

***Grant Final Report***

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**Toward an Optimal Patient Safety Information System  
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# Abstract

**Purpose:** This study was designed to understand the “landscape” of hospital incident reporting systems and to examine the use of health information technology to improve reporting, data analysis and learning from errors in health care.

**Scope:** The field agrees that standardized collection of patient safety data will help to identify causes, contributing factors and the effects of adverse events in order to learn from both medical errors and system-related failures.

**Methods:** Surveys were administered to U.S. hospitals to determine the current state of incident reporting systems and their perceived value. The Patient Safety Event Taxonomy was used to link disparate patient safety data from a sample of hospitals in order to assess the value of utilizing a common framework to analyze and produce standardized reports of patient safety data. The PSET and hospital incident report data were used to develop a hospital incident reporting ontology to enable adverse event data analysis.

**Results:** Perceptions of adverse event reporting are influenced by the type of system used, and by hospital patient safety culture. Although the majority of hospital incident reporting systems are paper/electronic combination, they vary significantly in the sources, type and use of information.

**Key Words:** patient safety, adverse events, incident reporting systems

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# Final Report

## Purpose

To date, no systematic estimates exist of the characteristics of reporting systems operated by U.S. hospitals or of how these systems are being used. A primary objective of this study was to better understand the “landscape” of patient safety reporting systems in U.S. hospitals and to examine the adoption and use of health information technology (HIT) to improve patient safety reporting, data analysis and learning from errors in health care and their associated causes. Additional objectives of the study were:

- To assess the perceived value of patient safety reporting systems
- To delineate the advantages and disadvantages of information technology applications in adverse event reporting and prevention
- To determine the perceived utility of using a standardized patient safety taxonomy (PSET) for classifying and organizing adverse event data from many disparate hospital incident reporting systems.
- To develop and test (proof of concept) a patient safety ontology for adverse events that would facilitate data mining, knowledge sharing and learning from adverse events.

## Scope

### Background and Context

Widespread efforts are underway to identify, analyze, and report adverse events in healthcare settings.(1) Unfortunately, the many private and public reporting systems that exist use different methods for collecting, classifying, and analyzing adverse event data. This makes comparisons of data between reporting systems difficult or impossible.(2) Nonetheless, each reporting system provides some value to the reporter and to the entity receiving the report.(3) However, the aggregation of adverse event data across systems will improve data quality, root cause analyses, knowledge sharing and learning from adverse events. Some experts believe that the prevention of adverse events cannot be achieved until there is a nationally linked network of reporting systems for the collection, analysis, and dissemination of information pertaining to adverse events.(4,5) Complete and accurate field data on adverse events across the nation are still scarce. Only large and resourceful healthcare organizations can afford electronic reporting systems that provide ready access to patient safety data.(6) There is general agreement in the patient safety field that timely, reliable, and standardized data that allow for data mining of causes, contributing factors and the effects of adverse events is needed in order to learn from both medical errors and system-

related failures.(7) In an effort to find widespread solutions to the problem of medical errors, and to make hospitals safer, many experts have encouraged research to understand the uses of health information technology and hospitals to embrace the technology available to them.(2,8,9,10,11) A major goal of this project was to use a common and standardized taxonomy (the PSET) to help link and manage disparate patient safety data in a consistent fashion (8) and to develop an ontology to help facilitate adverse event data analysis and data mining.

**Perceived Value of Adverse Event Reporting.** Understanding the perceived value of HIT in patient safety reporting is a prerequisite for its adoption and use. Advocating the use of advanced patient safety reporting systems to an organization, not unlike promoting a culture of safety, requires that healthcare professionals believe that the patient safety problem is real(12) and that remedies exist. More research is needed to substantiate the value of improved patient safety reporting at both the organizational level and at the level of the individual practitioner.

The organizational value of patient safety reporting must be better understood. Some organizational issues include: 1) lack of resources and expertise; 2) limitations in the amount and quality of data; 3) absence of response systems i.e. tools and methods to support the analysis and response to adverse events; 4) lack of mechanisms and collaboration to synthesize and improve the flow of information among reporting systems and to patients, provider organizations and practitioners.

In addition to the organizational value, the clinical value in reporting adverse events isn't clear. Many reporters receive little or no positive feedback for reporting adverse events.(13) Underreporting of adverse events creates challenges for those who collect and analyze data. Although many healthcare organizations have the health information technology to improve their detection of adverse drug events, medication errors and/or near misses, they rarely use the data from reporting systems to prevent future errors.(14) The analysis of near miss and adverse event data and dissemination of the findings through patient safety reports can facilitate system changes and risks reduction.(15,16) Constructive feedback to the reporter can affirm the high value an institution places on patient safety and instill a culture of safety.(17)

**Use of Standardized Patient Safety Event Taxonomy.** There is broad consensus among experts in health services research and informatics that a standardized taxonomy for adverse events and near misses can facilitate the management of data across reporting systems and should support patient safety data management innovation.(18,19) The 2003 IOM report, Patient Safety: Achieving a New Standard of Care, recommends that standardization and better management of patient safety information – near misses and adverse events- is needed in order to develop strategies that reduce the risk of preventable medical errors.(20)

**Use of a Patient Safety Ontology.** The 2003 IOM report suggested that better management of health information is a prerequisite to achieving patient safety and recommends a “foundation of systems, technology, applications, standards and policies” created by the federal government.(20) An ontology consists of vocabulary based concepts with precise definitions and relationships(21) that can be used in conjunction with a reporting system to facilitate data mining and enhance knowledge of patient safety. Development and use of a patient safety ontology is necessary to help link data and combine patient safety databases in a way that allows

the aggregation of information that can be used to meet the needs of quality improvement programs as well as other informational needs.(22,23)

## **Settings and Participants**

The study had three phases. During the first phase of the study, the Adverse Event Reporting Survey (AERS) was administered to a representative sample of 2,050 U.S. hospitals in order to gather information about the ‘landscape’ of hospital incident reporting systems in the United States. Of those sampled, 1,652 Risk Managers completed the survey (81% response rate). The survey sample included a full range of hospital types. Of the total sample, 63% were general medical-surgical hospitals and 19% were critical access hospitals. Seventy two percent of the hospitals in the sample were Joint Commission accredited.

For the second phase of the study, a stratified sub-sample of 489 hospitals was selected from AERS respondents to complete a questionnaire about their perceptions of their incident reporting system. Qualifying hospitals met the following criteria: the hospital had some type of incident reporting system in place (Q1); the system was capable of collecting patient age, sex or other demographic information, the type of occurrence, contributing factors, personnel involved and condition before and/or after occurrence (Q6) and severity of harm (Q7). Hospitals were excluded from phase 2 if errors where harm occurred to a patient were ‘never’ reported to their reporting system (Q15a). Risk Managers from the randomly selected sub-sample of eligible hospitals completed a ‘Value Questionnaire’ to assess the perceived value of their incident reporting systems. Of those sampled, 268 Risk Managers completed the survey (55% response rate).

