Adverse Events and Preventable Adverse Events in Children

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SPECIAL ARTICLE

Adverse Events and Preventable Adverse Events in Children

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ABSTRACT. *Context.* **Patient safety has been recognized as an important problem in health care. However, knowledge about adverse events and preventable adverse events in children is relatively limited.**

Objective. **To describe the incidence and types of adverse events and preventable adverse events in children.**

Design. **Analysis of pediatric hospitalizations in the Colorado and Utah Medical Practice Study, which involved a retrospective, 2-level (nurse and physician) medical record review of a population-based, representative sample of all pediatric hospital discharges.**

Main Measures. **Adverse events were defined as an injury caused by medical management rather than disease processes that resulted in either prolonged hospitalization or disability at discharge. A preventable adverse event was defined as an avoidable adverse event based on currently available knowledge and accepted practices.**

Patients. **3719 discharged hospital patients, 0–20 years old, and 7528 nonelderly (21–65 years old) discharged adult patients in Colorado and Utah.**

Setting. **All hospitals in Colorado and Utah.**

Results. **Adverse events occurred in 1% of pediatric hospitalizations in Colorado and Utah; 0.6% were preventable. Preventable adverse events rates were 0.53% in neonates and infants (0–0.99 years), 0.22% in children 1–12 years of age, and 0.95% in adolescents 13–20 years of age, compared with a rate of 1.50% in nonelderly adults. Of preventable adverse event types, birth related (32.2%) and diagnostic related (30.4%) events were the most common and were significantly more common than surgically related preventable adverse events (3.5%).**

Conclusions. **These data suggest that ~70 000 children hospitalized in the United States experience an adverse event each year; 60% of these events may be preventable. The epidemiology of adverse events and preventable adverse events in children is different than in adults. To reduce the adverse events that occur in hospitalized children, research should focus on adolescent hospitalized patients, birth-related medical care, and diagnostics in pediatric medicine.** ***Pediatrics*** **2005; 115:155–160;** ***adverse events, children, medical errors, pediatric, adverse drug reactions.***

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ABBREVIATIONS. IOM, Institute of Medicine; CI, confidence interval; OR, odds ratio.

The widely disseminated results of the Institute of Medicine's (IOM) report "To Err Is Human"[1] identified the significant problem of medical errors and related injuries that occur in hospitalized patients. However, the report and much of the subsequent literature about medical error have focused primarily on medical care for adults. Children are also vulnerable to adverse events and preventable adverse events, and such events have been relatively unstudied in children. Children differ from adults in many ways with regard to medical care; therefore, the epidemiology of adverse events and preventable adverse events in children is likely to differ significantly from that of adults.

Two population-based studies, designed to assess the incidence and types of adverse events and preventable adverse events that occur in the course of medical care, the Harvard Medical Practice Study[2] and the Colorado and Utah Medical Practice Study,[3] were the basis for the IOM report because the data from these studies were based on large random samples of medical records. More recent equivalent data have not been collected, and these data remain unique. Findings that pertain to the adult population have been widely reported,[1,3] but analyses about the pediatric population were not conducted.

Although most patient safety research on children has focused on medications,[4–7] 2 studies have more broadly examined patient safety problems in pediatric medical care.[8,9] One study, using administrative data, constructed indicators that theoretically are related to patient safety problems in children's medical care.[8] These "patient safety indicators," as advised by the authors, are not definitive measures of patient safety problems but rather are indicators to be used as a screening tool to guide additional assessment. The second study, also based on administrative data, used "external cause of injury" codes (E-codes) from the World Health Organization's *International Classification of Diseases, Ninth Revision* to identify errors.[9] The data from this study, together with the findings from studies based on administrative data, should offer the most compelling information currently available to determine specific priorities for pediatric patient safety interventions.

This study, using the Colorado and Utah Medical Practice Study data set, complements more general studies of pediatric adverse events by specifically estimating the baseline incidence and distribution of

adverse event and preventable adverse event types in hospitalized children.[3] It also provides the only comparisons of rates of occurrence of these events between children and nonelderly adults.

