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## Defining Patient Safety Events in Inpatient Psychiatry

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### Abstract

**Objectives**—The past 20 years have seen the emergence of a national movement to improve hospital-based healthcare safety in the United States. However, much of the foundational work and subsequent research have neglected inpatient psychiatry. The aim of this article was to advance a comprehensive approach for conceptualizing patient safety in inpatient psychiatry as framed by an application of the IOM patient safety framework.

**Methods**—This article develops a framework for characterizing patient safety in hospital-based mental health care. We discuss some of the conceptual and methodological issues related to defining what constitutes a patient safety event in inpatient psychiatry then enumerate a comprehensive set of definitions of the types of safety events that occur in this setting.

**Results**—Patient safety events in inpatient psychiatry are broadly categorized as adverse events and medical errors. Adverse events are comprised of adverse drug events and non-drug adverse events, including self-harm or injury to self, assault, sexual contact, patient falls and other injuries. Medical errors include medication errors and non-medication errors, such as elopement and contraband. We have developed clear definitions that would be appropriate for use in epidemiological studies of inpatient mental health treatment.

**Conclusions**—Psychiatry has not been an integral part of the national safety movement. As a first step toward breaching this chasm, we have considered how psychiatric events fit into the safety framework adopted across much of medicine. Patient safety should become a key part of inpatient psychiatry’s mission and pursued rigorously as the subject of research and intervention efforts.

## INTRODUCTION

The past twenty years have seen the emergence of a national movement to improve healthcare safety in the United States.<sup>1,2,3,4</sup> With the 2001 publication of the landmark Institute of Medicine (IOM) report, *To Err is Human*,<sup>5</sup> a coalition of leading clinicians, policymakers, payers, researchers, and patient advocates launched a national agenda to improve patient safety. “Fundamental” to this effort is the development and implementation of standardized, routine measures of clinically significant adverse events and medical

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errors.<sup>6</sup> In 2015, the National Patient Safety Foundation (NPSF) reviewed safety improvement efforts since the publication of the IOM report.<sup>7</sup> They concluded that although hospital care had become safer in selected areas, they emphasized the work ahead, not only in measurement and practice change, but also in the cultivation of local hospital leadership for safety, education and training of clinicians, and research on human factors, systems engineering, and implementation science.

Strikingly, however, neither the 2001 IOM report nor the 2015 NPSF evaluation *even mention* inpatient psychiatry or mental health care. Psychiatry’s absence can be traced back to the original Harvard Medical Practice Study, which excluded patients hospitalized for a primary psychiatric diagnosis. Psychiatric inpatients were similarly excluded from subsequent major studies of adverse events, adverse drug reactions, medical errors, and medication errors.<sup>8,9,10</sup> Patient safety events in psychiatry that have been studied have generally looked at individual types of events (e.g., falls, suicide attempts, assault and medication errors) using smaller samples and varied methods.<sup>11,12,13,14,15</sup> Particularly true for those published before the IOM report, many of these studies were unable to take advantage of the methodologic advances and their more consistent application, larger scale and scope, and increasing momentum of safety research that has occurred for the last 20 years.

An extensive review of mental healthcare research and practice observed that a systematic approach to patient safety has been lacking.<sup>16</sup> The authors noted that advances similar to those suggested in the IOM report are needed in many areas of psychiatry as well, including standardized measurement, priority setting, fostering leadership and a safety-sensitive culture, and evidence-based interventions. Needed precursors to these developments are the adoption of a patient safety framework along with standardized terminology and definitions – basic building blocks that the IOM report provided in medicine and surgery and have been further refined in other specialties.<sup>17,18</sup> The objective of this article is to describe patient safety in inpatient psychiatry as framed by an application of the IOM patient safety framework. We discuss some of the conceptual and methodological issues related to defining what constitutes a patient safety event in psychiatry.

## METHODS

### The IOM Framework for Patient Safety Events

The IOM framework categorizes patient safety events in terms of adverse events and medical errors. The framework defines these terms and describes the relationship between them with implications for measurement. An *adverse event* is defined as “an injury [or harm] resulting from commission or omission of care.”<sup>4,19</sup> A *medical error* is defined as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”<sup>4,20</sup> The standard for distinguishing erroneous care is “commission or omission [that] ... would have been judged wrong by skilled and knowledgeable peers at the time [it] occurred.”<sup>21</sup> Adverse events and medical errors are overlapping constructs. Medical errors can occur regardless of whether they result in an adverse event or cause no harm to the patient. Adverse events can result from either appropriate care or a medical error. For example, a patient who has been appropriately assessed for not being at-risk of a fall, but

then accidentally trips and incurs a fractured arm would be considered an adverse event, but not a medical error. On the other hand, a frail patient who has been assessed at-risk of a fall, but not given the requisite fall prevention implements and falls as a result yet does not experience injury would be considered to have experienced a medical error, but not an adverse event. An understanding of adverse events and medical errors, along with the relationships between them, is crucial when examining patient safety events. The purpose of delineating patient safety events with specificity is to permit reliable measurement of their frequency, and ultimately, to improve the safety of care through implementation of effective interventions.

