Evaluation of Development and Implementation of Hospital Formulary for Paediatric Department in a Rural Tertiary Care Teaching Hospital of South India

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Submitted: 15/11/2012 Accepted: 04/07/2013

ABSTRACT

Formulary is a continually revised compilation of pharmaceuticals and some important ancillary information that reflects the current clinical judgement of medical staff. This prospective survey study was carried out to develop a Hospital Formulary for the rural tertiary care teaching hospital. Well designed suitable questionnaires were piloted and given to the staff of Paediatric Department. Drug list was prepared and monographs were developed accordingly. The developed Paediatric Formulary was implemented in the Department of Paediatrics and later evaluated by using suitably designed feedback questionnaire.

Prepared paediatric hospital formulary consisted of 102 drugs of various categories. Availability of brands was from single to many and 49 brands of drug combinations were present. The prepared paediatric hospital formulary was implemented in the hospital.

The staff and postgraduate students of Department of Paediatrics were very satisfied with the implemented formulary and appreciated that the work was carried out to a great level. This provides them updated unbiased information about the drugs and available brands with cost in the hospital pharmacy. This formulary promotes the safe and effective use of medicines thereby reducing the total cost of treatment of the patient.

Keywords: Best practice, Drug list, Formulary, Questionnaires.

INTRODUCTION

Formulary is a continually revised compilation of pharmaceuticals and some important ancillary information that reflects the current clinical judgement of medical staff.[1, 2] One way of rationalizing the selection of drugs and improving prescribing, is the development of a general practice formulary.[3] Hospital formularies originally started life in hospitals as a collection of commonly prescribed pharmaceutical preparations, produced mainly for reference purposes. In present scenario, the hospital formulary (HF) was adopted to incorporate the detailed information on the increasing number and diversity of medicines.[4] It is difficult to achieve efficiency in the hospital pharmaceutical system if there are too many medicines incorporated into the hospital formulary.[5] However, these new and expensive preparations requires ever increasing funds and the formulary rapidly turned into a list of restricted medicines.[4] The most important function of Drugs and Therapeutics Committee (DTC) is to prepare and implement a formulary for the hospital. The committee should have sufficient members to represent all stakeholders, including, the clinical departments, the administration and the pharmacy.[5]

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WHO Formulary, British National Formulary, Indian National Formulary are some of the formularies used as standard references in many hospitals. Some of the hospitals in India have developed their own Hospital Formularies like Kasturba Hospital at Manipal, Christian Medical College Hospital at Vellore and KLE Hospital at Belgaum and many more.

The main reason for developing hospital formulary is to set standards for best practice, promoting high quality and evidence based prescribing thereby minimising the variation in the level of treatment provided to the patients. Hospital formulary is a tool for health care professionals mainly medical and nursing staffs make use of this tool periodically hence it is important that it should be complete, concise, updated and easy to use.[4]

All aspects of drug management, including procurement, storage, distribution and use are easier if restricted numbers of drugs are dealt with. Appropriate selection of drugs can achieve the following results:

- Cost containment and enhanced equity in access to essential medicines: Procuring fewer items in large quantities results in more competition and economies of scale with regard to quality assurance, procurement, storage and distribution. Such economies can lead to improved drug availability at lower costs, so benefiting those who are in most need.
- Improved quality of care: Patients will be treated with

fewer but more cost-effective medicines for which information can be better provided and prescribers better trained. Prescribers gain more experience with fewer drugs and recognise drug interactions and adverse drug reactions better. Quality of care will be further improved if medicine selection is based on evidence based treatment guidelines.

New drugs and treatments are emerging all the time, and without evaluation the formulary may become a collection of older, less effective drugs. Therefore, the entire formulary should be reviewed every 2–3 years.[5]

Children have the same rights as adults to receive safe and effective medicines. In such context, clinicians should be guided to ensure that children benefit from the medications they prescribe, for which a Pediatric Formulary would be useful.[6] Pharmacist plays a key role in developing policies and procedures governing the hospital formulary. Pharmacist should ensure that the quality of drugs is not compromised by economic considerations.[7]

A formulary aims to provide an-updated information about the use of medicines to physicians, pharmacists and other health care professionals in the hospital; hence the central goal of formulary is to help the prescribers in appropriate selection of the drugs for better patient care. Looking at the need of a formulary for the Department of Paediatrics, we projected to design and develop a specialty hospital formulary for quick reference of prescribers which ultimately benefits the paediatric population.

