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An alternative strategy for studying adverse events in medical care

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Summary

Background Data about the frequency of adverse events related to inappropriate care in hospitals come from studies of medical records as if they represented a true record of adverse events. In a prospective, observational design we analysed discussion of adverse events during the care of all patients admitted to three units of a large, urban teaching hospital affiliated to a university medical school. Discussion took place during routine clinical meetings. We undertook the study to enhance understanding of the incidence and scope of adverse events as a basis for preventing them.

Methods Ethnographers trained in qualitative observational research attended day-shift, weekday, regularly scheduled attending rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings in three study units as well as various departmental and section meetings. They recorded all adverse events during patient care discussed at these meetings and developed a classification scheme to code the data. Data were collected about health-care providers' own assessments about the appropriateness of the care that patients received to assess the nature and impact of adverse events and how health-care providers and patients responded to the adverse events.

Findings Of the 1047 patients in the study, 185 (17.7%) were said to have had at least one serious adverse event; having an initial event was linked to the seriousness of the patient's underlying illness. Patients with long stays in hospital had more adverse events than those with short

stays. The likelihood of experiencing an adverse event increased about 6% for each day of hospital stay. 37.8% of adverse events were caused by an individual, 15.6% had interactive causes, and 9.8% were due to administrative decisions. Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1.2% (13) of the 1047 patients made claims for compensation.

Interpretation This study shows that there is a wide range of potential causes of adverse events that should be considered, and that careful attention must be paid to errors with interactive or administrative causes. Health-care providers' own discussions of adverse events can be a good source of data for proactive error prevention.

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Introduction

Various terms are chosen to designate inappropriate care and adverse outcomes experienced by patients during their hospital care—adverse or untoward events, maloccurrences, complications, medical injuries, therapeutic misadventures, substandard care, unexpected outcomes, preventable deaths, iatrogenic injuries, mishaps, errors, negligence, or malpractice. This range of terms is complemented by an array of definitions chosen to suit the particular goals of the people using them. Within the hospital setting, the assessment of whether a health-care professional's action or inaction is appropriate or not may be undertaken for teaching purposes, for quality assurance purposes, for review of a provider's staff privileges, or to assess the provider's or hospital's potential legal liability. Outside researchers, using various methods, may enter the hospital environment with their own definitions of appropriate care to find out how the management of a particular type of diagnosis or treatment can be improved^{1,2} or to assess the costs of implementing legal changes in the handling of malpractice cases, such as through the adoption of a no-fault system.³⁻⁵

In social-policy debates, the many potential definitions

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of appropriate care are ignored. Instead, data about the frequency of adverse events related to inappropriate care in hospitals come from studies of medical records as if they represented a "true" record of adverse events. For example, the Harvard Medical Practice Study of medical records is often regarded as an accurate indicator of the rate of adverse events in hospitals. That study found that 3.7% of 30 121 patient records from New York hospitals contained an incident that met the study's definition of an adverse event, which required consensus by two physicians and a specified level of harm.

This low incidence of adverse events contrasts substantially with prospective studies of certain types of care. For example, Brook's classic 1970 study¹ found that only 27% of one cohort of patients seeking care in an emergency room received "effective medical care". Steel and colleagues² found that 36% of 815 consecutive patients had an iatrogenic illness, and 9% had an iatrogenic event that was life threatening or produced a disability. Meyers⁶ reported that "there is evidence, derived mainly from studies of hospital patients, that the denominator of iatrogenic illness and injury is large".

To find out more about the care that patients receive than can be shown by prospective studies of particular procedures or after-the-fact analyses of medical records, we undertook a prospective, observational study of the care of all patients admitted to three units of a large urban teaching hospital. Our strategy was to assess how health-care professionals identified adverse events in the course of their normal tasks. We saw three benefits to such an approach. Since these meetings were designed for other purposes (such as teaching and patient care), adverse events needed to be discussed for the system to function. Thus, there was likely to be a fuller and more open account of such events than might occur in a survey of health-care providers about adverse events or even a study of medical records. Second, by monitoring all adverse events that were discussed about a patient's care, rather than studying how well a particular diagnosis or treatment was undertaken, we could begin to assess adverse events that might be due to institutional decisions and constraints, not merely technical or cognitive deficiencies on the part of the individual provider. Third, it seemed more likely that adverse events could be prevented if the health-care providers recognised that they were making them. Brennan notes that, in theory, all adverse events are preventable.⁷

Methods

The study was carried out in three units at a large, tertiary care, urban teaching hospital affiliated to a university medical school. The providers were the attending surgeons and physicians, fellows, residents, interns, nurses, and other health-care practitioners on ten surgical services. The study was approved by the hospital's Institutional Review Board. The techniques of data collection and analysis that were used protected the confidentiality of the sources and the patients.

