ASHRM AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

Monograph

Modernization of patient safety event reporting: Surveillance and benchmarking

FOREWORD

This is part of a series of monographs prepared by ASHRM to explore the benefits of standard medical event taxonomy and how it supports surveillance techniques and benchmarking metrics. These concepts are linked through collective efforts to maximize the effectiveness of patient safety programs across the country.

As the title suggests, a bit of updating in risk management thinking and applications is in order if the strategies and techniques used in medical event (patient safety) reporting are to be advanced. The activity of medical event reporting is rapidly evolving from a paper-based to an electronic system.

No matter what medium is used, the activities of collecting medical event information should be aligned with the legal, regulatory, reimbursement and information technology environment. Creating this alignment in a dynamic healthcare environment is no easy task. There are many competing interests, not to mention stakeholders who have committed their professional lives to improving patient care and outcomes, that can support or impede change. Healthcare organizations must first be willing to examine their culture for any issues that could thwart their efforts to learn from experience. Recognizing issues of culture, and addressing them, is critical for healthcare leaders to address as they prepare to devote resources, both human and financial, to surveillance and benchmarking.

The momentum of consumerism, transparency and performance-based reimbursement is driving patient safety professionals to think more seriously about the impact of these drivers on their performance. It's also provoking serious thought about the systems and processes currently used to deliver care.

Understanding functions

Traditionally in healthcare organizations, risk management, quality, compliance, experience of care and safety functions have been designed and managed at the department level. These departments are responsible for overseeing and monitoring patient care delivery. Most commonly, these departments are known as Quality Management, Risk Management, Infection Control, Compliance, Medical Staff Office, Employee Health, and Patient Relations.

This structure may vary depending on the size of the organization. For example, smaller organizations may delegate responsibility for administering these programs to a single department or, in some cases, to an individual employee.

Regardless of the structure, these departments or individuals monitor certain aspects of patient care, usually in accordance with nationally accepted standards or quality and patient safety measures. Often these standards overlap, or the surveillance method of one department yields data that may be valuable to another department. Because of this, most employees working in these departments have recognized the importance of daily interaction during the normal course of business. In this way, common goals are identified and there is an appreciation for the subtle variations inherent to the process of achieving these goals. The goal, of course, is to improve the overall performance of the organization by assuring that patients receive the highest quality of care in the safest possible environment.

Healthcare market forces are escalating the responsibilities of these departments well beyond their design. The origin of these responsibilities can be traced to the regulatory environment of the Joint Commission as well as numerous governmental agencies such as CMS, CDC, FDA and OSHA. Dedicated departments were established as overhead cost centers for the purpose of ensuring compliance with

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increasing regulatory standards. However, as the industry adopts pay-for-performance models, embraces consumerism and transparency, and recognizes the opportunity to improve quality and safety while reducing cost, these departments will also become linked to cost containment, revenue cycle management, public relations/marketing and recruiting/retention programs.

Public reporting initiatives for quality and experience of care are more defined than safety reporting initiatives, at least with respect to data standardization and comparative analysis. Quality core measures have evolved into national standards and have been publicly available since July 2004.(2) The Health Care Acquisition Performance System (HCAPS) has progressed through development phases and is linked to fiscal year 2008 Medicare reimbursement.(3) The Patient Safety and Quality Improvement Act of 2005(4) afforded much needed legal protection so that healthcare organizations could begin to share quality and patient safety information without fear of discovery in a civil action. CMS(5) has announced that in 2008 it will no longer reimburse hospitals for care and treatment associated with certain "never events" that arise during a patient's hospitalization. These tangible changes provide enough incentive for organizations to begin or accelerate their modernization efforts toward a unified approach to patient safety.

REPORTING SYSTEMS

This monograph discusses three challenges specific to patient safety:

1) The evolution from data collection to actionable knowledge;

2) Improving safety surveillance techniques to address under reporting and minimize cultural variations across organizations; and

3) The need for careful planning, training and educational resources for the adoption of a standard taxonomy of error.

