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RESEARCH ARTICLE

A Study on Development and Evaluation of A Paediatric Formulary in A Tertiary Care Hospital

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ABSTRACT:
"The formulary is a continually revised compilation of pharmaceuticals, which reflects the current clinical judgment of the medical staffs including physicians, pharmacist and nurses and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health". The paediatric formulary is the formulary of paediatric medicines approved by Pharmacy and Therapeutic Committee for use in the Hospital. It helps to rationalize the therapy for children. Present study involved development of a formulary for the hospital and comparing it with the list of WHO Model Formulary, National Essential List of Medicine. The monograph contents were compared with National Formulary of India, British National Formulary and WHO Model Formulary. Prepared hospital formulary consisted of 84 generic drugs of various categories and 5 fixed dose combinations. Availability of brands varied from single to many. Monographs were prepared for all the selected 84 drugs in the hospital pharmacy with the following contents: Therapeutic category, Indication, Contraindications, Precautions/Warnings, Adverse reactions, Paediatric Dosage, Pregnancy, Drug interactions, Brands available. The prepared formulary was compared with WHO and IAP drug formulary on various parameters involved in formularies. This formulary promotes the safe and effective use of medicines.

KEYWORDS: Formulary, Pharmacy and Therapeutic Committee, National Formulary of India, British National Formulary and WHO Model Formulary, IAP drug formulary.

INTRODUCTION:
Paediatrics 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 off labelled use of drugs is frequently found among paediatric patients[1].

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Every year worldwide 7.6 million children die under five years of age (Children: reducing mortality, WHO media centre, 2010).Surprisingly; two-thirds of these deaths are due to common conditions that could be prevented or treated with access to simple, effective and affordable medicines[2]. Over 60% of the paediatric patients in hospitals and 90% of those in the intensive Care Unit receive unlicensed or off-label drugs[3]. Although most marketed drugs are used in paediatric 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 paediatric patients, especially in premature and newborn infants[5]. 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]. Hence, WHO launched campaign 'Better Medicines for Children' and "Make Medicines Child Size" to raise awareness and address the need to improve availability of safe and child-specific medicines for all children. A Model List of Essential Medicines for Children (EMLc) was also developed by WHO (WHO-EMLc, 2010). Subsequently; Indian Academy of Paediatrics

also prepared EMLc in July 2011 based on the WHO criteria for selection of essential medicines and the National Health Programmes (Indian Academy of Paediatrics, 2011).

In hospitals, drug and therapeutics (D and T) committees have been traditionally responsible for rational pharmacotherapy. Rational has been defined as evidence based effective, safe, convenient, and economic[8,9,10]. The use of hospital drug formularies (HDFs) is considered to combine education, management, and regulation[11,12].

Hospital formularies originally started life in hospitals as a collection of commonly prescribed pharmaceutical preparations, produced mainly for reference purposes. As time went on, the hospital formulary was adapted to incorporate the detailed information on the increasing number and diversity of medicines. However, these new and expensive preparations required ever increasing funds, and the formulary rapidly turned into a list of restricted medicines [13].

Formulary system works through a Formulary and Therapeutics Committee, which evaluates, and selects from the numerous available drug products those that are considered most efficacious, safe, and cost effective. A formulary system is a mechanism to streamline procurement activities, minimize institutional costs and optimize patient care. The result of the drug selection process is a drug formulary list [14].

The paediatric formulary is the formulary of paediatric medicines approved by Pharmacy and Therapeutic Committee for use in the Hospital. It helps to rationalize the therapy for children and also reducing the cost of therapy. The aim of the work were to design and develop Paediatric Formulary in tertiary care referral hospital and to compare the prepared Formulary with WHO and IAP list of essential medicines for children.[15]

MATERIALS AND METHODS:

