Medication Discrepancies Involving Hospitalized Children At A High-Complexity Public Hospital

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Abstract

Background: Children are more susceptible to medication errors and adverse reactions. In addition, variation in body mass and medication discrepancies are the major causes of medication errors, which pose a risk of harm to children. When unresolved, these issues can lead to longer hospital stays, increased hospital readmissions, and emergency room care that burden the healthcare system. Many organizations have struggled to implement medication reconciliation. In this context, studies demonstrated that reliability and improvement science methods can be used to implement a successful and sustained medication reconciliation process. One of the initial steps involved in medication reconciliation process is determining the sector for implementation. Therefore, the aim of this study was to determine the prevalence of medication discrepancies occurring throughout the course of a hospital stay and describe the types of discrepancies and medications most commonly involved in pediatric cases.

Methods: A cross-sectional study was carried out from July 2017 to March 2018 in the pediatric department of a high-complexity public hospital in Brazil. Data collection consisted of: collection of sociodemographic data, clinical interview with the patient's caregiver, registration of patient prescriptions, and evaluation of medical records. Discrepancies were classified as intentional or unintentional and included omission of medication, therapeutic duplicity, different dose, frequency, route of administration than prescribed. Study approved by the Research Ethics Committee (CAAE: 36927014.4.0000.5546).

Results: During care transitions, 114 children were followed. Patients presented unintentional discrepancies, of which 16 (14.0%) presented discrepancies at hospital admission, 42 (36.8%) during ward transfer, and 52 (45.6%) during discharge. Omission represented 74% (n=20) of the errors at admission, 38% (n=26) at ward transfer, and 100% (n=80) at discharge. The most frequent discrepancies in the three transitions were related to antimicrobials, representing 43.3% of discrepancies at admission, 38.8% at internal transfer, and 61.2% during discharge.

Conclusion: The results demonstrated that the main transition levels when unintentional discrepancies occurred in children in this hospital were during internal transfer and discharge and...
indicated difficulties in interprofessional communication and poor documentation. Evaluation of all transition points is essential for determining the most critical point in the quality of care provided at hospitals.

1. Introduction
The lack of studies on the efficacy and safety of medicines in children has engendered superficial knowledge regarding pharmacotherapeutic alternatives; thus, most pediatric prescriptions are based on empiricism or little clinical evidence [1]. As a result, children are more susceptible to medication errors, and adverse reactions [2]. In addition, variation in body mass and the high rate of prescription and administration of unlicensed or off-label medicines are the major causes of medication errors, with potential risk of harm to children and newborns [3, 4].

Another frequent cause of medication errors in children is medication discrepancies, which are defined as justified or unjustified differences in the pharmacotherapy of hospitalized patients. Discrepancies may occur and can be identified at any time from admission to discharge, including during bed changes [5]. When unresolved, these discrepancies can lead to problems, such as inadequate or ineffective pharmacotherapy, unnecessary treatment interruptions, increased susceptibility to adverse drug reactions, longer hospital stays, increased hospital readmissions, and emergency room care that burden the healthcare system [5, 6].

Medication discrepancies usually occur in the absence of a standardized medication reconciliation system and when communication between healthcare sectors and levels is poor [7, 8]. Medication reconciliation is defined as "the formal process in which health care professionals partner with patients to ensure accurate and complete medication information transfer at interfaces of care" and is considered one of the main strategies to ensure patient safety [9]. Many organizations have struggled to implement medication reconciliation, due to the resource intensity required to do medication reconciliation well, the interventions affect complex workflows at hospital, besides requiring a concerted inter-professional effort to understand existing workflows and to thoughtfully improve them [10, 11].

In this context, previous studies showed that reliability and improvement science methods can be
used to implement a successful and sustained medication reconciliation process [11, 12]. One of the initial steps involved in medication reconciliation processes is determination of the sector for implementation. Thus, this study aimed to (1) determine the prevalence of medication discrepancies occurring throughout the course of admission to discharge and (2) describe the types of discrepancies and medications most frequently involved in pediatric patients in a high-complexity public hospital in the Northeast of Brazil.

2. Methodology
2.1 Study Design
A prospective observational study was conducted on children admitted to the pediatric department of a high-complexity public hospital during admission to the emergency room, internal transfer, and discharge.