We identified potentially measureable safety events by conducting a qualitative analysis to identify a preliminary typology of patient safety events in inpatient psychiatric units as observed by treatment providers, including physicians, psychologists, nurses, and social workers from two inpatient psychiatry units.<sup>22</sup> Our in-depth semi-structured interviews were based on the available literature and included questions and probes focused on eliciting the types of errors and adverse events that occur in inpatient psychiatric care; the data derived from these interviews formed the preliminary list of patient safety events. Similar to the landmark Harvard Medical Practice Study which used trained nurses and medical record administrators to conduct medical record reviews<sup>23</sup> and other chart review studies which used research nurses, pharmacists and research assistants to detect adverse events and errors in general medicine settings,<sup>24</sup> we trained a team of medical records administrators (MRAs). We asked them to be highly sensitive in detecting safety events to overselect potential events and ensure that a broad range of safety events would be captured. The MRAs examined 1,000 medical records in two urban university-affiliated hospitals to identify charts with potential adverse events and errors. Weekly meetings with reviewers were held to discuss detected events throughout the duration of the review. These events were then carefully examined and enumerated (by authors SCM, RCH, SWC) to understand how they present themselves in hospital medical records. We then discussed identified potential events with a multidisciplinary advisory committee that included a team of senior inpatient psychiatrists and nurse managers. Based on this pilot work, the IOM definitions, and the relationship between the events and psychiatry's processes and outcomes of care, we created a taxonomy with clear definitions of all identified patient safety events. These were then categorized as either primarily adverse events or medical errors.

## RESULTS

As noted previously, all of the patient safety events we identified in inpatient psychiatry were categorized as either primarily adverse events or medical errors. Table 1 presents an overview of these patient safety events.

### Adverse events

By definition, adverse events are the result, at least partially, of the omission or provision of clinical care. These events can result from psychiatric illness, and are influenced by many patient, clinical, and social factors. They are additionally adverse events in the sense that a primary purpose of psychiatric hospitalization is to protect patients and/or their surrounding

communities from harm. This is particularly true in the present era when hospital admission is subject to medical necessity criteria, leading to an inpatient population that is severely ill. Much of the structure, staffing and clinical processes of inpatient psychiatric units are designed to minimize the likelihood of patient harm within this vulnerable population. Adverse events (AE) on inpatient units are categorized into two groups – non-medication related (non-drug AE) and medication-related (adverse drug events; AEs).

**Non-drug adverse events**—Inpatient non-drug adverse events include self-harm or injury, assault, sexual contact, falls, and other injuries.

**Self-harm or injury to self:** This category of events includes patient injuries that are: intentional injuries to self (i.e., acts of self-harm or self-injurious behavior, including suicide attempt) and unintentional injuries to self (other injuries experienced by the patient even if he or she did not intend to cause harm, such as punching a wall out of anger). In trying to distinguish gestures (e.g., suicidal ideation or threats unaccompanied by actions) from active self-harm or injury, we established a threshold that excludes superficial or minor injury, as indicated by the absence of bruising, swelling, bleeding, or treatment (e.g. punching wall without documentation in the chart of bruising, swelling, bleeding, or treatment). Our measurement of self-harm is construed more broadly than AHRQ’s patient safety indicator metric, which is focused on identifying deaths. Suicides among hospital inpatients is rare<sup>25</sup> whereas episodes of less severe self-harm are much more common on psychiatric units, providing a better opportunity to understand gaps in clinical practice that might prevent this type of patient harm.

**Assault:** Acting out, which can manifest itself in the form of violence toward others sometimes occurs on the inpatient psychiatric unit even though staff are trained to maintain order and deescalate conflicts between individuals. Assault is defined as “forcible” physical contact, which can include, but is not limited to: pushing, hitting, biting, punching, kicking, slapping, and pulling hair. The term “forcible” is used to distinguish an assault from lesser contact such as a poke or pat. Spitting with contact is also considered an assault. Assaults occur between two (or more) individuals – the patient and another patient, the patient and a visitor, or the patient and a staff member. The assault need not result in injury to be considered an AE. The exception, however is when a patient assaults a staff member, and then, it is only considered an AE if the staff member sustains injury. This higher threshold was established because some patients on the inpatient unit have issues with aggression that staff members are expected to manage as part of their clinical duties. Non-assaultive acts of violence, including destruction of property, are not considered patient safety events.

