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Drug Reconciliation Program as a Patient Safety Initiative in a Specialty Hospital in the Southeastern Region of Brazil: A Study Protocol

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Abstract

A common problem observed in patient safety is the lack of accurate and complete information about medications in regular use during transfers of care between different health facilities. In view of this, medication reconciliation is postulated as a barrier to reducing medication discrepancies and consequently medication errors. This project aims to evaluate the implementation of safe clinical practices conducted by clinical pharmacists. To this end, we will conduct a standardized process to obtain the best possible medication history (BPMH); assessment of the patient's level of understanding of pre-admission therapy; quantification, classification and analysis of discrepancies of unintentional drugs at hospital admission; effect of interventions conducted by clinical pharmacists and impact on patient safety. This prospective, pilot, descriptive, interventional and single-center study will be carried out in the Clinical Pharmacy Department of a large hospital in the state of São Paulo. In order to standardize the process of data collection and reconciliation of prescription drugs, the interview with the patient will be carried out using an adapted and modified form. After collecting information in the structured interview, clinical pharmacists will identify, analyze and classify possible discrepancies. All unintentional discrepancies found without any clinical justification will be considered medication errors. Finally, the degree of impact of each drug discrepancy will be defined as: clinically insignificant; clinically significant; serious and life-threatening.

Keywords: Medication reconciliation, patient safety, pharmaceutical intervention, pharmaceutical interview, clinical pharmacy, medication discrepancy.

INTRODUCTION

Global health expenditures have increased substantially in recent years, mainly due to population aging, increasing burden of chronic no communicable diseases, advances in new health technologies, variety of pharmacological options, polymorbidities, polypharmacy and the indiscriminate use of medicines [1–3]. A common problem observed for patient safety is the lack of accurate and complete information about medications in regular use during the course of care transfers between different health facilities [4, 5]. The safe use of medicines has therefore become an important challenge for all parties working in the health sector, including hospital accreditation organizations, technical-scientific societies and hospitals spread all over the world, regardless of their specialty [6].

Medication errors are basically classified as any preventable event that can cause or lead to inappropriate medication use or temporary or permanent harm to the patient [7]. Additionally, medication errors can lead to an increase in emergency room visits, an increase in hospital admissions, prolonged hospital stays, which in more severe cases can result in patient disability or death [8, 9]. The global annual cost associated with medication errors is estimated to be around 42 billion dollars [10]. Therefore, the lack of information caused by an incomplete, unstructured or outdated pharmacotherapeutic record can often lead to medication errors during different care transitions, bringing potential risk to the patient [11, 12]. In view of this, medication reconciliation is postulated as a barrier to reducing medication discrepancies and consequently

medication errors, especially when conducted by clinical pharmacists [13–15].

Medication reconciliation is basically defined as the formal process of obtaining, verifying and documenting a precise list of drugs used by the patient before hospital admission, including the name of the drug's active ingredient, dosage, frequency, route of administration and comparing them with the current medical prescription in order to identify possible drug discrepancies, consequently increasing patient safety and the results of their pharmacotherapy [16, 17]. The Qmentum International Excellence Program seeks best practices in health care to reduce potential adverse events and medication discrepancies. To achieve this goal, one of the ROPs (Required Organizational Practice) Qmentum describes the expectation for medication reconciliation of patients newly admitted to the health care institution. [18–20].

Several studies have reported that at least 50% of patients recently admitted to hospital units had some type of medication discrepancy in their aforementioned medical prescriptions [21–23]. Incomplete or poorly structured medication histories at the time of hospital admission were cited as the cause of up to 2/3 of prescription errors and could have relevant clinical consequences for the patient [24–26]. The error most commonly reported in different studies is the omission of one or more medications regularly used by the patient [27–29].

The agreement that medication reconciliation is a fundamental process during patient admission and that it contributes to their safety and better results from their medication therapy is unanimous among different health professionals, especially among nurses, doctors and pharmacists [30, 31]. To date, there is no consensus or determination on which professional should be responsible for the medication reconciliation process and who should be designated to obtain the best possible medication history (BPMH) [32]. Other challenges include: Absence of standardized processes, time constraints, inadequate records, reduced staff numbers, ineffective communication, and lack of familiarity with patient pharmacotherapy and pathophysiology [33, 34].

