RISK MANAGEMENT 2003

Goal: To recognize aspects of pediatric practice that have high risk for liability and malpractice claims and to understand ways to minimize the risk.

Objectives: Upon completion of this module, the pediatric resident will:

1. Describe professional liability risks that pediatric residents face.

2. Describe aspects of physician-patient communication that may lessen risks of malpractice claims.

3. Explain the importance and types of medical errors that occur in the United States.

4. Discuss risk factors for medication errors and adverse drug events as well as measures to minimize their occurrence.

5. Discuss the advantages and disadvantages of standardized medical protocols.

Pre-meeting Preparation:

First Session - Read:

1. Grupp-Phelan J, Reynolds S, Lingl LL. Professional liability of residents in a children's hospital. Arch Pediatr Adoles Med 1996;150:87-90.

2. Levinson W, et al. Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons. JAMA 1997;277:553-559.

3. Agency for Healthcare Research and Quality (AHRQ). Medical errors: the scope of the problem. Ahcpr.gov/qual.

→ Do Quiz questions 1-3 before coming to clinic.

Second Session - Read:

4. Kaushal R, et al. Medication errors and adverse drug events in pediatric inpatients. JAMA 2001;285:2114-2120.

5. WRAMC asthma protocol

→ Do quiz questions 4 and 5 before coming to clinic

DISCUSSION

1. What types of patient problems are commonly involved in pediatric malpractice cases?

2. According to the article by Levinson, et al, physicians who had no claims were more likely than physicians with claims to: (T/F)

   A. Give more factual information about the patient's disease process.

   B. Spend more time with their patients.

   C. Explain more about the process of the patient visit.

   D. Show more warmth during the visit.

   E. Use more facilitative comments.

3. What types of medical errors have you encountered in the hospital or clinic? What could have been done to prevent these errors?

Second Session:

4. In the article by Kaushal, et al, what were the most common types of drug errors? At what stage in the process did the error usually occur? What is currently been done in your work settings to minimize the risk of drug errors?

5. What are the advantages of standardized medical protocols, such as the WRAMC asthma protocols? What are the disadvantages? Why are they not used very frequently? Should we use them more frequently? How could this be done?

EDUCATIONAL INTERVENTIONS

Professional Liability of Residents in a Children's Hospital

Jacqueline Grupp-Phelan, MD; Sally Reynolds, MD; Laura L. Lingl, RN

Objective: To evaluate the risk of professional liability to house staff within a pediatric hospital setting.

Methods: A retrospective study describing the patients, allegations, areas within the hospital where complaints originated, and outcome of all malpractice suits involving residents from 1968 through 1992 at a large pediatric teaching hospital.

Results: There were 49 malpractice cases involving residents with or without attending physicians from 886 000 hospital admissions or emergency department visits over the past 20 years (5.5/100 000 patient encounters) compared with 185 malpractice cases involving attending physicians alone at the hospital (20.5/100 000 patient encounters). The incidence of cases originating from the emergency department was 1.8/100 000 compared with 13.9/100 000 from all other areas of the hospital combined. Fifty-two percent of patients had preexisting chronic medical problems. Forty-nine percent of cases were settled out of court, 2% went to trial with a decision in favor of the plaintiff, 22% were dismissed, and 27% of cases remained open as of June 1993. The mean award on behalf of patients from 1968 through 1979 was $580 000 per case with a median payment of $163 000. The mean award from 1980 through 1992 was $760 000 per case with a median payment of $275 000.

Conclusions: Malpractice risk is a serious concern for residents and a financial liability for hospitals. Resident physicians in a pediatric teaching hospital were named in 26% of malpractice cases. Most cases were settled or were dismissed and did not go to trial. Risk management training during residency may reduce resident involvement, and by extension, the teaching institution's involvement in malpractice litigation.

(Arch Pediatr Adolesc Med. 1996;150:87-90)

Editor's Note: It is alarming to note how many pediatric residents in this study had been implicated in malpractice litigation. Risk management should be included in the eduacation of physicians beginning in medical school and continued throughout their practice lifetimes. The only ones to lose from these efforts would be the lawyers.

Catherine D. DeAngelis, MD

PROFESSIONAL liability is a concern for physicians. Over the past 20 years, the number of malpractice claims has increased; from 1975 through 1985, claims rose by an average of 10% per year.[1] The median settlement grew from $2000 in the early 1970s to $20 000 in the mid 1980s, with a substantial proportion of fiscal settlements in excess of $1 million.[2] Although recent data suggest that the sharp rise in claims has slowed in the 1990s, given the volatility of malpractice trends over the past decade, the long-term trend remains to be seen.[3] Resident physicians (residents) are not immune to malpractice litigation. A 40-year review of malpractice cases involving residents showed that the incidence of cases escalated after 1975, paralleling the growth of malpractice cases nationally.[4] We undertook this study to describe the risk of resident liability in a pediatric hospital setting.

From the Division of General Academic and Emergency Pediatrics, Department of Pediatrics, Children's Memorial Hospital and Northwestern University, Chicago, Ill.

RESULTS

We identified 185 malpractice suits (20.5/100 000 patient visits). In 49 (26%) of these 185 cases, a resident was named as a defendant. Only two cases named residents alone, without an attending physi-

See Methods on next page

METHODS

We retrospectively reviewed all malpractice cases from 1968 through 1992 at Children's Memorial Hospital (CMH), a 265 bed, tertiary care center in Chicago, Ill. Forty-nine cases involving residents were identified by the hospital risk manager. Information from these 49 legal records included patient name, allegation, legal outcome, and settlement fee. The name and gender of the physician defendants were not supplied by the risk manager to maintain anonymity. Medical records were available for 42 of the 49 cases. Information from the medical record included age, sex, insurance status, hospital admitting and discharge diagnosis, chronicity of a patient's medical problem, if any, specialty service, and time of day of hospital admission.

We reviewed hospital data available for a 13-year period (1977 through 1990) to estimate the total number of hospital admissions, outpatient surgical procedures and emergency department (ED) visits, and to determine the mean age and insurance status of all patients admitted to the hospital during the 24-year study period. Gender data for inpatients were available only for the years 1986 through 1992; 44% were female. The specific legal allegations were divided into six general categories: a problem with technique, a failure to diagnose, a failure to diagnose and treat, a medication-related problem, a failure to monitor, and a treatment failure.

cian also being named. The incidence of malpractice cases involving residents was 5.5/100 000 patient visits.

PATIENTS

Thirteen (31%) of the 42 patients were female. The mean age was 3.7 years with ages ranging from newborn to 17 years. The mean age of all children admitted to the hospital over the study period was 3.9 years. Fifty-two percent of patients had preexisting chronic medical problems such as hydrocephalus, congenital heart disease, or severe prematurity. Although data are not available for the study period, chronically ill children made up approximately 55% of CMH admissions in 1993.[5] In 69% of cases, families had private or military insurance. In the remaining cases, CMH was reimbursed by Illinois Department of Public Aid (IDPA). Approximately one third of patients admitted to CMH during the study period were IDPA recipients.

ADMITTING SERVICE

At the time of the alleged malpractice, the medical service managed the care of 24 patients (57%) and the surgical service managed the care of 18 patients (43%). Patients on the medical service were of three general categories: 10 patients (24%) had chronic medical problems such as prematurity, diabetes, myasthenia gravis, and

Area and Allegation

	No. (%) of Complaints
Area	42
Inpatient unit	15 (36)
Operating room	13 (30)
Emergency department	9 (21.5)
NICU/PICU*	4 (10)
Cardiac catheterization laboratory	1 (2.5)
Allegation	49
Technique	13 (27)
Failure to diagnose	12 (25)
Failure to diagnose and treat	8 (16)
Medication error	7 (14)
Failure to monitor	5 (10)
Treatment failure	4 (8)

*NICU indicates neonatal intensive care unit; PICU, pediatric intensive care unit.

cardiac diagnoses; nine patients (21%) were admitted to the CMH medical service for management of general medical problems, including dehydration and well-controlled asthma; and five patients (12%) had infectious diseases such as meningitis, pneumonia and gastroenteritis. Patients on surgical subspecialty services included five (12%) on the cardiovascular surgical service, four (10%) each on the orthopedic and pediatric surgical services, three (7%) on the neurosurgical service, and one (2%) each on urology and otolaryngology surgical services.

AREA OF HOSPITAL AND ALLEGATIONS

The specific area of the hospital where complaints originated is shown in the **Table** along with categories of allegations. Note that the inpatient unit and operating rooms had the largest number of suits, with 36% originating from the inpatient unit and 30% originating from the operating room. Interestingly, of the eight closed inpatient cases, most were settled and only one was dismissed. The mean award in these cases was $1 765 600. In comparison, of the 10 closed operating room cases, four were settled and six were dismissed, with a mean award of $213 000. The origin of 21.5% of suits was the ED. Of the eight closed ED cases, seven were settled and one was dismissed. The mean award for ED cases was $213 000. During the 24-year study period, there were approximately 486 000 patient visits to the ED; 1.8/100 000 ED visits resulted in alleged malpractice by residents. There were an estimated 222 000 non-ED patients, including inpatients and surgical outpatients. The 24-year incidence of alleged malpractice cases originating from these units was 13.9/100 000 (ED relative risk=1.8/13.9=0.13).

The Table also shows the area of the hospital where the complaint originated and the breakdown of cases by allegation. We were able to separate the 49 allegations into six categories; each category is followed with an example. Categories include the following: a problem with technique (a retained foreign body); a failure to diagnose (the failure to diagnose meningitis); a failure to diagnose and treat (neurologic damage due to a failure to

diagnose to treat hydrocephalus); a medication error (an overdose of pyridostigmine bromide [Mestinon] leading to cardiac arrest); a failure to monitor (failure to monitor sodium levels following an overdose of charcoal and sorbitol); and a treatment failure (brain damage due to cardiopulmonary resuscitation).

LEGAL OUTCOME

Eleven cases were dismissed by the courts without payment to the plaintiff. Twenty-four cases (49%) were settled out of court and the subjects received a payment. The single case that went to trial ended with a financial decision in favor of the plaintiff for $3.4 million. Payments ranged from $10 000 to $6.9 million. Payments totaled approximately $25 260 000 during the 24-year study period, with a mean payment of $702 000 and a median payment of $203 500. In the 12 cases settled or dismissed from 1968 through 1980, the mean payment was $580 000, with a median payment of $163 000. In the cases settled, tried, or dismissed from 1980 through 1989 (n=24), the mean payment was $760 000, with a median payment of $275 500. Owing to the large variation of payments, the difference in mean and median award settlements between the 1970s and 1980s was not statistically significant. Thirteen cases remain open as of June 1993.

COMMENT

Physicians may have increased exposure to malpractice claims early in their careers, and although data are limited, this seems to include the residency training years.[4-6] For many reasons, residents are vulnerable to allegations of malpractice. They lack experience, have limited continuity of care with their patients, and work long hours. While being named in a malpractice suit is relatively uncommon for both attending and resident physicians, a recent review by Martin and Shapiro[7] found that residents represent one quarter of all named defendants in a teaching hospital environment, a finding consistent with our data.

The most frequent allegations in our study were those based on a failure to diagnose or a failure to treat. Most missed diagnoses were common but serious illnesses such as appendicitis or meningitis (41%). These allegations were similar to those against attending physicians in previous studies.[8] Another frequent allegation was a complication of treatment or a problem with technique (27%). Many of the cases in this category were operative complications.

A study in 1989 by the Risk Management Foundation of the Harvard medical institutions found that 75% of malpractice cases involving residents occurred in surgical subspecialties.[9] Surgical subspecialties were involved in only 45% of our cases. The direct supervision of surgical residents by attending physicians during all surgical procedures at our institution may be responsible for this difference. A recent study that found supervision an issue in 41% of claims involving surgical residents supports the concept that improving supervision may decrease risk.[10]

The ED has been considered an area of risk within a hospital setting.[7,11] Our study found that the ED had a markedly lower incidence of malpractice cases naming residents compared with other areas of the hospital. This is in contradiction to other studies and the reason for this is unclear. It is possible that residents are more sensitive to medicolegal issues in the ED and therefore document more carefully. Perhaps residents in the ED are quick to admit patients to the hospital, therefore transferring problems to the inpatient services. Additionally, residents were directly supervised from 8 AM to 11 PM by an attending physician in our ED. It has been shown that attending supervision is associated with a decrease in the number of malpractice cases in an ED setting.[12-14] This may not fully explain the lower incidence of cases.

As noted before, female patients made up approximately 44% of patients admitted to the hospital during the study period, yet made up only 31% of cases. In a study by Brennan et al,[15] gender did not appear to represent a risk factor for adverse events or negligence. How this translates into an eventual malpractice suit is unclear, but one would expect families of female patients to sue at rates proportionate to their representation in the hospital population.

Although not supported by other studies, it is the general perception that patients who receive public aid are more likely to sue than are insured patients.[16,17] In our study, 29 (69%) of 42 patients had private insurance compared with 13 (31%) who received IDPA. Approximately one third of patients admitted to CMH receive IDPA; therefore, IDPA recipients were not overrepresented in our sample.

It is unfortunate that we do not have data concerning hospial admissions and ED visits for the entire 24-year period. However, data from the 13-year period provide a reasonable estimate to calculate event rates. Also, caution must be taken before generalizing our findings to other hospitals. The results of our study may be limited to pediatric teaching or tertiary care hospitals. They may also reflect business practices and personnel characteristics unique to our institution.

