Program Brief
Network of Patient Safety Databases

Lessons From PSOs on Applying the AHRQ Common Formats for Patient Safety Reporting

Introduction

This *Educational Brief* is intended to help Patient Safety Organizations (PSOs) implement the Agency for Healthcare Research and Quality (AHRQ) Common Formats for patient safety reporting by health care providers. The Common Formats contain definitions and reporting formats that are designed to help providers consistently report patient safety events. This Brief is based on conversations with seven PSOs and one consultant (see Box A). It provides early insights on challenges and solutions to adopting the AHRQ Common Formats.

As background, the *Brief* provides a short introduction to—

- The PSO Program
- The AHRQ Common Formats
- PSO Challenges in Implementing AHRQ Common Formats

For clarity, the *Brief* describes—

- Objectives of the Brief
- How AHRQ Obtained PSO Contributions

The *Brief* reveals lessons from and for PSOs—

- Lesson 1: PSOs are integrating AHRQ Common Formats with hospitals in varying ways
- Lesson 2: Definitions of patient harm and other concepts vary across providers
- Lesson 3: Some of the delay in reporting to the PSO Privacy Protection Center is caused by internal hospital policies
- Lesson 4: PSOs need population counts to develop rates of safety events
- Lesson 5: Ongoing communication is essential for implementing the AHRQ Common Formats

The *Brief* shares PSO and provider suggestions for AHRQ and software developers on how the Common Formats could be made easier to implement—

- Suggestion 1: The AHRQ Common Formats should reflect workflow
- Suggestion 2: The AHRQ Common Formats should collect more types of aggregate event categories on the Healthcare Event Reporting Form (HERF)
- Suggestion 3: The AHRQ Common Formats should provide more detail on the factors contributing to safety events

Box A. PSO Contributors to the Brief

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In addition, Mike Personett of NextPlane Solutions contributed insights and text from his work with members of the Center for Patient Safety, MHA Keystone Center PSO, and North Carolina Quality Center PSO.

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- Suggestion 4: AHRQ should issue a more robust AHRQ Common Formats Minimum Dataset
- Suggestion 5: AHRQ should continue to publicize how the AHRQ Common Formats can improve analysis and learning
- Suggestion 6: AHRQ should address hospitals' fears of reporting to the PSOPPC
- Suggestion 7: AHRQ should continue to provide transparency into future plans for development of the AHRQ Common Formats

Each *Lesson and Suggestion* includes *AHRQ Notes*—comments from AHRQ staff on the issues raised by the PSOs. The *AHRQ Notes* in the *Lessons* section identify which approaches conform to the intent of the AHRQ Common Formats; the *AHRQ Notes* in the *Suggestions* section indicate whether and how the suggestions should be implemented.

The last section of the *Brief* summarizes the primary messages that emerged from this assessment and provides our outlook for the future of the AHRQ Common Formats.

AHRQ welcomes a continuing dialog. PSOs are encouraged to share their ideas with AHRQ on improving and streamlining the Common Formats to reduce the burden of data collection while maintaining essential information. This *Brief* is one approach for collecting and documenting those ideas. Another approach was a series of webinars held in 2014-2015 to solicit ideas on streamlining the Common Formats. AHRQ continues to welcome such ideas at the PSO Annual Meeting or at any time. Please reach out to AHRQ PSO Program staff at pso@ahrq.hhs.gov with your ideas.

The PSO Program

The U.S. Congress passed the Patient Safety and Quality Improvement Act (PSQIA) in 2005, which authorized the Patient Safety Organization program. AHRQ implemented the PSO program, which became operational in 2008 with approval and listing of the first PSOs. As of July 20, 2015, 82 PSOs were listed by AHRQ (see https://www.pso.ahrq.gov/listed).

The PSO program was authorized as a voluntary program. PSOs recruit health care providers to join

their PSO so that providers can share information about patient safety events without fear of legal discovery, can learn from those events, and can improve patient care. Under the Affordable Care Act of 2010, hospitals with 51 or more beds will be required by January 2017 to work with a PSO in order to contract with health plans in insurance exchanges.

Two entities are involved in establishing a national learning network for patient safety events. First, the PSO Privacy Protection Center (PSOPPC) receives information the PSOs submit. The PSOPPC renders the submitted data nonidentifiable with regard to patients, reporters, and individual and institutional providers. In addition to rendering individual reports nonidentifiable, the PSOPPC analyzes them to determine whether the volume is sufficient to prevent reidentification before the data can be submitted to the Network of Patient Safety Databases (NPSD). Second, the NPSD, when operational, will support a nationwide network for learning from these nonidentifiable data to improve the quality of care and patient safety.

AHRQ hired two separate contract teams to carry out these functions. The NPSD eventually will analyze the nonidentifiable data, produce aggregate reports, and develop a data resource for PSOs, providers, and others working to improve patient safety.

The AHRQ Common Formats

Nationwide data standards are essential for being able to aggregate and compare safety events as "apples to apples" across health care providers in the United States. Common definitions, data elements, classifications, and sharing processes—as envisioned for the PSO program—are needed before a national network of patient safety databases and learning can become a reality. Such a resource would build knowledge about the following:

- The most common types of safety incidents and the factors that contribute to them
- Near-misses and how actual harm was averted
- Unsafe conditions that set up the potential for patient harm
- Rare events involving disability or death and how to prevent them

As required by PSQIA, and early in the program, AHRQ developed standards for PSOs to use in collecting patient safety event reports. AHRQ intended the standards to be used by PSOs, software vendors, and facility system developers in building software for patient safety systems. To develop the standards, AHRQ first tapped the best minds on the subject: patient-safety and other subject-matter experts within and beyond the Federal Government. AHRQ then assembled an inventory of detailed information about 70 domestic and international patient safety event reporting systems. AHRQ and its experts examined commonalities of clinical definitions, taxonomies, and details collected about adverse events across systems.

The variety of approaches confirmed the need for a national set of standards. AHRQ built collection instruments for hospital inpatient care and skilled nursing facilities as the first settings of care to be addressed and vetted the instruments with the experts. AHRQ made the proposed standards available for public comment through the *Federal Register*, reviewed the comments with experts convened by the National Quality Forum, revised the instruments, and published the AHRQ Common Formats for use in reporting patient safety concerns in the United States. Version 1.2 is the current version of the AHRQ Common Formats as of August 2015.

The framework for the AHRQ Common Formats primarily is centered on patient safety events in that the event reports focus on the question, "What happened to the patient?" Information also is collected on events that did not reach the patient (e.g., near-misses that were averted by some action and unsafe conditions that set up the potential for future incidents).

The data collected about the events include generic and event-specific information. The *generic formats* include the following:

- Type of event (e.g., incident with or without harm, near-miss, unsafe condition, or one of nine specific incidents) (see Box B)
- Circumstances surrounding the event (e.g., timing, location, contributing factors, preventability, narrative story)
- Patient information (e.g., degree of harm, rescue interventions, effect on length of stay, notifications made about the event)
- Report date and reporter information

The *event-specific formats* include the following:

- Definitions of the event
- Processes and outcomes of patient care associated with such events
- Assessments, preventive actions, or other actions that should have been taken prior to the event to prevent it
- Details on circumstances of specific events

Box B. AHRQ Common Formats

Generic Formats

- Healthcare Event Reporting Form (HERF)
- Patient Information Form (PIF)
- Summary of Initial Report (SIR)

Event-Specific Formats

- Blood or blood product
- Device or medical/surgical supply, including health information technology
- Fall
- Healthcare-associated infection
- Medication or other substance
- Perinatal event
- Pressure ulcer
- Surgery or anesthesia
- Venous thromboembolism

PSO Challenges in Implementing the AHRQ Common Formats

The PSOPPC accepts PSO patient safety event reports in the AHRQ Common Formats only. PSQIA requires PSOs to collect providers' patient safety event reports in a standard format that is used by all of a PSO's members. However, PSOs may use the AHRQ Common Formats or their own format, provided that all of their members use the same reporting system. Some PSO formats exist because legacy patient safety, risk management, and mandatory reporting systems were in effect before the institution of the PSO program. PSOs newly engaged in patient safety reporting may have provider members tied to different vendor systems. In addition, PSOs may have member hospitals that have built their own management and reporting systems for patient safety monitoring.

