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Morbidity and Mortality Caused by Noncompliance With California Hospital Licensure: Immediate Jeopardies in California Hospitals, 2007–2017

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Objective: The California Department of Public Health investigates compliance with hospital licensure and issues an administrative penalty when there is an immediate jeopardy. Immediate jeopardies are situations in which a hospital's noncompliance of licensure requirements causes serious injury or death to patient. In this study, we critically examine immediate jeopardies between 2007 and 2017 in California.

Methods: All immediate jeopardies reported between 2007 and 2017 were abstracted for hospital, location, date, details of noncompliance, and patient's health outcome.

Results: Of 385 unique immediate jeopardies, 141 (36.6%) caused mortality, 120 (31.2%) caused morbidity, 96 (24.9%) led to a second surgery, 9 (2.3%) caused emotional trauma without physical trauma, and 19 (4.9%) were caught before patients were harmed. Immediate jeopardy categories included the following: surgical (34.2%), medication (18.9%), monitoring (14.2%), falls (7.8%), equipment (5.4%), procedural (5.4%), resuscitation (4.4%), suicide (3.9%), MD/RN miscommunication (3.4%), and abuse (2.3%).

Conclusions: Noncompliance to hospital licensure causes significant morbidity and mortality. Statewide hospital licensure policies should focus on enacting standardized reporting requirements of immediate jeopardies into an Internet-based form that public health officials can regularly analyze to improve hospital safety.

Key Words: medical errors, serious adverse events, hospital safety, surgical errors, never events

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In 1999, the Institute of Medicine's pivotal report *To Err Is Human: Building a Safer Health System* reported that hospital errors killed more Americans annually (98,000) than car accidents (43,348), breast cancer (42,297), or acquired immunodeficiency syndrome (16,516).[1] A review of 25 studies between 1991 and 2017 across 27 countries and 6 continents found that errors caused adverse events in 2.9% to 21.9% of hospitalized patients. The overall median of admitted patients affected by at least 1 adverse event was 10%; of these, 7.3% were fatal.[2] Although not all adverse events are preventable, some are and are caused by medical errors. Prior studies on this topic have used retrospective medical chart data but have not used state-mandated public health data.

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In 2007, the California Department of Public Health (CDPH) Center for Health Care Quality's Licensing and Certification Program began conducting inspections of every licensed acute care hospital, acute psychiatric hospital, and special hospital. These inspections are triggered by patient/family or staff complaint, facility self-reporting of incident, or routine state licensure renewal auditing.

California law requires reporting a subset of severe adverse events, called an "immediate jeopardy," which derive from events considered to have caused a serious injury or death to a patient because of noncompliance with 1 or more requirements of hospital licensure.[3] After the CDPH completes the investigation, a report is published publicly online (https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/Hospital-Administrative-Penalties-by-Year.aspx). Although reports have been collected for more than a decade, to our knowledge, they have never been aggregated and described. Our aim is to examine these individual reports of administrative penalties and summarize the types of immediate jeopardies collected over the last decade in the state with the largest population in the United States.[4] Unlike other studies, the data included in this article reflect the adverse events that were preventable, were tied to noncompliance with hospital licensure, and caused death or serious injury to a patient.

METHODS

Administrative Penalties

When the CDPH receives complaints from consumers, they are required to investigate the named healthcare facility within 30 days of receipt. Upon detection of a reportable adverse event, licensed healthcare facilities are required to self-report any medical error that is listed under the adverse event categories within 5 days of the incident and within 24 hours if the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, or led to a patient's death.[5] Hospitals report adverse events to the State and must also inform the patient or guardian of the adverse event by the time the report is made. The CDPH must then make an onsite visit within 48 hours of receipt of the report and complete an investigation within 45 days. Senate Bill 1301 defines errors (http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_1301-1350/sb_1301_bill_20060929_chaptered.html) that must be reported, sets timelines for reporting and inspection/investigation, and requires posting of substantiated event information for consumers on the CDPH website.

The CDPH audits facilities at least once every 2 years for state licensure renewal; for hospitals of 100 beds or more, the inspection team includes at least 1 physician, registered nurse, and persons experienced in hospital administration and sanitary inspections. If at any point the CDPH deems a facility not in compliance, they can issue a denial of payment for new admissions for Medi-Cal or Medicare patients and/or terminate Medicare payments.

