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

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ABSTRACT:
Background: Pharmacoeconomicscanbedefinedas"t hefieldofstudythatevaluatesthebehaviorof individuals, firms, and Markets relevant to the use of pharmaceutical products, services, andprograms,andwhichfrequentlyfocusesonthecosts (inputs)andconsequences(outcomes)ofthat use". The main aim of the study was to observe the patient's pharmaceutical treatment outcomeand pharmaceutical cost using Pharmacoeconomic analysis. The main objective of the study wasto observe the direct, indirect costs of investing in pediatric patients along with their therapeuticoutcomesusingtheassessmentscales'
Methods: This was a prospective, observational study carried out using 108 subjects with agegroups between 1-15 years. By using statistical analysis the direct and indirect costs (cost ofmedicines including in-pocket and out-pocket costs and loss of wages) were calculated based ondifferentfactors (age,gender,disease conditions).
Results: Theaveragedirectcostinvestedinthemanage mentofdifferentdiseaseswas67511.785±48083.335 INR. The average indirect cost invested in the management of differentdiseases 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% ofchildren got better clinical outcomes for the cost invested. Only less than 15% of the childrenhadn't got any therapeutic outcome and that was due to either patient-related problems or drug-relatedproblems.
Keywords: Pharmacoeconomics,Pharmacoeconomi csanalysis,directcost,indirectcost,therapeuticoutco me,consequences,patient-related problems,drug-related problems.

I. INTRODUCTION:
In pharmacoeconomics, the most widely used concept is efficiency which serves as the principletodesignusefulstrategiestobuypharmaceutic alsthathavegreaterbenefits[1]. Nowadaysthecostofpharmaceuticalsisincreasingrapi dly,sotocontrolsuchariseinthecostseconomicevaluati onsare being used widely by various bodies like governments, managed care groups [20]. In most ofthe countries the costs on pharmaceutical products accomplish for 10% and in some countries itmay be up to 30% of the total health care costs [6]. Though clinical trials reveal the efficacy andsafetyofthedrugsitisdifferenttodecideontheuseof drugsintherealworldfortreatment.Sopharmacoecono mic evaluations are used to make such decisions [4]. Pharmacoeconomics starteddeveloping in the 1970s. The concepts of cost-benefit analysis and cost-effective analysis werefirstintroducedbyMc.Ghan,Rowland,andBoot manin1978.Thetermpharmacoeconomicswasfirstus edinapresentationpublishedbyTownsendin1986[1,10]. Itissomewhatdifficulttoanalyzeandtounderstandtheb asicdrugpharmacologyandtoxicologyinthepediatricp opulationatstagesoftheirage.Nowadaysthereisascarc ityofhealthcareanditsassociatedresources,sotoalloca tethese resources by comparing their costs and benefits can only be achieved by the use of a goodanalyzingtoollikepharmacoeconomics analysis[7].

Typesofpharmacoeconomicevaluations:
Therearedifferent typesofpharmacoeconomicevaluationsandtheyare:-

- Cost-BenefitAnalysis
- Cost-EffectivenessAnalysis
- Cost-MinimizationAnalysis
- Cost-UtilityAnalysis
- Cost-ConsequencesAnalysis[7,1,3,10]

Cost-Benefit Analysis: Cost-benefit analysis is a tool used to analyze and choose betteralternativesbycomparingthebenefitsincludingtheparameterslikelabor, time,andcost [19].The CBA expresses both costs and consequences in the terms of monetary units [13,19,10].Ingeneral,CBAcomparesprogramsorinterventionsthatshowdifferentoutcomesandcalculate them as a cost to benefit ratio [3,2,19]. CEA and CUA are preferred over CBA asit is difficult to measure the consequences in terms of monetary units [13]. So the techniquenamely "willingness to pay" is generally used to determine or to calculate the life-yearsgained[11].

