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### *The Closed Claims Study*

THERE is a great need to define serious morbidity and mortality attributable to anesthesia, including their incidences and etiologies. Only with this knowledge continually reassessed can improvement in quality of anesthesia care be measured. To acquire this information, studies of great variety have been undertaken over the past 40 yr, all different in important design characteristics and all similar only in their good intentions. Studies were prospective or retrospective, voluntary or compulsory, selective or all inclusive. All were without uniform definition of the events recorded, without a consistent perioperative time frame for events, and without agreement on any system for classification. What evolved from this melange of data is a vague approximation of the incidence of certain outcomes of anesthesia described variously as accidents, mishaps, catastrophic outcomes, errors, misadventures, or simply mortality. At best these data provide a loose estimate of one subset of all adverse anesthesia outcomes, best described globally as the role of anesthesia in surgical morbidity and mortality. When this role is finally delineated, the first realistic estimate of the risks of anesthesia will be possible.

To this same end a new type of study appeared during this last decade as an outgrowth of the changed attitude of malpractice insurers regarding the confidentiality of their claim files. Traditionally these were regarded as business secrets that if known might reflect on the financial condition of the insurer. In response to the malpractice insurance crisis of the mid-1970s the National Association of Insurance Commissioners initiated collection of selected data of closed medical malpractice claims of large insurers

and made these abstracted data available to medical organizations. Those relating to the administration of anesthetics were summarized by Brunner.<sup>1</sup> Subsequently both Davis<sup>2</sup> and Solazzi and Ward<sup>3</sup> were successful in gaining direct access to some anesthesia claim files, permitting for the first time physician review and summary reports of the type of information available from this source. Based on demonstrated feasibility, the ASA Committee on Professional Liability in 1985 initiated a national study of closed claims by soliciting participation of a larger number of insurers. Under the vigorous leadership of Dr. Fred W. Cheney, some national and intrastate insurance carriers volunteered for this external review, believing that physician education in risk management based on these data might be more profitable than any risks of disclosure.

Where do these closed claims data fit into the melange of morbidity and mortality studies accumulated so far? Some powerful advantages of this type of study are obvious. First, closed claims provide a ready collection of anesthesia "events" whose unanticipated nature and severity led to claims of malpractice. No need to search tens of thousands of anesthetic records for adverse events. Here they are precollected for analysis—some catastrophic, some accidents, some errors, some not sure what they are. Second, by definition all are closed claims, meaning they have already been litigated and settled. There is no longer any threat to physicians or hospitals that disclosure might lead to litigation. Third, closed claim files are not only anesthesia "events" but a record of the process of malpractice claim settlement or litigation including their dollar outcomes. They provide a unique opportunity to study the system that provides justice in this peculiar arena.

But there are also powerful disadvantages. With scrupulous honesty, most of these have been pointed out in publications of the Closed Claims Study. The greatest disadvantage is that these data can never lead to an incidence

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of anything because the population of anesthetics from which these events were drawn is unknown. Nor can the study show whether claims are increasing or decreasing because not all insurers participate. In addition the sample of collected events is biased in several ways. Not all anesthesia-related adverse events are the basis of a claim; in fact, not all claims of anesthesia-related adverse events are related to anesthesia. Anesthesia-related events may lead to claims against hospitals or surgeons only. Most claims included in the sample have been litigated because they are best documented. Poorly documented claims were omitted. Adverse events without apparent cause, possibly of greatest interest in discovering new mechanisms, may not even be the basis of a claim because negligence was not apparent. Of further disadvantage is the time lag, which may be as much as 10 yr between an event and closing of a claim. The relationship of these past events to current practice can be a nagging limitation. Finally, the Closed Claims Study is another form of retrospective with all the limitations of this type of study. Critical information may be missing from the hospital or anesthesia record, notes may be illegible, and tests that could have clarified a sequence of events may not have been done or not recorded. The additional data available in the closed claim files in the form of narrative descriptions from the participants, depositions, expert reviews, and testimony can be helpful or confounding, considering the defensive biases and quality of memory that appear once a claim has been made.

