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Safety of Psychiatric Inpatients at the Veterans Health Administration

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Abstract

Objective—Although reducing adverse events and medical errors has become a central focus of the US health care system over the past two decades both within and outside the Veterans Health Administration (VHA) hospital systems, patients treated in psychiatric units of acute care general hospitals have been excluded from major research in this field.

Methods—The study included a random sample of 40 psychiatric units from medical centers in the national VHA system. Standardized abstraction tools were used to assess the electronic health records from 8,005 hospitalizations. Medical record administrators screened the records for the presence of 10 specific types of patient safety events which, when present, were evaluated by physician reviewers to assess whether the event was the result of an error, whether it caused harm, and whether it was preventable.

Results—Approximately one in five patients experienced a patient safety event. The most frequently occurring events were medication errors (which include delayed and missed doses) (17.2%), followed by adverse drug events (4.1%), falls (2.8%), and assault (1.0%). Most patient safety events (94.9%) resulted in little harm or no harm, and more than half (56.6%) of the events were deemed preventable.

Conclusions—Although patient safety events in VHA psychiatric inpatient units were relatively common, a great majority of these events resulted in little or no patient harm. Nevertheless, many were preventable, and the study provides data with which to target future initiatives that may improve the safety of this vulnerable patient population.

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Patient safety events, including adverse events resulting from medical intervention and medical errors, occur frequently and at great cost to the health care system.[1–3] The extensive body of research on patient safety in the provision of general medical care on acute medical and surgical units has provided models for understanding the nature, incidence and preventability of adverse events and medical errors in these settings[3,4] and has led to significant reforms and interventions.[1,5,6] Unfortunately, research has not focused on patients who are receiving inpatient psychiatric care in general hospital settings. Thus patient safety in mental health care has not received the focused attention that has proven invaluable for improving inpatient medical and surgical care.

In medical and surgical units, patients with comorbid psychiatric and medical disorders[7] are at increased risk of experiencing adverse events,[8] physical harm, and mortality.[9] A few small studies have focused on characterizing psychiatry-specific inpatient safety events,[10] such as medication errors,[11,12] adverse events resulting from seclusion and restraint[13,14] or electroconvulsive therapy (ECT),[15] violence,[16,17] falls,[18] and suicide[19–21] by patients with psychiatric disorders receiving care in inpatient psychiatric settings.

There are over one million discharges from psychiatric units of acute care hospitals annually,[22,23] approximately 100,000 of which are from the Veterans Health Administration (VHA) medical centers.[24] The VHA is one of the largest integrated health care systems in the country[24] and has a universal electronic medical record system, making it an ideal setting for examining patient safety in the provision of inpatient psychiatric care. This article describes a national, large-scale epidemiological patient safety study that examined adverse events and medical errors occurring in VHA hospital psychiatric units. This basic descriptive information on the prevalence, severity, and preventability of these events can help target future safety initiatives.

Methods

Building on the methods used in prior patient safety research, we conducted a medical record review of a random sample of discharges from inpatient psychiatric units in VHA general hospitals. The study utilized a two-tier chart review process. The first-tier review involved a preliminary review of records by screeners who “flagged” records for the presence of a possible patient safety event by using a structured instrument we designed specifically for the detection of events in this patient population. The second tier was a more extensive verification and review of the flagged chart by physician reviewers to assess the extent of harm experienced by the patient, determine the likelihood of a clinical error, and evaluate preventability.

Sample and Data Sources

The sample was drawn from the Patient Treatment File of the National Patient Care Database, which is maintained by the VHA Office of Information. Nationally, the VHA had 92,103 discharges from 105 medical centers with an inpatient psychiatric unit in 2012. For the purposes of this study, a random sample of discharges was selected by using an implicitly stratified two-stage probability proportional to size design. Hospitals were the primary sampling unit and selection of discharges within hospitals was inversely

proportional to the size of the hospital such that discharges from smaller hospitals were oversampled to fully represent all VHA facilities. The study included 8,052 discharges from 40 hospitals. Of these, a small number of charts were not located, resulting in a total of 8,005 discharges that were reviewed.

