Kathmandu University Journal of Science, Engineering and Technology, Vol. X, No. X, Month Year

Kathmandu University
Journal of Science, Engineering and Technology

Common errors in reconstituting oral antimicrobials: A survey of caregivers

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Abstract

Antimicrobial resistance (AMR) is a growing global health threat, particularly in low- and middle-income countries (LMICs). Inappropriate use of antimicrobials, including incorrect reconstitution of oral suspensions, contributes to AMR. This study investigates reconstitution practices among caregivers in Nigeria and their potential impact on AMR. A cross-sectional field-laboratory study was conducted in Abuja, Nigeria, involving 200 breastfeeding mothers who reconstituted two commonly used pediatric oral suspensions (artemether/lumefantrine and cefuroxime) using different water sources. The physicochemical properties of the reconstituted suspensions were analyzed, and the accuracy of reconstituted volumes was assessed. The study found significant variability in the physicochemical properties of the reconstituted suspensions, depending on the water source used. Only 17% of caregivers achieved correct reconstitution, with the majority (83%) committing errors that could lead to sub- or supra-therapeutic dosing. The patient-reported errors were often due to under- or over-dilution, resulting in deviations from the recommended final volumes. The study highlights the need for targeted interventions to address incorrect reconstitution practices among caregivers in Nigeria.

Keywords: Artemether/lumefantrine; Cefuroxime; Caregivers; Electrical conductivity; Total dissolved solids.

1. Introduction

Infectious diseases in children, whether bacterial, parasitic or viral, remain a major public health challenge, with young children experiencing on average six to eight episodes annually [1]. The introduction of antimicrobials revolutionised modern medicine, converting previously fatal infections into treatable conditions and enabling complex procedures such as surgery and chemotherapy [2]. The global rise of antimicrobial resistance (AMR) now poses a threat to these achievements causing more harm than HIV and malaria combined [3]. As microbes adapt to these medicines, they become increasingly resilient, requiring stronger doses or new treatments. Recent estimates attribute 1.27 million deaths in 2019 directly to bacterial AMR, with nearly 5 million additional deaths in which AMR was a contributory factor [3, 4]. It is projected that between 2025 and 2050, 39 million deaths could be directly associated with AMR, and another 169 million deaths potentially linked indirectly [3]. Additionally, the greatest burden falls on low- and middle-income countries [4].

A principal driver of AMR is inappropriate antimicrobial use across community and clinical settings, including overuse, misuse, and non-prescription access [3]. Such practices increase selective pressure on pathogens and accelerate the emergence and dissemination of resistant strains [5]. Public health responses, awareness campaigns, antimicrobial stewardship, and research into novel agents have been implemented but remain insufficient to reverse current trends [6]. One under-recognised mechanism of inappropriate use relates to errors in the preparation and administration of reconstituted oral antibiotic suspensions. Many paediatric antibiotic formulations are supplied as dry powders for reconstitution because active ingredients are often poorly soluble or chemically unstable in aqueous solution [7]. Moreover, liquid preparations remain the preferred dosage form for infants and young children, addressing problems of swallowability and dose flexibility [8]. As a result, correct reconstitution—involving the choice of diluent, precise measurement of volume, thorough mixing, and accurate dose administration—is essential to deliver the intended therapeutic concentration [7, 8].

Evidence from multiple countries demonstrates that caregivers frequently commit errors in reconstitution and dosing. These include incorrect diluent volumes, incomplete mixing, and the use of inappropriate measuring devices, leading to sub- or supra-therapeutic dosing with potential safety and efficacy consequences [9, 10, 11]. However, the implications of under-dosing extend beyond individual treatment failure. Pharmacokinetic and pharmacodynamic evidence indicate that inadequate antimicrobial exposure selects for resistant subpopulations, increasing the risk of resistance emergence and spread [12]. Thus, recurrent sub-therapeutic dosing, whether due to dilution errors, poor mixing, or inaccurate devices, constitutes a plausible and underexplored pathway contributing to AMR at the community level [13].

This problem is particularly salient in settings where antimicrobials are widely available without prescription. In Nigeria, weak regulatory enforcement and extensive informal drug markets en-

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able over-the-counter antibiotic sales and self-medication [14, 15]. Under these conditions, responsibility for correct reconstitution and dosing rests largely with caregivers, often without professional oversight. Consequently, errors in preparation and administration may exert both individual and population-level effects on antimicrobial efficacy and resistance dynamics.

