

## Pediatric Suspension Usage & Reconstitution Practices of Mothers in Zaria, Northwestern Nigeria

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

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### Abstract

**Background:** Dry powders for suspension are a common type of drug formulation used for children. Studies have shown that mothers and/or caregivers often have difficulties correctly reconstituting these powders, and accurately measuring out doses.

**Objectives:** To describe the pediatric suspension usage practices, reconstitution techniques and medication related knowledge of mothers attending the antenatal clinic of Ahmadu Bello University Medical Center, Zaria, Kaduna state.

**Methods:** A data collection instrument was used to interview 101 conveniently sampled women in October 2018. After answering the questions in three sections of the instrument, respondents were given a bottle of water and a medicine bottle containing flour. They were then asked to show the researchers how they would normally reconstitute a suspension, and asked to measure out specific doses using a measuring cup.

**Results:** Almost 40% of mothers stored reconstituted medication in the fridge, and less than 20% would administer a forgotten dose when they remembered and continue with the previous dosing times. Regarding reconstitution techniques, 26.7% of mothers initially shook the bottle to loosen the dry powder before adding water, and 39.6% added water in two steps. Less than 10% of respondents could correctly measure 7.5 mL using a measuring cup. Over 40% of them could not accurately calculate medication dosing times in the hypothetical scenario provided to assess their medication related knowledge.

**Conclusion:** The results show that some of the usage practices and reconstitution techniques of the mothers were sub-optimal. Pharmacists can help mothers reconstitute suspensions as part of their pharmaceutical care responsibilities.

**Keywords:** Mothers, Nigeria, Pediatric suspensions, Reconstitution technique

### INTRODUCTION

Oral suspensions are a common dosage form for pediatric medications. They offer several benefits like making the administration of child-specific doses easier and eliminating difficulties associated with getting children to swallow tablets (Juárez-Olguín *et al*, 2008). In addition, the oral suspensions of certain medications are more rapidly and better absorbed than their solid oral dosage forms (Tan, 1995). Depending on the active ingredient(s) present, suspensions can be

marketed in ready to use form like in the case of pediatric Ibuprofen and Co-trimoxazole suspensions, or come in powder form for reconstitution just before use.

Given the prevalence of several infectious diseases (IHME, 2018) and malaria (WHO, 2017) in Nigeria, it would be expected that anti-infective medicines are very commonly used in children. Children are particularly vulnerable to infections because of their developing immune system, and infectious diseases account for a sizeable portion of the country's under-

five mortality rate (Fadare *et al.*, 2015). It is therefore not surprising that several studies on pediatric drug utilization patterns within the country, have reported that antibiotics and antimalarials are some of the most prescribed medicines for children (Fadare *et al.*, 2015; Nduka *et al.*, 2017). One study carried out in the pediatric clinic of a tertiary hospital in southwestern Nigeria reported that the most prescribed drugs were antibiotics-in over 70% of patients-and antimalarials (Fadare *et al.*, 2015). Another study on pediatric prescribing patterns in two teaching hospitals in south eastern Nigeria reported similar results (Nduka *et al.*, 2017). In both studies, the most commonly prescribed antibiotics were the penicillins and cephalosporins; the pediatric formulations of which are marketed as powders for reconstitution. Similarly, several of the most commonly used antimalarials for children-drugs in the Artemisinin Combination Therapy (ACT) class (Udoh *et al.*, 2013; Fadare *et al.*, 2015) also come in powder form.

Several studies have shown that mothers and/ other caregivers often have difficulties correctly reconstituting pediatric suspensions and accurately

measuring out doses. One study in Taiwan, reported that only 2% of caregivers were able to correctly identify steps to reconstitute antibiotic suspensions after reading the medication leaflets (Hu *et al.*, 2013). Another study carried out in Canada reported relatively similar findings, with 46% and 56% of caregivers incorrectly reconstituting two different pediatric antibiotic suspensions (Berthe-Aucejo *et al.*, 2016). Similarly, problems have also been reported with caregiver medication measurement practices when using a variety of medication measuring devices. Estimates of caregiver error rates from these studies range from 50% - 80% (Almazrou *et al.*, 2014; Berthe-Aucejo *et al.*, 2016; Yin *et al.*, 2016).

To the best of our knowledge, no study has been carried out to assess caregiver reconstitution and medication measurement within Nigeria. Consequently, the aim of this study was to describe the pediatric suspension usage practices, reconstitution techniques and medication related knowledge of mothers attending antenatal clinic at Ahmadu Bello University Medical Center, Zaria, Kaduna state.

