Patient Safety Events in Utah, 2001: The First Statewide Assessment

Wu Xu, Ph.D.; Stephen Pickard, M.B.A.; Michael P. Silver, M.P.H.; Paul Hougland, M.D.; Carol Masheter, Ph.D.; Steve Donnelly, Ph.D.; Jonathan Nebeker, M.D.; Matthew Samore, M.D.; Scott D. Williams, M.D., M.P.H.

CORRESPONDENCE:
Carol Masheter, Ph.D.
Information Analyst II
Office of Health Care Statistics
Utah Department of Health
P.O. Box 144004
Salt Lake City, UT 84114-4004
801-538-6355
801-538-9916 (FAX)

This first statewide assessment is based on review of 1,962 randomly selected medical charts from all acute care hospitals in Utah. We discovered that for every 100 admissions, approximately 18 patients experienced at least one patient safety event during their stay in the hospital. Eleven out of 100 patients experienced medical injuries prior to their hospital admissions. Five in-hospital deaths were confirmed as medical injury mortality. The weighted population estimate indicates that medical injuries in Utah that contributed to deaths (407, 95% CI: 75-1067) were the eighth leading cause of deaths in 2001, similar to the national estimate.

Introduction

The Institute of Medicine (IOM) report "To Err is Human" estimated that 44,000 to 98,000 people die annually in the United States hospitals due to medical errors (Kohn, Corrigan, & Donaldson, 2000). Based on this estimate, medical errors were the fifth or the eighth leading cause of death in the United States in 1997 and 1998 (National Vital Statistics Reports, 1999). These research findings have brought patient safety to the forefront as one of the major initiatives in quality improvement for the nation's healthcare system.

The IOM's estimates of medical error mortality were based on two large studies conducted from 1984 to 1992. The Harvard Medical Practice Study provided the high end of estimate (n=98,000) based on examining medical records from 50 nonfederal acute care hospitals in New York in 1984 (Brennan et al., 1991). The low end of the IOM's estimates (n=44,000) was derived from the Utah/Colorado study conducted in 1992 (Gawande et al., 1999). The Utah sample for the 1992 study was collected from 19 out of 40 nonfederal acute care hospitals in Utah.

Utah traditionally has been rated as one of the healthiest states in the nation according to most ranking systems and enjoys a respected reputation for shorter hospital stays and lower health care costs than the national average. The release of the IOM study impelled Utah health policy makers to determine the role and priority for a public health response. Public health focuses more on medical injuries that include a wider range of patient safety events than medical errors (Layde, Cortes & Teret, 2002). Taking an epidemiologic approach, a retrospective surveillance of statewide patient safety events was proposed to document the distribution and nature of injuries associated with medical care among hospital patients. In turn this assessment could inform state healthcare policy making.

The Utah Department of Health, partnering with investigators at *HealthInsight*, the University of Utah, the Missouri Department of Health and Senior Services and the University of Missouri-Columbia, received funding from the Agency for Healthcare Research and Quality (AHRQ) to implement such a project in Utah and Missouri (Hougland, 2003). The Utah Department of Health Institutional Review Board approved this project. This article is one of series of reports based on the results from the project (Hougland et al., in press; Longo et al., 2005; Masheter, Hougland & Xu, 2005).

Sample, Definition and Method

Sample

This study was based on a stratified random sample that consisted of 1,962 medical charts representing 239,051 hospitalizations in 2001 from all 41 acute care hospitals in Utah (Utah Hospital Inpatient Discharge Database, 2001). Charts from small rural hospitals and charts with a length of stay greater than three days were over-sampled. Each hospital contributed two strata with at least 30 total cases. A total of 82 sample weights were applied to the population estimates to adjust for the 82 sample strata.

We conducted statistical tests on the sample and population's distributions of age and gender by the length of stay (<=3 days vs. >=4 days). The results (not reported here) showed that the means of age in the sample and the population were not significantly different from each other. However gender distribution in the sample was skewed toward females in the strata with greater than three days of hospital stay.

