

## Evaluation of Prescribing Pattern of Antibiotics in Pregnant Women and Pediatrics at Various Hospitals of Narasaraopet

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### I. INTRODUCTION

Drug usage is typical process. In any country a large number of socio cultural factors contribute to the ways drugs are used. In India, these include national drug policy, illiteracy, poverty, use of multiple health care systems, drug advertising and promotion, sale of prescription drugs without prescription, competition in the medical and pharmaceutical market place and limited availability of independent, unbiased drug information. The complexity of we means that optimal benefits of drug therapy in patient care may not be achieved because of under use, overuse or misuse of drugs.

Inappropriate drug use may also lead used cost of medical care, antimicrobial resistance, adverse effects and patient mortality. Hence in recent years studies on drug utilization have become a potential tool to be used in the evaluation of health systems. The interest in drug utilization studies began in the early 1960s and its importance has increased since then because of increase in marketing of new drugs, wide variation in the pattern of drug prescribing and consumption, growing concern about delayed adverse effects and the increasing concern regarding the cost of drugs.

In recent years pharmacists have been increasingly involved in many emerging areas of pharmacy in addition to drug therapy Pharmacists are expected to share their knowledge in improving policy decision in hospitals. At drug therapy level, pharmacists may utilize their expertise in making choice of drugs include or exclude in the formulary based on pharmaco-economics

The role of clinical pharmacists is to ensure rational, effective and safe treatment for the patient in their care. This involves interacting with patient to identify the medicines they have been

taking before they were admitted to hospital.

Pharmacists, by virtue of their expertise and their mission of ensuring optimal patient outcomes, should work in the process of medicine use improvement through DUE Drug utilization review (DUR) is defined as an authorized, structured, ongoing view of prescribing, dispensing and use of medication DUR encompasses a drug review against predetermined criteria that

In changes to drug therapy when these criteria are not met it involves a comprehensive review of patient's prescription and medication data before, during and after dispensing to ensure appropriate medication.

As a quality assurance measure, DUR programs provide corrective action, prescriber feedback and further evaluations. Include concept of appropriateness that must be assessed relative to the indication for the treatment, concomitant diseases (that might contraindicate or interfere with chose drug therapy) and the use of other drugs (interactions). Thus they document the extent of inappropriate prescribing of drugs and also the associated adverse, clinical, ecological and economic consequences.

- Review drug use and /or prescribing patterns
- Provide feedback of results to clinicians
- Develop criteria and standards which describe optimal drug use
- Promote appropriate drug use through education and other interventions. . Observe the patterns of drug use with current recommendations
- Guidelines for the treatment of a certain disease.
- Relate the number of cases of adverse effects to the number of patients exposed. If it is

possible to detect that the reaction is more common in a certain age group, in certain conditions or at a special dose level, then information on proper use of drug can be improved such as indications, contraindications, appropriate dose etc. so that withdrawal of drug may be avoided.

- Evaluate drug use at a population level, according to age, sex, social class etc. The DUE plays a key role in helping the health care systems understand, interpret and improve the prescribing, administration and use of medications. The principal aim is to facilitate rational use of drugs, which implies the prescription of drugs in an optimal dose on the right indication, with correct information at an affordable price. It also provides insight into the efficacy of drug therapy whether a certain drug therapy provides value for money. DUE research can thus help to set priorities for all rational allocation of health care budget.

The World Health Organization (WHO) addressed drug utilization as the marketing, distribution, prescription and use of drugs in a society, considering its use of drugs in society,

considering its consequences, medical and economic. Studies on the process of drug indication focus on the factors related to prescribing, dispensing, administering, and taking of medication, and its associated events, converting the medical and non-medical determinants of drug utilization, the effects of drug use beneficial or adverse.

DUR is classified in three categories

- Prospective-evaluation of a patient's drug therapy before medication is dispensed.
- Concurrent- ongoing monitoring of drug therapy during the course of treatment.
- Retrospective - review of drug therapy after the patient has received the medication.

### ANTIBIOTICS

Antibiotics are the substance produced by a microorganism [or a similar product produced wholly (synthetic) or partially (semi synthetic) by chemical synthesis] that is capable, in low concentrations, of inhibiting the growth of or killing other microorganisms

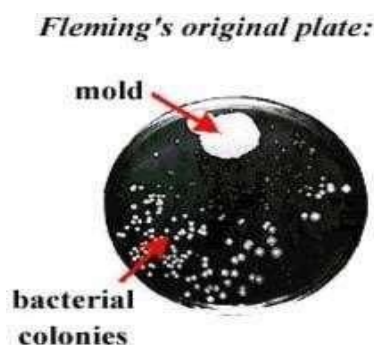


Figure.No.1.1 Flemings original plate

### NOBELISTS INVOLVED IN ANTIBIOTIC RESEARCH



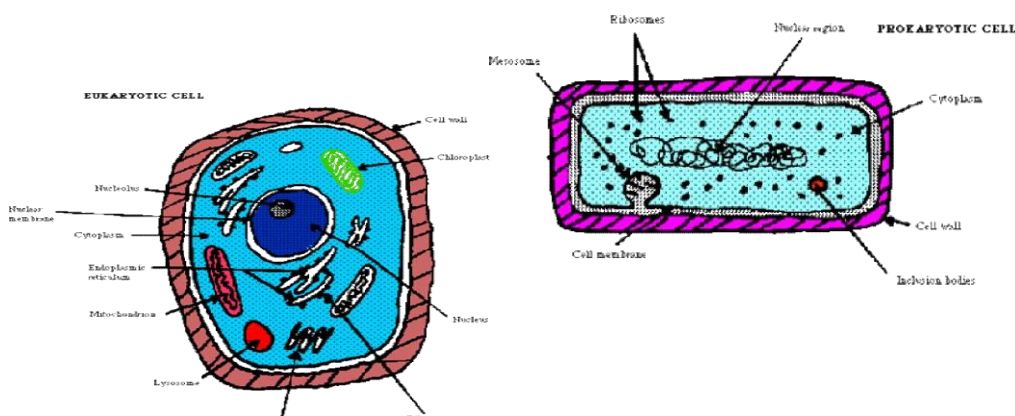
Gerhard Domagk Nobel Prize: 1939  
 Prontosil



Selman Waksman Nobel Prize: 1952 Streptomycin  
 Alexander Fleming Nobel Prize: 1945  
 Penicillin

	<b>EUKARYOTE</b>	<b>PROKARYOTE</b>
Size	5 - 10 $\mu\text{m}$	1-3 $\mu\text{m}$
Cell Wall	Only in fungi/algae	Present
Cytoplasmic membrane	Present	Present
Nuclear membrane	Present	Absent
Genetic information	DNA (>1 chromosome)	DNA (1 chromosome)

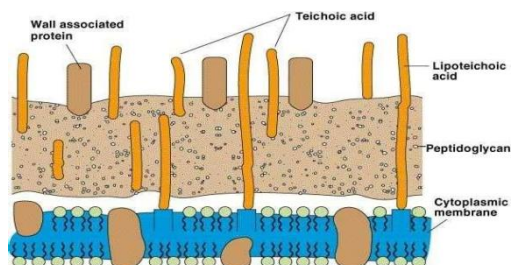
**Table.1.1 Comparison of Eukaryotes and Prokaryotes**



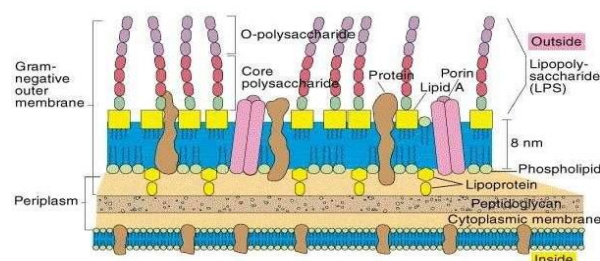
**Figure.1.2 Eukaryotic cell Figure.1.3. Prokaryotic cell**

**I. GRAM-POSITIVE and GRAM-NEGATIVE ORGANISMS**

Gram staining is based on the ability of bacteria cell wall to retain crystal violet dye during solvent treatment. The cell walls for Gram-positive microorganisms have a higher peptidoglycan and lower lipid content than Gram-negative bacteria.



