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Commentary

Improving patient safety reporting with the common formats: Common data representation for Patient Safety Organizations

Peter L. Elkin, MD [a,*], Henry C. Johnson, MD [b], Michael R. Callahan, JD [c], David C. Classen, MD [d,e]

[a] Department of Biomedical Informatics, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, SUNY, United States
[b] Henry Johnson Healthcare Consulting LLC, Tucson, AZ, United States
[c] KattenMuchinRosenman, LLP, United States
[d] Division of Clinical Epidemiology, University of Utah School of Medicine, United States
[e] Pascal Metrics PSO, United States

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ABSTRACT

Medical errors and patient safety issues remain a significant problem for the healthcare industry in the United States. The Institute of Medicine report To Err is Human reported that there were as many as 98,000 deaths per year due to medical error as of 1999. Many authors and government officials believe that the first step on the path to improvement in patient safety is more comprehensive collection and analysis of patient safety events. The belief is that this will enable safety improvements based on data showing the nature and frequency of events that occur, and the effectiveness of interventions. This systematization of healthcare practice can be a step in the right direction toward a value based, safety conscious and effective healthcare system. To help standardize this reporting and analysis, AHRQ created Common Formats for Patient Safety data collection and reporting. This manuscript describes the development of patient safety reporting and learning through the Patient Safety Organizations (PSO)s and the Common Formats and gives readers an overview of how the system is expected to function and the breadth of development of the Common Formats to date.

1. The motivation for the common formats

Medical errors and patient safety issues are a significant problem for the healthcare industry in the United States [1,2]. The Institute of Medicine report "To Err is Human" [3] reported that there were as many as 98,000 deaths per year due to medical error as of 1999 [4]. Approximately one in six hospitalizations has a medical error associated with the admission and a significant percentage of those patients came to harm. Newer Studies suggest that between 200,000 and 440,000 deaths may occur a year related to patient safety problems in hospitals [5].

The common formats are a set of standard forms for patient safety data collection and reporting. They are being picked up by virtually all patient safety reporting system vendors and as such patient safety officers need to familiarize themselves with the development and use of the common formats. All Medicare and Medicaid participating hospitals of more than 50 beds who want to qualify for health plan participation in affordable care exchanges (they receive a CMS certification number) will need to be a part of a Patient Safety Organization (PSO) or a Medicare QIO by January 1 of 2017 or be a participant in a Hospital Engagement Network (HEN). PSOs will expect member hospitals to report in common formats as a part of their participation.

Over the last 25 years virtually every study of patient safety in healthcare shows very high rates of harm occurring to patients across the continuum of care. One study in 2005 revealed that a third of patients admitted to the best hospitals in the United States experienced harm as a part of their care. No other industry in modern times tolerates this level of safety problems in its ongoing operations. Multiple IOM reports have outlined how unique this lack of basic safety is in healthcare is [3,10] and have called for healthcare to adopt many of the standard safety practices from other high risk industries such as nuclear power, aviation and natural gas [3].

Patient safety events continue to be significantly underreported in the United States [6]. This is a major challenge as the increasing focus on patient safety and patient safety interventions to improve safety of care occurs in an environment where most hospitals have inadequate systems for measurement of patient safety and thus no effective way to evaluate the impact of safety interventions. While

* Corresponding author at: 77 Goodell Street, Suite 540, Buffalo, NY 14203, United States.
E-mail address: Elkinp@buffalo.edu (P.L. Elkin).

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many barriers to reporting have been identified, the fears of retribution for reporting an event and of legal discovery of event details have been significant impediments to reporting. Systems used today collect data using differing definitions which inhibits aggregation of data and translating the results from one healthcare organization to another. This directly relates to recommendation's in several recent IOM patient safety reports [3,10]. In response to these issues, congress passed and the president signed the 2005 the Patient Safety and Quality Improvement Act (PSQIA), providing legal protections around reporting and analysis of patient safety events when reported to designated Patient Safety Organizations.

