# Barriers and incentives to reporting medication errors and near misses in a university hospital: perception of doctors, nurses and pharmacists

## *Barreiras e estímulos à notificação de erros de medicação e quase falhas em um hospital universitário: percepção de Médicos, Enfermeiros e Farmacêuticos*

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**ABSTRACT**
**Background:** Medication errors produce substantial damage to the health of patients and institutions, though they are often under-reported. **Objectives:** The goal of this study is to understand the barriers and incentives to the reporting of medication errors and near misses according to the perception of doctors, nurses and pharmacists, and to explore the understanding of the institution's medication error reporting systems. **Methods:** It is a qualitative study in which individual semi-structured interviews were carried out. The interviews were transcribed in full and submitted to thematic analysis of content. There were 15 in-depth interviews conducted. **Results:** Variations were identified among the professional groups regarding the previous realization of reports and the understanding of the current systems. The main incentives identified were: patient protection, professional responsibility, professional visibility, severity of errors, post-report feedback, non-punitive and personal approaches. The main barriers to reporting were: attribution of responsibility to another professional, conceptual problems, possibility of internal correction of the error, frustration when making mistakes, fear regarding the unfolding of the error and lack of knowledge of the reporting flows. **Conclusions:** The study made it possible to understand the factors related to the reporting of drug incidents in the institution where the research was carried out and also made it possible to draw parallels between the perspectives of the professional groups interviewed.
**Keywords:** Medication Error; Near Miss; Report; Doctors; Pharmacists; Nurses

**RESUMO**
**Introdução:** Os erros de medicação causam danos substanciais à saúde dos pacientes e às instituições, embora sejam frequentemente subnotificados. **Objetivos:** O objetivo deste estudo é compreender as barreiras e os estímulos para a notificação de erros de medicação e quase-falhas de acordo com a percepção de médicos, enfermeiros e farmacêuticos, e explorar a compreensão dos sistemas de notificação de erros de medicação da instituição. **Métodos:** Trata-se de um estudo qualitativo no qual foram realizadas entrevistas individuais semiestruturadas. As entrevistas foram transcritas na íntegra e submetidas à análise temática de conteúdo. Foram realizadas 15 entrevistas em profundidade. **Resultados:** Foram identificadas variações entre os grupos de profissionais com relação à realização prévia de notificações e quanto ao entendimento dos sistemas atuais. Os principais estímulos identificados foram: proteção do paciente, responsabilidade profissional, visibilidade profissional, gravidade dos erros, feedback pós-notificção, abordagens não punitivas e pessoais. As principais barreiras ao relato foram: atribuição de responsabilidade a outro profissional, problemas conceituais, possibilidade de correção interna do erro, frustração ao cometer erros, medo quanto ao desdobramento do erro e falta de conhecimento dos fluxos de relato. **Conclusões:** A metodologia qualitativa utilizada permitiu alcançar uma compreensão aprofundada dos fatores relacionados à notificação de incidentes com medicamentos na instituição onde a pesquisa foi realizada, além disso, permitiu estabelecer paralelos entre as perspectivas dos grupos profissionais entrevistados.
**Palavras-chave:** Erro de medicação; Quase-falha; Notificação; Médicos; Farmacêuticos; Enfermeiros

## Introduction

The World Health Organization (WHO) published in 2017 the third global challenge for patient safety, called Medication without harm, which aims to stimulate the reduction of medication errors frequency and unsafe practices during the use of medicines.[1] By analyzing the history, serious adverse events involving substances applied for curative, prophylactic, diagnostic or symptomatic purposes have contributed to change the view of societies on the use of medicines.[2-4]

The occurrence of fetal malformation associated with gestational exposure to thalidomide, which affected thousands of children between 1959 and 1961, triggered regulatory actions and monitoring of adverse drug reactions worldwide.[3,4] In 1999 the publication of the Institute of Medicine (IOM) drew attention to safety during drug use in a new perspective: that of preventable adverse events. Based on the extrapolation of two studies conducted in hospitals, the IOM estimated that, in the United States, medication errors were responsible for more than 7,000 deaths per year.[5]

Several other publications have shown the high frequency of medication errors occurring in the hospital environment, with the capacity to produce direct damages to the health of individuals and institutions, increase hospital stay and costs, also contributing to the loss of confidence in health systems and creating dissatisfaction in patients as well as in professionals.[6-8]

Although the repercussions of medication errors are widely reported in the literature, it is estimated that between 50% and 96% of errors occurring in hospitals are not reported.[6,9] According to the IOM publication, most errors do not reach the patient, but are early signs of system failure with the potential to cause serious harm or even death.[5]It is understood, therefore, that medication errors and near misses are preceded by the same pattern of failures and only the presence or absence of prevention mechanisms determines what the outcome of the incident will be.[10] In health services, near misses continue to be underreported.[11]

Quantitative and qualitative studies have been carried out to detect the barriers and stimuli to the reporting of medication incidents.[12-13] Considering the limited number of published researches involving medical doctors, nurses and pharmacists, this study aims to broaden the understanding of the factors influencing the reporting of medication errors and near misses in the hospital environment from the perspective of these professionals and to explore the knowledge of the Institution's medication error reporting system.