Learning from mistakes may be important in preventing future malpractice. Most cases of physician negligence never result in malpractice claims, but when they do, these data have been shown to be useful in identifying problem-prone diagnoses and suggesting interventions that may reduce negligence.[18] A survey of house officers revealed that those residents who were willing to take responsibility for their mistakes were more likely to report constructive changes in their practice.[19] Given that residents were named in 26% of all malpractice cases in our institution, it may be beneficial to use these cases as a nidus for risk management teaching and case management discussion.

Studies or surveys have shown that formal training in risk management issues,[3] appropriate medical record documentation,[20,21] and communication skills[22-24] for attending physicians make a difference in the future risk of malpractice. A residency is the ideal forum for laying the foundation for these skills, perhaps even reducing the risk of malpractice during the training period.

CONCLUSIONS

The risk of malpractice is a serious concern for residents. Our data demonstrate that resident physicians in a pediatric hospital setting were named in 26% of malpractice cases. Although most cases were either settled with a payment or were dismissed and did not go to trial, they represent a financial liability for hospitals. Just as risk management training for attending physicians decreases the potential for malpractice, we anticipate that such training during residency would reduce the incidence of resident involvement, and by extension, institutional involvement in malpractice litigation.

Accepted for publication March 26, 1995.

Elizabeth Powell, MD, Robert Tanz, MD, A. Todd Davis, MD, and Robert Winter, MD, provided editorial support.

Reprint requests to General Academic and Emergency Pediatrics, 2300 Children's Plaza, Box 16, Chicago, IL 60614 (Dr Reynolds).

REFERENCES

1. Danzon PM. The crisis of medical malpractice: a comparison of trends in the United States, Canada, the United Kingdom and Australia. *Law Med Health Care*. 1990;18:48-58.
2. DeAngelis C. *Pediatric Perspectives: Medical-Legal Issues in Pediatrics*. Columbus, Ohio: Report of the 18th Ross Round Table on Critical Approaches to Common Pediatric Problems; 1987:2-6.
3. Karcz A, Holbrook J, Auerbach BS, et al. Preventability of malpractice claims in emergency medicine: a closed claims study. *Ann Emerg Med*. 1990;19:865-873.
4. Helms L, Helms C. Forty years of litigation involving residents and their training in malpractice issues. *Acad Med*. 1991;66:718-725.
5. Desquin B. *Special Communication*. Chicago, Ill: Children's Memorial Hospital; 1995.
6. American Academy of Pediatrics. *AAP Periodic Survey of Fellows*. Elk Grove, Ill: Department of Research, AAP News; April 1994.
7. Martin PB, Shapiro C. A review of specialties and allegations in house staff claims and suits within the Harvard medical institutions. *Forum*. 1993;14:3-6.
8. Ricci PA, Lambert RJ, Steffes GS. Pediatrics and professional liability. *Pediatr Emerg Care*. 1986;2:109-112.
9. McDonough WJ. Residents and medical malpractice: risk management issues within the hospital. *Med Clin North Am*. 1989;73:1-12.
10. Bobbie A, Christian R, Ackroyd F, Weinstein D. Resident supervision in general surgery. *Forum*. 1993;14:8-10.
11. Trautlein JJ, Lambert RL, Miller J. Malpractice in the emergency department: review of 200 cases. *Ann Emerg Med*. 1984;13:709-711.
12. Reynolds SL, Glynn WM, Jaffe DM. Professional liability in a pediatric emergency department. *Pediatrics*. 1991;87:134-137.
13. Press S, Cantor J, Russell S, Jerez E. Full-time attending coverage in a pediatric emergency department. *Arch Pediatr Adolesc Med*. 1994;148:578-581.
14. Press S, Russell SA, Cantor JC, Jerez E. Attending physician coverage in a teaching hospital's emergency department: effect on malpractice. *J Emerg Med*. 1994;12:89-93.
15. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324:370-376.
16. Mussman MG, Zavistowich L, Weissman OS, Maltiz FE, Mariock [illegible]. Medical malpractice claims filed by Medicaid and non-Medicaid recipients in Maryland. *JAMA*. 1991;265:2992-2994.
17. Burstin HR, Johnson WG, Lipsitz SR, Brennan TA. Do the poor sue more? *JAMA*. 1993;270:1697-1701.
18. Kravitz RA, Rolph JE, McGuigan K. Malpractice claims as a quality improvement tool: I. epidemiology of error in four specialties. *JAMA*. 1991;226:2087-2092.
19. Wu AW, Folkman S, McPhee SJ, Lo B. Do house officers learn from their mistakes? *JAMA*. 1991;265:2089-2094.
20. Lyons TF, Payne BC. The relationship of physicians' medical records to their medical performance. *Med Care*. 1974;12:463-469.
21. Payne BC. The medical record as a basis for assessing physicians' competence. *Ann Intern Med*. 1979;91:623-629.
22. Valente CM, Antiz AM, Boyd MD, Troisi AJ. The importance of physician-patient communication in reducing medical liability. *Md Med J*. 1988;37:75-78.
23. Adams EK, Zuckerman S. Variation in the growth and incidence of medical malpractice claims. *J Health Polit Policy Law*. 1984;9:475-488.
24. Eisman SS, Glass CA, Hickson GB, Githens PB, Whetten-Goldstein K, Sloan FA. The relationship between malpractice claims history and subsequent obstetric care. *JAMA*. 1994;272:1588-1591.

Educational Interventions

Purpose: This section is intended to share information concerning educational efforts in the broad field of pediatrics. We welcome studies on the following topics: undergraduate and graduate education in medicine and allied health occupations; continuing education of health professionals; education of patients and families; and health education for the general public, the community, and organizations that contribute to the promotion and improvement of the health of children and adolescents.

Physician-Patient Communication

The Relationship With Malpractice Claims Among Primary Care Physicians and Surgeons

Wendy Levinson, MD; Debra L. Roter, DrPH; John P. Mullooly, PhD; Valerie T. Dull, PhD; Richard M. Frankel, PhD

Objective.—To identify specific communication behaviors associated with malpractice history in primary care physicians and surgeons.

Design.—Comparison of communication behaviors of "claims" vs "no-claims" physicians using audiotapes of 10 routine office visits per physician.

Settings.—One hundred twenty-four physician offices in Oregon and Colorado.

Participants.—Fifty-nine primary care physicians (general internists and family practitioners) and 65 general and orthopedic surgeons and their patients. Physicians were classified into no-claims or claims (≥2 lifetime claims) groups based on insurance company records and were stratified by years in practice and specialty.

Main Outcome Measures.—Audiotape analysis using the Roter Interaction Analysis System.

Results.—Significant differences in communication behaviors of no-claims and claims physicians were identified in primary care physicians but not in surgeons. Compared with claims primary care physicians, no-claims primary care physicians used more statements of orientation (educating patients about what to expect and the flow of a visit), laughed and used humor more, and tended to use more facilitation (soliciting patients' opinions, checking understanding, and encouraging patients to talk). No-claims primary care physicians spent longer in routine visits than claims primary care physicians (mean, 18.3 vs 15.0 minutes), and the length of the visit had an independent effect in predicting claims status. The multivariable model for primary care improved the prediction of claims status by 57% above chance (90% confidence interval, 33%-73%). Multivariable models did not significantly improve prediction of claims status for surgeons.

Conclusions.—Routine physician-patient communication differs in primary care physicians with vs without prior malpractice claims. In contrast, the study did not find communication behaviors to distinguish between claims vs no-claims surgeons. The study identifies specific and teachable communication behaviors associated with fewer malpractice claims for primary care physicians. Physicians can use these findings as they seek to improve communication and decrease malpractice risk. Malpractice insurers can use this information to guide malpractice risk prevention and education for primary care physicians but should not assume that it is appropriate to teach similar behaviors to other specialty groups.

JAMA. 1997;277:553-559

From the Departments of Medicine, Oregon Health Sciences University and Legacy Good Samaritan Hospital and Medical Center, Portland, Ore (Dr Levinson); School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Md (Dr Roter); Kaiser Foundation Hospitals Center for Health Research, Portland, Ore (Dr Mullooly); Department of Psychology, Portland State University, Portland, Ore (Dr Dull), and Department of Medicine, Highland Hospital, University of Rochester, Rochester, NY (Dr Frankel). Dr Levinson is now with the Section of General Internal Medicine, University of Chicago, Chicago, Ill.

Reprints: Wendy Levinson, MD, Section of General Internal Medicine, University of Chicago, MC6098, 5841 S Maryland Ave, Chicago, IL 60637-1470.

WHAT FACTORS put physicians at risk of being sued? The answer to this question is critical to physicians, malpractice insurance companies, and hospital systems that seek to provide the highest-quality care and minimize liability risk.

Studies have explored the relationship between physicians' claims experience and the quality of care they provide.[1-4] Surprisingly, the differences between sued and never-sued physicians are not explained by their quality of care or their chart documentation. Entman et al[3] showed that the quality of treatment as judged by peer review was not different in frequently sued vs never-sued obstetrician-gynecologists. This is consistent with other data indicating that the quality of care is apparently not the major determinant in a patient's decision to initiate a malpractice claim. While 1% of hospitalized patients suffer a significant injury due to negligence, fewer than 2% of these patients initiate a malpractice claim.[5] If quality of care, medical negligence, and chart documentation are not the critical factors leading to litigation, what factors are critical?

Patient dissatisfaction is critical.[6] The combination of a bad outcome and patient dissatisfaction is a recipe for litigation. When faced with a bad outcome, patients and families are more likely to sue a physician if they feel the physician was not caring and compassionate.[6-12] Breakdowns in communication between physicians and patients lead to patient anger and dissatisfaction and possible litigation. Conversely, effective communication enhances patient satisfaction and health outcomes.[13-15] Despite this recognition, studies to date have not informed physicians which specific com-

Table 1.—Physician Recruitment Rates by State, Specialty, and Malpractice Claims History

	No. Who Agreed/No. Solicited (%)		
	No Claims	≥2 Claims	Total
Primary care physicians			
Oregon	18/23 (78)	13/16 (81)	69/93 (74)
Colorado	17/29 (59)	21/25 (84)	
Surgeons			
Oregon	9/13 (69)	17/18 (94)	68/76 (89)
Colorado	19/21 (90)	23/24 (96)	

munication behaviors decrease or increase their malpractice risk.

What kinds of communication problems lead to patient dissatisfaction and possible litigation? In a recent study of obstetricians and gynecologists, Hickson and colleagues[16] found that patients of physicians with prior malpractice claims reported feeling rushed, feeling ignored, receiving inadequate explanations or advice, and spending less time during routine visits than patients of physicians with no prior claims. Overall, the patients of the high-frequency claims physicians had twice as many complaints about their care as the patients of the no-claims physicians. Similarly, a study of malpractice depositions by Beckman et al[9] identified communication problems between physicians and patients in 70% of cases. While studies point to an association between communication and malpractice,[8-10,12] no studies have analyzed this relationship by direct observation of physicians with their patients. Furthermore, previous studies have not identified specific communication behaviors physicians can use to prevent litigation.

The purpose of this study was to identify specific, routine communication behaviors associated with malpractice history in both primary care physicians and surgeons. While it is not feasible to prove a causal relationship between communication behaviors and malpractice, we believe that these results are important to physicians who seek to improve their communication skills, promote patient satisfaction, and decrease their malpractice risk. For the same reason, our results are important to insurance companies and physician organizations that seek to educate physicians.

METHODS

Overview

The study was designed to compare the routine communication styles of physicians with vs without a history of malpractice claims, stratified by years in practice and specialty. The study was conducted in Colorado and Oregon and included primary care physicians and surgeons. Routine communication was assessed using audiotapes of 10 sequential office visits for each of the 124 study physicians. Demographic information was collected for physicians and patients. The study was approved by the Institutional Review Board of Legacy Good Samaritan Hospital, Portland, Ore.

Participants

The study was conducted in 1993 with the cooperation of COPIC, a physician-controlled insurance company insuring 70% of the physicians in Colorado, and Northwest Physicians Mutual, which insures 40% of physicians in Oregon. No funds were provided by the companies.

All physicians were selected from the databases of these companies according to their lifetime malpractice claims history. A claim was defined as any patient request for funds, any malpractice suit filed by a patient, or any contact by an attorney who represented a patient in an action against the physician. Claims were included regardless of their outcome since any claim is likely to be costly to physicians and insurance companies. An incident, defined as an event reported to the insurance company by a physician fearing legal action, was not included as a claim. Computerized claims information plus hand audits of the files of individual physician's insurance records were reviewed for complete information on lifetime claims. Unique physician identifiers were assigned to ensure anonymity and the confidentiality of individual claims information.

Physicians were eligible if they were in active practice in Denver, Colo, or Portland or Salem, Ore, and had graduated from medical school at least 13 years prior to the study. Eligible primary care physicians included general internists and family practitioners (excluding those practicing obstetrics); eligible surgeons included general surgeons and orthopedic surgeons. Physicians were classified as midcareer (graduated 13-20 years before the study) or late career (graduated >20 years before the study).

Identified physicians were sorted by strata: specialty, claims status (no claims vs ≥2 claims), and years since graduation. The claims categories were selected to maximize the differences between groups. Physicians in each stratum were randomly assigned identification numbers between 0 and 1.0, and physicians were selected for recruitment based on the sampling proportion required to obtain the desired sample size for each stratum.