Patient safety has become more financially important to the healthcare industry as Medicare and some private insurers have stopped paying for treatment of complications that occur to inpatients, creating a powerful incentive for hospitals to decrease the rate of adverse events and subsequent harm to hospitalized patients [7]. Programs aimed at safety improvement are dependent on data to drive the clinical interventions. To improve patient safety and lower the complication rate, organizations will want to learn not only from their own experiences but also from the experiences of others nationally [8]. Without a national dataset each organization is left to deal with their patient safety problems on their own. Comparable data will allow patient safety officers to compare their progress with others nationally using data that has been collected and reported using the common formats that contain common definitions of their data elements. Under provisions of the PSQIA this is now possible by confidential and protected patient safety reporting to PSOs via standardized reporting with the common formats [9]. In this article, we show you how to report to a PSO, we discuss the legal protections under the law afforded to patient safety work product and we provide recommendations for further improvement of the common formats.

2. The history

One of the recommendations of the IOM report Patient Safety: Achieving A New Standard for Care, 2003 [10] was that Congress establish a reporting system for medical events similar to that for aviation events, the Aviation Safety Reporting System (ASRS), whereby anyone can anonymously report near-misses or unsafe conditions to NASA for analysis and reporting. With remarkable speed, the PSQIA made it through the House and the Senate and was signed into law by President George W. Bush in the summer of 2005 [11], providing legal protections around reporting and analysis of patient safety events when reported to designated Patient Safety Organizations. Patterned after the ASRS, the act was intended to lower barriers to reporting and analysis of patient safety events, near misses, and unsafe conditions, as well as facilitate analysis. Congress hoped this law would help remove the fear of reporting, creating a more open environment to promote a safer healthcare in the United States.

Since the act was passed numerous Patient Safety Organizations (PSOs) [12] have been put into place to improve the safety and quality of care regionally and nationally. Administered by the Agency for Healthcare Research and Quality (AHRQ), the PSQIA of 2005 has generated more than 80 Patient Safety Organizations in 29 states and the District of Columbia [13]. Over the course of the next year, the total number of PSOs stabilized at 81 in 29 states and the District of Columbia. Although 19 new ones joined during the year, 21 voluntarily withdrew, none "for cause," mostly they withdrew for business reasons. The current list of PSOs can be found on the AHRQ web site [14]. PSOs receive no public funds, and must run a regulated reporting and consulting service on a business basis for contracted providers and healthcare organizations already besieged with mandatory reporting at the state and federal level. Voluntary PSO reporting has to be added to their busy clinical operations.

Indeed the success of these patient safety organizations as part of a national system is only possible if patient safety data is collected in a standard format to avoid the aggregation of non-comparable data. The common formats have been created and maintained by AHRQ with public review with the help of the National Quality Forum (NQF) Common Formats Expert Panel. This is important for healthcare organizations that are committed to reducing medical error in their organization, their region, nationally and also because reporting patient safety work product to the PSOs can protect the submission from discovery through provisions of the Act. Annual PSO conferences have been held and currently both inpatient and outpatient Patient Safety common formats are available for use by PSOs and healthcare organizations for reporting.

Much as in aviation or nuclear power a key to learning from these reported safety events is a standard set of safety problem or event definitions that can be used to characterize these events so that reporting and learning can be derived from comparable data. To facilitate the standardization of categorization of these events, as well as analysis and improvement from these events as has been done in Aviation for the Aviation Safety Reporting System (ASRA) by the National Aeronautics and Space Agency (NASA). AHRQ has created a set of common formats for event reporting to create a common framework for the data related to patient safety. This common framework, similar to industrial standards such as standard gauge railroad beds, allows the data collected to gain greater value in the analysis period and allows the Network of Patient Databases created under the law to bring back conclusions and recommendations to the healthcare community.

AHRQ was charged with implementing the PSQIA. Data collection and any reporting to the Network of Patient Safety Databases (NPSD) would be the responsibility of Patient Safety Organizations, contracted on a voluntary basis with any individual or entity licensed or otherwise authorized under state law to provide health care services - with AHRQ operating the Network of Patient Safety Databases for national aggregation, reporting and analysis [15].

