Adverse Events in Primary Care Identified from a Risk-Management Database

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BACKGROUND. The inevitability of adverse events in medicine arises from human fallibility, negligent care, limits of medical knowledge, risks inherent in medical practice, and biological variability among individuals. A better understanding of the nature and causes of adverse events is necessary to reduce their occurrence and limit their harm. This study describes adverse events identified from a risk-management database that occurred in an outpatient primary care setting.

METHODS. Incident reports filed with the risk-management office of an academic medical center between January 1, 1991, and June 30, 1996, by eight primary health care clinics affiliated with the center were eligible for the study. Two independent reviewers assessed the incidents to determine whether there were adverse medical events. Incidents classified as adverse events were analyzed to determine the cause, potential preventability, and outcome.

RESULTS. The prevalence of adverse events was 3.7 per 100,000 clinic visits over a period of 5 1/2 years. Twenty-nine of 35 (83%) adverse events were due to medical errors and were considered preventable. The causes of the adverse events included 9 diagnostic errors (26%), 11 treatment errors (31%), and 9 other errors (26%). Of the adverse events attributed to medical errors, 4 (14%) resulted in a permanent, disabling injury and 1 (3%) resulted in a death.

CONCLUSIONS. Serious adverse events appear to occur infrequently in primary care outpatient practice, although these data probably underestimate the overall prevalence. To reduce or prevent the occurrence of adverse events in primary care, better systems for recognizing and tracking them and for assessing their causes are needed.

KEY WORDS. Diagnostic errors; medication errors; iatrogenic disease; primary health care; risk management; total quality management. *(J Fam Pract 1997; 45:40-46)*

The inevitability of adverse events in medicine arises from human fallibility, negligent care, the limits of medical knowledge, the risks inherent in medical practice even when the standard of care is followed, and the biological variability among individuals.[1] Adverse events include both those resulting from preventable errors or mistakes and unpreventable events. Even though risk and uncertainty in medicine preclude complete elimination of iatrogenic disease, a better understanding of the nature and causes of adverse events is necessary to reduce their occurrence and limit their harm. Understanding the consequences of adverse events is essential for improving the quality of medical care. The social and financial costs to the patient, the institution, and the health care system need to be considered in evaluating the impact of adverse events. The way in which physicians, other health professionals, and the medical system manage such events has the potential to either undermine or strengthen the physician-patient relationship.[2,3]

The potential for medical errors is enormous. It has been estimated that an average-sized teaching hospital dispenses more than 4 million drug doses a year.[4] Even if the health care system were to attain a 99.9% error-free rate, 4000 adverse events might occur annually solely as a result of medication errors. In a comprehensive study of adverse events in hospitalized patients in New York State, Brennan et al[5] found that 3.7% of admissions resulted in an adverse event, with more than two thirds of the events deemed to be preventable. A review of inci-

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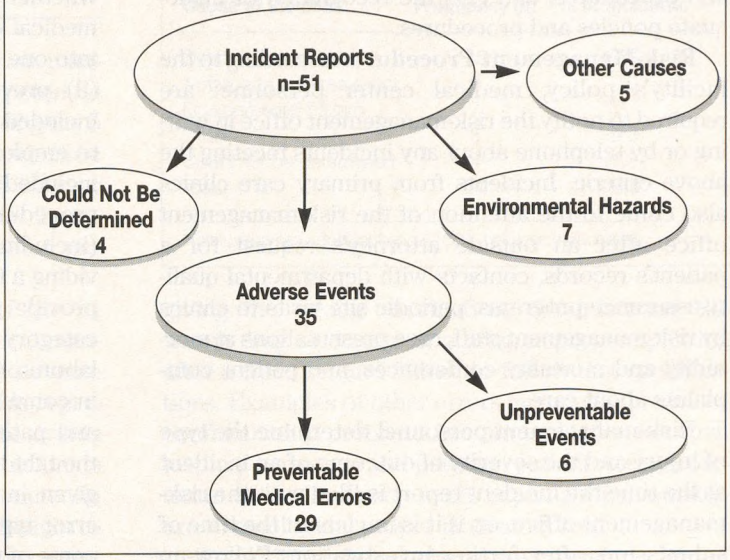
dent reports in a long-term care setting found an annual incidence of 553 adverse or unexpected events per 100 beds.[6]

While most studies have focused on inpatient populations, the study of adverse events in outpatient populations may be particularly important because the majority of medical encounters take place in this setting.[7] Based on the experience of the host institution in this study, the most common types of adverse events in the outpatient setting, ie, diagnostic errors, appear to differ from those in the inpatient setting, ie, technical errors. Moreover, the population of both patients and health professionals systematically differ between the two settings.

