

American Academy of Neurology (AAN) Legislative Position on Patient Safety-Key Considerations

Patient safety is an important public health issue and systems should be developed to mitigate error-related injuries and death -- as they were decades ago in other industries for which safety is of paramount importance, such as aviation and nuclear power. The Institute of Medicine (IOM) has recommended that an infrastructure for patient safety be developed, including a Center for Patient Safety Recommendations, in line with the position of the (AAN). The AAN is committed to establishing quality standards for patient care and has subcommittees including a Quality Standards Subcommittee, Therapeutics and Technology Assessment Subcommittee, Implementation and Outcomes Subcommittee, and a recently formed Patient Safety Work Group. We recommend:

Support Patient Safety Research

The AAN favors support of research on patient safety as a precursor and aid to relevant legislation and administrative rulings. Mitigating safety errors in medicine depends on knowing the type, frequency and severity of the errors that occur, as well as what actions lead to successful outcomes and in what particular set of circumstances. Error-reporting systems and a taxonomy or lexicon of errors are thus necessary. A multidisciplinary analysis of error reports can identify the cognitive or organizational stresses that contributed to the error and suggest mitigation strategies to relieve these stresses.

Adopt a Systems-Based Approach

Often the system is unsafe, not the practitioner or equipment. For this reason a systems-based approach is needed to assess the precursors of error and identify effective mitigation strategies. Healthcare errors will increase as business models and new administrative constraints are applied to healthcare institutions to reduce the redundancy that often characterizes highly reliable systems. More mistakes are inevitable when there are fewer and fewer nurses and physicians at the bedside, and reasonable practitioners are forced to act or "test the waters" at the boundaries of safety. This discrepancy is further compounded by inadequate systems for reporting and classifying errors in healthcare. Reliable and accurate healthcare error databases generally do not exist, due in part to culture, fear of reprisal and litigation, and ambiguity on what comprises an error.

Improve Reporting and Classification of Errors

Systems for reporting and classifying errors in healthcare are currently inadequate. Most errors in medical practice are reported at local levels, as with incident reports of nursing or medication error at hospitals, or in "Morbidity and Mortality" rounds, in which healthcare personnel (especially physicians) discuss complications of patient care, and how to improve related procedures and

practice. These reports are not systematically examined and the analysis is not disseminated broadly. Any lessons learned from the local analysis of errors are confined to a few people and are often forgotten by the larger organization.

Adopt Voluntary Reporting Standards

The AAN favors voluntary reporting of errors. An intrusive mandatory surveillance system runs against the cultural and ethical norms of many Americans.

Mandatory reporting systems often do not lead to mandatory reporting. No clear definitions of what comprises a reportable error exist. No reliable or fair means of dealing with non-reporters has been devised. Thus, contrary to traditional view of epidemiology and teaching on quality control, mandatory reporting may not generate objective "measurements" to track.

Voluntary report systems such as the Aviation Safety Reporting System (ASRS) depend on attempts to understand data from a smattering of reports. Close analysis of the details of these reports can remove some or all reporter bias. The ASRS is funded by the FAA and operated by NASA who contracted with Battelle in 1976 to do the day-to-day operations. Because the ASRS is operated by an independent agency, it has no licensing or legislative power. ASRS has no authority to direct that action be taken in potentially hazardous situations, but alerts those (FAA personnel) responsible for correcting the conditions. The ASRS acts both directly and indirectly to inform pilots, flight crews, air traffic controllers, airport managers, and others about potentially unsafe practices. In certain situations (such as 'altitude busts') there is an incentive for pilots to report unsafe practices to avoid penalty. Individuals who report incidents are granted confidentiality and immunity. Reports submitted to ASRS include the reporter's name, address, and phone number on a tear-off strip to be used for follow-up. When included in the database, the identifying information is removed.

Offer Transactional Immunity for Reporters

The AAN favors transactional immunity in healthcare safety reports as in aviation models. In aviation, "reporters are granted use immunity under FAR [Federal Aviation Rule] 91.25 which prohibits the FAA from using reports submitted under ASRS, or information derived from these reports, in any enforcement actions against reporters, provided that criminal offenses and accidents are not involved. The FAA's Advisory Circular 00-46 also provides for limited disciplinary immunity for pilots in conjunction with errors resulting from actions or lack of actions, if the following criteria are met:

- actions or lack of actions were 'inadvertent' violations;
- error or violation did not involve a criminal offense, accident, or action under Section 609 of the Federal Aviation Act which discloses a lack of qualification or competency;
- person has not been found in prior FAA enforcement action to have committed a violation in the five years preceding the date of the event reported; and

- airman submits a written report of the occurrence to ASRS within 10 days after the violation."

"Transactional immunity is a powerful incentive for reporting an unintentional violation of FAA rules because it 'inoculates' the reporting person against adverse certificate action or civil penalties. Once an individual has taken advantage of the immunity provision, the individual may not do so again for five years." (In: *A Review of the Aviation Safety Reporting System-August 1994*, a report by a Study Team of the National Academy of Public Administration for the FAA.)

Create Safe Harbors

A significant obstacle to obtaining accurate data on healthcare errors, even within a voluntary reporting structure, is the current lack of safe harbors. Voluntary reporting may be preferable to mandatory reporting, but could still produce discoverable evidence that could fuel litigation without elucidating the fundamental causes of medical errors. Persons who are aware of data on medical errors may not be reporting the data for fear of retribution to themselves or colleagues in terms of professional sanctions, civil or criminal liability, or economic loss. Physicians are reluctant to share data that has traditionally been managed in an adversarial manner. A culture change is required so that reporting is voluntary, viewed as supportive and part of a process of quality improvement.

Along these lines, the NASA ASRS model is being adopted by the Veteran's Administration (VA) Healthcare system. The VA is able to implement such a system with relative ease because of unique legal protections for VA Quality Assurance activities. The VA model uses reports that are voluntary and confidential to begin with and, in later stages, have been de-identified. The analyst can call the reporter back for further information and a better understanding of the mechanisms underlying an unsafe occurrence. The courts so far appear to have ruled that the de-identified database is "hearsay" and inadmissible, though it may be possible to identify some reports in the database for use in adversarial proceedings. Such "countermeasures" have been proposed as throwing out a random fraction of reports (so there is no guarantee that any actual event is present in the database even if it was reported), or inserting a proportion of "made up" cases.

In an Enterprise Liability model, a large healthcare entity such as an HMO would handle malpractice insurance and claims. This system might work because large enterprises can absorb statistical risks that a single practitioner cannot. Salaried employees would generally not be personally liable, except for the loophole of the National Practitioner Data Bank. The Enterprise would collect error reports from its employees with the understanding that some reports might aid a plaintiff's attorney, but most reports would help enhance the quality of patient care. Considered from a broad perspective, the report is likely to be only a neutral factor in a system unlikely to litigate a majority of the cases.