Table 2.—Characteristics of the Participating Physicians by Specialty

Characteristic	No. (%)*	
	Primary Care (n=59)	Surgery (n=65)
Male sex	52 (88)	64 (98)
Time since medical school graduation, y, median (range)	17 (14-41)	15.5 (12-41)
Time spent with patients, h/wk, mean (range)	45 (12-76)	58 (18-76)
Setting		
Solo practice	24 (41)	17 (26)
Group (single specialty)	26 (44)	44 (68)
Group (multi-specialty)	9 (15)	3 (5)
Other	0 (0)	0 (0)
Missing data	0 (0)	1 (2)
Race/ethnicity		
White	55 (90)	61 (94)
African American	1 (2)	2 (3)
Asian	0 (0)	0 (0)
Hispanic	2 (3)	0 (0)
Native American	1 (2)	1 (2)
Other	2 (3)	0 (0)
Missing data	0 (0)	1 (2)

*Unless otherwise indicated

Recruitment Process

Physicians.—Recruitment involved 2 steps. First, physicians were contacted by a letter endorsed by either the Colorado Medical Association and the Colorado Board of Medical Examiners or the Oregon Board of Medical Examiners. Second, 1 of the physicians who had signed the letters placed a telephone call to potential participants. Physicians were informed that the study explored communication style, specialty differences, and the relationship of communication to satisfaction and malpractice. In return for participation, physicians were offered individualized feedback about their communication style and a free continuing medical education program.

All participating physicians gave informed consent. Overall, 57 (81%) of 70 Oregon physicians and 80 (81%) of 99 Colorado physicians agreed to participate (Table 1). The physician recruitment strategy yielded a higher acceptance rate for surgeons (89% [68/76]) than for primary care physicians (74% [69/93]). Contrary to our initial expectations, physicians with claims were more likely to participate than physicians with no claims. Physicians who refused to participate refused because of lack of time or concern about the effect of audiotaping on office efficiency. Thirteen physicians who initially agreed to participate did not complete the data

Table 3.—Characteristics of the Participating Patients

Characteristic	Primary Care Patients, %* (n=598)	Surgery Patients, %* (n=672)
Median age, y	54	49
Female	53.2	55.7
Race/ethnicity		
White	81.6	87.8
African American	4.0	2.1
Asian	1.2	0.4
Hispanic	6.6	4.3
Native American	4.3	3.3
Other	1.5	1.0
Missing data	0.8	1.0
Marital status		
Married	64.2	65.6
Widowed	13.5	8.3
Single	8.4	11.2
Separated	1.3	0.4
Divorced	11.9	13.2
Missing data	0.7	1.2
Education		
<High school graduate	11.7	8.5
High school graduate	25.9	25.1
Some college	32.4	38.2
4 y of college	11.7	10.3
>4 y of college	17.2	16.8
Missing data	1.0	1.0
Income, $		
<20 000	26.3	23.7
20 000-39 999	32.4	31.0
40 000-59 999	18.6	22.6
≥60 000	17.4	17.6
Missing data	5.4	5.2

*Unless otherwise indicated.

Table 4.—Categories of the Roter Interaction Analysis System

Category	Communication Behavior	Example
Content	Question: asking related to medical condition	What can you tell me about the pain?
	Question: asking related to therapeutic regimen	How have you responded to the medication?
	Question: asking related to psychosocial and lifestyle issues	What's happening with your son?
	Giving information—medical	The medication may make you drowsy.
	Giving information—therapy	You'll need to take the antibiotics every day for 10 days to have it work.
	Giving information—psychosocial and lifestyle	It is important to get out and do something every day. The Senior Center is a great place for company and they'll give you lunch too.
	Counseling—medical/therapy	Call me if you aren't feeling better by next week.
	Counseling—lifestyle/psychosocial	You really need to get out and meet more people.
Process	Facilitation (asking for patient opinion, asking for patient understanding, paraphrasing and interpretation)	What do you think it is? Go on, yes, aha. Do you follow?
	Orientation (instructions and directions regarding the medical visit process, and transitional statements)	Get up on the table, take a deep breath. Well, okay, let's see.
Emotional affect	Shows approval	Good. I'm happy to hear you are feeling better.
	Concern, worry	I'm concerned that this may happen again in the future.
	Criticism of third party	It's pretty stupid of the insurance company to do that.
	Empathy	You look worried.
	Laughs, humor	My son said that college life is one big party. I said, "That's not what I want to hear, Andrew!"

collected. The final sample included 124 physicians, 74% were male and 92% were white (Table 2).

Patients.—Patients were eligible if they were older than age 18 years, spoke English, and were not in acute distress. To best capture routine communication and to avoid new visits, which are often lengthy, primary care patients were eligible only if they had at least 2 prior visits with the physician. Since ongoing relationships were much less common for surgical patients and their physicians, all patient visits other than those scheduled for a procedure only (eg, suture removal) were included.

Patients were recruited on a convenience basis from the physicians' waiting rooms immediately before their medical visit. A research assistant explained that audiotaping was designed to study communication between physicians and patients. Written consent was obtained. Recruitment continued until a minimum of 10 patient visits had been audiotaped for each physician. For a few physicians, 11 visits were recorded. Overall, 80% of eligible patients agreed to participate. Reasons for refusal included lack of time to complete questionnaires, concerns about privacy, and feeling ill at the time. The majority of patients were white (85%) and had some college education (63%). The median patient age was 51 years (range, 18-97 years), and 45% were male (Table 3).

Communication Behaviors

The 1265 audiotapes were coded for content by 3 trained, blinded coders using the Roter Interaction Analysis System (RIAS).[17] In this system, each statement or complete thought by either a patient or physician is coded into 1 of 38 mutually exclusive and exhaustive categories. Coding is done directly from audiotapes without transcription. The RIAS is well validated.[18-22]

The RIAS communication behaviors are organized into 3 categories: content, process, and emotional affect (Table 4). The content category includes all physician and patient discussion about both biomedical and psychosocial topics (asking questions, giving information, and counseling). The process category includes orientation about the flow of the visit (eg, "First I will examine you and then you will have some tests") and facilitation. Facilitation includes asking patients' opinions, checking their understanding, and comments such as, "Go on, tell me more." Typically, facilitation comments allow the patient to talk while the physician encourages conversation with brief comments. Emotional affect includes conversation that is explicitly emotional, both positive and negative statements. This category includes use of humor and laughter, statements of approval (eg, "You're doing great with your diet"), and statements of empathy (eg, "That must make it tough for you"). In addition, it includes physician comments indicating worry or concern (eg, "If we're having this problem, your blood pressure is too high") and criticisms of third parties (eg, "It's pretty stupid for the insurance company to do that").

Coders were trained in use of the RIAS by D.L.R. over several weeks using a coding manual with detailed definitions and using annotated examples and training tapes. Intercoder reliability was calculated based on 121 double-coded tapes. Selection of tapes for double-coding was random throughout the coding period, and double-coding was done by random pairs of coders. An interrater reliability coefficient[23] was calculated for each of the communication behaviors reflected in Table 4, and these coefficients were used in the analysis. The mean reliability coefficient was 0.80 for physician behaviors (range, 0.42-0.96) and 0.87 (range, 0.60-0.94) for patient behaviors. The lower reliability coefficients applied only to categories with very low frequencies, usually averaging less than 1 occurrence per visit; this was true for 2 variables in the final model for surgeons, criticism and empathy, each

Table 5.—Bivariate Analyses of Communication Behaviors for No Claims/Claims Status in Primary Care Physicians and Surgeons

Variable	Primary Care Physicians (n=59)		Surgeons (n=65)	
	No Claims (n=29)	Claims (n=30)	No Claims (n=25)	Claims
Total No. of utterances	387.6 (116.0)	304.4 (96.9)†	292.1 (92.8)	25
Visit length, min	18.3 (5.8)	15.0 (5.1)§	14.4 (5.3)	1
Ratio of physician to patient utterances	1.3 (0.3)	1.3 (0.3)	1.4 (0.3)	1.4 (0.2)
No. of utterances per 15-min visit				
Content				
Physician				
Asks questions—medical	18.3 (7.2)	16.9 (7.3)	16.2 (5.9)	17.5 (10.4)
Asks questions—therapy	5.6 (3.1)	5.0 (2.6)	3.1 (1.6)	2.8 (1.6)
Asks questions—psychosocial/lifestyle	4.2 (2.6)	3.5 (2.0)	2.8 (1.6)	2.8 (1.5)
Gives information—medical	28.5 (13.2)	26.3 (9.2)	39.8 (16.4)	40.1 (15.4)
Gives information—therapy	26.0 (8.5)	25.3 (9.2)	29.4 (10.2)	27.9 (7.2)
Gives information—psychosocial/lifestyle	4.6 (2.8)	4.3 (2.7)	3.4 (3.7)	3.7 (2.9)
Counsels—medical/therapy	16.7 (10.9)	13.9 (6.6)	20.3 (10.4)	17.1 (7.7)‡
Counsels—psychosocial/lifestyle	1.9 (1.6)	1.3 (1.9)‡	0.6 (0.6)	0.7 (1.0)
Patient				
Asks questions—medical	1.7 (0.7)	1.6 (0.6)	2.5 (1.4)	3.2 (2.3)‡
Asks questions—therapy	2.4 (1.4)	2.2 (1.0)	3.1 (1.8)	2.9 (1.4)
Asks questions—psychosocial/lifestyle	0.2 (0.2)	0.3 (0.3)‡	0.2 (0.2)	0.2 (0.2)
Gives information—medical	49.0 (13.2)	48.0 (12.6)	48.0 (11.2)	50.9 (9.9)
Gives information—therapy	16.9 (8.1)	14.6 (4.8)‡	10.4 (4.7)	9.1 (4.6)
Gives information—psychosocial/lifestyle	16.1 (5.6)	14.9 (5.0)	3.4 (2.0)	3.8 (1.8)
Ratio of biomedical to all content	0.85 (0.07)	0.86 (0.08)	0.91 (0.04)	0.91 (0.03)
Process				
Physician				
Facilitation	19.4 (10.2)	11.9 (6.2)§	15.9 (7.1)	14.1 (6.0)
Orientation	14.5 (8.2)	11.2 (3.1)§	10.9 (4.6)	11.2 (4.6)
Patient				
Checks	2.5 (0.8)	2.1 (1.0)‡	2.9 (1.4)	3.0 (1.6)
Procedural/flow of visit	9.9 (5.1)	8.4 (3.4)‡	7.1 (3.4)	8.2 (5.6)
Affect				
Physician				
Criticism of third party	0.1 (0.2)	0.1 (0.3)	0.2 (0.5)	
Laughs	4.8 (3.6)	3.4 (1.9)§	3.3 (2.3)	
Concern/worry	1.5 (1.0)	1.2 (0.3)‡	1.3 (1.0)	
Approval	3.3 (1.9)	2.6 (1.8)‡	3.7 (3.0)	3.5 (3.0)
Empathy	1.3 (1.0)	1.0 (0.6)‡	0.8 (0.6)	1.1 (0.9)‡
Patient				
Agreement	31.3 (13.0)	28.1 (5.6)‡	36.5 (11.7)	36.8 (12.4)
Laughs	7.8 (3.6)	7.5 (2.9)	7.2 (3.4)	9.2 (4.9)§

*Values are mean (SD).
†$P < .01$ for no claims vs claims.
‡These variables were considered for inclusion in multivariable models ($P < .25$).
§$P < .05$ for no claims vs claims.

with a reliability coefficient of 0.49. Reliability coefficients for all the other variables in the model ranged from 0.83 to 0.97. These levels of reliability compare favorably with those found in prior studies conducted by the present investigators and by others.[19-21]

Statistical Analysis

The unit of analysis for this study was the physician (n=124); hence, scores for each communication behavior (Table 4) were averaged over the 10 visits recorded for the physician. Primary care physicians and surgeons were analyzed separately because surgeons' communication patterns have not been analyzed previously and because we expected that surgeons' communication behaviors might differ from those of primary care physicians.

The overall goal of our analysis was to identify communication patterns associated with claims history (no claims vs ≥2 claims). Communication behaviors were grouped into the 3 conceptual categories—content, process, and emotional affect. Communication variables were defined as the total number of utterances of each type per minute. Table 5 shows the number of utterances for a 15-minute interview computed by multiplying the number of utterances per minute by 15. These variables were averaged over the 10 visits for each physician. Bivariate analyses were performed for physician demographic characteristics and communication behaviors. Subsequently, a multivariable analysis using logistic regression was employed to assess the combined and independent associations of communication patterns and claims history.

To decrease the number of variables in the multivariable analysis, communication behaviors from each category were selected based on the results of the bivariate analysis. The bivariate analysis was designed to guide but not to limit our selection of factors for the multivariable model; hence, we included variables with $P \leq .25$ as potential candidates for our multivariable models.[24] Length of visit was included in the multivariable analysis since this differed between claims categories. To compare across RIAS categories with different frequencies and variabilities, we expressed the communication variables in SDs. Odds ratios in this context estimate the relative risk of claim

ated [redacted] an increase of 1 SD in the pred[redacted]riable. The goodness of fit of m[redacted] was assessed using the Hosmer-Le[redacted]eshow χ^2 statistic.[35]

Finally, the ability of the model to correctly classify claims and no-claims physicians was assessed using logistic classification analysis. Unbiased assessments of predictive accuracies of the models were performed using a resampling procedure (the bootstrap method). This approach avoids overestimating predictive accuracy from the original sample to which the model was fitted. For primary care physicians, this involved resampling the study data 50 times by separately selecting 29 observations for no-claims physicians and 30 observations for claims physicians with replacement (ie, a physician could contribute more than 1 observation to each bootstrap sample). The claims and no-claims samples were combined, and the logistic model was estimated. Classification analysis was then performed using a cutpoint of 0.5, and the percentage correct, sensitivity, and specificity were calculated for each bootstrap sample. The classification rates for the 50 bootstrap samples provide unbiased estimates of the 90% confidence limits. A similar sampling procedure was used for surgeons.[36]

Table 6.—Logistic Regression Model for a History of Two or More Claims

Standardized Predictor	Odds Ratio (95% Confidence Interval)	P
Primary Care Physicians*		
Physician facilitation	0.49 (0.19-1.28)	.15
Physician orientation	0.37 (0.14-0.85)	.02
Patient gives information—therapy	0.54 (0.23-1.34)	.19
Physician counsels—psychosocial/lifestyle	0.80 (0.42-1.51)	.49
Physician laughs	0.43 (0.18-0.99)	.05
Visit length	0.31 (0.13-0.67)	.003
Surgeons†		
Physician facilitation	0.64 (0.37-1.12)	.12
Patient laughs	1.87 (0.92-3.84)	.09
Physician criticism of third party	0.40 (0.14-1.15)	.09
Physician empathy	1.71 (0.90-3.28)	.10

*Likelihood ratio for covariates: χ^2=25.98, df=6 (P=.001); Hosmer-Lemeshow goodness-of-fit statistic χ^2=7.70, df=8 (P=.46).
†Likelihood ratio for covariates: χ^2=13.39, df=4 (P=.01); Hosmer-Lemeshow goodness-of-fit statistic χ^2=4.03, df=7 (P=.78).