Cost-Effectiveness Analysis: Effectiveness can be termed as the performance of a drug oratreatmentunder normalcircumstancesorintherealworld[4].CEAaimsat theestimationof costs that are necessary to achieve a health benefit [12]. It mainly compares the cost ofinterventions or programs having standardized units of effectiveness [3,2]. WonderlingdefinedCEAasbothaneconomicalandmanagement tooltoanalyzethealternativewhichishighlycost-effective [19].Itisgenerallygiveninaformula as:

Costeffectivenessratio=Cost/Outcome
Itcanthusbeexpressedintermsofincrementalcost-effectivenessratioi.e.
ICER= (Cost of Drug 2) – (Cost of Drug 1) / (Effectiveness of Drug 2) – (Effectiveness of $Drug_1$)[19,11]

Cost-Minimization Analysis: Cost-Minimization Analysis is also called cost identificationanalysis [19]. It is useful to compare alternatives having similar outcomes and chooses thecheapest alternatives [3,2]. CMA can be applied at two levels namely micro and macrowherethecomparisonisdoneconsideringthecostoftwodrugswithequivalentactionandexamination of other factors like health budget, income status, etc., along with the costcomparison respectively [19]. The costs that are involved in CMA depend on perspectiveslike societal perspectives include costs of health services, costs imposed on patients andtheir families, etc.[14]. CMA is used to compare drugs that are therapeutic and genericequivalents[11].Anendpointcanbedefinedasthecompleteoutcomethatistobemeasuredby a clinical trial [9]. But in the case of CMA, it is not possible to get a particular endpointduring RCT because there is noguarantee that the drugs to be compared will haveequivalentaction[11].

Cost-UtilityAnalysis:Atpresent,thebestmethodtoallocatehealthresourcesiscost-utilityanalysis [15]. CMA is used tocompare the cost of a program or procedure with theimprovised 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-adjustedlifeyears(DALY)[15,19].QALYisgenerallymeasuredusingascalenamedRosserindexscalethathasreadingsinthelimitsof0and1,where0indicatesdeathand1indicatesa perfectlife[10].

$$ICER = C_2 - C_1/QALY_2 - QALY_1 [11]$$

Cost-Consequence Analysis: Cost consequence analysis is defined as pharmacoeconomicanalysiswhichevaluatesbothcosts andoutcomesof all alternativesandliststhemseparately. Unlike CEA and CUA it does not give an accurate cost-outcome ratio [5]. It isalsodefinedbyRussellasananalysisinwhichcostsandoutcomesarelistedseparatelybuttheyare notaggregatedintoQALYandcost-effectiveness ratio[8].

CostscomprisingPEevaluations:
Thecostsinvolvedinpharmacoeconomicevaluationsare:
Directcost:Itisdefinedasthecoststhataredirectlyrelatedtothehealthcareinterventions.Theyincludehospitalizationcosts,physicianfees,costofmedicines,etc.[10,16,5].
Indirectcost:indirectcostsincludelossofproductivityintheeconomy.Itincludeslossofwages,loss of time due to hospitalization, and transportation charges, etc. It can becalculated using two methods names human capital approach method and friction costmethod[5].
Intangiblecost:itisnotexactlyacostthatisitisnotcalculatedintermsofmonetaryunitsbutcan be calculatedin terms of quality of life.These costs include pain,anxiety,depression,anddistressthataresufferedbypatientsandtheirfamilies[10,16].

Perspectives:

Therearegenerally4perspectives inpharmacoeconomicevaluations

Patient's perspective: As patients are the ultimate consumers their perspective is alsoconsidered mostly. Generally, patients prefer to buy medicines that are of low cost andhavingbetterefficacy[17].

Provider perspective: Generally providers include hospitals, private- practicing doctors,etc. They are the ultimate providers of a product or service. So they prefer to charge moreamountsregardless ofpatients'economy[17].

Payer perspective: Payers include trustee hospitals, government hospitals, and insurancecompaniesthataffordpatients'treatmentand otherservices.Theygenerallygivereimbursementtoth epatients[17,18].

