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Pediatric palliative care in interface with clinical pharmacy service: scenario analysis in a University Hospital in Bahia

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Abstract

Objective: To analyze the scenario of pharmaceutical activities in Palliative Care developed in a Pediatric Center of a University Hospital in Salvador, Bahia. **Methods:** This is a descriptive cross-sectional study, carried out based on information present in medical records during the period from June 2018 to June 2020. As long as they were monitored by the Clinical Pharmacy Service, patients eligible for Palliative Care were characterized regarding their age, sex and main disease. Pharmaceutical procedures were categorized and interventions, if detected, were associated with the respective Medication-Related Problem. The medicines were classified using Anatomic Therapeutic Chemical, indicating whether they were used off-label. **Results:** Of the 370 patients selected, 31 were included in the study, as they had clinical monitoring from the pharmacist. Of these, 17 (54.84%) were male, with an average age of 6.19 years, ranging from 10 days to 18 years. The most frequent diagnoses were endocrine, nutritional and metabolic diseases (8; 25.80%). Pharmaceutical procedures included detection of adverse events (12; 19.04%), additional monitoring (2; 3.17%), guidance to the family or team (13; 20.63%) and interventions (36; 57.14%). The interventions were mainly related to safety (13; 36.11%). Of the prescribed medications, 91 (23.09%) were systematized in the alimentary tract and metabolism in the ATC, followed by nervous system (85; 21.57%) and antimicrobials for systemic use (61; 15.48%) 30 off-label prescribed items were identified, 3 of which were associated with suspected adverse reactions. **Conclusions:** The study identified limited pharmaceutical service, covering only 8.37% of the population analyzed. These results highlight the importance of expanding the integration of pharmacists into multidisciplinary palliative care teams to improve the quality of life of these patients. It is important to consider that, given that this is documentary research, memory and recording biases must be considered. These results are expected to foster improvements in this context, including the provision of a dignified quality of life from diagnosis onward, uniting voices so that this science ceases to be, in addition to being underutilized, synonymous with the end of life.

Key-words: palliative care; pediatrics; off-Label use; evidence-based pharmacy practice; clinical pharmacy service; patient safety

Cuidados paliativos pediátricos em interface com serviço de farmácia clínica: análise do cenário em um Hospital Universitário da Bahia

Resumo

Objetivos: Analisar o cenário de atividades farmacêuticas em Cuidados Paliativos desenvolvidas em um Centro Pediátrico de Hospital Universitário em Salvador, Bahia. **Métodos:** Trata-se de um estudo transversal descritivo, realizado a partir das informações presentes em prontuários durante o período de junho de 2018 a junho de 2020. Desde que acompanhados pelo Serviço de Farmácia Clínica, os pacientes elegíveis aos Cuidados Paliativos foram caracterizados quanto à idade, sexo e doença principal. As condutas farmacêuticas foram categorizadas, e, se intervenções, foram associadas ao respectivo Problema Relacionado a Medicamento (PRM). Os medicamentos foram classificados mediante *Anatomic Therapeutic Chemical*, sendo indicado se decorreu de uso off-label. **Resultados:** Dos 370 pacientes selecionados, 31 foram incluídos no estudo, pois tiveram acompanhamento clínico do farmacêutico. Destes, 17 (54,83%) eram de sexo masculino, com idade média de 6,19 anos, variando de 10 dias a 18 anos. Os diagnósticos mais frequentes foram de doenças endócrinas, nutricionais e metabólicas (8; 25,80%). As condutas farmacêuticas compreenderam detecção de eventos adversos (12; 19,04%), monitoramentos adicionais (2; 3,17%), orientações à família ou equipe (13; 20,63%) e intervenções (36; 57,14%). As intervenções estavam relacionadas principalmente à segurança (13; 36,11%). Dos medicamentos prescritos, 91 (23,09%) foram sistematizados em trato alimentar e metabolismo na ATC, seguidos de sistema nervoso (85; 21,57%) e antimicrobianos para uso sistêmico (61; 15,48%). Foram identificados 30 itens prescritos de forma off-label, sendo que 3 estavam associados a suspeitas de reações adversas.