This prospective study was carried out at ESI hospital, chennai. Medicines that were approved for use in the Hospital by Pharmacy and Therapeutic Committee and medicines preferred by the clinicians that have proven efficacy and safety on their practice were included in the study. A survey form was prepared to collect the information regarding availability of paediatric medicines, their dosage forms, and strengths. Availability of medicines was physically verified at pharmacy store and in paediatric wards. Monographs were prepared for all the selected drugs in the hospital pharmacy with the following contents: Therapeutic category, Pharmacokinetics, Indications, Contraindications, Precautions, Adverse reactions, Dosage, Administration, Pregnancy, Breast-feeding, Drug interactions, Poisoning, Brands available /strength /formulation. The prepared Paediatric Formulary were compared with WHO model list of Essential Medicines for Children 2011 and IAP list of essential medicines for children 2011 on the following parameters: Total number of drugs present, Class wise distribution of drugs, Number of brands available for generic drugs in Paediatric Formulary, Monograph content, Fixed drug combinations, and Number of vaccines.

RESULTS:

Comparison of Total Number of Pediatric Drugs Available In WHO/IAP/ESI

The prepared formulary in ESI contains 90 total number of drugs and WHO essential drug list contains 273 drugs and IAP contains 130 number of drugs.(figure1)

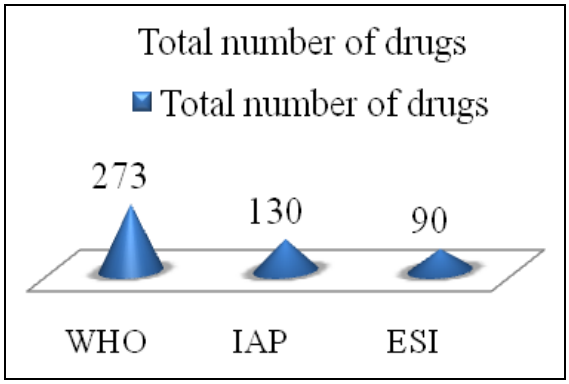

Fig 1. Comparison of available class of pediatric drugs in WHO/IAP/ESI

Out of 273 drugs in WHO, anti-infective, immunological products and vaccines, nutrition and blood products, skin disorders, CNS,CVS, respiratory, endocrine were 95(34.7%), 28 (10.25%), 31(11.35%) , 15(5.49%), 13(4.76%), 8(2.93%), 3(1.09%), 8(2.93%) drugs respectively. Gastrointestinal and anti-allergics consisted of 8(2.93%) and 5(1.83%).

Out of 130 drugs in IAP , anti-infective, immunological products and vaccines, nutrition and blood products, skin disorders, CNS, CVS, respiratory, endocrine were 49(37.6%), 10(7.69%), 14(10.76), 6(4.61%), 10(7.69%), 7(5.38%), 2(1.53%), 4(3.07%) drugs respectively. Gastrointestinal and anti-allergics consisted of 4 (3.07%), 5(3.84%).

Out of 90 drugs in ESI anti-infective, immunological products and vaccines, nutrition and blood products, skin disorders, CNS, CVS, respiratory, endocrine were 22(24.4%), 11(12.22%), 7(7.77%), 2(2.22%), 9(10%), 10(11.11%),8(8.88%), 2(2.22%) drugs and also 15(16.66%), 7(7.77%) in gastrointestinal and anti-allergics class.(figure 2)

