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National Estimates of Adverse Events during Non-Psychiatric Hospitalizations for Persons with Schizophrenia

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1. Introduction

The publication of The Institute of Medicine Report on medical errors a decade ago sparked a national dialogue regarding patient safety by highlighting the effects of medical mistakes on mortality and morbidity, and the resulting economic costs [1]. Since then, focus on patient safety has grown. In 2006, the President signed the Deficit Reduction Act requiring the Secretary of Health and Human Services to identify conditions that could reasonably have been prevented through the application of evidence-based guidelines. As of October 1st, 2008, Medicare no longer pays hospitals for the care they provide to treat some preventable injuries such as decubitus ulcers, pulmonary emboli, and objects left in a patient during surgery [2].

While patient safety issues are receiving increased attention, national estimates of adverse event rates for certain vulnerable populations are still missing. Persons with schizophrenia

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comprise an at-risk population with a mortality rate three times higher than the general population and a large burden of medical comorbid conditions [3]. This group may be disproportionately susceptible to medical injuries due to the need for multiple medications, communication difficulties, cognitive impairment, and a relative lack of social support [4]. Hospitalizations for medical or surgical problems may be especially risky for persons with schizophrenia if mental health status hampers ability to perceive and communicate medical symptoms [5]. Health care provider and system factors such as perceiving physical complaints as psychosomatic and potential for errors with psychotropic medications may also be responsible for adverse events in persons with schizophrenia hospitalized for non-psychiatric conditions [6].

The Patient Safety Indicators (PSIs) developed by the Agency for Healthcare Research and Quality (AHRQ) identify possible adverse events occurring during hospitalization by using readily available hospital inpatient data. Because hospital administrative data are collected routinely for billing purposes and are population-based, they provide an efficient source of information on medical injuries.

The purpose of this study was to determine the association between diagnosis of schizophrenia and adverse events during non-psychiatric hospitalizations. This study used data from the Nationwide Inpatient Sample to determine whether the cumulative incidence of patient safety indicators differed by schizophrenia status in non-psychiatric hospitalizations after adjusting for patient, hospitalization, and hospital characteristics. We hypothesized that adverse events would be more frequent in hospitalizations for persons with schizophrenia than the general population, especially those indicators that may be related to medication resulting in oversedation and decreased mobility.

2. Methods

2.1. Study population and data sources

We conducted a study of United States hospital discharges from 2002 to 2007 for adults 18 years and older with and without a secondary diagnosis of schizophrenia (ICDM-9 code 295). Eligible discharges included hospitalizations without a primary psychiatric diagnosis.

Six years of nonconfidential, deidentified data were obtained from the Nationwide Inpatient Sample (NIS), one in a family of databases in the Healthcare Cost and Utilization Project, a Federal-State-Industry partnership sponsored by AHRQ [7]. The NIS is the largest all-payer inpatient care database in the United States with each year containing approximately 8 million hospital stays from about 1,000 hospitals in 35 states. One year of the NIS approximates a 20-percent stratified sample of U.S. community hospitals. The NIS contains data on age, sex, length of stay, hospital charges, and ICD-9- CM codes for up to 15 diagnoses and 15 procedures. The NIS also contains information on hospital characteristics such as urban/rural location, teaching status, control of hospital (public vs. private), and discharge volume from the American Hospital Association's Annual Survey Database.

We created variables for analyses from the NIS. First, we used AHRQ software to create a set of discharge-level indicators of adverse events, or PSIs. We then used AHRQ's Clinical Classifications Software [8] to consider the following medical conditions from the Charlson Index as measures of comorbidity: congestive heart failure, chronic obstructive pulmonary disease (COPD), liver disease, kidney disease, diabetes, cancer, HIV/AIDS in addition to alcohol or drug abuse, other conditions known to be elevated in persons with schizophrenia [9].

To protect patient confidentiality, the NIS does not have identifiers to link hospitalizations to unique individuals. The Johns Hopkins (Baltimore, MD) Institutional Review Board deemed that this study, using secondary data, met criteria for exemption.

2.2. Patient safety indicators

The PSIs comprised our primary outcomes to identify adverse events occurring during hospitalization. These include complications of surgery, medical negligence, and iatrogenic conditions; each indicator has inclusion and exclusion criteria to identify appropriate risk pools and minimize uncertainty as to whether an event was preventable [10]. We used discharge-based PSIs to determine proportions of events with a denominator of a relevant group of discharges. For example, for pulmonary embolism or deep vein thrombosis (PE/DVT), the numerator is “cases of deep vein thrombosis or pulmonary embolism” and the denominator is “surgical discharges”.