Despite these formulation-related vulnerabilities, widespread caregiver errors, and unregulated antibiotic access, reconstitution practices remain largely absent from AMR surveillance, stewardship, and policy discourse. Addressing this gap requires systematic quantification of reconstitution-related variability, assessment of labelling and device adequacy, and design of context-appropriate interventions.

This study examines reconstitution practices among caregivers in Nigeria, quantifies common errors and their determinants, and evaluates the plausibility of these practices contributing to suboptimal dosing and, ultimately, AMR in the community.

2. Materials and methods

2.1. Study design and setting

A cross-sectional field–laboratory study was conducted within the Abuja metropolis, Nigeria, focusing on antimicrobial suspensions commonly used in paediatric care. A preceding health cost–benefit survey indicated that artemether/lumefantrine and cefuroxime were among the most affordable and accessible agents, frequently co-administered for malaria–typhoid coinfections.

2.2. Antimicrobial products and procurement

Two oral suspension formulations were selected for evaluation:

- Clartem® suspension (artemether 180 mg/lumefantrine 1080 mg; Batch No. 210718; NAFDAC No. B4-5562; manufactured 07/2021; expiry 07/2024; China)
- Skycip® suspension (cefuroxime axetil 125 mg/5 mL; Batch No. 0522092; NAFDAC No. C4-0769; manufactured 06/2022; expiry 07/2025; India)

A total of 200 bottles of each formulation were purchased from a licensed wholesale pharmacy. Bottles were coded, divided into four groups of 50, and assigned to different reconstitution conditions.

Figure 1: Image of oral suspension products in their original packaging, as used in the research study.

2.3. Study population and intervention

Bottles were distributed across the immunisation wards of selected primary healthcare centres in Abuja. Recruitment targeted 200 breastfeeding mothers with experience reconstituting oral powder suspensions, who were then instructed to reconstitute the suspensions strictly according to the manufacturer's leaflet instructions. Reconstitution was performed using one of four locally available water sources:

- Bottled water
- Sachet water
- Borehole water
- Freshly boiled and cooled purified water

2.4. Sample collection and handling

Following reconstitution by caregivers, all samples were retrieved from clinics and transported to the laboratory under controlled conditions. Bottles were shaken to ensure homogeneity before laboratory analysis.

2.5. Laboratory measurements

Volume Accuracy: Each reconstituted sample was transferred into a calibrated Class A 100 mL measuring cylinder to determine the actual volume achieved.

Bottle Mark Calibration: The manufacturer's calibration marks were independently verified by filling each bottle to the indicated line with distilled water, transferring contents to a measuring cylinder, and recording the measured volume.

Physicochemical Parameters: The pH, electrical conductivity (EC), and total dissolved solids (TDS) were determined for each sample using standard laboratory procedures.

To bridge the gap between physical measurements and clinical outcomes, the impact of volume deviations was interpreted using established Pharmacokinetic/Pharmacodynamic (PK/PD) indices. Specifically, the relationship between dosing errors and the Mutant Selection Window (MSW) was used to evaluate the potential for antimicrobial resistance selection.

2.6. Data analysis

Data were entered into Microsoft Excel, version 2021 for analysis. Continuous variables—pH, electrical conductivity (EC), and total dissolved solids (TDS)—were summarised as mean ± standard deviation. Categorical variables, including reconstituted volume categories (<recommended, =recommended, >recommended) and reconstitution correctness (correct vs. incorrect), were presented as percentages.

3. Results and discussion

Figure 2: Visual representation of suspensions after reconstitution, ready for lab analysis.

The physicochemical parameters of artemether/lumefantrine (Clartem®) and cefuroxime axetil (Skycip®) suspensions varied according to the source of water used for reconstitution (Tables 1–3).

The mean pH, electrical conductivity (EC), and total dissolved solids (TDS) values for the various water sources used in this study are presented in Table 1. Bottle water had the least values for EC and TDS, and the highest value for pH.

For artemether/lumefantrine, mean pH values ranged from 4.23 (bottled water) to 4.39 (freshly boiled, cooled water). Electrical conductivity (EC) was lowest with sachet water (422 ± 1.11 μS/cm) and highest with borehole water (488 ± 7.47 μS/cm). Corresponding total dissolved solids (TDS) values ranged from 879 to 989 ppm, again the highest with borehole water (Table 2).