## **METHODOLOGY**

### **Study Site**

This study was carried out at Ahmadu Bello University Medical Centre, a secondary hospital which offers a variety of general and specialist medical services and serves the population of Samaru and environs in Zaria, Kaduna State. The antenatal clinic of the hospital was chosen because one of the study objectives was to assess reconstitution technique of mothers. Hence, we wanted to recruit women when they did not have any child/children present to distract them.

### **Study Design and Sample Size Calculation**

The study was a prospective observational study. All of the women attending antenatal clinic at the study site were eligible to participate if they provided verbal consent, currently had at least one child aged five years or below, had completed primary level education at the minimum and understood either English or Hausa. A sample size could not be calculated for the study because there were no records of the total number of women attending the clinic at any given time. Women could walk in on any of the four clinic days per week, and be attended to. Thus, no sample size was calculated and recruitment was time based. Consequently, data was collected all through the month of October 2018 (four days per week, for four weeks).

### **Data Collection Instrument**

A data collection form was designed for the study. The first section of the instrument collected data on the demographic characteristics of the participants including age, highest level of education completed and number of children. The second section contained questions that aimed at assessing respondents' practices when reconstituting, using and storing oral suspensions. This section contained a mix of open and close ended questions. The third section contained a "yes or no" checklist that was used to assess the women's suspension reconstitution and measurement techniques. This checklist was created from a training video on how to reconstitute pediatric suspensions, created by the National University Hospital in Singapore (NUHS, 2017). Finally, the fourth section contained seven questions that tried to assess respondents' abilities to comprehend, calculate and process patient-specific information about paediatric medications. A hypothetical scenario was created around a bottle of paracetamol syrup. In addition to other questions, mothers were asked about the indication of the drug and asked to calculate dosing times if the drug was to be administered at eight hourly intervals etc. (See Table 1 for the questions asked in this section).

### **Data Collection**

Data was collected by interviewing respondents. All women attending the antenatal clinic during the study

period were initially approached by the investigators and asked whether they had other kids. If they answered yes, they were then asked about the age of their youngest child. If the child was less than five years, they were informed about the study objectives and invited to participate. If they agreed, they were then asked the questions in sections one and two of the data collection instrument. Answers to the open-ended questions in section two, were transcribed verbatim. For the checklist in section three, a specially designed label for a hypothetical drug containing written reconstitution instructions was created for the study. This label was stuck on glass medicine bottles and two tablespoonfuls of maize flour put into each bottle. Each mother was given one of these flour containing medicine bottles and a bottle of water and asked to show the researchers how she would normally reconstitute a suspension at home. After reconstitution, they were asked to measure out 5 mL

and 7.5 mL doses using a measuring cup that had 2.5 mL, 5 mL and 10 mL markings. If they correctly carried out a step on the checklist, a “yes” response was recorded, otherwise a “no” was written.

The seven questions in section four had right or wrong answers. Two photographs were printed out and used as props for some of the questions in the section. The first photograph showed the front packaging of a bottle of paracetamol syrup containing both brand and generic names, and the strength of the drug in mg/5 mL. The second picture showed the ingredient side of the packaging of a paracetamol-containing cough preparation. Women would be given one of the relevant pictures and allowed to study it for a while, before they were asked the question they needed it to answer. They were allowed to study the prop(s) for as long as they wanted, and were encouraged not to guess, and instead-admit they were unsure.

**Table 1: Questions asked to assess medication related knowledge of the mothers**

1. What drug does the medicine in the picture contain? (First Picture) _____
2. What symptoms can it be used to treat? _____
A doctor tells you to give your child 5 mL of this medicine every 8 hours. If you give your child the first dose at 7 a.m. in the morning, what time should you administer
3. The second dose _____
4. The last dose _____
A container of this medicine contains 50 mL of syrup.
5. Do you have enough syrup to use for five days, if you use it the way the doctor recommended in the previous question? _____
On the carton of this medicine, you see the following instruction “ <i>Do not use this medicine with other paracetamol containing products</i> ”.
6. Your child develops catarrh and you buy a new medicine for him (Second Picture). Should you give your child both medicines at the same time? _____
If the expiry date of a medicine is 19/06/18.
7. Is the medicine safe for use? _____

### STATISTICAL ANALYSIS

Data was coded and entered into a Microsoft Excel 2013 sheet (Microsoft Corp, US) for analysis, and descriptive statistics (frequencies & percentages) used to report the results obtained. Data from the open-ended questions in the second section was analyzed using summative qualitative content analysis by grouping similar responses together and quantifying them. For the seventh questions in the fourth section, “1” point was assigned for every correct answer, while “0” was given for every wrong answer or if the

respondent was unsure. For the second question in this section, if a woman provided at least one correct answer for the use of paracetamol syrup, she was scored the whole point. A total score/8 was then calculated for each participant.

