Patient safety and error from the perspective of complex thinking: documentary research

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Abstract: **Objective:** To analyze the concepts related to Patient Safety and Error expressed in Brazilian official documents, from the perspective of complex thinking. **Method:** Documentary research on the websites of the Federal Official Gazette, Ministry of Health, and Patient Safety of the Brazilian Health Regulatory Agency. The descriptors Patient Safety and Medical Error were used in the period from 1999 to 2020. The excerpts were treated following the Content Analysis technique, developed in three stages: pre-analysis; exploration of the material; and treatment of results. **Results**: Of the total of 498 documents, nine were selected and originated the categories: Meaning of patient safety and Concepts related to the meaning of error. **Final considerations**: Patient safety refers to protection, risk minimization and harm prevention, continuous improvements, good practices, and quality of care. An error refers to an incident, adverse event, and harm. To prevent an error, it is necessary to recognize and understand it as an event inherent to health services. Thus, rationality protects us from error and illusion, allows thought advancement, accepts self-criticism and argument contestation, expands understanding and development of knowledge.

➤ **Keywords:** Patient safety. Medical errors. Health policy. Quality of health care.

Introduction

Patient safety is a global public health issue that requires universal and effective health coverage from the systems. The harm caused to patients leads the causes of global diseases, with unsafe practices and medication errors as the main causes of preventable harm worldwide (WHO, 2018).

Annually, 134 million adverse events occur in hospitals of low- and middle-income countries, resulting in 2.6 million deaths from unsafe care. In primary care and outpatient services, four out of ten patients are harmed. Medication errors cost approximately 42 billion dollars every year (WHO, 2020). In the United States, errors related to health care are the third leading cause of death. In the United Kingdom, an average of one incident with patient harm is estimated every 35 seconds (WHO, 2017).

In Brazil, a study carried out between June 2014 and June 2016 shows that 63,933 adverse events related to health care were reported and it is believed that these events are underreported. Of this total, 417 (0.6%) died, and the main causes were failures during health care (MAIA *et al*., 2018).

The scientific literature has addressed the issue of the presence of error associated with health services. Studies indicate concern with the promotion of strategies to reduce the presence of errors in care, help prevent their occurrence, and search for practices that avoid any harm (INSTITUTE OF MEDICINE, 2000; MINUZZI *et al*., 2016; BALAKRISHNAN *et al*., 2019). Global challenges, combined with low reliability in health services, contribute to the presence of errors related to the service structure and work processes (BATISTA *et al*., 2019). The identification of these errors has been promoted by the Patient Safety Centers in the hospital environment (BASILE *et al*., 2019).

Errors are considered unintentional acts (OMS, 2011) and may be the result of individual failures or failures in the system (SOUZA *et al.,* 2019). The prevention of failures and the improvement of care require considering the people involved, as well as the complexity of the system (GONÇALVEZ *et al.,* 2019). Every failure that occurs during the execution of a planned action is considered an error, whether in the execution of an activity or a plan. It can be either taking the wrong action (commission) or not taking the right action (omission) at any stage of action. Errors increase the risk of incidents, even if they do not happen. Any event that could result

or resulted in harm to the patient is considered an incident, and every incident with harm is called an adverse event (WHO, 2011).

To avoid errors, health services shall promote safe practice, prioritizing patient safety as an action strategy. In 2004, during the 57th World Health Assembly, the World Health Organization created the World Alliance for Patient Safety to support the development of policies and practices internationally (WHO, 2011). Government and organizations have published guiding documents to guide actions in health services.

The procedures and treatment are complex and therefore the potential risk of harm to the patient in health services is real (ABI *et al.*, 2022). Error comprehension considers the interpretation of data by professionals (BALAKRISHNAN *et al.*, 2019). However, the error cannot be underestimated by people based on their subjective interpretation and their worldview, as denying its existence would be an illusion. The illusion refers to an understanding that is not consistent with reality, because reality is not easily readable. Ideas translate reality, and they can do so in an erroneous way. Error and illusion threaten knowledge and lead human beings to false conceptions about themselves, their actions, and the world (MORIN, 2011).

The error has its origins and is inseparable from knowledge, being seen as an occasional risk, but constituting a threat to life. This knowledge is necessary to face the permanent risks of error and illusion present in the human mind (MORIN, 2015a).

In view of the above, this study was guided by the question: What concepts involving patient safety and error have been presented in official Brazilian documents? The objective was to analyze the relation between the concepts Patient Safety and Error expressed in Brazilian official documents, from the perspective of complex thinking.