During the last phase of the study, a purposive sub-sample of 20 hospitals was selected from those who completed the Value Questionnaire in Phase 2. These hospitals provided the Joint Commission with 30 de-identified incident reports per month for 12 months (April 2007-March 2008). Seventeen of the 20 participating risk managers completed the follow-up survey, Value Questionnaire II.

## **Methods**

### **Study Design**

This project began October 1, 2004 and continued through March 31, 2008. There were three phases of the study.

### **Phase 1: Determining the Landscape of Adverse Event Reporting**

The goal of the first phase of the study was to understand how, and the extent to which, adverse events are reported in hospitals. The primary research questions for phase 1 were:

- What is the current level of adoption of patient safety reporting systems in U.S. Hospitals?

- How does the current level of adoption of patient safety reporting systems vary by organizational characteristics (hospital type, bed size, teaching status, and accreditation status)?

**Data Collection Instruments and Data Collection.** The Adverse Event Reporting Survey (AERS) was selected as the data collection instrument for Phase 1 of the study. The AERS was developed and pilot tested by Westat for the U.S. DHHS Quality Interagency Coordination Task Force. The AERS is a 31 question written survey that asks whether hospitals collect information on adverse events, what information is collected, who reports occurrences, how their privacy is protected, and how adverse event data is used. The AERS was tested by Westat through interviews with risk managers and hospital department heads which helped guide use of survey terminology, response options and overall survey design. Based on the field test data collected, Westat concluded that a survey of risk managers could “provide a relatively complete picture of adverse event reporting systems in hospitals....focusing on the main reporting vehicle for the hospital, describing reporting for the majority of adverse events....and would also give a picture of the types of events that are not reported in their systems.”(24)

In conjunction with study partners at RAND, the Joint Commission administered AERS to Risk Managers from a nationally representative sample of 2,050 hospitals from September 2005 – January 2006. The hospital risk manager to be surveyed was identified by an initial phone contact to each hospital in the sample. The survey was mailed to participants, followed by telephone follow-up interviews for those who did not complete the mail survey. The sampling frame consisted of 5,517 non-federal hospitals in the 2003 database of the American Hospital Association, excluding those in the southern portions of Louisiana and Mississippi due to the effects of Hurricane Katrina. The sample was stratified by Joint Commission accreditation status, hospital ownership, bed size, teaching status, urban/rural location, and multi-hospital system status.

## **Phase 2: Assessing the Perceived Value of Incident Reporting Systems**

During the second phase of the study, the primary research question was:

- What is the perceived value of incident reporting systems currently in place in U.S. hospitals for improving patient safety?

**Data Collection Instruments and Data Collection.** A Value Questionnaire was developed to determine risk manager’s perceived value of their hospital’s incident reporting system. The questionnaire is a 25 item written survey that asks about staff training on the hospital incident reporting system, utilization of the information gathered from the system, the impact of the system on clinical performance and clinical processes, and usefulness of the system to help improve patient safety. The questionnaire was developed by Joint Commission staff in conjunction with the project’s survey contractor, The University of Illinois at Chicago Survey Research Laboratory (SRL). The questionnaire was vetted through SRL’s Questionnaire Review Committee, which is composed of SRL staff members (appointed by the SRL Director) to ensure that all questionnaires administered by SRL follow ethical practices and adhere to the key principles of questionnaire construction.

The Value Questionnaire was pilot tested with a small group of hospitals (N = 14) in October, 2005. SRL provided the Joint Commission with a detailed report from the pilot test and changes were made to the survey to reflect pilot test feedback on question content, wording, order, and format.

In February, 2006 survey contractors at SRL mailed the Value Questionnaire to 489 hospital risk managers. The sampling frame consisted of 1,652 hospital risk managers who completed the AERS in Phase 1 of the study (see Settings and Participants for selection criteria). Reminder post cards and follow-up telephone interviews were conducted for those risk managers who did not respond to the mail survey. Data collection ended in April, 2006.

### **Phase 3: Incident Report Data Collection and Ontology Development**

During the final stage of the study two research questions were examined:

- What is the perceived value of PSET-based feedback reports for facilitating patient safety improvement efforts in hospitals?
  - How does the perceived value of these reports compare to the value of the information hospitals had been previously using?
- What do experts think will be the value of a Health Incident Reporting Ontology (HIRO) for improving patient safety?

**Data Collection Instruments and Data Collection.** Joint Commission project staff recruited risk managers from 20 hospitals (from respondents who completed the AERS and Value Questionnaire) to participate in the final phase of the project. Participants agreed to provide the Joint Commission with a random sample of 30 de-identified incident reports per month for 12 months. An online document management system was developed by project partners at Joint Commission Resources. This secured site enabled participating hospitals to upload their monthly sample of de-identified incident reports. Incident reports were then downloaded by Joint Commission project staff and labeled with a hospital code and incident report number.

**Incident Report Classification.** Three masters level RNs served as incident report coders during the third phase of the project. Each coder received one third of the monthly reports to classify using the National Quality Forum endorsed Patient Safety Event Taxonomy (PSET). The PSET is a translational tool used to combine data from different incident reporting systems in order to produce aggregate feedback to hospitals in a standardized fashion. The PSET was developed to organize patient safety data so that it can be easily accessed and utilized to help reduce medical errors. Attempts were made to ensure adequate inter-rater reliability between coders. Coders were oriented to the PSET and trained using multiple mock incident reports that they classified using the PSET. Responses were compared, discrepancies were discussed, and mutual agreement was established. Routine coder meetings occurred throughout the 12 months of incident report data collection to discuss reports that were difficult to code, and to establish group consensus on the coding approach. A PSET User Guide was developed to help guide the classification of different types of events and scenarios. The guide was intended to provide

greater reliability amongst coders when making classification decisions. On three occasions during the data collection phase, the inter-rater reliability of the three coders was tested. Coders were provided with the same 10 incident reports and asked to classify them. The coding decisions of the three reviewers were compared statistically in a pair-wise fashion. Agreement ranged between 60-100% depending on the category of the PSET (e.g. medical impact, communication type event, system failure). The wide variation in agreement was likely due to the multiple endpoints involved in classifying the adverse event reports using the PSET categories. The primary endpoints of agreement used in the inter-rater reliability analysis were: impact, type and cause of the adverse event. The secondary endpoints were: setting, staff involved, patient characteristics, reason patient entered the healthcare system (target), and prevention/mitigation efforts. When agreement was less than 80% on any endpoint, coders discussed the reasons for disagreement and established consensus on classification of the event. Contentious scenarios were documented in the PSET User Guide to help improve the reliability of similar types of events in the future.

