Review Article

Facilitating and hindering factors for reporting adverse events: an integrative review

Fatores facilitadores e dificultadores da notificação de eventos adversos: revisão integrativa

Factores facilitadores y dificultades en la notificación de eventos adversos: revisión integradora

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Abstract

Objective: To analyze the evidence available in scientific literature about hindering and facilitating factors for adverse event reporting.

Methods: This is an integrative literature review, with the guiding question based on the acronym PCC (Problem, Concept and Context): which factors facilitate and hinder that interfere with adverse event reporting in health services? The Preferred Reporting Items for Systematic Reviews and Meta-Analysis was used as a guide to report the review method; inclusion criteria were publications of primary studies between 2015 and 2019, in Brazilian Portuguese and/or Spanish and/or English. Publication search took place in March 2020 at the Virtual Regional Health Library, using "*erros médicos*" (medical errors) OR "*erros de medicação*" (medication errors) AND "*notificação*" (reporting), and in the National Library of Medicine and SCOPUS, using "risk management" OR "safety patient" AND "mandatory reporting".

Results: A total of 2,195 studies was found, of which 31 were eligible; after reading in full, 11 comprised the final sample. The facilitating factors were grouped, namely: institutional support to professionals; organizational safety culture; reporting system improvement; incentive to voluntary and confidential report. The hindering factors: lack of material/human resources; fear/shame; punitive institutional posture/lack of protection; lack of encouragement to reporting; gaps in knowledge.

Conclusion: The synthesis of these factors can be used to optimize care and management measures with the provision of material, personal resources, training and promotion of a safety culture, with a view to encouraging reporting, seeking reliable indicators of these injuries.

Resumo

Objetivo: Analisar as evidências disponíveis na literatura acerca dos fatores dificultadores e facilitadores para a notificação de eventos adversos.

Métodos: Revisão integrativa da literatura, com a questão norteadora embasada no acrônimo PCC (Problema, Conceito e Contexto): quais os fatores facilitadores e dificultadores que interferem na notificação de eventos adversos em serviços de saúde? Utilizou-se as diretrizes *The Preferred Reporting Items for Systematic Reviews and Meta-Analysis* como guia para reportar o método de revisão; os critérios de inclusão foram publicações de estudos primários entre 2015 e 2019, nos idiomas português e/ou espanhol e/ou inglês. A busca das publicações ocorreu no mês de março de 2020, na Biblioteca Regional Virtual de Saúde, com a estratégia "erros médicos" OR "erros de medicação" AND "notificação" e na *National Library of Medicine* e SCOPUS com "*risk management*" OR "*patient safety*" AND "*mandatory reporting*".

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Conflicts to interest: none.

Resultados: Foram encontrados 2195 estudos, dos quais 31 eram elegíveis; após a leitura na íntegra 11 compuseram a amostra final. Os fatores foram agrupados, sendo os facilitadores: apoio institucional aos profissionais; cultura de segurança organizacional; aprimoramento do sistema de notificação e incentivo ao relato voluntário e confidencial. Os dificultadores: falta de recursos materiais/humanos; medo/vergonha; postura institucional punitiva/falta de amparo; falta de estímulo à notificação e lacunas no conhecimento.

Conclusão: A síntese desses fatores pode ser utilizada para otimizar medidas assistenciais e gerenciais com provimento de recursos materiais, pessoais, capacitação e promoção da cultura de segurança, com vistas ao incentivo a notificação, buscando indicadores fidedignos desses agravos.

Resumen

Objetivo: Analizar las evidencias disponibles en la literatura acerca de los factores facilitadores y dificultades para la notificación de eventos adversos.

Métodos: Revisión integradora de la literatura, con la pregunta orientadora basada en el acrónimo PCC (problema, concepto y contexto): ¿Cuáles son los factores facilitadores y las dificultades que interfieren en la notificación de eventos adversos en los servicios de salud? Se utilizaron las directrices *The Preferred Reporting Items for Systematic Reviews and Meta-Analysis* como guía para reportar el método de revisión. Los criterios de inclusión fueron publicaciones de estudios primarios entre 2015 y 2019, en idioma portugués, español o inglés. La búsqueda de las publicaciones se llevó a cabo en el mes de marzo de 2020, en la Biblioteca Regional Virtual de Salud, con la estrategia "errores médicos" OR "errores de medicación" AND "notificación" y en la *National Library of Medicine* y SCOPUS con "*risk management*" OR "*patient safety*" AND "*mandatory reporting*".

