FITNESS TO PRACTISE PANEL
21 MARCH – 24 APRIL 2012
7th Floor, St James's Buildings, 79 Oxford Street, Manchester, M1 6FQ

Name of Respondent Doctor: Dr Jean Anne MONRO

Registered Qualifications: MRCS 1960 Royal College of Surgeons of England, LRCP 1960 Royal College of Physicians of London, MB BS 1960 University of London

Area of Registered Address: Hertfordshire

Reference Number: 0552174

Type of Case: New case of impairment by reason of misconduct

Panel Members: Ms E Samupfonda, Chairman (Lay)
Dr A Vaidya (Medical)
Mrs M Bamford (Lay)

Legal Assessor: Mr D Smith

Secretary to the Panel: Mr A Chan

Representation:
GMC: Mr Jeremy Donne QC, instructed by GMC Legal

Doctor: Dr Monro was present and represented by Mr Angus Moon QC, instructed by Nabarro LLP

ALLEGATION

"That being registered under the Medical Act 1983, as amended:

1. Since 1988 you have worked as the Medical Director of the Breakspear Hospital, ~~Hemel Hempstead~~ latterly the Breakspear Clinic, a private ~~day care~~ hospital specialising in environmental medicine and chronic fatigue disorders; **Admitted and Found Proved**

2. On or about 9 January 2009 Doctor's Data laboratory of Illinois, USA, reported the analysis of pre- and post-DMSA provoked urine samples obtained from Patient HB on 5 January 2009; **Admitted and Found Proved**

3. In a letter to HB's general practitioner ('GP') on 2 April 2009 referring to Dr G's letter dated 12 February 2009 and HB's urine toxic metal analyses you advised that HB should embark on a programme of chelation therapy as soon as possible to remove the lead from his body; **Admitted and Found Proved**

4. You did not

   i. measure HB's blood lead concentration, **Admitted and Found Proved**

   ii. refer HB to a specialist in toxicology or lead poisoning, **Admitted and Found Proved**

   iii. seek the advice of the National Poisons Information Service; **Admitted and Found Proved**

5. You did not explain to HB or his GP that

   i. the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of HB's blood lead concentration, **Admitted and Found Proved**

   ii. the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate; **Admitted and Found Proved**

6. You did not advise HB or his GP

   i. of the possible complications from chelation therapy, **Admitted and Found Proved in relation to HB's GP. Found Proved in relation to HP.**

   ii. that chelation therapy is available free of charge from the National Health Service if clinically required; **Admitted and Found Proved in relation to HB's GP. Found Proved in relation to HP.**

7. HB received chelation therapy at the Breakspear Hospital subsequent to you being notified by the GMC of his GP's complaint against you; **Admitted and Found Proved**

8. The amount of sodium calcium edetate administered to HB during his course of chelation therapy was substantially below the BNF recommended dose for patients with lead poisoning; **Admitted and Found Proved**

9. Your treatment recommendation at 3 above was

   i. made despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity, **Found Proved**

   ii. made despite you not having specialist training or expertise in

a. clinical toxicology, **Admitted and Found Proved**

b. the investigation and treatment of lead poisoning, **Admitted and Found Proved**

iii. based on inadequate evidence, **Found Proved**

iv. potentially harmful; **Found Proved**

10. Your conduct described in paragraphs 3,4, 5, 6, 7, 8 and 9 above was not in the best interests of the patient. **Found Proved in relation to paragraphs 3, 4 (in its entirety), 5 (in its entirety), 6(i) and 9 (in its entirety). Found Not Proved in relation to paragraphs 6(ii) and 7.**

And that by reason of the matters set out above your fitness to practise is impaired because of your misconduct."

Determination on facts

"Dr Monro:

At the outset of these proceedings, the Panel acceded to an unopposed application made by Mr Donne, on behalf of the General Medical Council (GMC), to replace the word 'performing' in paragraph 5(i) of the allegation with the words 'analysis of'.

Following this amendment, Mr Moon, on your behalf, made a number of admissions in relation to the amended allegation and the Panel announced the following paragraphs as admitted and found proved: Paragraphs 2, 3, 4 (in its entirety), 5 (in its entirety), 6(i) and 6(ii) in respect of not advising HB's GP, 7, 8 and 9(ii)(a).

During the course of the proceedings, Mr Donne made a further application to amend the allegation. He applied to replace the words 'Hemel Hempstead' in paragraph 1 of the allegation with the words 'latterly the Breakspear Clinic' and to remove the words 'day care' from that same charge. These proposed amendments were not opposed by Mr Moon and the Panel acceded to the application. Mr Moon, on your behalf, then admitted paragraph 1 as amended and the Panel announced it as being admitted and found proved.

After making his closing submissions on the facts, Mr Moon made a further admission on your behalf, namely, paragraph 9(ii)(b), which the Panel announced as being admitted and found proved.

The Panel has considered the outstanding paragraphs of the allegation separately. In doing so it has considered all of the evidence adduced in this case including your own oral evidence, the oral evidence from witnesses called by the GMC and by you, the documentary evidence placed before it, and the submissions of both Counsel.

The Panel has accepted the Legal Assessor's advice that the burden of proof rests with the GMC and that proof is to the civil standard.

At the outset of this determination, the Panel acknowledged that this is a complex and technical case concerning a specialised branch of medicine. This case concerns the alleged use of inappropriate methods by you, together with a former colleague, to diagnose and treat lead toxicity in a patient, HB.

The Panel's assessment of witnesses

The Panel has heard evidence of fact from Drs A and B, HB's General Practitioners. It also heard from Dr C, Consultant Chemical Pathologist and regards all three as credible and reliable witnesses.

Expert witnesses

Expert witnesses have been called by both sides. The GMC called two experts, Professor D, a Consultant Clinical Pharmacologist who holds a Chair in the University of Birmingham Medical School. He is the Director of the Birmingham unit of the National Poisons Information Service; the second witness, Professor E is not a clinician as he is not medically qualified, but holds a doctorate and an NHS post as a Consultant Clinical Toxicologist at King's College Hospital. He is also a visiting Professor in Analytical Toxicology at the University of Loughborough and an Honorary Professor of Analytical Toxicology at Queen Mary College, University of London.

Professor F was called on your behalf. Professor F is not a clinician but is Emeritus Professor of Medicinal Chemistry at the University of Sunderland, holds a PhD, Faculty of Medicine from the University of London and is, by election, a member of the Royal Institute of Chemistry. His main area of expertise is medicinal chemistry and, since 1997, has been heavily involved in the, "*emerging complex, chronic multi-system conditions (largely environmental) as a scientific advisor to many different groups of people*".

The Panel's assessment of the experts

The Panel accepted the Legal Assessor's advice that, "*An expert [is]…a witness who has acquired by study or experience sufficient knowledge of the subject to render his opinion of value in resolving the issues before the Panel. An investigation of the methods used by the witness in arriving at his opinion may be pertinent. If he does possess the necessary competence his evidence of opinion is admissible; the fact that an expert witness may have been discredited will go to the weight of the evidence, not to its admissibility*". It has considered the experience and background of all three experts and the manner in which they dealt with matters relevant to the charges of the allegation. The Panel was impressed by both Professors D and E, and

regards their opinions, based as they were, on substantial experience in both research and practice, as persuasive.

Although the Panel acknowledges that Professor F is an expert in his own field of medicinal chemistry, his professed expertise in the field of lead toxicity is limited. He stated in evidence that, prior to this case, he had no experience of lead toxicity. Further, he stated that he does not seek to compare his depth of knowledge with that of Professors D and E. He accepted that lead toxicity is a heavily researched area with in excess of 20,000 published papers in the last two or three decades alone; he admitted that he had only read, "*a big handful compared with the total*". The Panel has also noted that Professor F made an elementary mistake in preparing his evidence - his misinterpretation of some of the figures in table 1 in the learned article of Perrine Hoet et al entitled, "Clinical Evaluation of Lead Mobilization Test Using the Chelating Agent DMSA, Clinical Chemistry 52:1 88-96 (2006)". This served to undermine his professed expertise in the field of lead toxicity. The Panel has noted that Professor F's evidence is based solely on his interpretation of academic literature and does not derive from practical and direct experience in the field. The Panel could not give weight to his conclusions and opinions where they conflicted with those of the other experts.

The Panel's treatment of your evidence

The Panel noted that Mr Moon conceded on your behalf that you do not have specialist training or expertise in clinical toxicology or in the investigation and treatment of lead poisoning. However, it was argued on your behalf, and you asserted in your evidence, that you are an expert in the field of environmental medicine. Mr Moon invited the Panel to treat you as an expert in this field. In assessing whether it should do so, the Panel considered the following factors:

1. you do not have any formal recognised (by the GMC) qualification or training in occupational medicine within which the specialty of environmental medicine falls;

2. you have not produced any learned papers in the specialty you assert although you have been involved in some research in the area of environmental medicine;

3. you have not produced evidence of any post-qualifying experience or certificates in environmental medicine or in treating body burdens of lead, though you stated you have attended a variety of courses and received training.

The Panel has been presented with no evidence to substantiate your claim that you are an expert in environmental medicine and was not provided with your CV. Whilst the Panel acknowledges that you said in evidence that you are a fellow of the American Academy of Environmental Medicine and have a Diploma of an International Board in Environmental Medicine, it rejects your evidence and

Mr Moon's argument that this makes you an expert in environmental medicine. In the circumstances, the Panel has treated your evidence as equiDnt to any other witness appearing before a Panel.

Expert academic literature

The Panel has been presented with numerous academic papers from each party in support of its own case. The Panel has read and considered these articles in full and the arguments propounded by the authors. The Panel has reserved comment on these articles unless otherwise necessary in this determination. As a general comment, however, the Panel appreciates that mutually exclusive interpretations supporting opposing views have been presented.

The Panel's findings

Paragraph 1 as amended:

> "Since 1988 you have worked as the Medical Director of the Breakspear Hospital, ~~Hemel Hempstead~~ latterly the Breakspear Clinic, a private ~~day care~~ hospital specialising in environmental medicine and chronic fatigue disorders"

has been admitted and found proved

Paragraph 2:

> "On or about 9 January 2009 Doctor's Data laboratory of Illinois, USA, reported the analysis of pre- and post-DMSA provoked urine samples obtained from Patient HB on 5 January 2009"

has been admitted and found proved.

Paragraph 3:

> "In a letter to HB's general practitioner ('GP') on 2 April 2009 referring to Dr G's letter dated 12 February 2009 and HB's urine toxic metal analyses you advised that HB should embark on a programme of chelation therapy as soon as possible to remove the lead from his body"

has been admitted and found proved.

Paragraph 4:

> "You did not"

Paragraph 4(i):

> "measure HB's blood lead concentration"

has been admitted and found proved.

Paragraph 4(ii):

"refer HB to a specialist in toxicology or lead poisoning"

has been admitted and found proved.

Paragraph 4(iii):

"seek the advice of the National Poisons Information Service"

has been admitted and found proved.

Paragraph 5:

"You did not explain to HB or his GP that"

Paragraph 5(i) as amended:

"the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of HB's blood lead concentration"

has been admitted and found proved.

Paragraph 5(ii):

"the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate"

has been admitted and found proved.

Paragraph 6:

"You did not advise HB or his GP"

Paragraph 6(i):

"of the possible complications from chelation therapy"

has been admitted and found proved in respect of not advising HB's GP. Has been found proved in respect of not advising HB.

In finding this fact proved, the Panel noted your evidence that you had assumed that Dr G, a former colleague at the Breakspear Clinic, had advised HB of the possible complications from chelation therapy. However, in looking at HB's medical

records for the period in which Dr G saw him, the Panel could not find any reference to any advice given by Dr G of the possible complications of chelation therapy. Further, even if your assumption had been correct, the Panel considers that it would have been good practice for you to ensure that HB was again advised of the complications when you took over his care, particularly so given that more than six months had elapsed between Dr G's treatment recommendation and the actual chelation therapy taking place. The Panel considers that, as HB's treating physician at the time, it was incumbent upon you to advise him of the complications.