Societalperspective:Thedirectandindirectcostsare theoretically measuredin theperspective of society. Generally, it includes costs of patient's morbidity and mortality,costofinvestingonmedicalcare[17,18,10].

II. MATERIALS AND METHODS:

Studydesign:Itisaprospective,observationalandopen labelledstudy.

Sample size and recruitment: This study included a sample size of 108 patients. After gettingpermissionfromtheinstitutionalethicscommit teeofGGH, caseswerecollected according totherequirementsofcriteria.

Studyplace:Thisstudywasconductedinthedepartmen t ofpediatricsinGGHSrikakulam.

Studyduration:Thisstudywasconductedoveraperiod of6months.

Materials: Wong-Baker pain scale, Fever Assessment Tool, Respiratory Severity Rubric, SeizureseverityQuestionnaire,Indianpediatricsconse ntform,patientprofileforms.

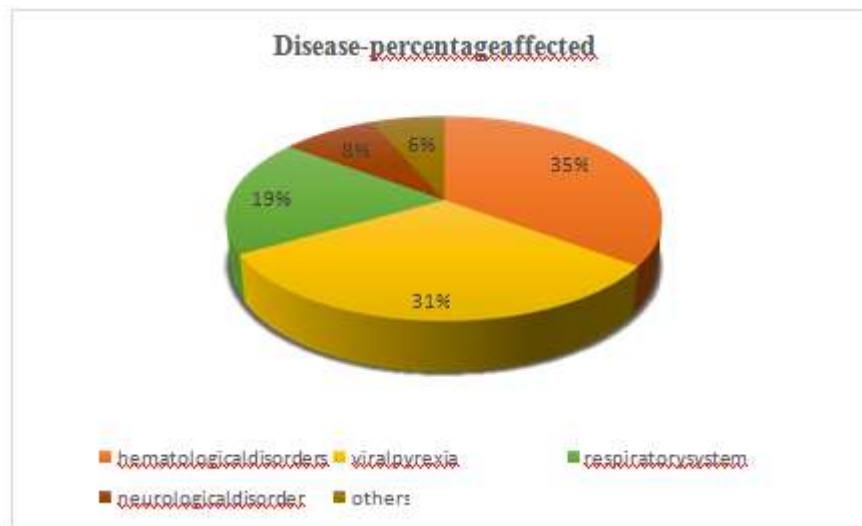Statisticalmethods:Theresultsofthestudywerecalcul atedbyusingchi-squaretestanddescriptive analysis (Mean±SD)inMicrosoftexcelsheet.

