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Study on the utilization and cost minimisation analysis of antibiotics in paediatric population in a tertiary care teaching hospital

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Abstract
Background: Antibiotics, like any other medicines, may be used inappropriately. A prescriber may choose an inappropriate type of Antibiotic, taking into account the clinical condition, resistance patterns and cost. Incorrect drugs, doses, dose-interval or duration may be prescribed, dispensed or administered. Antibiotics can also be very expensive, and in most facilities they constitute a major portion of the drug budget.
Objective: This study aims to document the use of antibiotics in paediatric wards and classify it according to the World Health Organisation classification which helps in forming future action plans and monitoring in the antibiotic usage and also to reduce the cost consumed by the antibiotic usage.
Materials and Methods: It was a prospective observational study, conducted in the Department of Paediatrics, Rajah Muthiah Medical College Hospital, Chidambaram for a period of six months (November 2017 to April 2018). The study was approved by Institutional Human Ethics Committee. A sample of 50 was collected who were treated with at least one Antibiotic. Demographic details of patients, patients prescribed with antibiotics were recorded; WHO Antibiotic classification was used to classify Antibiotics.
Results: In this study Beta-lactam group of antibiotics was mostly prescribed (69.11%), followed by quinolones (16.17%).one ADR (2%) was observed and reported during the study. The antibiotics prescribed in this study is classified into ACCESS,WATCH and RESERVE group by WHO guidelines, in which 46.96% of antibiotics comes under ACCESS group, 51.37% comes under WATCH group. Cost minimization analysis have been performed only for antibiotics prescribed after the study, by which 18.4% is reduced from actual antibiotic cost and 4.29% overall cost of the prescription can be reduced.
Conclusion: The study shows that 3rd generation cephalosporin was prescribed mostly during the study that comes under WATCH category by WHO, which further emphasises health care professionals to monitor closely, since Antibiotic resistance is a great threat to mankind. This study also shows that the substantial reduction in cost of prescription can be done by performing CMA for antibiotics, which consume 30-40 % of hospital budget.

Keywords: Antibiotics, use pattern, WHO classification, cost minimisation analysis

Introduction
Antibiotics, like any other medicines, may be used inappropriately. A prescriber may choose an inappropriate type of Antibiotic, taking into account the clinical condition, resistance patterns and cost. Incorrect drugs, doses, dose-interval or duration may be prescribed, dispensed or administered. Continuing Antibiotic misuse leads not only to poor patient outcome, unnecessary adverse reactions and wasted resources, but also to emerging resistance of bacteria to Antibiotics. Antibiotics can also be very expensive, and in most facilities they constitute a major portion of the drug budget.
This study aims to document the use of antibiotics in paediatric wards and classify it according to the World Health Organisation classification which helps in forming future action plans and monitoring in the antibiotic usage and also to reduce the cost consumed by the antibiotic usage.
At the Sixty-eighth World Health Assembly (WHA) held in May 2015, Member States adopted the Global Action Plan on Antibiotic resistance and the WHA urged Member States to implement the action plan recognizing this may need to be adapted to specific contexts and national priorities.

The Global Action Plan (GAP) has five objectives

1. Improve awareness and understanding of Antibiotic resistance;
2. Strengthen surveillance and research;
3. Reduce the incidence of infection;
4. Optimize the use of Antibiotic medicines; and
5. Ensure sustainable investment in countering Antibiotic resistance.

Specifically related to objective 4, Member States are requested to provide "stewardship programmes that monitor and promote optimization of Antibiotic use at national and local levels in accordance with international standards in order to ensure the correct choice of medicine at the right dose on the basis of evidence". Thus, an important element of the GAP is monitoring the consumption of Antibiotics. All countries have some data related to the import, procurement, distribution or clinical use of Antibiotics in their communities that can be used as the basis of stewardship and monitoring programs.