Method

This is a document analysis, which allows explaining or clarifying a question, according to the researcher's objective. A document allows understanding the social context and concepts, observing the recent past (COGO; LERCH, 2018). To ensure research credibility, the original documents were located on three official Brazilian websites: Federal Official Gazette (DOU), Ministry of Health (MS), and

the Brazilian Health Regulatory Agency (ANVISA). For the search, the descriptors Patient Safety and Medical Error were used, from January 1st, 1999 to December 31st, 2020. The descriptor Medical Errors did not show results in the search; therefore, Medical Error was used. The collection of documents was carried out from July to December 2019, and updated in January 2021. The initial selection of the year was due to the publication of the report *To Error is Human: building a safer health* system in 1999 (WHO, 2018).

Of the total of 498 documents, 453 were obtained for the Patient Safety descriptor, and 45 for the Medical Error descriptor. The documents found were saved in a file in PDF format. For the interpretation of the selected documents, content analysis was used, developed in three stages: pre-analysis; exploration of the material; and treatment of results (BARDIN, 2011). In the pre-analysis, a thorough reading of the text was carried out to identify the relationship with the objective of the study. In the second stage, material exploration, an in-depth reading of the documents took place, with only those presenting concepts related to Patient Safety and Medical Error being included. The excerpts containing these concepts were transferred to a Word® 2013 file.

Repeated documents or documents that did not meet the scope of this study, such as public notices, excerpts, notices, minutes, guidelines, decisions, processes, orders, decrees, agreements, electronic trading, projects, reports, terms, judgments, among others, were excluded.

Material exploration was carried out by coding the textual content, considering similarities and differences, as well as the properties and dimensions of the content related to the concepts of Patient Safety and Medical Error. In the phase of treatment of the results, the findings categorization and interpretation were carried out. The document selection process can be seen in Figure 1.

Figure 1. Flowchart of the documents search and selection synthesis according to the analysis stages.
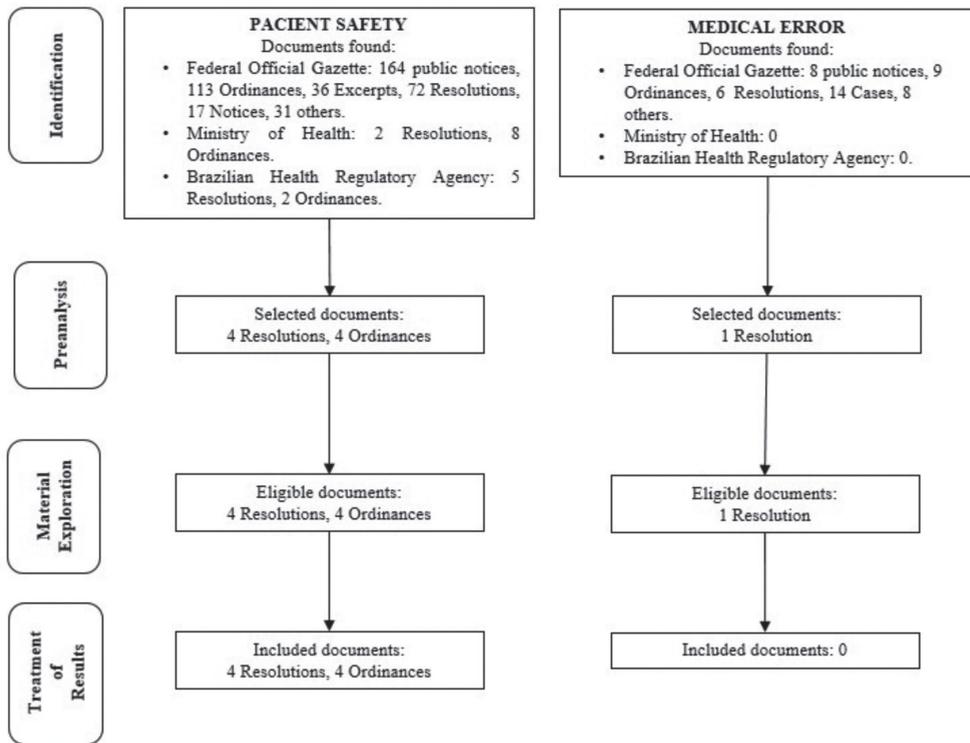

Source: Author elaboration

In the documents included, the presence of a concept for Medical Error was not identified, the reason for not including documents with this descriptor in the present study. However, the in-depth reading of the documents selected based on the Patient Safety descriptor allowed identifying the presence of concepts that refer to the meaning of Error, such as harm, incident, and adverse event, which were then included in the present study.