Further, the Panel noted your evidence that you told HB that, "*in general, it is a completely safe procedure in our hands. The second thing is I did say to him that we would be providing him with the nutrients that are required for replenishment*." The Panel has also had regard to the brochure entitled "Chelation Therapy" which is readily available at the Breakspear Clinic, a copy of which had been obtained by HB. Professor D stated that this brochure, "*is a helpful adjunct because patients often forget what they have been told in a consultation, so to have a booklet is an excellent idea as long as it is up-to-date and accurate*." However, he pointed out that, "*it does not mention the adverse effects of sodium calcium edetate at all when given intravenously, so HB could not have been informed about the potential adverse effects because it is not mentioned*."

You also stated in your evidence that, "*should [patients] require any further information about any of the things that we were proposing for them it was available to them. It is also on our notice boards that such information is available*." The Panel regards this to be insufficient in that it transfers responsibility to patients.

In all the circumstances, therefore, whilst it was helpful of you to have informed HB of potential nutrient depletion, this does not itself sufficiently alert patients to the potential complications of chelation therapy.

Paragraph 6(ii):

> "that chelation therapy is available free of charge from the National Health Service if clinically required"

has been admitted and found proved in respect of not advising HB's GP. Has been found proved in respect of not advising HB.

In finding this fact proved, the Panel considered your evidence that HB had a copy of the brochure. It was pointed out to the Panel that, within the introduction section of the brochure, it states,

> "*Chelation therapy is the standard treatment used in the UK National Health Service (NHS) for acute metal poisoning.*"

It was submitted on your behalf that this statement amounted to advice that chelation therapy was available free of charge on the NHS if clinically required. The

Panel considers that the statement in the brochure does not make this sufficiently clear; it is merely a statement informing a reader that chelation therapy is used in the NHS. Further, the Panel recognises that there are some clinical services which, although offered by the NHS, are not free of charge. The Panel considers that it would require a sophisticated patient to understand that the statement in the brochure indicates that chelation therapy is free of charge on the NHS.

Further, the Panel noted that, when you were asked a direct question as to whether your clinic would normally advise patients of the availability of treatment on the NHS if they were clinically indicated, you stated that chelation therapy was, "*suggested to his doctor",* and that, *"if his doctor wished to refer him, she was at liberty to do so, but, you know, it was her choice as to whether this should be pursued, and it was also the choice of the two doctors on the PCT Panel who decided to fund his treatment at the Breakspear rather than fund his treatment with the national poisons centre."*

The Panel considers that you were vague in answering the question and appeared to place the responsibility on HB's GP, Dr A. The Panel has heard from Dr A that, at that time, she did not know what chelation therapy was. You have admitted that you did not inform Dr A that chelation therapy is available free of charge. On the contrary, you advised that an extra contractual referral was required. It therefore could not have been possible for Dr A to have informed HB that it was available free of charge.

Paragraph 7:

> "HB received chelation therapy at the Breakspear Hospital subsequent to you being notified by the GMC of his GP's complaint against you"

has been admitted and found proved.

Paragraph 8:

> "The amount of sodium calcium edetate administered to HB during his course of chelation therapy was substantially below the BNF recommended dose for patients with lead poisoning"

has been admitted and found proved.

Paragraph 9:

> "Your treatment recommendation at 3 above was"

Paragraph 9(i):

> "made despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity"

has been found proved

In finding this fact proved, the Panel considered the ten factors you identified in your evidence upon which you relied in making your recommendation that HB embark upon a programme of chelation therapy as soon as possible. You dispute the allegation that it was made on the provoked urine sample alone. The Panel considered the letters to HB's GP, dated 2 April 2009 and 12 February 2009, informing the GP that HB should undergo chelation therapy and noted that none of the ten factors you identified as being pertinent to your decision in recommending chelation therapy was mentioned in either of these letters.

The Panel has noted Professor D's evidence in respect of urine samples as being a measure of lead toxicity. He stated that there is no national or international reference value for post provocation urine samples. He further stated that, "*you cannot use [it], even if you believe the provocation test has some value"*, as *"it could lead to misinterpretation."* He was of the opinion that, *"you have to measure the blood lead concentration."* He sought support for his opinion by reference to the American College of Medical Toxicology Position Statement on Post-Chelator Challenge Urinary Metal Testing, 31 March 2010, which states that,

> "*it is, therefore, the position of the American College of Medical Toxicology that post-challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning*."

Professor D stated that those practising in the United Kingdom would share the same view as this. He told the Panel that, "*we have debated this topic in the UK within the National Poisons Information Service, which includes all clinical toxicologists practising in the UK, and we are completely supportive of this document*."

Furthermore, the report from Doctor's Data providing the results of the post-urine test notes that, "*reference ranges are representative of a healthy population under non-challenge or non-provoked conditions. No safe reference levels for toxic metals have been established*."

Paragraph 9(ii):

> "made despite you not having specialist training or expertise in"

Paragraph 9(ii)(a):

> "clinical toxicology"

has been admitted and found proved.

Paragraph 9(ii)(b):

"the investigation and treatment of lead poisoning"

has been admitted and found proved

Paragraph 9(iii):

"based on inadequate evidence"

has been found proved

In finding this fact proved, the Panel again considered your ten factors. All the experts agreed that the combination of HB's symptoms were the classic non-specific symptoms of myalgic encephalomyelitis (ME) or chronic fatigue syndrome (CFS). In addition, the Panel noted that it was not presented with any blood lead level (BLL) or urine lead level readings prior to the commencement of HB's chelation treatment in 2010. The DNA adducts and the Biolab report you relied upon, were obtained nine and 11 years earlier in 2001 and 1999 respectively and were of no clinical diagnostic use.

With regard to the results of the Doctor's Data tests, the Panel accepted Professor D's view that, based on those results, there is no reasonable body of medical opinion that would support a diagnosis of lead toxicity. His view was unaffected by HB's history of potential environmental exposure to lead over the preceding decade, nor was his opinion tempered by HB's reported symptoms.

The Panel accepts that, whilst the ten factors may have been present and that the history of HB demonstrates that there was the potential for lead exposure, there was no independent or conclusive evidence to indicate that he in fact suffered from lead toxicity. You did not conduct the basic blood test which would have contributed to the assessment of levels of HB's lead toxicity. The Panel considers that none of the factors you identified, either taken individually or collectively, demonstrated that HB had lead poisoning; therefore, your recommendation that HB should embark on a programme of chelation therapy was based on inadequate evidence.

Paragraph 9(iv):

"potentially harmful"

has been found proved

In finding this fact proved, Professor D said that the predominant side effect of the chelating agent calcium disodium EDTA, is impairment of kidney performance, depending on the dose administered. He acknowledged that the low dose actually administered was unlikely to have had this effect. The Panel also noted that when a

blood lead concentration was measured prior to the extra contractual referral being sought, it revealed that he had a BLL of 2.9 µg/dL, which is not indicative of a high body burden of lead. Professor D stated that if chelation therapy using calcium disodium EDTA was embarked upon with a BLL of 2.9 µg/dL, then the risk was that it, "*would certainly produce zinc depletion, because that is characteristic with sodium calcium edetate, and if there is no lead there, then it would chelate zinc and excrete it*."

Paragraph 10:

> "Your conduct described in paragraphs 3,4, 5, 6, 7, 8 and 9 above was not in the best interests of the patient"

has been found proved in respect of paragraphs 3, 4 (in its entirety), 5 (in its entirety), 6(i) and 9 (in its entirety). Found not proved in respect of paragraphs 6(ii) and 7.

In determining whether your conduct was not in the best interest of HB in respect of the paragraphs in this head of charge, the Panel recognised that it had to first interpret 'best interests'. In doing so, the Panel noted Mr Moon's submission that, 'best interests' is a concept encompassing medical, emotional and all other welfare issues. He referred to the cases of R-B (A Patient) v The Official Solicitor [2000] Lloyd's Law Report: Medical 87 and Re SL (Adult Sterilisation [2000] Lloyd's Law Report: Medical 339. Mr Moon argued that you acted in HB's best interests in this wide sense.

The Panel has considered the advice of the Legal Assessor, Mr Smith, who stated that the cases identified by Mr Moon are of limited assistance since, "*the Panel's task is to judge whether, from a purely medical point of view, the chelation treatment was or was not in HB's interests. It is right in so doing to take account of HB's own wishes since his consent, far from being withheld, was gladly forthcoming. It cannot, however, be regarded as the deciding factor since chelation is treatment and treatment needs to be advised on medical grounds. "*

The Panel accepted Mr Smith's advice and has thus made the following findings under head of charge 10.

Paragraph 3

In finding paragraph 10 proved in respect of paragraph 3, the Panel noted Professor D's evidence that, *"no clinical toxicologist in the UK would treat a patient with this blood lead level concentration [2.9 µg/dL] with DMSA or sodium calcium edetate."* He went further and told the Panel that he is, *"aware of all the evidence for intervention in published and reputable journals to suggest that intervention with chelation should not be less than a concentration of 50."* He pointed out that he has "*read the alternative medicine literature and I am aware of patients being treated at*

very low concentrations" but does not consider them to be reasonable opinions as "*they give no support…that their intervention made any difference*."

The Panel accepts Professor D's evidence in respect of this matter.
It also notes that HB was a patient who suffered from numerous non-specific symptoms and was strongly motivated to find a cure for his CFS. Whilst HB was not a witness at these proceedings, it was adduced in evidence that he had researched and found your clinic. At a consultation at the Breakspear Clinic, chelation therapy was suggested to HB and he clearly wanted this treatment. However, notwithstanding what HB wanted, there was no objective or clinical indication that HB should embark upon such a programme. The Panel considers that you should not have intervened and chelated HB and it was therefore not in his best interest for you to have done so.

Paragraph 4(i)

In finding paragraph 10 proved in respect of paragraph 4(i), the Panel accepted Professor D's evidence that, *"HB had a variety of non-specific symptoms and he had a normal urine lead concentration. We do not have the advantage at that stage of having a blood lead concentration but we know later it was 2.9 micrograms per decilitre, so it is important when you are trying to discover the cause of non-specific symptoms to have all the relevant tests available that are easily available…that [blood lead concentration] would have been very informative because it would have told the clinicians concerned that this patient had a minimal body burden of lead and, therefore, the provocation test would not have been misinterpreted as it was."*

In light of Professor D's evidence, it was not in HB's best interests not to measure his blood lead concentration.

Paragraph 4(ii)

In finding paragraph 10 proved in respect of paragraph 4(ii), the Panel noted your evidence. You told the Panel that, *"I do not think that a toxicologist might have done anything for him, and I had the evidence of that in this hearing."* You went on, *"toxicologists seem to think that there is a threshold at which lead has an effect. In my opinion, lead has effects in the form of a continuum and that is not compatible with a threshold. You cannot have a threshold where a poison suddenly becomes not a poison."*

The Panel does not accept your evidence in this regard. As you do not have specialist training or expertise in clinical toxicology or in the investigation and/or treatment of lead poisoning, the Panel considers that you should have referred HB to a specialist who would have provided HB with complete advice.

Paragraph 4(iii)

The Panel's reasons for finding for paragraph 10 proved in respect of paragraph 4(iii) are the same as its reasons for finding paragraph 10 proved in respect of paragraph 4(ii). In

addition to those reasons, it noted Professor D's evidence that where a physician, who is not a specialist and is considering, for example, the results obtained from Doctor's Data, then that physician, "*should telephone the National Poison Information Service and discuss it with one of the consultants, which is precisely why the Department of Health funds the National Poisons Information Service to provide this expert advice*."

