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Research Article

Excipients Used in Pediatric Oral Dosage Forms: Challenges and Perspectives for Safe Hospital Practice

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Abstract

The pharmacological management of pediatric patients remains a major challenge, particularly in low-resource settings. Oral dosage forms, widely used in children, require appropriate excipients; however, some of these excipients may induce adverse effects. The aim of this study was to identify the excipients used in pediatric oral formulations available in community pharmacies in order to guide the development of safer hospital formulations. A descriptive study was conducted in a community pharmacy located in the suburbs of Dakar over a three-month period. Pediatric oral pharmaceutical products were surveyed, and for each product, the international nonproprietary name (INN), dosage form, packaging volume, therapeutic indication, and list of excipients were collected. Data were entered and analyzed using Microsoft Excel 2016. A total of 200 pharmaceutical products corresponding to 96 international nonproprietary names were identified. Solutions were the most frequent dosage forms (46.5%), followed by powders (31.8%) and suspensions (21.7%). The most common packaging volumes ranged from 51 to 100 mL, and antibiotics were the most frequently encountered therapeutic class. The most commonly used excipients were sucrose, sodium benzoate, and citric acid. Sucrose served as the main sweetener to mask the bitter taste of active ingredients, sodium benzoate acted as a preservative, and citric acid was used as a pH regulator. Flavoring agents and preservatives were the most represented categories. The findings highlight the widespread use of sweeteners and preservatives, which are essential for the acceptability and stability of liquid formulations, although several of these excipients may pose potential risks for infants. A better understanding of these substances is therefore necessary to optimize pediatric hospital formulations. The development of locally adapted formulations using safe and available excipients appears essential to improve the safety and efficacy of pediatric treatments in Senegal. Overall, excipients play a crucial role in pediatric drug formulation by influencing stability, preservation, and palatability, and this study underscores the need for increased vigilance regarding excipients with known effects while supporting the development of hospital preparations tailored to local needs.

Keywords: Pediatric oral dosage forms; Excipients; Pharmaceutical formulation; Hospital preparations; Drug safety

INTRODUCTION

The pharmacological management of pediatric patients represents a major public health challenge worldwide, particularly in low-resource settings. Neonates, infants, and children exhibit physiological immaturity, including digestive, metabolic, and enzymatic systems, which makes them particularly vulnerable to both active pharmaceutical ingredients and excipients present in medicinal products. However, the currently available pharmaceutical formulations do not always meet the specific needs of this population in terms of dosage, dosage form, and administration safety [1].

In the absence of suitable commercial formulations, some pediatric medicines are only available under temporary authorization for use or through extemporaneous preparations compounded upon medical prescription [2]. Due to the lack of appropriate dosage forms, healthcare professionals are often forced to rely on empirical practices such as crushing tablets, opening capsules, or performing approximate dilutions in liquids followed by estimated dosing using syringes [3].

These non-standardized practices expose patients to significant risks, including dosing errors, physicochemical instability of the drug, aspiration (particularly with solid dosage forms in children under six years of age, which are contraindicated by the French National Agency for Medicines and Health Products Safety – ANSM), and adverse reactions related to excipients.

Additionally, hospital pharmacy systems are often insufficiently digitalized, making it difficult to anticipate pediatric pharmaceutical needs, particularly for drugs under special authorization or requiring specific preparation [4].

In this context, liquid oral dosage forms (solutions, suspensions, syrups) appear to be the most suitable for pediatric patients, especially for children under six years of age. However, these formulations require the use of specific excipients, some of which may have well-documented adverse effects in children, particularly in neonates and infants. It is therefore essential to better understand, evaluate, and regulate the use of excipients in pediatric formulations.

This study was conducted to improve knowledge of excipients present in pediatric oral formulations available in a community pharmacy in Dakar, with the aim of guiding the development of safer and more appropriate hospital formulations.

