Systems Analysis of Adverse Drug Events

Lucian L. Leape, MD; David W. Bates, MD, MSc; David J. Cullen, MD; Jeffrey Cooper, PhD; Harold J. Demonaco, MS, RPh; Theresa Gallivan, RN; Robert Hallisey, MS, RPh; Jeanette Ives, RN, MSN; Nan Laird, PhD; Glenn Laffel, MD, PhD; Roberta Nemeskal, RN; Laura A. Petersen, MD, MPH; Kathy Porter, RN, MSN; Deborah Servi, MS; Brian F. Shea, PharmD; Stephen D. Small, MD; Bobbie J. Sweitzer, MD; B. Taylor Thompson, MD; Martha Vander Vliet, RN; for the ADE Prevention Study Group

Objective.—To identify and evaluate the systems failures that underlie errors causing adverse drug events (ADEs) and potential ADEs.

Design.—Systems analysis of events from a prospective cohort study.

Participants.—All admissions to 11 medical and surgical units in two tertiary care hospitals over a 6-month period.

Main Outcome Measures.—Errors, proximal causes, and systems failures.

Methods.—Errors were detected by interviews of those involved. Errors were classified according to proximal cause and underlying systems failure by multidisciplinary teams of physicians, nurses, pharmacists, and systems analysts.

Results.—During this period, 334 errors were detected as the causes of 264 preventable ADEs and potential ADEs. Sixteen major systems failures were identified as the underlying causes of the errors. The most common systems failure was in the dissemination of drug knowledge, particularly to physicians, accounting for 29% of the 334 errors. Inadequate availability of patient information, such as the results of laboratory tests, was associated with 18% of errors. Seven systems failures accounted for 78% of the errors; all could be improved by better information systems.

Conclusions.—Hospital personnel willingly participated in the detection and investigation of drug use errors and were able to identify underlying systems failures. The most common defects were in systems to disseminate knowledge about drugs and to make drug and patient information readily accessible at the time it is needed. Systems changes to improve dissemination and display of drug and patient data should make errors in the use of drugs less likely.

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MEDICAL therapy results in unintended injuries that have been estimated to affect 1.3 million people each year in the United States. Many of these injuries are unavoidable, but as many as two thirds may be secondary to errors in management.[1] Thus, to decrease injury it is clear that efforts must be directed to reducing errors. Because injuries caused by medications, which we call adverse drug events (ADEs), are common in hospitals,[2-4] we have focused our preventive efforts on ADEs.

We recently found that 6.5% of adult nonobstetrical patients admitted to two teaching hospitals suffered an ADE (see accompanying article by Bates et al in this issue of *JAMA*[5]). Twenty-eight percent of these were due to errors, and in an additional 5.5% of patients, a potential ADE was averted by chance or interception of the error. In the Medical Practice Study, ADEs accounted for 19.4% of all disabling adverse events[6]; 45% were due to errors.[1] In a large insurers' study, injuries due to drugs were the most frequent cause of a procedure-related malpractice claim.[7] Thus, errors in drug use are common, costly, and often result in injury.

Although human errors result from a number of complex cognitive mechanisms,[8-10] investigations of major accidents, such as Three Mile Island and the *Challenger* disaster, indicate that an accident is often the end result of a chain of events set in motion by faulty system design that either induces errors or makes them difficult to detect.[8,11] Many medical injuries may also result from systems failures.[10] Examples include work environments where there are frequent interruptions that lead a person to forget to do something, and the packaging of two drugs in similar containers so that one is easily mistaken for the other. Poor system design also makes errors difficult to detect in order for them to be intercepted before injury occurs. Poor system design creates "accidents waiting to happen."[11,12]

The concept of systems failures as the underlying causes of errors has not been widely accepted in the practice of medicine. Rather, traditional efforts at error reduction have focused on individuals and episodes, using training, exhortation, rules, and sanctions to improve performance.[10] Human factors specialists and error experts reject this approach, noting that it is more effective to change the system as a whole to reduce the likelihood of accidents.[13] The objectives of system design for safety are twofold: (1) to make it difficult for individuals to

err, and (2) to "absorb" errors that do occur, ie, permit their detection and correction before harm occurs.

If the systems theory of causation of errors is correct, then the first step in an error prevention program would be to identify the systems failures underlying the errors that occur. To this end, we investigated errors in the use of medications in hospitalized patients with the intent of discovering underlying systems failures that would be amenable to correction. Because most drug errors do not cause injury (missing a single dose of a drug may not be harmful, for example), we focused on errors that either caused ADEs or were judged to represent potential ADEs. The latter are errors that have the capacity to cause injury, but fail to do so, either by chance or because they are intercepted. If most errors can be traced to systems failures, and if many of the errors can be accounted for by a reasonably small number of systems failures, those systems would be obvious targets for change.

METHODS

Sample

The study population consisted of all nonobstetric adult patients at two tertiary hospitals, Brigham and Women's Hospital and Massachusetts General Hospital, admitted to any of 11 units over a 6-month period, February through July 1993, with the exception that at one hospital, patients from two surgical intensive care units were studied for the first 3 months, and then patients from a medical intensive care unit were studied for the final 3 months. The study units included five of 15 adult intensive care units (three surgical and two medical) and six of 46 adult nonobstetric general care units (four medical and two surgical) in the two hospitals.

Identification of ADEs and Potential ADEs

We identified actual and potential drug-related injuries as described elsewhere.[5] Briefly, trained nurse investigators visited each study unit at least daily to solicit voluntary reports from unit personnel regarding possible ADEs and potential ADEs. In addition, they reviewed each patient's hospital record each day to discover evidence of errors or complications related to drug use. If an error was found, further investigation was carried out. In questionable cases, the nurse investigators discussed the case promptly with a physician investigator (D.W.B., D.J.C., L.A.P., S.S., B.S.) who identified those that might be due to errors and were, therefore, potentially preventable.