In recent studies, a decrease in adverse drug events and a reduction in healthcare costs have been demonstrated with the involvement of clinical pharmacists in medication reconciliation during hospital admission [35–38]. As drug specialists, clinical pharmacists are more thorough than other healthcare professionals and are able to efficiently manage the drug therapy of the patient newly admitted to a hospital unit, thus ensuring better pharmacotherapy results based on the current clinical picture; prevention and detection of drug-related problems (DRPs); efficient and more complete collection of the history of medications used regularly; more accurate information on the patient's allergic profile (drugs and food); transferring and sharing important information in a timely manner and decreasing mortality rates [33, 35, 39].

The main objective of this project is to evaluate the implementation of safe clinical practices conducted by clinical pharmacists in a specialty hospital in the metropolitan region of São Paulo. To this end, we will conduct a standardized process of obtaining the best possible drug history; assessment of the patient's level of understanding of pre-admission therapy; quantification, classification and analysis of discrepancies of unintentional drugs at hospital admission; effects of interventions conducted by clinical pharmacists and impact on patient safety.

MATERIAL AND METHODS

Scenario and Study Period

This prospective, pilot, descriptive, interventional and unicentric study will be carried out in the Clinical Pharmacy Department of a Large Hospital, located in the southeastern region of Brazil. It is a private specialty hospital, a reference in the metropolitan region of São Paulo, with a structure of 257 beds and offering more than 190,000 medical consultations, 20,000 hospitalizations and 8,000 surgical procedures annually. The corresponding period of this study will be around three months or until we obtain the “n” of at least 385 patients recruited. This project will start after evaluation and approval by the Institutional Research Ethics Committee.

Patient Selection and Recruitment

Participants in this study will be considered eligible if they are hospitalized for at least 72 hours, regardless of gender, aged ≥ 18 years, admitted to either the adult emergency department (PSA) or elective procedures, and using ≥ 2regular prescription drugs. Eligible patients will be identified within the first 24 hours of hospitalization and will be contacted by a clinical pharmacist and invited to participate in the study, with the proper completion of the Informed Consent Form (ICF).

Patients whose medication history was not collected within the first 24 hours of hospital admission, patients who were unable to answer the necessary questions to complete the structured interview and who did not have a family member or caregiver who could be interviewed in their place, patients who were discharged or died before completing 72 hours of hospitalization and patients who were not interested in participating in the study or who are transferred to another hospital unit. Comatose, psychiatric, unresponsive patients with significant language limitations will also be excluded from the study.

Clinical Pharmacists Team

The entire clinical pharmacist team will conduct standardized training to obtain the best possible medication history (BPMH) upon hospital admission. Didactic training will include: review of core publications; review of general and specific medication reconciliation manuals; workflow guides; theoretical classes and didactic training evaluation. The service for interviewing and collecting the history of medication used in the past will operate 12 hours a day (07:00 to 19:00), 7 days a week, at the times of greatest volume of hospitalizations.

Medication Reconciliation Process

The complete history of the regular use of medicines will be obtained soon after the patient's hospitalization (prescription or non-prescription drugs, nutraceuticals, vitamins, herbal medicines, parenteral nutrition and herbal and homeopathic medicines) through the bedside interview, guaranteeing total confidentiality of the information provided and being complemented with other sources of information, including previous hospital records (present in our computerized system), medical prescriptions, examination of packaging, labels, bottles and medication boxes and interview with the family member, companion and/or caregiver, when possible.

In order to standardize the process of data collection and reconciliation of prescription drugs, highly trained clinical pharmacists conducted the entire process within the first 24 hours after hospital admission. The interview with the patient will be carried out using a form adapted and modified from other previous studies, which was standardized at the end by the team of clinical pharmacists [22, 40, 41] (Table 1). All clinical pharmacists involved in this study will use the designed and standardized form as a basic requirement in the hospital admission bedside interview.

