Conference Report

1986 Meeting of the International Committee for Prevention of Anesthesia Mortality and Morbidity

The International Committee on Prevention of Anesthesia Mortality and Morbidity derives from a group that first met in Boston in October, 1984, during the International Symposium on Prevention of Anesthesia Mortality and Morbidity. This meeting, held September 9, 1986 in Vienna, Austria, was the planned follow-up of those original discussions. It was organized by Jeffrey B. Cooper PhD and Richard J. Kitz MD of the Massachusetts General Hospital and Harvard Medical School and Ellison C. Pierce, Jr MD, of the Deaconess Hospital and Harvard Medical School, Boston, MA, USA. There were 62 participants representing 19 countries. Dr. Cooper opened the meeting by reviewing the objectives of this informal group and of the present meeting. He followed with an analysis of differences in anaesthesia mortality and morbidity data around the world. Reports of epidemiologic studies and patient safety activities in Canada (J. Margaret Davies MD, Foothills Hospital at the University of Calgary), France (J. M. Desmonts MD, Hôpital Bichat, Paris), United Kingdom (John L. Lunn MD, Welsh National School of Medicine, Cardiff, Wales), Netherlands (J.F. Crul MD, Katholieke Universiteit, Nijmegen) and the United States (Dr. Pierce) completed the morning session. In the afternoon, there were two discussion groups: "How to Resolve the Monitoring Controversy" (led by J.S. Gravenstein MD, University of Florida, Gainesville) and "Selection and Assessment of Anaesthetist" (led by Anthony Adams MB, PhD, Guy's Hospital, London). It was agreed to cooperate on conducting

surveys to assess the status of fatigue, of monitoring and of personality and to hold our next meeting at the World Congress of Anesthesiology on May 22, 1988. The following is a summary of these presentations and discussions.

Background

At the original ICPAMM meeting in 1984, we reviewed available data on anaesthesia mortality and morbidity and tried to estimate the rates in those countries where studies have been conducted.¹ Several schemes for classifying adverse events and their causes were proposed in an effort to promote consistency between future studies. Strategies for detecting and correcting problems were discussed. A list of attributes for a "good" anaesthetist was generated and there was intense debate about the appropriateness of various monitoring technologies. These and other discussions started a communication network among many individuals around the world who are interested in studying the basic problem of preventing deaths and serious injuries from anaesthesia. The objective of this group is primarily to share information about ongoing work and methodologies. The goal of the communication is to stimulate innovation in planning research and formulating strategies that will minimize the risk of anaesthesia.

Morning session

Are there differences in anaesthesia mortality and morbidity between countries? – J.B. Cooper

Anaesthesia practices vary considerably among the industrialized countries of the world. Do these differences result in differences in outcomes? There is a wide range of estimates of the rate of anaesthesia mortality and morbidity. It is fairly well accepted that the lack of control of

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definitions and methodologies between the various studies make it impossible to have meaningful comparisons. In this lecture, it was hypothesized that the variations in estimated mortality and morbidity rates are primarily a function of the differences in studies and that, by grouping studies according to their similarities, one finds greater similarities in those rates. Three hypotheses were proposed:

- 1 The reported rate of anaesthesia mortality is strongly correlated with the method used to collect the data. Differences in rates of anaesthesia mortality found in reported studies differ *primarily* because of differences in study methods.
- 2 The rates of anaesthesia mortality and morbidity are approximately the same in countries that have approximately the same life expectancy.
- 3 The anaesthesia community of a country reduces the rate of mortality to the level currently "acceptable" to society using techniques that fit the medical "culture" and historical traditions.

