Original Paper

Patient safety best practices related to medication management in two public hospitals

Clarice CHEMELLO
Renata GONÇALVES DINIZ
Mariana GONZAGA DO NASCIMENTO

Programa de Pós-Graduação em Medicamentos e Assistência Farmacêutica - Universidade Federal de Minas Gerais

Abstract

Objectives: This study aims to analyze the compliance with the ISEP-Brazil patient safety good practice indicators related to medication management. It also aims to evaluate the applicability and limitations of these indicators in these hospitals. **Methods**: This is a cross-sectional study conducted in two large hospitals (H1 e H2) of the Minas Gerais public hospital network. The Group 5 icators (medication management) and additional information on the safety profile were collected in both hospitals in February 2018, through an on-site visit. The difference between the proportions of the items met at H1 and H2 was evaluated using the Pearson chi-square test at a level of statistical significance of 5%. **Results**: Both hospitals satisfactorily meet more than 65% of the items evaluated (H1=71.2%, H2=66.7%), with H1 meeting three more items (n=42) than H2 (n=39). There was no statistically significant difference between the proportions of items in compliance at H1 and H2 (p = 0.69). However, through additional collection, activities that were not evaluated by the ISEP-Brazil indicators which may contribute to patient safety were detected, especially in H1. Examples are clinical activities, computerization of the dispensing and emergency carts, daily check of dispensing errors. **Conclusion**: A considerable proportion of subitems followed the ISEP-Brazil indicators in hospitals. Although there was no statistically significant difference between these proportions, the additional on-site diagnosis allowed identification of a safer medication system in H1.

Keywords: Hospital Pharmacy Service, Indicators of Health Services, Patient Safety, Safety Management

Boas práticas de segurança do paciente relacionadas à gestão da medicação em dois hospitais públicos

Resumo

Objetivos: analisar o cumprimento e avaliar a aplicabilidade e limitações dos indicadores de boas práticas de segurança do paciente ISEP-Brasil relacionados à gestão da medicação. **Método**: Estudo transversal, conduzido em dois hospitais (H1 e H2) de grande porte de uma rede hospitalar pública de Minas Gerais. Os indicadores do Grupo 5 (gestão da medicação) e informações adicionais sobre o perfil de segurança foram coletados em fevereiro e março de 2018 em uma visita *in loco* em ambos hospitais. Foi avaliada a diferença entre as proporções dos itens atendidos no H1 e H2 utilizando-se o teste qui-quadrado de Pearson sob um nível de significância estatística de 5%. **Resultados**: ambos os hospitais atendem satisfatoriamente a mais de 65% dos itens avaliados (H1=71,2%; H2=66,7%), sendo que o H1 cumpre com três itens a mais (n=42) do que H2 (n=39). Não houve diferença estatisticamente significativa entre as proporções de itens atendidos nos hospitais (p=0,69). Entretanto, mediante coleta adicional, verificou-se a realização de atividades não avaliadas pelos indicadores ISEP-Brasil, sobretudo no H1, que podem contribuir para a segurança do paciente como: realização de atividades clínicas, informatização da dispensação e estoque de carros de emergência, checagem diária de erros de dispensação. **Conclusão**: proporção considerável de subitens foi atendida nos hospitais. Apesar de não haver diferença estatisticamente significativa entre essas proporções, o diagnóstico adicional *in loco* permitiu identificação de um sistema de medicação mais seguro no H1.

Palavras-chave: Gestão da Segurança, Indicadores de Serviços, Segurança do Paciente, Serviço de Farmácia Hospitalar

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Correspondending Author:
Clarice Chemello
clachemello@gmail.com

Introduction

Patient Safety is defined by the World Health Organization (WHO) as reducing the reduction of risk harm associated with health care to an acceptable minimum.[1] It became prominent after the publication of the American study "*To err is human: building a safer health system*", which demonstrated that approximately 16% of all patients hospitalized in US hospitals presented at least one adverse events (AE).[2]

Against this backdrop, in 2004, WHO created the World Alliance for Patient Safety to idefine and identify priorities regarding patient safety in many parts of the world and contribute to a global agenda for action and research in the field. In this agenda, we highlight topics such as the prevention of AE related to medication errors and promotion of safety culture, focused on the process of responsibility for error.[3]

