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Article

Brazilian Hospital Pharmacy: perception of the clinical attributions of pharmacists in view of the Basel Declaration of the FIP

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This descriptive study analyzed the perceptions of Brazilian hospital pharmacists towards their clinical attributions related to "interventions in the prescription" and "monitoring the use of medication" in view of the current Basel Declaration of the International Federation of Pharmacists (*Federação Internacional de Farmacêuticos* - FIP). Brazilian hospitals of high and medium complexity were identified and a pre-tested questionnaire based on the 65 recommendations of the Basel Statments was sent via e-mail, directed to the pharmacists of the 2,054 hospitals. The results were categorized into: a) they meet the statement, b) they do not meet, or c) they did not respond. Pharmacists from 111 hospitals returned the survey. For the recommendations of the theme "influences on prescribing", the highest percentage of compliance was related to the effective performance of pharmacists in the Pharmacy and Therapeutics Committee (PTC), which occurred in 54.1% of the hospitals. While for the "monitoring the use of medication" was refered to the existence of an easily accessible system for notifying technical complaints, in 47.7 % of the hospitals. The results emphasize that these activities need to be reviewed and aligned, to offer better quality and more safety to the patient in relation to the use of medication.

Keywords: Pharmacy Service,Hospital. Patient Safety. Statements. Drug Monitoring. Pharmacy and Therapeutics Committee.

INTRODUCTION

The World Health Organization (WHO, 2010) has reported that more than half of all medication (drugs) prescribed and dispensed are used incorrectly. It is estimated that up to 50 % of patient safety incidents are medication-related (NCCMERP, 1998). In Brazil, between 2008 and 2012, 55,604,537 hospitalizations were registered in the Hospital Information System of the Public Health System (HIS-SUS), of which 289,039 were related to adverse drug events (ADE). A total of 2,528 of these admissions had an International Classification of Diseases (ICD-10) code for ADE in the "cause of death" field (Martins *et al.*, 2018). Specifically in the intensive care unit (ICU), the incidence of elderly patients with ADEs can reach 22.3 % (Gomes, 2017).

The occurrence of ADEs is of such magnitude and impact that the WHO (2017) launched *Medication Without Harm*, an initiative that aimed to reduce by 50 % the serious and preventable harm associated with medications in the subsequent five years. In Brazil, for the control and prevention of these occurrences related to medical-hospital care, the Brazilian Society of Hospital Pharmacy and Health Services (*Sociedade Brasileira de Farmácia Hospitalar e Serviços de Saúde*) encourages the safe and proper use of medication through the publication of minimum standards

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(SBRAFH, 2017). In line with this, the International Federation of Pharmacists (*Federação Internacional de Farmacêuticos* - FIP), with the aim of optimizing and promoting practices for the safe use of medication in hospital pharmacy, encouraged the development of the "*FIP Basel Statements on the Future of Hospital Pharmacy*", published for the first time in 2008 (FIP, 2009). In September 2015, the most updated version of the Basel Statements was released, with 65 recommendations, covering all areas of the medication use process in hospitals, from procurement to monitoring (FIP, 2015).

Since then, several countries and regions have explored the Basel Statements, with the aim of improving the safety and results of pharmacotherapy for patients or developing their own assessment tools (Al Sabban *et al.*, 2018; Lyons *et al.*, 2016; Penm *et al.*, 2013; Penm *et al.*, 2014; Penm, Chaar, Moles, 2015a; Penm, Chaar, Moles, 2015b; Penm *et al.*, 2015; Poh *et al.*, 2013; Stacey *et al.*, 2017). In the Brazilian context, recommendations 24-29 of the theme "influences on prescribing" and 49-55 of the theme "monitoring the use of medication" reflect on the clinical attributions of pharmacists in the country. These are regulated by the Federal Council of Pharmacy (*Conselho Federal de Farmácia* – CFF, 2013a) through Resolution No. 585 of 2013. However, there are still no Brazilian studies that assess the development of these attributions in hospitals based on the Basel Statements.

Therefore, this study aimed to analyze the pharmacist's perception in the scenario of the Brazilian hospital pharmacy, in relation to their clinical attributions of the Basel Statements.

METHODS

This is a descriptive study in which Brazilian high and medium complexity hospitals registered in the National Register of Health Establishments (*Cadastro Nacional de Estabelecimentos de Saúde* - CNES) were contacted through the available electronic address (http://cnes2.datasus.gov.br/) from February to September 2016. An invitation letter was sent to the hospitals' electronic addresses, requesting redirection to the pharmacists, inviting them to participate in the research, along with the Free and Informed Consent Terms Form (FICT), and the link to access the electronic questionnaire. Data collection took place from September 2016 to July 2017 and in the absence of responses, follow-up reminders were sent every ten days, totaling up to three reminders sent by email.