Investigation of ADEs and Potential ADEs

Because it is known that an observer's memory for details may decay quickly,[14] each possibly preventable ADE or potential ADE was investigated promptly to determine if there was an error, and if so, the circumstances and apparent proximal causes. All parties with knowledge of the incident were interviewed by a peer case investigator (eg, physician by physician, nurse by nurse, and pharmacist by pharmacist). Using a structured form to ensure that similar types of data were obtained for all cases, case investigators obtained details of the circumstances surrounding the incident and the interviewee's perception of why it occurred. Emphasis was placed on understanding the cause of the error, not on assigning responsibility. Respondents were assured that the information they gave would remain confidential and would not be used for disciplinary proceedings. The investigators and review boards agreed that if patterns of care that could be harmful to a patient or future patients were detected, that information would be brought immediately to caregivers and appropriate authorities. All data were recorded without names of respondents, and patient names and hospital numbers were removed from the records once all interviews were completed. The study was approved by the human subjects committees at both hospitals and at the Harvard School of Public Health.

Classification of Incidents

Each incident was classified independently by two physicians as an ADE, a potential ADE, or excluded. Adverse drug events and potential ADEs were further classified as to whether they were preventable (due to an error or other correctable cause) and, if due to an error, according to the type of error (wrong dose, known allergy, and the like).

Systems Analysis of ADEs and Potential ADEs

The results of the investigations of preventable ADEs and potential ADEs were analyzed at biweekly meetings in each hospital. The analysis group consisted of the principal investigators, nurse and physician case investigators, project manager, a systems analyst, and administrative leaders from nursing and pharmacy. Each event was first ascribed to failures in one or more of four sequential stages in the drug ordering-delivery system: (1) physician ordering, (2) transcription and verification, (3) pharmacy dispensing and delivery, and

(4) nurse administration to the patient. Some events were attributed to multiple errors. For example, if a patient was ordered for and received an overdose of a drug, an error was attributed to three stages: ordering, dispensing, and administration, because physicians, pharmacists, and nurses were all considered to have an opportunity to prevent this error at these stages.

Next, each error was classified according to its proximal cause. We defined "proximal cause" as the apparent "reason" the error was made. These are broad categories that are useful for focusing further inquiry; they are not true "causes," but domains where the underlying problems will be found. These categories were developed during the study as cases were analyzed and are illustrated in Table 1. The identification of proximal causes was based on the information obtained from the interviews of those who discovered the errors and those who made them, and represents a consensus of the systems analysis group as to the most likely cause. In some instances, more than one proximal cause was identified. For example, a preparation error could be due to lack of knowledge of the drug, lack of standardized solutions, or a simple slip (an inattention error of execution). For analytic purposes, we linked each error to the one proximal cause that the systems analysis group judged to be most important.

Finally, the underlying systems failures were identified and ideas were generated as to how systems could be redesigned to reduce the failures. "System" was defined as "an interdependent group of items, people, or processes with a common purpose."[15] Some systems are broadly inclusive and complex (such as the system for drug knowledge dissemination) while others are simpler (the system for dose checking). In this final stage, errors and proximal causes were sometimes linked to failures in more than one system.

RESULTS

During the study period, we identified 247 ADEs, of which 70 (28%) were due to errors, and 194 potential ADEs, which were errors by definition (see accompanying article by Bates et al[5] in this issue of *JAMA*). Thus, the total number of preventable events was 264. The systems analysis group identified errors in more than one stage in 55 (21%) of the preventable ADEs and potential ADEs, for a total of 334 errors associated with these 264 events. The following results use the error as the unit of analysis.

When we examined the distribution of the 334 errors by stage and by type of

Table 1.—Proximal Causes of Errors in Use of Medications

Proximal Cause	Definition	Examples
Lack of knowledge of the drug	Inadequate knowledge of indications for use, available forms, appropriate doses, routes, and compatibilities	At the physician ordering stage: excessive doses of haloperidol in the elderly; overdoses of various drugs in patients in renal failure At the nurse administration stage: rapid infusion of vancomycin that resulted in hypotension; administration of phenytoin in an incompatible solution
Lack of information about the patient	Nurse, physician, or pharmacist was unaware of an important aspect of the patient's conditon	Physician: ordering morphine for a patient with ileus; prescribing potassium chloride for a patient in renal failure Nurse: giving an antihypertensive medication to a patient with a low blood pressure measurement Pharmacist: dispensing an antibiotic to a patient with a known allergy
Rule violations	Failure to follow accepted and well-established procedures	Physician: failure to write orders in an acceptable form (eg, omitting route or frequency) Nurse: giving an infusion of red blood cells with 5% dextrose injection instead of 0.9% sodium chloride injection
Slips and memory lapses	Errors in which the individual "knew better" and could not explain why the error occurred, or just forgot	Physician: an order for 1 g of lorazepam instead of 1 mg; an order for acetaminophen per rectum following rectal surgery Nurse: missed or late doses due to memory lapses
Transcription errors	Unexplained errors associated with the order transcription and verification process	Includes a variety of omissions, inadvertent cancellations or duplications, and dose transcription errors, such as reversing the doses between two drugs, or charting a drug that is to be administered every 8 hours (q8h) as every 6 hours (q6h); mostly slips
Faulty drug identity checking	Pharmacists' and nurses' checking errors that resulted in patients' getting (or nearly getting) the wrong medication	Patient received phenylephrine instead of fentanyl by epidural catheter; ceftriaxone dispensed instead of clindamycin; errors due to confusion of drugs with similar names or similar packaging
Faulty interaction with other services	Problems in communicating with others (particularly physicians) and errors that occur when patients are in transition between services or units	Hypoglycemia due to lack of awareness that patient had received insulin prior to transfer; delay in filling order because of inability to verify with physician
Faulty dose checking	Failure to insure that proper dose was dispensed or administered	Overdoses because of errors in drawing up medications
Infusion pump and parenteral delivery problems	Errors in setting pumps; accidental tubing disconnections; confusion between central and peripheral lines	Overdose of heparin because of error in setting infusion pump; administration of parenteral nutrition fluid through peripheral line instead of central line
Inadequate monitoring	Failure to adjust the dose of a medication appropriately either because necessary monitoring (blood levels, vital signs, laboratory values) was not carried out or the changes were ignored	Seizures due to prolonged subtherapeutic doses of phenytoin; heparin dose not decreased despite increasing partial thromboplastin time
Drug stocking and delivery problems	Otherwise unexplained late or missing deliveries of medications to the patient care units	6- to 18-hour delays in receiving antibiotics for a patient with a serious infection
Preparation errors	Pharmacist and nurse errors in calculation and mixing of drugs that resulted in incorrect doses	Lorazepam drip solution prepared in too high a concentration; vasopressin dose excessive
Lack of standardization	Administration errors by nurses that resulted from nonstandard concentrations, dosing schedules, and infusion rates	10 times overdose of epidural fentanyl due to provision of vial with nonstandard concentration