Resultados: Se encontraron 2.195 estudios, de los cuales 31 eran elegibles. Luego de la lectura completa, 11 formaron la muestra final. Los factores fueron agrupados en dos, los facilitadores: apoyo institucional a los profesionales, cultura de seguridad organizacional, mejora del sistema de notificación e incentivo al relato voluntario y confidencial. Y las dificultades: falta de recursos materiales/humanos, miedo/vergüenza, postura institucional punitiva/falta de amparo, falta de estímulo para la notificación y vacíos en el conocimiento.

Conclusión: La síntesis de estos factores puede utilizarse para optimizar medidas asistenciales y de gestión, proporcionando recursos materiales, personales, capacitación y promoción de la cultura de seguridad, con el fin de incentivar la notificación y buscar indicadores fidedignos de estos agravios.

Introduction

Patient safety is a topic of discussion when identifying the occurrence of adverse events (AE) and proposing improvements for quality in health care.[1] Recognizing that AE are damage to patients not related to the natural evolution of the disease is perceived as necessary control and prevention actions, in the face of the potential for injuries to patients' recovery.[2] Although greater emphasis is placed on the hospital environment, the approach to patient safety is in continuous expansion, targeting the various aspects and health systems.[3]

It is considered that quality of care is related to AE identification, with the focus of detecting systemic failures, and not personal punishment, given that errors, although practiced individually, may result from structural or procedural failures of the health system or organization.[4] Knowing systemic weaknesses and failures that result in AE gives opportunity for planning preventive actions. Thus, the relevance of the reporting system in the process of continuous improvement of care and related to patient safety stands out.

The practice of reporting is supported by Brazilian law, which requires details of the characteristics of AE through Notivisa.[5] According to a report by the Ministry of Health (MoH), Paraná is the third state that most reports incidents in absolute numbers, with approximately 20 thousand cases in 2019. In Brazil, between July and December 2019, the main reported incidents were related to failures during health care, pressure injuries and failures involving venous catheters.[6]

A cross-sectional study conducted in a general hospital identified that inpatient and intensive care units stood out among the sectors with the highest records of spontaneous reporting; 71% were reported by nurses, being frequently related to the process of medicating and pressure injuries.[7] Underreporting is recognized as a hindrance to planning actions directed to systemic error-generating factors.[8] Therefore, the importance of investigating factors that hinder and facilitate the practice in order to promote this system is highlighted.

Considering the above, this review aimed to analyze the evidence available in scientific literature about hindering and facilitating factors for AE reporting.

Methods

This is an integrative literature review, which is an evidence-based method of practice that allows the deepening of a given theme by the synthesis and

analysis of studies' results for incorporation into clinical practice. The study followed six stages: guiding question elaboration; criteria establishment; categorization of primary studies; assessment; interpretation; synthesis.[9]

The question "What are the facilitating and hindering factors that interfere with reporting AEs in health services?" was based on PCC: P - Problem: factors that interfere with AE reporting; Concept: AE; Context: health services.

Two researchers, independently, searched in March 2020 using the strategy with the Health Sciences Descriptors (DeCS) and Boolean operators "medical error" OR "medication errors" AND "notification" in the Latin American & Caribbean Health Sciences Literature (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE) and Nursing Database (BDENF) databases through the portal Virtual Health Library (VHL). On the National Library of Medicine (PubMed) the descriptors of the Medical Subject Headings (Mesh) were applied, with the following strategy: "Risk Management" [Mesh] or "Patient Safety" [Mesh] and "Mandatory Reporting"; and Scopus, "Risk Management" or "Patient Safety" and "Mandatory Reporting" (Chart 1).

Chart 1. Strategies used in searching for and selecting the studies

	Strategy	Study databases and numbers
Strategy 1	"*erros médicos*" OR "*erros de medicação*" AND "*notificação*"	MEDLINE (595), LILACS (39) and BDENF (23)
Strategy 2	"*errores médicos*" OR "*errores de medicación*" AND "*notificación*"	MEDLINE (45), LILACS (25) and BDENF (14)
Strategy 3	"medical errors" OR "medication errors" AND "notification"	MEDLINE (966), LILACS (34) and BDENF (20)
Strategy 4:	"risk management" [Mesh] OR "patient safety" [Mesh] AND "mandatory reporting" [Mesh]	PubMed (453)
Strategy 5:	"risk management" OR "patient safety" AND "mandatory reporting"	Scopus (481)

Primary articles published from January 2015 to December 2019, in Brazilian Portuguese and/or Spanish and/or English, were included. Studies that did not answer the guiding question were excluded. The 2,195 publications resulting from the search were stored and organized with the aid of EndNote Basic, which removed those duplicates. Initially, the filters were applied and the titles and abstracts were read using the inclusion and exclusion criteria. Thirty-one articles were selected for full reading, of which 20 did not answer the guiding question and 11 were elected for synthesis of the review. The study selection process was presented using the Preferred Items for Systematic Reviews and Meta-Analysis (PRISMA)[10] (Figure 1).

