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Original Article

Hospital adverse events: analysis of internal reporting and reasons for underreporting in official systems*

Eventos adversos hospitalares: análise da notificação interna e dos motivos para subnotificação nos sistemas oficiais

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ABSTRACT
Objective: to analyze adverse events reported internally in different hospitals and the possible reasons for underreporting to official reporting systems. **Methods:** a mixed study was carried out in three hospitals, using secondary data from internal records and notifications from official systems. Interviews were conducted with 27 professionals. We used content analysis and statistical analysis of the text corpus using the software *Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires*. **Results:** of the 1,154 adverse events recorded internally, medication/intravenous fluid errors and clinical processes/procedures stand out. However, in the official systems, failure to identify falls appears as the most reported event. The prevalence of underreporting in the official systems was 34.4%, the main reasons being: difficulty of access, lack of knowledge, complexity of the systems, turnover, work overload, internal underreporting, and non-exclusive human resources at the center. **Conclusion:** The main internal notifications were of medication/intravenous fluid errors and clinical processes/procedures, but there was under-reporting to official systems due to human resources, infrastructure, and management issues. **Contributions to practice:** the role of managers, professionals, and the regulatory body in implementing actions to facilitate, train, and support those responsible for records stand out.
Descriptors: Patient Safety; Notification; Underregistration; Health Information Systems; Medical Errors.

RESUMO
Objetivo: analisar os eventos adversos notificados internamente em diferentes hospitais e os possíveis motivos da subnotificação aos sistemas oficiais de notificação. **Métodos:** estudo misto, realizado em três hospitais, a partir de dados secundários das fichas internas e notificações dos sistemas oficiais. Realizou-se entrevistas com 27 profissionais. Utilizou-se análise de conteúdo e análise estatística do corpus textual pelo *software Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires*. **Resultados:** dos 1.154 eventos adversos registrados internamente, destacam-se os erros de medicação/fluídos endovenosos e processos/procedimentos clínicos. Entretanto, nos sistemas oficiais, eventos de falha na identificação e queda aparecem como os mais notificados. A prevalência de subnotificação nos sistemas oficiais foi de 34,4%, tendo como principais motivos: dificuldade de acesso, falta de conhecimento, complexidade dos sistemas, rotatividade, sobrecarga de trabalho, subnotificação interna e recursos humanos não exclusivos no núcleo. **Conclusão:** as principais notificações internas foram de erros de medicação/fluidos endovenosos e processos/procedimentos clínicos, entretanto houve subnotificação aos sistemas oficiais motivadas por questões de recursos humanos, infraestrutura e gestão. **Contribuições para a prática:** destaca-se o papel dos gestores, profissionais e órgão regulador para a implantação de ações para facilitar, capacitar e dar suporte aos responsáveis pelos registros.
Descritores: Segurança do Paciente; Notificação; Sub-Registro; Sistemas de Informação em Saúde; Erros Médicos.

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Introduction

The high incidence of adverse events in hospitalized patients is a reality in Brazil and around the world[1]. It is estimated that 10% of hospitalized patients suffer some kind of adverse event during their stay in the institution, causing an increase in length of stay and costs, greater demand for care actions, and a higher risk of mortality[2].

Patient safety is based on reducing unnecessary harm related to healthcare to an acceptable minimum, contributing to safe, quality care[1-4]. An incident is a circumstance occurring during the provision of care that could result in or has resulted in avoidable harm to the patient, while an adverse event is an incident that has resulted in some harm, possibly leading to death[2–3].

Adverse event reporting is considered an important strategy for patient safety and a reactive risk management tool that helps to detect weaknesses, and threats and propose changes in organizational processes, to prevent incidents[3–4]. Through reporting, it is possible to analyze the event that occurred, identify the reasons, implement actions to mitigate the error, and offer feedback to the team to provide safer care[5].