Although the AHRQ Common Formats provide the key to uniform data for nationwide learning about patient safety events, they have been difficult for PSOs to implement. This difficulty stems in part from disparate legacy systems used by providers for patient safety, risk management, and accreditation. Providers must make major investments to revise their legacy definitions, taxonomies, and data structures to adopt the AHRQ Common Formats. Because compliance with the AHRQ Common Formats is *voluntary*, providers and vendors have limited incentive to make these investments.

Among organizations sharing information for this *Brief*, more than 4.6 million patient safety events (including near-misses and unsafe conditions) have been reported by their clients across varying periods over the last decade. Most of those reports have been made to legacy vendor systems that predate the PSO program, and few have been submitted to a PSO. Many of the safety reports from provider legacy systems probably never will be submitted to a PSO because they are not in a common PSO format (either one maintained by the PSO or the AHRQ Common Formats).

Nevertheless, PSOs are attempting to move their systems and members to the AHRQ Common Formats. The seven PSOs interviewed for this Brief had about 1.4 million events that were submitted. These events could be submitted to the PSOPPC and the NPSD if the reports were consistent with the AHRQ Common Formats.

Some PSOs have attempted to create this alignment by mapping data between their legacy formats and the AHRQ Common Formats. However, this mapping is difficult (if not impossible) because of differences in definitions of events, different taxonomies for classifying events, and uneven details about events. Ultimately, concepts that are not defined similarly cannot be combined with accurate meaning. An assessment of early data submitted to the PSOPPC under different "PSO-specific common formats" is that the data are so disparate as to be minimally useful for nationwide assessments.

Many PSOs are stymied by the plethora of systems used by their members. A solution is to move existing patient safety monitoring systems to the AHRQ Common Formats. However, a very strong business case is needed to motivate PSO members to adopt a new nationwide voluntary system, especially while multiple mandatory reporting systems already compete for and make demands on PSO members' resources (see Lesson 2 below).

Because of difficulties that PSOs voiced in submitting patient safety event reports to the PSOPPC in the AHRQ Common Formats, AHRQ defined a minimum data set derived from the full AHRQ Common Formats. Each report must include at least eight elements to be a valid submission to the PSOPPC (see Box C). In addition to the eight elements, most PSOs included a harm scale in their minimum data collection. Although AHRQ staff hoped this simplification would minimize mapping inaccuracies, this limited set severely restricts the learning originally envisioned through a common approach to data collection.

Box C. Minimum Requirements for Submission of AHRQ Common Formats Data to PSOPPC

- PSO Identifier
- Event Identifier
- Provider Identifier*
- Initial report date (HERF)
- Report type (incident, near-miss, unsafe condition) (HERF)
- Category(s) associated with event or unsafe condition (e.g., medication event) (HERF)
- Patient date of birth (HERF) or patient age (PIF)
- Patient sex (HERF)

*A nonidentifiable provider number.

Abbreviations: HERF, Healthcare Event Reporting Form; PIF, Patient Information Form

Objectives of the Brief

This *Brief* was designed to enable PSOs to share information and learn from each other about ways to implement the AHRQ Common Formats. The aim was twofold:

1. Share experiences of early adopters among PSOs that face the same challenges in creating patient safety event report data that align with AHRQ Common Formats (see section below on *Lessons for PSOs*).
2. Enable PSOs to share with AHRQ and software developers the aspects of the Common Formats that are most challenging (see section below on *Suggestions for AHRQ and Software Developers*).

The objective of this *Brief* was to reflect high-level experiences from all aspects of implementing standard data collection. It complements separate conversations between AHRQ and PSOs on revisions of the Common Formats specifications.

How PSO Contributions and AHRQ Insights Were Obtained

To understand how PSOs have approached the challenge of aligning patient safety event report data with the AHRQ Common Formats, AHRQ invited PSO leaders and experts to engage in discussions with AHRQ contract staff, and those discussions resulted in this *Brief*. AHRQ contacted 38 PSOs as followup to the 2014 PSO Annual Meeting, where attendees frequently raised the issue. The PSOs were contacted if they were in the LinkedIn™ network established by the PSOPPC for sharing ideas among PSOs. AHRQ also added a few other leaders to the list of PSOs.

Eight organizations generously offered their time (see Box A above). Of the eight, most were PSOs, some were a component PSO of a software vendor, and one was represented by a consultant to hospitals and PSOs (this individual previously was a director of a component PSO of a software vendor). Some contributors involved multiple staff in the candid conference call discussions.

Truven Health Analytics, one of AHRQ's contractors supporting the NPSD, facilitated and summarized separate conversations with the eight organizations during June and July 2014. Truven Health provided each participant with a list of topics relevant to applying the Common Formats (see Box D). The participants were encouraged to discuss any topic or deviate from the list of suggested topics with their own concerns. Participants later reviewed and edited the synthesis of lessons and issues Truven Health created.

AHRQ staff reviewed the draft *Brief* and appreciated the candor and contributions of these patient safety leaders. AHRQ provided comments to clarify features of the Common Formats and also emphasized the importance of implementing them in a way that preserves their integrity.

Box D. Suggested Topics for Discussion

- **Concepts, definitions, taxonomies:** How the PSO or provider event reporting system compares with the AHRQ Common Formats, and whether a mapping was done wholly or partially
- **Computer coding:** Techniques used in structuring or writing computer code to translate or map into the AHRQ Common Formats
- **Testing:** How PSOs tested the computer code developed
- **Analysis:** How PSOs analyze events and provide feedback to members
- **Submission to the PSOPPC:** How well the submission process works
- **Resources:** Time and money spent translating the PSO system into Common Formats including who performed this translation
- **Other:** Any other lessons to ease the burden and hasten the submission of data to the PSOPPC and the NPSD

Lessons From and for Patient Safety Organizations

PSOs and their hospitals and other health care providers want to adopt the infrastructure that AHRQ has built for a national learning environment—the AHRQ Common Formats for patient safety event reporting. From the PSO perspective, the challenge is moving from a collection of complex, disparate data systems to one that is uniform and not burdensome, satisfies facility managers' many needs, guarantees the anonymity and legal protection of event reporting, and streamlines reporting to multiple entities.

Below are five lessons from PSO experiences and their approaches to solving the challenge of moving providers and information system vendors to the AHRQ Common Formats. Under each section we present the importance of the issue, the PSO approach to solving it, and AHRQ notes on the issue.

Lesson 1: PSOs are integrating AHRQ Common Formats with providers in varying ways.

Importance. PSOs face hospital members who have long-established and disparate systems for reporting liabilities that hospitals must manage, including patient safety. Even vendors of patient safety systems who have registered as a PSO face multiple safety systems, because typically vendors allow their clients to customize the solution offered and hospitals frequently modify the vendor system. These customized systems are deeply embedded in the organization after a vast hospital staff is trained on the solution. From a hospital manager perspective, the issue of patient safety and the AHRQ Common Formats is entangled with other reporting systems—mandatory safety reporting to the State, reporting for accreditation, malpractice claims, reimbursement audits, clinical staff performance, etc. Most hospitals have purchased and installed risk management systems that record information associated with claims of liability against the hospital. Some large hospitals have developed their own reporting systems, including patient safety information technology. Hospitals would like to consolidate multiple information systems for different purposes. These circumstances complicate the process of moving legacy patient safety systems toward the AHRQ Common Formats.

