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DRUG UTILIZATION PATTERN IN A SPECIAL NEWBORN CARE UNIT AT A TERTIARY CARE HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Neonates represent a vulnerable population with unique pharmacokinetic and pharmacodynamic characteristics, making rational drug use crucial. Drug utilization studies in neonatal intensive care settings are essential for optimizing therapeutic outcomes and minimizing adverse effects. Objective of the study is to evaluate drug utilization patterns in the Special Newborn Care Unit (SNCU) of a tertiary care hospital, assess routes and doses of drug administration, and compare drug utilization between preterm and term neonates.

Methods: A prospective observational study was conducted over three months at the Centre of Excellence for Obstetrics and Neonatology, Government Medical College, Pudukkottai. A total of 150 neonates admitted to the SNCU who received pharmacological treatment were enrolled. Data on patient demographics, diagnoses, medications prescribed, dosage, route, frequency, and duration were collected from drug charts and analyzed using SPSS software.

Results: The mean number of drugs per neonate was 5.2 ± 2.1. Antimicrobials constituted 32.4% of all prescriptions, with Cefotaxime (38.2%) and Amikacin (24.6%) being most commonly used. Intravenous route was preferred in 89.3% of administrations. Preterm neonates received significantly more drugs (6.1 ± 2.3) compared to term neonates (4.5 ± 1.8) ($p<0.001$). Generic prescribing was observed in 76.8% of cases. Compliance with the National List of Essential Medicines was 84.2%. The overall survival rate was 96.6%.

Conclusion: This study reveals rational prescribing practices with predominant use of essential medicines and generic formulations. However, high antimicrobial usage warrants implementation of antimicrobial stewardship programs. Preterm neonates demonstrated higher medication burden, emphasizing the need for specialized protocols and continuous monitoring of drug utilization patterns.

Keywords: Drug utilization, neonatal intensive care, antimicrobials, preterm neonates, essential medicines, prescribing patterns

INTRODUCTION

Neonates admitted to intensive care units represent one of the most vulnerable patient populations in modern medicine, requiring complex therapeutic interventions for conditions ranging from prematurity and respiratory distress syndrome to neonatal sepsis and metabolic disorders. The

neonatal period, defined as the first 28 days of life, is characterized by rapid physiological maturation and development, resulting in substantial differences in drug absorption, distribution, metabolism, and elimination compared to older children and adults.(7,8) These unique pharmacokinetic and pharmacodynamic characteristics necessitate careful consideration when prescribing medications to this population.

The immature hepatic enzyme systems, reduced renal clearance, altered body composition with increased total body water, and developing blood-brain barrier in neonates significantly influence drug disposition and response.(8) Furthermore, the limited availability of age-appropriate formulations, paucity of pharmacokinetic data, and off-label use of medications add complexity to neonatal pharmacotherapy. Despite these challenges, sick neonates frequently require multiple medications simultaneously, including antimicrobials, respiratory support medications, cardiovascular agents, and nutritional supplements, making them susceptible to drug interactions and adverse effects.

Drug utilization research, as defined by the World Health Organization, involves the marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences.(6) Such studies are instrumental in identifying prescribing patterns, detecting irrational use of medications, and implementing corrective measures to optimize therapeutic outcomes. In the context of neonatal care, drug utilization studies assume particular importance given the unique challenges and potential consequences of inappropriate prescribing in this vulnerable population.

A concerning trend observed globally is the irrational use of antimicrobials in neonatal intensive care units, driven by diagnostic uncertainties, fear of missing early-onset sepsis, and pressure to initiate empirical therapy.(9,11) While antimicrobials play a life-saving role in treating neonatal infections, their indiscriminate use contributes to the emergence of multidrug-resistant organisms, disruption of the developing microbiome, and increased healthcare costs.(12) The judicious use of antimicrobials, guided by local resistance patterns and adherence to established guidelines, is therefore critical in neonatal care settings. Several studies from different geographic regions have documented varying patterns of drug utilization in neonatal intensive care units, with differences attributable to local disease epidemiology, available resources, prescribing cultures, and institutional protocols.(1-5,10) Understanding institutional prescribing patterns through systematic drug utilization studies enables identification of areas requiring intervention, facilitates development of evidence-based treatment protocols, and promotes rational pharmacotherapy.

