

Reporting Systems

Integrating Incident Data from Five Reporting Systems to Assess Patient Safety: Making Sense of the Elephant

Osnat Levtzion-Korach, M.D. M.H.A.; Allan Frankel, M.D.; Hanna Alcalai, B.P.T., M.H.A.; Carol Keohane B.S.N., R.N.; John Orav, Ph.D.; Erin Graydon-Baker, M.S., R.R.T.; Janet Barnes, R.N, J.D., C.P.H.R.M.; Kathleen Gordon, M.S.N., M.S.; Anne Louise Puopulo, B.S.N, R.N.; Elena Ivanova Tomov, M.B.A.; Luke Sato, M.D.; David W. Bates, M.D., M.Sc.

Since the publication of the Institute of Medicine's *To Err Is Human* report,¹ hospitals and other organizations have actively sought ways to become safer.²⁻⁴ Organizations use information about near misses, adverse events, and staff concerns to identify defects in processes of care and to develop and prioritize prevention strategies^{5,6} for adverse events, which have been defined as injuries resulting from a medical intervention.¹

Organizations gather safety issues and related information through an array of approaches, including voluntary incident reporting, direct observation, chart review, reports to risk management, malpractice claims filed against the hospital and staff, patient complaint databases, executive walk rounds, automated triggers, and patient interviews.⁷ These data sources vary in the timing of the reporting (retrospective or prospective), severity of the events, and profession of the reporters. For example, incident reports, filed mostly by nurses, usually involve events of lower severity than incidents identified through risk management reports, of which about half come from physicians.⁸⁻¹⁰ The Institute of Medicine has strongly recommended the use of incident reporting systems.¹ However, studies have shown that, in general, underreporting represents a major issue, with evidence that in some situations 95% of adverse events are not reported.¹¹⁻¹³ Hospital risk management gathers information about adverse events and errors in real time. In contrast, information regarding adverse events gathered from malpractice claims is retrospective and limited both by the timing with which errors are revealed and by selection bias. Studies demonstrate that malpractice claims represent only the tip of the iceberg compared with the rate of actual injuries to patients.¹⁴ Patient complaints describe dissatisfaction with care received; issues range from clinical events to communication issues to complaints about parking.^{15,16} Executive walk rounds represent a relatively new modality developed to establish bidirectional feedback and stimulated conversation between the hospital's

Article-at-a-Glance

Background: A study was conducted to examine and compare information gleaned from five different reporting systems within one institution: incident reporting, patient complaints, risk management, medical malpractice claims, and executive walk rounds. These data sources vary in the timing of the reporting (retrospective or prospective), severity of the events, and profession of the reporters.

Methods: A common methodology was developed for classifying incidents. Data specific to each incident were abstracted from each system and then categorized using the same framework into one of 23 categories.

Results: Overall, there was little overlap, although each reporting system identified important safety issues. Communication problems were common among patient complaints and malpractice claims; malpractice claims' leading category was clinical judgement. Walk rounds identified issues with equipment and supplies. Adverse event reporting systems highlighted identification issues, especially mislabelled specimens. The frequency of contributions of reports by provider group varied substantially by system. Physicians accounted for 50% of risk management reports, but in adverse event reporting, where nurses were the main reporters, physicians accounted for only 2.5% of reports. Complaints and malpractice claims come primarily from patients.

Conclusions: The five reporting systems each identified different yet complementary patient safety issues. To obtain a comprehensive picture of their patient safety problems and to develop priorities for improving safety, hospitals should use a broad portfolio of approaches and then synthesize the messages from all individual approaches into a collated and cohesive whole.

senior leadership and clinicians about patient safety.^{17,18} Each method has advantages and limitations.¹⁹⁻²¹

Moreover, it is challenging to combine the information from the different systems into one safety picture. Most hospitals do not use all these methods, and it is unclear to what extent the approaches produce different—versus overlapping—information, especially when different perspectives, such as those of providers or patients are used. The net result is that hospitals are confronted with multiple data feeds that cannot be readily combined, making it hard for hospitals to decide how to prioritize safety initiatives, and thus many hospitals adopt a reactive posture—responding to individual crises—which may inhibit improvement.

To address these issues, we examined multiple systems currently used to assess safety at one large academic hospital with a history of patient safety awareness.²² We sought to do the following:

- Evaluate what type of information is received by each system
- Develop a common framework for representing the identified safety issues
- Assess the correlation between types of information collected by the different systems
- Evaluate the overall safety picture

We also compared the frequency of safety issues by provider-oriented systems (incident reporting, risk management, and walk rounds) and the patient-oriented systems (complaints and claims).

Methods

We assessed the following areas: an incident reporting system, reports to hospital risk management, a patient complaints database, executive walk rounds, and malpractice claims.

STUDY SITE

This study was performed at Brigham and Women's Hospital (BWH; Boston), a 747-bed tertiary care academic medical center affiliated with Harvard Medical School. There are approximately 52,000 inpatient admissions and 950,000 outpatient visits annually. The hospital employs more than 12,000 people, of whom approximately 3,000 are physicians.

DATA

Data were collected from all the source systems for a 22-month period between May 10, 2004, through February 28, 2006. During this period, there was a small number of malpractice claims. To increase the sample size for malpractice

claims, the time period for these data was extended to 10 years (1996–2006) after a qualitative assessment revealed no major differences in claims issues during the extended period. Regulations in Massachusetts require reporting of certain types of adverse patient events, including the reporting of “Serious Reportable Events,” as defined by the National Quality Forum. Reporting is required by both the Massachusetts Department of Public Health as well as the Massachusetts Board of Registration in Medicine's Quality and Patient Safety Division.

Incident Reporting System. The hospital employed a commercially available Web-based incident reporting system during the study period. Hospital personnel could report confidentially through any hospital computer using a secure login and could report anything that they perceive might be an issue.

Each adverse event report contains the reporter's initial comments and a section for the departmental manager to clarify issues further and add comments and actions. The manager is responsible for reviewing each report and assigning one or more contributing factors from a drop-down list of 50 potential contributing factors. It is important to note that this selection of contributing factors does not have associated definitions to assist or guide this assignment. Management then closes the loop by direct conversation with the reporters after the evaluation is complete for the most important reports.^{10,22}

Risk Management. A nurse-lawyer [J.B.] leads the hospital's risk management team. Physicians and nurses, in about equal numbers, call the team to report adverse events and poor patient outcomes. Risk management staff members investigate each case and determine on the basis of the estimated risk whether to report the case to the malpractice carrier. This information is collected manually with no systematic categorization and is entered in an electronic index in an Excel[®] format. Risk management also provides information back to managers or frontline individuals so that risks can be mitigated.

Patient Complaints. The Family and Patient Relations Department responds to patient and family complaints (concerns), suggestions, and compliments. The department's coordinators receive the complaints, assign them to one of 20 categories and one or more of 118 subcategories, and process them into a database. The department works directly with the hospital risk management team [J.B., K.G.] and safety team [E.G.-B], which includes a physician, nurses, and safety analysts ([including E.G.-B.]; although the analysts mostly do not have a medical background, they are trained in patient safety).