MATERIAL AND METHODS

Stud design: This was a prospective survey based study.

Study Site: The study was conducted at Adichunchanagiri Hospital and Research Centre (AH & RC), a 1250 bedded multi-disciplinary hospital situated in Southern part of India.

Materials used: Questionnaires to the doctors for the inclusion of drug, drug contents in the forthcoming paediatric hospital formulary and feedback questionnaires for implemented paediatric hospital formulary, Master Drug List and standard Drug Information Resources.

Study Procedure:

From the WHO Model Formulary for Children 2010, a list of drugs was made and given to the staff of the Paediatric Department for the selection of drugs prescribed by them in the hospital to be included in the formulary. Two questionnaires were developed and designed by discussed with clinical pharmacist and paediatric doctors. It contained objective type of questions. These questionnaires were used to select the information like indications, precautions, dose, interactions, and adverse drug reactions to be included under each drug monograph.

Based on the information from the questionnaire, a drug list was prepared for the Paediatric department. By using Master Drug List (contains total number of branded drugs available in the hospital with their generic name, quantity and cost per unit) and some standard Drug Information resources, drug monographs were prepared. Each monograph provided the information of generic name, brand names, quantity, cost per unit, synonyms if any, indications, precautions, contraindications, paediatric dose, adverse drug reactions, interactions, practice points, administration and counselling points of drug. The drugs that were available in combinations were also mentioned separately at the end of the formulary along with their brand name, generic name, quantity and cost per unit. The resources used for collection of drug information were WHO Model Formulary for Children 2010[8], Micromedex[9], WHO Model Formulary 2008[10], Martindale The Complete Drug Reference[11], Goodman and Gilman's The Pharmacological Basis of Therapeutics[12], Australian Pharmaceutical Formulary and Hand book[13], Comprehensive Pharmacy Review[14], AHFS Drug Hand Book[15], Essentials of Medical Pharmacology[16] and CIMS[17].

The developed drug monographs were given to the staff of Department of Paediatrics for their opinion and suggestion towards the prepared drug monographs and modifications were made accordingly. General information which may be useful to the practicing prescribers was also included in the formulary. The developed Paediatric Formulary was implemented in the Department of Paediatrics and later evaluated by using suitably designed feedback questionnaire. It contained ten objective type of questions and one for comments if any (Annexure 1).

RESULTS

A total of 238 drugs were listed from WHO Model Formulary for Children 2010. Among 238 drugs, 102 were included in the formulary based on the opinion from the staff of the Department of Paediatrics and Clinical Pharmacy.

Drug use pattern in Department of Paediatrics:

Among 102 drugs included in the formulary, majority of them were Vaccines 16 (15.69%), followed by Anti-bacterials 15 (14.73%) as shown in Table 1.

Drug Formulations:

Among 102 drugs included in the formulary, 125 (49.41%) drugs were available as oral tablets and capsules followed by parenteral preparations 69 (27.27%) and oral syrups, suspensions, drops and other solutions 49 (19.37%) as shown in Table 2.

Annexure 1

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FEEDBACK QUESTIONNAIRES FOR IMPLEMENTED PAEDIATRIC HOSPITAL FORMULARY

§ ***Please, kindly give your valuable feedback*** ***Designation:***

1 Whether the order of contents in each monograph is convenient to refer?
To great extent o Somewhat o Very little o Not at all o

2. The content in each drug monograph is
Unacceptable o Below average o Average o Above average
Outstanding o

3. Is it useful to get aware of the brands available in the hospital pharmacy?
Very useful o Useful o No difference o Not useful o
not access it o

4. Whether this formulary is helpful in reducing the total cost of treatment of the patients?
Very helpful o Helpful o No difference o Not helpful o
Did not access it o

5. Whether this formulary promotes safe and effective use of medicines?
To great extent o Somewhat o Very little o Not at all o

6. Will it be useful in your clinical practice?
Very useful o Useful o No difference o Not useful o
Did not access it o

7. Extent of usage of the formulary
Always o Very frequently o Occasionally o Rarely o
Very rarely o Never o

8. Whether the formulary is handy?
Yes o No o

9. Are you satisfied with the developed formulary?
Very satisfied o Somewhat satisfied o Neither o Dissatisfied o

10. Do you feel that a clinical pharmacist is required in your daily practice?
Strongly disagree o Disagree o Neither o Agree o
Strongly agree o

11. Further comments if any:

Thank you for your kind co-operation….