III. RESULTS:
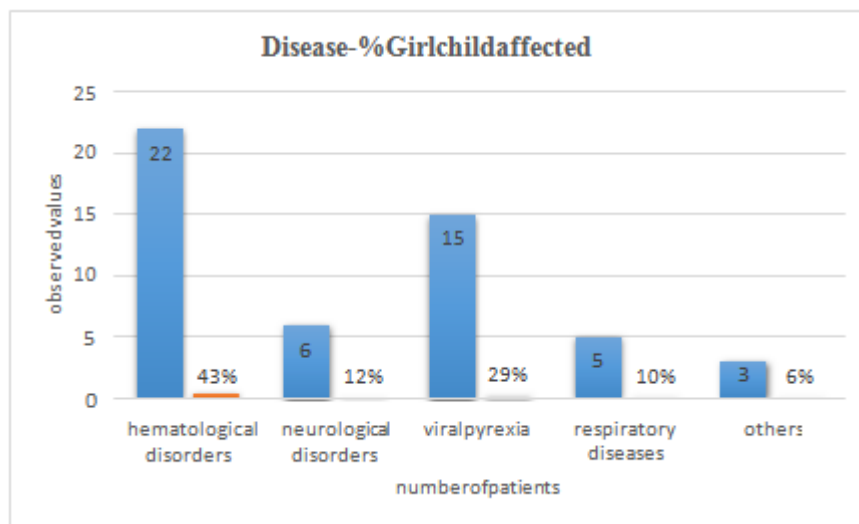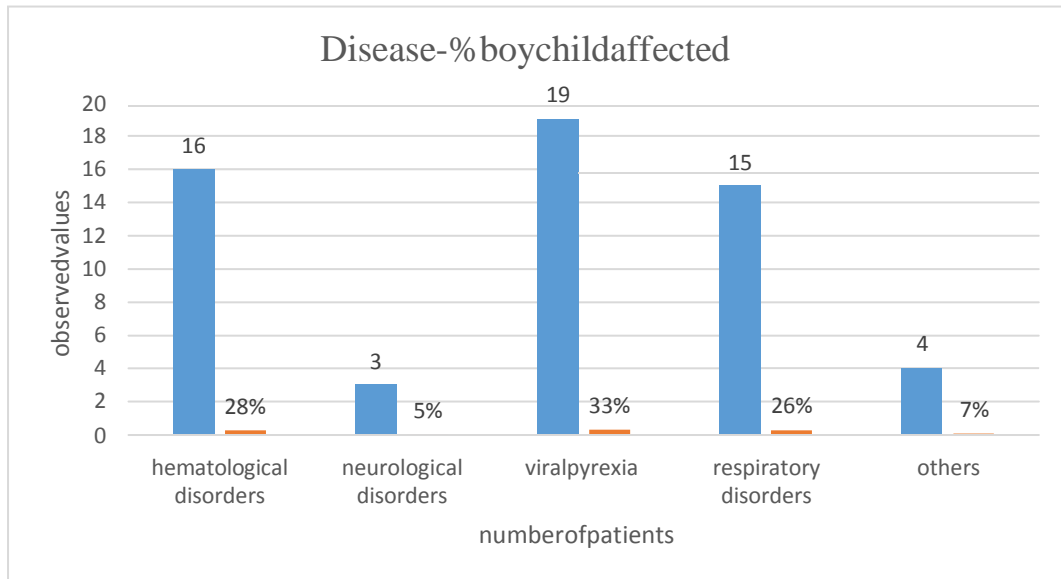
Demographicresults:
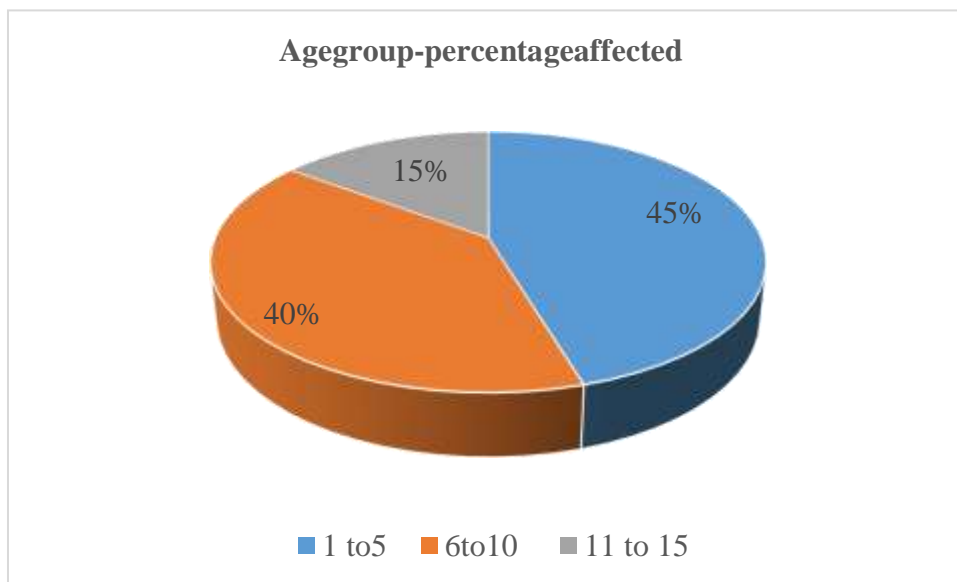
(Fig.1depictsthepercentageofdifferentagegroupsaffectedwithdifferentdiseases)