## Methods

### Study Design

It is a qualitative study that aims to understand the spectrum of opinions and the different representations of the matter in question.[15]

### Data Collection

Data collection was conducted through semi-structured interviews with a single respondent (in-depth interviews). In order to assist in the conduct of the interviews, a guideline topic was elaborated based on the literature review on the subject and on field recognition (S1 Appendix). The interviewer has been trained in qualitative methods of research in discipline offered at Federal University of Bahia.

The interview audio was recorded electronically after approval of the interviewees and afterwards all interviews were transcribed in full, word by word. The saturation criteria was used to determine the end of data collection. At one point the researcher realizes that new perceptions will not appear, and the saturation point of meaning is reached.[15] After the notion that the saturation point had been reached, two additional interviews were carried out that proved the evaluation because they did not provide new analytical insights.[16] All interviews were conducted at the participants' workplace.

### Place of Study

The study was carried out in a large public university hospital, of medium and high complexity reference, linked to the Sentinel Hospitals network

of the Agência Nacional de Vigilância Sanitária (ANVISA), that aims to train professionals for the public health service in Brazil, and has a Pharmacovigilance Center implanted 18 years ago. The Center conducts the evaluation, investigation and processing of reports of medication errors and near misses since 2011, when a physical form was developed and as of 2016 the hospital also had an electronic system to report these incidents.

### Selection of Interviewees

The interviews were conducted with doctors, pharmacists and nurses directly related to patient care in the Hospital's clinical wards. For inclusion in this study, professionals needed to have a minimum of six months of professional work in the institution, in order to guarantee knowledge of hospital protocols and policies. As exclusion criteria, invited professionals could not carry out their activities at the Pharmacovigilance Center, at the Medication Information Center or at the institution's surgical wards.

Participants were invited in person and, prior to conducting the interviews, the abstract and objectives of the study were explained, as well as the reasons and interests of the researcher on the topic of the study. Subsequently the consent form was presented for reading and approval. In all, sixteen professionals were invited. A professional informed that he preferred not to participate because of the unavailability of time. The interviewer has frequent contact with the pharmacists interviewed and is punctual with the other professionals, due to the activities developed at the Pharmacovigilance Center.

The qualitative research is not based on the numerical criterion to guarantee its representativeness, but it seeks to identify which social individuals have a more significant connection to the problem to be investigated. Adequate sampling is one that makes it possible to cover the whole problem investigated in its multiple dimensions.[17]

### Data Analysis

A thematic content analysis was performed, aiming at the interpretation of the meanings of the professionals' discourses and practices.[17] The texts were obtained from the literal transcript of the interviews. After that, audio listening was performed, as well as reading and re-reading of the transcripts, which allowed a general view and familiarization with the content. From the transcripts, the coding was performed in order to identify patterns and categories.[18] The codes identified were transferred to a spreadsheet in Microsoft Excel version 2010® and were related to the study objectives and identified by abbreviations to facilitate localization. For the summarization and organization of qualitative data, a thematic matrix was constructed, available in S2 Appendix. The generated matrix was used to classify and organize the data according to the main themes, concepts and emerging categories.[19]

The Consolidated Criteria for Reporting Qualitative Research (COREQ) was applied aims to promote complete and transparent reporting among researchers and indirectly improve the rigor, comprehensiveness and credibility of this study.[20]

### Ethical Considerations

The study was approved by the Institution's Research Ethics Committee under number 2.441.554. Issues related to anonymity and confidentiality were presented to participants.

## Results and discussion

Fifteen in-depth interviews were carried out between november 2017 and july 2018, involving 6 nursing professionals, 5 medical assistant preceptor and 4 pharmacists, all of whom are members of care teams of the institution's clinical units, being able to detect and report incidents with medications. The interviews lasted between 15 and 45 minutes. The characteristics of the participants are summarized in table 1. The interviewees were between 26 and 49 years old, 10 female and 5 male. With the exception of one participant, all had at least one postgraduate degree. One of the doctors interviewed was a risk manager in a previous employment relationship.