Table 1: Drug use pattern in prepared Formulary

S. No	Drug class	No. of drugs (n=102)	Percentage of drugs (%)
1	Anaesthetics	02	01.96
2	Non- Steroidal Anti-Inflammatory drugs	02	01.96
3	Anti-allergics and medicines used inAnaphylaxis	05	04.90
4	Antidotes used in Poisoning	04	03.92
5	Anti-epileptics	06	05.88
6	Anthelminthics	04	03.92
7	Anti-filarials	01	00.98
8	Anti-bacterials	15	14.73
9	Anti-tuberculosis Medicines	04	03.92
10	Anti-fungals	02	01.96
11	Anti-virals	01	00.98
12	Anti-amoebic and Anti-giardiasis medicines	01	00.98
13	Anti-malarials	05	04.90
14	Anti-pneumocystosis and Anti-taxoplasmosis Medicines	01	00.98
15	Cytotoxic Medicines	01	00.98
16	Haematinics	04	03.92
17	Blood products and Plasma Substitutes	03	02.94
18	Anti-hypertensives	01	00.98
19	Medicines used in Heart Failure	03	02.94
20	Antiseptics	01	00.98
21	Disinfectants	01	00.98
22	Diuretics	02	01.96
23	Antacids	01	00.98
24	Anti-emetics	01	00.98
25	Anti-diarrhoeals	02	01.96
26	Adrenal hormones and synthetic substitutes	01	00.98
27	Insulin	01	00.98
28	Thyroid hormones	01	00.98
29	Immunologicals	01	00.98
30	Sera and Immunoglobulins	01	00.98
31	Vaccines	16	15.69
32	Muscle relaxants and Cholinesterase inhibitors	01	00.98
33	Anti-asthmatic Medicines	02	01.96
34	Solutions correcting water, electrolyte and acid-base dis turbances	05	04.90

Distribution of brands according to generic name of drugs:

Out of 102 drugs, 24 (37.5%) drugs were available in single brand, 18 (28.12%) drugs were available in two brands, 06 (9.38%) drugs in three brands, 04 (6.25%) drugs in five brands, 03 (4.69%) drugs in four brands and 03 (4.69%) drugs in six brands as shown in Table 3.

Drug Combinations available in pharmacy:

A total of 49 brands were available in pharmacy as combination. Among them 28 (57.13%) brands were available as combination of two drugs, 10 (18.36%) brands as combination of four drugs, 09 (18.36%) brands as combination of three drugs and 02 (4.1%) brands as combination of five drugs as shown in Table 4.

Feedback:

Table 5 showed the comments for the feedback questionnaires by the Head, staff and postgraduate students of Paediatric Department. The feedback forms were distributed to 17 paediatricians of whom 14 responded. This was due to lack of availability of doctors. For the first question, 10 (71.43%) doctors had answered to great extent option in the form, 04

Table 2: Formulation category of drugs in the Prepared Formulary

Formulation	No. of formulations (n=102)	Percentage (%)
Oral- Tablets and Capsules	125	49.41
Parenteral preparations	69	27.27
Oral- Syrups, Suspensions, Drops and other solutions	49	19.37
Inhalation	07	02.77
Topical preparations	03	01.18

Table 3: Pattern of Brands available for generic drugs in the Hospital Pharmacy

Brands	Number of generic drugs(n=102)	Percentage (%)
Single brand	24	37.5
Two brands	18	28.12
Three brands	06	09.38
Four brands	03	04.69
Five brands	04	06.25
Six brands	03	04.69
Seven brands	01	01.56
Eight brands	01	01.56
Eleven brands	01	01.56
Twelve brands	01	01.56
Seventeen brands	02	03.13

Table 4: Details on Drug Combinations in Hospital Pharmacy

Combinations	Number of brands (n=49)	Percentage (%)
Two drugs	28	57.13
Three drugs	09	18.36
Four drugs	10	20.41
Five drugs	02	04.1

