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DRUG UTILISATION, ADVERSE DRUG REACTION PROFILE AND TREATMENT OUTCOME OF PNEUMONIA IN UNDER-FIVE CHILDREN IN A TERTIARY CARE HOSPITAL: A CROSS-SECTIONAL STUDY.

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ABSTRACT

Backgrounds
Childhood pneumonia is a leading cause of morbidity and mortality among children under 5 years old worldwide. Despite global efforts to prevent and manage this condition, the improper and irrational use of antimicrobials is one of the greatest hinderance to achieving the target.
Objectives: The study aimed to evaluate the drug utilization pattern, treatment outcome, and monitoring of frequency and severity of Adverse Drug Reactions (ADRs) with its causality assessment among under-five pneumonia cases.

Methods
This observational cross-sectional study was conducted on 118 diagnosed cases of pneumonia aged 2 months to 5 years. Data were collected from treatment records and parents' responses and analyzed using Microsoft Excel 2016 and SPSS version 22.0.

Results
Among 118 under-five pneumonia cases, 88.1% recovered and 11.9% required ICU care. Most were male (75.4%), aged 2–12 months (60.2%), and from rural areas (73%). Complications were linked to female gender and parental smoking. Adverse outcomes were associated with fever, cough, delayed treatment, prolonged hospitalization, and multiple antibiotic use. Prescription analysis (536 cases) showed polypharmacy (mean 4.52 drugs), universal antibiotic, and injection use, with 85.92% prescribed by generic name and 88.93% from the essential drug list. Of 50 ADRs, diarrhea (58%) from ceftriaxone was most common.
Interpretation: Female gender and parental smoking were associated with higher ICU admissions, highlighting the need for targeted clinical strategies in managing pediatric pneumonia.

Conclusion
The study concluded that prompt and appropriate treatment is pivotal for resolving pneumonia in children and reducing morbidity and mortality. Monitoring prescriptions and drug utilization studies helps in detecting and reducing irrational prescribing while offering feedback to prescribers.

Recommendation
Raising awareness among healthcare providers and caregivers, regularly educating on proper antibiotic use, implementing prescribing guidelines, and involving patients in ADR reporting can enhance treatment outcomes and minimize adverse drug reactions in under-five pneumonia cases.

Keywords: *Drug utilization pattern, Polypharmacy, Rational Antimicrobials, Under-five pneumonia, World Health Organisation -Uppsala Monitoring Center.*
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INTRODUCTION

Childhood Acute Respiratory Infection (ARI) is the prominent cause of morbidity amongst children under five years of age globally. Pneumonia is the most serious presentation, accounting for roughly one-fifth of the total mortality [1,2]. WHO and UNICEF launched the Global Action Plan for Pneumonia and Diarrhoea (GAPPD),

targeting zero preventable deaths by 2025, and advising governments on strategies to prevent, treat, and manage these illnesses in children. Despite this, only 60% of caregivers seek proper care for pneumonia, and only one-third of them receive correct antimicrobial therapy. WHO, with its recent revision of pneumonia classifications, delineates different and distinct treatment pathways. Cases labeled as "pneumonia," characterized by rapid breathing or chest in-drawing, can be managed effectively with oral Amoxicillin and home-based care. "Severe pneumonia" presentations in children aged 2–59 months, accompanied by danger signs, necessitate immediate parenteral administration of antimicrobials [3,4]. Pneumonia is responsible for 18% of Global Child Mortality (under five), with a higher impact in developing countries at 20% versus 4.3% in developed nations [5]. India leads in the incidence of lower respiratory tract infections, with a staggering 43 million cases [1]. The Child Health Epidemiology Reference Group (CHERG) and WHO data underscore pneumonia as a leading cause of mortality among post-neonatal children (1-59 months) in 2015 [7]. The rate of pneumonia is expected at 0.29 events each year in progressing countries. Pneumonia instigated the deaths of 408,000 children under five in India [6].

Bacterial pneumonia, constituting over two-thirds of cases, is often due to Streptococcus pneumoniae, Haemophilus influenzae type b (Hib), Klebsiella, and others. Atypical pathogens include Chlamydia and Mycoplasma spp. Pneumocystis jiroveci is usual in HIV patients [5,8].