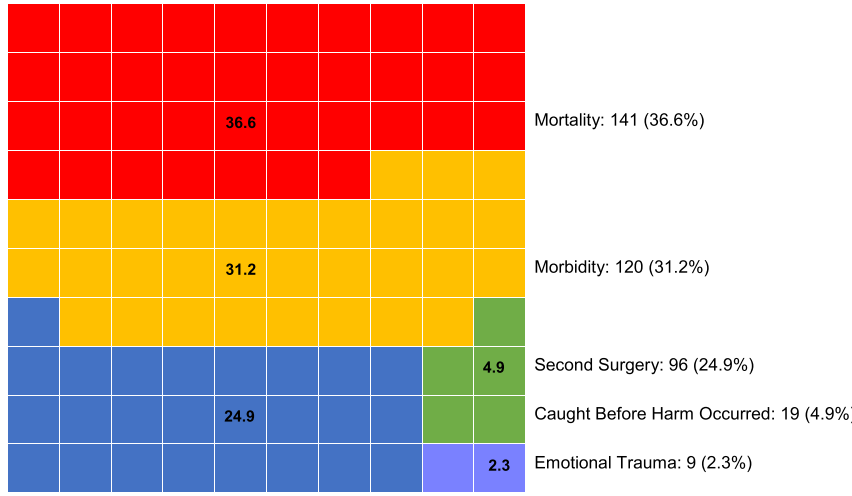

FIGURE 1. Patient outcomes of immediate jeopardies in California hospitals, 2007–2017 (N = 385), 2007–2017. Mortality, patient death due to error; morbidity, patient experienced physical health consequence because of error; second surgery, repeat surgery necessary because of a hospital error (only applicable for the surgical errors category); caught before harm occurred, no patients experienced any consequences directly because event was found on a routine audit before patient was harmed; emotional trauma, patient experienced primarily emotional trauma.

TABLE 1. Categories of Immediate Jeopardies, Their Descriptions, and Examples of Categories (N = 385)

Immediate Jeopardy Category	Description of Category	Example of Category	n (%)
Surgical	Error related to surgery	Wrong-sided nephrectomy performed.	132 (34.2)
Medication	Medication administration error	Patient given 50 times dose of heparin, which caused intracranial bleed and eventual death.	73 (19.0)
Monitoring	Lack of monitoring patient, giving care to patient (includes staff shortage), or accurately following up with patient results	Failure to monitor premature newborn's temperature correctly while under infant warmer resulted in temperature spike to 107.2F and full thickness burns to groin and thighs.	54 (14.0)
Falls	Failure to prevent falls in the hospital	High fall-risk patient on warfarin left unattended in radiology hallway, fell from gurney, sustained skull fracture, brain bleed, and eventual death.	30 (7.8)
Equipment	Equipment use error	Patient wheeled into MRI room without prescreening; metal wheelchair was immediately forcibly attracted by magnet to machine, trapping and crushing patient's leg.	21 (5.5)
Procedural	Not qualified to do procedure/procedural error	Placement of femoral central line by physician assistant not verified by x-ray. Patient had to undergo surgery to remove catheter; eventually required leg amputation.	21 (5.5)
Resuscitation	Failure to provide resuscitation or emergency care	Patient presenting to ED for stomach pain ignored for 30 min after sliding out of wheelchair and screaming in pain in ED lobby. Found in full cardiac/respiratory arrest; resuscitation unsuccessful.	17 (4.4)
Suicidal patient	Failure to protect suicidal patient from self-harm	Unmonitored suicidal patient found with shower head's flexible metal hose wrapped around neck; resuscitation unsuccessful.	15 (3.9)
MD and RN miscommunication	Failure of nursing to notify physician of clinical changes, doing something without orders, or not enacting physician orders	Patient with severe hyponatremia never administered 3% sodium chloride solution, which MD wrote 2 different orders for; patient required CPR, resuscitation unsuccessful.	13 (3.4)
Abuse	Patient experienced sexual assault or physical abuse in the hospital	Registered nurse kissed patient on mouth fondled breasts, and made her touch his penis with her hand after giving her hydromorphone and cyclobenzaprine.	9 (2.3)

All immediate jeopardies are deemed preventable, tied to noncompliance with hospital licensure requirements, and caused death or serious injury to a patient.