Executive Walk Rounds. Executive leadership walk rounds began at BWH in January 2001.^{22,23} Semiweekly, a member of the hospital leadership (hospital chief executive officer, chief

Table 1. Systems, the Number of Reports Collected, and Unit of Classification*

System	Number of Reports Submitted	Unit of Classification	Numbers of the Units Classified
Incident reporting	8,616 reports	50 contributing factors	13,255 actual contributing factors
Reports to risk management	1,003 reports	1,003 reports	1,003 reports
Patient complaints	4,722 reports	118 subcategories	6,617 specific problems, including subcategories
Executive walk rounds	61 walk rounds	51 categories	572 comments
Malpractice claims	322 claims	170 RMF issues	949 claims issues

* RMF, Risk Management Foundation.

medical officer, chief nursing officer, chief operating officer) accompanied by the hospital's safety officer, a safety analyst, and a pharmacy representative visits a different service in the hospital and engages with the staff (mainly nurses but occasionally also physicians) about safety concerns. In stimulated discussions, staff are encouraged to speak freely and make suggestions for improvement. The staff comments (negative and positive) are assigned one or more (out of 51) contributing factors and a priority score, which are then recorded in an electronic database. Analyses of the comments are then compiled into action items that are discussed with the accountable vice president.

Malpractice Claims. The malpractice insurer, CRICO/Risk Management Foundation (RMF; Cambridge, MA), has a system used for data collection called CMAPS (Claims Management, Analysis, and Processing System). Initial information is obtained from potential claim reports, hospital risk managers, or from formal malpractice claims and suits. Further information is added as it becomes available (for example, depositions, expert reviews, medical records, adjustor notes). Nurse coders assign one or more (from 170) risk management issues, factors that may have contributed to the allegation, injury, or initiation of the claim/suit. There are clear definitions, standardized coding algorithms, and collaboration between coders leading to high interrater reliability. The data are stored in an electronic database that is available for querying, analysis, and generation of reports. There are about 30 claims per year.

COMPARISONS

Because of the varied categorization schemata of the five systems, comparison of the information collected by them was not possible using each system's current classification methods. Therefore, we developed a new categorization scheme, which could be used to classify all the information.

This scheme includes 23 major categories (Appendix 1, available in online article). Each major category is further divided into subcategories (range, 3–9; average, 4.8 subcategories per major category). For the purpose of this study, the comparative analysis was done at the major categories level.

ANALYSIS

A physician reviewer [O.L.-K.] trained in patient safety classified the events captured in each of the five reporting systems using the newly defined categories and subcategories and using a guided implicit review approach; a 10% subset of the records was then validated independently by a second reviewer [H.A.] and we assessed the percent agreement between reviewers. Reviewers had access to the description of what had occurred and to the electronic medical record.

Investigators then calculated the frequencies of each of these events on the basis of the new categorization structure. Next, we assessed the overlap between rankings of the frequency of the different categories in the five systems both qualitatively and quantitatively. Correlations between different detection approaches were calculated using Pearson correlation coefficients.

Results

NUMBER OF DATA ELEMENTS

In classifying the different data sets, we evaluated 8,616 incident reports (involving 13,255 contributing factors), 1,003 risk management reports, 4,722 patient complaints (involving 6,617 specific problems), 61 walk rounds (involving 572 comments), and 322 malpractice claims (involving 949 issues).

CATEGORIES

Each category in the five data sets (Table 1, above) was classified by one individual [O.L.-K.] into one of the subcategories. The classification scheme was then validated independently,

with an interrater agreement rate of 89% overall (85% for the incident reporting database, 92.5% for the patient complaints database, 90% for the risk management database, and 87.5% for the executive walk rounds database).

Across the reporting systems, the leading major categories were communication, 11.6%; technical skills, 10.9%; and clinical judgment, 9% (Figure 1, page 406; available [in color] in online article). Each system had a different category that was most frequent. Clinical judgment was the leading category in the malpractice claims data (24.3%) but was barely represented in the incident reporting system (1.1%) and not represented at all in executive walk rounds.

Communication played an important role both in the malpractice claims (17.1%) and the patient complaints data (21.8%) but not in the hospital's risk management data (3%). Provider behavior accounted for 19% of complaints in the patient complaints system, second only to communication (clearly the two are closely related). However, provider behavior represented only 1.1% of the malpractice claims and 2.1% of reports to risk management and was not represented in the executive walk rounds or incident reporting system. Equipment (15.7%), electronic records (12.2%), and environment/infrastructure (12.1%) were the leading categories in executive walk rounds but were ranked low in the other systems. In the incident reports, identification issues (24.4%) and falls (16.8%) were the leading categories but were barely represented in the other systems.

PROFESSION

Profession plays an important role in which issues are considered important. The frequency of contributions of reports by provider group (Figure 2, page 406) varied substantially by system. Physicians accounted for 50% of risk management reports, but in adverse event reporting, where nurses were the main reporters, physicians accounted for only 2.5% of reports. The frequency of complaints and malpractice claims, which come primarily from patients, are shown in Figure 3 (page 406).

STATISTICAL CORRELATION

Table 2 (page 408) shows the correlation between the different categories across the systems. The highest correlations were between malpractice claims, reports to risk management, and patient complaints. The adverse event reporting system and executive walk rounds had low and negative correlation with the other four systems. Overall, across the five systems, Cronbach's standardized alpha was 0.22, suggesting a low level of consistency.

EXPENDITURES BY SYSTEM

Table 3 (page 408) shows the cost of the systems to the hospital. Costs were divided into software (usually a one-time expense + annual support) and labor. Overall, the hospital's expenditures on these systems were estimated to be a one-time cost of \$120,000 and an annual cost of almost \$1 million.

Discussion

Although much has been written about the different ways of collecting information regarding safety issues, few data are available comparing and evaluating the actual contribution of each approach. By using a single categorization framework for the five collection systems, we were able to individually assess and compare each system, while also evaluating them in aggregate. Our main findings were that each system produces a substantially different picture, and as individual systems, they all are incomplete. With a few exceptions, there was little correlation between the findings of the individual systems. This implies that to gain a full picture of the safety issues in an organization, it is essential to consider a composite perspective.

The purpose of this study was to compare the various approaches used to detect safety issues and to develop a taxonomy that allowed us to put all the types of issues identified into a single database, not to inform the hospital at an operational level regarding what to do next with respect to safety. Nonetheless, the results were presented to the hospital's leadership and have been invaluable to the institution in considering what issues to prioritize. We recognize that there are many safety taxonomies,^{24,25} and our intent was partly to develop a practical taxonomy that includes the everyday issues that hospitals face and that would enable us to cover all the issues in a single structure.

There is increasing recognition of the central importance in safe care delivery of good provider-to-patient and provider-to-provider communication,^{26,27} and these data reflect that. The communication category, overall, had the highest frequency of reports.

The highest correlation observed was between risk management reports and malpractice claims. However, even this correlation was only of medium strength because although hospital risk management provides malpractice claims with information on potential claims, there are a large number of cases in which the hospital risk management group is unaware of an incident until a claim is submitted. For example, a physician may not be aware for years of a missed or delayed diagnosis because the process of obtaining a correct diagnosis happens over a period of time, by different physicians, and in different settings. As a