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Conclusões: O estudo identificou cobertura limitada do serviço farmacêutico, abrangendo 8,37% da população analisada. Esses resultados destacam a relevância de ampliar a integração do farmacêutico às equipes multiprofissionais de Cuidados Paliativos, de modo a promover a qualidade de vida desses pacientes. Pondera-se que, se tratando de uma pesquisa documental, há vieses de memória e registro que devem ser considerados. Espera-se que esses resultados fomentem melhorias, desde a oferta de qualidade de vida digna a partir do diagnóstico, unindo vozes para que essa ciência deixe de ser, além de subutilizada, um sinônimo para o fim da vida.

Palavras-chave: cuidados paliativos; pediatria; uso off-label; prática farmacêutica baseada em evidência; serviço de farmácia clínica; segurança do paciente

Introduction

Historically, among the objects of science, the understanding of pathological processes and the related interventions for their treatment have been predominantly framed within a curative perspective. In this context, the foundations for training health professionals and for shaping their professional roles were established. In Brazil, one of the country's foremost public health scholars, Sérgio Arouca, produced an extensive body of literature on the emergence of preventive medicine as a critical movement against the dominance of curative medicine and on the impact of social structures within this scenario[1]. Despite continuous advancements and the surpassing of previously unimaginable limits, current scientific achievements are not sufficient to prevent individuals from dying as a result of the diseases and conditions that affect them. In light of the need to reframe care provided to individuals at the end of life, the World Health Organization defined Palliative Care as an integrated model of promoting quality of life through the "prevention and relief of suffering by means of early identification, impeccable assessment, and treatment of pain, as well as other problems—physical, psychosocial, and spiritual."[2]

The understanding of end-of-life becomes complex when it is not exclusively associated with the final days of life, but rather with the course of a life-limiting condition that may persist for days or years. Based on this premise, Palliative Care should be initiated at the moment a diagnosis or identification of such a condition is made, so that effective rapport with the multidisciplinary team can be established and outcomes can be aligned with the proposed goals[3].

Given this context, addressing the dying process of a child or adolescent challenges the social understanding and acceptance of a trajectory in which expectations for this individual extend into old age. Therefore, health and its determinants must be understood in order to support empathetic communication in this seemingly more delicate setting, represented by Pediatrics[4]. The contexts warranting the initiation of pediatric palliative care range from conditions for which cure is possible but may fail, to severe non-progressive disabling conditions[5].

In Pediatric Palliative Care, it is essential to consider the unique characteristics of this population. The developmental process of children and adolescents involves constant and rapid changes that must be acknowledged to guide the most effective and individualized care strategies. Furthermore, when a complex pathological condition affects a child, several pharmacotherapeutic approaches still lack adequate scientific support, although progress has been made[6]. With regard to adolescents, even when their bodies have reached relative physiological stability, maturation and endocrine, metabolic, and behavioral effects must still be considered when prescribing medications.

On this journey, according to the first edition of the *Palliative Care Manual* published by the National Academy of Palliative Care[7], the pharmacist is not formally integrated as a direct member of the core team. Their role consists of providing information on medication availability, pharmaceutical compounding possibilities, and legal aspects, in addition to offering guidance on storage. Despite advances, the scarcity of Brazilian studies on this topic remains evident. To date, the only Brazilian regulation addressing this issue, Ministry of Health Resolution No. 41/2018, does not specify which professionals should comprise the palliative care team, nor does it define their responsibilities.

From this same standpoint, considering the shortage of medications for pediatric use, particularly for children under two years of age, the prescription of off-label medications has become a routine practice in both hospital and outpatient settings[8]. Thus, while prescription quality is not necessarily compromised, its regulatory inconsistency warrants intensified monitoring. The pharmacist's presence within the care team becomes essential for identifying, validating, and assisting in the management of these medications, contributing to the reduction of Negative Outcomes Associated with Medication, in addition to the broader scope of practice inherent to their technical training[9].

Methods

This study employed a qualitative–quantitative approach, characterized as a documentary and exploratory investigation based on patient medical records. The temporal scope was retrospectively defined, covering the period from June 1, 2018, to June 30, 2020. All children and adolescents admitted to the Professor Hosannah de Oliveira Pediatric Center, part of the Professor Edgard Santos University Hospital Complex at the Federal University of Bahia, located in Salvador, Bahia, were included. Based on the hospital admission report organized according to the International Statistical Classification of Diseases and Related Health Problems (ICD-10), four care units that serve pediatric patients were selected.