**Table 1.** Characteristics of participants

| **Professional working time** | Nurse | Pharmacist | Doctor |
|---|---|---|---|
| ≥ 6 months < 5 years | 1 | 1 | 0 |
| ≥ 5 years < 10 years | 1 | 1 | 2 |
| ≥ 10 years | 4 | 2 | 3 |
| **Experience time at the institution** | | | |
| ≥ 6 months < 2 years | 3 | 1 | 0 |
| ≥ 2 years < 5 years | 3 | 2 | 3 |
| ≥ 5 years < 10 years | 0 | 0 | 1 |
| ≥ 10 years | 0 | 1 | 1 |

All interviewees reported having witnessed, experienced or became aware of situations in which medication errors or near misses occurred during their performance in the institution. Some have reported that these incidents have occurred daily and in great volume. Despite these reports, only seven reported having made at least one report. Only pharmacists described reporting of drug incidents as a routine activity. The interviewed doctors reported never having reported medication errors and near misses. In some statements it was pointed out that the frequency of report is below the number of incidents identified, as reported by a Pharmacist:

*"I do report it, but I believe I do it too little, much less than the actual occurrence of errors there"* (Pharmacist F02)

The factors that stimulate the reports in the interviewees' perception were grouped into four themes: factors related to professionals, factors related to patients, factors related to type, nature and consequences of medication error and organizational factors.

## Factors related to professionals:

The understanding that the accomplishment of the report allows the insertion of the pharmacists and promotes the recognition of their performance by the care team, was realized, according to the speech of pharmacists, as a motivating factor.

*"It's something [the report] that was not covered by another professional... and the staff here was very lacking in that and I think it was well embraced by that proposal... so covering that part of security was something I saw I could fit in, that was completely uncovered and that also would gave visibility to the profession."* (Pharmacist F01)

Doctors and nurses reported on the contribution of pharmacists to ensuring safe treatments:

*"with the role of the pharmacist, which I only had the pleasure of having here in the university hospital, I mean, I never had a pharmacist as present in the ward as we have here in the hospital and in the infirmary 'z' in particular. That was when I realized how many mistakes we had and how much we did not realize."* (Doctor M01)

The incentive associated with professional recognition was not described in previous publications, thus, being a contribution of this study. In the original paper by Hepler & Strand it is argued that a profession with a well-defined identity and a clearly articulated purpose has more contributions to offer the community. The authors consider it to be an essential element, the acceptance by the pharmacists of their direct responsibility for the patient, promoting effective cooperation with doctors and nurses as equal professionals.[21]

The perception of reporting as a form of self-protection, due to legal or punitive repercussions, was shared by nurses, who highlighted this incentive as one of the most relevant, especially in situations considered serious. This factor was previously explained by other authors.[22-23]

*"[The incentive is] to protect oneself too! That is what's most important, to be self-guarded. Because in the end everybody has to answer for it. It's not only the person who committed the error, I'll answer for it as supervisor [the nursing technician]. According to nursing legislation, I'm responsible for supervising your activity. You will not answer alone, so in the end the group has to answer for it"* (Nurse, E04)

In the report of pharmacists and nurses the act of making the report is associated with a sense of professional responsibility that brings a *"sense of duty fulfilled"*.

*"but the biggest reason is to prioritize our responsibility over what we have decided to do, which is patient care. Once I have promised to decide working in an area where I need to prioritize my patient, I think that it is crucial for me to make this report."* (Nurse, E06)

Previous studies have described the sense of responsibility as an incentive for reporting amongst nurses.[24-25] That is a behavior that may be related to the ideals of the profession, which include the idea that policy violations and procedures should be reported, based on an ethical conduct towards the patient.[26]

The understanding shared by pharmacists that reporting is a professional liability is not explicit in previously published research. The two contributions presented on the behavior of this professional regarding the reporting of incidents can be perceived within the framework of the maturation of the pharmacist who begins to make the commitment, shared with other professionals, in relation to the therapeutic results of the patient.[21] Hepler in his article entitled "A dream deferred" discusses that the pharmacist owes society the act of making pharmacy a clinical profession in its entirety based on ensuring safe and effective pharmacotherapy and protecting patients from predictable drug-related morbidity.[27] From this point of view, the result found is positive, since it shows that, in the studied context, pharmacists are assuming their social role and being able to communicate it to other professionals.

