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ORIGINAL RESEARCH

Antibiotic Prescription Patterns in the Neonatal Intensive Care Unit at District Civil Hospital Nuh Mandikhera

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Abstract
Neonatal infections are a leading cause of morbidity and mortality, necessitating widespread antibiotic use in Neonatal Intensive Care Units (NICUs). This study examines antibiotic prescription patterns in the NICU at District Civil Hospital Nuh Mandikhera, , between April 2023 and April 2024, through a prospective observational analysis of 50 neonates. The study evaluates antibiotic utilization, class distribution, duration, combination therapies, and adherence to national prescribing guidelines. Findings reveal a high antibiotic prescription rate of 100%, with an average of 3.02 antibiotics per neonate, predominantly involving aminoglycosides (amikacin), cephalosporins (cefotaxime), and carbapenems (meropenem). Combination therapies, particularly piperacillin with amikacin, were frequently prescribed, with limited reliance on bacterial culture data, as only 2% of cases yielded positive results. While 70.5% of prescriptions complied with the National Essential Drug List (NEDL), generic prescribing was entirely absent (0%), and prolonged therapy durations with a mean of 14.6 days further raised concerns about antimicrobial resistance. These findings underscore the urgent need for an NICU-specific antibiotic stewardship program to optimize empirical therapy, encourage microbiology-guided prescribing, enhance adherence to national guidelines, and mitigate the risk of antimicrobial resistance. Future multi-center studies are recommended to further validate these findings and guide policy interventions in neonatal antimicrobial management.

Keywords: antibiotic prescribing, neonatal intensive care unit, antimicrobial resistance, empirical therapy, antibiotic stewardship.

Introduction

Neonatal infections are a major cause of morbidity and mortality in Neonatal Intensive Care Units (NICUs) worldwide. Due to their immature immune systems and vulnerability to pathogens, neonates—especially preterm and critically ill infants—are at a heightened risk of developing severe infections, including sepsis, pneumonia, and meningitis. In such cases, antibiotics serve as a crucial line of defense, significantly improving survival rates and reducing complications. Consequently, antibiotics have become an essential component of neonatal care in the NICU, where prompt and effective antimicrobial therapy can be life-saving. However, despite their undeniable benefits, the widespread and often empirical use of antibiotics in NICUs has raised serious concerns regarding antimicrobial resistance (AMR), which has emerged as a global public health crisis.[1-3]

The overuse and misuse of antibiotics have been widely documented as key drivers of AMR, leading to the selection of resistant bacterial strains that render

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standard treatments ineffective. Neonates are particularly vulnerable to the consequences of AMR, as they have limited physiological capacity to handle infections and a reduced ability to clear certain drugs due to immature renal and hepatic functions. In the NICU setting, broad-spectrum antibiotics are frequently prescribed empirically—without laboratory confirmation of bacterial pathogens—due to the urgency of treating suspected infections. However, such practices contribute to the unnecessary exposure of neonates to antibiotics, promoting resistance, altering the normal gut microbiota, and increasing the risk of nosocomial infections caused by multidrug-resistant (MDR) organisms.[4-6]

In India, where neonatal mortality remains a significant challenge, antibiotic stewardship is critical to ensuring the rational use of antimicrobials while minimizing the risk of resistance. The National Essential Drug List (NEDL) and World Health Organization (WHO) guidelines provide recommendations for evidence-based antibiotic prescribing practices. However, adherence to these guidelines in NICUs varies widely due to factors such as physician discretion, institutional protocols, and the availability of diagnostic facilities. The choice of antibiotic regimens in NICUs is often influenced by several factors, including local microbial resistance patterns, infection severity, and the presence of co-morbidities in neonates. Furthermore, combination antibiotic therapy is commonly employed in NICUs to enhance efficacy against suspected multidrug-resistant organisms, yet such practices must be carefully evaluated to balance benefits with the risk of AMR.[7,8]

Given these concerns, it is imperative to analyze antibiotic prescription patterns in NICUs to identify trends, assess adherence to national and international guidelines, and evaluate the impact of prescribing behaviors on neonatal health outcomes. Understanding prescribing trends can help in developing targeted interventions, such as antibiotic stewardship programs, to optimize drug use, improve clinical outcomes, and reduce the burden of resistance.