2.2 Study Site
The hospital is located in the Northeast of Brazil, the main gateway of the Unified Health System for cases of medium and high complexity, with an average caseload of 14,000 patients per month in the urgency/emergency sectors, 13 wards, and 421 beds. The pediatric sector is divided into three units: emergency room (48 beds and one isolation bed), inpatient ward (43 beds and one isolation bed), and intensive care center (eight beds).

The emergency room is divided into risk classification areas, with seven beds in the red area, six beds in the yellow area, 14 beds in the green area, 20 beds in the blue area, and one isolation bed. With the exception of the red area, patients are admitted through the “reception” sector, where nurses determine the risk rating using the Manchester scale [13].

The inpatient ward has 44 beds divided into six wards:
- The sector one has 12 beds and houses children from 28 days to 12 years of age with neuropathies and little turnover.
- The sector two has five beds and houses children from 28 days to six months of age.
- The sector three has five beds and serves children from seven months to two years and 11 months of age.
- The sector four has two beds and serves children from three to six years of age.
- The sector five has 10 beds and serves patients from 28 days to 12 years of age. This is the postoperative ward (general surgery, plastic surgery, and orthopedics).
- Isolation has one bed but was not included in the study.

2.3 Study Population
Children admitted to the hospital pediatric department who met the inclusion criteria during the study were evaluated.

2.3.1 Inclusion and Exclusion Criteria
The study included patients admitted to the pediatric ward who had been hospitalized for at least 48 hours, were between 28 days and 12 years of age, and had no cognitive and/or physical impairment that prevented their participation—or that of their caregiver. After describing the study in detail to the potential participant, the caregiver/guardian signed the free and informed consent form in accordance with National Council of Health Resolution nº 466/2012.

2.4 Data Collection
The patients were evaluated and discrepancies were identified at the time of hospital admission, internal transfer, and discharge. Therefore, before the beginning of the study, the research pharmacist (TSA) responsible for data collection and evaluation conducted a pilot study, from July to August 2017, in order to become familiar with the hospital's care transition processes, adjust the pharmacotherapy data collection form, and improve the information collection method. Data were collected from patients who participated in the study from August 2017 to March 2018.

Data collection was performed at four stages through a structured questionnaire that was developed by the researchers and adapted from the literature [14-17]. At stage one, the research pharmacist and the pharmacy student (FCAN) collected the following data from the admission form: sociodemographic information, sector to which the patient was admitted, and reason for hospitalization. At stage two, the clinical interview was conducted with the patient's caregiver, with a focus on the following variables: medication acquisition, allergies (to medication, food, and others), alerts and special needs, and medications the patient was using before hospitalization. Medications that the patient was sporadically using, supplements, vitamins, and those of which caregivers could not remember the name were excluded.

At stage three, the researchers recorded the patient's first prescription by the admitting physician and the first prescription after the internal transfer. At time four, each patient's medical record was evaluated to obtain the history of pharmacotherapy recorded by the physician from the following
data: the patient's main complaint, history of previous illnesses, questions about previous medications and allergies, the patient's conduct, and the doctor responsible for admission and internal transfer.

In the last stage, after discharge of the patients included in the study, the medical records were analyzed to identify discrepancies at this time. In addition, information related to the length of stay, presence of a discharge report, and form of documentation of discharge prescriptions was analyzed. To obtain more accurate data, all available sources of drug information were evaluated such as the interview with the caregiver, medical records, and hospital transfer data (for cases in which the patient was admitted from another hospital). When the caregiver received the patient's medications and previous prescriptions, was also investigated.

2.4.1 Evaluation of Discrepancies
After collection, data analysis was performed to investigate discrepancies. In this study, unintentional discrepancies (UDs) were considered unjustified but documented differences between the patient's previous history of pharmacotherapy and prescription after hospitalization. Intentional discrepancies (IDs) were considered when the physician justified the reason for the change in pharmacotherapy in the medical record.

In this study, “lack of documentation” was defined as any situation in which there was no trace of clinical documentation. As the “lack of a documentation” did not allow to assess the presence or absence of discrepancies, we evaluated the possible hypothesis of “lack of documentation” was considered to be a discrepancy with the aim of considering the worst possible scenario [7].