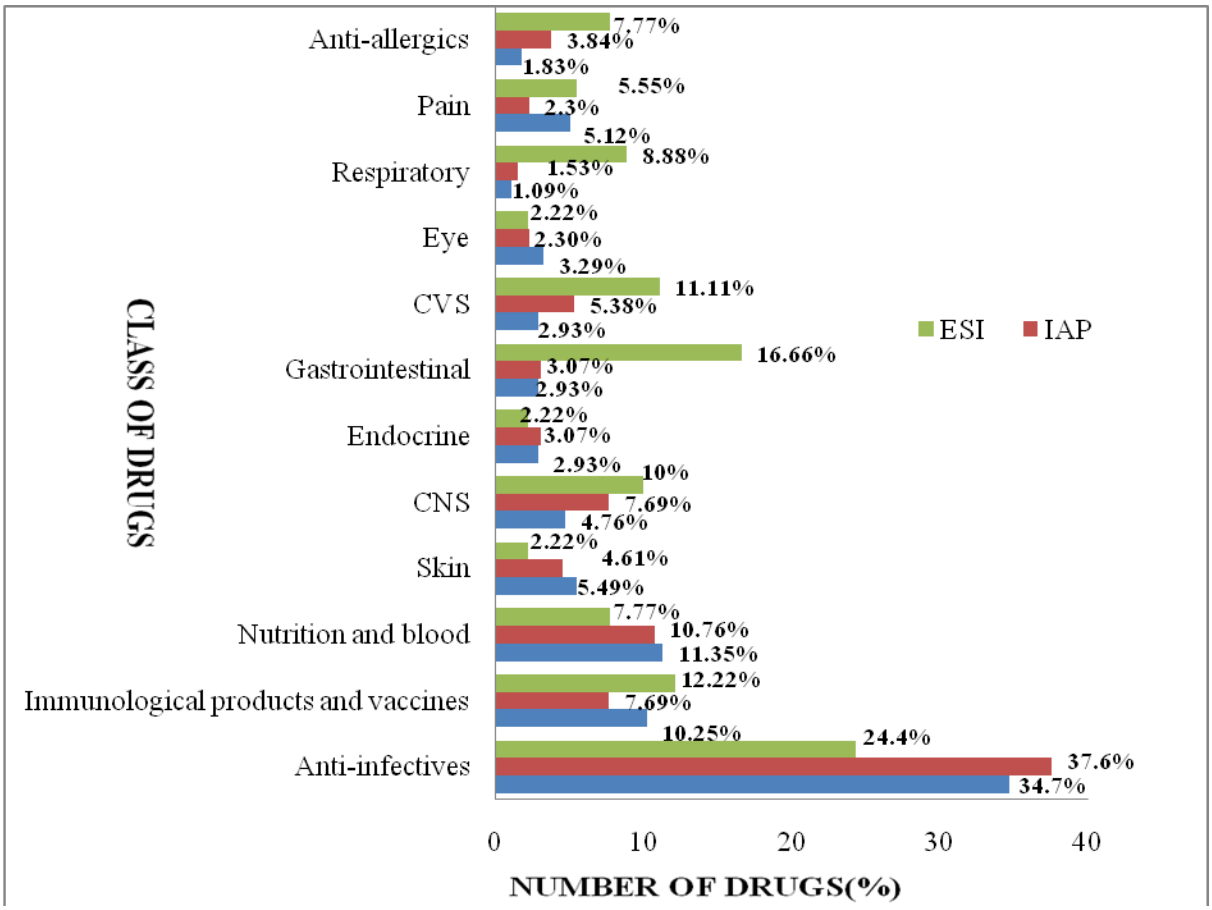

Fig. 2. Comparison of availbility of pediatric vaccines in WHO/IAP/ESI

From the study, number of vaccines in WHO is 23(8.42%) whereas in IAP it contains 7(5.38%) and ESI 6(6.66%). (figure 3)

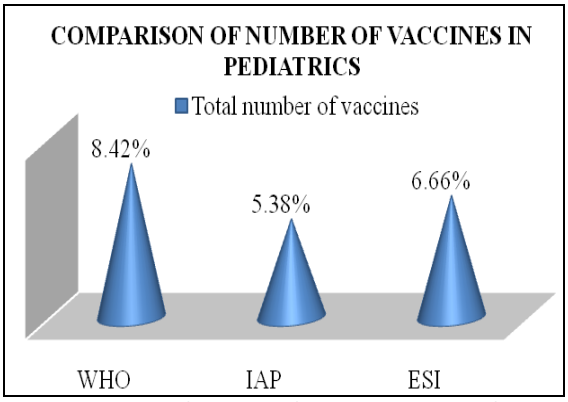

Fig. 3. Comparison of number of available pediatric fixed drug combinations in WHO/IAP/ESI

In ESI the fixed drug combinations were 7 out of 90 total number of drugs and in WHO and IAP it is same 12.(figure 4)