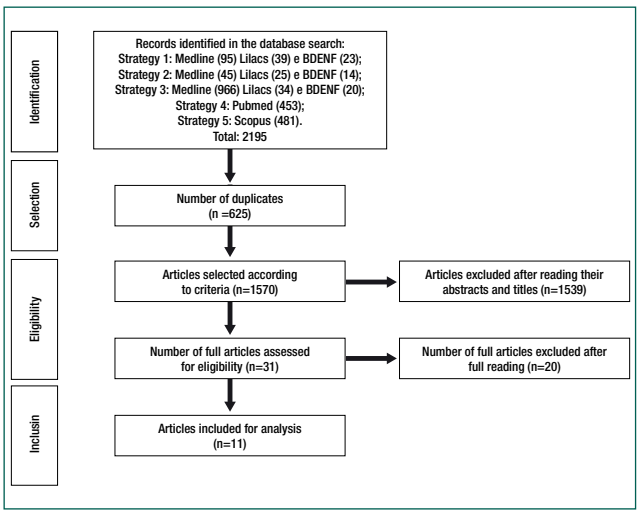

Figure 1. Flowchart of the study selection process

The selected studies were initially analyzed through a script developed by the authors containing: authors, country, year of publication, title, objective and level of evidence. In a second moment, the studies were grouped by similarity, identifying facilitating and hindering factors for AE reporting. The articles were classified according to level of evidence, from A (highest evidence) to D (less evidence), according to the parameters of the Oxford Centre for Evidence-based Medicine.[11] Knowledge interpretation and synthesis, for incorporation into clinical practice, were presented descriptively and in tabular format.

Results

The articles chosen were presented in Chart 2, with information related to authors, year, country of publication, title, objectives, and level of evidence.

Facilitating and hindering factors for AE reporting and corresponding articles were grouped in Chart 3.

Chart 2. Characterization of articles chosen for analysis

Nº	Authors, country and year of publication	Title	Objective	Level of evidence
1	Souza VS; Kawamoto AM; Oliveira JL; Tonini NS. Brazil, 2015.[12]	Errors and adverse events: The interface with health professionals' safety culture	Analyze the safety culture in relation to AEs.	2B
2	Koehn AR; Ebright PR; Draucker. United States, 2016.[13]	Nurses' experiences with errors in nursing	Explore decision-making in reporting medical errors.	2C
3	Jafree SR; Zakar R; Zakar MZ; Fischer F. Pakistan, 2016.[14]	Nurse perception of organizational culture and its association with the culture of error reporting: a case of public sector hospital in Pakistan	Investigate the association between organizational culture and reporting culture.	2B
4	Duarte SC; Bessa AT; Buscher A; Stipp MA. Brazil, 2016.[15]	Error characterization in intensive care nursing	Identify and discuss errors according to Human Error Theory.	2B
5	Lanzilloti L S; Andrade CL; Mendes W; Seta MH. Brazil, 2016.[16]	*Eventos adversos e incidentes sem dano em recém-nascidos notificados no Brasil, nos anos 2007 a 2013*	Analyze AEs and other incidents without damage.	2B
6	Siman AG; Cunha GS; Brito MJ. Brazil, 2017.[8]	*A prática de notificação de eventos adversos em um hospital de ensino*	Understand the reporting practice.	C
7	Marinho MM; Radunz V; Rosa LM; Tourinho FSV; Ilha P; Misiak. Brazil, 2018.[17]	*Resultados de intervenções educativas sobre segurança do paciente na notificação de erros e eventos adversos*	Assess the results of educational interventions in reporting.	2B
8	de Vos MS; Hamming JF; Hendriks JJ; Mheen PJ. Netherlands, 2019.[18]	Connecting perspectives on quality and safety: patient-level linkage of incident, adverse event and complaint data.	Establish a relationship between AEs and incident complaints.	2B
9	Pérez CD; Fuentes PS; García EJ. Spain, 2019.[19]	Addressing medical errors: an intervention protocol for nursing professionals.	Identify interventions to be included in a protocol in the face of serious AEs.	2B
10	Batista J; Cruz ED; Alpendre FT; Paixão DP; Gaspari AP; Mauricio AB. Brazil, 2019.[20]	*Cultura de segurança e comunicação sobre erros cirúrgicos na perspectiva da equipe de saúde*	Analyze the communication dimension of safety and reporting culture.	2B
11	Mascarenhas FA; Anders J C; Gelbcke FL; Lanzoni GM; Ilha P. Brazil, 2019.[21]	*Facilidade e dificuldade dos profissionais de saúde frente ao processo de notificação de eventos adversos*	Describe the facilitating and hindering processes in the reporting process.	2B