Table 5: Feedback of Doctors on implemented Paediatric formulary

S. No	Feedback questionnaire / Comment	No. of Doctors n=4 (%)	No. of PGs n=10 (%)	Totaln=14(%)
1	Whether the order of contents in each monograph is convenient to refer?			
	To great extent	04 (100)	06 (60)	10 (71.43)
	Somewhat	00 (00)	04 (40)	04 (28.57)
2	The content in each drug monograph is			
	Outstanding	01 (25)	01 (10)	02 (14.29)
	Above average	03 (75)	07 (70)	10 (71.43)
	Average	00 (00)	02 (20)	02 (14.29)
	3Is it useful to get aware of the brands available in the hospital pharmacy?			
	Very useful	02 (50)	05 (50)	07 (50)
	Useful	02 (50)	05 (50)	07 (50)
4	Whether this formulary is helpful in reducing the total cost of treatment of the patients?			
	Very helpful	01 (25)	02 (20)	03 (21.43)
	Helpful	03 (75)	08 (80)	11 (78.57)
5	Whether this formulary promotes safe and effective use of medicines?			
	To great extent	01 (25)	05 (50)	06 (42.86)
	Somewhat	03 (75)	05 (50)	08 (57.14)
6	Will it be useful in your clinical practice?			
	Very useful	00 (00)	03 (30)	03 (21.43)
	Useful	04 (100)	07 (70)	11 (78.57)
7	Extent of usage of the formulary			
	Always	01 (25)	01 (10)	02 (14.29)
	Very frequently	02 (50)	08 (80)	10 (71.43)
	Occasionally	01 (25)	01 (10)	02 (14.29)
8	Whether the formulary is handy?			
	Yes	04 (100)	10 (100)	14 (100)
9	Are you satisfied with the developed formulary?			
	Very satisfied	02 (50)	06 (60)	08 (57.14)
	Somewhat satisfied	02 (50)	04 (40)	06 (42.86)
10	Do you feel that a clinical pharmacist is required in your daily practice?			
	Strongly agree	00 (00)	03 (30)	03 (21.43)
	Agree	03 (75)	06 (60)	09 (64.29)
	Neither	01 (25)	01 (10)	02 (14.29)

(28.57%) had answered somewhat option; for second question, 02 (14.29%) of them had answered outstanding, 10 (17.43%) had answered above average and 02 (14.29%) had answered average; for third question 07 (50%) of them had answered very useful and 07 (50%) of them had answered useful; for fourth question 03 (21.43%) of them had answered very helpful and 11 (78.57%) of them had answered helpful; for the fifth question 06 (42.86%) of them had answered to great extent and 08 (57.14%) of them had answered somewhat; for sixth question 03 (21.43%) of them had answered very useful and 11 (78.57%) of them had answered useful; for seventh question 02 (14.29%) of them had answered always, 10 (71.43%) of them had answered very frequently and 02 (14.29%) of them had answered occasionally; for eighth question 100% of them had answered yes; for ninth question 08 (57.14%) of them had answered very satisfied and 06 (42.86%) of them had answered somewhat satisfied; for tenth question 03 (21.43%) of them had answered strongly agree, 09 (64.29%) of them had answered agree and 02 (14.29%) of them had answered neither.

DISCUSSION

A total of 238 drugs were listed from WHO Model Formulary for Children 2010, and among them 102 drugs were included in the formulary based on the opinion of the Staff of the

Department of Paediatrics and Department of Clinical Pharmacy. The first ever WHO Model Formulary for Children released by the WHO provides information on how to use the essential medicines for treating illness and disease in children. This formulary was primarily taken as a model for developing paediatric hospital formulary.[18]

The drug use pattern in Paediatric Department showed that Vaccines were used majorly. This might be because immunisation plays a major role in the prevention of infectious diseases in peadiatrics. The next major category was Anti-bacterials which might have been to susceptibility of children to infections.