Comparisons of several studies were given. Anaesthesia is involved as a causal factor in about ten per cent of surgical deaths, with a range of 6 to 17 per cent among studies in Australia, Finland, New Zealand, South Africa, The United Kingdom, the USA and the USSR.²⁻⁸ Large, well-controlled surveys in the United Kingdom and in France estimated anaesthesia-related mortality to be on the order of 1/10,000 patients.^{7,9} Among studies of death reports mandated by law in New South Wales, Australia and in North Carolina, USA, the anaesthesia death-rate was estimated to be about 1/25,000 patients.^{2,5} A recently published report of anaesthesia complications in Canada and a similar study in the USA found that about 18 per cent of patients experienced at least one "complication" in the perioperative period.^{10,11}

Dr. Cooper noted the current estimate that anaesthesia is the sole or substantial contributor to death in about one in every 10,000 operations. But, for the relatively healthy patient having a simple, elective procedure, the risk is far less, perhaps in the order of one in 50,000 or 100,000.

It was suggested that the theme of this meeting be to examine how each anaesthesia "culture" has found ways to minimize its anaesthesia risk. We should stress more about what we can learn from each other's approaches rather than concentrating and criticizing our differences.

Anaesthesia epidemiologic studies and patient safety activities around the world

Patient Safety Activities in Canada – J.M. Davies MD

Dr. Davies described the characteristics of Canadian health care that influence anaesthesia practices. Canada suffers from geographic isolation of its people, with only

16 per cent of the population living in six major cities. The low density and wide distribution of the small population has a strong effect on the availability of anaesthetic manpower.

All anaesthetists in Canada are physicians, but the training is highly variable – for example, in one of the ten provinces, 33 per cent of anaesthetists have one year or less of training. There is no overall regulatory body for licensing or for medical care standards for the country as a whole; health care policies vary considerably among the provinces. The Royal College of Physicians and Surgeons of Canada (RCPS) determines standards for specialist anaesthetists. The Canadian Anaesthetists' Society (CAS) provides guidelines for the practice of anaesthesia. The Association of Canadian University Departments of Anaesthesia (ACUDA) is in the process of providing guidelines for quality-of-care review. The Canadian Medical Protective Association, the major malpractice carrier, is also involved in this activity. Also, in each province there is a separate committee investigating anaesthesia morbidity and mortality. But no one committee has the overall task of coordinating those activities.

Anaesthetic equipment is well-regulated in Canada with the Bureau of Medical Devices carrying out programs designed to ensure the safety of medical equipment sold in Canada. The Canadian Standard Association (CSA) established the first comprehensive, but voluntary, standard for anaesthesia equipment. Adherence to the standard is a prerequisite for accreditation of hospitals by the Canadian Hospitals Association (CHA). The Canadian Anaesthetists' Society also published standards, but these too are voluntary. Recommendations for anaesthesia monitoring are minimal, including only cardiovascular measurements and not oxygenation. Health and Welfare Canada is a federal government department that, until recently, operated a project jointly with the Canadian Medical Association for reporting of medical-device problems.

Dr. Davies noted that while the perception is that Canadian and American medical standards should be equal, differences in the financial resources of the two countries mitigate such equivalence.

Patient safety activities appear to be motivated very much by increasing malpractice premiums (a 100-fold increase in the past ten years). The major emphasis for decreasing mortality and morbidity has been placed on increasing the number of anaesthesia specialists. Currently about 100 specialists per year are entering the work force, which represents a seven to eight per cent gain versus a previous four per cent loss.

There are several ongoing data-gathering projects in Canada. The Winnipeg study reported on the distribution of complications in a population of 112,000 patients in one teaching hospital.¹⁰ The International Multi-Center

Study of General Anaesthetics (IMCS-GA) is a randomized study of major anaesthesia techniques coordinated through Dr. James Forrest, McMaster University, Hamilton, Ontario (not yet published). Also, individual projects have been described, e.g., at the University of British Columbia, a recent survey of obstetric practices identified great variation among hospitals and anaesthetists throughout the province.¹²

There have been substantial improvements in anaesthesia equipment in Canada, but faulty or sub-standard equipment remains a concern, especially in rural areas. However, Dr. Davies noted that the major cause of anaesthetic mishaps in Canada, as in other countries, continues to be related to human error, particularly to a "lack of vigilance." She suggested that two major problem areas are the selection of people for this specialty and on the "aging" of the professional population.