**Figure.1.4 Gram positive organisms**



**Figure.1.5 Gram negative organisms**

Common Gram-positive organisms: Streptococcus  
 S. aureus Bacillus anthracis Clostridium botulinum  
 Common Gram-negative organisms: Klebsiella pneumonia Shigella Yersinia pestis Salmonella

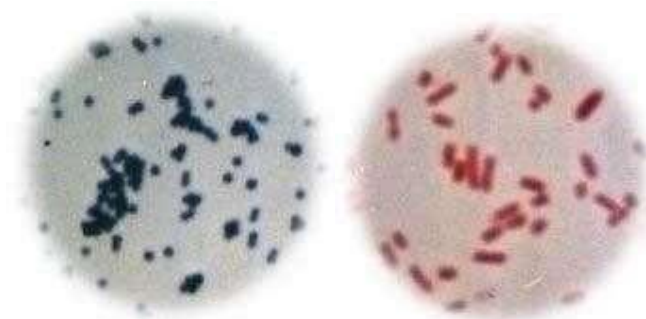


Figure.1.6. Gram positive Figure.1.7. Gram negative

II. PENCILLIN:

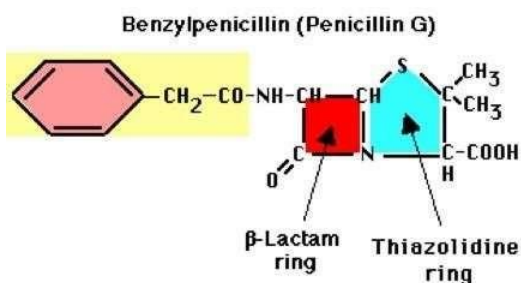


Figure.1.8. Benzyl Penicillin

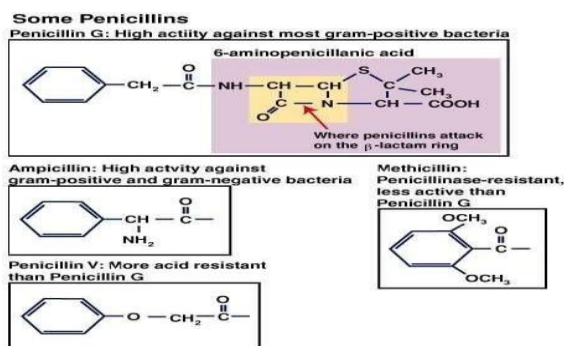


Figure.1.9. Some Penicillins

An expanded role for the penicillins came from the discovery that natural penicillins can be modified chemically by removing the acyl group to leave 6-aminopenicillanic acid and then adding acyl groups that confer new properties. These modern semi-synthetic penicillins such as Ampicillin, Carbenicillin, and Oxacillin have various specific properties such as: resistance to stomach acids so that they can be taken orally, a degree of resistance to penicillinase (a penicillin-destroying enzyme produced by some bacteria) extended range of activity against some Gram-

negative bacteria. Although the penicillins are still used clinically, their value has been diminished by the widespread development of resistance among target microorganisms and also by some people's allergic reaction to penicillin.

III. OTHER COMMON ANTIBIOTICS  
**Cephalosporins**

Beta-lactams with a similar mode of action to penicillin but with less allergenicity.

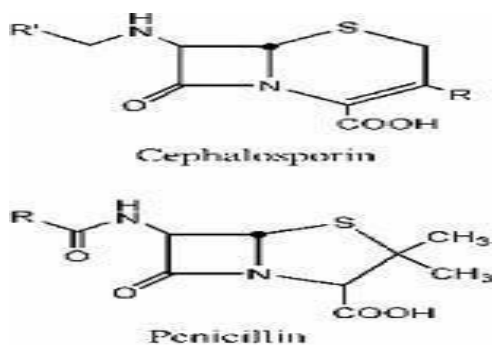


Figure.1.10. Cephalosporins Streptomyces-derived Antibiotics

Actinomycetes, especially the Streptomyces species, have yielded most of the antibiotics used today in clinical medicine. Examples: amphotericin B, erythromycin, streptomycin, tetracycline, neomycin, and vancomycin.

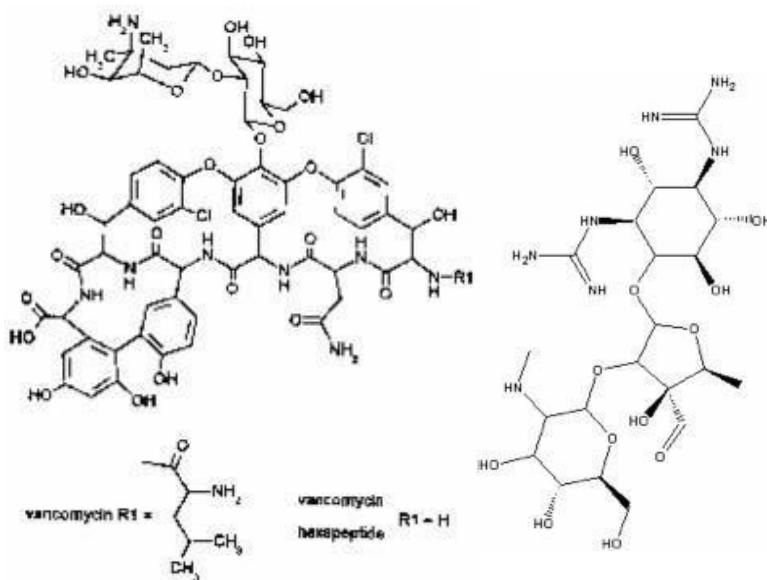


Figure.1.11. Streptomyces-derived Antibiotics  
 Figure.1.12. Streptomyces-derived Antibiotics

Mechanism of action	Antibiotic	Bacterial Target
Inhibition of cell wall synthesis	$\beta$ Lactams: Penicillin Cephalosporin Bacitracin Vancomycin	Transpeptidase Peptidoglycan Transporter Ala-ala dipeptide
Inhibition of protein synthesis	Aminoglycosides Streptomycin Neomycin Tetracyclines Erythromycin	30S ribosome Gentamycin 50S ribosome Free ribosomes
Inhibition of nucleic acidsynthesis	Quinolones, Rifampacin	DNA gyrase DNA- dependent RNA polymerase
Inhibition of cytoplasmic membrane function	Polymyxin	Membrane lipids
Anti metabolites	Sulfonamides	Folate synthesis

Table.1.2 Mechanism of Action of Common Antibiotics

Pencilling action

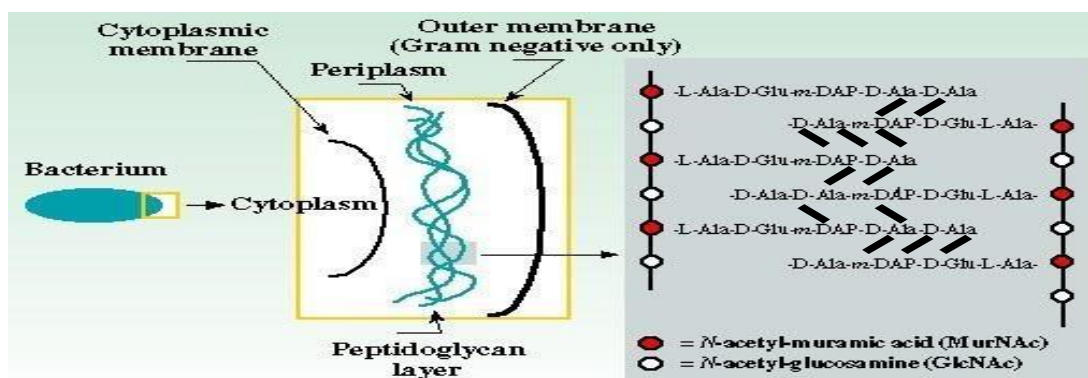


Figure.1.13.Pencillian action

### MECHANISMS OF ANTIBIOTIC RESISTANCE:

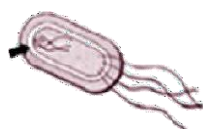
Current penicillin prescriptions such as augmentin contain beta-lactamase inhibitors to block cleavage of the penicillin.