## Related to patients:

All respondents considered that patient safety assurance is the main incentive for reporting, which could help prevent further incidents or minimize negative outcomes associated with the error. This stimulant factor has been described in a number of previously published studies.[22,28]

*"[the incentive is] so that other mistakes do not happen, so that we become aware, what was the reason for that mistake? So that we can make the diagnosis, what led to that mistake? And even because the medication error can have damaging consequences on the patient's life, don't they? It can be a threat to the patient's life."* (Nurse, E03)

## Type, nature and consequences of medication error:

Regarding the type of error, errors of dose omission, wrong medication administration or wrong dose, errors with high-alert medicines or involving professionals of another category were described as incentive to the report. These results have been described in previous research.[29]

According to the nature of the error, in the interviewees' perception of the three professional categories, the occurrence of a medication error causes greater stimulus to the report than the occurrence of a near miss, while the professionals recognize the high frequency in that near misses occur.

*"This, of errors, that is what reached the patient, so I end up prioritizing this, but near misses, is daily detecting near misses."* (Pharmacist F04)

*"it is fundamental to [report] the error because then it surpassed, passed through all the filters and ended up reaching, I mean, it reached the patient."* (Nurse, E03)

From these reports it is possible to understand that there is little understanding about the flows of occurrence of errors and near misses.[10] This result is similar to that of other published studies and shows that incident outcomes have a greater weight from the point of view of reporting than identification of sub-causes for occur.[29-30]

Regarding the consequences of the error, the main motivator to the report, present in the speech of the vast majority of those interviewed, is the severity of the outcomes. Practitioners have described that they are more likely to report error associated with harm, negative outcomes, such as clinical worsening and death, or those considered serious. This understanding is corroborated by previous studies.[21,24]

*"When it is something very rude, I think, let's say, I have ten prescription errors no matter which location, I think I'll report at most one, the most serious, something that puts the patient at risk. The simpler ones*

*that should be reported I guess they're not."* (Doctor M01)

## Organizational Factors:

This topic concerns the conditions related to the workplace that may stimulate reports. Pharmacists, nurses and doctors believe that reporting can be a tool to modify processes and prevent recurrence. This expectation was also described as an incentive to the report by other authors.[23,28]

*"I think that motivation has to be an evolution of the institution itself, to try to minimize mistakes, I think that has to be our motivation."* (Doctor M01)

*"Because what is underreported is unsolved! You do not solve what you did not identify as a problem. So, if I do not show that mistakes are happening there, no one will ever think about that ... and that may happen again ..."* (Nurse E04)

The non-punitive process-centered institutional approach, the confidential treatment of reported information, and the possibility of anonymity in incident reporting were factors considered as positive influences for reporting, which shows that in the view of some interviewees, the systemic approach is the most appropriate. In contrast, some respondents pointed to the use of reports to hold people accountable, as a means of promoting punishment of those involved, to increase vigilance over professionals, in order to increase personal attention or as a way to identify personal deficiencies. In some situations, personal and systematic ways of approaching the error were issued by the same person.

*"the first [obstacle] is the stigma, which most of the time ends up being directed to a person instead of verifying the process, so, sometimes I even agree with it because there are some people that you talk about, you explain, and it goes in one ear and out the other, and in my opinion, I've even talked about it once in the nursing ward, there has to be some punishment, because you can explain, you can guide, but people keep insisting on the mistake, so you'll have to take action."* (Pharmacist F03)

According to Reason the central idea of the systemic approach to errors is that it is not possible to change the fallible human condition, but it is possible to change the conditions in which people work.[31] Other authors describe that the non-punitive culture stimulates the realization of the reports.[25,32]

In contrast, according to Reason, in the people-centered approach, if something goes wrong, it seems obvious that an individual (or group of individuals) must have been responsible.[31] In other studies, the personal and punitive approach to errors has been observed as a barrier to reporting.[24,33] In this study, individual vision appears both as a barrier and as an incentive, which may influence the behavior of other team professionals in relation to incident reports.

The possibility of modifying the local culture was emphasized as an incentive by doctors and by one pharmacist, and it was previously exposed in the literature.[22-23]

*"I think it would be making the team aware of when these mistakes happen, these near misses, there isn't only one person responsible in the scene here, it is a whole process that was not adequate, there are several chains that did not work well for that to happen, so there's this, letting the team calm, so that reporting becomes simpler. And we also have to have the idea that it happens, that it is unfortunately more common than we imagine, and that it is an opportunity for improvement, I think if it becomes clear to the team, reporting, I believe it gets easier, right?"* (Doctor M04)

As for the reporting system, the feedback and deflagration of training and educational actions as a result of the reports were highlighted by pharmacists and nurses as factors that favor reports, as cited previously.[29,32]

*"I believe the feedback from the team that is investigating it is important because that way the person feels ... the reporter feels part of the situation, you see? To always leave the person updated on what has been defined, of what has been detected, so, I believe that this is important, the feedback after the reports."* (Pharmacist F04)

Factors perceived as barriers to reporting were grouped into five themes: factors related to professionals, factors related to patients, factors related to type, nature and consequences of medication error, factors related to the reporting system and organizational factors. The theoretical framework of stimulant factors is available in S3 Appendix.

