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Critical Review of HealthCare Incident Reporting Systems from the Perspective of Limitations, Barriers, Challenges, and the Impact on Patient Safety

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Abstract

Objectives:

1. Identify the importance of incident reporting.
2. Discuss the impact of incident reporting on medication errors.
3. Critically review the limitations and challenges of incident reporting.
4. Develop an idea of the best incident reporting methods.

Methods: A comprehensive critical literature review of international papers was carried out. The PubMed database was the primary source for retrieving documents and studies with various methodologies, including quantitative, qualitative, and mixed methods, using specific keywords, and determining inclusion and exclusion criteria.

Results: The critical review reveals that incident reporting systems led to exploring risk areas during healthcare procedures and steps. This significantly impacts medication safety, especially medication errors, so many countries have created incident reporting systems related to medication errors. There are multiple limitations, barriers, and challenges to reporting incidents by health care professionals, for example, lack of training, time, and feedback, furthermore, fear of litigation and disciplinary action of reporting. The best approach to incident reporting systems should enhance safety and motivate clinical staff to report without fear of consequences.

Discussion and Conclusion: Incident reporting systems are critical to discovering unsafe practices and procedures of health care organizations; in addition, all efforts should be undertaken by the health services organization to encourage professionals to report incidents. The reporting system should be designed to simplify reporting and ensure the safety of both staff and patients.

Introduction

Incident reporting is a well-known approach for enhancing safety in high-risk industries, such as commercial aviation, the rail industry, and others (Barach & Small, 2000a). In healthcare, incident reporting is "a process used to document occurrences inconsistent with routine hospital operation or patient care" (Aseeri et al., 2020). According to Anderson et al. (2013), incident reporting is a well-established process to improve patient safety in many countries worldwide.

In the United States, the National Academy of Medicine suggested adopting a patient safety reporting system (PSRS) to understand patient safety risks in healthcare facilities (Runciman et al., 2006). PSRS has been expanded universally through healthcare, for example, the Advanced Incident Management System under the Australian Patient Safety Foundation (Beckmann et al., 2003; Benveniste et al., 2005). In the United Kingdom (UK), the National Patient Safety Agency created the National Reporting and Learning System (NRLS) in 2003. This database has grown and receives over 1 million reports yearly in England. Such systems are becoming a compulsory requirement globally for governance and risk management. Sinclair et al. (2017) have stated that over 600,000 incidents were registered from October 2014 to March 2015 alone through the NRLS. Rooksby, Gerry, and Smith (2007) have emphasized that incident reporting is one of the main elements of operational risk management and a keystone for the National Health Services (NHS) organization in the United Kingdom. Furthermore, the financial loss due to the lack of incident reporting is a significant matter, according to NHS reports, with the additional cost of error in medication being around 2 billion pounds (Mahajan, 2010). Even with the extensive application of incident reporting, there is no substantial evidence that incident reporting has a massive impact on patient safety based on a recent assessment of incident reporting, which proposes an overestimation of its influence on patient safety (Vincent et al., 2008).

However, healthcare systems are vital in providing clients with the best healthcare services.

However, complications in medical technology and workload could make healthcare facilities a significant source of risk for patients themselves. Errors in medicine are common as they are in other life aspects. In the healthcare sector, although most medication errors have minimal harm to the patient, a few lead to severe complications and even death. According to the Institute of Medicine report, published in November 1991 under the title 'To Err is Human: Building a Safer Health System,' it was astonishing that about 100,000 deaths per year were related to medication errors (Bates et al., 2001).

Moreover, according to the study by Petschnig and Haslinger-Baumann (2017), the Institute of Medicine in the US announced that 44,000 to 98,000 Americans died because of medical preventable medical errors in 1991. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines medication error (ME) as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such events may relate to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use." (Aseeri et al., 2020).

There is a critical consideration of medication errors, being classified as one of the top ten causes of death. Interestingly, this came ahead of breast cancer and road traffic accidents. Consequently, procedures and healthcare professionals in healthcare settings were considered sources of risk to patients. Therefore, there is growing concern that medication error reporting is an influential instrument for evolving and maintaining mindfulness of medication errors within healthcare practice. It assists in clarifying the underlying roots of near-miss or error events that exacerbate risks in healthcare processes and procedures (Macrae, 2016).