(Fig.2depictsthepercentageofdifferentdiseasesaffectedinchildren)
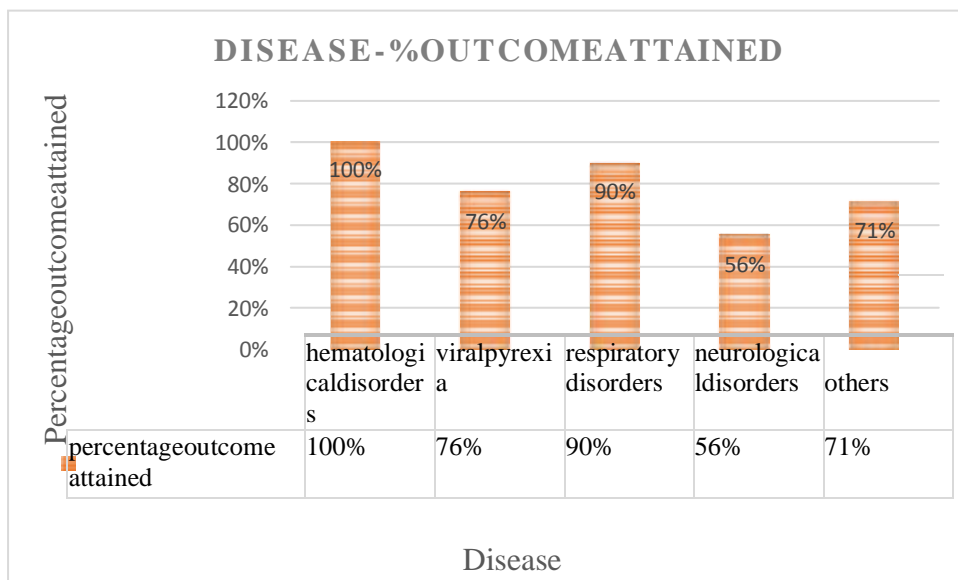

(Fig.3indicatesthepercentageofgirlchildrenaffectedwithdifferentdiseases)

(Fig.4showsthepercentageofboysaffectedwithdifferentdiseases)

Therapeuticoutcomes:

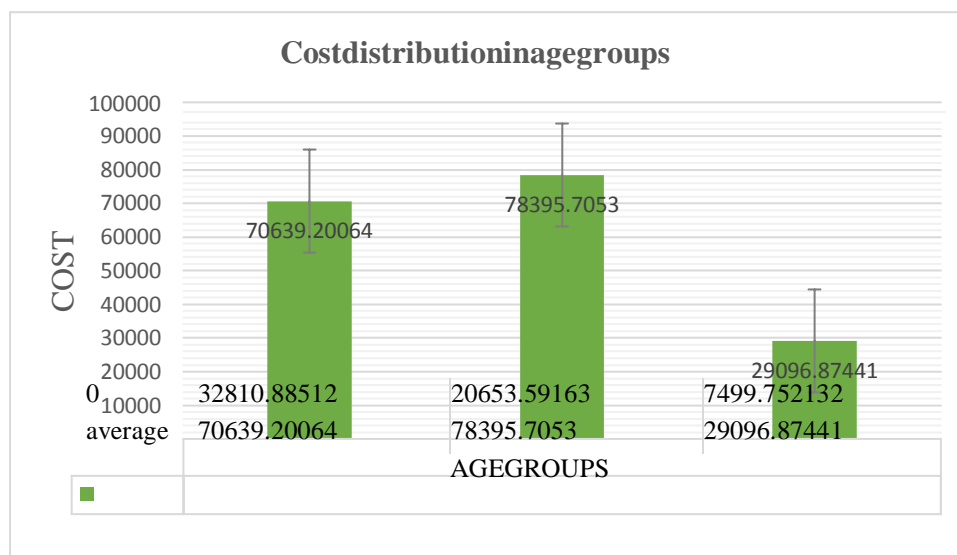| percentageoutcome attained	hematologi caldisorder s	viralpyrexi a	respiratory disorders	neurologica ldisorders	others
percentageoutcome attained	100%	76%	90%	56%	71%

