

## Classification of medical errors and preventable adverse events in primary care: A synthesis of the literature

NANCY C. ELDER, MD, MSPH; AND SUSAN M. DOVEY, PhD  
Cincinnati, Ohio, and Washington, DC

■ **OBJECTIVE** To describe and classify process errors and preventable adverse events that occur from medical care in outpatient primary care settings.

■ **STUDY DESIGN** Systematic review and synthesis of the medical literature.

■ **DATA SOURCES** We searched MEDLINE and the Cochrane Library from 1965 through March 2001 with the MESH term *medical errors*, modified by adding *family practice*, *primary health care*, *physicians/family*, or *ambulatory care* and limited the search to English-language publications. Published bibliographies and Web sites from patient safety and primary care organizations were also reviewed for unpublished reports, presentations, and leads to other sites, journals, or investigators with relevant work. Additional papers were identified from the references of the papers reviewed and from seminal papers in the field.

■ **OUTCOMES MEASURED** Process errors and preventable adverse events.

■ **RESULTS** Four original research studies directly studied and described medical errors and adverse events in primary care, and 3 other studies peripherally addressed primary care medical errors. A variety of quantitative and qualitative methods were used in the studies. Extraction of results from the studies led to a classification of 3 main categories of preventable adverse events: diagnosis, treatment, and preventive services. Process errors were classified into 4 categories: clinician, communication, administration, and blunt end.

■ **CONCLUSIONS** Original research on medical errors in the primary care setting consists of a limited number of small studies that offer a rich description of medical errors and preventable adverse events primarily from the physician's viewpoint. We describe a classification derived from these studies that is based on the actual practice of primary care and provides a starting point for future epidemiologic and interventional research. Missing are studies that have patient, consumer, or other health care provider input.

■ **KEY WORDS** Medical error; primary care physicians; family physicians. (*J Fam Pract* 2002; 51:927-932)

### KEY POINTS FOR CLINICIANS

- Little is known about medical errors and preventable adverse events in the primary care setting.
- Preventable adverse events reported from primary care practices include diagnostic, treatment, and preventive care incidents.
- Process errors reported from primary care practices can be categorized as clinician factors (judgment, decision making, skill execution), communication factors (between clinician and patient and between health care providers), administration factors (office and personnel issues), and blunt end factors (insurance and government regulations).
- Current knowledge of errors and preventable adverse events in primary care is missing input from patients and other health care providers.

Every primary care clinician in the United States knows the frustration of lost charts, misplaced reports, and messages from patients that should have been answered yesterday. These are some of the common frustrations and failures in day-to-day clinical practice. Many clinicians also know the guilt, shame, and self-doubt that occur when patients suffer a serious complication or die due to a mistake made by the clinician, health care team, or health care system. Between the common frustrations of practice and the rare patient death due to an error lies a large chasm, a rarely explored territory of relationships, causes and effects, and mitigating factors. Looking backward from a catastrophic patient outcome rarely goes beyond blaming the immediate per-

From the Department of Family Medicine, University of Cincinnati, Cincinnati, OH (N.C.E.) and the Robert Graham Center for Policy Studies in Family Practice and Primary Care, Washington, DC (S.M.D.). The authors report no competing interests. Address reprint requests to Nancy C. Elder, MD, MSPH, Associate Professor, Department of Family Medicine, University of Cincinnati, PO Box 670582, Eden Avenue and Albert Sabin Way, Cincinnati, OH 45267-0582. E-mail: eldernc@fammed.uc.edu.

son "at fault."<sup>1</sup> Looking forward from common charting errors rarely goes beyond a conclusion to be "more careful."

Hospital-based research has categorized preventable adverse outcomes and some process errors associated with them,<sup>2-4</sup> but this has not been done in primary care.<sup>5</sup> There are difficulties in studying errors in the primary care setting: care takes place in many locations; involves multiple visits; is provided in person, by phone, by mail, and even by computer; and involves interactions with many health care workers. However, it is important to study errors in primary care<sup>6</sup> because it is the location of most health care visits in the United States.<sup>7</sup>

A classification or taxonomy of errors and preventable adverse events is an important first step in improving patient care. Prevalence and epidemiology studies, clinical and system interventions, and even individual practice group databases of errors and adverse events<sup>8</sup> can more easily be developed if there is a beginning classification system. Just as clinicians use a differential diagnostic list for analyzing symptoms or a list of risk factors for assessing disease, so, too, can clinicians use a classification and listing of process errors and preventable adverse events to "diagnose" and "prevent" patient harm from medical care. Many taxonomies of medical error do exist and have been used in hospital accreditation or malpractice contexts for some time.<sup>9</sup> These taxonomies have not been generally available for purposes other than their intended use, ie, to help their developers understand the data they were dealing with, and because these data do not originate from primary care practice, it remains unknown how well the taxonomies might meet the needs of family physicians and other primary care researchers.