Data on the consumption of Antibiotics have a number of uses, including:

- To relate exposure to Antibiotics to the development of Antibiotic resistance;
- To identify and provide early warning of problems relating to changes in exposure and utilization and to develop interventions to address problems identified;
- Monitoring the outcomes of interventions aimed at changing exposure;
- Assessing quality of prescribing against practice guidelines;
- Raising awareness in health professionals, consumers and policy makers about the issues of Antibiotic resistance and the contribution of inappropriate use of Antibiotics in humans.

The Conference of Experts on the Rational Use of Drugs, convened by the World Health Organization (WHO) in Nairobi in 1985, defined rational use as follows:

"The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."

The requirements of the rational use of medicines can be fulfilled only if the process of both prescribing and dispensing is appropriately followed. This includes steps concerned with proper diagnosis, correct prescribing, dispensing, and giving proper information to the patient.

National policies greatly influence how medicines are used. Without a favourable policy framework, it will be very difficult to achieve and maintain improved antibiotic use. The Second International Conference on 'Improving the Use of Medicines' recommended that countries implement national programmes to monitor medicines use and to coordinate implementation of interventions, targeting multiple levels of the health care system in both public and private sectors, to improve use.

Objectives

- To observe the antibiotic use patterns as prescribed in paediatric wards.
- To classify the antibiotics according to The Selection and use of Essential Medicines by WHO.
- To perform cost analysis (CMA) for antibiotics prescribed.
- To provide feedback on the result of this study to the concerned physician.

Methodology

Study Type

Prospective - observational study.

Study Place

The study will be conducted in the department of paediatrics, Rajah Muthiah Medical College Hospital, Annamalai University, Annamalai Nagar, Tamil Nadu.

Study Period

The study will be carried out for a period of six months (November 2017-April-2018).

Study Recruitment Procedures

- The recruitment of subjects will be carried out with the help of physician who has the knowledge of patient's medical history.
- The subjects to be selected are the patients who will be treated as both outpatients and inpatients.
- The study procedure will be completely explained to the patient's caretaker and a patient consent form will be collected from them.
- The patients included in the study will be selected based on inclusion and exclusion criteria.

Inclusion Criteria

- ✓ Patients who were treated as both outpatients and inpatients with at least one Antibiotic.
- ✓ Patients of both the gender.
- ✓ Patients below 12yrs of age.

Exclusion Criteria

- ✓ Patients/Guardians who are not willing to participate.

Study Method

1. Approval from the Hospital authorities and Institutional Human Ethics Committee.
2. The study method involves selection of patients based on the inclusion criteria.
3. Classification of Antibiotics according to WHO.
4. Perform Cost Minimization Analysis.
5. Interpretation of results.
6. Conclusion.
7. Report submission.
8. Collected data will be stored in department library for future reference in the form of thesis book.

Institutional Human Ethics Committee Approval: since the study involves human subjects, the study was approved by the Human Ethics Committee. (IHEC/0319/2016)

Observation and Results

Table 1: Gender wise distribution of the patients enrolled in the study

S. No	Gender	Number of patients	Percentage
1.	Male	31	62%
2.	Female	19	38%
3.	Total	50	100%

A total of 50 children who has been prescribed with at least one antibiotic have been selected for the study. The above table and figure represents the gender wise distribution of the study population, which revealed that 62% of patients were male and 38% patients were female.

Table 2: Age wise distribution of patients enrolled in the study

S. No	Population	Age groups	Male	Female	Total	Percentage
1	New born	Birth to 1 month	0	0	0	0%
2	Infant	1 month to 2 years	9	9	18	36%
3	child	2 years to 12 years	22	10	32	64%

The above table-2 represents the age wise distribution of patients in this study. Out of 50 children maximum number of cases were between 2 years to 12 years i.e. n=32 (64%) in this group majority of them were male (68.75%) patients than female patients (31.25%)

Table 3: Various diseases pattern in paediatric wards during study period

S. no	Diagnosis	Number of cases	Percentage
1	LRTI	15	30%
2	UTI	4	8%
3	Walri	2	4%
4	Seizures	4	8%
5	Cellulitis	4	8%
6	Episodic Wheeze	5	10%
7	AGN	2	4%
8	Asthma	1	2%
9	Pneumonitis	1	2%
10	Add/Dehydration	4	8%
11	Colocolic Intussusception	1	2%
12	H,F,M Disease/Anemia	1	2%
13	Mesenteric Lymphadentitis	2	4%
14	Age	2	4%
15	Cystitis	2	4%

Majority of cases enrolled into the study are LRTI (30%) followed by episodic wheeze (10%) and UTI, seizure, Add/dehydration (8%).