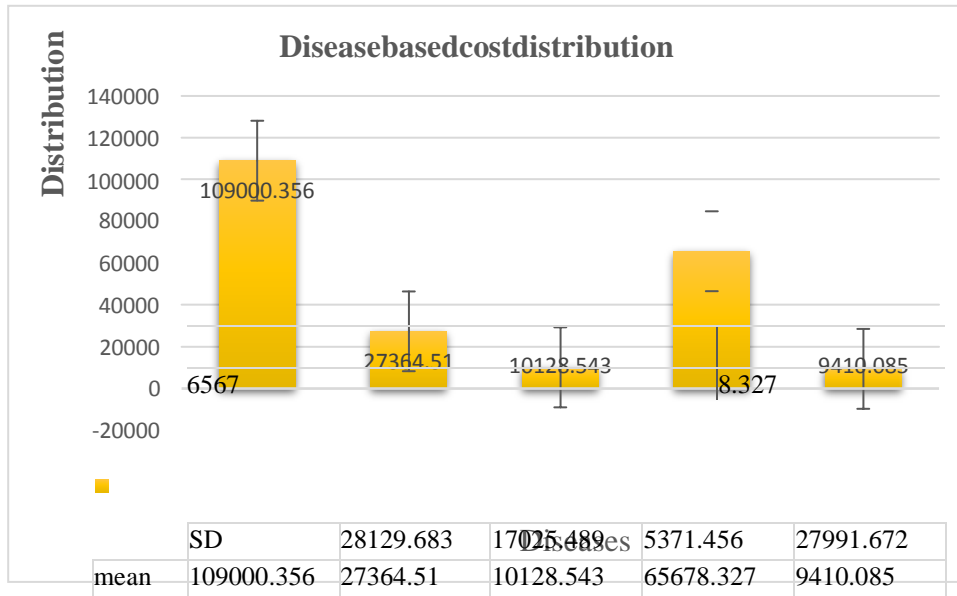(Fig.5showsthepercentageofoutcomeattainedindifferentdiseases)

Disease	Numberofcases	Percentageaffected	Outcomeattained	Percentagebenefited	P valueforoutcome attained	Costinvested oneach disease(INR)
Hematological	38	35	38	100		130700.442
Viralpyrexia	34	31	26	76	0.8	128955.875
Respiratory	20	19	18	90		56529.020
Neurological	9	8	5	56		20257.086
Miscellaneous	7	6	5	71		18820.171

(Table.1showsdataregardingnumberofpatientsaffectedwithdifferentdiseasesalongwiththeir percentages and outcomes, cost invested in different diseases and chi-square value foroutcome-attained)

Economicoutcomes:

(Fig.6showsthedistributionofcostsamongdifferentagegroupsi.e.1-5,6-10,11-15yearsrespectively.)

			SD		
SD	28129.683	17025.489		5371.456	27991.672
mean	109000.356	27364.51	10128.543	65678.327	9410.085