**Sexual contact:** Sexual contact is considered a patient safety event on the inpatient psychiatric unit because of concerns related to cognitive capacity to provide consent, sexually transmitted diseases, and possible pregnancy.<sup>26</sup> Drawing on legal statutes, sexual contact is defined as physical contact that includes, but is not limited to: intentional touching either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh, or buttocks. Some acts of sexual contact are dependent upon context. For example, whereas kissing between patients would constitute sexual contact, a patient kissing or hugging a

visitor in greeting or farewell would not. Unreciprocated sexual contact toward staff is not considered a patient safety event as staff may experience being the passive recipient of unwanted acts from patients who experience cognitive impairment or impulse control issues.

**Falls:** Inpatient falls, a longstanding focus of hospital safety in medicine as well as psychiatry,<sup>11,27,28</sup> are commonly understood as adverse events. The federal government at the Veterans Affairs defines a fall as “a loss of upright position that results in landing on the floor, ground, or an object or furniture, or a sudden, uncontrolled, unintentional, non-purposeful, downward displacement of the body to the floor/ground or hitting another object like a chair or stair; excluding falls resulting from violent blows or other purposeful actions”.<sup>29</sup> Our definition goes one step further to also exclude falls that occur secondary to a clinical event, such as a heart attack or seizure. Fall prevention activities have historically focused on *all* falls, regardless of whether they result in harm perhaps because falls in general have the potential to be associated with serious injuries and increased health care utilization.<sup>30</sup> Similarly, our definition includes all falls, with or without harm.

**Other injuries:** Because it is impossible to enumerate all the possible clinical events that occur during the course of care, this category includes all other forms of harm that are iatrogenic in nature. This includes injuries sustained as a direct result of clinical care (i.e., significant functional impairment resulting from ECT), including death.

**Adverse drug events (ADEs)**—Pharmacologic treatment, with both psychotropic and non-psychotropic medications (for comorbid medical conditions), is common on the psychiatric unit. Based on the literature, our pilot work, and consultation with the advisory panel, we adapted a list of clinical events established in medicine as sufficiently harmful or impairing to the patient to be considered an ADE. We also added clinical events commonly seen on psychiatric units. ADEs are defined as the negative, unintended consequences of a medication that result in functional impairment or other significant harm. Because it can be difficult to distinguish between significant adverse reactions to medication and expected or minor side effects of medication, we relied on previous literature in medicine<sup>31</sup> and consultation with our clinician advisory panel to create an algorithm for appropriately identifying ADEs. ADEs have to meet the following criteria: 1. there must be an adverse reaction/side effect (e.g., symptoms); 2. a medication needs to have caused the reaction; 3. at least one of the following – (a) the reaction is on a specified list of medication reactions that have been determined by previous research to always be categorized as an ADE (see Table 2);<sup>29</sup> (b) the reaction resulted in the medication being stopped, held, discontinued, or replaced by another medication because of the adverse reaction (this is a proxy for patient impairment); or (c) the reaction impaired the patient’s functioning (e.g., standing, walking, seeing, hearing, thinking, breathing). In addition, the reaction must be newly onset since the patient had been admitted or an acute worsening of symptoms while on the unit.

### Medical errors

Medical errors can be divided into two broad groups – those that are related to medications and those that are not.

**Medication errors**—Medication errors have been well studied in medical, surgical and inpatient psychiatric settings.<sup>32,33,34</sup> Based on previous research, medication errors are defined as when a medication is administered to the patient in a manner other than what was ordered. Medication errors are categorized by the following sub-type: wrong dose, missed dose, delayed dose, wrong drug, or wrong route of administration. Although medication errors may result from lapses or mistakes in administration, ordering, preparing, monitoring or transcribing, these attributions may not be documented in the charts, and thus, we limited our definitions to data typically available in medical records. Information about each of these types of events was typically documented as part of clinician notes and summaries, clinician orders, and medication administration forms, which include the date and time, dosage, and route of each medication as it is prescribed and provided to a patient. Delayed or missed doses are only counted if they are specifically noted as such in either the clinical notes or in the medication administration record. Based on the distribution of the timing of dosing seen in our pilot data, we established a delay threshold of at least three hours from the intended dosing time. We did not count as errors the following: intentional changes in administration, PRN medications that were not given when documented as not being clinically necessary (e.g., sleep medication not given because patient was already asleep), inappropriate use of topical medications, or medications refused by the patient.