In Brazil, the official reporting systems are the Brazilian Notification System for Health Surveillance (NOTIVISA, in Portuguese)[6] and the Notification System for Incidents Related to Medicines and Vaccines (VigiMed, in Portuguese)[7], both managed by the National Health Surveillance Agency (ANVISA, in Portuguese). However, the underreporting of adverse events compromises the reliability of the databases and creates a scenario that is different from the reality of health services, making it difficult to know the most prevalent data and implement preventive actions accurately[8].

Despite the existence of reporting systems in hospitals and health professionals being aware of them[9], reporting is still limited, accounting for around 7-15% of adverse events[10]. Underreporting makes it difficult to plan actions aimed at mitigating incidents related to health care and their recurrence, making it an obstacle to improving patient care and safety; these cannot be neglected by health professionals, especially by the nursing team, which acts directly and continuously in providing care.

In this context, knowing the reality of adverse events in hospital institutions and identifying whether there is underreporting in official systems is fundamental for drawing up public actions and strategies aimed at improving the quality of care. This gave rise to the questions that guided this study: what are the most frequently reported adverse events related to health care in general hospitals? Are these adverse events reported in official notification systems, or is there underreporting? If they are underreported, what are the possible reasons?

The purpose of this study was to analyze adverse events reported internally in different hospitals and the possible reasons for underreporting to official reporting systems.

Methods

A study of a mixed nature. Mixed studies work with quantitative and qualitative data that complement each other by interacting dynamically and can exclude any dichotomy[11]. The recommendations of the Consolidated Criteria for Reporting Qualitative Research (COREQ) were followed.

The study was carried out in three general hospitals located in Minas Gerais, Brazil. These settings serve the Brazilian Unified Health System (SUS, in Portuguese), private hospitals, and health insurance companies, and have a formally constituted Patient Safety Center (NSP, in Portuguese) registered with ANVISA's notification systems. To facilitate understanding and maintain the anonymity of the institutions, the hospitals were randomly named H1, H2, and H3. H1's NSP has six members, H2 has 11 members and H3 has 26 members.

For the quantitative approach, we used secondary data from the internal notification forms of the

three hospitals. These were the printed forms made available for staff to record adverse incidents/events, from 2013 to 2020, in the institutions surveyed. The data from the internal forms was collected in 2020 by the lead researcher.

After collecting data from internal notifications, identifying 1,154 adverse events, secondary data was collected from NOTIVISA (Health Care module) and VigiMed, delimiting the period from 2013 to 2020, for comparison purposes. This data was requested through the Electronic System for the Citizen Information Service (e-SIC).

Quantitative data were collected using a questionnaire with a World Health Organization script[12]. The following variables were considered for the data reported in both the internal forms and the official systems: classification of the type of adverse event; degree of damage; sector involved; period of the day and year of occurrence. The classification of the type of adverse event is related to the adverse event that occurred (fall, pressure injury; failure to identify, medication errors, among others). As for the degree of damage, it can be mild, moderate, severe, or death. VigiMed classifies the severity of the damage as serious or non-serious. The sector involved is where the adverse event occurred. The time of day indicates whether the adverse event occurred during the day (7 am to 7 pm) or at night/midnight (7 pm to 7 am). The year of occurrence is the year in which the patient was affected by the adverse event.

The data were analyzed using SPSS software, version 20.0. Quantitative data was described using absolute and relative frequencies. For the qualitative data, the participants were members of the NSPs of the three hospitals. The inclusion criterion was to be a formally appointed member of the nucleus. Those who were on leave or vacation during the collection period were excluded. In total, there were 43 members, and the final sample numbered 27. 16 professionals did not agree to take part, mainly medical professionals, and/or were not in the institution at the time of collection. Four professionals were interviewed in H1, seven in H2, and 16 in H3.

The interviews were conducted using a semi-structured script developed based on the initial quantitative results. The script contained questions about the appointment, composition, and performance of the NSP in the event of an adverse event; facilities and difficulties related to reporting in the systems; participation in training; knowledge of the reporting process; and the institution's performance after reporting the incident. There was also a survey of the participants' characteristics, such as gender, age, and profession. The script underwent a pilot test to assess adaptations, with no need for changes.

