EDITORIAL

# Audit, Ethics and the Scientific Process

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Clinical audit has been described as the systematic critical analysis of the quality of care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome as well as the quality of life for the patient.[1] Audit has been contrasted with research. Simply put, research is concerned with discovering the right thing to do; audit with ensuring that it is done right.[2] Doctors are trained to use scientific thought in deciding whether a patient requires treatment and what particular form of therapy needs to be given. This assumes greater importance now as alternative therapies are increasingly promoted. Doctors are required to give a sympathetic ear to the patient in history taking, perform a thorough physical examination and decide on appropriate diagnostic tests before deciding on treatment, if any, for the patient.

Some of the underlying principles of good ethical conduct are stated in the Ethical Code of the Malaysian Medical Association (MMA).[3] The code which is as old as the association itself recently underwent a review to keep it in touch with modern realities. It is ample proof that ethics is a "living" guideline rather than an outmoded antiquity of ancient medical practice. Ethics has been defined as a civil code of behaviour considered correct by members of a profession for the good of both the patient and the profession. Ethics outlines the borders of acceptable conduct where the borders are decided by the profession itself. The trust patients have in doctors goes beyond written words and leads the public at large to expect of the doctor not only a high standard of medical ability and skill but also impeccable behaviour. The need for a patient's trust in his doctor is the basis for ethical codes from many centuries ago as manifested in the traditions of all the major civilisations. The principles of good conduct would include:

- assuming overall responsibility for the care of the patient,
- ensuring that the appropriate choice of treatment is based on sound scientific evidence,
- ensuring confidentiality of patient information,
- consent for procedures and some investigations and
- confidentiality issues in relation to medical reports.

The ethical code also stresses that a doctor should guard against self-laudatory activities as well as advertising. He should also not associate with commercial concerns in such a way as let it influence or appear to influence the treatment of his patient. The MMA is committed to educating its membership on the principles of medical practice based on good ethical conduct. In any dispute regarding clinical audit, the MMA should stand by the ethical principles enunciated in the ethical code.

Doctors have always been trained to audit the way in which they practice so that their practice patterns may reflect the best way of managing their patients. Audit should ideally be self-driven and this has always been encouraged by the medical profession and the MMA. However, this process of self-audit may sometimes be affected by the fallacies of human behaviour. Thus clinical audit by one's peers has become an accepted way of review by the medical profession. The MMA should continue to strongly promote this practice in the medical profession.

In this issue of the journal, there are two articles on audit. One is a three-year audit on infected pseudoaneurysms managed in a vascular unit of a local hospital.[4] The findings may not reflect the patterns in a hospital in another area and therefore the recommendations the authors put forward may not be applicable to a practice elsewhere. The other is a national audit of

perioperative mortality.[5] Various important recommendations have been made which doubtless would be taken up for implementation by the administrators of public hospitals. A point to be noted is that the Perioperative Mortality Review (POMR) was initiated four years after the National Confidential Enquiry into Perioperative Deaths (NCEPOD) in the United Kingdom on which the local audit is modelled. A similarly well known audit, the Confidential Enquiries into Maternal Deaths (CEMD)[6], was started a year earlier to the POMR but nearly 40 years after the model in the United Kingdom. A number of recommendations affecting clinical practice patterns in obstetric care have been made and an audit of the level of implementation was undertaken in 1996, three years after the initial report was released in 1993. The level of implementation of the recommendations varied between 60 - 90 per cent in all institutions including the private sector.[7] The CEMD in Malaysia succeeded in overcoming the under-reporting of maternal deaths.[8] A particularly interesting point is that the audit in the local CEMD was undertaken very much sooner than in the UK where the first audit of the Confidential Enquiry system was undertaken in 1994 .[9]

Some of the ethical issues of concern in undertaking an audit are:

**Confidentiality:**

Data collected for audit are generally anonymised so that no conflict of issues relating to confidentiality ensues. Managers should only have access to aggregated anonymous data and there should be no way that a link could be made between the audit conclusions and named patients. Audit should never be seen as a threat to patient confidentiality. The MMA should take an uncompromising view of releasing information that betrays the patient-doctor confidentiality as a result of audit activities. This relates particularly to the present arrangements of foreign workers examination conducted by a third party.

