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Incident Reporting Systems: How did we get here and where should we go? A narrative review

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Abstract: Since the authoring of the seminal report by the Institute of Medicine (IOM) "To Err is Human: Building a Safer Health System" in 2000, there has been an increased focus on patient safety and the responsibility born by the healthcare system to reduce what are known as adverse events (AE). One of the recommendations of the IOM report was the establishment and development of Incident Reporting System (IRS) that would track AE resulting in serious injury and death. The Joint Commission in the USA similarly requires all hospitals have and use an IRS. The objective of this review is to explore barriers and feature of IRS and patient safety.

Keywords: Adverse Events; Incident Reporting System; Patient Safety; Risk Management

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1. Introduction

Since the authoring of the seminal report by the Institute of Medicine (IOM) "To Err is Human: Building a Safer Health System" in 2000 (1), there has been an increased focus on patient safety and the responsibility born by the healthcare systems to reduce what are known as adverse events (AE); defined as injury resulting from medical intervention (not the underlying disease) that prolonged hospitalization, led to a disability at time of discharge, or both (2, 3). One of the recommendations of the IOM report was the establishment and development of reporting systems that would track AE resulting in serious injury and death (1). Indeed, since the report was published, there has been more widescale adoption of such systems. For example, by 2005 all public hospitals in Australia, the United Kingdom, and Ireland had incident reporting system (IRS) in place by mandate (4). The Joint Commission in the USA similarly requires all hospitals have and use an IRS. The World Health Organization (WHO) also actively promotes the reporting of AE to aid global healthcare learning and has published several landmark guidelines to that effect including "WHO Efforts to Promote Reporting of Adverse Events and Global Learning" (5) and "WHO's International Classification for Patient Safety" (6).

The purpose of an IRS in healthcare is to collect information regarding patient safety events (PSE), which can include both AE and near miss events (NME); those incidents where an error occurred during the administration of health care that did not lead to patient harm either through chance or through early detection of the error (2), so as to help determine the causal chain that led to the PSE as well as the consequences of the event (5). The information gathered through the IRS should then be analyzed to help identify the underlying causes and weaknesses in process that led to the PSE with a data-driven actionable plan then implemented to correct the root cause and thereby decrease or eliminate the number of PSE (5). Not only does fewer PSE clearly lead to improved healthcare and better outcomes for patients, but it also stands to dramatically impact the costs associated with health care. A study by Van Den Bos et al. in 2011 dubbed measurable medical errors the $17 billion problem, estimating that as the cost of PSE to the healthcare system in the USA alone (7). So, even a modest 10% decrease in PSE stands not only to benefit patients and their wellbeing but save the healthcare system billions of dollars worldwide. Another way reporting has been utilized is creating mandatory reporting on common specific AE termed Hospital Acquired Conditions (HAC), such as Central Line Associated Blood Stream Infections (CLABSI) or Catheter Associated Urinary Tract Infections (CAUTI) and holding healthcare organizations accountable for their rates of these events to provide them with incentive to implement systemic, organizational change to improve the safety of patients (8). For instance, Medicare reduces payments to hospitals commensurate with their numbers for the various HACs they define (9). This utilization of reporting appears to be effective, with data published by the Agency for Healthcare Research and Quality (AHRQ) in 2017 demonstrating a continued downward trend in HACs, with a

decrease of 13% from 2014-2017, representing approximately $7.7 billion in costs saved and ~20000 HAC-related inpatient deaths averted (10).

Encouraging data such as that put out by the AHRQ along with the success of IRSs displayed in other high-risk industries underscores the huge potential upside of IRSs in healthcare and gives reason for their wide scale adoption.

Critical safety incidents in high-risk industries are the norm and healthcare is no exception, with up to 10% of patients expected to experience an AE during their hospital stay (11). The problem within healthcare specifically is that 50% of these AE are deemed to be preventable, with both values possibly understating the incidence of AE given the prevalent inadequate reporting of patient safety incidents due to a lack of resources for evaluating both patient safety and the effect of safety interventions in place. To help mitigate underreporting of incidents due to concerns of punishment or legal ramifications, the Patient Safety and Quality Improvement Act (PSQIA) was passed in the USA in 2005 to provide legal protection for those front-line workers submitting the incident reports (12).

2. What classification systems are used for reporting?

Following the lessons of other industries and for the most effective data analyses of large-scale data, patient data input into IRSs should follow a common format. The WHO publishes guidelines in the attempt to standardize reporting in patient safety which is utilized in many countries, particularly in Europe, as a key resource before modifications to reflect the localized healthcare contexts (13-15).