However, developing and applying incident reporting systems in healthcare facilities is essential to minimize avoidable patient damage and harm and enhance healthcare safety locally and internationally (Barach & Small, 2000b). Although incident reporting systems have been a strategic tool to advance security and improve organizational care outcomes, under-reporting is one of the crucial causes that lessens the capability of Incident reporting systems to boost the safety of patients, for example in the USA, 50% to 96% of incidents are not recorded (Noble & Pronovost, 2010). It is projected that this practice leads to delays and hinders the main goals of reporting, which include exploring and prioritizing patient safety risks and learning opportunities from such incidents. Archer et al. (2017) have suggested that there are a lot of barriers and challenges that lead to under-reporting by healthcare professionals. Many international papers have mentioned the foremost reasons and obstacles to under-reporting. These include fear of consequences of their reporting, vagueness about what to report, and absence of feedback, in addition to failing to achieve the constructive impact of writing most of the time (Michel, 2003). To enhance incident reporting, it is a practical and logical option to consider healthcare professionals' views and perspectives towards Incident reporting barriers and limitations from two sides (personal challenges and obstacles, also organizational or system challenges) because the percentage of reporting is less than expected. For instance, in the United States, up to

14% of incidents have been reported based on a report from the Inspector General of the Department of Health and Human Services in 2012 (Carlfjord et al., 2018), with the nature of patient safety culture itself in the organization possibly being a reason for this. The culture of patient safety should encourage reporting views expressed by staff during an interview done by Espin et al. (2015). Espin et al. added that according to healthcare professionals' perspectives, there is a substantial gap between policy and practice in real-life scenarios. At the same time, Hewitt, Chreim, and Forster (2016) emphasized that there was conservable diversity in Incident reporting analysis, evaluation, and feedback when applying two Incident reporting systems in the same facility.

Although the traditional approach in medicine has been to identify the individuals making the errors and punish them somehow, it has become increasingly clear that focusing on the systems through which care is provided is more productive. The designs could be set up to make errors less likely and identify those that occur, thereby substantially improving patient safety (Bates et al., 2001). Furthermore, creating an easy access, flexible, and modern reporting system could encourage healthcare professionals to be keener and more adherent to submit incidents, which could intensify levels of patient safety and learning opportunities within healthcare settings.

This paper will aim to critically review Incident reporting in healthcare systems concerning its limitation and impact on patient safety, taking into consideration the following objectives:

1. Identify the importance of incident reporting.
2. Discuss the effect of Incident reporting on medication errors.
3. Critically review the limitations and challenges of incident reporting.
4. Develop an idea of the best incident reporting methods.

Methods

To meet this critical review's objectives, a comprehensive review of international literature was carried out, focusing on studies that addressed the subject of Incident reporting systems and their limitations in the healthcare setting. The literature review included several studies and papers with contrasting methodology patterns, qualitative, quantitative, and mixed methods.

The PubMed database was used to retrieve relevant publications on the studied subject. The search strategy was built on keywords that reflected the concept of this critical review. The used keywords were: Critical Incident Reporting System, Clinical risks, Literature review, Patient Safety, Risk management, Healthcare system, Pharmacist-initiated medication, Medication error, Incident reports, Pharmacist, reporting systems, Practical barriers, Incident-reporting system, Attitudes and barriers to incident reporting.

The period and language of publications were determined from 2006 to 2020 and in English only. In addition to the terms applied, the included studies had to meet the eligibility criteria as detailed below.

Inclusion criteria

1. Studies exploring the importance or significance of Incident reporting systems in any healthcare facility (primary, secondary, or tertiary) and employing any study design (qualitative, quantitative, mixed methods).
2. Studies that reflect the impact and influence of Incident reporting on medication errors.
3. Studies report the perspective of healthcare professionals about Incident reporting systems, their limitations, challenges, and barriers.
4. Studies that propose the desirable features and characteristics of healthcare incident reporting systems by healthcare professionals.

Exclusion criteria

1. Studies with deficient power or limited sample sizes (less than 20 healthcare professionals)
2. Studies published before 2010 and not in the English language.

3. Studies that have no connection with the keywords, the title, or the abstract.
4. Studies that did not specify the limitations and barriers by healthcare professionals (grey results).
5. Studies report data related to the disclosure of incidents to patients.

Results

Recently published papers have been reviewed to gain an in-depth understanding of the importance of incident reporting. For instance, (Fukami et al., 2020) conducted a retrospective survey study to understand the significance of Incident reporting by medical staff to enhance patient safety and general quality in health care. The authors have analyzed all registered reports extracted from the electronic Incident reporting database at a 1000-bed academic hospital from April 1st, 2015, till December 31st, 2019. The total number of incidents reported was 43,775 incidents. Medical doctors submitted 8% (2943) of them.