Evolving from data collection to actionable knowledge

An objective of patient safety reporting systems is to provide meaningful information to the constituents of the system. This includes people who report events, department and unit managers who investigate and implement change to prevent them, committees, senior management, and the governing board as well as external agencies.

Reports and analyses focus on overall run rates and event specific action plans. The quality of the underlying data is the primary driver of the reporting system's output. Taxonomies must be standardized to ensure proper classification of events across organizations. And data collection methods must also be standardized – or at least improved – to ensure proper volume and coverage of the population at risk across organizations.

Numerous studies estimate that adverse events are under-reported by a factor of 5 to 10 when comparing traditional event reporting surveillance techniques to electronic surveillance.(8,9,10,11,12) Modernizing patient safety systems can include expansion of surveillance techniques beyond voluntary staff reporting and manual chart audits. This challenge is unique to patient safety due to the "exception only" nature of the data. Safety data differ from, for example, clinical quality benchmarking where the patient population constituting each study group has been pre-defined. The capture rate of defects in quality can be tracked across the specific population defined for each measure. Because the patient population can be anticipated, data collection can be built into the care delivery process. However, safety events cannot be anticipated in the same way to allow for the population at-risk to be defined and monitored for all defects.(6)

Impact of event capture rates, safety culture and surveillance techniques on benchmarking

Before drawing conclusions based on comparative information in safety, organizations must understand the culture and the survey techniques employed by the comparative group. Otherwise, an organization with a poor safety culture may compare favorably to a group with a strong patient safety culture. An organization that adopts e-surveillance techniques to pull event information from clinical information systems should not be compared to an organization that relies exclusively on voluntary reporting.

Finally, an organization that fails to recognize the wealth of data available from patient complaints, compliance programs, peer review and other surveillance sources will not be effectively mining those resources for patient safety information. Unless this data can be normalized along with demographic information, the utility of comparative analysis will be severely limited.

Actionable knowledge with process control

Healthcare organizations would be wise to achieve a culture where process control analysis is valued as a higher priority than the desire for benchmarking analysis. After all, an effective and reliable performance improvement program (as measured through process control analysis) is the factor most likely to result in significant gains in patient safety. Thus, an organization can anticipate favorable benchmark results by prioritizing process control to assure the success of continuous improvement programs. Benchmarking

data applied independent from process control merely indicate whether an organization is "good" or "bad" when compared to a peer group.(6) The application of process control focuses an organization on its own variation. It will also generate stronger opportunities for improving safety.

As patient safety systems evolve, actionable knowledge will expand to include benchmarking and other types of analysis that will improve the dissemination of improvement experiences and supporting data. By focusing on taxonomies, and then surveillance techniques, risk managers will clear two significant hurdles toward that goal.

ADOPTING A STANDARD TAXONOMY

Patient safety event taxonomies have evolved over the years to incorporate various components and best practices from industry stakeholders. These stakeholders recognized long ago that a standard taxonomy was needed in order to reduce the prevalence of adverse events. However, a standardized national taxonomy has remained elusive.

The momentum continues to build in favor of a national standard, most recently with the Patient Safety and Quality Improvement Act of 2005 and the addition of "never events" to Medicare reimbursement requirements. These forces serve as catalysts for healthcare organizations to assess their ability to migrate to a standard. Organizations that choose to work through this process now will be better prepared as patient safety organizations (PSO) evolve and reimbursement adjustments are realized.

Most healthcare organizations have created unique taxonomies based on their local needs. But while these taxonomies may vary from organization to organization, they are similar in that they typically have formed around the most common and frequent event types encountered in healthcare. The resulting event reporting system at the organization reflects an amalgamation from various groups supplemented by local objectives. Groups like MEDMARX, American Nursing Association, Institute for Healthcare Improvement, World Health Organization, Health Level 7, Joint Commission, and the National Quality Forum have been common sources for standard definitions. Many states have also passed legislation creating patient safety initiatives. In 2006, the National Quality Forum published "Standardizing a Patient Safety Event Taxonomy (PSET)" based on previous work sponsored by the Joint Commission.(1) This work created a homogenous framework for healthcare organizations considering many of the other available taxonomies.