Definitions

In this analysis, the term patient safety event is interchangeable with the terms of medical injury or adverse event (AE). Initially, the project intended to examine AEs that occurred in the hospital setting. The project's national panel of experts developed an implicit definition of an AE for this study, as:

> an undesirable and unintended injury resulting from a medical intervention (an act of care provided by the hospital or by the omission of necessary care), rather than from patient's underlying disease process; and where such injury occurs during an inpatient hospital stay (i.e., subsequent to admission) and results in or leads to patient harm.

The definition of patient harm was adopted from the Utah Administrative Rule R380-210, titled "Health Care Facility Patient Safety Program," with minor modifications. Patient harm means:

> death, prolonged hospital stay, or temporary or permanent impairment of body function or structure to a patient. The seriousness of harm should reflect changes that either resulted from or were necessitated by the injury event that require interventions such as (1) a change in monitoring the patient's condition; (2) a change in therapy; or (3) active medical or surgical treatment or attention, if an intervention is feasible or possible.

These definitions were operationalized in terms of causality of an injury and degree of harm to a patient. The causality score was based on a 6-point scale from 1 (Virtually certain evidence for disease causation) to 6 (Virtually certain evidence for management causation). Reviewers were also given the choice "Unable to determine" if they felt their level of expertise was not adequate to assign a causality score. The AEs included in the analysis had a causality score of 4 to 6, where 4 indicators "Case management causation more likely than disease"; 5 indicates "Moderate/strong evidence for management causation"; and 6 indicates "Virtually certain evidence for management causation."

The measure of harm was adopted from Kivlahan and associates' study to code harm by increased severity of injury and resources used for treatment (Kivlahan et. al, 2002). The harm measures include Level A (e.g., no clinical change),

Level B (e.g., minor change in condition), C (e.g., Vital signs changed), D (e.g., cardiac changes requiring intervention), E (e.g., cardiac/respiratory arrest) and F (death). Only events associated with a harm rating of Level B through Level F were included in the analysis.

Although the primary focus of the study was AEs that occurred in the hospital, the medical-chart reviewers also recorded a "pre-admission AE" if they found that "an AE led to admission". The first part of definition for inpatient AEs, "an undesirable and unintended injury resulting from a medical intervention (an act of care provided by the hospital or by the omission of necessary care), rather than from patient's underlying disease process," was used for pre-admission AEs. The reviewers only recorded one pre-admission AE per medical chart, according to the implicit AE definition, and did not collect additional information on causality and harm for AEs that led to hospital admissions. Preventability of an AE was not examined in the nurse reviews.

Method

The chart review instrument was a modified version of the tool developed by the previous Harvard Medical Practice and Utah/Colorado studies (Thomas et al., 1999). Trained nurses from *HealthInsight* were the primary reviewers of the medical charts for this study. All held a degree from an accredited school of nursing and a current (RN or LPN) license in good standing. All nurse reviewers had at least three years of experience in medical record abstraction as reviewers for the Health Plan Employer Data and Information Set (HEDIS) performance measures. This previous experience included work with ICD-9-CM (the International Classification of Disease 9th Edition Clinical Modification) clinical coding, data collection, tool completion and subsequent data entry. They also received an additional 40 hours of specialized training and were required to demonstrate competency prior to beginning the chart review. Throughout the project the review coordinator monitored quality and consistency by reviewing the descriptions and ratings of identified AEs.

Trained physicians, blinded to the results of initial nurse review, re-examined 153 of the nurses-reviewed charts. The sample of physician-reviewed charts was randomly selected from strata defined by the causality scores of nurse-detected inpatient AEs. The nurse-reviewed pre-admission AEs were not examined or verified by physician reviewers. The Kappa coefficient for physician and nurse review results at the chart level was 0.58 for AEs that occurred in the hospital and 0.36 for AEs that led to admission, which is considered moderate and fair agreement, respectively, by the Landis and Koch (1977) suggested interpretation of the kappa statistic. The inter-rater reliability between physician and nurse reviewers was comparable with the inter-rater judgment among physician reviewers in a previous study (Thomas, Studdert & Brennan, 2002).

All charts with inpatient AEs that probably contributed to death were reviewed by a nurse reviewer first then verified by a physician reviewer and/or the medical director of this project. The project's medical director also used additional information from the death certificates to verify and confirm the causality of each death as medical injury.

