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ASSESSMENT OF MEDICATION USE PATTERN FOR MANAGING NOENATAL SEPSIS AT TERTIARY CARE HOSPITAL: A PROSPECTIVE STUDY

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ABSTRACT: Introduction: Antimicrobial resistance is a burning problem globally due to irrational use of antibiotics. Drug utilization study is a strong tool for evaluating rational use of antibiotics. **Objective:** To evaluate the drug utilization pattern, to assess the risk factors associated with Neonatal sepsis & to encourage rational prescribing for these patients in tertiary care teaching hospital. **Materials and Methods:** It was a prospective study in NICU of tertiary care hospital for duration of one year. Case record forms were used to collect the information regarding demographic details, maternal and delivery details, symptoms and co-morbidities in neonates with sepsis, final diagnosis and medications administered. Antimicrobials and other drugs use data such as selection of drug, dosage form and route of administration, duration were collected as per WHO guideline for drug utilization study (core indicators) and were analyzed using SPSS. **Results and Discussion:** Majority of the patient (42.85%) had low birth weight of less than 2.5 kg. Prematurity is a major cause of low birth weight (less than 2.5kg). 82.5% of patients admitted were from early onset sepsis group which may be because of the fact that during early neonatal age neonates are more vulnerable to infection. We observed that all the patients received antibiotics, with majority (76.1%) of the patients were given 2 antimicrobials (cefotaxime in 54% of patients & amikacin in 39% of patients). The GARDP aims to develop an antimicrobial regimen for the empiric treatment in neonatal sepsis. **Conclusion:** Periodic analysis of drugs used in neonatal sepsis facilitates rational use of drugs in neonates to avoid adverse effects to their immature body functions. It also helps to establish therapeutic guidelines so that over usage of antimicrobials can be controlled and rationalize the drug usage.

INTRODUCTION: According to the World Health Organization (WHO), globally each year over 4 million neonates died within 28 days of birth¹. The main causes of neonatal deaths globally are prematurity (28%), sepsis (26%) and asphyxia/birth related hypoxia (23%)².

Neonatal sepsis refers to an infection involving bloodstream in newborn infants less than 28 days old. It continues to remain a leading cause of morbidity and mortality among infants, especially in middle and lower-income countries³.

Improving maternal health and nutrition, maternal immunization, clean delivery, intra-partum antibiotic prophylaxis, intravenous central line management, clean umbilical cord cutting, early detection and treatment of infectious disease, closed medication system, improvements perinatal care services, and producing trained health professionals, like skill birth attendants and

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neonatal nurses are important approaches to prevent neonatal sepsis ⁴.

Also, early neonatal sepsis is associated with a significant mortality rate of up to 54%. Early neonatal sepsis, which is commonly described as sepsis that occurs during the first 72 h after delivery, is a significant factor in neonatal sepsis ⁵. Even though we are implementing many approaches to prevent neonatal sepsis, if sepsis is been developed in neonate, it can be managed yearly diagnosis and using antimicrobial agent rationally in addition aggressive supportive care is necessary. Empiric treatment with antibiotics should be started as soon as sepsis is clinically suspected, even without confirmatory lab data. In general, antimicrobial resistance patterns of common bacteria in the neonatal intensive care unit can guide antibiotics' initial choice ⁶. Thus, the aim of this study was to determine the drug prescribing patterns for neonatal sepsis in hospital, with a focus on the most common therapeutic class prescribed.

METHOD: The prospective observational study was carried out for one year in GCS Medical College of Pharmacology Department, Ahmedabad, Gujarat, India. The study protocol was approved by the Institutional Ethics Committee.

Inclusion Criteria: Diagnosed cases of suspected neonatal sepsis as per the IMNCI guidelines with informed consent signed by parents. New born with 0-28 days of age group admitted in NICU (both female and male sex).

Exclusion Criteria: The parents/guardians of the neonate who did not give their written consent in an inform consent form were excluded. Patients who are more than 28 days old did not satisfy sepsis screening, of AIDS infected mother, healthy baby, septicemia due to viral or fungal infection, congenital abnormality, physiological jaundice, premature baby without sepsis, hypoxic ischemic encephalopathy and metabolic disorders without sepsis were not included in this study.