The final rule was published November 2008, and effective January 2009. Under the rule, providers can voluntarily collect and submit patient safety event and quality information to their Patient Safety Organizations (PSOs) (See Medication Adverse Event Report Case Insert) with the assurance of confidentiality and protections from discovery in a court of law. In turn, the PSOs work with their client providers to help create a culture of safety, and assist with analysis of quality and/or event data which may include root cause analysis, under the protections of the law. The PSQIA recognized the need for a common data structure, called common formats, to facilitate the flow of information and make national analysis possible. AHRQ established the common formats for use by providers at the point of service. PSOs are encouraged to submit standardized event information in the common formats for full deidentification by the PSO Privacy Protection Center [16]. After complete deidentification of both patient and healthcare facility identifiers the information is then aggregated, analyzed, and reported to the Network of Patient Safety Databases [17], and published annually in AHRQ's National Healthcare Quality and Disparities Reports [18].

3. Legal precedence

Given the broad scope of protections afforded PSOs and providers under the Patient Safety Act, legal challenges filed by plaintiff attorneys and others were inevitable. For example, most state statutes limit confidentiality and privilege protections to "peer

review" discussions and reports but the Act goes much further. It protects safety and quality data assembled and developed for the purpose of reporting to a PSO and patient safety activities including analysis and deliberations conducted in a Patient Safety Evaluation System. This information is collectively called "Patient Safety Work Product (PSWP)." Moreover, the Act provides the first federal, versus state, discovery and admissibility protections making future challenges likely. This is particularly true given the fact that some states, such as Florida and Kentucky, have either no or very limited protections for such information commonly found in other state statutes around the country.

Fortunately, as a general matter, courts that have addressed the question of whether PSQIA preempts existing state law that would otherwise allow discovery and have ruled in favor of applying the federal protections. For example, in the first states appeals court decision to examine the PSQIA, the Illinois Appellate Court affirmed the dismissal of a lawsuit filed by the Illinois Department of Financial and Professional Regulation against Walgreens when it refused to turn over reports of medication errors involving three of its pharmacists. Walgreens had collected these materials as part of its patient safety evaluation system and reported them to its component PSO. The court held that the PSQIA preempted Illinois law that otherwise would have required disclosure and that Walgreens had met its burden in establishing compliance with the Act's requirements and therefore, the reports were protected from discovery [19].

Since the Walgreens decision in 2012, there have been several other challenges which have reached the appellate and supreme courts in a number of states. Most notable is the Tibbs v. Bunnell case decided by the Kentucky Supreme Court, which later was appealed to the U.S. Supreme Court. In Tibbs, the Kentucky Court held that information and reports which a provider was required to collect and maintain pursuant to state laws could not be considered privileged Patient Safety Work Product (PSWP). In this case, the hospital had collected an incident report within its Patient Safety Evaluation System (PSES) after a patient's death and reported to its PSO. Because Kentucky law required that hospitals collect and maintain "incident investigation reports", the Court remanded the case back to the trial court to determine whether the incident report in question was one that needed to be collected and maintained pursuant to State law [20] [448 S.W.3d796 (Ky. 2014)].

The Tibbs case was appealed to the U. S. Supreme Court by the University of Kentucky Hospital which challenged this narrow interpretation of the PSQIA. The AHA, the AMA, The Joint Commission and many PSOs and several hospitals and health systems throughout the country supported the hospital through prepared amicus briefs. HHS in turn, issued a guidance on May 24, 2016 which essentially embraced the Tibbs analysis [HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations (Federal Register, vol. 81, No. 100 at p. 32655 (May 24, 2016)]. Based on this guidance and an amicus brief submitted by the Solicitor General which further supported Tibbs and the guidance analysis the Solicitor General recommended that the U. S. Supreme Court deny the petition. The Court did so on June 27, 2016.

The industry is closely following three pending decisions before the Supreme Courts in Florida [Charles v. Southern Baptist Hospital of Florida (SC 15-2180)], Kentucky [Baptist Health Richmond, Inc. v. Clouse (2015-SC-000657)] and Rhode Island [Carron v. Newport Hospital (SU-15-0212)].