Interestingly, these incidents reflect more excellent value on patient safety. Nurses submitted 30,392 incidents and other health care professionals 6488 during the search duration. According to the authors, the importance of incident reporting has assisted in identifying high-risk areas in the hospital and the significance of Incident reporting, especially medical doctors, because most of the valuable patient safety events were reported by medical doctors. In addition, this effort of doctors (reporting incidents) simplified the management of chronic and acute injuries. Despite that, the incident reporting system cannot reveal the actual hospital-wide events, and it is a helpful instrument of a data resource that could help identify concerns about the potential risk to patient safety. The authors added that Incident reporting by medical doctors is crucial to show the community transparency of health care settings. One major drawback of this study is that all medical staff submitted these reports without mentioning specific inclusion and exclusion criteria. Indeed, it is essential to build a solid long-term relationship with the community, especially within the medical field. However, depending on one specialty, such as medical doctors, to be the richest source of health care safety is inappropriate. Each member of the healthcare system is essential, and ignoring their role has severe repercussions on healthcare safety in general, some studies for instance, Tricarico et al. (2017) have stated that doctors have not entirely accepted the Incident reporting system as a big window for advancement in patient safety within the hospital.

Petschnig and Haslinger-Baumann (2017) conducted a systematic review of literature on accessible public resources on Incident reporting to determine the influence of Critical Incident Reporting Systems (CIRS) on the safety of patients in healthcare settings. The authors used several databases involving Cochrane Library, Google Scholar, MEDLINE, PubMed, CINAHL, and Thieme e-book library, using a variable mixture of German and English Keywords. This search was held from October 28th, 2014, until May 25th, 2015. They included keywords: Incident Reporting System(s), CIRS, patient safety, near miss(es), near miss reports, Voluntary Reporting System, reporting system, reporting (and) learning systems, patient safety strategies, error reporting systems, and near miss reports effectiveness. The exclusion criteria included irrelevant papers and studies in addition to outdated data. Based on the inclusion criteria, 36 studies, six textbooks, and 14 technical reports were available for data analysis. CIRS reports were produced from diverse clinical resources such as the ICU nursing department, and nurses raised most pieces. At the same time, physicians seldom participated in submitting reports compared with other studies. The authors concluded a strong connection between the creation of CIRS in healthcare society and patient safety, despite the lack of a measurable relationship between both. Moreover, CIRS identifies and operates suitable actions and strategies concerning patient safety issues.

Howell et al. (2015) used a broader database to examine the importance of Incident reporting on patient safety. The authors used the National Reporting and Learning System (NRLS), created by the National Health Service (NHS) in England in 2003. They used a mixed methods approach for assessing NRLS data. The research participants included all reports of patient safety incidents from NHS acute hospital trusts from January 1st, 2003, to the end of May 2013. Primary care, mental health services, and specialist hospitals such as neurosurgical or pediatrics centers were excluded. The authors collected 5,879,954 incident reports from acute hospitals during ten years from 148 hospital trusts. Fortunately, 70.3% of collected incidents did not harm the patients, and only 0.9% were associated with extreme damage to health. Elderly patients over 65 years old composed 60% of incident issues. The most no-harm events were reported from Obstetrics and Gynecology [OR 1.61(95%CI: 1.12 to 2.27), $p<0.01$].

In contrast, near misses from pharmacy [OR 3.03 (95%CI: 2.04 to 4.55), p<0.01]. Reporting death was related to physicians more than other health care professionals [OR 3.04(95%CI: 2.43 to 3.80) p<0.01]. The authors stated that despite NRLS being a significant patient safety reporting organization worldwide, there was no association, *among other things*, size of the hospital, staff level, patient satisfaction or mortality outcomes, and incident reporting rate. This is clear based on several litigation claims that were not reduced when incident reporting increased. These results were also mentioned by Hutchinson et al. (2009), as there is no apparent connection between reporting rate and safety purposes. In addition, it reveals that increased staffing levels lead to less harmful incident reporting. On the other hand, doctors were the most significant source of death incident reporters, and it shows that healthcare professionals' views of the Incident differ from specialty to specialty. One of the limitations of this explanation is that it needs to explain why doctors are the most significant source of incident reporting and which are the aspects of difference in Incident reporting views, *among other things*, health care professionals. Anderson et al. (2013) designed qualitative research by utilizing documentary analysis and semi-structured interviews of 62 healthcare professionals with experience in reporting and analyzing patient safety incidents in two large teaching hospitals in London; the first was providing acute care, while the second was mental health services. The participants were equally divided into 31 participants for each facility. The author stated that incident reporting had a constructive impact on patient safety in acute and mental health settings. This impact was not limited to process and procedure changing but expanded to altering staff attitude and knowledge; it is also a vital process to enhance safety and consciousness of high-risk practices within health care systems. There were several limitations to this study; for example, the sample size and representative of hospital staff, most of them were in management and operational panels, and they had experience reviewing and learning from reporting and how to deal with reported incidents.