Paragraph 5(i)

In finding paragraph 10 proved in respect of paragraph 5(i), the Panel first considered the proposition that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity. If it considered that there was no demonstrated benefit, then it should go on to consider whether you explained this to either HB or his GP.

In respect of the first issue, the Panel noted the following learned articles:

- Perrine Hoet et al – Clinical Evaluation of Lead Mobilization Test Using the Chelating Agent Dimercaptosuccinic Acid, Clinical Chemistry 52:1 88-96 (2006);

- Dilshad Ahmed Khan et al – Evaluation of Lead Body Burden in Occupational Workers by Lead Mobilization Test, Vol 59, No 6 June 2009;

- Walter J Crinnion, ND – The Benefits of Pre- and Post-challenge Urine Heavy Metal Testing: Part 1, Alternative Medicine Review, Vol 14, No 1 2009 and Part 2, Alternative Medicine Review, Vol 14, No 2 2009.

The Panel is aware that there are different interpretations of the value of lead mobilisation tests (LMT) as an indicator of body burden of lead. However, the very strong evidence of Professors D and E, and the footnote of the Doctor's Data laboratory, would indicate that this is not a reliable method of establishing a body burden of lead as there is no post-challenge reference data available against which this can be measured. Indeed, the position paper published by the American College of Medical Toxicology states,

> "*Currently, available scientific data do not provide adequate support for the use of post-challenge urine metal testing as an accurate or reliable means of identifying individuals who would derive therapeutic benefit from chelation.*"

Mr Moon submitted that, "*the essence of those articles is to extol the virtues of the post-challenge urine test and to point out the limitations of the blood lead tests. Blood lead tests were done by the authors, but it is nowhere suggested in those articles that they* ***have*** *to be done*" (Mr Moon's emphasis). The Panel has responded to Mr Moon's invitation to read all these articles carefully. That the authors do not state explicitly that BLL tests should be carried out is not to infer by default that they should ***not*** be carried out; nor is it to be inferred that LMTs alone have a sufficient diagnostic value. The Panel considers that LMTs are a contributive test and not a definitive diagnostic tool. It therefore concluded that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity.

Given this finding, it follows that it was not in HB's best interests not to have explained to him the limited value of a DMSA challenge test alone. Similarly, it follows that it was not in HB's best interests that you did not explain this to his GP, who needed to be informed of the proposed therapy in order to advise him appropriately and treat him if necessary.

Paragraph 5(ii)

The Panel noted that you admitted paragraph 5(ii). The Panel is of the view that the fact that you did not explain to HB or his GP that the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate could not have been in his best interest.

Paragraph 6(i)

In finding paragraph 10 proved in respect of paragraph 6(i), the Panel finds it axiomatic that not to advise either HB or his GP of the possible complications of chelation therapy was not in his best interests.

Paragraph 6(ii)

In finding paragraph 10 not proved in respect of paragraph 6(ii), the Panel finds that it is of no relevance to HB's welfare that this advice was not given.

Paragraph 7

The Panel could not find paragraph 10 proved in respect of paragraph 7 as there is no conduct alleged which can be regarded as not being in HB's best interests.

Paragraph 8

In finding paragraph 10 proved in respect of paragraph 8, the Panel noted that the dose administered was equiDnt to 30 mg/kg, which, according to Professor D, was substantially less than recommended for treating lead toxicity. He told the Panel that the British National Formulary recommends a dose of 80 mg/kg per day over five consecutive days. The Panel considers that, given there was no need to chelate HB it could not have been in his best interests to embark upon this therapy regardless of the low dose.

Paragraph 9(i), (ii)(a) & (b), (iii) & (iv)

Given that the Panel has found paragraph 9 proved in its entirety, it is axiomatic that your conduct was not in HB's best interests.

Having reached findings on the facts, the Panel will now invite further evidence and submissions from both Counsel as to whether, on the basis of the facts found proved, your fitness to practise is impaired by reason of your misconduct."

Determination on impaired fitness to practise

"Dr Monro:

The Panel has considered under Rule 17(2)(k) of the General Medical Council (Fitness to Practise) Rules Order of Council 2004 whether, on the basis of the facts found proved, your fitness to practise is impaired. In doing so, it has taken account of all the evidence adduced at the first stage, including your own oral evidence and all the documentary evidence. It has also considered the submissions of both Counsel.

Mr Donne, on behalf of the General Medical Council (GMC), submitted that your fitness to practise is impaired by reason of your misconduct. In respect of misconduct, he reminded the Panel that it has found proved that you,

- practised beyond your competence;
- utilised inappropriate and ineffective tests to make a diagnosis;
- recommended and conducted inappropriate and potentially harmful treatment.

Mr Donne also submitted that patient HB was placed at risk of harm in a variety of ways, including,

- side effects of unnecessary and/or inappropriate tests and treatment;
- the loss of or delay in other diagnostic opportunities; and
- the raising of hope that could not, on the evidence, have been fulfilled by the treatment provided. Although he accepted that HB experienced an amelioration of his symptoms following treatment, [this was] no doubt due to placebo (sic).

Mr Donne further submitted that damage was undoubtedly caused to the standing of the profession by the conflict that arose between HB and his "orthodox" medical advisors, Drs A, B and C, as well as by the undermining of trust in conventional diagnostic techniques.

Mr Donne submitted that you breached the following paragraphs of *Good Medical Practice* (November 2006):

- 2(b) and (c);
- 3(a), (b), (c) and (i);
- 12; and
- 14(c), (d), (e) and (f);

and, in the light of this, a finding of misconduct is inevitable and required in the public interest.

In respect of the issue of impairment, Mr Donne argued that the facts found proved, notwithstanding that they relate to a single patient, are to be considered in the context that they are representative of your practice over a considerable number of years and are reflected in the protocols of the Breakspear Clinic.

He reminded the Panel that she states, "*unequivocally that she is simply an adherent to an acceptable body of medical practice and opinion and in truth she is an adherent to a comparatively marginal and aberrant body of opinion.*" Mr Donne stated that, whilst complementary or alternative medicine is not, per se, outside accepted practice, its adherents must ensure they practise safe, evidence-based medicine that is truly in the patient's interests. He submitted, therefore, that you have no insight into your failings. He also argued that, given the views held by you which are deeply entrenched, the Panel cannot be sure that the conduct is, "*highly unlikely to be repeated*."

Furthermore, Mr Donne submitted that the level of criticism levelled against you by experts called on behalf of the GMC is of a magnitude that it requires intervention to maintain professional standards and public confidence in the profession. He concluded his submissions by reminding the Panel of Professor D's evidence that a doctor, *"must do no harm*".

Mr Moon, on your behalf, stated that, in respect of the issue of misconduct, it is only the facts which the Panel has found proved which can be considered. As to the nature of the misconduct, he directed the Panel to the cases of Meadow v GMC [2006] EWCA CIV 1390 and Calhaem v GMC [2007] EWHC 2606 (Admin). Mr Moon argued that your case concerns the treatment of one patient which was judged not to be in that patient's best interests. He submitted that it is rare that cases like this would amount to misconduct. He provided four points to support this submission:

1. that the Panel's findings relate to one patient;

2. that even on the Panel's findings, you are not a doctor who has embarked upon a course which was entirely unsupported by others; there was, he submitted, support for some of the things which you did;

3. that there is absolutely no evidence that HB was harmed. Mr Moon pointed out that all the evidence is to the effect that HB improved following treatment and suffered no ill effects following treatment. He reminded the Panel that this was treatment which HB wanted and referred the Panel to paragraph 3(d) of *Good Medical Practice* (November 2006).

4. that HB did not complain to the GMC and is a strong supporter of your treatment.

In addition to those four points, Mr Moon reminded the Panel that it has heard that Dr G was the subject of a complaint to the GMC and an allegation that his fitness to practise was impaired. Mr Moon stated that Dr G was the clinician who originally

recommended the chelation treatment and he was permitted by the GMC to take voluntary erasure. Mr Moon told the Panel that voluntary erasure is only available in cases in which the GMC considers that the doctor's conduct is not likely to give rise to a finding of impairment. Mr Moon submitted that the Case Examiners must therefore have considered that his conduct would not give rise to a finding of impairment and that this Panel may find that relevant to your case. The Panel will return to this later.

In respect of the issue of impairment, Mr Moon submitted that you have been in medical practice for over 50 years. He stated that there have been no findings of misconduct against you during this long career, which suggests that your fitness to practise is not impaired. In addition, he told the Panel that, whilst you did proceed with the chelation therapy, it is clear that you felt that you had HB's best interests at heart and there is no evidence to suggest that you acted other than in good faith.

As to the future, Mr Moon stated that, in light of the Panel's findings, you will undertake to cease pre and post challenge urine testing and will cease to provide chelation therapy.

Furthermore, Mr Moon contended that the Panel may consider that this is one of those cases in which a doctor should be given a very clear warning to comply with Good Medical Practice. He submitted that a warning, together with the Panel's findings, will satisfy the public interest.

So far as Mr Moon's submissions related to Dr G's voluntary erasure, the Panel has paid no regard to those circumstances since it has received no evidence and it considers that, in any case, such material would have been irrelevant and, therefore inadmissible. The Panel bore in mind the Legal Assessor's warning, given in his advice at the first stage, that speculation has to be avoided at all costs.

Whilst the Panel has borne in mind counsel's submissions, the decision as to whether your fitness to practise is impaired is one for it alone to reach, exercising its own judgement.

The Panel has already given a detailed determination in relation to the facts of this case and it has taken those matters into account in its finding on impairment.

Throughout its deliberations, the Panel has borne in mind that its primary responsibility is to protect the public interest. This includes not only the protection of patients, but also the maintenance of public confidence in the profession, and the declaring and upholding of proper standards of conduct and behaviour.

In determining whether your fitness to practise is impaired, the Panel applied the test referred to by Mr Smith, the Panel's Legal Assessor, as outlined by Cranston J in the case of Cheatle v GMC [2009] EWHC 645 (Admin), where at paragraph 19, he states that,

"Whatever the meaning of impairment of fitness to practise, it is clear from the design of section 35C that a panel must engage in a two-step process. First, it must decide whether there has been misconduct…Then it must go on to determine whether, as a result, fitness to practise is impaired. Thus it may be that despite a doctor having been guilty of misconduct, for example, a Fitness to Practise Panel may decide that his or her fitness to practise is not impaired."

In line with the above approach, the Panel first considered whether your actions constituted misconduct. In so doing, the Panel recognised that this case concerns the inappropriate methods used by you to diagnose and treat lead toxicity. You advised patient HB that he should embark on a programme of chelation therapy to remove lead from his body. You did not measure HB's blood lead concentration, nor refer him to a specialist in toxicology or lead poisoning nor seek the advice of the National Poisons Information Service. Further, you failed to explain to HB or his GP that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of blood lead concentration, or that the challenge test had been performed on HB using a substantially greater dose of DMSA than was either necessary or appropriate. In addition, you did not advise HB or his GP of the possible complications of chelation therapy.

The Panel has already determined that your recommendation that HB should embark on a programme of chelation therapy was made;

- despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity;

- despite you not having specialist training or expertise in clinical toxicology or in the investigation and treatment of lead poisoning;

- based on inadequate evidence; and was potentially harmful to HB. The Panel has found that your conduct in this regard was not in HB's best interests.

In determining whether your action amounts to misconduct, the Panel has considered paragraphs 2 and 3 of *Good Medical Practice* (November 2006).

Paragraph 2 states,

"*Good clinical care must include:*

…
(b) providing or arranging advice, investigations or treatment where necessary
(c) referring a patient to another practitioner, when this is in the patient's best interests."