PSO Approaches To Adopting the AHRQ Common Formats. Among the seven PSOs sharing experiences, three different solutions, discussed below, have emerged for adopting the AHRQ Common Formats, depending on the PSO's circumstances:

a. Incorporating into a relatively uniform system (of a PSO component of a software vendor)

b. Incorporating into hospital legacy systems

c. Manually re-entering safety event reports into a uniform system

a. **Incorporating into a relatively uniform system.** Providers using a system owned by a software vendor and component PSO have the most promising opportunity for adopting the AHRQ Common Formats. These PSOs can modify their system to accommodate the AHRQ Common Formats, push the new system to providers during an upgrade, and limit client modifications to the system. However, these PSOs typically allow provider clients to customize the software system.

One such PSO updated their system in 2010 after comparing and mapping the AHRQ Common Formats to their system. However, the mapping was not always straightforward. In some cases, an existing question could be relabeled and additional responses could be incorporated. For other questions, the detail required was not in the PSO's existing system. The PSO wanted to "go wholesale with the AHRQ Common Format mapping" but was concerned about overwhelming the frontline reporter with the detail. Therefore, rather than presenting an extensive array of followup questions based on selection of a limited set of event types, the PSO incorporated responses for several AHRQ Common Format questions into the event type taxonomy question, which was set as a mandatory question with an easy-to-use drop-down feature.

After the revision, the AHRQ Common Format event type taxonomy of 9 event types with 200 distinct subcategories for patient-related events increased to 23 patient-related event types with 424 distinct subcategories. Also, the PSO added more than 100 questions to its system to fully incorporate the AHRQ Common Formats. From this effort the PSO offered this advice for other PSOs: Involve information technology (IT) and clinical staff in the translation process, because the IT and clinical decisions were intertwined.

Another PSO component of a software vendor (Quantros Patient Safety Center) followed several sequential steps to move to the AHRQ Common Formats:

1. Two PSO physicians worked for 25 to 50 percent time for 1 month reviewing the AHRQ Common Formats to determine how many of the data elements were measurable within their commercial incident reporting system for hospital and ambulatory settings.
2. The physicians pared and refined their taxonomy to fit the AHRQ Common Formats.
3. PSO policy staff worked with software engineers to modify the PSO system to align better with the AHRQ Common Format definitions and taxonomies, adding some questions to their system and expanding drop-down lists.
4. PSO staff developed translations from their revised system to the AHRQ Common Format specifications for a database that can be submitted to the PSOPPC.
5. Quality assurance staff, who were separate from the developers on this project and had knowledge of software development, reviewed the translations and tested them on system data.

As a result of this process, this PSO says that 90 percent of what is sought in the AHRQ Common Formats is now answerable within their safety event software, although not always in a clean one-to-one mapping.

The Clarity PSO noted that having the same platform across member hospitals was essential for implementing the AHRQ Common Formats; their member hospitals typically have an IT administrator available to make changes. The PSO first tried to align their legacy system with the AHRQ Common Formats by cross-mapping, which required some manual data validation. They then decided that it would be more accurate and more in line with the true use of common formats if they used exact wording of the AHRQ Common Formats in their health care safety portal system, primarily for frontline reporting.

To accomplish this goal, they are taking an incremental approach. They started by implementing the generic formats: Healthcare Event Reporting Form (HERF), Patient Information Form (PIF), and Summary of Initial Report (SIR). They are now reporting specific event formats for falls, pressure ulcers, surgery and anesthesia, medications, and blood and blood products. Over the next 6 to 9 months they will add the formats for device or medical surgical supply, including health IT, as well as perinatal and venous thromboembolism events.

Definitions and semantics are still an issue for many of the data items. For example, classifying harm levels almost always requires some sort of clinical judgment and subjectivity. This PSO offered a view that if the PSOs and their providers can begin the conversion process, even if the data are not as complete as intended at the outset of the AHRQ Common Formats, at least some progress can be made toward their adoption.

Another PSO (Anesthesia Quality Institute) mapped from their specialty-based incident reporting system to the AHRQ Common Formats for the minimum dataset of 8 items that AHRQ requires for submitting data to the PSOPPC (see Box C). They initially spent about 300 hours to map their system and data into the correct format. Now it takes them less than 30 minutes per quarter to submit the 8 minimum data elements to the PSOPPC. After mapping those elements, plus the harm scale, they added anesthesiology-specific data elements that are not in AHRQ Common Formats. They are now considering gathering more data points from the AHRQ Common Formats.

Another PSO wants to take advantage of integration of the AHRQ Common Formats into RISKMASTER® Accelerator—a malpractice and liability claims system built by Computer Sciences Corporation (CSC) and used by many hospitals. CSC developed a patient safety module (in conjunction with the ECRI Institute PSO) that they call *Common Formats* Plus. Before considering integration of the additional CSC module, PSO IT and clinical staff mapped the RISKMASTER data to the AHRQ Common Formats where possible. Nursing staff were directly involved when translations were not straightforward; some clinicians saw the process as a matching exercise, others as a definitional challenge. They captured a little less than half of the fields on the three generic forms of the AHRQ Common Formats.

The utilization of the new CSC module is not in operation yet; the biggest challenge is who will "pay" to fully support effective integration of the new module. The vision is that corporate-level staff

will be able to go into RISKMASTER CF Plus and the hospital electronic health record (EHR) system and use relevant information streams to backfill the safety report for patient characteristics that frontline staff would not readily know. Currently, PSO IT staff extract submitted reports and convert them to a pared back version of the AHRQ Common Formats.

b. **Incorporating into a hospital legacy system.** NextPlane Solutions, a patient safety consulting organization, worked with 100 clinical leaders (e.g., heads of departments, infection control staff, pharmacists) at 15 mid-sized hospitals within one health system over a 3-month period to plan for converting hospital data into the AHRQ Common Formats. They started by identifying items in their health system's data that matched the AHRQ Common Formats and did not require reclassifying responses. Then they moved to mapping and reclassification, which was more complicated.

   The process resulted in an organization of the AHRQ Common Formats according to workflow. They attempted to organize data collection by what frontline staff versus investigating staff would know, with the aim of answering the full set of questions. Hospital leaders were "on board with the program" if it increased reporting and enabled better patient safety analysis. (See more detail below, The AHRQ Common Formats should reflect workflow.) Lingering concerns of the hospitals include the cost of training staff to learn the revised system.

   One PSO (Kentucky Institute for Patient Safety and Quality [KIPSQ]) targeted hospitals by vendor systems to identify where hospital systems using a common vendor could be mapped to the AHRQ Common Formats. The KIPSQ was able to offer mapping of one vendor system used by a hospital system to about 75 to 80 percent of the AHRQ Common Formats elements. They are continuing to work on the taxonomy to complete the mapping process. The PSO will probably not be able to offer mapping to all their hospital member's vendor systems because of the time cost.

   Another PSO (Center for Patient Safety [CPS]) receives reports either entered directly by hospital personnel to the CPS patient safety event reporting platform or formatted so the data can be mapped and electronically loaded into that platform. For hospitals needing a translation, CPS organized them by vendor systems to support mapping to the full AHRQ Common Formats. CPS was able to fund the mapping of a few vendor systems used by 10 hospitals to about 75 to 80 percent of the full AHRQ Common Formats Version 1.2. The process was costly and time consuming. It is unlikely that CPS will be able to cover the cost of mapping data from all of their member hospital systems without passing that cost on to hospital participants.