MATERIALS AND METHODS

A survey was conducted on pediatric oral pharmaceutical products in a community pharmacy in Dakar using ordering software (Extranet) and drug information leaflets available in the pharmacy. For each product, the international nonproprietary name (INN), dosage form, packaging volume, therapeutic indication, and list of excipients were collected. The data were entered and analyzed using Microsoft Excel 2016.

RESULTS

Distribution of International Nonproprietary Names

A total of 96 international nonproprietary names (INNs) were identified during the study. The ten most represented are shown in Figure 1.

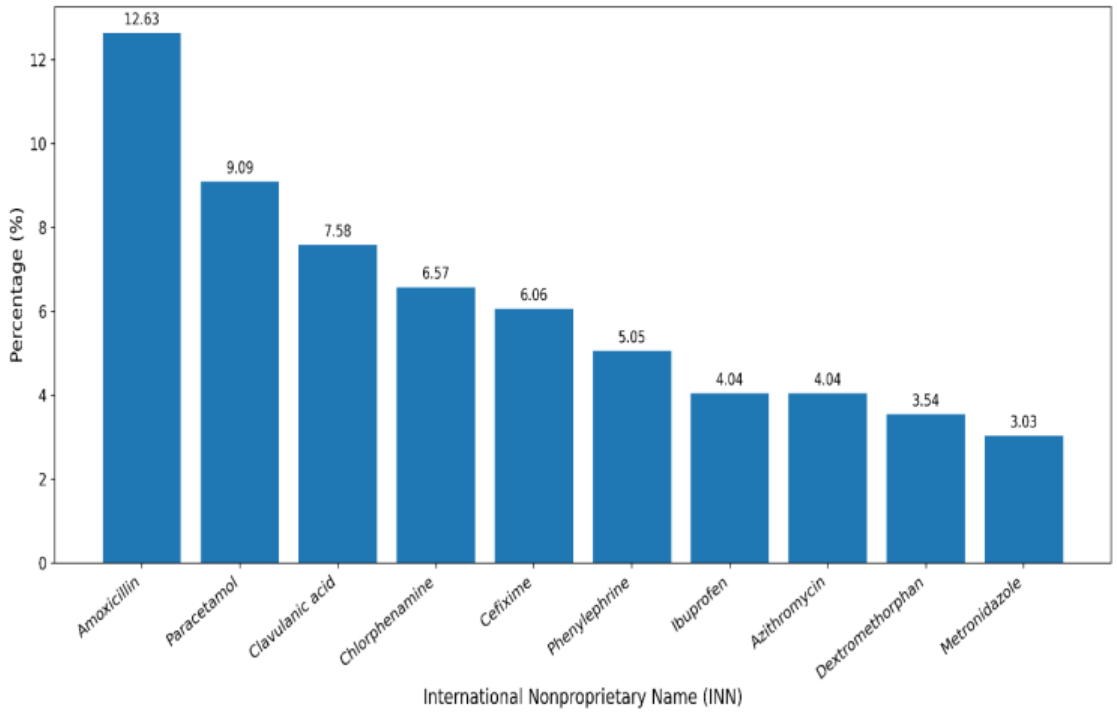

Figure 1: Distribution of the most represented international nonproprietary names (INNs)

Indications

The ten most frequently reported indications in pediatric formulations are presented in Figure 2.