Data were collected from the Computerized Patient Record System, the universal electronic medical record at the VHA. Each medical record includes detailed information about the patient's care while on the inpatient psychiatric unit, such as admission and discharges notes, clinical notes, nursing notes, progress notes, physician's orders, and medication administration records. The analysis data set did not contain any patient or staff identifiers. The U.S. Department of Veterans Affairs Central Institutional Review Board granted approval for the study.

Measures

To establish a systematic way to extract data from the electronic medical record, the study team developed instrumentation for reviewing charts that built on work from medical and surgical patient safety studies.[25,26] To tailor the tools to psychiatry, we drew upon an extensive review of the literature and our prior qualitative[27] and quantitative work in the field.[28] We developed two standardized abstraction tools, one for the screeners and one for the physician reviewers. The screening tool was designed to flag a broad range of potential patient safety events for further investigation and was modeled after the tools used in the landmark patient safety study, the Harvard Medical Practice Study (HMPS),[25] and the more recently developed Institute for Healthcare Improvement's Global Trigger Tool.[29] These types of "trigger tools" have been developed specifically for use during retrospective chart reviews in order to easily and efficiently abstract data and identify possible adverse events in medical records. Standardized review processes such as these have proven much more effective at detecting adverse events than conventional methods (for example, voluntary reporting).[30] As with the HMPS, we also developed a second-tier abstraction tool for medical records that were flagged with the indication of a possible patient safety event, so that they could be reviewed by a board-certified psychiatrist. This structured instrument was used to verify whether the flagged events met study criteria, determine the presence or absence of errors and adverse events, and assess harm and preventability.

Patient Safety Events: Medical Errors and Adverse Events

The tools we developed sought to collect information about the full range of safety events that occur in inpatient psychiatry. Patient safety events were broadly categorized as medical errors and adverse events. Medical errors were defined as the omission or commission of clinical care that has potentially negative consequences for a patient that would have been judged wrong by skilled and knowledgeable peers at the time the errors occurred, regardless of whether there were any negative consequences.[31] Adverse events were defined as the negative unintended consequences of clinical care that led to injury, impairment, or other harm.[29,32] In this study, events could fall into either or both of these categories. Using this conceptualization, we established a list of ten events to screen for in the medical record. The list included adverse events (including adverse drug events, self-harm, assault, sexual contact, and other nonmedication adverse events); medical errors (including medication and

nonmedication errors); and other patient safety events (including elopements, contraband and falls) that are proximal to the occurrence of harm and error (Table 1).

Study Process

We developed a training manual for the first-tier screening of charts that contained an overview of the study process and goals, as well as detailed definitions and examples of each patient safety event (Hermann RC, Cullen SW, Marcus SM, unpublished manuscript, 2014). We conducted a five-session training with five screeners, in which we reviewed the material, discussed vignettes, and assigned a selection of test charts with and without confirmed patient safety events to ensure adherence to study definitions before chart review began. During the course of the study, weekly phone calls and regular e-mail exchanges with the screeners addressed questions, and ambiguities in charts, and ensured adherence to study guidelines. We then conducted a four-session training with nine psychiatrist reviewers with our 46-page physician review training manual (Hermann RC, Cullen SW, Marcus SC, unpublished manuscript, 2015), which also contained detailed examples of each type of event and guidelines for assessing level of harm (based on the Agency for Healthcare Research and Quality's Harm Scale [33]), rating attribution of error, and determining preventability (defined as the extent to which an event could have been anticipated and prepared for but still occurred because of an error or other system failure) (34). The training included review of vignettes and a set of test charts. Regular phone calls and e-mails with the physician reviewers continued for the duration of their participation in the study.

Analysis

First, we calculated the proportion of discharges that contained each type of adverse event, error, or other patient safety event, as well as the rates of these events per 1,000 patient-days. Second, for each of the adverse events and other patient safety events, we examined whether it was likely (including responses of highly likely or likely) or not likely (responses of somewhat likely or not likely) to have resulted from a medical error. Finally, for each type of adverse event, error, or other patient safety event, we examined the level of harm to the patient (none or minimal, moderate, or severe) and the extent to which the event was preventable (highly likely and likely versus somewhat likely and not likely). All analyses were conducted in SAS, version 9.4, using PROC SURVEYFREQ and PROC SURVEYMEANS to accommodate the two-stage proportional sampling and the nesting (clustering) of charts within hospitals.