CPR, cardiopulmonary resuscitation; ED, emergency department; MRI, magnetic resonance imaging.

When a hospital is found to be nonadherent to hospital licensure regulations, an administrative penalty is issued, which includes a monetary fine, report of the deficiency, and a plan of correction for each occurrence. Using the CDPH civil penalty repository website, our investigators downloaded all publicly available PDFs. These are the subset of total complaints and voluntary facility reported incidents that were investigated by the CDPH that resulted in administrative penalties, which constituted an immediate jeopardy to the health and safety of a hospital patient. Immediate jeopardies are situations in which the hospital's noncompliance with 1 or more requirements of licensure has caused or is likely to cause serious injury or death to a patient.

Data Abstraction

We collected data from CDPH hospital administrative penalty reports of events occurring between 2007 and 2017 on February 20, 2020.[6] Data abstracted included the following: hospital name, location, date of error, summary of immediate jeopardy, and patient's health outcome after the error.

Quantitative Analysis

Rates and percentages were calculated by dividing by the denominator of total unique events (N = 385).

Qualitative Analysis

The CDPH investigation descriptions were summarized into concise statements. All statements were then qualitatively coded and organized. We developed a preliminary codebook using sensitizing concepts from coding the first 100 reports to define the error category. Two researchers coded these 100 reports to increase intercoder reliability and provided input on the precision of the codebook. We compared codes and discussed discrepancies until consensus was reached for all codes. Thematic saturation was reached after 68 reports. The remaining reports were then coded with this codebook. The reports were consolidated into 10 immediate jeopardy categories: abuse (sexual or physical abuse inflicted by a healthcare provider onto patient), equipment (failure of hospital equipment to work properly, leading to patient injury), falls (failure of hospital to prevent a high fall-risk patient from falling and injuring self), MD and RN miscommunication (discrepancy in physician orders and what was done at bedside by nursing staff), medication (errors in medication administration, usually erroneous dosage), monitoring (lack of proper clinical monitoring leading to morbidity or mortality), procedural (error occurring during a procedure; does not include surgical operations), resuscitation (failure to treat acutely decompensating patient in timely manner leading to inability to resuscitate a patient in time), suicidal patient (hospital failing to prevent patient from attempting self-injury while in hospital), and surgical (error occurring during surgical case). The outcomes of