The performance of clinical audit by non-medical third parties should be strongly opposed based on the ethical principles of trust by the patient, confidentiality, privileged communication and consent. We should also be strongly opposed to statutory requirements for clinical audit based on the same principles.

However, it is recognised that there is a public demand that the medical profession should be seen to improve its practice based on scientific evidence. It should therefore promote that the profession designs certain quality assurance indicators based on consensus in the profession and these would in future be available for public's information. A process of clinical audit would therefore need to take place in every medical practice either by the medical practitioner or by one's peers in order to determine performance standards in clinical practice. Clinical audit is part of the process of continuing medical education and therefore should be credited appropriately in the present system of MMC/MMA credit points.

**Data Sources:**

It is ethically acceptable in principle to use clinical records without approaching and involving the patients concerned, provided that confidentiality and anonymity are preserved. There is a duty to use available information for the common good where this can be done without detriment to anyone. The Royal College of Physicians concluded that medical audit was one of the activities that constitutes medical practice and as such does not require independent ethical review. [10]

**Use of scientifically valid methodology:**

Current practise has to be evidence based not anecdotal. This can be done with the use of meta-analysis which are based on carefully selected articles based on strict criteria. Although not perfect this is currently the most acceptable system and needs to be regularly updated. One of the first groups to come out with recommendations is in obstetrics and the database is available in CD-Rom making it easily accessible to the end users. Currently databases are available in various branches of medicine.

Differences between audit and research have been previously described. The striking similarity between the two have been the systematic, rigorous approach and a number of common methodologies. [12] There is a blending between the two modalities. Clinical audit is a tool that can be used by all health care professionals to improve the care given to patients. Administrators have often used audit exercises to recommend charges in an institution. The audits may be undertaken or initiated by the managers themselves. Recently there

was much controversy over an audit on maternity services undertaken in the United Kingdom which was published in 1997. [13] An editorial in the British Journal of Obstetrics and Gynaecology bemoaned the fact that there was a yawning gap between the standard of evidence required from clinicians and that required from those managing the health services [14]. It was claimed that the audit would not have stood up to the scientific process of peer review for publication in a journal. It is thus important that clinicians be acutely aware of the study design and eliminate possible confounders and biases in an audit process. It is equally vital that administrators scrutinise the scientific validity of audit procedures before they act on recommendations from such studies.

It is ethically wrong to proclaim a perceived benefit based on a scientifically flawed methodology. As the nation progresses on an avowed mission towards developed nation status, there is a need for training in rigorous research and audit methodologies for all clinicians and the need for regular review and evaluation of local audit activities. There is a need for professional bodies to play a leading role in this effort having many resourceful personnel. The setting up of ethical review committees to review all research proposals to ensure compliance to the ethical principles is strongly recommended.

### Provision of best possible care:

All health care professionals have a responsibility to provide the best possible care, which could be interpreted to mean that not to be involved in audit is a breach of the ethical code of conduct. The powers that be should recognise and award CME credits for audit activities.

### Conclusion:

It is important that doctors use all available means to engage in clinical audit that is meaningful, scientifically sound and ethically correct. The task of translating audit findings into practice is not nearly as straightforward as has been commonly assumed but it should be a priority for all those concerned about the quality of health care. The effectiveness and efficiency of health services could be substantially improved if clinical audit activities become the norm rather than the exception. I was once asked by a colleague "Who are you to audit me?" when I suggested that an audit was in order to assess whether a certain surgical procedure was being overdone. My response would be "A doctor concerned about doing the best for his patients."

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