Table 4: Various diseases pattern in paediatric wards by age distribution

S. No	Age Groups	lrti	Wheeze	Seizures	Dehydration	uti
1	Birth to less than 12 months	5	0	0	0	1
2	12 months to less than 5 years	3	4	4	4	2
3	5 years to 12 years	7	1	0	0	1

The above table-4 represents the age wise distribution of disease in the study. The study shows that age group of 12 months to less than 5 years have maximum number of cases which includes LRTI (30%), wheeze (10%), UTI (8%), seizures (8%) and dehydration (8%).

Table- 5: Categories of Antibiotics Prescribed

S. No	Category	No of Prescription	% of Prescription
1	B-Lactamase	20	29.32%
2.	Cephalosporins	27	39.61%
3.	Macrolides	9	13.23%
4	Aminoglycosides	10	14.7%
5.	Quinolones	1	1.47%
6	Oxazolidines	1	1.47%
	Total	68	100%

The above table-6 represents the category of antibiotics prescribed in paediatric ward. Cephalosporins is the common category of antibiotic (39.61%), followed by B-lactams (29.32%) and macrolides (13.23%) and amino glycosides (14.7%).

Table 6: Prescription pattern of Antibiotics

Antibiotics	No of Prescription	% of Prescription
B-Lactamase	20	29.32%
Ampicillin	3	4.41%
Amoxicillin	4	5.8%
Amox + Clav	11	16.17%
Amp + Clox	2	2.94%
Cephalosporins	27	39.61
Cefotaxime	12	17.64%
Ceftriaxone	10	14.7%
Cefpodoxime	4	5.8%
Ciprofloxacin	1	1.47%
Macrolides	9	13.23%
Azithromycin	8	11.76%
Erythromycin	1	1.47%
Aminoglycosides	10	14.7%
Amikacin	7	10.29%
Gentamycin	3	4.41%
Quinolones	1	1.47%
Ofloxacin	1	1.47%
Oxazolidines	1	1.47%
Linezolid	1	1.47%
Total	68	100%

The above table-6 represents the prescribing pattern of antibiotics in paediatric ward. Out of the 50 prescription b-lactam's is the common category of antibiotic, among these cefotaxime (17.64) is the most commonly prescribed antibiotic followed by amoxicillin + clavulanate (16.71%).

Table 7: Antibiotic therapy regimen

Type of therapy	No of prescription	% of prescriptions
Single therapy	28	56%
Dual therapy	13	26%
Triple therapy	8	16%
Quadruple therapy	1	2%