Results

The search for the descriptors Patient Safety and Medical Error during the document identification phase allowed observing the historicity of their use. From the year 2010, there was a progressive and considerable increase in the number of

documents using the expression Patient Safety (16) with a peak in 2014 (78) and the apex in 2019 (80), while for Medical Error a slight increase in the years 2012 (6) and 2013 (12) was observed, with a trend towards reduction and stabilization as shown in Figure 2.

Figure 2. Historical series of number of documents using the descriptors Patient Safety and Medical Error, from 1999 to 2020.
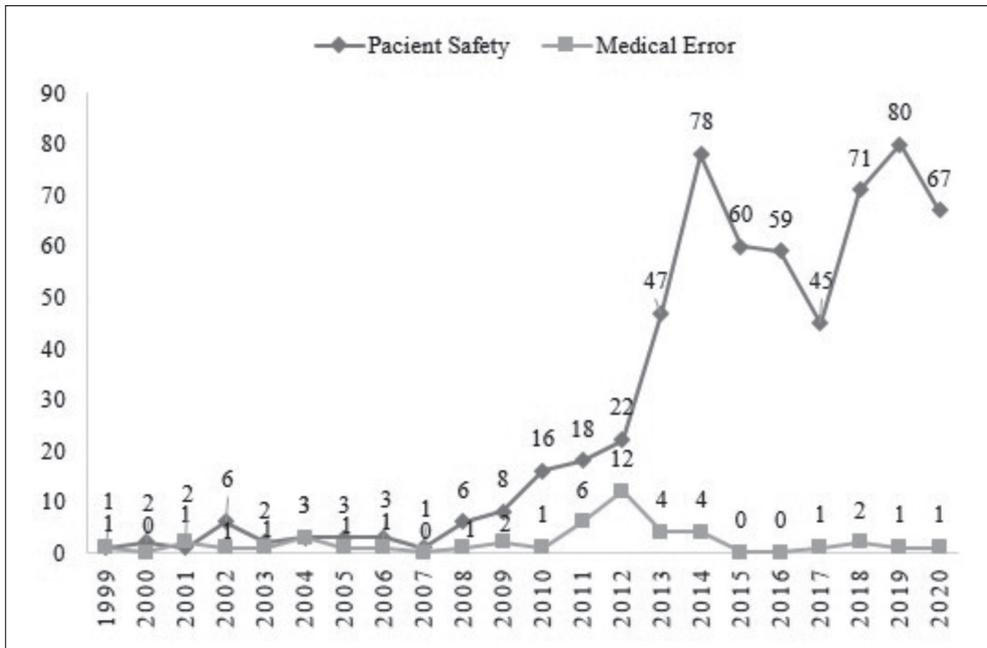
Source: Author. *No documents repeated in more than one website were considered.

In total, eight documents were included in the study, and the excerpts with the concepts can be seen in Chart 1.

Chart 1. Cutting-out of concepts for the Patient Safety descriptor presented in official documents, 1999 to 2020.

Concepts	Publication Years	Site
Patient Safety: set of actions aimed at protecting the patient against risks, adverse events, and unnecessary harm during the care provided in health services (BRASIL, 2011).	2011	DOU
Patient Safety: reduction, to an acceptable minimum, of the risk of unnecessary harm associated with health care (BRASIL, 2013b; 2013d; 2017a).	2013 2017	DOU, ANVISA, MS
Art. 11. The hospital care model will include a set of care devices that ensure access, quality of care, and patient safety. [...] § 9 Actions that ensure the quality of care and good health practices must be implemented to ensure patient safety with a reduction in unnecessary and preventable incidents, in addition to unsafe acts related to care (BRASIL, 2013c).	2013	DOU, MS
Patient safety plan in health services: document that points out risk situations and describes the strategies and actions defined by the health service for risk management aimed at preventing and mitigating incidents, from admission to transfer, discharge, or the death of the patient in the health service (BRASIL, 2013b; 2014a).	2013 2014	DOU, ANVISA, MS
Implement Patient Safety strategies in Primary Care, encouraging safe care practice, involving patients in safety, creating mechanisms to avoid errors, ensuring person-centered care, carrying out local patient safety plans, providing continuous improvement related to identification, prevention, detection and risk reduction (BRASIL, 2017b).	2017	DOU

Source: author.

The concepts that refer to the meaning of Error were identified in four documents, as can be seen in Chart 2.

Chart 2. Cutting-out of concepts about the meaning of Error presented in official documents, 1999 to 2020.

