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STUDY OF THERAPEUTIC OUTCOMES OF DIFFERENT DRUG THERAPIES AND THEIR PHARMACO ECONOMICS IN PEDIATRICS

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ABSTRACT:
Background: Pharmacoeconomics can be defined as "the field of study that evaluates the behavior of individuals, firms, and Markets relevant to the use of pharmaceutical products, services, and programs, and which frequently focuses on the costs (inputs) and consequences (outcomes) of that Use". The main aim of the study was to observe the patient's pharmaceutical treatment outcome and pharmaceutical cost using Pharmacoeconomic analysis. The main objective of the study was to observe the direct, indirect costs of investing in pediatric patients along with their therapeutic outcomes using the assessment scales'
Methods: This was a prospective, observational study carried out using 108 subjects with age groups between 1-15 years. By using statistical analysis the direct and indirect costs (cost of medicines including in-pocket and out-pocket costs and loss of wages) were calculated based on different factors (age, gender, disease conditions).
Results: The average direct cost invested in the management of different diseases was 67511.785±48083.335 INR. The average indirect cost invested in the management of different diseases was 73746.666± 70712.9414 INR. The study population consisted of 108childrendiagnosed with different diseases: 47.22% of the children were girls, while 52.77% were boys.Thetherapeuticoutcomeandmanagementdataof differentdiseaseswere:Blooddisorders100%,viral pyrexia 76%, respiratory diseases 90%, neurological disorders 56%, and other conditions71%.
Conclusion: On observation, we concluded that the therapeutic outcome of more than 80% of children got better clinical outcomes for the cost invested. Only less than 15% of the children hadn't got any therapeutic outcome and that was due to either patient-related problems or drug-related problems.

Keywords: Pharmacoeconomics, Pharmacoeconomic analysis, direct cost, indirect cost, therapeutic outcome, consequences, patient-related problems, drug-related problems.

I. INTRODUCTION:

In pharmacoeconomics, the most widely used concept is efficiency which serves as the principle to design useful strategies to buy pharmaceuticals that have greater benefits [1]. Now a days the cost of pharmaceuticals is increasing rapidly, so to control such a rise in the costs economic evaluations are being used widely by various bodies like governments, managed care groups [20]. In most of the countries the costs on pharmaceutical products accomplish for 10% and in some countries it may be up to 30% of the total health care costs [6]. Though clinical trials reveal the efficacy andsafetyofthedrugsitisdifferenttodecideontheuseof drugsintherealworldfortreatment.Sopharmacoeconomic evaluations are used to make such decisions [4]. Pharmacoeconomics started developing in the 1970s. The concepts of cost-benefit analysis and cost-effective analysis were first introduced by Mc.Ghan, Rowland, and Bootman in 1978. The term pharmacoeconomics was first used in a presentation published by Townsend in 1986[1, 10]. It is somewhat difficult to analyze and to understand the basic drug pharmacology and toxicology in the pediatric population at stages of their age. Nowadays the reisascarcity of health care and its associated resources, so to allocate these resources by comparing their costs and benefits can only be achieved by the use of a good analyzing tool like pharmacoeconomics analysis [7].

Types of pharmacoeconomics evaluations:
There are different types of pharmacoeconomics evaluations and they are:-

- Cost-Benefit Analysis

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- Cost-Effectiveness Analysis
- Cost-Minimization Analysis
- Cost-Utility Analysis
- Cost-Consequences Analysis[7,1,3,10]

Cost-Benefit Analysis: Cost-benefit analysis is a tool used to analyze and choose better alternatives by comparing the benefits including the parameters like labor, time, and cost [19]. The CBA expresses both costs and consequences in the terms of monetary units [13, 19,10]. In general, CBA compares programs or interventions that show different outcomes and calculate them as a cost to benefit ratio [3, 2, and 19]. CEA and CUA are preferred over CBA as it is difficult to measure the consequences in terms of monetary units [13]. So the technique namely "willingness to pay" is generally used to determine or to calculate the life-years gained [11].

Cost-Effectiveness Analysis: Effectiveness can be termed as the performance of a drug or a treatment under normal circumstances or in the real world [4]. CEA aims at the estimation of costs that are necessary to achieve a health benefit [12]. It mainly compares the cost of interventions or programs having standardized units of effectiveness [3,2]. Wonderling defined CEA as both an economical and management tool to analyze the alternative which is highly cost-effective [19].It is generally given in a formula as:

Cost effectiveness ratio=Cost/Outcome

It can thus be expressed in terms of incremental cost –effectiveness ratio i.e.

