International Journal of Advance Research in Science and Engineering
Volume No. 12, Issue No. 06, June 2023
www.ijarse.com
IJARSE
ISSN 2319 - 8354

COMPOUNDING FOR PEDIATRIC PATIENTS: CASE REPORT AND FORMULATION IN A HOSPITAL PHARMACY.

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ABSTRACT

Introduction: This case report highlights the significance of compounding in a hospital pharmacy to meet the unique medication needs of pediatric patients. Despite ongoing international efforts, many drugs administered to children must be compounded from dosage forms designed for adults because they remain unavailable in commercial formulations that suit their needs. Several therapeutic needs can be met by a compounded medicine such as dosing adjusted for paediatric patients, special drug combinations, medicines for patients allergic to a given excipient, and medicines for orphan drugs not provided by the pharmaceutical industry.

Aims: To design compounding formula for paediatric patients; case report and formulation

Objective: To design and prepare custom formulation suitable for paediatric patient need as per presenting case.

Keywords: *compounding, pediatric patients, hospital pharmacy, customized medications, formulation.*

Background

Pediatric patients require different oral drug delivery systems than other subsets of the population due to their continuing development hence dosing and administration requirements. Conventional formulations are not designed for this patient group; thus, manipulation and compounding has become common practice. Age-appropriate oral drug delivery systems specifically developed to meet the needs of the pediatric population are therefore desired. In terms of adherence and concordance geriatric patients would also benefit from patient-centric formulation design tailored to overcome the impaired physiological, visual, motoric functions and swallowing capabilities. The development of an age-appropriate formulation is a challenging task due to the broad range of pharmaceutical and clinical aspects that must be considered in order to ensure the quality, safety and efficacy of the final product. In particular, the development of pediatric formulations is complex due to the additional needs and demands of this target population with respect to adults. The pharmacokinetic and pharmacodynamic profile of a drug varies broadly depending on the developmental stage of a child, necessitating dose flexibility to suit the dosing requirements across all age groups. Excipients commonly regarded as safe may represent a safety risk for children adding other considerations into the formulation development. Palatability and ease of swallowing are also considered as critical attribute for the acceptability of medicines intended for children, who possess distinct preferences and swallowing abilities than other subsets of the population. In many cases, the dependence on caregivers also influences the administration and acceptability of medicines. (Lopez et al., 2015)

IJARSE
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Compounding is defined by the FDA as the combination, mixing, or alteration of drug ingredients to create medications tailored to individual patient needs. The United States Pharmacopeia (USP), which sets quality standards for drugs, describes compounding as "the preparation, mixing, assembling, altering, packaging, and labelling of a drug … in accordance with a licensed practitioner's prescription …" Put simply, it is the creation of a medication that is not commercially available. (Watson et al., 2021)

The Drug Quality and Security Act (H.R. 3204) defines compounding as "the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug." Compounding may hold different meanings for different pharmacists. It may mean the preparation of suspensions, topicals, and suppositories; the conversion of one dose (e.g., oral to rectal, injection to oral) or dosage form into another; the preparation of select dosage forms from bulk chemicals; the preparation of intravenous admixtures, parenteral nutrition solutions, and pediatric dosage forms from adult dosage forms; the preparation of radioactive isotopes; or the preparation of cassettes, syringes, and other devices with drugs for administration in the home setting. (Allen, n.d.)

Material and Method

Chemical and Reagent:

Vitamin C Syrup 100mg/5ml (Brand: Archy), Vitamin B-complex (Brand: Unique Pharmaceuticals), Multivitamin Syrup (Brand: Archy), Clindamycin 150mg (Brand: Dalacin C) Carbamazepine 200mg Tablet (Brand: Tegretol), Frusemide 20mg Tablet (Brand: Sanofi), Spironolactone 25mg Tablet (Brand: Aldactone) Ciprofloxacin 500mg Tablet (Brand: M&B) were all purchased in the hospital pharmacy unit.

Selection of Vehicle

The desired or required properties of the vehicle depend on the route of administration for the preparation and the type of solvent system needed. many pharmacies, particularly those in hospitals, made their own vehicles for compounding oral liquid dosage forms. Over the last few decades, many excellent liquid vehicles have become available commercially. Oral dosage forms should be palatable and well tolerated, provide accurate and consistent dosing, and maintain physical integrity throughout their shelf life. Physiochemical properties to consider when preparing oral liquid formulations include:

- Appearance
- Osmolality
- pH
- Presence of preservatives and dyes
- Viscosity
- Suspending agent used
- Taste

Special formulation requirements exist These might include vehicles that are preservative free or carbohydrate-free, vehicles requiring a very low osmolarity or a particularly low or high pH, and vehicles that meet patient preferences for flavours, components, or vehicle consistency.

Stability Studies:

physical appearance was investigated by visual inspection performed in a transparent glass vial, in order to check the initial color and opalescent aspect of the suspension. Osmolality and pH were also determined during the stability study, using a Precision System Osmette™ (Osmette™ Multiple-Osmette Osometer, Precition System 2430) and a pH-meter (Digital pH/TDS Meter With ATC pH Tester, High accuracy electrode), respectively. In addition,

General Procedure:

The oral suspensions were prepared in accordance with the standard guidelines according to the following standard operating procedure: -

- First, the exact amount of tablet/capsule powder was weighed in order to obtain the targeted concentration.
- The powder was triturated in a mortar until homogeneity was achieved.
- Add a small amount of vehicle to powder and levigate to a smooth paste with a pestle. Continue to levigate as vehicle is added in small amounts until a liquid is formed.
- Transfer liquid contents from mortar to graduate.
- Use a small amount of vehicle to rinse mortar and add it to graduate.
- Use vehicle to fill up to desired volume. Stir well.
- Transfer to amber bottle and label.

The entire procedure was carried out in a clean area, in order to limit microbiological contamination.

Discussion:

Compounding in a hospital pharmacy is essential for addressing the individual medication needs of pediatric patients. This case report developed a customized formulation for a pediatric patient with specific requirements. Pediatric formulation of Clindamycin, frusemide, spironolactone, carbamazepine, ciprofloxacin and others are rarely commercially available in Nigeria due to various factors like Drug shortages, commercial preparations may be available but expensive, and a compounded equivalent is more affordable such as Clindamycin when available it cost about 5000 naira while the compounded clindamycin cost less than 1000 naira. pharmacoeconomic factors, there are severe shortage of commercial drugs suitable for children, due to this there is a need for compounding preparations Clindamycin is the most compounded drug among pediatric patient usually prescribed for bone infection followed by carbamazepine for psychiatric disorders, Proper compounding techniques, quality control measures, and safety considerations are crucial in achieving optimal outcomes while ensuring the safety and well-being of pediatric patients. In order to ensure safety of the compounded formulations are prepared for two weeks only patient are followed up to ensure the safety and stability of the formulation, moreover the caregivers are counsel thoroughly on physical stability measure to assess before administering the drug every time.

Conclusion:

Compounding medications for pediatric patients is a valuable service provided by hospital pharmacies. This case report demonstrates the importance of compounding in meeting the unique medication needs of pediatric patients,

particularly when commercial formulations are not suitable or commercially available for pediatrics use. By tailoring medications to specific requirements, hospital pharmacies contribute to improving pediatric care and enhancing patient outcomes.

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