Concepts	Publication Years	Site
Incident: event or circumstance that could have resulted, or resulted, in unnecessary harm to the patient (BRASIL, 2013a; 2013b; 2013d; 2017a).	2013 2017	DOU, ANVISA, MS
Adverse event: incident that results in harm to the patient (BRASIL, 2013b; 2013d; 2017a).	2013 2017	DOU, ANVISA, MS
Harm: impairment of the structure or function of the body and/ or any effect arising therefrom, including disease, injury, suffering, death, disability or dysfunction, and may therefore be physical, social, or psychological (BRASIL, 2013b; 2013d; 2017a).	2013 2017	DOU, ANVISA, MS

Source: author.

In general, the documents with the highest number of concepts were: the National Patient Safety Program (BRASIL, 2013d) with four concepts, Resolution of the Collegiate Board - RDC no. 36 (BRASIL, 2013b) with five concepts, both published in 2013, and Consolidation Ordinance No. 5 (BRASIL, 2017a) with four concepts.

The findings were organized and interpreted, giving rise to two categories of analysis: Meaning of Patient Safety; and Concepts related to the meaning of Error.

The first category "Meaning of Patient Safety" refers to patient protection, risk minimization, and harm prevention, to achieve purposes such as continuous improvements, good practices, and quality of care (BRASIL, 2011; 2013b; 2013c; 2013d; 2017a; 2017b). The documents point to patient safety plans as an instrument for continuous improvement and the implementation of safe practices to prevent unwanted outcomes in patient care (BRASIL, 2013a; 2013b; 2017b).

The second category "Concepts related to the meaning of Error" presents the concepts of Incident, Adverse Event, and Harm which, in that order, refer to the severity of a negative action reaching the patient. The concept of incident expresses the possibility of an action negatively affecting the patient (BRASIL, 2013a; 2013b; 2013d; 2017a). Adverse event refers to the action that negatively affected the patient (BRASIL, 2013b; 2013d; 2017a). Harm appears with a definition directly related to an action that reached the patient and had negative consequences (BRASIL, 2013b; 2013d; 2017a).

Discussion

The results of this study reveal a considerable increase in the use of the term Patient Safety from the year 2010 onwards. This visibility can be understood as the growing concern for patient protection and, consequently, the status of care that should guide those involved in care, a fact that culminated in the publication of the National Patient Safety Program in Brazil in 2013, revealing the recognition of the relevance of the theme through a health policy.

All official documents identified on the MS and ANVISA websites were also found in the DOU, an expected fact, but which reaffirms the importance of this communication vehicle as a source of research. The results of the study point to the Meaning of Patient Safety, encompassing aspects of protection, risk minimization, and harm prevention. To this end, instruments such as the patient safety plan are needed to achieve the goals of continuous improvement, good practices and quality of care.

Thus, it can be observed that the concept used in the Brazilian legislation (BRASIL, 2013b; 2013c; 2017a; 2013d) is in line with the concept presented by the World Health Organization (WHO), which defines patient safety as "reducing the risk of unnecessary harm related to health care to an acceptable minimum" (WHO, 2011, p. 14). And yet, in some documents, words are added that expand this concept (BRASIL, 2011; 2017b). The organization of knowledge is a challenge that requires the connection of organizing principles to give meaning to knowledge, avoiding its sterile accumulation (MORIN, 2014), creating relevant knowledge and with conditions to contextualize it in a global view of the problems (MORIN, 2015a).

Despite this, the National Patient Safety Program adopts the expression to address issues related to physical safety, but does not include the violation of the rights of users, understood as people affected by health services (BEHRENS, 2019). Users need to be involved in safety assurance processes, so that they reinforce barriers to errors, identifying and reporting any signs of adverse events (BARBOZA, 2020). It is necessary to consider the inseparable elements that constitute the interactive and inter-retroactive whole between object of knowledge and context, and also the elements that constitute human, historical and social complexities (MORIN, 2011; 2015b).

Errors are considered a public health problem and also have serious consequences for health professionals, such as emotional distress and lack of institutional support

(PEREIRA *et al.*, 2020; PALOSKI *et al.*, 2021). Beyond the meaning, patient safety is reinforced by union and teamwork. It is a process of institutional and health system transformation, and requires the use of educational strategies such as permanent health education (WEGNER *et al.*, 2016). Education can help us become better and contribute to the development of knowledge, which becomes a means to avoid error and illusion. It is necessary to insert particular knowledge in its context and place it in the set. Knowledge with the ability to reconnect, contextualize, that is, to place information or knowledge in its natural context (MORIN, 2014; 2015b).

To promote safety, humanization in care is required, valuing embracement, touch, active listening, playful activities, and involving companions as users of the health service (WEGNER *et al.*, 2016). Valuing the users' participation contributes to achieving better results, respecting basic rights and allowing them to act as collaborators engaged with their safety and the quality of the health system (BRASIL, 2013d; BEHRENS, 2019). Thus, the union of unity and multiplicity leads to the comprehension of complexity (MORIN, 2011).