To discuss the impact of Incident reporting on medication errors particularly, Aseeri et al. (2020) conducted a study to evaluate and analyze medication error incidents. The descriptive analysis included 624 medication error reports extracted from the Safety Reporting System (SRS) of a 700-bed tertiary care hospital in Saudi Arabia from January 2015 to December 2015. The SRS applied a voluntary web-based form used by healthcare professionals to report any safety incidents, including medication errors. During the study period, 624 medication error reports were submitted. Most of the reported incidents were near misses (69.3%), which were intercepted before reaching the patients. Staff working in the inpatient setting reported medication errors more than in the outpatient setting (63.1%). High-alert medications were involved in almost half of the reported incidents (45%, n = 281). Medication errors occur at every step of the medication- use process. Dispensing was declared the most frequently involved stage in medication error (36.7%), followed by prescribing/ordering (34.1%). Proper utilization and analysis of medication error reports provide valuable insight into system-based pitfalls regardless of the care setting. This study showed that nearly half of the reported errors involved high-alert medications. Preventing them may be almost impossible, but reducing them should be a priority for directors of healthcare organizations. This study has revealed that Incident reporting significantly impacts patient safety, and it is an excellent tool for identifying system-based issues in the medication management system. As a solution and perfect strategy to minimize medication error and maximize the safety of medications, clinical pharmacists can assist healthcare professionals by reviewing medication dosages, gaining detailed medication history of patients, and conducting proper medication reconciliation (Bayazidi et al., 2012).

A systematic review was performed by Masmali et al. (2020) to evaluate the Medication Error Reporting and Monitoring Program (MERP) and its ability to inform how we ensure safety and prevention of harm to patients can be improved. The PubMed database was used for systematic search, and the main examination was conducted with the keywords "Medication Error Reporting and Monitoring Program" and "Medical errors." The inclusion criteria included international studies in the United Kingdom, Canada, Europe, New Zealand, and the USA) original articles, prospective and retrospective studies, cross-sectional studies, and surveys. As a result of this systematic review, The Canadian Society of Hospital Pharmacists initiated the national reporting program for medication errors (MEs). The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is concerned with reporting and prevention of ME incidences all over the nation. In Europe, the MERP provides a uniform method to report MEs. This program helps help healthcare professionals (HCPs) and practitioners across Europe to use medicines more safely. The European Foundation for the Advancement of Healthcare Practitioners (EFAHP) has developed Steering Committees in various European countries to examine adverse drug event issues. The Steering Committees are responsible for the specified countries' local medication safety knowledge programs. In the Unit-

ed States, MERP is a nationwide program wherein health professionals, who come across actual or potential MEs, can make a report to the United States Pharmacopoeia and are assured confidentiality and anonymity. MERP includes the data for various problems such as misinterpretations, miss administration, miscalculations, and difficulty interpreting handwritten orders. In New Zealand, the New Zealand Pharmacovigilance Center, which operates the Center for Adverse Reactions Monitoring program, developed a voluntary, web-based, confidential MERP to support learning more about MEs to prevent patient harm. The program is designed to capture and collate vital information about errors to identify priorities for improving medication safety quickly. It is hypothesized that incident reporting systems significantly impact medication errors, which is why many countries have developed suitable incident reporting systems related to medication errors to enhance their ability to limit medication errors and improve patient safety practices.

To explore the views and perspectives of healthcare professionals, in addition to determining limitations and challenges to incident reporting, a variety of studies have been conducted in the last few years. Gong et al. (2015) conducted semi-structured interviews and questionnaires of healthcare professionals in the Texas Medical Center to discover barriers and limitations to incident reporting. Thirty-four questionnaires were completed, and 16 interviews were conducted between April and July 2013. They included healthcare staff (physicians, nurses, managers, and technicians) with previous Incident reporting involvement. The authors came up with the main limitations according to the targeted person. There were four lacks associated with the incident reporting system which led to the restriction of reporting as stated by sampled staff:

1. Lack of instructions and training on patient safety reporting, i.e., there needed to be patient safety reporting drills. In addition, the aim and objectives of reporting Incidents should have been discussed with staff, which could affect the decision to register.
2. Lack of reporter-friendly classification, i.e., confusion in categorizing the analysis of patient safety events, affected the quantity and quality of the reports as stated by respondents.
3. Lack of time; one respondent stated, "Nurses are very busy. We must call the doctors, order X-rays, and care for the patients. And when we finish all the tasks, it is usually time for us to go home. There is just no time to write a report".
4. Lack of feedback; ten out of 16 participants (63%) did not receive any comment or feedback regarding what they had reported. On the other hand, 13 participants (81%) still need to obtain or remember any general patient safety status in their sections or organizations.