The existing research on adverse events in primary care is mainly limited to anecdotal reports,[8] family physicians' reports of their most memorable medical errors and their perceived causes,[9] research on the emotional impact of errors and physicians' willingness to support colleagues involved in an error or other adverse event,[10] and errors in prescribing long-term medications.[11] This study describes the prevalence of adverse events in an outpatient primary care setting that were identified through a risk-management database, and classifies the events by their causes, potential preventability, and resulting outcomes.

FIGURE

Classification of incident reports in the database of the risk-management office of the host academic medical center.



METHODS

This cross-sectional study was conducted at an academic medical center in the midwestern United States. Incident reports entered by eight primary care clinics into the database of the risk-management office of an academic center between January 1, 1991, and June 30, 1996, were eligible for the study. These clinics provide family practice, internal medicine, pediatric, and obstetric and gynecological outpatient services. Specialty services such as cardiology and neurology consultations were excluded from the analysis. The number of clinical visits during the study period was calculated from institutional reports on patient visits.

Definitions. Adverse events are defined in the literature as unintended injuries that result from medical management.[12] The incident reports available in the risk-management database included events resulting from environmental hazards that would not qualify as adverse events (Figure). If the incident was associated with an environmental hazard, it was placed in the environmental hazard category. This category includes such incidents as falling in the parking lot or tripping on medical equipment. For the purposes of this study, adverse events were defined as incidents resulting in, or having the potential for, physical, emotional, or financial liability to the patient. Adverse events were subsequently categorized as preventable or unpreventable events.

In its data-collection instrument, the facility defines reportable incidents for all institution-associated sites as: (1) falls or mishaps; (2) the occurrence of errors or unexpected complications or outcomes resulting from the administration of medications or transfusions; (3) complications or injuries from the administration of intravenous drips and other substances; (4) the occurrence or allegation of any complication or unexpected outcome of a procedure that results in unexpected increased disability or allegation of increased disability (temporary or permanent) or increased charges to a patient; (5) burns, pressure sores, and fire-related injuries; (6) procedural breakdowns involving a patient (eg, consent forms not signed, improper transport of a patient);

(7) patients leaving against medical advice; (8) equipment failure; (9) allegations of a breach of confidentiality; (10) failure to follow existing policies and procedures; and (11) the recognition of inadequate policies and procedures.

Risk-Management Procedure. According to the facility's policy, medical center personnel are required to notify the risk-management office in writing or by telephone about any incidents meeting the above criteria. Incidents from primary care clinics also come to the attention of the risk-management office after an outside attorney's request for a patient's records, contacts with departmental quality-assurance programs, periodic site visits to clinics by risk-management staff, case presentations at morbidity and mortality conferences, and patient complaints about care.

Risk-management personnel determine the type of injury and the severity of outcome of an incident at the time the incident report is filed with the risk-management office, or, if it is unclear at the time of submission, after further investigation. Follow-up investigations include consultations with medical personnel involved in the incident as well as with independent medical advisors. Injury categories include: (1) emotional or financial liability; (2) infection; (3) fracture or dislocation; (4) teeth injury; (5) contusion, cut, or laceration; (6) sprain or strain; (7) additional treatment required; (8) reduced life expectancy; (9) brain damage or injury; (10) death; and (11) other injury. The severity of the outcome is classified as: (1) emotional only; (2) temporary-insignificant (no delay in recovery); (3) temporary-minor or major (delay in recovery); (4) permanent-minor (nondisabling injury); (5) permanent-significant, major, or grave (disabling injury); or (6) death.

Only incidents that result in an injury, a potential injury, or financial liability to the patient are entered into the computer database. Other incidents are maintained in a paper file. The type of injury and severity of outcome are assigned based on what are believed to be the consequences of the incident and not on the underlying condition of the patient.

Classification of Adverse Medical Events. Two board-certified family physicians were recruited to independently review all the incident reports and associated risk-management records on all the outpatient events, and to determine whether an incident was associated with medical management or was due to some other cause, such as an environmental hazard.