Comparison of Issues Identified by the Five Reporting Systems

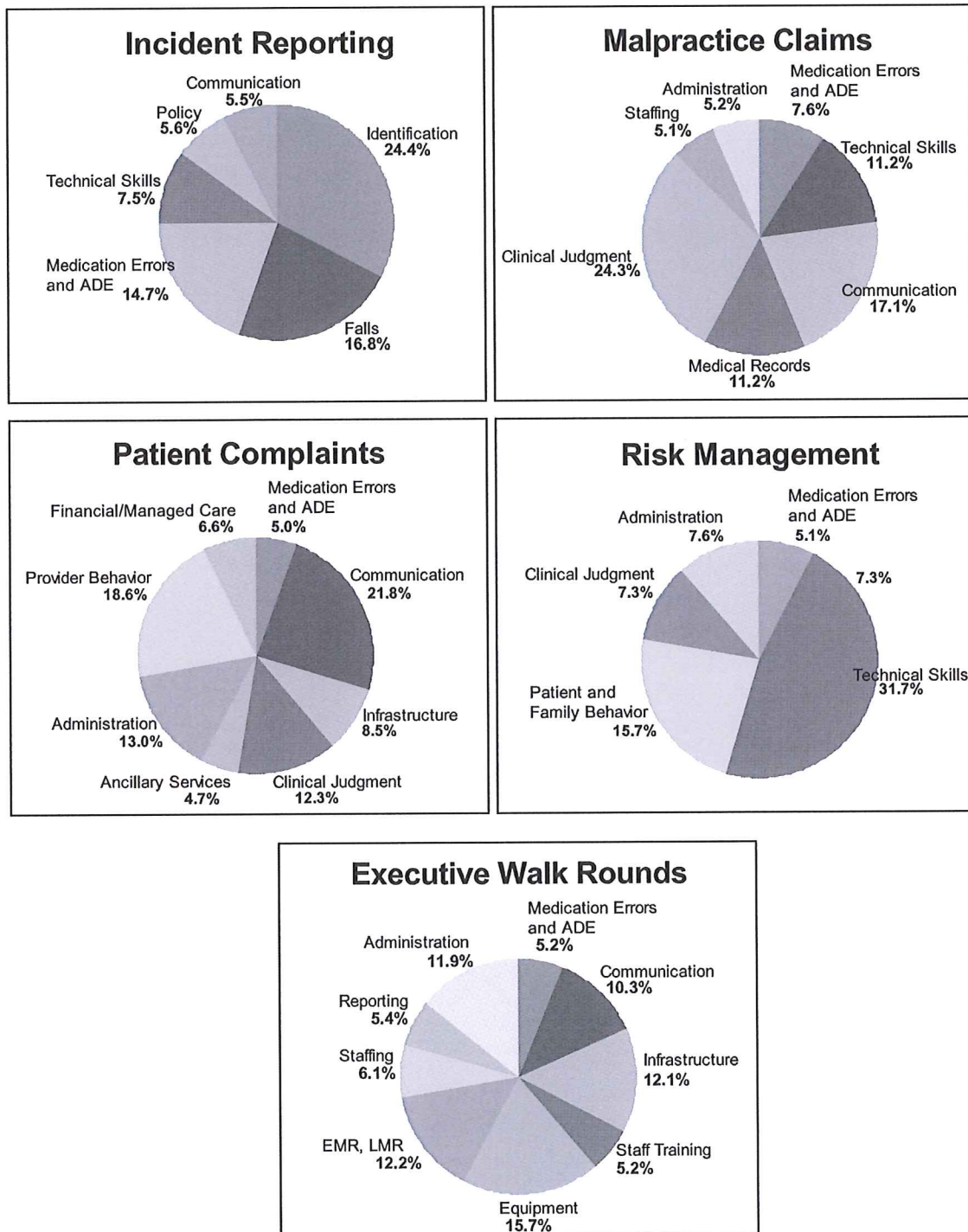


Figure 1. Across the five reporting systems, the leading major categories were communication (11.6%), technical skills (10.9%), and clinical judgment (9%); each system had a different category that was most frequent. ADE, adverse drug event; EMR, electronic medical record; LMR, longitudinal medical record.

Providers' View (Executive Walk Rounds, Risk Management, and Incident Reporting), Ordered by Frequency of the Category in Executive Walk Rounds

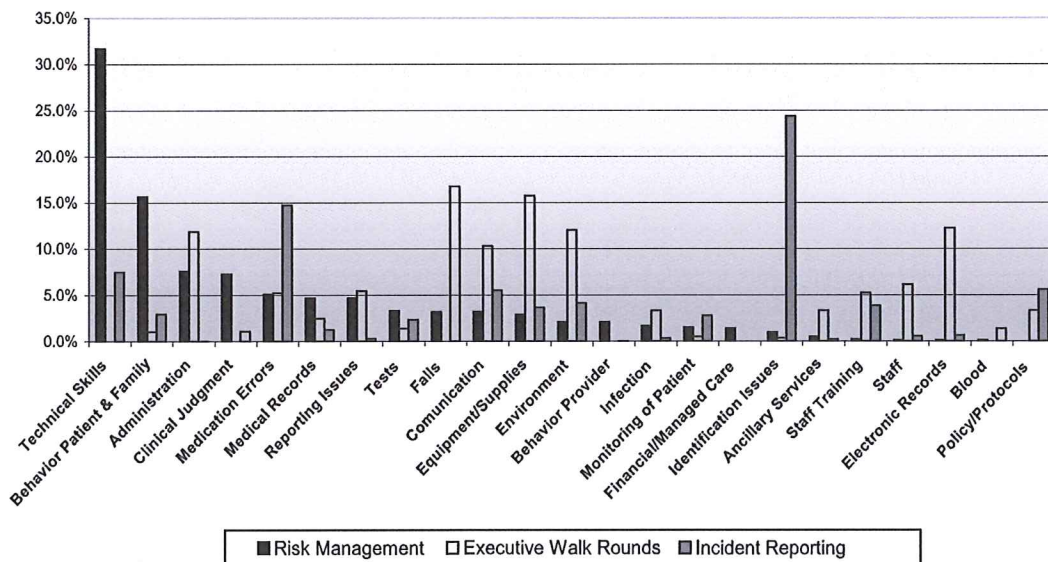


Figure 2. The frequency of contributions of reports by provider group vary substantially by system.

The Patient's View (Patient Complaints and Malpractice Claims), Ordered by Frequency of the Category in Complaints

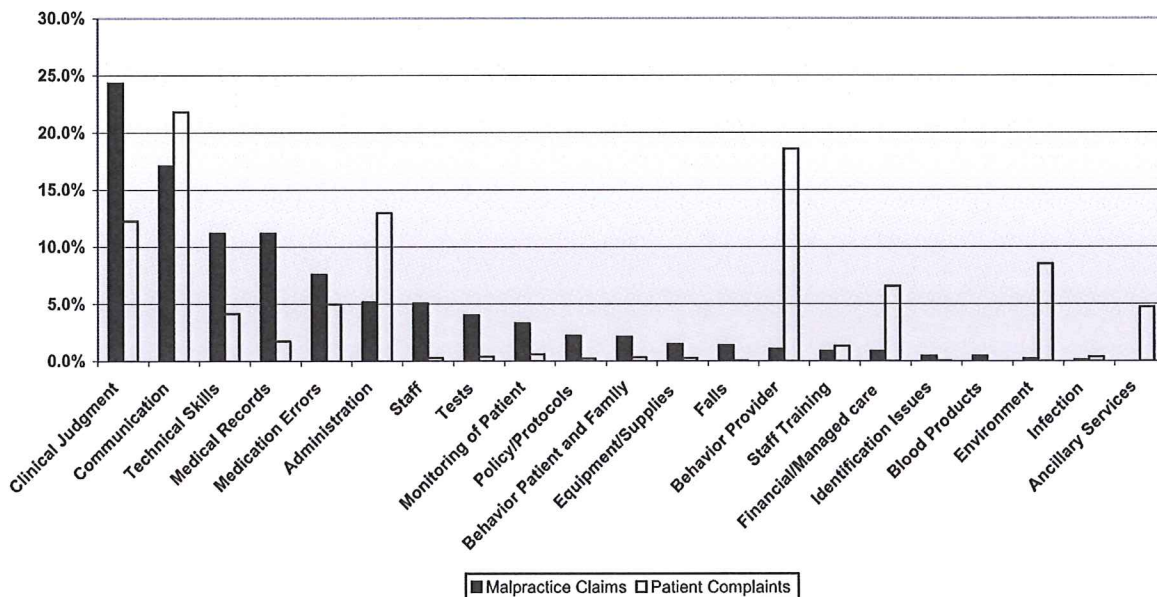


Figure 3. The frequency of complaints and malpractice claims, which come primarily from patients, is shown.