In 2007, Brazil joined this alliance and, in 2013, the Ministry of Health launched Ordinance No. 529/2013, instituting the National Patient Safety Program.[4] In this regard, the National Health Surveillance Agency (ANVISA) established the obligation to elaborate actions to promote patient safety in health services as defined in the Resolution of the Collegiate Board of Directors (RDC) 36/2013.[5] Also in 2013, as regulatory framework, Ordinance 2.095 was published, which approved Basic Protocols of Patient Safety and contemplated the protocol of safety in the prescription, use and administration of medications.[6] Several strategies to promote international patient safety and its evaluation have been stimulated in order to recognize the organizational conditions that may lead to AD and harm to patients in health services.[7]

With the goal of reducing serious and preventable drug-related harm by 50% in five years in March 2017, WHO has launched the third global patient safety challenge, called "Medication without Harm". This document highlights that unsafe practices and medication errors are a major cause of preventable harm in global health systems and are associated with approximately US$ 42 billion per year.[8]

To this end, WHO recommends improvements in medication systems and practices, and for its implementation and evaluation, it is important to adopt adequate tools for follow-up and assessment of care practices based on standardized indicators.[9] In this sense, it is important to highlight the ISEP-Brazil Project, which objective was to develop and validate indicators of good patient safety practices for the Brazilian context, which is a deployment and deepening of the project *Indicadores de Seguridad del Paciente* (ISEP) of the Spanish Ministry of Health.[10,11,12]

Considering this context, this study aims to describe and compare compliance with the ISEP-Brazil patient safety good practice indicators related to medication management in two public hospitals in Minas Gerais and to evaluate the applicability and limitations of these indicators in these scenarios.

Method

Design and location of study

This is a cross-sectional study conducted in two public hospitals characterized as general and large in the state of Minas Gerais, called Hospital 1 (H1), located in a city in the interior of the state with about 500,000 inhabitants and Hospital 2 (H2), located in the state capital, Belo Horizonte. Both hospitals belong to the state network and have implanted patient safety nucleus.

H1 was selected as the only institution in the network that had an accreditation history, receiving in 2013 an accreditation certificate at level 2 by the National Accreditation Organization (ONA),[13] but losing it in the year 2015 in the recertification process. H2, in turn, was never accredited and was selected because it is part of the same public network of Minas Gerais hospitals and has a size and health profile comparable to H1.

Data collection

To evaluate the adoption and implementation of good medication management practices, the information collected was based on the indicators of Good Practices for Patient Safety, Group 5 - Medication Management, of the ISEP-Brazil Project.[10] The collection and measurement of subitems in agreement or disagreement was performed by single on-site visit performed in February 2018 on H1 and March 2018 on H2, according to the methodology and form described in the ISEP-Brazil Project.[10] The ISEP-Brazil Project form is structured with 13 indicators related to medication management, of which 9 (nine) refer to the structure and 4 (four) to the work process.[10] These 13 indicators have a total of 69 sub-items.[10] The indicators measured by questionnaires were evaluated according to the statements answered by the health professionals. For the best practice of medication reconciliation, the following responses were considered: *"never"/"almost never"/"sometimes"/"almost always"/"always"*.

In order to analyze compliance with the audit indicators, the existence of protocols, norms and institutional policies.[10] Thus, it is considered "*Yes*" for the document evaluated that fulfilled all the requirements demanded in the indicator; "*Partly*" for those that complied in part and "*No*" for those that did not submit the requested documents during data collection.

In parallel, by means of a complementary collection on-site, additional data on the management profile of the institution's medication were documented that were directly or indirectly related to the items evaluated in ISEP-Brazil. For this, a collection form developed by the authors themselves was used. The form had all the items evaluated by ISEP-Brasil and had open fields that, besides presenting the purpose of facilitating the process of manual collection on-site, allowed the description of the process involved in each item, evaluated objectively by ISEP-Brazil (example: description of the process developed during the medication reconciliation and frequency of its accomplishment, hourly of each pharmacist acting in the hospital).