All classified incident reports were entered into an Access database designed to enable aggregation and comparison of incident report data between and within participating hospitals. Over the course of 12 months of data collection, nearly 7,000 incident reports were classified using the PSET.

**PSET Reports.** A SAS statistical program was developed to produce quarterly reports of the aggregate de-identified incident report data that was classified and analyzed using the PSET. Participating hospitals received detailed quarterly reports of their hospital's adverse event data, as well as de-identified comparative data for all other participating hospitals. Data that hospitals received was intended to assist in facilitating organizational or clinical process changes designed to improve patient safety.

**Value Questionnaire II.** At the end of 12 months of adverse event data collection, risk managers were asked to complete Value Questionnaire II to assess the perceived value of the PSET feedback reports. Value Questionnaire II is a brief questionnaire designed to examine the usefulness of the PSET feedback reports for generating awareness of patient safety issues, helping to improve communication about events, identifying trends to investigate root cause analysis and improving overall patient safety in hospitals. The questionnaire was developed by Joint Commission staff in conjunction with the project's survey contractor, The University of Illinois at Chicago Survey Research Laboratory (SRL). In November 2007 survey contractors at SRL mailed the Value Questionnaire II to the 20 hospital risk managers participating in Phase 3 of the project. Data collection continued through the end of January, 2008.

**Ontology Development.** Project partners at Language and Computing, Inc. (L&C) worked closely with Joint Commission staff to map existing ontological concepts with PSET concepts in order to develop and test the Hospital Incident Reporting Ontology (HIRO). L&C ontologists were provided with all de-identified hospital incident report data that was uploaded to the project's document management system. Mappings were developed and hospital incident report data was modeled into the ontology over the 12 month incident report data collection period. The mapped and processed data was used to build an incident report data warehouse and "Advanced Query Tool" to enable the extraction, processing and analysis of incident report data.



HIRO development was divided in to 4 sub-phases:

- 1) Development of HIRO
- 2) Incident Data Warehouse Building and Populating
- 3) Processing of Incident Reports and Testing/Validation
- 4) Development of HIRO/Instance Data Querying Environment

In addition to formal quality assurance processes applied during sub-phase1, traditional iterative unit testing methods, such as comparing the output from the Query Tool with the incident reporting data and HIRO results, were used. Additional tasks included:

- Sessions held between L&C ontology team and the Joint Commission Project Staff to compare the PSET with the HIRO mapping. Recommendations were made to both correct PSET mappings but to make some general modeling changes in the HIRO.
- For each hospital's 12 month data set, the content of column and row were compared against the warehouse database to identify errors in mappings. If needed, ontology modeling changes were made and action was taken to correct any import errors.
- The Query Tool was used to compare the PSET mapping with the HIRO concepts and incident reports and identify spurious findings. Every action performed by a modeler was stored in a log file. In the case of erroneous modeling, modelers were able to review the log files to identify inaccurate mappings and easily modify them. Action was taken to change the mappings or revise the assumptions in the Query Tool to reflect the appropriate mappings.

## Limitations

Phase 3 of the project presented a number of limitations that should be noted. The sample size for this phase was small (n = 20). This was due, in part, to the labor intensive task of classifying numerous adverse events with the PSET. The amount of staff time available to perform this task limited the number of hospitals who were able to participate in this phase. Although nearly 7,000 adverse events were classified with the PSET and used for ontology development, it should be noted that these adverse events came from a small purposive sample, not a representative sample of hospitals.

Hospitals that participated in Phase 3 of the project tended to be smaller, more rural/suburban, and non-teaching. Large, urban, and teaching hospitals were less interested in submitting incident reports for analysis with the Patient Safety Event Taxonomy (PSET). Recruitment interviews revealed that these hospitals often have commercially based or 'home grown' electronic systems that they believed were sufficient to meet their current needs. Many risk managers from larger, urban, and teaching hospitals did not feel that analysis of their incident report data with the PSET would provide them with more or better information than their current systems.

As the final phase of the project progressed, it became apparent that many of the incident reporting systems were far less sophisticated than originally expected. Participating hospitals had primarily paper based systems that were transposed into an electronic spreadsheet or database. This presented challenges for project partners at L&C during the development of the ontology. Instead of an electronic modeling process, project ontologists had to use a labor intensive manual process of modeling the incident report data into the ontology due to the primarily paper-based nature of the incident reporting systems.

The data dictionaries of participating hospitals indicated that most systems had numerous fields available to collect various types of information, but when the adverse event reports were uploaded to the project's document management system, much of the information was incomplete. All hospitals participating in Phase 3 indicated that their system allows for descriptive accounts of events. Descriptive accounts are particularly helpful in providing details of events for coders classifying the adverse event using the PSET. In many instances, the descriptive accounts of events were left blank or filled with very sparse detail of the event. This made fulsome classification with the PSET difficult and development and testing of the ontology challenging. In addition to the narrative description of the event, a number of fields in many of the adverse event reports were found to be substantially under-populated. This resulted in incomplete incident reports that did not always provide the information necessary for complete classification with the PSET.

Achieving a good level of inter-rater reliability between the three clinical coders was a challenge throughout the 12 months of incident report data collection and classification. This was due, in part, to the often sparse information on the incident reports. It was difficult for coders to classify events with the PSET without the incorporation of some level of subjectivity. Routine coder meetings to discuss a sample of events, mock event coding and development of common field notes were all attempts to improve inter-rater reliability. These strategies did help improve reliability in some areas, but due to the large number of endpoints involved in classifying adverse events with the PSET and the paucity of information on many of the events, it was difficult to achieve high inter-rater reliability across all of the PSET categories.

## **Results**

### **Phase 1: Determining the Landscape of Adverse Event Reporting**

The Adverse Event Reporting Survey (AERS) was administered to a representative sample of 2,050 U.S. hospitals in order to better understand the 'landscape' of hospital incident reporting systems in the United States. Sixty-three percent of the hospitals in the sample were general medical-surgical hospitals and 19% were critical access hospitals. Seventy-two percent of the sampled hospitals were Joint Commission accredited. Of those sampled, 1,652 Risk Managers completed the survey (81%).

## Phase 1: Overview of Aggregate AERS Data

AERS data were analyzed to determine how, and the extent to which, adverse events are reported in hospitals, the nature of the incident reporting systems used to collect adverse event data, and the uses of the data produced by hospital incident reporting systems.