AEs were grouped into three categories: adverse drug events (ADEs), surgery-related AEs, and medical/other treatment-related AEs. Each AE was classified into one category in the following hierarchy: (1) ADE, (2) surgery AE or (3) medical/other AE. Based on these categories, the study describes estimates of statewide incidence, incidence rates per 100 hospital inpatient admissions, and incidence rates per 1,000 inpatient days of hospital stay. These estimates of medical injuries were compared with the statistics from other statewide population-based databases: (1) the Utah Death Certificate Database for leading causes of death and (2) the Utah Hospital Inpatient Discharge Database for leading reasons for hospitalization.

We used a normal approximation method for the 95% confidence interval (95% CI) of population estimates of AEs and an exact binomial distribution method for low frequency events (medical injury deaths). The statistical software SAS

version 8 was used for most of the analyses; Stata version 9.1 was used for the approximation of the 95% CI for medical injury mortality using the exact method.

Findings

Table 1 reports the key results from the statewide assessment of patient safety events among the 41 Utah acute care hospitals in 2001. The upper panel presents findings of the AEs acquired in the hospitals; the lower panel contains information on AEs that led to hospital admissions.

Table 1. Number of Adverse Events (AEs) and Estimated AE Rate for 41 Utah Acute Care Hospitals: 2001

Type of AEs	Sample		Population Estimates				
	No. of Discharges*	No. of AEs*	Estimated Discharges		Estimated Rate Per 100 Admissions		Estimated Rate per 1,000 Inpatient Days
			N	95% Confidence Interval	%	95% Confidence Interval	
AEs acquired in hospital							
All AEs acquired in hospital	403	606	41977	36941-47012	17.6%	15.5%-19.7%	47.4
Number of patients died due to AE	5	6	407	75-1067***	0.17%	0.03%-0.44%	0.46
Adverse drug events (ADEs)	218	264	22786	19118-26454	9.5%	8.0%-11.1%	25.7
Surgery-related AEs	137	182	15340	12290-18388	6.4%	5.1%-7.7%	17.3
Medical and other AEs	125	160	11942	9404-14480	5.0%	3.9%-6.1%	13.5
AEs that led to admission**							
All AEs that led to admission	254	254	25918	21822-30014	10.8%	9.1%-12.6%	n.a.
Adverse drug events (ADEs)	91	91	9119	6657-11580	3.8%	2.8%-4.8%	n.a.
Surgery-related AEs	84	84	9463	6928-11998	4.0%	2.9%-5.0%	n.a.
Medical and other AEs	79	79	7336	5264-9408	3.1%	2.2%-3.9%	n.a.
Total cases in sample or population	1962		239051		100%		885312

Sources: The 2001 Utah Patient Safety Stratified Random Sample and Utah Hospital Inpatient Discharge Database.
**** One discharge may have two or more types of AEs.***
***** Only one AE that led to admission was recorded.***
******Approximate confidence interval based on estimate rate in a sample of 1,962 discharges***

Adverse Events Acquired in the Hospital

Overall, the chart reviewers discovered 606 AEs acquired in the hospital among 403 inpatients from the sample of 1,962 medical charts. The weighted population estimates suggest that for every 100 admissions, approximately 18 patients (17.6%, 95% CI: 15.5%-19.7%) experienced at least one AE during their hospital stay. This estimate suggests that in 2001 approximately 41,977 (95% CI: 36,941-47,012) patients experienced various medical injuries in Utah hospitals.

The reviewers and the project's medical director also identified and confirmed five deaths in the sample that could be attributed to medical care management. Because of the low frequency of the events, we used an exact binomial distribution method for estimating a 95% confidence interval. The weighted population estimate of the medical-injury mortality among all Utah inpatients in 2001 was 407 (95% CI: 75-1,067) or 0.17% (95% CI: 0.03%-0.44%) of the entire inpatient population.