Any discrepancies found between the patients' medication list and prescriptions were classified as follows [18]:

Intentional discrepancies (ID): addition of a new drug justified by patient assessment; medical decision to not prescribe a drug or change its dose, frequency, or route of administration based on the patient's clinical situation; drug replacement.

Unintentional discrepancies (UD): omission, duplication, or substitution of medicines; dose, frequency, or route of administration different from that used by the patient; medication administration time; pharmacotherapy duration.

2.5 Sample Size Calculation
The following formula was used to calculate the minimal sample size for inclusion in the study:
\[ n = P \times (1 - P) \times z^2 / d^2 \]

Where “P” is the prevalence of medication discrepancies, where 22% of pediatrics patients were found to have at least one UD in a previous study conducted in Toronto, Canada [16].

While “d” is the desired precision (10%), and “z” is equal to 1.96, corresponding to a 95% level of confidence. Based on this formula, a minimum sample size of 66 patients was considered representative for the purpose of this study.

2.6 Ethical Considerations
This study was approved by the Research Ethics Committee of the University Hospital of the Federal University of Sergipe (CAAE number: 36927014.4.0000.5546) according to National Council of Health Resolution nº 466/2012. Patient information was assured by data confidentiality.

2.7 Statistical Analysis
The collected data were tabulated using EpilInfoTM software (version 3.5.4). Sociodemographic data and discrepancy profiles were subjected to descriptive statistical analysis, which was used to determine the frequency, mean/median, and standard deviation (SD)/interquartile range. To analyze the factors (gender, age, race, income, number of morbidities) associated with the occurrence of discrepancies in the care transition sites, the chi-square test was performed. The difference between the occurrence of discrepancies in admission, internal transfer, and discharge was assessed using the nonparametric Friedman test. This test was chosen because the same individuals were evaluated in three different situations (paired samples). For post hoc testing, the Wilcoxon test was used. A value of \( p < 0.05 \) was considered to indicate statistical significance.

3. Results
Between August 2017 and March 2018, during care transitions, 114 children aged 28 days to 12 years were followed and met the inclusion criteria. The mean age (SD) of the patients was 5.87 (3.33) years, and 60 (52.6%) were male. Table 1 presents the characteristics of the patients.
Table 1
- Sociodemographic characteristics

| Characteristics          |         |         |
|--------------------------|---------|---------|
| Genre, n (%)             | Male    | 60 (52.6) |
|                          | Female  | 54 (47.4) |
| Age, mean ± SD           |         | 5.87 ± 3.33 |
| Color, n (%)             | White   | 23 (20.18) |
|                          | Black   | 13 (11.40) |
|                          | Yellow  | 4 (3.51) |
|                          | Brown   | 73 (64.04) |
|                          | Indian  | 1 (0.88) |
| Origination, n (%)       | Capital city | 30 (26.3) |
|                          | Town    | 84 (73.7) |

Most patients had at least one unintended discrepancy in pharmacotherapy, of which 16 (14.0%) patients were in admission, 42 (36.8%) patients in transfer to the ward, and 52 (45.6%) patients in discharge. UD by omission represented 20 (74%) errors on admission, 26 (38%) on transfer to the ward, and 80 (100%) on discharge. Dose discrepancies represented 5 (19%) errors on admission and 29 (42%) on ward transfer (Tables 2 and 3).

Table 2
- Discrepancy profile identified in a admission, internal transfer and hospital discharge

|                      | Admission n (%) | Transfer n (%) | Discharge n (%) | Total n (%) |
|----------------------|-----------------|----------------|-----------------|-------------|
| Intentional          | 3               | 30             | 0               | 33          |
| discrepancy          |                 |                |                 |             |
| Unintentional        | 27              | 69             | 80              | 176         |
| discrepancy          |                 |                |                 |             |
| Total                | 30              | 99             | 80              | 209         |

Table 3
- Unintentional discrepancy profile identified in a admission, internal transfer and hospital discharge

|                      | Admission n (%) | Transfer n (%) | Discharge n (%) | Total n (%) |
|----------------------|-----------------|----------------|-----------------|-------------|
| Omission             | 20 (74)         | 26 (38)        | 80 (100)        | 126 (72)    |
| Dose                 | 5 (19)          | 29 (42)        | -               | 24 (19)     |
| Frequency            | 2 (7)           | 8 (12)         | -               | 10 (6)      |
| Route                | 1 (1)           | 1 (1)          | -               | 1 (1)       |
| Different drug       | -               | 5 (7)          | -               | 5 (3)       |
| Total                | 27 (100)        | 69 (100)       | 80 (100)        | (100)       |

The drug prescriptions were also classified according to the Anatomical Therapeutic Chemical
classification. This classification is adopted by the World Health Organization and aims to classify drugs according to their therapeutic properties, chemical substance, and the anatomical system in which they operate.