Table 2. Correlations Between Systems*

	Incident Reporting	Patient Complaints	Risk Management	Malpractice Claims	Executive Walk Rounds
Incident reporting	1.0	-0.2 ($p = .36$)	0.09 ($p = .68$)	0.26 ($p = .23$)	-0.02 ($p = .92$)
Patient complaints	-0.2 ($p = .36$)	1.0	0.40 ($p = .06$)	0.46 ($p = .03$)	-0.03 ($p = .90$)
Risk management	0.09 ($p = .68$)	0.40 ($p = .06$)	1.0	0.55 ($p = .007$)	-0.11 ($p = .60$)
Malpractice claims	0.26 ($p = .23$)	0.46 ($p = .03$)	0.55 ($p = .007$)	1.0	-0.13 ($p = .54$)
Executive walk rounds	-0.02 ($p = .92$)	-0.03 ($p = .90$)	-0.11 ($p = .60$)	-0.13 ($p = .54$)	1.0

*1 = perfect correlation; 0 = no correlation; 0.5 = medium-strength correlation.

Table 3. Estimated Costs of Systems*

	Incident Reporting	Patient Complaints	Risk Management	Malpractice Claims†	Executive Walk Rounds
Software					
One-time expense	\$72,400	\$42,580	\$0	\$0	\$0
Annual support	\$9,000	\$3,395	\$0	\$0	\$0
Manpower					
Annual support	\$43,340 (0.5 FTE PS manager) \$18,000 (0.2 FTE RM analyst) \$4,500 (0.1 FTE PS analyst)	\$540,000 (12 FTE PS analyst)	\$318,500 (3.5 FTE risk management analyst)	\$0	\$17,380 (0.2 FTE PS manager) \$12,780 (0.3 FTE PS analyst) \$10,500 (a weekly hour of CEO, CMO, CNO, and COO)
Sum					
One-time expense	\$72,400	\$42,580	\$0	\$0	\$0
Annual support	\$74,840	\$543,395	\$318,500	\$0	\$40,660

* FTE PS, full-time equivalent patient safety; FTE RM, full-time equivalent risk management; CEO, chief executive officer; CMO, chief medical officer; CNO, chief nursing officer; COO, chief operating officer.

† Not directly supported by the institution.

result, the first insight to a potential problem may be the malpractice claim itself.

In evaluating patient complaints and malpractice claims, we found a comparatively higher correlation. Previous research has demonstrated correlations between the number of complaints against a specific physician, poor communication with patients, and the physicians' risk of being sued.²⁸⁻³⁰

The incident reporting system had little correlation with the other systems. As found in previous research,^{10,31} in our study identification issues and falls were the leading categories, together capturing 41% of the contributing factors; these two

categories represented between 0% to 3% in the other systems. In this institution, nurses primarily file reports through the electronic reporting system, whereas physicians contribute very little to it. This may account for the weighting of these two categories, which reflect tasks specific to nursing care delivery. Considering only this reporting source as representative of the underlying safety issues in an institution may divert the focus from other safety concerns.

Executive walk rounds had a negative correlation with all the other systems, which probably related to the different method for obtaining information combined with the opportunity to

informally discuss operational concerns such as lack of supplies, problems with the electronic medical record, lack of space, and administrative issues.

Our data show that each of the systems provides a different view of the overall safety picture. The traditional information source, the incident reporting system, shows only a small part of the picture and has very low correlation with other systems. Thus, using findings solely from the incident reporting system would mislead hospital leadership in deciding what to emphasize with respect to safety. To best use safety information, leadership should recognize the added value of each system and know the main topics that each system handles. For example, in evaluating the causes for claims, greater understanding is possible from looking at both risk management data and patient complaints.

From a broader perspective, the major implication is that studies or reports commenting on only one of these inputs will necessarily produce an incomplete picture of safety. For example, it is common for those reporting on national results from incident reporting databases to reach conclusions about their data and then attempt to generalize broadly to hospitals. Of other studies that have assessed the relative contributions of several different approaches for finding adverse events, most have found that there is relatively little overlap between approaches and that the approaches are complementary.^{32,33} Risk management organizations tend to emphasize claims, but claims also represent a biased version of the safety issues in an organization. To maximally improve safety, an organization's focus must be broader than claims alone.

IMPLICATIONS

This study has multiple implications. Organizations typically have several of these systems in place; the challenge is for administrators to look across and make rational decisions on the basis of a comprehensive assessment of their safety issues. The framework presented here collects a broad swath of information and may make building a safety picture easier, even though it is still incomplete. For example, hospitals also have morbidity and complication reports from the specific medical disciplines as well as infection control data. The data from this study suggest that reports that use data from only one domain such as incident reporting will misrepresent the "national picture" of safety problems, such as medication safety. Similarly, data from malpractice claims, although useful, have inherent biases. We believe that the future in this area will involve synthesizing the results from approaches such as these with new approaches, such as the computerized detection of adverse

events—using tools that search electronic records for signals suggesting the presence of these events.³⁴ In the interim, institutions should consider using trigger tools on a random sample of charts to objectively assess the frequency and types of adverse events.³⁵

If hospitals use classification approaches such as the one we have reported here, they will be able to obtain an objective view of the frequency and severity of harm in their institutions, which will in turn allow rational prioritization and selection of solutions. Too often, such selection is made on the basis of what the latest accident was or who has complained the most. At BWH, these data emphasized that we still have important opportunities for improvement in a number of areas, including but not limited to patient identification, making and following up on important diagnoses, improving communication between patients and providers and provider groups, and improving skills in specific technical areas. Specific initiatives are under way to address a number of these issues, with one example being patient identification at the time of laboratory testing.³⁶

LIMITATIONS AND STRENGTHS

This study has a number of limitations. Notably, it included only a single academic medical center, so the results may not be generalizable to other academic centers or types of institutions. However, the types of data analyzed are likely available at most hospitals. As noted earlier, we did not include all possible types of safety data—for example, the infection control data and data from a computerized adverse drug event monitoring approach. Yet, the study also has a number of strengths. The classification scheme used was broad. The institution evaluated had more independent data sources than is the norm and was also willing to allow all its defect data to be closely examined.

