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Extemporaneous Compounding in a Sudanese Tertiary Hospital: A Cross-Sectional Analysis of Patterns, Prevalence, and Drivers

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Abstract

Background: The deficit of suitable pharmaceutical dosage forms, particularly for pediatric and geriatric patients, remains a major challenge in healthcare. Extemporaneous Preparations (EPs) are individually compounded to meet specific patient needs, but data on their use in low-resource settings like Sudan are scarce. **Objective:** This study aimed to evaluate the patterns, prevalence, and primary drivers of extemporaneous compounding in a leading Sudanese tertiary care hospital. **Methods:** A descriptive, cross-sectional study was conducted at the inpatient pharmacy of Royal Care Hospital in Khartoum from April to June 2022. Data were prospectively collected from all medical prescriptions requesting EPs using a structured checklist. Descriptive statistics were used. **Results:** Out of 502 EP prescriptions analyzed, the majority originated from inpatient departments (58%). Pediatric patients (≤1 year) constituted the largest group (41.85%). The most frequently compounded preparations were hydroxyurea syrup 20.9%), potassium chloride mixture (17.5%), and sodium bicarbonate solution (16.5%). The primary reason for compounding was the complete unavailability of a licensed medicine (63.3%). **Conclusion:** Extemporaneous compounding is a critical service, primarily driven by market unavailability of essential medicines. These findings highlight a significant gap in Access to suitable dosage forms and underscore the urgent need for national policies to improve drug availability.

Keywords

Extemporaneous Preparations, Compounding, Drug Availability, Pediatrics, Geriatrics, Sudan

1. Introduction

The use of licensed, mass-produced medicines represents the gold standard for ensuring quality, safety, and efficacy in patient care (Jackson & Lowey, 2010). However, there are frequent clinical scenarios where no licensed product fully meets the needs of a specific patient (Brion et al., 2003; Mohiuddin, 2018). This is particularly true for pediatric and geriatric populations, who often face difficulties swallowing solid dosage forms and require personalized, weight-based dosing (Lajoinie et al., 2016; Logrippo et al., 2017). The deficit of age-appropriate formulations forces healthcare professionals to resort to the unauthorized use of adult medications, a practice associated with dosing errors and compromised therapeutic outcomes (World Health Organization, 2009).

Extemporaneous Preparation (EP) is the process by which a pharmacist combines, mixes, or alters ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription (U.S. Food and Drug Administration, 2021). While the prevalence of EPs has declined in high-income countries due to the wider availability of specials and licensed alternatives, it remains a vital service in many parts of the world (Carvalho, 2013; Gubara et al., 2016). In Sudan, economic challenges, drug shortages, and a lack of a National List of Essential Medicines for Children have created an environment where EPs are not just an exception but a necessity (Gubara et al., 2018; Ali & Yahia, 2012).

Despite its critical role, the practice of extemporaneous compounding carries inherent risks, including formulation errors, microbial contamination, and a lack of stability data (Belayneh & Tessema, 2021; Brion et al., 2003). Understanding the extent and nature of this practice is the first step toward mitigating these risks and ensuring patient safety. While a previous study in Khartoum reported that community pharmacists compound 1 - 5 prescriptions weekly (Gubara et al., 2016), there is a notable lack of data from hospital settings, where the demand for complex and critical care medications is higher. Therefore, this study aimed to evaluate the patterns, prevalence, and drivers of oral extemporaneous preparations in a major tertiary hospital in Sudan, to provide a foundational evidence base for future interventions and policy decisions.

2. Methods

2.1. Study Design and Setting

An observational, descriptive, cross-sectional study was conducted at the inpatient pharmacy of Royal Care Hospital in Khartoum, Sudan. Royal Care Hospital is a 150-bed tertiary care facility with a dedicated pharmaceutical manufacturing unit for extemporaneous compounding.

2.2. Study Population and Data Collection

The checklist was pre-tested by a group of 5 pharmacists who reviewed 6 pre-

scriptions independently; a sample of 6 historical prescriptions was not included in the study. Data entry accuracy was ensured through double data entry (Microsoft Excel spreadsheet), with discrepancies resolved by a third reviewer.

Complete unavailability was defined as the absence of any licensed, commercially manufactured form of the active pharmaceutical ingredient (API) in the Sudanese markets at the time of prescribing.

Unavailability of a required dosage form or strength was defined as the licensed product containing the API was available, but the formulation was not suitable (e.g., liquid vs. tablet) or strengthened for the specific patient (e.g., a low-strength liquid for a pediatric dose).

