RESEARCH PAPER

Drug-Related Problems in the Neonatal and Pediatric Intensive Care Units: Incidence, Predictors, and Impact of Clinical Pharmacist Interventions

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ABSTRACT

Background

Drug-related problems (DRPs) pose a significant risk to critically ill neonates and children due to polypharmacy, off-label drug use and immature pharmacokinetics. However standardized comparative data across both the Neonatal and Pediatric Intensive Care Unit (NICU & PICU) remain scarce in tertiary care settings.

Objective

To identify, classify and evaluate DRPs in the NICU and PICU using the Pharmaceutical Care Network Europe (PCNE) classification v9.1; to assess incidence, causes, and independent predictors; to document pharmacist intervention acceptance and DRP resolution rates.

Methods

A 6-month prospective interventional study enrolled 286 patients (NICU: n=67; PICU: n=219) at a tertiary care teaching hospital in India. DRPs were identified through daily medication review, classified using PCNE v9.1 and pharmacist-led interventions were proposed with acceptance and resolution outcomes documented. Independent predictors were identified using multivariable binary logistic regression.

Results

A total of 168 DRPs were identified (NICU-43; PICU-125) with treatment ineffectiveness and adverse drug events predominating in the NICU and treatment effectiveness and safety issues in PICU. Drug selection errors were the leading cause in both units. Of 195 pharmacist interventions proposed, the acceptance rates were 95.3% (NICU) and 93.4% (PICU), with resolution rates of 76.7% and 88.8% respectively. The number of prescribed drugs was the sole independent predictor of DRPs in both units.

Conclusion

DRPs are prevalent in critically ill neonates and children, with polypharmacy as the sole independent risk factor. High pharmacist intervention acceptance and resolution rates support integration of clinical pharmacists into intensive care teams though the single-center design, limited study duration and exclusion criteria may restrict generalisability.

Keywords: Drug-related problems; polypharmacy; NICU; PICU; pharmacist interventions.

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INTRODUCTION

Infants and young children represent a particularly vulnerable population in clinical pharmacotherapy. Physiological immaturity, rapid developmental changes in organ function, weight-dependent dosing and unique pharmacokinetic and pharmacodynamic profiles collectively heighten susceptibility to DRPs [1,2].

DRPs are defined as events linked to medication use that either directly cause or have the potential to cause interference with the expected or desired therapeutic outcomes in a patient. Critically ill neonates and children frequently receive multiple concurrent medications, require ongoing dose adjustments and must be monitored amid rapidly changing clinical conditions, creating a high-risk environment for DRPs [3–5]. Significant DRP rates in these settings have been reported across diverse clinical contexts with consequences including therapeutic failure, adverse drug events and prolonged hospitalization[5,6]. Clinical pharmacists are recognized as vital members of multidisciplinary critical care teams, contributing to medication safety through therapeutic drug monitoring, prospective prescription review and direct clinical intervention[3–5]. Their integration into NICU and PICU care has been associated with improved dosage accuracy, reduced prescribing errors and more effective treatment strategies[6,7]. Most prior investigations have assessed DRPs in either neonatal or pediatric populations separately, restricting comparative knowledge across age groups and units[8,9]. The PCNE classification system v9.1 offers a standardized and validated structure for categorizing DRPs[10].

The aim of this study was to utilize the PCNE classification v9.1 to prospectively identify, classify, and evaluate DRPs in the NICU and PICU of a tertiary care hospital; to assess their incidence, types, causes, and independent predictors; and to implement and evaluate pharmacist-led interventions.

METHODS

Study Design and Setting: A prospective interventional study spanning six months was carried out in the NICU and PICU of a tertiary care teaching hospital.