Conclusion

The five reporting systems each identified different yet complementary patient safety issues, analogous to the fable of the blind men and the elephant. To obtain a comprehensive picture of their patient safety problems and to develop priorities for improving safety, hospitals should use a broad portfolio of approaches and then synthesize the messages from all individual approaches into a collated and cohesive whole. Data collection should include more sources than those used in most organizations today. ■

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Osna Levzion-Korach, M.D., M.H.A., formerly Research Associate, Division of General Internal Medicine, Brigham and Women's Hospital, Boston, and Harvard Medical School, Boston, is Deputy Director, Assaf Harofeh Medical Center, Zerifin, Israel. **Allan Frankel, M.D.**, formerly Director of Patient Safety, Partners Healthcare, Boston, is Clinical Co-Lead, Pascal Metrics, Inc., Washington, DC. **Hanna Alcalai, B.P.T., M.H.A.**, is Research Project Manager, Division of General Internal Medicine, Brigham and Women's Hospital. **Carol Keohane, B.S.N., R.N.**, is Project Director, Center of Excellence for Patient Safety Research and Practice, Division of General Medicine, Brigham and Women's Hospital. **John Orav, Ph.D.**, is Associate Professor of Medicine, Department of Biostatistics, Harvard Medical School. **Erin Graydon-Baker, M.S., R.R.T.**, formerly Director for Patient Safety, Brigham and Women's Hospital, is Patient Safety Program Manager, Partners Healthcare. **Janet Barnes, R.N., J.D., C.P.H.R.M.**, is Executive Director, Clinical Compliance and Risk Management, Brigham and Women's Hospital. **Kathleen Gordon M.S.N., M.S.**, formerly Director, Family and Patient Relations Department, Brigham and Women's Hospital, is Associate Chief Nurse, Brigham and Women's Faulkner Hospital, Boston. **Anne Louise Puopolo, B.S.N., R.N.**, is Director, Loss Prevention and Patient Safety, CRICO/Risk Management Foundation, Cambridge, Massachusetts, and **Elena Ivanova Tomov, M.B.A.**, is Manager of Advanced Analytics. **Luke Sato, M.D.**, is Chief Medical Officer, CRICO/Risk Management Foundation, and Assistant Professor of Medicine, Harvard Medical School. **David W. Bates, M.D., M.Sc.**, is Chief, Division of General Internal Medicine, Brigham and Women's Hospital, and Medical Director of Clinical and Quality Analysis, Partners Healthcare. Please address requests for correspondence to David W. Bates, dbates@partners.org.

Online-Only Content

See the online version of this article for

Figure 1. Comparison of Issues Identified by the Five Reporting Systems (color version)

Appendix 1. Classification Approach with Definitions and Examples

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Figure 1. Comparison of Issues Identified by the Five Reporting Systems

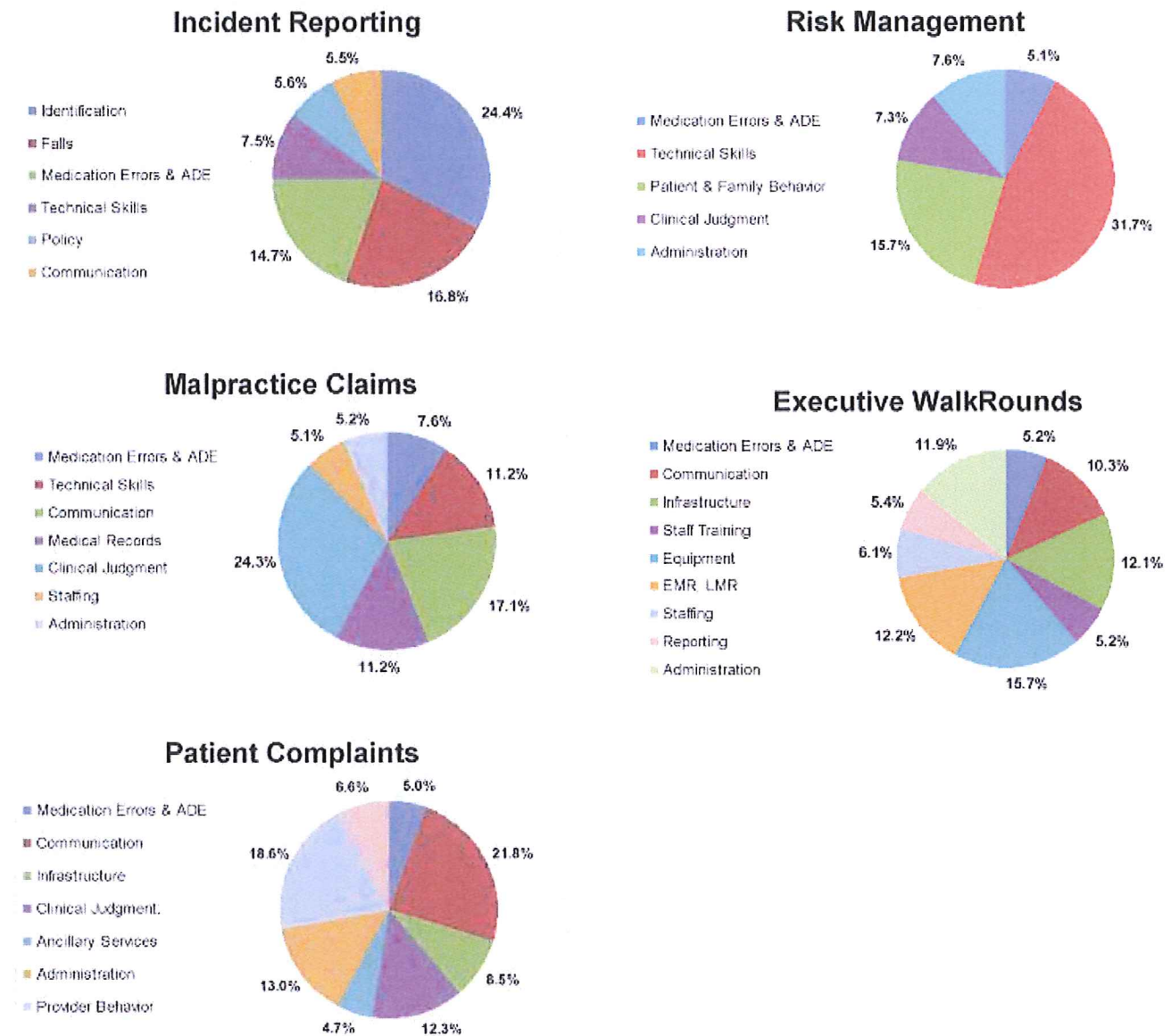


Figure 1. Across the five reporting systems, the leading major categories were communication (11.6%), technical skills (10.9%), and clinical judgment (9%); each system had a different category that was most frequent. ADE, adverse drug event; EMR, electronic medical record; LMR, longitudinal medical record.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
1	Staff		
1.1	Work overload	This code should be used when staffing levels are not sufficient to properly care for the patient. This includes issues with work overload, long hours, and fatigue.	Nurses are worried that while taking care of an acute patient other patients do not receive enough attention.
1.2	Inappropriate provider (profession / expertise)	This code should be used when the patient was referred to a setting/provider whose expertise did not meet the patient's clinical needs. This includes issues with providers that practice beyond their expertise.	An MD who did not have IVC credentials did the anesthesia during a bronchoscopy.
1.3	Supervision	This code should be used when there was a lack of appropriate supervision.	The student-nurse gave a medication in the absence of the supervising nurse.
1.4	Staff, general	This code should be used for all other staff issues not addressed in other subcategories.	
2	Staff Training / Staff Education		
2.1	Staff training / education issues – personal	This code should be used when a staff member was lacking the knowledge or the experience to provide the expected care (if it is a knowledge that is beyond the expected, it belongs to 1.2). This includes issues with training and orientation.	A resident injected local anesthesia for the first time, it was done incorrectly.
2.2	Staff training / education issues – institutional	This code should be used when there was a lack of knowledge across the institution.	It was found that there is a wide lack of knowledge regarding the correct approach to TB isolation.
2.3	Lack of / inappropriate teamwork	This code should be used when there was a lack of coordination among team members and/or a lack of defined roles for each team member. Note: Issues due to miscommunication should be classified under category 13.1.	1. There is difficulty in scheduling and performing rounds with the MD and RPh participation. 2. Coordination of treatment among MDs was lacking.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
3	Technical Skills		
3.1	Incorrect performance of procedure	This code should be used when the <u>technical performance</u> (rather than clinical judgment) of the clinical care was deficient. e.g. complications during a procedure for preventing pressure ulcer in a patient.	1. Resident intubated the patient but it was noticed later that the tube was in the right main stem bronchus and only one lung was ventilated. 2. The tube was not taped correctly and was mistakenly pulled out. 3. During surgery traction was not removed on time causing an abrasion.
3.2	Incorrect identification of organ	This code should be used when there was a misidentification of an organ. Misidentification includes “known and mistakenly recognized” or “mistakenly identified”.	1. A recurrent laryngeal nerve was mistakenly dissected during a thyroidectomy. 2. Amputation of the left leg instead of the intended right leg.
3.3	Retained foreign body	This code should be used when a foreign body was left in the patient’s body. This includes cases where a piece of equipment was broken and left in a body part.	After the surgery was over it was noticed that a forceps was missing, and the patient was had to return to the operating room.
3.4	Incorrect usage of equipment	This code should be used when the adverse event was a result of improper operation of the equipment (i.e. the human factor).	Nurse did not use sphincter implant correctly.
3.5	Incorrect count of instruments in the operating room	This code should be used when the count of instruments was wrong even when no foreign body was retained.	Unofficial count was taken when the surgeons were scrubbing one suture was not found during this count or during counts afterwards The floor, trash, drapes, etc were checked. An x ray was taken and found negative.
3.6	Technical skills, general	This code should be used when there was a technical problem in the performance of the care/procedure not addressed in other subcategories.	