Patient safety activities in France – J.M. Desmonts MD

Dr. Desmonts concentrated his presentation on describing the recent study by the Institut National de la Santé et de la Recherche Médicale (INSERM).⁹ This project was conceived of in 1976 and conducted between 1978 and 1982. The prospective study under the sponsorship of INSERM was reported in the Canadian Anaesthetists' Society Journal.⁹ Private and public hospitals representative of the entire country participated. Five-hundred twenty-seven institutions were solicited and 468 accepted. The duration of the mortality and serious morbidity survey in each hospital varied according to the hospital size; in smaller hospitals the duration was longer. Only anaesthetics under the direction of a certified anaesthetist were included. A total of approximately 200,000 anaesthetics were documented. Of these, there was one death totally attributable to anaesthesia per 13,000 cases. The perioperative period within 24 hours of anaesthesia was included. When coma was included, 1/8,000 patients was affected. There were 268 "major" (life-threatening) complications. The problem most frequently identified to be associated with death was post-anaesthetic respiratory depression. There were 15 ASA physical status I patients with such an outcome; five died. All but one of these was associated with a narcotic and relaxant technique that had not been reversed with an anti-cholinesterase.

It was determined from the study that only 30 per cent of patients were admitted to a Recovery Room following anaesthesia; 50 per cent returned directly to the ward, most without monitoring. The prognosis of complications on the ward was much worse than those occurring in the Recovery Room.

Equipment failure was identified as being involved in only five serious anaesthesia-related complications; one

patient died. This translates to a rate of one major complication associated with equipment failure in every 40,000 cases (approximately 3.5 million anaesthetics are given in France annually).

Separate from the INSERM study, an equipment survey was conducted among teaching hospitals in Paris. It was found that only 28 per cent of the machines had an oxygen pressure fail-safe; 16 per cent had oxygen analyzers; 37 per cent had a low-pressure or low-volume alarm.

These studies have had a direct impact on the improvement of patient safety in France. As a result of the findings, three specific strategies have been taken to improve safety: an extensive equipment replacement program was initiated; a program to improve the organization and development of Recovery Rooms in hospitals was started; efforts at improved teaching, particularly regarding the need for reversal of relaxants was undertaken. Of course, it is difficult to assess the effectiveness of these strategies because of the relatively low incidence of serious outcomes.

During the questioning period, it was noted that the fairly common French practice of not reversing following a narcotic/relaxant technique is very rare in both the United States or the United Kingdom. But it is believed that the curare-like drugs are typically given in much higher doses in the UK. It was also suggested that, despite the remarkable difference in the use of Recovery Rooms and relaxant/reversal between France and the UK or the US, there does not appear to be a dramatic difference in anaesthesia-related mortality.

Patient safety activities in the United Kingdom –

J.L. Lunn MD

Dr. Lunn concentrated his presentation on a progress report of the "Confidential Enquiry into Perioperative Deaths." This is a cooperative study between anaesthetists and surgeons. The study is of perioperative mortality within 30 days following surgery. Dr. Lunn noted the extraordinary difficulty of getting these two disparate specialties to work together.

The study involves assessors: 80 anaesthetists and approximately 300 surgeons. Ninety-five per cent of the consultants in the participating hospitals have agreed to report into the study. Three regions in the UK, different from the five in the original study, are involved. These represent three different populations – metropolitan, industrial, and rural. All information is maintained confidential and anonymous. Maternal deaths and deaths following cardiac surgery are not included because separate systems are in place for those. Mortality following diagnostic radiologic procedures is not included.