METHODS

Definitions

Throughout this article, the following definitions are used. An adverse event is an injury that is caused by medical management, not the disease process, and has led to a prolonged hospital stay or disability at discharge. A preventable adverse event is an injury that is caused by medical intervention or management (rather than the disease process) and either prolonged hospital stay or caused disability at discharge, where there was enough information currently available to have avoided the event using currently accepted practices.

The Colorado and Utah Study Sample

The Colorado and Utah Medical Practice Study collected data on adverse events and preventable adverse events through retrospective medical record review of a representative sample of all hospital discharge records in Colorado and Utah in 1992. The sample for the Colorado and Utah Medical Practice study was selected to enable the estimation of population-based epidemiologic results. The method used for sample selection characterized all hospitals by size, location (urban, rural), teaching status, and ownership (for-profit, not-for-profit, government). Next, strata that represented all possible combinations of these characteristics were created, and each hospital in Colorado and Utah was placed into the appropriate stratum. At least 1 hospital from each stratum was invited to participate in each state, and no invited hospital refused. Veterans Administration, psychiatric, rehabilitation, and drug and alcohol diagnosis–related groups and hospitals were excluded.[3]

A random sample of 1992 records from all hospital discharge records in Utah (5000) and Colorado (10 000) was selected. The number of records per hospital was proportional to the number of discharges at each hospital relative to the total discharges of all of the hospitals in the study.[3,10]

Trained nurse reviewers first reviewed all of the sampled records according to standardized criteria associated with an adverse event (eg, Was there hospital-incurred trauma? Was there an adverse drug event? Was treatment or operation performed because of damage to organ or organ systems subsequent to an invasive procedure?). This first level of review identified 1978 Colorado records and 842 Utah records with a potential adverse event.[3] Physicians then further reviewed these records. The physician-reviewers graded, on a 6-point confidence scale, their confidence that an adverse event had occurred. A score of 4 or higher was required for the event to be classified as "adverse." The κ statistic for interrater reliability of the classifications indicated 79% agreement ($\kappa = .4$).

A total of 587 adverse events were identified (Colorado: 418; Utah: 169). Adverse events that were caused by medical management during hospitalization but discovered after discharge were not included in the annual incidence of adverse events. Including such adverse events would have resulted in an overestimate of the incidence because such events would logically be linked to a sampled hospital discharge at some later time.[3] Adverse events were classified into mutually exclusive types depicting the aspect of medicine (eg, medication, surgical), the "covering" service (eg, pediatrics, family practice, obstetrics), and the location in which the event occurred (eg, patient's room, operating room, nursery). Two study investigators then determined the preventability of the event on the basis of a 6-point scale according to the study definition.[10] This method has been considered "the benchmark for estimating the extent of medical injuries occurring in hospitals."[1,11]

The Colorado and Utah Pediatric Sample

All hospital discharge records in the Colorado and Utah Medical Practice Study of patients from birth through 20 years of age were included. The resulting sample consisted of 3719 pediatric hospital discharge records.

Analysis

Characteristics of the pediatric sample from the Colorado and Utah Medical Practice Study were compared with those of all pediatric hospital discharges in Utah and Colorado during the same period to assess the representativeness of the study sample. Incidence rates of adverse events and preventable adverse events were estimated for children of all ages and by age group. Frequencies and confidence intervals (CIs) were estimated for the types of adverse and preventable adverse event, for the service responsible for the medical care at the time of the event (covering service), and for the location in which the event occurred. χ^2 tests were used to detect differences in frequencies of event types between children and adults. Population estimates for adverse events and preventable adverse events were also determined.[3]

RESULTS

The study sample demonstrated a similar demographic distribution (proportion from each state, mean age, gender) to that of the entire discharged hospitalized pediatric population in Colorado and Utah. The sample included 67.7% newborns and infants (0–1 year of age), 9.6% toddler and school-aged children (2–12 years of age), and 22.7% adolescents (13–20 years of age). Newborns and infants represented the largest group of hospitalized children in both the study sample and the hospitalized pediatric population. The high proportion of newborns and infants was anticipated because birth is the most common reason for hospitalization among children, as nearly all US newborns are delivered in a hospital.