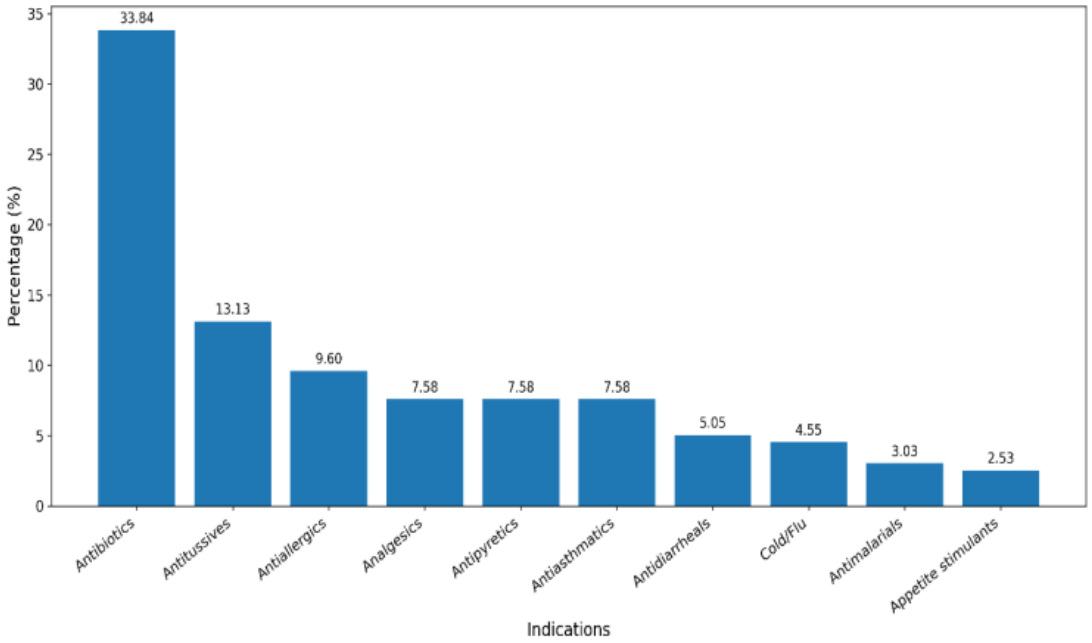

Figure 2: Distribution of the most represented therapeutic indications

Dosage forms: The different dosage forms identified are presented in Figure 3.

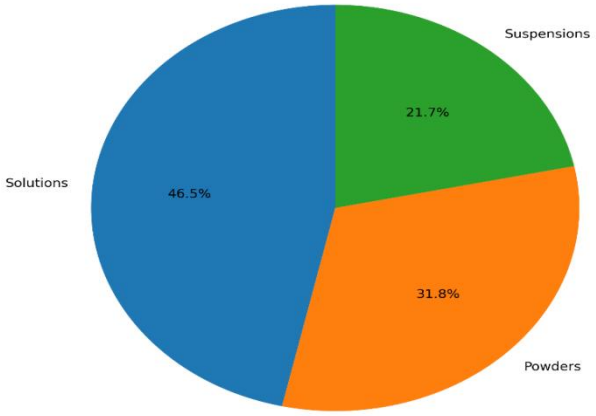

Figure 3: Distribution of pediatric oral dosage forms.

Packaging volumes: The various packaging volumes are presented in Figure 4.

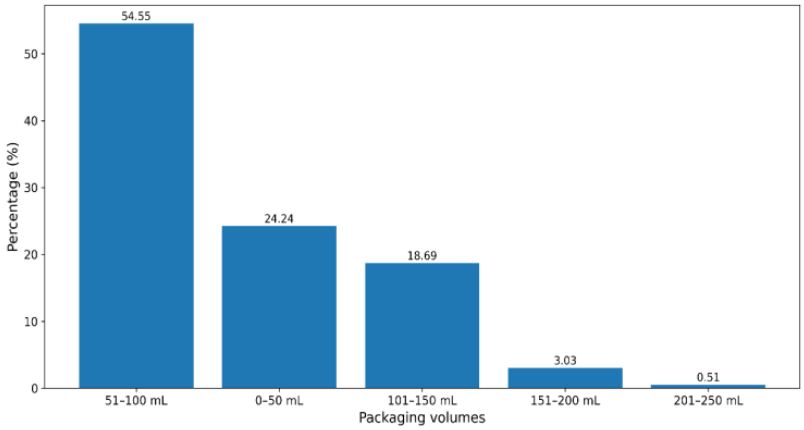

Figure 4: Packaging volumes

Most commonly used excipients

The eleven most frequently encountered excipients in oral dosage forms are presented in Figure 5.