Patient safety, as an organizational culture, has been adopted by health services, starting from problems and seeking solutions, so that professionals feel empowered to participate, reviewing work processes, suggesting and inducing a change in behavior for safer attitudes (MINUZZI *et al.*, 2016). When simplifying thinking fails, complexity arises, integrating everything that establishes order, clarity, distinction, and precision in knowledge, leading to new knowledge and organization (MORIN, 2015b). Safety culture represents the result of individual and group values, attitudes, and behaviors that translate into institutional commitment (COSTA *et al.*, 2018) and encourages the development of an organizational environment favorable to understanding and managing errors (DUARTE *et al.*, 2020).

The search for paths that are proven to lead to results can be understood as an exercise of rationality, avoiding the errors of reason. The rational activity of the mind is what allows differentiating the imaginary from the real, therefore being one of the forms of protection against error and illusion. Rationality shall not be closed in itself, at the risk of losing its power of self-criticism and becoming a doctrine, converting itself into rationalization, which denies arguments contestation and empirical verification, that is, the error of reasoning (MORIN, 2011). In this regard, evidence-based practices, for example, shall allow for self-criticism, contesting and reconstructing, or even reaffirming the evidence.

The Patient Safety Plan is presented as one of the instruments for the search for continuous improvement, establishing good practices and achieving quality in care (BRASIL, 2013b). The plan shall be built collectively, presenting actions, goals, and describing the activities to be monitored (SIMAN; BRITO, 2018). However, there is no certainty that the purity of the means leads to the desired ends (MORIN, 2011). The part (plan) needs to be impregnated with the whole (health service), allowing the plan to represent the service and the service to be represented in the plan, according to the hologrammatic principle of complexity (MORIN, 2015b).

The category "Concepts related to the Meaning of Error" allows viewing an association with: incident, that is, the possibility of an action negatively affect the patient; adverse event, the action that affected the patient negatively; and harm, the action that affected the patient negatively with impairment of body structure or function. These concepts are in line with those used by the WHO (2011). The monitoring of indicators related to these concepts, together with processes based on best practices and scientific evidence, guide risk management to achieve the expected health results (TSAI *et al.*, 2020).

Admitting the possibility and presence of error during care is essential to prevent it and to implement a safety culture (WEGNER *et al.*, 2016), adopting strategies to recognize the error, minimize its effects, and avoid it (OLIVEIRA *et al.*, 2022). The error is not an isolated act, it results from a sequence of events (MINUZZI *et al.*, 2016). Therefore, it can be understood as something collective, a source of teaching, alerting professionals about health practices, an opportunity to generate knowledge (WEGNER *et al.*, 2016). In this sense, conceiving the context, the global, the relationship of the whole and the parts, the multidimensional and the complex, grants knowledge the attribute of pertinence. However, knowledge carries in itself the risk of error and illusion (MORIN, 2011).

Knowledge is the result of a construction of language and thought that externalizes human uncertainty and, therefore, is somehow threatened by error and illusion. Error and illusion lead to the blindness of knowledge because they parasitize the human mind, leading to false conceptions from which no one is free (MORIN, 2011; 2014). Recognizing this situation is a challenge that requires awareness. This begins when one understands that error, ignorance, and blindness advance concomitantly with knowledge (BARBOZA *et al.*, 2020).

In general, health facilities do not prepare professionals to provide information about an error made (BEHRENS, 2019). A study carried out in southern Brazilian hospitals revealed that 17.6% of workers believe that their errors and failures can be used against them (SIMAN; BRITO, 2018). Feelings of shame, guilt, fear of judicial, ethical, and social punishments, added to the little instrumentalization offered by training are factors that interfere with the way professionals deal with errors (WEGNER *et al.*, 2016). Judicialization experiences can collaborate for institutions to establish barriers that prevent errors and legally support professionals (SOUZA *et al.*, 2019).

It should be noted that from the perspective of complex thinking, there are two errors regarding Error: one is to overestimate it and the other is to underestimate it. The ignored error is harmful, and the recognized, analyzed, and overcome error is positive. In view of the objective of understanding and intervening in the causes of errors, compared to Hippocratic medicine, punishment is only the treatment of symptoms and not of the causes (MORIN, 2015a). This way, errors can be sources of learning: instead of serving to blame and punish, they allow the adoption of less complicated and more efficient processes (SEIFFERT *et al.*, 2020).