As methods of collection, interviews, questionnaires, audits and direct observation were used. The interviews and questionnaires were applied to the professionals involved in the medication management of each hospital to enable elucidations about the processes developed and availability of resources, allowing for a more in-depth analysis of each ISEP-Brazil item. During the direct observation, the structure and process indicators were analyzed in the hospital environment. All data collected were recorded in a database specifically developed for the present study in the *software Microsoft Excel*® 2010.

Data analysis

The absolute and relative frequencies of the subitems met, not met and partially met, as well as the management profile of the medication detected in the complementary collection were described.

We also compared the proportions of subitems met and not met at both hospitals (H1 and H2) using the Pearson chi-square test using the module "*Stat Calc*" of *software EpiInfo*® version 72.2.6, adopting the level of 5% statistical confidence. For purposes of this comparison, subitems met partially were considered as "not met".

Ethical aspects

This study was approved by the Ethics and Research Committees of the Hospital Foundation of the State of Minas Gerais (FHEMIG), CAAE 80293517.5.3001.5119, and the Federal University of Minas Gerais (UFMG), CAAE 80293517.5.0000.5149, according to the ethical principles contained in Resolution No. 466/12 of the National Health Council.[14] Participants signed the Informed Consent Form (ICF).

Results

Both hospitals satisfactorily met more than 65% of the subitems evaluated. In the case of H1, considering that its emergency service was closed, the subitems referring to this area were disregarded (10 sub-items in total). Thus, of the 59 remaining H1 subtopics, 71.2% were met (n=42), 25.4% were not met (n=15) and 3.4% were partially met (n=2). For H2, all 69 sub-items were evaluated, 66.7% were met (n=46), 29.0% were not met (n=20), and 4.3% were partially met (n=3). Excluding the 10 items referring to H2 care sector, the proportions found were: 66.1% met (n=39); 28.8% were not met (n=17); and 5.1% partially met (n=3). Table 1 shows the indicators collected and Table 2 shows the data collected on-site complementing the indicators.

Table 1. Patient Safety Indicators - Group 5 Medication Management of the ISEP-Brazil Project in the 2 hospitals studied.

INDICATORS	H1*	H2**
BEST PRACTICE 17: MEDICATION RECONCILIATION		
17.1 Review of all medications used by the patient before the prescription (percentage of "always" response)	0%	0%
BEST PRACTICE 18:PHARMACY LEADERSHIP STRUCTURE AND SYSTEMS		
18.1 Presence of Pharmacist (physical or localized) 24 hours a day	YES	YES
18.2 Protocol for identification, documentation and reporting of medication errors related to the pharmacy service	YES	YES
18.3 Protocol for the storage, preservation and replanishment of medications in the pharmacy service	YES	YES
18.4 Standards for the maintenance of emergency carts	YES	YES
18.5 Protocol for identification and repackaging of medications distributed in unit dose	YES	YES
18.6 Appropriate storage of medications in satellite pharmacies	31%	57%
18.7 Appropriate storage of medications and products in emergency carts	99%	99%
18.8 Appropriate storage of medications in the central pharmacy service	100%	100%
18.9 HAM # List	NO	NO
18.10 Rules on HAM# administration	NO	NO
18.11 Labeling and storage standards for HAM#	YES	YES
18.12 Access to unit dose medication dispensing	PARTIAL	PARTIAL

H1* = Hospital 1; H2** = Hospital 2; POP*** = Standard Operating Procedure; HAM# = High-alert medication.

Table 2. Further information on Indicator Patient Safety - Group 5 Medication Management of the ISEP-Brazil Project in the 2 hospitals studied.(Continue)