Given the still incipient landscape of Pediatric Palliative Care availability, diagnoses and conditions susceptible to a limited prognosis were identified using the SUS Hospital Morbidity Tabulation List, which applies ICD-10 codes. Initially, all pediatric patients whose coding matched this selection were included. Following a careful review—considering that diagnoses recorded in free-text fields or with nonstandard terminology could introduce bias and lead to underestimation—a second screening was conducted. This step included codes requiring additional investigation and codes needing dual criteria review.

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Based on this selection, the medical records of eligible patients were examined to assess follow-up by the clinical pharmacist through documents recorded as "Pharmacy Admission," "Pharmacy Progress," and "Pharmaceutical Discharge." These records were chosen following prior consultation with a pharmacy leadership representative, who confirmed that these were the only pharmacist-authored documents in the electronic medical record. To facilitate visualization of the therapeutic plan and clinical course, each patient was evaluated only once, even when multiple hospitalizations occurred, provided they fell within the study period. Therefore, all pediatric patients whose primary condition fit the predefined selection and who were followed by the Clinical Pharmacy Service were included. The main exclusion criterion was insufficient information in the medical record for analysis. Subsequently, data from eligible patients were collected using a pre-approved form on the KoboToolbox® platform. Although data collection was conducted by a single researcher, the information was regularly checked by other team members, and all operational steps were performed based on group consensus. The collected variables included: sex and age, anthropometric data (weight and height), ICD-10 codes for the hospitalization-related condition and primary diagnosis, classification of DRP (if identified), description of pharmaceutical interventions and outcomes, medications and dosages used during hospitalization, and suspected Adverse Drug Reactions. Descriptive statistical analysis was then performed to present the findings.

This study was approved by the Research Ethics Committee of the university hospital under CAAE number 56235522.0.0000.0049 and opinion no. 5.304.541.

Results

As shown in Figure 1, a total of 2,361 patients were admitted to the hospital's pediatric units during the study period. After the initial screening, 370 patients had a condition consistent with a limited and life-threatening prognosis, according to the predefined list of diseases. Of these 370 patients, 31 children and adolescents were followed by the clinical pharmacist during their hospitalizations, corresponding to those who met the eligibility criteria.

Based on the information collected in this study, it is not possible to determine the causes associated with the relatively small proportion of included patients. Nonetheless, the absence of an institutional selection of follow-up criteria at the time highlights weaknesses in the triage protocols for patients eligible for palliative care. It is important to note that cases whose medical records contained only laboratory requests or lacked documented clinical progress notes were excluded.

If this patient were a child, what would they be like?

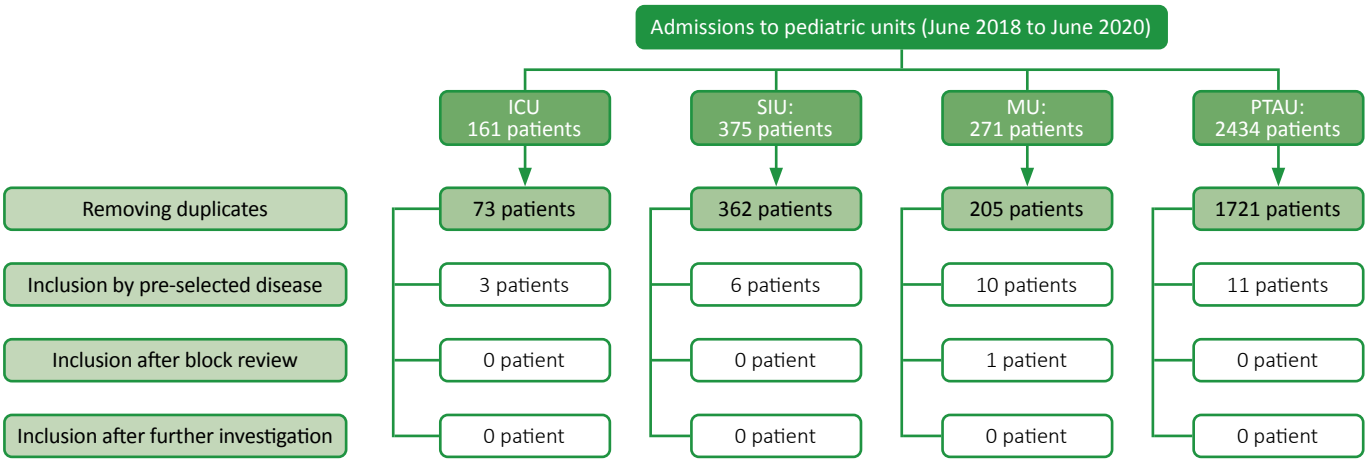
Among the eligible patients, 17 (54.83%) were biologically male. The mean age was 6.19 years (standard deviation: 6.32), ranging from 10 days old (0.027 year) to 18 years old. Figure 2 presents the distribution of life-limiting diseases and conditions according to ICD-10. Regarding mortality, 5 patients (16.12%) died, including 4 infants and 1 adolescent (14 years old). Based on the most frequent findings, if it were possible to personify the child represented in this study, they would be a boy approximately 6 years old with a life-limiting metabolic disease manifesting primarily through hepatic complications (Figure 3).