Chart 3. Hindering and facilitating factors for reporting adverse events

Facilitating factors	Articles	Hindering factors	Articles
Institutional support for professionals	1,2,3, 4,6,9	Lack of material/human resources	5,6,7,8, 9,10,11
Organizational safety culture	3,5,7, 8,10	Fear/shame	1,2,6,7, 10,11
Reporting system improvement	2,5,7,8	Punitive institutional stance/lack of protection	1,2,4,5, 7,9
Encouraging voluntary and confidential reporting	2,6,7,9	Lack of encouragement to reporting	2,3,4,8, 9,11
Educational activities	1,7,9	Gaps in knowledge	6,7,9,11
Inclusion of patients and family members, and use of complaints as triggers to recognize adverse events	2,11	Failure in communication	1,2,10
Involvement of professionals responsible for direct assistance in planning safety actions	1	Decision not to report by personal judgment	2,7
Indicators for monitoring adverse events	2	Absence of formal system	3,11
Systematization of assistance for changes in culture	3	Bad relationship between leaders and followers	6,10
Senior leadership participation	7	Reporting restricted to nurses	7

Discussion

Factors were grouped for organization and synthesis, resulting in 10 facilitators, pointed out 28 times, and 10 facilitators, pointed out 39 times in the articles. All studies presented at least one aspect that facilitates and hinders AE reporting. The number of facilitating factors shows that the reporting system is not incipient,[22] as demonstrated in the studies analyzed in this review.

Institutional support to professionals was the factor most frequently pointed out in scientific productions, and includes ensuring the confidentiality of AE reporting, highlighted in a similar study, as well as the feeling, by the professional reporting, that it will be supported by colleagues and the institution.[23]

Organizational safety culture was also highlighted. There is a strong correlation between the provision of safe care and the culture of safety,[24] and this affects the act of reporting, since there is recognition of underreporting, both in Brazil and in others countries.[25] As reporting is essential for the calculation of AE rates and the production of quality of service indicators, underreporting implies unreliable data on the provision of safe care and assistance quality, hampering the construction of strategies to improve patient care and safety.[24]

Spontaneous reporting, by filling out forms, printed or electronic, is the main means of report-

ing and considered low cost; however, it requires the involvement of assistance, administrative and support professionals.[7] It is a system with co-participation, which depends on individual and collective motivation, subject to managerial changes and the institutional security culture.

Systematic educational activities minimize the lack of knowledge about what type of incident characterized, such as, for example, error in the preparation or administration of medications, and even doubts about how to perform the reporting.[25] Nurses report difficulties in using means for reporting, and ignorance of the flow, demonstrating that improving systems and seeking other methods of searching for AE, in fact, can contribute to the improvement in communication and detection of these diseases.[26]

One of the facilitating factors presented was the inclusion of patients and family members and the use of their complaints as triggers to track events. The fact of being present in two (18.1%) of the studies reflects that, although this approach is not common, the participation of patients and their families in AE recognition is innovative. So much so that identification tools consider complaints as a trigger for the quantification of occurrence and recognition of injuries.[27] Encouraging the participation of patients, in their own safety, and that of family members, is part of patient safety management strategies.[28]

Four facilitating factors were mentioned only once, namely: involvement of professionals responsible for direct assistance in planning safety actions; indicators for monitoring adverse events; systematization of assistance for changes in culture; senior leadership participation. As they are related to the development of safety culture, these potentially favor reporting, in the sense that each non-notified event loses an opportunity to correct possible failures of the system.[7] It is noteworthy that in the institutions where Systematization of Nursing Care is established, the care related to the six patient safety protocols, recommended by the Brazilian MoH,[29] are included in the prescription of nursing. In this way, AE related to these are registered in the medical record, favoring the identification of diseases and the corresponding reporting.