4. Common formats development and implementation

Most U.S. hospitals have some system for reporting errors, near misses, and/or adverse events. Organizations can and do differ in the way they collect data, which makes it very difficult to track patient safety trends accurately or reliably across healthcare organizations. In a report on patient safety in 2004 the Institute Of Medicine (IOM 2004) called for reporting of safety problems with a common reporting format so that these problems could be aggregated and collated from a wide variety of organizations [9]. This aggregated data was felt to have significant opportunities for learning, but only if it used common definitions and formats for reporting. Thus, as part of the PSO law, a set of patient safety common definitions and reporting formats has been developed, which is now known as the AHRQ common formats.

These common formats specify the clinical definitions and technical requirements that allow health care providers to exchange data with PSOs and contribute to the Network of Patient Safety Databases in a standardized manner [21]. The goal over time is to move toward greater levels of interoperability [22]. These AHRQ common formats are standardized and simple reporting formats for reporting patient safety problems. They consist of both general/summary reporting forms and event specific forms. The questions and list of answers are developed at AHRQ and then undergo a period of public comment. The comments are then reviewed by the NQF Common Format Expert Panel, with final comments submitted to AHRQ to inform the final format creation or revision.

The PSO Privacy Protection Center web site provides a listing of the current types of forms available [23] and Table one gives an example of Summary of Initial Report form (SIR) and an event specific form (the "Fall" form), and the event description for falls as well. It was recognized that these event specific forms needed an organizing taxonomy to help providers and PSOs understand how to organize and categorize event specific reporting and to help the analysis of such events within the NPSD. These forms contain both general event information and a more comprehensive and event specific set of data elements for an initial patient safety report. These formats are currently undergoing a significant revision to lessen the burden of reporting by creating a two tiered approach to the formats allowing for identification of a minimal data set for transmission to the NPSD and a larger data set for use by local PSO's. As such, some PSOs may collect additional data reflective of the services they offer to providers, with the intent that PSOs would collect more information and if needed to facilitate their safety improvement work with individual contracted providers.

The Hospital Acquired Infection common format has been aligned with the Centers for Disease Control and Prevention (CDC) National Hospital Surveillance Network data collection methods. It was also believed that PSOs would collect this minimum event dataset electronically and thus these formats would be merely content guides for the electronic forms created by PSOs. As such technical specifications were developed for generic and event specific modules to help guide PSOs in the integration of these forms into their existing electronic systems.

The first common formats were focused on actual events (more broad than medical error), unsafe conditions and near misses. This initial set of common formats was developed for the hospital setting and has been expanded to include venous thromboembolism, and health information technology safety issues. Draft formats for Skilled Nursing Facilities have been created, with future areas of expansion to include ambulatory settings. The concept is that the common formats will expand beyond sole event reporting and offer a patient safety life cycle of standardization from detection to analysis to learning and ultimately improvement.

5. Vendor integration into electronic systems

Adverse event reporting systems have been working to incorporate the common formats into their systems. This necessarily includes the Medication Adverse Event Reporting Systems often referred to as MERS. It is intended that vendors of these systems

will be encouraged to integrate the common formats into their MERS offerings. The major HIT and Patient Safety vendors have been attending NQF and AHRQ sponsored software developers' meetings that review for vendors the distribution format for the questions and answers for the common formats. While many vendors have expressed concerns regarding the detailed data entry required of end users of the Formats, others have noted that they are not complete. Most all agree that the common formats represent a solid step forward toward obtaining comparable adverse event data from healthcare organizations. This we believe will facilitate improved and national epidemiological studies that we believe will lead to the safer practice of healthcare.

To date, almost all adverse event reporting systems are provided to hospitals via standalone systems that require data entry at the point of care or by secondary care personnel such as event coordinators or nursing supervisors into defined screens in separate systems. Some of this data is available from the electronic health record (EHR). However, thus far, most systems have not been able to upload electronic health record data that would provide answers to some of the common formats' questions. The use of existing EHR data to pre-populate some of the information collected could decrease the data entry burden on healthcare organizations reporting in the common formats.

In order for EHR data to be used safely to answer questions across healthcare organizations, the common formats will need to adhere to relevant national coding standards. A lack of standardization can lead to inconsistent use of terms across the formats and hamper aggregation and reusability of data elements. These include codification with SNOMED CT [24]; the Systematized Nomenclature of Medicine, a general purpose medical terminology, RxNorm [25]; the national standard for representing drug information and LOINC [26]; Logical Observations Identifiers Names and Codes, a coding system that has been adopted as a method for coding sections of the record and laboratory test results. There have been some early efforts by AHRQ to codify the common formats in SNOMED CT as well as LOINC.