Paragraph 3 states,

> "*In providing care you must:*
>
> *(a) recognise and work within the limits of your competence*
> *(b) prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health, and are satisfied that the drugs or treatment serve the patient's needs*
> *(c) provide effective treatments based on the best available evidence…*
> *(i) consult and take advice from colleagues, when appropriate…*"

The Panel is of the opinion that, in recommending a potentially harmful treatment to HB, you acted beyond the level of your qualifications, competence and expertise. As highlighted above, you failed to perform adequate diagnostic tests and did not advise HB or his GP of the complications of such treatment. The Panel considers that, in this respect, you have breached fundamental tenets of the profession and concludes that your errors amount to misconduct.

The Panel next considered whether, as a result of your misconduct, your fitness to practise is currently impaired. In doing so, the Panel noted paragraph 32 of Meadow, which states,

> "*In short, the purpose of [fitness to practise] proceedings is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The FTPP thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past.*"

Paragraph 22 of Cheatle, which states,

> "*the context of the doctor's behaviour must be examined. In circumstances where there is misconduct at a particular time, the issue becomes whether that misconduct, in the context of the doctor's behaviour both before the misconduct and to the present time, is such as to mean that his or her fitness to practise is impaired. The doctor's misconduct at a particular time may be so egregious that, looking forward, a panel is persuaded that the doctor is simply not fit to practise medicine without restrictions, or maybe at all. On the other hand, the doctor's misconduct may be such that, seen within the context of an otherwise unblemished record, a Fitness to Practise Panel could conclude that, looking forward, his or her fitness to practise is not impaired, despite the misconduct.*"

In determining whether your fitness to practise is impaired, the Panel noted your dual role at the Breakspear Clinic; you are the Medical Director and a clinician. As such, the Panel considers that you have a duty to provide good medical care to all of your patients. When you took over the care of HB from Dr G, you had every

opportunity to review HB's case and it was your responsibility to consider whether chelation therapy was clinically indicated. However, you did not do this and without carrying out a blood lead level test, you proceeded to support an application for extra-contractual funding so that you could embark on a programme of chelation therapy.

Mr Donne's submission that it is implicit in your evidence that your conduct in regard to HB is representative of your practice in the field of heavy metal toxicity; that, "*It is not a one-off mistake, this is the way she works*", requires careful scrutiny. The GMC has produced evidence concerning only one patient on one occasion. While you have steadfastly sought to justify proceeding to undertake chelation therapy on what you have consistently maintained were adequate test results, in the absence of evidence of other patients similarly treated, the Panel is unable to extrapolate and to conclude that this is representative of your methods of your practice generally.

Another important factor to be taken into consideration about which the Panel heard evidence, was the role of the Primary Care Trust (PCT). The application for extra-contractual funding for the treatment was originally refused following tests at NHS hospitals which indicated that the blood and urine (pre and post) lead levels were all within the normal range. On appeal, however, the PCT approved the proposed treatment stating, "*due to conflicting evidence on clinical effectiveness of this particular treatment, the Panel have decided on this occasion to approve the request*." The decision by the PCT to commit NHS funding for the treatment must, therefore, mitigate to a degree any criticism that would otherwise attach to your acting beyond your competence and the other findings of facts determined by this Panel.

HB was happy with your treatment and did not support the proceedings brought against you. He did not agree that the treatment was not in his best interests.

The Panel took into account that you produced some evidence to support your views, that you have been a medical practitioner for over 50 years and there has been no adverse finding against you by your regulatory body.

Furthermore, the Panel considers that your appearing before your regulatory body would in itself have had a salutary effect upon you. It has also noted that, through Mr Moon, you have freely and unequivocally undertaken to this Panel that you will cease to carry out pre and post challenge testing of urine and will cease to provide chelation therapy. This is a factor which has played a significant part in this Panel's decision at this stage. Congruent with current authority (Cheatle), the Panel looks forward and not back.

The Panel has had regard to the wider public interest and to whether public confidence in the profession would be undermined if a finding of impairment were not made in the circumstances of this case.

The Panel does not condone your misconduct; it is on the cusp of a finding of impairment. However, the Panel determines, on balance, in the light of all the recent authorities, all the circumstances which have been drawn to its attention, and the context, there is insufficient evidence to lead to a judgement that your fitness to practise is impaired.

The Panel will now invite submissions as to whether a warning should be imposed in this case."

Determination on a Warning

"Dr Monro:

Having found that your fitness to practise is not impaired, the Panel has considered whether to impose a warning on your registration. In doing so, it has taken into account the submissions of both Counsel.

Mr Donne, on behalf of the General Medical Council (GMC), submitted that a warning would be appropriate in your case. In making this submission, he reminded the Panel that it has made a finding of misconduct; that your misconduct was on the cusp of a finding of impairment; that you have accepted that a warning would be appropriate; and that you have undertaken not to carry out urine challenge testing and chelation therapy. He also suggested that the undertaking which you offered should be expressed in the formal warning.

Mr Moon, on your behalf, accepted that a warning would be appropriate.

In making its decision, the Panel has given detailed consideration to the GMC's Guidance on Warnings. Consistent with that guidance, it has applied the principle of proportionality.

Paragraph 11 of the guidance is particularly relevant:

> "*Warnings allow the GMC to indicate to a doctor that any given conduct, practice or behaviour represents a departure from the standards expected of members of the profession and should not be repeated. They are a formal response from the GMC in the interests of maintaining good professional standards and public confidence in doctors…*"

The Panel's earlier determination makes clear that you breached fundamental tenets of the profession and *Good Medical Practice*. Whilst it has determined that your fitness to practise is not impaired, it did consider that your misconduct is on the cusp of a finding of impairment. The Panel also noted that you have accepted that a warning would be appropriate in the circumstances. It has further considered your previous good history and the fact that you have undertaken not to carry out pre and post urine challenge testing and chelation therapy.

In deciding whether to issue a warning, the Panel has balanced your interests with the public interest and concluded that the need to uphold and declare standards of conduct and behaviour and to maintain public confidence in the profession outweighs your own interests.

The Panel considers that the public interest would not be served if it concluded your case without the imposition of a warning. In all the circumstances, the Panel has determined that it is appropriate and proportionate to impose a formal warning as follows:

"Dr Monro

In April 2009, you advised HB that he should embark on a programme of chelation therapy to remove lead from his body. You did not measure HB's blood lead concentration, refer him to a specialist in toxicology or lead poisoning or seek the advice of the National Poisons Information Service. Further, you did not explain to HB or his GP that the DMSA challenge test alone has no demonstrated benefit in the diagnosis of lead toxicity compared with analysis of HB's blood lead concentration or that the challenge test had been performed using a substantially greater dose of DMSA than was either necessary or appropriate. In addition, you did not advise HB or his GP of the possible complications from chelation therapy. Your recommendation that HB should embark on a programme of chelation therapy was made despite a provoked urine sample alone not being an appropriate test upon which to base a diagnosis of lead poisoning or toxicity; made despite your not having specialist training or expertise in clinical toxicology or in the investigation and treatment of lead poisoning; based on inadequate evidence; and potentially harmful to HB. The Panel has found that your conduct in this regard was not in HB's best interests.

This conduct and behaviour does not meet the standards required of a registered medical practitioner and breaches provisions of *Good Medical Practice*. It is misconduct which undermines the public's confidence in the profession and risks bringing the profession into disrepute. The required standards are set out in *Good Medical Practice* (November 2006), namely, paragraphs 2 and 3. Whilst this misconduct in itself is not so serious as to require any restriction on your registration, it is necessary in response to issue this formal warning.

Further, you must not carry out any procedures which are inconsistent with the unequivocal guarantee that you have publicly given to this Panel, namely pre and post urine challenge testing and chelation therapy. Failure to comply with your guarantee may be regarded in its own right as giving rise to an allegation of further misconduct."

This warning will be published on the List of Registered Medical Practitioners (LRMP) for a period of five years and will be disclosed to any person enquiring about your fitness to practise history. After five years, the warning will cease to be published on LRMP. It will however be kept on record and disclosed to employers on request.

That concludes this case."

Confirmed

Date: Chairman: Ms Evis Samupfonda

FITNESS TO PRACTISE PANEL
31 JANUARY – 8 MARCH 2011
7th Floor, St James's Buildings, 79 Oxford Street, Manchester, M1 6FQ
Room 6

Name of Respondent Doctor:	Mr Ahmed Aly Mohamed SHAHEEN
Registered Qualifications:	MB BCh 1973 Ain Shams University
Area of Registered Address:	Lincolnshire
Reference Number:	3047761
Type of Case:	New case of impairment by reason of: misconduct
Panel Members:	Prof. S Miller (L) – Chair Dr A Mourant (M) Mr B Payne (L) Dr M Vickers (L)
Legal Assessor:	Mr D Smith
Secretary to the Panel:	Ms C Beard

Representation:

GMC: Mr Selva Ramasamy, Counsel, instructed by Field Fisher Waterhouse Solicitors.

Doctor: Present and represented by Mr Angus Moon, Counsel, instructed by Ryan Solicitors.

EXCLUSION OF PRESS AND PUBLIC

The Panel passed a resolution, under XXX of the General Medical Council (Fitness to Practise) Rules 2004, that the press and public be excluded from those parts of the hearing where the Panel considered the XXX of the practitioner.

ALLEGATION

The Panel will inquire into the following allegation against Mr Ahmed Aly Mohamed Shaheen, MB BCh 1973 Ain Shams University.

"That being registered under the Medical Act 1983, as amended:

1. Between 1997 and 25 February 2008 you worked as a Consultant Obstetrician and Gynaecologist at the Pilgrim Hospital in Boston, Lincolnshire ("the Hospital"); **Admitted and found proved.**

2. In 1999 you became aware that your health status was as set out in Schedule A; **Admitted and found proved (as amended).**

3. In around February 2000 you returned to work at the Hospital under an agreement that in the course of your clinical duties

a. you would not conduct XXX, **Found proved.**

b. where you decided that a patient needed to undergo XXX, that the patient's care would be taken over by a ~~consultant~~ colleague; **Amended following an application under Rule 17(3). Admitted and found proved (as amended).**

4. Between February 2001 and July 2007 you

a. performed the procedures as set out in Schedule B, **Found proved in relation to the following patients as set out in Schedule B: 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 24, 27, 29, 32, 33, 34, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 51, 52, 54, 55, 57, 59, 60, 61 and 62. Found not proved in relation to patient 28.**

b. knew or should have known that the procedures at 4a above were to be regarded as XXX, **Found proved in respect of "should have known" in relation to the "Modified TVT" procedures in Schedule B. Found not proved in respect of "you knew" in relation to the Modified TVT in Schedule B performed up to July 2001. Found proved in respect of "you knew" in relation to the Modified TVT Schedule B performed after July 2001. Found proved in respect of "you knew" and "should have known" in relation to the non-modified TVT, TOT, Manchester Repair, Vaginal Vault Repair and Division of Vaginal Adhesions procedures as set out in Schedule B. Found proved in respect of "should have known" in relation to the Posterior Vaginal Repair procedures as set out in Schedule B. Found not proved in respect of "knew" in relation to the Posterior Vaginal Repair procedures as set out in Schedule B.**

c. thereby breached the agreement set out at 3 above, **Found proved in relation to those procedures found proved at paragraph 4(b).**

d. relied on your own assessment of risk to patients arising from

i. your health status, **Admitted and found proved.**

ii. any modifications to the procedures at 4a above; **Admitted and found proved.**

5. On 3 July 2007 you

a. conducted a diagnostic laparoscopy on the patient referred to in Schedule C, **Admitted and found proved.**

b. performed a laparotomy, which is XXX, **Admitted and found proved.**

c. did not call for assistance from a colleague, **Admitted and found proved.**

d. did not ensure that the patient's care was taken over by a colleague, **Admitted and found proved.**

e. thereby breached the agreement set out at 3 above; **Admitted and found proved.**

6. Following the procedure set out at 5 above you

a. did not take ~~any or any~~ sufficient steps to advise colleagues as to the possible XXX risk to the patient, **Amended following an application under Rule 17(3). Admitted and found proved (as amended).**

b. did not advise the patient as to her possible XXX in light of your status as set out in Schedule A; **Admitted and found proved.**

7. Your conduct at 4, 5 and 6 above was

a. inappropriate, **Admitted and found proved in relation to paragraphs 4(d), 5(a), 5(b), 5(c), 5(d), 5(e) in respect of paragraph 3(a), 6(a) and 6(b). Found proved in relation to paragraphs 4(a), 4(b) and 4(c) and 5(e) in respect of paragraph 3(a).**

b. not in the best interests of your patients, **Admitted and found proved in relation to paragraphs 4(d), 5(a), 5(b), 5(c), 5(d), 5(e) in respect of paragraph 3(a), 6(a) and 6(b). Found proved in relation to paragraphs 4(a), 4(b) and 4(c) and 5(e) in respect of paragraph 3(a).**

c. irresponsible. **Admitted and found proved in relation to paragraphs 4(d), 5(a), 5(b), 5(c), 5(d), 5(e) in respect of paragraph 3(a), 6(a) and 6(b). Found proved in relation to paragraphs 4(a), 4(b) and 4(c) and 5(e) in respect of paragraph 3(a).**

And that by reason of the matters set out above your fitness to practise is impaired because of your misconduct." **Found proved.**

Determination on facts

Mr Shaheen: At the start of the proceedings, the Panel passed a resolution, under XXX of the General Medical Council (Fitness to Practise) Rules 2004 (the Rules), that the press and public be excluded from those parts of the hearing at which XXX was under consideration.