For cefuroxime suspensions, the mean pH was lower overall, ranging from 3.67 (sachet water) to 4.00 (freshly boiled, cooled water). EC was lowest with sachet water (55 ± 1.61 μS/cm) and highest with borehole water (162 ± 2.91 μS/cm). TDS values similarly spanned 111 to 324 ppm, with borehole water yielding the highest values (Table 3).

Table 1: pH, Electrical conductivity (EC), and Total dissolved solids (TDS) values for various water sources used in the study.

Water Source	pH	EC (μS/cm)	TDS (ppm)
Bottle water	6.51±1.88	6±0.91	5±2.05
Sachet water	6.06±0.28	9±1.06	6±3.15
Borehole water	5.04±2.80	56±3.03	98±1.19
Freshly boiled, cooled	6.22±1.75	23±1.12	44±3.35

Table 2: pH, Electrical conductivity (EC), and Total dissolved solids (TDS) values for reconstituted artemether/lumefantrine suspension.

Reconstituted with	pH	EC (μS/cm)	TDS (ppm)
Bottle water	4.23±2.01	444±2.51	879±0.61
Sachet water	4.28±0.31	422±1.11	882±1.01
Borehole water	4.30±2.81	488±7.47	989±2.21
Freshly boiled, cooled	4.39±0.21	481±3.11	959±2.71

Table 3: pH, Electrical conductivity (EC), and Total dissolved solids (TDS) values for reconstituted cefuroxime suspension.

Reconstituted with	pH	EC (μS/cm)	TDS (ppm)
Bottle water	3.70±2.50	65±2.48	172±5.22
Sachet water	3.67±0.79	55±1.61	111±2.32
Borehole water	3.88±1.19	162±2.91	324±1.11
Freshly boiled, cooled	4.00±2.00	84±3.01	168±2.21

All bottles were calibrated correctly by the manufacturers to ensure accuracy, while analysis of reconstituted volumes revealed considerable variability across water sources.

In reconstituting the cefuroxime suspension, less than half of the subjects achieved the recommended 70 mL final volume. Using bottled water, 42.9% of reconstitutions were <70 mL, 28.6% reached exactly 70 mL, and 28.6% exceeded 70 mL. Similar patterns were observed with sachet water and borehole water, while freshly boiled, cooled water showed the highest proportion of underfilled suspensions (55.6%) (Figure 3).

For artemether/lumefantrine suspensions, the majority of reconstitutions with bottled water (85.7%) and sachet water (71.4%) were below the recommended 60 mL. Borehole water produced the greatest variability, with 56.6% exceeding 60 mL. Freshly boiled, cooled water yielded 57.1% underfilled, 14.3% correct, and 28.6% overfilled suspensions (Figure 4).

Overall, the majority of participants did not achieve correct reconstitution according to the manufacturer's instructions. For both cefuroxime and artemether/lumefantrine suspensions, 83% of subjects reconstituted incorrectly, while only 17% achieved correct reconstitution (Figures 5–6). Errors were mainly due to under- or over-dilution, resulting in deviations from the recommended final volumes.

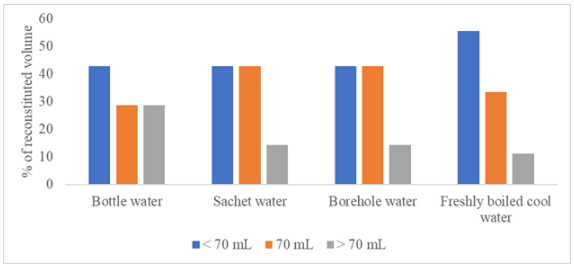

Figure 3: Chart showing distribution of subjects and volumes of reconstituted cefuroxime suspensions.

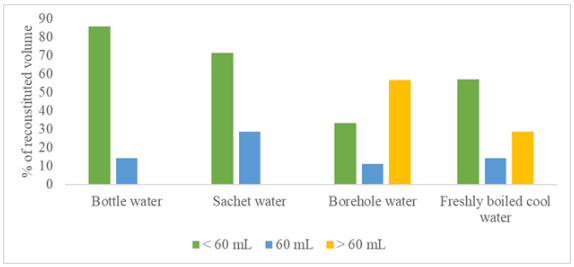

Figure 4: Chart showing distribution of subjects and volumes of reconstituted artemether/lumefantrine suspensions.