The interviews took place from March to May 2023, conducted by the main researcher. They were individual and took place in the workplace, in private places, so as not to disturb or inhibit the participant's spontaneity. Before starting, authorization to record was requested, and the participants received clarification on the content of the study and its ethical aspects and signed the Informed Consent Form. A smartphone voice recorder was used for later manual transcription and analysis by the researcher. The interviews lasted between ten and forty-six minutes.

To ensure the anonymity of the interviewees, the interviews were coded by the letter "E" for interview, followed by an Arabic numeral, according to the order in which they were conducted. For the coordinators of the centers, the letter "C" was added after the letter "E".

The data were transcribed in full, thoroughly read, and organized. Analysis was carried out using the Content Analysis method[13], which is a set of techniques based on an exhaustive process of divisions, calculations, and refinements that combine systematization strategies to increase statistical rigor without losing the subjectivity of the analysis. The following stages were carried out: pre-analysis (organization of the textual material and floating reading); exploration of the material (coding of the data according to

the objectives of the study using thematic analysis of the frequency type); treatment of the results and interpretations. This enables the creation of categories, subcategories, recording units (themes), and context units. The context unit corresponds to the segment of the message used to understand the record unit[13].

Each interviewee's response was taken as a Context Unit, and the themes (recording units) that appeared in the context were marked. Once the themes had been identified and given a code, the material was transferred to an Excel analysis grid to filter and standardize the codes grouped into their respective categories. Two categories with their respective subcategories emerged from this frequency-type categorical-thematic technique. After the manual stage, the content of the interviewees' statements in the two categories was subjected to automated analysis using the *Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires* (IRaMuTeQ) software. This is free software that is anchored in the statistical environment of the R software and is suitable for carrying out statistical analysis of textual data. This program allows for various analyses, including the Descending Hierarchical Classification (DHC) used in this study.

In all stages, the ethical aspects were respected with the approval of the project by the Research Ethics Committee of the Federal University of Viçosa, with an opinion of 2,957,054/2018 and a Certificate of Presentation of Ethical Appreciation: 99312718.3.0000.5153.

Results

Based on a quantitative analysis of the consolidated internal notification forms from the three institutions, 1,154 adverse events were identified. Of these, 755 (64.4%) were registered in NOTIVISA. The most reported adverse events are described in Table 1. Two adverse events (0.2%) were reported on VigiMed. The prevalence of underreporting of adverse events was 34.4%.

Table 1 – Classification of the type of adverse event reported on internal forms and in the health surveillance reporting system. Viçosa, MG, Brazil, 2023

Types of adverse events	Internal files n (%) (n=1,154)	NOTIVISA* n (%) (n=755)
Medication errors/intravenous fluids	251 (21.8)	21 (2.8)
Clinical process/procedure	179 (15.5)	32 (4.3)
Pressure injury	130 (11.3)	47 (6.2)
Fall	99 (8.6)	51 (6.7)
Failure to identify	96 (8.3)	64 (8.5)
Nutrition	51 (4.4)	33 (4.4)

*NOTIVISA: notification system for health surveillance

In terms of severity, there was a predominance of adverse events with mild damage. In the internal files, 859 (74.4%) were mild; 269 (23.4%) moderates; 13 (1.1%) severe, and 13 (1.1%) deaths. In NOTIVISA, 585 (77.5%) were mild, 154 (20.4%) moderate, 11 (1.4%) severe, and five (0.7%) deaths. In VigiMed, there was one serious adverse event related to a probable allergic reaction to the chemotherapy Taxol and one non-serious event related to a probable reaction to meropenem.

The year with the highest number of notifications was 2015, both on internal forms (411/1,154) and on NOTIVISA (341/755). On the internal forms, 160 incidents occurred during the day shift, 112 during the night shift, and 882 were not reported. In NOTIVISA, 483 incidents occurred on the day shift, 192 on the night shift and 80 lacked this information. The hospitalization sector, the emergency room, and the intensive care unit were the sectors with the most incidents.

