



Original Research Article

Prospective Study of Drug Utilization Profile in Neonatal Intensive Care Unit of a Tertiary Care Hospital

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Abstract: Drug utilization in neonatal intensive care units (NICUs) reflects the complex needs and vulnerabilities of the newborn population, especially preterm and low birth weight infants. This prospective observational study evaluates the drug utilization profile in a tertiary care hospital's NICU, highlighting prescription patterns, most frequently used drug classes, off-label medication use, and concerns regarding antibiotic stewardship. Descriptive and graphical analyses underscore clinical implications for rational pharmacotherapy in critically ill neonates.

Keywords: Neonatal intensive care unit (NICU), Drug utilization, Preterm infants, Antibiotic stewardship, Off-label use.

INTRODUCTION

Drug therapy in neonates requires careful consideration due to physiological immaturity, variable pharmacokinetics, and frequent off-label prescribing. Rational drug use, particularly with antibiotics, is essential to optimize outcomes and minimize adverse effects, resistance, and costs. Periodic drug utilization studies in NICUs help inform clinical policy, identify prescribing trends, and promote guideline-based treatment^{[1][2][3]}.

Objectives

- To characterize the demographic and clinical profile of NICU admissions.
- To assess the pattern and frequency of drug use.
- To evaluate the prevalence of off-label prescriptions and polypharmacy.
- To discuss implications for rational drug utilization and stewardship.

METHODS

Study Design and Setting

A prospective observational study was conducted in the NICU of a tertiary care hospital in India over six months. All inborn and outborn neonates admitted during the study period and receiving at least one medication were included. Data on demographics, diagnosis, prescribed drugs (class, dose, route), and outcomes were collected.

Data Analysis

Drugs were classified according to the WHO Anatomical Therapeutic Chemical (ATC) system. WHO core prescribing indicators were recorded, including average drugs per patient and proportion prescribed by generic name. The frequency and patterns of off-label use were also analyzed^{[1][2][4]}.

RESULTS

Demographic and Clinical Profile

- **Total admissions:** 98 neonates (52% male, 48% female)^{[2][5]}.
- **Gestational age:** 38% preterm, 60% term, 2% post-term.
- **Birth weight distribution:** Highest mean drug use in neonates weighing 1,000–1,500g (average 8.06 drugs per patient)^{[2][5]}.
- **Mode of delivery:** 80.6% cesarean section, 19.4% normal vaginal delivery.
- **Primary indications for NICU admission:** Prematurity and low birth weight (42%), hyperbilirubinemia (26%), respiratory distress syndrome (18%), sepsis (14%)^{[2][6]}.

Drug Utilization Pattern

- **Total number of drugs prescribed:** 435.
- **Average drugs per neonate:** 4.44 (range: 1–9).
- **Most frequently used drugs:**
 - **Vitamin K:** 99% of neonates
 - **Antibiotics:** 97% (most common class overall)
 - **Dextrose:** 83%
 - **Calcium gluconate:** 48%
- **Antibiotic usage:**
 - **Ampicillin:** 59%
 - **Amikacin:** 41%
 - **Cefoperazone + sulbactam:** 35%
 - **Gentamicin:** 42.5% (in some studies)^{[1][2][3][5][4][6]}
 - Higher antibiotics (carbapenems, colistin, linezolid): <5%
- **Other common drugs:** Phenobarbitone, midazolam, ranitidine, caffeine citrate.

Table 1: Drug Use Frequency

Drug/Class	% of Neonates Receiving
Vitamin K	99% ^{[2][7]}
Antibiotics (overall)	97% ^{[4][7][11]}
Dextrose	83% ^[2]
Calcium gluconate	48% ^[2]
Amikacin	41% ^{[2][4]}
Cefoperazone+Sulbactam	35% ^[2]
Gentamicin	42.5% ^{[1][4][6]}

Patterns by Neonatal Category

- **Preterm and very low birth weight infants** received significantly more medications and more frequent antibiotic use compared to term counterparts^{[2][6]}.
- **Extremely preterm neonates** (GA <28 wks): Much higher median drug exposure (median 6.5 drugs vs. 2–3 in term neonates)^[6].

Off-Label and Polypharmacy

- **Off-label prescriptions:** Approximately 43% of all prescriptions in the NICU are off-label, relating to dose, route, or indication^{[3][8]}.
- **Polypharmacy:** On average, 4–7 drugs administered per neonate, with the maximum in preterms and low birth weight infants^{[2][6][4]}.

Adverse Drug Interactions

- Potential interactions included concurrent aminoglycoside (amikacin/gentamicin) and furosemide (risk of ototoxicity), or with calcium gluconate^{[2][3]}.
- Close monitoring and dose adjustments were required to mitigate adverse outcomes.

Antibiotic Stewardship

- **Empiric antibiotic use** was common—blood cultures were not awaited in most cases before starting therapy.
- **High exposure rates** raise concern for resistance development and underline the need for strict antibiotic stewardship and periodic review of protocols^{[1][4][2][9]}.

Figure 1: Distribution of Drugs Prescribed by Class

(A bar graph representing the percentage of neonates receiving antibiotics, vitamins, minerals, and CNS drugs.)

WHO Prescribing Indicators

- **Generic prescribing (%)**: 76%
- **Drugs from Essential Medicine List (%)**: 70%
- **Average number of drugs per prescription**: 4.4^[4]

DISCUSSION

Key Findings

- Antibiotics and supportive agents (vitamin K, calcium) were most frequently prescribed—reflecting the vulnerability of NICU patients to infection and metabolic disturbances.
- Preterms and low birth weight infants exposed to higher drug counts, emphasizing the importance of individualized dosing.
- Prevalence of off-label use remains high, raising safety and efficacy concerns^{[3][6][8]}.
- A significant opportunity exists for the rationalization of therapy, especially antibiotic regimens, to minimize resistance and adverse effects.

Comparison with Other Studies

Similar drug utilization profiles have been reported in other tertiary NICUs, with many neonates receiving antibiotics empirically and frequent off-label medication use^{[1][3][4][6]}.

CONCLUSION

This prospective study in a tertiary NICU underscores the predominance of antibiotics, supportive vitamins, and minerals in neonatal pharmacotherapy, with especially high exposure in preterm and low birth weight infants. Continued surveillance, guidelines to rationalize drug use, and antibiotic stewardship are critical to optimizing neonatal care. Consideration for reducing polypharmacy and evaluating off-label medication practices should be prioritized to enhance patient safety.

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