   Health systems reap the economies of mapping the AHRQ Common Formats for a number of hospitals, but reclassifying data is too difficult for individual small hospitals to accomplish. They can seek out vendors for this purpose, but vendors charge between $5,000 and $15,000, which many hospitals view as too costly for complying with a voluntary system. Alternatives that cost from $1,500 to $3,000 are being introduced to the market through PSO partnerships.

c. **Manually re-entering safety event reports into a uniform system.** Some PSOs have attempted to have hospitals manually re-enter event reports from one or more internal reporting systems into a separate system the PSO provides. One PSO (CPS) has a reporting platform that was newly built around the AHRQ Common Formats for use by certain staff of a provider to enter data directly into the PSO platform. However, many of the participating hospitals have legacy systems for frontline clinical staff or designated data-entry staff. Others have no system other than hard copy or rudimentary methods to report events.

Data that have been submitted to the PSO have been re-entered into the PSO Web portal by safety or quality department staff at the hospital. The PSO is working with a consultant to help safety staff at a few of its providers export data from hospital event reporting systems and map data into a "streamlined" AHRQ Common Formats file. This file contains about 150 data elements that the PSO has identified as valuable, consistently available, reported to the PSO, and less prone to data errors.

AHRQ Notes. The mapping of legacy systems into the AHRQ Common Formats, while understandable for providers and PSOs invested in those systems, creates the potential for noncomparable data and misleading inferences from the PSO network. In fact, AHRQ views the mapping of legacy systems into the AHRQ Common Formats as an unworkable approach to adopting them. AHRQ has reviewed many PSO systems and observed that mapping from legacy systems can result in differences in definitions of safety events, varied interpretations of important concepts such as contributing factors, and unknown confusion about difficult-to-measure subjective concepts such as level of harm. The designers of the AHRQ Common Formats expected vendors to adopt various features of the AHRQ Common Formats wholesale: the data elements to be collected; definitions of those elements; taxonomies of events, harm, and causes of harm; and detailed inquiries about care processes and whether they were followed. AHRQ also expected vendors to upgrade existing systems to conform completely to the Common Formats.

As the above mapping examples suggest, the reality has been very different. A confounding factor is that vendors customize their software systems to the needs and preferences of each provider client in order to sell systems and services. Vendors do not feel they can impose a system on clients, especially when providers have made big investments and have large workforces trained in customized solutions. Furthermore, some large hospitals and health systems developed and operate safety systems independently, and historically they have not considered data sharing outside their own institutions a priority. Education on the value of standardization is essential to move the health care industry toward standard patient safety data collection and the national learning that will reduce patient harm.

Lesson 2: Definitions of patient harm and other concepts vary across providers.

Importance. PSOs reported that assessment of patient harm, which is deeply embedded in existing hospital reporting systems, is especially challenging to change and standardize. Definitions differ and longstanding, competing taxonomies exist. Staff who are familiar with the hospital system must be retrained to move to the AHRQ Common Format harm scale. Unfortunately, such training is difficult to complete because of the size of the workforce to be trained and the extreme demands on frontline staff time. Commitment from the highest levels of the organization is needed to make such a change for harm or other concepts.

PSO Approaches. A component PSO of a software vendor addressed this problem by combining their legacy taxonomy with the AHRQ Common Format taxonomy while preserving the ability to represent the full details of both. They first ensure that the minimum dataset questions remain mandatory. They then collapse the responses of several AHRQ Common Format questions into a mandatory, drop-down event taxonomy question, which ensures that a core set of questions is answered.

The PSO made other modifications to accommodate and move closer to the AHRQ Common Formats on other concepts while still allowing its members a certain degree of flexibility and customization. They found that almost every hospital hides some of the AHRQ Common Format data elements that are specified on the PSO Web portal. Among those consistently hidden are diagnosis and procedure codes, race/ethnicity, and the International Standard for Blood and Transplant (ISBT) codes for blood products. The PSO expanded questions about falls because of member desires to report to the National Database of Nursing Quality Indicators (NDNQI®). Throughout the Web portal, some questions are targeted to frontline staff and others to review or risk managers.

For the harm scale, the PSO removed the *unknown category* because checking *unknown harm* was an easy way out of answering the question. They added the choices of *near-miss* and *unsafe condition* as additional descriptors on the harm scale to make reporting these events more habitual and relevant to more situations. In addition, each item of the harm scale was assigned a number 1 through 9. This numeric scale resonates with reporters because it is similar to the pain assessment scale.

Another health system representing five acute care

Box E. Hospital "Mandatory" Safety Reporting

Although the PSO program is voluntary for hospitals, many other reporting programs are mandatory or perceived as mandatory by hospitals:

- More than half of all States have mandatory safety reporting systems. Most of those States mandate reporting of the National Quality Forum's *Serious Reportable Events*, which are also referred to as *never events*.
- The Food and Drug Administration (FDA) requires manufacturers to report adverse events related to devices. The FDA asks hospitals to report these events voluntarily.
- The Joint Commission, which accredits hospitals, strongly encourages them to report serious adverse events. Hospitals can perceive this request as essentially mandatory.
- The Centers for Medicare & Medicaid Services requires reports of central-line-associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), and surgical site infections (SSIs) among other infections, as defined by the Centers for Disease Control and Prevention, National Healthcare Safety Network (NHSN).

hospitals restructured questions about harm. They first ask frontline staff, "Did the event reach the patient?" and then, "Was the patient injured?" Responses to these questions provide enough information to alert managers and others without asking frontline staff for the detail required by the harm scale. If an event reaches the patient, the AHRQ Common Format harm scale is then assigned by a smaller group of professionals at the health system.

AHRQ Notes. Having *unknown* as an option on the harm scale keeps responders from making a choice when the degree of injury is not known. It would be better to determine this response after investigation or after an intervention to reduce the harm. It is difficult to know the degree of patient injury when an incident first occurs. Additionally, the specifications of the AHRQ Common Formats assign near-miss and unsafe conditions to an *event type* at the outset and bypass the harm scale because it does not apply.

The approach of assigning certain questions to more knowledgeable staff, as exemplified in the final example above, conforms to the way the Common Formats were intended to be used.

Lesson 3: Some of the delay in reporting to the PSOPPC is caused by internal hospital policies.

Importance. Many health care providers report patient safety events to mandatory or voluntary reporting systems (see Box E). Hospitals have internal rules that require reporting patient safety events to mandatory reporting systems before reporting to the PSO. Hospitals have correctly interpreted the PSQIA law as saying that once patient safety work product (PSWP) is submitted to the PSO it cannot be used for other purposes, including defense in court cases and mandated reporting. For those purposes, hospitals may use non-PSWP (e.g., medical records, internal safety systems, personnel records). Because of these complexities, hospitals set internal policies to withhold PSWP from the PSO or their own Patient Safety Evaluation System (PSES) until they have satisfied certain mandatory requirements.

PSO Insights. One software vendor that also operates a PSO has collected one million safety events from its hospital clients for internal hospital safety management activities. The vendor has received member authorization to submit only about 120,000 of those reports to its component PSO. The PSO attributes the underreporting to policies established by hospitals to satisfy mandatory reporting systems before satisfying voluntary policies such as reporting to a PSO.

AHRQ Notes. The U.S. Department of Health and Human Services (HHS) is aware of this issue and is actively working to help providers understand how to handle their PSWP. For example, the Centers for Medicare & Medicaid Services (CMS) sometimes requests safety event reports for Medicare monitoring, and hospitals have interpreted PSQIA correctly as prohibiting the release of such reports once they are submitted to the hospital's PSO. HHS is developing guidance on when such reports may and may not be shared.

Lesson 4: PSOs need population counts to develop rates of safety events.

Importance. PSOs and their health care providers need rates of adverse events to track their progress toward patient safety. However, most PSOs only have counts of safety reports. They usually do not know the population at risk, which is needed to calculate the rate of an event. For example, to calculate the rate of central-line bloodstream infections, data are needed on the number of central line insertions.

