Ethics of Investigation

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Sir Francis Avery Jones (1977) has contrasted the high standards demanded and undertaken in the introduction of new drugs with those required for new diagnostic techniques and instruments which have developed rapidly and have become widely used long before they have been adequately assessed in main centres. The dictum 'have bought a new endoscope will travel' is all too true. Sir Francis recommended that procedures should be monitored to answer the crucial question 'whether the discomfort and the risk to the patient is commensurate with the benefit in the management of the patient's illness'. In other words, the ethical basis of each investigation needs critical evaluation.

The most important factor in determining the ethical basis for an investigation is the risk to the patient who may, because of age, intelligence, and ability to cooperate, or because of associated disease, present a poor risk. He may not be able to give adequate informed consent. Across the Atlantic, litigation has placed the unfortunate investigator in an impossible situation, for he may be sued for not having fully specified in writing all known contra-indications, complications or sequelae of a test or, if he fights shy of a procedure, deemed by his jurist opponents to have been necessary, may be sued for failing to perform it.

Risks may be inherent in the instrument, which may be obsolete, poorly maintained, or faultily sterilised, the risks of infection with Australia antigen virus being particularly hazardous.

Hazards inherent in the technique itself begin with the preparation of the patient where even simple intubation or the administration of enemata carry some risk. More serious and unpredictable are allergic reactions to contrast media, premedication drugs or anaesthetics. Hazards involved in such techniques as laparoscopy or liver biopsy include haemorrhage, perforation, or biliary leakage. Careful and expert monitoring after the procedure is also crucial, making in-patient procedures far less hazardous than those undertaken on out-patients.

The operator himself may be inexperienced in the technique or poorly supervised if under training. Even an experienced operator, through carelessness or forgetfulness, may fail to observe routine precautions.

Finally, serious hazard may lie in the erroneous interpretation of visual or pathological findings. Visual instruments may have deteriorated, poor quality X-rays may have been taken or the pathologist supplied with inadequate or unrepresentative material.

It is therefore very difficult to say where precisely in the chain of events the true hazard or risk occurs and it is even more difficult to obtain finite statistics on the true evaluations of the risk or value of a procedure. Clinicians using a test should know its true mortality and morbidity figures, which are almost impossible to obtain as they require an answer to the equation:

| Number of accidents encountered | Total number undergoing investigation |
|--------------------------------|--------------------------------------|
|                                 |                                      |

There is always a reluctance to report accidents or fatalities and also the numbers of incomplete or useless investigations produced by technical faults or lack of cooperation by the patients. The collection of such data seems much easier on a national than on a local basis as judged by the success of surveys undertaken by the British Society of Digestive Endoscopy in which it has proved possible to document all endoscopies performed in 175 centres, with the complications encountered, and also to combine the study with a survey giving the cost effectiveness of the techniques (Colin Jones et al., 1978).

Factors very hard to quantify in the value or ethics of any test are the degree of discomfort experienced by the patient in its performance. How much anxiety and pain accompany it? What discomforts accompany prolonged fasting or immobility and how unpleasant are the adverse effects produced by drugs or anaesthetics used in the test? Late sequelae may accompany the procedure, such as residual phlebitis following an injection, an aspiration pneumonitis following endoscopy or, more seriously, haemorrhage following biopsy.

The ethical justification for the vast sums spent on fibre-optic endoscopy is in the vastly improved visualisation of the organs examined with the facilities to take biopsies and to perform cannulation, and also in the marked reduction in the risks involved, which are apparent if the data in Table 1 are studied.

It will be seen that in over 100,000 rigid oesophagoscopies the risk of perforation was 0.17 per cent but could be as high as 1.9 per cent. This figure was reduced to a fifth by fibre-optic oesophago-gastroscopy, to 0.035 per cent in nearly 400,000 patients. An almost identical figure was observed in a recent survey conducted by the British Society of Digestive Endoscopy in 1975, in which the perforation rate was 0.04 per cent (one in every 2,350 examinations) (Colin Jones et al., 1978). Mortality from rigid oesophagoscope averaged 0.02 per
cent but could be as high as 0.5 per cent but was strikingly reduced in the massive series of fibre-optic examinations to an average 0.005 per cent. It is interesting that the mortality was not reduced in the British series, remaining at 0.02 per cent (one in every 4,400 examinations), a fact explained by Schiller and Prout (1976) on the basis that only the best series of rigid or semi-rigid endoscopy was reported. Vastly more endoscopies are now performed, estimated at 54,000 annually in 1975, and examinations are undertaken by more highly trained operators, often on poor-risk patients in emergency situations. Complications are recognised earlier and are more effectively treated. Thus, fibre-optic endoscopy emerges as one of the most significant and ethically sound diagnostic advances in the last decade.

Percutaneous transhepatic cholangiography (PTC) has been transformed into a safe and valuable procedure by modification of the needle used and the technique employed. It had previously been regarded as a highly dangerous one (Table 2). Okuda and his colleagues (1976), by employing a fine needle, a lateral approach, prophylactic antibiotics and an injection rather than an aspiration technique in over 1,000 examinations, reduced the overall complication rate to one-fifth, to 0.76 per cent, the mortality to nil and the serious complications of sepsis and biliary peritonitis to 0.1 per cent and 0.5 per cent respectively. PTC has therefore become a thoroughly ethical procedure and an accepted part of the investigation of obstructive jaundice.

In deciding where responsibility lies to ensure that only ethically correct, safe and worthwhile procedures are performed on patients, we have to consider the physician's, the patient's and the institution's point of view.

The physician must first ensure that the indications, content and possible sequelae of the procedure are explained to the patient and that his signed informed consent is obtained. He must ensure that the patient is correctly prepared and meticulously cared for during and after the procedure. He must guarantee that his training for the procedure is adequate, that the correct indications and contra-indications have been observed and that the procedure is performed to the best of his ability, and that the data obtained are correctly interpreted by himself at the time and by a colleague radiologist or pathologist who will have to interpret films or pathological material obtained from the patient at a later time.

While the physician is pondering whether or not to undertake a particular test, he should search his heart to be certain that the test is truly required in the diagnosis and management of the patient and not merely to allow him or his staff to become more proficient in the technique or to enlarge any investigative series he may have in hand. Obviously, junior staff must be trained and research into new techniques conducted, but such activities should take place in centres which have the number of patients, the staff and the facilities to undertake them.

What should be the responsibilities of the institution where investigations are performed? The authorities should respect and be loyal to their medical staff and provide adequate facilities to undertake the necessary investigation of patients admitted to or attending the hospital. They should allow supervised training of junior medical staff and approve research into the assessment of new diagnostic techniques. By an efficient records system they should encourage physicians to keep detailed records of all procedures performed and all complications encountered. Institutions would do well to set up medical audit committees to supervise medical investigations.

A scheme for the maintenance of medical ethics in medical investigation is put forward in Fig. 1, which is similar to one that I suggested to augment the workings of Institutional Medical Ethical Committees supervising clinical research (Watkinson, 1977). A convening local,
Consultant bodies, created by the national specialist societies and government agencies, would be responsible for collecting a data bank on current clinical procedures, instruments, diagnostic agents and radiological procedures and be available to advise smaller audit committees. Federal agencies should review the reports from local audit committees at least annually, convene informal periodic meetings of chairmen of such committees, if necessary arrange site inspections of procedural methods and if necessary withhold funds if standards are not maintained.

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