INDICATORS	H1 Supplementary collection	H2 Complementary collection
BEST PRACTICE 17: MEDICATION RECONCILIATION		
17.1 Review of all medication used by the patient before the prescription	• Five (5) pharmacists were interviewed, and reported not performing the activity in any of the sectors. • There is SOP*** for the evaluation of the patient's home use medications that will continue to be used during his hospital stay.	• Three (3) pharmacists were interviewed, and reported reported that they did not perform the activity under any circumstances.
BEST PRACTICE 18: PHARMACY LEADERSHIP STRUCTURE AND SYSTEMS		
18.1 Presence of Pharmacist (physical or localized) 24 hours a day (specify if there is a clinical specialist title)	• Total pharmaceutical workload of 1,400 hours/month • Pharmacists do not hold the title of clinical specialist. • Clinical pharmacy activities are performed for patients: under psychiatric treatment; in use of tuberculostatic; critical patients. • There is SOP*** for clinical pharmacy activities and monitoring by means of indicators.	• Total pharmaceutical workload of 1,560 hours/month • No clinical pharmacy activities are performed
18.2 Protocol for identification, documentation and reporting of medication errors related to the pharmacy service	• Dispensing errors are evaluated daily (minimum = 5 prescriptions orders/day/pharmacist) and indicators are monitored.	• Medication errors are recorded, and indicators are monitored.
18.3 Protocol for the storage, preservation and replanishment of medications in the pharmacy service	• Medications arranged in alphabetical order. • At the central pharmacy and satellites, the bins are different by color (antibiotics=green, injectables=blue, tablets, suppositories and eye drops=white; HAM#=yellow; medications of Ordinance 344/1998=black; tuberculostatic=beige). • There is differentiation of medications with similar names in upper case. • Maximum stacking is observed in the storage of medications. • Daily room and refrigerator temperature recording is performed on a standard worksheet.	• Medications arranged in alphabetical order. • At the central pharmacy and satellites, the bins of HAM# are differentiated in yellow. • There is differentiation of medications with similar names in upper case. • Maximum stacking is observed in the storage of medications. • Daily room and refrigerator temperature recording is performed on a standard worksheet.

H1* = Hospital 1; H2** = Hospital 2; SOP*** = Standard Operating Procedure; HAM# = High-alert medication.

Table 2. Further information on Indicator Patient Safety-Group 5 Medication Management of the ISEP-Brazil Project in the 2 hospitals studied. (Conclude)

INDICATORS	H1 Supplementary collection	H2 Complementary collection
BEST PRACTICE 18: PHARMACY LEADERSHIP STRUCTURE AND SYSTEMS		
18.4 Standards for the maintenance of emergency carts	• Emergency carts with computerized stocks. • Monthly conference by the nurse and pharmacist.	• Monthly conference by the nurse and pharmacist.
18.5 Protocol for identification and repackaging of medications distributed in unit dose	• The hospital has a machine for unitization of oral solids. • Only oral solids are dispensed in unit doses.	• The hospital has a machine for unitization of oral solids. • Only oral solids are dispensed in unit doses.
18.6 Appropriate Storage of medications in satellite pharmacies	• Hospital does not have an emergency room unit (10 subitems evaluated less than H2). • Hospital does not present a label with dilution guidelines for lidocaine, morphine and potassium chloride (3 sub-items did not fulfill requirements).	• Hospital does not present a label with dilution guidelines for lidocaine, morphine, sodium bicarbonate and chlorpromazine (4 sub-items did not fulfill requirements). • Access to medications under special control is not limited (1 subitem did not fulfill requirements).
1**8.7** Appropriate Storage of medications and products in emergency carts	• Available 12 emergency carts. • There is a standardization list of cart items. • Emergency carts with computerized stocks. • Drawers labeled on the outside with the materials contained therein. • Medications arranged in alphabetical order, easy to locate and labeled with quantity available. • Of the 80 items checked, 2 items were at odds with the standardized list (1 sub-item with partial suitability).	• Available 20 emergency carts. • There is a standardization list of cart items. • Emergency carts organized with easily located medications. • HAM Alert# available in the cart and in the cart items. • Of the 110 items checked, 1 item was at odds with the standardized list, and 1 item with expired validity (2 sub-items with partial suitability).
18.8 Appropriate of medications in the central pharmacy service	• No easy access, list of antidotes, definition of minimum stock of antidotes, (3 inadequacies).	• No easy access, restricted access to special control medications, ambient refrigeration, list of antidotes, definition of minimum stock of antidotes, storage under adequate refrigeration (6 inadequacies were identified).
18.9 HAM# List	• None.	• None.
18.10 Rules on HAM# administration	• Hospital does not have standard for administration of HAM# or information on maximum dose, duration/route/administration technique, double dose checking procedures.	• Hospital does not have standard for administration of HAM# or information on maximum dose, duration/route/administration technique, double dose checking procedures.
18.11 Labeling and storage standards for HAM#	• Institution does not have standard for labeling and storage of HAM#.	• Institution has standard for labeling and storage of HAM#, but it was updated since 2015.
18.12 Access to unit dose medication dispensing	• Unit dose of oral solids available for all sectors. • The distribution system is individualized for 12 hours. The medications are all packed in the same plastic bag for the patient.	• Unit dose of oral solids available for all sectors. • The distribution system is individualized for 12 hours. The medications are all packed in the same plastic bag for the patient.