Study Population: Eligible participants included neonates and pediatric patients aged 0-18 years of either sex, admitted to the NICU or PICU, receiving at least one medication and hospitalized for more than 24 hours. Individuals undergoing chemotherapy and those infected with Methicillin-resistant *Staphylococcus aureus* (MRSA), Hepatitis C virus (HCV), or Human immunodeficiency virus (HIV) were excluded. Electrolyte solutions, parenteral nutrition, whole blood products and diagnostic agents were not evaluated. Participants were monitored prospectively from the time of admission up until the patient was either transferred, discharged or death. The study enrollment and methodology workflow are illustrated. [Refer Figure 1]

Data Collection: Using a standardized data collection form, four investigators prospectively gathered daily data from drug administration charts, physician notes and nursing records, capturing patient demographics, clinical diagnosis, prescribed medications and duration of hospital stay. Clinical diseases were classified using the World Health Organization International Classification of Diseases, 11th Revision (WHO-ICD11)[11] and medications were categorized with the help of the World Health Organization Anatomical Therapeutic Chemical (WHO-ATC) classification system[12]. Patient age groups were defined according to the International Council for Harmonization guideline E-11[7].

Identification and Classification of Drug-Related Problems: DRPs were detected through daily prospective drug assessment and classified using the PCNE classification v9.1[10]. Each identified DRP was reviewed and discussed with the clinical team members. Pharmacist-led interventions were proposed for each DRP, prescriber acceptance was documented and resolution status was assessed at discharge or transfer.

Statistical Analysis: Descriptive statistics were applied to summarize the demographic characteristics of patients and the nature DRPs. Categorical variables are reported as frequencies along with their corresponding percentages, while continuous variables are presented either as mean ± standard deviation (SD) or as median with interquartile range (IQR), depending on the nature of the data. Binary logistic regression analysis was performed to determine the independent predictors of DRPs. Variables that achieved statistical significance with a p value below 0.05 in the univariable analysis were subsequently included in a multivariable logistic regression model to account for potential confounding factors. Both crude odds ratios and adjusted odds ratios along with their 95 % confidence intervals (CI) are reported accordingly. Individual regression models were developed separately for the NICU and PICU populations. A p value of less than 0.05 was considered statistically significant and exact p values are provided throughout the analysis. All statistical analyses were carried out using SPSS software version 26.0. There was no instance of loss to follow up and no missing data were observed for any of the variables that were incorporated into the regression models.

RESULTS

Study Population and Demographics: Of the 530 neonates screened in the NICU, 67 (12.6%) satisfied the eligibility criteria and were subsequently included; the remainder received only supportive interventions such as phototherapy, kangaroo mother care or nutritional supplements. Of the 271 pediatric patients screened in the PICU, 219 (80.8%) were eligible and enrolled. Demographics characteristics, clinical diagnosis and medication patterns for both units are summarized. [Refer Table 1]

Incidence and Classification of DRPs: In total, 43 DRPs were detected among 67 NICU patients and 125 DRPs among 219 PICU patients. In the NICU, 28 DRPs occurred in males and 15 in females; in the PICU, 78 occurred in males and 47 in females. The distribution of DRPs by PCNE problem domain is presented in Table 2. In the NICU, treatment effectiveness issues were the predominant concern, followed by treatment safety. In the PICU, both treatment effectiveness and treatment safety were major problem domains, with a notably higher proportion of unnecessary drug treatment compared with the NICU. [Refer Table 2]

Causes of DRPs: A overall of 40 underlying causes were identified within the NICU. Drug selection issues were the leading category (80%, n=32), driven primarily by inappropriate drug combinations (C1.3, n=22), no or incomplete treatment despite an existing indication (C1.5, n=5) and too many different drugs (C1.6, n=4). Dose selection causes accounted for 10% (n=4), with each of drug dose too low (C3.1), drug dose too high (C3.2), dosage regimen not frequent enough (C3.3), and dosage regimen too frequent (C3.4) identified once. Treatment duration (C4.2, n=1) and patient transfer-related issues (C8.1, n=1) each contributed 2.5% and other causes (C9.2, n=2) accounted for 5%.

A total of 120 causes were identified in the PICU. Drug selection remained the most frequently observed domain (44.67%, n=56), with no or incomplete drug treatment despite an existing indication (C1.5, n=17) and unsuitable drug combinations (C1.3, n=16) as the most common causes. Dose selection was the second most prevalent category (31.67%, n=38), driven by dosage regimen too frequent (C3.4, n=14), drug dose too high (3.2, n=7) and incorrect or unclear dose timing instructions (C3.5, n=7). Patient-related causes also constituted (13.33%, n=16). Treatment duration (5%, n=6), drug formulation (1.67%, n=2), dispensing issues (0.83%, n=1) and other causes (0.83%, n=1) comprised the remaining categories.

