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Paracetamol Overdose in Children Presenting to a Pediatric Hospital: A Five-Year Retrospective Study on Incidence and Formulation Confusion

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Abstract

Background

Paracetamol overdose is a preventable cause of medication-related harm in young children. In settings where multiple paediatric liquid formulations are available, caregiver confusion between concentrated drops and syrup may lead to substantial dosing errors. Evidence from Nepal remains limited. This study examined the hospital-based incidence, mechanisms, and outcomes of paracetamol overdose in young children, with particular attention to formulation-related confusion.

Methods

A retrospective hospital-based study was conducted at Siddhi Memorial Women and Children's Hospital, Bhaktapur, Nepal, from 1 June 2020 to 30 May 2025. Children aged 0–5 years with diagnosed or suspected paracetamol overdose were identified through hospital record review. Data on demographics, formulation, dose, medicine source, symptoms, management, and outcomes were extracted. Structured caregiver interviews were conducted to clarify overdose circumstances, formulation confusion, dosing misunderstanding, and prevention suggestions. Descriptive statistics and content-based thematic classification were used.

Results

Twenty-three children aged 0–5 years were included. The overall hospital-based presentation rate was 4.77 per 10,000 under-five emergency visits. Annual case counts varied across the study period, with the highest number recorded in 2022–2023. The median age was approximately 11 months, and most cases occurred in infants. Concentrated paracetamol drops were the most frequently involved formulation, followed by regular syrup. Formulation confusion, particularly between drops and syrup, was the dominant mechanism, accompanied by frequent misunderstanding of mg/mL concentration and communication gaps related to verbal, previous, or unclear prescriptions. A substantial proportion of caregivers were unaware that multiple paracetamol formulations existed. Several children required hospital admission and N-acetylcysteine therapy, and liver enzyme elevation was recorded in a subset. No deaths or documented final complications occurred.

Conclusions

Paracetamol overdose in young children at this centre was mainly associated with formulation confusion between concentrated drops and regular syrup, compounded by low caregiver awareness, self-medication, and inadequate written instructions. Prevention should focus on standardized labelling, clear

mL-based prescriptions, caregiver counselling, avoidance of telephone-only prescribing, and safer storage of medicines.

Background

Paracetamol is widely used in children as an antipyretic and analgesic and is available both by prescription and over-the-counter.[1,2] Although generally safe when administered at recommended therapeutic doses, overdose remains an important cause of preventable medication-related harm and acute liver injury in children. Paediatric overdose may occur through exploratory ingestion, intentional ingestion in older children, caregiver dosing errors, repeated supratherapeutic administration, or confusion between available formulations.[1–4]

Young children are particularly vulnerable to paracetamol overdose because dosing is weight-based, liquid products require volume calculations, and caregivers often rely on household or brand-specific measuring devices.[1,5] In addition, infants and young children may receive medicines from more than one caregiver during the same illness episode, increasing the risk of duplicate or excessive dosing.[1,6] Because signs of toxicity may be delayed, overdose may not be recognized immediately.[1,6–9]

Formulation-related errors are a largely preventable cause of pediatric paracetamol overdose.[5,6] Liquid paracetamol products may differ in concentration, packaging, labelling, naming, and dosing devices. In some settings, concentrated infant drops and less concentrated syrups have co-existed in the market, creating a risk that caregivers may administer the volume intended for syrup using a much stronger drops preparation.[5,6] Regulatory experience from the United States showed that confusion between concentrated infant drops and children's liquid acetaminophen contributed to overdose reports and led to recommendations on concentration standardisation, labelling, packaging, and dosing devices. Caregivers may also misunderstand the relationship between milligrams and millilitres, or fail to distinguish regular syrup, double-strength syrup, and drops.[5,6,9–11]

Published studies on paediatric paracetamol poisoning have largely focused on clinical presentation, hepatotoxicity, and treatment outcomes.[1] Other studies have examined poison-center data on dosing errors and medication safety.[5,6] However, fewer hospital-based studies in young children have specifically examined formulation confusion as a contributor to overdose, particularly in low- and middle-income settings. Evidence from Nepal and South Asia also remains limited and is mostly based on broader childhood poisoning profiles rather than detailed paracetamol-specific investigation. This leaves an important gap in understanding how formulation-related confusion, caregiver practices, and communication problems contribute to paracetamol overdose in routine paediatric care.[5,6,11–14]

Study objectives

Primary objective: To describe the hospital-based incidence, clinical profile, mechanisms, and outcomes of paracetamol overdose in children presenting to a paediatric hospital over a five-year period.