For complexity, different elements are inseparable and constitute a whole, an interdependent fabric (MORIN, 2011). Thus, the error shall be approached in a systemic way, in a safe and trusting environment, so that professionals can talk about it, analyze it, and monitor it (SIMAN; BRITO. 2018). Thus, there is a duality between fear of making mistakes and the desire to create a safe environment. Clear exposure about the error, carried out in the midst of trust, promotes discussion and intervention in the work and education processes that strengthen workers for the development of a culture of safety and safe health care (TEODORO *et al.*, 2020), as well as the sharing of responsibilities in collective work (SANTOS, 2020).

What causes the error comes from the way we organize ideas and knowledge (MORIN, 2015b) and put them into practice. Error permeates human perceptions and senses and generates illusion (MORIN, 2011). Intellectual errors refer to the theories and ideologies that underlie our systems of ideas, and are also subject to error and illusion, while protecting them. Inconvenient information, contrary arguments, or those that cannot be understood by our system of ideas, find in us the tendency to resist its assimilation (MORIN, 2011). The identification of an adverse event, that is, an unintentional error (PEREIRA *et al.*, 2021) allows us to understand

that "adverse events are not caused by bad people, but by systems that were poorly designed and produce bad results. This concept is transforming the previous focus on individual error into a focus on system defects" (BRASIL, 2014b, p. 17).

Final considerations

This study qualitatively analyzed, in official Brazilian documents, the concepts related to Patient Safety and Error, giving rise to two thematic categories, discussed in the light of complex thinking. Patient safety refers to protection, risk minimization, and harm prevention, which aims at continuous improvement, good practices, and quality of care.

The results also point to the meaning of Error related to incident, adverse event and harm, and refer to the severity of a negative action reaching the patient. It is necessary to (re)cognize the error as an event inherent to health services, and to understand it, to prevent it, since denying this reality is an illusion.

This careful understanding instigates rethinking aspects of professional practice, considering human complexity from points that may seem invisible in health work. This way, the use of rationality protects us from error and illusion because it allows the advancement of thought, expanding understanding and the development of knowledge.

Rationality offers the opportunity to rethink pre-established practices, towards promoting safe and quality care, overcoming the reductionism of simplistic thinking. Nevertheless, rationality shall not be closed in itself, at the risk of losing its power of self-criticism and denying arguments contestation and empirical verification, that is, the error of reasoning. It is necessary to seek relevant knowledge, with conditions to contextualize the different situations and provide a global view of the problems.

The search for concepts exclusively in Brazilian official documents can be considered a limitation of this study, considering that patient safety is an international concern. Thus, it is suggested that future research broaden the search for documents and identify how patient safety has been regulated in different contexts.

It is believed that the present study contributes to professional practice as workers understand the error as an intrinsic phenomenon to care, allowing self-questioning and self-criticism about their actions and judgments, and transforming feelings such as guilt, shame and fear in untiring strength to overcome illusion, understanding

and preventing any risk that could lead to error and interfere with patient safety. This understanding can be considered an important step towards patient protection and the quality of health care.[1]

Acknowledgements

References

ABI, A. X. C. F. *et al.* O Healthcare Failure Mode and Effect Analysis como ferramenta de avaliação de protocolos assistenciais. *Revista Brasileira de Enfermagem.* v. 75, n. 3, 2022.

BALAKRISHNAN, K. *et al.* Patient safety/quality improvement primer, part ii: prevention of harm through root cause analysis and action (RCA2). *Otolaryngology– Head and Neck Surgery.* v. 161, n. 6, p. 911-921, 2019.

BARBOZA, T. C. *et al.* Retrospective study of immunization errors reported in an online Information System. *Revista Latino-Americana de Enfermagem*, v. 28, 2020.

BARDIN, Laurence. *Análise de Conteúdo.* Trad. de Luís Antero Reto, Augusto Pinheiro. Lisboa: Edições 70; 2011.

BASILE, L. C. *et al.* Análise das ocorrências de incidentes relacionados aos medicamentos potencialmente perigosos dispensados em hospital de ensino. *Revista Gaúcha de Enfermagem.* v. 40, n. esp, 2019.

BATISTA, J. *et al.* Cultura de segurança e comunicação sobre erros cirúrgicos na perspectiva da equipe de saúde. *Revista Gaúcha de Enfermagem.* v. 40, n. esp., 2019.

BEHRENS, R. Segurança do paciente e os direitos do usuário. *Revista Bioética*, v. 27, n. 2, p. 253-260, 2019.

BRASIL. Conselho Federal de Farmácia. *Resolução nº 585 de 29 de agosto de 2013.* Regulamenta as atribuições clínicas do farmacêutico e dá outras providências. Conselho Federal de Farmácia, 2013a.