## Factors related to professionals:

An important category identified is related to the sense that another professional is in charge of reporting incidents with medication. The responsibility for the report was a matter of doubt among the interviewees, which shows little understanding about the institutional policies regarding report of errors and near misses. Pharmacists expressed the view that other professionals attribute responsibility over the report to them and pointed out that they do not perceive responsibility on the part of medical professionals in that sense. A nurse described that nursing technicians attribute responsibility over the report to nurses. From the doctors' point of view, it is possible to infer that there is a notion that another person performs or should perform this activity, being mentioned in their speech that a pharmacist or a resident doctor should be responsible for it. Therefore, one can associate this belief to the doctors' precept that *"we were never told to do that [to report]"*, either during the training or in the professional practice. In interpreting the statements of doctors and nurses, it is possible to understand that the pharmacist is placed as the main responsible for monitoring, identifying and reporting errors and near misses.

> *"Maybe there is something else, the fact that I report a lot and the staff knows it, they prefer to throw [the responsibility] and, like, that is as if everything is thrown in one person, but if we consider this perspective here, no-one reports*." (Pharmacist F01)
>
> *"the pharmacist here is paying vary close attention to this, to the prescriber and to the person who administers the medication as well."* (Nurse E03)
>
> *"Not specifically [I've never reported], but since there is a clinical pharmacist who is very important, then usually the said pharmacist is the one who links this assistance to the events' part."* (Doctor M03)

The divergences on who is responsible for reporting were previously described in other studies.[28,32] Among doctors, this perception was more marked, which reveals aspects related to training and professional identity, which may impact their participation in the reporting systems. According to Nguyen, Weinberg, Hilborne, doctors tend to assume a passive position with regard to incident reporting, resulting in an underutilization of institutional systems,[34] which agrees with the result found in this study, that doctors were unaware of the institutional reporting systems, with the exception of one interviewed doctor.

This understanding was shared by other researchers, who attribute these behaviors to the medical culture, which promotes privacy, uses fewer directives, and demonstrates social models virtually non-existent in relation to incident reporting.[32-33]

Another barrier exposed by the three professional groups refers to difficulties in the definition, recognition and identification of errors and near misses. In some situations, professionals describe errors or near misses occurring in their units of action, and contradictorily, at other times they affirm that they have not made previous reports for never having witnessed or experienced these situations. Conceptual domain problems were more frequent among doctors and nurses. It was noted that there is ignorance of terminologies, attribution of incomplete definitions, expressed with uncertainty or with conceptual mistakes. For most interviewed doctors, the term "near miss" was unknown. The definition was correctly assigned only by the doctor with previous experience as a risk manager.

> *"[underreporting may occur by] simply not being identified the error or the near miss. It was not identified because the preceptor did not realize that he/she was wrong, or who administered it as well. Apparently, there was no perception of the error, they did not realize that it was an error"* (Doctor M04)
>
> *"I just discovered a concept of near miss, so I know what a near miss is, but I did not know that there was the term near misses, so there's no doubt that there's little clarity"* (Doctor M01)

When questioned about what the concept of medication error would be, a nurse said:

> *"I had a wrong view of medication error because I thought that medication error was you making a medication, for example, wrongly, diluting wrongly ... that case of a patient having an allergy I thought it wasn't an error of medication, but it is, right? [administering a medication to which the patient is allergic]"* (Nurse E01)

The perceptions above impact on the decision about when a situation is susceptible to reporting, as described by the pharmacist:

*"as a rule, I have the notion of what to report and so on, but sometimes I run into some situation like this and wonder: is it susceptible to reporting or not?"* (Pharmacist F04)

The identified barriers related to misunderstanding the concept of medication error and near misses contribute to underreporting. A possible explanation is related to the existence of multiple definitions, which may generate doubts among professionals.[35] Another aspect is related to deficiencies in training. With the aim of promoting education for patient safety among different health professions, WHO has published a multi-professional curriculum guide to overcome gaps in training.[36] In this study, deficiencies of understanding were pointed out as reasons for underreporting and linked to lack of training on the subject, similar results to those found in other studies.[23]

In particular nurses expressed feelings of frustration and dissatisfaction at acknowledging their own mistake, an obstacle to reporting expressed in the context of belief that errors can be totally avoided. In some statements, interviewees said that *"thanks to God"* they never had to report, that they had never experienced the *"displeasure"* of reporting, or that when such situation occurs, they *"feel lost"*.