**Non-drug medical errors**—The study of medical errors other than medication errors have long been the focus of research in medicine<sup>35</sup> and surgery,<sup>36,37</sup> but have not been as well studied in psychiatry. Such patient safety research, however, is closely related conceptually and methodologically to the study of quality of care, which has been conducted extensively in outpatient psychiatry.<sup>38</sup> Much of that work focuses on identifying breakdowns in appropriate processes of care. From our pilot work, we were able to identify specific events that constitute errors in the provision of care. The medical record also allowed us to identify events that, although not themselves errors, were the direct result of errors. For instance, the term contraband is often used when documenting the discovery of a prohibited, potentially dangerous item on an inpatient unit. Detection of contraband is not an error; the associated error could have been an incomplete body and belonging search. However, the latter is rarely documented in the medical record, but must have occurred for the former to be present. Thus, we considered the presence of contraband to be a proxy for an unspecified error in clinical care that allowed it to occur. Likewise, elopements are typically documented in a medical chart and although they are not errors, they are likely to be caused by an error, such as an unlocked door or window or unguarded elevator. The three categories of non-drug medical errors are errors proximal to contraband, errors proximal to elopement, and other errors.

**Errors proximal to contraband:** Contraband consists of dangerous or potentially harmful items on the inpatient unit that have serious safety implications. These include the following: razors, knives, box cutters, sharp objects/weapons, scissors, safety pins, matches, lighters, plastic bags, balloons, alcohol, illegal drugs, prescription medication, belts, shoelaces, pantyhose, neckties, headphone wires, electrical cords, and other rope-like items. These items are not permitted on the unit and indicate an error because of a breakdown in

procedure as they should have been detected as part of a body and belongings search on admission.

**Errors proximal to elopement:** Elopement involves patients leaving the locked inpatient unit, hospital facility, or grounds without permission. Attempted, unsuccessful elopements are not included.

**Other errors:** This category of events includes any other medical errors that occur during the hospitalization. While on the unit, patients are often given orders to undergo tests to assess their clinical condition or procedures related to their treatment and breakdowns can occur in this process. Examples of other errors include, but are not limited to, the following: wrong test or procedure performed; test or procedure ordered but not performed; and other care provided counter to what was specifically prescribed in the medical record (i.e., patient receiving food when known allergy is documented in chart). Some of these errors involve care delivered by the inpatient treatment team whereas others involve ancillary services, such as the pharmacy, laboratory, respiratory therapy, and dietary. We also included events related to the environment of care, such as a wet floor contributing to a patient fall or an unlocked unit door leading to an attempted, but unsuccessful elopement.

### **Other considerations**

Seclusion/restraints. Physical restraint and seclusion are common subjects in discussions of psychiatric inpatient safety, and hospital incidence rates are often reported to internal<sup>39</sup> and external entities specifically if they result in patient death.<sup>40</sup> However physical restraint of a patient is not a patient safety event and a higher restraint rate does not indicate less safe care. Restraint and seclusion, when used appropriately, can protect patients and staff from being injured, for example, a patient with psychosis and agitation, who had not responded to lesser interventions. Thus, simply counting or measuring rates of seclusion and restraints in and of themselves does not contribute to our understanding of patient safety, because it is difficult to tell from the medical record whether it was applied appropriately and/or out of clinical necessity. Instead, we believe that if an adverse event or error in care occurs that is related to seclusion/restraints it will be captured in one of the other categories described previously (e.g., other injuries).

### **Limitations**

There are other errors that might result from non-adherence to policies and procedures that are in place to promote the safety of inpatients, but whose absence is often not documented in the patient medical record. These include the following: the serial assessment of patient clinical and risk status; monitoring at regular intervals (eg, every 30, 15, 5 minutes, or continuous observation); improper use of chemical restraints; errors in diagnosis; and omission and commission of care associated with the prescribed treatment plan. It can be difficult to accurately measure from a medical record breakdowns in the numerous and collectively complex processes requiring coordination across individuals, roles, and shifts. In numerous cases, we encountered description of events suggestive of an error, but found that available information in the patient chart insufficiently supported the conclusion. Ultimately, despite the fact that chart review research has long been considered an important<sup>41</sup> and

effective<sup>42</sup> method of detecting patient safety events in a time- and cost-efficient manner,<sup>43</sup> the medical record is still an imperfect tool for providing a comprehensive understanding of patient safety within the context of the system of care. Many events, particularly those that did not lead to patient harm (an adverse event) may have not been documented in the medical record; therefore, incident rates resulting from our methods may err on the side of undercounting events. Finally, the presence of psychological harm or trauma is difficult to ascertain in a chart review and thus, unfortunately, was not included here either. However, interventions that result from chart review data should consider viewing patient safety in inpatient psychiatry through a trauma-informed lens as psychological or emotional harm to patients or providers, while difficult to measure, may have significant repercussions for the milieu of the unit and the extent to which patients and staff feel safe there.