Denominator data for safety reports can be difficult to obtain. Each type of event requires a specific definition of the population at risk for that event. For some events, such as medication safety events in hospitals, all admissions to the hospital might be a reasonable denominator because virtually all hospital patients receive medications. For other events, the risk group should be specific to an intervention or a condition, such as individuals who receive a high-risk drug or those with a specific condition.

Because the ability to track rates of adverse events is crucial to the PSO mission to improve patient safety, some PSOs have attempted to address this issue.

PSO Insights. Even without denominator data, one component PSO of a software vendor reviews reporting trends over time to identify areas for improvement and to understand the impact of risk reduction strategies on event reporting. This PSO can look at trends by the number of reports as well as the rate of reporting (e.g., per staffed bed, inpatient days, or visits). The PSO noted that organizations with lower numbers of reported events are not necessarily safer. In fact, organizations often see a rise in reporting after implementation of a reporting system. As they develop their culture of safety and focus on prevention and apply harm scales that have high inter-rater reliability, they also should see a rise in near-miss and unsafe condition reporting. Patient harm should decline as the facility corrects the identified causes of harm. With surveillance systems that accumulate denominator data, the same phenomenon should be evident—increased rates of adverse events, increased rates of near-misses and unsafe conditions, and reduced rates of serious harm over time as the facility addresses its safety issues.

AHRQ Notes. The AHRQ Common Formats were designed to collect information about events in real time, when facts are fresh and maximally available. AHRQ and its advisors focused the Common Formats on the essential step in setting standards for patient safety reporting—defining patient safety events. Denominators necessary to establish rates for events, which must be collected over a period of time, are not available in real time when event-reporting systems are used.

AHRQ developed the Quality and Safety Reporting System (QSRS) as a hospital surveillance system to track safety and quality problems through retrospective review of medical records. Users can compile detailed information about adverse events accompanied by appropriate denominators. When and if QSRS is implemented in a hospital, managers would be able to assemble: (1) incidents defined according to the AHRQ Common Formats for surveillance, (2) specific denominators that align with specific types of incidents, and hence (3) rates of specific types of incidents.

Lesson 5: Ongoing communication is essential for implementing the AHRQ Common Formats.

Importance. Communication among PSOs, vendors, and providers is crucial to successful implementation of the AHRQ Common Formats, compilation of *comparable* event reports, and learning from a database network of patient safety events. Communication is essential because PSOs have little control over what a provider adopts for frontline staff reporting of safety events. Vendors naturally put their client's desires and priorities before the promise of a learning network.

Providers are mandated to report safety events to a multitude of oversight organizations. However, providers have not been mandated to report to a PSO and the PSOPPC in a uniform fashion, although standardization is encouraged and expected as part of the law. This has led to enormous challenges and frustrations for PSOs that aim to recruit and work with providers and to influence vendors who supply risk management and reporting software to PSO member providers. Business interests, financial constraints, and low priority for reporting to a PSO impede adoption of the AHRQ Common Formats and heighten the need for exacting communication.

In particular, moving legacy systems into AHRQ Common Format data collection requires PSOs and software developers to convey the following to their clients:

- The AHRQ Common Formats—their purpose, design, legal underpinnings, and the benefits they would enable
- Examples of how collection of adverse events in a common format can build the evidence across health systems that is needed to learn about and improve the safety of patient care
- A clear understanding of why content cannot be modified without destroying the ability to learn nationally from patient safety events
- Acknowledgment of health care providers' constraints of patient care demands and need for efficiency as a business
- An awareness that content can be reorganized to align reporting with the workflow of the health care system
- Creative thinking to address providers' concerns, in tandem with communication with AHRQ to maintain the integrity and increase the probability of adoption of the AHRQ Common Formats.

PSO Insights. One PSO has hired a consultant to foster such specialized communication. The consultant has worked with the PSO, its member providers, and AHRQ to persuade a number of hospital clinicians of the value of standardized patient safety reporting, despite the high hurdles of moving individual hospitals to a national standard.

Another PSO said that a strong IT department staff is only one component needed to implement AHRQ Common Formats. Their adoption will be stymied if client-facing staff do not fully understand and convey their intent to members. In addition, if software engineers do not comprehend the intent and importance of common data elements, the software development process will generate problems for members and lead to flawed data.

This PSO also noted that the development process requires patience and time. Implementation of standards in other parts of health care confirms this observation. For example, application of the uniform bill developed by third-party payers is an ongoing process. Even with those standards, data sources modify their own systems and create barriers to data assembly and analysis later in the process. (See *Outlook for the Future*, for more on this topic.)

Suggestions for AHRQ and Software Developers

The suggestions below come from the contributing PSOs and from work by Mike Personett of NextPlane Solutions with input from PSO member providers who voluntarily attempted to implement the AHRQ Common Formats. The PSOs made these suggestions for AHRQ and/or software developers to consider.

As in the *Lessons* section, we present *AHRQ Notes* related to these suggestions. These Notes aim to help PSOs understand AHRQ's approach to patient safety event reporting and to encourage further dialog between PSO and AHRQ staff about these suggestions.

Suggestion 1: The AHRQ Common Formats should reflect workflow.

Importance. Hospital leaders state that frontline staff cannot answer all the Common Format questions, especially given their busy routines and the high priority they must place on patient care. Furthermore, frontline staff have a limited view of patient events and activities that surround them. PSOs also have found that safety officers in hospitals do not promote the AHRQ Common Formats because they foresee difficulty and resistance to implementing them within the workflow environment of the hospital.

Hospital and PSO Insights. Hospital leaders suggest the AHRQ Common Formats would be more readily adopted by hospitals if their branching logic were restructured to reflect staff members' workflow and knowledge. Questions should be organized into what can be addressed by frontline staff, specialists, managers, and investigators (e.g., safety officers or risk managers). For example, many items on the HERF and PIF can be addressed through frontline knowledge, but some of the questions should be pulled out and others added for frontline staff.

Generic Formats: One question is which hospital personnel should respond to the generic information on the HERF, PIF, and SIR. For example—

- Frontline staff can identify near-misses, unsafe conditions, and incidents.

- Frontline staff also can judge whether harm occurred in terms of yes, no, or unknown (if no other option is provided for the unknown category).
- However, frontline staff typically cannot determine whether harm is temporary or permanent; the risk manager or safety officer should determine the level of harm.

Event-Specific Formats: Another question is which hospital personnel should address the detailed event module. The most appropriate responder varies by type of event. The following are examples:

- **Medications.** Pharmacists argue that they should handle the medication module because frontline staff do not always understand medications. Pharmacists want space on the form for a narrative explanation of what happened, because they want one system to capture all the information they need.
- **Falls.** Falls can be handled at the frontline. Frontline staff generally are comfortable with all the fall event questions. In fact, if frontline staff answer fall-related questions, they can immediately learn from these incidents.
- **Infections.** Infection control specialists want to report healthcare-associated infections (HAIs). Frontline staff do not have the information to answer these questions. They often do not know whether an infection is healthcare acquired. (Because CMS now requires hospitals to use the NHSN, hospitals primarily use NHSN rather than the AHRQ Common Formats to report HAIs.)

As part of one PSO's effort to implement the Common Formats, 100 hospital employees (infection specialists, obstetrics department directors, and pharmacists across 15 hospitals) reviewed the AHRQ Common Format elements. They agreed to adopt 95 percent of the items. The key to obtaining their support was directing different questions or data elements on the event reporting form to different staff and departments. Once these inquiries were addressed, clinical leaders agreed to implement the AHRQ Common Formats.