**Reporting System Characteristics.** The majority of risk managers (70.73%, n = 1131) indicated that the incident reporting systems their hospitals use are a combination of paper-based and electronic systems. Far fewer report using paper only systems (16.51%, n = 264), and electronic only systems (12.76%, n = 204)

**Software Used by Incident Reporting Systems.** Hospital risk managers indicated that more than one type of software may be used by their incident reporting system. Over half of risk managers (51.20%, n = 703) report that their hospital's system uses standard office software (e.g. Excel, Access, Word), 37.34% (n = 516) report that pre-packaged patient safety software (e.g. RiskMaster, Meditech, DoctorQuality) is used, 23% (n = 175) report that non-commercial hospital specific software is used and 12.89% (n = 175) indicate that software designed for external reporting systems is used by their hospital's system. Thirty-four percent (n = 235) of respondents indicated that their system uses some other type of software not specified in the survey.

**Information Collected by Incident Reporting Systems.** The information collected by hospital incident reporting systems appears to be quite homogenous. Over three quarters of risk managers reported that their incident reporting systems collect all of the listed data elements, except for one. Only 58% (n = 961) of respondents indicated that their hospital's system collects information on relevant patient medical history.

**Use of Adverse Event Data.** Nearly all (90.81%, n = 1502) respondents report that their hospitals always or often use adverse event data to identify trends of occurrences. Over three quarters of the respondents (83.84%, n = 1385) indicate that their hospital always or often uses adverse event data to perform actions to improve performance in their hospital. Approximately three quarters of risk managers (74.92%, n = 1234) claim that adverse event data are always or often used to educate or train, and 72.5% (n = 1195) report that the data are always or often used to develop performance or quality indicators. Half of respondents (50.56%, n = 806) indicated that adverse event data are always or often used to fill a state or federal agency's requirement. Approximately one third of respondents (34.38%, n = 559) report that their hospital always or often uses adverse event data to compare against other hospitals, while 30.38% (n = 494) report that adverse event data is sometimes used for comparison purposes, and 35.24% (n = 573) report that it is rarely or never used for making comparisons to other hospitals.

**Distribution of Reports of Adverse Events.** As Table 1 shows, nearly all risk managers (98.63%, n = 1587) reported that their hospitals produce reports (aggregate) of adverse event data, and 70.38% (n = 1131) claim that the reports are distributed within their hospitals. Nearly half (47.85%, n = 769) of respondents indicated that reports of adverse event data are distributed monthly, while 36% (n = 580) indicated that reports are distributed on a quarterly basis, and

10.27% (n = 165) indicated that reports are distributed at some other time interval (not specified by the survey).

**Table 1. Distribution of adverse event data (Q24a)**

|                                      | <b>Number (n = 1607)</b> | <b>Percentage</b> |
|--------------------------------------|--------------------------|-------------------|
| <b>Produce reports</b>               | <b>1587</b>              | <b>98.63%</b>     |
| Produce reports: Frequency—Weekly    | 26                       | 1.62%             |
| Produce reports: Frequency—Monthly   | 769                      | 47.85%            |
| Produce reports: Frequency—Quarterly | 580                      | 36.09%            |
| Produce reports: Frequency—Yearly    | 22                       | 1.37%             |
| Produce reports: Frequency—Other     | 165                      | 10.27%            |
| <b>Distribute within hospital</b>    | <b>1131</b>              | <b>70.38%</b>     |

## Phase 1: Analysis of AERS Data by Organizational Characteristics

This portion of the analysis examined the extent to which reporting systems, the reporting process, and the use and dissemination of adverse event data is impacted by four key organizational characteristics: hospital size, hospital type, Joint Commission accreditation status, and teaching status.

**A. Sources of Reports of Adverse Events.** Significantly more Joint Commission accredited hospitals than non-Joint Commission accredited hospitals indicated that they learn about adverse events through hotline calls ( $p < .001$ ), committee meetings ( $p < .001$ ), rounds ( $p = < .001$ ) and by patients notifying the hospital directly ( $p < .001$ ). The sources of adverse event reports vary across large (300+ beds), medium (100-299 beds) and small hospitals (1-99 beds) as well as between non-government/non-profit hospitals, for-profit and non-profit hospitals. With regard to teaching status, significantly more teaching hospitals learn about adverse events through hotline calls ( $p < .001$ ).

With regards to the staff groups that report adverse events, there are significant differences across for-profit, non-profit/non-government and government hospitals. Overall, less than 10% of government, non-profit and for-profit hospitals report that all or most of their adverse events come from other medical staff, technologists/technicians/therapists, and pharmacy staff. Over 90% of small, medium and large hospitals indicated that all or most of their adverse event reports come from nursing staff.

Significantly more Joint Commission accredited hospitals indicated that physicians who work in the hospital, but are not employed by the hospital, report adverse events to the reporting system than non-Joint Commission accredited hospitals ( $p < .001$ ). The rate at which non-hospital employee physicians report adverse events varies by whether they work for non-profit/non-government, for-profit, or government hospitals as well as if they work for large, medium or small hospitals.

There are significant differences in the anonymous reporting of adverse events in for-profit, non-profit/non-government and government hospitals and large, medium and small hospitals. More Joint Commission accredited hospitals ( $p = < .001$ ) always allow anonymous reporting while teaching hospitals are more likely than their non-teaching counterparts to allow for anonymous reporting ( $p = 0.001$ ).

**B. Hospital Adverse Event Reporting Systems.** The characteristics of adverse event reporting systems vary among hospitals in the study sample. Of all analyzed strata, only Joint Commission accredited hospitals are significantly more likely to store adverse event data in a central location ( $p = .027$ ). Across all identified strata, the majority of hospitals utilize paper/computer combination systems. A greater proportion of government hospitals, small hospitals, non-teaching hospitals and non-Joint Commission accredited hospitals use paper-only reporting systems while for-profit and large hospitals are more likely to use electronic-only reporting systems to store adverse event data.

Across all identified strata, the most common software used in hospital adverse event reporting systems is standard office software (e.g., Excel, Access, Word). The majority of small hospitals and non-accredited hospitals use this software in their systems. Nearly half of large, teaching, and Joint Commission accredited hospitals use pre-packaged patient safety software in their reporting systems.

Hospital patient safety programs are typically responsible for the organization of adverse event data and coordination of patient safety activities. Joint Commission accredited hospitals ( $p < .001$ ) are significantly more likely to have patient safety programs.