Antibiotic resistant genes

Pumping mechanisms to remove antibiotic from bacterial cell

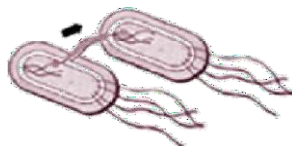
Enzymes that modify antibiotics

Bacteria acquire genes conferring resistance in any of three ways.



**Figure.1.14. Spontaneous DNA mutation**

In **spontaneous DNA mutation**, bacterial DNA (genetic material) may mutate (change) spontaneously arises this way. (indicated by starburst). Drug-resistant tuberculosis



**Figure.1.15. Transformation**

In a form of microbial sex called **transformation**, one bacterium may take up DNA from another bacterium. Penicillin-resistant gonorrhoea results from transformation.



**Figure.1.16. Plasmid**

Most frightening, however, is resistance acquired from a small circle of DNA called a **plasmid** that can flit from one type of bacterium to another. A single plasmid can provide a slew of different resistances. In 1968, 12,500 people in Guatemala died in an epidemic of Shigella diarrhoea. The microbe harboured a plasmid carrying resistances to four antibiotics.

#### 1.2.1 For all Quinolones/Fuoroquinolones

The indications in the table below should be restricted for all quinolones/ fluoroquinolones containing products in order to be used only when it is

considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.

Therefore the following text should be added in Section 4.1 as relevant:

“In [indication] [name of product] should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.”

<ul style="list-style-type: none"> <li>• Uncomplicated cystitis</li> <li>• Simple uncomplicated acute cystitis</li> <li>• Acute cystitis in women</li> <li>• Simple uncomplicated acute cystitis in the premenopausal adult women</li> <li>• Recurrent cystitis in women</li> <li>• Acute uncomplicated infection of lower urinary tract (simple cystitis)</li> </ul>
<ul style="list-style-type: none"> <li>• Acute exacerbation of chronic bronchitis and of chronic obstructive pulmonary disease</li> <li>• Acute exacerbation of chronic obstructive pulmonary including chronic bronchitis</li> <li>• Acute exacerbations of chronic bronchitis</li> <li>• Exacerbation of chronic obstructive pulmonary disease</li> </ul>
<ul style="list-style-type: none"> <li>• Acute bacterial rhinosinusitis</li> <li>• Acute sinusitis</li> <li>• Acute bacterial sinusitis</li> </ul>
<ul style="list-style-type: none"> <li>• Otitis media acute</li> </ul>

**Table.1.3. Infections**

**Amendments of indications for specific Quinolones/Fluoroquinolones** Additionally for the following active substances, the following indications should be amended as recommended below:

**Ciprofloxacin**

Current indications in product information of ciprofloxacin containing products	Recommended wording
Adults	
Urethritis and cervicitis due to bacteria susceptible to Fluoroquinolones	Gonococcal urethritis and cervicitis due to susceptible Neisseria gonorrhoeae
Bone and joint infections	Infections of the bones and joints



Treatment of infections in neutropenic patients Infection in immune compromised patients	Ciprofloxacin may be used in the management of neutropenic patients with fever that is suspected to be due to abacterial infection
Urinary tract infection	Uncomplicated acute cystitis Acute pyelonephritis Complicated urinary tract infections Bacterial prostatitis
Children and adolescents	
Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa	Bronchopulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis

**Table.1.4.Ciprofloxacin**

**Levofloxacin**

Current category 1 indications in product information of levofloxacin	Recommended wording category of 1 indications
Pyelonephritis and complicated urinary tract infections (see section 4.4)	Acute pyelonephritis and tract complicated urinary infections (see section 4.4)
	Acute exacerbation of chronic obstructive pulmonary disease including bronchitis

<p>Acute exacerbation of chronic bronchitis (lastline)</p>	<p>In [indication] [name of product] should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.</p>
<p>skin and soft tissue infections skin and soft structure infections</p>	<p>Complicated skin and soft tissue infections / Complicated skin and skin structure infections        In [indication] [name of product] should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.</p>

**Table.1.5. Levofloxacin**

**Moxifloxacin**

<p>Current category 1 indications in product information of moxifloxacin</p>	<p>Recommended wording of category 1 indications</p>
	<p>Acute exacerbation of chronic obstructive pulmonary diseaseincluding bronchitis             In [indication] [name of</p>

<p>Acute exacerbation of chronic bronchitis (lastline)</p>	<p>product] should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.</p>
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**Table.1.6. Moxifloxacin**

**Ofloxacin**

<p>Current indications in product information of ofloxacin containing products</p>	<p>Recommended wording</p>
<p>Pyelonephritis and complicated urinary tract infections</p>	<p>Acute pyelonephritis and complicated urinarytract infections</p>

<p>Prostatitis, epididymo-orchitis            Chronic bacterial prostatitis            (complicated or uncomplicated) o Prostatitis by E. coli o Prostatitis, epididymo-orchitis o Prostatitis, infection of the epididymis and the testicle            Severe prostatitis</p>	<p>Bacterial prostatitis, epididymoorchitis</p>
<p>• Pelvic inflammatory disease, in combination treatment o            Acute pelvic inflammatory diseaseo Pelvic inflammatory disease,in combination treatment</p>	

<ul style="list-style-type: none"> <li>• Pelvic region infection in women (in combination with other antibiotics)</li> <li>• Inflammatory pelvic disease, in combination treatment</li> <li>• Upper genital tract infection in women</li> </ul> <ul style="list-style-type: none"> <li>• (see 4.4) (complicated or uncomplicated)</li> </ul> <ul style="list-style-type: none"> <li>• Upper gynaecological tract infections, including infections due to susceptible strains of Neisseria gonorrhoeae</li> </ul>	<ul style="list-style-type: none"> <li>• Pelvic inflammatory disease, in combination with other antibacterial agents</li> </ul>
<ul style="list-style-type: none"> <li>• Sepsis due to above-mentioned genito-urinary infections</li> </ul>	<ul style="list-style-type: none"> <li>• Urosepsis (only applicable for i.v. formulation)</li> </ul>

<ul style="list-style-type: none"> <li>• Uncomplicated cystitis (last line) o Uncomplicated cystitis</li> <li>o Uncomplicated cystitis (should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment</li> </ul>	<ul style="list-style-type: none"> <li>• Uncomplicated cystitis In [indication] [name of product] should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.</li> </ul>
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<p>of these infections)</p> <p>o Uncomplicated cystitis (XX should only be used if antibacterial treatment considered as first choice of treatment is deemed unfit/inappropriate)</p>	
<p>• Urethritis (last line) o Urethritis (should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections)</p>	<p>Urethritis</p> <p>[indication] [name of duct] should be used when it is sidered inappropriate use other antibacterial nts that are commonly ommended forthe</p>
<p>Urethritis (XX should only be used if antibacterial treatment considered as first choice of treatment is deemedunfit/inappropriate)</p>	<p>atment of these ections.</p>

**Table.1.7. Ofloxacin**

### Amoxicillin:

Amoxicillin, an acid stable, semi-synthetic drug belongs to a class of antibiotics called the Penicillins (antibiotics). It is shown to be effective against a wide range of infections caused by wide range of Gram - positive and Gram- negative bacteria in both human and animals<sup>1-4</sup>. It is a congener of ampicillin (a semi-synthetic amino penicillin) differing from the parent drug only by hydroxylation of the phenyl side chain.