The Government Medical College and Hospital, Pudukkottai, serves as a tertiary referral center for neonatal care in the region, with its Special Newborn Care Unit (SNCU) catering to sick neonates from surrounding districts. Given the absence of published data on drug utilization patterns from this institution and the region, this study was undertaken to systematically evaluate current prescribing practices, identify potential areas for improvement, and establish baseline data for future quality improvement initiatives.

METHODOLOGY

Study Design and Setting

This prospective observational study was conducted at the Special Newborn Care Unit (SNCU) of the Centre of Excellence for Obstetrics and Neonatology, Government Medical College and Hospital, Pudukkottai, Tamil Nadu, India. The SNCU is a 40-bed tertiary care facility equipped with modern neonatal life support systems, including mechanical ventilators, continuous positive airway pressure (CPAP) devices, phototherapy units, and comprehensive laboratory support. The unit serves as a referral center for high-risk neonates from multiple districts in southern Tamil Nadu.

Study Duration and Sample Size

The study was conducted over a period of three months from May – July 2024. Based on the average monthly admissions and considering a 10% dropout rate, a sample size of 150 neonates was

determined to be adequate for meaningful analysis of prescribing patterns and comparison between subgroups.

Patient Selection

Consecutive sampling was employed to enroll neonates meeting the inclusion and exclusion criteria. All neonates less than two months of age admitted to the SNCU during the study period were screened for eligibility. Neonates who received any pharmacological treatment beyond routine prophylactic medications (vitamin K and vaccines) were included in the study. Babies admitted solely for observation without requiring therapeutic interventions were excluded from analysis. Informed consent was obtained from parents or legal guardians of all enrolled neonates prior to data collection.

Data Collection

A structured data collection form was designed to capture comprehensive information regarding patient demographics, clinical characteristics, and medication details. For each enrolled neonate, the following information was systematically recorded: gestational age at birth, birth weight, postnatal age at admission, gender, mode of delivery, primary indication for admission, need for respiratory support, final diagnosis, and clinical outcome (survived or expired). Detailed medication data included name of each drug prescribed, dose, route of administration, frequency, date of initiation, and date of discontinuation or discharge.

Data were prospectively collected from multiple sources including medication administration records, drug charts maintained in the SNCU, nursing kardex, and electronic medical records where available. Each prescription was carefully reviewed to ensure accuracy and completeness of information. For the purpose of analysis, neonates were categorized as preterm (gestational age less than 37 completed weeks) or term (gestational age 37 weeks or more). Medications were classified according to their therapeutic categories based on the Anatomical Therapeutic Chemical (ATC) classification system.

Data Analysis

All collected data were entered into Microsoft Excel spreadsheets with built-in validation checks to minimize data entry errors. Following data cleaning and validation, the dataset was exported to SPSS version 26.0 for statistical analysis. Descriptive statistics were computed for demographic and clinical variables, with continuous variables expressed as mean ± standard deviation or median with interquartile range depending on distribution, and categorical variables presented as frequencies and percentages.

The average number of drugs per prescription was calculated by dividing the total number of drug prescriptions by the total number of patients. Route-wise distribution of drug administration was analyzed and presented as percentages. Prescriptions were evaluated for generic versus brand name usage, and compliance with the National List of Essential Medicines (NLEM) India 2022 was assessed.

Comparative analysis between preterm and term neonates was performed using appropriate statistical tests. Independent samples t-test was employed for comparing continuous variables with normal distribution, while Mann-Whitney U test was used for non-parametric data. Chi-square test or Fisher's exact test was utilized for comparing categorical variables between groups. A p-value of less than 0.05 was considered statistically significant for all analyses.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee of Government Medical College and Hospital, Pudukkottai, prior to study commencement. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Patient confidentiality was maintained throughout the study, and all data were anonymized before analysis.

The study was purely observational with no intervention in routine clinical care, and no additional costs were incurred by the patients or their families.

RESULTS

Demographic and Clinical Characteristics

During the three-month study period, a total of 214 neonates were admitted to the SNCU. Of these, 150 neonates who received pharmacological treatment were enrolled in the study, while 64 neonates admitted for observation or managed with supportive care alone were excluded. The demographic and clinical characteristics of the study population are presented in Table 1.