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
4	Equipment / Supplies		
4.1	Lack of equipment / supplies medical	This code should be used when there was a lack of medical equipment needed for the appropriate patient care (absolute lack of equipment or lack of availability).	1. In the OR the correct hip implant was missing. 2. There is a lack of monitors on the unit.
4.2	Lack of equipment / supplies non-medical	This code should be used when there was a lack of non-medical equipment needed for the appropriate patient care or for the ease of the work (absolute lack of equipment or lack of availability).	There are not enough phones in the unit.
4.3	Equipment malfunction	This code should be used when the adverse event occurred was due to failure of the equipment used	Missing vaporizer spacing ring caused a large leak.
4.4	Inappropriate equipment maintenance	This code should be used when the maintenance of the equipment was not according to the manufacturer recommendations.	1. The IV pumps should be calibrated every months – this requirement was not followed. 2. Problems in the code cart "cables on defibrillator tangled, difficulty unlocking wheels on code."
4.5	Equipment / supplies, general	This code should be used for any other issues dealing with equipment not addressed in other subcategories.	
5	Medication Errors and Adverse Drug Events		
5.1	Order of incorrect / inappropriate drug	This code should be used when the choice of medication was not appropriate for the patient's condition. This includes both the cases when the med chosen was not the most appropriate and where the med is contraindicated. Note: A doctor's wrong decision on a medication would appear here and not in clinical judgment.	1. Moxypen was ordered for a typical pneumonia instead of the preferred macrolide 2. Amiodarone was administered while taking Coumadin without adjustment of its dose causing a stroke.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
5.2	Order of incorrect / inappropriate dose	This code should be used when the order was for incorrect dose. This category includes calculation error, etc.	The MD ordered an underdose of a medication.
5.3	Incorrect / incomplete transcription of orders	This code should be used when the transcription of the order had an error.	An order for morphine twice a day was transcribed as once a day.
5.4	Incorrect dispensing / filling orders	This code should be used for dispensing problems such as when the wrong drugs/doses were dispensed and when the drug ordered was missing. This also includes other pharmacy issues.	The pharmacy dispensed diluted heparin as non diluted heparin.
5.5	Administration of incorrect / inappropriate drug	This code should be used when the medication or the drug administered was not the ordered drug.	Patient received morphine instead of the Fentanyl that was ordered.
5.6	Administration of incorrect / inappropriate dose	This code should be used for the order/administration of an incorrect dose. This includes calculation errors, wrong pump settings, etc.	1. Patient ordered for KCl 1mEq/100 ml but pharmacist entered order into new TPN as KCL 1 mEq/ml. 2. Chemotherapy infusing at slower rate than ordered.
5.7	Administration of incorrect / inappropriate route / method	This code should be used when the route of the drug administration (IV/IM/PO/ intrathecal etc) was not the intended route/ method.	The medication was supposed to be administered IV, but instead it was given IM.
5.8	Inappropriate monitoring / medication regimen	This code should be used when the follow up or monitoring of a patient receiving a medication did not comply with the standard of care.	A patient that had a hemorrhagic stroke with an INR of 7 while taking warfarin without the proper follow up.
5.9	Medication errors and adverse drug events, general	This code should be used for medications errors and adverse drug events not addressed in other subcategories.	

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
6	Identification Issues		
6.1	Incorrect patient identification	This code should be used when a patient was not identified correctly and/or when the patient's identification bracelet was incorrect or not present at all.	A patient without an identification bracelet.
6.2	Incorrect / mislabelling of test / specimen	This code should be used when a lab sample or a test identification label was incorrect.	A lab specimen that had no name on it.
6.3	Mixing information from different patients	This code should be used when information of one patient was confused with that of another patient.	A patient who mistakenly receives the CT results of another patient.
6.4	Patient identification, general	This code should be used for patient identification issues not addressed in other subcategories.	
7	Monitoring of Patient		
7.1	Physical status	This code should be used when the physiologic status was not monitored appropriately for the patient's clinical problem.	1. A patient with chest pain not monitored. 2. A pressure ulcer developed while a patient was in the unit.
7.2	Failure / delay in response to alarm	This code should be used when there was not an adequate response to an alarm or alarming information.	A peripherally inserted central catheter (picc) line was inserted and was used prior to looking at an x-ray performed after the procedure showed that it was misplaced.
7.3	Failure / inappropriate follow-up	This code should be used when the follow-up of the patient was not appropriate. This includes both when there was a correct plan that was not followed and when there was no plan at all. Note: Medication follow up should be classified under category 5.8.	A note in the medical record of a patient, who had a colonoscopy, stated that he needs another colonoscopy within 5 months however the patient was not informed and the follow up was not performed on time. A year later the patient came back with a malignant lesion.
7.4	Monitoring of patient, general	This code should be used for issues of follow-up not addressed in other subcategories.	

