Reflections on patient safety incident reporting systems

Reflexões sobre sistemas de notificação de incidentes de segurança do paciente

Reflexiones sobre sistemas de notificación de incidentes de seguridad del paciente

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ABSTRACT

Objective: To reflect on the main characteristics and recommendations of Incident Reporting Systems, discuss the population's participation in reporting, and point out challenges in the Brazilian system. **Method:** Reflection study, based on Ordinance No. 529/13, which instituted the National Patient Safety Program, under Collegiate Board Resolution (CBR) No. 36/13; reflections by experts were added. **Results:** Reporting systems are a source for learning and monitoring, allow early detection of incidents, investigations and, mainly, the generation of recommendations prior to recurrences, in addition to raising information for patients and relatives. There is little participation of the population in the reporting, regardless of the type of system and characteristics such as confidentiality, anonymity, and mandatory nature. **Final Considerations:** In Brazil, although reporting is mandatory, there is an urgency to advance the involvement and participation of the population, professionals, and institutions. To simplify data entry by improving the interface and importing data from the reporting system is an objective to be achieved.

Descriptors: Health Services; Patient Harm; Patient Safety; Hospital Administration; Patients.

RESUMO

Objetivo: Refletir sobre principais características e recomendações de Sistemas de Notificação de Incidentes, discutir a participação da população na notificação e pontuar desafios no sistema brasileiro. **Método:** Estudo de reflexão, com base na Portaria nº 529/13, que instituiu o Programa Nacional de Segurança do Paciente, na RDC nº 36/13; acrescentaram-se reflexões de especialistas. **Resultados:** Os sistemas de notificação são fonte para aprendizado e monitoramento, permitem detecção precoce de incidentes, investigações e, principalmente, geração de recomendações ante recorrências, além de suscitar informações para pacientes-familiares. Existe pouca participação da população nas notificações, independentemente do tipo de sistema e de características como confidencialidade, anonimato e obrigatoriedade. **Considerações finais:** No Brasil, embora a notificação seja obrigatória, é urgente avançar no envolvimento e participação da população, profissionais e instituições. Simplificar a inserção de dados melhorando a interface e a importação de dados do sistema de notificação é um objetivo a ser alcançado.

Descritores: Serviços de Saúde; Dano ao Paciente; Segurança do Paciente; Administração Hospitalar; Pacientes.

RESUMEN

Objetivo: Reflejar sobre principales características y recomendaciones de Sistemas de Notificación de Incidentes, discutir la participación de la población en la notificación y puntuar desafíos en el sistema brasileño. **Método**: Estudio de reflexión, con base en Decreto nº 529/13, que instituyó el Programa Nacional de Seguridad del Paciente, en la RDC nº 36/13; acrecentaron reflexiones de especialistas. **Resultados:** Sistemas de notificación son fuente para aprendizaje y monitoreo, permiten detección precoz de incidentes, investigaciones y, principalmente, generación de recomendaciones ante recurrencias, además de suscitar informaciones para pacientes-familiares. Hay poca participación de la población en las notificaciones, independientemente del tipo de sistema y de características como confidencialidad, anonimato y obligatoriedad. **Consideraciones finales:** En Brasil, aunque la notificación sea obligatoria, es urgente avanzar en envolvimiento y participación de la población, profesionales e instituciones. Simplificar inserción de datos mejorando interface e importación de datos del sistema de notificación es un objetivo.

Descriptores: Servicios de Salud; Daño al Paciente; Seguridad del Paciente; Administración Hospitalaria; Pacientes.

INTRODUCTION

Health care incidents happen with unacceptable frequency and affect patients who seek health services to prevent, diagnose, treat, or rehabilitate themselves. When an incident, with or without damage, occurs, it is essential to understand the causes and contributing factors, as well as their consequences, to enable the development of mitigating actions and solutions that could prevent it. An incident is defined as an unintentional circumstance or error that caused or could have caused damage to the patient[1].

20 years after the publication of the report *To Err is Human*: *Building a Safer Health Care System*, which revealed the weaknesses of health services in the United States of America (USA), many actions and campaigns were developed and implemented, in several countries, in favor of patient safety (PS). Despite the progress, it is necessary to move forward so that institutions learn from past mistakes, work as a team, improve the training of health professionals, apply evidence-based knowledge, and listen to patients and family members[2].