RESULTS

Nature of the Visits

Primary care physician visits lasted a mean of 16.5 minutes (SD, 5.7 minutes) and included discussion of a median of 3 (range, 1-12) patient concerns as defined by the coders. The most frequent diagnostic problems included hypertension, depression, diabetes mellitus, gastrointestinal disorders, and musculoskeletal problems.

Visits with surgeons lasted a mean of 13.6 minutes (SD, 4.4 minutes) and included discussion of a median of 2 (range, 1-8) concerns. For orthopedic surgeons, the most common reasons for visits were shoulder disorders, acute knee injuries, and fractures. For general surgeons, the most common reasons included breast disease, abdominal hernia, and cholecystitis or cholelithiasis.

Communication Patterns and Claims History

Bivariate Analyses.—*Primary Care Physicians.*—For primary care physicians, the total number of utterances (P=[redacted]) and the overall length of the vis[redacted] significantly higher for the no-[redacted] physicians (P=.03). In the content domain, no significant differences (P=.05) were found between claims and no-claims physicians (Table 5).

In the process domain, no-claims physicians used more facilitation statements (P=.02) and provided more orientation about the flow of the visit (P=.05) than claims physicians. In the affect domain, no-claims physicians used humor more often and laughed more (P=.05).

Surgeons.—Fewer differences in communication were found between the no-claims and claims surgeons than between the no-claims and claims primary care physicians. Among the surgeons, there were no statistically significant differences in either total utterances or length of visit, although the mean length of visit was longer in the no-claims group (14.4 vs 13.0 minutes). No significant differences between claims and no-claims surgeons were detected in the content of discussion.

In contrast to the primary care physicians, the process domain demonstrated no significant differences between claims and no-claims surgeons. In the affect category, patients of no-claims surgeons laughed significantly less often than patients of claims surgeons (P=.05).

Multivariable Analyses.—All communication variables with P<.25 in the bivariate analyses were considered for inclusion in the multivariable analyses. We attempted to include communication variables from each of the conceptual categories (content, process, and affect) in the final models, and we included variables that improved the predictive accuracy of the models (Table 6).

Primary Care Physicians.—For primary care physicians, the length of the visit (process) and communication behaviors (affect) significantly contributed to predicting claims status. No content variables made significant independent contributions to the model. The model demonstrated that no-claims physicians had longer visits, made more statements orienting the patient to the flow of the visit, and used more humor and laughed more often than claims physicians. In addition, no-claims physicians tended to use more facilitation in their visits, and their patients provided more information about therapy.

The predictive accuracy of the model was estimated using the bootstrap method to be 80% (90% confidence interval [CI], 68%-88%). A 51% correct rate would be expected by chance alone. The sensitivity was 75% (90% CI, 59%-90%), and the specificity was 84% (90% CI, 73%-93%). The model was more accurate in identifying no-claims physicians than in identifying physicians with claims.

Surgeons.—For surgeons, the model was unable to correctly classify better than the 61% expected by chance alone. In fact, no communication variables in any of the domains had a significant and independent effect. Using the bootstrap method, predictive accuracy was 69% (90% CI, 58%-79%), sensitivity was 46% (90% CI, 22%-65%), and specificity was 82% (90% CI, 73%-90%). As with the primary care physicians, the model was more accurate in identifying no-claims surgeons.

COMMENT

Routine physician-patient communication is different for primary care physicians who have and do not have malpractice claims. We were unable to demonstrate significant differences in routine communication behaviors between claims and no-claims surgeons. The relationship between communication behaviors and malpractice history appears to differ between specialties. While it is not feasible to prove a causal relationship, our study is the first to identify specific, routine communication behaviors associated with malpractice risk for

primary care physicians. Further research is needed to understand the relationship between communication behaviors and malpractice risk in surgeons.

With the intense pressure in many health care organizations to shorten routine office visits,[2] it is critical to know if shorter visits might increase malpractice risk. We found that routine visits with no-claims primary care physicians were longer than those with claims physicians (18.3 vs 15.0 minutes). Furthermore, we found that the length of routine primary care visits did contribute to predicting the malpractice claims status of primary care physicians. Prior studies have indicated that patients who actually sue report that their visits felt hurried and rushed,[7,10] and we have demonstrated that the length of routine, everyday visits is associated with malpractice history for primary care physicians. In contrast, we conclude that the length of routine visits does not have the same significance for surgeons as for primary care physicians.

In addition to length of visit, what specific elements of communication matter? For primary care physicians, this study provides important answers. In particular, the process and emotional affect of routine interviews together predicted malpractice risk. Primary care physicians with no claims oriented patients to the process of the visit more often than physicians with claims. Orienting comments include statements such as, "First I'll examine you and then we will talk the problem over" or "I will leave time for your questions." Orienting statements help the patient develop appropriate expectations about a medical visit. They may also inform the patient about when during the interview to raise concerns and may help to prevent patients from presenting new problems in the closing moments of the interview.

In addition, the use of facilitation tended to distinguish no-claims primary care physicians from claims physicians. Facilitative comments include statements such as, "Go on, tell me more about that." They also include asking patients their opinions about their medical problems or treatment, such as, "What do you think caused that to happen?" or "What do you think about taking these pills?" These comments allow patients to talk and also indicate physicians' interest in their opinions, confirming studies that indicate the importance of allowing patients to talk without interruption.[33,34] The technique of "active listening" is effective in eliciting important clinical information from patients and in making them feel that the physician cares for them.[33,34] Facilitating comments are relatively simple to use, and physicians can learn to incorporate them into their routine communication.[35,36]

The study also demonstrated that no-claims primary care physicians laughed and used humor more often during visits than claims primary care physicians, indicating warmth and friendliness. This is a particularly interesting finding, suggesting that how a physician says something may be as important as what is said. Studies by Roter et al[37] and Hall et al[38] have shown that the emotional tone of a visit may be as strongly predictive of patient satisfaction as the content. Similarly, Lester and Smith[12] used videotapes of simulated visits to measure how likely patients were to sue a physician in the event of a bad outcome; they found that a friendly manner was important in preventing a litigious attitude. More laughter and more use of humor by the no-claims primary care physicians indicate a warmer personal relationship and are consistent with our belief that patients want to be personally connected with their physicians. A warm relationship with the physician may make the patient feel that he or she is a real person in the physician's eyes, rather than a disease. As Anatole Broyard[39] said about his own illness, "I would also like a doctor who enjoyed me. I want to be a story for him." The desire for a connection with the physician is particularly important in long-term relationships, such as a relationship with a primary care physician.

It is surprising that the content of conversation did not predict the claims status of primary care physicians. Since prior studies have found that patient satisfaction is associated with physicians asking and counseling about psychosocial issues, we had anticipated that no-claims primary care physicians would spend more time than claims physicians attending to the psychosocial aspects of care. While there was a bivariate trend for psychosocial and lifestyle counseling to be associated with no-claims status, this did not have a significant effect on the model. In addition, prior communication studies have demonstrated that providing patients with more biomedical information is important to patient satisfaction and adherence. We did not find an association between the provision of information and malpractice claims history. Our finding of the lack of association between the content of conversation and malpractice claims supports our conclusion that what the physician says may be less important than the process and tone of visits for predicting malpractice claims.

Our study did not identify communication styles that predicted malpractice claims for surgeons. To date, the literature on communication has been based almost entirely on primary care visits, and there has been little study of differences in communication between specialties. To our knowledge, this is the first study to audiotape surgeons. It is possible that routine communication is not as important as how surgeons communicate when things go wrong. Perhaps the critical times for communication are when surgeons need to break bad news[40-42] or inform patients about poor surgical outcomes or mistakes.[43,44] It is also possible that communication with surgeons is less important to patients initiating a suit than factors not measured in this study, including true negligence, surgical complications, or financial incentives.[11,45] Furthermore, the expectations of patients visiting surgeons may be distinctly different than the expectations of patients visiting primary care physicians. Patients visiting surgeons may be seeking advice from a technical expert and may expect a businesslike manner. We are conducting qualitative analyses to better understand the communication patterns of surgeons.

Our study has several limitations. The cross-sectional nature of the design makes it impossible to establish causal relationships. It is plausible that the communication behaviors characterizing claims physicians constitute a response to being sued rather than a risk factor for a suit. For many physicians, malpractice litigation touches the very core of professional identity and self-esteem.[46,47] It is such a pivotal experience that it may act to transform the physician's approach to medical practice, including communication style. However, it is unlikely that some of the communication behaviors of the claims physicians, such as the use of fewer orienting statements or less facilitation, are the consequence of being sued. It is more likely that these behaviors led to physicians' increased vulnerability to litigation. In addition, while the primary care model has moderate predictive accuracy, the precision of the individual odds ratios and correct classification rates is limited by the relatively small numbers of claims and no-claims physicians. A larger sample of surgeons may be needed to explore important but weaker associations of communication and malpractice.

This study identifies specific, routine communication behaviors associated with malpractice risk in primary care. Physicians can incorporate these behaviors into routine office practice as they seek to improve their com-

tion skills and ...ease their malprac- ...e risk. Conti... ...g medical education ...ams can h... ...primary care physi- ... improve... ...heir communication sk...s.[48,49] Furth... ...ore, malpractice pre- vention progra... ...should not assume that the same skills are appropriate for different specialty groups. Further research on surgeons is needed to identify teachable skills that might improve communication and decrease malpractice risk.

This study was supported in part by grant R01 07289 from the Agency for Health Care Policy Research, Rockville, Md.

We thank John Santa, MD, Michael Graham, MD, George Thomasson, MD, and Robert Brittain, MD, for their help in physician recruitment. In addition, we appreciate the help of Nigel Chaumeton, PhD and Lauren Haworth, MA, in data analysis.

