

## **Fitness to Practise Panel Determination**

The following case was heard by a Fitness to Practise Panel. It is presented here to give an example of one possible outcome of breaching this principle. It is not intended to give a clear threshold between acceptable and unacceptable behaviour. Each case which comes before a Fitness to Practise Panel is judged on its own merits and assessed on the particular circumstances of the case.

### **Summary:**

The doctor failed to take appropriate action with regard to a particular procedure; conducted trials without research approval or patient consent, pretended to be ill when not in fact unwell and therefore failed to attend a clinic session, was not available to deal with post operative complications and made exaggerated claims when publishing information about services.

### **Relevant paragraphs of *Good Medical Practice***

This case relates to the Good clinical care section of GMP, specifically paragraphs 2b and 3h on providing good clinical care.

This case relates to the Relationships with patients section of GMP specifically paragraph 30 on being open and honest with patients if things go wrong and paragraph 36 on consent.

This case relates to the Working with colleagues section of GMP, specifically paragraph 41b on working in teams and 46 on respect for colleagues.

This case relates to the Probity section of GMP, specifically paragraphs 56 in Being honest and trustworthy and 60 in Providing and publishing information about your services and 71 in Research.

### **Determination on impaired fitness to practise**

Dr X: The Panel has made its findings on the facts. It has heard the submissions made by Counsel and has accepted the advice of the Legal Assessor as to whether on the basis of the facts found proved your fitness to practise is impaired.

Patients must be able to trust doctors with their lives and well-being. To justify that trust, doctors must maintain a good standard of practice. Good Medical Practice (May 2001 edition) states “In particular as a doctor you must:

- Make the care of your patient your first concern;
- Respect patients' dignity and privacy;
- Respect the rights of patients to be fully involved in decisions about their care;
- Be honest and trustworthy;
- Work with colleagues in the ways which best serve patients' interests.”

This case centres on five specific areas in which misconduct is alleged, namely:

1. Failure to take appropriate action with regard to the implantation of faulty Aquasense intraocular lenses.
2. Conducting two separate but connecting trials without the approval of a Research Ethics Committee or the consent of patients.
3. Failure to attend a XXX clinic on [date removed] by purporting to be ill when in fact you were not ill.
4. Failure to make yourself available to deal with post operative complications when it was expected by your colleagues that you would be available and, in the aftermath of the complications which did arise, acting in an inappropriate manner towards clinic staff.
5. Making exaggerated claims in a brochure as to your role in the development of various surgical techniques.

### **1. Failure to take appropriate action with regard to the implantation of faulty Aquasense intraocular lenses.**

At the material time you held practising rights as a Consultant Ophthalmic Surgeon at the XXX Hospital (formally XXX Hospital) in XXX. You have admitted that on [date removed], you carried out a right cataract extraction and lens replacement procedure of Mrs A. As part of the operation you implanted an “AquaSense” intraocular lens manufactured by Ophthalmic Innovations International Inc. You carried out post operative reviews of Mrs A on [date removed] and [date removed]. No further review of Mrs A was undertaken after [date removed].

In or around [date removed], you were notified by letter of problems with clouding of AquaSense intraocular lenses. You made no attempt in response to the notification to contact all patients in respect of whom you had implanted AquaSense lenses during the relevant period. Specifically you made no attempt to contact Mrs A following the notification and therefore did not contact all potentially affected patients.

In about [date removed], you were made aware that the Healthcare Products Regulatory Agency had issued a "Medical Device Alert" in respect of AquaSense lenses. You discussed the alert with Mrs B, the Clinical Services Manager and told her that you had reviewed all relevant patients post operatively and there was no problem with them, that you had treated patients who had presented with a problem following the operation and that it was unnecessary to contact all patients in respect of whom the AquaSense lens had been implanted during the period identified in the Medical Device Alert.

The Panel has found that your conduct with respect to these matters was irresponsible, seriously below the standards to be expected of a registered medical practitioner and not in the best interest of the patients.

You disregarded the GMC's publication Good Medical Practice [2001 edition] (paragraph 2) which states that:

"Good Clinical Care must include:

- Taking suitable and prompt action when necessary."

## **2. Conducting two separate but connecting trials without the approval of a Research Ethics Committee or the consent of patients.**

You have admitted and the Panel has found proved that between [date removed] and [date removed] you were a Director at the [XXX] Clinic in [XXX]. From [date removed] you were a paid Consultant to [XXX] the company which manufactured the [YYY] lens and from [date removed] you carried out clinical research as to the efficacy of the [YYY] lens. You implanted 118 [YYY] Lenses into one or both eyes of 72 patients undergoing refractive lens exchange surgery at the [XXX] Clinic. You collected pre and post operative data for the purposes of evaluating the safety and efficacy of the [YYY] Lens as an accommodating lens in pursuance of your research and this included testing and data collection. Such tests included measurement of amplitude of accommodation, measurements of lens shift and measurement of distance corrected near vision. The [YYY] Lens was self certified as "CE marked" by [XXX] in [date removed] and your research constituted a clinical trial. You did not seek ethical approval for the trial from a Research Ethics Committee, nor did you seek specific patient consent to participation in the trial nor did you comply with the [XXX] Clinic Research Policy.