The two reviewers were also asked to determine whether an adverse event was the consequence of a medical error, and if it was, to categorize the error into one of four types: (1) diagnostic; (2) treatment; (3) preventive; and (4) other. Diagnostic errors included failures or delays in diagnoses and failures to employ proper diagnostic tests. Treatment errors included technical errors in the performance of a procedure, errors in administering a treatment (including medications), and avoidable delays in providing a treatment. Preventive errors were failure to provide preventive treatments. The "other" errors category included improper medical staff behavior, laboratory errors, equipment failures, and problems in communication between a medical staff member and patient or among staff members. If reviewers thought that more than one error occurred during a given incident, they were instructed to select the error type that most likely led to the injurious outcome of the adverse event.

Finally, reviewers were asked to classify the adverse event as preventable or unpreventable. Events were defined as preventable if they were the result of substandard care, or if the resulting complication had a high probability of occurrence and might be expected when low levels of care were employed. Events were classified as unpreventable if the complication could not be prevented given the current state of knowledge.

The categories and definitions described above were adapted from Leape et al.[4]

Resolving Reviewers' Differences. Differences in the two reviewers' assessments of the types of errors and preventability of adverse events were resolved by an intense review by the study investigators (G.F. and M.D.F., board-certified family physician). Their decision was based on an assessment of the original risk-manager officer investigation, follow-up interviews with the investigating risk-management officer, and analysis of the independent reviewers' comments. In six particularly difficult cases, the investigators (G.F. and M.D.F.) also reviewed the hospital inpatient record to classify the incidents. Review of the outpatient records from the multiple primary care sites was not feasible. If more than one type of injury was listed for a given incident, the most severe injury was used in the final analysis.

The study was approved by the institutional review board of the host academic center.

RESULTS

There were 51 incidents reported to the risk management office that resulted in an injury, potential injury, or financial liability to the patient during the 5 1/2-year study period. There were an estimated 948,628 clinic visits during this time, so the 5 1/2-year prevalence of incidents that resulted in an injury, potential injury, or financial liability was 5.4 per 100,000 clinic visits.

Incident Classification. Thirty-five of the 51 injurious incidents were attributed to medical management and were therefore considered adverse events as defined in this study (Table 1). This represents a 5 1/2-year prevalence of 3.7 adverse events per 100,000 clinic visits. Of the remaining incidents analyzed, seven were the result of environmental hazards, five were due to other causes not thought to be medically related, and in four cases there was not enough information in risk-management and patient records for the reviewers to make an accurate assessment. The average age of the patients was 34 years, and a slight majority (60%) of the affected patients were female.

In 22 of the 51 incidents (43%), the two independent reviewers agreed on the error classification. In 24 of the 51 incidents (47%), the independent reviewers agreed on the preventability classification. The areas of nonagreement primarily resulted from one reviewer's conclusion that the medical error type and preventability could not be determined in 23 (45%) and 24 (47%) of the cases, respectively. In the cases of disagreement between the independent reviewers, two of the study investigators (M.D.F. and G.F.) made an intense assessment as described above in Methods.

Cause Assessment. Based on this two-step evaluation process, 29 of 35 (83%) adverse events were judged to be the result of preventable medical errors. The causes of the adverse events included 9 diagnostic (26%), 11 treatment (31%), and 9 other errors (26%) (Table 2). There were no identified adverse events resulting from preventive care errors or failures to employ prophylactic treatments or follow-up. Conditions in which there were delays or failures in diagnoses included cancers, heart disease, and appendicitis. Examples of treatment errors included giving the wrong vaccination, administering the wrong drug or dosage of a drug, improper splinting after a fracture, and failure to follow test specifications. Examples of other errors included a breach of confidentiality, problems in communication between medical personnel and patients, patient misinterpretation of medical personnel's explanations, and failure to employ the proper laboratory test.

TABLE 1

Classification of Incidents Reported to Risk-Management Office Between January 1991 and June 1996

Cause of Incident	Frequency (n)	% of Incidents
Due to adverse event	35	68.6
Not due to adverse event	0	0.0
Environmental hazard	7	13.7
Other	5	9.8
Could not be determined	4	7.8
Total	51	99.9*

*Total percentage does not equal 100% because of rounding.

Six (17%) of the adverse events were considered unpreventable since there was believed to be no errors in medical management. This was because either the adverse event was due to a common complication of the patient's underlying condition that could not be avoided given the current medical knowledge (n=2), or the event was the result of patient behavior (n=4), such as failing to keep scheduled appointments or exhibiting inappropriate behaviors toward staff.