Results

Across all medical records reviewed, there were 2,232 patient safety events. Table 2 shows the population distribution of these events, by type, per 100 patient discharges and per 1,000 patient-days. Overall, the prevalence of any event occurring was 27.9 per 100 patient discharges and the rate was 36.4 events per 1000 patient-days. The prevalence per 100 discharges was 6.0 for any adverse event, 18.2 for any medical error, and 3.7 for any other patient safety event. The most frequently occurring patient safety events were medication errors (17.2 per 100 discharges, or 17.2%) (including dispensing delays of greater than three hours), followed by adverse drug events (4.1%) and patient falls (2.8%). Among the detected

medication errors, the most common type of errors were missed doses (N=767, 59.7%), followed by delayed doses (N=478, 37.2%), other errors (N=22, 1.7%), wrong doses (N=11, .8%), and wrong drug (N=5, .4%).

Most patient safety events (94.9%) resulted in little harm or no harm (Table 3). Although 97.6% of medical errors and 97.7% of other patient safety events resulted in little or no harm, 15.0% of the adverse events resulted in moderate or severe harm. With regard to preventability, a majority of events (56.6%) were rated as likely or highly likely to have been preventable. Medical errors were likely or highly likely to have been preventable (73.5%), but few of the adverse events (19.2%) and other patient safety events (33.8%) were deemed to be so. Specifically, the events most likely to be preventable were nonmedication errors (87.0%) and contraband (77.2%), and those deemed least likely to have been preventable were patient assault (11.1%) and adverse drug events (18.2%). Events were deemed likely or highly likely to have been preventable among 42.5% (95% confidence interval [CI]=37.9–47.1) of patients with minimal or no harm and among 60.2% (CI=48.3–72.0) of patients with moderate or severe harm (F=7.92, df=1 and 39, p=.008).

Discussion

Our study found that one in five patients receiving mental health care on an inpatient psychiatric unit of a VHA hospital experienced a patient safety event. The three most common types were medication errors, adverse drug events, and falls. It is not surprising that two of the most common types of events detected were related to medication, because a large component of treatment in inpatient psychiatric units includes prescribing, dispensing, and monitoring medications. Our finding aligns with research on adverse events among inpatients hospitalized for treatment of general medical–surgical (nonpsychiatric) conditions, where medication-related events are the second most common type of event (behind operation-related events) (35). In comparison with a study of medication errors in three (nonpsychiatric) medical units where the medication error rate was .3 medication errors per patient-day (36), our finding of .02 per patient-day suggests that differences may vary across both setting (medical versus psychiatric) and patient population. Although medication errors were common in our study, the vast majority of such errors were missed or delayed doses that did not result in patient harm. The rates of medication errors in our study may be higher than rates studied in other hospital types because the VHA uses a barcode medication administration system that tracks delayed and missed doses, whereas most prior work has been conducted in settings without this technology.

Adverse drug events were the second most common type of patient safety event in our study. The rates of adverse drug events were lower than those in a previous study that was conducted in a psychiatric hospital setting (5.4 versus ten events per 1,000 patient-days) (37) but closer to those in another study of rates of adverse drug events in medical and surgical units (4.1 per 100 discharges in our study versus 6.5 per 100 admissions in the other study) (38). Falls were the third most common type of patient safety event experienced by patients in our study (3.66 falls per 1,000 patient-days), a rate similar to those in acute care medical units (3.56–3.73 falls per 1,000 patient-days) (39,40). With the exception of medication errors, the most common patient safety events in inpatient psychiatry occurred at rates

comparable to those identified in general medicine and surgery. Nevertheless, the overall rate of 36 events per 1,000 patient-days for inpatient psychiatry was significantly lower than the rate in a broader study of all hospitalizations, in which 91 events per 1,000 patient-days were detected (30). However, differences in methodology and patient populations across studies limit the direct comparability of these rates.

