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On Attributing Critical Incidents to Factors in the Environment

To the Editor:—Dr. Eichhorn's interesting investigation[1] should not be used to draw conclusions regarding the effect monitoring standards on anesthesia safety. Despite the lack of statistical significance in the study as a whole, Dr. Eichhorn argues that additional monitoring devices could have provided early indications of what were to become disasters. Drawing conclusions in this fashion constitutes hindsight bias and weak counterfactual reasoning.[2] This particular type of retrospective analysis can support virtually limitless numbers of interpretations regarding hypothetical interventions. Accidents are rarely caused by single factors; rather they represent the confluence of multiple events, alone insufficient but in combination leading to disaster.[3] The highly connected and interdependent nature of operating room systems largely invalidates independent elemental analyses.[4]

It is possible, however, to draw conclusions about the genesis of those critical incidents that lead to both near misses and bad outcomes.[5,6] Formal methods for investigating critical incidents are available and have been used successfully in other domains as well as in anesthesiology.[7] These methods reconstruct the unfolding incident including available cues, those cues actually noted by participants, and participant's interpretation in the immediate, larger institutional, and professional context. To use incident analysis to understand the actual effect of monitoring devices, experimental designs should include critical incidents from comparable monitored and unmonitored situations.[8]

The kinds of records available to Eichhorn are insufficient for such detailed analysis. Capturing these sorts of data requires early, in-depth investigation of multiple sources of information. This is only possible in a positive environment, one where it is clear from the outset that data will be used to understand the practice of anesthesia itself rather than the role of any single practitioner and where the first goal is understanding rather than assignment of blame. Methodologically sound analysis of cases offers the best prospect for insight into anesthesia accidents. The challenge of anesthesia safety in 1989 is to devise practical methods of uncensored and detailed investigation of incidents *as they occur.*

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Did Monitoring Standards Influence Outcome?

To the Editor:—Eichhorn[1] presented important data on the incidence of intraoperative anesthesia-related patient injuries. Collection and publication of these data is welcome, worthwhile, and has important implications for patient care, but we have several questions regarding his analysis and conclusions. Although the Harvard monitoring standards[2] were adopted in July 1985, many (most) physicians in the nine component hospitals of the Harvard Department of Anaesthesia undoubtedly had been using these standards routinely long before mandatory use was decided upon. Therefore the division of patients into two cohorts, namely one cared for "without" standards and a cohort cared for "with" standards may not, in fact, be valid. Other epidemiologic studies have discussed the difficulty in precisely defining the starting point or "zero time" when a new treatment is introduced.[3] The phenomenon of "zero-time shift," also called "lead-time bias,"[3] may have influenced the results of Dr. Eichhorn's study.

Next, although Dr. Eichhorn indicated that the data were not statistically significant, he implied that such significance was achievable with a relatively small number of additional "post-standards" cases. Using his database, we were interested in determining the actual sample size that would be necessary to achieve statistical significance at a 0.05

level. We therefore performed a power analysis.[4] * Using Eichhorn's patient injury incidence of 1/75,700 for cases done before adoption of the Harvard monitoring standards, and his patient injury incidence of 1/244,000 for cases done following adoption of the standards, we found that 5,707,181 cases before plus 1,839,424 cases following implementation of standards would have had to be reviewed to achieve a statistical power of 0.80 (probability of detecting a statistically significant difference between two groups) to detect a $P < 0.05$ difference in the rates Eichhorn observed. Eichhorn would have needed a total of 7,546,605 cases; 6,545,605 more than actually reported for these ratios to have a reasonable chance (0.80) of achieving a statistically significant difference ($P < .05$). Seventy-five intraoperative patient injuries before and eight injuries following adoption of standards would have had to occur in this expanded population. On the other hand, if the "pre-standards" cohort is assumed to be fixed, it would take 3,361,080 "post-standards" cases with 14 intraoperative accidents to achieve statistical significance at the "post-standards" occurrence rate Eichhorn reported. Assuming the current Harvard caseload is maintained and records of injuries archived, an appropriate sample size would not be available until approximately 2030! The above assumes no changes in medical practice, no new drugs, no new monitors etc., during all this time. The differences in rates reported by Eichhorn are not statistically significant, and achievement of significance is not "just around the corner."

Finally, many studies are published where n = 10 or 20, and where the authors try to say ". . . the differences did not achieve statistical significance," implying that just a few more experiments are needed. Here, with a database of 1,001,000, Eichhorn's results are not significant. The reported differences in incidence could have occurred by chance alone. Perhaps the Eichhorn study is valid as it really stands, namely that the standards did not influence the incidence of poor outcome. We wonder why the insurance companies, with their vaunted actuarial skill, jumped to reduce rates based on these numbers. We speculate that they did so because of a real (*i.e.*, significant) trend toward a declining incidence, not with any clear-cut step down just at the time of imposition of the mandatory standards. We also speculate that pulse oximetry/capnometry had an equal if not greater role than the standards.

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In Reply:—I urge both sets of commenters not to focus on the standards, pieces of equipment, or statistics. All these are merely vehicles. Rather, the emphasis should be on the behaviors that constitute safety monitoring, which will, by definition, provide the earliest possible warning of untoward intraoperative anesthetic developments.

Contrary to the assertion of Drs. Cook, Woods, and McDonald, safety monitoring does not consider single independent elements. Regardless of the precipitating events, the final common pathway to all intraoperative anesthetic catastrophes involves derangement of ventilation, oxygenation, and/or circulation. Safety monitoring targets exactly this "highly connected and interdependent" path in order to provoke early remedial intervention.

"Hindsight bias and weak counterfactual reasoning," of course, are not desirable. However, these seem unnecessarily harsh charges when: 1) there is agreement that the large majority of major accidents involve unrecognized hypoventilation; and 2) guaranteed continuous monitoring will identify ventilation mishaps as soon as they occur and before the patient exhibits the changes in vital signs that previously were the first signal of a problem. Likewise, matched-control studies of incidents with monitored and unmonitored patients would be beneficial, but the "no monitoring" control group is now legally and ethically impossible. Critical incidents detected by monitoring are being sought for study (reports welcome); but would a summary of these be subject to the same charge of bias? Further, it would be interesting to have mobile "crash teams" (analogous to the FAA teams that rush to the scene of an airliner crash to investigate) available to immediately visit the site of an anesthesia catastrophe and do an in-depth reconstruction of the event. Medical legal issues must be considered, but interest from potential sponsors and participants is welcome. Finally, Dr. McDonald's department has an interest in computerized anesthesia records that automatically capture monitoring data. When free of artifacts, these records, of course, would be a major asset in analysis of intraoperative catastrophies.

Drs. From, Pearson, and Tinker are concerned about the statistics. It might have been better to present the data in textual form rather than a table because they are closer to epidemiologic observations than the more traditional physiologic data with which Dr. Tinker and his colleagues are so familiar. I never implied statistical significance was