The questionnaire was built from the Basel Statemets (2015) in the Portuguese version, transforming each statement into questions to measure complience. This was previously tested by about 25 health professionals, students, including postgraduate, and professors at the Federal University of São João del-Rei (UFSJ).

To assess the fulfillment of the pharmacist's clinical attributions, a descriptive analysis of the recommendations related to the domains related to "influence on prescribing" and "monitoring the use of medication" of the Basel Statements was carried out, stipulating a cutoff point of 50 %. The results were categorized into: a) they meet the statement, b) they do not meet, or c) they did not respond. Frequencies were presented in absolute and relative terms. The answers of the questions from number 24 to 29, and 49 to 55 of the questionnaire were evaluated. The statements were transformed into questions that the participants had to answer "YES", "NO", "In implementation", or "Not applicable", according their perception of the issues. (Rocha *et al.*, 2021; Rocha *et al.*, 2022).

The answers were weighted (No = 0, Yes = 1, In implementation = 0.5) and the results were divided between those that comply with the Basel Statements and those that do not comply, and those that did not respond (Rocha *et al.*, 2021; Rocha *et al.*, 2022).

More methodological details can be found in Rocha *et al.* (2021) and Rocha *et al.* (2022).

The project was approved by the Ethics Committee for Research involving Human Beings at UFSJ, Campus Centro Oeste Dona Lindu (CCO) CAAE:56738416.3.0000.5545. The study was conducted in accordance with the ethical precepts of the National Health Council Resolution 466/2012 (Brasil, 2012).

RESULTS

Of the 2,054 eligible Brazilian hospitals, pharmacists from 111 hospitals completed the survey. For the Basel

Statements 24–29 recommendations on the topic "influence on prescribing", only one recommendation had a compliance rate greater than 50 %, with effective action by pharmaceutical professionals in the Pharmacy and Therapeutics Committee (PTC) (Table I).

TABLE I - Percentage of the pharmacist's perception of the adequacy of Brazilian hospitals according to the "interventions in the prescription" domain of the Basel Declaration in 2017, Brazil (n = 111)

	Recommendation	Met n (%)	Unmet n (%)	No response n (%)
24	Hospitals should utilize a medication listing or therapeutic form (local, regional and/or national) linked to treatment guidelines and protocols based on the best available evidence.	52 (46.8%)	49 (44.1%)	10 (9.0%)
25	Hospital pharmacists must be key members of the PTC to oversee all medication management policies and procedures, including those related to off-label use and in clinical research.	60 (54.1%)	43 (38.7%)	8 (7.2%)
26	Hospital pharmacists should play a key role in educating prescribers, at all levels of training, in accessing and providing evidence for the responsible use of medication, including required monitoring parameters and subsequent prescribing adjustments.	35 (31.5%)	68 (61.2%)	8 (7.2%)
27	Hospital pharmacists should be part of the multidisciplinary team responsible for making therapeutic decisions in all areas of patient care.	43 (38.7%)	62 (55.8%)	6 (5.4%)
28	Hospital pharmacists must promote unceasing care, contributing to the transfer of information about medication, whenever patients move between and within levels of health care.	44 (39.6%)	60 (54%)	7 (6.3%)
29	Appropriately trained and credentialed hospital pharmacists should participate in collaborative prescribing.	15 (13.5%)	79 (71.1%)	17 (15.3%)

PTC = Pharmacy and Therapeutics Committee

With regard to "monitoring the use of medication", no recommendation met the 50% compliance rate. These refered to aspects in terms of structures, processes, and results in which the use of medication must be monitored. Recommendations 49 and 50 address the existence of an easily accessible system for notifying technical complaints and ADEs (Table II).

TABLE II - Percentage of the pharmacist's perception of the adequacy of Brazilian hospitals according to the "monitoring the use of medication" domain of the Basel Declaration in 2017, Brazil (n = 111)

	Recommendation	Met n (%)	Unmet n (%)	No response n (%)
49	An easily accessible system for reporting technical complaints must be established and maintained. Medication technical complaint reports must be reviewed internally and forwarded in a timely manner to regional or national pharmacovigilance regulatory programs and to the manufacturer.	53 (47.7%)	50 (45.0%)	8 (7.2%)
50	An easily accessible system for reporting ADE should be in place and maintained. Adverse reaction reports must be reviewed internally and submitted in a timely manner to regional or national pharmacovigilance regulatory programs. These data should be regularly reviewed to improve the quality and safety of medication use.	46 (41.4%)	57 (51.3%)	8 (7.2%)
51	An easily accessible, nonpunitive reporting system for medication errors, including near miss events, should be implemented and maintained. Medication error reports should be reviewed internally and forwarded to regional or national pharmacovigilance regulatory programs. These data should be regularly reviewed to improve the quality and safety of medication practices.	44 (39.6%)	56 (50.4%)	11 (9.9%)
52	Medication use practices must be evaluated and compared with other services and with good practices, aiming to improve safety, clinical effectiveness and cost-effectiveness.	48 (43.2%)	56 (50.4%)	7 (6.3%)
53	The medication use process should be reviewed through an external audit or quality improvement program. Hospitals must act on reports to improve the quality and safety of their practices.	42 (37.8%)	60 (54.0%)	9 (8.1%)
54	The clinically relevant activities of pharmacists must be documented, collected, and analyzed to improve the quality and safety of medication use and therapeutic outcomes for patients. Activities that significantly impact patient care should be documented in the patient's record.	39 (35.1%)	57 (51.3%)	15 (13.5%)
55	Systematic approaches (e.g., adverse reaction trackers) should be used to provide quantitative data on ADE and appropriate medication use. These data should be regularly reviewed to improve the quality and safety of medication practices.	25 (22.5%)	72 (64.8%)	14 (12.6%)