Selection of observers

To chronicle the discussion of adverse events, we chose four ethnographers trained in qualitative observational research; such individuals have been used successfully in other studies of medical errors in hospitals.^{8,9} Although the ethnographers had previous field-work experience, they were given a month of additional training to enable them to carry out field work in a medical setting. The training included attendance at the full orientation programme for new surgical residents and

participation in a series of seminars focused on the important published work on the relevant areas of medical sociology and medical anthropology, and on adverse events.

Before beginning data collection, each of these ethnographers attended, with a project investigator, various rounds, meetings, and conferences. Each ethnographer/project investigator pair independently recorded adverse events, and then the pair compared notes and resolved disagreements. Then, they attended rounds, meetings, and conferences in observer pairs to assess again their understanding of the types of adverse events that were to be recorded. We defined adverse events as situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen. The focus was on whether at the time the particular medical decision was made (knowing the facts as they were at that moment) the action was appropriate. This is similar to the instruction given by Rubin et al¹⁰ to reviewers "to evaluate the process of care considering information available to providers at that point in time".

Observers were placed in each setting and the project was discussed. Then, for 9 months, they attended day-shift, weekday, regularly scheduled attending rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings in the three study units. They also attended meetings held at the section or departmental level such as morbidity and mortality conferences and quality assurance reviews. These informal and formal meetings made up an exhaustive set of the organised settings in which health-care providers discussed adverse events in the care of their patients.

Observers recorded information about all adverse events in patient care discussed at these meetings. They recorded a description of the adverse event, who identified it, what was said to be the cause, what the effect was on the patient, whether anyone was blamed, and whether any response to the event was mentioned. Observers did not ask questions, and they did not make medical judgments. They recorded what was said by health-care professionals about the event in that setting. Since observers did not ask questions, important data about an individual event were sometimes missing (ie, whether the particular event resulted in serious harm). We included an adverse event even if in a particular case it did not result in harm because, if the adverse event were repeated, it might lead to harm to that patient or to another patient. Thus, we were interested even in what we termed "aborted" adverse events—ie, those that would have resulted in serious harm if it had not been for chance or intervention of another health-care professional.

After data had been collected for 2 months, starting from coding frameworks previously developed for the Medical Feasibility Study^{11,12} and GAO¹³ studies, an event classification scheme was developed. There were 368 specific categories of incidents that met the study definition of adverse events, grouped into nine large areas: diagnosis (48 categories; eg, failure to order indicated tests, misplaced test results, and incorrect conclusion from test information), surgery (38 categories; eg, inadequate preparation of patient for surgery, inappropriate technique, and surgery not indicated), anaesthesia (11 categories; ie, improper dosage or improper monitoring), treatment (25 categories; eg, delay in undertaking treatment, unnecessary treatment, or failure to order indicated treatment), nutrition problems (five categories; eg, failure to consider food allergies), drugs (20 categories; eg, failure to provide the ordered drug), monitoring and daily care (97 categories; eg, not taking proper antisepsis steps, improper extubation, and wrong placement of drainage/stent tubes), complications (112 categories; eg, leaking of anastomosis or muscle necrosis due to inappropriate health-care decisions, rather than because of the inherent risk of the procedure), and other (12 categories; eg, patient's chart not properly updated or miscommunication with patient). For each of the nine categories, the adverse event was the result of an action or inaction when, at the time, an appropriate alternative course could have been chosen. There were 40 categories of causes in three main areas: individual causes, interactive causes, and administrative causes. The

Characteristic	Number
Sex	
M	547 (52.2%)
F	500 (47.8%)
Race	
White	483 (46%)
African-American	448 (43%)
Other	41 (4%)
Not recorded*	75 (7%)
Payment source	
Third party payor	49.5%
Medicaid or uninsured	21.2%
Medicare	29.3%

*In hospital records.

