

**Study of Pediatric Drug Formulations at Drug Store in a Tertiary Care Hospital.**

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Conflicts of Interest: Nil

Abstract

Objectives: To find out the availability of essential medicines (drug, formulations) as given by National List of Essential Medicines for children (NEMLC) by IAP (October 2011) in the hospital drug store of a tertiary care hospital Maharashtra.

Methods: This cross sectional study was conducted during April to May 2017. The availability of essential medicine for children (drugs and formulations) were noted down. Substitutes for not in stock medicines were also noted separately and impact of non-availability of medicines on prescribers was assessed by interviewing them with the help of a pre-validated questionnaire.

Results: Out of the drugs listed in NEMLC, 93% drugs and 57% of pediatric formulations were available in the hospital drug store as specified in NEMLC. For drugs like Ibuprofen (Tab, OL), Budesonide (Inhalation), Gentamicin (eye drops), and Prednisolone (OL) substitute medicines were available.

Conclusion: Majority of the drugs available in hospital drug store are in accordance to NEMLC but moderate deficiency of formulations were noted. A separate list of essential medicines with child friendly formulations should be prepared at institution level.

Keywords: Children, Drugs, Formulations, IAP, NEMLC.

1. Introduction

Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected on the basis of disease prevalence, evidence on efficacy, safety and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford [1]. Children deserve medicines that are adapted to their needs [2]. They 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 [3]. Unavailability of pediatric medicines and their formulations makes it difficult to treat such patients. Children are often unable to take the dosage forms that are designed for adults. For example, tablets that allow for adult doses may need to be split before being given to younger children, based on an undemonstrated assumption that the distribution of the active substance within the tablet is uniform [4]. This can give rise to treatment failure or medication errors due to wrong dose administration and wastage of unused

medicines. Hence to increase the global awareness of essential medicines for children WHO initiated 'Better Medicines for Children initiative and 'Make medicine child size' campaign [5] The Indian Academy of Pediatrics (IAP) Essential Medicines List for children (NEMLC) of India covers the basic needs for the majority of children seeking health care in the country. The medicines were selected based on the WHO criteria for selection of essential medicines and the National Health Programmes in India. This is the first edition of the IAP EMLC 2011 and it contains 134 medicines. [6]

In spite of this the availability of pediatric medicines in appropriate dosage formulations and strength is not satisfactory at public health facilities. In the past and unfortunately still today, a large proportion of medicines were given to children in an "off label" manner or even without a license/marketing authorization [3]. WHO "levels and trends in child mortality 2014" show that 6.3 million children under the age of five years died in 2013. Among these most of these early child deaths could be prevented. India (21%) and Nigeria (13%) together account for more than one third of under five children death [7].

Hence the present study is carried out to assess the availability of pediatric medicines and their dosage formulations in a hospital drug store as per Essential Medicines List for children (NEMLC) and its perception among the prescribers.

2. Methodology

This was an observational cross sectional study. It was conducted in a hospital drug store and pediatric department of a tertiary care hospital in Maharashtra over a period of 2 months i.e. from April 2017 to May 2017 after getting an approval from Institutional Ethics Committee.

Existing hospital pediatric medicines list was obtained from chief pharmacist along with their dosage forms. Availability of pediatric medicines and pediatric formulations at hospital drug store, pediatric and related wards for example emergency department, pediatric intensive care units, operation theatre etc. were physically verified by data collector.

Each medicine with dosage form was listed separately and compared with the Indian Academy of Pediatrics (IAP) Essential Medicines List for children (NEMLC) oct 2011 which was downloaded from the official website. [8]. Substitutes for not stocked medicines were also noted separately.

The impact of non-availability of medicines on prescribers was assessed by interviewing them with the help of a prevalidated questionnaire containing questions related to awareness and need of pediatric medicines, their monthly requirement or consumption, use of substitutes, alternative practices adopted and the clinical response.

Data was entered in Microsoft Excel sheet 2013 and the percentage availability of the medicines along with dosage forms were noted.

3. Results

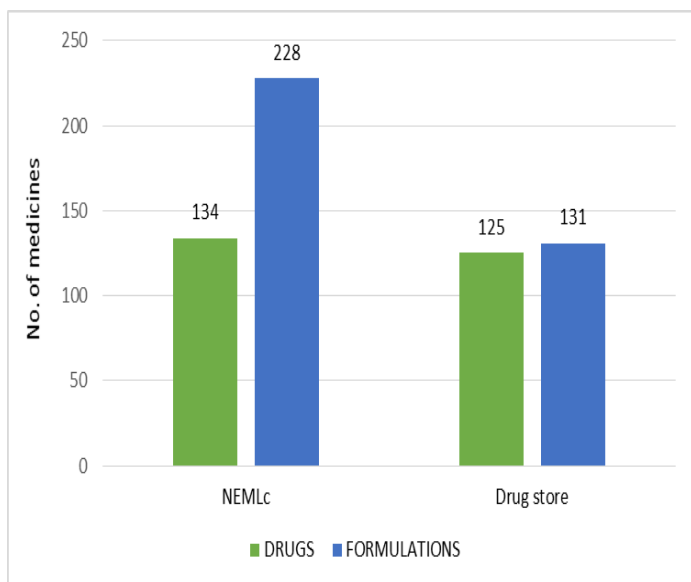
Drug groups

As per NEMLC total 22 different drug groups should be available in the hospital drug store. In our hospital drug store all 22 drug groups were available (Table-1).