Incidence

On the basis of the review of 3719 pediatric hospital discharge records, 39 adverse events and 22 (59%) preventable adverse events were identified. This results in an annual adverse event rate of 1% (95% CI: 0.7%–1.3%) and an annual preventable adverse event rate of 0.6% (95% CI: 0.4%–0.8%) in hospitalized children.

Table 1 shows the adverse event rates by age group. Adolescents have the highest rate of adverse events. The adverse event rate for the nonelderly adult population (21–65 years of age) is also provided for comparison. Nonelderly adults were nearly 4 times more likely to experience an adverse event than children. Although infants and adolescents experienced lower rates of adverse events when compared with the nonelderly adults, the pro-

TABLE 1. Rates and of Preventable Adverse Events by Age Group

Age Group (Years)	Adverse Events Rate (95% CI)	Proportion of Preventable Adverse Events	Preventable Adverse Events Rate (95% CI)
0–0.99	0.63 (0.43–0.83)	78.0	0.53 (0.33–0.73)
1–12.99	0.92 (0.62–1.22)	10.8	0.22 (0.12–0.32)
13–20.99	3.41 (3.36–3.46)	78.6	0.95 (0.65–1.25)
21–65.99	3.84 (3.79–3.89)	40.7	1.50 (1.20–1.80)

portion of their adverse events that were judged to be preventable was considerably higher. Seventy-eight percent of adverse events that involved newborns and infants, 10.8% of adverse events that involved a toddler or a school-aged child, and 78.6% of adverse events that involved an adolescent, compared with 40.7% of the adverse events that involved a nonelderly adult, were determined to be preventable.

Adolescents had the highest rate of preventable adverse events, resulting from a high rate of adverse events and a high rate of these events being preventable, nearly twice the rate of newborns and infants and nearly 3 times the rate of toddlers and school-age children. The rates of both adverse events and preventable adverse events among newborns and infants were relatively low; nevertheless, the majority (59.1%) of all pediatric preventable events occurred in this age group. For adolescents, the rates of adverse events and preventable adverse events were higher, and adolescents experienced more than one third (36.3%) of all preventable adverse events. In comparison, nonelderly adults experienced a preventable adverse event rate of 1.5% of hospitalizations. Thus, nonelderly adults were 2.5 times more likely to experience a preventable adverse event than were children.

Types of Adverse Events and Preventable Adverse Events

Most adverse events were birth related, but this proportion was not significantly higher than other types of adverse events (Table 2). Most preventable adverse events were also birth related (32.2%), followed by diagnostic-related (30.4%) and system-related preventable adverse events (27.3%). The proportions of these preventable adverse events all were significantly greater than surgical (3.5%), therapeutic (2.8%), and nonsurgical preventable adverse events (1.1%). Medication-related preventable adverse events (21.3%) and postpartum-related preventable adverse events (8.7%) were not significantly different from other types. In comparison, most preventable adverse events in nonelderly adults were related to surgical procedures.

Odds ratios (ORs) were calculated to determine the relative likelihood of children, compared with nonelderly adults, experiencing a preventable adverse event in the context of a particular type of medical care as shown in Table 3. A child is half as likely as a nonelderly adult to experience a preventable adverse event. The only type of medical care in which children are more likely to experience a preventable adverse event is in the area of diagnostics, where a child is 1.35 times more likely than an adult to experience a preventable diagnostic adverse event. In all other types of medical care, the odds of experiencing a preventable adverse event were greater for nonelderly adults than for children.