Risk factors for pneumonia include Low Birth Weight (LBW), malnutrition, Vitamin A deficiency, absence of breastfeeding, passive smoking, poor socio-economic status, large family size, family history of bronchitis, overcrowding, indoor and outdoor air pollution, lack of vaccinations, no separate kitchens, low maternal education, delayed healthcare seeking, and inadequate treatment [8]. To avoid pneumonia, paramount efficient immunizations are for Hib, measles, whooping cough, and pneumococcus. Available vaccines include PCV 7/Prevnar for children under two, and PPV 23/Pneumovax for pneumococcal diseases [5,9]. In 2009, WHO and UNICEF launched a plan to combat childhood pneumonia, promoting exclusive breastfeeding, hand hygiene, reduced indoor pollution, vaccinations, and access to antibiotics. Child mortality from pneumonia in under-fives has decreased threefold, from 2.34 million to 808,920 annually from 1990-2017[5,10].

Prompt and appropriate treatment is pivotal for resolving pneumonia in children and averts complications from lung abscess, pleural effusion, and even death. Monitoring prescriptions and drug utilization studies helps in detecting and reducing irrational prescribing while offering feedback to prescribers. There is a lack of data to evaluate the effects of the prescribed medications on under-five children. The influence of antibiotic use on treatment outcomes remains underexplored, and it could benefit from an analysis of the broader social determinants of health, which may affect treatment efficacy. [11,12,14] So, the study aimed to evaluate the drug utilization pattern, treatment outcome, and to monitor the frequency and severity of ADR during treatment in these cases.

The objectives

- To assess sociodemographic risk factors of under-5 pneumonia
- To study the Drug utilization pattern as per the WHO core indicators
- To assess the treatment outcome in terms of cure /death/shift to ICU
- To assess the ADR profile and causality assessment of ADRs

MATERIAL AND METHODS

Study Design

This was an observational, cross-sectional study designed to evaluate the drug utilization pattern, treatment outcomes, and ADR profile in pneumonia among under-five children.

Study Setting

The study was conducted in the Department of Pharmacology in collaboration with the Department of Paediatrics at Maharaja Krushna Chandra Gajapati Medical College and Hospital (MKCG MCH), Berhampur, Odisha. MKCG MCH is a tertiary care teaching hospital serving patients from urban and rural areas of southern Odisha.

Selection of study population

This study included all diagnosed cases of pneumonia in children under five years of age who were admitted to the pediatrics in-patient department during the study period.

Inclusion criteria

- Patients within 2 months to 5 years of age
- Diagnosed case of pneumonia
- Parents who agreed to participate their child in this study

Exclusion criteria

Pneumonia secondary to other diseases like malaria, pulmonary tuberculosis, meningitis, viral encephalitis, and fungal infections
Viral pneumonia

Sample size

The sample size of the study was calculated as 118 by using the formula **$n=Z2P(1-P)/d2$**

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(Where n=sample size, Z =statistic corresponding to level of confidence, P =expected prevalence, and d =precision)

Here, Prevalence is taken as 8%, and precision is taken as 5.

During the study, 118 diagnosed pneumonia patients were enrolled as per the inclusion and exclusion criteria.

Study procedure

Data were collected from treatment records and by asking questions to parents, which were recorded in pre-approved CRFs. Socio-demographic parameters such as age, sex, socioeconomic status, and education status of parents, rural or urban habitat, etc., history regarding immunization, and exclusive breastfeeding were also noted. Drug utilization patterns as per WHO guidelines, like drug, dose, dosing interval, duration of the treatment, generic drug, route of the drug administration, number of drugs per prescription, number of antibiotics per prescription, treatment outcome, and ADRs observed were noted. The causality assessment of ADRs was done by using the WHO-UMC scale.

Study tools

- Case Record Form
- WHO core drug use indicators
- WHO-UMC causality assessment scale

Statistical analysis

Data were analyzed using Microsoft Excel 2016 and SPSS version 22.0. Descriptive statistics such as frequency, percentage, mean, and standard deviation were computed for continuous variables and categorical variables. The chi-square test and odds ratio were used to analyze factors associated with treatment outcomes. The p-value of <0.5 was considered statistically significant.