Study Procedure: Total 126 suspected sepsis cases were enrolled in this study. Written informed consent was obtained from the parents/guardians. Data were collected in a predesigned case record form, from hospital record like age, sex, birth weight, gestational age, antibiotics used were recorded. In culture positive cases, causative microorganism isolated was also noted. Antimicrobials use data such as selection of drug, dosage form and route of administration, duration were collected as per WHO guideline for drug utilization study. The patients were followed up daily during the hospital stay to collect the data about change in drugs & days of hospital stay. Demographic details, the diagnosis with comorbidities of each newborn, and the drugs given to them (except intravenous fluids, vaccines, Vitamin K, oxygen, and blood products) along with the doses and routes of administration were recorded

Statistical Analysis: Data was recorded on Microsoft excel sheet 2007. Average number of antimicrobials prescribed per patient and average duration of the hospital stay were calculated by using means. Other statistical tools were used wherever necessary. Recorded data was analyzed using SPSS-20. Results were expressed in terms of descriptive statistics

RESULTS: In this study population with 126 neonates with suspected sepsis among which 40 neonates (i.e 31.74%) were having birth weight between 2.5 to 3kg & 32 neonates (25.39%) were weighing more than 3kg. But low birth weight of less 2.5kg was observed in 54 neonates (42.85%) **Table 1.** The occurrence of EONS (Early onset neonatal sepsis) was more common (82.5%) than LONS (Late onset neonatal sepsis -i.e17.4%) **Table 1.** Majority of neonates were full term accounting for 116 (92%) followed by preterm of 10(8%). Out of 10 Preterm, 4 were having LBW babies were more severely associated with the symptoms of sepsis **Table 1.**

TABLE 1: DEMOGRAPHIC CHARACTERISTICS OF NEONATES WITH SEPSIS IN NICU

Characteristics	No. of patients (N=126)	%
Birth weight: LBW (less than 2.5kg)	54	42.85
A (2.5 - 3.0 kg)	40	31.74
B (more than 3kg)	32	25.39
Type of sepsis: Early onset sepsis	104	82.5
Late onset sepsis	22	17.4

Time of childbirth: Preterm	10	8
Full term – Normal delivery	84	66.66
Full term- Caesarean Section	32	25.39

Neonates with suspected sepsis shows various symptoms among which fever and breathlessness was observed in 122 & 19 patients respectively, while yellowish skin/sclera was observed in 15 and skin rashes in 7 patients. Dehydration, grunting, intrauterine growth retardation was also observed among some of the neonates **Table 2**.

TABLE 2: CLINICAL SYMPTOMS OBSERVED IN PATIENTS OF NEONATAL SEPSIS

Clinical Presentation	No. of patients (N=126)
Fever	122
Breathlessness	19
Yellowish skin/ sclera	15
Skin Rash	07
Pustules	05
Dehydration	04
Grunting	04
IUGR	04
Improper feed intake	37
Cyanosis	02
Seizure	02
Small for gestational age	08
Excess Crying	01
Vomiting	01
Umbilical discharge	01

Other co morbidities like hyponatremia & pneumonia was seen in 2.3% of the neonates while hyperbilirubinemia, hypocalcaemia, respiratory distress, transient tachypnoea of new born was also observed in some of the neonates **Table 3**.

TABLE 3: OBSERVED CO-MORBIDITIES AMONG NEONATES WITH SEPSIS

Co-morbidities	No. of patients (N=126)
Hypernatremia	03
Pneumonia	03
Hyperbilirubinemia	02
Hypocalcaemia	02
Indirect hyperbilirubinemia	02
Respiratory distress	02
Transient tachypnoea of new born	02
Conjunctivitis	01
Meconium aspiration syndrome	01
Meningitis	01
Tongue tied	01

Prescribed drugs were analyzed using WHO core prescribing indicator. Average number of drugs prescribed per encounter was 2.23. 67% of drugs were prescribed from National list of Essential Medicines.

Out of total 281 drugs prescribed among 126 neonatal patients, 244 (87%) were prescribed by brand name while 37 (13%) were prescribed by generic name **Table 4**.