### Pharmacology

Amoxicillin is bactericidal against susceptible micro-organisms through the inhibition of biosynthesis of cell wall mucopeptide during bacterial multiplication. It acts by binding to penicillin binding protein 1A (PBP1A) located inside the bacterial cell wall. The penicillins (amoxicillin), acylate the penicillin sensitive transpeptidase C terminal domain by opening the lactam ring causing inactivation of the enzyme, prevents the formation of a cross link of two linear peptidoglycan strands, inhibiting the third and last stage of bacterial cell wall synthesis, which is necessary for cell division and cell shape and other essential processes; and thus, the lethality of penicillin for bacteria involves both lytic and non lytic mechanisms. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that amoxicillin interferes with an autolysin inhibitor.

The imperfect cell wall synthesis make bacterial cells to absorb water by osmosis; as gram positive & gram negative bacteria have 10, 30 & 35 times intracellular osmotic pressure than external environment. Amoxicillin is more effective against gram positive than gram negative micro organisms and it demonstrates greater efficacy to penicillin, penicillin V and comparable to other antibiotics, e.g. ampicillin, azithromycin, clarithromycin, cefuroxime and doxycycline in treatment of various infections/ diseases.

### Pharmacokinetics

Amoxicillin is well absorbed (at different rate and extent from various regions of gut) from GIT. It enjoys widespread clinical use, not only because of its broad antibacterial spectrum but also because of its high oral bioavailability (70-90%) with peak plasma levels occurring within 1 to 2 hrs. and is dose dependent, generally be 1.5-3 times greater than those of ampicillin after equivalent oral doses.

The Apparent volume of distribution of amoxicillin is approximately 0.26

- 0.31 L/kg and widely distributed to many tissues including liver, lungs, prostate (human), muscle, bile, ascitic, pleural and synovial fluids, and ocular fluids, accumulates in the amniotic fluid and crosses the placenta, but penetrates poorly into the central nervous system unless inflammation is present (1060% of those found in serum). Very low levels of the drug are found in the aqueous humor, and low levels found in tears, sweat and saliva.

It is approximately 17-20% bound to human plasma proteins, primarily albumin. Excretion of amoxicillin is predominantly renal, and >80% of which 50-70% unchanged (of administered doses) is recoverable in the urine, leading to its use in dentistry. Amoxicillin is susceptible to degradation by  $\beta$ -lactamase producing bacteria, and so may be given with  $\beta$ -lactamase inhibitor such as clavulanic acid.

### Adverse Effects

A pharmacovigilance study conducted for documenting side effects of drugs within the WHO Programme for International Drug Monitoring from January 1988 up to June 2005, the GIF database collected 37,906 reports, of which 1095 were related to amoxicillin alone and 1088 to amoxicillin in combination (amoxicillin/clavulanic acid). The percentage of skin reactions was higher for both amoxicillin alone (82%) and amoxicillin in combination (76%); on the contrary, the percentage of gastrointestinal, hepatic and haematological reactions.

CEFTAZIDIME (for pseudomonas aeruginosa) further expansion of Gm negative spectrum to include hard treating organisms such as Enterobacter, Serratia, and Pseudomonas. In addition to better Gm negative spectrum, this group has improved pharmacokinetic properties (longer half-lives) that allow once daily dosing with some agents. In general, activity toward Gm+ bacteria is reduced. These are specialty antibiotics that should be reserved for specific uses.

- Enterobacteriaceae that are almost always sensitive (>95% sensitive)
- E.coli
- Proteus mirabilis (indole-)
- Proteus vulgaris (indole+)
- Klebsiella pneumoniae
- Gram negative bacilli that are generally sensitive (>75% sensitive)
- Morganella morganii
- Providencia rettgeri
- Citrobacter freundii

Antibiotics are the pillars of modern medical care and play a major role both in the prophylaxis and treatment of infectious diseases. Excess of drug utilization studies focused on assessing patterns of drug prescribing as a mean of pinpointing areas for improper prescribing cannot be overlooked. Improper prescribing can cause toxicity for patients and will be a waste of money and time. It can also cause therapeutic failure that results in progress of disease conditions and worsening of the patient health condition. The improper prescribing and excessive use of antibiotics can lead to loss of the effectiveness of currently used antibiotics.

Antibiotics are among the class of drugs with the most potential impact on preventable mortality in developing countries. Antimicrobial resistance is emerging as a complex problem driven by many interconnected factors especially the use and misuse of antimicrobials. Many patients believe that newer and expensive antibiotics are more effective than older agents; this belief is shared by some prescribers and results in unnecessary use of newer agents.

This practice causes unnecessary health care expenditure and encourages the development of resistance. Cephalosporins are a commonly used group of antibiotics in hospitals and health care facilities around the world. In the developed countries the use of older cephalosporins is decreasing, that of the newer generations has increased.

#### **Beta-Lactam antibiotics**

Beta-lactam antibiotics are a broad class of agents consisting of all antibiotic agents that contain a beta lactam ring in their molecular structures. These antibiotic agents include penicillins derivatives (penams), cephalosporins (cephems).

#### **Mechanism of action:**

Cephalosporins are bactericidal agents and have the similar mode of action as beta-lactam antibiotics (such as penicillins) but are less susceptible to penicillinases. Cephalosporins inhibit the synthesis of the peptidoglycan layer of bacterial cell walls. The peptidoglycan layer is important for cell wall structural integrity. In the final step of the transpeptidation in which the synthesis of the peptidoglycan is facilitated by peptidases known as penicillin-binding proteins (PBPs). PBPs bind to the D-Alanine-D As at the end of mucopeptides (peptidoglycan precursors) to crosslink the peptidoglycan - lactam antibiotics mimic the D-Alanine - D-Alanine site, thereby irreversibly

inhibiting penicillin-binding proteins (PBP) crosslinking of peptidoglycan.

In gonorrhoea the first choice of the treatment is a single dose of ceftriaxone 250mg intramuscularly. Ceftriaxone is also used if prescribed for the treatment of confirmed atloxacin-resistant gonorrhoea, and the prescription is endorsed accordingly. Research shows that ceftriaxone attains the optimal concentrations to prevent the development of step wise mutations and resistance in *Neisseria gonorrhoea*. Ceftriaxone has been shown to be greater than 95% effective. Therefore a repeat test to ensure cure is not usually required as long as the patient is asymptomatic after treatment.

Anthromycin is also routinely given when treating gonorrhoea, because co-infection with chlamydia is common. Ciprofloxacin (500mg stat) is an alternative to ceftriaxone if cephalosporins are contraindicated (most often due to documented allergy to beta-lactam antibiotics) or if the isolate is known to be sensitive to ciprofloxacin. Increasing of ciprofloxacin resistance is becoming common. The prevalence of resistance is varying by location. Broad-spectrum treatment is used in pelvic inflammatory disease (PID) because the consequences of untreated infection can be serious, Infertility and ectopic pregnancy.

The recommended treatment which covers *N. Gonorrhoea*, *Chlamydia trachomatis* and anaerobe is ceftriaxone 250mg IM, stat and doxycycline 100mg, two times daily and Metronidazole 400mg, two times daily, for two weeks.

In the regimen primarily Ceftriaxone is included to cover *N. gonorrhoea*. Patients should be advised to inform sexual partners that they need to be screened and treated if positive for gonorrhoea and Chlamydia. Ceftriaxone 250mg IM stat in combination with doxycycline 100mg, two times daily, for two weeks is recommended for epididymo orchitis. Sexually transmitted infections (mostly Chlamydia or gonorrhoea) are the suspected cause.