These supply gaps were clarified by the dispensing pharmacist at the time of prescription receipt by checking the hospital's stock records and, if necessary, confirming with major national distributors (agency or company).

The study population included all medical prescriptions requesting oral EPs received by the pharmacy department from April to June 2022. Total coverage sampling was employed, with no exclusion criteria.

Data were collected prospectively using a structured checklist designed to capture: prescription source (inpatient/outpatient); patient demographics (age, weight, gender); drug name, indication, and therapeutic class; dosage form, strength, and regimen; and reason for compounding.

2.3. Data Management and Analysis

Data were extracted from prescription sheets and entered into a Microsoft Excel spreadsheet. They were then analyzed using SPSS® version 26.0. Descriptive statistics, including frequencies and percentages, were used to summarize the data. The percentage distribution of EPs by drug, therapeutic class, patient age, and reason for compounding was calculated.

2.4. Ethical Consideration

Ethical approval was obtained from the research committee at the University of Khartoum and the Sudanese Federal Ministry of Health.

3. Results

3.1. Prescription and Patient Characteristics

A total of 502 prescriptions for EPs were analyzed; the total number of prescriptions that were dispensed during the three-month study period was (19.7%, n = 99). The majority originated from inpatient departments (58%, n = 291), with the remainder from outpatient clinics (42%, n = 211). Pediatric patients (≤1 year old) constituted the largest patient group (41.85%, n = 203), followed by elderly patients (60 - 70 years old, 20.61%, n = 100). A detailed breakdown of patient demographics is presented in Table 1.

Table 1. Patient demographics for extemporaneous preparations (n = 485*).

Age Group	Weight	Male	Female	Frequency	Percent
<2 years	Up to 3 - 19 kg	68	135	203	41.85%
60 - 70 years	≥ 50 kg	56	44	100	20.61%
2 - 4 years	10 - 16 kg	29	63	92	18.96%
Adult	≥ 50 kg	22	19	41	8.45%
5 - 8 years	17 - 28 kg	14	19	33	6.80%
9 - 12 years	25 - 34 kg	7	9	16	3.29%

Note: *Total does not equal 502 because 17 prescriptions are incomplete, due to missing patient information and demographic data (age, weight, gender).

3.2. Most Common Extemporaneous Preparations and Indications

The 502 prescriptions encompassed 27 different drugs. The most frequently compounded EPs were hydroxyurea syrup (20.9%, n = 105) for sickle-cell disease, KCL mixture (17.5%, n = 88) for hypokalemia, and $NaHCO_3$ solution (16.5%, n = 83) used as an antacid and for metabolic acidosis. The top ten preparations are detailed in Table 2.

Table 2. The most common extemporaneous preparations and indications (n =502)

Percent	Frequency	Indications	EPs
20.91%	105	Sickle-cell disease	Hydroxyurea
17.52%	88	Hypokalemia	KCLmixture
16.53%	83	Metabolic acidosis	Na bicarbonate solutions
6.57%	33	Oedema in CHF + renal disease	Furosemide suspension
5.77%	29	Seizures	Phenobarbitone sodium
5.57%	28	Spasticity, muscle spasm	Baclofen suspension
4.98%	25	Seizures	Pheytion syrup
4.58%	22	Asthma	Prednisolone suspension
3.58%	18	Heart failure	Digoxin elixir
2.58%	13	Procedural sedation	Chloral hydrate liquid

3.3. Reasons for Compounding and Therapeutic Classes

The primary driver for compounding was the complete unavailability of a licensed medicine on the market (63.3%, n = 318). The second most common reason was the unavailability of a required dosage form or strength (36.7%, n = 184). The therapeutic classes most reliant on EPs were electrolyte and nutrient replacements (34.1%, n = 171), antimetabolites (20.9%, n = 105), and cardiovascular drugs (15.7%, n = 79), as shown in Table 3.

Table 3. Therapeutic classes of extemporaneous preparations.

Therapeutic Class	Frequency	Percent
Electrolyte and nutrient replacement	171	34.1%
Antimetabolite	105	20.9%
Cardiovascular	79	15.7%
Anti-epileptic	55	11.0%
Muscle Relaxant	28	5.6%
Immunosuppressant	24	4.8%
Gastrointestinal	17	3.4%
Hypnotic	13	2.6%
Antibiotic	8	1.6%
Anti-glaucoma	2	0.4%

4. Discussion

This study provides the first comprehensive analysis of extemporaneous compounding in a Sudanese hospital, revealing it as a widespread and essential practice. The high volume of 502 prescriptions over three months underscores the heavy reliance on EPs to bridge critical gaps in the drug supply.