Aligning expectations: overview of pharmaceutical actions

The information documented in the "conducts" section of the clinical follow-up forms was analyzed. It is recognized that pharmacists perform numerous routine activities that were neither quantified nor described in this study, as the aim was to approximate the profile of clinical actions to the context of Palliative Care.

From the consolidated data, 21 patients (67.74%) presented at least one DRP (Drug-Related Problem) that prompted pharmaceutical interventions, grouped in Table 1. Among the 63 actions identified, 13 were categorized as counseling (20.63%), 2 as the need for additional monitoring (3.17%), and 12 as adverse event detection (19.04%).

Figure 1. Patient selection flowchart



ICU: Intensive Care Unit; SIU: Small Infants Unit; MU: Metabolic Unit; PTAU: Pediatric Teaching and Assistance Unit.
Comments:
1- Duplicate patients were removed through double-checking of name and medical record number.
2- Block review: ICD codes with a high number of hospitalizations and requiring additional assessment.
3- Need for further investigation: ICD code initially not eligible, but with a guarded prognosis under conditions specified by the care team.

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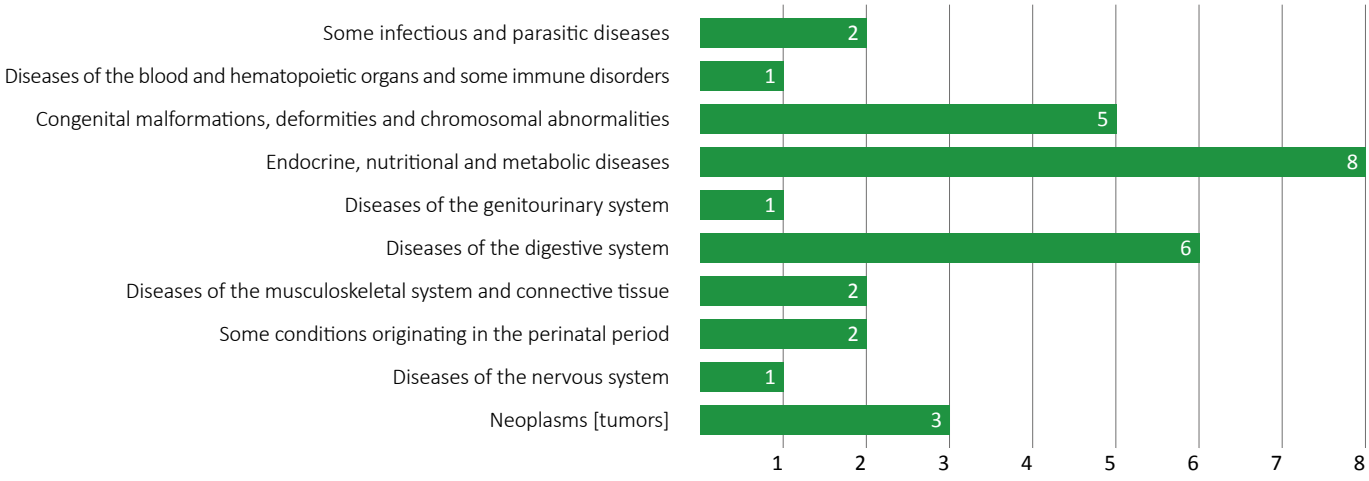
Figure 2. Distribution of the main diseases of the patients included and monitored by the Clinical Pharmacy Service