As mentioned by the Gong et al. study participants, lack of time and workload is a fundamental barrier to incident reporting, and this is a common factor among all healthcare professionals worldwide.

Varallo et al. (2018) used a conversation group approach consisting of ten multidisciplinary health teams. Each group included at least one member of each profession (social worker, nutritionist, physiotherapist, psychologist, Pharmacist, pharmacy technician, speech therapist, occupational therapist, physician, and nursing staff) to examine healthcare professionals' perceptions and behaviors regarding practice and procedure of incident reporting. The total number of participants was 65, and the RATS guideline (relevance, appropriateness, transparency, and soundness) was implemented. The authors have stated barriers to incident reporting, including the feeling of guilt resulting from the Incident that revealed inappropriate practice during health care procedures. In addition to ignorance of the Incident itself, especially for minor ones, and shyness in reporting incidents with no fundamental evidence, e.g., one participant stated, "I am not sure about which drug was responsible for the incident." The results also include a need for more feedback and the nonexistence of a culture that enhances reporting. The most remarkable finding of Varallo et al. was lack of accountability, i.e., there was a conception, *among other things*, participants that the nurse should fill out the reporting form, their role being only to refer the Incident to the nursing staff, for example, one participant stated that "I identify the incident and communicate it to the nurse." This concept will dramatically affect the quality and quantity of Incident reporting; above all, it will load nursing staff more and more. Evans et al. (2006) designed a cross-sectional anonymous survey of doctors and nurses from November 2001 to June 2003 in six South Australian hospitals to determine barriers to incident reporting. Nineteen possible reasons for limited reporting were given to the participants using the 5-point Likert scale (1=strongly agree, 5=strongly disagree). The authors have determined the main barriers and challenges for nurses to report were lack of feedback (61.8%), in addition, there was a belief of no need to report near misses (49.0%), moreover missing to write while the ward was too busy (48.1%). Nurses with five years of experience and more had

stronger belief of this than joiner nurses (52.5% v 44.0%; RR 1.19, 95% CI 1.06 to 1.34), although senior nurses had more knowledge to submit reports than junior ones (100.0% v 88.0%; RR 1.14, 95% CI 1.09 to 1.18). On the other hand, the main barriers to reporting from doctors' perspectives were lack of feedback (57.7%), time-consuming to complete reporting (54.2%), and a belief that the Incident was insignificant itself (51.2%), i.e., doctors tend to report when there is a severe incident. The author mentioned 80.9% of doctors would report wrong medication to patients, while 57.3% would report incidents related to unnecessary remedies. The author added that senior doctors had less trend to report significant incidents, for example, patient fall incidents vs. joiner doctors (38.1% v 74.4%; RR 0.51, 95% CI 0.30 to 0.87). They summarized that lack of feedback was the fundamental barrier to reporting for doctors and nurses (57.7% and 61.8%, respectively).

From previous study results, we are confident that the incident reporting system is suboptimal due to fear of lawsuits and disciplinary actions, which play a negative factor for health care professionals to submit incidents, moreover, lack of time and feedback.

Hewitt and Chreim (2015) used a qualitative study approach to interview 40 healthcare providers {8 physicians (Chief Physician, clinical observer, clinical reviewers, physicians), 15 registered nurses, registered practical nurses clerks, and others from different hospital departments} in a tertiary care hospital in Ontario, Canada. Their work focused on General Internal Medicine in the hospital. The recruitment of participants was based on recommendations from the Chief Physician and Clinical Director. The findings of Hewitt and Chreim reveal that when healthcare providers fix an issue related to patient safety, they forget to report it. This happens when encountering many scenarios, dealing with near misses considered worse to say, and facing repeated patient safety problems. The authors added that healthcare providers report the inability to solve that problem. They found that healthcare cannot report when the event could be solved.