The AHRQ created the Common Formats for Patient Safety for both collecting and reporting data and is one of the commonly used standards in the USA (16, 17). Another commonly utilized format was developed by the National Quality Forum (NQF), with more than half of US states utilizing at least some aspect of the NQF definitions in the reporting of AE (17, 18). Despite the variation that exists in the reporting of AE, common themes persist throughout the various formats that may help to shine light on the core requirements needed for a functioning IRS. Serious reported AE are those that are deemed preventable through widespread dissemination of guidance or safety recommendations for specific AE to provide systemic barriers to protect patients. When these guidelines are followed they should allow for the decline of the associated AE (19). The Keystone ICU Project that took place in Michigan in 2006 to research ways to reduce CLABSI are an example of this, with their 5 simple interventions in regards to central lines leading to sustained reductions in CLABSI at 18 months (20). These findings from the trial were later reflected in the CDC's Guidelines for the Prevention of Intravascular Catheter-Related infections. Those events that have occurred in the past and run the risk of recurrence have specific attention paid to them among the various frameworks for IRS (19). Reporting on avoidable or unexpected death or serious injury, or even the potential for these to occur is another common theme among different frameworks for IRSs, as are reporting on those events where there is potential for significant learning for the creation of guidelines or recommendations that would in turn reduce the incidence of the AE in question (19). Finally, incidents must be recognizable in clinical practice with clear demarcations between events such that they are quantifiable, classifiable, and feasible for inclusion in an IRS (19, 21, 22). In spite of these common themes among definitions and classifications of AE, inconsistencies abound and likely hinder the translatability of data across healthcare systems (23). With the enormous variation among patient populations and healthcare systems within one country like the USA, let alone internationally, some flexibility with regards towards standardizing definitions and reporting is required. The essential requirements of any IRS should be the capture of data on serious AE such that systemic learning may occur to prevent their recurrence (19).

3. What are the barriers of an effective IRS? What conditions foster a more effective IRS?

As beneficial as it is to have an IRS, there are some barriers that limit its implementation and efficacy. Such barriers include a lack of awareness of the reporting system (21, 22, 24-26). For example, in one survey conducted in the USA, they identified that 41% of internists were unfamiliar with the safety process in their institution (27). Similarly, providers also believe that reporting such incidents was too time consuming and the effort required to undergo reporting training was not futile (26). Other limitations of an effective IRS include fear of punishment, legal and financial penalties, lack of knowledge of what constitutes an error, and the belief that reporting does not actually improve patient outcomes (28-30). Interestingly, one survey found that 50% of physicians considered an incident too insignificant compared to approximately 40% of nurses (26). This suggests the type of provider and specific occupation can affect reporting. The same study also noted that over 50% of providers who did report, did not hear back from their institution and were unsure if their report was heard. This can hinder IRSs because providers are left in the dark as to if their complaint helped improve patientcare (26). There are also significant costs associated with implementing an effective IRS.

These costs are associated with training the providers on using the IRS, collecting data, and analyzing it (31). There is also sentiment that the money is better spent elsewhere, such as implementing best practices, instead of an IRS. Best practices include fall risk assessment, medication modification, and bed alarms, which can improve patient outcomes (31). Likewise, hospitals are not incentivized to report incidents because they are not financially compensated for it. Hospitals earn money for treating patients, not preventing errors

(32).

On the other hand, there are also many factors that can foster an effective IRS. A successful IRS requires an established aim of improving patient outcomes and this is done through a rewarding organizational culture, and competent data input, data analysis, and feedback (33). A successful organizational culture is one that is void of judgments and rewards its provider to report incidents. It should also support their providers and prioritize patient safety (34-36). Similarly, the institution should define what their goals are, in terms of patient safety, and these goals must be communicated. This can help providers be more comfortable in participating in an IRS (37).

Appropriate training should also be provided to healthcare providers as this can make them feel more comfortable and encourage reporting34. Next, incident report and data collection should be done in an efficient manner. Such strategies include a reporting time of less than five minutes, a user-friendly interface, and a concise reporting form (35, 38, 39). Data and report analysis is equally as important and should be done by experts in the field in a manner that is both comprehensive and prompt (36). This process should also be standardized and transparent (33). It is also helpful to not bombard the system with too many reports as this can hinder effective analysis. However, the IRS is essentially useless if there is no feedback. Thus, feedback should be provided to both the reporter as well as members of the institution (36). This can also include devising recommendations to prevent future errors, contacting institution vendors, and emphasizing the value of the initial report (39). Finally, other conditions that can facilitate a strong IRS include, provider protection, anonymous reporting, and compliant role models (40).

4. How cost effective are IRS, and how much do they cost to implement?

Earlier, we discussed the costs associated with implementing an IRS, which included training providers, collecting reports, and analyzing data. Moreover, we can focus specific costs that have been determined in the literature. In a retrospective study, medication incident reporting summaries from a pediatric hospital were analyzed to determine the staff time and cost needed to complete a report (41). This study found that each incident report completed cost $337.16. Furthermore, this study noted that the cost per minute for different types of healthcare providers. For instance, per minute of time devoted to incident reporting, nurse managers had a cost of $2.32, deputy managers had a cost of $1.98, staff nurse cost $1.67, and pharmacists had a cost of $1.57 per minute (41). The study also found that each completed incident report had ~19 staff inputs, including doctors, nurses, pharmacists, and managers (41). While a cost of $337.16 per incident form may not be extravagant when considering total healthcare costs, as well as the cost savings of improved patient safety, the higher cost may be associated through lost productivity hours from the large numbers of staff required to complete each form (41).