It is well established that the development of adverse drug reactions presents distinct nuances in children and adolescents when compared to predisposing factors in adults, and underlying diseases also play an important role in this context. However, even considering the inherent clinical vulnerability of patients requiring Palliative Care, it remains unclear whether this relationship constitutes an aggravating factor in the occurrence of adverse events.

The landscape of pharmaceutical interventions at the end of life First, it is necessary to understand prescription characteristics and medication profiles. In total, 412 medications were evaluated: 28 (6.79%) were prescribed at the physician's discretion, 47 (11.40%) as symptomatic treatments, and 337 (81.79%) as scheduled medications. Regarding the Anatomic Therapeutic Chemical (ATC) subclasses, the most frequently prescribed groups included systemic antibiotics (11.89%), analgesics and antipyretics (8.73%), and electrolyte solutions (4.12%). Among scheduled medications, the mean number prescribed was approximately 10.87 per patient (standard deviation: 5.51). This high number not only reflects the therapeutic complexity but also strongly underscores the need for structured and systematic pharmaceutical follow-up.

Although systemic antimicrobials represented the third most frequently prescribed class in quantitative terms, it is noteworthy that 74.19% (n = 23) of the patients received at least one of these medications for the treatment of an active infection, even when concomitantly on antimicrobial prophylaxis. Regarding symptomatic medications, anti-inflammatory drugs, analgesics, antipyretics, and antiemetics predominated, except in cases requiring specific guidance for hypoglycemia or hypertensive spikes.

In further detail, the medications most frequently associated with drug-related problems were antibiotics (n = 4), omeprazole (n = 3), morphine (n = 3), and antifungals (n = 2). As shown in Table 1, ensuring pharmacotherapeutic safety was the most common opportunity for pharmaceutical interventions, accounting for 36.11%. Among the interventions performed, 6 (16.66%) involved high-alert medications (midazolam, heparin, amphotericin, and morphine), all of which were accepted by the multidisciplinary team. Regarding outcomes, some interventions lacked explicit documentation in the medical record concerning the prescriber's acceptance or rejection, resulting in 2 (5.55%) inconclusive outcomes, 28 (77.77%) accepted interventions, and 6 (16.66%) not accepted. When not accepted, justifications were not provided in the forms.

Figure 3. Defining the persona

Source: author-created image using BioRender software.

Another relevant aspect was the identification of the clinical pharmacist's contribution to promoting strategies for the acquisition or safe provision of non-formulary medications and other health technologies.

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Table 1. Categorization of interventions identified based on patient needs

Category	n (%)
Indication (n=4)	
Access to non-formulary medication enabled	4 (11.11%)
Effectiveness (n=11)	
Dose increase	6 (16.67%)
Administration recommendation	2 (5.56%)
Medication optimization	1 (2.78%)
Best available therapeutic option	1 (2.78%)
Incompatibility alert	1 (2.78%)
Safety (n=13)	
Dose reduction	7 (19.44%)
Frequency adjustment	1 (2.78%)
Deprescribing recommendation	4 (11.11%)
Care recommendation after adverse event	1 (2.78%)
Convenience (n=8)	
Change in medication formulation	3 (8.33%)
Schedule adjustment	1 (2.78%)
Ensuring access for treatment continuity	3 (8.33%)
Medication optimization	1 (2.78%)
Total n: 36 interventions	

These actions included issuing positive technical opinions, guiding the team on use and storage, advising regarding patient-owned medications, and even coordinating with the municipal Out-of-Home Treatment service to obtain patient-supplied medication.

