quires that a large number of procedures be carried out to allow accurate calculation of true risk of morbidity/mortality. Furthermore, anaesthetic related complications may occur in the first post-operative week, <sup>3</sup> and these are not usually noted on the anaesthetic record, nor are they always recognised. But, for the clinical anaesthetist, in-hospital audit provides the best method of self and peer monitoring.

Reports to medical protective societies are made in two situations: (1) involvement in an incident which may have potential for litigation and (2) involvement in a lawsuit. Every year the societies publish a report of "interesting cases;" in 1979, the Medical Defence Union of the United Kingdom reviewed<sup>4</sup> anaesthetic accidents during 1970–77. Of the 71 cases of cerebral damage, faulty technique was responsible for 60.6 per cent and "anaesthesiologist failure" for 4.2 per cent. This latter category was defined as "absence of the anaesthesiologist from the operating room when something went wrong with the patient," an indefensible situation.

Retrospective studies have been the major method of investigating problems with anaesthesia. However, the disadvantages are multiple: failure to record significant events at the time of occurrence, failure to store records leading to loss, a changing pattern of clinical practice, and in the case of multicentre studies which these often are, a lack of uniformity of assigned values. An example of the latter is the definition of death associated with anaesthesia. Harrison's 1978 study<sup>5</sup> defined death as "occurring during or within 24 hours of anaesthesia" and showed a frequency of 1/4537 anaesthetics whereas the Association of Anaesthetists of Great Britain and Ireland in 1982 reported<sup>2</sup> a death rate of 1/10,000 for a six-day postanaesthetic period.

Specific anaesthetic-related problems usually surface in the medical press, first in the correspondence column or as a leading article, and then, as a report of a study. An example is the National Halothane Study, which probed the problem of halothane-associated hepatitis with a retrospective study of some one million patients in 34 institutions. Only seven patients were found where the consensus was that halothane might have been responsible, an apparent incidence of 1/10,000.

Prospective studies are the best way of investigating medical problems. However, there must be a working hypothesis and, when looking for rarities, large numbers of patients need to be studied, often requiring the expenditure of large numbers of dollars. An example of this is a multicentre study of four general anaesthetics in 25,000 patients over two years at a cost of US\$1,000,000, currently being carried out in North America.

In conclusion, there are many methods of monitoring anaesthetic practice, from peer review to international enquiry. The specialty of anaesthesia has recognised that problems exist and is making attempts to quantify these and address possible solutions.<sup>3</sup>

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## Postoperative assessment of the effects of anaesthetic agents

J.R. Maltby MA MB BCHIR FRCP(C), Clinical Associate Professor, Department of Anaesthesia, Foothills Hospital at the University of Calgary, Calgary, Alberta.

In North America each year approximately 8.5 per cent of the population or 21 million patients receive general anaesthesia for surgery and 235,000 of

these patients die. What contribution the anaesthetic technique or drugs may make to mortality is not precisely known, but it may be as high as ten per cent. Mortality is at one end of the spectrum of postoperative outcomes which extends through major complications such as myocardial infarction and respiratory failure to the discomforts of muscle pains, sore throat and nausea.

Most studies of anaesthetic agents and techniques have looked at specific aspects of drug action and have provided information on cardiorespiratory effects, neuromuscular interactions, sensitisation to catecholamine-induced dysrhythmias, and toxicity and metabolism of agents. Knowledge from these studies has enabled anaesthetists to think they know what is best for each individual patient. Yet there has never been a large-scale study on the comparative safety, efficacy, side effects and complications of different anaesthetics in the clinical setting. Information is lacking as to whether or not attempts to keep physiological parameters within normal limits during anaesthesia necessarily leads to better results in the postoperative period. Nor is it known if the theoretically greater safety of one agent during anaesthesia is offset by its higher postoperative incidence of side effects and morbidity.

To determine the relative importance to postoperative outcome of such factors as type of surgery, condition of the patient and anaesthetic drugs, a large-scale prospective study is being undertaken. The International Multicentre Study of General Anaesthesia is now in progress and uses methodology developed during the clinical evaluation of isoflurane.2 The aim of the study is to determine, in 26,000 patients over the next two years, the safety and efficacy of the four commonly used supplements to nitrous oxide: enflurane, halothane, isoflurane and fentanyl. Ten university teaching centres in Canada and the United States are participating, with organisation and data collection centred at McMaster University. All centres follow the same protocol for anaesthetic agents and data collection. With the exception of pregnant women, any patient aged 18 years or older may be included, provided there is no specific contra-indication to any of the four agents. One only of the agents is used in each patient, assigned randomly to avoid anaesthetist bias.

Outcomes are divided into four categories. Type I includes death, myocardial infarction and stroke, events which are uncommon and not expected to be

related causally to the specific agent used. Type II is major complications which may be life threatening and include respiratory failure, anuria and hepatitis. Type III is a mixture of safety and efficacy factors including shivering, nausea, headache, speed of recovery and a pain score in the recovery room. Type IV represents the patient's subjective symptoms. These are determined by a questionnaire, completed both pre- and postoperatively, which includes questions concerning feelings of weakness, dizziness and ability to concentrate. Patients are followed for up to seven days postoperatively to detect delayed complications and side effects and to determine how long these last. All results will be analysed by computer and the results are expected to be available during 1986.

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## When all else fails - CMPA?

F. Norman Brown MD FRCS(C), Secretary-Treasurer, Canadian Medical Protective Association, Ottawa, Ontario.

It is not inappropriate that a seminar on Monitoring in Anaesthesia should consider the medico-legal implications. Any review of legal problems resulting from anaesthetic mishaps leads to the unequivocal conclusion that monitoring of the anaesthetised patient is indeed relevant.

Anaesthetists, like doctors in a number of specialties and more than in some, have been caught up in a disturbing trend in this country towards more and more costly lawsuits. By year end (1983), nearly 600 new malpractice lawsuits will have been