Following the reading of the allegation, Mr Moon, on your behalf, admitted paragraphs 1, 2, 4(d) in its entirety, 5(a), 5(b), 5(c), 5(d) and 6(b). He also admitted paragraph 7 insofar as it related to the admissions in relation to paragraphs 5 and 6. These paragraphs have been announced as admitted and found proved.

During the course of the proceedings, Mr Ramasamy, on behalf of the General Medical Council (GMC), made applications, under Rule 17(3) of the Rules, to amend Schedules A and B and paragraphs 3(b) and 6(a) of the allegation. Mr Moon did not oppose these applications. The Panel was satisfied that these amendments could be made without injustice and acceded to the applications. The allegation has been amended accordingly.

Following the amendments, Mr Moon made a number of further admissions on your behalf, as follows: paragraphs 3(b)(as amended), 5(e) in relation to paragraph 3(b)(as amended) and 6(a)(as amended). He also admitted paragraph 7 in relation to paragraphs 4(d) in its entirety, 5(e) and 6(a)(as amended).

In reaching its decisions on the facts, the Panel has considered all the evidence adduced in the case, both oral and documentary, and has taken account of Mr Ramasamy's submissions, on behalf of the GMC, and those of Mr Moon, on your behalf.

The Legal Assessor advised the Panel on the following matters:

- The functions of the Panel;
- The burden and standard of proof;
- Expert evidence;
- Separate consideration of paragraphs of the allegation;
- Deciding only the matters alleged;
- Fading recollections of witnesses;
- Your good character;
- Inference and speculation;
- The particulars of the allegation;
- Descriptions in operation notes;
- Knowledge;

- The effect of tacit approval;
- The assessment of witnesses;
- The meaning of “irresponsible”;
- The giving of reasons for decisions.

The Panel has borne in mind that the burden of proof rests on the GMC and that the standard of proof to be applied is that applicable to civil proceedings, namely the balance of probabilities. It has noted that it is entitled to draw inferences from the evidence presented and to give such weight to the evidence as it considers appropriate.

The Panel is aware that the events referred to occurred between 2000 and 2007. It has noted that recollection of the events may have been affected by the passage of time. The Legal Assessor advised the Panel that if it is satisfied that the witness is a truthful witness, it is right to give an appropriate allowance, where inaccuracies are found, for the frailty of the human mind in recalling events of long ago exactly as they took place.

In relation to paragraph 3, the Legal Assessor reminded the Panel that it is accepted by you that you returned to work under an agreement and that the area of dispute relates to the terms of that agreement. He advised the Panel that, having garnered all the relevant evidence, it should consider the three questions: “Why”, “How” and “What”. In relation to the “Why”, he advised the Panel to consider the provenance of the need for an agreement. In relation to the “How”, he advised the Panel to consider whether the list identified all the XXX such that any operation not included in the list could not be XXX even if a particular procedure had not been contemplated when the list was compiled. In relation to the “What”, he advised the Panel to consider what terms an objective observer would have considered were agreed between you and those representing the Trust on the basis of their words and conduct.

In relation to paragraph 4, the Legal Assessor advised the Panel that paragraph 4(a) alleges the “carrying out of acts”, paragraph 4(b) alleges a “specific state of mind whilst carrying out the alleged acts”, and paragraph 4(c) sets out the “consequence of (a) and (b) together being found proved”.

In considering paragraph 4(b), the Panel asked itself the following questions:
1. What is XXX?
2. Did you modify the procedures as set out in Schedule B?
3. Did you know that the procedures as undertaken were to be regarded as XXX?
4. Should you have known that the procedures as undertaken were to be regarded as XXX?

The Panel has considered each paragraph of the allegation separately. It has made the following findings on the facts:

Paragraphs 1 and 2 have been admitted and found proved:

"1. Between 1997 and 25 February 2008 you worked as a Consultant Obstetrician and Gynaecologist at the Pilgrim Hospital in Boston, Lincolnshire ("the Hospital");

2. In 1999 you became aware that your health status was as set out in Schedule A;"

The stem of paragraph 3 and paragraph 3(a) have been found proved:

"3. In around February 2000 you returned to work at the Hospital under an agreement that in the course of your clinical duties

a. you would not conduct XXX,"

The Panel has considered all the evidence – oral and documentary – placed before it in relation to the agreement.

In reaching its decision, the Panel has noted that your health condition, as set out in Schedule A, XXX. The Panel has borne in mind that your work as a Consultant Obstetrician and Gynaecologist involved performing surgery, and that one of the concerns raised when you returned to work in February 2000, was the risk to patients were you to conduct certain types of procedure, XXX.

The Panel has noted that a meeting was held in early 2000 and that, following this, a letter dated 7 February 2000 was sent to you to record the decisions taken during the course of the meeting. The letter stated, amongst other things, that at the meeting there was, "… agreement… that you would gradually return to clinical duties excluding performance of XXX". It also recorded that, "To avoid any possible doubt, a list of XXX [was] attached together with a list of XXX".

Mr Moon submitted that the letter did not, in itself, constitute the agreement and he drew the Panel's attention to some inaccuracies in the letter which he said demonstrated that it was not a faithful record of the meeting. You told the Panel that you believed that the agreement was that you refrain from carrying out only those procedures specified as XXX on the list attached to the letter. In particular, you stated that the agreement was that you should avoid all procedures labelled "H" (High Risk XXX) and any procedures labelled "P" (Possible XXX) that you judged were incapable of being conducted in a XXX. Mr Moon also submitted that such an interpretation was consistent with the evidence of Mr H, NHS Business Manager for Obstetrics and Gynaecology Services at the Trust in 1999.

The Panel has heard from Dr F, Consultant Physician and formerly the Medical Director of the Trust, that the underlying principle of the agreement was that you were not to undertake XXX. He further stated that in his view the list attached to the letter was merely intended to be a helpful guide as of that point in time and that it was self-evident that the list would change.

The Panel considered that, given the history and circumstances of your case, it was not plausible that the Trust would have agreed to anything short of a general prohibition on your performance of XXX.

In all the circumstances, the Panel has concluded that you returned to work at the Hospital under an agreement that in the course of your clinical duties you would not conduct XXX.

Paragraph 3(b)(as amended) has been admitted and found proved:

> "b. where you decided that a patient needed to undergo XXX, that the patient's care would be taken over by a colleague;"

The stem of paragraph 4 and paragraph 4(a):

> "4. Between February 2001 and July 2007 you
>
> a. performed the procedures as set out in Schedule B,"

The Panel has borne in mind all the evidence placed before it, which included contemporaneous medical records, the expert reports, the GMC expert's oral evidence and your oral evidence.

The Panel has not drawn any inference from the fact that Schedule B numbers 63 cases, whereas there are only 52 patient cases that stand to be considered.

In reaching its determination on this paragraph, the Panel has considered whether you performed the procedures listed in Schedule B and whether those procedures are adequately described in column 4 of the Schedule. It has focussed on whether the label reasonably reflects the general features and intended outcomes of your procedure, and not whether you employed all the techniques normally associated with that label.

The Panel has addressed the precise detail of your operative technique in reaching its determination on paragraph 4(b) i.e. in considering whether you knew or should have known that the procedures were to be regarded as XXX.

Paragraph 4(a) has been found proved in relation to the following patients as set out in Schedule B: 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 24, 27, 29, 32, 33, 34, 36, 38, 39, 41, 42, 43, 44, 45, 46, 47, 49, 50, 51, 54, 60 and 62.

In all the circumstances, the Panel was satisfied on the balance of probabilities that the tension-free vaginal tape (TVT) and transobturator tape (TOT) operations you performed on these patients were as set out in Schedule B.

The Panel has noted that Mr Moon, on your behalf, submitted that you accepted that you performed operations, as set out in Schedule B, on these patients,

although he urged the Panel to note his submission that you did not perform them in a “classic” or “non-modified form”.

Paragraph 4(a) has been found not proved in relation to patient 28.

The Panel has noted that you denied conducting this operation. You accepted that you assisted at a laparoscopy but denied performing the subsequent laparotomy as detailed in Schedule B. You told the Panel that a junior colleague who was in training conducted both operations on your advice and that she closed the abdomen on your instruction after you left the theatre.

The Panel has borne in mind that the operation note lists three surgeons as having been present at the operation; this was unusual. It has noted that the GMC did not call either of the other two surgeons who were present.

The Panel has borne in mind that shortly after you performed a laparotomy on another patient (patient 63), concerns were raised by several colleagues that you had apparently performed XXX. The Panel considered that, had you performed a laparotomy in the case of patient 28, similar concerns would have been raised.

In all the circumstances, the Panel was not satisfied, on the balance of probabilities that you performed the operation on this patient as set out in Schedule B.

Paragraph 4(a) has been found proved in relation to patient 40.

The Panel has borne in mind that you denied performing a TVT operation on this patient and claimed that the procedure was a TOT.

The Panel has noted that the patient was consented for a “Trans obturator tape or tension free vaginal tape” operation. You also made a detailed contemporaneous operation note, which stated that the operation you undertook was a “Modified TVT” and you drew a diagram of a TVT operation not a TOT. In addition, your discharge letter to the patient’s GP referred on several occasions to a modified TVT having been performed. The Panel has noted that there was an overwhelming number of references in the contemporaneous medical notes to your having performed a modified TVT operation on this patient.

The Panel has noted that there were references in other sections of the patient records to the performance of a TOT. However, the Panel placed greater weight on the contemporaneous operation notes, the diagram and the discharge letter.

In all the circumstances, the Panel was satisfied, on the balance of probabilities, that the operation you performed was as set out in Schedule B.

Paragraph 4(a) has been found proved in relation to patients 48 and 57.

The Panel has borne in mind that you disputed performing Manchester Repairs on these patients. You stated that you had used a purse-string stitch to achieve a repair.

The Panel has considered the descriptions of the Manchester Repair from both experts in their written reports and by the GMC expert during the course of his oral evidence.

The Panel has noted that there was an overwhelming number of references in the contemporaneous medical notes to your having performed a Manchester Repair or Manchester-type Repair on these patients.

Furthermore, many features of the classic Manchester Repair, such as the anterior repair, amputation of cervix, and ligamentous sutures to correct a prolapse, are mentioned in your operation notes and discharge letter. The Panel was satisfied that the procedures performed on these patients can be reasonably described as Manchester Repairs.

Paragraph 4(a) has been found proved in relation to patients 52 and 61.