(Fig.7showsthecostdistributionindifferent
diseaseslikehematological,respiratory,neurological,viralpyrexia,miscellaneousdiseasesrespectively.)
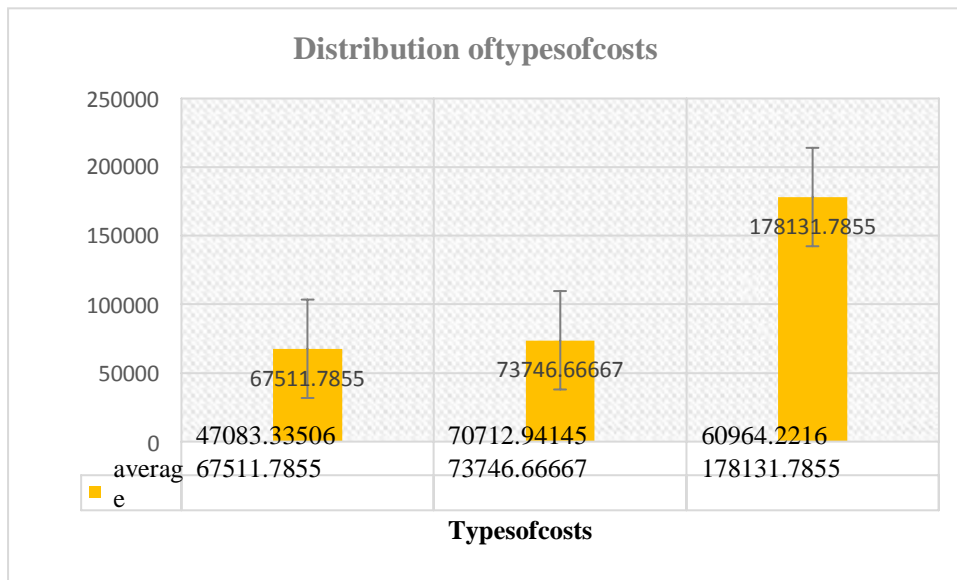
(Fig.8showsthedistributionofdifferent typesofcostsalongwithtotalcosti.e.direct,indirect,totalcostsrespectively.)
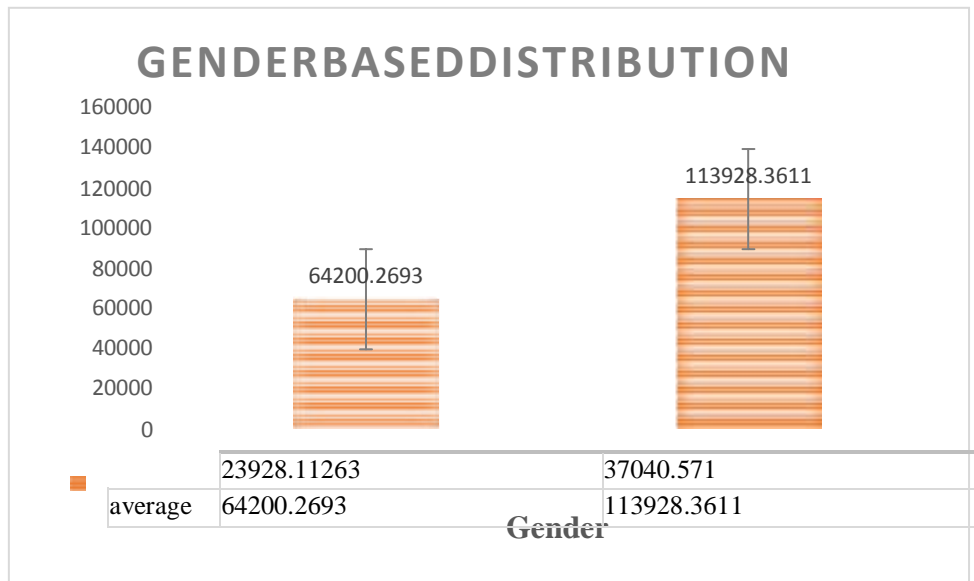
(Fig.9showsthedistributionofcostsindifferentgenderslikeboychildrenand girlchildrenrespectively.)