Most guidelines recommend this regimen in less than 35 years old men. Urethral discharge and more than one sexual partner in the last 12 months are the other risk factors for sexually transmitted infections. Any patients with suspected meningitis should be immediately transferred to hospital. Ceftriaxone is an alternative to benzyl penicillin for suspected meningitis. IM or IV benzylpenicillin should be given while transfer to hospital is being arranged. People with suspected





	CEFROXADINE	
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SECOND	CEFACTOR, CEFONICEID, CEFUROXIME, CEFOTETAN, CARBACEPHEMS: LORACARBEF	Gram-Positive: Less than first- generation. Gram-negative: Greater than first generations: HEN (Haemophilus influenzae, Enterobacteraerogenes and some Neisseria + the PECK described above.
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THIRD	CEFCAPENE, CEFDALOXIME, CEFDINIR, CEFDITOREN, CEFETAMET, CEFIXIME, CEFMENOXIME, CEFODIZIME, CEFOTAXIME, CEFOVECIN, CEFPIMIZOLE, CEFPODOXIME,	Gram-positive: some members of this group (in particular, those available in an oral formulation, and those with anti pseudomonal activity) have decreased activity against gram positive organisms Gram-negative: Thrid-generation cephalosporins have a broad spectrum of activity and further increased activity against gram-negative organisms. They are also able to penetrate the CNS, making them
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Third generation Cephalosporins- with anti pseudo monal activity	CEFTERAM, CEFTAMERE, CEFTIBUTEN, CEFTIOFUR, CEFTIOLENE, CEFTIZOXIME, CEFTRIAZONE, CEFOPERAZONE, CEFTAZIDIME	useful against meningitis caused by pneumococci, meningococci, H.influezae, and susceptible E.coli, Klebsiella, and penicillin-resistant N.gonorrhoeae.
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FOURTH	CEFCLIDINE, CEFEPIME, CEFOSELIS, Note: Cefquinome human use. It is medicine. CEFLUPRENAM, CEFOZOPRAN, CEFPIROME, CERQUINOME, is not approved for veterinary Medicine.	Gram-Positive: They are extended spectrum agents with similar activity against gram-positive organisms generation cephalosporins. Gram-negative: Fourth generation cephalosporins are zwitterions that can penetrate the outer membrane of gram negative bacteria. They also have a greater resistance to bet-lactamases than the third generation cephalosporins. Many can cross the blood-brain barrier and are effective in meningitis...
FIFTH	CEFTOBIPROLE, CEFAROLINE,	Ceftobiprole has powerful anti pseudomonal characteristics and appears to be less susceptible to development of resistance. Cetaroline has also been described as " fifth-generation" cephalosporin, but does not have the anti- pseudomonas or VRE coverage of ceftobiprole

**Table.1.8. Classification of Cephalosporins**

**SPECTRUM & USES**

First Generation Cephalosporins - Spectrum

- Prototype Drugs are CEFAZOLIN (IV use) and CEPHALEXIN (oral use).
- Staph aureus - excellent activity against b-lactamase-producing strains

Not effective against the methicillin-resistant staph aureus and epidermidis

- Streptococci - excellent activity versus Streptococcus sp.
- Not effective against the penicillin-resistant strep. Pneumonia CEFTAZIDIME (for pseudomonas aeruginosa.)

Further expansion of Gram negative spectrum to include hard treating organisms such as Enterobacter, Seratia, and Pseudomonas. In addition to better Gm negative spectrum, this group has improved pharmacokinetic properties ( longer half-lives) that allow once daily dosing with some agents. In general, activity toward Gm+ bacteria is reduced. These are specialty antibiotics that should be reserved for specific uses.

- Enterobacteriaceae that are almost always sensitive (>95% sensitive)
- E.coli
- Proteus mirabilis (indole-)
- Proteus vulgaris ( indole+)

- Klebsiellapneumoniae
- Gram negative bacilli that are generally sensitive (>75% sensitive)
- Morganellamorganii
- Providenciaretgerri
- Citrobacterfreundii

## II. AIM AND OBJECTIVES

### AIM:

- To evaluate the use of antibiotics in pregnant women and pediatric patients in various hospitals of Narasaraopet.

### OBJECTIVES:

- To evaluate the utilization of antibiotics in pregnant women and pediatric patients we are collecting the prescriptions at various hospitals of Narasaraopet for the duration of 3 months (April 2021- June 2021).

## III. LITERATURE REVIEW

**Remesh, Samna Salim et al. (2014)** done a cross-sectional prospective study on antibiotic prescribing pattern in the inpatient departments of tertiary care hospital was carried out in 100 inpatients in six departments. The mean duration of hospitalization among the study population was 5.48 (64.28). Among these 410 medicines prescribed, antibiotics contributed 151 (36.8%). They were indicated for respiratory infections, and the most common antibiotic was Beta-lactams 250. Interestingly, 89 antibiotics (60%) were administered as injections. About 70 of the antibiotics were prescribed without any combinations. The adherence to World Health Organization's essential medicines list was 122 (81%). A total of seven adverse drug reactions were reported in the current study. Their conclusion was physicians prescribed antibiotics more rationally with no banned drugs and less newer drugs. Rational prescribing of antibiotics would help avoid polypharmacy and prevent drug resistances.

**Pandlamuninj et al (2014)** done a study on prescribing pattern of antimicrobial agents in the medical intensive care unit of a tertiary care hospital in Puducherry union territory south India. 100 consecutive inpatient records of patients admitted to the teaching hospital in Puducherry union territory during September to December, 2013 were studied. The results showed average number of antibiotics per patient was found to be 1.13. Cephalosporins and ceftriaxone. Organisms isolated in the culture and sensitivity tests were sensitive to imipenem and piperacillin-tazobactam in common. No adverse drug reaction was observed

for any antibiotic. and name of the drugs and parenteral administration were preferred by the physicians for prescribing the antibiotics. Most antibiotic prescriptions were made without bacteriological culture and sensitivity testing evidences. They concluded that need for motivating the physicians to prescribe antimicrobial agents by generic names with bacteriological evidences.

**Shwanthm et al (2014)** was conducted a prospective, observational study on assessment of drug utilization in hospitalized children at a tertiary care teaching hospital in department of pediatrics total of 150 patients aged 1-5 years were analyzed, which included 80 males and 70 females. The duration of hospitalization was 4-5 days. Respiratory diseases were accounted for 33.33%, followed by intestinal diseases (19.33%). Among majority of cases were pneumonia (56%) and acute gastroenteritis (82.75%). In all patients total 854 drugs were prescribed. most commonly prescribed drug classes were antimicrobial agents (28.10%) drugs acting on respiratory system (12.18%) and NSAIDs (7.50%). penicillins (28.75%) agents followed by aminoglycosides (21.33%) & cephalosporins (17.5%) salbutamol aerosol (48.08%) inhaled salbutamol+ipratropium (1.15%). paracetamol (90.63%) was most extensively prescribed. NSAID ibuprofen+PCT (83.7%) 49.06% of drugs were injectables (IV/IM), 44.73% oral and 6.21% average number of drugs prescribed per encounter was 5.69 (62.30%) of drugs were prescribed by their generic name. 86.42% were from EML. This study concluded that better prescribing practices as suggested above would lead to improvement in quality of health care provided to children. Educational interventions towards improving prescribing practices are required.

**Vinod S. Deshmukh et al. (2013)** conducted a retrospective cross sectional study carried on study of prescribing pattern of antimicrobial agents in inpatient departments of a tertiary care hospital in 130 patients which results most commonly prescribed antimicrobial agent was cefotaxime (21.7%) in medicine and metronidazole in surgery (30.6%) department. The average number of antimicrobials per patient was found to be 1.7 and 3.02 in medicine and surgery department respectively. The switch on therapy from parenteral to oral route was employed in 16.15% patients in medicine department and 11.82% patients in surgery department. As per Kunin's modified criteria, 86.2% and 58.06% patients received antimicrobial therapy appropriately in Medicine and Surgery department

respectively. In conclusion this study highlights the problem of overuse in bronchopneumonia. Ceftriaxone was the commonly prescribed empirical antibiotic. Patients who received therapy with cephalosporin derivatives (Ceftriaxone and cefoximadwer) had a mean duration of hospital stay, less than days.