The reviewers determined three specific types of AEs. ADEs comprised the largest group of medical injuries acquired in the hospital (22,786; 9.5%), followed by surgery AEs (15,340; 6.4%) and medical and other AEs (11,942; 5.0%). Among all types of AEs, the percentage distribution of ADEs among all inpatients (95% CI: 8.0%-11.1%) was significantly higher than surgical AEs (95% CI: 5.1%-7.7%) and medical/other AEs (95% CI: 3.9%-6.1%).

The AE incidence rates were also measured in terms of AEs per 1,000 inpatient days of hospital stay. Number of days the patient stayed in the hospital could be considered the patient's "exposure" to the complicated health care system. The more interactions occurred or treatments that hospitals provided, the higher likelihood for a patient to experience an AE during a hospitalization (Andrews et al., 1997). For every 1,000 inpatient days in Utah in 2001, hospitalized patients experienced 47.4 AEs. Again, ADEs had the highest rate (25.7 per 1,000 days), followed by surgical AEs (17.3 per 1,000 days).

Adverse Events That Led to Admissions

The analysis of AEs that led to admission also included sample statistics and weighted population estimates (see Table 1 lower panel). The study detected 254 patients who arrived at the hospital with at least one AE that led to hospital admission. The numbers of discharges and AEs that led to admission were identical in this section, because the nurse reviewers were asked to record only one pre-admission AE per medical chart. The population estimate of patients with AEs that led to admission was 10.8% (95% CI: 9.1%-12.6%) of all hospitalized patients in Utah, which was equivalent to approximately 25,918 admissions (95% CI: 21,822-30,014) in 2001.

The chart reviewers identified 79 to 91 cases with pre-admission AEs for each AE type. After weighting for the sample strata, the population estimate of patients with surgery-related AEs was the largest category (n=9,463, 95% CI: 6,928-11,998) among the three AE groups. However the percentage distributions of the three types of pre-admission AEs were not statistically different from each other.

DISCUSSION

A Leading Cause of Death

The estimates of statewide medical injuries were compared with other statewide population-based indicators in Table 2 and Table 3. Medical injury mortality was compared with the leading causes of death derived from the state death certificate database (Utah Death Certificate Database, 2001). We adopted the National Center for Health Statistics classification of the 50 leading causes of death as the reference categories, which was published on the Utah Indicator-based Information System for Public Health (Utah IBIS-PH, 2004). Table 2 shows that medical injuries that contributed to deaths were the eighth leading cause of deaths in Utah for 2001, making medical injury mortality a serious public health concern.

A Leading Reason for Hospitalization

Table 3 presents the commonly-used Major Diagnosis Categories (MDC) to classify the reasons for hospitalizations (Utah Health Data Committee, 2002). We provided a baseline of top six reasons for hospitalizations in all 41 study hospitals in 2001. The estimated number of AEs that led to admissions (n=25,918) was just below the top two reasons for hospitalizations in Utah: (1) pregnancies and childbirths (n=50,445), and (2) newborns (n=49,139).

Assessing AEs that led to hospital admission was not a primary focus of the study. However, the high proportion of patients in our sample who arrived at hospitals with pre-existing AEs was noteworthy. This finding points to the need for examining patient safety beyond hospitals. Medical injuries occur throughout the health care community. Those AEs that led to admissions could be the result of previous health care provided at physician offices, medical or dental clinics, previous hospital visits, nursing homes, as well as patient homes and residential facilities. Strategies to prevent medical injuries need to focus on all of these settings.

Standards for Measuring Patient Safety Events

The Harvard Medical Practice Study in 1984 reported that the rate of AEs was 3.7% of hospitalizations with 13.6 percent leading to death of the patients (Brennan et al. 1991). This Utah 2001 assessment found a higher percent of AEs (17.6%)

Table 2. Leading Causes of Death and Estimated Medical Injuries That Contributed to Death: Utah, 2001

Rank	Cause of Death*	Deaths
		No.
1	Diseases of heart	2,875
2	Malignant neoplasms	2,304
3	Cerebrovascular diseases	867
4	Unintentional injuries	631
5	Chronic lower respiratory diseases	522
6	Diabetes mellitus	509
7	Influenza and pneumonia	412
	Medical injuries that contributed to deaths (estimate)	**407**
8	Intentional self-harm (suicide)	316
9	Alzheimer's disease	314
10	Nephritis, nephrotic syndrome and nephrosis	177
	…	
Total number of deaths of Utah residents in 2001		12,607
Estimated number of population in Utah, 2001		2,305,652

