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The milestones in patient safety

The Harvard Medical Practice Study I, Study II and Study III

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Over the past decade there has been a steady increase in the number of malpractice claims brought against healthcare providers [1,2] and in the monetary damages awarded to plaintiffs [1,3]. This increase has precipitated numerous state programs designed to moderate the number of claims and encourage providers to develop quality of care initiatives [4,5].

It is important to develop more reliable estimates of the incidence of adverse events and negligence in hospitalized patients. An adverse event is defined as an injury caused by medical management (rather than the underlying disease) that prolongs the hospitalization and results in disability at the time of discharge, or both. Negligence is defined as care that has fallen below the standard expected of physicians in their community.

The Harvard Medical Practice Study (HMPS) was first published in 1991 and was based on 1984 case records of more than 30,000 randomly selected records from 51 randomly selected acute care, non-psychiatric hospitals. The study attempts to measure the extent of medical malpractice in hospitals in the state of New York, and compare the resulting patterns with the negligence claims actually filed [6-8].

The HMPS reviews randomly selected records with disability injuries caused by medical treatment. To establish that an adverse event or negligence has occurred, it uses as a criterion an average confidence score of four or more (on a six point scale). Data identified are age, sex, and primary discharge diagnosis.

The significance of the differences in rates of adverse events and negligence according to sex and age were tested.

The state-wide incidence rate of adverse events was 3.7% (95% confidence interval 3.2 to 4.2). The percentage of adverse events due to negligence was 27.6% (95% confidence interval 22.5 to 32.6) [6,7].

Negligence was more frequent in patients who had more severe adverse events. Of the adverse events that led to temporary disability lasting less than 1 month, 22.2 (2.8%) were caused by negligence. On the other hand, of those that caused permanent total disability, 34.4 (8.1%) were caused by negligence. In addition, 51.3 (6.9%) of the deaths from adverse events were caused by negligence. These differences in the percentage of negligence according to category were significant [7].

It is interesting to note that the incidence of adverse events increased with age.

There was not, after standardizing for age and DRG risk category, significant gender differences in rates of adverse events or in the percentage of adverse events due to negligence.

Nearly 48% of the adverse events were from surgical complications, but only 17% of these were judged to be secondary to negligence [8]. Rates of adverse events and negligence varied widely among specialties [7].

At least one of the two physician reviewers identified management errors in 58% of all the adverse events, but only 28% of the events ultimately met study criteria for negligence [7]. "Errors of omission" were the highest percentage of medical error.

It's possible to observe that University teaching hospitals had an adverse event rate of 4.1%, nearly double that of non teaching hospitals (2.3%). However, only 10.7% of the adverse events at university hospitals were ascribed to negligence, versus 26.9% in the non-teaching hospitals [8].

The HMPS estimates that the state-wide ratio of adverse events caused by negligence (27179) to malpractice claims (3570) is 7.6 to 1 [8].

The principal conclusions are: malpractice was frequent in the hospitals studied; a high toll of avoidable medical injury nationwide can be inferred from this frequency rate; and relatively few of the injured patients actually sued. From this it is deduced that the "real problem" is not that there is too much malpractice litigation but that there is too little, and that the admittedly high rate of meritless suits against physicians is preferable to reform of the tort system [7].

It is likely that the findings indicate that there are certain risk factors, many definable, for the occurrence of adverse events and negligence.



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Although the prevention of many adverse events must await improvements in medical knowledge, the high proportion that are due to management errors suggest that many others are potentially preventable now. Reducing the incidence of these events will require identifying their causes and developing methods to prevent error or reduce its effects.

References

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