This study aims to comprehensively assess antibiotic prescribing patterns in the NICU at District Civil Hospital Nuh Mandikhera, a tertiary care center in Nuh Mandikhera . The primary objectives include evaluating the types of antibiotics prescribed, their frequency of use, duration of therapy, and the rationale behind their selection. Additionally, the study seeks to assess adherence to evidence-based guidelines, determine the extent of generic prescribing, and analyze the use of combination therapies in neonatal infections. By identifying gaps in prescribing practices, the study will contribute to the growing body of research on neonatal antibiotic use and offer insights into strategies for improving antimicrobial stewardship in NICUs.

Materials and Methods

Study Design and Setting

This study was designed as a prospective observational study conducted in the Neonatal Intensive Care Unit (NICU) of District Civil Hospital Nuh Mandikhera, , a tertiary care center known for its specialized neonatal services. The study was carried out over a nine-month period from April 2023 to April 2024 following ethical approval from the District Civil Hospital Nuh Mandikhera.

Study Population and Eligibility Criteria

A total of 50 neonates admitted to the NICU were enrolled in the study. Written informed consent was obtained from parents or legal guardians before participation, ensuring adherence to ethical standards.
Inclusion criteria encompassed all neonates admitted to the NICU during the study period, irrespective of diagnosis or gestational age.
To maintain the homogeneity of the study population and avoid confounding factors, neonates were excluded if they were immunocompromised, diagnosed with grade 4 malnutrition, malignancies, or were extremely premature, defined as birth weight less than 1 kg or gestational age below 34 weeks. Cases where parental or legal guardian consent was not obtained were also excluded from the study.

Data Collection and Variables Assessed

Comprehensive data were collected for each enrolled neonate, including demographic details such as age at NICU admission, gender distribution, and primary diagnosis with associated co-morbidities.

Antibiotic prescription data included the name of the antibiotic prescribed, its drug class, route of administration (intravenous, oral, or intramuscular), dosage regimen per kilogram of body weight, and duration of therapy. Combination therapies were noted, including specific antibiotic pairings and their indications.

Microbiological and bacterial sensitivity data were collected, focusing on blood culture reports, presence or absence of bacterial or fungal growth, and antibiotic susceptibility patterns when applicable.

To assess adherence to national and international guidelines, prescriptions were compared with the National Essential Drug List (NEDL) to determine compliance. The proportion of antibiotics prescribed by generic name versus brand name was evaluated in alignment with WHO recommendations. The study also analyzed whether antibiotics were prescribed based on empirical clinical suspicion or targeted therapy guided by microbiological evidence.

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To evaluate prescribing appropriateness, WHO Core Prescribing Indicators were assessed, including the average number of antibiotics per prescription, the percentage of drugs prescribed by generic name, the percentage of encounters with at least one antibiotic prescribed, and the percentage of drugs prescribed from the National Essential Drug List.

Data Analysis

All collected data were systematically recorded in Microsoft Excel for statistical analysis. The results were expressed as means, standard deviations, percentages, and proportions where applicable. Continuous variables, such as the duration of antibiotic therapy and number of antibiotics prescribed per patient, were analyzed using Student's t-test to assess statistical significance. Discrete categorical variables, such as gender distribution and presence or absence of bacterial growth in cultures, were evaluated using non-parametric tests such as the Chi-square test. A p-value of less than 0.05 was considered statistically significant for all comparisons, ensuring rigorous interpretation of findings.

Ethical Considerations

The study was conducted following ethical principles outlined in the Declaration of Helsinki and received prior approval from the DISTRICT CIVIL HOSPITAL NUH MANDIKHERA Institutional Ethical Committee. Confidentiality and anonymity of patient data were strictly maintained, and informed consent was obtained from all participants' guardians before inclusion in the study. No additional risks or interventions were introduced beyond standard NICU care.