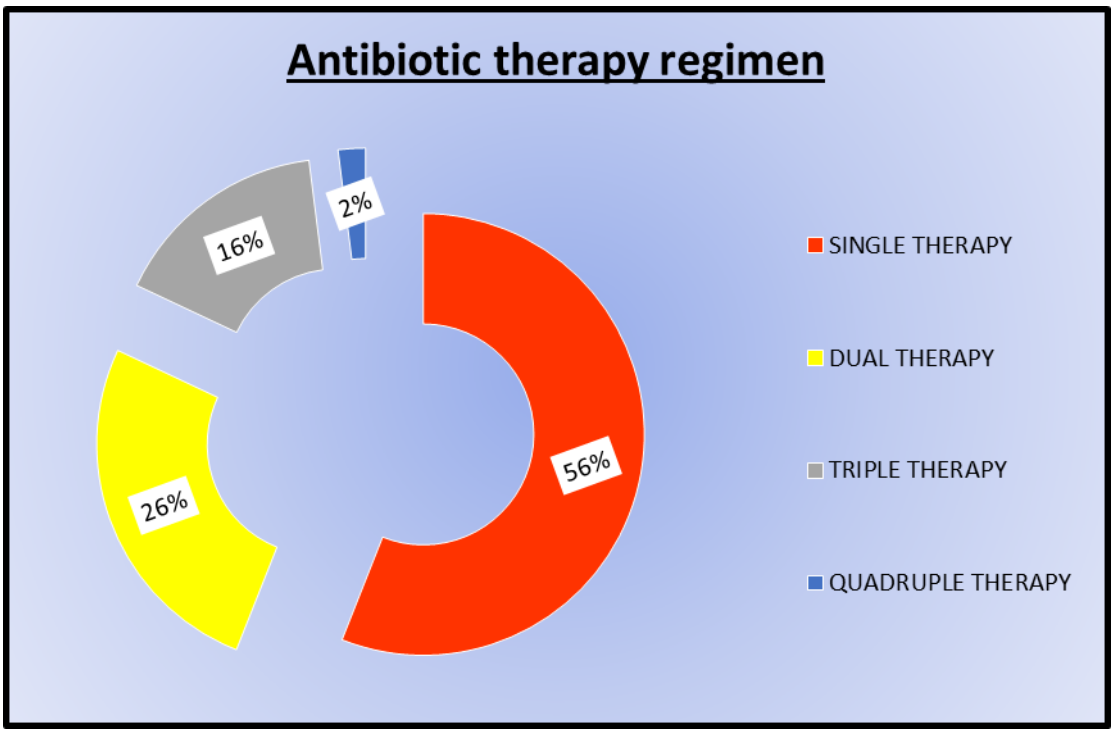

Fig 1: Antibiotic therapy regimen

The above table-7 and figure-1 represents the drug therapy regimen in this study. Out of 50 prescriptions mostly single antibiotic therapies (56%), followed by dual antibiotic therapy (26%) has been observed.

Table 8: Antibiotics frequency and pattern of course of the therapy

Antibiotics	No of Prescription	Min Days	Max Days	Average
B-Lactamase	20			
Ampicillin	3	4	5	4.5
Amoxicillin	4	2	5	4
Amox + CLAV	11	1	6	4
Ampi + Clox	2	3	5	4
Ceohalosporins	27			
Cefotaxime	12	3	8	5
Ceftriaxone	10	3	7	4
Cefpodoxime	4	3	5	7
Ciprofloxacin	1	4	4	4
Macrolides	9			
Azithromycin	8	3	7	4
Erythromycin	1	9	9	9
Aminoglycosides	10			
Amikacin	7	2	7	
Gentamycin	3	7	10	4
Quinolines	1			
Ofloxacin	1	5	5	5
Oxazolidines	1			
Linezolid	1	4	4	4

The above table-8explains the frequency of the antibiotics prescribed in this study and its minimum and maximum course prescribed. In which cefotaxime is averagely prescribed for 5 days (n=12).

Table 9: Antibiotics frequency pattern for various diagnoses

Antibiotics	LRTI	Wheeze	Cellulitis	Seizure
Ampicillin	1			
Cefotaxime			3	3
Ceftriaxone	7			
Cefpodoxime	1	1		
Amox + Clav	6	3		
Ampi + Cloax			1	
Azithromycin	5	1		1
Amikacin	2			
Linezolid			1	

The above table-9 explains the frequency of antibiotics prescribed for various diagnoses from this study. LRTI is mostly ceftriaxone (33.33%), amoxicillin + clavulanate (28.57%) and azithromycin (23.80%).

Table 10: Average no of days hospitalized with diagnosed condition

Disease	No of Cases Out of 50 Cases	% of Prevalence	Average No of Days Hospitalized
LRTI	15	30%	5 Days
Wheeze	5	10%	4 Days
Cellulitis	4	8%	4 Days
Seizure	4	8%	4 Days

The above table-10 explains about the average number of days a patient is hospitalized with a diagnosed disease/condition in this study. Where (30%) LRTI patients of total study hospitalized averagely for 5 days.