Pediatric Medicines

In NEMLC total 134 drugs (comprising 22 drug groups) with 228 different pediatric dosage forms are listed. In our hospital drug store 125 drugs (93.28%) with 131(57.45%) pediatric dosage forms were available (Fig-1).

Fig. 1: Total number of pediatric medicines and formulations available in a hospital drug store.



NEMLC- National Essential Medicines List for children,
Drug store- Tertiary care hospital.

The essential medicines found to be deficient were Cefadroxil (OL, tab), Spironolactone (OL, tab), Digoxin (OL) Hydroxyurea (tab), Charcoal activated (powder), Zinc sulphate (tab), Vitamin A, Cholecalciferol, Mercaptopurine (Tab) (Table 1). These drugs & formulations are acquired by local purchase as and when required.

Table 1. Pediatric medicines not stocked at hospital drug store but made available as required.

S. No	Pediatrics medicines and their formulations not stocked in hospital drug store	Group of the Drug NEMLC
1.	Cefadroxil OL: 125mg / 5ml, 250mg/5ml, Tab: 250mg	Anti-infective
2.	Spironolactone- OL: 2 mg/ml; 5 mg/ml. Tab: 25 mg.	Medicines used in heart failure
3.	Digoxin- OL: 50 micrograms/ml.	
4.	Hydroxyurea- Tab: 250 mg.	Antianaemia medicines

5.	Charcoal, activated Powder: 25 g; 50 g.	Antidotes
6.	Zinc sulphate- Tab (dispersible, scored): 20 mg	Gastrointestinal Medicines
7.	Vitamin A- Oral oily sol: 1,00,000 IU (as palmitate)/ml in multidose dispenser. Tab: 50,000 IU. Cap: 50,000 IU; 100,000 IU	Vitamins And Minerals
8.	Cholecalciferol- Solid oral dosage form: 400 IU; 1000 IU.	
9.	Mercaptopurine- Tab: 50 mg.	Antineoplastic Medicines

OL: Oral Liquid, Tab –Tablets, Sol: solution.

The drugs like Naloxone, Pyrantel, Diethylcarbamazine, Pentamidine isethionate, Sodium stibogluconate and Procaine benzylpenicillin are listed in NEMLC but their stock is not maintained in hospital drug store as they are not required.

For drugs like Ibuprofen (Tab, OL), Budesonide (Inhalation), Gentamicin (eye drops), and Prednisolone (OL) etc. substitute medicines were available. (Table 2)

Table 2. Paediatric medicines for which substitute medicines were available

S. No	Pediatrics medicines and their formulations <u>not</u> stocked in hospital drug store	Substitute medicine used in hospital	Group of the Drug NEMLC

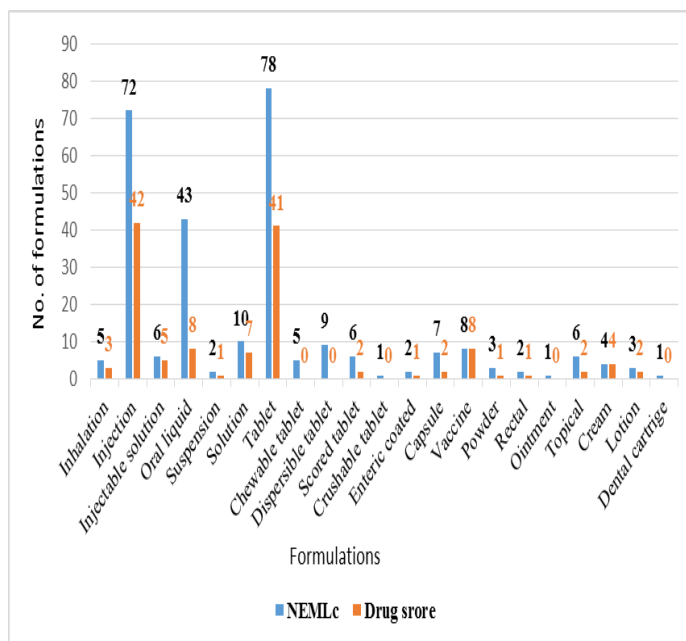
1.	Ibuprofen- Tab:200 mg. OL: 100 mg/5 ml.	Paracetamol- OL: 125/5ml	NSAIDs
2.	Budesonide- Inhalation (aerosol):100 µgm/dose.	Fluticasone- Inhalation	Medicines Acting On the RT
3.	Gentamicin- Sol (eye drops): 0.3 % (sulfate).	Tobramycin- Sol (eye drops)	Ophthalmological Preparations
4.	Prednisolone- OL: 3 mg/ml; 5 mg/ml.	Prednisolone 5mg Tablets are fragmented and used	Anti-allergic