ICER= (Cost of Drug 2) – (Cost of Drug 1) / (Effectiveness of Drug 2) – (Effectiveness of$_{Drug1)}$[19,11]

Cost-Minimization Analysis: Cost-Minimization Analysis is also called cost identification analysis [19]. It is useful to compare alternatives having similar outcomes and chooses the cheapest alternatives [3,2]. CMA can be applied at two levels namely micro and macro where the comparison is done considering the cost of two drugs with equivalent action and examination of other factors like health budget, income status, etc., along with the cost comparison respectively [19]. The costs that are involved in CMA depend on perspectives like societal perspectives include costs of health services, costs imposed on patients and their families, etc.[14]. CMA is used to compare drugs that are therapeutic and generic equivalents [11].An endpoint can be defined as the complete outcome that is to be measured by a clinical trial [9]. But in the case of CMA, it is not possible to get a particular endpoint during RCT because there is no guarantee that the drugs to be compared will have equivalent action [11].

Cost-Utility Analysis: At present, the best method to allocate health resources is cost-utility analysis [15]. CMA is used to compare the cost of a program or procedure with the improvised health [11]. It is generally measured in terms of quality-adjusted life years(QALY) that is life years gained due to a particular program or procedure, disability-adjusted life years (DALY)[15,19]. QALY is generally measured using a scale named Rosser index scale that has readings in the limits of 0 and 1, where 0 indicates death and 1 indicates a perfect life [10].

ICER=$C_2 – C_1/QALY_2 – QALY_1$ [11]

Cost-Consequence Analysis: Cost consequence analysis is defined as pharmacoeconomics analysis which evaluates both costs and outcomes of all alternatives and lists them separately. Unlike CEA and CUA it does not give an accurate cost-outcome ratio [5]. It is also defined by Russell as an analysis in which costs and outcomes are listed separately but they are not aggregated into QALY and cost-effectiveness ratio [8].

Costs comprising PE evaluations:

The costs involved in pharmacoeconomics evaluations are:

Direct cost: It is defined as the costs that are directly related to the health care interventions. They include hospitalization costs, physician fees, cost of medicines, etc.[10,16,5].

Indirect cost: indirect costs include loss of productivity in the economy. It includes loss of wages, loss of time due to hospitalization, and transportation charges, etc. It can be calculated using two methods names human capital approach method and friction cost method [5].

Intangible cost: It is not exactly a cost that is it is not calculated in terms of monetary units but can be calculated in terms of quality of life. These costs include pain, anxiety, depression, and distress that are suffered by patients and their families [10,16].

Perspectives:

There are generally 4 perspectives in pharmacoeconomics evaluations

Patient's perspective: As patients are the ultimate consumers their perspective is also considered mostly. Generally, patients prefer to buy medicines that are of low cost and having better efficacy [17].

Provider perspective: Generally providers include

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hospitals, private- practicing doctors, etc. They are the ultimate providers of a product or service. So they prefer to charge more amounts regardless of patients' economy [17].

Payer perspective: Payers include trustee hospitals, government hospitals, and insurance companies that afford patients' treatment and other services. They generally give reimbursement to the patients [17,18].

Societal perspective: The direct and indirect costs are theoretically measured in the perspective of society. Generally, it includes costs of patient's morbidity and mortality, cost of investing on medical care [17,18,10].

II. MATERIALS AND METHODS:

Study design: It is a prospective, observational and open labelled study.

Sample size and recruitment: This study included a sample size of 108 patients. After getting permission from the institutional ethics committee of GGH, cases were collected according to the requirements of criteria.

Study place: This study was conducted in the department of pediatrics in GGH Srikakulam.