Of the 2,232 patient safety events identified, only 13 (.6%) were associated with harm that was severe. When harm occurred, it was primarily a result of nonmedication adverse events resulting from clinical care (for example, ECT), assault, and patient self-harm. Although there were no completed suicides documented during our study, patient self-harm is distinctly associated with inpatient psychiatric settings and can be influenced by both the clinical care provided (for example, monitoring) and the physical environment of the unit. Fortunately, suicide is a relatively uncommon event in the VHA with only 42 completed suicides identified over a six-and-a-half year period in VHA hospitals (20). Other studies have estimated that the rate of suicides is 1.24 per 1,000 patient discharges across units at hospitals across the world (41).

Many of the patient safety events in our study were assessed as preventable. Thus, although the VHA has developed specific guidelines and policies for providing safe care, there is room for improvement. For the patient safety events that are common not just to psychiatry, but also to general medicine and surgery, we can draw upon existing, established prevention strategies and tailor them to this setting. For example, fall prevention strategies developed for general medical and geriatric hospitalizations suggest that multicomponent interventions, which include risk assessments and specific recommendations for clinical care (for example, footwear and medication review) may reduce the risk of falls by up to 30% (42). Preventing adverse drug events is another area of research that has received considerable attention both inside and outside psychiatry and is particularly relevant given the large number of medication-related errors and adverse drug events in our study. Although the VHA has developed some strategies to reduce medication errors, such as its electronic clinician prescription ordering system, other strategies in general medicine and surgery have focused on the early detection and notification of adverse drug events so that physicians can make necessary dosage or drug changes before the reactions become more severe (43).

Many of the events that are uncommon outside inpatient psychiatry, such as unforeseen self-harm and “random acts of violence” which by their very nature are difficult to predict, are hard to prevent. Appropriate clinical care around the provision and monitoring of medication and surveillance of patients is critical to eliminating errors and minimizing patient harm. However, inpatient mental health care attempts to achieve a balance between additional patient protections and restrictions on one hand and personal freedom and mobility on the other. Providing a safe and therapeutic environment is an essential component of inpatient psychiatric care, and thus identification and implementation of interventions that reduce adverse events and errors should be a priority (44,45).

Our study had limitations. First, unlike prospective patient-shadowing studies, chart reviews are limited in that they may not document the complete nature and outcomes of care. However, studies have found that the sensitivity and specificity of retrospective chart reviews

and of prospective data collection are comparable (46). Retrospective chart reviews are more likely than voluntary reporting and incident reports to detect adverse events but are, unsurprisingly, less sensitive than direct observation at detecting these events (47). In one study, structured chart review methods were more effective at identifying events than either patient safety indicators or provider-reported events (48). Thus medical record reviews have long been considered an important source for detecting adverse events among hospitalized medical-surgical patients (49) and are useful for epidemiological studies because they provide a large sample and generalizable findings in a cost- and time-efficient manner (50).

Second, it can be difficult to quantify the level of harm, error, and preventability. However, we used standardized abstraction forms and a manualized process, with clear guidelines, training, and monitoring to rigorously measure these constructs (49). Third, our analysis did not include detailed information about staffing composition or other key functional unit characteristics, which could be added to future studies to further contextualize these findings. Finally, the results of this study are limited to patients receiving mental health care on VHA inpatient psychiatric units, and estimates of the prevalence of patient events, medical errors, and harm may not be generalizable to a broader patient population or to care received in other settings. Despite these limitations, this study provides the first large-scale examination of patient safety events experienced by patients receiving inpatient psychiatric care at VHA hospitals.

Conclusions

Findings from this large-scale study suggest that although patient safety events were common in inpatient psychiatry units at VHA hospitals, very few events resulted in serious harm to patients. Nevertheless, many of the events detected were potentially preventable, and efforts should continue to enhance the safety of care provided to these patients. This study developed the tools necessary to measure patient safety events in hospital-based psychiatry and then used them to gauge the extent, nature and preventability of events. There has been a long-standing call for more data regarding the frequency and consequences of safety events in inpatient psychiatry (11) and our findings begin to fill this important gap by providing insight into potential targets of prevention efforts.