Local reporters within participating hospitals report each patient death. The surgeon and the anaesthetist involved send a report which they fill out and return to the main office. After being rendered anonymous, the report is reviewed by an assessor for each relevant specialty. Disappointingly, only five per cent of anaesthetists and surgeons have sought a report of the assessment of the death in which they were involved. NOTE: The complete study has recently been published¹³ and summarized elsewhere.^{14,15}

Patient safety activities in Holland – J.F. Crul MD

Following several dramatic, published anaesthesia accidents, a subcommittee of the Dutch Health Council was formed in 1974 to examine anaesthesia practices and outcomes. Under the chairmanship of Dr. Crul, the Committee included 30 individuals most of whom were anaesthetists, but with many other specialties represented. The first report was approved in 1978 and dealt primarily with equipment. Standards for anaesthesia machines, ventilators, and gas pipelines were recommended. Requirements for operating rooms, recovery rooms, and outpatient care were recommended. In addition, a standard of minimal patient monitoring was suggested. This monitoring standard has been adopted. It is based upon the required *availability* of certain monitoring devices. The decision regarding the *use* of each device is not mandated, but is left to the discretion of the anaesthetist. Dr. Crul reports that, to the best of his knowledge, in any legal action where a monitoring device has not been used, the anaesthetist's explanation for why it was not used has been accepted. Several firms have manufactured anaesthesia machines that include monitoring instrumentation to meet the standard.

A second report was issued by the committee addressing the manpower problem. Dr. Crul believes that the unavailability of the anaesthetist remains the major underlying cause of anaesthesia accidents today. But the acceptance of a standard of one anaesthetist per patient is not yet realized. Presently, the practice is to have one anaesthetist per two locations, supervising a certified anaesthesia nurse or technician.

There have been no formal studies of anaesthesia outcomes in Holland; but a national survey of anaesthetists solicited self-reports of accidents that may have resulted in anaesthesia-related deaths within 48 hours of operation. From those data, an estimate of 1 death/13,000 cases has been made. This was consistent with an estimate taken from court records in which 100 deaths were found, representing 1.2 million anaesthetics per year, for a rate of 1/12,000 cases.

During the discussion period, the question about the

source of funding for monitoring was again asked. Dr. Crul explained that hospitals individually requested funds, and, in the case of his hospital, a special allocation was made from the Ministry of Health. His committee report required compliance with the standards within three years.

Patient safety activities in the United States –

E.C. Pierce, Jr MD

Interest in anaesthesia patient safety has markedly increased in the past two years in the United States. Dr. Pierce first reviewed some practices in the U.S. and then described examples of the patient-safety activities.

There are approximately 30,000 anaesthetizing locations, 20,000 certified-registered nurse anaesthetists (CRNA's), 15,000 anaesthetists and approximately another 3400 trainee physician and other assorted specialists who may administer anaesthesia. The distribution of these providers varies considerably geographically, with some areas having one anaesthetist per anaesthetizing location while others have between one to two and one to four.

In contrast to Holland, CRNA's in the U.S. do administer drugs and have some decision-making responsibilities. Again, this varies considerably among localities. In less than 10 per cent of all cases, CRNA's are supervised only by the surgeon with an anaesthetist being unavailable. There is a clear trend of more US medical students entering anaesthesia training and a decline of the number of nurse-anaesthetist training programs. Almost 100 per cent of all patients in the U.S. are admitted to a Recovery Room following an operation.

Over the years, there have been several studies that have attempted to look at anaesthesia mortality in the U.S. The most recent was a study of cardiac arrest at one university-teaching hospital.¹⁶ Dr. Pierce noted his own impression from these studies that at least 70 per cent of anaesthetic accidents are preventable. The American Society of Anesthesiologists (ASA) has prepared a series of video-tape programs on patient safety topics. The topics include: overview of the problem, disconnection, anaesthesia record-keeping, machine check-out, human error, what to do after an adverse event, patient monitoring, anaesthesia equipment maintenance. The ASA has offered these tapes to all the component societies of the World Federation of Societies of Anesthesiologists free of charge.