For the qualitative approach, 27 NSP members were interviewed, three of whom (11.1%) were coordinators. Their ages ranged from 26 to 57, with 24 (88.9%) women and three (11.1%) men. In terms of education, 17 (63%) were nurses, three (11.1%) were work safety technicians, two (7.4%) were administrators, two (7.4%) were pharmacists, one (3.7%) was a nutritionist, one (3.7%) was a nursing technician and one (3.7%) had completed high school.

Based on the data from the interviews, thematic content analysis of the frequency type gave rise to two categories and subcategories: 1) Factors that interfere with the notification of adverse events in official systems, with the subcategories: a) Gaps in knowledge on the subject, b) Performance of the patient safety center, c) Facilities and difficulties related to official systems, d) Notification system for health surveillance, e) Notification system for incidents related to medicines and vaccines, and f) Involvement of senior management. 2) Recognition of underreporting, with the subcategory: a) Underreporting.

Factors that interfere with reporting adverse events in official systems

This category brought up reasons for under--reporting in official systems: lack of training related to the process of reporting, the weaknesses and difficulties experienced by members of the NSP, lack of knowledge and complexity of the systems, and a fundamental point for adherence to reporting, which was pointed out by the participants, the lack of support from senior management.

Gaps in knowledge on the subject

This subcategory describes the scenario of unfamiliarity with the official systems and their functionalities, with emphasis on the lack of training and lack of access to the systems by members other than the coordinator of the center: *I can't tell you which notifications go to NOTIVISA, I don't know it. I've never heard of VigiMed* (I14). *I wasn't told that other people could use NOTIVISA* (IC15).

The role of the patient safety center

The data showed that there is a need to set up NSPs with more active, participative members who know and value the importance of patient safety in the institution. The testimonies showed a superficial performance by the members, activities carried out by the coordinator, discontinuity of actions, and members who don't feel they belong to the nucleus: *I take part in meetings, I give opinions. But I have no role in the center* (I4). *The members don't understand the importance of patient safety. Everyone talks about it, but when it comes to acting, it's always very difficult. We have a beautiful nucleus, but who carries it out? When we go after people, they don't understand* (I7). *There have been several periods when we haven't continued with the nucleus' actions. There was discontinuity* (I12).

Facilities and difficulties related to official systems

In this subcategory, the professionals who were able to report facilities and difficulties related to the systems were the members who had already acted as coordinators or held this position at the time of the interview. Factors that make it difficult to use the systems outweigh the facilities, such as instability of the system, difficulty in accessing it, delay in making notifications, and long forms. The following were listed as facilities: checkbox fields and data recorded in one system: *Sometimes, you've done the whole notification and when you save it, it crashes. You must do it all over again. Sometimes it takes a while to log in, we can't access NOTIVISA. Once you've logged in, the system is all checkboxes. You don't have to write much. It's the only facility I can see* (I7). *I find the system vague and flawed in some ways. The fact that it's just an open field to write down what happened is not enough. We can't always classify our view within the options that NOTIVISA offers. In terms of facilities, I think it's this compilation* (IC11).

Notification system for health surveillance (NOTIVISA)

This subcategory highlights some of the reasons for underreporting in the system: some items lack clarity, and it takes time to notify I find notification in NOTIVISA difficult: *At the same time as it gives you several options in one item, the options are vague* (I7). *According to the coordinator, some things are not clear when it comes to making the notification* (I12).

Notification System for Incidents Related to Medicines and Vaccines (VigiMed)

About VigiMed, it was possible to observe that the members who had never held a coordination position were unable to give their opinion on the system. The statements showed that some members were unaware of the system and considered it more complex and more difficult to operate when compared to NOTIVISA: *I know VigiMed exists, but I've never used it* (I3). *I find it much more complicated than NOTIVISA. With VigiMed, I confess that I leave the notification in the corner. ... It's more complex than NOTIVISA* (IC11).