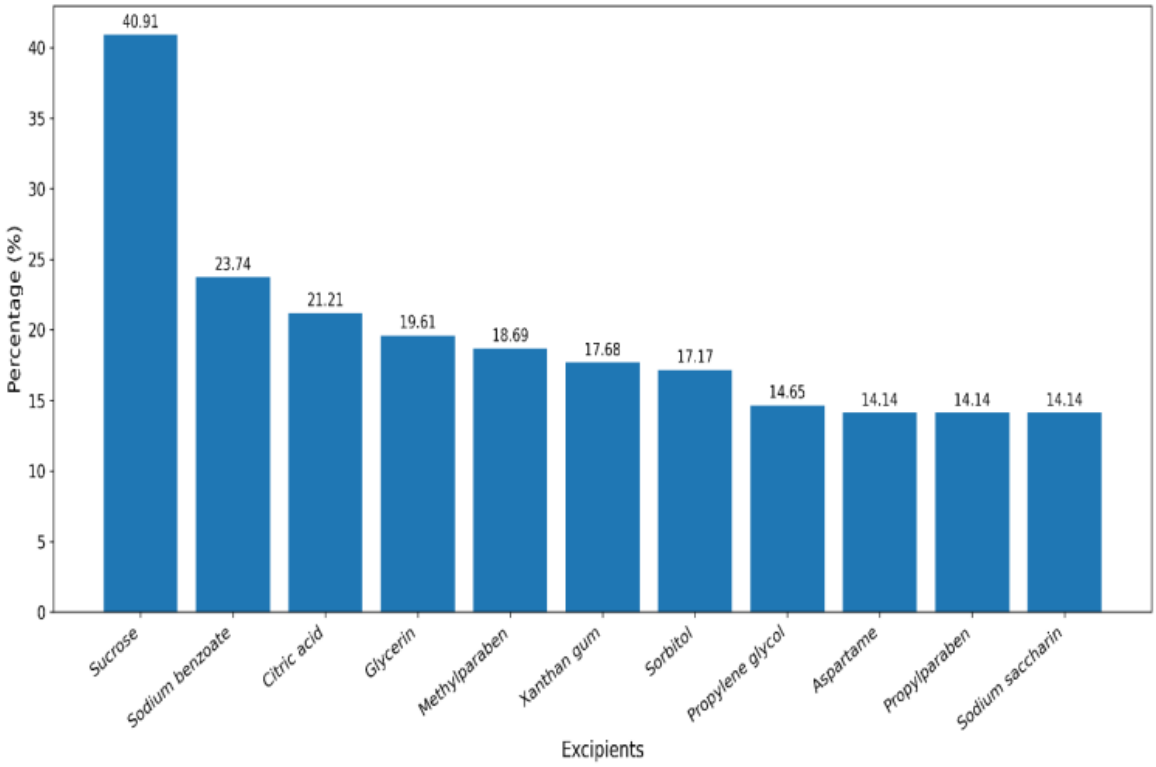

Figure 5: Most commonly used excipients

Role of excipients

The different roles of excipients identified are presented in Figure 6.