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
8	Clinical Judgment: Diagnosis and Treatment		
8.1	Incorrect assessment (obtaining key relevant information, choice of tests, using results appropriately)	This code should be used when the physician did not assess the patient correctly due to a failure to obtain the full relevant history, incorrect choosing of tests, inappropriate usage of accurate test results, narrow differential diagnosis, and/or over-reliance on previous provider's diagnosis.	1. A physician did not ask about contraceptive use in a young woman who presented with chest pain and was later diagnosed with a PE. 2. An asthmatic patient who presents with a cough was not sent within an appropriate timeframe for further imaging. The patient was later diagnosed with lung cancer.
8.2	Missed / incorrect / delayed diagnosis	This code should be used when the physician reached an incorrect diagnosis or when he reached the correct diagnosis with a delay. Note: When it is obvious that the assessment was wrong category 8.1 should be used.	1. A painful knee with torn ligaments was diagnosed incorrectly as a cartilage wear. 2. A patient with prolonged heartburn is diagnosed 6 months later with gastric cancer.
8.3	Clinical judgment: diagnosis, general	This code should be used for diagnostic issues not addressed in other subcategories.	
8.4	Incorrect choice of treatment	This code should be used when the treatment selected was inappropriate according to the current standard of care. This includes failure to order a medication (order of incorrect medication should be classified under category 5.1) or blood product, failure to choose the correct surgical procedure, etc. Includes maternity and labor.	A decision not to give blood to a patient with Hemoglobin of 8 who presented with syncope.
8.5	Failure / delayed treatment	This code should be used when the correct treatment was chosen but delayed. Includes maternity and labor.	An orthopaedic surgery is delayed because the implants did not arrive on time.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
8.6	Clinical judgment and treatment, general	This code should be used for treatment issues not addressed in other subcategories.	
9	Medical Records		
9.1	Missing / lost / failure to preserve	This code should be used when there was a missing document/medical record. Includes the various reasons for the missing documents (missing, lost or failure to preserve).	The delivery monitor strip is missing from the medical chart.
9.2	Insufficient / lack of documentation	This code should be used when there was a lack of documentation of the patient's history, adverse events, clinical rationale, phone advice to a patient, refusal to treatment, suggested follow up etc. delayed documentation belongs here.	1. The physician decided not to do another CT scan for a patient who presented with a cough but did not note the clinical reasoning in the chart. 2. An allergy to morphine was not noted in the chart. The patient was given morphine and subsequently developed hypotension. 3. A surgeon offered a patient surgery and the patient declined, but the patient denial was not noted in the chart. The patient later blamed the surgeon for not suggesting surgery as an option.
9.3	Inaccurate documentation	This code should be used when an error/mistake in information (deliberate or unintentional) occurred in documentation excluding errors in transcribing and writing orders.	1. Vital signs were ordered after a patient fainted however no vital signs were taken. 2. The orthopaedic physician mistakenly wrote that the problem was in the right leg when it was the left leg. 3. The nurse wrote that she assessed the skin for pressure ulcers when she had not really done so.
9.4	Illegible documentation (illegible handwriting)	This code should be used when the documentation is illegible due to handwriting or abbreviation.	1. A handwritten order was mistakenly interpreted and the patient got a higher dose of ferrous sulfate. 2. The u in an order of 13u of insulin was interpreted as 130 (the u was interpreted as a zero).

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
9.5	Informed consent form issues: lack/misuse	This code should be used when issues regarding the informed consent occur. This includes missing, incomplete, and/or wrong forms.	A missing informed consent for a surgery.
9.6	Medical records, general	This code should be used for documentation issues not addressed in other subcategories. E.g. incorrect method of correcting errors.	The physician found that he mistakenly wrote that there was no abdominal tenderness. When he found his error a few days later he cancelled, erased his previous note, and wrote a new one.
10	Tests Reconciliation Issues (All: Radiology, Labs)		
10.1	Problems with test orders and requisitions	This code should be used when the issues were with the test orders and test requisition, that are incorrect, not the right forms, right lab tubes, incomplete.	The MD did not state correctly the x-ray needed, and the wrong imaging was subsequently performed.
10.2	Commission and completion of tests and handling of tests (and specimens)	This code should be applied to issues that deal with the handling of the tests and specimens (such as the transportation of the specimens) and the actual performance of the tests.	1. The x-ray that was performed was not the one ordered. 2. A specimen taken from a tumor excision did not reach the lab. 3. Blood that was drawn and sent through the tube system did not reach the lab.
10.3	Misinterpretation of test results	This code should be used when interpretation/results of tests were incorrect (x-ray, labs etc.) Whether it is the result of human error or a reagent issue.	A breast biopsy was interpreted as normal, but in retrospect it was malignant.
10.4	Transmission of test results to providers	This code should be used when the test results and reports are not available to the physician in a timely fashion (results transferred to another MD, filed before reviewed, long turn over for test results etc.).	An MRI was done prior to an orthopedic surgery, but the results "disappeared" and the surgery had to be postponed.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
10.5	Communication of results from the provider to the patient	This code should be used when there was a problem with the management of the results from the lab/MD to the patient.	The patient was told to call the lab for thyroid results, however when he did, they could not locate the results.
10.6	Tests, general	This code should be used when there are test issues that do not fit previous categories.	
11	Falls		
11.1	Falls due to patient action / medical conditions	This code should be used when the fall occurred due to a patient medical/mental state condition or due to a patient's action.	1. The patient was confused after surgery and fell while attempting to get out of bed. 2. The patient left his bed independently after he was advised not to and subsequently fell. 3.
11.2	Fall due to environmental causes	This code should be used when the patient tripped/fell due to an obstacle on the ground fall.	The patient slipped on the wet floor and broke his hip.
11.3	Fall due to lack of supervision	This code should be used when the patient fell due to lack of expected supervision.	The nurse did not close the bed rails and the patient fell.
11.4	Falls, general	This code should be used when there are fall issues that do not fit previous categories.	
12	Communication		
12.1	Communication among providers	This code should be used when there are communication problems among the providers, such as not reading the other consultants notes, not communicating well regarding patient's condition, or a poor professional relationship.	A consultant wrote his note recommending a head CT prior to discharge. The discharging provider did not read the consult and the patient was discharged without the CT exam.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
12.2	Communication between providers and patients	This code should be used when there are problems with communication between providers patients and their families such as; language barriers, misunderstanding of the providers instructions re discharge, follow up, possible medication risks events, instructions on taking the meds, informing the patient of an adverse event that occurred. Inappropriate explanation of informed consent belongs here.	1. The MD told the patient to take insulin six times a day before meals; the patient took the insulin only twice a day after meals. 2. A Spanish speaking patient could not understand the physician's instructions – and there was no interpreter available on site.
12.3	Communication , general	This code should be used when communication issues that did not fit the previous categories occur, such as communication equipment involving the telephone, fax or email issues.	The patient faxed the insurance papers to the clinic, but the clinic never received them.
13	Administration		
13.1	Failure to schedule	This code should be used when the scheduling process itself was a problem.	A patient tried to call and schedule an appointment, but the lines were constantly busy.
13.2	Failure to identify the appropriate providers	This code should be used when the appropriate provider for the patient's clinical problem was not identified.	A patient was referred to the orthopedic clinic due to joint pain instead of the rheumatologist.
13.3	Lack of availability of services / access delays	This code should be used when there is inability to get timely access to a provider, a service, or a test. This will include a long waiting time for an appointment.	1. Difficult to get anaesthesia help for sedation out of the OR. 2. A patient waited too long to have an echo done and then had additional waiting time in the echo room. 3. The medical unit complained that it was hard to get labs performed during the weekends.
13.4	Delay and mishandling of patient issues	This code should be used when the non-clinical side of an institution's relationship with a patient is not handled appropriately.	A patient filed a complaint and received no response.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
13.5	End of life issues	This code should be used when there are end of life issues.	A patient had a living will describing his wish not to be intubated, but upon arrival to the ED resuscitation efforts were performed.
13.6	Admission issues	This code should be used when there is a problem with the admission (administration and bed placement) such as uneven admissions to the different medical units, too many patients admitted during a short time, admission to the incorrect unit.	Seven patients were admitted from the ED to the department at once.
13.7	Discharge issues	This code should be used when there are issues with discharge whether it has to do with the destination or the medical condition at discharge.	A patient complained that his discharge to a rehabilitation center was wrong and he should instead have been discharged home.
13.8	Administration, general	This code should be used when administration issues that do not fit previous categories occur.	
14	Environment / Infrastructure		
14.1	Ground maintenance	This code should be used when an adverse event occurred as a result of inappropriate ground maintenance such as wet floors.	A visitor tripped on the wet floor and broke his leg.
14.2	Hazardous material	This code should be used when the adverse event occurred due to hazardous material.	Leakage of gas in the laboratory.
14.3	Security	This code should be used when there are security issues related to patients/visitors. Security includes theft and belonging that were left behind and not found.	1. Staff were worried and concerned about dangerous and drug-seeking patients coming in. 2. A patient complained that he left his watch behind and it was not found.
14.4	Lack of appropriate working atmosphere	This code should be used when the working atmosphere is not appropriate and there are distractions such as noise which might cause the medical staff to make mistakes.	1. The nurse was constantly disturbed during medication preparation. 2. The lab tech had to answer many phone calls during specimen analysis.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
14.5	Lack of space	This code should be used when the lack of space clinical/non-clinical or storage space rises as an issue.	1. There was not enough space in the radiology recovery area. 2. Bathroom was too small for bariatric patients. 3. There was no place to put extra stretchers on the unit.
14.6	Infrastructure design issues	This code should be used when the design of the room is problematic. Privacy and issues of disturbance by room mate will belong here as well.	From the nursing unit one cannot see 4 rooms.
14.7	Malfunction of facilities	This code should be used when facilities and utilities are malfunctioning.	1. Intercom system between desk and rooms is bad – lots of static, hard to hear. 2. A sink is leaking.
14.8	Environment / infrastructure, general	This code should be used when there are other issues regarding the environment or infrastructure that do not fit into previous categories.	
15	Financial / Managed Care		
15.1	Financial barriers for providing care	This code should be used when provision of the appropriate medical care was compromised due to financial barriers.	A patient could not buy a critical medication because of lack of money.
15.2	Managed care barrier for providing care	This code should be used when any barriers to the standard quality of care due to managed care issues such as; as access to specialists, tests, ED denial/termination of benefits.	The orthopedist ordered an MRI but the primary care provider did not approve it.
15.3	Financial / managed care, general	This code should be used when there are financial/managed care issues that do not fit previous categories.	

