

## Original Research

# Improving pediatric liquid medication labeling of the hospital information system in Malaysia: qualitative analysis of pharmacists' perceptions

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### ABSTRACT\*

**Background:** Inadequacies of drug labeling have been frequently reported among Malaysian healthcare institutes, in which the Hospital Information System (HIS) is used.

**Objective:** To identify potential areas to improve the existing labels used for pediatric liquid medications.

**Methods:** This study was qualitative in nature, whereby focus group discussions (FGDs), face-to-face interviews (FTFIs), and onsite observation were used for data collection. Pharmacists stationed at three units (outpatient, inpatient and clinical pharmacy) of a tertiary hospital were targeted. Both FGDs and FTFIs were facilitated using a semi-structured interview guide, video-recorded and transcribed verbatim. All transcripts were thematically analyzed using content analysis approach.

**Results:** Thirteen pharmacists participated in FGDs, while five were approached for FTFIs. Data analysis resulted in four major themes: format of labels, presentation of medication instructions, insufficiency of information, and the need for external aids and education. Participants unanimously agreed on the need for enlarging font sizes of key information. Suggestions were made to use more specific instructions for administration times and pictograms to illustrate important directions. The absence of information about storage, stability and handling of liquid medications was also highlighted. While discussion mainly focused on improving drug labeling, participants consistently stressed the need for an instruction sheet and pharmacist-based, one-to-one education regarding medication instructions.

**Conclusion:** This study provides important insights into critical shortcomings in current labeling practice, underlying the need for developing a new label that incorporates a new format, additional information and pictograms for pediatric liquid medications.

**Keywords:** Child; Drug labeling; Medication Errors; Hospital Information Systems; Pharmacy Service, Hospital; Malaysia

### INTRODUCTION

The high prevalence of out-of-hospital medication errors among infants and children has been widely reported.<sup>1-4</sup> In the United States alone, one child receives a wrong medication or dose in the household every 8 minutes, and nearly half of the caregivers made errors in administering liquid medications to their children.<sup>3,5</sup> The evidence of adverse drug events and mortality due to inappropriate use of liquid medications has been disclosed, highlighting the need for ensuring drug safety in the pediatric population.<sup>3</sup>

While the underlying factors contributing to pediatric medication errors vary, poorly designed instructions are likely to be one of the major causes.<sup>6,7</sup> Current labeling for both the prescription and over-the-counter medications often fails to support caregivers' comprehension of instructions.<sup>8,9</sup> As a result, a considerable proportion of caregivers, especially those with limited health literacy, measured the doses of liquid preparations incorrectly and demonstrated poor medication knowledge.<sup>6,10-12</sup> At the same time, the collective results of published literature suggest that the Malaysian population generally have poor medication label literacy<sup>13,14</sup>, however, the existing interventions to improve drug labeling focused merely on adult patients with chronic diseases.<sup>15</sup>

As a strategy to improve quality of patient care, the Hospital Information System (HIS) has been widely used among the Malaysian public hospitals to manage medical and administrative information.<sup>16</sup> A medication label generated by this system should legitimately consist of basic information including patient's particulars, medication name, dosage form, strength or concentration, dose, frequency and other cautionary instructions.<sup>17</sup> Reports on inadequacies of drug labeling have been frequently received by hospital pharmacists<sup>15</sup>, yet there is scarcity of information with regard to this issue. Therefore, this study aimed to incorporate pharmacists' perspectives into improvement of medication communication with children's caregivers, mainly by identifying potential areas to improve the existing labels used for pediatric liquid preparations.

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## METHODS

### Setting

This study was undertaken in the Pharmacy Department of Sultanah Bahiyah Hospital, Alor Setar, a government-funded public hospital in Northern Malaysia. As a tertiary care hospital, it is also the regional referral center for pediatric intensive care and adolescent medicine in Kedah State. The HIS was introduced in this hospital in 2007, and pharmacists have been using this system to facilitate prescription screening and medication dispensing processes, including the printing of medication labels. On average, 200 prescriptions are received from the Pediatric Department daily; all liquid medications are dispensed to caregivers with a label affixed to the bottles (Figure 1).