Dhamanti, Leggat, and Barraclough (2020) employed a mixed methods approach using a concurrent quantitative and qualitative parallel design in three East Java provinces, Indonesia hospitals. The inclusion criteria were as follows: public hospitals that had obtained accreditation status within the last five years, hospitals that acted as the referral center for their area, and hospitals with 150-650 beds. Using the quantitative approach, the authors surveyed 1121 health workers with at least one year's experience. In this phase, the participants were from 11 hospital working units. The participants were divided into three categories: 1. witnessed an incident but had not reported it (non-reporting group) 325 (28.9%); 2. witnessed and reported an incident (reporting group) 341 (30.5%); 3. had not witnessed an incident 455 (40.6%). On the other hand, the qualitative phase included a phenomenology design using interviewing. It recruited 27 managerial and supervisor members from selected hospitals. The analysis of the authors' findings for the quantitative phase of reporting and the non-reporting group showed that the top four practical barriers to reporting among the non-reporting group were:

1. Did not know how to report, n=147 (45.2%).
2. Too busy, n=134 (41.2%).
3. Did not know where to report, n=127 (39.1%).
4. Lack of feedback, n=96 (29.5%).

On the other hand, the top four practical barriers, *among other things*, in the reporting group were:

1. Lack of feedback, n=177 (51.9%).
2. Too busy, n=138 (40.5%).
3. Did not know how to report, n=101 (29.6%).
4. Did not know where to write, n=94 (27.6%).

The significance between these two groups was linked to "Did not know how to report" and "Lack of feedback." In contrast, the main finding of the quantitative phase regarding cultural barriers was "did not want conflict" as the significant factor for reporting barriers. In the qualitative assessment, most of the interview participants (supervisory level) said a lack of knowledge and lack of socialization or training as practical barriers to reporting incidents. Furthermore, hesitancy and fear of reporting were stated as cultural barriers by

most of the interviewees. This study resulted in important findings. There were significant differences in professions and work units, and participation in quality and safety training, between those who reported incidents and those who witnessed incidents but did not report them. The quantitative and qualitative analyses revealed deficient knowledge was a significant practical barrier to reporting incidents. In addition, there was a discrepancy between the quantitative and qualitative findings related to practical obstacles. The survey results showed that lack of feedback was a significant barrier; conversely, the interviewed participants were more concerned about the lack of organizational socialization in the incident reporting system. One major criticism of Dhamanti, Leggat, and Barraclough's work is that the qualitative phase was limited to supervisors and managers, which reflects the upper management's point of view and not junior staff, which explains why they did not mention lack of time and workload.

Archer et al. (2017) conducted an extensive systematic theoretical framework to assess factors that act as barriers to incident reporting. The authors used an electronic search from three database resources: Embase, Ovid MEDLINE(R), and PsycINFO. These resources were comprehensively reviewed from 1980 until May 2014 for publications in the English language. A comprehensive search strategy, including MeSH terms and keywords, was developed to identify related articles. The inclusion criteria included studies reporting factors relevant to Incident registering engagement by any health care facility (primary and secondary care) and using any study methodology (quantitative, quantitative, mixed methods). Studies related to Incident reporting, the effectiveness of interventions to enhance safety, and studies related to disclosure of patient safety events were excluded, as well as studies with barriers and challenges in its result that needed to be clarified or determined. The literature searches of Archer et al. have identified 3049 possibly suitable articles. Only 110 pieces (76 quantitative, 21 qualitative, and 13 mixed- method studies) met the inclusion criteria. These 110 articles involved more than 29726 participants. The mean and median participant per study was 285.83 and 134.00, respectively.

Generally, 748 barriers were suggested by participants. These articles included views and perspectives of healthcare professionals from 4 continents and had more than 20 countries, with most studies from the USA (n=33), the UK (n=24), Australia (n=8), and Canada (n=8). The top three most frequent barriers to reporting incidents were: fear of adverse consequences (161/748), process and systems of reporting (110/748), and incident characteristics (92/748). The most common reasons for fear of adverse consequences were; fear of implications associated with incident reporting (51/161), fear of litigation (30/161), fear of blame (24/161), and fear of judgment (22/161). The most common reasons for the process and systems of reporting factor were; the time needed to complete incident reporting, the complexity of methods, and the confidentiality and privacy of reporters. Regarding incident characteristics that were cited as a barrier to reporting 92 times, level of harm, cause of Incident, and frequency of Incident were the most frequent Incident characteristics acting as barriers to reporting (40/92, 19/42, and 18/92, respectively). However, healthcare professionals were less likely to report an incident if the patient experienced no or minimal harm.