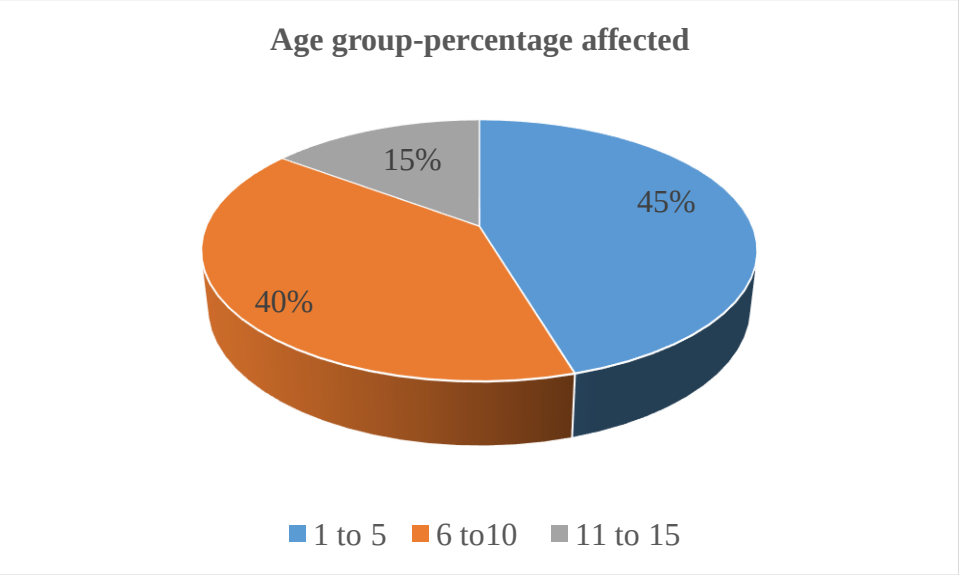
Study duration: This study was conducted over a period of 6 months.

Materials: Wong-Baker pain scale, Fever Assessment Tool, Respiratory Severity Rubric, Seizure severity Questionnaire, Indian pediatrics consent form, patient profile forms.

Statistical methods: The results of the study were calculated by using chi-square test and descriptive analysis (Mean±SD) in Microsoft excel sheet.

III. RESULTS:

Demographic results:



(Fig.1depicts the percentage of different age groups affected with different diseases)

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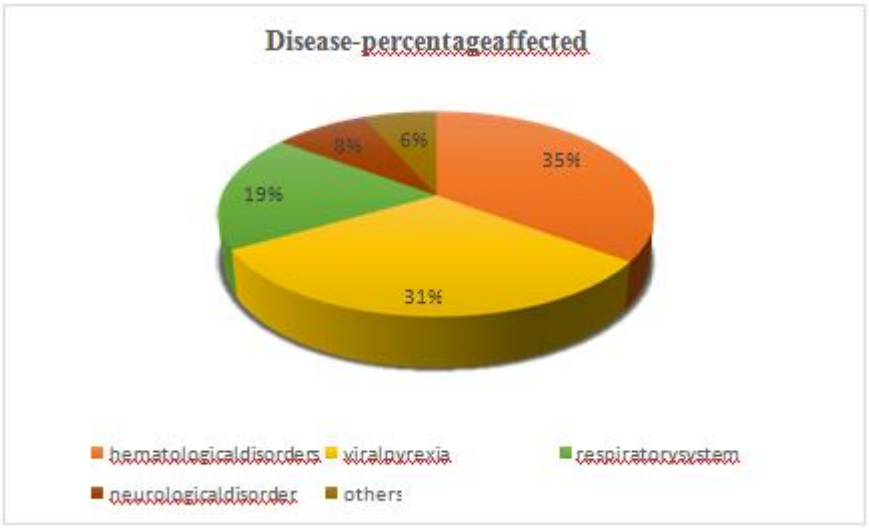
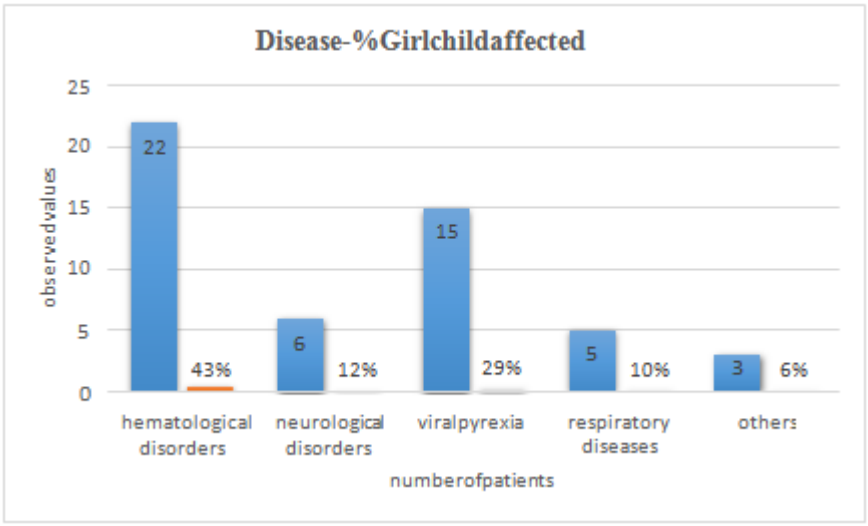