BRASIL. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução da Diretoria Colegiada - RDC nº 36, de 25 de julho de 2013.* Institui ações para a segurança do paciente em serviços de saúde e dá outras providências. Brasília: Ministério da Saúde, 2013b.

BRASIL. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução da Diretoria Colegiada - RDC nº. 63 de 25 de novembro de 2011.* Dispõe sobre os requisitos de boas práticas de funcionamento para os serviços de saúde. Brasília: Ministério da Saúde, 2011.

BRASIL. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. *Resolução da Diretoria Colegiada - RDC nº 11, de 13 de março de 2014.* Dispõe sobre os requisitos de boas práticas de funcionamento para os serviços de diálise e dá outras providências. Brasília: Ministério da Saúde, 2014a.

BRASIL. Ministério da Saúde. *Documento de referência para o Programa Nacional de Segurança do Paciente* / Ministério da Saúde, Fundação Oswaldo Cruz, Agência Nacional de Vigilância Sanitária. Brasília: Ministério da Saúde, 2014b.

BRASIL. Ministério da Saúde. Gabinete do Ministro. *Portaria de Consolidação nº 5, de 28 de setembro de 2017.* Consolidação das normas sobre as ações e os serviços de saúde do Sistema Único de Saúde. Brasília: Ministério da Saúde, 2017a.

BRASIL. Ministério da Saúde. Gabinete do Ministro. *Portaria n. 3.390, de 30 de dezembro de 2013.* Institui a Política Nacional de Atenção Hospitalar. Brasília: Ministério da Saúde, 2013c.

BRASIL. Ministério da Saúde. Gabinete do Ministro. *Portaria nº 2.436, de 21 de setembro de 2017.* Aprova a Política Nacional de Atenção Básica, estabelecendo a revisão de diretrizes para a organização da Atenção Básica. Brasília: Ministério da Saúde, 2017b.

BRASIL. Ministério da Saúde. Gabinete do Ministro. *Portaria nº 529, de 1 de abril de 2013.* Institui o Programa Nacional de Segurança do Paciente. Brasília: Ministério da Saúde, 2013d.

COGO, S. B. L.; LERCH, V. Diretivas antecipadas: uma análise documental no contexto mundial. *Texto & Contexto - Enfermagem.* v. 27, n. 3, 2018.

COSTA, D. B. *et al.* Patient safety culture: evaluation by nursing professionals. *Texto & Contexto - Enfermagem.* v. 27, n. 3, 2018.

DUARTE, S. C. M. *et al.* Boas Práticas de segurança nos cuidados de enfermagem em Terapia Intensiva Neonatal. Revista Brasileira de Enfermagem. v. 73, n. 2, 2020.

GONÇALVES, A. F. *et al.* Estratégias e implicações da segurança do paciente na prática do cuidado de enfermagem. *Brazilian Journal of Health Review.* v. 2, n. 1, p. 378-393, 2019.

INSTITUTE OF MEDICINE (US). Committee on Quality of Health Care in America. Kohn LT, Corrigan JM, Donaldson MS, editors. *To err is human: building a safer health system.* Washington (DC): National Academies Press (US). v. 32, n. 9, 2000.

MAIA, C. S. *et al.* Notificações de eventos adversos relacionados com a assistência à saúde que levaram a óbitos no Brasil, 2014-2016. *Epidemiologia e Serviços de Saúde.* v. 27, n. 2, 2018.

MINUZZI, A. P. *et al.* Contribuições da equipe de saúde visando à promoção da segurança do paciente no cuidado intensivo. *Escola Anna Nery.* v. 20, n. 1, p. 121-129, 2016.

MORIN, E. *A cabeça bem-feita***.** 21ª ed. Rio de Janeiro: Bertrand Brasil; 2014.

MORIN, E. *Ensinar a viver: manifesto para mudar a educação.* Trad.: Edgar de Assis Carvalho e Mariza Pesassi Bosco. Porto Alegre: Editora Sulina, 2015a.

MORIN, E. *Introdução ao pensamento complexo.* 5ª ed. Porto Alegre (RS): Editora Sulina, 2015b.

MORIN, E. *Os sete saberes necessários à educação do futuro.* 2ª ed. São Paulo: Editora Cortez, 2011.

OLIVEIRA, T. G. P. *et al*. Involvement of companions in patient safety in pediatric and neonatal units: scope review. *Revista Brasileira de Enfermagem*. v. 75, n. 3, 2022.