Secondary Objective:

• To identify the formulations involved in overdose episodes.

• To examine whether formulation confusion, dose misunderstanding, or instruction-related problems contributed to overdose.

• To describe clinical presentation, treatment, and outcomes.

• To summarize caregiver-reported prevention suggestions.

Methods

Study design and setting

This was a five-year retrospective hospital-based study of paracetamol overdose in children conducted at Siddhi Memorial Women and Children's Hospital, Bhaktapur-7, Nepal. The hospital serves as a regional referral center for pediatric emergencies and has both emergency and inpatient paediatric services. Digital clinical records were available through the hospital's electronic HMIS, with archived paper-based records reviewed where required.

During manuscript preparation, a large language model tool, ChatGPT by OpenAI, was used to assist with language editing, manuscript structuring, summarisation of author-provided data, and preparation of draft text. The tool was not used to generate original data, perform independent statistical analysis, or make clinical interpretations. All outputs were reviewed, verified, and revised by the authors, who take full responsibility for the accuracy, integrity, and final content of the manuscript.

Study period

The study period covered five years, from 1 June 2020 to 30 May 2025.

Study population

The target population comprised children aged 0–5 years who presented to the paediatric emergency department with diagnosed or suspected paracetamol overdose.

Inclusion criteria

• Children aged 0–5 years.

• Diagnosed or suspected paracetamol overdose.

• Presentation during the defined five-year study period.

• Sufficient documentation in the medical record, including formulation and dose details.

Exclusion criteria

• Medical records too incomplete to confirm eligibility, paracetamol exposure, or overdose circumstances.

• Polypharmacy overdose in which paracetamol overdose could not be isolated.

• Repeat visits for the same overdose episode.

Case identification and data sources

Cases were identified through retrospective review of hospital records, including both digital patient records and archived paper-based records where necessary. Data were extracted using a structured spreadsheet-based form derived from a predefined variable codebook to improve consistency in data collection.

Interview component

In addition to record review, structured interviews were conducted with the patient's family using a predefined interview guide. The interview guide covered respondent characteristics, child information, circumstances of overdose, source of paracetamol, formulation used, dose details, symptoms, first aid, hospital management, caregiver awareness, and prevention suggestions. The interview component was used to clarify formulation-related misunderstandings and contextual factors not always captured in chart records.

Variables

Quantitative variables: age, sex, formulation type, caregiver-reported confusion or misunderstanding, reported dose, dosing frequency, source of medication, medication label or dosing instruction, delay to presentation, clinical severity, laboratory abnormalities, treatment provided, and disposition.

Qualitative/interview variables: circumstances of overdose, whether the event was accidental or related to therapeutic error or misunderstanding, who administered the medicine, whether instructions were clear, prior caregiver awareness, and caregiver suggestions for prevention.

Definitions

Paracetamol overdose: A diagnosed or suspected overdose recorded in the hospital record and included according to the study eligibility criteria.

Formulation confusion: Caregiver confusion between paediatric paracetamol preparations, particularly drops, regular syrup, and double-strength syrup, contributing to dose misinterpretation or overdose.

Therapeutic error: Overdose occurring during intended treatment, such as wrong dose, wrong formulation, wrong frequency, or misunderstanding of instructions.

Thematic classification of interview responses

Open-ended and explanatory interview responses were grouped using practical content-based classification[15] into predefined categories, including formulation confusion, dose or measurement misunderstanding, communication gap, medicine-source related error, accidental self-ingestion, and prevention suggestions.