Table 1: Patient characteristics

observers took part in developing the codes, and then double coded sets of data forms, regularly in the beginning, then intermittently, to ensure consistency in classifying events and other information. Disagreements about categories were discussed and resolved in group meetings of the observers, other project personnel, and the principal investigators.

Patients

The patients whose care was being discussed were those in the three study units (two intensive care units and one surgical care floor) from July 1, 1989, through March 31, 1990. Patient and provider responses to events that occurred during that time were reported until March 31, 1992—the end of the generally applied 2-year statute of limitations period for suits based on events that occurred during the observation period of the project. Follow-up data about the outcome of claims were obtained on March 31, 1996.

Hospital data systems

The study team was given unprecedented access to the hospital information system, patient charts, incident report forms, potential claim files, claim files, complaint letters from patients, and patient requests that their records be sent to other doctors, lawyers, or to themselves. These sources allowed us to code demographic information about the patients (race, age, marital status, insurance status) and to assess responses that patients made to the adverse events.

Results

Patients

During the study there were 1047 patients in the three units (mean age 46.5 years [SD 20.3], range 6 months–95 years); one-third of them were admitted more than once for a total of 1716 admissions. The patients were evenly distributed by sex and race, and their source of payment reflected the national distribution (table 1).

411 (39.3%) patients were in an intensive care unit at some point during the study. Median length of stay in the hospital (during all admissions that overlapped the research period) was 12.5 days (range 1–>274 days; beyond the complete length of the study). 554 patients (52.9%) had at least one admission that was classified as an unscheduled, emergency admission. The disorders most frequently treated were diseases of the colon and liver, traumatic injuries such as burns, and malignant neoplasms.

Events and causes

The rounds and clinical meetings attended by observers provided a rich data source for studying adverse events. At the surgical morbidity and mortality meetings, there were extensive discussions of inappropriate care, such as

Problem area	All adverse events	Serious adverse events
Diagnosis	164 (7.5%)	24 (5.2%)
Surgery	230 (10.5%)	91 (19.7%)
Treatment	293 (13.4%)	42 (9.1%)
Monitoring and daily care	639 (29.3%)	79 (17.1%)
Drugs/medication	204 (9.3%)	27 (5.8%)
Nutrition	51 (2.3%)	2 (0.4%)
Anaesthesia	27 (1.2%)	11 (2.4%)
Complications	425 (19.5%)	176 (38.1%)
Other	150 (6.9%)	10 (2.2%)

Table 2: Categories of adverse events

the failure to order a white blood count for a patient who otherwise had symptoms of appendicitis. At conferences for the particular services, the care of each current patient was discussed, including any adverse events during the patient's care, such as the use of an inappropriate type of vascular surgery, that resulted in harm. At rounds, while new information about patients was discussed outside the doorway of their rooms, adverse events were also highlighted, such as the failure to have ordered a toxicity test for a certain medication, leading to a toxic reaction that required remedial treatment.

Health-care providers identified an adverse event in 480 (45.8%) of the 1047 patients (mean 4.5 events per patient). In 185 patients (17.7%), the adverse event was serious; this ranged from temporary physical disability to death. 191 patients (18.2%) had events of which seriousness was not discussed. There were a total of 2183 events; 462 (21.2%) were serious, in 1360 (62.3%) the seriousness was not monitored, 40 (1.8%) were minor, and in 321 (14.7%) there was no harm to the patient. The highest proportion of adverse events occurred not in surgery itself but in the subsequent monitoring and daily care (table 2).

The causes of adverse events that were identified by the health-care worker could be grouped into three main types: individual, interactive, and administrative. One or more causes were mentioned for just over half the adverse events; 37.8% were said to have been caused by an individual—for example, by poor technical performance, poor judgment, or failure to act on or to obtain information. 15.6% of adverse events had causes related to the interaction between individuals, or between individuals and hospital entities, or between hospital entities, such as the failure of a consultant team to communicate adequately with the requesting team. 9.8% of adverse events had causes related generally to administrative decisions and protocols—eg, defective or unavailable equipment or inadequate staffing.