Ethical Consideration

The study was conducted following approval from the Institutional Ethics Committee (IEC) of M.K.C.G. Medical College, Berhampur (Approval No. 1142/Chairman-IEC, M.K.C.G. Medical College, Berhampur-4, dated:13.07.2022. Prior to enrolment, written informed consent was obtained from the parents or legal guardians of all participating subjects, in accordance with the ethical principles outlined in the Declaration of Helsinki.

RESULTS

TABLE NO 1 ASSOCIATION OF SOCIODEMOGRAPHIC VARIABLES WITH TREATMENT OUTCOME AMONG UNDER-5 PNEUMONIA CASES (N=118)

Variables	Category	Cured	Shifted to ICU(Complicated)	Odds ratio	95% Confidence interval	P value
Age	**2-12 months**	62	9	0.82	0.25-2.61	0.48
	13-60 months	42	5			
Gender	**Male**	82	7	3.727	1.18-11.75	**0.04**
	Female	22	7			
Residence	**Rural**	74	13	0.19	1.024-1.51	0.07
	Urban	30	1			
Socioeconomic status	**Poor**	50	9	0.51	0.16-1.63	0.39
	Good	54	5			
Birth weight	**LBW**	60	6	0.4	0.07-2.06	0.26
	Normal	50	2			
Educational status of the mother	**Literate**	67	6	2.41	0.77-7.49	0.14
	Illiterate	37	8			
Exclusive Breastfeeding	**Yes**	98	12	2.722	0.43-15.03	0.24
	No	6	2			
Malnutrition	**Yes**	51	6	1.28	0.41-3.957	0.66

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status	**No**	53	8			
Immunization status against Hib	**Yes**	86	9	2.654	0.79-8.86	0.145
	No	18	5			
Vitamin A status	**Yes**	62	7	1.476	0.482-4.51	0.49
	No	42	7			
Cooking fuel	**Yes**	73	12	0.392	0.083-1.858	0.34
	No	31	2			
Parental smoking	**Yes**	88	14	0.863	0.798-0.932	**0.02**
	No	16	0			
Crowded home	**Yes**	88	11	1.5	0.37-5.98	0.69
	No	16	3			
Safe drinking water	**Yes**	31	3	1.55	0.40-5.97	0.75
	No	73	11			
Hand hygiene	**Yes**	41	6	0.86	0.28-2.68	0.80
	No	63	8			
Toilet use	**Yes**	43	6	0.94	0.30-2.90	0.91
	No	61	8			

Table No. 1 displayed the association of various sociodemographic variables with treatment outcome such as cured or complicated (sent to ICU). The variable like female gender and parental smoking were significantly more associated with complicated cases which were send to ICU compared with cured cases. But there was no significant association with age, socioeconomic status, education of the mother, residence, birth weight, malnutrition, immunisation status, Vit-A status, cooking fuel, crowded home, safe drinking water, hand hygiene, and toilet use in this population.

TABLE NO 2 ASSOCIATION OF CLINICAL FEATURES AND TREATMENT-RELATED FACTORS WITH TREATMENT OUTCOME (n=118)

Factors		**Cured**	**Shifted to ICU**	**Odds ratio**	**95% Confidence interval**	**P value**
Fever	Yes	95	10	4.22	1.09-16.22	**0.04**
	No	9	4			
Cough	Yes	54	13	0.083	0.01-0.65	**0.003**
	No	50	1			
Rapid Breathing	Yes	84	11	1.14	0.29-4.49	0.54
	No	20	3			
Grunting	Yes	79	12	0.52	0.11-2.51	0.33
	No	25	2			
Chest Indrawing	Yes	21	3	0.92	0.23-3.62	0.57