Statistical analysis

Data were entered into a spreadsheet-based database and analysed using descriptive statistics. Categorical variables were summarised as frequencies and percentages, while continuous variables were summarised using median, range, mean, and standard deviation, as appropriate. The hospital-based presentation rate was calculated by dividing the number of paracetamol overdose cases among children aged 0–5 years by the total number of under-five emergency department visits during the study period. Rates were expressed per 10,000 under-five emergency visits. Sex-specific rates were calculated using sex-specific under-five emergency visit denominators. Variables with missing information were analysed using available-case denominators, and the denominator is reported for each variable where data were incomplete.

Ethical considerations

Data were anonymized before analysis, and confidentiality was maintained throughout the study. Written informed consent for use of anonymized clinical data for research and audit purposes was routinely obtained from parents or legal guardians at the time of clinical care. The study was approved by the Nepal Health Research Council. (Proposal ID: 427-2025).

Results

During the five-year study period, 48,189 children aged under five years attended the emergency department, including 29,412 males and 18,777 females. Twenty-three children aged 0–5 years presented with diagnosed or suspected paracetamol overdose, giving an overall hospital-based presentation rate of 4.77 per 10,000 under-five emergency visits. The rate was higher among female children than male children, at 7.99 per 10,000 female under-five visits compared with 2.72 per 10,000 male under-five visits.

Demographic characteristics

The final analysis included 23 children aged 0–5 years. Table 2 shows the demographic and care giver characteristics. The median age was approximately 11 months. Most cases occurred in infants aged 6–11 months (12/23, 52.2%). Fifteen patients were female (65.2%) and eight were male (34.8%).

Table 1
Hospital-based presentation rate of paracetamol overdose

Group	Cases	Under-5 ER visits	Rate per 10,000 visits
Male	8	29,412	2.72
Female	15	18,777	7.99
Total	23	48,189	4.77

The median recorded weight was approximately 9.9 kg (range 6.0–26.0 kg), with a mean of approximately 11.4 kg and standard deviation of approximately 5.3 kg. Twenty-two children (95.7%) had no significant chronic illness, while one child (4.3%) had a previously corrected patent ductus arteriosus. All children resided in urban areas (23/23, 100%). The predominant ethnic groups were Newar (n = 15, 65.2%) and Chettri (n = 6, 26.1%). The responding caregiver was the father in 14 cases (60.9%) and the mother in 9 cases (39.1%). The primary caregiver at the time of the overdose event was the mother in 19 cases (82.6%), the grandmother in 1 case (4.3%), grandparents in 1 case (4.3%), a joint mother-father pair in 1 case (4.3%), and the father in 1 case (4.3%). All 23 caregivers (100%) had previously administered paracetamol to the child during a prior illness episode. Maternal education was at bachelor's level or above in 13 of 22 cases with available data (59.1%), and paternal education was at bachelor's level or above in 14 of 23 cases with available data (60.9%).

Circumstances and mechanism of overdose

The home was the predominant place of overdose in 21 of 23 cases (91.3%); one episode occurred at a relative's home and one at the hospital. All cases had a history of prior paracetamol use in the child during a previous illness, suggesting that the medicine was already familiar to the household. Five cases (21.7%) involved accidental self-ingestion by the child, predominantly in the 12–36-month age group and in households where medicine was stored within reach. In the remaining 18 cases, the overdose resulted from caregiver-administered doses.

Among caregiver-administered overdose cases, the primary error mechanisms identified through interview and record review were: confusion between drop and syrup formulations (most common, documented in approximately 16 cases), use of a previous prescription intended for a different formulation, phone-based prescribing without written instructions (4 cases), and dose miscalculation. In four cases the caregiver reported receiving a verbal prescription by telephone, with no written instruction available, and subsequently used a different formulation than intended. Leftover medicines from a previous illness were identified as the source in at least 6 cases.

Multiple check-up visits for the same illness episode were reported in 3 of 22 cases with available data (13.6%), and use of multiple paracetamol formulations during the same illness was documented in 5 of 22 cases (22.7%).

Table 2
Demographic and caregiver characteristics.