Results

The study analyzed a total of 50 neonates admitted to the NICU, with a mean age of 3.94 days (SD ± 5.51). The gender distribution revealed a higher proportion of male neonates compared to females, with a female-to-male (F:M) ratio of 16:34. Notably, all 50 neonates (100%) received antibiotics during their NICU stay, reflecting the high infectious burden and the critical need for antimicrobial therapyin this population.

Table 1: Demographic Characteristics and Antibiotic Use in NICU

Parameter	Value
Total Patients	50
Mean Age (days ± SD)	3.94 ± 5.51
Median Age (days)	1
Gender (F:M)	16:34
Patients Receiving Antibiotics (%)	100% (50/50)

The disease distribution among the neonates was predominantly characterized by respiratory conditions, particularly preterm infants diagnosed with Respiratory Distress Syndrome (RDS), which accounted for 66% of cases. Additionally, 12% of neonates had RDS with associated central nervous system (CNS) abnormalities, while another 12% had RDS with cardiovascular abnormalities. Other conditions included intrauterine growth retardation (IUGR) in 2%, gastrointestinal disorders such as hypertrophied pyloric stenosis and jejunal atresia in 4%, full-term sepsis and cellulitis in 2%, and post-operative diaphragmatic hernia in another 2%. The overwhelming majority of cases were related to complications of prematurity, highlighting the need for aggressive antimicrobial interventions in this vulnerable population.

Table 2: Disease Distribution in NICU

Diagnosis	No. of Cases (% of Total)
Preterm with Respiratory Distress Syndrome (RDS)	33 (66%)
Preterm with RDS and CNS Abnormality	6 (12%)
Preterm with RDS and Cardiovascular Abnormality	6 (12%)
Preterm with Intrauterine Growth Retardation (IUGR)	1 (2%)
Gastrointestinal Conditions (e.g., Hypertrophied Pyloric Stenosis, Jejunal Atresia)	2 (4%)
Full-Term Sepsis and Cellulitis	1 (2%)
Post-Op Diaphragmatic Hernia	1 (2%)

Antibiotic prescription distribution varied among neonates, with most patients receiving multiple antibiotics during their NICU stay. The majority (48%) received two antibiotics, followed by 30% who were prescribed four antibiotics. A smaller proportion (18%) received three antibiotics, while 2% of patients received either a single antibiotic or as many as five antibiotics. In total, 141 antibiotic prescriptions were recorded among the 50 neonates, yielding an average of 3.02 antibiotics per patient. This high antibiotic burden emphasizes the reliance on combination therapies and broad-spectrum antimicrobials in neonatal care.

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Table 3: Antibiotic Prescription Distribution by Number per Patien

Number of Antibiotics Prescribed	No. of Patients (%)	Total Antibiotics Used
1	1 (2%)	1
2	24 (48%)	48
3	9 (18%)	27
4	15 (30%)	60
5	1 (2%)	5
Total	50 (100%)	141

The analysis of antibiotic classes prescribed in the NICU revealed that aminoglycosides were the most frequently used class, accounting for 35.5% of prescriptions, with amikacin being the most commonly administered drug. Cephalosporins, particularly third-generation cephalosporins such as cefotaxime, comprised 19.1% of prescriptions. Carbapenems (16.3%) and ureidopenicillins (16.3%) were also frequently prescribed, primarily for severe infections. Polymyxins, including colistin, accounted for 12.8% of prescriptions, followed by metronidazole (5.7%), fluoroquinolones (3.5%), macrolides such as tobramycin (3.5%), beta-lactam/beta-lactamase inhibitor combinations (3.5%), and tetracyclines (0.7%). The frequent use of broad-spectrum antibiotics and last-resort agents like colistin underscores concerns about antimicrobial resistance and the need for stewardship interventions.