6. Reporting

The final rule provides for confidentiality and certain privilege protections from disclosure for patient safety data collected for reporting to a PSO. Once submitted to a PSO the information becomes fully protected in all state and federal proceedings as Patient Safety Work Product ("PSWP"). Note that there are certain exclusions from the definition of PSWP, such as medical record information, information needed for reporting to mandatory state systems, and information needed for other purposes such as risk management which are unrelated to patient safety activities.

7. Experience to date

Patient Safety Organizations have been created as a way to aggregate and protect patient safety data while working with their clients to improve care. PSOs provide a good social model for collecting patient safety data. Most PSOs use electronic systems for capturing patient safety events. These events can be quite broad (See Sidebar 1: Illustrative Case Study). This case shows a dosing error in a pediatric patient and the way that it would be reported using the common formats. In this example, reporting led to a change in clinical processes to prevent further such incidents by instituting a stop order for daily oral dosing of methotrexate. Here we see how easy it is for the reporting clinician to enter the event with a relatively minimal yet rich set of data. This case study is a good example of where a root cause analysis can quickly lead to a system change that can have a broad effect on errors of this type (out of range dosing errors).

Table 1
List of common formats as of September 17, 2016.

Generic formats
HERF (Health Event Reporting Form)
PIF (Patient Information Form)
SIR (Summary of Initial Report Event Description)
Event-specific formats
Blood or blood product
Device or medical/surgical supply, including HIT
Fall
Healthcare-associated infection
Medication or other substance
Perinatal
Pressure ulcer
Surgery or anesthesia
Venous thromboembolism

Common formats have been created for the reporting of safety problems in the following areas: Healthcare Devices including HIT systems, Adverse Drug Events, Falls, Pressure Ulcers, other conditions and demographics such as Patient Information Form and a Hospital Event Report Form (see Table 1). The common formats ask questions with standard multiple choice answers with the goal of making collection of information related to the event or condition as easy as possible. The formats have intentionally been designed to be concise to promote reporting by staff at the point of care. As the Formats expand, they can be used for the reporting of events or conditions in ambulatory or outpatient settings. These standard questions and answers have gone through a rigorous review and evaluation process with subsequent resolution and publication of all comments received from the public. The formats are published by AHRQ to be incorporated into patient safety event reporting systems at the local level.

Each question and its associated answer values have metadata definitions (i.e. descriptions of the meaning of the data elements) which are kept consistent across the formats through AHRQ efforts. The PSOs and their work with the AHRQ common formats comprises a model for how to implement standardized patient safety reporting and encourage the aggregation and analysis of such data across provider groups (i.e., those working with and across PSOs) under the protections of the law. The PSOs can provide feedback to their associated healthcare organizations when they discover trends in HIT data. Healthcare organizations can share PSWP with their contracted HIT vendors. If the information remains confidential and protected in the hands of the vendor then it is still considered protected PSWP.

Some vendors have expressed that there is a data entry burden associated with the common formats. We believe that this has (a) been minimized under the careful watch of AHRQ and the NQF Expert Panel and (b) is necessary if we as a nation have any chance of broadly reducing patient safety events. The diffusion of innovation curve teaches us that early adopters are the norm as innovation moves into the practice. If we look at the diffusion of electronic health records it had a similar curve to what we see for the common formats. Entering data into the formats takes more time than free text entries but leads to standardization necessary for comparable data across institutions. We believe that the common formats are on track to be fully adopted as healthcare organizations better understand the legal protections that reporting of patient safety work product affords them and they realize direct benefit to their patient care processes.

8. Future data architecture

As the common formats become more extensive computable knowledge representation using standard models and terminologies will be required to maintain consistency of meaning across

the common formats. As representation schemes such as the common formats become large, the ability for humans to keep consistent the definitions of the forms, the questions and the possible responses including their context becomes impossible. For the last 25 years or more the informatics community has worked diligently to create a set of standard models to provide context [28,29] and Terminologies for standardized coding of clinical data [24,30,31] that have the capacity to put in place formal (computable) definitions that can represent the forms, questions and answers associated with the common formats.