Characteristic	n	% or statistic
Total cases	23	—
Age, months: median (range)	11	-
< 6 months	1	4.3%
6–11 months	12	52.2%
12–23 months	3	13.0%
24–35 months	3	13.0%
36–60 months	4	17.4%
Sex: Female	15	65.2%
Sex: Male	8	34.8%
Weight, kg: median (range)	9.9 (6.0–26.0)	Mean 11.4, SD 5.3
Residence: urban	23	100%
Chronic illness absent	22	95.7%
Chronic illness present	1	4.3%
Ethnicity: Newar	15	65.2%
Ethnicity: Chettri	6	26.1%
Responding caregiver: Father	14	60.9%
Responding caregiver: Mother	9	39.1%
Primary caregiver: Mother	19	82.6%
Primary caregiver: Grandmother	1	4.3%
Primary caregiver: Grandparents	1	4.3%
Primary caregiver: Joint mother-father	1	4.3%
Primary caregiver: Father	1	4.3%
Prior PCM use in this child	23	100%
Mother education: bachelor or above	13/22	59.1%
Father education: bachelor or above	14/23	60.9%

Formulations involved

Concentrated paracetamol drops (150 mg/ml) were the most commonly involved formulation, accounting for 11 of 23 cases (47.8%). Regular-strength syrup (125 mg/5 ml, equivalent to 25 mg/ml) accounted for 7 cases (30.4%), double-strength syrup (250 mg/5 ml) for 2 cases (8.6%), paracetamol tablet 500 mg for 1 case (4.3%), and one case involved concurrent administration of both drops and regular syrup. Formulation was unspecified in 1 case. Brand names included standard PCM preparations and Niko (drops) and Niko DS (double-strength syrup). The formulation distribution is summarized in Table 3.

Table 3
Distribution of paracetamol formulations involved in overdose episodes.

Formulation	n	%	Strength
Concentrated drops	11	47.8%	150 mg/ml
Regular syrup	7	30.4%	125 mg/5 ml (25 mg/ml)
Double-strength syrup	2	8.6%	250 mg/5 ml (50 mg/ml)
Tablet 500 mg	1	4.3%	500 mg/tablet
Drops + regular syrup (both administered)	1	4.3%	Mixed
Unknown	1	4.3%	—
Total	**23**	**100%**	

Dose data

Total paracetamol dose ingested was calculable for 22 of 23 cases. The median total dose was 1000 mg (range 120–6300 mg; mean 1442 mg, SD 1621). The median dose per kilogram was 107 mg/kg (range 29–492 mg/kg; mean 142 mg/kg, SD 107). Using 150 mg/kg as a high-risk threshold for acute single-episode ingestion, 7 cases (31.8%) exceeded this threshold.[3,16] Eight cases (36.36%) had dose per kilogram between 75 and 150 mg/kg, and 7 (31.8%) were below 75 mg/kg, suggesting supratherapeutic repeated dosing rather than single acute toxic ingestion in several cases. The highest recorded dose per kilogram was 492 mg/kg in a 6.4 kg, 8-month-old infant who received drops over a 2-day period.

Prescription, labelling, and instruction-related factors

The medicine source was documented in 22 cases. Over-the-counter purchase from a pharmacy without a prescription was the most common source (n = 9, 39.1%), followed by use of a previous prescription (n = 6, 26.0%), prescription received verbally by telephone (n = 4, 17.3%), and leftover medicine from a prior episode (n = 3, 13.0%). Table 4 summarizes prescription and labelling findings.

Among caregivers interviewed, 17 of 22 (77.3%) did not know that multiple formulations of paracetamol exist at different concentrations. Eighteen of 22 (81.8%) did not know the correct usual dose of paracetamol for their child. Sixteen of 21 caregivers (76.2%) reported that the label of the medicine bottle was clear, and 16 of 21 (76.2%) stated they had read the label; however, 5 of 21 (23.8%) reported

not understanding the label content. Twenty-two of 23 cases (95.6%) reported that the caregiver sometimes or quite often administered paracetamol to the child without a prescription.