Table 1: Standardized form for the bedside interview

HOSPITAL ADMISSION			
PATIENT'S FULL NAME:			
INTERNATIONAL SECTOR:		**BED:**	**ATTENDANCE:**
DATE AND TIME OF HOSPITALIZATION:			
DATE AND TIME OF BEIRA-LEITO PHARMACEUTICAL VISIT:			
DURATION OF BEIRA-LETO VISIT:			
DEMOGRAPHIC AND CLINICAL-PATHOLOGICAL DATA			
AGE:	**GENDER:** MALE ☐ FEMALE ☐	**WEIGHT:**	**HEIGHT:**
EDUCATIONAL LEVEL: ☐ WITHOUT EDUCATIONAL LEVEL ☐ COMPLETE ELEMENTARY SCHOOL ☐ COMPLETE HIGH SCHOOL ☐ COMPLETE HIGHER EDUCATION ☐ COMPLETE LATU SENSU POSTGRADUATE ☐ COMPLETE STRITU SENSU POSTGRADUATE			
PROFESSION:			
SMOKE: YES ☐ NO ☐		**IF YES, HOW MANY PACKS/DAY?**	
ETHYLIST: YES ☐ NO ☐		**IF YES, HOW MANY DRINKS/WEEK?**	
PHYSICAL ACTIVITY PRACTITIONER: YES ☐ NO ☐		**IF YES, FREQUENCY AND DURATION?**	
HAVE SOME DEFICIENCIES: ☐ PHYSICAL OR MOTOR ☐ LOOK ☐ HEARING ☐ INTELLECTUAL ☐ DOES NOT HAVE			
RESIDENCE: ☐ LIVE ALONE ☐ LIVES WITH FAMILY ☐ LIVES WITH A CAREGIVER ☐ LIVES IN A RETIREMENT HOME			
CAUSE OF HOSPITALIZATION/ACTIVE PROBLEMS:			
OTHER COMMODITIES:			
PREVIOUS HOSPITALIZATIONS: YES ☐ NO ☐		**IF YES, WHY AND FOR HOW LONG?**	
BEST POSSIBLE MEDICATION HISTORY (BPMH)			
SOURCE OF INFORMATION OBTAINED: ☐ INTERVIEW WITH THE PATIENT ☐ INTERVIEW WITH THE FAMILY ☐ INTERVIEW WITH THE CAREGIVER ☐ MEDICAL PRESCRIPTION ☐ REVIEW OF PREVIOUS RECORDS			

☐ DRUG BOTTLES AND BOX PACKAGING							
HAS SOME HYPERSENSITIVITY/ALLERGY: YES ☐ NO ☐			**IF YES, TO WHICH MEDICINES AND EFFECTS PRESENTED?**				
FORM OF HOSPITAL ADMISSION ☐ ADULT EMERGENCY AID ☐ ELECTIVE PROCEDURE							
PRE-ADMISSION MEDICATION (TRADE NAME AND/OR ACTIVE PRINCIPLE)	**USED DOSE**	**ROUTE OF ADMINISTRATION**	**FREQUENCY**	**DURATION OF TREATMENT**	**NO DISCREPANCY**	**JUSTIFIED DISCREPANCY**	**UNINTENTIONAL DISCREPANCY**