The development process for the PSIs included a detailed evidence-based review of candidate indicators and their reliability and validity followed by clinical and coding expert review, revision of the candidate indicators, and empirical testing with hospital administrative data for the indicators rated as valuable by the expert review. The PSIs are thought to have reasonable validity and specificity when used as screening tools for examining incidence and risk factors associated with medical adverse events [11,12]. However, because the data are collected for billing purposes, the PSIs are not meant to be used as authoritative measures of patient safety, but to recognize areas where quality of care may need more in-depth investigation.

To avoid unreliable statistical measures from indicators with very low numbers of events, we decided *a priori* to select a threshold of 70 events per cell to include a PSI in the analysis [13]. From all 16 discharge-level non-obstetric PSIs for years 2002 to 2007, the following had an adequate number of events to be included: decubitus ulcers; infection due to medical care; accidental puncture or laceration; iatrogenic pneumothorax; postoperative respiratory failure; postoperative sepsis; postoperative PE/DVT; and postoperative hemorrhage or hematoma.

2.3. Statistical analysis

We determined the nationally weighted proportions of patient, hospitalization, and hospital characteristics in hospitalizations for patients with and without a secondary diagnosis of schizophrenia. Differences in characteristics between hospitalizations with and without schizophrenia were tested using the Wilcoxon rank sum for continuous variables and Chi-squared tests for categorical variables. We also determined the nationally weighted cumulative incidences of PSIs in hospitalizations for patients with and without a secondary diagnosis of schizophrenia.

To test the hypothesis that hospitalizations for patients with a secondary diagnosis of schizophrenia are more likely to have certain adverse events, we developed logistic regression models to obtain odds ratios (ORs) for each PSI taking into account the NIS sampling design and sample discharge weights. In these weighted, logistic regression models, we adjusted for the patient characteristics of age, sex, payer (commercial insurance, Medicaid, Medicare, self-pay), median income for zip code (quartiles), emergency room admission, and indicators of medical comorbid conditions: disease of the circulatory system (congestive heart failure, valvular disease; pulmonary circulation disorders, peripheral vascular disorder, and hypertension); chronic obstructive pulmonary disease (COPD); liver disease; diabetes/obesity; HIV/AIDS, and substance abuse (drugs or alcohol). Non-postoperative adverse events were also adjusted for medical vs. surgical diagnosis upon

admission. Race was missing for approximately 30% of observations, and known race did not change effect sizes so it was not included in the models. In the full models we also adjusted for the hospital characteristics of urban/rural location, teaching status, hospital control (public, private, public and private collapsed category), and hospital discharge volume quartile. No interaction by year was found in regression models so we pooled years 2002 to 2007.

Tests were two-sided and p-values were considered significant at the 0.05 alpha level. Since the unit of observation was hospitalization and not person, multiple hospitalizations per patient were likely. Survey design-based variance estimators used in the analyses take into account this within-respondent correlation. All analyses used SAS 9.2 (SAS Institute Inc.) or SAS-Callable SUDAAN 9.2 (Research Triangle Institute).

3. Results

3.1. Characteristics of hospital stays for patients with and without schizophrenia

Between 2002 and 2007, the NIS contained 3,605 hospitals, 269,387 non- psychiatric hospitalizations for adult patients with a secondary diagnosis of schizophrenia, and 37,092,651 hospitalizations for those without a secondary diagnosis of schizophrenia (Table 1). Weighted comparisons between admissions for patients with and without schizophrenia showed that those with schizophrenia were more likely to be nonwhite, male, have a medical admission (versus surgical), and were over twice as likely to have a non-elective admission (versus elective). Almost 87% of admissions for patients with a secondary diagnosis of schizophrenia had either Medicaid or Medicare as payers compared with about 58% in those without schizophrenia. Persons with schizophrenia were more likely to live in a zip code with the lowest quartile of median income. Reflecting the established burden of comorbid medical conditions in persons with schizophrenia, admissions for patients with a secondary diagnosis of schizophrenia had a substantially higher percentage of congestive heart failure, COPD, liver disease, diabetes, HIV/AIDS, and substance abuse compared with those without schizophrenia. In addition, discharges for persons with schizophrenia were more likely to include an in- hospital death and had higher median charges and length of stay than discharges without schizophrenia.