### Ethics Statement

This study forms part of a larger project, which aims to develop and assess usefulness of a new label for commonly prescribed pediatric medications. The protocol was registered with the National Medical Research Register (NMRR-14-1324-23088), and approved by the Medical Research Ethics Committee in Malaysia.

### Recruitment of Study Participants

Pharmacists stationed at the hospital and involved in clinical activities, including medication supply (outpatient and inpatient pharmacy services) and medication review (ward pharmacy services), were

targeted. Interns (provisionally-registered pharmacists) serving the Pharmacy Department under supervision were excluded. Pharmacists representing three units, namely outpatient, inpatient and clinical pharmacy units, were approached using a combination of purposive and snowball sampling techniques.<sup>18</sup> The initial group of participants was nominated by a senior pharmacist; each of them was asked to nominate other possible candidates from the same units.

### Development of Interview Guide

Data collection was facilitated by a semi-structured interview guide (Table 1), which was designed based on the literature of drug labeling and allowed participants to suggest how the existing labels could be improved.<sup>6,12,19-21</sup> It was presented to two pharmacists serving another hospital in which the HIS was used (Sultan Abdul Halim Hospital, Sungai Petani) and was pre-tested with three pharmacists. As a result, minor changes were made in wording of questions, and some probing words were added to the final version.

### Data Collection and Analysis

Data were collected using qualitative approaches, including focus group discussions (FGDs), face-to-face interviews (FTFIs) and onsite observation. FGDs initially helped to identify a range of perspectives, while FTFIs were mainly used to further validate the findings and enhance data richness.<sup>22</sup> Both FGDs and FTFIs were conducted

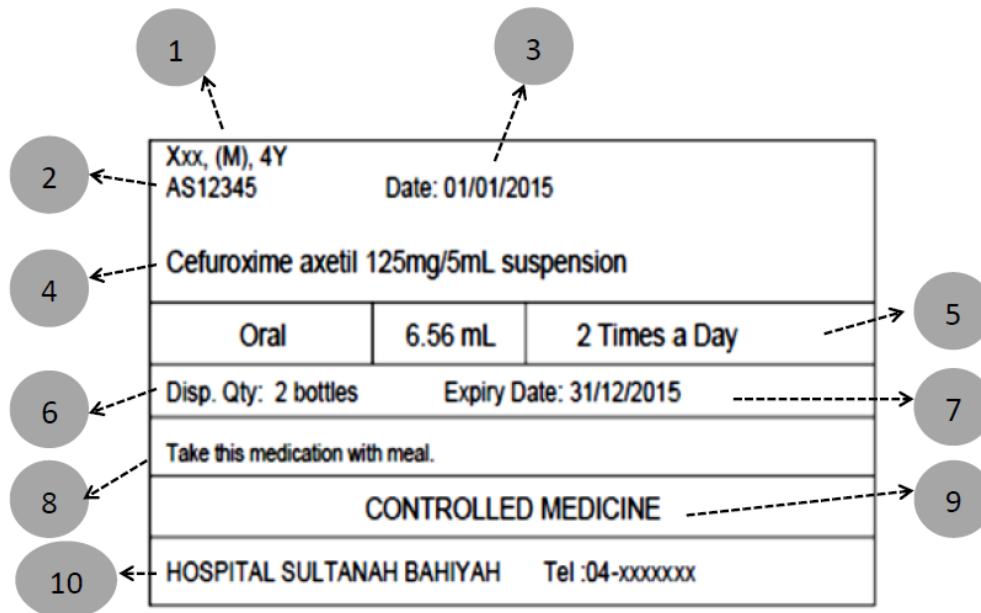


Figure 1. Sample of a text-only label used for liquid medications (English version).