Preparing for change

Comparing an organization's current taxonomy to another existing taxonomy is a valuable exercise. It can provide important insight to the organization about its readiness to adopt a different taxonomy.

Change requires planning, and the following are a few considerations:

- **Organization participation rates:** One critical concern is to ensure level or increasing event reporting participation rates as organizations adopt a standard patient safety taxonomy. Some organizations have already experienced this phenomenon in the course of migrating from a paper event reporting process to a Web-based reporting process. Confusing questions, poor organization of forms or online screens, too many questions, and too many required fields... all can lead to lower participation rates. For organizations contemplating such a migration to a Web-based reporting system, great care should be taken to capture the reporter's experience through a pilot phase. Feedback sessions should be targeted at ease of use, comprehension of the new definitions and choices, and the user's willingness to participate. This feedback should be incorporated into the final form or screen(s).

- **Coordination with current software provider and IT Department:**
  If an organization already has an electronic patient safety event reporting system, it will need to consult with its software provider and/or IT Department to determine a strategy for adopting new taxonomies in the future. How will changes to the taxonomy affect the organization's automated system? Can the vendor support the organizations requirements to adapt the taxonomy? And, how will the software provider enable the organizations participation with external and component PSOs.

- **Impact on reporting and analysis:** The adoption of a standard taxonomy may require changes to existing data elements and data collection processes that may, in turn, have implications for the organization's internal stakeholders. For example, multiple departments and review committees within a healthcare organization come to rely upon certain reports. To use these reports effectively, there must be familiarity with the underlying data. If a new taxonomy is adopted, healthcare organizations will need to devote additional resources, not only to educate key stakeholders but also to address any information technology issues that may be required for a successful conversion of existing data. A review of this nature may identify opportunities to improve the flow of information and create a structure that will be receptive to future changes to the taxonomy.

(For more on this subtopic, see "Tackling patient safety taxonomy: A must for risk managers" posted on the Monographs page of www.ashrm.org.)

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IMPROVING SAFETY SURVEILLANCE

Reporting barriers influence event capture rates

By its very nature, an event worth reporting is one that involves a departure or deviation from the delivery of care as it was intended to be delivered. Thus, there is often reluctance by an individual to report the event, for this would expose flaws and imperfections in human behavior and/or organizational processes (which also happen to be designed by humans!).

Before an event can be reported, there must be an awareness that an event has occurred. This typically involves a witness. Sometimes, the only witness is the individual who caused the event. The organizational culture may inadvertently discourage self-reporting in these instances, particularly when the culture is perceived as punitive. A punitive culture leads to fear of retribution or disciplinary action on the part of the reporter.

There are other common barriers known to interfere with an effective, voluntary event reporting system. For example, if reporters perceive that the reporting process requires too much time and/or effort, they are less likely to utilize the system. Even more significant is that many reporters will choose not to report because they believe the organization is not using the information to effectuate change. Due to these barriers, the event capture rate has been estimated to be between 10 percent and 20 percent of the total number of events that actually occur. This is an issue that can be mitigated through collaboration with the organization's information technology staff who may need to collaborate with software vendors to eliminate delays in the reporting system. Likewise, leaders may need to reassess their organizational culture and assure that a non-punitive philosophy is not only communicated, but demonstrated in response to each report that is submitted.(8,9,10,11,12)

Leaders need to assure that a non-punitive philosophy is not only communicated, but demonstrated.

In addition to improving the reporting culture, other tools can be used to improve the capture rate for safety events.

Chart audits are routinely conducted at most healthcare organizations as a proactive method for identifying variation from expected norms. These audits produce statistics that are used for external reporting purposes. Chart audits may also be driven by a particular performance improvement project. Less commonly, chart audits may be conducted for a specific legal or risk management purpose, to measure compliance with newly introduced evidence-based protocols or to measure the success of an action plan in response to a sentinel event.

Chart abstraction is typically centralized within the Quality Management or Health Information Management Department. The patient population is sampled using a recognized sampling methodology and the abstractor reviews the chart with the assistance of a chart audit tool. This tool enables the reviewer to identify a number of different exceptions. This method is useful to identify safety issues proactively that would otherwise go unreported through a voluntary reporting system alone.