The most appropriate standard currently available for representing the information in the questions is the Clinical Document Architecture (CDA) from HL7 [32], a healthcare standards development organization. The top levels of the CDA can provide context for the common formats that will allow us to aggregate and compare data across the common formats. The CDA is a set of extensible markup language (XML) [33] structures that are HL7 [27] conformant and that define sections and individual items which can be documented and stored as both text and codified information. This codified information can contain information from formal terminologies such as SNOMED CT that use description logic definitions for their concepts [34–37].

We recommend that the common formats be should be represented in a codified format to ensure that they are interoperable across the common formats and with electronic health records (EHR). Specifically, the common formats should:

- Code the section's headings and Laboratory Results in LOINC
- Code the diagnoses and findings in SNOMED CT [22] as well as with ICD10-CM [37]
- Codify Medications using RxNorm (this item is currently underway at AHRQ)

As an example, SNOMED CT is a description logic based terminology, and as such, has formal definitions so that we can use computers to ensure that the meaning of each question when used across forms or answer are used across questions we can be sure that they have the same meaning. These standards are capable of representing the information from the common formats in a way that is understandable by a computer program as well as a human being (healthcare worker or patient safety expert). This methodology has the potential to allow the common formats to be automatically populated from electronic health records.

By adopting standardized coding practice the common formats become a living set of reporting standards that can grow with confidence without the risk of the development of unrecognized ambiguity which can, and likely will, occur as the common formats are disseminated and continue to grow. This level of interoperability will facilitate where the data is available pre-populating the common formats from EHR data, saving data entry time and decreasing data entry errors. The PSO model for the collection of patient safety data has been supported by CMS as evidenced by the requirement that qualified health plans participating in the ACA state insurance exchanges can only contract with hospitals which have more than 50 beds if participating in a PSO, the preferred option, or a HEN or QIO. The government's support of PSOs is further evidenced by the AHRQ common formats when enhanced by Informatics' standard models and terminologies represents a technology that has the potential to improve our ability to more broadly and accurately capture patient safety data in a consistent and interoperable fashion.

Healthcare organizations need to make patient safety reporting a priority. We show our commitment to our patients in part by the efforts we make to ensure that the care we provide is safe and effective. The common formats are one part of this reporting equation. Hospitals and other healthcare organizations must embrace standardized patient safety reporting and show their commitment to improving the safety of the care that they provide to their communities and to their healthcare workforce.

9. Conclusion

To achieve best practice, patient care must be provided safely within and across healthcare settings. Working toward high levels of safety in clinical practice requires data to drive the reengineering processes and it must come directly from the sharp edge of practice, be collected in a standardized fashion, and be aggregated to identify systematic error within the healthcare practice domain.

Patient Safety Organizations are the data aggregators for patient safety reports for their subscribed providers, and can work with their members to improve care facilitated by the protections of the PSQIA of 2005. They also represent a set of interested organizations that can serve to educate the clinical staff toward improved safety of their clinical practice in the future. They can serve to recommend safe care processes and can and should become experts on data standardization and reporting.

The AHRQ common formats are a standard set of forms, designed to collect the appropriate minimum dataset for patient safety reporting. These forms have been developed by AHRQ then opened to comment by the public, with review by the National Quality Forum's Common Formats Expert Panel, a big step toward common data reporting of medical error and patient safety events in general. By developing this common data reporting mechanism AHRQ shows its continued commitment toward the safe practice of healthcare. Healthcare organizations should adopt the common formats for their patient safety event reporting and drive developers of reporting software to develop systems that will ultimately contribute to early identification of problems across healthcare and effective strategies to address them.

Patient Safety Organizations have exhibited a proof of concept for the effective implementation of nationalized common formats and the benefits that can accrue from the aggregation and sharing of such standardized information to ultimately improve safety and quality in healthcare. PSOs have now increasingly become more mature in terms of their data collection, all are now electronic and most have adopted the common formats. Most PSOs have shown an interest in working with healthcare providers' EHRs, which has the potential to enable data sharing across PSOs and with the Network of Patient Safety Databases via the PSO Privacy Protection Center.