Table 2.—Errors by Type of Adverse Drug Event (ADE) and Stage of Drug Ordering and Delivery*

	Physician Ordering, No. (%)	Transcription and Verification, No. (%)	Pharmacy Dispensing, No. (%)	Nurse Administration, No. (%)	All, No. (%)
Preventable ADEs	41 (32)	2 (5)	4 (11)	40 (32)	87 (26)
Potential ADEs, nonintercepted	26 (20)	25 (63)	21 (55)	84 (67)	156 (47)
Potential ADEs, intercepted	63 (48)	13 (33)	13 (34)	2 (2)	91 (27)
Totals	**130** (100)	**40** (100)	**38** (100)	**126** (100)	**334** (100)
% by stage	39	12	11	38	100

*Percentages may not add to 100% due to rounding.

event (Table 2), we found that most errors occurred in the physician ordering (39%) and nurse administration (38%) stages. The remainder were nearly equally divided between transcription and pharmacy dispensing. Although there were almost as many errors in the administration stage as in ordering (126 vs 130), nurses were the ones most likely to intercept errors, especially those made by physicians. Nearly half of physician errors (63) were intercepted, 55 by nurses and eight by pharmacists. About one third of transcription and dispensing errors were intercepted—again, largely by nurses prior to administration. In contrast, only 2% of drug administration errors were intercepted. Overall, nurses were responsible for 86% of all interceptions, and pharmacists for 12%.

Types of Errors

Dosing errors were by far the most common type of error, occurring more than three times as frequently as the next most numerous error type and accounting for 28% of all errors (Table 3). Most of the wrong dose errors (50 of 95) occurred in the physician ordering stage. Thirty-five (70%) of these were intercepted, whereas only two (6%) of the 34 wrong dose errors in the nurse administration stage were intercepted. Of the common errors, wrong choice and wrong dose were most likely to have actually caused an injury (42% of all ADEs), while errors in frequency or timing seldom caused an ADE. Wrong choice errors were judgment errors in which the reviewers disagreed with the choice of drug or dose for a particular patient. Most orders involving errors were handwritten, but approximately 12% were entered by computer, and 3% of errors involved a telephone order.

Proximal Causes

As with errors, proximal causes often cut across multiple stages (Table 4). Overall, lack of knowledge of the drug was the most common proximal cause, accounting for 72 (22%) of 334 errors. At the physician ordering stage, these included such things as lack of awareness of drug interactions (such as warfarin and trimethoprim-sulfamethoxazole) and use of inappropriately large doses of haloperidol in the elderly. At the nurse administration stage, examples were overdose of antiemetics, mixing drugs in incompatible solutions, and overly rapid infusions of intravenous (IV) drugs.

Lack of information about the patient was second in frequency, with 48 errors (14%). Examples are an order for potassium by a physician who did not know the patient was in renal failure, and an order for morphine for a patient who the

Table 3.—Types of Errors by Stage of Drug Ordering and Delivery*

Error	Physician Ordering, No. (%)	Transcription and Verification, No. (%)	Pharmacy Dispensing, No. (%)	Nurse Administration, No. (%)	All, No. (%)
Wrong dose	50 (38)	5 (13)	6 (16)	34 (27)	95 (28)
Wrong choice	25 (19)	0 (0)	0 (0)	5 (4)	30 (9)
Wrong drug	3 (2)	0 (0)	11 (29)	15 (12)	29 (9)
Known allergy	15 (12)	5 (13)	0 (0)	7 (6)	27 (8)
Missed dose	0 (0)	9 (23)	5 (13)	10 (8)	24 (7)
Wrong time	1 (1)	1 (3)	12 (32)	9 (7)	23 (7)
Wrong frequency	8 (6)	10 (25)	0 (0)	2 (2)	20 (6)
Wrong technique	2 (2)	0 (0)	0 (0)	18 (14)	20 (6)
Drug-drug interaction	5 (4)	1 (3)	0 (0)	3 (2)	9 (3)
Wrong route	3 (2)	0 (0)	0 (0)	3 (2)	6 (2)
Extra dose	0 (0)	1 (3)	0 (0)	3 (2)	4 (1)
Failure to act on test	3 (2)	0 (0)	0 (0)	1 (1)	4 (1)
Equipment failure	0 (0)	0 (0)	0 (0)	3 (2)	3 (1)
Inadequate monitoring	1 (1)	0 (0)	0 (0)	1 (1)	2 (1)
Preparation error	0 (0)	0 (0)	2 (5)	0 (0)	2 (1)
Other	14 (11)	8 (20)	2 (5)	12 (10)	36 (11)
Totals	**130** (100)	**40** (100)	**38** (100)	**126** (100)	**334** (100)

*Percentages may not add to 100% due to rounding.

physician did not know had ileus. Drug administration errors included giving furosemide to a hypotensive patient and insufficient premedication prior to chemotherapy. Lack of information about the patient also included 15 orders for medications to which the patient had known allergies as documented in the hospital chart.