References

1. Rolph J, Kravitz ... McGuigan K. Malpractice claims data as a g... improvement tool, II: is targeting effective? ...*MA*. 1991;266:2093-2097.
2. Taragin M, Sonn... ...rg F, Karns M, Trout R, Shapiro S, Carson ... physician performance explain interspecia... differences in malpractice claims rates? *Med ...* 1994;32:661-667.
3. Entman SS, Glas... Hickson GB, Githens PB, Whetten-Goldstein ... Sloan FA. The relationship between malpractice... ...ms history and subsequent obstetric care. *JAM...* 1994;272:1588-1591.
4. Charles S, Gibbo... Frisch P, et al. Predicting risk for medical mal... ...ice claims using quality-of-care characteristi... *West J Med*. 1992;157:433-439.
5. Localio AR, Law... ... AG, Brennan TA, et al. Relation between m... ...actice claims and adverse events due to negli... ... results of the Harvard Medical Practice Stu... *III. N Engl J Med*. 1991; 325:245-251.
6. Levinson W, Phys... ...-patient communication: a key to malpractice ...vention. *JAMA*. 1994;273: 1619-1620.
7. Adamson TE, Tso... ...JM, Guillion DS, Oppenberg AA. Health car... ...overy: physician communication skills and ... ...actice claims: a complex relationship. *West J ...* 1989;150:356-360.
8. Hickson GB, Clay... ...C, Githens PB, Sloan FA. Factors that prompt ... ...milies to file malpractice claims following peri... ...injury. *JAMA*. 1992;287: 1359-1363.
9. ...man HB, M... ...akis KM, Suchman AL, ... RM. The do... ...plaintiff relationship: lessons from plaintiff c... ...tions. *Arch Intern Med* 1994;154:1365-1370.
10. Shapiro RS, Simo... ...DE, Lawrence SL, et al. A survey of sued and ... ...ued physicians and suing patients. *Arch Inter... ...d*. 1989;149:2190-2196.
11. Penchansky R, M... ...ee C. Initiation of medical malpractice suits: a co... ...tualization and test. *Med Care*. 1994;32:813-831.
12. Lester GW, Smit... ... Listening and talking to patients: a remedy f... ...alpractice suits? *West J Med*. 1993;158:268-27...
13. Hall JA, Dornan ... Meta-analysis of satisfaction with medical ... description of research design and analysis ... ...erall satisfaction levels. *Soc Sci Med*. 1988;27:... ...644.
14. Kaplan SH, Gree... ... S, Ware JE. Assessing the effects of physicia... ...ient interactions on the outcomes of chronic ... ...se. *Med Care*. 1989;27: S110-S127.
15. Greenfield S, Kap... ...H, Ware JE, Yano EM, Frank HJ. Patients' p... ...ipation in medical care: effects on blood sugar ... ...trol and quality of life in diabetes. *J Gen Inter... ...d*. 1988;3:448-457.
16. Hickson GB, Clay... ...W, Entman SS. Obstetricians' prior malpra... ...xperience and patients' satisfaction with car... ...*MA*. 1994;272:1583-1587.
17. Roter DL. *The Roter Interaction Analysis System (RIAS) Coding Manual*. Baltimore, Md: School of Hygiene and Public Health, Johns Hopkins University; 1991.
18. Inui T, Carter W, Kukull W, Haigh V. Outcome based doctor-patient interaction analysis, I: comparison of techniques. *Med Care*. 1982;20:535-549.
19. Wolraich ML, Albanese M, Stone G, et al. Medical communication behavior system: an interactional analysis system for medical interactions. *Med Care*. 1986;24:891-903.
20. Wissow L, Roter DL, Wilson M. Pediatrician interview style and mothers' disclosure of pyschosocial issues. *Pediatrics*. 1994;93:289-295.
21. Hall J, Irish J, Roter DL, Ehrlich C, Miller L. Gender in medical encounters: an analysis of physician and patient communication in a primary care setting. *Health Psychol*. 1994;13:384-392.
22. Roter DL, Stewart M, Putnam SM, Lipkin M, Stiles W, Inui TS. Communication patterns of primary care physicians. *JAMA*. 1997;277:350-356.
23. Snedecor GW, Cochran WG. Correlations. In: *Statistical Methods*. 8th ed. Ames: Iowa State University Press; 1989:185-186.
24. Hosmer DW, Lemeshow S. Model building strategies and methods for logistic regression. In: *Applied Logistic Regression*. New York, NY: John Wiley & Sons Inc; 1989:82-134.
25. Hosmer DW, Lemeshow S. Assessing the fit of the model. In: *Applied Logistic Regression*. New York, NY: John Wiley & Sons Inc; 1989:135-175.
26. Efron B, Tibshirani R. Cross-validation and other estimates of prediction error. In: *An Introduction to the Bootstrap*. New York, NY: Chapman & Hall; 1993:237-257.
27. Efron B, Gong G. A leisurely look at the bootstrap, the jacknife, and cross-validation. *Am Stat*. 1983;37:36-48.
28. Harrell FE, Lee KL, Mark DB. Multivariate prognostic models: issues in developing models, evaluating assumptions and adequacy, and measuring and reducing errors. *Stat Med*. 1996;15:361-387.
29. Emanuel EJ, Dubler NN. Preserving the physician-patient relationship in the era of managed care. *JAMA*. 1995;273:323-329.
30. White J, Levinson W, Roter D. "Oh by the way . . .": the closing moments of the medical visit. *J Gen Intern Med*. 1993;9:24-28.
31. Lipkin M. The medical interview and related skills. In: Branch WT, ed. *The Office Practice of Medicine*. Philadelphia, Pa: WB Saunders Co; 1987: 1287-1306.
32. Beckman HB, Frankel RM. The impact of physician behavior on the collection of data. *Ann Intern Med*. 1984;101:692-696.
33. Stewart M, Brown JB, Weston WW. Patient-centered interviewing, III: five provocative questions. *Can Fam Phys*. 1989;35:159-161.
34. Cohen-Cole SA. Function 2: building rapport and responding to patients' emotions. In: *The Medical Interview: The Three-Function Approach*. St Louis, Mo: Mosby-Year Book; 1991:21-27.
35. Gask L, McGrath G, Goldberg D, Millar T. Improving the psychiatric skills of established general practitioners: evaluation of group teaching. *Med Educ*. 1987;21:362-368.
36. Beckman HB, Frankel RM, Kihm J, Kulesza G, Geheb OR. Measurement and improvement of humanistic skills in first year trainees. *J Gen Intern Med*. 1990;5:42-45.
37. Roter D, Hall J, Katz N. Relations between physicians' behaviors and analogue patients' satisfaction, recall, and impressions. *Med Care*. 1987; 25:437-451.
38. Hall J, Roter D, Rand C. Communication of affect between patients and physicians. *J Health Soc Behav*. 1981;11:18-30.
39. Broyard A. The patient examines the doctor. In: *Intoxicated by My Illness: And Other Writings on Life and Death*. New York, NY: Clarkson N Potter Inc; 1992:33-58.
40. Strauss RP, Sharp MC, Lorch SC, Kachalia B. Physicians and the communication of "bad news": patient experiences of being informed of their child's cleft lip and/or palate. *Pediatrics*. 1995;96:82-89.
41. Fallowfield LJ, Lipkin M. Delivering sad or bad news. In: Lipkin M, Putnam SM, Lazare A, ed. *The Medical Interview: Clinical Care, Education, and Research*. New York, NY: Springer-Verlag NY Inc; 1995:316-323.
42. Fallowfield LJ, Baum M, Maguire GP. Effects of breast conservation on psychological morbidity associated with diagnosis and treatment of early breast cancer. *BMJ*. 1986;293:1331-1334.
43. Christensen J, Levinson W, Dunn P. Heart of darkness: the impact of mistakes on physicians. *J Gen Intern Med*. 1992;7:424-431.
44. Applegate WB. Physician management of patients with adverse outcomes. *Arch Intern Med*. 1986;146:2249-2252.
45. Vincent C, Young M, Phillips A. Why do people sue doctors? a study of patients and relatives taking legal action. *Lancet*. 1994;343:1609-1613.
46. Charles SC, Wilbert MA, Franke KJ. Sued and nonsued physicians' self-reported reactions to malpractice litigation. *Am J Psychiatry*. 1985;142:437-440.
47. Charles SC, Warnecke RB, Nelson BA, Psykoty CE. Appraisal of the event as a factor in coping with malpractice litigation. *Behav Med*. 1988;14:148-154.
48. Roter DL, Hall J. Improving physicians' interviewing skills and reducing patients' emotional distress: a randomized clinical trial. *Arch Intern Med*. 1995;155:1877-1884.
49. Levinson W, Roter DL. The effects of two continuing medical education programs on communication skills of practicing primary care physicians. *J Gen Intern Med*. 1993;8:318-324.

Medical Errors: The Scope of the Problem

An Epidemic of Errors

The November 1999 report of the Institute of Medicine (IOM), entitled To Err Is Human: Building A Safer Health System, focused a great deal of attention on the issue of medical errors and patient safety. The report indicated that as many as 44,000 to 98,000 people die in hospitals each year as the result of medical errors.

Even using the lower estimate, this would make medical errors the eighth leading cause of death in this country—higher than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). About 7,000 people per year are estimated to die from medication errors alone—about 16 percent more deaths than the number attributable to work-related injuries.

The President ordered the Quality Interagency Coordination Task Force to make recommendations on improving health care quality and protecting patient safety in response to the IOM report. The Report to the President on Medical Errors was issued in February 2000. For more information on medical errors, select www.ahrq.gov/qual/errorsix.htm.

Where Errors Occur

Errors occur not only in hospitals but in other health care settings, such as physicians' offices, nursing homes, pharmacies, urgent care centers, and care delivered in the home. Unfortunately, very little data exist on the extent of the problem outside of hospitals. The IOM report indicated, however, that many errors are likely to occur outside the hospital. For example, in a recent investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in the State.

Costs

Medical errors carry a high financial cost. The IOM report estimates that medical errors cost the Nation approximately $37.6 billion each year; about $17 billion of those costs are associated with preventable errors. About half of the expenditures for preventable medical errors are for direct health care costs.

Not a New Issue

The serious problem of medical errors is not new, but in the past, the problem has not gotten the attention it deserved. A body of research describing the problem of medical errors began to emerge in the early 1990s with landmark research conducted by Lucian Leape, M.D., and David Bates, M.D., and supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality (AHRQ).

The final report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, released in 1998, identified medical errors as one of the four major challenges facing the Nation in improving health care quality. Based on the recommendations of that report, President Clinton directed the establishment of the Quality Interagency Coordination Task Force (QuIC) to coordinate quality improvement activities in Federal health care programs.

The QuIC includes: the Departments of Health and Human Services, Labor, Veterans Affairs, Commerce, and Defense; the Coast Guard; the Bureau of Prisons; and the Office of Personnel Management. AHRQ Director John M. Eisenberg, M.D., serves as the operating chair of the QuIC.

Public Fears

While there has been no unified effort to address the problem of medical errors and patient safety, awareness of the issue has been growing. Americans have a very real fear of medical errors. According to a national poll conducted by the National Patient Safety Foundation:

- Forty-two percent of respondents had been affected by a medical error, either personally or through a friend or relative.
- Thirty-two percent of the respondents indicated that the error had a permanent negative effect on the patient's health.

Overall, the respondents to this survey thought the health care system was "moderately safe" (rated a 4.9 on a 1 to 7 scale, where 1 is not safe at all and 7 is very safe).

Another survey, conducted by the American Society of Health-System Pharmacists, found that Americans are "very concerned" about:

- Being given the wrong medicine (61 percent).
- Being given two or more medicines that interact in a negative way (58 percent).
- Complications from a medical procedure (56 percent).

Most people believe that medical errors are the result of the failures of individual providers. When asked in a survey about possible solutions to medical errors:

- Seventy-five percent of respondents thought it would be most effective to "keep health professionals with bad track records from providing care."
- Sixty-nine percent thought the problem could be solved through "better training of health professionals."

This fear of medical errors was borne out by the interest and attention that the IOM report generated. According to a survey by the Kaiser Family Foundation, 51 percent of Americans followed closely the release of the IOM report on medical errors.

It's a Systems Problem

The IOM emphasized that most of the medical errors are systems related and not attributable to individual negligence or misconduct. The key to reducing medical errors is to focus on

improving the systems of delivering care and not to blame individuals. Health care professionals are simply human and, like everyone else, they make mistakes. But research has shown that system improvements can reduce the error rates and improve the quality of health care:

- A 1999 study indicated that including a pharmacist on medical rounds reduced the errors related to medication ordering by 66 percent, from 10.4 per 1,000 patient days to 3.5 per 1,000 patient days.
- The specialty of anesthesia has reduced its error rate by nearly sevenfold, from 25 to 50 per million to 5.4 per million, by using standardized guidelines and protocols, standardizing equipment, etc.
- One hospital in the Department of Veterans Affairs uses hand-held, wireless computer technology and bar-coding, which has cut overall hospital medication error rates by 70 percent. This system is soon to be implemented in all VA hospitals.

Types of Errors

The IOM defines medical error as "the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim." An adverse event is defined as "an injury caused by medical management rather than by the underlying disease or condition of the patient." Some adverse events are not preventable and they reflect the risk associated with treatment, such as a life-threatening allergic reaction to a drug when the patient had no known allergies to it. However, the patient who receives an antibiotic to which he or she is known to be allergic, goes into anaphylactic shock, and dies, represents a preventable adverse event.

Most people believe that medical errors usually involve drugs, such as a patient getting the wrong prescription or dosage, or mishandled surgeries, such as amputation of the wrong limb. However, there are many other types of medical errors, including:

- Diagnostic error, such as misdiagnosis leading to an incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results, and failure to act on abnormal results.
- Equipment failure, such as defibrillators with dead batteries or intravenous pumps whose valves are easily dislodged or bumped, causing increased doses of medication over too short a period.
- Infections, such as nosocomial and post-surgical wound infections.
- Blood transfusion-related injuries, such as giving a patient the blood of the incorrect type.
- Misinterpretation of other medical orders, such as failing to give a patient a salt-free meal, as ordered by a physician.

Preventing Errors

Research clearly shows that the majority of medical errors can be prevented:

- One of the landmark studies on medical errors indicated 70 percent of adverse events found in a review of 1,133 medical records were preventable; 6 percent were potentially preventable; and 24 percent were not preventable.
- A study released last year, based on a chart review of 15,000 medical records in Colorado and Utah, found that 54 percent of surgical errors were preventable.

Other potential system improvements include:

- Use of information technology, such as hand-held bedside computers, to eliminate reliance on handwriting for ordering medications and other treatment needs.
- Avoidance of similar-sounding and look-alike names and packages of medication.
- Standardization of treatment policies and protocols to avoid confusion and reliance on memory, which is known to be fallible and responsible for many errors.

Next Steps

President Clinton, in an Executive Order dated December 7, 1999, requested that the QuIC develop and submit recommendations to him within 60 days on improving health care quality and protecting patient safety in response to the IOM report. That report was released by the White House on February 22 and may be accessed online at http://www.quic.gov/report/.

Print copies of the report may be obtained by calling 1-800-358-9295; from outside the United States, call (410) 381-3150; toll-free TDD services for the hearing impaired only 888-586-6340.

AHRQ is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, improve patient safety, address medical errors, and broaden access to essential services.

To interview AHRQ's Director, John M. Eisenberg, M.D., contact: Karen J. Migdail at (301) 594-6120 or kmigdail@ahrq.gov.

Publication No. AHRQ 00-PO37
Current as of February 2000

Internet Citation:

Medical Errors: The Scope of the Problem. Fact sheet, Publication No. AHRQ 00-P037. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/errback.htm

---

Return to Medical Errors & Patient Safety
Quality Assessment
AHRQ Home Page
Department of Health and Human Services

ORIGINAL CONTRIBUTION

Medication Errors and Adverse Drug Events in Pediatric Inpatients

Rainu Kaushal, MD, MPH
David W. Bates, MD, MSc
Christopher Landrigan, MD, MPH
Kathryn J. McKenna, MS, RN
Margaret D. Clapp, RPh
Frank Federico, RPh
Donald A. Goldmann, MD

Context Iatrogenic injuries, including medication errors, are an important problem in all hospitalized populations. However, few epidemiological data are available regarding medication errors in the pediatric inpatient setting.

Objectives To assess the rates of medication errors, adverse drug events (ADEs), and potential ADEs; to compare pediatric rates with previously reported adult rates; to analyze the major types of errors; and to evaluate the potential impact of prevention strategies.