BEST POSSIBLE MEDICATION HISTORY (BPMH)			
DO YOU USE ANY MEDICATION WITHOUT MEDICAL PRESCRIPTION? YES ☐ NO ☐	**IF YES, WHAT MEDICINES, DOSE USED, FREQUENCY AND ROUTE OF ADMINISTRATION?**		
DO YOU USE ANY SUPPLEMENTS, MINERALS OR VITAMINS? YES ☐ NO ☐	**IF YES, WHAT IS THE COMPOSITION, DOSE USED, FREQUENCY AND ROUTE OF ADMINISTRATION?**		
DO YOU USE ANY HERBAL-BASED PREPARATIONS OR PHYTOTHERAPY AND HOMEOPATHIC PRODUCTS? YES ☐ NO ☐	**IF YES, WHAT IS THE COMPOSITION, DOSE USED, FREQUENCY AND ROUTE OF ADMINISTRATION?**		
THERAPY UNDERSTANDING LEVEL			
	PATIENT'S UNDERSTANDING LEVEL ABOUT PRE-ADMISSION MEDICINES (GLOBAL SUBJECTIVE ASSESSMENT)		
	TOTAL	**PARTIAL**	**LOWER**
DOES THE PATIENT KNOW WHY HE/SHE IS USING HIS/HER MEDICATIONS?			
IS THE PATIENT ADEQUATELY AWARE OF HIS/HER COMORBIDITIES?			
DOES THE PATIENT KNOW IN DETAIL THE DAILY DOSE OF HIS/HER MEDICATIONS?			
DOES THE PATIENT USE THE MEDICATION CORRECTLY (ROUTE OF ADMINISTRATION AND DOSAGE)?			
DOES THE PATIENT HAVE AN UNDERSTANDING OF THE DURATION OF THEIR TREATMENT?)			
DOES THE PATIENT KNOW ABOUT THE RISKS IF THE TREATMENT IS NOT DONE CORRECTLY?			
PUNCTUATION • TOTAL (5 POINTS) • PARTIAL (3 POINTS) • LOWER (1 POINT)			
LEVEL OF UNDERSTANDING • HIGH LEVEL (23 - 30 POINTS) • MODERATE LEVEL (14 - 22 POINTS) • LOW LEVEL (6 - 13 POINTS)	**HIGH LEVEL**	**MODERATE LEVEL**	**LOWER LEVEL**

PHARMACEUTICAL INTERVENTION			
UNINTENTIONAL DRUG DISCREPANCIES • For all cases in which there was no clarification based on the patient's clinical condition or care plan, it will be considered a medication error.			
DRUGS	**TYPE OF ERROR**	**INTERVENTION PERFORMED**	**ACCEPTED OR RESOLVED WITHIN 72 HOURS POST-HOSPITALIZATION**

A complete history of regular drug use will be obtained before hospital admission (prescription or non-prescription drugs, nutraceuticals, vitamins, herbal preparations, parenteral nutrition and herbal and homeopathic products) by the bedside interview, ensuring total confidentiality of the information provided and being complemented with other sources of information, including previous hospital records (present in our computerized system), medical prescriptions, examination of packaging, labels, bottles and medication boxes and interview with the family member, companion and/or caregiver, when possible. All available information sources used to obtain the best possible medication history (BPMH) will be recorded in the *Philips Tasy* system. In addition, the BPMH will include information on relevant demographic and clinical data, adverse drug events previously experienced by the patient, social history, level of adherence, and pre-admission drug understanding. Patients' level of understanding of their pre-admission therapy will be assessed as high, medium, or low, depending on whether the patient could provide the name, dose, route of administration, frequency, accuracy of time of use, and its recommendation [42–44].

A comparison of the patient's pre-admission medication list with the current medical prescription will be conducted to identify any medication discrepancies, determine possible reasons, and attempt to resolve them within 72 hours. All fully completed forms will be included for data analysis. No intervention or alteration in medical prescription will be carried out without the consent of the clinical team, who will be completely free to deny the suggestion proposed by the clinical pharmacists.

Classification of Discrepancies and Severity of Error

After collecting information in the structured interview, clinical pharmacists will identify, analyze and classify discrepancies according to the process developed by Northwestern Memorial Hospital, called the *MATCH Toolkit* [45]. The discrepancies found will be classified as: no discrepancy (total reconciliation); justified and/or intended discrepancy (with substitution with a drug from the same pharmacological group or appropriate based on the patient's plan of care) and unintentional discrepancy (required clarification because there was no explanation based on the patient's clinical condition or plan of care) [46].

All unintentional discrepancies found without any clinical justification will be considered medication errors and classified in one of the following categories: medication omission (patient used a necessary medication that is not prescribed and without any clinical justification for non-continuation of treatment); dosage (drug dose different from usual use without justification for your clinical situation, such as alteration in renal or hepatic function); frequency (cases in which it will be necessary to adjust the drug administration interval); route of administration (cases in which the route of administration is changed without clinical justification) and therapeutic duplication (use of two or more drugs of the same therapeutic class prescribed for the same clinical condition, resulting in unnecessary duplication) [47].