*"I was like this because I hate to make a mistake, you know? Then when I got it, I looked at all the prescriptions, I noticed there was one I had done too, and I felt bad because I also saw it, I did it and I didn't see it was wrong. I didn't like it! I'd rather not making the mistake."* (Nurse E01)

*"I think that dissatisfaction is generated around oneself. Because we work with people and take care of human beings, we want to do everything 100% better 100% correct and then when we realize that we almost failed, I think it generates dissatisfaction with ourselves."* (Nurse E06)

Some practitioners' approach to the causes of medication error demonstrates a people-centered view and may reinforce the idea that they should be infallible. In some reports, practitioners say they believe that errors happen by *"doing things without thinking"*, *"malpractice, recklessness, and negligence"* or that after an error has occurred, one must identify *"who was the responsible professional"*.

These findings, widely discussed in the literature,[37,14] show that professionals are imbued, albeit unconsciously, with fears related to a punitive culture. As a result of this thinking, feelings of frustration, fear, dissatisfaction, anguish, and guilt are revealed, which have been identified in other studies.[25,28]

Non-recognition of the importance of reporting was described by the three categories of interviewees as an obstacle. A doctor and a pharmacist have pointed out that there may be a lack of personal interest in reporting. This understanding is corroborated by the results of other publications.[22,38]

*because from the moment you do not report, when you fail to report something of this gravity, then I think you may not be aware of the importance of all this"* (Nurse E03)

**Factors related to the type, nature and consequences of medication errors:**

The professionals expressed that they feel less stimulated to report the errors without damage, near misses and common mistakes, which is compatible with several studies.[29] In contrast, the occurrence of negative damage or outcome associated with an error may act as an impediment to the report, described in the perception of a pharmacist in relation to the nursing professionals and confirmed by the nurses' speech. This result is compatible with other described.[28]

*"reporting something like this... I think, in my case, if I had done something, a medication error, if I would want to report it... it is true, a patient with an injury, which led to death, I'd be afraid of some legal punishment."* (Nurse E01)

The possibility of taking local corrective actions and of correcting incidents internally has been understood as an obstacle to reporting. This practice hinders institutional learning and the systemic correction of errors. The study by Hewitt and Chreim described that health professionals, after identifying an error, tend to correct it and move on, except when there is harm to the patient.[39] According to Nguyen, Weinberg, Hilborne, the internal review of error situations is part of the medical culture of self-regulation and confidentiality, producing a sense of protection that, however, does not produce generalized discussions to prevent future situations.[34]

*"sometimes the doctor prescribes dipyrone, picks up the first option that is dipyrone ampoule, but for oral use. We always ask the intervention to modify it, but we don't necessarily report it, because it is very common to happen and then we end up not reporting"* (Pharmacist F02)

*"we signal error, it is something that I very much have learned to try to do, I have tried to do, even in my role of preceptor of realizing the error, I drawn attention to it, but I don't report it"* (Doctor M01)

## Organizational Factors:

The reporting barriers related concern or fear were organized in the following subcategories: fear of error exposure, fear of punitive repercussions, concern to seem incompetent, and concern about judicial implications. All these subcategories were relevant in the nurses' report.

*"Because when we talk about reporting, then the technician, the whole team gets all scared, thinking, like, after the report, what comes next? A squad after the person, get it??"* (Nurse E01)

*"If some event's report comes to the point of punishing you, that will certainly not have an effect, you see? What will happen is that the professionals will be afraid, it's always like that, but some time there will be an error ... and after that error what will happen to us, get it? In which ways we'll be punished, then we think, I'm going to lose my COREN? I always refer to the nurse category because we are on the front line and so we always receive the effects, the person who's on the front line always receives the outcome, the others end up escaping a little, or trying to, but those who administered, those who committed the error, those who committed a near miss will be really punished."*(Nurse E03)

Medical professionals also reported concerns or fears, but from the perspective of the error being documented and of related judicial repercussions.

*"if an error is documented, right, then later [judicial] consequences, I think that this fear exists."* (Doctor M02)

Another category identified as an impediment is related to corporatism, manifested as difficulty in reporting the mistake of another professional in order to maintain good relations or to protect professionals of the same category.