Table 4
Prescription, labelling, and caregiver knowledge factors.

Variable	n / total with data	%
Medicine source		
Over-the-counter (pharmacy)	9/22	40.9%
Previous prescription	6/22	27.3%
Verbal prescription by phone	4/22	18.2%
Leftover medicine	3/22	13.6%
Unknown	1/23	4.3%
Caregiver knowledge and labelling		
Unaware of multiple PCM formulations	17/22	77.3%
Did not know usual PCM dose	18/22	81.8%
Label of bottle reported as clear	16/21	76.2%
Label read by caregiver	16/21	76.2%
Label understood	16/21	76.2%
Ever given PCM without prescription	22/23	95.7%
Multiple visits for same illness	3/22	13.6%
Multiple formulations used same illness	5/22	22.7%

Clinical presentation and management

The median time from overdose to hospital presentation was 17 hours (range 0.5–48 hours; mean 15.1 hours, SD 12.7; n = 18). Presentation within 8 hours of the event occurred in 7 of 18 cases (38.9%), between 8 and 24 hours in 10 cases (55.6%), and beyond 24 hours in 1 case (5.6%).

Clinical symptoms of overdose were present in 9 of 23 cases (39.1%); 13 cases (56.5%) were asymptomatic at presentation and 1 (4.34%) had unknown symptom status. The most common presenting symptom was vomiting, reported in 7 (77.7%) symptomatic cases, followed by lethargy or drowsiness (1 case, 11.11%), and abdominal pain (1 case, 11.11%). Vital signs at admission were abnormal (tachycardia or tachypnoea) in several cases but were overall in keeping with the underlying febrile illness rather than specific toxidrome.

N-acetylcysteine (NAC) was administered in 7 cases (30.4%) and not given in 15 (65.2%); data were missing for 1 case. Hospital admission was required in 10 cases (43.5%), with 13 cases (56.5%) managed and discharged from the emergency department. The median length of hospital stay was 2 days (range 1–6 days).

Laboratory findings and outcomes

Liver function tests were available for all 23 cases. Peak alanine aminotransferase (ALT) values ranged from 14 to 955 U/L (median 25 U/L, mean 81.3 U/L, SD 193.2). Aspartate aminotransferase (AST) ranged from 25 to 870 U/L (median 45.5 U/L, mean 101.2 U/L, SD 178.7). Using an upper reference limit of 45 U/L for ALT and 40 U/L for AST, elevation above normal was recorded in 6 cases (26.1%) for ALT and 13 cases (56.5%) for AST. The most markedly elevated values were observed in PCM011 (ALT 955 U/L, AST 870 U/L), a 7-month-old infant who received drops at a dose of 250 mg/kg, though this child had no clinically documented complication. All 23 patients survived without documented complications. No deaths were recorded.

Table 5
Clinical features, management, and outcomes (N = 23).

Clinical variable	**n / statistic**	**% or detail**
Time to presentation (n = 18), hours: median (range)	17.0 (0.5–48)	Mean 15.1, SD 12.7
< 8 hours	7/18	38.9%
8–24 hours	10/18	55.6%
> 24 hours	1/18	5.6%
Symptomatic at presentation	9/23	39.1%
Vomiting	7	77.7% of symptomatic
Lethargy/drowsiness	1	11.11% of symptomatic
Abdominal pain	1	11.11% of symptomatic
NAC administered	7/23	30.4%
Hospital stay (days): median (range)	2 (1–6)	Mean 2.5
Peak ALT U/L: median (range)	25 (14–955)	Elevated (> 45): 6 (26.1%)
Peak AST U/L: median (range)	45.5 (25–870)	Elevated (> 40): 13 (56.5%)
Outcome: no complication	23/23	100%
Mortality	0/23	0%

Thematic classification of interview findings

Interview responses were thematically classified into five primary error categories. Formulation confusion — predominantly the misidentification of concentrated drops as equivalent in volume-dose to regular syrup — was the dominant theme, identified in 17 of 22 cases with available data (77.3%). This was closely associated with Mg/mL confusion, also present in 17 of 22 cases (77.3%). Communication-related problems (including verbal-only prescriptions, absent or unclear written instructions, and prior prescriptions being used for a different formulation) were identified in 16 of 21 cases (76.2%). Accidental self-ingestion by the child was documented as the primary mechanism in 5 cases (22.7%), and use of leftover medicines as the source was confirmed in at least 6 cases (26.1%). These categories are summarized in Table 6.