Table 4: Antibiotic Classes Prescribed in NICU

Antibiotic Class	No. of Prescriptions (% of 141)	Most Common Drug(s)
Cephalosporins (Third Generation)	27 (19.1%)	Cefotaxime
Aminoglycosides	50 (35.5%)	Amikacin
Carbapenems	23 (16.3%)	Meropenem
Ureidopenicillins	23 (16.3%)	Piperacillin
Polymyxins	18 (12.8%)	Colistin
Antiprotozoal (Metronidazole)	8 (5.7%)	Metronidazole
Fluoroquinolones	5 (3.5%)	Ciprofloxacin
Macrolides (Topical Tobramycin)	5 (3.5%)	Tobramycin
Beta-Lactam + Beta-Lactamase Inhibitor	5 (3.5%)	Amoxicillin-Clavulanic Acid
Tetracyclines	1 (0.7%)	Tetracycline

The duration of antibiotic therapy in the NICU varied widely, with a total therapy duration ranging from 7 to 37 days, averaging 14.6 days (SD ± 6.8). The number of antibiotics used simultaneously ranged from one to four, with a mean of 3.02 antibiotics per patient (SD ± 0.92). Additionally, the total number of antibiotics prescribed per patient throughout hospitalization ranged from one to five, with an average of 3.54 (SD ± 1.12). The extended duration of therapy and high number of concurrent antibiotic prescriptions suggest a strong inclination toward prolonged empirical treatment, which may contribute to antimicrobial resistance if not closely monitored.

Table 5: Duration of Antibiotic Therapy in NICU

Parameter	Range (days)	Mean ± SD (days)
Simultaneous Antibiotics	1–4	3.02 ± 0.92
Total Antibiotics per Hospital Stay	1–5	3.54 ± 1.12
Total Duration of Therapy	7–37	14.6 ± 6.8

Combination antibiotic therapies were frequently used, particularly in neonates with respiratory infections. The most common combination was piperacillin and amikacin, prescribed in 45.5% of respiratory cases, followed by meropenem and colistin (30.3%) and cefotaxime with amikacin (24.2%). For gastrointestinal infections, cephalosporin-aminoglycoside and ureidopenicillin-aminoglycoside combinations were each prescribed in 50% of cases. Additionally, a meropenem-aminoglycoside combination was also used in one gastrointestinal case. The extensive use of combination therapies suggests an empirical approach aimed at covering a broad spectrum of potential pathogens, yet it also highlights the need for culture-guided treatment strategies.

Table 6: Combination Therapies in NICU

Condition	Combination	No. of Cases (% within Condition)
Respiratory Cases	Piperacillin + Amikacin	15 (45.5%)
	Meropenem + Colistin	10 (30.3%)

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	Cefotaxime + Amikacin	8 (24.2%)
GIT Cases	Cephalosporin + Aminoglycoside	1 (50%)
	Ureidopenicillin + Aminoglycoside	1 (50%)
	Meropenem + Aminoglycoside	1 (50%)

The WHO Core Prescribing Indicators assessment revealed an average of 3.02 antibiotics per prescription, which is considerably high compared to standard recommendations. Notably, none of the antibiotics were prescribed by generic name (0%), suggesting a preference for brand-name medications, which may have cost implications and affect accessibility. All patients (100%) received at least one antibiotic during their NICU stay, further confirming the high dependency on antimicrobial therapy in neonatal care. Adherence to the National Essential Drug List (NEDL) was observed in 70.5% of prescriptions, indicating a moderate level of compliance with national guidelines. However, the lack of generic prescribing and the excessive use of broad-spectrum antibiotics indicate potential areas for improvement in prescription practices.