Although the authors tried to include multiple approaches for study design to maximize the generalizability to identify as much relevant literature as possible, they included quantitative, qualitative, and mixed-methods research and have not restricted the literature to specific Incident reporting systems, that is, departmental, local, regional and national. In addition, the studies included a vast array of healthcare settings and providers, maximizing the generalizability of the results. However, one question that needs to be asked is whether literature published after the last search could help test the validity of the theoretical framework. Furthermore, the development of incident reporting systems, particularly after 2017, could positively impact fear or repercussions of incident reporting.

Although the World Health Organization has developed multiple guides and recommendations to help countries to innovate their incident reporting systems to advance the safety of patients, deciding which incident reporting system is the best is a crucial question for all patient safety organizations worldwide to enhance efficacy and learning of reporting, in addition to engaging all health care staff in reporting. Okafor et al. (2015) researched to explore how a web-based, password-protected tool incident reporting system could improve incident reporting and patient safety at two sites receiving approximately 60,000 visits per year. This incident reporting system was voluntary, simple to use, non-punitive, confidential, timely, responsive, and system-oriented. Data entry was limited to a single page and standardized based on the Incident's nature. Emergency Medicine (EM) faculty, residents, and advanced practice providers (APP) had access to the system. All reported data was stored on a password-protected database accessible solely by the Quality Assur-

ance (QA) committee members. The outcomes of Okafor et al. showed that between March 2009 and December 2012, 1,229 incidents were reported.

The total Incident reports for 2009, 2010, 2011, and 2012 were 81, 177, 410, and 561, respectively. Compared to the Emergency Department (ED) visits over this period, the rate of reported incidents was 0.07%, 0.15%, 0.34%, and 0.44% for the fiscal years 2009 to 2012, respectively. Notably, the most commonly reported incidents were postponement of care and administration issues. EM faculty participants were amplified yearly; 33% reported an incident in 2009, while 76% reported an incident in 2012. Similar results were noted with resident and APP participation. Resident participation increased from 24% of residents reporting an incident in 2009 to 72% reporting an incident in 2012, and APP participation increased from 4% of midlevel clinicians reporting an incident in 2009 to 61% reporting an incident in 2012. The most significant advantage of this method is that error reporting frequency can be dramatically improved by using a web-based, user-friendly, voluntary, and non-punitive reporting system.

On the other hand, the main areas for improvement of the study are the failure to address a true denominator to measure error reporting rates. However, they provided a rate of incident reports compared to total emergency department visits for the respective years to elucidate that the reported incidents represented an increase in incident reporting. Moreover, it is very hard to outline the impact on patient outcomes of increased Incident reporting in this type of work.

To find the fundamental and strategic features of an internet-based Incident reporting system in primary care, Klemp et al. (2015) conducted a literature review by inviting international expert boards from different countries (United et al.) with experience in Incident reporting systems to review all relevant articles in the literature. The data from the literature review was summarized and given to the expert board, then used as background information to develop the best features for an incident reporting system for primary care. Articles published in English and German related to the development or implantation of incident reporting and publications, which gave lessons learned regarding personnel and organizational barriers and limitations that affect incident reporting processes, were included. Publications that discussed patient safety and reporting systems in a general manner were excluded. In order to determine the motivating factors of medical incident reporting, the expert group amassed recommendations on the desirable features of an incident reporting system for European primary care of the six dimensions that were retrieved from the literature review. The following requests were made on the hypothesis that the legal and social environment favors the application of reporting systems and acknowledges its importance for patient safety developments. The recommendations comprise six areas and refer to the literature search results.

Aims of reporting: To systematically gather analyses and take lessons from patient safety incidents.

To increase patient safety and patient safety culture.

The objective is not to produce a quantifiable record of actual events.

Reporting individuals

Any member of staff who observed or participated in a patient safety incident or its outcome.

Approach of reporting

Confidential, with the chance to report namelessly.

Design considerations

The system is planned to assist the reporting route and analysis via:

Easy access to the system.

A simple definition of the events to be reported.

Use of a standard classification system.

Use of individual and aggregated data.

Web-based, supporting safe printouts (without identifiers).

To be launched locally and linked with other systems if desired.

Feedback

Three types of feedback are required:

To the individual reporter to acknowledge the effort ('Thank you for the report' and details how it will be processed).

Feedback to a target group (e.g., physicians or laboratory staff) with the purpose of learning from it. This will encompass details of the analysis and the subsequent explanation.

The overall feedback to the community to reassure cultural change and stimulate reporting and learning.