However, chart audits require substantial human and financial resources. Thus, there are limitations that reduce the impact of this surveillance method. An organization may wish to consider alternative methods by focusing on other sources of patient safety data. A wealth of data can be mined from root cause analysis results, malpractice claims and patient complaints, or simply through direct observation during senior team rounding.

Electronic surveillance (e-surveillance)

Electronic surveillance, commonly known as "e-surveillance," involves the application of computerized algorithms to use available data elements that are gathered as part of the care delivery process.

For example, an algorithm can be designed to help identify those patients who are at increased risk for falls. To accomplish this, the algorithm might be designed to select patients with ICD-9 codes associated with certain conditions, such as cerebral vascular accidents (CVAs), transient ischemic attacks (TIAs) or pneumonia. Or, the algorithm may query the multiple data references within the EMR to identify inpatients older than 50 who also carry a CVA diagnosis and are being prescribed laxatives, diuretics or other medications known to increase the risk for falls. In this way, the chart audit process becomes partially automated.

This method does not replace any of the previous surveillance methods. It does, however, allow an organization to increase the coverage of surveillance without increasing manual chart reviews. Rather, the organization can rely on the algorithms to electronically monitor and report variances. With continued technological advances in the field of health data management, more opportunities will develop to hone and expand the utility of algorithms to capture, triage, and review safety related information.(7)

Surveillance issues to consider

As risk management strives to develop better data surveillance methods, there are a number of issues that the organization may wish to consider:

1. If the current volume of safety data were to double, would existing resources be sufficient to manage this data? Will the Risk Management Department be prepared to respond to this data?
2. Will increased safety data permit specific departments or programs to improve performance? For example, will the data improve the ability to identify compliance issues, peer review triggers or infections?
3. If increased safety data adversely influence public reporting measures, what are the consequences to the organization?
4. Will increased safety data require more disclosure? If so, will this disclosure affect claims frequency, claims and litigation?
5. If new data elements are identified, can these be incorporated into an existing algorithm, or will new algorithms need to be designed?

The objective for e-surveillance should be to generate information that yields a safer environment.

The effectiveness of e-surveillance is relative to the organization's ability to use the information to improve safety. The objective should not be to continuously increase the event capture rate and simply collect more data. The objective for e-surveillance should be to generate information that yields a safer environment.

E-surveillance brings a new dimension to the improvement process by providing automated, and, in some cases, real-time surveillance rather than retrospective review. Therefore, the design and management of the algorithms must be carefully planned to ensure effective and timely use of the available data. An organization should consider the following elements when developing and reviewing algorithms:

- **Define the objective:** Each algorithm should include a defined objective that describes how the information will be used to improve safety and exactly what the data will measure. Malpractice, quality and current safety information is helpful to consider at this stage. In some cases, an algorithm may measure the same information currently tracked through voluntary reporting or chart review. The application of the algorithm would then improve the capture rate and provide real-time opportunities for the organization to consider.
- **Define the patient population and service(s):** Each algorithm should include a defined patient population and service area(s). This will allow the organization to identify the coverage provided by the e-surveillance program and identify gaps for necessary expansion. Priority of algorithms may be determined based on the level of risk to the patient, malpractice or incident experience, financial risk, etc.
- **Identify available data sources:** This is also a common step to any measurement project. When applied to e-surveillance, it requires significant knowledge of existing healthcare data standards. The adoption of new technology expands the opportunity to derive safety information from available data sources. Data standards should be reviewed along with the organization's current technology platform to determine what data elements are available. For example, there are multiple versions of Health Level 7 (HL7 is part of the American National Standards Institute, a community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information). Within a particular HL7 version, an organization may elect not to collect certain types of information. In addition, an algorithm may be more meaningful if previous safety events or complaint information is included. Alignment with the organization's health data management plan will ensure the e-surveillance program maximizes its benefit from new technology as it is adopted.
- **Set the criteria for maintenance and yield:** Each algorithm should yield meaningful safety information for identifying risk and improving safety. If the yield of effective change is minimal, then the algorithm should be modified or retired. A periodic review of this yield should be conducted for each algorithm as part of the e-surveillance program. All stakeholders should be included in this review. The IT Department can provide an update on changes to available data standards and adoption of new technology which may lead to new information to use in the e-surveillance program or specific algorithm. The reviewers will provide information on effort and volume and software enhancements; safety committee members will offer information on the utility of the information to improve safety, etc.