Senior management involvement

Another aspect identified was the management's attitude, which corroborated negatively with the notification process. The lack of recognition of the importance of the center, of investment, of human resources to carry out the activities related to the center, and of knowledge about the center's work was highlighted: *When I joined, they didn't see the sector as essential. Today, they give it more importance. But there still needs to be more investment in the sector, investment in human resources would be essential* (I10). *About managers and coordinators, I try to talk to them. I've talked to the administrative staff, to the superintendent, about the non-punitive culture. But we still have people who have a certain difficulty with non-punitive behavior* (IC15).

Recognizing underreporting

This category corresponds to the explicit declaration of underreporting in official systems by the participants. Internal underreporting is the main reason for this underreporting.

Underreporting

In this subcategory, the interviewees expressed their experiences and justifications for this underreporting, such as internal underreporting, exceeding the deadline for notifying the system, difficulty of access, and/or the absence of a responsible professional: *We know that there is underreporting. Sometimes we identify things that happen, but they don't arrive in the form of a notification* (I10). *Some I didn't notify because they had a deadline, so there wasn't time* (IC15). *Many notifications went unnoticed due to difficulties in accessing the system, when I was without a professional and when I had a professional but couldn't access the system* (I17).

To make the analysis more robust, we opted to add to the content analysis the statistical analysis of the textual corpus made up of fragments from the 27 interviews, already separated into the two categories, using IRaMuTeQ.

Analysis of the corpus revealed 12,285 occurrences (words, vocabulary) distributed in 1,595 forms. Using DHC, 354 text segments were analyzed, with 80.51% of the corpus being used. After processing and grouping the occurrences of words, the DHC gave rise to two thematic categories and five classes, as shown in the dendrogram (Figure 1). The dendrogram showed the association between the classes and the percentage of text segments in each class.

The categories and classes were named by the researcher, considering the most significant segments of text, the meanings of the words in each class, and the objectives of this study.

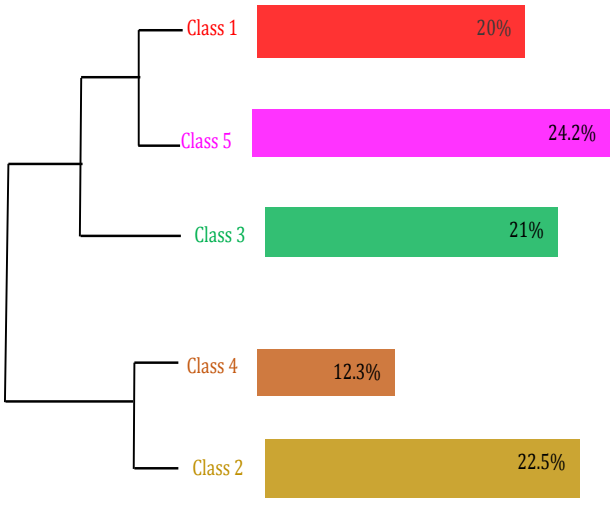
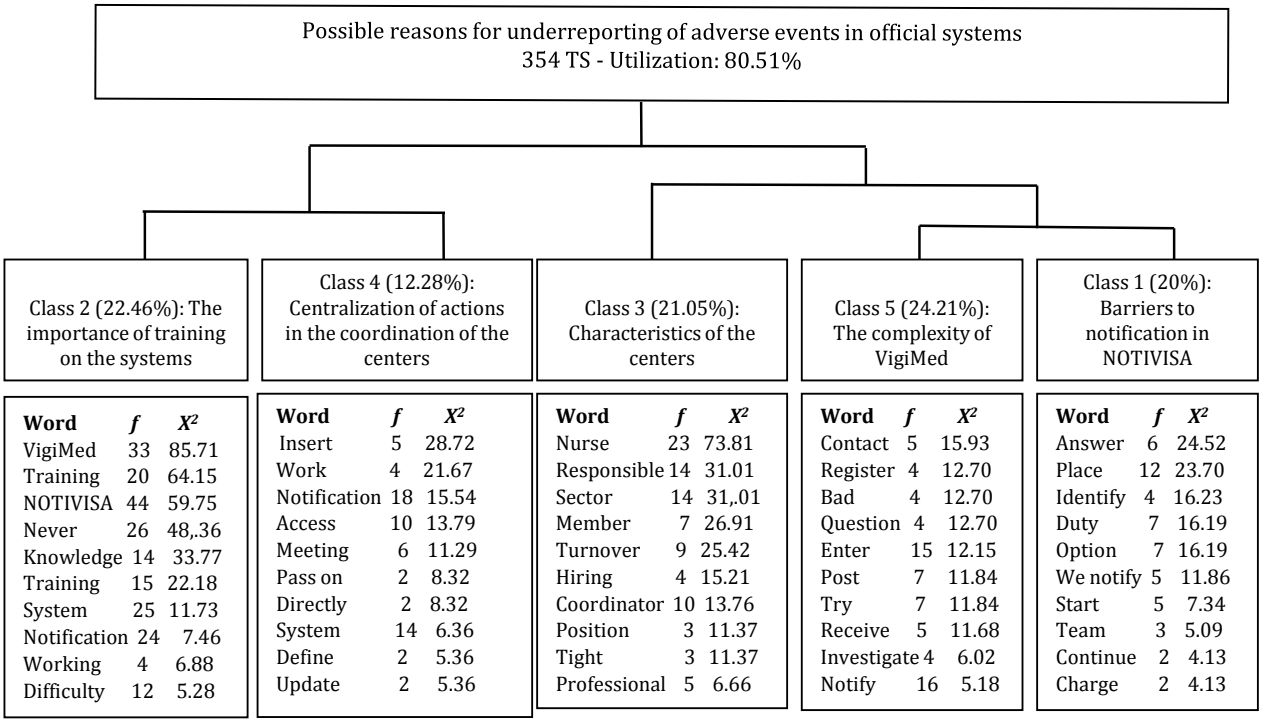