One-way Analysis of Variance (ANOVA) test was used to test for statistically significant differences in mean medication knowledge score (dependent variable) across the various demographic sub-groups (independent variables).

**RESULTS**

**Demographic Characteristics of Respondents**

Half (48.5%) of the mothers were aged between 26-30 years. Around 40% had completed either a Bachelor’s degree /Higher National Diploma (38.6%). They were

mostly government employed (44.6%), and 36.6% of the mothers had at least one child. For those who earned an income, majority of the mothers fell into the income bracket of N18, 001 - N50, 000 (Table 2).

**Table 2: Demographic Characteristics of Respondents**

Characteristic	Variable	n (%)
<b>Age range (years)</b>	Less than 25	16 (15.8)
	26-30	49 (48.5)
	31-35	22 (21.8)
	Above 36	14 (13.9)
<b>Highest educational level completed</b>	Primary School	4 (4.0)
	Senior Secondary School	25 (24.8)
	NCE/OND	17 (16.8)
	Bachelor’s degree/HND	39 (38.6)
	Masters	12 (11.9)
	PhD	4 (4.0)
<b>Occupation</b>	Government employed	45 (44.6)
	Self employed	11 (10.9)
	Stay at home mum	23 (22.8)
	Student	22 (21.8)
<b>Number of children</b>	1	37 (36.6)
	2	24 (23.8)
	3	22 (21.9)
	4 or more	18 (17.8)
<b>Income</b>	< 18, 000 NGN	2 (3.7)*
	NGN 18, 000 – N50,000	30 (55.6)
	NGN 50, 001 –N100, 000	4 (7.4)
	> N100, 001 NGN	18 (33.3)

*NCE-National Certificate of Education, OND-Ordinary National Diploma, HND-Higher National Diploma, PhD- Doctoral Degree, NGN-Nigerian Naira, \* Values in cell do not sum up to total because only women who were working responded to the question*

Majority of the mothers (n=93, 92.1%) reported having used at least one medication in dry powdered form that required reconstitution within the last six months. When asked about the reason for use of these medicines, most of them (n=77, 82.8%) said they were prescribed for a wide variety of ailments.

Respondents said they obtained information on how to reconstitute these dry powders from health care providers or vendors at point of purchase (n=47, 46.6%), or from the drug packaging and/ information leaflets (n=47, 46.6%). When asked whether they had ever used leftover reconstituted suspension for another illness, 98 of them (97%) said no.

Many of the mothers (62.4%) did not keep reconstituted suspensions in the refrigerator (Table 3). These women reported that they kept the suspensions in various locations including on tables, in baskets or cupboards, and even under beds. When asked what

they normally did if they forgot to give their children a dose of suspension at the right time, different actions were reported, though 19 (18.8%) respondents said they had never forgotten to give a dose before. Almost half (48.8%) of those who answered the question said they would give the dose when they remembered, and adjust subsequent timing (Table 3). In the same vein, when asked what they would do if their child vomited immediately after a dose of suspension, most of the mothers (74.3%) said they would repeat at least some of the dose (Table 3). However, the actual quantity of dose they would re-administer varied widely and was dependent on several factors including the quantity of drug seen in the vomitus. In addition, while some mothers would repeat the vomited drug immediately, others would wait for up to an hour before re-administering the medication.

**Table 3: General Suspension Usage Practices of Respondents**

	Variables	n (%)
Type of water used to reconstitute dry powder	Bottled water	60 (59.4)
	Sachet water	23 (22.8)
	Boiled and then cooled water	18 (17.8)
Storage location of reconstituted suspension	Refrigerator	38 (37.6)
	Others	63 (62.4)
Respondents action if they forgot to give their child a dose of suspension at the right time	Skip dose	27 (32.9)*
	Give dose on remembering, and adjust timing of subsequent doses	40 (48.8)
	Give dose on remembering, and continue with usual timing	15 (18.3)
Respondents action if their child vomited immediately after taking a dose of suspension	Would repeat dose	75 (75.8)*
	Would not repeat dose	24 (24.2)

\* Values in cell do not sum up to total because some respondents did not answer

**Reconstitution & Measurement Techniques**

Despite the fact that there were detailed reconstitution instructions written on the medication label that was designed for the study, majority of the mothers

(67.3%) did not read these instructions (Table 4). Similarly, most of them did not first shake the bottle to loosen the powder (73.3%), add water in two steps (60%) or correctly measure out 7.5 mL (86.1%).