Table 1: Demographic and Clinical Characteristics of Study Population (N=150)

Characteristic	Value
Gender, n (%)	
Male	88 (58.7%)
Female	62 (41.3%)
Gestational Age	
Mean ± SD (weeks)	36.2 ± 2.8
Preterm (<37 weeks), n (%)	67 (44.7%)
Term (≥37 weeks), n (%)	83 (55.3%)
Birth Weight	
Mean ± SD (grams)	2420 ± 645
Low birth weight (<2500g), n (%)	82 (54.7%)
Mode of Delivery, n (%)	
Normal vaginal delivery	76 (50.7%)
Lower segment cesarean section	68 (45.3%)
Assisted vaginal delivery	6 (4.0%)
Postnatal Age at Admission	
Mean ± SD (days)	3.2 ± 4.6
Day 1 of life, n (%)	94 (62.7%)
Respiratory Support Required, n (%)	58 (38.7%)
Mean Duration of Hospital Stay	
Mean ± SD (days)	8.4 ± 5.2
Outcome, n (%)	
Survived	145 (96.6%)
Expired	5 (3.4%)

The study population demonstrated male predominance with 58.7% male neonates. Nearly half of the enrolled neonates (44.7%) were preterm, and 54.7% had low birth weight. The majority of admissions (62.7%) occurred on the first day of life, reflecting the unit's role in managing early neonatal complications. Respiratory support was required in 38.7% of cases, indicating the significant burden of respiratory morbidity. The overall survival rate was 88.7%, with mortality primarily attributable to extreme prematurity, severe birth asphyxia, and overwhelming sepsis.

Indication for Admission and Final Diagnoses

Table 2 presents the distribution of primary indications for admission and final diagnoses. Respiratory distress syndrome was the leading indication for admission (28.7%), followed by neonatal sepsis (24.0%) and prematurity-related complications (21.3%).

Table 2: Primary Indications for Admission (N=150)

Indication	Frequency	Percentage
Respiratory distress syndrome	43	28.7%
Neonatal sepsis (suspected/confirmed)	36	24.0%
Prematurity (without RDS)	32	21.3%
Birth asphyxia	18	12.0%
Hyperbilirubinemia requiring phototherapy	9	6.0%
Meconium aspiration syndrome	6	4.0%
Congenital pneumonia	4	2.7%
Others	2	1.3%

Drug Utilization Pattern

A total of 784 drugs were prescribed to 150 neonates during the study period, yielding an average of 5.2 ± 2.1 drugs per neonate. The distribution of number of drugs prescribed per patient is shown in Table 3.

Table 3: Distribution of Number of Drugs per Neonate

Number of Drugs	Number of Neonates	Percentage
1-3	52	34.6%
4-6	78	52.0%
More than 7 drugs	20	13.4%

The majority of neonates (52.0%) received 4-6 medications during their hospital stay. Around 13.4% of neonates received 7 or more drugs, representing the most critically ill patients with multiple organ system involvement.

Route of Drug Administration

Analysis of routes of administration revealed that the intravenous route was the most commonly utilized (89.3%), followed by oral/orogastric route (7.8%) and topical/others (2.9%), as detailed in Table 4.

Table 4: Route-wise Distribution of Drug Administration

Route of Administration	Number of Prescriptions	Percentage
Intravenous	700	89.3%
Oral/Orogastric	61	7.8%
Topical/Eye drops	18	2.3%
Intramuscular	5	0.6%
Total	**784**	**100%**

Therapeutic Categories of Drugs

Drugs were classified into therapeutic categories, with antimicrobials constituting the largest group (32.4%), followed by supportive medications including vitamins and minerals (18.6%), cardiovascular agents (14.3%), and respiratory medications (12.2%), as shown in Table 5.

Table 5: Therapeutic Categories of Prescribed Drugs

Therapeutic Category	Number of Prescriptions	Percentage
Antimicrobials	254	32.4%
Vitamins and minerals	146	18.6%
Cardiovascular agents	112	14.3%
Respiratory medications	96	12.2%
Anticonvulsants	42	5.4%
Gastrointestinal agents	38	4.8%

Analgesics	28	3.6%
Diuretics	24	3.1%
Antifungals	18	2.3%
Others	26	3.3%
Total	**784**	**100%**

Most Commonly Prescribed Drugs

The top 15 most frequently prescribed individual drugs are presented in Table 6. Cefotaxime was the most commonly prescribed drug (38.2%), followed by Amikacin (24.6%) and calcium gluconate (22.0%).