Pharmacist Interventions: In the NICU, 43 interventions were proposed for the patients. Prescriber-level interventions predominated (62.79%, n=27), with informing the prescriber (I1.1, n=21) being the most common. Drug-level interventions comprised 23.25% (n=10), including dosage change (I3.2, n=3), instructions for use changed (I3.4, n=2), drug pause (I3.5, n=2), drug initiation (I3.6, n=2) and drug substitution (I3.1, n=1). Patient/caregiver-level interventions (I2.4, n=3) and side effects reported to authorities (I4.2, n=2) comprised the remainder of the studies.

In the PICU, 152 interventions were proposed. Prescriber-level interventions accounted for 48.68% (n=74) with informing the prescriber (I1.1, n=42) being the most frequent. Drug-level interventions constituted 30.26% (n=46) with dosage change (I3.2, n=21) and drug pause or discontinuation (I3.5, n=12) being the most common. Patient and caregiver-level interventions accounted for 17.11% (n=26). Side effects reported to authorities (I4.2, n=6) represented 3.95%.

Intervention Acceptance and DRP Resolution: In the NICU, 41 of 43 interventions (95.3%) were accepted: 27 (62.79%) fully accepted and implemented (A1.1), 6 (13.95%) partially implemented (A1.2) and 7 (16.28%) accepted but not implemented (A1.3). One intervention (2.33%) was not accepted. Of 43 DRPs, 27 (62.79%) were completely resolved (O1.1) and 6 (13.95%) were partially resolved (O2.1). Eight DRPs (18.60%) remained unresolved — 6 attributable to lack of prescriber cooperation (O3.2) and 2 due to lack of patient cooperation (O3.1).

In the PICU, 142 of 152 interventions (93.4%) were accepted: 101 (66.45%) were fully implemented (A1.1) and 33 (21.71%) were partially implemented (A1.2). Of the 125 DRPs, 86 (68.8%) were completely resolved (O1.1) and 25 (20%) partially resolved (O2.1). Eleven DRPs (8.8%) remain unresolved: 3 due to lack of patient cooperation (O3.1), 4 due to lack of prescriber cooperation (O3.2) and 4 where the intervention proved ineffective (O3.3).

Predictors of DRPs: Binary logistic regression results are illustrated in Table 3. In NICU, length of stay was significant in the univariable analysis (COR- 1.043; 95% CI 1.000–1.087; P=0.048) but did not retain significance after multivariable adjustment (AOR- 1.001; P=0.985). The total count of medications

prescribed was the sole independent predictor of DRPs in the NICU (AOR-1.653; 95% CI 1.232–2.218; P=0.001). In the PICU, clinical condition (multiple vs. single) was significant in the univariable analysis (COR-1.861; P=0.024) but not after adjustment (AOR-1.674; P=0.074). The number of prescribed drugs was again the sole independent predictor of DRPs in the PICU (AOR-1.180; 95% CI 1.064–1.310; P=0.002). Sex, gestational age (NICU), age (PICU) and length of stay were not independently associated with DRPs in either unit. [Refer Table 3]

Figure 1. Study Methodology Flowchart:

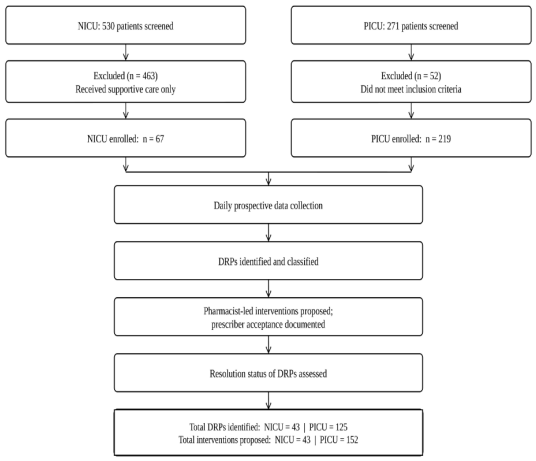

Figure 1. Study Methodology Flowchart. The flowchart outlines patient screening, enrollment, and the sequential steps from data collection through DRP identification, pharmacist intervention, and outcome assessment.

