Original Article

DEVELOPMENT AND IMPLEMENTATION OF PEDIATRIC FORMULARY & DRUG THERAPY GUIDE IN A TERTIARY CARE HOSPITAL IN INDIA

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ABSTRACT

Objective: To collect informational resources and Compilation of Drug information to formulate an Ideal Pediatric Drug Formulary. Formulary is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflect the current clinical judgment of the medical staff. Hospital formulary is a comprehensive list of every drug and therapeutic agent stocked by the pharmacy of that hospital.

Methods: Prospective & developmental study.The study was carried out in Department of Pediatrics & Neonatology in Amrita Institute of Medical Sciences (AIMS) a 1200 bedded tertiary care referral hospital in Cochin.

Results: The first edition of pediatric formulary & drug therapy guide was published in June 2013 and has been using in Pediatrics & Neonatology department

Conclusion: The Pediatric formulary & drug therapy guide is of course first of its kind in the country. It proved to be a reliable guide in individualization of drug therapy and serves as a channel for enhancing clinical efficacy and reducing the untoward outcomes. The drug monographs included in this formulary is indeed a worthful reference resource with all the necessary informations for all pediatric practitioners.

Keywords: Hospital formulary, Pediatric Drug Formulary, Drug information, Individualization.

INTRODUCTION

Pediatrics is the branch of medicine dealing with the disease, development and disorders of children. Children are not just "little adults," and lack of data on important pharmacokinetic and pharmacodynamic differences has led to instances of untoward outcomes in pediatric care. Children are found to be more sensitive than adults to medications because of the variations in pharmacokinetics as well as pharmacodynamic factors. Unlabelled or offlabelled use of drugs is frequently found among pediatric patients. Over 60% of the pediatric patients in hospitals and 90% of those in the intensive Care Unit receive unlicensed or off-label drugs [1].Although most marketed drugs are used in pediatric patients, only 1/4th of the drugs approved by the Food and Drug Administration (FDA) have indications specific for use in the pediatric population. The use of untested medicines and dosage forms in paediatric patients increase the potential for undesirable outcomes [4].

Variations in absorption of medications from the gastrointestinal tract, intramuscular injection sites, and skin are important in pediatric patients, especially in premature and newborn infants [5]. The functional development of organs and the absorption, distribution, metabolism, and elimination of drugs differ not only between pediatric versus adult patients but also among pediatric age groups. The effectiveness and safety of drugs may vary among various age groups and from one drug to another in paediatric versus adult patients. Irrespective of whether a drug is in development or already available on the market, the current paradigm for paediatric dose selection does not guarantee safe and effective dosing recommendation for children unless there is pharmacokinetic data available [6]. The normalization of the adult dose according to age, body weight or any other demographic covariate without prior evidence of how these factors contribute to differences in drug exposure may lead to poor and unsafe estimates of the paediatric dose [7].

Formulary is a continually revised compilation of pharmaceuticals and important ancillary information that reflect the current clinical judgment of the medical staff. Hospital formulary is a comprehensive list of every drug and therapeutic agent stocked by the pharmacy of that hospital [8]. A formulary includes a list of the drugs; monographs with information on each drugs and a general reference section with information that might be helpful in treating patient. The main advantages are it ensures quality and appropriateness of drug use and educate practitioners regarding most therapeutically effective agents and economic benefits [9] .

An ideal hospital formulary includes hospital policies and procedures relating to the drugs, hospital regulations governing the prescribing, dispensing and administration of drug along with drug monographs. The potential benefits of a formulary system are threefold [10]:

(l) Therapeutic. (2) Economic. (3) Educational.

The therapeutic aspect of a formulary system provides the greatest benefit to the patient and physician in that only the most efficient products are listed and available. The economic merit also has a double benefit in that the formulary which eliminates duplication thus reducing inventory duplication and the opportunity for volume purchasing means lower charges to the patient.