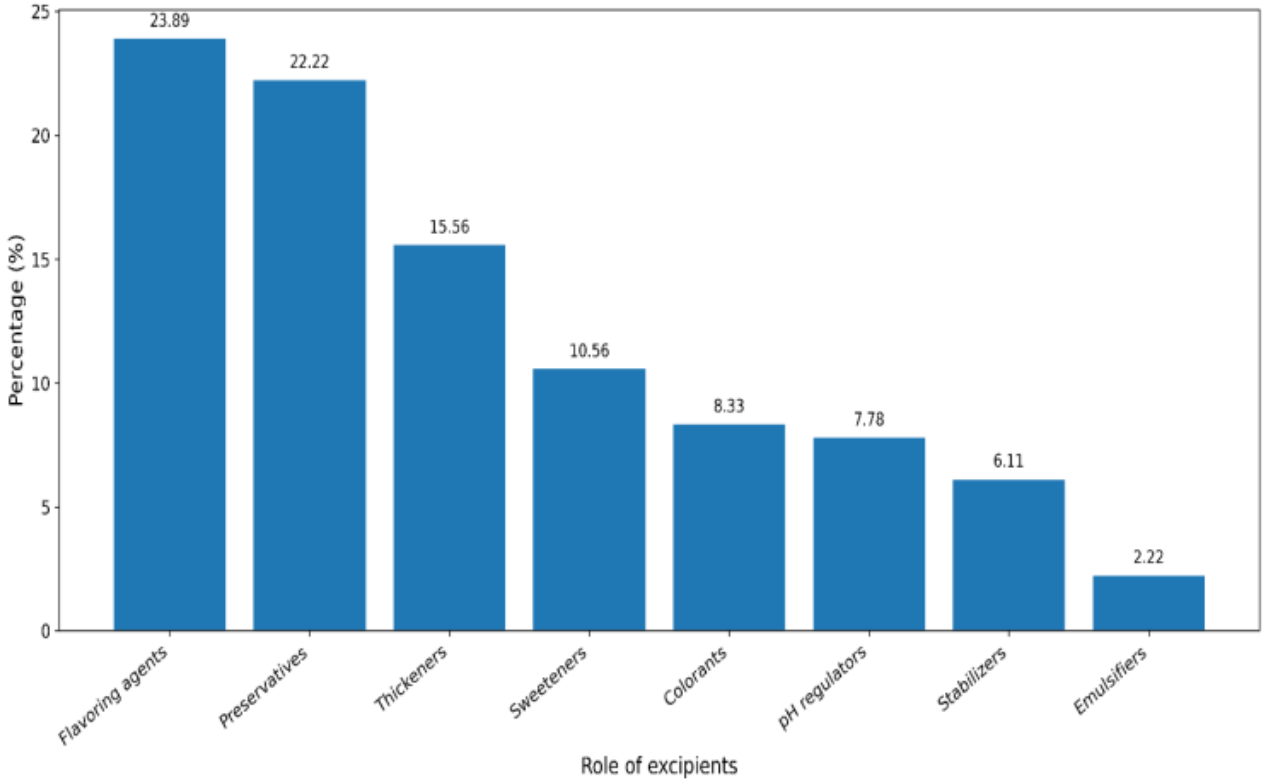

Figure 6: Role of excipients

Excipients according to dosage form

Excipients in powders

A total of 63 excipients were identified in powder formulations. The ten most frequently used are shown in Figure 7.