OL: Oral Liquid, Tab –Tablets, NSAIDs- Non-opioids and non-steroidal anti-inflammatory medicines, NEMLC- National list of Essential Medicines for Children of India.

Pediatric Formulations

A moderate deficiency of child specific dosage formulations especially injections, oral liquids, powder for injections, capsules, tablets, chewable, scored and dispersible tablets was observed in hospital drug store when compared with NEMLC (Fig.2).

Fig. 2: Availability of child specific formulations in tertiary care hospital



In our hospital drug store total 131(57.45%) pediatric formulations were available. The deficient formulations are acquired by local purchase as and when required.

Practices among Prescribers

Total 14 pediatricians including teaching faculties and residents were interviewed with the help of a pre-validated questionnaire containing questions related to practices adopted in case of non-availability of a suitable dosage form. Majority (79%) of them admitted of using fragmented adult formulations for children, 89% experienced drug administration problem with fragmented adult formulations and 37% observed poor clinical response.

Furthermore, 92% of the prescribers stressed the need of Probiotics, Multivitamin drops, Tab-Sildenafil 25mg, Inj & syrup- Capnea(cafeine), Inj-Levofloxacin, Syrup-Cetirizine, Syrup- Zinc, Adenosine-2mg/2ml syringe, Vitamin D drops, Inj-vit D, Iron drops (1ml=250mg), Syrup- Ca+Phosphorus (5ml=250mg), Syrup- Furosemide, Vit- K1(tab, inj) in addition to those included in the NEMLC.

4. Discussion

Our study demonstrated that 93% availability of pediatric medicines and modest scarcity of pediatric formulations at a hospital drug store of a tertiary care hospital when compared with NLEM. The poor availability pattern of pediatric 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, Ranganathan et al., 2008) [9]. The deficiency in pediatric medicines is found to be less (Total 9 medicines) than those reported in previous studies done by Vijayakumar et al., 2015 [10] where 10 medicines were deficient.

The not stocked medicines particularly Spironolactone, Digoxin oral liquid, oral zinc and Charcoal activated, Hydroxy urea etc. is a matter of worry. These medicines have been included in the NLEM and recommended in treatment guidelines for the management of Edema (due to cardiac, nephrotic, hepatic), diarrhoea and drug poisoning and sickle cell anaemia. As demand is less their stock is not maintained in hospital drug store but they are acquired by local purchase as and when required. For Ibuprofen (Tab, OL), Budesonide (Inhalation), Gentamicin (eye drops), and Prednisolone (OL) etc. Substitute medicines were available.

A moderate deficiency of pediatric formulations particularly Injections, Oral liquid, Tablets, Scored, Crushable, Dispersible and Chewable tablets was found. Our results are similar to those reported in the previous studies done by Desai et al., 2012. [11].

Shortage of appropriate formulations indicates that adult formulations were handled at ward by nursing staff or parents at home to meet the need for small doses in pediatric patients. Such handlings may involve cutting or grinding up tablets or dispersing or mixing drugs with food or water before administration. Pediatric specific

formulations are worldwide concern. It has been accepted that child friendly formulations are more expensive than adult dosage forms, requires more space to store and special facility to maintain the stability in extreme of temperature. The demand is limited which therefore leads to restricted market. Thus pediatric formulations are either not indent or not quoted by sellers in public health facilities due to limited market.

Under the Better Medicines for Children (BMC) initiative of the WHO, the two states in India namely Chhattisgarh and Orissa revised Essential Medicine List (EML) and incorporated substantial number of pediatric formulations. However Gitanjali B et al., 2011 observed that, only 7% - 17% pediatric medicines were existing at their institute. [9]

In order to get the precise picture of actual practice, prescribers were interviewed. The pediatricians every day practices clearly replicated of using fragmented adult medicines for pediatric patients and experienced drug administration problem.

5. Conclusion

Majority of the drugs available in hospital drug store are in accordance to NLEM. The hospital drug store maintains most of the drugs as per utility analysis. Considering the need of some additional drugs in the hospital a separate list of essential medicines at institution level should be prepared.

Acknowledgment- Nil

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