AHRQ Notes. AHRQ has not attempted to specify which personnel in the hospital should respond to different parts of the Common Formats. AHRQ views its role as defining the clinical content for reporting safety events. The organization of the content for collection in facilities should be addressed by PSOs and software vendors. Software developers with provider input can and should organize questions according to staff roles and who would be expected to know answers to questions. It is most important to collect the content as specified in the AHRQ Common Formats, because it will allow PSOs to share comparable data and learn from the NPSD.

Suggestion 2: The AHRQ Common Formats should collect more types of aggregate event categories on the Healthcare Event Reporting Form.

Importance. Hospitals are interested in tracking and analyzing a wide range of safety events, quality issues, and other occurrences that hospitals need to manage. They would prefer one system for tracking events that involve any type of liability. The AHRQ Common Formats are intended to track only patient-safety-related events. Three PSOs said that the AHRQ Common Formats classified only about 50 percent of the hospital legacy system events by type; the remaining 50 percent are entered as "other." How should the "other" 50 percent be classified in the AHRQ Common Formats data? – Should they be classified as safety events or outside of patient safety? The answer is important for an accurate local, health system, for nationwide accounting of patient safety events, and for equitable comparisons.

PSO Insights. NextPlane worked with PSOs and providers to devise a list of events reported in existing hospital safety, quality, and risk management systems that they identified as not classified among the aggregate event categories on the HERF in the AHRQ Common Formats (see Box F). Examples of events hospitals want to track that are not related to patient care safety include criminal events (whether perpetrated from within or outside the hospital) and patient noncompliance with treatment. Furthermore, it is unclear to the providers whether they should report such events in the AHRQ Common Formats. Currently, the *other event type* category on the HERF contains no instruction, other than "please specify."

The providers and PSOs suggest that HERF documentation make clear whether hospitals may report more types of events in its aggregated categories. Hospital clinicians and administrators want the HERF to be expanded to capture everything they think relates to patient safety as well as every other liability they need to track. They do not see an easy way to combine

Box F. Patient Safety Event Type Suggestions From Legacy Systems

PSOs recommend further development of the AHRQ Common Formats to address additional event types:

- Patient consent currently is not obtained, and PSOs think that it would be appropriate.
- Diagnostics—test, timing, interpretation.
- Infection prevention—hand hygiene, screening, precautions. (Hospitals advised collecting hospital-acquired infection data separately from frontline reporting, possibly through the National Healthcare Safety Network.)
- Patient security—abduction, assault, exposure, property.
- Patient behavior—left without being seen or against medical advice, elopement, refused treatment, noncompliant with treatment, self-injury, abusive action, suicide attempt.
- Treatment—delays, documentation, patient identification, policies ignored.
- Intravenous access—infiltration, in place following discharge, repeated attempts, clamped inappropriately.
- Skin integrity—laceration, tear, abrasion, in addition to pressure ulcer.

Source: Personett M. NextPlane's work with members of the Center for Patient Safety, North Carolina Quality Center PSO, and MHA Keystone Center PSO. Personal Communication, August 2014.

or reconcile systems such as their legacy systems and the AHRQ Common Formats. They view the process of reconciling systems as complicated, so they delay or resist implementing AHRQ Common Formats.

AHRQ Notes. The Common Formats are limited to incidents that result in direct harm to the patient resulting from exposure to the health care system or associated near-misses or unsafe conditions that can lead to patient safety events. The Common Formats are *not* intended to describe events that relate to the natural course of disease or relate to poor quality of health care (i.e., suboptimal care that results in a less favorable outcome for the patient). If the AHRQ Common Formats were used in their current form to track everything that individual hospitals want to track (e.g., criminal behavior), the addition of safety events not related to patient care could undermine the ability to identify, count, track, and compare patient safety locally, at the PSO level, and across the network of PSOs.

The HERF is a tool for reporting all patient-care-related safety events, and the included taxonomy facilitates the use of the nine event-specific Common Formats modules, when applicable. The list of event categories on the HERF cascades into queries that ask details about the nine specific event types. These nine event types together make up a substantial majority of all care-related adverse events occurring in hospitals. Rare events that do not fall into any of the nine categories may still be reported under the category "other," which allows collection of standardized information on the HERF, Patient Information Form (PIF), and Summary of Initial Report (SIR), as well as the opportunity to add narrative about the nature of the specific event being reported. The SIR also captures the *NQF Serious Reportable Events*.

AHRQ considers it appropriate for local entities to track other types of events of interest that may not meet AHRQ Common Formats criteria as a patient safety event. However, only patient safety events that fall within the framework of the AHRQ Common Formats should be submitted to the PSOPPC and the NPSD at this time. Examples of events that should not be reported include:

- Events that reflect the wider rubric of health care quality, such as diagnostic error, should not be submitted currently.
- Events that do not qualify as PSWP, such as violence against patients or any unlawful activity, should not be protected and thus should never be submitted to the PSOPPC and NPSD.
- Events that are outside the control of providers, such as "patient left the hospital against medical advice," should not be counted as patient safety events.
- Events that are unrelated to patient care, such as "patient lost car keys" (which some hospitals record in incident reporting systems) should not be submitted to the PSOPPC or the NPSD.

PSOs should not report such events. If some PSOs include these types of events in "other," numbers of patient safety events will be distorted and will not be comparable across facilities.

This is not to say that providers should not report patient-care-related safety events not reflected among the categories specified on the HERF or SIR. If there is no category on the HERF or SIR that reflects a particular patient safety event, it still can be recorded in full narrative and with other structured data items in the generic Common Format and it should be categorized

as "other" event type and explained on the HERF. Note, however, that there are hundreds of event types already specified in the Common Formats that are nested within the more general list included within the HERF. Lists of all event types can be found in the "*…Aggregate Reports*" associated with the HERF, SIR, and the event-specific modules (see https://www.psoppc.org/web/patientsafety/version-1.2_documents).

In the future, AHRQ may add other safety events to the taxonomy—events that are important (frequent and/or of potential serious harm to patients) and that do not already exist as specific structured modules in the current Common Formats. For example, after the initial version of the Common Formats, health care providers noted that venous thromboembolism (VTE) was not captured except in "other," so AHRQ added an event-specific module on VTE.

Version 2.0 of the AHRQ Common Formats will provide two tiers of information: (1) a core of essential questions and (2) an update of the full AHRQ Common Formats. The core of essential questions will streamline the detail of the current Common Formats and should be adopted by patient safety reporting systems that claim to conform with the AHRQ Common Formats. It will provide a core of data to be collected by providers who want to contribute data to the PSOPPC and the NPSD for nationwide learning about patient safety.

Suggestion 3: The AHRQ Common Formats should provide more detail on the factors contributing to patient safety events.

Importance. Hospitals will be more willing to invest in the effort to answer AHRQ Common Format questions if they are comprehensive enough to help avoid incidents in the future. One weakness of the AHRQ Common Formats is the limited data asked about the cause of events. Only one question on a generic form is asked about contributing factors for all event types, and that one response is insufficient for knowing how to reduce safety events.

Hospital and PSO Insights. Hospital managers want more structured questions and space for narrative about the cause of the event. The structured questions should include the following:

- A page of general questions or categories to identify the causes of an event, which typically number 5 to 10; the reporter should be able to select all that apply and indicate whether they were primary or secondary causes.
- Within each event type (e.g., falls, medications), questions of cause tailored to the type of event, with the reporter being able to select all that apply.

Of equal importance to the list is space for causal narrative; hospitals need this narrative to understand the nuances of an event.

Although implementation of this recommendation would add detail to the AHRQ Common Formats, hospitals and other providers may view the information as helpful to identifying and solving safety problems, especially where causes can be tailored to specific high-frequency event types. The initial list of causes would need to reflect what frontline staff know at the time of reporting.