Hospital patient safety officers are incented to utilize the common formats to report to PSOs as they will enjoy the benefits of learning from one another toward safer and more cost effective care locally and nationally.

Conflict of interest

The authors have no conflicts of interest.

Human subjects

This is an anonymized case report and review of the literature.

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Appendix A. Supplementary material

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References

[1] S.N. Weingart, O. Pagovich, D.Z. Sands, J.M. Li, M.D. Aronson, R.B. Davis, R.S. Phillips, D.W. Bates, Patient-reported service quality on a medicine unit, Int. J. Qual. Health Care 18 (2) (2006) 95–101.

[2] A.K. Jha, D.C. Classen, Getting moving on patient safety–harnessing electronic data for safer care, N. Engl. J. Med. 365 (19) (2011) 1756–1758 (November 10).

[3] Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson (Eds.), IOM Report, To Err is Human: Building a Safer Healthcare System. <http://www.nap.edu/openbook.php?isbn=0309068371> (visited November 23, 2014).

[4] P.A. Honoré, D. Wright, D.M. Berwick, C.M. Clancy, P. Lee, J. Nowinski, H.K. Koh, Creating a framework for getting quality into the public health system, Health Aff. (Millwood) 30 (4) (2011) 737–745.

[5] J.T. James, A new, evidence-based estimate of patient harms associated with hospital care, J. Patient Saf. 9 (3) (2013) 122–128.

[6] D.J. Noble, P.J. Pronovost, Underreporting of patient safety incidents reduces health care's ability to quantify and accurately measure harm reduction, J. Patient Saf. 6 (4) (2010) 247–250. Review. PMID: 21500613.

[7] M.B. Rosenthal, Nonpayment for performance? Medicare's new reimbursement rule, N. Engl. J. Med. 357 (2007) 1573–1575 (October 18, 2007).

[8] S. Saint, R.N. Olmsted, M.G. Fakih, C.P. Kowalski, S.R. Watson, A.E. Sales, S.L. Krein, Translating health care-associated urinary tract infection prevention research into practice via the bladder bundle, Jt. Comm. J. Qual. Patient Saf. 35 (9) (2009) 449–455.

[9] C.M. Clancy, Common formats allow uniform collection and reporting of patient safety data by patient safety organizations, Am. J. Med. Qual. 25 (1) (2010) 73–75 (January–February).

[10] P. Tang, M. Coye, Ed, IOM report Patient Safety Achieving a New Standard of Care. <http://www.iom.edu/Reports/2003/Patient-Safety-Achieving-a-New-Standard-for-Care.aspx> (reviewed November 23, 2014).

[11] Patient Safety and Quality Improvement Act of 2005 Statute and Rule. <http://www.hhs.gov/ocr/privacy/psa/regulation/index.html> (reviewed November 23, 2014).

[12] A.G. Gosfield, Using patient safety organizations to further clinical integration, J. Med. Pract. Manage. 29 (5) (2014) 278–281 (March–April).

[13] Patient Safety Organization (PSO) Program. <https://www.pso.ahrq.gov/> (reviewed November 23, 2014).

[14] Federally Listed PSOs. <http://www.pso.ahrq.gov/listing/alphalist.htm> (reviewed November 23, 2014).

[15] C.M. Clancy, New patient safety organizations lower roadblocks to medical error reporting, Am. J. Med. Qual. 23 (4) (2008) 318–321 (July–August).

[16] Patient Safety Organization (PSO) Program Resources. <http://www.pso.ahrq.gov/regulations/regulations.htm> (reviewed November 23, 2014).

[17] Patient Safety Organizations. <https://www.pso.ahrq.gov/about/org> (reviewed January 26, 2015).

[18] National Healthcare Quality & Disparities Reports. <http://www.ahrq.gov/research/findings/nhqrdr/> (reviewed January 26, 2015).