Table 7: WHO Core Prescribing Indicators in NICU

Indicator	Result
Average No. of Antibiotics per Prescription	3.02
% of Drugs Prescribed by Generic Name	0%
% of Encounters with Antibiotics	100%
% of Drugs from NEDL	70.5%

Microbiological evaluation revealed that all 50 neonates had blood cultures performed, yet only one (2%) yielded a positive result, which identified Candida species rather than a bacterial pathogen. Given that antifungal therapy is required for fungal infections, this finding suggests that bacterial infections may have been overestimated, leading to unnecessary antibiotic use. Additionally, drug sensitivity testing was performed in only one case, and no specific antibiotic was noted to be effective against the identified pathogen. The absence of bacterial culture positivity in most cases suggests that antibiotic prescriptions were primarily empirical rather than based on microbiological evidence. Importantly, no adverse drug reactions (0%) were reported during the study period, though this may indicate under-reporting rather than a true absence of drug-related complications.

Table 8: Bacterial Sensitivity and Adverse Drug Reactions

Parameter	Result
Blood Culture Performed	50 (100%)
Positive Sensitivity Result	1 (2%) – Candida species
Drug Sensitivity Tested	1 (2%) – No specific drug noted
Adverse Drug Reactions	0 (0%)

Overall, the study highlights the significant burden of antimicrobial use in the NICU, characterized by frequent empirical prescriptions, extensive combination therapies, and prolonged treatment durations. The findings emphasize the urgent need for antibiotic stewardship programs, improved adherence to national and international guidelines, and increased reliance on microbiological evidence to guide therapy in neonatal care.

Discussion

The findings of this study highlight the extensive use of antibiotics in the NICU at District Civil Hospital Nuh Mandikhera, with a 100% prescription rate among the 50 neonates studied. The average number of antibiotics prescribed per patient was 3.02, which is substantially higher than the average reported in other hospital settings, including pediatric wards (1.63) and pediatric intensive care units (PICU) (2.22). The significantly higher rate of antibiotic use in the NICU ($p = 0.001$) underscores the critical nature of neonatal infections, particularly in preterm and low-birth-weight infants, who are highly susceptible to bacterial sepsis and other life-threatening conditions. The predominance of respiratory-related infections (90%) as the primary indication for antibiotic use further emphasizes the vulnerability of neonates to pulmonary complications, especially in cases of respiratory distress syndrome (RDS), intrauterine growth restriction (IUGR), and other preterm-associated morbidities.

Aminoglycosides, particularly amikacin, and third-generation cephalosporins, such as cefotaxime, were the most frequently prescribed antibiotics. This prescribing pattern aligns with studies conducted in other South Asian settings, such as Nepal and Bangladesh, where aminoglycosides and cephalosporins were also the most commonly used agents in neonatal care. However, a notable

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distinction in this study was the absence of cloxacillin, which has been reported as a commonly used antibiotic in NICU settings in other regions. The frequent use of broad-spectrum antibiotics, including carbapenems (meropenem) and polymyxins (colistin), indicates a proactive approach to managing severe neonatal infections. This prescribing trend reflects concerns about multidrug-resistant (MDR) pathogens in NICUs and suggests a heightened focus on empirical treatment protocols to ensure rapid infection control. However, the extensive reliance on broad-spectrum agents raises serious concerns regarding antimicrobial resistance (AMR), which has become a growing challenge in NICU settings worldwide.[9-11]

The widespread use of combination therapy was another key observation in this study. The most frequent antibiotic combination observed was piperacillin and amikacin, particularly in neonates diagnosed with respiratory infections. This combination aligns with empirical treatment protocols that prioritize Gram-negative coverage, especially in preterm neonates at high risk for sepsis caused by Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa. Other commonly used combinations included meropenem with colistin and cefotaxime with amikacin, which were also frequently employed in respiratory cases. The high rate of combination therapy suggests an intensive approach to infection control, particularly in neonates suspected of having sepsis or hospital-acquired infections. While combination therapy is often necessary in critically ill neonates, its routine use without microbiological confirmation increases the risk of drug resistance, alters neonatal gut microbiota, and may contribute to long-term complications such as late-onset sepsis or necrotizing enterocolitis.[12,13]