Two task forces have been organized; one to coordinate a study to measure the incidence of anaesthesia mortality and morbidity, and the other to examine safety in the Recovery Room. A patient-safety exhibit has been established at the Annual Meeting and distributes many patient-safety materials.

Via its committee on professional liability, the ASA is sponsoring a program to analyze closed anaesthesia-malpractice claims. So far, about 400 cases have been analyzed. (Update: the study now includes more than 1000 cases; a report is being prepared.)

Manuals on Peer Review and on Quality Assurance have been completed and distributed. A subcommittee on standards of anaesthesia care has been organized. That committee has come forth with its first set of recommendations — a set of requirements for minimum monitoring during anesthesia, derived from standards promulgated at Harvard Medical School.¹⁷ Dr. Pierce noted how this activity has captured the attention of the national American press. This has had a very positive impact on the image of anaesthesia in the United States. (Update: the ASA standards were officially adopted at the 1986 Annual Meeting.)

The U.S. Food and Drug Administration Bureau of Devices and Radiologic Health has sponsored the development of a set of guidelines for pre-use inspection of anaesthesia apparatus, which were distributed via the Anesthesia Patient Safety Foundation Newsletter and the Newsletter of the American Society of Anesthesiologists. The FDA considers anaesthesia devices and instrumentation to be one of its highest priorities.

In October, 1985, the private Anesthesia Patient Safety Foundation was founded. Its mission is "to assure that no patient shall be harmed from the effects of anesthesia." Its specific purposes are to foster investigation that will provide a better understanding of preventable anaesthetic accidents, to encourage programs that will reduce the number of anaesthetic injuries, and to promote national and international communication of information and ideas about the causes and prevention of anaesthetic injuries. Research awards have been granted and a patient-safety newsletter has been established.

Many U.S. insurance companies are taking an active role in promoting anaesthesia safety. The Harvard Hospitals Insurance Company (CRICO) has established a risk-management newsletter that has frequently highlighted anaesthesia topics.

The Emergency Care Research Institute (ECRI), a private, non-profit company dedicated to medical equipment has taken a very active interest in promoting anaesthesia safety. They recently published a monograph analyzing the causes of anaesthesia deaths¹⁸ and have often featured anaesthesia equipment in their evaluations published in *Health Devices*.

Dr. Howard Zauder, president-elect of the American Society of Anesthesiologists, briefly emphasized the ASA interest in patient safety activities. It presently donates \$100,000 annually to the Anesthesia Patient Safety Foundation and has dramatically increased its

internal budget for its own Patient Safety and Risk Management committee. He noted the strongest support and backing for the conduct of a national anaesthesia mortality and morbidity study.

Dr. Zauder noted the history of the creation of the close cooperative efforts between the ASA and the U.S. government FDA. The FDA, several years ago, sponsored a study of accidental breathing-systems disconnections. The ASA provided a forum for presentation of that work at its annual meeting. In a manner similar to that described by Dr. Crul in Holland, some dramatic anaesthesia accidents caught the attention of the public and the U.S. Congress. The communication that had been established with the FDA led to a cooperative arrangement towards patient-safety activities in anaesthesia. The FDA's support in production of the patient-safety video series was absolutely vital. Dr. Zauder reflects that all of this focus on patient safety had a more positive effect on the image of anaesthesia than any event since "ether was first dropped."

Discussion of morning presentations

There was debate about the influence of the American legal system on the increased interest in patient safety. Dr. Cooper felt that, despite the problems created, the legal system has had a positive influence. Dr. Ronald Katz (University of California Medical Center, Los Angeles), strongly disagreed, arguing that there has not been much of a change in the number of cases or payout and that patient safety is just something whose time has come. Dr. Lunn felt that the system in the U.K., whereby the employers pay directly for malpractice damages, has led them to take a much keener interest in providing resources toward improved patient safety.