## CONCLUSION

The patient safety paradigm is part of a broader model of measurement-based quality assessment and improvement, which originated in the manufacturing industry and has been implemented to a varying extent throughout health care.<sup>44,45</sup> In this model, patient care is seen as a complex system with inputs, outputs, and mediating processes. Medical errors are defects in processes. Adverse events are negative outputs or outcomes of care. Events are evaluated by reviewing the most serious occurrences individually and measuring the incidence of other events by type, comparing rates among facilities with similar patient populations. Facilities providing care that perform well may be sources of best practices. Facilities performing poorly are encouraged to improve their performance by adopting best practices or implementing interventions that have been shown to improve safety. In psychiatry, as in elsewhere in medicine, this systems perspective of clinical care is intended to augment rather than replace the clinical focus on the individual patient.

Establishing the basic components of a patient safety framework provides us with a starting ground for addressing many of the unique challenges facing inpatient psychiatry. The framework presented here establishes the tools necessary for hospitals to evaluate their psychiatric settings and measure the extent to which adverse events and errors occur – essential knowledge to any patient safety improvement efforts. In medical and surgical settings, this type of work has been conducted using a parallel patient safety framework. Preliminary safety efforts in these fields also began with measuring the extent to which AEs and errors occur<sup>1,2,46</sup> to develop targeted interventions and improve direct patient care. Similarly, to begin expanding these efforts to psychiatric settings, our framework has been used in two large studies examining the epidemiology of adverse events and medical errors in inpatient psychiatric units, one in the Veterans Healthcare Administration<sup>47</sup> and one in a sample of community-based general hospitals.<sup>48</sup> The results of these studies will allow us to more accurately identify targeted intervention strategies for improving care in inpatient psychiatry.

Patient safety should be a key part of inpatient psychiatry's mission and should be the subject of continued research and reduction efforts. However for historic reasons, psychiatry has not been part of the national safety movement of the past 20 years. As a first step toward breaching this chasm, we have sought to consider how psychiatric events fit into



the safety framework adopted across much of medicine. While any individual conceptual or methodologic decision we have made might be considered preliminary and subject to consensus among multiple stakeholders, organizations developing quality measures for mental health care may want to head in this direction.

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**Table 1**

Patient safety events in inpatient psychiatry

Adverse events	Medical errors
Non-drug adverse events	Medication errors
Self-harm/injury to self	Wrong drug
Assault	Wrong dose
Sexual contact	Wrong route
Patient fall	Delayed dose
Other injuries	Missed dose
Adverse drug events	Non-drug errors
	Errors proximal to elopement
	Errors proximal to contraband
	Other errors

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**Table 2**

Reactions to medications that constitute an adverse drug reaction

Reaction that is newly onset since admission or acute worsening on the unit	Examples or lab values related to reaction (where relevant)
Allergic reaction to a medication	Shaking, chills/fever/rash, anaphylaxis
Bradycardia	Heart rate of less than 60
Tachycardia	Heart rate greater than 120
Syncope	
Jaundice	
Urinary incontinence	
Colitis	
Dyspepsia	Only include moderate to severe; exclude mild
Altered mental status	Confusion
Internal bleeding	
Hematocrit	6 point drop in the absence of another explanation
Cardiac toxicity	Cardiac conduction delay
Renal toxicity	Creatinine (Cr) doubled from baseline and above upper limit of normal
Liver toxicity	Liver function tests (LFTs) doubled from baseline and above upper limit of normal
Hypertensive blood pressure	Systolic BP above 220; diastolic BP above 125
Hypotensive blood pressure	90/60 or lower
Dystonia secondary to antipsychotic drug	Stiffness, e.g., jaw, neck
Vomiting	
Oral thrush	
Muscle cramps	
Pedal edema	
Gastrointestinal bleed	
Hypoglycemia in patient treated with insulin or other medication for diabetes	Blood glucose of less than 70 AND symptoms of hypoglycemia (e.g., anxiety, sweating, palpitations, nausea, and/or weakness)

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