In this scenario, the incident reporting systems (IRSs) appear as a strategy that helps in the identification of risks, contributes to data collection, analysis, and implementation of a PS culture[1]. IRSs main objectives are: to promote the return of information to reporting parties, associating the results obtained with the preventive measures and detection of risks in care; determine the causes of incidents; and propose safe harm reduction practices[1]. The IRSs, sometimes called critical incident systems, or PS learning systems, are defined as structured reports with grouping and analysis of reported incidents in health services[3].

For some years, health IRSs have focused on classifying incident occurrences for statistical purposes to provide a basis for political decision-making. Over time, and due to the increase in publications in the field, it was noticed that the comparison of data collected in different systems and countries has become difficult, in view of the lack of consensus in the concepts used in these systems in regards to the standardizing of classification[1].

Brazil has an IRS called NOTIVISA 2.0 (Health Care module), instituted from the publication of Ordinance No. 529, of April 1, 2013, which established the Programa Nacional de Segurança do Paciente (PNSP) [National Patient Safety Program][4]. Subsequently, CBR No. 36/2013[5] was published, which provides guidance on the operationalization of the PNSP. The national IRS enables reporting done by citizens, health professionals, and by the Núcleos de Segurança do Paciente (NSPs) [Patient Safety Centers], a health service instance created to promote and support the implementation of actions aimed at PS. Citizen reporting is voluntary, while reporting of adverse events (AEs) by NSPs is mandatory. The data are analyzed by the Agência Nacional de Vigilância Sanitária (Anvisa) [National Health Surveillance Agency] and disseminated in aggregate in specific bulletins for this purpose[4-5].

Prior to the creation of the aforementioned IRS, there are several initiatives on PS that were implemented with or without an IRS, such as the Programa Nacional de Acreditação Hospitalar [National Hospital Accreditation Program], Rede Sentinela [Sentinela Network], Política Nacional de Segurança com Hemoderivados [National Security Policy for Blood Products], Programa Nacional de Avaliação em Serviços de Saúde [National Health Services Evaluation Program],

among others. It is believed that the reflection proposed in this text goes through the importance of IRSs as a source for learning, monitoring trends, and underlying patterns to allow early detection of incidents, investigations and, mainly, generation of comprehensive and contemporary recommendations to be made in case of possible recurrences, as well as to provide accurate information to patients and/or family members about reported incidents.

OBJECTIVE

To reflect on the main characteristics and recommendations of Incident Reporting Systems (IRSs), discuss the population's participation in the reporting, and point out challenges in the Brazilian reporting system.

METHODS

This is a reflection study, built on the basis of Ordinance No. 529, of April 1, 2013, from the Ministry of Health, which instituted the PNSP and considered the priority of PS in health services on the political agenda of the WHO Member States, of which Brazil is a part[4].

This reflection was also based on CBR nº 36, of July 25, 2013, which instituted, among other actions, that of surveillance, monitoring, and notification of AE by health services, through the electronic tools provided by Anvisa, constituting an online reporting system, with a guaranteed return to the reporting units[5]. In addition to this legal documentation, reflections on IRSs were added by experts in PS, members of the Rede Brasileira de Enfermagem e Segurança do Paciente (REBRAENSP) [Brazilian Network of Nursing and Patient Safety]; and those extracted from literature review.

The text is organized in three parts: the first, on characteristics and recommendations of IRSs in different countries, followed by the participation of the population in the reporting of incidents and, finally, on the challenges for the Brazilian incident reporting system.

RESULTS

Characteristics and recommendations of incident reporting systems

Among the main characteristics of the IRSs, we can highlight data confidentiality, the anonymity of the person who is reporting, and the mandatory reporting of incidents, as determined by specific legislation[1]. Another relevant aspect, which results from the proper functioning of an IRS, is the development of the PS culture, in which management and other professionals involved in patient care take responsibility for their own safety, colleagues, patients, and family members[4]. As previously pointed out, a worrying fact about reporting is the lack of uniformity in what is being notified, because, when it is performed, important information is left out or lacking details.