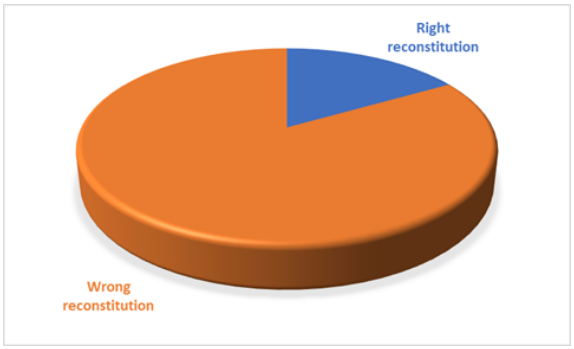

Figure 5: Chart showing the total percentage of subjects and whether they reconstituted cefuroxime suspensions correctly or not.

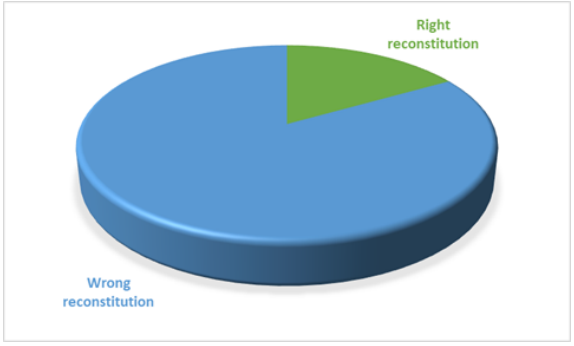

Figure 6: Chart showing the total percentage of subjects and whether they reconstituted artemether/lumefantrine suspensions correctly or not.

This study demonstrates that a substantial proportion of Nigerian caregivers incorrectly reconstitute paediatric oral suspensions, most often by adding either too much or too little water. These errors produce suspensions of unpredictable concentration, which in turn increase the likelihood of sub- or supra-therapeutic antibiotic exposure. Subtherapeutic dosing is particularly concerning because even marginal under-dosing can allow microbes to survive, thereby facilitating the selection of resistant subpopulations [16, 10]. In our setting, many caregivers did not adhere to labelled instructions, reflecting similar findings from earlier Nigerian studies that reported high frequencies of suspension reconstitution and dosing errors in paediatric care [17]. When considered together, these errors compromise treatment efficacy, predispose children to persistent infections, and create an environment conducive to the emergence of AMR.

Our findings are consistent with observations from other low- and middle-income countries (LMICs), where inappropriate reconstitution and dosing of paediatric suspensions are widespread. For example, in Sri Lanka, it has been reported that fewer than 60% of caregivers correctly topped up suspensions to the marked line, a finding they linked to unresolved infections and increased AMR risk [10]. Another study found that most caregivers relied on household spoons rather than calibrated devices, further amplifying dosing errors [18]. Even in settings with relatively better compliance, such as Palestine, gaps in knowledge about dosing intervals persisted [1]. Taken together, these studies confirm that poor reconstitution and measurement practices are not isolated occurrences but a widespread challenge across LMICs, and our findings extend this concern to the Nigerian context.

The implications of these errors extend beyond individual treatment outcomes to broader community-level resistance dynamics. Any sub-lethal antibiotic concentration, whether caused by incorrect dilution, a missed dose, or an incomplete course, exerts selective pressure that favours resistant strains [5]. This concern is heightened in Nigeria, where antimicrobials are widely accessible without prescription and frequently used without professional guidance [14]. Under these circumstances, caregivers often discontinue treatment once symptoms improve or retain partly used suspensions for future use, both of which expose microbes to non-lethal concentrations that accelerate resistance. Comparable patterns have been reported elsewhere: in Bangladesh, more than half of adults admitted to using antibiotics for viral illnesses, underscoring how misuse at the household level fuels AMR [19]. In Nigeria's densely populated communities, similar behaviours are likely to magnify the spread of resistant organisms. Although this study did not measure resistance phenotypes directly, by applying the Mutant Selection Window (MSW) framework, we can infer that the observed deviations in volume—particularly under-dilution or over-dilution—lead to drug concentrations that fall between the Minimum Inhibitory Concentration (MIC) and the Mutant Prevention Concentration (MPC). When a caregiver provides a sub-therapeutic dose due to over-dilution, the drug concentration in the patient's serum may be sufficient to kill highly susceptible bacteria but insufficient to inhibit the growth of resistant mutants. This selective window allows resistant strains to proliferate, effectively converting a common infection into a resistant one through simple preparation errors.