The Panel has borne in mind that you disputed performing Vaginal Vault Repairs on these patients. You stated that you used a purse-string stitch to achieve these repairs.

In relation to patient 52, the Panel has noted that the patient was consented for an "Anterior Vaginal Wall Repair". In your operation note you described the procedure as "vault repair vaginally". In your referral letter to the patient's GP you also stated that you, "proceeded to a vault repair vaginally with buttressing sutures".

In relation to patient 61, the Panel has noted that the operation note and discharge summary both detailed a "Vaginal Vault Repair…" having been performed. In addition, your letter of referral to the patient's GP stated that, "Repair of her vault prolapse was performed".

In all the circumstances, the Panel was satisfied that the procedures you performed on these patients were as set out in Schedule B.

Paragraph 4(a) has been found proved in relation to patient 55.

The Panel was satisfied that the procedure you performed on this patient was as set out in Schedule B.

The Panel has noted that Mr Moon, on your behalf, accepted that you performed the procedure on this patient, although he urged the Panel to note his submission that you did not perform it in a "classic" or "non-modified form".

Paragraph 4(a) has been found proved in relation to patient 59.

The Panel has noted that you stated that you employed a purse-string stitch on this patient and that the procedure should not be described as a posterior vaginal repair.

However, the Panel has noted that the patient records show that the patient was admitted for a “posterior repair”. The operation notes by you state that a “posterior repair (small repair)” was performed. The referral letter to the patient’s GP also indicates that this was the procedure performed.

In all the circumstances, the Panel was satisfied that the procedure you performed on this patient was as set out in Schedule B.

Paragraph 4(b):

> “b. knew or should have known that the procedures at 4a above were to be regarded as XXX,”

The meaning of XXX

The Panel first considered what is meant by XXX. In so doing, it has noted the United Kingdom Health Departments’ document (1998) (the Guidance) and the list from the United Kingdom Advisory Panel (UKAP) supplied to you. The Panel also noted the oral evidence of the large number of witnesses as to their understanding of the term XXX.

XXX.

Approach to paragraph 4(b)

Paragraph 4(b) alleges that you knew or should have known that the procedures you were conducting were to be regarded as XXX. In reaching its determination, the Panel considered this charge in relation to each of the procedures (e.g. TVT or TOT) that it has determined you performed, as set out in Schedule B.

The Panel first considered whether each procedure should be classified as XXX. In so doing, it took a view, on the basis of the evidence, as to how you carried out that procedure and whether that particular approach rendered it XXX.

For those procedures which it considered to be XXX, the Panel then determined whether you (i) should have known and (ii) knew that the procedure was to be regarded as XXX.

For the avoidance of doubt, the Panel has taken the statement “you knew…that the procedures…were to be regarded as XXX” to mean that you were aware that they were to be treated as XXX. That interpretation does not imply that you necessarily believed that they were actually XXX.

TVTs

The Panel has heard conflicting evidence as to the manner in which you conducted the TVT operation. XXX. Your operation notes and the accounts given by Mr A, Clinical Director and Consultant Obstetrician and Gynaecologist, Dr W, Occupational Health Physician and the Head of Occupational Health Services, and Mr M,

Consultant Obstetrician and Gynaecologist at the Hospital, about your discussions with them also suggest that you were committed to using this kind of approach.

Against that, the Panel has heard from Mr R, Nurse Theatre Practitioner, that you performed the operation in the same way as other surgeons XXX. Dr N, Consultant Epidemiologist and Consultant in Public Health Medicine, and Medical Secretary for UKAP, stated that he thought it would be difficult to perform the operation in XXX repeatedly and Mr B gave similar evidence. XXX.

For these reasons, the Panel has concluded that it would be unlikely that you were capable of maintaining XXX at all times. However, even if you did, for the reasons set out below, the panel would still regard the procedure as XXX. Therefore, it did not reach a formal determination on the way in which you performed the TVT procedure.

Paragraph 4(b) in respect of "should have known" has been found proved in relation to the TVT procedures in Schedule B

The Panel noted that the Guidance defines, XXX. It also accepted the evidence of Dr F, Mr A, Dr W, and others that, at the relevant time, this particular guideline functioned as the working definition of XXX within the Gynaecology Department (the working definition). The Panel also noted that, in September 2010, in response to a formal enquiry from the GMC's solicitors, UKAP had been unwilling to give an opinion as to whether a procedure carried out in the way you now claim would or would not be XXX.

The Panel considered that you were the person charged with the critical task of avoiding XXX, and that you should not have relied solely on the narrow definition contained in the Guidance. In particular, Dr W advised you to seek wider professional advice on your technique, which you did not do. You should have considered the guidance more broadly, looking at all the steps involved in the TVT operation, and at the fundamental issue of whether you would be able to avoid the risk XXX.

There is an argument that when contemplating a modified TVT for the first time, and given the working definition referred to above, you might reasonably have concluded that it could be regarded as a XXX.

Accordingly, even if the TVT procedure had been carried out consistently by XXX, the Panel has concluded that you should have known that the procedure was to be regarded as XXX.

Paragraph 4(b) in respect of "you knew" has been found not proved in relation to the TVT performed up to July 2001

The Panel has heard from you, and other consultants, that it was widely known that you were performing TVT operations. You had made no attempt to conceal the performance of these procedures, and made reference to them in your appraisal reports and applications for merit awards. In addition, you told the Panel that you did

not consider the technique to be XXX in the way you performed it and you made representations to UKAP in this respect. The Panel has concluded that you neither knew, nor believed, that the TVT was to be regarded as XXX.

In all the circumstances, the Panel found this charge not proved in respect of the TVT operations performed between February 2001 and July 2001.

Paragraph 4(b) in respect of "you knew" has been found proved in relation to the TVT performed after July 2001

Dr A told the Panel that he recalled discussing the TVT procedure with you and indicated that you should stop carrying out the procedures until further advice had been received. The Panel concluded that this discussion took place in or around July 2001 as evidenced by the memorandum from Dr L, Consultant Microbiologist working at the Hospital, to Mr H, dated 12 July 2001, and copied to you. This indicated that further information regarding XXX had been forwarded to UKAP for consideration at its next meeting.

The Panel took the view that the concerns raised by Dr A would have signalled to you that the status of your procedure was in question, and that that, in itself, would have led you to conclude that TVTs were to be regarded as XXX.

In December 2002, UKAP wrote to you stating that your technique was to be regarded as XXX, subject to any further submissions you might make. In the Panel's view, if any doubt had remained, the response to your letter to UKAP in December 2002, should have settled the matter. Furthermore, in your own evidence, you acknowledged that the implication of the UKAP letter indicated to you that there may have been XXX.

In all the circumstances, the Panel found this charge proved in respect of the TVT operations performed after July 2001.

Paragraph 4(b) in respect of "you knew" and "should have known" has been found proved in relation to the TOT procedures as set out in Schedule B

The majority of the witnesses said they believed the TOT procedure to be more XXX than the TVT procedure, although the Panel has noted that Mr R said that it was his understanding that the TOT procedures were less XXX.

Mr B described the TOT procedure as potentially more XXX than the TVT. He stated that, as the operation was carried out with the needle travelling from outside to inside, there was an increased risk of XXX. You claimed that you could pull the vagina down so it was flush with the skin, but Mr B stated that this would have resulted in an increase in the extent of distortion of the vagina with the result that it would be more difficult XXX.

The Panel has borne in mind that the TOT procedure is similar to the TVT procedure. Having received the response from UKAP in 2002, which stated that the TVT procedure was to be regarded as XXX, the Panel concluded that you knew the

TOT procedure was also to be regarded as XXX since it involved similar procedures XXX.

In all the circumstances, the Panel found this charge proved in respect of the TOT procedures performed.

Paragraph 4(b) in respect of "you knew" and "should have known" has been found proved in relation to the Manchester Repair procedures as set out in Schedule B

The Panel has heard that in their classic form these operations are inherently XXX.

In relation to patient 48, the Panel has noted that the patient was consented for a "…vaginal stitch / ? Repair". In your contemporaneous operation note, you noted "…Fothergills sutures (Repair Small)". Both the discharge summary, signed by you, and the discharge letter, dictated by you, to the patient's GP, stated that a "Manchester Repair" had been performed. Furthermore, when describing your surgical technique you used phases such as, "anterior repair", "amputation of cervix" and "Fothergills suture to correct the prolapse".

In relation to patient 57, the Panel has noted the operation note and discharge summary detail a "Manchester Repair" having been performed. In addition, you stated in your discharge letter to the patient's GP that the operation had been a "Modified Manchester type stitch/repair".

The Panel has noted that three steps of a "classic" Manchester Repair, as described by Mr B, were detailed in your contemporaneous notes.

The Panel has noted that at no point in the contemporaneous medical records did you record having done a purse-string stitch.

In view of your precise use of surgical terminology in the operation notes, the Panel found the account you gave in evidence to be implausible.

The Panel was of the view that it did not have sufficient evidence to draw any relevant inferences from the duration of the operation or the length of the post-operative stay in hospital.

The Panel concluded that these operations could not have been conducted without XXX.

In all the circumstances, the Panel found this charge proved in respect of the Manchester Repairs procedures performed.

Paragraph 4(b) in respect of "you knew" and "should have known" has been found not proved in relation to the Vaginal Vault Repair procedures as set out in Schedule B

The Panel has considered the description of the surgical technique of the Vaginal Vault Repairs as described by both experts in their written reports and by the GMC expert during the course of his oral evidence.

The Panel has noted that Mr B conceded that a vaginal vault repair could have been performed using XXX in certain circumstances.

The Panel has noted that there is little detail in your operation notes as to the technical aspects of the procedures you performed, for example, the exact stitches you used.

However, the Panel felt that the GMC had not brought sufficient evidence for it to conclude that there was a risk XXX in these procedures.

In all the circumstances, the Panel found this charge not proved in respect of the Vaginal Vault Repair procedures.

Paragraph 4(b) in respect of "knew" and "should have known" has been found not proved in relation to the Posterior Vaginal Repair procedures as set out in Schedule B

There were features of your operation note and referral letter to the patient's GP, which led Mr B to conclude that you had performed a "classic" procedure, rather than the modified version as described by Mr C, your expert witness.

However, the Panel has noted that Mr B accepted that the procedure described by Mr C, in his written report, would have been possible to perform in XXX way.

The Panel considered that there was insufficient evidence to be satisfied that you had conducted this procedure in a manner which rendered it XXX.

Accordingly, the Panel was not satisfied, on the balance of probabilities, that you knew, or should have known, that this procedure would have been regarded as XXX.

Paragraph 4(b) in respect of "knew" and "should have known" has been found proved in relation to the Division of Vaginal Adhesions procedure as set out in Schedule B

The Panel has accepted your oral evidence that, when you performed the operation, the adhesions were situated in a band across the middle of the vagina. It has also noted that you stated that the vaginal tissues above and below the adhesions would have some elasticity.

Nevertheless, the Panel has noted that the pre- and post-operative letters from you to the patient's GP indicate that the adhesions were situated at the top of the vagina. The patient notes also contain a diagram which indicates this. The Panel has concluded that when you began the operation, you believed the adhesions were at the top of the vagina. The Panel has heard from Mr B that unless the adhesions

were low down in the vagina it was highly unlikely that it would have been possible to pull them to, or close to, the introitus.

The Panel found this paragraph proved on the balance of probabilities in respect of the Division of Vaginal Adhesions procedure.

Paragraph 4(c) has been found proved in relation to those particulars of the allegation found proved in paragraph 4(b):

"c. thereby breached the agreement set out at 3 above,"

The Panel was satisfied that in performing those procedures set out in Schedule B, which you knew, or should have known, were to be regarded as XXX, you breached the agreement under which you returned to work at the Hospital.