To facilitate uniformity in reporting systems, the WHO standardized the minimum information model, called the *Minimal Information Model for Patient Safety Incident Reporting and Learning Systems* (MIM OS), or Modelo de informações mínimas para a notificação de incidentes e sistemas de aprendizagem para SP (MIM SP) [Minimum information model for incident reporting and learning systems for PS], in order to present a list of categories of

minimum information that must be collected when reporting an AE[1].

IRSs are complex and the professionals involved in their processes face difficulties, mainly in learning from the reporting generated[6]. From this perspective, the main issues to be discussed are: At what level of governance should reporting systems operate? Whose responsibility is it to determine the reporting obligatoriness? When can it be voluntary? What type of incidents should be reported? How to ensure that reporters are not penalized[1]? Based on the understanding and clarification of these issues, it is possible to know the dimension of the problem, investigate, and analyze the data obtained, in addition to enabling the development of solutions for its prevention.

In the publication of the subgroup *The reporting and learning system* of the working group *Patient Safety and Quality of Care*, of the European Commission, the authors cite the main characteristics and recommendations for the construction and viability of IRSs, listed below[6].

Chart 1 - Characteristics of incident reporting systems in some European countries as to who is authorized to report incidents and their legal regulation

Country	Health professionals	Health organization	Patients	Others	Public	Regulated by law
Austria	Voluntary	No	No	No	No	No
Belgium	Voluntary	No	Voluntary	No	No	Partially
Croatia	Mandatory	No	Voluntary	No	No	Partially
Cyprus	Voluntary	No	No	No	No	No
Czech Republic	Voluntary	No	No	No	No	No
Denmark	Mandatory	No	Voluntary	Voluntary	No	Yes
Estonia	Mandatory	No	No	No	No	Partially
France	Mandatory	No	Voluntary	Voluntary	Voluntary	Partially
Germany	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	-
Hungary	Voluntary	Voluntary	No	No	No	No
Ireland	Mandatory	Yes	No	No	No	Partially
Italy	Mandatory	Yes	No	No	No	Partially
Latvia	Voluntary	No	No	No	No	Partially
Luxembourg	Voluntary	No	No	No	No	No
Netherlands	Voluntary	No	No	No	No	Partially
Norway	Mandatory	No	No	No	No	Yes
Slovakia	Voluntary	Mandatory	No	No	No	No
Slovenia	Voluntary	Mandatory	No	No	No	No
Spain	Voluntary	No	No	No	No	No
Sweden	Mandatory	Mandatory	Voluntary	Voluntary	Voluntary	Yes
United Kingdom	Voluntary	Mandatory	Voluntary	Voluntary	Voluntary	Partially

Note: Adapted from the European Commission, Patient Safety and Quality of Care working group. Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe, 2014[6]. Translation performed by the authors.

1. There are mandatory and voluntary IRSs in the Member States of the European Commission. Each type of IRS has its advantages and disadvantages.
2. A mandatory IRS must be accompanied by regulations on sanction exemptions for the reporter and clear rules on data confidentiality.
3. The types of incidents that can be reported vary. However, a broad definition allows for the reporting of any incident, including near misses and incidents da do not result in damage, providing a valuable resource for learning and system improvements.
4. All health service workers, and not just health professionals, must be able to report incidents related to PS.
5. Reporting by patients and family members should be encouraged, as they are important resources for learning and improving PS.
6. IRSs must be separated from complaints, disciplinary actions, and litigation procedures. Health professionals who report incidents must be protected from disciplinary or legal actions. The confidentiality of the reporter and anonymity of data must be ensured.
7. Anonymous reports must be published regularly; and learning, widely disseminated, to support the development and monitoring of initiatives to improve patient safety and prevent incidents.

It is worth illustrating characteristics of IRSs in some European countries, such as: whether reporting is voluntary or mandatory, who is authorized to report incidents, and whether they are regulated by laws (Chart 1)[6]. This table helps analyze the progress of the national system in comparison with international implementations.