The purpose of this study was to use published data from original research to understand and classify process errors and preventable adverse events associated with primary medical care. Through a systematic review and synthesis of the medical literature, we developed a classification of medical errors relevant to primary care.

## METHODS

To identify eligible published English-language original research articles, we searched MEDLINE and the Cochrane Library from 1965 through March 2001 with the MESH search term *medical errors*, modified by adding *family practice*, *primary health care*, *physicians/family*, or *ambulatory care* to the primary term. Published bibliographies from the National Patient Safety Foundation (NPSF) and the Institute for Healthcare Improvement (IHI) were also reviewed. The Web sites of the American Academy of Family Physicians, the American College of Physicians–American Society of Internal Medicine, the Institute of Medicine, the NPSF, and

the IHI were also reviewed for unpublished reports, presentations, and leads to other sites, journals, or investigators with relevant work. Additional papers were identified from the references of the papers reviewed, from seminal papers in the field, and from discussion with others working in the field of patient safety or quality improvement in primary care.

We reviewed titles of 379 articles identified by electronic searches for inclusion. We excluded papers if they related to comparisons of different approaches to diagnosis or treatment of specific diseases, the evaluation of teaching or research tools, or exclusively to hospitalized patients. If there was uncertainty as to the appropriateness of an article, we read the abstract. We reviewed complete papers if they appeared from the title and abstract to report original research involving a broad assessment of medical errors and preventable adverse events in primary care. Data relating to topic, study quality, and research results were abstracted from identified papers. Both authors performed independent MEDLINE searches and reviewed citations in the papers. To broaden the search for potential studies, one author searched Web sites and NPSF and IHI bibliographies. Both authors agreed on the inclusion of the chosen studies, appraised them independently, and abstracted key classification components. One author (N.C.E.) initially prepared the classification system presented here; it was then reviewed by both authors and revised after their discussions.

## RESULTS

Four original research studies directly studied and described medical errors and preventable adverse events in primary care.<sup>10-13</sup> Three other studies peripherally addressed primary care medical errors as part of an investigation with another central focus<sup>14-16</sup> (Table 1).

### Outcome measures

Bhasale and colleagues<sup>10</sup> and Fischer and coworkers<sup>13</sup> collected patient outcome data; they specifically examined incidents that had "harmed" patients or had "potential for harm." Ely and associates<sup>12</sup> also studied incidents causing patients harm by investigating possible causes of these incidents. Dovey and colleagues<sup>11</sup> reported physician-observed errors regardless of whether they were associated with an adverse event. Britten and coworkers<sup>16</sup> analyzed misunderstandings between patients and physicians that had adverse consequences for taking medicines. Gandhi and associates<sup>14</sup> described communication between primary care physicians and specialists. Holden and colleagues<sup>15</sup> investigated deaths in general practices.

All these studies attempted some categorization of medical errors. Bhasale and associates<sup>10</sup> and Fischer and colleagues<sup>13</sup> defined 4 incident cate-

**TABLE 1**

<b>Primary care studies describing medical error</b>				
<b>Study</b>	<b>Research purpose</b>	<b>Definition of error</b>	<b>Method</b>	<b>Pertinent results</b>
<b>Primary care studies directly describing medical error</b>				
Bhasale et al <sup>10</sup>	Describe incidents occurring in general practice	An unintended event, no matter how seemingly trivial or commonplace, that could have harmed or did harm a patient	Self-report by 324 Australian sentinel research network FPs using reporting cards	805 incidents reported, 76% preventable; categories were drug management, non-drug management, diagnosis, and equipment; causes included communication, actions of others, and clinical judgment errors
Ely et al <sup>12</sup>	Describe the causes to which family physicians attribute errors	Act or omission for which the physician felt responsible and which had serious consequences for the patient	30-min interviews with 53 randomly chosen Iowa FPs	53 errors reported: delayed diagnoses, surgical and medical treatment mishaps; causes included physical stressors, process of care factors, patient-related factors, and physician characteristics
Dovey et al <sup>11</sup>	Describe medical errors reported by FPs	Something in one's practice that should not have happened, that was not anticipated, and that makes one say, "I don't want it to happen again"	Self-report by 42 American research network FPs using electronic and reply card reporting	330 reported errors, 83% from health care system and 13% from knowledge and skills; subcategories were office administration, investigations, treatments, communication, execution of clinical tasks, misdiagnosis, and wrong treatment decision
Fischer et al <sup>13</sup>	Describe the prevalence of adverse events in a risk management database	Incidents resulting in, or having the potential for, physical, emotional, or financial liability for the patient	Review of incident reports entered by 8 primary care clinics into risk management database	Prevalence of adverse events was 3.7/100,000 clinic visits, 83% were preventable; categories included diagnostic, treatment, and preventive and other errors
<b>Primary care studies peripherally describing medical error</b>				
Holden et al <sup>15</sup>	Determine patterns of death and potential preventive factors		Formal review of all patient deaths in a group of general practices	5.1% of deaths due to preventable FP factors; 2 main categories were delay of diagnosis and treatment and lack of prevention with aspirin therapy
Gandhi et al <sup>14</sup>	Evaluate primary care and specialist inter-physician communication		Surveys in academic medical center	Main issues for doctors were lack of timeliness and inadequate content
Britten et al <sup>16</sup>	Describe misunderstandings between patients and FPs		Qualitative study using 5 data sources	14 categories of misunderstandings were identified