Dr. Leslie Rendell-Baker (Loma Linda University School of Medicine, Loma Linda, California) described the American standards' body activities in improving the labeling on drug containers as another example of an important safety-related activity for anaesthesia in the U.S.

Dr. Patricia Mackay (Royal Melbourne Hospital, Victoria) commented on the patient safety-related activities in Australia. Two states presently have mortality study committees. In New South Wales reporting is mandatory. In Victoria it is voluntary. Safety and teaching guidelines are promulgated by state faculty committees. The Australian Council for Hospital Standards approves hospitals and has a strong influence on upgrading standards of care, particularly in remote areas.

Dr. Mackay voiced her concern over an increasing trend toward the administration of anaesthesia outside of operating rooms, particularly for diagnostic radiology. Dr. Pierce noted that a standard of practice has recently

been promulgated by the Harvard Anesthesia Risk Management Group specifically addressed to the problem of making appropriate facilities available for anaesthesia in such areas.

Dr. Chris Borton (Westmead Hospital, New South Wales, Australia), remarked that the great success of the New South Wales Mortality Committee can be attributed to the confidentiality of reports guaranteed by law. It is his personal experience that reports to the committee are strikingly honest and often-times too self-accusatory.

Dr. Ronald Green reported that there is an alarming increase in the amount of claims paid for anaesthesia malpractice in the U.K. Dr. Pierce said that there appears to be a drop in the outlay for anaesthesia claims relative to other specialties in the U.S. His belief is that this is largely due to the increasing attention paid to patient safety in the operating room.

Afternoon session

How to resolve the monitoring controversy?

Dr. E.S. Siker and Dr. Keith Sykes presented opposing views about the advantages and disadvantages of the increasing presence of monitoring instrumentation in anaesthesia. Dr. Siker took the position that the availability of new technologies for monitoring by itself so clearly would prevent many accidents that we are obliged to adopt many of them. He noted, in particular, the recent strong demand for the availability of pulse oximetry throughout the U.S. Dr. Sykes argued for a stronger emphasis on the primacy of adequate training of new anaesthetists. He went on to describe the numerous ways in which common monitoring modalities can fail to perform their intended function under some circumstances, e.g., oxygen analyzers are not easily made effective in Mapleson D type systems, airway-pressure alarms can be fooled by back pressure in the presence of a disconnection, there are many ways in which end-tidal CO₂ sampling can provide incorrect information.

There ensued some debate about the advantages and disadvantages of more monitoring technologies. Dr. Cooper described preliminary results from a study that they have been conducting in which, upon admission of a patient to the Recovery Room, anaesthetists document "complications" which occurred in the Operating Room. This documentation has been used to examine the impact of the introduction of pulse oximetry into all anaesthetizing locations. While problems with the methodology of this study make conclusive interpretation difficult, there is a strong suggestion that this particular monitoring modality has reduced the rate of hypotensive events. Dr. Cooper suggested that it is only by replication of such

studies that the monitoring controversy can be better clarified (NOTE: this study has since been published).¹¹

There was much discussion about the relationship between fatigue and adverse outcomes with sentiment expressed for recommendations for a cap on continuous working hours. A suggestion was made to conduct a survey of attitudes on this issue (NOTE: a pilot survey has since been conducted and a larger survey is now being organized).

Selection of anaesthetist – A.P. Adams MD

Dr. Adams reviewed the criteria list that had been generated at the Boston meeting in 1984. He reasoned that more importance should be placed on identifying the "wrong" people for anaesthesia training rather than energy directed toward finding the "ideal" candidates. There was discussion about the rejection rate of residents from training programs and about their ultimate professional disposition. Dr. Katz reported that over the past 13 years, an average of two trainees per year have been dropped from his teaching program: a rate of ten per cent. Yet, in every case, the individual was able to find another anaesthesia position. Dr. Siker expressed the feeling that chairmen of departments are "deluding" themselves about their interview skills for the most part.

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