In the physician ordering stage, two proximal causes, lack of knowledge of the drug and lack of information about the patient, accounted for 60% of all proximal causes. Other major proximal causes in the first stage were rule violations (19%) (especially those related to improper ordering of potassium chloride), simple slips (inattention errors) and memory lapses (11%), and inadequate monitoring (8%).

In the nurse administration stage, lack of knowledge of the drug was also the most common proximal cause and accounted for 15% of the problems in this stage. Misuse of infusion pumps and other parenteral delivery systems was next (13%), followed by slips and memory lapses (12%). Faulty drug identity checking (10%) led to 12 patients' receiving the wrong drug. Faulty dose checking (10%) in two instances led to patients' receiving 10 times the ordered dose. Interaction problems with other services also accounted for 10% of problems in this stage. Lack of information about the patient (10%) led nurses to administer drugs to five patients known to be allergic to them (but they also intercepted 10 other such orders).

In the transcription stage, 29 (73%) of 40 errors were due to slips (such as a misprint) and memory lapses, followed by lack of knowledge of the drug (15%) and lack of information about the patient

(mostly faulty allergy checking) (10%). Transcription slips comprised half of all slips and 9% of all errors, more than were caused by faulty drug identity checking or dose checking, for example.

Failures in drug identity checking (29%) and stocking or delivery problems (29%) were the leading proximal causes of errors related to the pharmacy dispensing stage. Sound-alike names and look-alike packaging were prominent causes of identity errors.

Relationship of Proximal Causes to Error Types

A single proximal cause can result in a variety of types of errors. For example, lack of knowledge of the drug was most likely to result in an improper dose, but wrong choice of medication and wrong technique of administration were also seen frequently (Table 5).

Conversely, one type of error can result from several different proximal causes (Table 6). A patient may receive the wrong dose of a medication because a physician lacks knowledge of the drug, but it can also result from a rule violation by nurse or physician, a failure of dose checking by pharmacist or nurse, or a slip at any stage.

Systems Failures

The systems analysis groups identified 16 major systems failures underlying the errors and proximal causes that were recognized (Table 7). The systems described are broadly defined. For example, "drug knowledge dissemination" is typically viewed as drug education, whether in medical school, during residency, at hospital conferences, at a postgraduate course, or by continuing self-education, but it can also be usefully

considered as the sum of methods that are used to make information about drugs available to physicians, nurses, and pharmacists at the time of use.

1. Drug Knowledge Dissemination (98 Errors).—Physicians made many prescribing errors that appeared to be due to deficiencies of knowledge of the drug and how it should be used. These included incorrect doses, forms, frequencies, and routes of administration, as well as errors in the choice of drug. Examples include failure to order a test dose of amphotericin B and an order for amitriptyline for an elderly patient (amitriptyline is strongly anticholinergic and gerontologists recommend using other antidepressants in the elderly). Nurses also made errors related to lack of understanding of the drug, but these were less frequent and less likely to lead to an ADE.

2. Dose and Identity Checking (40 Errors).—The systems for verifying that the proper drug is delivered in the proper dose sometimes failed in both the pharmacy dispensing and nursing administration stages. A significant cause of identity errors was look-alike packaging and sound-alike names for drugs. Quality control for these functions still relies entirely on inspection.

3. Patient Information Availability (37 Errors).—Information about the patient's condition, results of laboratory tests, current medications, and recent doses (particularly of narcotics) was sometimes not easily accessible when it was needed, leading to prescribing errors as well as inappropriate administration of ordered drugs. Pharmacists sometimes lacked information about clinical characteristics of patients and results of laboratory tests that would have enabled them to intercept an improper order. While most of the needed patient information was available somewhere, it was not always readily accessible. For example, from a remote location a covering physician often could not easily determine all the medications a patient had recently received.

4. Order Transcription (29 Errors).—The need to manually transcribe physicians' orders onto medication sheets leads to errors because unit secretaries lack medical training and physicians' handwriting is often illegible. Error detection depends on subsequent inspection by nurses.

5. Allergy Defense (24 Errors).—Patients sometimes received medications to which they had known allergies, even when the physician had noted the allergy in the admission workup and even when a notation was present on the medication administration record. The system depends on manual checks that are unreliable, and the system did not en-

Proximal Cause	Physician Ordering, No. (%)	Transcription and Verification, No. (%)	Pharmacy Dispensing, No. (%)	Nurse Administration, No. (%)	All, No. (%)
Lack of knowledge of the drug	47 (36)	6 (15)	0 (0)	19 (15)	72 (22)
Lack of information about the patient*	31 (24)	4 (10)	0 (0)	13 (10)	48 (14)
Rule violations	25 (19)	0 (0)	6 (16)	2 (2)	33 (10)
Slips and memory lapses	14 (11)	0 (0)	0 (0)	15 (12)	29 (9)
Transcription errors	0 (0)	29 (73)	0 (0)	0 (0)	29 (9)
Faulty drug identity checking†	0 (0)	0 (0)	11 (29)	13 (10)	24 (7)
Faulty interaction with other services	1 (1)	0 (0)	3 (8)	13 (10)	17 (5)
Faulty dose checking	0 (0)	0 (0)	3 (8)	13 (10)	16 (5)
Infusion pump and parenteral delivery problems	0 (0)	0 (0)	0 (0)	16 (13)	16 (5)
Inadequate monitoring	11 (8)	0 (0)	0 (0)	4 (3)	15 (4)
Drug stocking and delivery problems	0 (0)	0 (0)	11 (29)	0 (0)	11 (3)
Preparation errors	0 (0)	0 (0)	4 (11)	6 (5)	10 (3)
Lack of standardization	0 (0)	0 (0)	0 (0)	8 (6)	8 (2)
Unclassified	1 (1)	1 (3)	0 (0)	4 (3)	6 (2)
Totals‡	130 (100)	40 (100)	38 (100)	126 (100)	334 (100)

*Includes 24 errors related to medications to which patients had known allergies.
†Includes 10 cases involving errors due to name confusion.
‡Percentages may not add to 100% due to rounding.

sure that physicians, nurses, and pharmacists had drug allergy information when they needed it.