Factors related to experiencing an event

The numbers of patients experiencing an initial adverse event were broadly similar irrespective of ethnicity, sex, or payor class (table 3). The mean age of persons with events was 48.0, compared with 45.8 in patients without events.

More patients with a serious illness (as judged by whether the patient spent time in an intensive care unit during the stay in which the initial event occurred, whether the patient began that stay as an emergency admission, and the length of that stay in hospital) than without a serious illness had an initial adverse event (table 3). The mean length of stay was 8.8 days for patients without adverse events and 23.8 days for those with adverse events. The likelihood of experiencing an adverse event increased about 6% for each day of hospital stay.

	Patients with adverse events (n=73)	All other patients (n=567)
Length of hospital stay (days)*	23.8	8.8
Emergency admission (%)*	59.6	47.3
ICU stay (%)*	50.8	29.5
Gender (%F)	47.9	47.6
Payment (% insured)	64.8	66.1
Ethnicity (% white)	50.9	52.7

*During study. ICU=intensive care unit.

Table 3: Comparison of patients who had adverse events with all other patients

	Patients with initial serious adverse events (n=73)	All other patients (n=974)
Length of hospital stay (days)*	22.2	15.3
Length of hospital stay (days)†	32.0	21.1
Emergency admission (%)†	63.0	52.2
ICU stay (%)†	54.8	38.1
Gender (%F)	48.0	47.7
Payment (% insured)	72.6	65.0
Ethnicity (% white)	56.7	51.5

*During first stay during study; †during entire study period; ICU=intensive care unit.

Table 4: Comparison of patients who had initial serious adverse events with all other patients

Ethnicity, sex, payor class, and age of patients experiencing a serious initial adverse event were broadly similar to those of patients without adverse events (table 4). The mean age of patients with serious initial adverse events was 51.1, compared with 46.4 for the other patients. Of the indicators of seriousness of illness, only having been in an intensive care unit during the stay in which the event occurred was related to having a serious initial event. 54.8% of patients who were in an intensive care unit at some time during their stay had a serious initial event compared with 38.1% of those who were never in an intensive care unit. The mean length of stay of patients with a serious illness adverse event was 22.2 days compared with 15.3 days for the other patients.

Event history analysis assesses causes and effects over time within a regression-like framework and is often used in analyses of survival data.^{14,15} Patients who had a serious adverse event were 74% less likely to be discharged from the hospital on any given day (after the event) than were patients who did not have a serious event. This indicates that adverse events caused patients to need longer stays in hospital.

Even though 17.7% of patients had serious adverse events during their care, and adverse events led to longer hospital stays and thus increased costs to patients, only 13 patients of the 1047 total patients (1.2%) made claims. 11 of the 13 had been identified by the study as having an adverse event. For these 11 claiming patients the number of adverse events per patient ranged from one to 33 (mean 9.6 events per patient). As of March, 1996, 4 years after the statute of limitations for filing suits on the adverse events had ended, three of the 13 claiming patients had received compensation, eight claims had been dropped, and two cases were still pending.

Discussion

There is a growing published work of empirical investigations of the epidemiology of adverse events in the hospital setting. The most far-reaching research project studying adverse events to date has been the Harvard study of 30 121 New York hospital patients' records. The investigators defined adverse events according to a legal-policy model since their goal in measuring the event rate

in hospitals was to determine the feasibility of a no-fault system of compensation for medical malpractice. They required that two physicians agreed that an incident was an adverse event and that the event caused serious harm. The investigators noted¹⁶ that "because we wanted to assess only injuries that might have been covered by the tort system or broader compensation schemes, we did not label errors, however egregious, as adverse events unless they resulted in disability". Using their stringent criteria, they found that 3.7% of records described such errors.

Unfortunately, in legal-policy debates in the USA, the Harvard study's results have been generalised to circumstances far beyond the study design. The proportion of patients in the Harvard study who experienced adverse events are multiplied over the entire population of patients in the USA and then displayed as an inclusive account of how many patients have errors in their care. This underestimates the error rate in three important ways. First, it only considers patients whose errors resulted in a specified level of harm. Second, it only includes errors that are documented in patient records. Third, it underestimates the number of patients with potential legal claims because, since it only takes one credible expert witness in the USA to prove the case for a patient, the two-physician standard of the Harvard study does not mirror what actually occurs in the courts.