Outcomes. In most cases (55%) where an adverse event was attributed to a medical error, the

TABLE 2

Frequency and Percentage of Adverse Events, by Type of Error

Type of Error	Frequency (n)	% of Total
Diagnostic	9	25.7
Treatment	11	31.4
Preventive care	0	0.0
Other	9	25.7
No error*	6	17.1
Total	35	99.9†

*Includes adverse events due to unpreventable complications of medical management and patient behaviors.

†Total percentage does not equal 100% because of rounding.

TABLE 3

Frequency and Percentage of Adverse Events, by Type and Attribution of Injury

Event Attribution/ Type of Injury	Frequency (n)	% of Total
Attributed to medical error		
Emotional or financial liability	14	48.3
Contusion, cut, or laceration	2	6.9
Additional treatment required	5	17.2
Reduced life expectancy	3	10.3
Brain injury	1	3.4
Death	1	3.4
Other injury	3	10.3
Total	29	98.0*
Not attributed to medical error		
Emotional or financial lability	2	33.3
Contusion, cut, or laceration	3	50.0
Additional treatment required	1	16.7
Total	6	100.0

*Total percentage does not equal 100% because of rounding.

resulting injury was emotional or financial, or was a minor contusion, cut, or laceration (Table 3). In 5 cases the adverse events were due to medical errors, and additional treatment was required. Brain damage, a reduced life expectancy, or death occurred as a result of medical errors in 5 of the 29 cases. For adverse events not attributed to medical errors, 1 of 6 resulted in the need for additional treatment.

Eighteen (62%) of the 29 adverse events attributed to medical errors resulted in either emotional or temporary physical injury that did not delay recovery, whereas 6 (21%) resulted in temporary injuries that delayed the patient's recovery (Table 4). Four of the 29 (14%) adverse events attributed to medical errors resulted in a permanent disabling injury, and one (3%) resulted in the death of the patient. Most of the adverse events that could not be attributed to medical errors resulted in non-severe injuries.

DISCUSSION

Based on these data obtained from a risk management database, the prevalence of adverse events over 5 1/2 years was 3.7 per 100,000 visits. The actual prevalence is almost assuredly higher. Although few in number, some of the outcomes of individual cases were severe: five cases deemed preventable resulted in permanent disability or death.

Underreporting. These data most likely underestimated the actual occurrence of adverse events for the following reasons: (1) time constraints inhibited filing of incident reports; (2) the incident or its outcome may have gone unrecognized; (3) the outcome of an incident may have been attributed to the normal risks inherent in medical practice rather than to an iatrogenic event; (4) involved personnel may have attempted to manage incidents without reporting them; (5) risk-management personnel may not have recognized an incident as having caused an injury; or (6) the incident may never have been reported if it was discovered at a facility not overseen by the host institution's risk-management office.

Data from the hospital literature consistently indicate underreporting of adverse events. The percentage of adverse events in a hospital setting that are actually reported to risk management was estimated by the American College of Surgeons to be between 5% and 30%.[13] In another study of hospitalized patients, only 1.5% of adverse events identified through a review mechanism established for study

TABLE 4

Frequency and Percentage of Adverse Events, by Attribution of Event and Severity of Outcome

Event Attribution/Severity of Outcome	Frequency (n)	% of Total
Attributed to medical error		
Emotional	14	48.3
Temporary—no delay in recovery	4	13.8
Temporary—delay in recovery	6	20.7
Permanent—nondisabling	0	00.0
Permanent—disabling	4	13.8
Death	1	3.4
Total	29	100.0
Not attributed to medical error		
Emotional	2	33.3
Temporary—no delay in recovery	2	33.3
Temporary—delay in recovery	2	33.3
Total	6	99.0*

*Total percentage does not equal 100% because of rounding.

purposes were reported to the risk-management department.[14] A study of adverse drug events in hospitals found that only 3 of 54 (6%) events were reported to risk management.[15] In another study of adverse events occurring in a hospital setting,[5] 12% of 172 controls (patients discharged with having no adverse event reported to risk management during their hospitalization) were identified through physician chart reviews as having experienced adverse events; this study also found that medical record review had a sensitivity of 80% for finding adverse events when risk-management records were considered the reference standard.

Documentation. Risk-management records may represent a better assessment of the causes of adverse events and medical errors than patient record reviews. Quality assurance data, including risk-management records, are generally protected from legal discovery. Thus, sensitive information that is absent from patient records may be included in incident reports. Moreover, at the host institution in our study, risk-management personnel frequently investigate the cause when an event occurs. On the other hand, the validity and reliability of incident reports probably vary greatly across institutions since the degree to which incident reporting is emphasized and enforced as a quality assurance tool varies. The results of this study, therefore, may not be generalizable to other institutions.