Table 6: Top 15 Most Commonly Prescribed Drugs

Drug Name	Number of Prescriptions	Percentage of Total Patients
Cefotaxime	97	38.2%
Amikacin	62	24.6%
Calcium gluconate	56	22.0%
Caffeine citrate	48	19.5%
Vitamin K	46	18.7%
Multivitamins	44	17.9%
Dopamine	38	15.4%
Phenobarbitone	34	13.8%
Surfactant	15	10.0%
Meropenem	28	11.4%
Dobutamine	26	10.6%
Furosemide	24	9.8%
Amphotericin B	18	7.3%
Vancomycin	16	6.5%
Midazolam	14	5.7%

Antimicrobial Prescribing Pattern

Given that antimicrobials constituted nearly one-third of all prescriptions, a detailed analysis of antimicrobial usage was undertaken. Table 7 shows the pattern of antimicrobial prescriptions.

Table 7: Antimicrobial Prescribing Pattern

Antimicrobial Agent	Frequency	Percentage of Antimicrobial Prescriptions
Cefotaxime	97	38.2%
Amikacin	62	24.4%
Meropenem	28	11.0%
Vancomycin	16	6.3%
Ceftazidime	14	5.5%
Piperacillin + Tazobactam	12	4.7%
Ampicillin+Sulbactum	11	4.3%
Gentamicin	8	3.1%
Linezolid	6	2.4%
Total	**254**	**100%**

The most common antimicrobial combination used as empirical therapy for suspected early-onset sepsis was Cefotaxime followed by amikacin. For late-onset sepsis or healthcare-associated infections, escalation to meropenem with or without vancomycin was observed in 11.4% of cases.

Compliance with National List of Essential Medicines

Evaluation of prescribed medications against the National List of Essential Medicines (NLEM) India 2022 showed that 84.2% of all prescriptions were from the essential medicines list. Non-essential medicines primarily included specific vitamin combinations, certain third-generation antibiotics, and specialized neonatal formulations not included in the NLEM.

Comparison between Preterm and Term Neonates

Comparative analysis between preterm (n=67) and term (n=83) neonates revealed significant differences in drug utilization patterns, as shown in Table 8.

Table 8: Comparison of Drug Utilization between Preterm and Term Neonates

Parameter	Preterm Neonates (n=67)	Term Neonates (n=83)	p-value
Mean number of drugs	6.1 ± 2.3	4.5 ± 1.8	<0.001
Antimicrobial usage (%)	92.5%	78.3%	0.018
Respiratory medication usage (%)	68.7%	19.3%	<0.001
Cardiovascular support (%)	44.8%	21.7%	0.003
Mean duration of therapy (days)	11.2 ± 6.1	6.4 ± 3.8	<0.001

Preterm neonates received significantly had longer duration of therapy compared to term neonates. The higher medication burden in preterm infants was primarily attributable to increased requirements for respiratory support medications (caffeine citrate, surfactant), cardiovascular agents, and prolonged antimicrobial therapy.

Dosage Form Analysis

Injectable formulations constituted the majority of dosage forms (89.3%), followed by oral liquids/syrups (7.8%) and others including eye drops and topical preparations (2.9%). The predominance of injectable formulations reflects the critical nature of illnesses requiring SNCU admission and the need for reliable bioavailability in unstable neonates.

Adverse Drug Reactions

During the study period, 8 suspected adverse drug reactions (ADRs) were documented in 8 different neonates (5.3% of study population). These included thrombocytopenia associated with antimicrobial therapy (n=3), electrolyte disturbances with diuretic use (n=2), extravasation injury from intravenous medications (n=2). All ADRs were managed appropriately with medication adjustment or discontinuation, and no serious or life-threatening ADRs were observed.

DISCUSSION

This prospective observational study provides comprehensive insights into drug utilization patterns in a Special Newborn Care Unit at a tertiary care hospital in southern India. The findings reveal a rational prescribing approach with predominant use of essential medicines, appropriate generic prescribing, and judicious medication use. However, the high proportion of antimicrobial prescriptions and the significant medication burden in preterm neonates warrant careful consideration and potential interventions.

The mean number of drugs per neonate observed in our study (5.2 ± 2.1) is comparable to findings from similar studies conducted in Indian neonatal intensive care settings. Chatterjee et al.(1) reported an average of 4.8 drugs per prescription in a study conducted in eastern India, while Chauthankar et al.(2) documented varying drug burdens depending on the severity of illness and gestational age. International literature suggests considerable variation in medication burden across different neonatal intensive care units globally, with the pooled mean ranging from 1.7 to 11.1 drugs per infant, as documented in a comprehensive review by Al-Turkait et al.(3) Our findings fall within the expected range for a tertiary care SNCU managing moderately to severely ill neonates.