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
16	Behaviour Related: Patient and Family		
16.1	Compliance	This code should be used when the patient did not comply with the provider's directives, such as; failing to appear for follow up, for further testing, or prescribed medication or other treatment regimen. Whether the declared his refusal or refused by actions.	A patient taking warfarin was told to have repeated blood/level test and to come for a follow-up appointment in 2 months, but he did not do the testing and he returned to the MD 6 months afterwards with a stroke.
16.2	Bizarre behaviour	This code should be used when the patient acts in a bizarre way.	A patient complained that he was poisoned by the staff.
16.3	Other family member	This code should be used when another family member is involved.	The patient's son had a panic attack in the unit.
16.4	Behaviour / action / situation due to / under medical condition	This code should be used when the patient's actions were due to a nursing / medical condition such as: incontinence, hydration, previous chemotherapy, high BMI, etc. When there are falls that relate to patient condition they should be classified under 12.1.	Patient arrived to the OR with a bruise over his arm due to capillary fragility.
16.5	Behaviour related: patient and family, general	This code should be used when issues regarding patient's and family behavior that do not fit into previous categories.	Patient was overall not satisfied with the care in the unit.
17	Behaviour Related: Provider		
17.1	Inappropriate behaviour	This code should be used when the staff's behaviour was inappropriate it can range from being impolite to the extreme of sexual misconduct.	A patient complained that a staff member was yelling at him.
17.2	Breach of confidentiality	This code should be used when there was a breach of confidentiality by the staff/ administration.	An MD was discussing a patient's medical condition in the elevator.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
17.3	Behaviour related: provider, general	This code should be used when there are other provider's behavior related issues that do not fit into previous categories.	
18	Reporting Issues (To Authorities)		
18.1	Reporting issues	This code should be used when there are issues with reporting within the hospital and outside of it. This code should be used for cases that were not a result of improper action on behalf of the hospital staff.	1. Staff complaining that there are too many questions which they do not know how to answer. 2. Report to the DPH regarding a young lady who came to the ED with a ruptured aneurysm who died within 30 minutes.
19	EMR, LMR New Technologies		
19.1	Documentation issues lack / incorrect	This code should be used when there is a lack or incorrect documentation in the computer due to a problematic process related to computers, otherwise it should be classified under category 10.	In the physical examination the liver was noted as normal while it was enlarged.
19.2	Computer system failure	This code should be used when there are issues with the computers system's failure.	The nurses could not enter the vital signs to the patient's medical chart because of a system failure.
19.3	Bar coding system / electronic medication administration record	This code should be used when there are issues with the bar coding system or the EMR.	A medication appeared in the system as if it was given when in fact it was not administered.
19.4	Practical issues that rise from work with the various technology systems	This code should be used when there are suggestions/issues that are raised regarding the various technologies.	There is a need for a flag in the system that a woman is pregnant.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
19.5	New technologies, general	This code should be used when there are issues regarding new technologies that did not fit into previous categories.	
20	Infection		
20.1	Infection control	This code should be used when there are concerns with infection control.	Infection control concerns with babies whose bassinets are in close physical proximity.
20.2	Contaminated devices	This code should be used when there are concerns/issues regarding usage of contaminated devices.	A patient with a suspected infectious disease was operated on, but there was a concern that one of the tools was still contaminated.
20.3	Nosocomial infection	This code should be used when there is a nosocomial infection or concerns regarding nosocomial infections.	A patient returned to the hospital after he was hospitalized for a UTI with MRSA septicemia.
20.4	Infection, other	This code should be used when there are infection issues that do not fit into previous categories.	
21	Ancillary Services		
21.1	Patient transport, general	This code should be used when there are issues regarding patient transport. Whether it is technical issues, problems with the transport's equipment, delay in transportation, supervision of transported patients etc.	1. Stretchers from transport broken - need to use step-stools to help patients into bed since they cannot be slid off. 2. Transport brings patients and leaves them in their rooms without notifying UC, PCA, or RN that they are back. Especially dangerous in the case of fall-risk pts who need particular attention.
21.2	Transport of material, equipment (usually with regard to patient lifts)	This code should be used when there are issues with transport of equipment	Transport of trash in the public elevators.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
21.3	Parking	This code should be used when there are issues concerning parking whether it is lack of parking, high cost or a problematic service.	Complaint regarding the high cost of parking.
21.4	Kitchen	This code should be used when there are issues concerning the food provided, whether it is quality or service.	A diabetic patient complained that he was served food containing sugar.
21.5	House-cleaning staff	This code should be used when there are issues with the cleaning of the facility, whether it is quality or service issues.	Complaints regarding dirty rooms.
21.6	Ancillary services—other		
22	Policy / Protocols		
22.1	Lack of policy / protocol	This code should be used when there is a lack of policy where needed (administrative or clinical).	There is no policy on how to prepare the inpatient units for a biologic threat.
22.2	Lack of adherence to policy / protocol	This code should be used when there is a protocol but it was not followed.	MD does not wear laser eye protection during procedure where this is standard protocol. Patient has a ring on during a surgical procedure.
22.3	Policy / protocols, general	This code should be used for other issues concerning protocols that do not fit previous categories.	
23	Blood		
23.1	Lack of following / implementing orders	This code should be used when orders are followed and implemented inappropriately with regard to blood and blood products (not lab specimen).	Blood was transfused over 2.5 hours instead of the intended 4 hours, the patient subsequently developed respiratory distress.
23.2	Problems with the order requisition	This code should be used when there are problems with order requisition of blood and blood products.	The order requisition stated 1 unit of PRBCs instead of the correct order which was intended for 2 units of PRBCs.

Appendix 1. Classification Approach with Definitions and Examples

Number	Category	Definitions	Examples
23.3	Lack of appropriate evaluation of need	This code should be used when there was a request for more blood/products than actually needed or when there was underestimation of the need.	2 units of platelets were requested for a patient in the OR. These were issued but never infused. The platelets were returned to the blood bank 3 hours later and discarded.
23.4	Blood, general	This code should be used when there are issues regarding blood that did not fit previous categories.	Factor IX complex not available for patient with intracerebral hemorrhage while on warfarin.