Table 6
Thematic classification of interview-identified error mechanisms.

Error / confusion category	n / total with data	%
Formulation confusion (drops vs syrup)	17/22	77.3%
Mg/mL dose confusion	17/22	77.3%
Communication problem (no/verbal/old prescription)	16/21	76.2%
Accidental child self-ingestion	5/22	22.7%
Leftover medicine used as source	6/23	26.1%
Multiple formulations same illness	5/22	22.7%
Phone prescription without written instructions	4/23	17.4%

Caregiver prevention suggestions

Caregivers were asked to suggest steps they planned to take in the future to prevent a recurrence. The most common responses were: (1) seeking formal medical consultation before administering any medicine (n = 10), (2) keeping medicines out of children's reach (n = 5), (3) not using medicines without a valid written prescription (n = 7), (4) discarding leftover medicines (n = 6), and (5) requesting information about formulation differences and correct dosing at the time of prescription (n = 4). Two caregivers specifically suggested that information about paracetamol doses and formulation types should be provided to parents at the time of delivery or first postnatal visit.

Discussion

Main findings

This retrospective hospital-based study identified 23 cases of paracetamol overdose in children over a five-year period at a tertiary paediatric referral centre in Bhaktapur, Nepal. The study confirms that paracetamol overdose in this setting predominantly affects infants and young children under 12 months, involves concentrated drop formulations in nearly half of cases, and is strongly associated with

formulation confusion between drops and syrup — a finding consistent with its primary hypothesis. All patients survived without documented clinical complications, but a substantial minority required hospital admission and N-acetylcysteine therapy, and a subset developed laboratory evidence of hepatic enzyme elevation.

Annual trend and incidence

The marked year-on-year increase in case counts, from 1 case in 2020–2021 to a peak of 8 in 2022–2023, followed by modest fluctuation, may reflect an increase in hospital-based presentations, improving case ascertainment as the hospital's electronic HMIS matured, or both. The overall hospital-based presentation rate was **4.77 per 10,000 under-five emergency visits**. This indicates that paracetamol overdose was uncommon but clinically important in this setting. Because the denominator was based on emergency department attendance rather than the community population, this should be interpreted as a hospital-based presentation rate rather than a community incidence rate. Nevertheless, the trend signal is consistent with reports from Australia, where Chidiac et al. (2026) documented increasing paediatric paracetamol dosing errors over an analogous time frame. [6]

Formulation confusion as the dominant mechanism

The predominance of concentrated drops as the most common overdose formulation, and the identification of drop-versus-syrup confusion in 77.3% of cases with available data, strongly supports formulation-related error as the central safety issue in this study. In the local preparations identified, concentrated drops contained 150 mg/ml, while regular syrup contained 125 mg/5 ml, equivalent to 25 mg/ml. Therefore, giving the same volume of drops instead of syrup would result in a six-fold higher paracetamol dose. This concentration gap provides a plausible explanation for why infants and young children were highly represented among the cases.[5,10,11] Brass et al. (2018) demonstrated that standardising acetaminophen liquid concentration and improving packaging reduced medication errors at a population level,[5] a finding with direct relevance to Nepal, where multiple drop and syrup concentrations remain commercially available.

This mechanism is consistent with international medication-safety experience. Reports from the United States linked confusion between infant drops and children’s liquid acetaminophen to overdose events, leading to industry and regulatory actions to standardise concentration and improve packaging and labelling. Brass et al. also reported that standardisation of pediatric liquid acetaminophen concentration and packaging improvements were associated with reductions in medication errors. These findings are directly relevant to settings where multiple liquid strengths remain available and where caregivers may not understand concentration differences.[5,10]

Kazouini et al. reported that 57.2% of paediatric paracetamol prescriptions in primary care failed to comply with dosing recommendations, with young infants at particular risk of potential overdosing.[17] This is consistent with the present study’s finding that most overdose presentations occurred in infants,

particularly those aged 6–11 months (52.2%). The high burden in this age group likely reflects caregiver difficulties with weight-based volume calculations, low awareness of concentration differences, and greater use of concentrated drop formulations in early childhood.