**C. Types of Information Collected.** The majority of respondents indicate that their reporting systems collect specific information about the details surround adverse events in their hospitals. The information collected by reporting systems is significantly different across large, medium and small hospitals and across for-profit, non-profit/non-government and government hospitals. Reporting systems in Joint Commission accredited hospitals are more likely to collect patient demographics ( $p = < .001$ ), administrative follow-up actions ( $p = .01$ ) and severity of harm to the patient ( $p < .001$ ) and more non- Joint Commission hospitals collect information on personnel involved in the event ( $p = .04$ ). The systems in non-teaching hospitals are more likely to collect information on the personnel involved in the event and if any action was taken ( $p < .001$ ). More than half of the respondents from for-profit hospitals, small hospitals, non-Joint Commission accredited hospitals, and non-teaching hospitals generally report nosocomial infections to their reporting systems.

**D. Use of Adverse Event Data.** Adverse event data can be used in a multitude of ways to improve patient safety in hospitals. Discussing adverse event data in hospital committees is one way of increasing awareness of patient safety and generating ideas to address identified issues. The committees with which adverse event data are shared are significantly different in large, medium and small hospitals and in for-profit, non-profit/non-government and government hospitals. Adverse events that occur in teaching hospitals are more likely to be discussed in morbidity and mortality conference ( $p = 0.00$ ), while non-teaching hospitals are more likely to discuss events in their medical executive committees ( $p = 0.006$ ). Joint Commission accredited hospitals are significantly more likely to discuss adverse events in all committees except for medical executive and risk management committees.

Adverse event data can be used for many different purposes. Approximately three quarters of small hospitals use adverse data for education/training, taking actions to improve performance, to develop performance/quality indicators, and observing trends. More than two thirds of large hospitals use adverse event data for education/training, taking actions to improve performance, developing performance/quality indicators, observing trends and conducting root cause analyses. Adverse event data is more likely to be used for failure modes and effects analyses (FMEA) ( $p =$

0.007) and root cause analyses (RCA) ( $p < .001$ ) in teaching hospitals while non-teaching hospitals are more likely to use adverse event data for counseling physicians ( $p = 0.043$ ) and counseling employees ( $p < .001$ ). Joint Commission accredited hospitals are more likely to use adverse event data for counseling physicians ( $p = 0.005$ ), observing trends ( $p = 0.006$ ), conducting FMEAs ( $p < .001$ ), conducting RCAs ( $p < .001$ ), comparing against other hospitals ( $p < .001$ ) and reporting sentinel events to the Joint Commission ( $p < .001$ ). Conversely, non-Joint Commission accredited hospitals are more likely to use adverse event data for education/training ( $p = 0.01$ ), counseling employees ( $p = 0.035$ ) and fulfilling state/federal requirements ( $p = 0.005$ ).

The ways in which hospitals learn about adverse events can impact the way in which events are addressed. There are significant differences in whether action was taken as a result of learning about adverse events through occurrence reports, rounds, telephone calls or attending meetings across in small, medium and large hospitals and across for-profit, non-profit/non-government and government hospitals. Overall, immediate action taken as a result of learning about adverse events in any of the ways described above does not occur very frequently. Similarly, learning about adverse events through occurrence reports, making rounds, telephone calls and attending meeting did not result in the development of quality improvement initiatives in most hospitals.

The dissemination of adverse event reports is necessary in order for actions to be taken to improve patient safety. Summary reports of adverse events are distributed in the majority of sampled hospitals and significantly more within Joint Commission accredited hospitals ( $p < .001$ ). The distribution of reports to specific hospital departments is as follows: the departments to which reports are distributed differ across for-profit, non-profit/non-government and government hospitals as well as across small, medium and large hospitals. Reports from Joint Commission accredited hospitals are distributed more often to nursing staff ( $p = 0.005$ ), pharmacy ( $p < .001$ ) and transfusion medicine ( $p < .001$ ), while reports are distributed less often to infection control ( $p = 0.012$ ), medical leadership ( $p < .001$ ), and central hospital administration ( $p = 0.004$ ). Reports from teaching hospitals are distributed to laboratory medicine ( $p = 0.006$ ) and transfusion medicine ( $p < .001$ ) significantly more often, while reports from non-teaching hospitals are distributed more often to infection control ( $p = 0.036$ ) and central hospital administration ( $p = 0.002$ ).

## **Phase 2: Assessing the Perceived Value of Incident Reporting Systems**

**Value Questionnaire I.** A stratified sub-sample of 489 hospital risk managers were selected from AERS respondents and asked to complete Value Questionnaire I. Of those sampled, 52% of Risk Managers completed the survey ( $n = 256$ ). Risk managers were asked how many occurrence reports were entered into their occurrence reporting system for 2005. The number of occurrence reports ranges widely. Fifty-Eight of the respondents (23%) indicated that their hospital entered between 0-500 reports, while only 5 respondents (2%) indicated that their hospital entered more than 5000 reports. The majority of respondents (61%,  $n = 154$ ) indicated that 2000 or fewer reports were entered in their system.

Risk managers were asked about the dissemination of occurrence reports in their hospital. Nearly all of the respondents (92%,  $n = 235$ ) indicated that reports about occurrences at their hospital are disseminated in their hospital. Seventy-seven respondents (30%) reported that

comparative information from other healthcare organizations was included in these disseminated reports.

The questionnaire asked a series of questions about training on the hospital incident reporting system. Over 90% of respondents indicate that nursing staff, pharmacy staff, technologists/technicians/therapists and administrative staff are offered training on their hospital's incident reporting system. Far fewer respondents indicated that training was offered to other medical staff (Nurse Practitioners and Physician Assistants), physicians, and physicians in training.

Of those who were offered training on the occurrence reporting system, the questionnaire asked what percentage of staff received the training. Risk managers indicated that the majority of staff members have received training. 87% of risk managers (n = 222) said that 76-100% of nurses received training on the system, 84% (n = 215) said that 76-100% of pharmacy staff received training, 78% (n = 199) said that 76-100% of technologists/technicians/therapists received training, and 74% (n = 188) said that 76-100% of administrative staff received training on the system. 41% (n = 104) of risk managers indicated that 76-100% of other medical staff received training, 26% (n = 67) said that 76-100% of physicians received training, and 23% (n = 60) indicated that 76-100% of physicians in training receive training on the system. 47-69% of risk managers did not indicate whether physicians, physicians in training, and other staff have received training.

Respondents report that for most staff groups, training on their incident reporting system is mandatory. Over 70% of risk managers indicate that training is mandatory for nursing staff (n = 214, 84%) pharmacy staff (n = 200, 78%), technologists/therapists, and administrative staff (n = 195, 76%). Fewer risk managers indicate that training is mandatory for other medical staff (n = 96, 38%) other physicians (n = 64, 25%), and physicians in training (n = 59, 23%).

There are many missing responses for some of the staff groups. Sixty-six percent (n = 170) of risk managers did not indicate whether training was mandatory for physicians in training, 50% (n = 129) did not indicate whether training was mandatory for other physicians, and 45% (n = 114) did not indicate whether training was mandatory for other medical staff.