In this study, we classified the drugs identified as UDs according to their therapeutic purpose to determine which pharmacological class had the most drug discrepancies. The classification revealed that the highest occurrence of discrepancies in the three transitions corresponded to antimicrobials, representing 44.8% at admission, 38.8% at internal transfer, and 61.3% at discharge.

INSERT Table 4
Regarding the level of documentation at discharge, the discharge of only 57.2% of patients was documented in this study. Of these, 31.57% (36) received discharge prescriptions that were documented in the medical records; however, only 19.4% (7) of the patients had full documentation of their medications, such as dose, pharmaceutical form, and dosage.

There was no significant association between gender, race or age and the occurrence of discrepancies in any of the care transition sites (p > 0.05). Income greater than one minimum wage and higher
A number of morbidities were related to discrepancies in hospital admission only (p < 0.05).

3. Discussion

Most studies on the prevalence of drug discrepancies have been conducted in adult populations, usually focusing on a transition point in care [7, 19, 20]. However, a few similar studies in children have been reported [21–23]. In contrast, this is the first study to assess the discrepancy rate in children at three hospital transitions: admission, internal transfer, and discharge. In clinical practice, assessing all possible transition points is essential for determination of the most critical point in the quality of care provided in the hospital, thus favoring the establishment of problem-focused strategies and improvement of work processes.

In this regard, diagnosis is one of the stages involved in implementation science, which is essential for resource-poor countries and communities such as Brazil because resource poverty requires novel solutions to ensure that research results are translated into routine practice and benefit maximum number of people [24]. Thus, implementing medication reconciliation with a focus on the most critical point of care through implementation science can optimize time and resources in countries like these, increasing service sustainability and consequently reducing the damage caused by these problems.

Previous studies in adult populations reported the identification of many Uds (6,7,25). Only a few drug records of the patients evaluated in this study revealed at least one UD at hospital admission. A similar result was reported by Abu Farha et al. (2018) [26] at admission in a university hospital in Jordan, where only 13% (13 of 100) of the pediatric patients had a UD. Another study conducted in a pediatric hospital also reported similar findings, identifying 22% (59 of 272) of patients with these discrepancies [16]. This low proportion of UD at hospital admission may be explained by the fact that children generally use fewer continuous-use medications compared with adults.

Other causes of the lower number of UD identified in this study were related to the profile of acute health conditions, i.e., most patients did not use medicines at home. In contrast, previous studies revealed lower rates of UD in hospitals that implemented medication reconciliation [27–29]. For example, in a discharge study from a pediatric hospital in London, 33% (47 of 142) of patients had at least one discrepancy [28]. A lower rate was also identified by Gattari et al. (2015) [27] at a pediatric hospital...
hospital in the United States, with 26% (18 of 69) of patients experiencing a UD. Thus, in addition to reducing the rate of UD, medication reconciliation provides guidance on the medications that will be used after hospital discharge.

Regarding the classification of discrepancies, omissions were the most common type of UD in this study as well as in the literature, and may occur when history of drug use is not evaluated or data on drug use are not obtained before admission [30]. In many countries, drug information is recorded and transferred when a patient transitions to the next level of health care, thereby increasing patient safety [31]. However, despite considerable progress over the past 20 years, including investments in human resources, science, and technology, some challenges persist in the Unified Health System in Brazil as there is no integrated healthcare information system, such as a health system database or integrated community pharmacy data [32]. Thus, there is a need to establish a process of collecting accurate and complete medication history of patients and allowing all professionals access to this information.