1. Patient's name, gender and age
2. Registration number
3. Dispensing date
4. Name and strength of medication
5. Route of administration, volume to measure and frequency of use
6. Dispensed quantity
7. Expiry date of the unopened/ unconstituted medication
8. Advices on food intake
9. The terms "controlled medicine" (legislative requirement)
10. Name of hospital and contact number

Interview/ Discussion outlines	Key questions
Identifying weaknesses in the existing labels	<ul style="list-style-type: none"> <li>Do you believe that there is a weakness in our labels currently used for pediatric liquid medications?</li> <li>What are the weaknesses? Please elaborate. <i>(Probes: design, font style and sizes, presentation of key information, content.)</i></li> </ul>
Suggesting how to improve the drug labeling	<ul style="list-style-type: none"> <li>Do you think that there is a need to make a major change to our labels currently used for pediatric liquid medications?</li> <li>What are your recommendations? Please elaborate. <i>(Probes: design, font style and sizes, presentation of key information, content)</i></li> </ul>
Confirming the needs for supplementary information	<ul style="list-style-type: none"> <li>Do you believe that caregivers have been receiving enough resources to educate themselves about liquid medication administration?</li> <li>Besides labels, do you think that there is a need for additional materials that provide supplementary information to promote safe medication use among caregivers? <i>(Probes: instruction sheet, booklet, pamphlet)</i></li> <li>How effective is patient education and counseling in our practice? What are the challenges? <i>(Probes: caregiver-related factors, pharmacist-related factors, limitations of time and resources)</i></li> </ul>

in English. Two focus group discussions were undertaken on 19 and 20 June 2015, each lasting approximately for one hour. A U-shaped seating arrangement was used, and each session was facilitated by a moderator (HKC) and note-taker (NAG) in accordance with recommendations of several guidelines.<sup>23,24</sup> Pharmacists who did not participate in the focus groups were invited to take part in a 30-minute interview (by HKC) within the subsequent two weeks. Onsite observation of labeling and dispensing processes in the Pharmacy Department was also conducted (by HKC) to verify the findings of FGDs and FTFIs.

Both FGDs and FTFIs were video-recorded and transcribed verbatim. Notes taken from FGDs, FTFIs and onsite observation were compared with transcripts for discrepancies. The finalized transcripts were independently analyzed (by HKC and NAG) using content analysis approach, in which codes derived from data were categorized into meaningful themes and sub-themes.<sup>25</sup> Constant comparison was made between FTFIs, and recruitment continued until data saturation was achieved.<sup>26,27</sup> All investigators agreed on the themes and quotes selected to exemplify the findings.

## RESULTS

A total of 13 pharmacists were enrolled in FGDs,

while 5 participants consented to FTFIs. Sociodemographic characteristics of participants are summarized in Table 2. All participants (n=18) believed that there was an obvious weakness in the existing labels, and major changes were needed. Findings are categorized into four themes as follows:

### Theme 1: Format of labels

(i) Font size. An important concern cited by all participants was the use of small font sizes throughout the labels, especially for crucial information such as patient's particulars (9-point), drug name (10-point), dose and frequency (10-point), and advices on food intake (8-point). Overall, participants emphasized the need for enlarging font sizes of medication-related instructions.

The font sizes used for important things [information], especially the instructions [for] dose, frequency and food intake, should be enlarged. (P13; FGD)

(ii) Letter case and bolding. There was a lack of consensus among participants as to whether or not patient's name and drug name should be fully printed in capital letters; nevertheless, the majority agreed on the existing format of labels, in which only the first letters were capitalized.

It is difficult to read patient's name [fully printed] in capital letters; rather, I prefer

Variables	FGD 1 (n=6)	FGD 2 (n=7)	FTFI (n=5)
Participant code	P1-P6	P7-P13	P14-P18
Gender (frequency)			
Female	6	4	4
Age (range, years)	26-41	25-33	28-34
Service experiences (range, years)	3-15	2-9	5-10
Working location (frequency)			
Outpatient pharmacy	2	2	1
Inpatient pharmacy	1	3	2
Clinical pharmacy	3	2	2

FGD, focus group discussion; FTFI, face-to-face interview.

bolding or bigger font sizes. (P5; FGD)

(iii) Spacing. Most participants believed that the labels made the best of spacing; however, one participant noted that appropriate spacing should be ensured after enlarging the font sizes of key information.

I believe [that] the spacing [is] acceptable... however, the spacing should be maintained if a larger font size is used. (P17; FTFI)

(iv) Colour. All participants agreed that labels should only be printed in black and white. One participant recommended the use of colours to highlight patient's name and dosing instructions, but the corresponding printing cost was of concern.