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	No	83	11			
Chest Pain	Yes	1	1	0.12	0.007-2.141	0.22
	No	103	13			
TLC count	Normal	21	0	1.16	1.07-1.26	0.07
	High	83	14			
Duration of hospital stay	<7 days	70	4	5.14	1.50-17.60	**0.007**
	>7 days	34	10			
Onset Of Treatment	Early	31	0	1.19	1.08-1.30	**0.02**
	Delayed	73	14			
No of Antibiotics used	Single	42	7	0.67	0.22-0.97	**0.03**
	More than one	62	7			

The clinical features, like cough and fever were more associated with complications, whereas other signs and symptoms like rapid breathing, grunting, chest in drawing and chest pain were not significantly associated with pneumonia related complications. Other parameters like >7 days hospital stay, delayed onset of treatment and >1 antibiotic used were significantly associated with complications as outcome (Table No-2).

TABLE NO 3 WHO CORE DRUG PRESCRIBING INDICATORS Vs WHO OPTIMAL VALUE AMONG UNDER-5 PNEUMONIA CASES (n=536)

Prescribing indicators	**Findings**	**WHO optimal value**
Average number of drugs per prescription	4.52±1.62	1.6-1.8
Percentage of drugs prescribed by generic name	85.92%	100%
Percentage of encounters with an antibiotic	100%	20.0-26.8%
The percentage of encounters with an injection	100%	13.4-24.1%
Percentage of drugs from the essential drug list	88.93%	100%

In Table no 3, Prescriptions averaged five drugs, indicating polypharmacy. Most drugs (85.92%) were generic. All patients received antibiotics and injectables. Only 88.93% were essential drugs.

TABLE NO:4 DRUG UTILIZATION OF ANTIBIOTICS AMONG UNDER-5 PNEUMONIA CASES (n=536)

Name of the antibiotics used	**Dose given (mg /Kg body wt)/day**	**Recommended Dose (mg /Kg body wt)/day**	**Dosage form**	**Route**	**Dosing schedule**
Amikacin	25-30	15-20	Liquid	Intravenous	OD/ BD/ QID
Gentamicin	5-7	5-7.5	Liquid	Intravenous	OD
Ceftriaxone	40-50	50-75	Liquid	Intravenous	BD/TDS
Azithromycin	20	10	Solid	Oral	OD
Meropenem	45	60	Liquid	Intravenous	TDS

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Doxycycline	8	2-5	Liquid	Intravenous	TDS
Linezolid	15-20	20	Liquid	Intravenous	TDS
Vancomycin	60	40	Liquid	Intravenous	TDS
Piperacillin /tazobactam	270-375	300-400	Liquid	Intravenous	TDS
Metronidazole	15	15-20	Liquid	Intravenous	TDS

Upon observation of Table No. 4, except for azithromycin (Oral), all antibiotics were administered via IV route. In this study, the dosing schedule for amikacin and ceftriaxone showed patient-to-patient variation. Antibiotics doses were mostly with recommended level.

TABLE NO:5 ASSESSMENT OF TREATMENT RELATED ADR AMONG UNDER-5 PNEUMONIA CASES (n=50)

ADR	Suspected drug	Frequency
Diarrhea	Ceftriaxone	29
	Vancomycin	4
	Piperacillin/tazobactam	4
	Linezolid	4
Vomiting	Vancomycin	3
	Linezolid	1
Constipation	Meropenem	2
Rash	Ceftriaxone	1
Itching	Piperacillin/tazobactam	2

In the table no 5, it was found most ADRs were gastrointestinal, like diarrhoea, vomiting, and constipation, primarily caused by Ceftriaxone, Vancomycin, and Meropenem. Rash was also common with ceftriaxone.

TABLE NO:6 WHO-UMC CAUSALITY ASSESSMENT SCALE (n=50)

Suspected drug	ADR	Categories	Percentage (%)
Ceftriaxone	Diarrhea	Possible	58
	Rash	Probable	2
Vancomycin	Diarrhea	Possible	8
	Vomiting	Possible	6
Piperacillin/tazobactam	Diarrhea	Possible	8
	Itching	Probable	4
Linezolid	Diarrhea	Possible	8
	Vomiting	Possible	2
Meropenem	Constipation	Possible	4

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In Table No. 6, it was observed that ADRs like diarrhea were possible in 58% of cases treated with Ceftriaxone, followed by Vancomycin, Piperacillin/tazobactam, and Linezolid, each in 8% of cases. Vomiting was associated with Vancomycin (6%), followed by Linezolid (2%). Constipation was associated with Meropenem (4%). Rash and itching were linked to Ceftriaxone (2%) and Piperacillin/tazobactam (4%). It was noted that all antibiotic dosages were within therapeutic recommendations.

