Ethical, professional, and legal obligations in clinical practice: a series of discussion topics for postgraduate medical education

Introduction and topic 1: *informed consent*

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Introduction

Postgraduate education in ethical, professional, and legal obligations of clinical practice has been neglected with the result that the training of junior doctors in these matters is intermittent and incomplete. In order to remedy this failure, short sessions were held in our hospital every three weeks or so over a six month period during which a range of important topics was discussed. The sessions were informal, learner based, and problem based. The sessions were prepared with reference to readily available non-academic publications. While this series was planned for a general surgical unit, a similar series could easily be prepared for a different specialty.

Never before has the conduct of doctors been the object of such intense scrutiny by the media and the public, and no branch of medicine is immune from censure. Ethical standards are incorporated into the "Duties and responsibilities of doctors" produced by the General Medical Council (GMC),¹ which form the core of our professional obligations. These are not statutory legal obligations as such but they do carry a good deal of weight in law since the GMC is itself a statutory body. In certain instances statute law is relevant; in many other instances common law and case law (precedent) guide medical practice. Although medical schools are obliged by the GMC to educate medical students in good ethical, professional and legal practice,² many junior doctors lack confidence in these subjects. A Medline search found no useful literature on postgraduate education in ethical, professional, or legal matters.

As a specialist registrar working in a busy surgical unit at a medium sized district general hospital I felt it would be worthwhile to facilitate short sessions dealing with these subjects as part of the unit educational commitment. These informal discussions were geared towards trainees and included cases typical of those with which the unit dealt. The sessions took place every three weeks or so and soon gave rise to much lively debate among all the unit staff from house officer to consultant.

Throughout the series we kept to the basics of good clinical practice. The sessions were not meant to be a formal ethics and law course. Their purpose was to address common problems in general surgery.

The literature to which I refer is mostly readily available from the GMC and the medical defence organisations. The very lack of academic references is a bonus; any motivated

practitioner can devise a similar programme for his/her own specialty with reference only to day-to-day experience and readily available non-academic literature. The following discussion topic is based on one of our sessions; a further four discussion topics will be published in the next four issues of this journal.

Topic 1: informed consent

An adult patient of sound mind has the right to refuse any treatment whatever the consequences.^{3,4} Unauthorised interference with a person is *battery* in law whether actual physical injury occurs or not.⁴ Handling of a patient must occur with consent. Consent may be implicit, for example, when a patient presents for examination or offers an arm for phlebotomy. Procedures performed under sedation or anaesthesia, or of a significantly invasive nature, are generally considered to require explicit written consent.

The legal concept of *negligence* is different; a practitioner is negligent when, having a duty of care, he/she has failed in that duty and as a consequence injury has arisen.⁵ As described in the GMC's *Good Medical Practice*,¹ a doctor has an ethical and professional duty of care for the patient, and to fulfil this duty that doctor must not only practice within the limits of his or her competence, but also inform the patient of possible adverse consequences.

The concept of *informed consent* is well established in case law, and so doctors are obliged ethically, professionally, and legally to address this before performing many procedures. Debate about informed consent concerns how much information about the nature of the procedure and its consequences is adequate, and to what extent the patient comprehends the information. Consent is hardly ever *fully* informed: even with an abundance of information, a patient is unlikely to have as complete a picture as a senior clinician experienced in that procedure.

Precedent of *Bolam*, *Sidaway*, and *Bolitho*

Case law is very relevant in matters of consent.⁴ In the *Bolam* case it was held that a doctor is not negligent if he acts in accordance with practice accepted as proper by a responsible body of medical opinion; a doctor needn't inform the patient of a possible complication if it is accepted medical practice not to do so. Of course this begs the question of how "accepted

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medical practice" is defined. This was addressed in the *Sidaway* case in which a patient had suffered paraplegia after elective spinal surgery. The law lords confirmed the doctor's duty to provide adequate information, but accepted that there is a limit to the range of possible adverse outcomes about which the patient should be counselled.