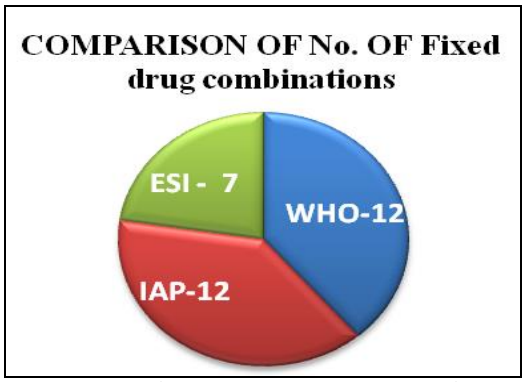

Fig. 4. Comparison Of Monograph Content In Who/Nfi/Esi

Monograph content of prepared paediatric formulary was compared with national formulary of India and WHO model formulary. Most of information about the indications, adverse reactions, drug interactions, dosage strength were present in the formulary. Category, drug interactions were absent in WHO model formulary whereas it is present in prepared paediatric formulary.(figure 5)

Monograph content	WHO	NFI	ESI
Generic name	Present	Present	Present
Therapeutic category	Absent	Present	Present
Pharmacokinetics	Present	Absent	Absent
Pharmacology	Present	Present	Present
Indication	Present	Present	Present
Contraindication	Present	Present	Present
Precautions	Present	Present	Present
Adverse effects	Present	Present	Present
Dosage strength	Present	Present	Present
Administration	Absent	Present	Present
Pregnancy	Absent	Present	Present
Breast feeding	Absent	Absent	Present
Drug interactions	Absent	Present	Present

Fig. 5

DISCUSSION:

Children are often considered as young adults. However, pharmacologically they form a heterogeneous group with markedly different pharmacokinetics from that in adults. Children, particularly infants and newborns suffer from different disease than adults and thus require tailor made specific medicines in correct dose and appropriate dosage formulations.

This study showed deficiency and scarcity in pediatric medicines at tertiary care hospital , when compared to WHO formulary and Indian academy of pediatrics list.
Out of 90 drugs anti-infective, immunological products and vaccines, nutrition and blood products, skin disorders, CNS, CVS, respiratory, endocrine were 22(24.4%), 11(12.22%), 7(7.77%), 2(2.22%), 9(10%), 10(11.11%), 8(8.88%), 2(2.22%) drugs and also 15(16.66%), 7(7.77%) in gastrointestinal and anti-allergics class. Anti-infectives were found to be more compared to other category of drugs.

The poor availability pattern of paediatric medicines in public health facilities has been similar in other states of India, and resource limited countries (Gitanjali and Manikandan, 2011; Robertson et al., 2009, Rangnathan et al., 2008).

The content of the monographs of the prepared formulary was compared with that of the WHO Model Formulary. Most of the information was similar, except that WHO Model Formulary does not include synonyms of the drug, pregnancy risk factor, drug interactions, formulation and cost.

It has been observed that even if paediatric formulations are incorporated in EML, wide gap has been noted between EML and the procured medicines. Under the Better Medicines for Children (BMC) initiative of the WHO, the two states in India namely Chhattisgarh and Orissa revised EML and incorporated substantial number of paediatric formulations.

Despite this only 7% - 17% paediatric medicines were procured (Gitanjali B, 2011). These observations call for engaging the health care policy makers, decision makers, health care professionals and prescribers to undertake the task seriously to improve the access of paediatric medicines that will have a significant impact on child morbidity and mortality.(Mira Desai et al.,2012)

CONCLUSION:

Children are often considered as young adults. However pharmacologically they form a heterogenous group with markedly different pharmacokinetics from that in adults. The IAP (Indian Academy of Paediatrics) Drug

Formulary, WHO essential list for children were used to compare the prepared Paediatric Formulary. The prepared Paediatric Formulary consisted of 90 drugs i.e. 183 drugs less than WHO list and 40 drugs less than IAP drug list. The contents of the monographs of the prepared formulary was compared with WHO model formulary and national formulary of India. Most of the information was included in the prepared formulary. The prepared formulary can be used as a vehicle to provide information to the physicians about the available drugs in the hospital pharmacy and can be used to rationalize the medicines used in the hospital. It has been observed from the study that even if pediatric formulations are incorporated in EML, wide gap has been noted between EML and procured medicines. It has been concluded that availability of pediatric medicines in appropriate dosage formulations and strength is not satisfactory at health services.

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