The United States of America (USA) does not have a single IRS, but 21 of the 50 states operate it on a mandatory basis, and in many, it has been a requirement for decades. In addition, the types of reportable events vary widely. In Brazil, IRSs are found both through public initiative[4] as well as private initiative, as well as in the National Accreditation Organization System, by ONA Integrare, among others with different levels of support, participation, and functionalities.

In order to make better use of IRSs, it is important to comply with the following steps in order to favor the analysis of data in the system[7].

1. Data entry: there must be a culture of independent and non-punitive learning;
2. Data collection: the way in which information is collected and handled is important to determine the quality of reporting;
3. Data analysis: IRS data should be analyzed to determine lessons learned and improvement measures and trends;
4. Feedback: must address specific vulnerabilities, disseminate lessons learned, and address improvement measures to individuals and organizations;

5. Monitoring the effects of the measures adopted and their contribution to changing the attitude and knowledge of the people involved.

In practice, the success of IRSs also runs through issues related to the reporting party, which can be understood as impeding factors for reporting: punitive institutional culture, a complicated reporting process, lack of anonymity and confidentiality, increased work load and hours, lack of clarity and definition of who and what to report, fear of negative response and of being seen as incompetent by coworkers, not believing that the incident could happen again, assuming that the incident has happened before and has already been reported, a lack of feedback and belief that reporting will lead to change[7].

IRSs and their reports have recognized value when a constructive response is obtained and health professionals note that the institution is willing to change based on their comments, thereby contributing to the solidification of the safety culture. According to the WHO, the most important measure for the success of IRSs is the use of the results of the analysis of the reported incidents to formulate preventive measures and recommendations for changes in the system, as well as to return the data analysis to the reporting parties[1].

The participation of the population in incident reporting

Patients and families can provide information about the success and failure of care, perceptions that are rarely detected by other methods. According to the WHO, reporting can be done by health organizations, caregivers, professionals, patients, family members, or even by consumer protection agencies[1]. In Brazil, notifications from patients and families became possible with the creation of the IRS, however they are still rare. A research carried out in Denmark, whose IRS has been in effect since 2004, shows that the number of reporting filled out by patients are also low[8].

To improve this scenario, healthcare professionals should encourage patients and families to report security incidents from their perspective, in order to help healthcare organizations broaden their understanding of the location of failures and gaps, as well as to identify their causes and mitigate damage. Improvement actions can be implemented, namely: involving the patient and family in the therapeutic plan, while changing shifts at work, in the transfers of care between units (*handovers*), at hospital discharge, in home care, and in referral to other levels of assistance. An interesting experience was cited by the Great Ormond Street Hospital for Children, in London, which uses the Self-reporting Real-time Bedside instrument, in which patients and families can report the incident, and the information is analyzed on the same day by an institution committee, which makes immediate improvements in assistance and feedback to the reporting party[9].

Data collection, performed routinely with patients, is also considered a strategy to encourage the reporting of incidents by the population. Patient participation represents a unique and valuable perspective on their own care, planned and unplanned, which contributes to learning and to creating people-centered health services. This information can be obtained through questionnaires and pre-established questions in a simple and quick way, or just through active listening during the performance of care, valuing the effective communication between patient, family, and professional[7].

It is worth noting that the IRS reporting form, to be used by patients and family members, must meet the needs of this population, which has little knowledge of technical terms and does not receive training in its use. It should be emphasized to patients and family members to be aware that the reporting of incidents is not a formal complaint for litigation procedures[6], but, rather, contributes as a lever to improve care and safety.

Challenges to the Brazilian incident reporting system

The challenges to the IRS in Brazil include: 1) speed up the implementation of the PNSP; 2) implement the multiprofessional composition, maturity and strengthening of NSPs; 3) strengthen the PS culture; 4) evaluate the current system, which includes the quality of the information obtained, in order to promote the learning of professionals and the improvement of the organization's systems and processes; 5) expand information on the existence of and possibility of anonymous reporting, for professionals and users; 6) generate constructive feedback, that is, with recommendations for reporters, among others.