The *Bolam* criterion of a "responsible body of medical opinion" was questioned in the recent *Bolitho* case concerning a child with croup who developed respiratory obstruction and hypoxic brain damage. It was concluded that appeal to authority is not in itself an adequate defence; the doctor must be able to produce evidence of the good sense and logic of a decision. Doctors must therefore be aware of the best available evidence when planning procedures.

Informed consent in practice

It is widely believed that risks which occur in fewer than 1% of cases need not be discussed. There is no legal precedent for this practice and it is immediately questionable on grounds of statistical accuracy. While the limitation of informed consent was accepted in *Sidaway*, there is a trend to more extensive counselling of risk.⁴ If an uncommon complication would be especially grievous for that patient, then the doctor should inform the patient of it. For example a public speaker should be told of the risk of superior laryngeal nerve injury in thyroid lobectomy; although unusual, it would have particular significance for his/her career.

Unusual complications are sometimes so profound or have such a public profile that it is wise to specifically mention them. A surgeon may, for example, choose to tell a patient undergoing cholecystectomy that, although the laparoscopic technique is standard, there is a marginally increased risk of suffering bile duct injury.

Patients undergoing sterilisation procedures should always be warned of a risk of failure, although the risk is usually much less than 1%.⁴

Must we warn the patient of the general risks associated with staying in hospital?

In *Sidaway* the importance of counselling for risks *special in kind or magnitude* was emphasised. In the UK at present it is not common practice to counsel patients about general complications not directly related to the procedure, unless they are in particular danger. While patients need not normally be counselled about chest infection as a general complication of laparotomy, they ought to be so counselled if they have chronic pulmonary disease.

What is the value of a consent form?

A consent form if used properly will provide a defence against allegation of battery by demonstrating that the patient agreed to the procedure, so long as the procedure and its expected consequences are described in plain language.⁴ Furthermore if the possible adverse outcomes which are discussed are carefully annotated on the consent form, the case for claiming that the doctor was negligent by not counselling about such adverse outcome is weaker. Moreover a

carefully completed consent form, or similar written and signed information in the clinical notes, shows sincerity and good practice.

Do consent forms go "out of date"?

Not as such. If there has been no change in circumstances since obtaining written informed consent then that documentation remains valid. It is the responsibility of the operating surgeon to decide whether this is so.³

Who should obtain informed consent?

The practitioner who is performing the procedure should counsel the patient, obtain informed consent, and complete consent forms. If this is not possible, that doctor should ensure that the delegated doctor knows about the procedure and its risks.³ Consent for complex procedures should not be left to the preregistration house officer.

Case 1

Mrs A has been admitted for wide local excision and axillary clearance. She knows she has breast cancer. How should she be advised before surgery such that she can give informed consent?

- Mrs A must be told the reason for the operation, the nature of the operation itself, and what will happen afterwards (drainage from the axilla, adjuvant treatment). She must be told the more common complications: shoulder stiffness, swelling of the arm, numbness in the armpit. She should also be told of the possibility of a further operation if the pathology margins are not clear. All these should be annotated in plain language on the consent form.

Case 2

Mr B suffers from limiting bilateral claudication. He is admitted for lower limb diagnostic arteriography. The procedure itself is uneventful but you are called to see him shortly after his return to the ward as his left foot is very painful. This foot is pale, paraesthetic, and cold. Treatment for the acute occlusion is unsuccessful. Mr B ultimately requires a below knee amputation. What should Mr B have been warned about when his consent was obtained for this investigation?

- Mr B should have been warned about the real risk that the arteriogram might make his circulation worse. Some surgeons present felt that the risk of toe or limb loss should be explicitly mentioned. As a radiological procedure, however, the radiologist should be responsible for informed consent.

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1 General Medical Council. *Good medical practice*. London: GMC, 1998.

2 General Medical Council. *Tomorrow's doctors: recommendations on undergraduate medical education*. London: GMC, 1993.

3 General Medical Council. *Seeking patients' consent: the ethical considerations*. London: GMC, 1998.

4 Medical Defence Union. *Consent to treatment*. London: MDU, 1997.

5 Medical Defence Union. *Medical negligence*. London: MDU, 1997.