*"I think you have to have that responsibility, you have to know how to separate things, even if you have a very good friendship interaction with the team, it has to be put in the right place at the right time, right?... So, what really makes people not repot, in my opinion, is the fear of what comes after. How will it be? In this relationship, how things will be with him/her then? How will it be the within the team? How will the team see me then, right? How will they look at me, treat me? I think that's it..."* (Nurse E06)

*"well, to be honest, that's right, I kind of neglected the error in the prescription. So usually when I report the error, it would be that of an inadequate via, or an error of its dispensation, I asked for one thing and another came, that I usually report. I also don't know if that is protectionism, but I never reported a colleague's error of having mistaken the prescription."* (Doctor M01)

Fear of repercussions and protectionism have been previously described and are related to a view that culture is punitive.[33,37] These cultural conceptions are more difficult to undo and may require specific modes of intervention, possibly at all levels of the organization, from policy makers to practitioners.[40]

The lack of change in processes has been described by doctors and pharmacists as a disincentive to reporting, a result often described in other publications.[22,38] Issues related to infrastructure, such as the absence of sufficient terminals for reporting, were previously scored and described.[23]

## Factors related to the reporting system

Regarding the manner of making the report, pharmacists stated using the printed form for report while nurses described the electronic system as a means of communicating the incidents. With the exception of the doctor with previous experience in the area, all doctors, besides a nurse, were unaware of the current systems. The lack of knowledge about institutional reporting flows was an obstacle described in other studies.[23,33]

*"I really do not know the form. I really do not know the logistics of it; I, for example, did not know of*

*this near miss, I do not know about form".* (Doctor M02)

In the view of pharmacists, the absence of return or the prolonged time for it appears as a limiting factor. This result demonstrates that there is the understanding that reporting is part of a process of evaluation, action and communication. Problems in the transmission of research results have been highlighted in other studies as an important hindrance.[30,32]

*"So, the fact that there is no return, the feeling is that I'm going to do it here and it will not work. So, I think the report falls into this, it's an extra role to fill, it's an added obligation and it does not seem like it's going to have any return ..."* (Pharmacist F01)

### Work or extra time

Interviewees from all three categories reported that other routine activities may prevent reporting of incidents. Other factors were the volume of forms and forms to be filled by nursing staff, the need to transmit the data to different sectors and the existence of more than one system in place by pharmacists. The issues related to work overload and overtime were scored in several studies.[28-29]

*"I think there's the practical question of you taking the time to do that. I think that is the main thing, the investment of attention and time to report, within a busy routine like ours"* (Doctor M02)

*"The routine sometimes ends up consuming us so that we cannot report everything we should"* (Nurse E04)

### Limitations

Due to the qualitative nature of this research, it is not appropriate to generalize the results perceived to other populations, although they are compatible with studies carried out in the same context.[41-42] It should be considered that practices reported in interviews may be influenced by memory recalling point of view and/or the attempt to provide socially desirable responses.[43] To control this bias, the interpretations are not made based on an isolated report, but from a set of experiences. It should also be stressed that it is not possible to isolate the knowledge produced from the person who produced it.[44-45]

## Conclusion

According to the reviews conducted, this was the first study carried out in Brazil with the aim of finding out about the perceptions and attitudes of professionals who provide direct patient care regarding the reporting of drug incidents.

This study allowed us to broaden our understanding of the barriers and incentives to reporting medication errors and near misses, to explore knowledge about the current reporting systems in place at the institution and to understand how professionals understand the concepts of medication errors and near misses, with a view to reducing underreporting and improving patient safety. The inclusion of pharmacists made it possible to increase the knowledge base on the perceptions of this professionals about reporting incidents involving medications. In addition, the study contributed to comparisons between the perspectives of the groups interviewed.

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# S1 Appendix - Guide topic for semi-structured interview

## First part:

- Survey of sociodemographic data:
- Name;
- Age;
- Sex;
- Professional qualification;
- Time of professional experience;
- Experience in the institution.