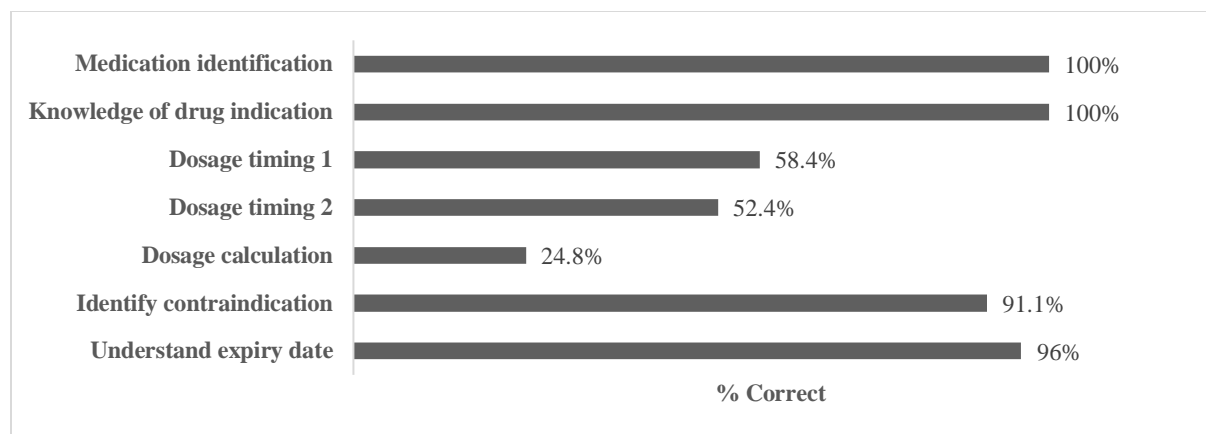
**Table 4: Reconstitution & Measurement Technique of Respondents**

Assessment items	Yes n (%)	No n (%)
1. Read instructions on label	33 (32.7)	68 (67.3)
2. Shook bottle to loosen powder	27 (26.7)	74 (73.3)
3. Added water halfway to the mark	40 (39.6)	61 (60.4)
4. Shook bottle to mix the suspension while looking out for clumps	79 (78.2)	22 (21.8)
5. Added up the remaining water to the required mark	40 (39.6)	61 (60.4)
6. Correctly measured out estimated 5 mL volume at eye level	58 (57.4)	43 (42.6)
7. Correctly measured out estimated 7.5 mL volume at eye level	14 (13.9)	87 (86.1)

**Assessment of Medication Related Knowledge**

Total scores in this section ranged from 3-7, and the average score was 5.2. All of the mothers were able to correctly identify Paracetamol and state at least one correct indication for use of the drug. Majority of them were also able to correctly identify the contraindication in question six (91.1%), and correctly interpret the expiry date in question seven (96%). Conversely, they generally performed poorly on questions requiring calculation (Figure 1).

Using the One-Way Analysis of Variance (ANOVA) test, there was no statistically significant difference in average total scores across the various respondent age groups (p=0.64). No differences in mean total test scores were also seen when the scores were stratified into groups based on the number of children the women had (p=0.24), or the highest educational level they had completed (p=0.99)



**FIGURE 1: Correct responses to the questions assessing medication related knowledge**

## DISCUSSION

The aim of this study was to describe the pediatric suspension usage practices, reconstitution techniques and medication related knowledge of respondents. From our results, less than half of the mothers stored reconstituted medication in the fridge, and less than one-fifth would administer a forgotten dose when they remembered and continue with the previous dose timings. With regards to reconstitution and measurement techniques, majority of them did not initially shake the bottle to loosen the dry powder, or add water in two steps. In addition, very few respondents could correctly measure 7.5 mL using the measuring cup. Finally, while all of the mothers were able to correctly identify Paracetamol and state at least one correct indication for use of the drug, they did not do very well on the questions requiring calculations.