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- **Consider the impact on workflow:** Part of the requirement when defining an e-surveillance algorithm should be the appropriate electronic workflow and triaging process. Some algorithms can simply populate the event system for trending on a predefined basis. Some could be closed upon the collection of just one or two additional pieces of information. In this case, the system should minimize the navigation and access process for the required reviewer to get in and out as efficiently as possible. Other algorithms may identify an event that is also reported voluntarily. In these cases, the duplicate matching process within the system will need to handle the combination of the dual reports while the event is in the workflow process. This will keep the review on track and provide the reviewer with both sources of information.

If the estimations of under-reporting are accurate, an organization could expand its current volume by a factor of 5 to 10 times its current experience.

Risk managers should consider the impact of each algorithm on the existing workflow and triaging processes. Will low-severity events or near misses require risk management review? Most organizations have a process to filter events by severity when determining the appropriate level of investigation. Although this process can be automated, someone will typically be responsible for reviewing the initial report. Some organizations have delegated this responsibility to the department manager where the event occurred. Other organizations may route the reports to individuals with expertise according to the event type. For example, all medication events might be routed to a pharmacist. Regardless of the filtering process, the organization will need to determine whether all events are individually reviewed, or whether a subset of events is more efficiently trended instead.

Real-time opportunities

In addition to having access to more relevant data from the care delivery process, the growth of advances in IT interoperability increases the timeliness of the information.(7)

How will the organization respond to information captured while the patient is still engaged in the care delivery process? For example, if fall protocols are documented at the bedside electronically, what happens when the data points to a variance? The algorithm could use previous safety events for this patient combined with the current fall assessment. If the appropriate fall protocol is not properly implemented and the patient is still in house, what is the safety professional's role? What opportunities exist to reallocate the safety professional's time and effort if he or she no longer spends as much time chasing a paper process or triaging every single event?

IT administration

The administration of e-surveillance technology will require participation and support from the IT and Health Information Management departments. Interfaces to clinical and financial systems, as well as sharing information between the aforementioned departments, will require technical skills for a smooth integration. Changes and refinement to the algorithms and to regulatory requirements should be anticipated and procedures to support those requests should be designed at the outset. The IT Department will also need to support and maintain the necessary interfaces from the source data. Most organizations have interface engines that process the second-by-second interoperability requirements to keep the care delivery process flowing efficiently. But in some cases, the organization may need to commit additional resources to acquire this technology. Either way, the success of an e-surveillance program will depend upon the organization's willingness to leverage this technology.

Legal protections

The Patient Safety and Quality Improvement Act of 2005(4) established federal protections for patient safety work product, but many questions remain as to the true extent of this protection. (ASHRM's comments on this legislation can be found on www.ashrm.org's Advocacy page.) The organization's legal counsel should be consulted to assure that the organization has taken the proper precautions to preserve this protection.

The impact e-surveillance has on the event reporting process is the primary reason organizations should make plans now. As the event capture rate increases, the current review process will likely become stressed and create a backlog and frustration with the entire effort. Without proper planning, the participation and satisfaction of all stakeholders could decline rapidly

CONCLUSION

The momentum of consumerism, transparency and performance-based reimbursement forces patient safety professionals to consider the impact these changes will have on their systems and processes. An assessment considering the above scenarios and questions will result in a strong plan for an organization to make key decisions, such as selecting a PSO(s) and investing in enabling technology to manage the increase in volume as the industry races to 100 percent event capture rates. Prioritizing the desired objectives will help organizations stay on the path to modernization and achieve their goals as the industry momentum continues to accelerate.

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