Cultural and legal preconditions must be satisfied if the system is to be effective:

Non-punitive: Reports cannot deliver the foundation for lawful action vs. those who participated in an incident and should not be used in a court of law.

A just or no-blame-cultural environment, including admiration for professional responsibility.

Robust management throughout the practice or organization by management and respected front-line staff.

A shared understanding of a patient safety incident and the aim of incident reporting.

One major criticism of Klemp et al. work is that the development of the recommendations and the subsequent reporting model were based on the experiences of an expert team that came from only some European countries. However, the authors tried to overcome this shortcoming by not restricting the literature search to specific countries.

Naomi et al. (2020) conducted a cross-sectional study at Mbarara Regional Referral Hospital (MRRH) in Southwestern Uganda to explore features of medical Incident reporting practices, which inspired factors that could engage healthcare providers and motivate them to practice reporting incidents. The sample size involved 158 Health care workers from different specialties (doctors, clinical officers, nurses, dispensers, laboratory personnel, pharmacists, theatre assistants, and anesthetists) who were interviewed. The included participants needed at least one year's experience at MRRH. The authors discussed the motivation factors from two sides. Firstly, personnel motivating agents had; prizes and inducements to health workers, sound communication systems, corrective action in the design, training of health workers on incident reporting, support from the administration, and knowledge of incidents.

The second aspect was organizational factors which involved; the existence of a reporting system, the presence of written guidelines, the company of an open-door policy, the presence of a no-blame approach, and the practice of teamwork. The presence of a reporting system stimulates incident reporting, the presence of written guidelines and standards of incident reporting promotes reporting in the organization, the implementation of teamwork in hospitals and health care facilities promotes incident reporting, and ease of access to ward in-charges and administrators (open door policy) influences incident reporting, the practice of no-blame attitude to those who report incidents powers incident reporting.

Again, the World Health Organization's characteristics of successful incident reporting, non- punitive, confidential, independent, expert analysis, timely, system-oriented, and responsive (World Health Organization, 2005), maybe the backbone of any reporting system worldwide. However, it has to be taken into consideration that incident reporting systems have to be consistent with the practice

scope of the organization in addition to its vision and mission, viz reporting systems in primary care may be different from secondary and tertiary care, furthermore they may differ from department to department within the same organization.

Discussion and Conclusion

Incident reporting is a vital process to discover areas and practices of risk within healthcare facilities. In addition, it reflects transparency and trust between community and healthcare organizations. This system can assist in obtaining data on safety incidents from practices of daily work routines to convert them into safer practices. Moreover, it could help in changing unsafe rules and regulations.

Incident reporting systems also have a central impact on medication errors, as long as numerous errors occur repeatedly, especially in inpatient settings. However, many errors continue to appear in different healthcare facilities, and implementing new technologies, such as electronic health records and computerized physician order entry, also brings many new challenges. To build a safer healthcare system, learning from previous errors is essential. These medication errors can be collected from several resources, such as direct observation, claims data, administrative databases, and chart review. Although the recurrence of these medication errors is usually related to inappropriate workflows during the medication distribution process, incident reporting systems provide an excellent opportunity to improve the quality of patient care and further understand the nature and root causes of medication errors.

Healthcare providers' progressive engagement in an incident reporting system is pivotal for ongoing system growth. This engagement could reach high levels if we worked on barriers, challenges, and limitations to report incidents, viz fear or worry. Disciplinary actions due to reporting incidents are fundamental barriers to reporting; lack of training on what, how, and where to say is another main limitation. Furthermore, a lack of feedback on what healthcare professionals have written would negatively affect reporting. For these reasons, reporting should be non-punitive, confidential or anonymous, independent, timely, systems-oriented, and responsive, and it should enable a systematic root cause analysis.

The system of Incident reporting itself should also be designed in a modern manner to encourage reporting by focusing on functions that effectively support the improvement of patient safety so that the reporters would better accept the system. Timely analysis of reported incidents is also a vital feature of the system. The system should generally consider individual weaknesses and workflow-procedure pitfalls, which can be extracted from reported incidents to be analyzed and reviewed.

In summary, having an incident reporting system is vital to explore unsafe practices and procedures of health care organizations. Hence all efforts should be undertaken by the health services organization to sensitize professionals to report incidents, and, more importantly, they should feel safe and be recognized in this participation and realize that reporting is worthwhile. In addition, more effort is needed to make reporting more accessible and less bureaucratic and to invest and take advantage of the learning opportunities that arise from incident reporting systems to expand the safety field of health care.

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