Design, Setting, and Patients Prospective cohort study of 1120 patients admitted to 2 academic institutions during 6 weeks in April and May of 1999.

Main Outcome Measures Medication errors, potential ADEs, and ADEs were identified by clinical staff reports and review of medication order sheets, medication administration records, and patient charts.

Results We reviewed 10778 medication orders and found 616 medication errors (5.7%), 115 potential ADEs (1.1%), and 26 ADEs (0.24%). Of the 26 ADEs, 5 (19%) were preventable. While the preventable ADE rate was similar to that of a previous adult hospital study, the potential ADE rate was 3 times higher. The rate of potential ADEs was significantly higher in neonates in the neonatal intensive care unit. Most potential ADEs occurred at the stage of drug ordering (79%) and involved incorrect dosing (34%), anti-infective drugs (28%), and intravenous medications (54%). Physician reviewers judged that computerized physician order entry could potentially have prevented 93% and ward-based clinical pharmacists 94% of potential ADEs.

Conclusions Medication errors are common in pediatric inpatient settings, and further efforts are needed to reduce them.

JAMA. 2001;285:2114-2120 www.jama.com

IATROGENIC INJURIES OCCUR FREquently in hospitalized patients and often have serious sequelae.[1] The Harvard Medical Practice Study estimated that 3.7% of hospitalized patients experienced an adverse event related to medical therapy in New York State in 1984.[1] Of these iatrogenic injuries, 69% were preventable.[2] A more recent study reached similar estimates.[3] An Institute of Medicine report in 1999 estimated that 44000 to 98000 people die each year at least in part because of medical error.[4] Although there has been some controversy about the accuracy of these extrapolated estimates,[5-7] the report dramatically increased awareness of the problem of medical errors.

In the Harvard Medical Practice Study, the most common adverse events were complications of medication use (19.4% of all events).[8] Thirty percent of patients with drug-related injuries died or were disabled for more than 6 months, although not all morbidity and mortality was directly attributable to these drug-related injuries.[1] In response to these concerning findings, the Adverse Drug Event Prevention Study was performed, which addressed medication errors and adverse drug events (ADEs) in hospitalized adults in more detail.[9,10] It found that ADEs were common (occurring at a rate of 6.5 per 100 adult admissions), costly, and often had severe sequelae.[9,11] Other studies largely confirmed these findings.[12,13]

Several studies suggest that about one third of ADEs are associated with medication errors and are thus preventable.[9,14] Bates et al[15] found that medication errors were common, occurring at a rate of 5 per 100 medication orders. However, only 7 in 100 medication errors had significant potential for harm, and 1 in 100 actually resulted in an injury.[15]

Analysis of the origin of errors has suggested that specific improvements in the medication ordering and processing system might reduce the risk of error.[10] Several studies have demonstrated that some of these interventions can be effective. In particular, physician computer order entry reduced medication errors significantly in an academic medical center,[16] as did a dedicated clinical pharmacist in an academic intensive care unit (ICU).[17] Similarly, a computerized clinical decision support program dramatically de-

Author Affiliations: Departments of Medicine (Drs Kaushal, Landrigan, and Goldmann) and Quality Improvement and Risk Management (Ms McKenna), Children's Hospital, Boston, Mass; Division of General Internal Medicine, Brigham and Women's Hospital, Boston (Drs Kaushal and Bates); Pharmacy, Massachusetts General Hospital, Boston (Ms Clapp); and Risk Management Foundation, Cambridge, Mass (Mr Federico).
Corresponding Author and Reprints: Donald A. Goldmann, MD, Children's Hospital, Enders 609, Longwood Avenue, Boston, MA 02115 (e-mail: Don.Goldmann@tch.harvard.edu).

creased antibiotic-associated medication errors and ADEs, as well as total costs for patients in an ICU.[18]

Less information is available regarding the epidemiology and prevention of medication errors and ADEs in pediatric inpatient settings.[19] Children pose unique challenges to the system for ordering, dispensing, administering, and monitoring medications. For example, since weight-based dosing is needed for virtually all drugs in pediatrics, ordering medications typically involves more calculations than for adults. Dispensing drugs in pediatrics is also error-prone because pharmacists often must dilute stock solutions. Young children do not have the communication skills to warn clinicians about potential mistakes in administering medications, or about adverse effects that they may experience. Finally, all children, especially neonates, may have more limited internal reserves than adults with which to buffer errors. For example, the cardiovascular system of a premature baby may be unable to cope with even a small error in the dosage of an inotropic agent.

To assess the epidemiology of medication errors, potential ADEs, and ADEs in hospitalized children, we performed a prospective cohort study in 2 academic institutions. Our goals were to (1) determine the rates of medication errors, potential ADEs, and ADEs; (2) compare rates in a pediatric hospital setting with previously reported rates in adult hospitals; (3) analyze the major types of errors; and (4) assess the potential impact of prevention strategies.

METHODS

Study Sites

The study was conducted at 2 urban teaching hospitals with socioeconomically diverse patient populations. One hospital (hospital A) is a freestanding pediatric institution. The other hospital (hospital B) treats both adult and pediatric patients, but has a geographically and administratively distinct pediatric service. Adults comprise less than 5% of patients treated on the pediatric wards. They generally have complex long-term medical and surgical conditions, such as congenital diseases (eg, cystic fibrosis, cardiac anomalies, metabolic diseases, sickle cell disease), multiple disabilities, immunosuppressive conditions, and eating disorders.

At hospital A, we studied 2 randomly selected general medical wards, 1 randomly selected general surgical ward, the short-stay medical ward, and the pediatric medical/surgical ICU (which has few cardiac patients because there is a separate cardiac ICU). The oncology ward and neonatal ICU (NICU) were not studied at this hospital because these units were preparing for possible introduction of computerized order entry. At hospital B, all pediatric wards were studied, including the general medical/surgical wards (including oncology patients), the pediatric medical/surgical ICU, and the NICU. In total, we studied 9 wards. There were clear differences in case mix, as well as staffing, among individual wards of the 2 hospitals.

Medication Systems

Physicians at both hospitals currently handwrite orders, copies of which are sent to the pharmacy. At hospital A, nurses transcribe orders into the medication administration record (MAR). Hospital A has satellite-based pharmacists who dispense ready-to-administer doses to the floor, but do not actively participate in other activities, such as ward-based rounds.

At hospital B, clerks transcribe orders into the MAR. A supply of medications is provided to the units, with nurses subsequently performing dose calculations and drug administration. Pediatric clinical pharmacists attend work rounds, monitor transcriptions, and assist nurses with calculations. Since these pharmacists are assigned to multiple units daily, they have limited time to spend on each unit.

Definitions

Medication errors were defined as errors in drug ordering, transcribing, dispensing, administering, or monitoring. An example is an order written for amoxicillin without a route of administration. Some medication errors have significant potential for injuring a patient and are considered potential ADEs. Potential ADEs may be intercepted before reaching the patient. An example of an intercepted potential ADE would be an order written for a 10-fold overdose of morphine that is intercepted and corrected by a pharmacist before reaching the patient. A nonintercepted potential ADE would be an overdose of acetaminophen administered to a patient who does not experience any sequelae. ADEs are injuries that result from the use of a drug. Some ADEs are associated with a medication error and therefore are considered preventable, while some are not associated with a medication error and therefore are considered nonpreventable. An example of a preventable ADE is the development of rash after the administration of ampicillin/sulbactam to a patient known to be allergic to penicillin. In contrast, a nonpreventable ADE would be development of *Clostridium difficile* colitis after appropriate antibiotic use. Finally, rule violations are faulty medication orders with little potential for harm or extra work because nursing and pharmacy staff typically interpret them correctly without additional clarification. An example is a pain medication ordered on a per need basis for a postoperative patient without an explicit reason for administration stated. Rule violations were not considered medication errors.

Case Finding

One physician (R.K.) trained all data collectors, who were nurses, pharmacists, and physicians, in an identical manner. During the 2-week training period, the unique perspectives of these different disciplines were shared to maximize appreciation of potential error types and to develop a comprehensive, uniform approach to error detection. We determined inter-rater reliability by a random sampling of 10% of the data collected at each institution by a data collector from the other institution.

Data collectors identified medication errors, potential ADEs, and ADEs

Table 1. Rates of Medication Errors and Adverse Drug Events (ADEs)*

	Total	No. per 100 Orders	No. per 100 Admissions	No. per 1000 Patient-Days
Medication orders	10778	NA	962	2741
Medication errors	616	5.7	55	157
Potential ADEs	115	1.1	10	29
ADEs	26	0.24	2.3	6.6
Preventable ADEs	5	0.05	0.52	1.8
Nonpreventable ADEs	21	0.20	1.9	5.3

*NA indicates data not applicable.

by voluntary and verbally solicited reports from house officers, nurses, and pharmacists; and by medication order sheet, MAR, and chart review of all hospitalized patients on study wards. On a given day, 1 data collector was assigned to each study ward based on individual availability. Data collected for each incident included name, dose, route and category of drug, point in the system where the error occurred, and type of error. Data collectors worked 5 days per week, with recording of weekend data on Mondays for patients still hospitalized. At the end of the study, we obtained administrative data for each patient hospitalized on the study wards, including age, sex, and race.

Reliable detection of medication errors requires cooperation and engagement of the staff, which depends in large measure on reducing suspicion and fear of reporting. Before initiating this study, we gained the support of the leadership of nursing, pharmacy, medical staff, and administration at each hospital. House staff, nurses, and pharmacists received informal seminars that emphasized the roles of complex systems and human factors in predisposing to error, as opposed to individual blame. We stressed the importance of understanding the epidemiology and causes of error, and reinforced the multidisciplinary nature of systems improvement. We performed the study over 6 weeks in April and May of 1999, after obtaining institutional review board approval at each institution.

Review Process

Two physicians (D.W.B. and D.A.G.) independently reviewed suspected ADEs and potential ADEs and classified them as ADEs, potential ADEs, medication errors, and rule violations. The physician reviewers rated ADEs and potential ADEs according to the severity of injury to the patient using a 4-point Likert scale. They also rated ADEs on preventability using a 5-point Likert scale and attribution (ie, the likelihood that the incident is due to the specific drug) using the Naranjo algorithm.[20] The 2 evaluators resolved all disagreements through discussion and consensus.

Statistical Methods

We report rates of errors per 100 orders, 100 admissions, and 1000 patient-days. We did subanalyses of preventable and potential ADEs. We measured age-specific rates per 100 admissions, and analyzed them assuming that the number of errors occurring during an admission followed a Poisson distribution. We measured ward-specific rates per 100 orders and compared them using the χ^2 test for categorical variables since it was extremely rare for more than 1 error to occur during a single order. Similarly, we compared rates per 100 orders between adult and pediatric hospital settings and analyzed them using the χ^2 test. When we assumed that the number of errors per order followed a Poisson distribution, we obtained similar results, so we report only the χ^2 test results. The SAS statistical package (for Windows 6.12) was used (SAS Institute Inc, Cary, NC).

We calculated inter-rater reliabilities using the percentage of agreement and the κ statistic. The data collectors and physician reviewers had moderate-to-excellent agreement with 87%-to-100% agreement and κ statistics of 0.65 to 1.0.

RESULTS

The 36-day study period included 1120 admissions and 3932 patient-days, during which 10778 orders were written. The patients included 183 (16%) neonates, 326 (29%) infants, 223 (20%) preschoolers, 161 (14%) school-aged children, 191 (17%) teenagers, and 36 (3%) adults. Of the children, 525 (49%) were female, 731 (65%) were white, 139 (12%) were Hispanic, and 79 (7%) were black.

There were 616 medication errors (5.7%) or 55 medication errors per 100 admissions (TABLE 1). In total, 320 patients accounted for these medication errors and 64 patients had 3 or more errors. We found 26 ADEs (0.24%), of which 5 (19%) were preventable. In addition, we identified 115 potential ADEs (1.1%), which occurred at a rate of 10 potential ADEs per 100 admissions.

Medication errors occurred more frequently in adults compared with other age groups (86 vs 62 for neonates, 41 for infants, 48 for preschoolers, 58 for school-aged children, and 63 for teenagers per 100 admissions; $P = .006$). The rate of potential ADEs was considerably higher in neonates than in other age groups (20 vs 5 for infants, 8 for preschoolers, 12 for school-aged children, 11 for teenagers, and 14 for adults per 100 admissions; $P < .001$).

Given the high rate of neonatal potential ADEs, we performed a subanalysis comparing the 54 neonatal patients in the NICU with the 129 neonatal patients in other wards. The NICU neonates were primarily premature with low birth weights and respiratory and nutritional issues, while non-NICU neonates were primarily admitted for infections or congenital abnormalities. Neonates in the NICU experienced significantly higher medication error and potential ADE rates (91 and 46 per 100 admissions, respectively) than neonates in other wards (50 and 9 per 100 admissions, respectively) ($P < .001$ for both comparisons).

Error rates were similar across units (5.5 errors per 100 orders for the NICU, 5.7 for pediatric ICUs, 6.0 for medical wards, 6.1 for combined medical/

surgical wards, and 4.7 for the surgical ward; $P=.31$). However, the NICU had a significantly higher rate of potential or preventable ADEs compared with other wards (2.8 per 100 orders vs 0.78 for medical wards, 0.44 for surgical wards, 0.77 for combined medical/surgical wards, and 1.3 for pediatric ICUs; $P<.001$).

Most medication errors were dosing errors (28%), followed by route of administration, MAR transcription and documentation, date, and frequency of administration errors (TABLE 2). Similarly, most potential ADEs were due to dosing errors (34%), followed by frequency and route errors. The most common stage for medication errors and potential ADEs was physician ordering (74% and 79%, respectively), followed by transcription and nurse administration. The most common drugs involved in medication errors and potential ADEs were anti-infective agents, analgesics and sedatives, electrolytes and fluids, and bronchodilators. The drug routes of medication errors and potential ADEs were most commonly intravenous followed by oral and inhalation.