TABLE 3. Comparison of Types of Preventable Adverse Events Between Children and Adults

Types of Preventable Adverse Events	OR	*P* Value
Diagnostic	1.352	<.001
Surgical	0.107	<.001
Postpartum	0.527	<.001
Nonoperative procedure	0.016	<.001
Medication	0.346	<.001
Therapeutic	0.099	<.001
All types	0.501	<.001

Adverse Events and Preventable Adverse Events by Service

Adverse events were also classified by the type of service that was responsible for the child's medical care at the time of the event (Table 4). Most adverse events were attributed to the obstetrics service (34.2%). Adverse events were significantly more common on the obstetric service compared with family practice (10.3%; $P < .05$), pharmacy (9.4%; $P < .05$), or gynecology (1.6%; $P < .05$). Seventy-six percent of the obstetric adverse events were determined to be preventable. All pharmacy adverse events were determined to be preventable, and more than three quarters of the family practice adverse events were determined to be preventable. In comparison, only 21% of the surgical adverse events were determined to be preventable.

Most preventable adverse events were attributed to obstetricians (38.6%), followed by pharmacists (21.4%), family practice physicians (16.7%), pediatricians (11.4%), and finally surgeons (8.5%). However, there were no significant differences in these proportions of preventable adverse events.

Adverse events were also classified by location of the event. Most adverse events occurred in the labor and delivery suite (26.2%). The difference in proportion of adverse events by location was significant

TABLE 2. Distribution of Adverse Events and Preventable Adverse Events by Type: Children and Nonelderly Adults

Type	Proportion (%) of Adverse Events (95% CI)*	Proportion (%) of Preventable Adverse Events (95% CI)	Proportion of Preventable Adverse Events (95% CI) in Nonelderly Adults
Birth related	29.6 (17.1–42.2)	32.2 (15.8–48.6)	—
Diagnostic	21.3 (12.5–30.1)	30.4 (14.3–46.5)	10.1 (5.2–15.0)
Medication	19.1 (12.1–26.1)	21.3 (6.9–35.7)	6.6 (2.5–10.4)
Surgical	16.3 (4.4–28.2)	3.5 (<0–9.9)	54.6 (47.3–61.9)
Postpartum	6.1 (1.9–10.3)	8.7 (<0–18.6)	5.5 (<0–11.0)
Therapeutic	0.8 (0.4–1.2)	2.8 (<0–8.6)	5.7 (11.9–9.5)
Nonsurgical procedures	7.7 (<0–17.2)	1.1 (<0–4.8)	9.6 (5.4–13.8)

* Sum may be >100% as a result of rounding.

TABLE 4. Estimated Frequency Distribution of Pediatric Adverse Events and Preventable Adverse Events by Covering Service and Location of the Event

	Adverse Events (95% CI)	Preventable Adverse Events (95% CI)
Service		
Obstetrics	34.2 (47.4–21.0)	38.6 (20.9–55.7)
Surgery	18.0 (7.9–28.1)	8.5 (<0–18.3)
Pediatrics	14.5 (15.2–23.8)	11.4 (0.3–22.5)
Family practice	10.3 (2.3–18.3)	16.7 (3.6–29.8)
Pharmacy	9.4 (1.7–17.1)	21.4 (7.0–35.8)
Gynecology	1.6 (<0–5.8)	6.8 (2.9–10.7)
Location		
Labor and delivery	26.2 (13.8–38.6)	26.2 (10.8–41.6)
Pharmacy	14.9 (10.7–19.1)	21.4 (7.0–35.8)
Ambulatory care	17.8 (9.0–26.6)	18.9 (5.2–32.6)
Operating room	19.5 (8.4–30.6)	11.0 (<0–22.0)
Patient room	11.8 (1.7–21.9)	15.7 (2.9–28.5)
Newborn nursery	4.8 (<0–10.6)	6.9 (<0–15.7)

only for labor and delivery and pharmacy (14.9%; $P < .05$) and the newborn nursery (4.8%; $P < .05$).

The highest proportion of preventable adverse events occurred in labor and delivery (26.2%), followed by the pharmacy (21.4%). Although, this study was hospital based, 18.9% of the preventable adverse events that were detected in the medical record were attributable to medical management that occurred before the hospitalization. Eleven percent of preventable adverse events occurred in the operating room, 6.9% occurred in the nursery, and 15.7% occurred in the patient's room. There were no significant differences among the proportions of the location of occurrence of preventable adverse events.