Table 11: Adverse drug reaction associated with drug therapy

Total no of Patients	No of ADRS Identified
50	1(2%)

One ADR was observed during this study which was due to the antibiotic (amoxicillin+clavulanate) caused diarrhoea and patient recovered when the antibiotic was changed.

Adverse Drug Reaction

Out of 50 patients enrolled in our study 1 patient (2%) experienced adverse drug reaction. The observed adverse drug reaction was rated as 'Possible' on the Naranjo Scale For Casuality Assesment.

Table 12: Antibiotics Categorized by "The Selection and Use of Essential Medicines" by Who Expert Committee, 2017

Catogery	Antibiotic	Frequency
Access (46.96%)	Amikacin	7
	Ampicillin	3
	Amoxicillin	4
	Metronidazole	2

	Gentamycin	3
	Amox + Clav	11
	Ampi + Aclox	2
Watch (51.37%)	Azithromycin	8
	Cefotaxime	12
	Ceftriaxone	10
	Ciprofloxacin	1
	Erythromycin	1
	Ofloxacin	1
Reserve (1.47%)	Linezolid	1

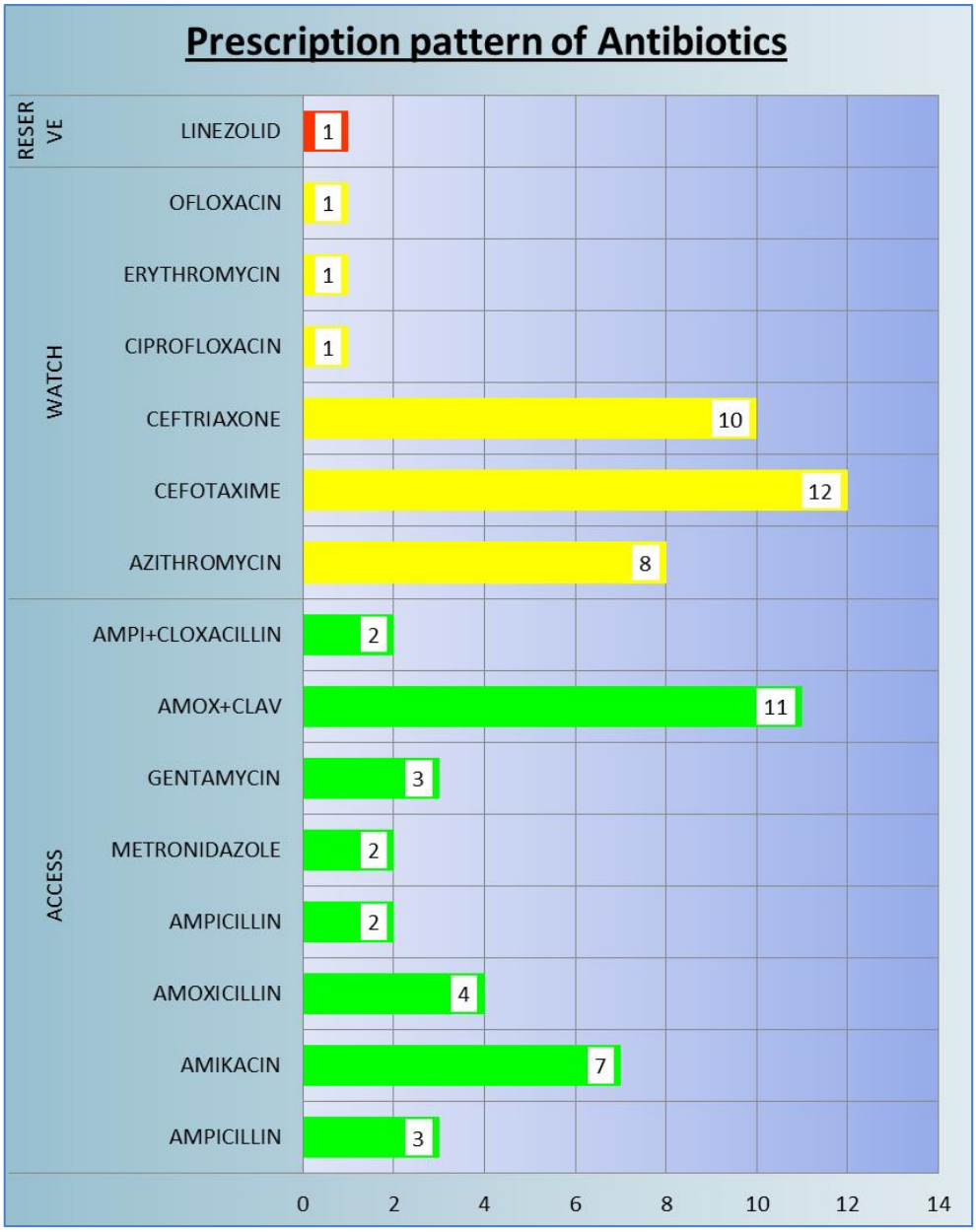

Fig 2: Antibiotics Categorized by "The Selection and Use of Essential Medicines" by Who Expert Committee, 2017

The above table-12 & figure-2 shows how the antibiotics prescribed out of 50 cases has been classified according to the selection and use of essential medicines by WHO expert committee-2017.

Table 13: Cost Minimization Analysis

CMA	Cost Excludind Antibiotics	Cost of Antibiotics	Total
Cost of Medicines	29855	14462	44317
Average Cost of 1 Prescription	597.1	289.24	886.34
Percentage %	67.36%	32.63%	100%
Cost After CMA	29855	11804.01	41695
Average Cost of 1 Prescription after CMA	597.1	236.08	833.1
Percentage %	71.67%	28.33%	100%

The above table-13 shows that overall prescription amount is 44317.00 in which antibiotic consumes 14462.00 (32.63%), the average cost of single prescription is 886.34 and antibiotic cost of single prescription is 289.24. cost minimization analysis is done for antibiotics prescribed and actual cost of prescription 14462.00 is reduced to 11804.01 i.e. antibiotic cost is reduced by 18.4%.the over all cost of prescription is reduced to 4.29%.