**Second Part:**

- Activities and routines developed in the Institution;
- The reporting of events and their insertion in the routine;
- Understand what comes to one's mind, what one thinks about medication errors and about near-misses;
- Check if it's considered important to report these incidents and why;
- Understand the sensation after making a notification;
- Identify the personal understanding of the concepts of medication error and near-misses;
- Understand to what the professional attributes, in the personal and collective scope, the occurrence of underreporting;
- Understand what motivates, in the personal and collective scope, the act of reporting;
- Ask what are the greatest barriers and incentives to reporting;
- Evaluate the knowledge about the process for reporting these incidents with drugs in the institution; Check if there was any guidance on this process; Personal evaluation of hospital reporting systems;
- Proposals for strategies to encourage reports;
- Identify whether respondents often report errors and near-misses and how often;
- Understand whether, depending on the situation, the act of reporting is more important;
- Raise expectations after reporting;
- Identify positive or negative experiences as a result of a reporting;
- Free additional placement on the theme;

# S2 Appendix – Thematic Matrix of Factors that stimulate the notification

| THEMES | CATEGORY | INTERVIEWEE (CODE) |
|---|---|---|
| Related to professionals | Professional recognition | F01 (L1-L2) |
| | Professional responsibility | F01 (L3); F02 (L8); F04 (L3) |
| | | E03 (L9); E06 (L4) |
| | Self-protection | E03 (L5); E04 (L4); E06 (L3) |
| Related to patients | Patient safety | F01 (L2) |
| | | E03 (L2-L4; L6); E06 (L3-L4) |
| | | M01 (L4-L5); M02 (L3); M03 (L2); M04 (L2; L4); M05 (L3) |
| Related to type, nature and consequences of medication error | Error associated with harm, negative outcomes or those considered serious | F01 (L4-L6); F02 (L2-L4; L6); F03 (L6) |
| | | E03 (L2 – L5; L7); E05 (L4); E06 (L5); |
| | | M01 (L4-L5); M02 (L3); M03 (L2); M04 (L5); M05 (L5) |
| | Medication error | F02 (L2); F04 (L2) |
| | | E03 (L7); E06 (L5) |
| | Errors of dose omission, wrong medication administration or wrong dose, errors with high-alert medicines | F01 (L5) |
| | | E06 (L5) |
| | | M05 (L4) |
| | Error involving professionals of another category | F01 (L7); F04 (L10) |
| | | M01 (L3) |
| | Repeat erros | F02 (L3) |
| Organizational Factors | *Feedback* and deflagration of training and educational actions | F02 (L3); F03 (L5); F04 (L5-L6) |
| | | E03 (L8); E04 (L3; L6); E05 (L2) |
| | | M01 (L9-L11); M02 (L18); M03 ( L22; L30; L31); M02 (L18); M05 (L5) |
| | Modify processes and prevent recurrence | F02 (L5-L7); F03 (L3); F04 (L4) |
| | | E01 (L2); E02 (L3); E03 (L2; L6; L10); E04 (L2-L3; L6); E05 (L2; L5); E06 (L3) |
| | | M01 (L2); M02 (L2-L3); M03 (L3); M04 (L2-L4); M05 (L2-L3) |
| | Non-punitive approach, modifying the local culture, the confidential treatment and anonymity | F03 (L2) |
| | | E01 (L3); E02 (L2); E04 (L3; L5); E05 (L2) |
| | | M03 (L5); M04 (L4; L6); M02 (L2); M05 (L3) |
| | Hold people accountable, increase vigilance over professionals, increase personal attention and identify personal deficiencies | F03 (L9) |
| | | E06 (L2-L3); E04 (L2); E05 (L5); E02 (L3) |
| | | M03 (L4) |

# S3 Appendix – Theoretical framework 1: Barriers to notification of medication errors and near misses

| THEMES | CATEGORY |
|---|---|
| Related to professionals | Another professional is in charge of reporting, was not guided as being professional |
| | Difficulties in the definition, recognition and identification of errors and near miss |
| | Non-recognition of the importance of reporting |
| | Frustration and dissatisfaction at acknowledging their own mistake |
| | Lack of personal interest |
| Related to type, nature and consequences of medication error | Correcting incidents internally |
| | Prescription near miss and common mistakes |
| | Errors without damage, near miss |
| | Error with damage |
| Organizational Factors | Concern about judicial implications |
| | Fear of error exposure, concern to seem incompetent, difficulty in reporting own error |
| | Fear of punitive repercussions, fear of being hampered in professional progression |
| | Difficulty in reporting the mistake of another professional, maintain good relations, corporatism |
| | Lack of change in processes |
| | Infrastructure |
| Related to the reporting system | Existence of more than one notification route |
| | Lack of knowledge about institutional reporting flows |
| | Difficulty in accessing the form |
| | Unnecessary information required |
| | The absence of return or the prolonged time for it |
| Work or extra time | Time spent on other routine activities, time necessary to report errors, dynamics of the wards |
| | Volume of forms to be filled, need to transmit the data to different sectors/ systems |