Addressing these challenges requires interventions at multiple levels, beginning with clinical practice. At the point of care, healthcare providers must not only prescribe antibiotics but also demonstrate correct reconstitution and dosing techniques. Pharmacies could further support this process by either pre-reconstituting suspensions or ensuring that caregivers demonstrate competence before leaving the facility. Each prescription should be accompanied by a calibrated dosing device, preferably an oral syringe, alongside clear verbal and written instructions [1, 18]. Evidence consistently shows that calibrated devices reduce dosing errors, with syringes proving the most reliable [18]. Consequently, pharmacists, in particular, are well placed to reinforce these practices by reviewing caregiver calculations, monitoring adherence, and advising on storage and completion of therapy [20].

Our findings show that households relying on borehole water are particularly vulnerable to producing suspensions with altered physicochemical properties. Significant differences in pH, electrical conductivity, and total dissolved solids may affect the rheological properties of the drugs, potentially influencing their solubility, stability and uniformity of the suspension, bioavailability, and absorption of the active ingredients [21]. Furthermore, the significant variability in pH, EC, and TDS observed with borehole water source suggests a secondary pathway to AMR through altered pharmacokinetics. For time-dependent antibiotics like cefuroxime, the primary pharmacodynamic index for efficacy is the time that the unbound drug concentration remains above the MIC ($T>$MIC). If the high TDS or altered pH of the water source reduces the solubility or chemical stability of the cefuroxime molecule, the rate of absorption in the gastrointestinal tract may be compromised. This reduction in bioavailability lowers the peak serum concentration ($C_{\max}$), thereby shortening the duration of $T>$MIC and failing to reach the required threshold for pathogen eradication. Consequently, these physicochemical shifts create a predictable environment for treatment failure and the subsequent selection of resistant pathogens.

Public health authorities should therefore launch targeted education campaigns that explain not only the correct methods for mixing and measuring suspensions but also the consequences of using inappropriate water sources. By integrating this messaging into maternal-child health services, such as antenatal clinics, immunisation programmes, and community health worker visits, the reach of these campaigns can be maximised. Household practices around antibiotic reconstitution should also be incorporated into AMR surveillance frameworks. Data on prescribing patterns, caregiver knowledge, and reconstitution behaviours collected through pharmacy audits and community surveys would enable policymakers to identify high-risk practices and adapt stewardship strategies accordingly [22, 23]. Linking such behavioural data with microbiological resistance patterns would provide a more comprehensive understanding of how household-level errors contribute to community AMR dynamics.

Regulators should also strengthen product standards by mandating the inclusion of water for reconstitution in the packaging of dry oral suspensions. To minimise user error, instructions should be simplified and supported with pictograms, and critical details could be printed directly on bottles or dosing devices. Such measures are in line with global calls to tighten oversight of medicine quality and dispensing practices, thereby reducing non-lethal antimicrobial exposures that contribute to resistance [22].

4. Limitations

This study has several limitations that should be considered when interpreting the findings. First, the sample size was restricted to two commonly used antimicrobial suspensions (artemether/lumefantrine and cefuroxime), which may limit the generalisability of the results to other formulations or brands. Second, reconstitution was observed in a specific population, primarily breastfeeding mothers attending immunisation wards in Abuja, which may not fully represent practices in other regions or demographic groups across Nigeria. Third, while physicochemical parameters such as pH, EC, and TDS were measured, the study did not include microbiological testing to directly demonstrate the impact

of reconstitution errors on antimicrobial activity or resistance development. Fourth, caregiver practices were assessed under study conditions and may differ from unobserved home environments, potentially leading to underestimation of error rates. Finally, the cross-sectional design precludes causal inference regarding the relationship between reconstitution errors and antimicrobial resistance outcomes.

5. Conclusion

This study highlights that incorrect reconstitution of paediatric oral suspensions is a widespread but under-recognised contributor to subtherapeutic dosing and antimicrobial resistance in Nigeria. Errors in water volume, mixing, and dosing devices compromise drug concentration, reduce treatment efficacy, and create conditions that favour the emergence of resistant pathogens. The physicochemical variability observed across commonly used water sources further underscores the vulnerability of households to inconsistent drug preparation. By targeting this overlooked pathway, Nigeria and similar LMICs can strengthen antimicrobial stewardship, improve paediatric treatment outcomes, and slow the spread of resistance within communities.

Conflict of Interest

All authors declare no conflict of interest.

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