Discussion

An attempt was made to study the patterns of antibiotics use in paediatric wards. A total of 50 patients were enrolled into the study based on the common disease conditions observed in paediatric wards. Patients between 4-weeks to 12 years of age were taken into study and majority of the patients enrolled (64%) were between 2 years - 12 years of age. Patients were enrolled in the study irrespective of their gender and majority of the patients were males (62%).The average number of days of a patient gets hospitalised is 4 days. n our study, prevalence of LRTI during the study period is (30%) followed by episodic wheeze (10%).Different types of antibiotic regimen used for treatment in paediatric patients were studied out of which single antibiotic (56%) was frequently used. In this study B-lactam's group of antibiotics was mostly prescribed (69.11%), followed by quinolones (16.17%).one ADR (2%) was observed and reported during the study. The antibiotics prescribed in this study is classified into ACCESS, Watch and Reserve group by WHO guidelines, in which 46.96% of antibiotics comes under ACCESS group, 51.37% comes under Watch group followed by 1.47% of antibiotics prescribed comes under Reserve category. Cost minimization analysis have been performed only for antibiotics prescribed after the study, by which 18.4% is reduced from actual antibiotic cost and 4.29% overall cost of the prescription can be reduced.

Conclusion

- The study shows that 3rd generation cephalosporins was prescribed mostly during the study that comes under WATCH category by WHO, which further emphasises health care professionals to monitor closely, since Antibiotic resistance is a great threat to mankind.
- This study also shows that the substantial reduction in cost of prescription can be done by performing CMA for antibiotics, which consume 30-40 % of hospital budget.

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