ADE = Adverse Drug Events

DISCUSSION

The recommendations of the themes "influence on prescribing" and "monitoring the use of medication" are relevant for the improvement of the clinical performance of pharmacists in the hospital environment and are regulated by the Federal Council of Pharmacy (CFF, 2013a) through Resolution No. 585 of 2013. In general, the low percentage reported by pharmacists when asked about fulfilling the attributions related to these themes can be explained by

several factors found in other Brazilian studies. These studies highlight that, in the view of the managers, the pharmacist is not recognized as a professional with clinical practice or there is no interest in implementing this type of activity, making it difficult for them to be integrated into the multidisciplinary team. They also point to a lack of infrastructure to carry out clinical activities and multiple administrative and logistical functions, which compromise the entire workload and compliance with the minimum requirements to ensure patient safety. Finally, academic and technical training is flawed in terms of stimulating and developing clinical skills (Rocha *et al*., 2021; Magarinos-Torres, Osorio-de-Castro, Pepe, 2007; Freitas *et al*., 2016). The implementation of clinical services provided by pharmacists can also be affected in a multifactorial way, by attitudinal, political, technical and administrative aspects (Onozato *et al*., 2020; Oliveira *et al*., 2023).

Other studies using the Basel Statements presented difficulties similar to those of the Brazilian context in relation to the performance of the proposed recommendations (Penm *et al*., 2013; Penm *et al*., 2014; Penm, Chaar, Moles, 2015a; Penm, Chaar, Moles, 2015b; Penm *et al*., 2015). China highlighted the lack of hospital administrative support and government policies, in addition to the shortage of pharmaceutical professionals and the lack of training to develop clinical activities (Penm *et al*., 2014). In the Western Pacific Region, lack of support from physicians and patients also makes it difficult to consistently implement clinical services provided by pharmacists (Penm, Chaar, Moles, 2015a). In Saudi Arabia, developing these functions requires more resources than are available in the country, and the lack of trained pharmacists is the greatest barrier encountered in providing such services (Al Sabban *et al*., 2018). In Pacific Island countries, although there are limited numbers of these professionals, to expand clinical activities, additional support is needed in the team building and communication skills of pharmacists (Penm, Chaar, Moles, 2015b).

Regarding the low compliance with Basel Statements 49–55 on the topic "monitoring the use of medication" in Brazilian hospitals (Table II), another part of this same study, involving recommendations 19, 38, 39, 46 and 51 of the Basel Statements focused on patient safety, found that the hospital pharmacist multitasked without meeting the minimum requirements to promote patient safety in this environment, and that much still needs to be done to meet international standards (Rocha *et al*., 2021; Rocha *et al*., 2022).

In Brazil, even though ADE notification by the Patient Safety Center (PSC) is mandatory in health services, as recommended by RDC No. 36/2013, there are still constant challenges in medication safety surveillance. The low equity in the allocation of pharmacovigilance resources and the culture of disrespect for legislative norms, combined with the ineffective inspection of regulatory agencies, contribute to the underreporting of ADEs (Moscou, Kohler, MaGahan, 2016; Varallo *et al*., 2019; Viana *et al*., 2021). Another Brazilian study presented the needs and challenges faced by hospital pharmacists, with emphasis on medication monitoring and causality attribution, in addition to the shortage of professionals to assist in pharmacovigilance activities (Andrade *et al*., 2020). Faced with these difficulties, it is believed that local changes, the effective participation of a pharmacist, and a joint effort by regulatory agencies, at all hierarchical levels of pharmacovigilance, are necessary (CFF, 2011).

The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* - Anvisa) provides ADE monitoring systems, such as VigMed and Notivisa, free of charge. There are also CFF regulations that provide for the registration and notification of clinical activities performed by the pharmacist (CFF, 2011; CFF, 2013a). In Resolution No. 585 of 2013, among these attributions, the development of actions for the prevention, identification, and notification of incidents and technical complaints related to medication stands out, as well as the participation of the pharmacist in commissions and committees within the scope of health institutions and services, aimed at promoting the rational use of medication (RUM) and patient safety (CFF, 2013a). In view of this, the need to develop institutional policies and professional training is evident (Lima *et al*., 2018).