AHRQ Notes. AHRQ supported extensive collection of narratives throughout the Common Formats. AHRQ staff also note that the suggestion on contributing factors involves both event reporting and root cause analysis (RCA). The AHRQ Common Formats are an event reporting system. With respect to the suggestion above, providers may need to execute an RCA to determine the specific contributing factors for a specific event. Contributing factors often are discovered only after a period of investigation following an initial report. Providers must manage the separate tasks of event reporting and RCAs, but they should combine the information into one system. AHRQ will continue to focus on event reporting; local sites must conduct RCAs,

which will vary from event to event. As RCAs reveal frequent safety problems over time, they can be built into the AHRQ Common Formats contributing factors, as appropriate.

Suggestion 4: AHRQ should issue a more robust AHRQ Common Formats Minimum Dataset.

Importance. If AHRQ can streamline the AHRQ Common Formats and still retain the essential elements for improving patient safety, PSOs think the field will shift toward supporting them.

PSO Insights. NextPlane's experience in working with hospitals to review and adopt the AHRQ Common Formats revealed nearly 25 data elements from the HERF, PIF, SIR, and a few of the specific event types that will be of greatest value to hospitals. These could start their movement toward greater uniformity. Hospitals place high importance on being able to analyze the types of events occurring in a facility and the causes of those events. See Box G for the suggested minimum data elements.

AHRQ Notes. The list in Box G is useful for identifying important items for the AHRQ Common Formats Minimum Data Set, which is being revamped. The list needs further consideration to be certain that all these items are essential and feasible. For example, the principal diagnosis typically would be assigned by the attending physician after the patient is discharged from the hospital, so the principal diagnosis most likely would not be available when an event is reported while the patient is in the hospital. In fact, some component PSOs of software vendors have said that hospitals do not want to ask their frontline staff to enter the patient's principal diagnosis in their event reporting system.

Suggestion 5: AHRQ should continue to publicize how the AHRQ Common Formats can improve analysis and learning.

Importance. The issues described throughout this *Brief* highlight the challenges of motivating providers to adopt the AHRQ Common Formats as they were intended—with consistent definitions, taxonomies, data elements, and event details. Most providers of health care are relatively uneducated about the PSO program and its potential for improving the care they provide. Education of providers on the value of implementing the AHRQ Common Formats, as designed, must be compelling and ongoing.

PSO Insights. Providers must plan for and incur labor and technology costs to adapt the AHRQ Common Formats to local systems, to submit data, and to remain current with changes. Providers must see a compelling value to using a new system while abandoning their local system—a system that works for them and has been tailored over the years by their teams. In short, the AHRQ Common Formats must prove its value in opening a data stream to the "safety network" offered by PSOs.

AHQR is authorized to promulgate Common Formats, and each PSO is required to use some type of common formats for patient safety reporting across all its participating providers. But PSOs currently do not

Box G. High-Value Data Elements for Hospital Use From the AHRQ Common Formats

- Event discovery date
- Summary report date
- Category associated with event (expand)
- Report type—incident, near miss, unsafe condition
- Extent of harm and anticipated duration of harm
- Injury type typically collected for malpractice claims (e.g., dislocation, fracture, burn, death)
- Patient age
- Patient sex
- Principal diagnosis at discharge
- Location of event
- Contributing factor(s)
- Incident preventability
- Description of event (free text)
- Family or guardian notification
- Physician notification (add)
- Fall—unassisted or assisted
- Fall—patient activity immediately prior to the fall
- Medication—stage when the event originated
- Medication—generic and brand names
- Any intervention that was attempted in order to "rescue" the patient
- Contributing factors specific to differing event types (expand)

Source: Personett, M., NextPlane Solutions Safety Redesign Projects with 20 Hospitals and Over 100 Clinical Leaders. Personal Communication, August 8, 2014.

have to use the AHRQ Common Formats to meet this requirement. Hence they are free to use either AHRQ's Common Formats or others of their own choosing. To adopt the AHRQ Common Formats, PSOs and vendors need (1) a compelling list of benefits for collecting the AHRQ Common Formats, (2) a change-management plan for implementing the Common Formats, and (3) examples of how health professionals have used the Common Formats as a tool to reduce adverse events.

AHRQ should describe for hospitals and others the value of the analytics that will be possible from data that hospitals will supply. For example, a hospital wanting to implement the AHRQ Common Formats could spend $40,000 on the effort. AHRQ could explain that if this hospital adopts the AHRQ Common Formats, their PSO will receive the following benefits as a result of the data they submit:

- The types of events that occur at this hospital compared with other hospitals
- The general causes of this hospital's events compared with other hospitals
- Standardized detail about specific events (e.g., type of injuries resulting from falls, types of medication events, severity of pressure ulcers)
- Advice on how to reduce those events through their PSO

Hospitals will be motivated to join the program if they see powerful examples from hospitals that have identified and reduced safety events as a result of implementing the AHRQ Common Formats.

AHRQ should foster PSO collaboration on focused patient safety priorities that leverage the AHRQ Common Formats as the key measurement tool. For example, the Partnership for Patients might be a model to establish a collaboration specific to use of the AHRQ Common Formats for a particular safety improvement effort. Such collaboration should support a specific improvement—preferably linked to hospital financial implications—while establishing the infrastructure of the AHRQ Common Formats.

AHRQ Notes. The PSQIA and its accompanying regulations were developed with an understanding that large, comparable datasets would be essential for developing insights into patient safety events as well as for other issues affecting quality of care. Therefore, one provision required PSOs to collect data in a standardized manner that permits valid comparisons of similar cases among similar providers. While PSQIA did not mandate use of AHRQ Common Formats, it authorized AHRQ to promulgate them; their use is essential for providers to obtain the full promise envisioned by PSQIA.

Use of the Common Formats enables providers to benefit from the insights that a PSO can develop based on a larger pool of events than any single provider can aggregate, no matter how large the provider's health system. By aggregating nonidentifiable data in Common Formats from all PSOs that choose to send data, the NPSD will constitute an unprecedented pool of events for even greater insights, comparisons, and learning.

Providers are free to choose not to adopt Common Formats, but this decision may limit the national comparisons offered by the PSOs with which they work. In addition, neither providers nor PSOs are required to send data to the NPSD. Choosing not to send data will not affect the protections for data assembled or developed by providers in accordance with the law. Thus, while many aspects of this system are voluntary, the full benefits envisioned by PSQIA will only be achieved if all parties recognize the value of participation.

AHRQ staff also point out that the Partnership for Patients model in which AHRQ participated had funding well beyond AHRQ resources. However, with PSO leadership, AHRQ could support collaboration among PSOs to publicize the value of using the AHRQ Common Formats. The first step would be to determine the best way to disseminate information about Common Formats, starting with the points made above: (1) describe the benefits, (2) list PSO examples of reduced adverse events, (3) select a specific area for improvement, and (4) suggest a change management plan for implementation. The objective would be to stimulate hospitals to adopt the Common Formats for data collection and to share the information with PSOs. The PSOs in turn could create and implement a distributed analysis plan and share the information with providers. These ideas should be discussed further among PSOs and with AHRQ.

Suggestion 6: AHRQ should address hospitals' fears of reporting to the PSOPPC.

Importance. Many hospitals appreciate the value of becoming a member of a PSO, especially in States that do not have peer-review laws that protect information about patient safety events from legal disclosure (e.g., Florida and Kentucky). The Federal PSO program protects PSWP from disclosure and limits the use of PSWP to learning. Despite this legal protection, one

PSO said that hospitals are fearful of submitting safety event data to the AHRQ PSOPPC and eventually to the NPSD: "Hospitals have an unfounded fear that their adverse event rates will be disclosed." Hospitals cite their experience with the CMS program promoting meaningful use of health IT, which opened hospitals to audits.