Abbreviations: NICU, Neonatal Intensive Care Unit; PICU, Pediatric Intensive Care Unit; DRP, drug-related problem; PCNE, Pharmaceutical Care Network Europe.

Table 1. Demographic Characteristics, Clinical Diagnosis and Medication Patterns of Study Populations

VARIABLE	NICU (n=67)	PICU (n=219)
Sex, n (%)		
Male	39 (58.2%)	120 (54.8%)
Female	28 (41.8%)	99 (45.2%)
Gestational age, weeks[a] mean ± SD (median; IQR)	34 ± 4 (33; 30-38)	—
Age, months[b] mean ± SD (median; IQR)	—	67.8 ± 62.1 (48; 12-120)
Length of hospital stay, days mean ± SD (median; IQR)	16.7 ± 13.2 (11; 8-24)	8.7 ± 7.5 (7; 5-10)
Common clinical diagnosis (WHO-ICD11), n (%)		
Respiratory disorders	40 (59.7%)	91 (41.6%)
Cardiovascular/circulatory disorders	8 (11.9%)	47 (21.5%)
Neurological disorders	7 (10.4%)	68 (31.1%)
Common prescribed drug classes (WHO-ATC), n (%)		
Anti-infectives for systemic use	185 (42.2%)	422 (25.2%)
Alimentary tract and metabolism	114 (26.0%)	437 (26.0%)
Nervous system	73 (16.7%)	295 (17.6%)

SD, standard deviation; IQR, interquartile range; WHO-ICD11, World Health Organization International Classification of Diseases 11th Revision; WHO-ATC, World Health Organization Anatomical Therapeutic Chemical classification system. [a]Gestational age reported for NICU neonates only. [b]Age in months reported for PICU patients only. Only the three most common diagnoses and drug classes are shown for each unit.

Table 2. Distribution of Drug-Related Problems by PCNE Problem Domain in the NICU and PICU

Domain	Code	Problem	NICU (n)	NICU (%)	PICU (n)	PICU (%)
Treatment Effectiveness	P1.1	No effect of drug treatment despite correct use	2	69.8	0	44.8
	P1.2	Effect of drug treatment not optimal	23		44	
	P1.3	Untreated symptoms or indication	5		12	

Treatment Safety	P2.1	Adverse drug event occurring	12	27.9	46	36.8
Other	P3.1	Unnecessary drug treatment	0	2.3	16	18.4
	P3.2	Unclear problem or complaint	1		7	
Total			**43**		**125**	**100**

PCNE, Pharmaceutical Care Network Europe; NICU, Neonatal Intensive Care Unit; PICU, Pediatric Intensive Care Unit. Domain-level percentages are shown where the domain total is meaningful.

Table 3. Binary logistic regression analysis of predictors of DRPs in the NICU and PICU.

Variable	Univariable COR (95% CI)	P value	Multivariable AOR (95% CI)	P value
NICU				
Gestational age	1.001 (0.893-1.123)	0.983	1.170 (0.963-1.420)	0.113
Sex (female vs. male)	0.681 (0.254-1.823)	0.445	0.404 (0.107-1.530)	0.182
Length of stay	1.043 (1.000-1.087)	0.048	1.001 (0.936-1.070)	0.985
Clinical condition (multiple vs. single)	0.682 (0.258-1.800)	0.439	0.328 (0.083-1.287)	0.110
Number of drugs[a]	**1.355 (1.145-1.604)**	**0.001**	**1.653 (1.232-2.218)**	**0.001**
PICU				
Age	1.003 (0.999-1.008)	0.145	1.004 (0.999-1.009)	0.099
Sex (female vs. male)	0.718 (0.419-1.232)	0.229	0.815 (0.461-1.440)	0.481
Length of stay	1.040 (0.996-1.086)	0.077	0.999 (0.956-1.044)	0.979
Clinical condition (multiple vs. single)	1.861 (1.084-3.196)	0.024	1.674 (0.951-2.947)	0.074
Number of drugs[a]	**1.186 (1.082-1.300)**	**0.001**	**1.180 (1.064-1.310)**	**0.002**

COR, crude odds ratio; AOR, adjusted odds ratio; CI, confidence interval. Bold values indicate statistically significant results (P < 0.05). [a]Significant independent predictor on multivariable analysis in both units.