The ultimate goal of pharmacy services should be the safe and proper use of medication. The FIP points out that pharmacists must ensure the adequacy of prescriptions at

the beginning of treatment; security in care transitions; accurate and adequate supply of medications; ensure that patients are using their medications correctly; and identify and solve problems related to the use of medication (Brodie, Benson, 1976; FIP, 2020). In this sense, Brazil has a lot to advance, since more than half of Brazilian hospitals (50.6 %) did not even have a hospital pharmacist on their health team (Santos *et al*., 2018).

In contrast, even though the country is still experiencing a phase of implementation and standardization of Clinical Pharmacy, it is clear that this movement is consolidating, and there are efforts to redirect pharmaceutical practice (Fonseca, *et al*., 2017, Siqueira, Neto, Gonçalves, 2021). In 2009, the Resolution of the Collegiate Board (RDC) 44 regulated the practice of Pharmaceutical Care as one of the services that must be offered in pharmacies or drugstores (Brasil, 2009). In 2013, CFF Resolution No. 585 regulated the clinical attributions of the pharmacist, focusing on patient, family, and community care. Allied to this, Resolution nº 586 regulates pharmaceutical prescription. (CFF, 2013a; CFF, 2013b). In 2014, Law nº 13,021 started to consider pharmacies as health establishments destined to the provision of Pharmaceutical Assistance (Brasil, 2014).

Another important advance is the curricular guidelines for the undergraduate course in Pharmacy, published in 2017. This resolution constitutes a regulatory framework for the training of pharmacists in the country, since it structures training into three axes, and determines how much class time should be dedicated to each axis, stating that 50 % percent of it should be dedicated to the Health Care axis (Brasil, 2017).

In view of the facts presented, a strategy to make these recommendations a reality in Brazil would be to define priorities and discuss how to implement them according to the local reality. In this sense, Lyons *et al*. (2016) developed and validated an assessment tool considering levels of stratification to achieve the standards proposed in the Basel Statements. For this, they considered the profile of the hospital pharmacy, recognizing that the locations differed in terms of resources, training, and support. They propose that hospitals should achieve the "Good Practices in Hospital Pharmacy", that are important for patient safety (Level 1) before starting clinical services (Level 2) and then extending them to all patients (Level 3).

Limitations, potentialities and applicability

The reduced response rate is a limitation of the present study; this can be explained by incorrect addresses or by outdated registration, by the habit of deleting messages from unknown sender, and also by the concern with messages containing viruses or that are in the sense of evaluating the work that is being carried out. However, hospitals from all geographic regions of Brazil participated. In addition, it is important to highlight that the survey was sent to an institutional electronic address, and perhaps this was not directed on to the pharmacist. Strategies were used to increase this response rate, such as sending reminders every ten days and extending the survey deadline. However, the low response rate may also be related to non-response bias. The intense hospital routine and the multiple pharmaceutical functions in hospitals can influence the unwillingness or decision not to respond to the research. Another aggravating factor for this reduced participation is mainly due to the fact that 2,426 (50.6 %) of the Brazilian hospitals that were registered with the CNES (n=4,790) did not have a pharmacist on the team (Santos *et al*., 2018).

In contrast, this study is the pioneer in addressing the domains "interventions in the prescription" and "monitoring the use of medication" of the Basel Declarations (2015) in order to analyze compliance with them by Brazilian hospitals from the perspective of pharmacists. Drawing this profile, in line with an international standard, is important to identify strategic points for improving the pharmacist's clinical performance and the quality of care provided.

To conclude, the low percentages of compliance with statements related to "interventions in the prescription" and "monitoring the use of medication" addressed by the FIP Basel Declaration emphasize that these activities in Brazil need to be reviewed and aligned to offer better quality and more patient safety. Despite this, it may be necessary to adapt these recommendations, in order to define priorities and discuss how to implement them, according to the Brazilian reality and the profile of the

hospital pharmacy. Furthermore, in order to consolidate the practice of these activities, it is believed that a joint effort by institutions and regulatory agencies at all hierarchical levels, local changes, and allocation of competent pharmacists committed to their role in the health system is necessary. There is also a need for continued training, awareness of managers, and even patients regarding the importance of these services.

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CONTRIBUTORS

All authors contributed to this work.

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COMPETING INTERESTS

None declared.

PATIENT CONSENT FOR PUBLICATION

Not required.

ETHICS APPROVAL

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PROVENANCE AND PEER REVIEW

Not commissioned; externally peer reviewed.

DATA AVAILABILITY STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information.

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