PSO Insights. One PSO asked AHRQ to speak with their member hospitals and develop materials that can be used to assure hospitals that their safety event information submitted to the PSOPPC will be protected. This PSO believes that the country needs a national conversation among acute care providers to understand why they fear reporting to the PSOPPC and NPSD. Providers and their safety officers need to understand that the goals for the data are to draw comparisons and create national benchmarks rather than to disclose their information. These goals should be communicated to health care attorneys and risk managers through the American 8Health Lawyers Association and the American Society of Healthcare Risk Managers to improve the education of professionals on these issues.

AHRQ Notes. AHRQ staff point out that they previously developed statements to combat fears of submitting data to the PSOPPC and NPSD (shown in Box H). PSOs can use those arguments with their members. AHRQ has worked with the American Hospital Association and the American Medical Association to disseminate information to hospitals and physicians. PSQIA provisions have been challenged in court and the PSO community is watching carefully as the decisions unfold.

Box H. Combating Hospital Fears of Submitting Data to the PSOPPC and NPSD

- The Patient Safety and Quality Improvement Act (PSQIA) protects patient safety work product (PSWP) from legal discovery. This law encourages sharing of information on adverse events, near misses, and unsafe conditions in order to learn how to improve patient care. Several court cases have upheld the protection of PSWP from discovery in the judicial process.
- Submitting PSWP to the Patient Safety Organization Privacy Protection Center (PSOPPC) does not put providers at risk of disclosure of such information. The PSOPPC is prohibited by law from disclosing PSWP submitted to the PSOPPC. Furthermore, the PSOPPC is required to de-identify any data that eventually will be used for nationwide learning through the Network of Patient Safety Databases.
- The PSQIA statute placed responsibility for implementing its provisions with the Agency for Healthcare Research and Quality (AHRQ), not with the Centers for Medicare & Medicaid Services (CMS). Data collected under PSQIA for learning how to improve safety may not be used for other purposes, such as regulating providers or publicly reporting their performance.
- AHRQ has a long history of data protection and collaboration with data contributors, and its reputation is strong. For more than 30 years, AHRQ has protected data from the Medical Expenditure Panel Survey (MEPS) and the Healthcare Cost and Utilization Project (HCUP). Disclosures of individuals and provider institutions are never made by AHRQ, and researchers who may have access to patient- and provider-level records must sign data use agreements promising never to attempt to identify either. Also, release of aggregate data at a geographic level that may be sensitive for HCUP States is made only with the State Partner's knowledge and consent.

Suggestion 7: AHRQ should continue to provide transparency into future plans for development of the AHRQ Common Formats.

Importance. Health care providers frequently absorb regulatory change and modify their information systems accordingly. The AHRQ Common Formats represent a voluntary request for use of standard data collection procedures.

PSO Insights. Given the environment described above, AHRQ should continue to provide transparency into their plans for developing or enhancing the Common Formats and adopt a change management process that PSOs, vendors, and providers can consult to inform resource planning. PSOs on limited budgets, health care providers working through the huge shifts in payment models, and vendors responding to client needs must plan far ahead for the evolution of the AHRQ Common Formats. Their inherent costs need to become a component of doing business in safety rather than expenditures on a one-time project or an exception to normal operating procedures.

AHRQ Notes. AHRQ staff are open to suggestions regarding how the agency can increase the transparency of its processes. AHRQ discusses plans informally through PSO quarterly calls, special webinars on Common Format versions, PSO Annual Meetings, and NQF expert panel meetings (which are open to the public). AHRQ decided not to issue the Common Formats as a regulation so that AHRQ could react

quickly to changes in clinical science and user feedback. However, PSOs and vendors have requested that AHRQ issue updates no more often than every 2 years. The most recent AHRQ Common Formats version was issued more than 2 years ago.

Outlook for the Future

Two high-level messages emerge from this assessment of the AHRQ Common Formats by Patient Safety Organizations (PSOs). First, the process of voluntary adoption of data standards for safety event reporting by health care providers is lengthy and requires patience. Second, the Common Formats should be modified based on early PSO attempts to foster their adoption within hospitals. Heeding provider suggestions will expedite AHRQ's efforts to meet their goal of developing a resource for national aggregation of safety reports through the PSOPPC and NPSD.

The AHRQ Common Formats clearly are competing with the legacy of patient safety content in information systems that were designed and built long before the Common Formats were conceived. In discussions with PSOs, two mentioned hope that electronic health records (EHRs) will make patient safety reporting more feasible for hospitals in the future. However, EHRs face the same dilemma as any information system—without established standards, the definitions, taxonomies, and data will not be comparable across facilities or locales. Also, AHRQ has determined that almost two-thirds of the queries of the Common Formats typically would not be contained within an EHR (e.g., contributing factors, near-misses, unsafe conditions).

There is no way around the hard work of creating and implementing data standards. Until there is consensus regarding the information that is required to be recorded in EHRs at the point of care regarding patient safety events, EHRs will not be able to lighten the data collection burden through provision of standardized data electronically to either event-reporting or surveillance systems. The Common Formats for surveillance can provide a beginning point for such standardized EHR definitions.

Prior experiences of developing national standards for the U.S. health care system provide insight into the complexity involved in adopting health data standards:

- The Uniform Committee on Vital and Health Statistics started the process of setting standards for hospital discharge data in 1969 and recommended their use in 1972, but by the late 1970s standards still were not being used.[1] Standards for hospital discharge data evolved into standards for the uniform bill that providers submit to insurers for payment. The National Uniform Billing Committee (NUBC) started in 1975 and has met continually to improve billing standards. For example in 2007, the NUBC added *present on admission* flags for each diagnosis recorded on hospital bills to improve risk adjustment for various program purposes. In addition to the NUBC directives, CMS provided a powerful incentive by requiring the use of uniform billing formats in order for providers to be reimbursed.
- The AHRQ Healthcare Cost and Utilization Project (HCUP) has assembled uniform discharge and billing claims for decades from State data organizations. Some data elements are collected consistently and are exceptionally clean (e.g., age, sex, diagnoses, procedures), whereas others are problematic because definitions are set by the States (e.g., payer categories related to small or local government programs, Medicaid waivers, and uninsured patients). Despite excellent uniform data standards in this arena, the process of assembling, checking, and cleaning data and promoting the use of data standards is ongoing.

The AHRQ Common Formats were issued for use in 2008, making them very new compared with other health data standards. Given that the Federal Government has not funded the PSOs nor supported them with grants to develop their information systems or to jumpstart the standards, it is remarkable that there is commitment on the part of the PSOs to move toward using them. Every PSO we interviewed wants to implement the Common Formats. Their energy and momentum around how to establish them for standard patient safety reporting portend well for the future.

[1]Kanaan SB. The National Committee on Vital and Health Statistics 1949-1999: A History. National Committee on Vital and Health Statistics Web site; 2000. http://www.ncvhs.hhs.gov/ncvhs-50th-anniversary/ncvhs-50-year-history/

The variability and incompatibility of information collected through existing approaches—by hospitals within their own systems, by PSOs relying on legacy systems, and by vendors who have different systems—stymies a national data repository. By not requiring standard patient safety data elements, comparisons are compromised, lessons are lost, and the patient safety field is deprived of perhaps its most powerful method for improvement: scientifically valid and consistent measurement tools and benchmarks. The field also is deprived of the learning that could result from their use.

PSOs understand the high stakes in patient safety, the importance of data for determining how well providers are meeting safety goals, and the necessity of data standards for developing comparative analytics and national benchmarks for safety. PSOs also understand the challenge of convincing providers to adopt the standard within complicated work environments. The insights shared by the PSOs offer an opportunity to widen the dialog on how AHRQ should modify the Common Formats to make them essential to health care providers who, without exception, want to enhance patient safety.

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