(Fig.2depicts the percentage of different diseases affected in children)



(Fig.3indicates the percentage of girl children affected with different diseases)

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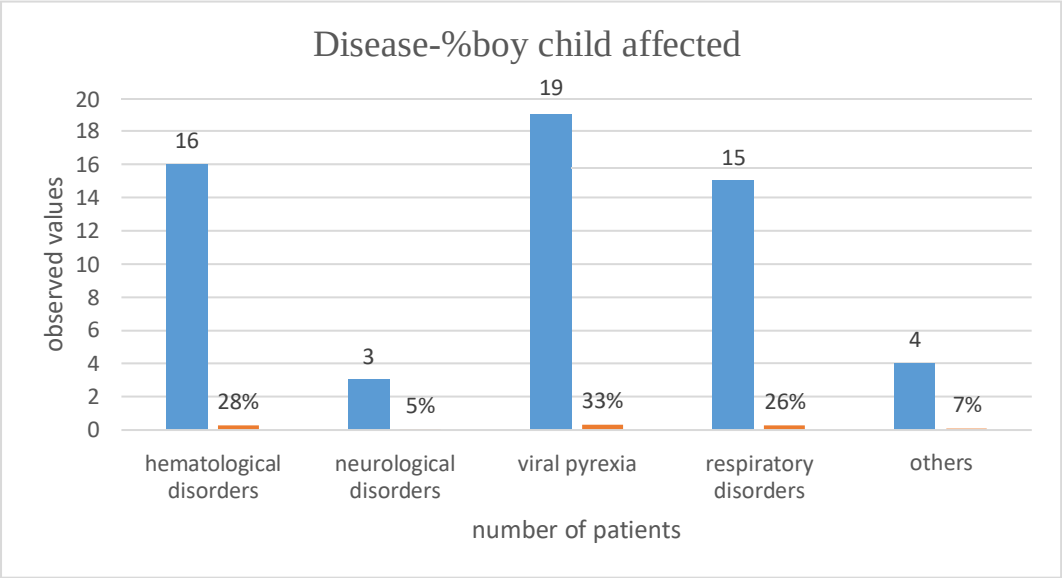
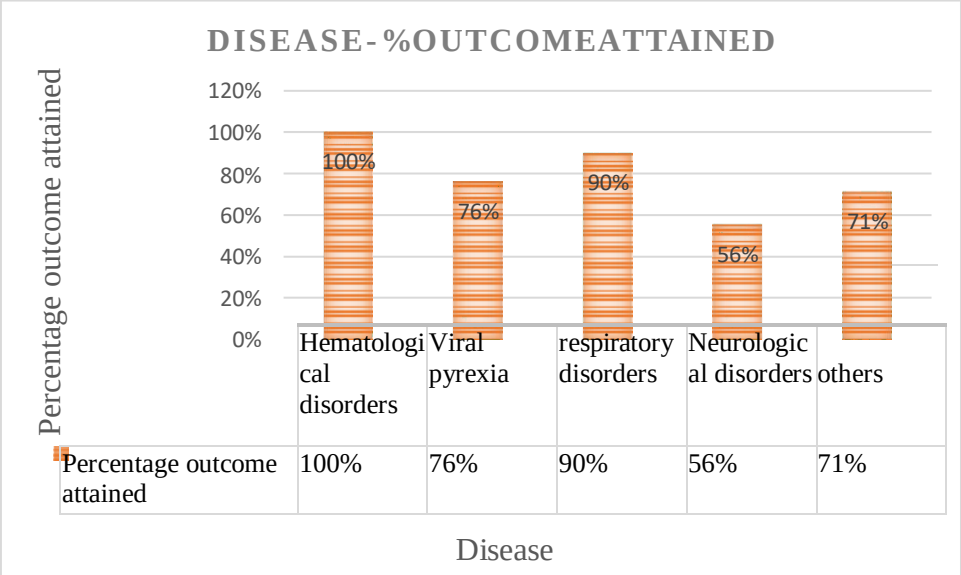