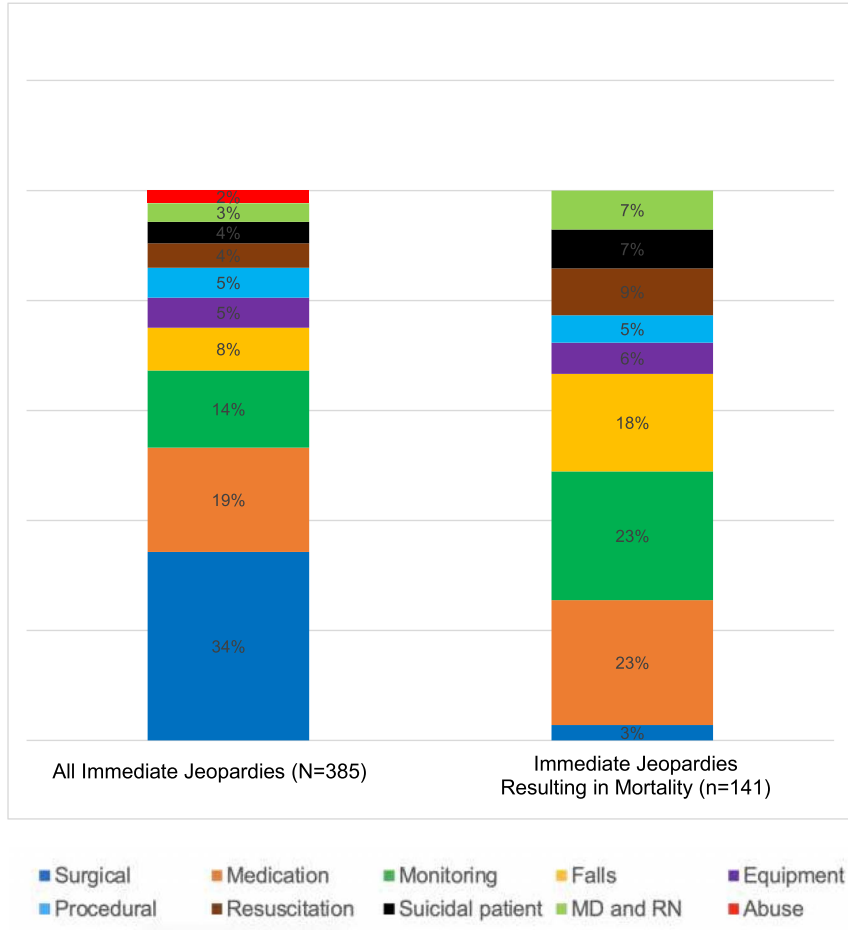

FIGURE 2. All immediate jeopardies versus immediate jeopardies resulting in mortality by category, 2007–2017.

each immediate jeopardy were ascertained by reading each report and cataloguing into 5 categories: mortality (patient died because of error), morbidity (patient experienced physical health consequence because of error), second surgery (repeat surgery necessary because of a hospital error, only applicable for surgical errors category), emotional trauma (patient experienced primarily psychological harm because of error), and caught before harm occurred (no patients experienced any consequences because event was found on a routine audit of the facility before patient was directly harmed).

RESULTS

There were 385 unique events that received administrative penalties categorized as an immediate jeopardy between January 01, 2007, and December 31, 2017.[6] During this period, there were 196 hospitals that had 2 or more events. Figure 1 shows that of the 385 total immediate jeopardies, 141 (36.6%) caused mortality, 120 (31.2%) caused morbidity, 96 (24.9%) led to a second surgery, 9 (2.3%) caused emotional trauma without physical trauma, and 19 (4.9%) were caught before harm occurred.