A major concern raised by this study is the low reliance on bacterial culture and sensitivity data to guide therapy. Despite 100% blood culture testing, only 2% of cases (one neonate) yielded a positive result, identifying Candida species rather than a bacterial pathogen. The lack of bacterial culture positivity in the majority of cases suggests that empirical antibiotic use was based primarily on clinical suspicion rather than confirmed microbiological evidence. This finding is concerning because empirical therapy should ideally be guided by local antibiogram data, ensuring the most appropriate antibiotic selection and reducing unnecessary exposure to broad-spectrum agents. The limited drug sensitivity testing, performed in only one case, with no specific drug noted, further highlights a gap in microbiological confirmation. This reliance on empirical therapy without routine culture-directed adjustments not only increases antibiotic overuse but also fails to identify the actual pathogens responsible for neonatal infections, which is a key factor in AMR development.[14,15]

Another critical issue identified was the poor adherence to generic prescribing practices. In this study, 0% of antibiotics were prescribed using their generic names, despite WHO recommendations emphasizing the importance of cost-effective prescribing practices. The preference for brand-name medications in the NICU could contribute to higher treatment costs, reduced accessibility, and potential disparities in healthcare affordability. However, adherence to the National Essential Drug List (NEDL) was observed in 70.5% of prescriptions, suggesting a moderate level of compliance with national guidelines. While adherence to NEDL is encouraging, improving generic prescribing rates could enhance cost efficiency and align with WHO's rational prescribing principles.

The mean duration of antibiotic therapy was 14.6 days, with some neonates receiving treatment for as long as 37 days. Such prolonged antibiotic courses raise concerns regarding long-term antibiotic exposure in neonates, which is associated with gut microbiome dysbiosis, increased susceptibility to opportunistic infections, and heightened AMR risk. The extended therapy duration is likely attributable to the severity of conditions such as RDS and neonatal sepsis, where prolonged antibiotic treatment is often warranted. However, it also reflects the lack of de-escalation strategies, where antibiotic therapy should ideally be adjusted or discontinued based on clinical improvement and microbiological results. Implementing a structured antibiotic stewardship program could help optimize therapy duration and prevent unnecessary prolonged antibiotic use in NICU settings.

One limitation of this study is the small sample size of 50 neonates, which limits the generalizability of findings to other NICU populations. A larger, multi-center study would provide a broader and more representative analysis of antibiotic prescribing trends in neonates. Another limitation is the single-center focus, which may not reflect prescribing variations across different hospitals or regions. Additionally, the absence of reported adverse drug reactions (ADRs) may suggest under-detection rather than a true lack of adverse effects. In neonates, ADRs can be subtle and difficult to detect, often manifesting as feeding intolerance, metabolic disturbances, or hematologic changes rather than overt clinical symptoms. Future studies should incorporate active pharmacovigilance strategies to improve ADR detection in neonatal antibiotic therapy.

Overall, this study underscores the extensive use of broad-spectrum antibiotics, frequent empirical prescribing, and prolonged therapy durations in NICU neonates. While the high antibiotic use reflects the critical need for infection management in neonates, it also highlights potential areas for improvement, including greater reliance on microbiological

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evidence, increased adherence to generic prescribing, and implementation of antibiotic stewardship programs. Strengthening these areas could help reduce antimicrobial resistance, enhance cost-effectiveness, and improve overall neonatal care outcomes. Future research should focus on evaluating antibiotic resistance patterns in NICUs, assessing the long-term impact of neonatal antibiotic exposure, and developing strategies for optimizing antibiotic prescribing practices in neonatal healthcare settings.

Conclusion

Antibiotic use in the NICU at District Civil Hospital Nuh Mandikhera is marked by high prescription rates, frequent broad-spectrum use, and empirical therapy, with 70.5% adherence to NEDL but no generic prescribing. The predominance of combination therapies and prolonged durations raises concerns about antimicrobial resistance and cost-effectiveness. The low reliance on microbiological confirmation highlights the need for culture-guided prescribing. An antibiotic stewardship program is essential to optimize therapy, reduce resistance, and ensure rational use. Larger, multi-center studies are needed to validate these findings and improve neonatal antibiotic practices.

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