6. Medication Order Tracking (18 Errors).—The system for processing a medication order from ordering through administration of the drug to the patient is complex, involving multiple individuals, groups, and departments. There is no mechanism for easily identifying at any instant where the order or medication is in the process. Consequently, a great deal of time is wasted by nurses (primarily) and others in finding out where an order or medication is when it is not processed efficiently. It is sometimes difficult to tell from the data recorded if or when a medication has been given, missed, discontinued, or changed. Because doses are sometimes recorded in more than one location, it may be difficult to discern the extent of cumulative doses of some drugs (especially narcotics).

7. Interservice Communication (17 Errors).—Communication between personnel from different services was sometimes poor. For example, it was sometimes difficult for a nurse or pharmacist to determine which physician had written an order for a drug or dose that seemed inappropriate and to contact that physician. Nurses also sometimes had trouble contacting pharmacists.

8. Device Use (12 Errors).—The variety of types of infusion pumps (eight in one hospital) makes it difficult for nurses to obtain and maintain the expertise needed to use them properly.

9. Standardization of Doses and Frequencies (12 Errors).—There are no hospital-wide standards for dosing schedules, and even generally accepted doses and dosing schedules were often not followed

by physicians. In addition, the hours when medications are given vary among patient care units. Lack of standardization of orders greatly increases the time and thought that must be given to medications by the nurses, and increases the likelihood of errors. In one hospital, physicians used six different variants of the "K-scale" (a graduated scale for giving potassium replacement).

10. Standardization of Drug Distribution Within Unit (11 Errors).—Medications are delivered by pharmacy technicians to a central repository bin on each floor, but what happens next varies from unit to unit, as well as by time of day. There is no standardized system for ensuring that the medications get to the correct medication drawer at the right time for use by the patient.

11. Standardization of Procedures (10 Errors).—The locations and use of medication drawers, order sheets, medication administration records, and IV supplies vary substantially from unit to unit. Because physicians, pharmacists, and nurses care for patients on many different units, these variations lead to reduced efficiency and increased risk of error.

12. Preparation of IV Medications by Nurses (Six Errors).—Approximately 40% of IV medications are prepared by nurses in the units. In addition, for some medications, the doses are calculated and drawn up by the nurse from bulk supplies on the floor. Each of these operations provides opportunities for multiple errors: in calculating the amounts, in drawing up, in mixing, and in labeling.

13. Transfers/Transition Problems (Four Errors).—Errors in the administration of drugs sometimes occurred

when a patient was in physical transition from one place to another, such as during transfer from one unit to another or when off the unit, eg, for an x-ray or test. This appeared to result in part from ambiguity about who was responsible for the patient and in part from suspension of the usual unit procedures that help to ensure safe administration of drugs to patients.

14. Conflict Resolution (Four Errors).—Although there are some procedures for dealing with conflicts, such as when a nurse or pharmacist questions a physician's order and is rebuffed, many nurses and pharmacists were unaware of the procedures or did not feel they were workable or effective.

15. Staffing and Work Assignments.—Three deficiencies were noted: (1) excessive workloads due to inability to match staffing assignments to the clinical load when there were fluctuations in patient census and severity of illness, (2) variations in the availability of experienced nurses, so that novice nurses were sometimes inadequately supervised and assisted, and (3) the structuring of the patient care environment so that most nurses work autonomously most of the time. The last sometimes led nurses to fail to seek assistance when needed. Staffing and work assignment deficiencies were thought to be major causes of a large number and variety of errors.

16. Feedback About ADEs.—Physicians and nurses received little follow-up information about drug-related errors, even when they were discovered.

Although these systems are technically "subsystems" of the larger system for medication delivery, even these sys-

Table 5.—Types of Errors Caused by a Single Proximal Cause: Lack of Knowledge of the Drug (72 Errors)

Error	No. (%)
Wrong dose	29 (40)
Wrong choice	11 (15)
Wrong technique	11 (15)
Wrong drug	4 (6)
Drug-drug interaction	4 (6)
Other	13 (18)

Table 6.—Proximal Causes Resulting in a Single Type of Error: Wrong Dose (95 Errors)

Proximal Cause	No. (%)
Lack of knowledge of the drug	29 (31)
Rule violation	17 (18)
Faulty dose checking	13 (14)
Slips	9 (9)
Other	27 (28)

tems might advantageously be subdivided. The design of a system for making patient information available in a useful form at the time and place it is needed by physicians, for example, might well differ considerably from that for making the same information available to a pharmacist dispensing drugs in the central pharmacy.

Failures in seven systems: drug knowledge dissemination, dose and identity checking, availability of patient information, order transcription, the allergy defense system, medication order tracking, and interservice communication, accounted for 78% of the errors.

