a syringe driver, say, at home?
A Yes.

Q It was suggested to you that the significance of the experience of a clinical assistant like Dr Barton would be affected by whether their experience had been or had not been subject to any checks and balances in the sense of other people having some input into what they did. Were you aware that before Dr Lord and before Dr Reid were consultants, there were also consultants – I think Dr Wilkie was one name, Dr Grunstein may have been another, although I may not be remembering them correctly – who were in place right from the time that Dr Barton started as a clinical assistant?
A I was unaware of that.

Q Were you aware that we have an example in this case in 1991 of Dr Logan, another consultant who was in post at the time, giving clear indications as to what he thought was appropriate with regard to the administration in particular of diamorphine?
A No, I did not have that information.

Q In terms of the *BNF* I think it was put to you that it had been in existence for 300 years – unless I misheard the evidence. What was the position with regard to the length of time the *BNF* has been in existence so far as you are aware?
A Certainly not more than 40 years.

Q We can check on that. You were also asked about the question of acceptable risk with regard to anticipatory prescriptions. Obviously this is clear, there is no dispute about it, that with an anticipatory prescription which has a range there is a dose range, quite a wide dose range, there is a risk that a member of the nursing staff might administer to a patient an unacceptably high dose of analgesic, within the range but unacceptable because it did not meet the patient's condition. You indicated that of course there is a risk; does the nature of the risk, the degree of the risk, depend on the trust the prescribing doctor has in her nursing staff?
A Yes, a nurse under these circumstances is perfectly entitled to give a patient a pump with 200 mg for 24 hours because they have made the assessment that that patient needs it. So there is a degree of trust and there is no evidence from the 12 cases that that was happening.

Q Would the degree of trust placed by a doctor in her nursing staff depend on her experience of their actions over a period of time?
A It would.

MR LANGDALE: A question was asked by a member of the Panel about the issue of dementia. Sir, the reason I am not going to pursue this with Professor Sikora is because I think I know which patient may have been in the Panel member's mind but I do not think it is appropriate to ask Professor Sikora about it because I shall immediately go into what were the other features of the patient's case, so I am going to specifically avoid going into a specific patient. That concludes what I have to ask; thank you very much.

THE CHAIRMAN: Thank you, Professor. That then completes your testimony. We are most grateful to you for coming to assist us today. As you will have gathered there are a lot of issues that at the end of the day the Panel are going to have to wrestle with and reach a conclusion on; your expert assistance in that area is of course greatly appreciated and we thank you very much indeed for coming. You are free to go.

(The witness withdrew).

MR JENKINS: Sir, you will recall that at the start of the day I was intending to call a witness but after some discussion with Mr Kark and your learned Legal Assessor we delayed that witness and sent them home. I would like nonetheless to call that witness and a couple of others tomorrow. I know that there is objection from Mr Kark.

THE CHAIRMAN: Just that witness or the other couple as well?

MR JENKINS: They are in a similar category to the witness and so the argument that we are about to embark on relates to all three of them. Sir, you now get some legal argument – you may want to take a break first or you may be happy to embark on it. I do not think it will be terribly long.

THE CHAIRMAN: We may want to take a break after we have heard it and consider it.

MR JENKINS: You will certainly have to take time to consider it. The issue is this: if I am allowed to call the witnesses then obviously they can come tomorrow. If I am not allowed to call the witnesses I do not want them to come tomorrow and then be told to go away again. If it were possible I would be very grateful if a decision were reached today. You will be aware, I am sure, of the practice that is sometimes followed at the GMC where Panels deliberate, reach a decision and give the parties their decision and hand down reasons for the decision at a later time. If that were something that was convenient to the Panel I would be very grateful if that could be followed today because I recognise, of course, that on occasion it is the drawing up of the reasons for the decision that may take a longer period of time – the decision itself may be taken relatively shortly.

THE CHAIRMAN: We are certainly happy to attempt to embark on that course but I do observe that we are already past twenty-five to five. If the arguments are of themselves both quickly put and relatively straightforward we might be able to accommodate you, but if there is anything of substance we may not be able to. We are certainly willing to try at this stage.

MR JENKINS: Why do I not crack on? The rules that govern these proceedings – at the moment we are rule 27(g) which is the rule that says:

> "The Practitioner may then address the Committee concerning any charge which remains outstanding and may adduce evidence, oral or documentary (including his own) in his defence."

Clearly, we are at the defence part of the case where the defence are calling such witnesses and such evidence as they wish. There is a fetter on that and we have looked at rule 50 before that deals with evidence. Can I remind you what it says? It is in these terms:

> "The Professional Conduct Committee [this is a Fitness to Practise Panel but it is under the Old Rules] may receive oral, documentary or other evidence of any fact or matter which appears to them relevant to the inquiry into the case before them, provided that ..."