The next section of the survey presented respondents with a series of statements about adverse events, adverse event reporting systems and the data produced by these systems. Respondents were asked to indicate the extent to which they agreed or disagreed with each of the statements. Answer choices included, "strongly agree," "somewhat agree," "neither agree nor disagree," "somewhat disagree," and "strongly disagree." Over three quarters of the respondents either strongly agreed or somewhat agreed with all except one statement that asked if the number of adverse events and near misses reported to their system are an accurate reflection of the number of near misses and adverse events that occur in their hospital. Forty percent (n = 103) somewhat agreed that the number was an accurate reflection of the number of adverse events and near misses that had occurred, while one quarter (25%, n = 64) somewhat disagreed that the number was an accurate reflection. Nearly half of the respondents (n = 124, 48.4%) somewhat agreed or strongly agreed (n = 113, 44.1%) that clinical performance is improved through information gathered in their hospital's incident reporting system. Over half of the respondents (n = 129, 50.4%) strongly agreed and 45.7% (n = 117) somewhat agreed that clinical processes improved based on information gathered in their hospital's reporting system. Nearly two thirds of respondents (n = 153, 60%) strongly agreed and 37.5% (n = 96) somewhat agreed that occurrence reporting contributes to patient safety improvement at their hospital. Forty-two percent (n = 107) somewhat agreed and 39.4% (n = 101) strongly agreed that reports that their

hospital currently disseminates have been very helping in improving patient safety at their hospital.

**Value Questionnaire I: Qualitative Analysis.** Two open ended questions in the Value Questionnaire asked respondents what additional information or changes would help improve patient safety in their hospitals (Q24 and Q25).

Five overarching themes emerged from respondent comments to these questions:

1. Improvements/changes to adverse event reporting processes and systems
2. Improved patient safety culture
3. External data sharing
4. Access to robust internal data/information
5. Access to additional resources

Suggested improvements or changes to adverse event reporting processes and systems focused on simplifying the reporting process, instituting anonymous reporting, and shifting to electronic reporting systems in an effort to enhance data integration and linkage to other platforms, including patient records for more comprehensive analyses. One respondent commented, “Paper systems are not the easiest and timeliest for producing useful data. We are moving to an electronic system soon which will allow us to more easily generate data and also to compare this data with other hospitals in our hospital system.” Respondents also indicated the need for a clear and uniform definition of what an occurrence is, as well as the ability to accurately capture potential occurrences or near misses, and why actual incidents occurred. One comment pointed out that “reporting tools should focus on capturing more information on ‘why’ the occurrence happened (the cause) as much as capturing the who, what, when and where”. Other comments reflected the need to involve more staff in reporting processes, such as greater physician involvement and wider dissemination of adverse event information. One respondent commented, “Too often information gets reported to the directors, physicians and committees and seems to stop there – never getting to the line staff at the point of care.”

Comments that focused on improving the culture of patient safety recognized the need for greater support and involvement from executive level leadership and suggested that a blame-free culture would encourage more reporting of adverse events. One respondent emphasized that “Managers who have internalized the concept of a non-punitive environment are more successful in obtaining and utilizing (adverse event) information”. Another suggested that “Root Cause Analysis (RCA) helps staff to understand the importance of patient safety in a non-blaming way”.

The concept of a blame-free environment also surfaced in comments regarding external data sharing: “It would be wonderful if all sentinel event data could be protected from litigation so that all hospitals could freely share what issues are out there and what practices have been successful to address them”. Other comments on external data sharing suggested that evidence-based guidelines and information on interventions and initiatives that have reduced errors would fuel improvement. “Any information distributed by health care organizations regarding common occurrences or unusual occurrences helps me to stay on track at my facility. Sharing information



is good.” Other comments on external data sharing emphasized desires for comparative data on occurrences from organizations that have similar characteristics, such as size, patient demographics, region, and state. The need for uniform definitions of event types and a standard national reporting format was also mentioned by several respondents. As one person pointed out, “Standardization of indicators across healthcare organizations would impact event reporting and make for more meaningful patient safety data sharing”.

Access to robust internal or hospital-specific information was also reported as necessary to improving patient safety. Respondents indicated that information related to patient and family-specific perceptions of care and suggestions would be useful, as well as staff surveys to identify processes with potential risk. Case examples of actual patient safety improvements and access to information gleaned from safety rounds, peer reviews, and committee/team discussions were also identified as desirable for patient safety efforts. Additional comments identified reports from failure modes and effects analyses (FMEA), root cause analyses (RCA), and hospital-wide monitoring as useful for performance improvement activities and implementing risk reduction strategies.

The need for additional resources to improve patient safety was indicated by several survey respondents. “Patient safety costs money...and more money in the budget for these activities is needed.” This was the sentiment of several individuals who suggested that state and/or federal funding to hire more quality-focused staff and conduct more patient safety activities would do the most to further patient safety in their hospitals. Others suggested that access to more staff development opportunities such as patient safety seminars, and more educational materials for patients and their families would be most useful.

### **Phase 3: Incident Report Data Collection and Ontology Development**

**Value Questionnaire II.** Hospital Risk Managers who participated in Phase 3 of the project were asked to complete Value Questionnaire II in December, 2007. Of the 20 participating risk managers, 85% completed the survey (n = 17). An analysis of the survey results, conducted by project partners at University of Illinois Survey Research Laboratory (SRL), is described below.

Risk managers were asked how many occurrence reports were entered into their occurrence reporting system for 2006. The number of occurrence reports ranged widely from 344 to 7,263. Seven of the respondents (41%) indicated that their hospital entered between 800 and 1,600 reports, while four respondents (24%) indicated that their hospital entered less than 400 reports and five (29%) respondents indicated that their hospital entered 2,000 or more reports.

Subsequent sections of the questionnaire asked respondents to consider, for each statement, whether the information from the quarterly reports added value beyond what their own incident reporting system provides. Respondents were then asked to indicate the extent to which they agree or disagree with statements related to the PSET quarterly feedback reports received from The Joint Commission. Answer choices included “strongly agree,” “somewhat agree,” “neither agree nor disagree,” “somewhat disagree,” and “strongly disagree.” Over half of respondents (N = 9, 52.9%) somewhat agreed that information contained in The Joint Commission PSET quarterly feedback reports was routinely shared and discussed with hospital staff .

With regard to whether hospitals routinely use information contained in the quarterly reports to implement interventions designed to improve patient safety, only three (17.7%) respondents either strongly agreed or somewhat agreed. Seven (41.2%) respondents neither agreed nor

disagreed, four (23.5%) somewhat disagreed, and three (17.6%) strongly disagreed with the statement.