IV. DISCUSSION:

Thisisthetypeofpharmacoeconomicsstudyt hatwasconductedfromtheperspectiveofboththepayer sandsocietyinthepediatricpopulationinSrikakulam.T hisstudyinthegovernmentgeneralhospital included different diseases affected in the pediatric population. We collected the dataregardingdrugsusedinpediatricsalongwiththeirc ostsfromthecentraldrugstoreofGGHusingthe 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 byhematologicaldisordersandchildrenaffectedwithv iralfeverwerenearly30%.Thechildrenwithblood disorders were mostly affected by thalassemia and sickle cell anemia, they cannot be curedbut they were managed by regular blood transfusions. Hence these conditions were managedsuccessfully having a 100% outcome. The least outcome attained conditions were neurologicaldisorders having an outcome percent of 56%. The cost analysis depicted that indirect cost (cooli,farmer,others)accountedforthemaximumcost ascomparedtodirectcost.Thecostthathadbeeninveste d in children with age groups between 6 to 10 years was more than the cost that had beeninvested in children with other age groups. The cost that had been invested in females was morethan the cost that been invested in males. The total costs of treating different diseases in childrenin a government hospital are approximately 178131.785±60964.221 INR. The costs that

wereafforded 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.Theindirectcostthatwasafforded bychildren isapproximately73746.666±70712.941 INR.

As the hospital is a government hospital, there are no costs for physician visits and negligiblecharges 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 directcostburden fallsonpatientfamiliesonlywhentheybuythemedicine sfromoutsideorwhentheyperform the lab investigations away from the hospital. The indirect cost includes loss of wages,lossofschooldays,travelingcharges,etc.werein vestedbythepatients'families.Themostwidelybought outside medication by the patient representatives throughout this study was "ParacetamolInfusion".This study includes the consideration of both direct and indirect costs which wereinvested by both government and patients' family and the in-pocket cost which is invested by thepatients'familyonbuyingmedicinesfromoutsideor performinglabinvestigationsawayfromthehospital which is also a part of direct cost, thus this study regards the perspective of both payersand society. The parameters that were considered in the direct cost were only the medication costand in the indirect cost were only the loss of wages of the

patients'representative.Therapeuticoutcomewascalculatedusingdifferentassessmentscalesandtheoutcomeswerecomparedtocostinvested, through the principle of time horizon that is every disease gets cured within a specificperiod, for example, viral pyrexia and respiratory diseases can be cured within 3-5 days afterhospitalization. So, we observed the time horizon and compared the costs to know whether thepatient was beneficial with the treatment.The limitations of this study are the small sample sizeand consideration of fewer parameters, not taking of cases with complications which could createbias in the results. This study observes the percentage outcome attained but doesn't give the exactreasonfornon-outcome.Itjustgivesanideathatpatient-relatedproblemsordrug-relatedproblemsmaybethecauseofthe non-outcome. The calculations of this study were done using the descriptive analysis method (Mean± SD) andthe 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 thelevelofsignificanceourhypothesisis accepted.

V. CONCLUSION:

Inourstudy,weconcludedthatboysweremoreproneto diseasesthangirls.Butthecostinvestedongirlswasmorethanthecostinvestedonboys.Mostofthechildrenwereaffectedbyblooddisorders. Viral pyrexia stands next to blood disorders. The cost invested on blood disorders wasmorethanthecost investedonothersbecausethebloodbagsrequired forbloodtransfusionsweremostlysuppliedbythegovernmentalongwiththecostneededforcompatibilitytests. Theindirectcostinvestedwasmorethanthedirectcostbecausethetravelingchargesofpatientrepresentativeswere greater than the direct cost that was invested by the government. While observing thetherapeutic outcome more than 80% of the children got better clinical outcomes for the costinvested.Onlylessthan15%ofthechildrenhadn'tgotatherapeuticoutcome.Thestudyconcludesthat the reason for non-outcome chronic diseases may be due to patient-related problems and inacute conditions was maybe due to drug- related problems. This is one of the limitations of thestudy. As the study mainly focuses on cost and outcomes it helps the payer to frame a betterhospitalformulary.

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