H1* = Hospital 1; H2** = Hospital 2; SOP*** = Standard Operating Procedure; HAM# = High-alert Medicaton.

Comparing the proportions of met and unmet items in both hospitals (Table 3), no statistically significant difference was detected between the two hospitals (p=0.69).

Table 3. Comparison of the proportions of the subitems met and not met in Hospital 1 and Hospital 2.

Place	Items Met	Items not Met	Total
	n (%)	n (%)	n (%)
Hospital 1*	42 (71.2)	17 (28.8)	59 (100)
Hospital 2**	39 (66.1)	20 (33.9)	59 (100)
Total	81 (68.6)	37 (31.4)	118 (100)

*There was no statistically significant difference between the proportions of adequate items in the two hospitals under study.

Discussion

A significant proportion of the sub-items in both hospitals was met and there was no difference in the proportion of items completed between hospitals. This is possibly due in large part to the implementation and activity of the Patient Safety Nucleus in both hospitals and standardization of a large part of the hospital procedures at the central level of administration of the hospital network, which, although recommended in legislation , has not yet been adopted in many Brazilian institutions.[15,16] However, as already identified in other hospitals in Brazil, it is still necessary to perform an intensive cycle of quality improvement in both hospitals and in the activities of the Patient Safety Nucleus, in order to me*et a*ll the recommended indicators and avoid exposing patients to unnecessary risks.[15,16]

H1 had only three more items met than H2, related to the restricted access to medications subject to special control in the central pharmacy, air conditioning system and the quantity of adequate stock in the emergency cart that refer primarily to the local physical structure. On the other hand, the complementary collection allowed the additional diagnosis on-site, identifying a more secure medication management system in H1.

Both hospitals had pharmacists during the 24-hour operating period, respecting national legislation.[17,18,19] These results, however, depart from the study based on the National Registry of Health Establishment (CNES), which identified that a considerable number of Brazilian hospitals (50.6%) did not present a pharmacy registry in their team.[20] According to ISEP-Brazil, this indicator aims to verify the availability of this professional for activities such as "prescription order review, dispensing, monitoring of medications and care.[10] However, none of the professionals available at the hospital were specialists in the clinical area, as proposed by ISEP-Brazil, and the presence of the pharmacist showed no relation to the performance of clinical activities. This was corroborated by the fact that despite the 24-hour availability in both hospitals and the overall pharmacy workload being higher in H2, clinical activities are only performed on H1. Performing clinical activities by the pharmacist has a considerable impact on the prevention of drug-related adverse events and should be a priority for promoting patient safety.[21,22] The qualification of human resources for this should, however, be encouraged and adopted in the selection of professionals, since Brazilian studies already indicate the relationship between the level of expertise of the pharmacist and the performance of clinical and non-clinical activities in the hospital setting.[23]

Also regarding the clinical activities, the availability of pharmacists also was not translated in the accomplishment of medication reconciliation. The ISEP-Brazil indicator for this item proposes the measurement of the proportion of professionals who answered "always" to perform the medication reconciliation activity.[10] However, it is important to assess the suitability of the hospital also according to how often the activity is performed. In the case of both institutions evaluated, the report of "never" performing the activity shows that the scenario is more worrisome than the one measured by the indicator, although H1 has a process of evaluating the patients' home use medications when they will continue to be used in a hospital environment. Medication reconciliation has been shown to be effective in preventing medication errors in different institutions and its adoption is encouraged by the WHO, since transitions in care, particularly admission and hospital discharge, are fragile points of the medication system.[9,24-28] Its accomplishment, therefore, should not be limited to the process of hospital admission, but should contemplate all stages of transition of care, with emphasis also for hospital discharge.[27,28] Thus, the ISEP indicator is limited to evaluating the initial reconciliation without specific description of the activity frequency, which may differentiate the degree of intrahospital safety.