Paragraph 4(d) in its entirety has been admitted and found proved:

"d. relied on your own assessment of risk to patients arising from

i. your health status,

ii. any modifications to the procedures at 4a above;"

Paragraphs 5(a), 5(b), 5(c) and 5(d) have been admitted and found proved:

"5. On 3 July 2007 you

a. conducted a diagnostic laparoscopy on the patient referred to in Schedule C,

b. performed a laparotomy, which is XXX,"

c. did not call for assistance from a colleague,

d. did not ensure that the patient's care was taken over by a colleague,"

Paragraph 5(e):

"e. thereby breached the agreement set out at 3 above;"

Paragraph 5(e) has been found proved in relation to paragraph 3(a).

The Panel has noted that Mr Moon accepted that this paragraph only remained outstanding as paragraph 3(a) had not been admitted.

Paragraph 5(e) has been admitted and found proved in relation to paragraph 3(b).

Paragraph 6 in its entirety has been admitted and found proved:

"6. Following the procedure set out at 5 above you

a. did not take sufficient steps to advise colleagues as to the possible XXX risk to the patient,"

b. did not advise the patient as to her possible XXX in light of your status as set out in Schedule A;"

Paragraphs 7(a), 7(b) and 7(c):

"7. Your conduct at 4, 5 and 6 above was

a. inappropriate,

b. not in the best interests of your patients,

c. irresponsible."

Paragraph 7 in its entirety has been found proved in relation to paragraphs 4(a), 4(b) and 4(c).

In finding paragraphs 4(a) and 4(b) proved, the Panel has noted that the Legal Assessor advised that paragraph 4(a) alleges the carrying out of acts; 4(b) alleges a specific state of mind whilst carrying out the alleged acts; and 4(c) sets out the consequence of (a) and (b).

Paragraph 7 in its entirety has been admitted and found proved in relation to paragraph 4(d) in its entirety.

Paragraph 7 in its entirety has been admitted and found proved in relation to paragraphs 5(a), 5(b), 5(c) and 5(d).

Paragraph 7 in its entirety has been found proved in relation to paragraph 5(e) in respect of paragraph 3(a).

Paragraph 7 in its entirety has been admitted and found proved in relation to paragraph 5(e) in respect of paragraph 3(b)(as amended).

Paragraph 7 in its entirety has been admitted and found proved in relation to paragraph 6 in its entirety.

Having reached its findings on the facts, the Panel invites Mr Ramasamy and Mr Moon to adduce any further evidence and make any further submissions as to whether, on the basis of the facts found proved, your fitness to practise is impaired by reason of your misconduct.

Determination on impaired fitness to practise

Mr Shaheen: Having announced its findings on the facts, the Panel has now considered whether, on the basis of the facts found proved, your fitness to practise is impaired by reason of your misconduct. In so doing, the Panel has considered all the evidence adduced in this case, both oral and documentary, and has taken account of the submissions made by Mr Ramasamy, on behalf of the General Medical Council (GMC), and those of Mr Moon, on your behalf.

Mr Ramasamy submitted that the facts found in your case are serious and repeated, and that they amount to misconduct. He further submitted that, in light of the seriousness of the misconduct, and the evidence in relation to your having a lack of insight, your fitness to practise is impaired by reason of your misconduct. He referred the Panel to case law relevant to this stage of the proceedings and to the standards of conduct set out in Good Medical Practice.

Mr Moon submitted that you accept that it is not appropriate to resist a finding of impairment. He submitted that you accept what you did was wrong and that you explicitly apologise for your actions. He invited the Panel to consider the context of your actions at the sanction stage of the proceedings.

Whilst the Panel has borne in mind the submissions made, the issue of impairment is one for it to determine exercising its own judgment.

In approaching its task, the Panel has accepted the advice of the Legal Assessor. He reminded the Panel that a finding of impairment involves two elements: firstly the Panel must determine whether the facts found proved amount to misconduct. Secondly, if they do, the Panel must decide whether, in the light of all the circumstances of the case, the doctor's fitness to practise is impaired because of that misconduct.

The Panel has noted the case law to which it has been referred.

The case of Cheatle v GMC [2009] EWHC 645 (Admin), states that:

> "…the context of the doctor's behaviour must be examined. In circumstances where there is misconduct at a particular time, the issue becomes whether that misconduct, in the context of the doctor's behaviour both before the misconduct and to the present time, is such as to mean that his or her fitness to practise is impaired. The doctor's misconduct at a particular time may be so egregious that, looking forward, a panel is persuaded that the doctor is simply not fit to practise medicine without restrictions, or maybe at all. On the other hand, the doctor's misconduct may be such that, seen within the context of an otherwise unblemished record, a Fitness to Practise Panel could conclude that, looking forward, his or her fitness to practise is not impaired, despite the misconduct."

The Panel has borne in mind the case of Yeong v GMC [2009] EWHC 1923 (Admin), which establishes that in cases where misconduct arises not from clinical errors or incompetence, but from particularly serious acts of misconduct, the issue of

remediability may be of less significance because of the need to maintain public confidence in the medical profession and to declare and uphold proper standards of conduct and behaviour.

In the case of Roylance v GMC [2000] 1 AC 311, Lord Clyde stated:

> "Misconduct is a word of general effect, involving some act or omission which falls short of what would be proper in the circumstances. The standard of propriety may often be found by reference to the rules and standards ordinarily required to be followed by a medical practitioner in the particular circumstances."

The Panel has also noted that Sir Anthony Clarke MR stated in Meadow v General Medical Council [2006] EWCA Civ 1390; [2007] 1 QB 462, that:

> "In short, the purpose of [fitness to practise] proceedings is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The FPP thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past."

Throughout its deliberations, the Panel has borne in mind its responsibility to promote and protect the public interest. The public interest includes, amongst other things, the protection of patients, the maintenance of public confidence in the profession, and the declaring and upholding of proper standards of conduct and behaviour.

The Panel has already given a detailed determination in relation to the facts of your case and it has taken those matters into account during its deliberations on impairment.

The Panel has noted that in February 2000, you returned to work at the Hospital under an agreement that, in the course of your clinical duties, you would not conduct XXX, and that where you decided that a patient needed to undergo XXX the patient's care would be taken over by a colleague. By means of that agreement the Hospital aimed to strike a reasonable balance between allowing you to continue to practise as a surgeon and protecting patients from XXX. In short, the Hospital trusted you to act in accordance with that agreement.

Between February 2001 and July 2007 you performed the following XXX on a number of patients:

- TVTs;
- TOTs;
- Manchester Repairs; and
- Division of Vaginal Adhesions.

The Panel has found that you knew, or should have known, that those procedures were to be regarded as XXX.

Therefore, you breached the agreement you had with the Hospital. You relied on your own assessment of risk to patients arising from your health status and any modifications to those procedures.

In addition, you performed a laparotomy, which is an XXX, on a patient in July 2007. You did not call for assistance from a colleague. Nor, did you ensure that the patient's care was taken over by a colleague.

In performing that procedure, you breached the agreement you had with the Hospital. Following the procedure you did not take sufficient steps to advise colleagues as to the possible XXX risk to the patient. Nor, did you advise the patient as to her possible XXX in light of your health status.

On the basis of the above findings, the Panel found that your conduct was inappropriate, not in the best interests of your patients, and irresponsible.

Throughout its deliberations, the Panel bore in mind the principles contained within Good Medical Practice (1998, 2001 and 2006 editions, which were applicable at the time). In relation to the duties of a doctor registered with the GMC, it states that:

> "Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life and you must:
>
> - Make the care of your patient your first concern
>
> …"

It goes on to state, in relation to XXX

The Panel first considered whether the facts of your case amount to misconduct.

Over a period of six years, you repeatedly breached the agreement you had reached with the Hospital. In so doing, you relied on your own assessment of risk to patients arising from your health status and any modifications to those procedures. Furthermore, following one procedure, a laparotomy, which you knew to be XXX, you did not take sufficient steps to advise colleagues as to the possible XXX risk to the patient. Nor, did you advise the patient as to her possible XXX in light of your health status.

You placed patients at serious risk of harm and demonstrated disregard for patient safety.

The Panel has found that your conduct was inappropriate, not in the best interests of your patients, and irresponsible.

The Panel is of the view that your actions amounted to serious breaches of the GMC's guidance in relation to professional standards. Cumulatively, these breaches

constituted a grave abuse of a doctor's position and your conduct fell far below the standards expected of all registered medical practitioners. The Panel was of the view that such behaviour would be regarded as deplorable by the public, patients and fellow practitioners.

The Panel is in no doubt that your actions amount to misconduct.

The Panel went on to consider whether your fitness to practise is impaired by reason of your misconduct.

The Panel has not received any evidence that you have taken steps to remedy your conduct, which, in the Panel's view is, by its very nature, not easily remediable.

The Panel is of the view that even if you could demonstrate that you had made efforts to address your behaviour, the nature of your misconduct was so egregious that a finding of impaired fitness to practise was inevitable. Such a finding is necessary in order to protect the reputation of the profession and maintain and uphold proper standards of conduct.

In all the circumstances, the Panel has determined that your fitness to practise is impaired by reason of your misconduct.

The Panel now invites Mr Ramasamy and Mr Moon to adduce any further evidence and make any further submissions as to the appropriate sanction, if any, to be imposed on your registration. Submissions on sanction should include reference to the Indicative Sanctions Guidance (dated April 2009 and updated in August 2009), using the criteria set out in the guidance to draw attention to the issues which appear relevant in this case.

Determination on sanction

Mr Shaheen: Having determined that your fitness to practise is impaired by reason of your misconduct, the Panel has now considered what sanction, if any, should be imposed upon your registration. In so doing, the Panel has considered all the evidence adduced in this case, both oral and documentary. This includes the additional evidence presented by Mr Moon, namely testimonials, information relating to your fundraising work, determinations from the Interim Order Panel and a report from Professor O, dated 26 January 2010. In reaching its decision, the Panel has also taken account of the submissions made by Mr Ramasamy, on behalf of the General Medical Council (GMC), and those of Mr Moon, on your behalf. It has approached its task in accordance with the advice of the Legal Assessor.

Mr Ramasamy submitted that in view of the serious nature of your misconduct and your lack of insight, it would be appropriate for the Panel to erase your name from the Medical Register. He drew to the Panel's attention its findings in relation to impairment and to relevant parts of the Indicative Sanctions Guidance.

Mr Moon, on your behalf, offered undertakings and invited the Panel to accept them. The undertakings included a commitment to maintain a log of your medical practice

and to restrict yourself to the performance of ultrasound scans. He reminded the Panel that it would also be open to it to suspend your registration, and that a future Panel could then impose conditions if that Panel thought it appropriate to do so. He submitted that it would be neither appropriate, nor in the public interest, to erase your name from the Medical Register. He drew to the Panel's attention parts of the evidence and sections of the Indicative Sanctions Guidance which supported his submissions.

Whilst the Panel has borne in mind the submissions made, the issue of sanction is one for it to determine exercising its own judgment.

In reaching its decision, the Panel has taken account of the GMC's Indicative Sanctions Guidance (dated April 2009 and updated in August 2009). It has borne in mind that the purpose of a sanction is not to be punitive, but to protect patients and the public interest, although it may have a punitive effect. Throughout its deliberations, it has applied the principle of proportionality, balancing your interests with the public interest. The public interest includes, amongst other things, the protection of patients, the maintenance of public confidence in the profession, and the declaring and upholding of proper standards of conduct and behaviour.

The Panel has already given detailed determinations in relation to the facts found proved in your case and in relation to impairment, and it has taken those matters into account during its deliberations on sanction.

The Panel first considered whether to conclude the case by taking no action. It has determined that in view of the serious nature of your misconduct, it would be neither sufficient, proportionate nor in the public interest, to conclude your case by taking no action.