It then goes on to say if it would not be admissible under criminal proceedings the Panel can receive it if they have received advice from the Legal Assessor and they think that their duty of making due inquiry into the case before them makes its reception desirable.

What I would like to call is evidence from three individuals, two of whom are patients of Dr Barton and all three of whom have had a parent treated by Dr Barton at the Gosport War Memorial Hospital at the time when Dr Barton was there, that is before she resigned in early 2000. The patients themselves are able to speak about their treatment by Dr Barton; each of them can speak of the way in which Dr Barton treated the parent. Two of them are nurses and one of them is the practice nurse at the general practice where Dr Barton works and has done for many, many years.

The evidence of those individuals obviously includes an opinion as to how Dr Barton treated the patients – whether that be the witness or their parent – it includes evidence as to how Dr Barton treated her patients at the War Memorial Hospital during the relevant time. It obviously includes a view as to how conscientious Dr Barton was and the extent to which she was acting in the best interests of the patients.

I know there is an objection to calling evidence about other patients and the objection is this, that you as a Panel are only dealing with the 12 individuals listed in the Notice of Hearing and in respect of, let us say, Patient A, part of the allegation relates to a specific prescription and the suggestion is that that prescription was or was not appropriate or not in the patient's best interest.

I agree entirely that the evidence of other individuals relating to other patients does not assist you as to whether a specific prescription for Mr Pittock was appropriate for his then needs or not, but there are of course other allegations against Dr Barton included in the Notice of Hearing. It is alleged in respect of every single patient that Dr Barton failed to assess them before prescribing for them, it is alleged in respect of certainly two of the patients that Dr Barton did not carry out an assessment or an examination of that patient.

On those allegations any evidence that goes to Dr Barton's conscientiousness, of her wish to do what was best for the patient, is evidence in respect of the suggestion that she did not assess the 12 patients in front of you. It is evidence as to disposition, it is evidence as to her general commitment to patient care, it is relevant evidence on factual allegations that you have to determine.

To take a different example, if someone were accused of dishonesty on a specific occasion the defence would obviously be entitled to call evidence to say this man is honest; he is honest on other occasions. It is evidence as to disposition and it is plainly relevant on factual matters that have to be determined. I say exactly that analysis applies here to the allegations in the Notice of Hearing that Dr Barton failed to assess any of the 12 patients.

There are issues in this case. You have heard general allegations about Dr Barton's practice. You have heard allegations about how she dealt with relatives, how she dealt with patients. You have heard from about four individuals the suggestion that she was brusque or cruel – I think that was one word used of her conversation with one of the relatives. We are entitled to meet that evidence otherwise the evidence that you hear is entirely one-sided, and we are entitled to meet that by calling evidence, evidence from witnesses who were there when a patient was spoken to or who are patients themselves.

The case has ranged fairly widely so far as the Gosport War Memorial Hospital is concerned. One of the panellists – sir, I think it was you – asked one witness whether the wards were "safe". We are entitled to call evidence to deal with that allegation if it is a concern that the panellists have, any one of them or all of them. We must be entitled to call evidence to deal with that suggestion.

What I say – keeping it short because of the time – is that we are entitled to call evidence from other patients, from the relatives of patients who have seen how Dr Barton deals with patients and patients at the War Memorial Hospital, and that that evidence is relevant to the

hearing that you are embarked upon. That is the application and the basis upon which I make it.

THE LEGAL ASSESSOR: Sir, I do not wish to add unnecessarily to the length of time but I simply would like to establish this if I can, Mr Jenkins. If one looks at rule 27(2) when the Panel retires at the first stage it has to consider two matters, firstly whether the remaining facts alleged in the charge are proved and, secondly, whether such facts would be insufficient to support a finding of serious professional misconduct.

I obviously would like to keep my advice as short as possible and I wonder whether Mr Jenkins is able to concede that the evidence he proposes to lead is not relevant to the issue of serious professional misconduct. If that concession is not made it may well be that I do have to give some advice to the Panel about that because that would affect the issue of that evidence's admissibility.

MR JENKINS: I am sorry, could you say that again? The difficulty with 27(2) is that it has got a double negative in it and sometimes it is difficult to quite understand what is meant. The Panel are enjoined to consider, once they have considered factual questions and made determinations on the facts –

> "The Panel shall consider whether such facts as have been so proved or admitted would be insufficient to support a finding of serious professional misconduct and shall record their finding."