[19] The Ill. Dep't of Fin and Prof'l Regulation v. Walgreens Co., 2012 IL App (2d) (May 29. 2012). <http://caselaw.findlaw.com/ky-supreme-court/1676250.html> (reviewed November 23, 2014). See Fancher v. Shields (No. 10C1-4219, Jefferson Circuit Court, Kentucky (August 16, 2011) (trial court held that incident report and root cause analysis protected from discovery in malpractice case under the Patient Safety and Quality Improvement Act of 2005 citing to KD ex rel. Dieffenbach v. United States, 715 F. Supp 2nd 587 (D. Del. 2010) as support. But see Norton Hospitals, Inc. v. Cunningham, et al. (No. 2012 – CA – 000746 OA (Ky. App) (August 16, 2012) where Kentucky Court of Appeals imposed a significant limitation on discovery protections. <http://www.kentuckypatientsafety.org/documents/FancherOpinion.pdf> (reviewed November 23, 2014).

[20] D. Steinwachs, A. Hinshaw, IOM Report: Keeping Patients Safe: Transforming the Work Environment of Nurses. <http://www.iom.edu/Reports/2003/Keeping-Patients-Safe-Transforming-the-Work-Environment-of-Nurses.aspx> (reviewed November 23, 2014).

[21] P.L. Elkin, D. Froehling, B.A. Bauer, D. Wahner-Roedler, S.T. Rosenbloom, K. Bailey, S.H. Brown, Aequus communis sententia: defining levels of interoperability, Stud. Health Technol. Inform. 129 (Pt 1) (2007) 725–729.

[22] AHRQ Common Formats. <https://www.psoppc.org/web/patientsafety/commonformats> (reviewed November 23, 2014).

[23] International Health Terminology Standards Development Organization. <http://www.ihtsdo.org> (reviewed November 23, 2014).

[24] S.J. Nelson, K. Zeng, J. Kilbourne, T. Powell, R. Moore, Normalized names for clinical drugs: RxNorm at 6 years, J. Am. Med. Inform. Assoc. 18 (4) (2011) 441–448 (July–August).

[25] Logical Observations Identifiers Names and Codes. <http://loinc.org/> (reviewed November 23, 2014).

[26] AHRQ Common Formats Overview. <http://www.pso.ahrq.gov/formats/commonfmt.htm> (reviewed November 23, 2014).

[27] Health Level Seven Standards Development Organization. <www.hl7.org> (reviewed November 23, 2014).

[28] ASTM International, Committee E31 on Healthcare Informatics. <http://www.astm.org/COMMIT/COMMITTEE/E31.htm> (reviewed November 23, 2014).

[29] Unified Medical Language System's RxNorm. <http://www.nlm.nih.gov/research/umls/rxnorm/> (reviewed November 23, 2014).

[30] S.J. Nelson, K. Zeng, J. Kilbourne, T. Powell, R. Moore, Normalized names for clinical drugs: RxNorm at 6 years, J. Am. Med. Inform. Assoc. 18 (4) (2011) 441–448 (July 1, Epub 2011 April 21).

[31] HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 – US Realm. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258> (reviewed November 23, 2014).

[32] w3c SDO, XML Technology. <http://www.w3.org/standards/xml/> (reviewed November 23, 2014).

[33] P.L. Elkin, B.E. Trusko, R. Koppel, T. Speroff, D. Mohrer, S. Sakji, I. Gurewitz, M. Tuttle, S.H. Brown, Secondary use of clinical data, Stud. Health Technol. Inform. 155 (2010) 14–29.

[34] P.L. Elkin, D. Froehling, D. Wahner-Roedler, S.H. Brown, K. Bailey, Comparison of NLP biosurveillance methods for identifying influenza from encounter notes, Ann. Int. Med. 156 (1 Pt 1) (2012) 11–18 (January 3).

[35] H.J. Murff, F. FitzHenry, M.E. Matheny, N. Gentry, K.L. Kotter, K. Crimin, R.S. Dittus, A.K. Rosen, P.L. Elkin, S.H. Brown, T. Speroff, Automated identification of postoperative complications within an electronic medical record using natural language processing, JAMA 306 (8) (2011) 848–855 (August 24).

[36] W3c OWL 2 The Web Ontology Language. <http://www.w3.org/TR/owl2-overview/> (reviewed November 23, 2014).

[37] World Health Organization ICD10. <http://apps.who.int/classifications/icd10/browse/2015/en> (reviewed January 26, 2015).