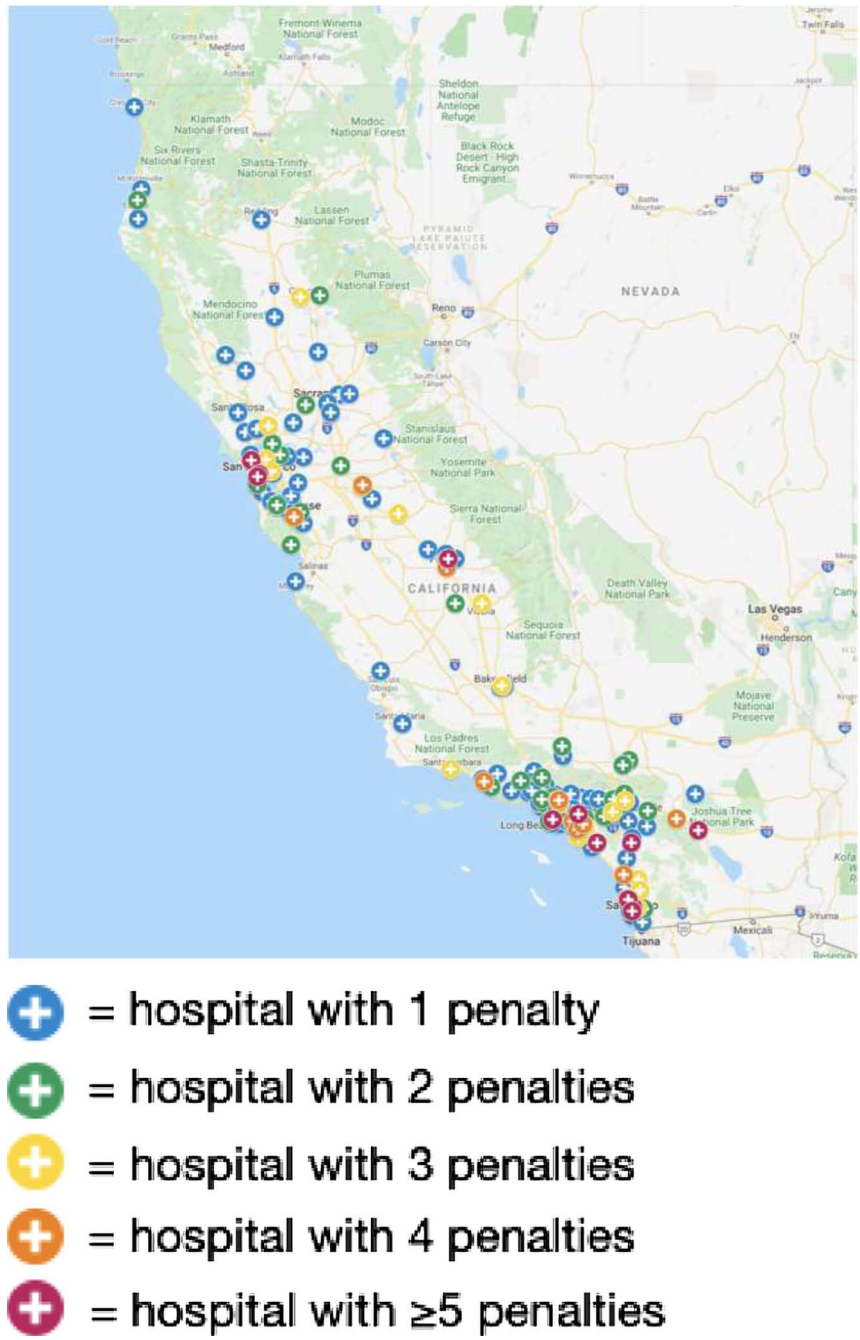

FIGURE 3. Map of immediate jeopardies in California by hospital, 2007–2017. Mapping done on Google Maps: https://www.google.com/maps/d/drive?state=%7B%22ids%22%3A%5B%221JuKECAbSJDhCiZUaU44TRluvcNo8VYGM%22%5D%2C%22action%22%3A%22open%22%2C%22userId%22%3A%221104466323289424692 98%22%7D&usp=sharing.

Table 1 describes the definitions of how immediate jeopardies were categorized and examples. The most common type was surgical (34.2%), followed by medication (19.0%) and monitoring (14.0%). Figure 2 demonstrates that the top 3 events that directly led to mortality were monitoring (23%), medication (23%), and falls (18%).

Figure 2 illustrates that the most common immediate jeopardies were not the ones that led to the most deaths. Although surgical was the most common category overall, surgical was the second to least common category that led directly to death behind sexual abuse, which did not lead to any deaths. Instead, medication was the most likely category to directly cause a patient's death. Figure 3 displays the geographical spread of the hospitals where the reports were generated and color codes each hospital by their number of penalties from 2007 to 2017.

DISCUSSION

In this study, we describe a decade of statewide hospital events deemed to be immediate jeopardies (i.e., directly led to or potentially led to serious patient morbidity or mortality). The number of events that constituted immediate jeopardies is likely highly underreported given the facility self-reported and complaint-based nature of penalties. Only 4.9% of all events were in the "caught before harm occurred" category, meaning that the penalty was found on a routine audit.

More than one third of the patients included in this retrospective analysis died because of the reported event. Another one third were physically harmed, and one fourth required a second surgery. Although the most common category of event was surgical, surgical jeopardies had a lower likelihood of resultant mortality compared with other categories as depicted in Figure 2. Instead, medication (e.g., overdose in hydromorphone leading to respiratory failure) and failure to monitor patients (e.g., failure to monitor hyperkalemia promptly leading to cardiac arrest) were the highest contributors to mortality. This may reflect the nature of surgical errors (e.g., retained foreign objects, wrong-sided nephrectomy) being able to be ameliorated with a second surgery (e.g., removal of foreign object) compared with the devastating nature of certain medication errors (e.g., immediate death after fatal overdose of medication).

Other larger-scale cross-sectional multicenter studies have found hospital error rates to range from 2.9% to 21.9% of hospitalized patients, with a median 7.3% of errors causing mortality.[2] It should be noted that error rates are based on error reporting, which may be an unreliable source of data. In this study, the mortality rate of 36.6% is higher than previous studies' mortality rates. However, this percentage reflects the reports that were already serious enough to be investigated by the CDPH and deemed to meet criteria for an immediate jeopardy. Previous studies focused on 1 or several hospitals, whereas this study included hundreds of California hospitals, including both academic and community settings. Similar to other studies, we found that surgical errors were the most common type of hospital error.[2,7] Disturbingly, 2.3% of the events were sexual or physical abuse that occurred within the hospital. There are limited data on sexual abuse in hospitals. However, 1 Nordic study found that of 3641 surveyed women, 13% to 28% had a lifetime experience of abuse in healthcare.[8] This remains an important topic that requires further investigation. In this study, all hospital errors that were labeled as "emotional trauma" described patients who experienced abuse. Unfortunately, there are no follow-up data on these and other patients, so it is unknown how these events contributed to future morbidity or mortality.