3.2. Adverse events for patients with and without schizophrenia during hospitalization

In both hospitalizations with and without schizophrenia, the highest cumulative incidences of patient safety indicators were for decubitus ulcer, respiratory failure, pulmonary embolism/deep venous thrombosis, and sepsis (Table 2). After adjusting for patient and hospital characteristics, the odds ratios of the following PSIs were significantly higher for hospitalizations with a secondary diagnosis of schizophrenia compared to those without a secondary diagnosis of schizophrenia: decubitus ulcer (1.43, 95% CI: 1.36–1.51), infection due to medical care (1.19, 95% CI: 1.08–1.30); postoperative respiratory failure (1.96, 95% CI: 1.67–2.30), sepsis (1.59, 95% CI: 1.25–2.02), and pulmonary embolism/deep venous thrombosis (1.23, 95% CI: 1.13–1.35). The PSIs of iatrogenic pneumothorax (1.12, 95% CI: 0.94–1.33) and postoperative hemorrhage (1.07, 95% CI: 0.88–1.31) were not significantly elevated in discharges for patients with a secondary diagnosis of schizophrenia. Adjusted odds of accidental puncture were significantly reduced in hospitalizations with a secondary diagnosis of schizophrenia (OR=0.66, 95% CI: 0.58–0.74).

4. Discussion

In the United States from 2002 through 2007, we found hospitalizations for persons with a secondary diagnosis of schizophrenia had increased odds of decubitus ulcer, infection due to

medical care, postoperative respiratory failure, sepsis, and pulmonary embolism/deep venous thrombosis when compared to the general population. Accidental puncture was significantly reduced for hospitalizations with a secondary diagnosis of schizophrenia. Adjusting for hospital characteristics had little influence on these odds ratios.

Little is known about optimal perioperative management of medications in patients with schizophrenia. However, over-dosing, under-dosing, and interactions between analgesics, anesthetics and patients' regular psychotropic medications may lead to postoperative delirium, confusion or oversedation which could cause aspiration and other respiratory complications following surgery [14,15]. The odds of postoperative respiratory failure were almost twice as high in hospitalizations for persons with schizophrenia compared to those without schizophrenia, the most elevated for all of the measured patient safety indicators.

Postoperative delirium and other behavioral issues not uncommonly result in sedation and restraints for patients with schizophrenia [5]. By reducing mobility, sedation or the use of restraints may increase the risk of decubitus ulcers, venous thromboembolism, nosocomial infection, and post-operative respiratory failure in persons with schizophrenia. In addition, behavioral aspects of the psychiatric disorder [16], reduced pain sensitivity [17], and effects of sedation may reduce the recognition of these complications following surgery.

We also found that the adjusted odds of accidental puncture or laceration were significantly decreased when comparing hospitalizations with a secondary diagnosis of schizophrenia to those without. This may be explained by the potentially lower rate of risky surgical procedures for persons with schizophrenia. The denominator for this complication includes all types of surgical discharges so that it does not control for the seriousness of the procedure or the number of procedures during hospitalization. A previous study found that individuals with mental illnesses were substantially less likely to obtain revascularization procedures following a myocardial infarction than persons without SMI [18].

A previous study determined the odds ratios of various adverse events associated with a secondary diagnosis of schizophrenia in Maryland hospitals for 2001 to 2002 [19]. Infections due to medical care, postoperative respiratory failure, sepsis, and venous thromboembolism all had increased odds in hospitalizations with schizophrenia, however the magnitude was higher for nosocomial infections and thromboembolism compared to the results of this study. Unlike the current study, the Maryland study did not find increased odds for decubitus ulcers. These differences may be due to geographic differences, a smaller sample, differences in the variables available in the Maryland hospital data, or the earlier version of the PSI software available at that time.

The relationship between schizophrenia and patient safety indicators may be subject to geographical variations because of differences in the way persons with schizophrenia receive care in different parts of the country. For example, a study conducted by Betempts *et al.* found that hospital geographic location was significantly associated with differences in use of seclusion and restraint, citing different standards of practice or laws between states [20]. In addition, the authors found the group most often secluded or restrained were persons with schizophrenia. Sample size limitations did not permit us to examine the interaction between schizophrenia diagnosis and state on the occurrence of adverse events.

4.1. Methodological strengths and limitations

The AHRQ Patient Safety Indicators provide a screen for a variety of potential adverse events during hospitalizations. Many previous investigations of medical injuries rely on medical record abstraction. These studies can provide information on clinical variables during hospitalization and a better understanding of the preventability of a patient safety

event. However, creating standard and accepted definitions for preventability in patient safety is challenging. Chart abstraction studies require medical expertise to perform and are costly [21]. As a result, most of these studies are limited to relatively small sample of patients and cannot provide a cost-effective way of screening for adverse events for special populations, nor could they address the scope of the problem on a national scale. This analysis uses data stratified and weighted to the general U.S. population of patients attending community hospitals that are already collected for management and billing purposes. The large size of the dataset makes it suitable to study small subgroups such as persons with schizophrenia that may be more vulnerable to adverse events.