In addition, physician reviewers judged that 93% of the potential ADEs were potentially preventable by physician computer order entry with clinical decision support, 94% by ward-based clinical pharmacists, and none by computerized MAR. Finally, they judged that computerized physician order entry could have prevented 4 of the 5 preventable ADEs and that ward-based clinical pharmacists could have prevented 4 of the 5 preventable ADEs. For these judgments, the role of the clinical pharmacist included full-time participation in work rounds, monitoring the MAR transcription process, communicating with satellite pharmacies, and assisting nurses with medication dose calculation and administration.

During the study period, 26 ADEs were identified, 5 of which resulted from medication errors and thus were judged to be preventable (TABLE 3). The preventable ADEs included excessive sedation, hypothermia, worsening pain, a rash, and stool impaction. Errors associated with these 5 incidents included 2 overdoses, a missing dose, a drug administration error, and administration of a medication to a patient with a known allergy. Two events involved narcotics, 1 an analgesic, 1 an antibiotic, and 1 a laxative. The route of 2 medications

Table 2. Types of Medication Errors and Potential Prevention Strategies*

Variable	Medication Errors (n = 616)	Potential Adverse Drug Events (n = 115)
Error type		
Dose	175 (28)	44 (34)
Frequency	58 (9.4)	23 (20)
Route	109 (18)	16 (14)
Medication administration record transcription or documentation	85 (14)	9 (7.8)
Wrong drug	8 (1.3)	6 (5.2)
Wrong patient	1 (0.16)	1 (0.86)
Known allergy	8 (1.3)	5 (4.3)
Illegible order	14 (2.3)	2 (1.7)
Missing or wrong weight	23 (3.7)	1 (0.86)
No or wrong date	74 (12)	0 (0)
Other	61 (9.9)	8 (7)
Stage of error		
Physician ordering	454 (74)	91 (79)
Transcribing	62 (10)	13 (11)
Nurse administering	78 (13)	5 (4.3)
Pharmacy dispensing	6 (0.97)	4 (3.5)
Patient monitoring	4 (0.65)	0 (0)
Missing	12 (1.9)	3 (2.6)
Drug category		
Anti-infective drugs	120 (20)	32 (28)
Analgesics and sedatives	101 (16)	19 (17)
Electrolytes and fluids	162 (26)	17 (15)
Bronchodilators	44 (7.1)	11 (9.6)
Other	166 (27)	36 (31)
Missing	23 (3.7)	0 (0)
Drug route		
Intravenous	337 (55)	62 (54)
Oral	126 (21)	25 (22)
Inhalation	46 (7.5)	14 (12)
Other	82 (13)	14 (12)
Missing	25 (4.1)	0 (0)
Potential prevention strategy		
Ward-based clinical pharmacist	587 (95)	108 (94)
Computerized physician order entry with decision support	419 (68)	107 (93)
Computerized medication administration record	110 (18)	0 (0)

*Values are expressed as number (percentage).

Table 3. Preventability and Severity of Adverse Drug Events (ADEs) and Potential ADEs

	No. (%) of ADEs		No. (%) of Potential ADEs	
Level of Severity	Not Preventable (n = 21)	Preventable (n = 5)	Not Intercepted (n = 47)	Intercepted (n = 68)
Fatal or life-threatening	2 (10)	0 (0)	2 (4)	16 (23)
Serious	5 (24)	4 (80)	24 (51)	28 (41)
Significant	14 (66)	1 (20)	21 (45)	24 (35)

Table 4. Comparison of Medication Errors and Adverse Drug Events (ADEs) in Pediatric and Adult Hospital Settings

	No. (%)		
	Pediatric (n = 10 778)	Adult* (n = 10 070)	*P* Value
Medication errors	616 (5.7)	530 (5.3)	.15
Potential ADEs	115 (1.1)	35 (0.35)	.001
ADEs	26 (0.24)	25 (0.25)	.92
Preventable ADEs	5 (0.05)	5 (0.05)	.91
Nonpreventable ADEs	21 (0.20)	20 (0.20)	.95

*Prior study carried out at Brigham and Women's Hospital with similar methods in 1992.[15]

was intravenous, 1 oral, 1 epidural, and 1 via suppository. Physician reviewers classified 4 of the preventable ADEs as serious and 1 as significant. Of the 21 nonpreventable ADEs, 14 were related to antibiotic use, including *C difficile* infections, rashes, allergic reactions, gastrointestinal tract distress, and a yeast infection. The remaining 7 were narcotic-related, including respiratory depression, sedation, and gastrointestinal tract and allergic reactions. Fifteen of the medications were administered intravenously, 5 orally, and 1 via epidural.

Of the 115 potential ADEs, 68 (59%) were intercepted while 47 (41%) were not (Table 3). The physician reviewers determined that 18 (16%) of the potential ADEs were potentially fatal or life-threatening, 52 (45%) were serious, and 45 (39%) were significant. Examples of potentially fatal or life-threatening intercepted potential ADEs included physician orders for a heparin overdose, a digoxin overdose, and amoxicillin for a patient with a previous anaphylactic reaction to penicillin. Among the most common errors associated with potential ADEs were physicians ordering inappropriately high or low does of medications, ordering medications despite known allergies, ordering medications without routes, and the pharmacy dispensing incorrect medications.

COMMENT

We found that medication errors were common in the inpatient pediatric setting. Potential ADEs occurred more frequently in neonates, particularly in the NICU. The rate of medication errors was higher in adults cared for in the pediatric hospital setting. Errors occurred most commonly at the stage of drug ordering. Dosing errors and errors involving the intravenous route were most frequent. The drug classes associated most frequently with errors were anti-infectives, electrolytes and fluids, and analgesics and sedatives. Most errors appeared to be preventable by physician computer order entry with clinical decision support or full-time, ward-based clinical pharmacists.

We compared the results of this study to a 1992 study using similar methods in an adult patient population (TABLE 4).[15] In 1992, physicians at the adult hospital hand-wrote orders, clerks primarily transcribed orders to the MAR, and pharmacists were primarily satellite-based, with some ward-based involvement in the medical ICU. Both studies had similar rates of medication errors, ADEs, and preventable ADEs; however, the rate of potential ADEs was about 3 times higher in this pediatric study (1.1% vs 0.35%; $P<.001$). Interinstitutional comparisons can be difficult to standardize, although in this case 1 physician (D.W.B.) was involved in both studies.

Relatively little research has addressed the problem of medication errors and ADEs in pediatric inpatient settings. Reliable error detection requires intensive, comprehensive, and active ward-based data collection. We used a multidisciplinary approach that examined all aspects of the medication system, from the physician's order through administration of the drug to the patient. Moreover, we encouraged voluntary reporting by emphasizing the role of systems problems in the origin of errors and by nurturing a blame-free environment. In a previous pediatric study by Folli et al,[19] errors were detected solely by pharmacist review of physician orders, and lower error rates of 0.45 to 0.49 per 100 orders were found. Although 74% of errors in our study occurred in drug orders, many of these errors were detected and corrected prior to the order reaching the pharmacy.

As expected, we found that the errors with potential for harm occurred most often in the youngest, most vulnerable patients cared for in the NICU. Neonatal weights change rapidly, making appropriate dosing particularly difficult. Moreover, medication errors in critically ill neonates may have more serious consequences compared with relatively healthy neonates or older children because they have limited ability to buffer errors. Pharmacists also face special challenges with neonatal drugs because medications generally are not supplied in dosages suitable for neonates and must be diluted.

The relatively small number of adult patients also had significantly higher medication error rates. This may be due to the typically high medical complexity of adult patients cared for in pediatric settings, or the lack of familiarity of pediatric house staff with adult dosing.

The high risk of medication errors highlights the importance of developing, testing, and implementing effective error-prevention strategies in pediatrics. Cogent theories regarding the origin of errors (often categorized as human factor research)[21] have been developed. Most investigators have focused on problems in health care delivery systems that predispose to error, rather than emphasizing the role of individuals.[22-26] Human fallibility is magnified substantially by complex and poorly designed systems, poor teamwork, and psychological and environmental stressors such as fatigue, anxiety, poor lighting, and noise. The safest work environments address these issues by designing systems to prevent errors, make errors visible, and mitigate the effects of errors.[22] Ongoing multidisciplinary analysis of incidents, also

termed root cause analysis, is important for developing further system improvements.[27]

While a number of interventions based on these principles have been studied in adults, few data are available in pediatrics. The study by Folli et al[19] demonstrated that pharmacy review of medication orders could prevent erroneous orders from being implemented at a rate of 14 to 18 per 1000 patient-days. Unfortunately, other interventions remain largely untested in children.

Review of preventable and potential ADEs by the physician evaluators in this study suggested that the majority could potentially have been prevented by computerized physician order entry with clinical decision support (eg, drug-allergy checks, drug-dose checks, drug-drug interaction checks). This finding is not surprising since 79% of the potential ADEs occurred at the stage of ordering of medications. Common types of ordering errors included physician omission or incorrect choice of dose, route, or frequency; order illegibility; and physician use of nonstandard terminology.

Studies in adult hospitals have demonstrated the impact of computerized physician order entry on error reduction. Computerized physician order entry reduced the rate of nonintercepted serious medication errors by 55% in a large tertiary care adult hospital.[16] In another study of this system, limited decision support decreased the medication error rate by 64%, and with more developed decision support the error rate decreased by 81%.[28] Coupling physician order entry with a computerized MAR is likely to reduce transcription errors, a common class of inpatient medication errors (10% in this study).

It is important to recognize, however, that some of the factors making children vulnerable to errors also complicate development of computerized pediatric systems. For example, pharmacokinetics and appropriate drug doses change rapidly as a premature neonate gains weight and renal and hepatic drug elimination systems mature. A pediatric computer order entry system will have to be sufficiently flexible to respond to these changes.

Review of preventable and potential ADEs by the physician evaluators in this study suggested that full-time, ward-based clinical pharmacists potentially could have prevented the majority of errors. Traditionally, physicians decide on drug therapy, and pharmacists and nurses implement these decisions. The presence of clinical pharmacists on work rounds may lead to more informed clinical decisions by physicians, as well as interception of errors before medication orders are finalized. Their presence on the wards should facilitate communication between clinical staff and the pharmacy. In addition, clinical pharmacists could independently monitor the transcription process, assist nurses with drug preparation and administration, and monitor the drug preparation, storage, and distribution systems. They also could be involved in developing education programs and drug therapy protocols. Although ward-based pharmacists were present in one of the hospitals we studied, they were not involved full time in work rounds, monitoring the transcription process, or other ward-based error prevention activities.

A clinical pharmacist participating in physician rounds in an adult ICU decreased preventable ADEs by 66%.[17] In addition, ward-based interventions may reduce costs of care. During a 3-month study, a clinical pharmacist made 345 interventions in an adult ICU, leading to a $24 000 cost reduction.[29] However, the impact of ward-based clinical pharmacists has not been assessed in pediatrics.

Our study has several limitations. We studied 2 academic institutions, so our results may not be generalizable to nonacademic hospitals in which most children receive care. Despite a comprehensive multidisciplinary approach to data collection, we probably failed to detect some errors, particularly administration errors detected more reliably by trained observers following nurses during routine patient care activities.[30] Also, we did not attempt to detect inappropriate drug choice, which is detected most reliably using explicit criteria based on evidence, rather than implicit criteria based on clinical judgment.[31] Because nurses and physicians on the study wards were aware of the study, the Hawthorne effect could have affected both the occurrence and detection of errors. In addition, the incidence of errors could have been reduced as the study progressed because we were obliged to take corrective action when we identified serious practice problems. For example, an incorrect preparation of insulin was dispensed to one of the medical floors resulting in mild hypoglycemic events in children with diabetes, and we notified the pharmacy immediately.

Classification bias may have affected our finding that the highest rate of potential ADEs occurred in neonates, since we used expert clinical judgment and consensus to classify incidents. The 2 investigators who made these determinations may have been inclined to consider errors as potentially harmful when they occurred in critically ill neonates. However, the potential ADE rate was so much higher in this group that it is unlikely to be completely attributable to subjectivity. Furthermore, 3 of the 5 preventable ADEs occurred in neonates in the NICU.

The development and testing of medication error reduction interventions is important in pediatrics, especially in the NICU, given the increased medical vulnerability and decreased communication ability of small and critically ill children, the need for weight-based dosing, and the need for pharmacy dilution of stock medications. To reduce the rates of potential and preventable ADEs in pediatrics, the most effective interventions are likely to be computerized physician order entry with integrated clinical decision support and full-time, ward-based clinical pharmacists.

Author Contributions: *Study concept and design:* Kaushal, Bates, Landrigan, McKenna, Clapp, Federico, Goldmann.
Acquisition of data: Kaushal, Landrigan, McKenna, Goldmann.
Analysis and interpretation of data: Kaushal, Bates, Landrigan, Federico, Goldmann.
Drafting of the manuscript: Kaushal, Goldmann.
Critical revision of the manuscript for important intellectual content: Bates, Landrigan, McKenna, Clapp, Federico, Goldmann
Statistical expertise: Kaushal, Landrigan.
Obtained funding: Kaushal, Bates, Landrigan, McKenna, Goldmann.
Administrative, technical, or material support: Bates, Landrigan, McKenna, Clapp, Federico, Goldmann.
Study supervision: Bates, Goldmann.