It is difficult to read instructions on [a] coloured label... unless colour is used to highlight [key information] such as patient's name and doses... however, high printing cost may be a burden to the hospital. (P12; FGD)

## Theme 2: Presentation of medication instructions

(i) Clarity of dosing instructions. Liquid medications were provided to caregivers with oral syringes (1mL, 3mL, 5mL or 10mL) in the hospital. Unanimous agreement was achieved on maintaining the use of "mL" as the measurement unit, yet some participants expressed their concern about unfamiliarity with such terminology among caregivers. The need for a clearer presentation of dosing instructions was emphasized.

The use of mL [as the measurement unit] is acceptable... but some parents may be unfamiliar with the SI [International System] units... we need to make sure [that] the instruction is well understood. (P16; FTFI)

Furthermore, most participants believed that there is a benefit of tying medication use to specific time periods of a day. Instead of specifying the time points for administration, the majority agreed on the use of the "four-time period" – morning, noon, evening and bedtime.

As a parent, I strongly disagree on [specifying] times [for administration]... this will make administration less flexible and increased the risk of missed dosing... rather, I prefer to use 'morning', 'noon', 'evening' and 'night' [bedtime]. (P7; 5 FGD)

(ii) Presentation of decimal numbers. Several participants noticed that doses were sometimes rounded by the HIS to two decimal places, which were beyond the lowest measurable doses of most syringes (3mL, 5mL and 10mL). This was believed to be unnecessarily confusing to caregivers.

In some cases, the system [HIS] rounds the volume [doses] to two decimal places... parents can't take [draw up] two decimal places using our syringes." (P8; FGD)

(iii) Language and comprehensibility. The hospital serves a multiethnic community with generally low socioeconomic status. Most participants were concerned about caregivers' difficulty in comprehending information which was fully text-based and presented in Malay, the national language of Malaysia; thus, a number of them suggested the use of pictographs to illustrate dosing and other important instructions.

I always come across parents who do not understand our labels... pictograms can be used to explain [illustrate] the important information, [such as] dosing and instructions for taking [a medication] with or without food. (P9; FGD)

## Theme 3: Insufficiency of information

(i) Advices on food intake. The absence of instructions for food intake (before or after meal) in a number of liquid medications was highlighted by some participants. They strongly felt that such information should be made available for all medications, including liquid preparations.

Instructions for food [intake] are not available for certain [liquid] preparations... it is important to standardize [design of] the labels. (P14; FTFI)

Moreover, one participant stressed the need for a more detailed instruction in relation to timing of medication administration before and after meals.

Instructions should be specific... for example, "taking this medication 30 minutes before meal". (P11; FGD)

(ii) Issues with stability and handling. The lack of several key instructions was widely regarded among the participants as a critical weakness in the labels: proper storage after reconstitution, expiration date after opening, and the need for shaking a medication well before use.

No instructions were given for storage of syrup [liquid medications] after opening... expiry date [provided] is only applicable to undiluted [powder] or unopened medications. (P1; FGD)

A lot of the liquid medications are suspensions... instructions for shaking [the medicines] well [before each use] are important. (P5; FGD)

(iii) Issues with antibiotic use. Antibiotics have been among the most commonly prescribed medications for children in this hospital. There was a concern that the labels did not help caregivers to differentiate antibiotics from non-antibiotic preparations.

The label doesn't tell whether [or not] it's an antibiotic... antibiotics are different from cough and cold medicines... it is important for parents to identify [an antibiotic], and help their children finish taking it. (P3; FGD)

#### Theme 4: The need for external aids and education

(i) Instruction sheet for medication reconstitution. A number of oral antibiotics for children commonly used in this hospital were manufactured in powder form. Due to manpower and time limitations, these antibiotics were very often dispensed to caregivers in unreconstituted form, with only verbal instructions for reconstitution given by pharmacists. Participants agreed on the use of written instructions for medication reconstitution but were concerned about the complexity of label content. Instead, suggestion was made to use a separate instruction sheet for reconstitution-related information.