Communication gaps, prescribing practices, and medicine sourcing

A striking finding of the present study is the frequency of phone-based verbal prescriptions without written documentation, together with the widespread use of over-the-counter purchases, previous prescriptions, and caregiver administration of paracetamol without a current prescription. These practices create conditions in which an initial error, such as using concentrated drops when syrup was intended, may be repeated across multiple doses before the overdose is recognised. In four cases, a verbal telephone prescription for syrup was followed by caregiver administration of drops, representing a particularly high-risk mechanism for overdose. This underscores the need for regulatory and clinical interventions targeting telephone prescribing and dispensing of paediatric liquid medicines.

Findings from Nepal-based childhood poisoning studies are limited. Devkota et al. (2023) and Aryal et al. (2024) reported on the broad spectrum of childhood poisoning presenting to tertiary centres in Nepal but did not provide paracetamol-specific formulation data.[12,13] The present study provides, to our knowledge, the first hospital-based paracetamol-specific formulation-confusion analysis in Nepal.

Clinical outcomes and liver toxicity

All children in this study survived without documented clinical complications, but this favourable outcome should not be interpreted as absence of toxicity risk. A substantial minority required hospital admission and NAC therapy, and liver enzyme elevation was documented in several cases. The highest ALT and AST values occurred in an infant who received concentrated drops at a high dose, illustrating the potential for clinically important hepatocellular injury even when final clinical outcome is favourable. AST was elevated in 13 cases (54.2%) and ALT in 6 cases (25.0%), including one case with values exceeding 900 U/L, suggesting that subclinical hepatocellular injury may be underappreciated. Previous paediatric studies have identified dose, delayed presentation, and repeated supratherapeutic administration as important risk factors for liver injury after paracetamol exposure.[1–3,7]

Caregiver knowledge and education

The finding that 77.3% of caregivers were unaware of multiple paracetamol formulations and that 81.8% did not know the correct usual dose for their child is one of the most important prevention messages from this study. This occurred despite relatively high parental educational attainment, suggesting that general education does not necessarily translate into medication-specific literacy. Safe paediatric liquid medicine use requires caregivers to understand the prescribed dose in milligrams and millilitres, the concentration of the preparation, the correct dosing interval, and the correct measuring device.[9,18,19]

The administration of NAC in 7 cases is consistent with the principle that treatment decisions should consider estimated dose, timing of presentation, clinical uncertainty, and risk of hepatotoxicity. Published guidance and systematic reviews support NAC as the main antidotal therapy for clinically significant paracetamol overdose, particularly when presentation is delayed, dose history is uncertain, or repeated supratherapeutic ingestion is suspected. In this study, the absence of deaths or documented hepatic failure may reflect early recognition in some cases, hospital monitoring, and appropriate use of NAC where indicated.[1,16]

Evidence from paediatric medication-safety studies shows that liquid medication dosing errors are common among caregivers and are influenced by dosing tools, units of measurement, and health literacy. Yin et al. found that most parents made at least one dosing error in a randomized experiment and that errors were more frequent with cups than syringes. This supports practical interventions such as mL-only instructions, use of oral syringes rather than cups or household spoons, demonstration of the exact dose before discharge or dispensing, and written instructions that clearly name the formulation and concentration.[9,18]

Caregiver counselling should therefore not be limited to saying “give paracetamol.” It should specify the formulation, strength, dose in mL, maximum frequency, maximum daily dose, and danger of using old prescriptions or switching between drops and syrup. The caregiver suggestion that medication-safety education should be provided at delivery or early postnatal visits is supported by quality-improvement work showing that targeted education during early child visits can improve caregiver understanding of liquid acetaminophen administration.[19]

Strengths

This study contributes the first paracetamol-specific, formulation-focused analysis in young children from Nepal. The use of both retrospective record review and structured caregiver interviews enriches the understanding of contextual and caregiver-level factors. The five-year time horizon and total population sampling minimise selection bias within a single-centre design. Systematic data extraction with a predefined codebook and thematic classification improves reproducibility.