The system with the highest number of errors was the system for disseminating drug knowledge, particularly to physicians. Errors attributed to lack of knowledge about drugs accounted for 91 (35%) of the 264 preventable ADEs and potential ADEs in this study. These errors appeared to reflect lack of knowledge not only about dosage and routes, but also about drug interactions and contraindications in certain patients (such as the elderly). The system with the next highest number of errors was the system for dose and identity checking, both in dispensing drugs and in administering them to patients. This system relies heavily on manual inspection at each step of the process. The system for making patient information available when it is needed was the next most frequent cause of errors. Combined with failures in the allergy defense system, together these two systems accounted for 14% of the errors we found.

Interhospital Comparison of Systems Failures

The majority of the systems failures were identified at both hospitals. Problems resulting from defects in drug knowledge dissemination, dose and

identity checking, patient information availability, interservice communication, nurses' preparation of medications, and standardization of doses and procedures were all common at both hospitals. However, there were also substantial differences. One hospital identified the allergy defense system, conflict resolution, and transfer procedures as major systems problems, while the other emphasized staffing and work assignments, medication order tracking, and device utilization as more important.

COMMENT

Using prompt, intensive investigation followed by multidisciplinary systems analysis, we uncovered both proximal and systemic causes of the errors that resulted in 264 preventable ADEs and potential ADEs. This systems approach is based on the concept that although individuals make errors, characteristics of the systems within which they work can make errors more likely and also more difficult to detect and correct. Further, it takes the position that while individuals must be responsible for the quality of their work, more errors will be eliminated by focusing on systems than on individuals. It substitutes inquiry for blame and focuses on circumstances rather than on character. This approach is fundamentally different from the search for "outliers" that has characterized much of medical quality evaluation. It is worth noting that during our study we found no instance of an individual with a pattern of repeated egregious errors.

The Search for Third -Order 'Whys'

Our approach to understanding the causes of errors can be conceptualized as a "search for the third order 'why?' ": (1) why did the incident occur? (2) why did the error occur? (3) why did the proximal cause occur? In other words, what was the error, what was its proximal cause, and what were the underlying system failures?

As an example, consider an elderly patient who has become obtunded from haloperidol: (1) Why did the patient became comatose? Answer: She received too large a dose ("wrong dose") of the drug. (2) Why did the patient get the wrong dose? Answer: The physician didn't know the proper dose of this drug for elderly patients. (3) Why didn't the physician know the correct dose? Answer: The drug knowledge dissemination system is inadequate. While this method of analysis is simple and straightforward, in practice it is seldom followed; the third-order "why?" is rarely asked.

Three aspects of this strategy of error investigation deserve emphasis.

First, it is not until one gets to the third-order "why" that useful insights for designing effective remedial measures begin to be achieved. Even deeper inquiry is often needed—fourth- or fifth-order "whys." Underlying causes are seldom solitary or linear, but they can usually be identified. Reason and others have stressed that "quick fixes," corrective measures directed at preventing a specific error (or preventing a specific individual from making an error), have short-lived benefit.[8]

Errors are like symptoms of diseases—they can be caused by multiple conditions, and treatment of the error or symptom does not correct the underlying malfunction. In both errors and symptoms, "cure" requires attacking the underlying causes. It is modification of these underlying causes, or systems failures, that is most likely to be successful in reducing errors.[8] In the example given, providing a suggested dose (such as by a computerized system that presents the information at the time the order is written) could potentially eliminate a multitude of dosing errors by many parties, whereas concentrating on one individual's defective knowledge improves the performance of one physician regarding one drug.

Second, most preventable injuries are not due to just one system failure, but result from breakdowns at several points in the system.[8] Our present drug-ordering and delivery systems already have safety nets, so several defenses must often be breached for injury to occur. For example, a notation regarding medication allergy is usually placed in the patient history, on the medication order sheets, on the medication record form, and on the front of the hospital chart. However, a failure to copy the notice onto subsequent forms combined with a telephone order from a "covering" physician to a new nurse can result in the patient receiving the medication.

Third, how one defines the "system" that fails has a powerful effect on remedial strategy. In the example given above of a physician prescribing an incorrect dose, it is traditional to ascribe the error to the individual's failure to learn, remember, or know when to look it up. A systems approach might assign the responsibility instead to the educational process. However, one could just as readily claim that the error resulted from a failure of (1) availability of critical information at the time it is needed for decision making, or (2) the dose-checking and dose-monitoring system (computerized or human) to detect erroneous doses, or (3) the system for assessing physicians' drug knowledge, or all of the above, or other as yet untried alternative systems.

Table 7.—Systems Failures

System	Attributed Errors, No. (%)
1. Drug knowledge dissemination	98 (29)
2. Dose and identity checking	40 (12)
3. Patient information availability	37 (11)
4. Order transcription	29 (9)
5. Allergy defense	24 (7)
6. Medication order tracking	18 (5)
7. Interservice communication	17 (5)
8. Device use	12 (4)
9. Standardization of doses and frequencies*	12 (4)
10. Standardization of drug distribution within unit*	11 (3)
11. Standardization of procedures*	10 (3)
12. Preparation of intravenous medications by nurses	6 (2)
13. Transfers/transition procedures	4 (1)
14. Conflict resolution	4 (1)
15. Staffing and work assignments*	. . .
16. Feedback about adverse drug events*	. . .

*Systems failures that underlie a variety of errors and other systems failures. Attributed errors for these systems refer to those for which no other causes were identified. Staffing and work assignment deficiencies, for example, were believed to be the underlying causes of a broad range of errors such as slips, dose- and identity-checking errors, breakdown of allergy defense, and the like.

Evidence that the current drug education system is inadequate suggests that remedial strategies directed toward other alternatives might be worth considering. Multiple systems changes may be needed. For example, humans make fewer errors when shown only appropriate alternatives,[16] which can be done using menus at the time of ordering by computer. Dose checking is also probably most efficiently handled by computer. On the other hand, changes in physicians' decisions regarding the choice of drug, which requires a change in belief, may be most successfully effected by a person-to-person encounter, eg, by counter detailing by academically based pharmacists.[17,18] All these systems changes relate to improving the drug knowledge dissemination system.