You have admitted that your conduct with regard to these matters was irresponsible and not in the best interests of the patients. The Panel has also found that your conduct fell seriously below the standard to be expected of a registered medical practitioner and was dishonest.

You have admitted that you also carried out research involving a comparison of the safety and efficacy of the [YYY] lens and the “[ZZZ] lens”. The Panel has found that in pursuance of this research you took for your own use [ZZZ] lenses from the lens store at the [XXX] Clinic without the permission or knowledge of your colleague Mr E. The [ZZZ] lenses which you took and used had been supplied by the manufacturers for the sole use of Mr E in accordance with strict protocols.

You have admitted that in respect of seven patients operated on by you at the [XXX] Clinic you implanted a [ZZZ] lens into one eye and a [YYY] lens into the other in pursuance of your comparative research. You collected pre and post operative data and undertook post operative testing in pursuance of the research. Further, you failed to adhere to the manufacturer's protocol when using the [ZZZ] lenses. You have admitted that this research also constituted a clinical trial for which you did not seek ethical approval from a Research Ethics Committee or patient consent nor did you comply with the research policy of your own clinic.

You have admitted that your conduct with respect to these matters was irresponsible and not in the best interests of the patients. The Panel has also found that your conduct fell seriously below the standards to be expected of a Registered Medical Practitioner and was dishonest.

Good Medical Practice [2001 edition] (paragraph 52) states:

“If you participate in research you must put the care and safety of patients first. You must ensure that approval has been obtained for research from an independent research ethics committee and that patients have given consent. You must conduct all research with honesty and integrity.”

Paragraph 19, states:

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

Respect the right of patients to decline to take part in teaching or research and ensure that their refusal does not adversely affect your relationship with them.”

Paragraph 17, states:

“You must respect the right of patients to be fully involved in decisions about their care. Wherever possible, you must be satisfied, before you provide treatment or investigate a patient's condition, that the patient has understood what is proposed and why, any significant risks of side effects associated with it, and has given consent. You must follow the guidance in Seeking Patients' Consent: The Ethical Considerations.”

That GMC guidance, entitled “Research: The Role and Responsibilities of Doctors”, published in February 2002, states at paragraph 8:

“You must conduct all research with honesty and integrity and, in designing, organising and executing research, you must always put the protection of participants' interests first.”

Paragraph 15, states:

“Seeking consent is fundamental to research involving people.”

### **3. Failure to attend a [XXX] clinic on 21 May 2004 by purporting to be ill when in fact you were not ill.**

On a date in [date removed], you were booked to undertake an operating list at [XXX] Laser Eye Clinic, but you informed [XXX] that you would not be able to attend, as you were ill. The Panel has found that you were not ill and that your conduct in this regard was irresponsible and dishonest.

### **4. Failure to make yourself available to deal with post operative complications when it was expected by your colleagues that you would be available and, in the aftermath of the complications which did arise, acting in an inappropriate manner towards clinic staff.**

In [date removed], you were asked by Ms H, the Clinic Manager, whether you would be available to provide cover over the Christmas period and you said that you were. You indicated that you would be available to deal with any early post operative complications in accordance with Clinic Policy. On [date removed], you carried out an implantable contact lens procedure on a patient, following the operation the patient suffered a serious complication which required urgent medical attention. You had by then gone abroad without informing the practice manager or your colleagues that you were unavailable to deal with the post operative complication. When Ms H told you that you should not have operated and then gone abroad without telling anyone, you told her that she must not question your judgement, that the matter should never be discussed again and threatened her with a written warning. The Panel has found that your conduct was irresponsible, not in the best interest of the patient and intimidating in respect of Ms H.

Good Medical Practice [2001 edition] (paragraph 3) states:

“In providing care you must:

- Keep colleagues well informed when sharing the care of patients.”

And also states at paragraph 39:

“You must be satisfied that, when you are off duty, suitable arrangements are made for your patients' medical care. These arrangements should include effective hand-over procedures and clear communication between doctors.”

### **5. Making exaggerated claims in a brochure as to your role in the development of various surgical techniques.**

In a brochure for the Clinic ["XXX"] you stated that you had "pioneered the techniques of implantable contact lens and Intacs surgery in the UK", which you subsequently amended to state that you "helped to pioneer the techniques of implantable contact lens and Intacs surgery in the UK". The Advertising Standards Authority found these statements to be in breach of clauses 3.1 (substantiation), 7.1 (truthfulness) and 19.1 (other comparisons) of the Committee of Advertising Practice (CAP) Code and told you to withdraw both of them.

The Panel has found that your conduct in relation to the advertising material was dishonest.

Good Medical Practice [2001 edition] (paragraph 48) states:

"If you publish information about the services you provide, the information must be factual and verifiable. It must be published in a way that conforms with the law and with the guidance issued by the Advertising Standards Authority."

Paragraph 49 also states:

"The information you publish must not make any unjustifiable claims about the quality of your services..."

This is a record of serial breaches of GMC guidance and a disregard to the fundamental principles of Good Medical Practice. Your behaviour has fallen seriously below the standards to be expected of a registered Medical Practitioner. You have accepted through your Counsel that on the basis of the findings of fact made by the Panel it is inevitable that your fitness to practise must be considered impaired.

The Panel has accordingly determined that your fitness to practise is impaired by reason of your misconduct.