DISCUSSION

This study provides a comprehensive evaluation of DRPs in NICU and PICU of a tertiary care teaching hospital in India, an area that remains insufficiently investigated, particularly given the simultaneous assessment of both neonatal and pediatric critical care populations within a single institution. By applying PCNE classification v9.1 and multivariable logistic regression, this study provides a more comprehensive insight into the occurrence, distribution and determining factors of DRPs than prior single-unit studies[8,9]. The overall DRP incidence observed was consistent with earlier reports from Kumar et al[5] and AlAzmi et al[13], who documented comparable rates in pediatric critical care populations in India and Saudi Arabia, respectively. A male predominance in DRP occurrence was noted in both units, consistent with Ghanbarlou et al[14]. However, Sabzghabaee et al[15] reported that sex does not significantly influence DRP occurrence in hospitalized children. Respiratory diseases were the most frequently observed reason for ICU admission in both units, consistent with Sabzghabaee et al[15]. Antimicrobial agents intended for systemic administration were the most commonly prescribed and implicated drug class in the NICU, consistent with AlAzmi et al[13], reflecting the high burden of neonatal sepsis and infection-related morbidity. Nunes et al[16] similarly associated a high proportion of DRPs with antimicrobial use in a neonatal ICU, whereas in PICU,

medications acting on the digestive system and metabolic pathways were the most frequently involved.

Using the PCNE classification, treatment ineffectiveness and adverse drug reactions were the predominant problem domains in the NICU, consistent with Leopoldino et al[8] study. In the PICU, treatment safety and effectiveness issues were major concerns, with a higher proportion of unnecessary drug treatments than in the NICU. Drug selection errors were the leading cause in both units.

Intervention acceptance rates were high in both the NICU (95.3%) and PICU (93.4%), substantially exceeding the 51.7% acceptance rate reported by Robert et al[17]. While Elhabil et al[18] reported a higher DRP resolution rate of 92.1% in a pediatric cardiology unit, the resolution rates in the present study (76.7% in NICU; 88.8% in PICU) remain clinically meaningful, with the majority of unresolved DRPs attributable to lack of prescriber or patient cooperation rather than to inadequate interventions.

Regarding predictors of DRPs, Leopoldino et al[9] identified gestational age, low Apgar score and comorbidities as key risk factors in NICU. However in the current investigation, number of prescribed drugs emerged as the sole independent predictor of DRPs in both the NICU (AOR 1.653; P=0.001) and PICU (AOR 1.180; P=0.002). This finding aligns with the established pharmacological principle that polypharmacy compounds the likelihood of medication interactions, prescribing errors and adverse drug events and is consistent with prior pediatric and neonatal literature emphasizing medication burden as a central driver of DRPs[1,5,8,9].

The results highlight the critical importance of clinical pharmacists in NICU and PICU, consistent with Malfara et al[19], who demonstrated that the involvement of clinical pharmacists in the PICU considerably descreased pharmacotherapy-related problems. In the Indian context, the growing integration of clinical pharmacists through training and institutional support further strengthens their potential contribution to the safety of medicines in critical care. Routine pharmacist participation in ward rounds, medication reconciliation and prospective prescription reviews should be considered a standard of care in these settings.

LIMITATIONS: The drawbacks of this study include its single center approach, limited number of participants and short study duration, which may restrict generalisability, limit the diversity of DRPs captured and preclude assessment of seasonal variation or long-term pharmacist intervention impact.

CONCLUSIONS: DRPs are prevalent in severely ill neonates and pediatrics, with polypharmacy as the sole independent risk factor in both the NICU and PICU. Drug selection errors represent the predominant casual category whereas treatment effectiveness and safety are the dominant problem domains. High pharmacist intervention acceptance and DRP resolution rates support the integration of clinical pharmacists as standard members of neonatal and pediatric intensive care teams. Routine prospective medication review and participation in multidisciplinary clinical rounds should be considered essential components of medication safety programs in these high-risk settings.

DECLARATIONS

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Data availability statement: No further data are available beyond those presented in the main document. Data are limited to the aggregated results reported in the main document.

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