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Table 1

Definitions of patient safety events documented among psychiatric inpatients

Type of event	Definition
Adverse Events	The negative unintended consequences of clinical care that lead to injury, impairment or other harm.[29,32]
Adverse drug event	The negative, unintended consequences of a medication that results in functional impairment or other significant harm. In order to distinguish adverse drug reactions from the side effects often associated with psychotropic or other medications, adverse drug reactions had to meet one of the following criteria: 1) be on a specified list of medication reactions that have been determined by prior research to always be categorized as an adverse drug reaction;[41] 2) resulted in the medication being stopped, held, discontinued or replaced by another medication due to the adverse reaction; or 3) the reaction or symptom(s) impaired the patient's functioning. Because it can be difficult to distinguish between adverse reactions to medication and side effects of medication, we relied upon methodology previously established for appropriately identifying adverse drug event.[41]
Patient self-harm or injury	Harm or injury experienced by the patient due to his or her own actions, regardless of intent. The most extreme case of patient self-harm is suicide. Patient injury can also occur even if the patient did not intend to harm him or herself (for example, patient punches wall out of anger and sustains a laceration). Exclusions: suicidal ideation or threats unaccompanied by actions to harm self; and superficial or minor injuries indicated by the absence of bruising, swelling, bleeding or treatment.
Patient assault	Forcible physical contact with staff, other patients or visitors on the unit. This category includes patients who are the victim or the perpetrator of an assault. Exclusions: altercations that are only verbal in nature or characterized as only light or minimal physical contact and assault to staff without documented injury experienced by the staff member.
Patient sexual contact	Incidents of a sexual nature between a patient and another patient, a visitor, or a staff member. Sexual contact is defined as physical contact and includes, but is not limited to intentional touching either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh or buttocks. Exclusions: non-physical contact (for example, blowing a kiss or sexual talk); physical contact without implication of sexuality (for example, pat on the back); kissing or hugging in greeting or farewell between a patient and a visitor; and events where a staff member was a passive and unwanted recipient of sexual contact from a patient.
Other nondrug adverse events	Events that resulted in stopping treatment and/or functional impairment (that is, impairing a basic function such as thinking, standing, walking, seeing, hearing, breathing, etc.)
Medical Errors	The omission or commission of clinical care with potentially negative consequences for a patient that would have been judged wrong by skilled and knowledgeable peers at the time the error occurred, regardless of whether there were any negative consequences.[31]
Medication error	When a medication is administered to the patient in a manner other than what was ordered, including dosing and administration issues, such as when a patient receives the wrong dose or wrong drug or receives it through the wrong route of administration. Missed doses or delays of three or more hours were included because they may be related to medication ordering processes or interface between the pharmacy and the unit. Exclusions: patient refusal of medication; medications intentionally delayed, held or not given at the discretion of staff based on their clinical judgment (for example, sleeping medication skipped because patient was already asleep, patient was off unit); medications characterized in the reconciliation log as not on formulary; and topical and over-the-counter medications.
Nondrug medical errors	Incorrect, omitted, or delayed tests or procedures. Other errors may be related to the practices and procedures of the unit that are in place to protect and keep patients safe, such as ensuring adequate assessments and level of observation or monitoring, ensuring appropriate treatment, minimizing communication errors, and eliminating environmental dangers (for example, a locked door on a locked unit that is left unsecured or wet floors without proper signage).
Other Patient Safety Events	Events that may occur during the course of a hospitalization that are proximal to harm (adverse event) and error.
Elopement	Patients leaves the unit, hospital or grounds without permission including failure to return from a pass, home visit or other approved departure from the unit. Does not include attempted but unsuccessful elopements.
Contraband	Potentially dangerous items on the inpatient unit, including sharp objects (razors, knives, box cutters, scissors, or pins); matches and lighters; plastic bags and balloons; alcohol, illegal drugs and prescription medications; and ropelike items (belts, shoelaces, pantyhose, neckties, headphone wires, electrical cords, etc.).
Patient fall	Falls regardless of the extent of the fall (to the floor or onto the bed) or whether the patient experienced harm or required treatment. Exclusions: events documented as intentional or faked and falls secondary to a primary medical event, such as during cardiac arrest or seizure