Parents will feel overwhelmed if all the information [about medication reconstitution] is included in the labels... I prefer to explain the steps [of reconstitution] in a separate instruction sheet. (P10; FGD)

(ii) Pharmacist-based education. While both FGDs and FTFIs mainly focused on improvements that could be made to medication labels, participants consistently highlighted the need for providing one-to-one education regarding medication instructions to caregivers. Most participants underscored that well-designed labels should not be viewed as a replacement for pharmacist-based education; however, time pressure was perceived as a barrier to effectively communicate with caregivers.

We can't solely depend on labels to tell everything... we still need to talk to patients and educate them properly... but time limitation is always an issue" (P6; FGD)

#### DISCUSSION

Developing simple, concise and clear instructions for liquid medications is essential, as medication labels are considered as an important source of information by most parents in Malaysia.<sup>28</sup> Findings of this study add to the existing literature that supports the need for promoting drug safety in children by improving and standardizing labeling of liquid medications.<sup>6,12,29,30</sup>

Although participants varied in ages, years of service and working locations, they unanimously affirmed numerous weaknesses in the existing labels and stressed the need for a major change. Recommendations of several international guidelines on font sizes, letter case and bolding, spacing and contrast were supported by the participants.<sup>31,32</sup> The use of Arial, a plain and non-decorative sans-serif font, is regarded as appropriate in drug labeling; nonetheless, the font size should be made as large as possible, with a minimum of 12 points for critical information.<sup>21</sup> In parallel with previous findings, the participants also emphasized the need for judiciously using spacing and capitalization to improve legibility of drug labels.<sup>21,33-35</sup>

Besides, suggestions made to maintain the use of "mL" as the measurement unit and four time points to denote times for administration are consistent with those of prior studies.<sup>19,35</sup> This study has also provided a new perspective on presenting fractions, suggesting that doses should not be unnecessarily presented in multiple decimal places. Effectiveness of pictographs incorporated into written instructions to improve medication safety is supported by the existing literature; however, it is important to avoid the use of complex images.<sup>36-38</sup>

One of the major concerns raised was the absence of information about storage, stability and handling of liquid medications. This placed heavy responsibility on pharmacists to verbally educate patients. Indeed, it is evident that such information is more effectively communicated with written instructions or pictographic illustrations.<sup>39</sup> Additionally, consistent with a prior study, advices on food intake were deemed unclear as the timing of medication administration before or after meals was not specified.<sup>35</sup> Furthermore, the pressure to help patients differentiate an antibiotic from non-antibiotic preparations was reported, as a previous study attributed non-compliance with oral antibiotics among children to ineffective communication.<sup>40</sup> Despite all the suggestions made to add new information to labels, developing a strategy to identify the optimal balance between richness of content, spacing and design is crucial.<sup>35</sup>

Dispensing oral antibiotics in unreconstituted form was found to be routine practice in this hospital. Recommendation on the use of a separate instruction sheet to illustrate reconstitution-related instructions is supported by a Taiwanese study.<sup>39</sup> Nevertheless, supplying concentrated powder to caregivers could lead to inappropriate self-medication and medication errors, as misconception of antibiotics is still very common.<sup>41</sup> Thus, further discussions on appropriateness of such practice are clearly needed. Lastly, the importance of pharmacist-based education regarding medication instructions was highly acknowledged. Hu et al suggested that written instructions are more helpful if used together with verbal education.<sup>39</sup> On the other hand, however, time pressure was highlighted as a barrier to perform one-to-one education. This view is in parallel with previous findings and suggests the need for further studying the challenges that exist among hospital pharmacists.<sup>42,43</sup>

Several limitations of this study should be noted. First, it relied on a relatively small group of pharmacists from one hospital, and therefore, the findings may not be representative of other hospitals that used the HIS in Malaysia. In addition, participants were recruited using non-random sampling methods, which might further limit generalizability of the findings. Finally, all the proposed changes to be made to labels were solely based on pharmacists' opinions and experiences, and effectiveness of these changes to improve drug safety is yet to be confirmed.

## CONCLUSIONS

A number of weaknesses in the existing labels used for pediatric liquid medications were identified, underlying the need for developing a new label that incorporates a new format, additional information and pictograms. Future research should explore experiences of pharmacists in other hospitals, develop a standardized label for all hospitals that use the HIS in Malaysia, and assess its effectiveness to improve drug safety.

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## CONFLICT OF INTEREST

None.

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