I am prepared to make the concession and I do not invite the gloss that I know the Legal Assessor was considering when he and I discussed the matter at an earlier stage. What I say simply is that the evidence I seek to call from other patients and others who are the relatives of patients treated by Dr Barton and at the War Memorial Hospital during the relevant period is directly relevant to some of the factual findings that the Panel have to make and it is certainly relevant to other evidence that has been given, other issues that have been raised, including raised by the Panel in the evidence that you have heard so far.

R KARK: I do not perhaps need to say very much because Mr Jenkins has not only presented his own argument but he has anticipated, on this occasion correctly, mine, so I can be quite short.

This really is simply character evidence. Of course there are circumstances where you should receive character evidence, we all know about the case of *Campbell* and the line that was followed thereafter, but what those cases provide is that you have to consider what evidence is actually relevant and is going to help you in relation to the specific charges that you are considering. For instance, if a doctor is charged with offences of dishonesty it is obviously appropriate that you should hear evidence that that doctor has not been convicted previously of offences of dishonesty and has a good character, so the only issue is whether it is going to help you to hear from either the relatives or the patients themselves who have been treated properly.

The GMC have not suggested to you that other than in relation to these 12 cases that have been put before you Dr Barton otherwise generally was not assessing her patients properly or prescribing properly. These charges are what you have to do. There may be all sorts of other cases where she has assessed patients properly.

Mr Jenkins wants to call some evidence as I understand it from people who have nothing to do with these patients that you are dealing with at all to say that they were properly treated. It is not going to be any part of my speech that anybody else was not properly treated; I am concentrating for my part on behalf of the GMC on these patients and these issues. It is entirely a matter for you to decide whether you think this sort of evidence is going to help you to make those decisions or not.

*MR JENKINS: Can I reply? You do have evidence about other patients. If you go to tab 6 of bundle 1 you have got the information from Giffin, Tubritt and others relating to patients whose details we have never seen; we do not know who those individuals are. You have been asked to look at that evidence relating to other patients. Shirley Hallman has talked about at least one other patient – we know nothing about that patient. We do not know who they are, we have been in no position whatsoever to contradict what has been advanced. Mr Kark has called that evidence in front of you and for him to say we are only concerned with these 12 is not right. He has placed evidence in front of you in relation to others. We have not objected because it was part of the history and we have allowed that to go before you, but to say you are only concerned with these 12 is simply not right. It is true that you only have to make factual findings in respect of 12 but the case is wider than that and many, many questions have been asked that go far wider than the 12 patients. It has been suggested by Mr Kark or raised as a question did she do this in every case? We have not seen the records of every case that Dr Barton did. We have been in absolutely no position to respond to that sort of suggestion. There were hundreds or thousands of patients that went through the system – we have seen the notes I think of 42 and you have got 12.

All we can do to respond to that sort of suggestion is to call evidence in respect of other patients. That is what we are seeking to do. It would be wholly wrong for us to be shut out from doing that.

Patient B, the allegation in the Notice of Hearing at 3(d) is:

> "In relation to your management of Patient B you
>
> (i) did not perform an appropriate examination and assessment of Patient B on admission;
> (ii) did not conduct an adequate assessment as Patient B's condition deteriorated."

Where is the evidence as to that? The evidence is that there is a lack of a note. Have you heard from a single witness who says there was no assessment undertaken? No, there is not. What you have got to do is to deal with the evidence that you have heard, but if there is more evidence in addition to some of the nurses that you have heard from and Dr Barton herself, who would say, "Yes, she was a very conscientious doctor, she always wanted to do what was best for her patients" that must be relevant to the issue is Dr Barton likely to be right when she says she did perform an examination and assessment, she did conduct an assessment as Patient B's condition deteriorated. Of course it is relevant and of course we should be allowed to call it.

Forgive the vehemence but it is a way of keeping the submissions short.

THE CHAIRMAN: Thank you very much Mr Jenkins. I will hear now from the Legal Assessor.

THE LEGAL ASSESSOR: Sir, I hope to be short without being vehement. Mr Jenkins seeks to call certain evidence from three individuals relating to the character, skills and patient examination practices of Dr Barton – I hope that that summarises the situation fairly.

Mr Kark seeks to put down a marker at this stage concerning the timing of that evidence and the use to which that evidence may be put. He is concerned as to whether Mr Jenkins is straying into the area of pure character evidence. I only offer advice, what you decide is entirely a matter for you.

We have heard character evidence already from some of the witnesses called on behalf of Dr Barton and from other witnesses. That frequently happens in cases before the GMC, sometimes because of timetabling difficulties, but more often because the witness concerned is able to give mixed evidence as to fact and character. It would be a waste of time and resources to have to call that witness twice over at different stages of the proceedings.