DISCUSSION

This study, Table No.1, showed that infants were more affected by pneumonia, similar to studies conducted by Khaja et al., Palikhe N et al., and Hassan MZ et al. Additionally, this study revealed a male preponderance, which was consistent with previous studies by Khaja et al., James Stephen at Tufts Medical School and New England Medical Center, Patel et al., and Shankar et al. The reasons for this difference may be attributed to stronger humoral and cellular immune responses in females, which render them less susceptible to lower respiratory tract infections, as reported by Ashmi et al. and Maximilian Muenchhoff et. In this study, female children and parental smoking were found to be significant risk factors for complications when they were shifted to the ICU. This result was aligned with prior studies that identified parental smoking as an independent risk factor for poor outcomes.

Table no 2 depicted that clinical features like fever and cough were more associated with complications than cured, i.e., a p-value of 0.04 and 0.003, respectively, whereas other signs and symptoms like rapid breathing, grunting, chest indrawing, and chest pain are not significantly associated with pneumonia-related complications. Other parameters like more than 7 days of hospital stay, delayed onset of treatment, and more than one antibiotic used are significantly associated with complications as outcomes, i.e., p-values of 0.007, 0.02, and 0.008, respectively. Fever and cough were significantly associated with complications ($p=0.04$ and $p=0.003$, respectively), suggesting that these initial symptoms may predict disease severity. Delayed initiation of treatment, prolonged hospital stays, and multiple antibiotic use were also strongly associated with poor outcomes ($p<0.05$), underlining the critical importance of timely, targeted treatment.

Table No. 3 depicted that ceftriaxone was the most frequently used antibiotic, followed by amikacin. All of the antibiotics were used as empirical therapy. These findings differ from the World Health Organisation (WHO) and Integrated Management of Neonatal and Childhood Illness (IMNCI) guidelines, published in 2021, which recommended chloramphenicol and amoxicillin as first-line drugs for severe pneumonia and pneumonia, respectively [4,15]. However, our study result was similar to other studies from India, which reported that ceftriaxone was the most commonly used antibiotic, followed by amikacin [9,22,24]. The use of ceftriaxone as the primary antibiotic diverged from WHO and IMNCI guidelines that recommend amoxicillin and chloramphenicol. This empirical use reflects current prescribing practices in tertiary centers in India. The observed polypharmacy and parenteral antibiotic usage exceeded WHO optimal values, raising concerns about rational drug use and highlighting the need for stewardship interventions.

Table No. 4 showed that polypharmacy practice and generic drug prescription, injectable antibiotics, and drugs chosen from the essential drug list were different from the WHO optimal values [16]. A similar result of the practice of polypharmacy and the use of parenteral antibiotics was reported by Chavda et al and Patel et al [12,19].

Table No. 5 depicted that, though around 90% of patients were treated with IV antibiotics, very few patients received azithromycin through the oral route in this study. It is also found that the dosing schedule of amikacin and ceftriaxone varied from patient to patient. The doses given for different antibiotics were nearly around the therapeutic recommendation value. These observations were similar to the previous studies [19]. It shows that nearly 90% of patients received IV antibiotics, indicating a preference for parenteral therapy. Oral azithromycin was used sparingly, likely due to selective indication. Dosing variations in amikacin and ceftriaxone suggest individualized treatment, though all doses remained within therapeutic limits.