**Vipal D. prajapati et al. (2012)** carried out a retrospective study on prescribing patterns of antimicrobial agents in the pediatric wards at a tertiary teaching care hospital, Gujarat. They collected 350 prescriptions of antimicrobial agents in the pediatric department at Sri Sayajiro General (SSG) Hospital, Vadodra to assess the prescribing patterns of antimicrobial agents. Total 350 prescriptions containing 690 antimicrobial drugs were prescribed in patients. Drugs were prescribed in patients and study of them: Cephalosprins (176; 25.5%). Average numbers of antimicrobials per prescription was 1.97. Out of 690 antimicrobials 576 (83.81%), while only 91 (13.18%) antimicrobials were prescribed by oral route. They concluded that antimicrobials were frequently prescribed for treating respiratory tract infections.

**Frehiwot Amare Abebe et al. (2012)** drug use evaluation of ceftriaxone: the case of Ayder referral hospital, Mekelle, Ethiopia. The study was conducted by reviewing medication records of 296 patients who received ceftriaxone during hospitalization at Ayder referral Hospital from September 11, 2009 to September 2010. The duration of therapy was found to be high in the range 2-7 days (51.9%). Ceftriaxone was mainly used as preoperative prophylaxis (38.8%) for the justification of use. Most of the inappropriate uses were seen in terms of duration. Consistency of prescribing to the treatment regimens implemented in most of the cases was without doing any culture sensitivity test which leads to irrational prescribing. Adverse reactions caused by  $\beta$ -lactam antibiotics in reports of adverse reactions caused by  $\beta$ -lactam antibiotics collected in the hospital 2007 and 2009. The result was, in 113 cases of ADR involved 17 kinds of  $\beta$ -lactams and headed by ceftriaxone sodium. The most common manifestation was skin and eye damage, nervous system and gastrointestinal system damage were also easier to find, the administration route was mainly intravenous infusion. The clinical application of  $\beta$  antibiotics should pay attention to adverse reaction monitoring and rational drug use to reduce the incidence of adverse reactions. The final conclusion was clinical application of antibiotics should pay attention to adverse reaction

monitoring and rational drug use to reduce the incidence of adverse reactions.

**Dongsik Jung et al. (2009)** carried out an evaluation of ceftriaxone utilization at a multicenter study, prospectively evaluated the appropriateness of antibiotic usage in 400 adult patients who received ceftriaxone between February 1, 2006 and June 30, 2006. The results show utilization of ceftriaxone was appropriate in 262 cases (5%) for the justification of use, while inappropriate use was observed in 138 cases (34.3%). Common reasons for inappropriate use of ceftriaxone included continued empiric use for presumed infections, prophylactic preoperative injection, and empiric therapy for fever. Most of the critical indications showed a high rate of suitability (66.5-98.5%). Complications occurred in 37 cases (9.3%). With respect to outcome measures, clinical responses were observed in 60.7% of cases, while only 15.7% of cases showed evidence of infection eradication via negative cultures. In conclusion, appropriate use (65.5%) of ceftriaxone was higher than inappropriate use (34.5%) at a university hospital in Korea. Inappropriate utilization, however, including continued empiric use for presumed infections and prophylactic preoperative injection remained high. Intensification of educational programs and antibiotic control systems for ceftriaxone is needed to improve the suitability of antimicrobial use.

**Palikhe N et al. (2005)** was done a prospective follow up study on prescribing pattern of antibiotics in a pediatric hospital of Kathmandu valley. 121 patients were included in the study. The average number of drugs per patient was 5.0111.36 and antibiotics per each patient were  $2.41 \pm 1.02$ . More than 98% of the patients were exposed to at least two drugs. In total 121 patients clinically diagnosed with infectious diseases and treated with antibiotics, specimens were taken for culture in only 24 cases i.e. (19.8%) to identify pathogenic organisms. Only 13 specimens showed positive culture cases of adverse reactions caused by  $\beta$ -lactam antibiotics in reports of adverse reactions caused by  $\beta$ -lactam antibiotics collected in the hospital 2007 and 2009. The result was, in 113 cases of ADR involved 17 kinds of  $\beta$ -lactams and headed by ceftriaxone sodium. The most common manifestation was skin and eye damage; nervous system and gastrointestinal system damage were also easier to find, the administration route was mainly intravenous infusion. The clinical application of  $\beta$  antibiotics should pay attention to adverse reaction

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**Ryuck lee, Dongsik Jung et al. (2009)** carried evaluation of ceftriaxone utilization at multicenter study, prospectively evaluated the appropriateness biotic usage in 400 adult patients who received ceftriaxone between February 1, 2006 and Jane 30, 2006. The results shows utilization of ceftriaxone was appropriate in 262 cases (85.59%) for the justification of use, while inappropriate use was observed in 138cases (34.3%). Common reason for inappropriate use of ceftriaxone included continued empiric use for presumed infections, prophylactic preoperative injection, and empiric therapy for fever. Most of the critical indications showed a high rate of suitability (66.5-98.5%). Complications occurred in 37 cases (9.3 %). With respect to outcome measures, clinical responses were observed in 60.7% of cases, while only 15.7% of cases showed evidence of infection eradication via negative cultures. In Conclusions, appropriate use (65.5%) of ceftriaxone was higher than inappropriate use (34.5%) at university hospital in Korea. Inappropriate Utilization, however, including continued empiric use for presumed infections and prophylactic preoperative injection remained high. Intensification of educational programs and antibioti control systems for ceftriaxone is needed to improve the suitability of antimicrobial use percentages of the total antibiotics were administered parentally. Cephalosporins were the top est frequently prescribed antibiotics followed by penicillin group. His final conclusion was ren below 1 year or infants are at special risk of receiving multiple courses of antibiotics, ther with the knowledge that antibiotic resistance develops in

this setting, suggest that ategies to control antibiotic use should focus on these patients' populations.

**P.R. Shankar, P. Subish et al. (2004)** was done a study on Cephalosporin utilization in the patient wards of a teaching hospital in western Nepal. In this study Nine thousand eight hundred and forty-five patients were admitted to the inpatient wards during the study period. Eight hundred and forty-one patients (8.54%) were prescribed antibiotics. A total of 252 patients (2.56%) were prescribed cephalosporins. Cephalosporins were prescribed in 73 of the 2097(3.48%) surgical inpatients, 50 of the 1726 (2.9%) patients admitted in the obstetrics and gynecology wards and 25 of the 927 patients (2.7%) admitted in orthopedics. Among pediatric and internal medicine inpatients the percentage was 2.85 % (57 of 2000 inpatients) and 1.51% (27 of the 1824 patients) respectively. They concluded the use of cephalosporins in our hospital was lower than that reported in the literature which is a welcome trend and has to be encouraged. Antibiotic use policies for postoperative prophylaxis and infection control policies for the wards arerequired.

**METHODOLOGY**

**Methods**

**Study Design and Site**

This is an observational and prospective study which was carried out in 300 bedded hospital It was performed at pregnant women and paediatrics of various hospitals at Narasaraopet for the duration of 3-months(Apr 2021 - June 2021).

**Study Population and sample**

Patients both genders are included in paediatrics and pregnant women 300 patients were selected based on age ,inclusion and exclusion criteria.We visited the hospitals and collected the requireddata.

**Study Criteria:**

**Age Criteria in Paediatrics**

Categories	Age Groups
Neonatal	0 days -1 month
Infants	From birth to 1 year old
Early Childhood	2Years-5Years
Middle Childhood	6Years-12Years

**Table.4.1. Age Criteria in Paediatrics Age criteria inpregnantwomen 19-40 years**

**InclusionCriteria:**

The criteria were included in the study of Paediatric

Patients of either sex age 0- 12 years and patients of pregnant women aged19-40years.