The full extent of untoward events can never be determined exactly. There will always be some events of which neither the patient nor the provider are aware. Some events will be disguised or misrepresented. The observational study reported here showed a higher proportion of patients with one or more events resulting in serious harm during the observation period than were reported in the Harvard study—17.7%. Even if we consider that in some proportion of our events the original action was indeed the correct one when it was taken, we still have an estimate substantially higher than that from the Harvard study. Yet our estimate is almost certainly an underestimate since the seriousness of 1360 events—affecting 191 patients—was not mentioned by the individuals discussing them; another reason why it is probably an underestimate is that we only studied discussions of adverse events at regularly scheduled daytime meetings. Additional discussions, perhaps about other adverse events, doubtless occurred in more casual settings, such as the cafeteria, and at other times.

Our study showed a greater rate of adverse events for sicker patients and for those with long stays in hospital. Both being in an intensive care unit and length of stay present more opportunities for an error in care, in the sense of providing more exposure.

Our results point out the need for attention to a wide range of potential causes of errors. Although the practice of medicine is often viewed as an individual effort between doctor and patient (and most policy recommendations and preventive strategies are focused on that individual effort), the proportion of errors with interactive or administrative causes (25.4%) underscores the influence of the inter-relationship among health-care professionals and administrative actions on errors. The study also challenges the portrayal of patients as over litigious since, despite 17.7% of patients experiencing a serious adverse event, only 1.2% made a claim for compensation.

Doctors and nurses candidly discuss adverse events in patient care at work rounds and clinical meetings. Such

discussions are viewed as crucial to a teaching hospital's dual missions of providing high quality care and educating future physicians. Analyses of adverse events discussed in these setting, because they rely on health-care professionals' own assessments, may provide the starting point for proactive error-prevention, thus improving clinical teaching and the quality of care, potentially decreasing the number of malpractice suits, and showing patients and regulatory bodies that a hospital and its professional staff are working to prevent the harm to patients caused by departures from optimum care.

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Diagnosis of viral infections of the central nervous system: clinical interpretation of PCR results

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Summary

Background Standard laboratory techniques, such as viral culture and serology, provide only circumstantial or retrospective evidence of viral infections of the central nervous system (CNS). We assessed the diagnostic accuracy of PCR of cerebrospinal fluid (CSF) in the diagnosis of viral infections of the CNS.

Methods We examined all the CSF samples that were received at our diagnostic virology laboratory between May, 1994, and May, 1996, by nested PCR for viruses associated with CNS infections in the UK. We collected clinical and laboratory data for 410 patients from Oxford city hospitals (the Oxford cohort) whose CSF was examined between May, 1994, and May, 1995. These patients were classified according to the likelihood of a viral infection of the CNS. We used stratified logistic regression analysis to identify the clinical factors independently associated with a positive PCR result. We

calculated likelihood ratios to estimate the clinical usefulness of PCR amplification of CSF.

Findings We tested 2233 consecutive CSF samples from 2162 patients. A positive PCR result was obtained in 143 patients, including 22 from the Oxford cohort. Logistic regression analysis of the Oxford cohort showed that fever, a virus-specific rash, and a CSF white-cell count of 5/μL or more were independent predictors of a positive PCR result. The likelihood ratio for a definite diagnosis of viral infection of the CNS in a patient with a positive PCR result, relative to a negative PCR result, was 88.2 (95% CI 20.6–378). The likelihood ratio for a possible diagnosis of viral infection of the CNS in a patient with a negative PCR result, relative to a positive PCR result, was 0.10 (0.03–0.39).

Interpretation A patient with a positive PCR result was 88 times as likely to have a definite diagnosis of viral infection of the CNS as a patient with a negative PCR result. A negative PCR result can be used with moderate confidence to rule out a diagnosis of viral infection of the CNS. We believe that PCR will become the first-line diagnostic test for viral meningitis and encephalitis.

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Introduction

Viral infections of the central nervous system (CNS) are often difficult to diagnose because conventional

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