It does not mean that all the evidence you have so far heard is relevant to the first stage of your deliberations. In due course I will give a detailed advice as to precisely what evidence you can take into account at each of the stages of your deliberations, but I give the following advice now. When you go into camera during the first stage of your deliberations, you are considering not just whether you find the outstanding facts proved but thereafter also whether any facts proved or admitted would be insufficient to support a finding of serious professional misconduct. That latter part of the process I will not address again, given the concession made by Mr Jenkins.

There are, you may think, two possible uses to which the proposed evidence could be put at this stage. First, to the issue whether Dr Barton is guilty of the allegations. It is said that, because Dr Barton treated other witnesses well and considerately, that tends to show that the allegations are not made out; and, secondly, it is evidence as to Dr Barton's skill and character generally.

In order to be relied upon by you, any evidence must be relevant to the specific allegations faced by Dr Barton. You may find it helpful to consider separately the issues of good character and general medical skills on the one hand and Dr Barton's examination practices on the other. Although it is a matter entirely for you, you will no doubt wish to consider the position very carefully before you conclude that any character evidence as to the medical skills is relevant to the fact finding part of the first stage. This is because the allegations are patient specific, they are not general allegations as to, for example, the overall competence of Dr Barton generally. You will decide the allegations on the evidence you have heard. Some of the unadmitted allegations relate not to the issue of whether Dr Barton did or did not do something, but to the issue whether what she did was, for example, inappropriate. You may think that there, the proposed evidence, whether as to skills, character or examination practices, would certainly be of little assistance to you in your fact finding process. Furthermore, you will hear in due course that Dr Barton is agreed to be a person of good character. If that is the case, I will advise you formally in due course that her good character may be taken into account when you consider her credibility and any allegation that she has acted discreditably. Do these aspects, namely the general medical skills and character, amount purely to personal mitigation? It is a matter for you.

Moving on, some of the allegations do allege that Dr Barton did not do something, for example assess a patient. Mr Jenkins wishes to call evidence as to the fact that Dr Barton properly did assess other patients. It is not in dispute that Dr Barton clearly did assess patients with the exception of the patients charged. Moreover, the fact that she assessed one patient does not mean that she necessarily assessed the patients you are considering. You may also wish to take into account that the evidence Mr Jenkins wishes to call in this respect is not professional medical evidence. It is clearly the case that purely personal mitigation is not to be taken into account by you at the fact finding stage. The issue for you to consider is to what extent, if at all, the proposed evidence goes beyond mere personal mitigation and assists you as to a live issue at the fact finding stage.

I conclude by saying that it is open to you to admit a part only of the disputed evidence.

THE CHAIRMAN: Thank you Legal Assessor. Mr Kark, do you have any observations on the advice just tendered?

MR KARK: No.

THE CHAIRMAN: Mr Jenkins, do you have any observations?

MR JENKINS: No, thank you.

THE CHAIRMAN: We will go into camera now. We will call you back reasonably shortly to tell you how we are getting on and how we propose to handle things.

STRANGERS THEN WITHDREW, BY DIRECTION OF THE CHAIR AND THE PANEL DELIBERATED IN CAMERA

STRANGERS HAVING BEEN READMITTED

THE CHAIRMAN: Welcome back, everyone. I will put you out of your misery quickly, Mr Jenkins. We cannot give you an answer today. If we could have done, we would have done, but not just your vehemence, but the strength of your arguments has convinced us that this is something that should be given proper weight and proper consideration. At this end of the day, even if it were just to reach a decision, it would still be taking us a substantial period of time.

We have done our best to crystal-ball gaze as to how much time the process will take us, starting from 9.30 tomorrow. Our most realistic estimate is that we should say to you not before two o'clock. By that time we should have both an answer and a full written determination for you.

There is always the possibility in these cases, as you know, that we run into difficulty and discussion and require further legal advice, in which case, before we can take that advice we need to call the parties so that they can hear it and comment on it. For that reason, what I am going to do is to ask the lawyers in the case, please, to ensure that the Panel Secretary has a contact detail for each that will allow her to call you and get you to this room within about 30 minutes of the call. I think you can safely say in any event, it would not be before, say,

10.30. We are unlikely to plough straight into difficulties, but if we do have those, we will not want to wait and delay you until 2 o'clock before we can put them before you.

MR JENKINS: Thank you for that. I quite understand.

THE CHAIRMAN: Please make sure before you depart that the Panel Secretary has those details. We will resume in camera tomorrow morning at 9.30, and we are hoping at this stage that we will be able to go back into open session not before 2 o'clock which, hopefully, will not be too long after two.

Thanks you very much, ladies and gentlemen.

(The Panel adjourned in camera until not before 2.00 p.m. on Thursday 30 July 2009)

(Parties were released until 2.00 p.m. on Thursday 30 July 2009
but to be contactable after 10.30 a.m.)