There were only 3 penalties issued for pressure ulcers, which is unlike the Agency for Healthcare Research and Quality's previous reporting on hospital-acquired conditions, where pressure ulcers had the second highest incidence of hospital-acquired conditions.[9] This may reflect that pressure ulcers in this study rarely led to serious injury or death and were therefore not identified by the CDPH to qualify for the designation of an immediate jeopardy.

Compliance of reporting is regulated by the Licensing and Certification Program of the CDPH. Complaints filed via an online form, by phone, or written letter are investigated by health facilities surveyors and prioritized based on the severity and scope of the deficiency. Hospitals themselves are also required to report adverse events to the CDPH; however, it is unknown what the rate of compliance of self-reporting is.

The major limitation of this study is that we rely on administrative penalty reports that are either completed after a facility self-reports an error, patient or staff complaint has been filed, or routine auditing has discovered safety issues. Events likely have gone unreported because of multiple factors, including lack of hospital self-reporting and noncompliance with reporting requirements, limited ability of the CDPH to conduct routine auditing because of budget or staffing constraints, and lack of transparency of processes for patient or staff to file complaints. Other limitations include missing data, small sample size of hospitals with penalties, and potentially biased or medically inaccurate reports written from the point of view of a state auditor with no medical training. There was a discrepancy between the new CDPH State Enforcement Actions Dashboard and the total penalties listed on the immediate jeopardies website; the CDPH could not provide these missing reports because of their 4-year record retention policy. Immediate jeopardies were categorized using qualitative coding, which creates abridged human constructs for very complex and multifaceted components that contribute to a patient death or harm. Although this may simplify the true reality of why each immediate jeopardy occurred, we believe that our study is still important in being the first attempt at describing these data in a summarized format and hope that it will be used for policy change.

New reporting systems implemented after publication of *To Err Is Human* held promise of a dynamic system to identify and incorporate real-time changes when immediate jeopardies occur.[1] Nonetheless, patient safety reporting systems nationwide continue to lack real-time reporting.[10] Previously, facilities in California had to manually edit a PDF to submit an incident, which was eventually faxed to the CDPH and scanned into their system. The new State Enforcement Actions Dashboard (https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/StateEnforcementActionsDashboard.aspx) released by the CDPH in September 2019 is a substantial improvement in sharing these data but lacks some information that may aid in analysis of data, such as categories of error and whether errors led to mortality. A more efficient method of collecting data would be to require facilities to fill out an Internet-based form that automatically populates a spreadsheet that could be vetted and then easily analyzed by public health officials and researchers.

To our knowledge, this data set has not been used to inform policies and practice on a systems level. The lack of standardized reporting of immediate jeopardies and plans of correction to ameliorate common deficiencies make it difficult to analyze improvement. Increasingly complex levels of hospital medicine may contribute to this.[11] Incorporation of big-data would allow regulators and researchers better access to reliable data in lieu of individual reports.[12] The federal government should enact policies, which require standardized hospital reporting of errors in a national database, such as with the Controlled Substance Utilization Review and Evaluation System. The data can then be more easily analyzed and help inform policies to improve patient safety.

CONCLUSIONS

This study is the first to systematically analyze statewide data on immediate jeopardies that have previously not been examined by researchers. It provides a descriptive and decade-long view of the most serious causes of injury and death to hospitalized patients in California. It is likely that these data only represents a small fraction of the true magnitude of severe hospital errors that affect patient health outcomes in California, the most populated state of the United States. Although it has almost been 2 decades since the Institute of Medicine published its formative report on hospital errors, as hospital-based healthcare becomes increasingly complex, medical and surgical errors continue to be a major issue that requires attention and intervention by policymakers. The primary difference in our study and other previous adverse event studies is that we used an already available statewide legally mandated database that has never before been summarized into a way that can contribute to larger-scale quality improvement in California hospitals. Without the ability to analyze reportable data, it can be argued that the legally mandated collection of data is not useful for larger-scale quality improvement. Our hope is that this study will show the need for a better collection and reporting system for immediate jeopardies, so that other hospitals and states can learn from devastating events to prevent patient harm before it occurs. This study shows the necessity of reforming the way that the California Department of Public Health collects and shares data with the public to allow for quality improvement.

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