MATERIALS AND METHODS

Design of study

Prospective developmental study

Duration of study

6 months (December 2012 to June 2013)

Settings

The study was carried out in Department of Pediatrics & Neonatology in Amrita Institute of Medical Sciences (AIMS) a 1200 bedded tertiary care referral hospital in Cochin. The department of Pediatrics & Neonatology provide medical expertise for the treatment and prevention of diseases and disorders in children in specialties like medicine and surgery, neonatology medicine and surgery, oncology, rheumatology, cardiology, neurology, nephrology, ortho, endocrinology and gastroenterology.

Study population

Children under 16 yrs of age who are admitted under Pediatrics and Neonatology department. Newborn infants born before 37 weeks of gestational age are termed premature; those between 1 day and 1 month of age are neonates; 1 month to 1-year old infants; 1 year to 11 years of age, children; and 12 to 16 years, adolescents.

Data collection tools

- AIMS Pediatric Formulary
- Primary, Secondary and Tertiary Drug Information Resources

Development Method for Pediatric Formulary & Drug Therapy Guide in AIMS

Phase 1: Data Collection

- Selection of drugs as per Pediatric Formulary drug list 2013.
- Collection of policies, protocols & guidelines approved by P&T Committee of AIMS
- Preparation of drug monograph from standard drug information resources of primary, secondary and tertiary
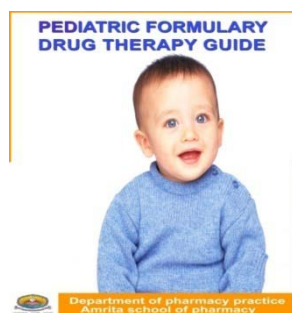

Fig. 2: Formulary Designing

RESULTS &DISCUSSION

RESULTS

The first edition of pediatric formulary & drug therapy guide was published in June 2013 and has been using in Pediatrics & Neonatology department. Many pediatricians and neonatologists had an opinion in publishing a second edition of the book.

DISCUSSION

The approach to pediatric drug dosing needs to be based on the physiological characteristics of the child and the pharmacokinetic parameters of the drug. The developmental physiological changes that occur throughout childhood termed ontogeny, Organ function development, disease state, genetic makeup and environmental influences should be considered and dosage modification should be based on absorption, route of absorption, physicochemical properties of the drug and age of the child [1,2].

The volume of distribution is a relevant pharmacokinetic parameter as it may be widely altered in children. Hydrophilic drugs with a high V_d in adults should be normalized to bodyweight in young children (age <2 years) whereas hydrophilic drugs with a low V_d in adults should be normalized to body surface area (BSA) in these children. For drugs that are metabolized by the liver, the effect of the V_d becomes apparent in children<2 months of age. In general only the first dose should be based on the V_d subsequent doses should be determined by the clearance. Pharmacokinetic studies on renal and

liver function clarify that a distinction should be made between maturation and growth of the organs. After maturation process has finished, the main influences on the clearance of drugs are growth and changes in blood flow of liver and kidney [4]. Drugs that are primarily metabolized by the liver should be administered with extreme care until the age of two months. Modification of dosing should be based on response and on therapeutic drug monitoring. At the age of 2-6 months, a general guideline based on bodyweight may be used. After 6 months of age, BSA is a good marker as a basis for drug dosing. However even at this age drugs that are primarily metabolized by cytochrome P450 2D6 and uridine diphosphate glucuronosyl transferases should be normalized to body weight. In the first 2 years of life, the renal excretion rate should be determined by markers of renal function, such as serum creatinine and p-aminohippuric acid clearance. A dosage guideline for drugs that are significantly excreted by the kidney should be based on the determination of renal function in first 2 years of life. After maturation, the dose should be normalized to BSA.[3,5]

Pediatric formulary and drug therapy guide is of paramount importance in pediatric care as it comprises all the relevant drug information related to children.

CONCLUSION

The Amrita pediatric drug information software is found to be a reliable guide in individualization of drug therapy and serves as a channel for enhancing clinical efficacy and reducing the untoward outcomes. The drug monographs included herein is a reference resource with all the necessary informations.The software has been accepted wholeheartedly by the pediatric &neonatology department and has been received enormous appreciations all around. The software has been considered as a great achievement of Department of pharmacy practice for better clinical practice and improved patient care.

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