66.5% was prescribed the drugs by parenteral route and 33% were prescribed drugs in the form of drops. (Dosage form)

TABLE 4: ANALYSIS OF PRESCRIPTION USING THE WHO PRESCRIBING INDICATORS

S. no.	WHO prescribing indicator	Number/Percentage
1	Average number of drugs per encounter	2.23
2	Percentage of drugs prescribed by generic name	13.1%
3	Percentage of encounters with antibiotics prescribed	100%
4	Percentage of encounters with injections prescribed	66.5%
5	Percentage of drugs prescribed from essential drug list 2022	67%

Number of antimicrobials prescribed to a patient during the course of the therapy ranged from 1 to 3, more number of patients, i.e. 96 (76.19 %) received 2 antimicrobials, which was followed by 17

patients (13.49%) receiving 1 antimicrobial, 13 patients (10.31%) receiving 3 antimicrobials during the course of therapy **Table 5**.

TABLE 5: NUMBER OF ANTIMICROBIALS PRESCRIBED PER PATIENT

No. of antibiotics prescribed	No. of patients (N= 126)	%
01	17	13.4
02	96	76.1
03	13	10.3

Results showed that for neonatal sepsis, most frequent prescribed antimicrobials were cefotaxime (69 patients) & amikacin (49 patients). Least prescribed antimicrobials were cefoperazone +

salbactam (10 patients) combination, meropenem (6 patients) & neomycin (2 patients) **Table 6.** Apart from antimicrobial drugs, majority of the neonates (73%) were given multivitamins. Paracetamol,

calcium gluconate, midazolam, furosemide and dexamethasone was also prescribed to some the neonates **Table 6.**

TABLE 6: FREQUENCY OF DRUGS PRESCRIBED FOR TREATMENT OF NEONATAL SEPSIS IN NICU

Class of drugs	Examples	No. of patients
Cephalosporin	Cefotaxime	69
	Cefoperazone (in combination with Salbactam)	10
Aminoglycosides	Amikacin	49
	Neomycin	2
Beta lactamase inhibitor	Salbactam (in combination with Cefoperazone)	10
Beta lactum	Meropenem	6
NSAIDs	Paracetamol	12
Multivitamins (Calcimax)	Calcium carbonate, Mg hydroxide, Zinc gluconate, Vit D3	92
Corticosteroids	Dexamethasone	1
	Calcium gluconate	29
High ceiling diuretic	Furosemide	2
Benzodiazepam	Midazolam	10
	Total	281

Duration of hospital stay during the treatment in majority group of patients (69.04%) was 4-8 days while some patients with concomitant conditions

eg. Respiratory distress, pneumonia etc. stayed for 8-14 days **Table 7.**

TABLE 7: DURATION OF HOSPITAL STAY DURING THE TREATMENT

Duration of hospital stay	No. of patients (126)	%
0-4 days	11	8.7
4-8 days	87	69.04
8-14 days	28	22.22

DISCUSSION: Neonatal sepsis is a major cause of morbidity worldwide and one of the three primary causes of 2.7 million deaths every year ¹. Over 600,000 of these deaths are attributed to infections alone (United nations) and 99% of these deaths take place in developing country settings. (7) Neonatal sepsis requires urgent and specific antimicrobial treatment depending on the causative organism and their sensitivity pattern, however it has been observed that the etiological agents and their sensitivity towards AMAs keep on changing over a period of time, so for optimum management of neonatal sepsis we need data of all these important variables, which can be provided via drug utilization study.

In the present study, we collected data of 126 neonates with sepsis admitted to NICU, at GCS Hospital, a tertiary care teaching hospital attached to Medical College, Ahmedabad. Data of the neonates such as birth weight, type of sepsis, mode of delivery, clinical presentation of neonates, drug therapy with dosage form, prescribing indicators &

duration of NICU were collected and analyzed. This study showed that majority of the patient (42.85%) had low birth weight of less than 2.5 kg while 31.74 % had normal birth weight between 2.5 to 3kg. Our results correlates with systemic analysis done by Sharrow *et al* where it was observed that prematurity is a major cause of low birth weight (less than 2.5kg) in preterm babies ⁸.

In this study, among the 126 patients of neonatal sepsis, 82.5% of patients admitted were from early onset sepsis group while 17.4% were of late onset sepsis group which may be because of the fact that during early neonatal age neonates are more vulnerable to infection. Our finding corroborates with other study conducted in a Tertiary Care Hospital of Tanzania ⁹ and Odhisha, India where number of cases with early onset sepsis were more compared to late onset sepsis ¹⁰. Many researchers had postulated that maternal genital tract as the source of infection in neonatal sepsis especially early onset neonatal sepsis (EONS) ^{11, 12}.