As Reason has found in industrial studies,[8] we observed that a single proximal cause or a single system fault could result in a variety of types of errors, and a single type of error resulted from several different proximal causes and systems failures. Thus, our findings support his contention that attempts to eradicate a single type of error (the usual approach in most hospitals) are unlikely to have a major impact on the overall problem. Unless the underlying systems failures are corrected, new errors will crop up.

Types of Systems Failures

The first seven systems failures (defects in drug knowledge dissemination, dose and identity checking, availability of patient information, order transcription, the allergy defense system, medi-cation order tracking, and interservice communication) all have in common impaired access to information. They result primarily from design faults. These include defects in conceptualization and planning, failure to recognize service needs, and failure to adapt systems to changing demands and changing technology. Some of these systems were never "designed" in any formal sense at all. Others were designed when the practice of medicine was much simpler. Because design defects result from actions in the past by individuals at higher levels of the organization, they are well beyond the ability of frontline operators (physicians, nurses, pharmacists) to control or, in many cases, even recognize. Failures in these seven systems alone accounted for 78% of the errors we uncovered.

In contrast, most of the remaining systems failures (Nos. 8 through 16) represent failures primarily in management and training, although these defects, too, obviously have design components and involve information processing. Inadequate standardization—of doses, frequencies, and distribution of drugs, and procedures for their use—is the major managerial failure we identified. Although it is sometimes difficult to attribute specific errors to it, lack of standardization underlies many of the other systems failures as well. Breakdowns in dose checking and the allergy defense systems, for example, are in part the result of nonadherence to standard procedures. Given the success of standardization in industry, for example, in aviation, where it has been found to be one of the most powerful means of reducing error, increased standardization should be effective in hospital care as well. These kinds of changes (for example, hospital-wide standardization of doses) require top-level decisions. Other defects, such as those in staffing and work assignments, can sometimes be dealt with by unit-level management, although choices may be constrained by higher level decisions concerning resource allocation. As with design failures, however, frontline operators—those who make the errors in drug use—have limited ability to correct these systems problems on their own.

An Illustrative Example: The Allergy Defense System

The allergy defense system in place at one of the hospitals at the time of the study illustrates how a poorly designed system can result in errors despite the best intentions of providers. Recording of allergies could be done by as many as six individuals in various parts of the medical record. Each medication order was required to be checked at each stage for allergies. The admitting physician made a note in the patient history, but there was no single place that a subsequent physician could reliably find allergy information. At the transcription stage, the person stamping up each order sheet was supposed to write the allergies on the top of every order page, but this rarely occurred, and even when it did, it was sometimes ineffective: there were instances in which an allergy to a medication was recorded, but an order for the same medication was written immediately below it! Nurses entered allergy information from intake interviews on the medication sheets. At the dispensing stage, the pharmacists were expected to perform a visual check on their computer screens each time they dispensed a medication, but this checking was not automated, and only allergies that were noted in the orders were known to the pharmacy. Finally, nurses were supposed to check each medication against the medication administration record for allergies before administering medications. Despite all of the above, it was easy for harried physicians to write erroneous orders, and about a third of these slipped through the rest of the system.

Systems Changes to Reduce Errors

Remedy of design deficiencies requires top-level management decisions and, usually, commitment of additional resources. Management and training deficiencies are also often institution-wide problems that require top-level action and commitment. However, some managerial problems, such as inappropriate work schedules, can be corrected by middle managers without additional resources. Enlisting frontline personnel—nurses, pharmacists, and physicians—in the process by means of quality improvement teams may be an fruitful way to ensure that changes are appropriate and that they are effectively implemented.

One of the most effective methods of reducing systems failures is to simplify the systems. Complex systems provide multiple opportunities for errors. For example, the elaborate multistage system of ordering, transcribing, verifying, and transmitting medication orders from order book to pharmacy offers several opportunities for errors. In addition, complex systems are more likely to be "opaque." That is, because of nonlinear and interlocking relationships of components, the causes of failures in complex systems are sometimes not apparent to frontline operators, who may therefore be unable to take corrective action in time.[11]

A major common theme underlying the systems failures that we identified was impaired access to information. Physicians, nurses, and pharmacists need to have a great deal of information about drugs, including mechanism of action, side effects, dosing options, and interactions, to be able to use them wisely and safely. They also need ready access to patient information, such as blood levels, results of laboratory tests, and the amount of narcotics received in the preceding 24 hours. Both kinds of information must be available when they are needed and in a form that is useful.

These problems in information collection, retrieval, and display are those for which computers are particularly suited and about which considerable expertise exists.[19-21] While there has been an interest in the subject of "computers in medicine" for more than 30 years, in 1995 most hospitals have only rudimentary systems for collecting and retrieving clinical information, and few are able to present information in a manner that facilitates bedside use. Even fewer have the capability to pull data from different systems and present it at the time of ordering when it can have the greatest impact. Nurses, pharmacists, and physicians still usually seek drug information in printed references, which can be hard to locate at the time they are needed. Our findings make a compelling case for accelerating the computerization of both drug and clinical information to make it available to all who need it, at each stage of the process, in a form that is easy to use and understand.

In one of the hospitals, a computerized physician order entry system has recently been implemented that provides dosing information and gives reminders about drugs at the time orders are written. This system addresses the twin objectives of systems changes: decreasing the likelihood that an error will occur and increasing the chances of intercepting errors that do occur. The computer system will reduce the likelihood of errors by facilitating access to information at the time it is needed for ordering and by reducing the number of choices to be made by the physician by showing only acceptable doses and frequencies. It also will include "forcing functions"[9] that make certain types of errors impossible, such as refusal to execute an order that does not specify the time schedule for dosing. By providing the orders to nursing and pharmacy simultaneously, it will eliminate transcription errors. It will increase the likelihood of intercepting errors by means of checks and reminders (eg, for drug-drug interactions) that identify errors before the order is executed.