ORGANIZAÇÃO MUNDIAL DA SAÚDE. Direção-Geral da Saúde. *Estrutura Conceitual da Classificação Internacional sobre Segurança do Doente.* Relatório Técnico Final. Genebra: OMS, 2011.

PALOSKI, G. R. *et al*. Segurança do paciente: compreensão de estudantes de enfermagem, medicina e direito acerca do erro assistencial ao paciente. *Cad. Ibero-amer. Dir. Sanit.* Brasília, v. 10, n. 4, 2021.

PEREIRA, A. S. N.; PORTO, C. C.; ALMEIDA, R. J. Erro médico e seu potencial Iatrogênico: Uma revisão sistemática. *Brazilian Applied Science Review,* v. 5, n. 1, 2021.

SANTOS, T. *et al*. Protocolo para uso seguro de medicamentos em serviço de transplante de medula óssea. *Cogitare Enfermagem,* v. 25, 2020.

SEIFFERT, L. S. *et al*. Indicadores de efetividade da assistência de enfermagem na dimensão segurança do paciente. *Revista Brasileira de Enfermagem,* v. 73, n. 3, 2020.

SIMAN, A. G.; BRITO, M. J. M. Dimension prescribed and reality of practices of health professionals in the context of patient safety. *Revista Enfermagem UERJ*, v. 26, 2018.

SOUZA, C. S. *et al*. Cultura de segurança em unidades de terapia intensiva: perspectiva dos profissionais de saúde. *Revista Gaúcha de Enfermagem,* v. 40, n. esp., 2019.

SOUZA, V. S. *et al*. Desdobramentos judiciais do erro na enfermagem. *Acta Paulista de Enfermagem,* v. 32, n. 6, p. 700-706, 2019.

TEODORO, R. F. B, *et al*. Análise da notificação de eventos adversos através da pesquisa de cultura de segurança do paciente. *Rev Fun Care Online*, v. 12, p. 463-470, 2020.

TSAI, J.; PONTES, L. C. F.; CAPUCHO, H. C. Processo de autoavaliação nacional das práticas de segurança do paciente em serviço de saúde, de 2016 a 2019: uma análise sob a óptica da vigilância sanitária. *Vigilância Sanitária em Debate,* v. 8, n. 4, p. 47-56, 2020.

WEGNER, W. *et al*. Education for culture of patient safety: Implications to professional training. *Escola Anna Nery*, v. 20, n. 3, 2016.

WORLD HEALTH ORGANIZATION. 71st World health assembly 2018 side event – summary. *Global Action on Patient Safety for Achieving Effective Universal Health Coverage.* Geneva: WHO, 2018.

WORLD HEALTH ORGANIZATION. *Patient safety.* Geneva: WHO, 2020.

WORLD HEALTH ORGANIZATION. *Patient safety: making health care safer.* Geneva: WHO, 2017.

Note

[1] F. K. Metelski e F. D. Engel: conception of the study, data collection, analysis, and interpretation, manuscript writing and critical review, approval of final version to be published. A. L. S. F. de Mello: conception of the study, manuscript writing and critical review, approval of final version to be published. B. H. S. Meirelles: conception of the study, approval of final version to be published.

Resumo

A segurança do paciente e o erro sob a perspectiva do pensamento complexo: pesquisa documental

Objetivo: Analisar os conceitos relacionados à Segurança do Paciente e ao Erro expressos nos documentos oficiais brasileiros, sob a perspectiva do pensamento complexo. **Método**: Pesquisa documental nos sites: Diário Oficial da União, Ministério da Saúde e Segurança do Paciente da Agência Nacional de Vigilância Sanitária. Utilizou-se os descritores Segurança do Paciente e Erro Médico no período de 1999 até 2020. Os excertos foram tratados seguindo a técnica de Análise de Conteúdo desenvolvida em três etapas: pré-análise; exploração do material; e tratamento dos resultados. **Resultados**: Do total de 498 documentos, foram selecionados nove e originaram as categorias: Significado de segurança do paciente e Conceitos relacionados ao significado de erro. **Considerações Finais**: Segurança do paciente remete a proteção, minimização de riscos e prevenção de danos, melhorias contínuas, boas práticas e qualidade da assistência. Erro refere-se a incidente, evento adverso e danos. Faz-se necessário reconhecer e compreender o erro como um evento inerente aos serviços de saúde para ser possível preveni-lo. Assim, a racionalidade nos protege do erro e da ilusão, possibilita o avanço do pensamento, aceita a autocrítica, a contestação de argumentos, amplia a compreensão e o desenvolvimento do conhecimento.

➤ **Palavras-chave:** Segurança do paciente. Erros médicos. Política de saúde. Qualidade da assistência à saúde.