On the other hand, the Closed Claims Study has partially remedied a serious weakness common to all previous studies of anesthesia mortality, that of data storage for retrieval and subsequent review. In this study one reviewer abstracts one or more selected claim files at the offices of the insurer. In addition to providing a brief summary of the sequence of events, details of the patient, the anesthetic, and the injury are entered into a form listing almost 150 items designed for computer storage. Many items list data with little room for equivocation such as age, sex, drugs, and monitors used. Other items, however, require judgements by the reviewer as to cause of the mishap, classification by diagnostic category, appropriateness of anesthetic care, whether human error was involved and preventability by better monitoring or pre- and postoperative care. In this manner a computerized database of almost 2,000 closed claims has been established. In itself this is a remarkable achievement because no one who published large-scale anesthesia mortality data in the remote or recent past ever recorded the events they considered mortalities as one would in a summary case report. Those events remain mythical, recorded only in terms of the final judgements made by the authors and reflecting the biases that existed at the time of review.

Descriptions of these past events are unavailable for reexamination, which may be warranted because of new knowledge of diseases or mechanisms of injury or new anesthesia practices. The Closed Claims Study has for the first time created a database of adverse outcomes available for reexamination, limited only by the information selected for storage. Thus one can now readily review 227 instances of nerve injury following anesthesia to test the hypothesis that injury was related to the administration of nitrous oxide. By contrast, a test of the hypothesis that nerve injury was related to a preoperative antibiotic requires a return to the original claim files, provided they remain available. Despite this limitation, the Closed Claims Study filled a long-recognized need for a repository of documented adverse events available for retrieval and examination.

The Closed Claims Study, however, is not free of the other major weakness of all past anesthesia mortality studies which published judgements rather than descriptions of events and supported the validity of judgements by consensus of a committee. Considering the error-blame bias that pervades anesthesia mortality studies,<sup>4</sup> the quality of the judgements entered into the database is of concern. Recognizing this limitation, one of their early studies was an examination of interrater reliability in judgements of appropriateness of care, human error, and preventability by monitors.<sup>5</sup> Considering the pervasive error bias, high interrater reliability should have been expected. And indeed the investigation found interrater reliability was statistically significant on all three issues, even though "approximately one fourth of the participants disagreed with their peers on each issue."<sup>5</sup> Chinks began to appear in the comfort level effected by the statistically significant reliability when equally statistically significant differences appeared in judgements as to appropriateness of care depending on severity of outcome.<sup>6</sup> When brain damage, for example, followed an incident, the reviewer was more likely to find inappropriate care, than if, for example, peripheral nerve injury was the outcome. Further, judgements as to cause of the injury no longer seem so secure. Claims with a sequence of events which only 2 yr ago would have been categorized as inadequate ventilation now appear in the same sequence but with an oximeter in place and no desaturation preceding the event.\* Clearly the initial event was cardiovascular, not inadequate ventilation. Further studies by these investigators on the quality of judgements are continuing and may be the greatest ultimate reward of the Closed Claims Study. Considering the implications of judgements in peer review, expert witness testimony, legal standard of care is-

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\* Cheney FW: Personal communication.

sues, and establishment of practice standards, a critical study of the quality of judgements could hardly be more timely.

The Closed Claims Study describes itself as "a structured evaluation of anesthetic mishaps . . . to identify causes of anesthesia related injury and the contribution of substandard care to those injuries."<sup>7</sup> Their analysis of mishaps collected to date was sufficiently rigorous to justify six peer-reviewed publications in quality journals, their latest on nerve injuries appearing in this issue.<sup>8</sup> The rewards of this study seem best when their data describe patterns of anesthetic mishaps as they did with the pathogenesis of circulatory collapse during spinal anesthesia and the inadequate resuscitation that followed,<sup>9</sup> the unreliable physical signs of esophageal intubation,<sup>10</sup> and the need to reexamine the pathogenesis of nerve injury after anesthesia.<sup>8</sup> The rewards seem least when their data summarize judgements of uncertain quality on preventability of mishaps by additional monitoring.<sup>11</sup> The Closed Claims Study was provided a remarkable opportunity to analyze a large collection of anesthesia mishaps, otherwise attainable only by laborious, expensive, time-consuming surveys that are not themselves free of many of the same limitations as the study of closed claims. The other essential ingredient was a group of interested energetic and critical investigators fully aware of the biases and limitations who analyzed the data with integrity. The Closed Claims Study is an exciting supplement to other efforts to describe the role of anesthesia in surgical morbidity and mortality. In addition they can explore the untouched areas of quality of judgements and consensus, quality of expert testimony, processes of claims management and settlement, and the economic consequences. The potential of the Closed Claims Study is just now becoming apparent.

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