The adverse events in this study were limited to incidents that resulted in an injury, potential injury, or financial liability for the patient. Although the risk-management office of the host institution collects information on incidents that do not necessarily lead to injury, there is no systematic review of such incidents by the office. Of the total number of inpatient and outpatient incidents reported to the risk-management office during a recent 1-year period, only about 47% were entered into the computer database and analyzed.

For more than one half of the incidents, the independent reviewers could not agree on medical error classification or preventability. This underscores the limitations of information collected for litigation prevention rather than explicitly for quality improvement purposes, as well as the inherent difficulty in defining when medical mismanagement occurs. Errors may be the result of an individual's mistake or a failure in the system. In either case, the goal should be to determine whether the adverse event was preventable and how preventive measures might be implemented.[16] To accomplish this, the underlying cause of an error needs to be assessed.

In this study it was difficult to determine whether a diagnostic error was the result of a failure to obtain a complete history, a failure to conduct a proper physical examination and diagnostic test(s), or a failure in the systematic procedures for evaluating a condition. Errors in treatment, such as administering the wrong vaccination or drug dosage, may have been due to a failure to review a patient's chart, a misunderstanding between the person ordering the treatment and the person administering it, or the mislabeling of medications. Many diagnostic and treatment errors may have the same root causes. Finally, how patient behaviors might contribute to adverse events could not be accurately assessed from the data.

A taxonomy focusing on the causes of an adverse event rather than the context in which it occurs would have more meaning in quality improvement efforts. A project currently underway at this study's host institution seeks to categorize incidents by their root causes, such as clinical judgment, technical skills, systems failure, staffing, documentation, inadequate data, and improper supervision of residents. A potential problem in such a system is determining who decides on the causes of mistakes and how such information is incorporated into continuous quality improvement efforts.

Tracking Systems. The limitations of this study suggest the need for more comprehensive systems for detecting and tracking adverse events in primary care. If the goal of risk management is to uncover underlying problems in medical management for the purpose of improving the quality of care rather than just to reduce litigation, then risk-management tracking systems need to be adjusted to assess these outcomes. Incidents often go unreported because the system relies on staff to follow administrative policies and procedures that may be viewed as disciplinary devices rather than learning tools; staff may believe that the process does not result in constructive changes; and medical personnel may believe that the information will be used against them in legal action.[15] Efforts using a more participatory approach, in which medical staff help develop criteria for assessing adverse events and help implement changes, have the potential to result in more comprehensive and meaningful qual-

ity assurance outcomes.[16]

Most of this study and discussion have focused on adverse events that are due to errors; however, adverse events may also be due to the limitations of medical knowledge and an individual patient's biologic variability. Although these types of risks may be predictable, they may not be preventable. Perhaps the only way to minimize the consequences of such events is through informed consent. If the expected risks are not discussed in an understandable way with the patient, then the adverse outcome should be assessed as an error in patient management. Recent research illustrates patients' clear preferences to be informed after an adverse event occurs.[17]

CONCLUSIONS

Despite the limitations, this study raises important concerns and issues that must be addressed to improve the quality of medicine in primary care. First, there appears to be little effort to track the total quality of care in outpatient settings. Before such tracking can begin, a taxonomy and a reliable system of reporting adverse events need to be developed within the context of the primary care setting. Second, risk-management efforts that are focused on reducing litigation rather than promoting the continuous improvement of care cannot sufficiently fulfill a quality assurance mission of identifying underlying problems in medical management. Third, to improve the tracking system, the mechanism for reporting mistakes and adverse events should be presented as a teaching tool to avoid the possible perception that it is a punitive system. Fourth, the potential costs of errors are as yet unrecognized in the outpatient setting. Both the costs to the individual, such as added medical expenses, lost wages, and a reduced quality of life, and the costs to medical institutions must be assessed to fully appreciate the impact that adverse events and medical mistakes have on the system of care.

Other underresearched areas relating to adverse events include: (1) physicians'[8-10] and patients'[17] perspectives on the occurrence and management of adverse events; this information would help medicine better understand the nature and causes of adverse events in the primary care setting; (2) how error rates might be affected by such factors as the time of day and the age and experience of the providers; and (3) how institutional care policies contribute to or prevent the occurrence of adverse events.

Since initiatives to understand and reduce adverse events serve the best interests of patients, clinicians, administrators and payers, the potential benefits of more intensive research on the causes of adverse events in primary care appear to be very great.

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