Respondents were asked whether the use of the quarterly reports has resulted in a greater awareness of patient safety in their hospital. While no respondents strongly agreed with this statement, five (29.4%) somewhat agreed and six (35.3%) neither agreed nor disagreed. The remaining 6 respondents (35.3%) either somewhat disagreed or strongly disagreed.

With regard to whether the quarterly reports have helped hospitals improve feedback and communication about events that have occurred, the same number of respondents agreed and disagreed with the statement. Seven respondents (41.2%) either somewhat or strongly agreed, and seven respondents (41.2%) either somewhat or strongly disagreed. The remaining three respondents (17.6%) neither agreed nor disagreed.

Only three respondents (17.6%) either somewhat or strongly agreed that quarterly reports helped their hospitals identify trends to investigate root causes of adverse events,. Seven (41.2%) neither agreed nor disagreed, and seven (41.2%) either somewhat or strongly disagreed with the statement.

Almost a quarter of respondents (N = 4, 23.6%) agreed the training that staff receive on their incident reporting system has been impacted by the information provided in the quarterly reports. However, five (29.4%) neither agreed nor disagreed, and eight (47.0%) either somewhat or strongly disagreed.

Respondents were asked if they find the quarterly reports useful to their hospital. Nearly half of respondents (N = 7, 41.2%) agreed that the reports were useful. Five (29.4%) neither agreed nor disagreed, and five (29.4%) either somewhat or strongly disagreed.

Respondents were asked to describe the ways in which they found information from quarterly reports useful. Of the 17 respondents, six (35%) provided open-ended answers. In general, these respondents found that the information provided by the quarterly reports helps to accurately organize various categories of incidents and helps to identify and prioritize areas that need improvement.

Respondents were asked whether the quarterly reports have contributed to patient safety improvement in their hospital. The same number of respondents agreed and disagreed with this statement. Almost a third (n = 5, 29.4%) of respondents somewhat or strongly agreed and another third (N = 5, 29.4%) somewhat or strongly disagreed. The remaining six (35.3%) neither agreed nor disagreed.

The questionnaire ends with three open-ended questions asking for additional feedback about the quarterly reports.

Fourteen respondents answered the first question, which asks how the quarterly reports could have been made more useful. Overall, respondents stated their belief that reports could have been more specific and timely, and could have included regional comparisons. Other respondents noted that the reports could have been more consistent with their hospital's definitions and categories. One respondent noted that the coding scheme would have been more useful had they been more applicable to a psychiatric setting.

Eleven respondents answered the second question, which asks what additional information would help improve patient safety in their hospital, beyond the occurrence information that their hospital currently utilizes. These open-ended answers focused on the need for up-to-date information, shared information, such as lessons learned from other institutions, benchmarks from similar institutions, and more communication and educational resources.

The last open-ended question asks respondents to share any additional comments. Seven respondents answered this question. The majority of these respondents suggested that their current systems were more appropriate to meet their needs than organization of adverse event data with the PSET.

**Hospital Incident Reporting Ontology (HIRO) Focus Group.** Five experts in the field of patient safety and health information technology received a detailed demonstration of the HIRO by Joint Commission and L&C project staff followed by a focus group to discuss the value of the HIRO for improving patient safety. The focus group participants were:

- John Clarke, MD – Professor of Surgery, Drexel University
- Suzanne Bakken, RN, DScN – Professor of Biomedical Informatics, Columbia University
- David Classen, M.D., M.S. – Vice President, First Consulting Group
- Raed Khoury - Director of Risk Management, John Muir Health System
- Charlotte Shell, RN – Army Nurse and former Joint Commission fellow

Focus group participants were presented with six discussion questions:

- 1) What type of organization would find the HIRO most useful?
- 2) Who would be the end-user of this type of application?
- 3) What kind of training is needed in order to use this application?
- 4) What features, terminologies, and/or meta-domains need to be added or mapped to the HIRO in order to make it operational and useful?
- 5) What are the benefits and drawbacks of this application?

Focus group participants felt that the HIRO could be most useful for multiple hospital systems or patient safety organizations (PSOs) that are looking to aggregate large amounts of patient safety data, but noted that smaller single site hospitals may still find it very useful. Participants commented that smaller hospitals would most likely use the HIRO for root cause analyses and performance measurement, where larger hospital systems and PSO's would most likely use the data for learning. Whether the HIRO is used in a PSO or a single hospital, one participant noted, "It is not enough to simply give organizations information about ontologies. It has to be built in to an actual application that will be useful for learning or reporting purposes." Some participants noted that medical errors and the need to improve performance are what typically garner the attention of hospital executives. The HIRO is primarily a learning system, not a performance measurement system, and as one participant suggested, "There needs to be a business case made to upper level management for the need for an application like this."

Participants all agreed that the HIRO is most useful for analysts working to re-design hospital systems at the patient level, application developers, vendor staff, those responsible for hospital terminology maintenance and analysts working for PSOs. One participant noted that “The analyst will be able to take the information produced by the ontology and create insight into many problems.” Some participants cautioned that use of an ontology isn’t easy and that adequate technical staff must be available to ensure that the output of the ontology is understandable and useful for managers, executives and other decision makers.

All participants agree that regardless of how much technical support is present, training for this type of application will be a challenge. Participants felt that there are a limited number of people who will be familiar enough with ontologies to be able to grasp the use of HIRO thoroughly and quickly. One participant noted, “Use of an ontology requires a very specific type of knowledge – not many people will be able to use it. The application must be built in a way that is intuitive and does not require a lot of head scratching, or it won’t be useful to anyone.”

In order to make the HIRO operational and useful to organizations, focus group participants suggested that it would be helpful to load the HIRO into OWL format. However, one participant noted that, “Although this (HIRO) would be useful in OWL format, places like Columbia University, University of Utah and Mayo Clinic have the capability and capacity to do this, but most hospitals do not.” Participants suggested that the HIRO would be more useful if it was harmonized with MERS-TH and mapped to the Unified Medical Language System (UMLS) and the International Classification for Patient Safety (ICPS). One participant suggested sending the HIRO to the International Organization for Standardization (ISO) because, “ISO is a place where one could take the ontology through the standards setting process and give it credibility internationally.” Additionally, some participants felt that adding a reporting feature to the HIRO would be useful for hospitals, but one participant cautioned that, “All numbers are subjective to some degree, so reporting about adverse events with numbers isn’t always the best way to go. It is inevitable that people will want numbers in order to make a business case...and for people to listen to what you have to say, but we should remember that there is always subjectivity to those numbers.”