Interestingly, we can also take the next step in our review to discuss the costs associated with implementing safety practices to improve patient outcomes as this is also a common goal of IRSs. For example, one study examined the implementation of using erythropoietin to decrease transfusion-related adverse events. This had an expense of US $4,700,000 to avoid one adverse event from a transfusion reaction (42). Another paper focused on decreasing the likelihood of catheter associated bloodstream infection by comparing chlorhexidine gluconate and povidone-iodine antiseptics for the catheter site. They found that chlorhexidine gluconate was cost effective in that it saved CAN$ 9.98 per central line catheter and CAN$ 0.45 per peripheral catheter (43).

Similarly, another study demonstrated comparable results as they also found chlorhexidine was the financially sound choice saving CAN$209 per catheter (44).

One report examined implementation of a Keystone ICU patient safety program to decrease the rate of central line associated bloodstream infection (CLABSI). This study determined that the money spent when a CLABSI occurs can range from US$12,208 to $56,167. On the flip side, though, the cost needed to prevent a CLABSI is US $ 5,404. This shows this program is economically advantageous and results in a net positive financial stream (45). Another arena in which the economics of safety practices was analyzed included retained surgical foreign bodies. Various strategies were studied, which included no sponge tracking, standard counting, bar coded sponges, and so on. The researchers determined that in comparison to no counting, standard counting had a cost of US $1,500 for each foreign body detected. Bar-coded sponges, with respect to standard counting, had an associated cost of US $95,000 for each surgical foreign body detected (46). Lastly, it has also been estimated that implementing deep vein thrombosis assessment and medication prophylaxis can reduce costs by US $1.9 million, representing a very cost-effective measure to better patient care (47).

5. How effective are IRS in improving patient safety?

The goal of an IRS in healthcare is to track data of serious AE in order to drive quality learning that improves patient safety (5). Since the IOM report in 2000 they have become widespread among various healthcare systems internationally, and at no small cost, and naturally concern for measuring whether IRSs achieved these goals arose. When compared to other methods for tracking AE, with retrospective chart reviews being the most common alternative, interesting differences emerged. While both modalities appeared to capture serious AE, differences in the types of events became evident. For example, the IRS received data on equipment problems and AE related to handoff teams which did not appear in patients' medical charts, as well as data on NME (48). Whereas medical charts contained information on events including iatrogenic infections, unrelieved pain, and breathing

problems that did not appear in the IRS (48). Multiple studies found large differences in the numbers of incidents detected by IRSs when compared with retrospective chart review, with the fewer reports seen in the IRSs being attributed to chronic underreporting of serious AE (49-51). Two studies that compared IRSs equipped with standardized reporting formats to manual reporting of the same incidents found that IRS resulted in more complete documentation with greater utility (52, 53). These findings do not demonstrate that IRSs perform superiorly when compared to other common modalities, rather they seem to demonstrate the need for multiple avenues of recording and monitoring for serious AE, which appears reasonable when considering such a complex multifaceted issue as patient safety.

Healthcare may be viewed on a macro scale, nationally/internationally, through to an institutional level, down to the micro departmental scale (54). IRS driving change at the national level was seen primarily with drugs; following analyses of voluntary reports of warfarin usage in the USA from 2002-04 resulted in changes to patient care including increased monitoring and protocol changes (55), or the FDA routinely using reports of adverse drug reactions to guide updates to warnings and labeling, as well as the removal of drugs from the market entirely (56). At the institutional and departmental level reporting on AE drove change in different ways including remaking various guidelines and policies such as the implementation of checklists and time-outs before the administration of radiation therapy in a Chicago hospital (57) or requiring two people to sign off the dispensing of medications (58). IRS also spurred the adoption of technological innovation such as utilizing barcode technology to reduce the incidence of transfusion errors (59, 60) or having an electronic system allowing for pharmacy to immediately contact doctors who submitted erroneous orders to decrease the rate of prescribing errors (61).

6. Conclusion

IRSs are here to stay in today's healthcare institutions. While they may not have resulted in the advancements in patient safety that many hoped for, they represent an important portion of the overall effort towards tackling the heterogenous challenge presented by patient safety. With successful widescale adoption of IRSs in many countries, the focus now should be on standardizing the data received via IRSs and utilizing it for the implementation of patient safety interventions. Additionally, providing more ownership of IRSs at the departmental level is likely to improve frontline commitment to the IRS model as well as result in successful changes in processes and clinical settings to improve patient safety.

7. Declarations

7.1. Acknowledgement

None.

7.2. Authors' contribution

KK, SA, RP contributed to the conception and the drafting of the paper. MA participated and supervised the elaboration and every step of the paper writing process and as a corresponding author, will handle correspondence at all stages of refereeing, publication and post publication. All the authors contributed to drafting the manuscript and approving the final manuscript.

7.3. Conflict of interest

The authors declare that no competing interests.

7.4. Funding

None.

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