The predominant use of the intravenous route (89.3%) in our study aligns with standard neonatal intensive care practice and is consistent with findings from other studies. (1,2,4) The preference for intravenous administration in critically ill neonates is justified by the need for rapid onset of action, predictable bioavailability, and the frequent inability of sick neonates to tolerate enteral medications. However, this also highlights the importance of maintaining aseptic techniques and vigilance for complications such as extravasation injuries and catheter-related bloodstream infections.

Antimicrobials constituted 32.4% of all prescriptions in our study, which is slightly higher than the 30.2% reported by Chatterjee et al.(1) but lower than rates reported from some international NICUs.(10) The high antimicrobial usage in neonatal units globally is driven by multiple factors including the high incidence of neonatal sepsis, difficulty in distinguishing between sepsis and other conditions clinically, limitations of diagnostic tests in neonates, and the potentially catastrophic consequences of untreated bacterial infections.(11) The most commonly used antimicrobial combination in our unit – cefotaxime plus amikacin represents a rational choice for empirical coverage of early-onset sepsis, providing activity against group B streptococci, Escherichia coli, and other common pathogens.

However, the substantial antimicrobial usage observed in our study underscores the urgent need for implementing antimicrobial stewardship programs in neonatal units. (12,14) Such programs should focus on adherence to evidence-based guidelines for sepsis evaluation, timely discontinuation of empirical antimicrobials when cultures are negative, optimization of dosing based on therapeutic drug monitoring, and periodic review of local resistance patterns to guide empirical therapy selection. Recent studies have demonstrated that neonatal antimicrobial stewardship initiatives can successfully reduce unnecessary antimicrobial exposure without compromising patient outcomes. (13,14)

The significantly higher medication burden observed in preterm neonates compared to term infants (6.1 vs 4.5 drugs; $p<0.001$) reflects the complex medical needs of premature babies. Preterm neonates are at increased risk for multiple complications including respiratory distress syndrome requiring surfactant and caffeine therapy, hemodynamic instability necessitating inotropic support, and infections requiring prolonged antimicrobial therapy. Additionally, preterm infants receive various supportive medications including vitamins, minerals, and nutritional supplements to support growth and development.

Compliance with the National List of Essential Medicines (84.2%) in our study demonstrates appropriate alignment with national guidelines and rational pharmacotherapy principles. (15) Essential medicines are selected based on considerations of public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. The relatively high compliance rate suggests that most neonatal conditions can be effectively managed using essential medicines. The 15.8% of non-essential medicine use primarily involved specialized neonatal formulations and certain antimicrobials not included in the NLEM, which may warrant consideration for future inclusion given their importance in neonatal care.

The overall survival rate of 96.6% in our study population is encouraging and comparable to outcomes reported from other tertiary care NICUs in India. Mortality in our SNCU was primarily attributable to extreme prematurity with very low birth weight, severe birth asphyxia with multi-organ dysfunction, and overwhelming sepsis. These findings emphasize the continued need for improved antenatal care to reduce preterm births, enhanced obstetric services to minimize birth asphyxia, and infection prevention strategies to reduce healthcare-associated infections.

The documentation of adverse drug reactions in 5.3% of neonates, while relatively low, highlights the importance of pharmacovigilance in neonatal care. Neonates are at increased risk for ADRs due to immature drug metabolism, organ function, and limited ability to communicate subjective symptoms. The ADRs observed in our study were consistent with known adverse effects of the medications involved and were appropriately managed. Strengthening ADR reporting systems, providing education to healthcare providers about neonatal pharmacotherapy, and implementing clinical decision support systems can further enhance medication safety in NICUs.

CONCLUSION

This prospective study demonstrates generally rational prescribing practices in our Special Newborn Care Unit, with appropriate use of essential medicines (84.2%) and high generic prescribing rates (76.8%). The mean medication burden was 5.2 drugs per neonate, with antimicrobials constituting 32.4% of all prescriptions.

The substantial antimicrobial usage warrants implementation of targeted stewardship programs to optimize selection, dosing, and duration while minimizing resistance emergence.Continued surveillance through periodic drug utilization reviews will be essential for maintaining quality pharmacotherapy in neonatal care.

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