Overall, participants felt that the HIRO provided an efficient method of managing information over time and that there were many benefits to this application. One participant felt that, “The HIRO could be the state of the art in how people build terminologies. These days, the movement is away from lists of information and towards multi-dimensional ontologies. It’s the right way to go and we should take advantage of these automated classifications.”

Participants felt that the major drawback of the HIRO was that it contained a lot of information – perhaps too much information for the end-user. They also noted that when codification of information occurs, it results in less flexibility for the inclusion of new terms as time progresses. Participants stressed the importance of maintaining the dynamic quality of the HIRO over time by building in a mechanism to keep the ontology up to date. Participants all agree that if the HIRO is not updated regularly the searching function will be very difficult and the impact that this application can truly have on patient safety will be substantially minimized.

## **Conclusions**

As patient safety becomes a focus in many hospitals, there is an increased awareness among healthcare providers and policy makers for the need to strengthen adverse event reporting processes and practices. Very little is actually known about the nature of hospital adverse event

reporting systems, the perceptions that risk managers have of these systems, or the usefulness of utilizing standardized patient safety classification tools (PSET and HIRO) to organize and analyze patient safety data. Findings from this project begin to answer these questions and provide preliminary direction for patient safety planning activities at the national and local levels.

A large percentage of hospitals in this study reported having centralized adverse event reporting systems, but the nature of these systems varied greatly across hospitals. The majority of hospitals use basic office software (e.g., Word or Excel) with paper/electronic combination systems. For-profit and larger hospitals are more likely to have sophisticated electronic systems. This is likely due to the greater resources these hospitals have to support the technology, infrastructure, maintenance, and training associated with electronic systems.

The results show that across most hospitals, the majority of adverse events are reported by nursing staff and the fewest adverse events are reported by physicians. Findings of low participation in adverse event reporting by physicians has been found in numerous other studies in the U.S. and in other countries.(25,26,27,28,29) Explanations provided for low physician participation in adverse event reporting include liability risk, professional embarrassment, cumbersome reporting processes, time required for reporting, perceptions of the clinical importance of adverse events, and a lack of ownership in the adverse event reporting process.(30,31,32,33,34,35) Results show that reporting is more likely to occur by physicians in large and physicians in Joint Commission accredited hospitals who are not employed by the hospitals they work in. The data reveal that large and Joint Commission accredited hospitals are more likely to always permit anonymous reporting of adverse events, perhaps making physicians feel less threatened by the reporting process.

Lack of training may play a role in the lower reporting rates among physicians and physicians in training. The perception of the majority of risk managers in the study is that nearly all staff are trained on their adverse event reporting processes, the notable exception being physicians and physicians in training. It is possible, however, that physician participation may be higher than the data indicate if other staff (i.e. nurses) are being asked to complete adverse event reports on behalf of physicians and physicians in training. Findings also show that relatively few adverse events come from other medical staff (i.e. nurse practitioners, physician assistants), technicians, technologists, therapists, and pharmacy staff in certain types of hospitals (government, non-profit and for-profit hospitals). It is quite possible that many of the same explanations that apply to low physician reporting apply to these staff groups, as well. Additional research is needed, however, to examine these issues and to attempt to enhance reporting among physicians and other low-reporting staff groups.

The ways in which hospitals learn about adverse events can impact what steps are taken to address patient safety related problem in hospitals. This study found that the ways in which hospitals learn about adverse events varies significantly between hospitals. Learning about adverse events through channels such as hotline calls, direct calls to the hospital, and occurrence reports sometimes results in the development of a quality improvement initiative to address identified issues. This, however, does not occur frequently or consistently across all hospitals. Furthermore, learning about adverse events through any of the identified channels does not frequently lead to immediate action to address patient safety issues.

While nearly all hospitals indicate that they produce summary reports of adverse events, the use of these reports varies widely between hospitals. There is substantial variation in the frequency with which summary reports are distributed, and the departments and committees to which they are distributed. In some cases, this may limit the amount and type of information that

is available to key decision makers regarding patient safety issues, bringing into question the likelihood that hospitals will take action to change practices and processes in order to improve patient safety.

Despite questions the data raise concerning the dissemination and use of adverse event data to facilitate patient safety improvements, the majority of respondents felt that occurrence reporting contributes to patient safety improvement at their hospital, and believed that the summary reports (of adverse events) disseminated by their hospital are helpful in improving patient safety. The data suggest that under-reporting is likely a problem in many hospitals and that reporting systems do not accurately capture the number of adverse events and near misses that occur in many hospitals. To address this issue, there is a need for improved patient safety culture, “buy-in” from senior level and executive staff, and adoption of a blame-free environment where reporting is supported and encouraged.

Adverse event data from a small sub-sample of participating hospitals was classified using the PSET. Conclusions drawn from this portion of the study are not generalizable to any larger population due to the small sample size for this portion of the study, and the small number of risk managers that shared their perceptions of the value of the aggregate PSET feedback reports they received. In addition, the lack of complete information in the adverse event reports received from hospitals limits the usefulness of the PSET feedback reports that were produced from their data (See Limitations section). However, findings from this portion of the study can begin to provide direction for future patient safety activities and policy making at the local and national level. Of those risk managers that responded, the PSET feedback reports were not perceived to be very valuable for their hospitals. On the whole, information contained in the PSET feedback reports was not routinely shared and discussed with hospital staff, was not used to implement patient safety intervention in their hospitals, and was not used to identify trends to investigate root cause analyses. The majority of respondents suggested that their current reporting systems were better suited to meet their needs than classification of adverse event data with the PSET. Findings indicate that reports would be more useful to hospitals if they were less ‘high level’ with a greater level of specificity, contained regional comparative information, and adopted terminology that was more consistent with hospital definitions. These findings are particularly interesting in light of the fact that a key goal of this study was to test the use of a standardized method for classifying and analyzing adverse event data from across disparate incident reporting systems. The identified problem is that adverse event data is not collected in a uniform fashion and this makes comparison of data between hospitals and at a national level virtually impossible. Without a standardized set of terms and common formats, large-scale comparison of data, data mining, and identification of patient safety issues on a local, regional and national level is impossible.

The ability to conduct large-scale data mining of adverse events has been identified as a primary goal within patient safety circles, both domestically and internationally. The development of the HIRO may be the first step towards addressing this goal. Findings from this study indicate that the HIRO is perceived by experts in the patient safety field as being an excellent tool for managing patient safety data over time. It would be very useful for multiple hospital systems or patient safety organizations (PSOs) that are aggregating large amounts of patient safety data on a routine basis. The HIRO does, however, have its drawbacks. Most notably, it is a very complicated tool that must be built into a more ‘user friendly’ application and supported by adequate technical assistance and resources from executive level leadership in order for it to be fully functional and truly useful for the field.

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## List of Publications and Products

None provided.