There are several measures that can be taken to reduce the occurrence of medication errors that focus on the medication as a product, including appropriate medication labeling, storage, dispensing and administration.[29] For example, the availability and disclosure of a list of high-alert medications with their maximum doses, form of administration (reconstitution, dilution, infusion time, route of administration"), indication and usual dose is recommended in the protocol of safety in the prescription, use and administration of medications.[30] It is also recommended in the protocol that, for doses of "), high-alert medications, double checking is carried out at the stage of prescription calculations and pharmaceutical prescription review prior to dispensing.[30] It was possible to notice, however, that the evaluated hospitals still need improvements in this sense, since they do not have a list of "), high-alert medications or information about any item related to this group of medications. Unit dose warnings for high-alert medications such as lidocaine and morphine have also not been identified in any of the hospitals.

On the other hand, in H1, improvements have been implemented in the medication system that may have an impact on patient safety. As examples, we can mention the collection and analysis of dispensing errors in all pharmacies and the process of computerization of the stock of emergency carts and the dispensation process, carried out in 2013, which allows the traceability of medications and facilitates the realization of clinical pharmacy activities.

Greater similarity among the hospitals regarding the compliance profile of subitems regarding the availability and profile of protocols related to the organization of the stock (pharmacy and emergency cart), record of medication errors and dosage unitarization process was identified. This is probably due to the standardization of procedures adopted at the central level of management of these two hospitals, which are passed on to all hospitals in the network. In addition, both institutions have an automated oral dosage unitization process, which, although not evaluated by the ISEP-Brazil, has the potential to reduce the incidence of errors in unit dose labeling/labeling.

The indicators of good practices related to the medication management of ISEP-Brazil were easily and objectively applicable in the institutions evaluated and it is believed that their effective implementation in hospitals can contribute to the initial modeling of safer processes. However, it is still possible to have improvements and expansion in these indicators, since their isolated collection, according to the proposed protocols, made it impossible to identify peculiarities of the management system that may impact on patient safety and which were identified by collection.

The complementary collection demonstrated, for example, a more mature and safe medication system in H1, both in terms of its structure (e.g. computerization, refrigeration of the pharmaceutical supply center, packaging of special control medications and emergency cart structure), as regards work processes (e.g. clinical activities, validation of home-use medications, daily evaluation of dispensing errors). Such a qualitative difference is possibly since the hospital has undergone a process of adequacy for accreditation, although it does not have a current seal. On the other hand, the inadequacy of representative items and the loss of accreditation in H1, which reflected in the absence of a difference in the proportion of items met between H1 and H2, reinforce the challenge of attending to the process of continuous improvement required in the accreditation process.

To our knowledge, this study is the only one to apply the ISEP-Brazil Project tool after its development and validation in 2016, which highlights its pioneering nature, but limits its scope by making it impossible to compare it with other studies.

Conclusion

The indicators of good practices related to medication management were easily and objectively applicable in the institutions under study. A considerable proportion of subitems was met in both H1 and H2, and although there was no statistically significant difference between these proportions, the diagnosis of the additional collection *in loco* allowed the identification of a safer medication system in H1. It is suggested, therefore, that the application of the ISEP-Brazil indicators be accompanied by a detailed observational qualitative analysis of the scenario to better target the priorities and quality improvement strategies to be implemented.

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Contributors

CC, RGD and MGN collaborated in the development of the study and elaboration of the article, working on designing and designing or analyzing and interpreting data, writing and reviewing the article, final approval of the version to be published and all are responsible for all work information, ensuring the accuracy and integrity of any part of the work.

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Conflicts of interest

The authors declare no conflicts of interest.

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