Financial Disclosure: Dr Bates has received honoraria for speaking from Eclipsys Corp, which has licensed the rights for possible commercial development to Brigham and Women's Hospital Clinical Information System. Dr Bates is coinventor on patent No. 6029138 held by Brigham and Women's Hospital on the use of decision support software for medical management, licensed to Medicalis Corp. He holds a minority equity position in Medicalis, a privately held company that develops Web-based decision support for radiology test ordering. He also serves as a consultant to Medicalis. Dr Bates is also a consultant and serves on the advisory board for McKesson MedManagement, a company that assists hospitals in preventing adverse drug events. He has received honoraria for speaking from Automated Healthcare, which makes robots that dispense medications. He is also on the clinical advisory boards for Becton Dickinson, which develops drug delivery systems; Zynx Inc, which develops evidence-based algorithms; and SoCurious Inc, which compiles information on compliance for drug companies; and he is a consultant for Alaris, which makes intravenous drug delivery systems.
Funding/Support: This work was supported by a grant from the Risk Management Foundation. Dr Kaushal was partially supported by grant T32 HS00063 from the Agency for Healthcare Research and Quality.
Acknowledgment: We would like to thank John Orav, PhD, for his statistical assistance, and Erin Hartman, MS, for her review of the manuscript. In addition, we would like to thank Priscilla Dasse, RN, MPH, Alan Ezekowitz, MD, PhD, Constance Crowley Ganzer, MS, RN, and Ronald Kleinman, MD, for their support.

REFERENCES

1. Brennan TA, Leape LL, Laird N, et al. Incidence of adverse events and negligence in hospitalized patients: results from the Harvard Medical Practice Study I. *N Engl J Med.* 1991;324:370-376.
2. Leape LL, Lawthers AG, Brennan TA, Johnson WG. Preventing medical injury. *Qual Rev Bull.* 1993;19:144-149.
3. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care.* 2000;38:261-271.
4. *To Err is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 1999.
5. Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA.* 2000;284:95-97.
6. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA.* 2000;284:93-95.
7. Brennan TA. The Institute of Medicine report on medical errors—could it do harm? *N Engl J Med.* 2000;342:1123-1125.
8. Leape LL, Brennan TA, Laird NM, et al. The nature of adverse events in hospitalized patients: results from the Harvard Medical Practice Study II. *N Engl J Med.* 1991;324:377-384.
9. Bates DW, Cullen D, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA.* 1995;274:29-34.
10. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA.* 1995;274:35-43.
11. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. *JAMA.* 1997;227:307-311.
12. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality. *JAMA.* 1997;277:301-306.
13. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA.* 1998;279:1200-1205.
14. Bates DW, Leape LL, Petrycki S. Incidence and preventability of adverse drug events in hospitalized adults. *J Gen Intern Med.* 1993;8:289-294.
15. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape LL. Relationship between medication errors and adverse drug events. *J Gen Intern Med.* 1995;10:199-205.
16. Bates DW, Leape LL, Cullen DJ, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA.* 1998;280:1311-1316.
17. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999;282:267-270.
18. Evans RS, Pestotnik SL, Classen DC, et al. A computer-assisted management program for antibiotics and other antiinfective agents. *N Engl J Med.* 1998;338:232-238.
19. Folli HL, Poole RL, Benitz WE, Russo JC. Medication error prevention by clinical pharmacists in two children's hospitals. *Pediatrics.* 1987;79:718-722.
20. Naranjo CA, Busto O, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther.* 1981;30:239-245.
21. Reason J. *Human Error.* Cambridge, England: Cambridge University Press; 1990.
22. Leape LL. Error in medicine. *JAMA.* 1994;272:1851-1857.
23. Perrow C. *Normal Accidents.* New York, NY: Basic Books; 1984.
24. Forrester JW. Counterintuitive behavior of social systems. *MIT Technol Rev.* 1971;73:52-68.
25. Berwick DM. Continuous improvement as an ideal in health care. *N Engl J Med.* 1989;320:53-56.
26. Glauber J, Goldmann DA, Homer CJ, Berwick DM. Reducing medical error through systems improvement: the management of febrile infants. *Pediatrics.* 2000;105:1330-1332.
27. Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook.* Oakbrook, Ill: Joint Commission on Accreditation of Healthcare Organizations; 1999.
28. Bates DW, Teich J, Lee J, et al. The impact of computerized physician order entry on medication error prevention. *J Am Med Inform Assoc.* 1999;6:313-321.
29. Katona BG, Ayd PR, Walters JK, Caspi M, Finkelstein BW. Effect of a pharmacist's and a nurse's interventions on cost of drug therapy in a medical intensive-care unit. *Am J Hosp Pharm.* 1989;46:1179-1182.
30. Allan EL, Barker KN. Fundamentals of medication error research. *Am J Hosp Pharm.* 1990;47:555-571.
31. Asthon CM, Kuykendall DH, Johnson ML, et al. An empirical assessment of the validity of explicit and implicit process-of-care criteria for quality assessment. *Med Care.* 1999;37:798-808.

Pediatric Asthma Encounter Form: see attached DD Form 2005 for Privacy Act Statement

Today's Date:
Date of Last Visit:
Check In Time:

☐ Initial Visit ☐ Follow-up visit
Referring Facility:
Referring Physician:

SECTION 1: CONCERNS FOR TODAY'S ASTHMA VISIT

1.

2.

3.

Current Age: | Age of diagnosis: | Race:

SECTION 2: INTERVAL HISTORY AND PERTINENT REVIEW OF SYSTEMS

ASTHMA TRIGGERS

Have triggers been identified? YES NO

Dust	Roaches
Exercise	Seasonal allergies
Fumes	Sinusitis
GE Reflux / heartburn	Smoke
Head/Chest Colds	Stress
Molds	Temperature extremes/changes
Pets	Other:

Has allergy testing been performed? YES NO N/A Refused

Peak Flow: (if applicable)
Recent am/pm rates: / Best:

Other Historical Details:

RISK ASSESSMENT SCREENING QUESTIONS

Enrolled in EFMP?	YES NO
Eczema?	YES NO
Household smokers?	YES NO
Household pets? (type:)	YES NO
Family history of asthma?	YES NO Unknown
Shortness of breath with exercise or play?	YES NO
Rescue medicine use >2 times per week?	YES NO
Nocturnal symptoms >2 times per month?	YES NO
Food Allergies?	YES NO
Current Asthma Action Plan?	YES NO
Spacer use?	YES NO
Instructed in peak flow meter use?	YES NO N/A Refused
Number of days missed from school for asthma flares in the past 3 months?	
Number of days missed from work due to child's asthma in the past 3 months?	
Times needing an unscheduled medical visit in the past 3 months for an asthma flare?	
Times admitted to an ICU for an asthma flare?	
Times on a mechanical ventilator for an asthma flare?	
Date of last hospital admission for an asthma flare?	

SECTION 3: MEDICATIONS

Current Asthma Management:	dosage form	dose	frequency
Relievers			
Controllers			
Nasal Steroid			
Nasal Antihistamine			
GERD Controller			

Other Medications (incl. OTC & Herbals):

SECTION 4: MEDICATION ALLERGIES / REACTIONS / CONTRAINDICATIONS

☐ Beta-Blockers ☐ Aspirin ☐ Other

SECTION 5: IMMUNIZATIONS

☐ VARICELLA VACCINATION OR ACTUAL DISEASE ☐ ANNUAL FLU IMMUNIZATIONS (date) ☐ PNEUMOVAX (age >2 w/ chronic disease)

Patient's Identification:

Walter Reed Army Health Care System
Asthma Centers

DACH 703-805-0850 **WRAMC** 202-782-7457 **KACC** 301-677-8243

WRAMC FORM 19
Jun 02

SECTION 6: VITAL SIGNS

T	BP	P	R	pOx	Wt	Ht	Pain

SECTION 7: PHYSICAL EXAMINATION

HEENT:

Chest wall:

Lungs:

Heart:

Abdomen:

Extremities/Skin:

SECTION 8: SPIROMETRY / RADIOLOGY / LAB

	PRE	POST % change
FVC (L)		XXXXXXXXXXXX
FEV1 (L)		
FEV1/FVC (%)		XXXXXXXXXXXX
FEF 25-75% (L/sec)		
PEFR (L/sec)		

Date of last PFT: _____

Lab Findings:

CXR FINDINGS:

SECTION 9: ASSESSMENT

1.)	☐ MILD INTERMITTENT	☐ MILD PERSISTANT	☐ MODERATE PERSISTANT	☐ SEVERE PERSISTANT
Symptom Frequency	≤ 2 / week	> 2 / week	Every day	Continuous
Nocturnal Symptoms	≤ 2 / month	> 2 / month	> 1 / week	Frequent
Peak Flow (% max)	≥ 80%	≥ 80%	≥ 60 & < 80%	< 60 %
Bronchodilator use	≤ 1 / week	PRN to 2 puffs qid	≤ 10 puffs / day	> 10 puffs / day
Management	Reliever	Reliever and mild controller	Reliever and moderate dose controller	Reliever, high dose controller, Ped Pulm. or Allergy assessment

2.)

3.)

SECTION 10: PLAN & PREVENTION

MEDICATION CHANGES, EVALUATIONS, AND / OR RECOMMENDATIONS

1.

2.

3.

4.

ASTHMA EDUCATION: (PREVENTION)

☐ Asthma Action Plan ☐ Medication Function ☐ What is Asthma ☐ MDI/Spacer ☐ Environmental Triggers ☐ Use of Peak Flow Meter ☐ ☐ ☐

FOLLOW-UP IN: ☐ 1 month ☐ 3 months ☐ 6 months ☐

WITH: ☐ Primary Care Manager ☐ Allergist ☐ Asthma Center ☐ Pulmonologist ☐

☐ Allergy Consult (if appropriate)

☐ Immunizations → ☐ Flu Shot ☐ Pneumovax

☐ Recommend EFMP Enrollment

☐ Annual bone densitometry (consider in patients on high dose steroids or as clinically indicated)

☐ Patient / Care Provider verbalizes understanding of plan.

HEALTH CARE PROVIDER

ATTENDING

MEDICAL RECORD-SUPPLEMENTAL MEDICAL DATA

For use of this form, see AR 40-66; the proponent agency is the Office of The Surgeon General.

TITLE
ASTHMA HOME MANAGEMENT PLAN

OTSG APPROVED (Date)

TELEPHONE NUMBERS: Primary Provider _____ Emergency Center _____

GREEN ZONE: Doing Well

- No cough, wheeze, chest tightness, or shortness of breath during the day or night
- Can do usual activities

And, if a peak flow meter is used,
Peak flow: more than _____
(80% or more of my best peak flow)

My best peak flow is: _____

Take These Long-Term-Control Medicines Each Day (include an anti-inflammatory)

Medicine	How much to take	When to take it

Before exercise ☐ _____ ☐ 2 or ☐ 4 puffs 5 to 60 minutes before exercise

YELLOW ZONE: Asthma Is Getting Worse

- Cough, wheeze, chest tightness, or shortness of breath, or
- Waking at night due to asthma, or
- Can do some, but not all, usual activities

-Or-

Peak flow: _____ to _____
(50% - 80% of my best peak flow)

FIRST: **Add: Quick-Relief Medicine – and keep taking your GREEN ZONE medicine**

_____ ☐ 2 or ☐ 4 puffs, every 20 minutes for up to 1 hour
(short-acting beta$_2$-agonist) ☐ Nebulizer, once

THEN: If your symptoms (and peak flow, if used) *return to GREEN ZONE* after 1 hour of above treatment:
☐ Take the quick-relief medicine every 4 hours for 1 to 2 days.
☐ Double the dose of your inhaled steroid for _____ (7-10) days.

-Or-

If your symptoms (and peak flow, if used) *do not return to GREEN ZONE* after 1 hour of above treatment:
☐ Take: _____ ☐ 2 or ☐ 4 puffs or ☐ Nebulizer
(short-acting beta$_2$-agonist)
☐ Add: _____ _____ mg. per day For _____ (3-10) days
(oral steroid)
☐ Call the doctor ☐ before/ ☐ within _____ hours after taking the oral steroid.

RED ZONE: Medical Alert!

- Very short of breath, or
- Quick-relief medicines have not helped, or
- Cannot do usual activities, or
- Symptoms are same or get worse after 24 hours in Yellow Zone

-Or-

Peak flow: less than _____
(50% of my best peak flow)

Take this medicine:

☐ _____ ☐ 4 or ☐ 6 puffs or ☐ Nebulizer
(short-acting beta$_2$-agonist)
☐ _____ _____ mg.
(oral steroid)

Then call your doctor NOW. Go to the hospital or call for an ambulance if:
- You are still in the red zone after 15 minutes AND
- You have not reached your doctor.

DANGER SIGNS

- Trouble walking and talking due to shortness of breath
- Lips or fingernails are blue

- Take ☐ 4 or ☐ 6 puffs of your quick-relief medicine *AND*
- Go to the hospital or call for an ambulance (_____) *NOW!*

ASTHMA SEVERITY LEVEL: ____Mild Intermittent ____Mild Persistent ____Moderate Persistent ____Severe Persistent
COMMENTS:

PREPARED BY (Signature & Title)	DEPARTMENT/SERVICE/CLINIC	DATE (Typed or printed)

PATIENT'S IDENTIFICATION (For typed or written entries give: first, middle; grade; date; hospital or medical facility) Name – last,

☐ HISTORY/PHYSICAL ☐ FLOW CHART
☐ OTHER EXAMINATION OR EVALUATION ☐ OTHER (Specify)
☐ DIAGNOSTIC STUDIES
☐ TREATMENT

DA FORM 4700, MAY 78

WRAMC OVERPRINT 5
MAR 01

USAPPC V2.00

*U.S. GPO: 2001-616-835/95603