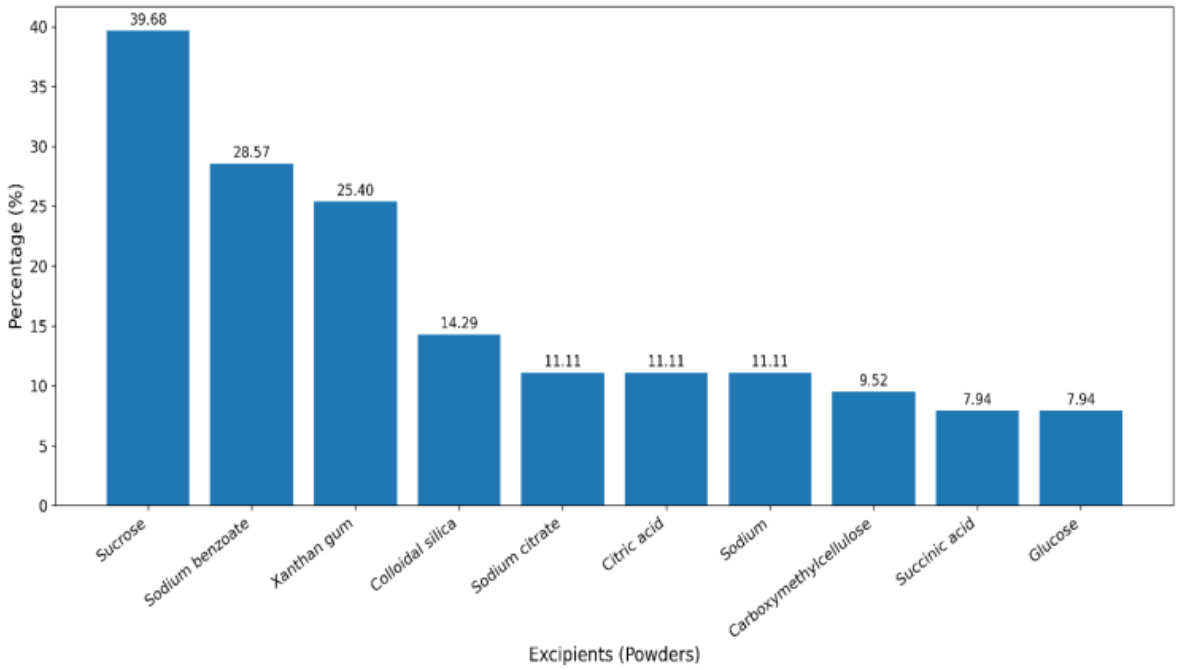

Figure 7: Excipients in powders

Excipients in solutions

A total of 92 excipients were identified in solution formulations. The ten most frequently used are presented in Figure8.