FP, family physician.

gories and then assessed preventability. Dovey and coworkers<sup>11</sup> and Ely and associates<sup>12</sup> placed medical errors into categories, and Bhasale and colleagues<sup>10</sup> listed a number of contributing factors. Britten and coworkers<sup>16</sup> and Gandhi and associates<sup>14</sup> categorized clinician communication problems. Holden and colleagues<sup>15</sup> classified clinician actions that led to preventable deaths.

Due to the multiple methods used in the 7 studies and the descriptive nature of the studies, a standard assessment of quality and quantitative synthesis of data were not possible. Six studies used practicing community-based primary care physicians as their main study group. The study by Gandhi and coworkers, of communication between primary care physicians and specialists,<sup>14</sup> was performed in an academic institution.

**Classification system**

We derived the following classification system (outlined in Tables 2 and 3) from the errors and preventable adverse events reported in these 7 studies.<sup>10-16</sup> Table 2 defines the three main categories of preventable adverse events related by primary care physicians: diagnosis, treatment, and preventive services. These offer descriptors of

**TABLE 3**

**Classification of process errors in primary care**

**Clinician factors**

- Clinical judgment
- Procedural skills error

**Communication factors**

- Clinician-patient
- Clinician-clinician or health care system personnel

**Administration factors**

- Clinician
- Pharmacy
- Ancillary providers (physical therapy, occupational therapy, etc)
- Office setting

**Blunt end factors**

- Personal and family issues of clinicians and staff
- Insurance company regulations
- Government regulations
- Funding and employers
- Physical size and location of practice
- General health care system

**TABLE 2**

**Classification of preventable adverse events in primary care**

**Diagnosis**

- Related to symptoms
  - Misdiagnosis
  - Missed diagnosis
  - Delayed diagnosis

- Related to prevention
  - Misdiagnosis
  - Missed diagnosis
  - Delayed diagnosis

**Treatment**

- Drug
  - Incorrect drug
  - Incorrect dose
  - Delayed administration
  - Omitted administration
- Non-drug
  - Inappropriate
  - Delayed
  - Omitted
  - Procedural complication

**Preventive services**

- Inappropriate
- Delayed
- Omitted
- Procedural complication

what went wrong in the care of the patient but not of the level of harm. For example, a patient who was prescribed and took an incorrect drug has experienced a preventable adverse event. As a consequence, that patient may suffer no ill effects (a near miss), may die from anaphylaxis, or may experience some intermediate outcome (such as a rash).

Table 3 outlines “process errors” that clarify *why* something went wrong. For example, Why was the patient prescribed an incorrect drug? The answer may lie with a *clinician* factor (the doctor took an inadequate history), a *communication* factor (not dealing with a language or cultural barrier), an *administrative* factor (the medical chart was missing), or a *blunt end* factor (Medicare regulations). Often, multiple factors may be involved.

**DISCUSSION**

The results of this literature synthesis are important for 3 main reasons. First, they offer a summary of the current state of published research. Second, by synthesizing the results of this small body of literature, we were able to develop a working classification system of preventable adverse events (what went wrong) and process errors (why did it go wrong). Third, this classification may clarify the relations between patient safety, process errors, and preventable adverse events in primary care.