Beyond the label: off-label medications in Palliative Care

Among the 412 prescribed items evaluated, 30 (7.28%) were classified as off-label prescriptions, involving 18 (58.06%) of the 31 included patients (Table 2). Most off-label prescriptions were related to therapeutic indication (18 cases; 60.0%), such as the use of zinc acetate in electrolyte disorder protocols (23.30%) and the prescription of domperidone for children under 12 years of age (13.35%). Next, situations related to route of administration were notable (10 cases; 33.30%), including subcutaneous administration of teicoplanin (3.33%) and sublingual administration of atropine (13.35%). Finally, two prescriptions (6.70%) were associated with dose adjustments for ursodeoxycholic acid and hydrochlorothiazide. Although not validated, three of these prescriptions were associated with adverse drug reactions, underscoring the clinical impact of off-label use and the need for continuous pharmaceutical monitoring.

The pharmacist's perspective as a preface: treatment adherence

Although not classified as an intervention in its entirety, pharmaceutical counseling provided to the family—when not preceded by the identification of a DRP—serves as an important facilitator in Palliative Care, as it anticipates the needs of both the patient and their support network.

In the present study, 13 counseling actions performed by the clinical pharmacists were identified, 6 of which were directed to the family and the patient. Of these, five occurred at hospital discharge and one took place during hospitalization, when medication use interfered with breastfeeding dynamics.

Table 2. Description of prescription items identified as off-label medications

Category	n (%)
Indication; 18 (60.0%)	
Indication of zinc acetate in the PEM protocol	7 (23.30%)
Indication of ferric polymaltose for infants < 1 year	1 (3.30%)
Indication of domperidone in children < 12 years of age	4 (13.35%)
Indication of loperamide below labeled weight	1 (3.30%)
Pediatric use of pamidronate	2 (6.70%)
Pediatric use of fenofibrate	1 (3.30%)
Indication of erythromycin for gastroparesis	1 (3.30%)
Use of chlorhexidine for gingivitis in age below labeling	1 (3.30%)
Administration; 10 (33.3%)	
Administration of teicoplanin via subcutaneous route	1 (3.30%)
Administration of atropine via sublingual route	4 (13.35%)
Administration of omeprazole via gastrostomy or tube	2 (6.70%)
Administration of calcium carbonate via gastrostomy	1 (3.30%)
Administration of miglustat via tube	1 (3.30%)
Administration of furosemide via continuous infusion	1 (3.30%)
Dose; 2 (6.7%)	
Prescribed dose of ursodeoxycholic acid	1 (3.30%)
Prescribed dose of hydrochlorothiazide	1 (3.30%)

PEM: Protein–Energy Malnutrition

Discussion

This study offers a new perspective on pharmaceutical care applied to Palliative Care and is possibly the first to address the topic by integrating professional competencies and skills, exploring a complex framework within a large healthcare institution, and thus establishing an initial foundation for understanding this subject matter.

Throughout the development of this research, it became evident that there is a scarcity of studies in Palliative Care—particularly at regional or national levels—that directly report pharmaceutical activities related to DRPs and their impact in the context of negative outcomes associated with medication. In this regard, the present study sought to discuss these data at an institutional level in order to demonstrate the relevance of incorporating a pharmacist into the care team.

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When examining the most prevalent conditions among the patients included in the study, a discrepancy becomes apparent in comparison with the existing literature, which highlights the diseases most frequently associated with Palliative Care. In this context, malignant neoplasms were expected to predominate. However, it must be considered that this hospital is not designated as the reference center for oncology care within the state health regulation system. Therefore, the observed pattern reflects the institution's operational dynamics at the time. Furthermore, this finding underscores that structuring pediatric Palliative Care services must extend beyond Oncology and equally encompass other highly complex chronic conditions.

In describing the clinical pharmacy service actions, this study moves beyond the view of the clinical pharmacist as merely a prescription reviewer—a perspective suggested in a prospective observational study[6] —and highlights the broader contributions of this professional within the team, aiming to reduce the likelihood of negative outcomes.