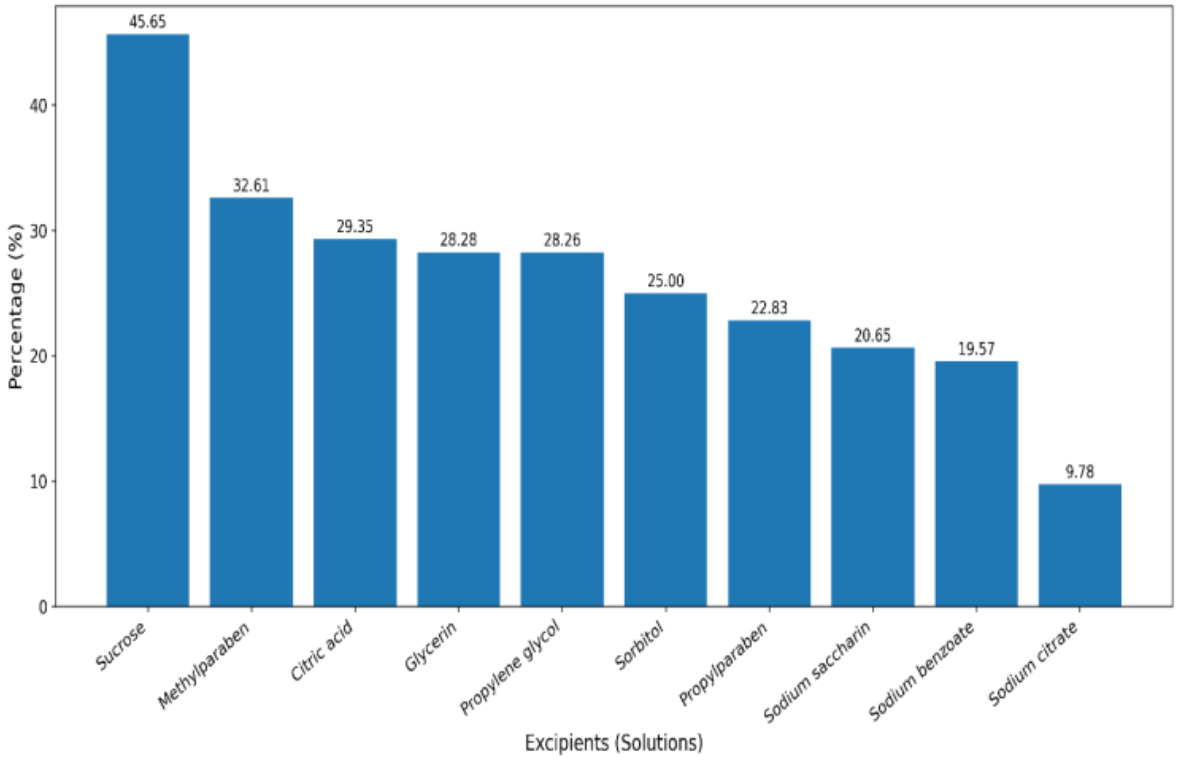

Figure 8: Excipients in solutions

Excipients in suspensions

Figure 9 presents the ten most frequently used excipients in suspensions out of the 43 identified in this study.

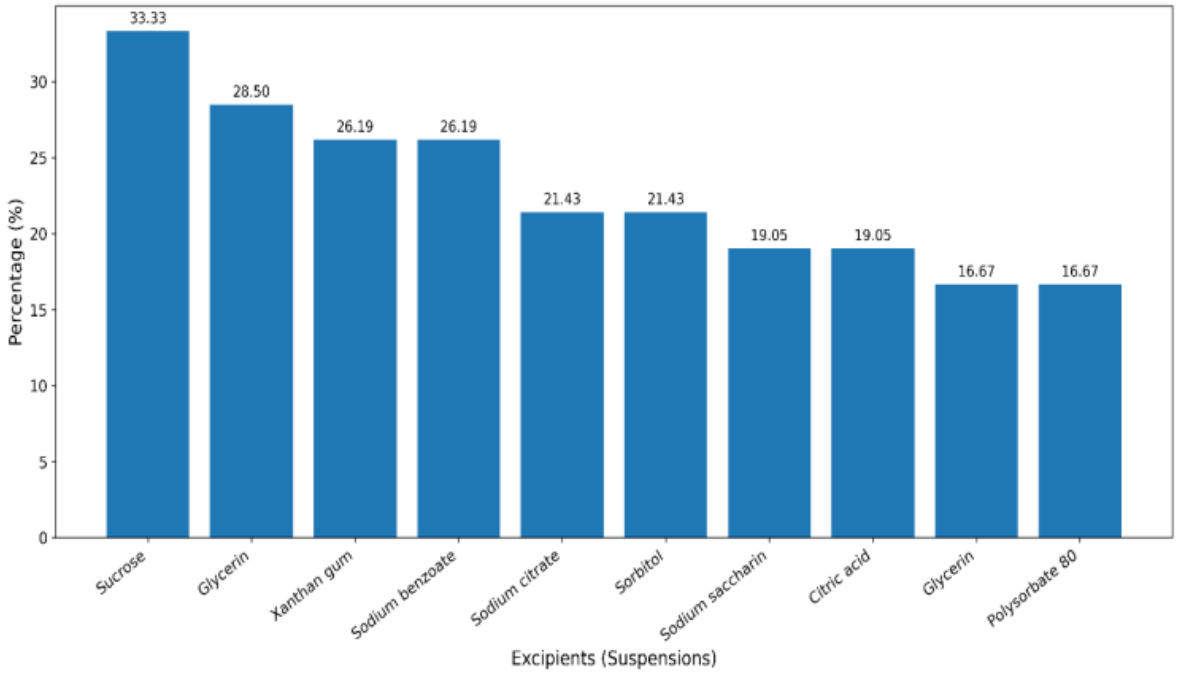

Figure 9: Excipients in suspensions

DISCUSSION

This study identified 200 pediatric pharmaceutical products corresponding to 96 international nonproprietary names (INNs) available in a community pharmacy in Dakar. Although this number is relatively substantial, it remains limited considering the wide diversity of pediatric pathologies encountered. This situation is not specific to Senegal, as many low-resource countries face a restricted pediatric pharmaceutical supply, often inadequate in terms of dosage, dosage forms, and safety of use [5].