Population Estimates of Preventable Adverse Events

The sample was weighted to represent the populations of Colorado and Utah.[3] Of the 160 151 pediatric hospital discharges in the 2 states, 1694 (95% CI: 1200–2100) children were estimated to have experienced an adverse event in 1992, and 1185 (95% CI: 860–1500) children were estimated to have experienced a preventable adverse event.

DISCUSSION

This study found that substantial numbers of children experience adverse events and preventable adverse events and supports the findings of previous studies[8,9] based on administrative data. The baseline adverse event rate is 1% and the preventable adverse event rate is 0.6% in children. These results are based on the pediatric data from the Colorado and Utah Medical Malpractice Study and therefore are directly comparable to those reported in the IOM report about the adult population.

The 1% adverse event rate, although somewhat lower than that reported by Slonim et al[9] (1.81%–2.96%), is comparable to the 1.15% rate reported by Miller et al[8] based on patient safety indicator events. The differences in rates may be related to differences between the studies in definitions and measures. This study considers only adverse events that resulted from medical management that occurred before or during a hospitalization and led to prolonged hospitalization or disability at discharge and therefore resulted in some level of harm as distinguished from deterioration of the patient's condition. Such criteria do not detect errors, whether minor or major, that do not result in an adverse event or harm. Studies that are based on administrative data do not permit the distinction of harm as a result of medical management from deterioration of the patient's condition and therefore may include both situations. In general, administrative data are not gathered for clinical purposes, and administrative data also experience problems of coding accuracy and coding variation[12]; this problem may be more widespread for E-codes because they are less habitually applied.

This study found that most adverse events and preventable adverse events occur during the context of birth, in the labor and delivery suite, and on the obstetric service. These findings concur with the results described by Miller et al,[8] who reported "birth trauma" as the highest frequency patient safety indicator with a rate of 1.5% of birth related discharges. Birth seems to be a unique, still poorly understood context of medical risk. Clinicians who are involved in obstetrics and gynecology in addition to pediatrics and family practice must be part of any activities to improve the safety of medical care for children. The level of detail, even in a medical record review, still is not sufficient to provide specific information about the risk factors, mechanisms, or remedies. More information about the human factors and systemic contexts around birth and labor and delivery that lead to these problematic situations is clearly needed.

This study finds that adolescents experience the highest rates of both adverse events and preventable adverse events. This finding concurs with the results based on patient safety indicators[8] but differs from those using E-codes.[9] To better assess patient safety risks for adolescents, studies that focus on the specific risks experienced by adolescents in the context of medical care are needed

Medication administration in children is complex, and medication errors have been the most studied aspect of patient safety problems in children's medical care. In a previous study, medication errors were found to be very common, whereas adverse events that resulted from medication errors were relatively infrequent.[4] Serious potential medication errors were found to be 3 times more frequent in children, and very young children, in particular, are vulnerable to dangerous 10-fold errors in dosing.[4–7] However, within this broad assessment of pediatric adverse events, medications did not emerge as a highly frequent source of adverse events or preventable adverse events. This finding is similar to the results reported by Kaushal et al,[4] which showed a high rate of potentially serious medication errors but low rates of adverse drug events (0.24%) and preventable adverse drug events (0.05%). Our findings also concur with those of Slonim et al,[9] who found, based on E-codes, rates of 0.03% to 0.13% between 1988 and 1997.

Diagnostic-related adverse events and preventable adverse events are important problems for children. The odds of having a diagnostic-related preventable adverse event for children is greater than for noneld-

erly adults (OR: 1.35). The higher OR may be related to the more varied presentation of symptoms of illness in children, both within and across age groups. Clinical findings may be more subtle, and both history taking and physical examination can be more challenging in children. More study is needed to determine the specific factors that contribute to the increased diagnostic-related adverse event risk for children.

The most common adverse events and preventable adverse events in adults[13]—surgically related events—seem to be less common in children. The surgical procedures that have been associated with a high frequency of events in adults are rarely, if ever, performed in children; only 2 are routinely done in children. The considerably smaller number of pediatric admissions for surgery and the difference in types of surgery performed on children may explain, in part, the relatively lower frequency of adverse events and preventable adverse events in children.