Residual confounding is a common limitation to using large administrative databases. For example, since persons with schizophrenia tend to be poorer and have only public insurance, they may be more likely to be admitted to lower quality hospitals. Although adjusting for hospital characteristics thought to be associated with hospital quality did not result in large changes to the ORs, we cannot rule out the role hospital quality plays in the elevated rates of some of the PSIs.

Residual confounding from undetected or unreported medical disease in hospitalizations for patients with schizophrenia could also explain part of the associations we found between schizophrenia and the PSIs. Persons with schizophrenia also have a higher rate of lifestyle risk factors (e.g. obesity and smoking) which may not be fully captured by the variables available in the data [4]. These lifestyle factors may increase a patient's susceptibility to experiencing an adverse event. For example, the extremely high rates of smoking in people with SMI are likely to play a role in respiratory function, infection, and hypercoagulability, making persons with schizophrenia at greater risk of adverse events from respiratory failure, nosocomial infection, and deep vein thrombosis, respectively.

Accuracy of clinical coding on hospital discharge summary and medical billing records affects every variable in our analysis, from the main exposure of schizophrenia to patients' comorbidities, demographic characteristics, and the PSIs. Previous studies have found that administrative database tools have had low sensitivity, but high specificity for adverse events, thus injuries are often underreported [22]. However, we do not believe coding should be systematically different for hospitalizations for persons with schizophrenia compared to the general population.

4.2. Implications

The AHRQ Patient Safety Indicators are not definitive measures of adverse events, yet they emphasize areas of concern for quality of care that warrant further study. This analysis suggests that persons with schizophrenia may be more vulnerable to some types of medical injuries that can occur during hospitalization, and these differences often persist after controlling for known patient, hospitalization, and hospital characteristics. Higher rates of adverse events for hospitalizations in persons with schizophrenia raise questions about effective communication among healthcare providers and between health care providers and this vulnerable patient population. Improved understanding of factors related to hospital quality of care and outcomes in this group will be important to plan interventions to enhance patient safety for persons with schizophrenia.

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Table 1

Characteristics of United States' hospitalizations for patients with and without secondary diagnosis of schizophrenia in U.S. hospitalizations from 2002 to 2007 ^{a b}

	Without Schizophrenia (n=37,092,651)	With Schizophrenia (n= 269,387)
Mean age, years	57.4	56.2
Median age, years (inter-quartile range)	59.0 (38.7 – 75.1)	55.0 (49.0 – 66.9)
Gender, %		
Male	38.1	48.1
Female	61.9	51.9
Race, %		
White	50.9	45.9
Nonwhite	20.0	26.8
Missing	29.1	27.3
Primary payer, %		
Medicare	45.2	60.0
Medicaid	13.1	26.7
Private	33.4	7.1
Other	8.3	6.2
Median household income national quartile for patient ZIP code, % ^c		
Quartile 1 (lowest)	28.4	40.2
Quartile 2	25.9	26.1
Quartile 3	23.8	19.8
Quartile 4 (highest)	21.9	14.0
Region of country for hospital, %		
Northeast	19.7	25.0
Midwest	23.3	24.9
South	38.7	33.7
West	18.3	16.4
Teaching hospital (vs. non-teaching)	43.9	46.8
Urban hospital location (vs. rural)	85.7	86.5
Hospital bed size ^d		
Small	12.4	13.1
Medium	24.9	26.6
Large	62.8	60.3
Hospital volume, % ^e		
Quartile 1 (lowest)	24.9	27.1
Quartile 2	25.1	28.3
Quartile 3	25.0	23.1
Quartile 4 (highest)	25.0	21.5

	Without Schizophrenia (n=37,092,651)	With Schizophrenia (n= 269,387)
Hospitalization characteristics, %		
Elective admission (vs. non-elective) ^f	29.1	11.5
Medical admission (vs. surgical)	65.3	81.9
Death in hospital	2.6	2.7
Admission source, %		
ER	48.8	70.2
Another hospital	3.5	3.3
Another facility including long-term care	1.5	5.3
Court/law enforcement	0.0	0.2
Routine/birth/other	46.3	21.1
Comorbid illness, %		
Congestive heart failure	7.7	9.6
Chronic obstructive pulmonary disease	15.6	26.6
Liver disease	1.7	3.2
Renal failure	6.0	6.0
Diabetes mellitus	18.4	23.2
Any malignancy	4.8	3.0
HIV/AIDS	0.2	0.6
Deficiency anemia	11.3	14.6
Alcohol abuse	2.7	7.0
Drug abuse	1.9	7.8
Any substance abuse	4.1	12.1
Median length of stay, days (inter-quartile range)	3.6 (2.3 – 5.9)	4.6 (2.8 – 7.6)
Median total charge, \$ (inter-quartile range)	13,538 (7,319 – 26,868)	14,675 (7,954 – 28,972)

^aResults are nationally weighted and account for stratified sampling.