Sources: Table 1. Utah Death Certificate Database, Population Estimates, and Inpatient Hospital Discharge Database Retrieved on February 2004 and March 14, 2006 from Utah Department of Health, Center for Health Data, Indicator-based Information System for Public Health (IBIS-PH) at http://ibis.health.utah.gov/.
**** Causes of death were based on the classification determined by the National Center for Health Statistics.***

Table 3. Leading Reasons for Hospitalization and Estimated Adverse Events (AEs) That Led to Admission Among 41 Utah Acute Care Hospitals: 2001

Rank	Major Diagnosis Category (MDC)	Discharges
		N
1	Pregnancy, childbirth and puerperium	50,445
2	Newborn and other neonates (perinatal period)	49,139
	AEs that led to admissions (estimate)	**25,918**
3	Circulatory system	24,559
4	Musculoskeletal system and connection tissue	19,887
5	Digestive system	16,624
6	Respiratory system	16,123
	…	
Total number of hospitalizations among Utah residents in 2001		231,581
Estimated number of population in Utah, 2001		2,305,652

Sources: Table 1. Utah Population Estimates and Inpatient Hospital Discharge Database Retrieved on February 2004 and March 14, 2006 from Utah Department of Health, Center for Health Data, Indicator-based Information System for Public Health (IBIS-PH) at http://ibis.health.utah.gov/.

but a lower percent of AE mortality (0.17%) than the Harvard Medical Practice Study. We also detected a higher rate of surgical AEs (6.4%) than the 1992 Utah/Colorado study (1.7% to 2.1%) (Gawande et al. 1999). These differences might come from different definitions of the AEs, study populations, and study methods. Our study attempted to capture all medical injuries. The above researches focused on medical errors, a subset of medical injuries. Standardized measures of patient safety events are needed for an ongoing surveillance program. State public health agencies wish to use standardized measures and consistent methods to conduct periodical assessments on the same population and community.

Policy Implication and Limitation

State public health agencies and patient safety organizations can use statewide patient safety or medical injury surveillance to monitor trends and develop strategies for reducing these events. Until now, patient safety was a "missing category" in the traditional approach to assessing leading causes of deaths, leading reasons for hospitalizations, and other state public health injury surveillance systems. This first statewide assessment of patient safety events in Utah established a surveillance methodology and a baseline that will allow public health agencies to track facility reported medical injuries into the future.

The statewide assessment also can be used for priority settings for patient safety improvements in Utah. Our study showed that ADE was the largest group of medical injuries among hospital patients. This evidence supports the Utah Department of Health's initial patient safety initiative, that is, to have implemented two administrative rules (R380-200 and R380-210) to require health care facilities to report inpatient sentinel events (severe harm due to medical care such as permanent harm and death) and ADEs since 2001. Our findings also indicate that current patient safety reporting systems in Utah are likely to suffer from underreporting. This assessment is consistent with a joint assessment previously made by the Utah Department of Health, Utah Hospitals and Health Systems Association, and *HealthInsight* (2003).

A limitation of this assessment is lack of information on preventability of each adverse event detected by the nurse reviewers. Some of the events, such as some adverse drug reactions, might not be preventable at the point of patient care. Preventability study would also provide more actionable recommendations for system-wide patient safety improvement in hospitals.

Defining the nature of a problem is a first and essential step towards strategizing solutions. All 41 acute care hospitals in Utah voluntarily participated in this assessment, indicating Utah hospitals' support the statewide patient safety initiative. Successful attempts to reduce medical injuries will require a variety of systems, organizations, and individuals (i.e., policy-makers, providers, patients, and researchers) to work together in order to learn about and prevent these injuries from occurring. Utah has been leading the nation in conducting patient safety research and innovation in large urban hospitals (Evans et al. 1991). This statewide assessment may increase broader awareness of the patient safety problem and assist dissemination of existing best practices to more hospitals in Utah.

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