Figure 1 – Dendrogram of the classes provided by the IRaMuTeQ software (n=27). Viçosa, MG, Brazil, 2023

Category A: Challenges to reporting adverse events in official systems comprised 65.2% of the proposed text corpus, with the following classes: 1) Barriers to reporting in NOTIVISA; 5) The complexity of VigiMed and 3) Characteristics of the hubs. Category B: Weaknesses of the Patient Safety Centers comprised 34.8% of the corpus, with the classes: 4) Centralization of actions in the coordination of the center and 2) The importance of training on the systems.

IRaMuTeQ also provides a presentation of the results based on the different words and variables associated with each of the CHD classes, obtaining statistically significant words, and enabling a more qualitative analysis of the data (Figure 2).



ST: Number of text segments,; f: Number of text segments containing the word in the class; x2: Chi-square of association of the word with the class (x2>3, the higher this value, the more the word is associated with the class)

Figure 2 – Diagram of the Descending Hierarchical Classification classes and their statistically significant words (n=27). Viçosa, MG, Brazil, 2023

In classes 1 and 5, the words contact, response, put, bad, launch, and charge, shown in Figure 2, denote the professionals' conception of the challenges experienced about recording notifications in the systems. Among these challenges, the testimonies highlighted the difficulty of accessing the systems, restricted options for responses, the complexity of the systems, and the need to charge after notification. This was also evidenced by the content analysis in the subcategories: facilities and difficulties related to official systems; notification system for health surveillance (NOTIVISA); notification system for incidents related to medicines and vaccines (VigiMed) and underreporting. It should be noted that the statistical analysis of the textual corpus revealed a possible reason not detected in the content analysis "Charges after notification": *Some days, NOTIVISA is very bad. It takes a long time to log in; we can't access it* (I10). *Sometimes, when I get to the end of the notification, I can't send it, and then I must start from scratch* (IC1). *Some things aren't notified so that we don't shoot ourselves in the foot. When we notify, it's charged for, and people don't want to be charged. If I notify them, health surveillance will come and investigate and will demand a position from the institution. So, there are things we don't notify, even though we know we should* (I7).