This investigation was based on a rigorous and well-tested study design, used a population-based sample, included detailed review of all available clinical information in the medical chart, and included several quality control measures. There are, however, clear limitations inherent in the identification of adverse events and preventable adverse events when using retrospective chart review. Medical record completeness is a consistent problem,[14] and the judgments are not highly reliable.[15] The necessary information to assess whether an adverse event occurred might not have been included in the chart, and potential cases would then be excluded. Errors do not always result in significant adverse events that result in increased hospital stay or disability because the error is identified in time, that is, before interaction with the patient, or the patient is resilient or just lucky.[11] The original study was not specifically designed to measure pediatric adverse events but rather the broad range of adverse events in hospitalized patients. Therefore, the sample used in this study probably represents a conservative estimate of the frequency of pediatric adverse events and preventable adverse events. Judgments about adverse events and preventable adverse events were made by general medicine, internal medicine, and family practice physicians in consultation with obstetricians and pediatric generalist and specialist physicians, as needed. Although there is considerably more clinical information available for this determination than is available in administrative data, it is possible that an event may have been determined to be preventable when it was not or vice versa. However, we do not believe that a bias in the determination of preventability operated in any specific direction. As such, we have confidence in the relative proportions of preventable events across provider types and locations. Therefore, we believe that these data and the findings generated from them are useful for directing future research and improvement efforts.

CONCLUSION

This study found an adverse event rate of 1% and a preventable adverse event rate of 0.6% for hospitalized children. Although a rate of 1% may not initially seem to be particularly disturbing, this rate represents ~1200 to 2100 children, who, in just 2 states, experienced a prolonged hospitalization or a disability as a result of an adverse event during a single year (1992) and, for 860 to 1500 of these children, the event was deemed to be preventable. At the national level, ~4 million births occur annually.[16] Assuming that ~7 million children are discharged from a hospital each year in the United States[17] and applying the estimated 1% annual adverse event rate for hospitalized children, ~70 000 hospitalized children experience an adverse event each year, 60% of which may be preventable.

This study corroborates many of the results found in other studies about patient safety problems in children.[4,8,9] The slightly lower adverse event rate may be attributable to the more conservative definitions of adverse event used in this study compared with other studies.

Pediatric medication error studies in particular suggest that children have different risk profiles from adults.[4–7] The findings from this study further support the notion that adverse event risk for children differs significantly from that of adults and suggests that the processes, mechanisms, and systems that lead to adverse events for children may differ significantly from those for adults.

This study suggests that to reduce the substantial number of adverse events in hospitalized children, research interventions should begin by focusing on adolescent hospitalized patients, birth-related medical care, and diagnostics in hospitalized children. More generally, this study suggests that future patient safety research needs to include pediatric-specific studies to explore the different processes, mechanisms, and systems of pediatric health care—studies that will require considerably larger-than-usual samples of pediatric patients to obtain more precise estimates.

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NIH UNDER FIRE

"The National Institutes of Health (NIH), long a sacred cow in Washington, is coming under fire from the very Congress that once showered it with funds. . . . [L]awmakers are pressing agency officials to explain how they spend all the money, and why there isn't more bang for these bucks. More ominously for the agency, congressional investigators have launched a high-profile probe into the outside activities of NIH scientists, many of whom already enjoy special exemptions from civil-service salaries and command salaries of as much as $200,000 a year. The congressional probe is delving into potential conflicts of interest within NIH. . . . It is an unusual battering for NIH, whose 27 component institutes and centers have long been admired as the crown jewel of America's biomedical research effort. . . . [T]he agency's growing budget has brought a different kind of scrutiny to NIH. Some legislators see it as an agency that is never satisfied. Sen. Pete Domenici (R, NM) raised eyebrows all over the science community this spring when he said of NIH, 'They've turned into pigs.' A recent study by the Rand Corporation, the California think tank, found that nearly half of the federal research and development budget is going to medical schools."

Wysocki B. *Wall Street Journal*. June 22, 2004

Noted by JFL, MD