The degree of impact of each drug discrepancy will be defined as: clinically insignificant (discrepancy unlikely to cause discomfort or clinical deterioration to the patient); clinically significant (discrepancy with the potential to cause mild to moderate discomfort and may require further monitoring); severe (a discrepancy that has the potential to cause significant harm and is likely to require additional intervention or may require prolonged hospital stay) and life-threatening (a discrepancy that has the potential to cause patient death or is likely to lead to death without the use of emergency intervention interventions). life support). This classification method was proposed by *The National Coordinating Council for Medication Error Reporting and Prevention* (NCC MERP) [47, 48].

Discrepancies that need clarification will be communicated to the specialist physician accompanying the patient through one or more of the following forms of communication: oral, telephone, text message, communication application or recording in the patient's medical record. In any case, any signal to the medical team, regardless of the means of communication used, will be recorded in an electronic medical record. Interventions that result in correction within the first 72 hours of hospitalization will be considered accepted.

In order to identify possible predictors of unintentional medication discrepancy, we will correlate the discrepancies with the different data collected in the present study, such as: demographic factors (age, gender, education, professional status and life habits); clinical characteristics (comorbidities, history of adverse drug reactions, type and length of previous hospital stay, and number of active drugs in the outpatient profile) and patients' level of understanding of their pre-admission treatment.

The ATC classification (Anatomical, Therapeutic, Chemical Classification System) will be used in the analysis of drugs with justified and/or

intended discrepancy and unintentional discrepancy, with the list of molecules included in each group [49].

Statistical Methods

All data will be tabulated in an Excel spreadsheet and descriptive statistics will be used to analyze the characteristics of patients and the data collected. The following tests will be used for parametric data: Student's t test for continuous variables in independent samples and chi-square test for categorical variables. For non-parametric data, the Mann-Whitney test will be used for continuous variables in independent samples. The significance threshold will be 0.05, except for multiple comparisons performed using Bonferroni correction.

Risk factors for drug discrepancy will be analyzed with Pearson's correlation tests for parametric variables and with Spearman's correlation tests for non-parametric variables. Correlations will be calculated between the number of discrepancies and the following variables: age, sex, number of comorbidities, allergy and number of pre-admission medications. Only values with strong correlations will be reported ($r \leq 0.6$ or $r \geq 0.6$).

As this is a pilot study, we did not calculate our sample with a small margin for maximum estimation error. Therefore, our sample size was estimated at 385 patients, considering a 95% confidence interval (CI) and a 5% margin of error.

All analyzes will be performed using SPSS version 22.0.1 (Statistical Package for the Social Sciences IBM, Inc. Boston, MA, USA), a software for statistical computing and graphics [50].

DISCUSSION

Recent studies have shown that drug reconciliation programs led by clinical pharmacists is a promising strategy for safe patient transitions [51, 52]. The American Society of Health-System Pharmacy (ASHP), for example, recommends that clinical pharmacists not only design and manage patient-centered medication reconciliation processes, but also provide education to patients, families and caregivers, advocate for patients on its integral pharmacotherapy and oversee the development of internal policies and protocols for patient safety practice and standardized workflows [38, 53].

Therefore, our hypothesis is that obtaining, verifying and documenting an accurate list of medications used by the patient prior to hospitalization, conducted by a clinical pharmacist, can reduce medication errors and, consequently, the costs associated with these events. In addition, this study will contribute to the knowledge base, providing more evidence of the importance of medication reconciliation to improve patient safety, even though it is an activity that requires inexpensive financial resources.

Approval by the research ethics committee: Approval by the Research Ethics Committee: This project is in the final phase of evaluation by the Institutional Human Research Ethics Committee. Data from this study will be disseminated to researchers, clinicians, health managers and multidisciplinary health teams in scientific presentations, conferences and scientific articles.

Informed consent: We will obtain consent from all participants who will be recruited into our study.

Conflict of interest: The authors declare that there is no conflict of interest in this project.

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