In the prepared Hospital Formulary, it was found that majority of the drugs available were oral tablets and capsules followed by parenteral preparations and oral syrups, suspensions, drops and other solutions. The prepared formulary contained many single branded drugs available in market followed by two and three brands. Out of 102 drugs 24drugs were available in single brand. There were two brands for eighteen drugs, three brands for six drugs (Prednisolone, Metronidazole, Co-trimoxazole, Folic acid, Polyiodine and Budesonide), four brands for three drugs (Phenytoin, Chloroquine and Digoxin), five brands for four drugs (Carbamazepine, Valproic acid, Amoxicillin and Cefalexin), six brands for three drugs (Ciprofloxacin, Ofloxacin and Fluconazole), seven brands for Albendazole, eight brands for Salbutamol, eleven brands for Paracetamol, twelve brands for Azithromycin and seventeen brands for Amoxicillin+Clavulanic acid and Ceftriaxone each. The reason attributed for the availability of more than three brands for a single drug may be due to the promotion of Pharmaceutical companies, physician's choice and cost variation within the brands of the same generic drug. For better inventory control and to avoid zero stock level, it is recommended to limit the number of brands for each generic drug based on the availability and sales of the drug.[19]

In the prepared Hospital Formulary majority of the drug combinations were found to be vaccines followed by antibiotics and analgesics. Similarly in one study conducted at Kasturba hospital the majority of the combinations were analgesics, followed by antimicrobials, multivitamins and cold or cough mixtures.[4]

The feedback questionnaire consisting of 10 questionnaires prepared by the clinical pharmacist was given to doctors to get the response from them. The enthusiasm and response from the health care professionals of Paediatric department was overwhelming for the formulary development and its implementation. This work was acknowledged by the doctors as this formulary comprised the wealth of information of the drugs making them aware of all the brands including their cost available in the hospital pharmacy which in turn felicitate the professionals to prescribe the cost effective drug thereby reducing the total cost of the treatment of the patients. According to the Paediatricians this formulary promotes safe and effective use of medicines as it provides necessary information about like indication, precaution, paediatric dose, adverse drug reactions, interactions and practice points. The extent of usage of the formulary was very frequent by the Paediatricians since it avoids consuming the time in referring various resources for the drug information in their daily practice. The information was compiled in such a way that it can be referred very easily whenever required.

Some valuable suggestions were also rendered by the physicians in formulating the formulary like the inclusion of data regarding anaesthetic drugs, antidotes for poisoning, nutritional supplements, newer Anti-Epileptics, Amino glycosides and their safety levels. They commented that formulary has to be reviewed on yearly basis and newer approved drugs (with updated information) have to be included in the formulary. They also appreciated the Clinical Pharmacy services provided in the Paediatric department.

Limitations:

- Lack of availability of some branded drugs at the time of collection of brands from the hospital pharmacy.
- Unavailability of the doctors because of their busy schedule.

Future directions:

- The existing formulary may require further implementation from time to time to inculcate current update on drugs like FDA approved drugs for specific indications, newer brands and generic drugs.
- Further studies are required to assess the attitude of health care professionals towards prescribing practices as per hospital formulary to ensure better patient care.
- Cost effectiveness parameter requires to be added to ensure the provision of cost effective treatment especially for poor patient population and also the poisoning information and nutritional supplements for the paediatrics should be included.

CONCLUSION

The staff and postgraduate students of Department of Paediatrics were highly satisfied with the implemented formulary and appreciated the work that was carried out to a great level. The formulary provides updated unbiased information about the drugs and available brands with cost in the hospital pharmacy. The formulary is handy, user friendly and saves the precious time of busy physician. It also promotes the safe and effective use of medicines thereby

ensuring cost minimisation benefiting the patients. The physicians highly appreciated the pivotal role played by the clinical pharmacists in providing unbiased information and promoting better pharmaceutical care and opined that the services of clinical pharmacist are very much essential to optimise their daily practice.

ACKNOWLEDGEMENTS

We are very thankful to Dr. Shiva Prakash Head, Staff and Postgraduate students of the Paediatric Department, Chief Pharmacist and staff of the hospital pharmacy for their encouragement and support to carry out the study. Also we acknowledge our beloved Principal Dr. B Ramesh for financial support. Due thanks to Medical Superintendent Dr. Vasanth Kumar, AH & RC, Principal Dr. Shivaramu, AIMS. We also thank all the staff and students of Department of Clinical Pharmacy, SAC College of Pharmacy.

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