(Fig.4shows the percentage of boys affected with different diseases)

Therapeutic outcomes:



(Fig.5shows the percentage of outcome attained in different diseases)

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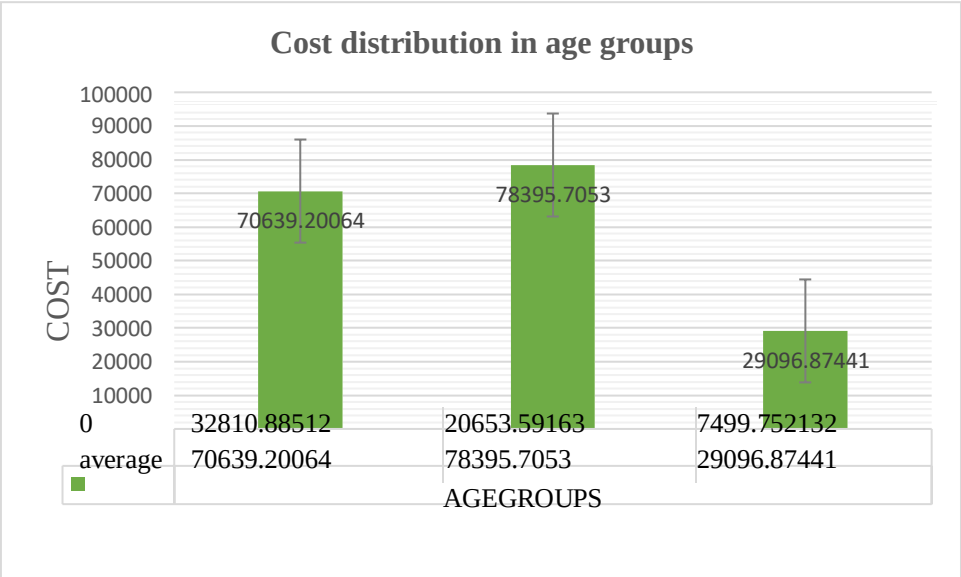
Disease	Number of cases	Percentage affected	Outcome attained	Percentage benefited	P value for outcome attained	Cost invested on each disease(INR)
Hematological	38	35	38	100	0.8	130700.442
Viral pyrexia	34	31	26	76		128955.875
Respiratory	20	19	18	90		56529.020
Neurological	9	8	5	56		20257.086
Miscellaneous	7	6	5	71		18820.171

(Table.1shows data regarding number of patients affected with different diseases along with their percentages and outcomes, cost invested in different diseases and chi-square value for outcome-attained)

Economic outcomes:



(Fig.6shows the distribution of costs among different age groups i.e.1-5, 6-10, 11-15years respectively.)