Other published classification systems of medical errors and preventable adverse events range from sparse (3 categories with 19 root causes)<sup>17</sup> to dense (80 categories with more than 12,000 branching trees).<sup>18</sup> They generally derive from stud-

ies of safety in non-medical industries<sup>17</sup> or from studies emphasizing hospital care.<sup>2,18</sup> In a recent review of the medical literature, Wilson and Sheikh noted the lack of a typology of medical errors in primary care and reasoned that the key safety issues in primary care are in the arenas of diagnosis, prescribing, communication, and organizational change.<sup>5</sup> Their conclusions are congruent with ours, and our more structured classification system contains these arenas.

The classification in Table 3 was generated from research in primary care settings by using data from practicing family physicians and general practitioners. (A more complete version of Table 3 may be found at <http://www.jfponline.com>.) If the classification is valid and useful, it should assist clinicians and researchers in understanding how process errors and preventable adverse events happen during the practice of primary care. Models assist us in understanding these relations. Among previously proposed models are the "Swiss Cheese"<sup>19</sup> and the "Toxic Cascades."<sup>20</sup> The Swiss Cheese model postulates that barriers exist to prevent adverse events, but they are like slices of Swiss cheese with many holes (or errors) in them. Adverse events happen when the holes in many layers temporarily line up. The Toxic Cascades model conceptualizes 4 levels of threats to patient safety: trickles, which leave little trace of their existence; creeks, which have potential seriousness; rivers, which are the actual errors that harm patients; and torrents, which are errors that lead to a patient's death or serious injury. From our classification, we can define some of the holes in the Swiss Cheese and name many trickles and creeks in primary care Toxic Cascades.

However, we found a striking gap in the literature of an absence of discussion of the contribution of patient factors to medical errors, despite a logic suggesting these are important issues.<sup>21,22</sup> A new model of patient safety dynamics should incorporate features of these models and add patient issues. Our proposed "Hourglass" model, derived from the classification system, incorporates 4 potential components of preventable adverse events in the primary care setting: 2 relating mainly to the primary health care system (process errors and patient safety factors) and 2 relating mainly to patients (patient risk factors for adverse events and patient-controlled patient safety factors; Figure). At the top of the hourglass, patient encounters enter like pieces of sand that flow through a health care system full of process errors that happen regularly. But, as in the Swiss Cheese model, there are barriers (patient safety factors) stopping these process errors from becoming preventable adverse events. Unfortunately, these barriers sometimes allow errors to slip through and a bad outcome results. Luckily, only a small number of patient encounters likely exits the primary health care system with a

preventable adverse event, as demonstrated by the narrow part of the hourglass.

Outside the doctor's office, factors in the patient's milieu influence the probability of a preventable adverse event occurring. We postulate an experience analogous to that within the health care system. There are more factors increasing a patient's likelihood of suffering a preventable adverse event,<sup>23</sup> but there are also patient-controlled factors serving as barriers against errors and their consequences. These are not well researched<sup>24</sup> but occur, for example, when a patient receives a blue pill from the pharmacy that had been pink in the past. The patient may prevent an adverse event by not taking the pill and double-checking with the clinician and pharmacist.

The order in which various process errors and safety factors interact with each other likely varies with each encounter and episode. Interactions within the classification suggest that, for any episode of disease or preventive care, the hourglass gets shaken and turned over numerous times as the health care system and patient factors interact with each other at multiple levels.

## FUTURE RESEARCH NEEDS

The literature review that led to our classification system and the proposed model of interaction have identified specific areas for future study. These include assessing patients' perspectives, investigating prevalence and causality, and testing interventions designed to improve patient safety. The current medical literature based primarily on physician reports describes events that are meaningful to the physician half of the dyad between patient and physician. Patients' opinions about what constitutes error and the role of patients as active participants in error and safety are unknown,<sup>24</sup> although preliminary studies are currently underway.<sup>25</sup>

No published studies to date have explored the prevalence of preventable adverse events and errors in primary care. Physician self-report biases reporting toward remembered events and errors. In addition, medical error studies to date have not directly studied causal links between errors and adverse events.<sup>26,27</sup> Observational and epidemiologic studies incorporating multiple methods may be necessary to ascertain and compare all components of the medical error equation: the amount of harm done, the preventable adverse events and near misses, the process errors, and the error-free functioning of the health care system. Although observational studies have assessed adverse events in a hospital setting<sup>28</sup> and described primary care practices,<sup>29</sup> they have not been used to assess preventable adverse events in the primary care setting.

This literature review and synthesis may have missed some studies that merited inclusion. Only

English-language studies were included. Studies pertaining to specific diseases, diagnoses, or treatments or from non-primary care settings may have shed light on the interaction of errors, adverse events, and harm but could not have helped in defining a classification system for primary care errors. The small number of studies available and their small sample sizes also limit the depth and breadth of derived classification components.