Among the hindering factors, lack of material and human resources was the most pointed out, being cited in seven of the 11 articles analyzed. This factor is in line with a study in which nursing professionals declare that there are insufficient number of health professionals, with a consequent overload of activities[30] factor that implies underreporting, since this record may not be perceived as a priority compared to direct patient care.

An important point identified was the fear or shame by professionals, which corroborates with another pointed factor, which corresponds to institutional punitive posture/lack of protection. These facts reflect a precarious safety culture, when organization does not support professionals and does not see them as second victims of the system.[8] Fear, the most frequently mentioned hindering factor, is also related to the hierarchical relationship quality between leaders and subordinates.

In a study that aimed to identify reasons for non-reporting, 70.1% of professionals reported that some medication errors are not reported for fear of the responsible nurses' reaction.[25] In this way, underreporting can also be associated with the leadership's attitude towards error, which is desirable in an inclusive, supportive and corrective, rather than intimidating attitude, which allows AE concealment. The nursing team recognizes that the reporting of these events, especially the most serious ones, is important and has consequences, but they crave the support of nurses and, when this does not happen, they fail to report.[21]

The finding of underreporting usually comes from the punitive institutional stance, a hindering factor mentioned in six articles, reinforcing that fear can interfere with personal judgment of either reporting or not.[30] Change in the approach, from punitive to educational, is also applicable to the formal teaching environment, in which teachers' attitudes influence, in an important way, students' attitudes towards AE.

Gaps in knowledge about the topic, or how to make reporting, were also cited as a reason for not reporting, demonstrating the need for educational investment of what characterizes AE, how and where to report.[25] On the other hand, the record-

ing and investigation of events contribute to direct continuing education practices, feedback and qualify assistance.[24] In this context, communication failures are frequent in the health area, considered a complex system with multiple actors interacting simultaneously.[31] Reporting is perceived as a means of communication that alerts the institution about failures and errors, and provides the creation of a guiding database for planning preventive actions and providing safer care.[21]

In this communication process, feedback has a relevant role as a stimulus for reporting. The return to the notifier strengthens the non-punitive character, the learning environment with the error and, mainly, allows the reflection on the assistance provided and factors that influence error occurrence. Thus, this is a strategy that provides reflection and the feeling of being part of the solution, fundamental to preventive actions. These factors can reverse the decision not to report by personal judgment, another of the hindering factors pointed out in this study.[21]

Upon receiving the feedback of the reporting, professionals have the opportunity to assign greater value to this practice, i.e., to realize that their attitude has been recognized and is important for organization. Considering the strength and the characteristic of the work developed, nurses are a key professional in the reporting systems, both in Brazil and in other countries. They are the ones that most report and generally formalize the reporting originated from the assistance of other professional categories.[7] It is inferred that, on the other hand, the nature of their activity, characterized by direct and uninterrupted patient care, is a hindering factor in the face of work overload, in addition to the multiple responsibilities.

Adherence to reporting by other professionals can also be improved with the use of formal (institutional) systems, which are simple and take up little time already scarce for assistance.[26]

Most of articles analyzed showed a good level of evidence (2B), corresponding to cohort studies, adding greater reliability to the results of this analysis.

Among the limitations of this study, we point out the time frame and search strategies that may have hindered the identification of more publications. Among the opportunities to deepen the theme of this research, and from the factors that hinder the reporting of events identified in scientific literature, there is a need to explore, mainly, professionals' feelings of fear and shame and their relationship as the punitive aspects and lack of institutional support and encouragement, as they are modifiable and strongly associated with organizational safety culture. Considering the relevance of the relative knowledge of why, how and when to report, this gap, although not identified more frequently in studies, indicates an important aspect to be explored in the context of training and professional practice in health.

Conclusion

Lack of preventive actions against AE, lack of human and material resources and encouragement to report, associated with fear of reporting were the main hindering factors identified in the study, and these should be recognized as barriers to the identification of systemic problems associated with the occurrence of these injuries. Actions are recommended to minimize institutional and behavioral barriers that hinder AE reporting and the use of continuing education as an instrument for its promotion. Likewise, the strengthening of the identified facilitating factors can contribute to the robustness of the reporting system, focusing on learning from error. It is expected that the synthesis of the main factors identified can be used in research and care and management measures, with a view to data quality and reliability, supporting the planning of targeted and possibly more assertive actions that result in patient safety.

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