Dry powders for suspension require clean water for reconstitution, and proper storage conditions to maintain their stability (Al-Ramahi *et al.*, 2015). While most mothers in this study used appropriate sources of purified water, many of them admitted to storing reconstituted medication outside the fridge. A study in Palestinian mothers reported similar findings,-with almost half of their respondents also not storing reconstituted suspensions in refrigerators (Al-Ramahi *et al.*, 2015). While refrigeration might not be necessary for suspensions used for relatively short periods (three days or less), it is essential for others - especially antibiotics that may be used for longer periods. A study has shown that pediatric antibiotic suspensions stored at room temperatures within the country rapidly degrade and lose potency over a period of one week (Nwokoye *et al.*, 2012). This highlights the need for pharmacists to provide adequate directions to mothers/caregivers on how to properly store medication.

Missed doses-either due to forgetfulness or vomiting in the recipient can affect the efficacy of anti-infective treatment (NHS, 2016). Almost half of the mothers in this study said that they would give a forgotten dose immediately they remembered, and adjust subsequent dose timings. Ideally, when the dose of an anti-infective drug is missed, that dose should be administered to the child as soon the mother remembers, and the normal dosing schedule maintained (NHS, 2016). Similarly, with regards to vomiting-majority of mothers in this study said they would repeat the vomited dose. However, the actual quantity of dose they would re-administer varied widely, and was generally based on maternal discretion. Other studies have also reported sub-optimal medication re-administration practices by mothers/caregivers after vomiting occurs in sick children (Sil *et al.*, 2017; Hassan *et al.*, 2018). The current consensus from experts is to re-administer the entire dose of vomited medication if it is visible in the vomitus or if vomiting occurs within 15 minutes or less after ingestion of the dose (Kendrick *et al.*, 2012). Suspension reconstitution and dose measurement errors are very common sources of medication administration errors in pediatrics (Berthe-Aucejo *et al.*, 2016). Interestingly, while almost half of mothers said they obtained information on how to reconstitute suspensions from written instructions on packaging or medication bottles, only around a third actually read the instructions on the bottle given to them during the assessment. Given the large number and varieties of suspensions available within the country, mothers reconstituting suspensions without first reading instructions may be potentially harming their children. Most of the mothers also did not first shake the bottle to loosen the powder. This can cause difficulties in forming a homogenous suspension (Berthe-Aucejo *et*

al., 2016). Similarly, while a few suspensions require a fixed volume of water to be added in a single step, others do not. For these other suspensions, adding water in two steps allows for better mixing and the final solution is more likely to be of the desired concentration (Berthe-Aucejo *et al.*, 2016). Many of the mothers in this study did not add water in two steps. Furthermore, when mothers were asked to measure out 5 and 7.5 mL doses using a measuring cup, several of them did not measure either dose at eye level. While we were unable to quantify the actual doses measured by the mothers, wide variations in measured doses could be clearly seen. Others studies have reported that parental dosing errors are more common with medication cups than with other types of medication measuring devices, and overdosing when using cups is more likely (Sobhani *et al.*, 2008; Almazrou *et al.*, 2014; Yin *et al.*, 2016).

If medicines are to be used safely and effectively in children, mothers/caregivers need to be able to understand and comply with medication related information and/instructions (Bailey *et al.*, 2009). Mothers in this study were able to correctly identify a drug commonly used in children (Paracetamol) and state at least one correct indication for use of the drug. Majority of them were also able to correctly identify the contraindication in the provided scenario and correctly interpret expiry dates. They however had difficulties in correctly estimating dosing times and calculating drug quantity. Similar results have been reported by other studies on the topic, all of which have reported that parents/caregivers have difficulties with “implicit” directions/ directions that require them

to do some calculations (Wallace *et al.*, 2012; Ubavić *et al.*, 2018)

Limitations of this study include the fact that women from only one hospital were surveyed and no sample size could be calculated, thus potentially limiting the generalizability of the results. In addition, as earlier mentioned, we were unable to measure the actual volume of suspension measured out by respondents. Thus, we only visually assessed measurement technique.

## CONCLUSION

The results of this study suggest sub-optimal knowledge of correct usage practices as well as reconstitution and measurement techniques by several mothers at the study site. Pharmacists can help mothers reconstitute suspensions as part of their pharmaceutical care responsibilities, and better counsel them on proper suspension storage and measurement techniques. This may help to reduce potential medication errors that could arise from incorrect reconstitution, unsuitable storage conditions etc.

## DECLARATIONS

### Ethical approval

Ethical approval was sought for and obtained from the Human Research Ethics Committee of Ahmadu Bello University before the study began (Approval number: ABUCUHSR/2018/UG/003). In addition, no potentially identifying information was collected from the mothers.

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