Table 2

Prevalence and rates of patient safety events among psychiatric inpatients

		Events per 100 Patient Discharges (N=8,005)		Events per 1000 Patient-Days (N= 61,274)	
	N	**Prevalence**	**95% CI**	**Rate**	**95% CI**
Any Event	2,232	27.88	23.32–32.44	36.43	30.34–42.51
Adverse Events, All	478	5.97	5.05–6.89	7.80	6.65–8.95
Adverse drug event	330	4.12	3.37–4.88	5.39	4.42–6.35
Patient self-harmor injury	37	.46	.29–.63	.60	.39–.82
Patient assault	81	1.01	.65–1.37	1.32	.85–1.79
Patient sexual contact	10	.12	.04–.21	.16	.05–.27
Other nondrug adverse events	20	.25	.11–.38	.33	.15–.50
All medical errors	1,455	18.17	14.10–22.25	23.75	18.27–29.22
Medication error	1378	17.21	13.16–21.26	22.49	17.03–27.94
Nondrug medical errors	77	.96	.63–1.30	1.26	.82–1.69
Other patient safety events, All	299	3.73	3.01–4.46	4.88	3.97–5.79
Elopement	18	.22	.04–.41	.29	.05–.54
Contraband	57	.71	.45–.97	.93	.60–1.26
Patient fall	224	2.80	2.22–3.38	3.66	2.91–4.40

Table 3

Severity of Harm and Preventability of Patient Safety Events (n=2,232) among psychiatric inpatients

Event		Severity of harm						Preventability			
		None or Minimal		Moderate		Severe		Not likely or Somewhat likely		Likely or Highly likely	
	N	%	CI	%	CI	%	CI	%		%	CI
Overall	2,232	94.9	93.3–96.5	4.5	2.7–6.2	.6	.0–1.1	43.4	39.0–47.7	56.6	52.2–61.0
Adverse Events	478	84.9	81.3–88.6	13.8	10.0–17.6	1.2	.0–2.5	80.7	76.9–84.6	19.2	15.4–23.1
Adverse drug event	330	84.8	80.5–89.1	13.6	9.3–18.0	1.5	.0–3.3	81.8	77.4–86.2	18.2	13.8–22.5
Patient self-harm/injury	37	75.7	59.8–91.6	24.3	8.4–40.2	0		70.3	53.3–87.2	29.7	12.8–46.7
Patient assault	81	98.8	96.3–100.0	1.2	.0–3.7	0		88.9	81.7–96.1	11.1	3.9–18.3
Patient sexual contact	10	100.0		0		0		50.0	17.6–82.4	50.0	17.6–82.4
Other nondrug adverse events	20	40.0	18.3–61.7	55.0	33.3–76.7	5.00	.0–15.2	65.0	48.6–81.4	35.0	18.6–51.4
Medical errors	1,455	97.6	96.6–98.6	2.0	.9–3.0	.4	.0–.8	26.5	22.3–30.6	73.5	69.4–77.7
Medication	1,378	98.0	97.1–98.9	1.7	.7–2.6	.4	.0–.7	27.2	22.8–31.5	72.8	68.4–77.1
Non-medication	77	90.9	84.0–97.8	7.8	2.1–13.5	1.3	.0–3.9	13.0	4.1–21.8	87.0	78.2–95.9
Other Patient Safety Events	299	97.7	96.4–99.6	1.7	.2–3.1	.3	.0–1.0	65.9	60.0–71.7	33.8	27.9–39.7
Elopement	18	94.4	83.2–100.0	5.5	.0–16.7	0		38.9	17.3–60.5	61.1	39.5–82.7
Contraband	57	100.0		0		0		21.0	10.4–31.7	77.2	65.7–88.6
Patient fall	224	97.8	95.7–99.8	1.8	.0–3.6	.4	.0–1.4	79.5	73.4–85.5	20.5	14.5–26.6