As a reflection of the aforementioned challenges, it is worth remembering that, in Brazil, according to CBR nº 36, the reporting of incidents is mandatory in health institutions, at all levels of complexity, with the exception of medical practices, clinical laboratories, mobile services, home, and long-term care[5]. In agreement with other researchers, it is understood that the national strategy to make the implementation of the PNSP mandatory is positive, since it encourages institutions to take responsibility for its learning and reorganization, according to the reported incidents, being that an approximation with reality facilitates decision making[10].

Our country has approximately 134,000 health institutions that meet the mandatory criteria, of which at least 6,760 are hospitals. However, the number of NSPs, according to the latest disclosure by ANVISA, is 4,356, and the number of NSPs that made at least one notification was only 1,664[11], suggesting that the creation of these nuclei may have happened only to comply with legislation, and was not, in fact, incorporated as an effective tool, capable of generating changes in the health system and consolidating a culture of safety. In this sense, it is believed that, six years after the current legislation on IRS was promulgated, with intense dissemination, there is no more space for its non-compliance and that, perhaps, it is necessary to bring state and municipal surveillance services closer to institutions of health, with the purpose not only of inspecting, but also of developing partnerships, given the importance of this for the safety of users in health systems.

The national IRS has a complex navigability and raises doubts for the reporting party as to the correct place to report and in specifying the type of incident. It is noteworthy that this IRS should be unique or have a single platform, to facilitate the details of the incident when filling in the fields and sending the data, as the current reporting procedure occurs on three different bases: NOTIVISA 1.0, NOTIVISA 2.0 and, recently, VigiMed. An important aspect to be considered is that damages can lead to the judicialization of cases,

in the pursuit of material and/or moral damages and, consequently, property losses of the institutions or professionals involved. On this subject, just in 2016, according to the data from the Report of the National Council of Justice, 57,739 cases related to medical errors were processed in the courts of Brazil[12]. This report does not define what is classified as a medical error, but it probably considers all the clinical errors that motivated the opening of cases. Due to the judicialization of cases, IRSs must guarantee the confidentiality and protection of data to protect professionals and dispel the fear of reporting, retaliation, and exposure.

Regarding the culpability of the professionals involved in AE, there has been an evolution in this direction, with analysis in light of accountability. Currently, three countries have legislation that, in addition to focusing on patient safety, also protects professionals from legal proceedings: Denmark (2004), United States (2005 and 2016), and Italy (2017)[13].

Italian law is based on three principles: safety is a right for everyone in any health service; if the guidelines and safe practices, established by the National Institute of Health, are observed, the professional will be protected from lawsuits, including in case of adverse results; and legal actions against professionals will only be possible when there is malice or serious negligence[13].

Brazil needs to move forward in terms of protecting the professionals involved in AE, although compliance with legislation regarding patient safety and the investigative role of class councils is observed.

Contributions to the Nursing field

The reflection study highlights the importance of IRSs as a source of learning and, in turn, of incident prevention by nursing teams.

FINAL CONSIDERATIONS

Most IRSs studied share characteristics such as guaranteeing data confidentiality, the reporter's secrecy, and the mandatory nature of reporting. The participation of the population in the reporting of incidents is encouraged, as the importance of the information that patients and families can provide is recognized; nevertheless, reports have shown minimal percentages, both in Brazil and abroad. Among the main challenges for the Brazilian incident reporting system is the strengthening of NSPs, the unification of the platform to carry out reporting, and the consolidation of the safety culture. And for better system viability, it is recommended that a distinction be made between incidents and complaints, disciplinary actions and litigation procedures.

IRSs should enable the generation of reports automatically and add value to their implementation; to do so, it is necessary to make the use simpler, prioritize the events to be reported, measure the progress made through the analysis of the records, and give feedback with recommendations to the reporting parties, allowing them to create barriers and mitigate risks. It is worth shedding some light to the fact that the existence of different IRSs in Brazil creates operational difficulties for professionals in the analysis of reporting and, consequently, in the construction of public policies aimed at safe care.

It is hoped that, with the information, involvement, and participation of the population and health professionals, associated with the maturity acquired over time and the accumulated experience, the national IRS, as well as other existing IRSs in health institutions can improve currently conflicting and/or diversified aspects; and they can also contribute to the construction of a safe practice environment, which makes it possible to reduce risks for all.

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