For example, the new allergy reaction prevention system takes advantage of computerized order entry. All orders, including notes of allergies, are entered directly into the computerized hospital information system by physicians; nurses and pharmacists can also record allergies to medications. This allergy information is a permanent part of a patient's file, obviating the need to write it down in multiple places. When each order for a medication is written, the computer automatically checks it against the patient's allergy profile, and if an allergy is identified, the physician receives a message at the time the order is written. It is anticipated that the number of allergy-related errors will be dramatically decreased.

Both hospitals are implementing a number of other systems changes as a result of this study. Among the most interesting is an enhancement of the role of the pharmacist by increasing his or her participation on the unit as a member of the patient care team, including participation in physicians' rounds. Others include making drug information electronically accessible so it is more readily available to nurses and pharmacists, standardization of doses and procedures, and management changes to enhance supervision and interdependence of nurses. One hospital has standardized the times of medication administration across all units in the hospital. The efficacy of these interventions is currently being evaluated in a randomized controlled trial.

Prior Experience With Systems Analysis in Medicine

Classic systems analysis is a discipline that grew out of operations research and has been used successfully by the military and industry. Typically, it describes organizational structure in terms of models and mathematical equations. Others, like ourselves, have used the term "system analysis" to refer to a qualitative evaluation of the interrelationship of various components of an organization.[15,22-24] In an early study, Cooper et al[25] explored the underlying failures behind observed errors in anesthetic management. Gaba et al,[26] focusing on anesthesia, have constructed a model of the cognitive processes of the anesthetist to determine the stages in anesthetic care where errors occur and why. They have recommended various systems changes in anesthetic procedures to minimize error, including training and revision of workload distributions and team interrelationships.[26,27]

Cook and Woods[28] have noted that the practice of medicine has many of the characteristics of complex systems and stressed the need for systems analysis to get beyond individual human error. As Van Cott observes, "[The] health-care system [is] an intricate network of individuals and teams of people, procedures, regulations, communications, equipment, and devices that function in a variable and uncertain environment...."[29]

Systems Success

It is important to note that, overall, the medication system works well most of the time. Indeed, in terms of opportunities for error, the error rates are quite small. We estimate that study patients received approximately 700 000 doses of medications during the study period. Thus, while an error causing an ADE or potential ADE occurred in 7.3% of admissions, expressed in terms of serious errors per dose administered, the rate was only five in 10 000. In addition, the error detection system worked in a quarter of the cases, ie, the intercepted errors. In the system studied every order was processed by several individuals. Having multiple "handlers" increases the opportunities for errors, but it also increases the chances that an error made by one person will be detected by others. Nurses were the principal interceptors, detecting half of physician ordering errors and intercepting one third of transcription and pharmacy dispensing errors as well. The actual interception rate may well be considerably higher, since there would be no record, for example, of an erroneous telephone order if the error was detected by the nurse and the physician changed the order before the nurse wrote it down.

Feasibility of Systems Analysis

Nurse investigators were able to obtain sufficient information from caregivers and the hospital records to permit identification of underlying proximal causes of errors in most cases. Even for errors that appeared to be the result of simple slips or memory lapses, characteristics of the systems that led to those slips were frequently recognized as important proximal causes. Similarly, when these errors and proximal causes were analyzed, we found recurrent themes that experienced hospital staff readily recognized as underlying systems failures. Rasmussen[30] has observed that how human error is defined depends heavily on context and group norms. Among nurses, physicians, and pharmacists we found a high level of consensus about how to characterize errors and underlying causes.

Analysis of the underlying causes of errors cannot be performed, however, if, as is often the case, hospital personnel are afraid to discuss their mistakes

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because they are accustomed to being punished for them.[10] As industry has learned, a major requirement for implementing continuous quality improvement is to "drive out fear." The Federal Aviation Administration long ago recognized that pilots were much more likely to report errors if they were given immunity from disciplinary action.[11] To overcome these fears, we conducted our investigations in a nonjudgmental manner, in which the caregiver was promised confidentiality and was asked to help determine what went wrong rather than identify who made a mistake. As a result, we found hospital personnel were usually cooperative, willing, even eager, to discuss and think about their errors. Similarly, O'Neil et al[31] found that house officers were willing to report their errors when the environment was supportive rather than punitive.

This study has several limitations. The two hospitals are large, urban academic medical centers that may have different rates or different types of ADEs than community hospitals. Second, although our investigations were intense, yielding high injury and error rates compared with previous studies, we do not know the completeness of our error identification; undoubtedly, some escaped detection. On the other hand, we found common events—errors that physicians, nurses, and pharmacists everywhere are familiar with. Therefore, our findings are probably qualitatively applicable to most hospitals. While the rates of ADEs and potential ADEs may differ, many of the systems problems are likely to be similar. Finally, because systems failures are multiple and occur at various levels of organization, the failures we have identified are assuredly not the only causes of the errors we found.

CONCLUSIONS

The problem of errors in the use of medications in hospitals is substantial, despite extensive programs of surveillance and reporting, and extensive education and training of physicians, nurses, and pharmacists. Preventive efforts that focus solely on individuals or rely on inspection have been shown to have little impact in other settings. Analysis and correction of underlying systems faults is more likely to result in enduring changes and significant error reduction. Regarding errors as primarily the result of systems failures is an idea whose time has come. When hospital personnel were given the opportunity, we found that they were quite capable of identifying system malfunctions that led to errors and of redesigning the systems. Further research is needed to determine if such systems changes will, in fact, bring about substantial reductions in drug-related injuries.

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