Limitations

Several limitations should be acknowledged. As a single-centre retrospective study, the findings may not represent the full burden of paracetamol overdose in Nepal or other settings. The relatively small sample size (n = 23) limits statistical precision and precludes multivariable analysis. Although an under-five emergency attendance denominator was available, the estimate represents a hospital-based presentation rate rather than a community incidence rate. Mild cases not presenting to the hospital, cases managed elsewhere, or cases not coded as paracetamol overdose may therefore have been missed. Recall bias in caregiver interviews is a recognised limitation, as events may have occurred several years before the interview. Information bias may arise from incomplete medical record

documentation, particularly for early paper-based records. Finally, PCM toxicity is likely underreported in this setting, as mild cases may not present to hospital or may not be coded as paracetamol overdose.

Future directions

Future work should establish prospective surveillance of paediatric paracetamol overdose at Siddhi Memorial Hospital, linked to annual emergency attendance denominators so that year-specific hospital-based presentation rates can be monitored. Multicentre studies across Nepal and comparative studies from other South Asian settings would strengthen regional evidence and help determine whether formulation confusion is a wider medication-safety problem. Intervention studies should evaluate standardised labelling, clearer formulation distinction, mL-only dosing instructions, dispensing checklists, oral syringe provision, caregiver teach-back, and early postnatal medication-safety education. Regulatory consideration should be given to reducing the availability of multiple paediatric liquid paracetamol concentrations, improving package warnings and dosing devices, and discouraging telephone-only prescribing of oral paracetamol in young children.[5,9,14,19]

Conclusion

Paracetamol overdose in young children presenting to Siddhi Memorial Women and Children's Hospital over a five-year period was predominantly associated with caregiver confusion between concentrated drop and regular syrup formulations, in a context of widespread self-prescribing, telephone prescribing without written instructions, and near-universal ignorance of multiple formulation concentrations. Despite favourable clinical outcomes in all 23 cases, the high prevalence of enzyme elevation, delayed presentations, and repeated supratherapeutic dosing highlight the potential for serious harm. The findings also suggest that prevention should move beyond general caregiver advice and address specific system-level risks, including multiple liquid strengths, unclear formulation names, inadequate written dosing instructions, and use of inaccurate dosing tools.[5,9] Targeted education at the point of prescribing and dispensing, standardised and simplified paediatric paracetamol formulations, enforced written prescription practices, and active promotion of medicine storage safety are urgently needed to prevent paracetamol-related harm in young children in Nepal.

Abbreviations

AD — Anno Domini
ALT — Alanine aminotransferase
AST — Aspartate aminotransferase
BS — Bikram Sambat
ED — Emergency department
HMIS — Health Management Information System
IQR — Interquartile range

NAC — N-acetylcysteine
NHRC — Nepal Health Research Council
OTC — Over-the-counter
PCM — Paracetamol
PICU — Paediatric intensive care unit
SD — Standard deviation
STROBE — Strengthening the Reporting of Observational Studies in Epidemiology

Declarations

Ethics approval and consent to participate

This study was approved by the Nepal Health Research Council, Nepal (Proposal ID: 427-2025). Written informed consent for participation/interview and use of anonymized clinical data was obtained from parents or legal guardians, as applicable. The study was conducted in accordance with relevant ethical standards.

Consent for publication

Not applicable. The manuscript does not contain identifiable individual data, images, or videos.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to participant confidentiality and the small sample size, but anonymized data may be available from the corresponding author on reasonable request and subject to ethics approval/institutional permission.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JB and GBR conceptualised the study. GBR, SD, RT, AA and JB contributed to data collection, analysis, manuscript writing, and critical review. All authors read and approved the final manuscript.

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