The National Medicine and Poisons Board in Sudan mandates that pharmacies engaged in compounding must have a dedicated facility. The compounding unit at Royal Care Hospital adhered to basic quality control measures: it was a separate room with adequate lighting, ventilation, and a water supply. The unit was equipped with electronic scales, glass mortars and pestles, calibrated flasks, and magnetic stirrers. Surfaces were cleaned with appropriate detergents and sanitized with 70% alcohol before and after use. Personnel used personal protective equipment such as gloves and masks. While this describes a structured environment, it is important to note that formal stability testing and rigorous analytical assays for the final compounded products were not routinely performed.

A key finding is the disproportionate impact on vulnerable populations. The fact that 41.85% of EPs were for children under one year of age is a stark indicator of the severe lack of licensed pediatric formulations in Sudan. This aligns with studies from Ghana and Nigeria, which also reported high use of EPs in children due to market failures (Ankrah et al., 2016; Yusuff, 2019). Similarly, the significant use in elderly patients (20.61%) highlights challenges such as dysphagia, which are not adequately addressed by available adult dosage forms (Logrippo et al., 2017).

The profile of the most compounded drugs is highly revealing. The top three—hydroxyurea for sickle-cell disease, KCL for hypokalemia, and NaHCO3 for acidosis—are not obscure medications but essential, life-saving drugs. Their unavailability in suitable forms points to a systemic failure in the pharmaceutical market to serve patients with chronic and acute conditions. The high prevalence of cardi-

ovascular EPs further confirms that this is not a niche issue but affects core therapeutic areas.

Geographical Context and Frequency The percentage of prescriptions allocated to extemporaneous compounding (19.7%) in this Sudanese hospital is significant and underscores a vital reliance on this procedure. Although direct, comparable hospital-based prevalence data from sub-Saharan Africa are limited, our findings indicate a greater dependence on compounding than what has been reported in many bordering countries. A study in Nigeria, which encounters comparable pharmaceutical issues, documented significant extemporaneous compounding but did not quantify it as a percentage of overall prescriptions, concentrating instead on the categories of medications compounded (Yusuff, 2019). The elevated incidence at Royal Care Hospital probably indicates the cumulative impact of Sudan's particular economic difficulties, foreign currency deficits, and supply chain interruptions, which have been intensified by recent worldwide occurrences (Eliseo et al., 2020). This disparity highlights that compounding is not a marginal activity but a fundamental aspect of the medication-use system, addressing needs that in countries with stronger regulatory and manufacturing capabilities may be fulfilled by the commercial market or imported "specials" (World Health Organization, 2009). The results necessitate additional systematic, multi-center research to establish a standard for compounding prevalence in the region, which is crucial for promoting policy reforms and securing investment in local pharmaceutical production of key pediatric and specialist formulations.

The primary rationale for compounding in this investigation was the unavailability of medications (63.3%) and the unavailability of required dosage forms or strengths (36.7%). This suggests that EPs in this context are not merely for personalization but are a fundamental public health response to drug stockouts and market absence. This situation is likely exacerbated by Sudan's economic instability and the COVID-19 pandemic, which have severely disrupted pharmaceutical supplies (Eliseo et al., 2020). Our findings on therapeutic classes are consistent with regional studies. Research from Nigeria also identified cardiovascular drugs and electrolyte replacements as leading categories for compounding (Yusuff, 2019), indicating a common pattern of pharmaceutical gaps across similar healthcare systems.

Limitations:

This study was conducted in a single, large tertiary hospital in the capital city, which may limit the generalizability of findings to rural or smaller healthcare facilities in Sudan. Furthermore, the study design was descriptive and did not assess clinical outcomes or the quality of the compounded products.

Moreover, the study design was descriptive and failed to evaluate clinical outcomes or the quality of the compounded medicines. The absence of demographic data for 17 prescriptions, including a mere 3.4%, may introduce a slight bias; nonetheless, it is improbable that it will substantially affect the reported age distribution, which was predominantly skewed towards pediatric patients.

5. Conclusion

This study demonstrates that extemporaneous compounding is a cornerstone of clinical care at Royal Care Hospital, essential for managing a wide range of conditions, especially in pediatric and geriatric patients. The practice is predominantly driven by the profound unavailability of essential medicines in suitable dosage forms. These findings serve as a critical call to action for hospital administrators, policymakers, and the pharmaceutical industry. There is an urgent need to develop a National List of Essential Medicines for Children, encourage the local production of pediatric formulations, and establish standardized, quality-assured compounding protocols to ensure that this vital practice is conducted as safely and effectively as possible.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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