^bAll characteristics are significantly different except renal failure.

^cFor median income of patient zip code: quartile 1 means the patients zip code is in the 0–25th percentile of all zip codes, quartile 2 is 26th to 50th percentile, quartile 3 is 51st to 75th percentile, and quartile 4 is 76th to 100th percentile.

^dCutoff points for bed size were made so that approximately one-third of the hospitals in a given region, location, and teaching status combination would fall within each bed size category.

^eFor hospital volume quartile: quartile 1 means the hospital has between 0 and 9,109 annual discharges, quartile 2 has 9,110 to 17,171 discharges, quartile 3 has 17,172 to 26,442, and quartile 4 has over 26,442 annual discharges.

^fNon-elective admissions include emergency, urgent, newborn, delivery, and trauma.

Table 2

Cumulative incidence of adverse events per 1,000 U.S. hospitalizations from 2002 to 2007 for patients with and without a secondary diagnosis of schizophrenia *

	Incidence With Schizophrenia (95% CI)	Incidence Without Schizophrenia (95% CI)
Patient Safety Indicators	n=269,387	n=37,092,651
Decubitus ulcer	36.6 (34.8–38.6)	27.7 (26.9–28.5)
Infection due to medical care	3.4 (3.1–3.7)	2.16 (2.09–2.2)
Accidental puncture or laceration	1.5 (1.4–1.7)	3.36 (3.2–3.5)
Iatrogenic pneumothorax	0.6 (0.5–0.7)	0.61 (0.59–0.6)
Postoperative		
Respiratory failure	24.2 (21.1–27.7)	9.2 (8.8–9.5)
Sepsis	23.2 (18.7–28.8)	11.9 (11.4–12.4)
Pulmonary embolism or deep venous thrombosis	16.9 (15.5–18.5)	10.6 (10.2–11.0)
Hemorrhage or hematoma	3.2 (2.6–3.8)	2.7 (2.6–2.8)

Abbreviation: CI, confidence interval.

* Results are nationally weighted and account for stratified sampling.

Table 3

Odds ratios of adverse events in U.S. hospitalizations from 2002 to 2007 for patients with and without a secondary diagnosis of schizophrenia ^a

Patient Safety Indicators	Unadjusted OR (95% CI)	Patient Characteristics Adjusted OR (95% CI) ^b	Patient and Hospital Characteristics Adjusted OR (95% CI) ^c
Decubitus ulcer	1.34 (1.28–1.40)	1.44 (1.37–1.52)	1.43 (1.36–1.51)
Infection due to medical care	1.57 (1.45–1.70)	1.20 (1.10–1.32)	1.19 (1.08–1.30)
Accidental puncture or laceration	0.45 (0.40–0.49)	0.65 (0.58–0.73)	0.66 (0.58–0.74)
Iatrogenic pneumothorax	1.04 (0.88–1.21)	1.12 (0.94–1.34)	1.12 (0.94–1.33)
Postoperative			
Respiratory failure	2.68 (2.33–3.09)	1.95 (1.66–2.28)	1.96 (1.67–2.30)
Sepsis	1.98 (1.60–2.46)	1.57 (1.23–1.99)	1.59 (1.25–2.02)
Pulmonary embolism or deep venous thrombosis	1.61 (1.48–1.75)	1.23 (1.13–1.34)	1.23 (1.13–1.35)
Hemorrhage or hematoma	1.18 (0.98–1.42)	1.07 (0.88–1.31)	1.07 (0.88–1.31)

Abbreviation: OR, odds ratio; CI, confidence interval.

^a Results are nationally weighted and account for stratified sampling.

^b Adjusted for age, sex, primary payer, median income (national quartile for patient zip code), admission from emergency room, disease of the circulatory system, COPD, liver, diabetes/obesity, HIV, substance abuse, surgical vs. medical admission. Postoperative adverse events not adjusted for medical vs. surgical admission.

^c Adjusted for urban vs. rural hospital location, hospital teaching status, hospital control, and hospital volume quartile in addition to patient characteristics above.