The Panel next considered whether it would be sufficient to accept the undertakings offered by you. In so doing, it has taken into account the GMC's Procedure and Guidance Note on Undertakings (dated August 2009). It has borne in mind that any undertakings would need to be specific, measurable, attainable and realistic; further their acceptance would have to be a proportionate response to the misconduct.

The Panel has rejected the undertakings offered on your behalf. In the Panel's view, these would not adequately mark the seriousness of its findings, nor would they be sufficient to promote and protect the reputation of the profession and uphold proper standards of conduct and behaviour.

The Panel next considered whether it would be sufficient to impose conditions on your registration. It has borne in mind that any conditions imposed would need to be appropriate, proportionate, workable and measurable.

Whilst the Panel is of the opinion that it could formulate conditions which could address the issue of patient safety, it was of the view that, as with undertakings, conditions would not adequately mark the seriousness of its findings, nor address other aspects of the public interest.

The Panel then went on to consider whether it would be sufficient to suspend your registration. In so doing, it has taken into account paragraph 69 of the Indicative Sanctions Guidance which states that:

> "Suspension has a deterrent effect and can be used to send out a signal to the doctor, the profession and public about what is regarded as behaviour unbefitting a registered medical practitioner. Suspension from the register also has a punitive effect, in that it prevents the doctor from practising (and therefore from earning a living as a doctor) during the period of suspension. Suspension will be an appropriate response to misconduct which is sufficiently serious that action is required in order to protect patients and maintain public confidence in the profession. However, a period of suspension will be appropriate for conduct that falls short of being fundamentally incompatible with continued registration and for which erasure is more likely to be the appropriate response (namely conduct so serious that the Panel considers that the doctor should not practise again either for public safety reasons or in order to protect the reputation of the profession). This may be the case, for example, where there may have been acknowledgement of fault and where the Panel is satisfied that the behaviour or incident is unlikely to be repeated. The Panel may wish to see evidence that the doctor has taken steps to mitigate his/her actions..."

The Panel has also taken into account the relevant factors, as far as suspension is concerned, set out at paragraph 75.

The Panel has found that over a period of six years, you repeatedly breached an agreement you had reached with the Hospital, which included your not conducting XXX and that, where you decided that a patient needed to undergo XXX, the patient's care would be taken over by a colleague. In breaching this agreement, you relied on your own assessment of risk to patients arising from your health status and from any modifications to those procedures. Furthermore, following one procedure, a laparotomy, which you knew to be XXX, you did not take sufficient steps to advise colleagues as to the possible XXX risk to the patient; nor did you advise the patient as to her possible XXX in light of your health status.

The Panel has found that your conduct was inappropriate, not in the best interests of your patients, and irresponsible.

Your actions amounted to serious breaches of the GMC's guidance in relation to professional standards and, cumulatively, these constituted a grave abuse of a doctor's position. Your conduct fell far below the standards expected of all registered medical practitioners.

Against the features set out above, the Panel has had regard to the positive testimonials from colleagues and patients which attest to your having excellent clinical skills. In addition, they attest to your being an outstandingly caring doctor and indicate that you were held in high regard by both your colleagues and patients. Several of the authors comment that they could not imagine that you would intentionally put any patient at risk of harm.

The Panel has borne in mind that everyone working in the Department was aware that you should not perform XXX. You did not attempt to hide the fact that you were performing TVTs and TOTs from those at the Trust. On the contrary, the Panel has heard that the Clinical Tutor at the time approved your request for an application to undertake training in relation to the TVT procedures. The Panel has noted that there appears to have been some confusion as to what was, and what was not, XXX in the Department where you worked.

Whilst the Panel has determined that you placed patients at risk of serious harm and demonstrated disregard for patient safety, it has formed the opinion that it was unlikely that you believed that the procedures you carried out were XXX such that patients were placed at an additional risk of harm XXX.

The Panel has noted that you have not practised surgery since you resigned from the Trust in 2008. The Panel has heard that you now only perform ultrasound scans at the Brayford Studio Limited in Lincolnshire and that this sonography does not require you to hold registration with the GMC.

The Panel has noted that you have been subject to an interim order of conditions since 2007. It has borne in mind that there has been no suggestion that you have breached these conditions.

You now accept that you should not have relied solely on your own assessment of the risk you posed to patients. The evidence suggests that you now have some insight into your misconduct and that you have shown contrition for the consequences of your actions.

In reaching its decision on sanction, the Panel has balanced the aggravating features with the mitigating features. It has also taken into account both your interests and the interests of the public.

In the light of all the evidence presented to it, the Panel considered that you have learnt a salutary lesson from these proceedings, and that your proposal not to practise as a gynaecological surgeon would reduce any future risk XXX to a negligible level.

The Panel considered this to be a borderline case between suspension and erasure. Whilst the Panel has noted that it is unlikely that you will ever return to unrestricted medical practice, it was of the view that it would not be in the public interest to deprive patients indefinitely of your services in non-surgical aspects of the practice of obstetrics and gynaecology.

Given the circumstances of this case, including the substantial mitigation put forward, the Panel has concluded that your conduct, though falling far below the standard expected of a registered medical practitioner, is not fundamentally incompatible with continued registration.

It has, therefore, determined that it would be sufficient, proportionate and in the public interest, to suspend your name from the Medical Register.

In considering the length of the period of suspension, the Panel has borne in mind that you repeatedly breached the GMC's guidance in relation to professional standards and, therefore, undermined the trust that the public is entitled to place in the medical profession. It concluded that, in order to send a clear signal to the public and profession as to the seriousness with which it views your misconduct, it was necessary to impose the maximum period of suspension available, namely 12 months.

Before the end of the period of suspension, a Panel will meet to review your case. You will be informed of the date of that hearing, which you will be expected to attend. At that hearing, the Panel will wish to be satisfied that you have gained full insight into your behaviour. In addition, the Panel will be assisted by receiving:

- Evidence that you have kept your medical knowledge up-to-date during the period of suspension;
- Testimonials from persons of standing which attest to your good character during the suspension period;
- Evidence to show that you have reflected on, and further gained insight into, your misconduct; and
- Any other evidence that you feel will assist the Panel in reviewing your case.

The effect of this direction is that, unless you exercise your right of appeal, your registration will be suspended for twelve months, beginning 28 days from the date when written notice of this direction is deemed to have been served on you. A note explaining your right of appeal will be given to you.

Having concluded that your name be suspended from the Register, the Panel will now go on to determine whether it considers it necessary for the protection of members of the public, or in your own interests, to order that your registration shall be suspended forthwith.

The Panel now invites submissions on this matter.

Determination on immediate sanction

Mr Shaheen: Having determined that your registration be suspended for a period of 12 months, the Panel has now considered, in accordance with Section 38(1) of the Medical Act 1983, as amended, whether your registration should be suspended immediately.

In so doing, the Panel has considered all the evidence adduced in this case, both oral and documentary, together with its previous determinations. It has also taken account of the submissions made by Mr Ramasamy, on behalf of the General Medical Council (GMC), and those of Mr Moon, on your behalf. The Panel has also noted the advice of the Legal Assessor, in particular, that it must consider the proportionality of its decision.

Mr Ramasamy reminded the Panel that if you were to lodge an appeal you would be able to practice unrestricted until the appeal was decided. He submitted that in view of the Panel's findings as set out in its determination on sanction it would be appropriate to suspend your registration immediately.

Mr Moon submitted that it is not necessary for the protection of members of the public, nor in the public interest, nor in your interests, to impose an immediate order. He submitted that you would continue to abide by the restrictions placed upon you by the Interim Orders Panel.

In reaching its decision, the Panel has taken account of the GMC's Indicative Sanctions Guidance (dated April 2009 and updated in August 2009). In particular, it has noted paragraph 122 which states that:

> "The Panel may impose an immediate order where it is satisfied that it is necessary for the protection of members of the public, or is in the public interest, or is in the best interests of the practitioner."

In view of the serious nature of its earlier findings, the Panel has determined that it is necessary for the protection of members of the public, and further it is in the public interest and proportionate, to make an order immediately suspending your registration.

The effect of this direction is that your registration will be suspended from the date upon which written notice of this determination is deemed to have been served upon you. Unless you exercise your right of appeal, the substantive order of suspension will take effect 28 days after notice of the outcome of this hearing is deemed to have been served upon you. The immediate order for suspension will remain in place until the substantive order takes effect.

The interim order currently imposed on your registration will be revoked when notice is deemed to have been served.

That concludes the case.

Confirmed

8 March 2011 Chairman

<u>Schedule A</u> - Amended following an application under Rule 17(3).

XXX

Schedule B - Amended following an application under Rule 17(3).

Case	Patient	Date of Procedure	Type of Procedure
1	XXX	08/02/2001	TVT
2	XXX	~~14~~ 15/02/2001	TVT
3	XXX	22/02/2001	TVT
4	XXX	28/02/2001	TVT
5	XXX	~~07~~ 08/03/2001	TVT
6	XXX	22/03/2001	TVT
7			
8	XXX	29/03/2001	TVT
9	XXX	~~11~~ 12/04/2001	TVT
10	XXX	~~25~~ 26/07/2001	TVT
11	XXX	25/07/2001	TVT
12	XXX	05/04/2001	TVT
13	XXX	~~05~~ 06/09/2001	TVT
14	XXX	06/09/2001	TVT
15	XXX	01/11/2001	TVT
16	XXX	22/02/2001	TVT
17	XXX	02/05/2002	SPARC/Modified TVT

Case	Patient	Date of Procedure	Type of Procedure
18	XXX	02/05/2002	SPARC/Modified TVT
19	XXX	25/07/2002	Modified TVT
20			
21			
22			
23			
24	XXX	17/10/2002	IVS Tunnelar TVT
25			
26			
27	XXX	16/12/2004	TOT
28	XXX	21/04/2005	Laparotomy & Bilateral Salpingo-oophorectomy
29	XXX	26/05/2005	TOT
30			
~~31~~	XXX	~~23/06/2005~~	~~Refashioning of Episiotomy Scar~~
32	XXX	21/07/2005	TOT
33	XXX	21/07/2005	TOT
34	XXX	21/07/2005	TOT
~~35~~	XXX	~~04/08/2005~~	~~Refashioning of episiotomy and Fentons operation~~

Case	Patient	Date of Procedure	Type of Procedure
36	XXX	05/08/2005	TOT
~~37~~	XXX	~~06/10/2005~~	~~Fenton's operation~~
38	XXX	24/11/2005	TOT
39	XXX	24/11/2005	TOT
40	XXX	23/03/2006	Modified TVT
41	XXX	27/04/2006	TOT
42	XXX	24/08/2006	TOT
43	XXX	15/09/2006	TOT
44	XXX	19/10/2006	TOT
45	XXX	24/11/2005	TOT
46	XXX	01/12/2006	TOT ~~and anterior vaginal repair~~
47	XXX	05/01/2007	TOT
48	XXX	26/01/2007	Manchester Repair
49	XXX	08/02/2007	TOT ~~and anterior vaginal repair~~
50	XXX	08/02/2007	TOT
51	XXX	15/02/2007	TOT
52	XXX	01/03/2007	~~Laparoscopic bilateral salpingo-oophorectomy &~~ vaginal vault repair

Case	Patient	Date of Procedure	Type of Procedure
53			
54	XXX	22/03/2007	TOT
55	XXX	26/04/2007	Division of vaginal adhesions
~~56~~	XXX	~~27/04/2007~~	~~Anterior repair~~
57	XXX	27/04/2007	Manchester repair
58			
59	XXX	11/05/2007	Posterior vaginal repair
60	XXX	28/06/2007	TOT
61	XXX	~~16/02/2007~~ 28/06/2007	~~16/02/2007: Laproscopy sacrocolpopexy~~ 28/06/2007: TOT, vaginal vault repair and repair of cystocele
62	XXX	05/07/2007	TOT

Schedule C

Case	Patient	Date of Procedure	Type of Procedure
63	XXX	03/07/2007	Laparotomy