As shown in Figures 1 and 2, class 3 is associated with classes 1 and 5. The words "turnover", "sector", "person in charge" and "function" show the reasons for the occurrence of the challenges pointed out by these classes, such as the turnover of professionals in the sector, making it impossible to continue actions and deepen knowledge about notification systems, and the person in charge of the center answering for another sector, leaving this professional overloaded and compromising the execution of their functions. The discontinuity of actions was also found in the subcategory "performance of the patient safety center", but class 3 made it possible to detect the turnover of professionals and work overload as possible reasons for underreporting: *We had a high turnover of professionals and professionals who did not give good continuity. The turnover at the center is enormous* (I17). *When I joined the Hospital Infection Control Committee and the center, there was no coordinator at the center for three months. I joined this committee, but here there was one nurse for both sectors* (I10). *There was no exclusive nurse, in fact, the institution never had an exclusive nurse for patient safety. I was the first to have this position* (IC11).

Classes 2 and 4 are correlated, as shown in Figures 1 and 2. In class 2, the words "capacitation" "training," "never," and "know" revealed a lack of knowledge and training about the systems, especially among the members who had never held a coordination position, making it impossible for the interviewees to give their opinions on the facilities and difficulties related to the systems. Corroborating what was said in class 2, in class 4, the words insert, notification, and access demonstrated the centralization of actions in the coordination of the nucleus. These findings ratified the possible reasons detected in the subcategories "gaps in knowledge on the subject," "performance of the patient safety center," and "system for reporting incidents related to medicines and vaccines (VigiMed)", giving more robustness to the content analysis: *I've never done training on NOTIVISA reporting. I've never heard of VigiMed. Only NOTIVISA, but I don't know which notifications go to NOTIVISA* (I9). *She (the coordinator) notified me of all the events and some suspicious products, but I've never used them. I don't know if the platform is easy to access; I don't know anything* (I21).

Discussion

The study made it possible to identify the main adverse events related to health care reported internally in the hospital environment and the possible reasons for under-reporting to official systems. The results provoke reflection on the magnitude of the problem in the country and the need to treat the issue as a priority. The innovative aspect lies in the evaluation of adverse events reported internally in the services and which did not reach the official systems, characterizing significant underreporting.

The identification of underreporting of adverse events reported internally and not recorded in official systems reinforces the importance of a more assertive policy involving health professionals in reporting incidents and mitigating errors[14]. It should be noted that medication/intravenous fluid errors and clinical processes/procedures were the two main adverse events reported internally, but only 8.4% and 17.8% of these were reported in official systems. It is believed that under-reporting is associated with fear of external prosecution by the regulatory body, given the potential impact of the events.

After more than 10 years of the National Patient Safety Program, the lack of knowledge about how to report, the fear of punishment, and centralizing reporting in the hands of nurses are aspects that limit reporting[15].

In terms of severity, according to international literature, 42.0% of adverse events can result in mild harm to the patient, 18.0% moderate, and 2.0% severe[16]. In a teaching hospital belonging to the SUS, 91.5% of adverse events caused mild patient harm, 6.9% moderate, 0.2% severe, and 0.3% death[5]. These results are like those found in this study, in which most adverse events reported resulted in mild harm, followed by moderate harm. However, it cannot be ignored that in the different studies, incidents generated serious harm and deaths, representing lives lost because of avoidable incidents and unsafe healthcare practices. In our study, of the 13 deaths notified internally, only five were reported in NOTIVISA. This sho-

ws that adverse events remain insufficiently reported, investigated, and neglected, even though they are a potential factor in mortality, morbidity, and economic, social, and psychological costs.