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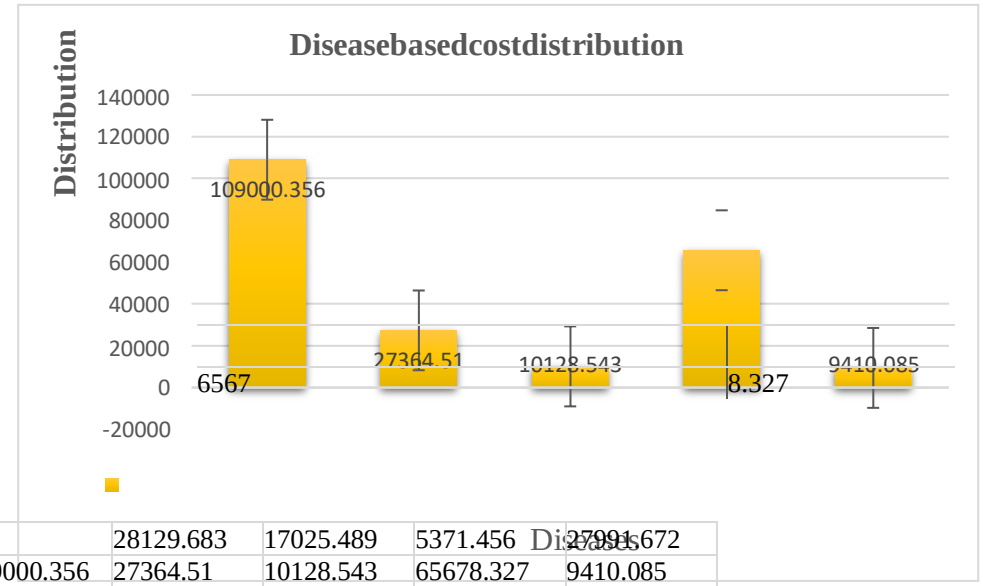
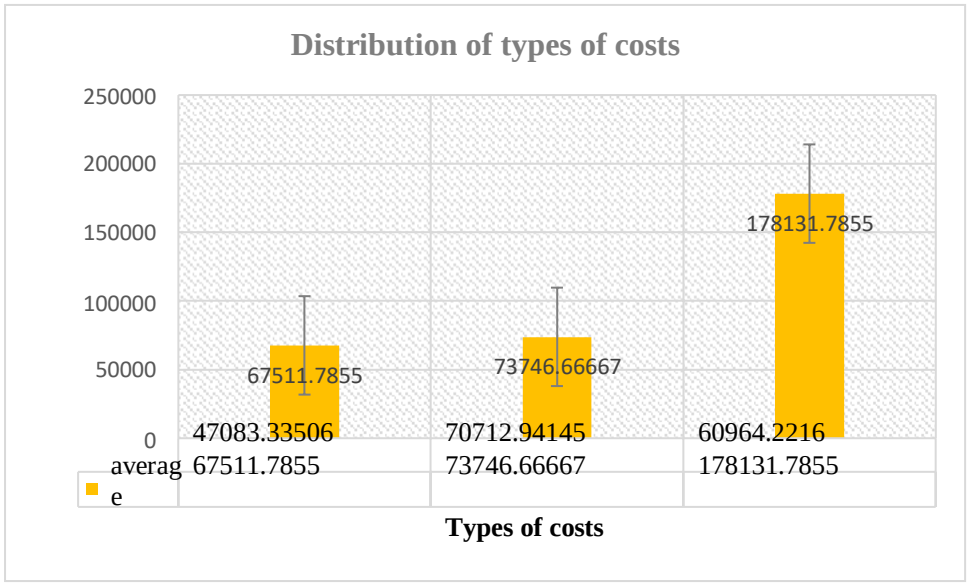


	SD	28129.683	17025.489	5371.456	27991.672
mean	109000.356	27364.51	10128.543	65678.327	9410.085

(Fig.7shows the cost distribution in different diseases like hematological, respiratory, neurological, viral pyrexia, miscellaneous diseases respectively.)



(Fig.8shows the distribution of different types of costs along with total cost i.e. direct, indirect, total costs respectively.)

Cost

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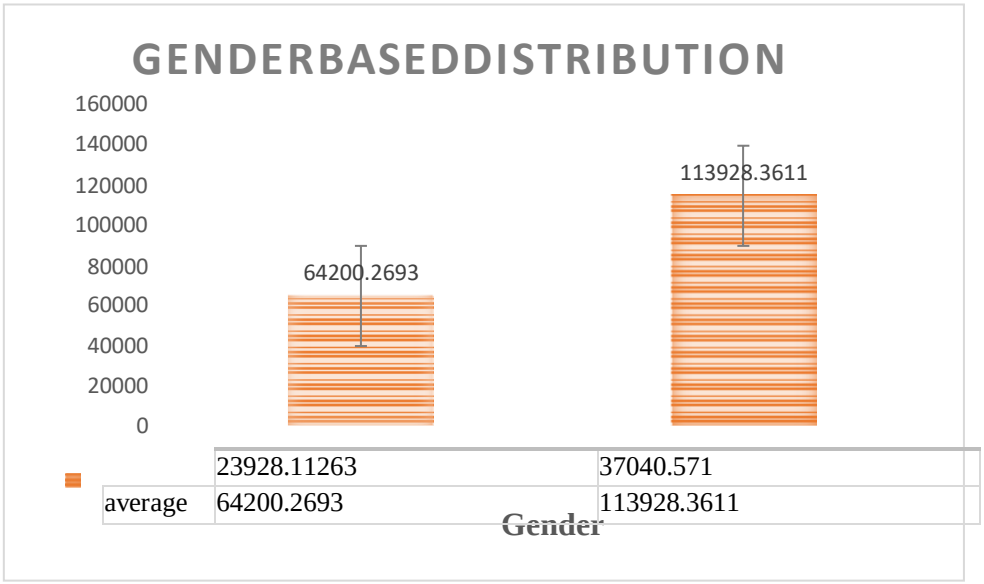

(Fig.9shows the distribution of costs in different genders like boy children and girl children respectively.)