#### Exclusion Criteria

The criteria were excluded from the study patients of either sex aged >12 years of age in paediatrics, patients of pregnant women aged >40 years.

#### IV. DISCUSSION

Among total patients Cefotaxime (72.30%) was most commonly used ophalospirin than other cephalosporin's followed by ceftriaxone (13845) This way shows the wider usage of third generation cephalosporin in hospitalized pediatric patients testings are similar to the study conducted by Mahendrakianer et al. UNICER and WHO have guidelines for treating pneumonias. According to the guidelines, Cefotaxime and amoxicillin are effective drugs against bacterial pathogens and are often used to treat child with pneumonia. In this study most of the drugs prescribed were cephalosporin's to treat pneumonia.

It was found out that 97% of cephalosporins were prescribed for parental administration, while only 3% were for oral route in paediatric patients. A study carried out in Kathmandu valley (2004) showed that, 75% antibiotics were given by injections. Among 80 patients 63 (78.75%) patients were immunized and 17 (21.29%) patients were not immunized. These findings are related to the study conducted by Lexley M Pinto Pereira. Immunization will reduce the severity of occurrence of infection. In this study on ADRs were observed among the patients on using the therapy.

All patients were adherent for the drugs and shows compliance. This may be because all patients are inpatients and they are regularly monitored by the nurses, physicians and pharmacists. In total 80 prescriptions 74 drug-drug interactions were found. Among them major found to be 1, moderate was found to be 64 and minor was 11. The all interactions were potential drug interactions and no one interaction is observed among 28 interactions.

Cefotaxime with Amikacin was 19 (68%), Ceftriaxone with Amikacin was 7 (25%), Cefotaxime with Gentamycin was 1 (3.5%) and Ceftriaxone with Gentamycin was 1 (3.5%).

Our study had a number of limitations. The study was prospective observational and seasonal variations were not considered. The patient care indicators were not studied. The study was limited to only a paediatric department. Also, further studies for a longer period of time in all the clinical departments are required. The data

presented here will be useful in future, long term and more extensive drug utilization studies in the hospital and in promotion of rational prescribing and drug use in hospitals.

Drug utilisation evaluation (DUE) is a systematized approach designed to control rational use of drugs. The study on drug utilization will identify problems like irrational drug adverse drug reactions, patient non adherence, drug interactions and drug cost. Cephalosporins are currently the most commonly prescribed drugs in hospitals, worldwide. But, excessive and inappropriate use of Cephalosporins, may lead to drug related problems like increased drug resistance. Total 80 patients were included in the study. Among them 49 (61.25%) patients were the male and 31 (38.75%) patients were female. These results are similar to by Vishwantham et al. (2016) study Assessment of drug utilization in hospitalized children at a private hospital which reveals predominance of males (53.33%) than females.

Considering the age group the majority number of patients was in 1 day - 1 year age group 38 (47.5%) followed by 27 (33.75%) patients are in 1-5 years. These findings were in related P Khajamoinuddin et al. study of prescribing pattern of antibiotic in pediatric pneumonia. In our study most of the patients were diagnosed for respiratory tract infections i.e. 25 followed by 17 patients were diagnosed for fever. This result shows that pneumonia is common in pediatric departments and it is more prevalent among children.

Epidemiology states that over 1090 India children under five years of age die every day prompt treatment of pneumonia is usually with a full course of appropriate antibiotics like Cephalosporins. For various indications, 511 different drugs were prescribed for treating. Among them majority of drugs were NSAIDs (16.04%) followed by cephalosporin's (12.72%) and (11.15%) of the drugs were antibiotics other than cephalosporin's.

These findings are in contrast to the Nema Pallavi et al. study where in their study the beta-lactam antibiotics are majorly prescribed drugs than cephalosporins. The cephalosporins were the most common drugs prescribed for treating pneumonia infections. The prescribing of cephalosporin's for treating normal fever is unnecessary (10) Among 65 cephalosporin prescribed patients majority of the patients 22 (33.84%) were prescribed cephalosporin's with the duration of 5-6 days, followed by 7-8 days and 19

patients ( 29.23%) these results were similar to the pandiamunian j et.al.study.

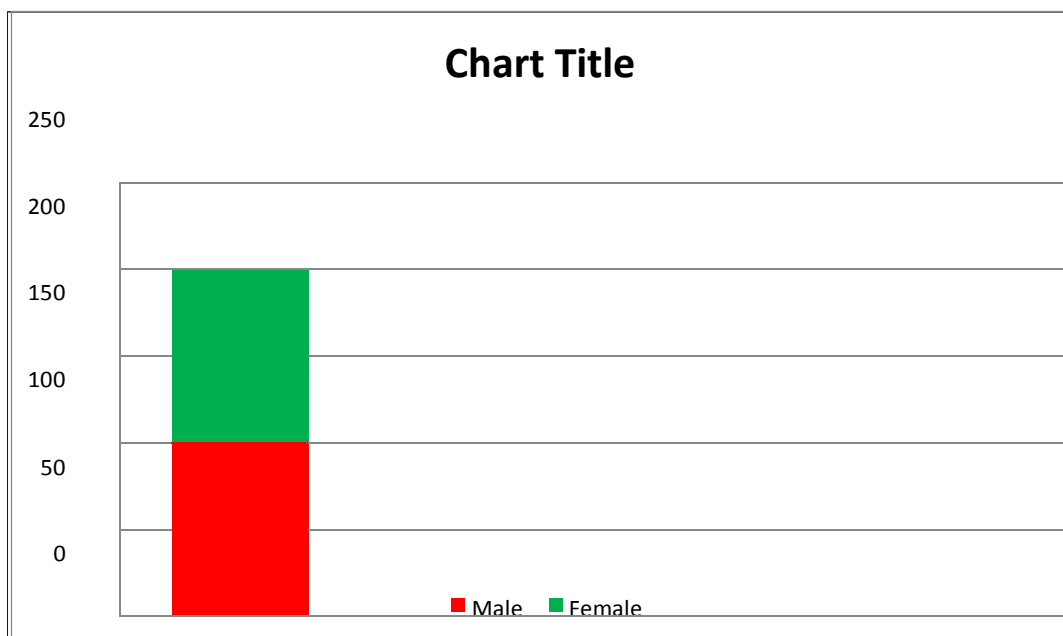
Gender:  
 Among 200 paediatric prescriptions we observed 96 are of male patients and 104 are of female patients.

### V. RESULTS

Classification of paediatric patients based on

Gender	Number Of Patients
Male	96(53%)
Female	104(57%)
Total	200(100%)

**Table.6.1: Paediatrics (Gender of patients observed in the study)**



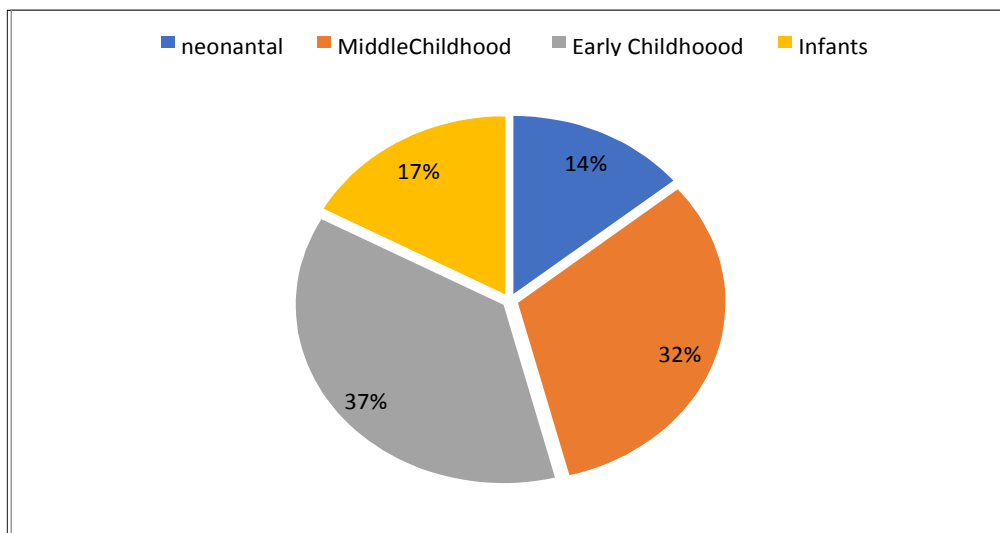
**Figure.6.1 Classification of paediatric patients based on Gender**

Classification of paediatric patients based on Age group:

All the Paediatric patients were divided into 4 groups based on the age of the patients.