This study showed that out of 126 patients admitted, 10(8%) patients were pre-terms and 116 (92%) were full terms, while Neubert *et al.* (2010)¹³ have reported admission of 69% preterm infants. Results in our study are not similar to the findings of previous studies. Another study done by Shrestha *et al.*¹⁴ showed that number of pre-term neonates admitted were 33%. The reasons for the lower admission rate of pre-term in this study may be better prenatal care in suspected pre-term delivery cases.

In this study, commonly observed comorbid condition was hypernatremia, pneumonia, hyperbilirubinemia, respiratory distress and transient tachypnea of newborn. Transient tachypnea of newborn (TTN), respiratory distress syndrome (RDS), feeding difficulties and hypothermia are common in infants born at 37 and 38 weeks of gestation than infants born after 38 weeks of gestational age¹⁵.

Common clinical symptoms among neonates with sepsis were fever, improper feed intake, breathlessness and yellow sclera/skin illustrated in **Table 2**. Other symptoms like skin rashes, pustules, dehydration, grunting etc was also observed which correlates as per the symptoms mentioned in Nelson Textbook of Pediatrics¹⁶.

In the present study, medicines were prescribed by generic name in 13% of cases only. Majority of the drugs were prescribed by brand name which adds to the cost of therapy. Generic prescribing would rationalize the use and reduce the cost of drugs¹⁷. Also majority of drugs were given by parenteral route (66.5%) while some neonates were also prescribed drops and ointment. In neonatal sepsis, as faster onset of action is usually needed and in neonates oral administration is difficult, most of the drugs are prescribed by parenteral route only. Our study correlates with the study conducted by Chatterjee *et al.* where 92.1% of neonates were prescribed drugs by intravenous route¹⁸.

Percentage of drugs prescribed per patient was approximately 2 or 3 while percentage of drugs prescribed from National List of Essential Medicine (India) was 67%. However, more drugs should be prescribed from the essential medicine list. But in fewer cases of neonatal sepsis some

antimicrobials are prescribed according to the culture sensitivity report so in such cases newer effective antimicrobials are preferred which may not be in NLEM.

Out of total patients of neonatal sepsis, we observed that all the patients received antibiotics with majority (76.1%) of the patients were given 2 antimicrobials. Our study complies with study of Narendra Behra *et al.*¹⁰ where maximum number of patients were prescribed 2 antimicrobials.

We observed that during the study period most frequent prescribed antimicrobials were cefotaxime in 54% of patients & amikacin in 39% of patients, and cefoperazone + salbactam combination in 8% of patients. The identification of new antimicrobial regimens for treatment of neonatal sepsis is one of the goals of the Global Antibiotic Research and Development Partnership (GARDP). In particular, the GARDP aims to develop an antimicrobial regimen for use in LMICs for the empiric treatment of neonatal sepsis in locations with increasing resistance to current WHO-recommended treatments¹⁹. This is evident from our study too, where cefotaxime and amikacin were used as first-line therapy. Meropenem was prescribed 5% of patients. Prescribing meropenem in neonatal sepsis was well established in data of real world by Guangna Cao *et al.*²⁰. They showed the data that neonates on meropenem who were suspected of serious sepsis with related symptoms may be administered an empirical extended infusion.

Multivitamins was prescribed to 73% of patients. Vitamins are essential micronutrients in many biological mechanisms and serve as antioxidant, anti-inflammatory and regulation of gene transcription²¹.

In our study average duration of hospital stay among majority of patients (69.04%) was 4-8 days. While another study conducted by Meshram RM *et al.*²² showed average hospital stay of 9.7 days which shows that various factors can affect time to recovery from neonatal sepsis. Earlier discharge of patients on recovery avoids undue prolongation of hospitalization which may itself increase chances of nosocomial infection in neonates. Thus, drug utilization research holds crucial place in clinical practice as it forms the basis for establishment of

formularies and amendments in drug dispensing policies at local and national levels. Present study further provides a broader evaluation of efficacy of drugs in NICU. Less sample size and confined study to only one teaching hospital was our limitation.

CONCLUSION: To conclude, periodic analysis of drugs used in neonatal sepsis facilitates rational use of drugs in neonates to avoid adverse effects to their immature body functions. It also helps to establish therapeutic guidelines so that over usage of antimicrobials can be controlled and rationalize the drug usage.

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