IV. DISCUSSION:

This is the type of pharmacoeconomics study that was conducted from the perspective of both the payers and society in the pediatric population in Srikakulam. This study in the government general hospital included different diseases affected in the pediatric population. We collected the data regarding drugs used in pediatrics along with their costs from the central drug store of GGH using the RTI act. More than 40% of the children affected were under the age of 5 years. More than50% of the children affected were males. More than 33% of the children were affected by hematological disorders and children affected with viral fever were nearly30%. The children with blood disorders were mostly affected by thalassemia and sickle cell anemia, they cannot be cured but they were managed by regular blood transfusions. Hence these conditions were managed successfully having a 100% outcome. The least outcome attained conditions were neurological disorders having an outcome percent of 56%. The cost analysis depicted that indirect cost (cooli, farmer, others) accounted for the maximum cost as compared to direct cost. The cost that had been invested in children with age groups between 6 to 10 years was more than the cost that had been invested in children with other age groups. The cost that had been invested in females was more than the cost that been invested in males. The total costs of treating different diseases in children in a government hospital are approximately 178131.785±60964.221 INR. The costs that were afforded to children of age group between 6 to10 are approximately 78395.705±20653.591 INR. The costs that were afforded to female children are approximately 113928.361±37040.571 INR. The indirect cost that was afforded by children is approximately 73746.666±70712.941 INR.

As the hospital is a government hospital, there are no costs for physician visits and negligible charges for the nurses. The direct costs like medical costs, cost invested in laboratory tests, etc. were invested by the government, hence there is no burden on the patient's family. So, the direct cost burden falls on patient families only when they buy the medicines from outside or when they perform the lab investigations away from the hospital. The indirect cost includes loss of wages, loss of school days, traveling charges, etc. were invested by the patients' families. The most widely bought outside medication by the patient representatives throughout this study was “Paracetamol Infusion”. This study includes the consideration of both direct and indirect costs which were invested by both government and patients' family and the in-pocket cost which is invested by the patients' family on buying medicines from outside or performing lab investigations away from the hospital which is also a part of direct cost, thus this study regards the perspective of both payers and society. The parameters that were considered in the direct cost were only the medication cost and in the indirect

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cost were only the loss of wages of the patients' representative. Therapeutic outcome was calculated using different assessment scales and the outcomes were compared to cost invested, through the principle of time horizon that is every disease gets cured within a specific period, for example, viral pyrexia and respiratory diseases can be cured within 3-5 days after hospitalization. So, we observed the time horizon and compared the costs to know whether the patient was beneficial with the treatment. The limitations of this study are the small sample size and consideration of fewer parameters, not taking of cases with complications which could create bias in the results. This study observes the percentage outcome attained but doesn't give the exact reason for non-outcome. It just gives an idea that patient-related problems or drug-related problems may be the cause of the non-outcome.

The calculations of this study were done using the descriptive analysis method (Mean± SD) and the chi-square test was used to determine the p-value. The p-value of this study was found to be0.8481it isintherangebetween0and1.Thelevelofsignificance was0.05.Ifthevalueisgreaterthan the level of significance, then the hypothesis is accepted. As our p-value is greater than the level of significance our hypothesis is accepted.

V. CONCLUSION:

In our study, we concluded that boys were more prone to diseases than girls. But the cost invested on girls was more than the cost invested on boys. Most of the children were affected by blood disorders. Viral pyrexia stands next to blood disorders. The cost invested on blood disorders was more than the cost invested on others because the blood bags required for blood transfusions were mostly supplied by the government along with the cost needed for compatibility tests. The indirect cost invested was more than the direct cost because the traveling charges of patient representatives were greater than the direct cost that was invested by the government. While observing the therapeutic outcome more than 80% of the children got better clinical outcomes for the cost invested. Only less than 15% of the children hadn't got a therapeutic outcome. The study concludes that the reason for non-outcome chronic diseases may be due to patient-related problems and in acute conditions was maybe due to drug- related problems. This is one of the limitations of the study. As the study mainly focuses on cost and outcomes it helps the payer to frame a better hospital formulary.

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