Antimicrobials were the drugs most commonly involved in UDs of children in the three transitions analyzed in this study. Alghamdi et al., (2019) [18] reported that antimicrobials were the drugs most frequently involved in potential adverse events and medication errors. The high rate of antimicrobial use in children can be explained by the high prevalence of infectious diseases in this population [33, 34]. According to the literature, the lack of clinical protocols in hospitals and the limited scientific evidence related to pharmacotherapeutic treatment of children cause prescribers to rely on empiricism, leading to frequent changes in pharmacotherapy and medication errors [35–36]. Thus, the implementation of medication reconciliation can ensure the continuity of antimicrobial use, reducing UDs.

Regarding the level of documentation at discharge, just over half of the patients had discharge reports in this study. Although problematic, there are not many studies that assess the level and quality of documentation in hospitals. However, in a systematic review on communication during transfer between hospitals and primary care, discharge report availability was only 12–34%, and when present, the documentation quality was poor [37]. Inadequate discharge documentation leads to
misinformation, duplication of tests or interventions, delayed or failed referrals, discontinuity of care, medication errors, and potential patient harm, thus increasing the likelihood of hospital readmission, morbidity, and mortality [38, 39]. According to Blaine et al. (2018) [40], documentation gaps at discharge create the opportunity for one of the indispensable components for hospital discharge, the medication reconciliation and to establish healthcare education plans in partnership with patients, parents, and health professionals throughout the care cycle.

Based on these findings, the use of quality improvement strategies, staff training, prioritization of accurate and complete medication history collection, and implementation of medication reconciliation through implementation science methodologies are potential focus areas for future interventions. Curatolo et al. (2014) [12], for example, used the Plan-Do-Study-Act (PDSA) quality improvement strategy, an approach that gradually tests changes and/or improvements to implement and sustain medication reconciliation at a hospital in France, achieving reduced UD rates through three PDSA cycles. Thus, the use of this methodology ensures that the service is guided by quantified objectives, using the minimum available resources and generating means for the evaluation of processes at each cycle until incorporation in the hospital. Thus, it is possible to systematically monitor the actions taken and the results achieved.

3. Strengths And Weaknesses
This is the first study to assess the discrepancy rate in children at three hospital transitions: admission, internal transfer, and discharge. In clinical practice, assessing all possible transition points is essential for determination of the most critical point in the quality of care provided in the hospital, thus favoring the establishment of problem-focused strategies and improvement of work processes. However, this study has limitations. Regarding discrepancy analysis, it was only possible to classify discrepancies into two types (intentional or unintentional; when there was no documentation) rather than three (intentional, unintentional documented and unintentional undocumented). Although the lack of documentation may be random, this problem may generate other systematic errors. This analysis was performed on purpose because this work is part of a pre-analysis for the implementation of medication conciliation and also a clinical trial study in this hospital. In this hospital
there is no Clinical Pharmacy service, and this was one of the first works to be performed. Thus, in order to avoid contamination of health professionals regarding service processes, it was not possible to analyze the intentionality of discrepancies in a traditional way. Subsequently, the purpose of the intervention implemented in the hospital will also involve improving the documentation of the institution's professionals.

4. Conclusion
This study revealed that the main transition levels at which UD s occurred in children in this hospital were internal transfer and discharge, with omission being the most common type of UD at the three care points and antimicrobial drugs the most commonly involved. Moreover, this study indicated the existence of difficulties in interprofessional communication and poor quality of documentation. In this regard, the evaluation of all possible transition points was essential for determination of the most critical point in the quality of care provided at the hospital. Thus, the results may guide the direction of strategies, such as implementation of medication reconciliation, focused mainly on the optimization of internal transfer and discharge. In addition, this study will serve as a basis for deploying services in hospitals with similar characteristics.

5. Declarations

5.1 Ethics approval and consent to participate
This study was approved by the Research Ethics Committee of the University Hospital of the Federal University of Sergipe (CAAE number: 36927014.4.0000.5546) according to National Council of Health Resolution nº 466/2012. Patient information was assured by data confidentiality.

5.2 Consent for publication
Not applicable

5.3 Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

5.4 Competing interests
The authors declare that they have no competing interests
5.5 Funding

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5.6 Authors' contributions

All authors substantially contributed to conception or design the manuscript. TSA, FCAN, HFL, DCSAA, JMS contributed to acquisition, analysis, or interpretation of data. TSA, FCAN, DCASAA, wrote the paper. All authors critically revised the manuscript for important intellectual content and accepted the final version of the manuscript.

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