The analysis revealed a predominance of antibiotics, mainly in the form of powders for oral suspension, which is consistent with findings from studies conducted in Nigeria and India, where more than 60% of available pediatric formulations are anti-infective agents [6]. This high representation can be explained by the prevalence of infectious diseases in children in tropical regions and the preference of prescribers for liquid formulations that allow flexible dosing. However, this predominance raises concerns regarding repeated exposure to certain excipients, particularly preservatives and sweeteners with known effects [7,8].

From a galenic perspective, oral solutions (46.5%) were the most common dosage forms, followed by powders for reconstitution (31.8%) and suspensions (21.7%). These proportions are consistent with those reported in other African studies [9,10]. Oral solutions offer advantages such as ease of administration and dose uniformity, but they require the addition of preservatives, sweeteners, and acidifying agents to ensure stability, palatability, and microbiological safety [11]. However, these excipients may present potential adverse effects in infants [12].

Sucrose, identified as the main sweetener, is widely used to mask the bitterness of active pharmaceutical ingredients. Nevertheless, excessive use may increase the risk of dental caries, glycemic imbalance, and infantile colic due to poor absorption of simple sugars. Safer alternatives such as sorbitol or maltodextrin are recommended, although their local availability and cost may represent constraints [13]. In infants, sucrose concentrations exceeding 20% should be avoided due to the risk of osmotic diarrhea [14].

Sodium benzoate, the second most frequently identified excipient, acts as an antimicrobial preservative. While commonly used in pediatric syrups, it may cause hypersensitivity reactions, gastric irritation, and, at high doses, neonatal hyperbilirubinemia due to competition with bilirubin for hepatic conjugation. The European Medicines Agency (EMA) recommends limiting its use in neonates and clearly labeling its presence [15].

Citric acid is used as a pH regulator and chelating agent. Although generally considered safe, its association with acidic sweeteners may affect the stability of pH-sensitive active ingredients [16]. It may also enhance the perception of acidity, requiring additional flavoring agents, thereby increasing formulation complexity [17].

In oral suspensions, xanthan gum is commonly used as a viscosity-enhancing agent to improve stability and texture. However, excessive concentrations may reduce fluidity and complicate administration, particularly in infants. Glycerin, often combined with xanthan gum, acts as a humectant and co-solvent but may induce laxative effects at high doses [18].

From a safety perspective, potentially harmful excipients (PHEs) are present in medications administered to hospitalized neonates. These include propylene glycol, ethanol, parabens, and polysorbate 80, whose effects on hepatic metabolism and intestinal barrier function remain insufficiently documented in pediatric populations [19]. In the African context, these risks may be exacerbated by the lack of local databases on pediatric excipients and the limited availability of safe hospital-based formulations [5].

The findings of this study highlight the need to strengthen pharmaceutical vigilance regarding excipients in pediatric formulations marketed in Senegal. The establishment of a national registry of excipients used in pediatric medicines, inspired by the European model (EudraVigilance Excipients Database), would improve traceability and risk management. Furthermore, the development of hospital-based compounded formulations using safe and locally available excipients (such as maltodextrin, gum arabic, stabilized honey, and sorbitol) represents a strategic approach to improving the safety and acceptability of pediatric treatments in public healthcare settings [20].

CONCLUSION

This study highlights both the diversity and the limitations of pediatric oral formulations available in a community pharmacy in Dakar, particularly the frequent use of excipients with known effects in a highly vulnerable population. While liquid dosage forms facilitate administration, they expose neonates and infants to a wide range of technological additives whose safety requires careful consideration.

These findings emphasize the need for increased vigilance in the selection of excipients and support the development of safer and more appropriate hospital-based pediatric formulations tailored to local needs.

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Ethical Approval: This study was conducted in accordance with ethical standards. It is a descriptive survey based on data collected from pharmaceutical products available in a community pharmacy and does not involve direct experimentation on human or animal subjects. Therefore, formal ethical approval was not required.

Conflicts of Interest: The authors declare that they have no conflicts of interest related to this work.

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