Regarding off-label medication use, the findings align with the literature[6], with therapeutic indication being the primary reason for off-label prescribing. In this context, enhanced monitoring practices and strategies aimed at preventing medication errors are expected to be particularly robust. Such findings may support institutional Pharmacovigilance policies, aligned with the activities of the Pharmacy and Therapeutics Committee (PTC), such as developing specific protocols for off-label use, prioritizing interventions for vulnerable groups, and structuring internal workflows. It is also essential to encourage reporting of suspected adverse drug reactions associated with these medications, as doing so may inform practical and timely management strategies for recurrent events, particularly in situations where the medication cannot be avoided.

From a care standpoint, the principle of non-maleficence is highly valued, and the safety profile of medications—along with all related processes—constitutes a key factor when considering supportive therapies, modifications, continuations, or discontinuations of treatment. In Pediatrics, Pharmacovigilance has advanced as a robust field, already incorporating "systems biology methodologies and novel informatics to improve pediatric medication safety,"[10] as well as the use of genetic markers for event prediction[11]. In the present findings, gaps remain in the process of detecting suspected adverse drug reactions, communicating them back to the team, and evaluating their impact on clinical outcomes.

It is also important to highlight that establishing professional trust is essential for promoting practices aligned with patient needs. Scholars have reported on the attitudes and involvement of healthcare professionals in Palliative Care, noting a small proportion of pharmacists with prior training on the subject, which was associated with inadequate confidence, knowledge, and skills[12]. To strengthen professional competence when dealing with such a sensitive context for all involved, incorporating Palliative Care into undergraduate curricula, clinical training programs, and residency programs, along with support from regional and federal Pharmacy Councils in promoting continuing education opportunities, are potential strategies to bridge this gap.

The data and interpretations presented resulted from the researchers' understanding of the operational dynamics of the institution studied, as well as the availability of information in the literature.

Even though the analysis was grounded in a broad scenario of conditions and diagnoses that led to the need for hospital care, this approach proved to be the most appropriate to avoid favoring results that might reflect institutional performance rather than reality.

It is also acknowledged that memory and recording biases should be considered when evaluating the demonstrated impact. It is necessary to recognize the limitations associated with the small number of patients included in this research, which may affect the generalizability of the results. Currently, conducting studies using real-world data remains challenging, especially regarding the structuring of electronic medical records, the harmonization of terminology, and variations in natural language[13]. These limitations may be overcome with the use of Artificial Intelligence, which has been gaining prominence in ongoing discussions. Nonetheless, it must be recognized that AI also imposes other constraints, such as the need for investment in financial and human resources, in addition to the training of professionals working in multidisciplinary teams.

Conclusion

The study identified limited pharmaceutical service coverage for patients eligible for Palliative Care, encompassing only 8.37% of the population of 370 patients who could potentially have been monitored, according to the predefined list. In cases where follow-up occurred, pharmaceutical interventions were predominantly focused on treatment safety (36.11%), with emphasis on the high occurrence of polypharmacy and off-label medication use (58.06%). These findings highlight significant challenges for clinical practice and underscore the importance of expanding the integration of pharmacists into multidisciplinary Palliative Care teams to promote the quality of life of these patients.

As demonstrated, pharmacists fulfill essential responsibilities that deserve recognition, being capable of proposing practices grounded in scientific evidence. Thus, it is expected that the results of this study will stimulate improvements in this setting, so that pharmacists and healthcare managers may be increasingly engaged and committed to the principles of Palliative Care, guided by preventability and the provision of dignified quality of life from the time of diagnosis onward—joining efforts so that this field ceases to be not only underutilized but also wrongly perceived as a synonym for end-of-life care.

It becomes evident that the work of clinical pharmacists in pediatric Palliative Care requires not only technical competence but also ethical sensitivity, effective communication, and a broadened understanding of human suffering. The results illustrate the urgent need to incorporate Palliative Care into pharmaceutical education, from undergraduate training to continuing professional development. By revealing gaps in clinical practice, particularly in pediatric contexts, this study reinforces the importance of preparing pharmacists to manage complex situations, promoting more humanized, safe, and fully integrated care within multidisciplinary teams.

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Contributors

MCNR, PMS, PLG: project conception, data analysis and interpretation; MCNR: manuscript writing; MCNR, PMS, PLG: critical review of content relevant to intellectual merit. All authors approved the final version of the manuscript, ensuring the accuracy and integrity of the information presented.

Conflict of Interest

The authors declare no conflict of interest concerning this article.

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