Age Group	Number of Patients
Birth-12 months	27(15%)
13months-2years	33(18%)
2years-5years	67(30%)
6years-12years	73(50%)

**Table.6.2. Age groups of patients observed our study (n=200)**

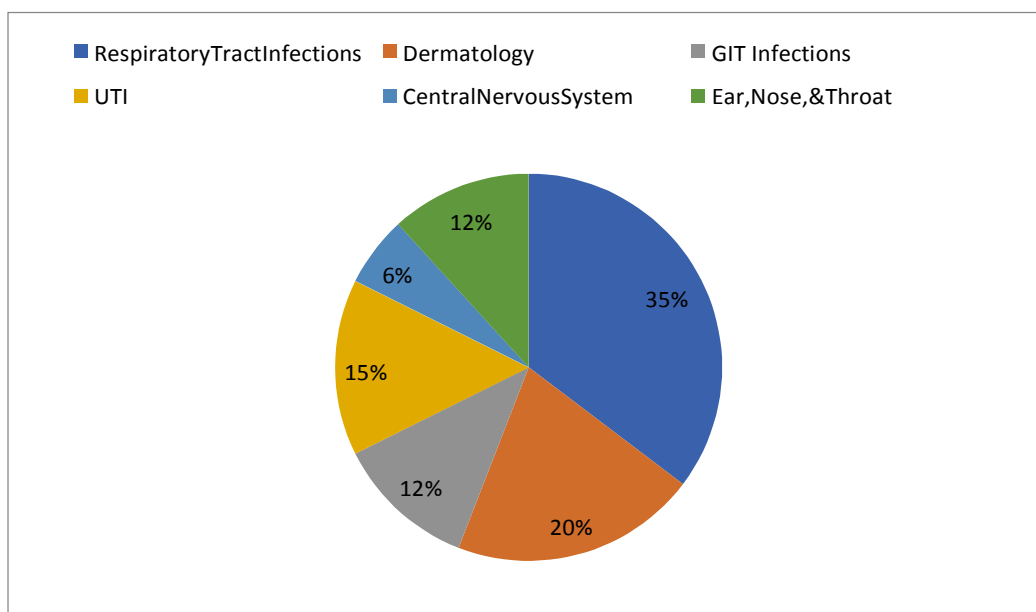


**Figure.6.2 Classification of paediatric patients based on Age group**

Classification of paediatric patients based on Infections:  
 We have observed various kinds of infections in paediatric patients during our study

Types of infections	Number of Patients
Respiratory Tract Infections	90(30%)
Dermatology	30(10%)
Gastrointestinal Infections	20(6.6%)
Urinary tract infections	98(40%)
Ear ,Nose, and Throat	50(16.6%)
Others	12(4%)

**Table6.3. List of Infections and system affected to patients**



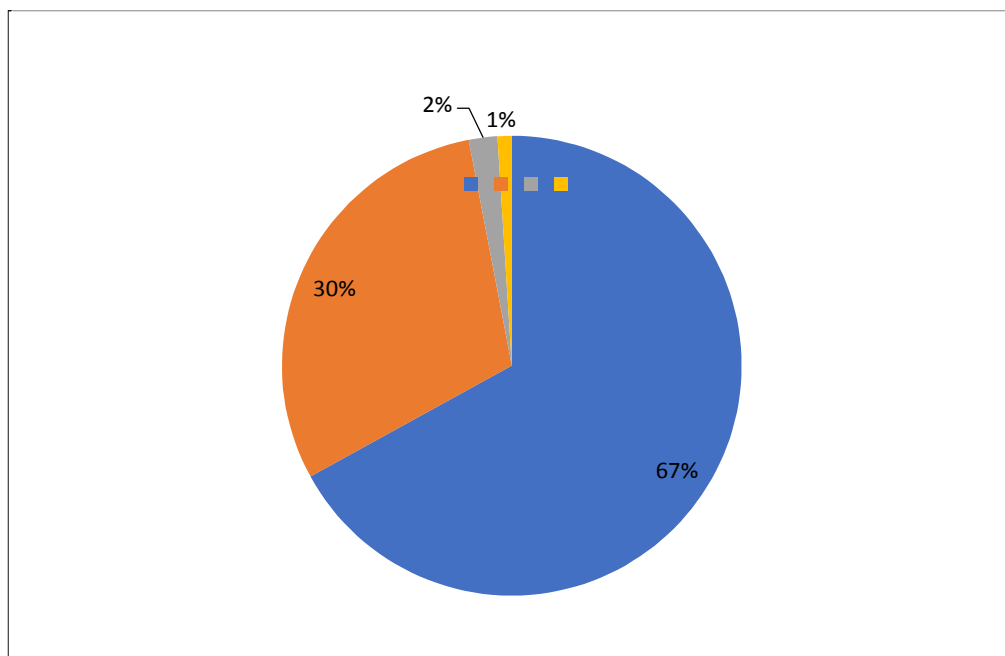
**Figure.6.3. Classification of paediatric patients based on Types of Infections**



The Antibiotics that have been used to various paediatric patients for treating the infections are divided into macrolide, flouroquinolones, nitroimidazoles, penicillin, cephalosporin and lincomycin.

List of class of Antibiotics	Number of Patients(%)
Macrolides	27(13%)
Flouroquinolones	14(7%)
Nitroimidazoles	13(6%)
Penicillin	56(50%)
Cephalosporin	75(60%)
Lincomycin	15(6%)

**Table.6.4. Pharmacological classification of antibiotics prescribed to paediatrics ( n=200)**



**Figure.6.4 Pharmacological Classification of Antibiotics Prescribed to Paediatrics**

We have observed in our study that some combination of 2 or more antibiotics have been given at a time to the same patient to increase the

efficacy of the drug the following are most commonly used combination of antibiotics that have identified from our study.

Combination of Antibiotics	Class of Antibiotic	Number Of Patients
Cefixime + Azythromycin	Cephalosporin +Macrolides	4

Ofloxacin + Metranidazole	Flouroquinolones + Antiprotozoal drug	5
Amoxicillin + Clavulanic Acid	Penicillin + beta lactase inhibitor	10

**Table.6.5 Antibiotics Combination Prescribed in Paediatrics**

The most commonly used antibiotics in pregnant women are

List of class of Antibiotic	Number of Patients (%)
Ofloxacin	10
Amoxicillin + Potassium Clavulanate	30
Ceftriaxone and Sulbactam for Injection	20
Ceftriaxone Injection IP	50

**Table.6.6 Pharmacological Classification of Antibiotics Prescribed in Pregnant Women**

We have observed from our study some antibiotics are prescribed to pregnant women to treat various infections.

## VI. CONCLUSION

### Paediatrics

Among the Total Paediatric Patients Penicillins are mostly used Antibiotics In that group of antibiotics amoxicillin with clavulanic Acid is most widely used antibiotic to treat Various Kinds of infections in paediatric population. We have observed That cephalosporine (cefexime, and cefpodoxime proxetil) are most Commonly used oral Antibiotics After Amoxicillin.

### pregnant woman

Amoxicillin + Potassium clavulanate is most widely used in pregnant women so, Amoxicillin is most Safely used Antibiotic in all Categories of patients.

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