Decreasing medical errors and increasing patient safety are important parts of quality health care.<sup>30</sup> Currently, the research agenda aiming to identify effective error reduction strategies appears to be based more on ease of study subject or accessibility of patients than on the severity or importance of the problem.<sup>31</sup> By categorizing process errors and preventable adverse events and studying their relations more thoroughly and by adding the patient's perspective, interventions can be designed that address the most common and the most serious of preventable adverse events in primary care.

#### REFERENCES

1. Leape LL. Error in medicine. *JAMA* 1994; 272:1851-68.
2. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997; 277:312-7.
3. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324:377-84.
4. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000; 38:261-71.
5. Wilson T, Sheikh A. Enhancing public safety in primary care. *BMJ* 2002; 324:584-7.
6. Wilson T, Pringle M, Sheikh A. Promoting patient safety in primary care: Research, action, and leadership are required. *BMJ* 2001; 323:583-4.
7. Green L, Fryer G, Yawn B, Lanier D, Dovey S. The ecology of medical care revisited. *N Engl J Med* 2001; 344:2021-5.
8. Sheikh A, Hurvitz B. Setting up a database of medical error in general practice: conceptual and methodological considerations. *Br J Gen Pract* 2001; 51:57-60.
9. Victoroff MS. The right intentions: errors and accountability. *J Fam Pract* 1997; 45:38-9.
10. Bhasale AL, Miller GC, Reid S, Britt HC. Analysing potential harm in Australian general practice; an incident-monitoring study. *Med J Aust* 1998; 169:73-6.
11. Dovey SM, Meyers DS, Phillips RL Jr, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002; 11:233-8.
12. Ely JW, Levinson W, Elder NC, Mainous AG III, Vinson DC. Perceived causes of family physicians' errors. *J Fam Pract* 1995; 40:337-44.
13. Fischer G, Fetters MD, Munro AP, Goldman EB. Adverse events in primary care identified from a risk-management database. *J Fam Pract* 1997; 45:40-6.
14. Gandhi TK, Sittig DF, Franklin M, Sussman AJ, Fairchild DG, Bates DW. Communication breakdown in the outpatient referral process. *J Gen Intern Med* 2000; 15:626-31.
15. Holden J, O'Donnell S, Brindley J, Miles L. Analysis of 1263 deaths in four general practices. *Br J Gen Pract* 1998; 48:1409-12.
16. Britten N, Stevenson FA, Barry CA, Barber N, Bradley CP. Misunderstandings in prescribing decisions in general practice: qualitative study. *BMJ* 2000; 320:484-8.
17. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001; 76:125-33.
18. Runciman WB, Helps SC, Sexton EJ, Malpass A. A classification for incidents and accidents in the health-care system. *J Qual Clin Pract* 1998; 18:199-211.
19. Reason J. Human error: models and management. *BMJ* 2000; 320:768-70.
20. Toxic cascades: a comprehensive way to think about medical errors. *Am Fam Phys* 2000; 62:848.
21. Barach P, Moss F. Delivering safe health care. *BMJ* 2001; 232:585-6.
22. Deyo R. A key medical decision maker: the patient. *BMJ* 2001; 323:466-7.
23. Kohn L, Corrigan J, Donaldson M. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.
24. Pizzi L, Goldfarb N, Nash D. *Other Practices Related to Patient Participation in Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Rockville, MD: Agency for Healthcare Quality and Research; 2001. AHRQ publication 01-E058.
25. Kuzel A, Woolf S, Engel J, et al. Characterizing medical error in primary care settings. Paper presented at: North American Primary Care Research Group 29th Annual Meeting; 2001; Halifax, Nova Scotia.
26. Hofer TP, Kerr EA, Hayward RA. What is an error? *Effect Clin Pract* 2000; 3:261-9.
27. Brennan TA. The Institute of Medicine report on medical errors—could it do harm? *N Engl J Med* 2000; 342:1123-5.
28. Andrews LB, Stocking C, Krizek T, Gottlieb LKC, Vargish T, Siegler M. An alternative strategy for studying adverse events in medical care. *Lancet* 1997; 349:309-13.
29. Stange KC, Zyzanski SJ, Jaen CR, et al. Illuminating the "black box." A description of 4454 patient visits to 138 family physicians. *J Fam Pract* 1998; 46:377-89.
30. Committee on Health Care Quality in America. *Crossing the Quality Chasm. A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.
31. Ioannidis J, Lau J. Evidence on interventions to reduce medical errors. *J Gen Intern Med* 2001; 16:325-34.

**JFP**