The qualitative findings reinforce the quantitative ones, denoting underreporting in official systems, resulting from situations such as missing the deadline for registering in the systems, difficulty in accessing the systems due to the turnover of the coordinator of the center, work overload, internal underreporting, gaps in knowledge, as well as difficulties in operating the system and lack of investment by senior management in human resources to work exclusively in the NSP. In Brazilian health services, among the reasons for under-reporting are high turnover, lack of time to report, forgetfulness, lack of knowledge of how to report, and work overload[15,17]. There is also a lack of incentive to report, forms that are difficult to understand, long and complex, fear/shame, and a punitive institutional attitude[6,18]. A punitive environment focused on blame, fear of punishment, lack of feedback, and absence of a learning culture were listed by professionals working in intensive care units as reasons for underreporting[19].

This is not just a national reality. In Indonesia, a lack of understanding of the benefits of reporting, a lack of knowledge about reporting, and a lack of a reporting culture were found to be contributing factors to underreporting in a reporting system implemented almost two decades ago, where only 334(12%) of the 2,877 hospitals reported[20].

Among the obstacles to reporting adverse events in official systems, professionals listed: instability of the system, difficulty of access, lack of clarity in some items, and lengthy forms. An evaluation of the performance of NOTIVISA-medications considered it to be complex and with low potential for acceptability due to the large number of variables to fill in[21].

Cases of adverse drug reactions due to COVID-19 were not reported by 11 states on VigiMed[22], which raises doubts about the cause, i.e. whether the lack of reporting was due to the absence of adverse reactions in patients, operational and structural difficulties faced by states and municipalities, or whether there was underreporting. In this regard, a study on COVID-19 identified 182 cases of adverse drug reactions, but only 28 reports were reported to VigiMed, confirming the hypothesis of underreporting[23].

The panorama of patient safety in Latin American hospitals has shown the importance of interaction between professionals and teamwork in improving patient safety[24]. However, according to the reports, there is fragility in recognizing the importance of the NSP's role in improving the quality of care and the centers still lack human resources to effectively carry out their competencies.

The lack of material and human resources has also been pointed out by other authors as contributing factors to underreporting[17]. In this context, it is important to implement actions to help reduce underreporting, such as appointing more active professionals who have autonomy in the institution and understand their role as a member of the NSP, with a dedication to this function and not the overload of roles to be played in the institution. In addition to registering and granting access for other users to make notifications, not just the coordinator, training in the use of ANVISA's official systems, redesigning processes, and institutional strategic actions after the adverse event has been notified and has occurred.

Study limitations

As a limitation, a descriptive study based on secondary data has its data quality limitations. In addition, the study was carried out using data from three institutions, so the findings cannot be generalized.

Contributions to practice

The results showed that, in addition to internal underreporting, which has already been widely discussed in the literature, there is still underreporting of adverse events to official systems. The findings make it possible to reflect on the important role of managers, professionals, and the regulatory body in the

notification process, as well as the need for improvements in information systems to reduce underreporting, such as the availability of a more agile communication channel with those responsible for the systems, insertion of open fields for a better description of the incidents that have occurred and short forms for quicker completion.

It is believed that the results could support the planning of actions to facilitate, train, and support the professionals responsible for recording adverse events in different contexts. These actions should range from ongoing training programs for the entire care team, with the involvement of senior management, to the development of public policies that encourage and favor the reporting process, thus strengthening patient safety.

Conclusion

Among the adverse events reported internally in the different hospitals, those associated with medication/fluid errors and clinical processes/procedures stand out. On the other hand, in the official systems, the main notifications were of adverse events related to failure to identify and falls.

The prevalence of underreporting of adverse events to official systems was 34.4%, the main reasons being: difficulty of access, complexity and instability of official systems, lengthy forms, lack of knowledge about official systems and the competencies of members of the center, turnover of professionals, work overload, as well as lack of investment, training and human resources to work exclusively in the NSP, prioritizing patient safety.

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Authors' contributions

Conception and design or analysis and interpretation of data, drafting of the manuscript, relevant critical revision of the intellectual content, and final approval of the version to be published; responsibility for all aspects of the text in ensuring the accuracy and integrity of any part of the manuscript: Ferreira EC, Arcanjo RA, Toledo LV, Siman AG.

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