In Table No. 6, the majority of the ADRs originate from the gastrointestinal system, specifically diarrhea, vomiting, and constipation. Diarrhoea was the most frequently observed and possible ADR due to ceftriaxone, followed by vancomycin, piperacillin/tazobactam, and linezolid. Vomiting was a possible ADR of vancomycin and linezolid. Ceftriaxone and piperacillin/tazobactam were the probable cause of ADRs like rash and itching. Previous studies also produced similar results. [23,25-28] The observed similarity in ADR patterns across studies can be attributed to several factors. First, the pharmacokinetics and pharmacodynamics of ceftriaxone, vancomycin, piperacillin/tazobactam, and linezolid are well-documented, with known gastrointestinal effects due to their impact on gut microbiota and mucosal integrity. Second, the consistent reporting of diarrhea, vomiting, and constipation suggests a fundamental mechanism related to antibiotic-induced dysbiosis and local irritation. Additionally, demographic and clinical characteristics of study populations, such as age, underlying conditions, and concurrent medications, likely contribute to the reproducibility of these findings.

GENERALIZABILITY

Although conducted in a single tertiary care center, the findings are broadly applicable to similar public health hospitals in resource-constrained settings across India. The demographic characteristics and drug use patterns mirror trends seen in other parts of the country. However, further multicentric studies are required to validate and expand upon these findings.

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CONCLUSION

The study concluded that pneumonia affected infants and males disproportionately. Sociodemographic variables didn't impact treatment outcomes significantly. Ceftriaxone was the most used antibiotic. Polypharmacy was evident, with prescriptions averaging five drugs. Most adverse drug reactions were linked to gastrointestinal, particularly diarrhea. The prescribing pattern of antibiotics was different from the WHO & IMNCI guidelines.

LIMITATIONS

The study has several limitations, such as
1. It was a single-center study, which may not fully represent India's diverse population
2. The sample size of 118 patients might not be adequate to draw definitive conclusions about the entire population,
3. Excluding certain pneumonia cases secondary to other diseases could underestimate the overall burden,
4. The cross-sectional design provides only a snapshot of the situation, limiting assessment of changes over time
5. Lack of follow-up after discharge hinders understanding of long-term outcomes, 6. Polypharmacy prevalence might confound results related to Adverse Drug Reactions (ADRs).

RECOMMENDATIONS

It can be recommended that conducting awareness programs at all levels of health care providers and care givers of the children, reviewing and educating on proper antibiotic use periodically, implementing guidelines to improve prescribing and educating and involving patients in ADR reporting may increase the treatment outcome and reduce the ADR among under-5 pneumonia cases.

LIST OF ABBREVIATIONS

Abbreviation	Full Form
ADR:	Adverse Drug Reaction
ARI:	Acute Respiratory Infection
BD:	Bis in Die (Twice Daily)
CHERG:	Child Health Epidemiology Reference Group
CRF:	Case Record Form
GAPPD:	Global Action Plan for Pneumonia and Diarrhoea
Hib:	Haemophilus influenzae type b
HIV:	Human Immunodeficiency Virus
ICU:	Intensive Care Unit
IEC:	Institutional Ethics Committee
IMNCI:	Integrated Management of Neonatal and Childhood Illness
IV:	Intravenous
LBW:	Low Birth Weight
MKCG MCH:	Maharaja Krushna Chandra Gajapati Medical College and Hospital
OD:	Omni Die (Once Daily)
PCV:	Pneumococcal Conjugate Vaccine
PPV:	Pneumococcal Polysaccharide Vaccine
QID:	Quater in Die (Four Times Daily)
SPSS:	Statistical Package for the Social Sciences
TLC:	Total Leukocyte Count
TDS:	Ter Die Sumendum (Three Times Daily)
UMC:	Uppsala Monitoring Centre
UNICEF:	United Nations Children's Fund
WHO:	World Health Organization

DATA AVAILABILITY

The data supporting the findings of this study are derived from structured case record forms filled during patient evaluation at the Department of Paediatrics, MKCG Medical College and Hospital, Berhampur. These data include sociodemographic details, clinical profiles, drug prescription patterns, treatment outcomes, and adverse drug reactions.

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CONFLICT OF INTEREST

The authors report no conflicts of interest in this study.

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27. Safety of Antibiotics in Hospitalized Children in Romania: A Prospective Observational Study Noémi-Beátrix Bulik 1, †, Andreea Farcas, 2,*,†, Camelia Bucs, a 2,†, Irina Iaru 3,† and Ovidiu Oniga 1

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