Influences of a Pilot Pictogram-Incorporated Label for Liquid Medications on Understanding, Dosing Accuracy and Preferences among Children’s Caregivers in Malaysia

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Introduction (1)

- In the US alone, one child receives a wrong medication or dosage in the household every 8 minutes.¹
- Nearly half of the caregivers have been making errors in administering liquid medications to their children.²
- The existing labeling for both prescription and over-the-counter (OTC) medications often fail to support caregivers’ comprehension of instructions.³

Introduction (2)

The Most Common Home Pediatric Medication Errors (2002-2012) ¹

- Giving medications multiple times
- Incorrect doses
- Confused by units of measure
- Giving wrong medications

In HSB, a great majority (94.2%) of children’s caregivers had limited health literacy.

Most of them (81.2%) reported difficulty in reading text-only medication labels used for pediatric medications.

The risks of dosing errors and misinterpretation of medication instructions are exceptionally high.\(^4\)

A systematic review showed that during administration of liquid medications, the use of pictograms in written instructions has the potential to:

- Reduce dosing errors.
- Reduce misinterpretation of instructions.
- Improve adherence.

Objectives

• To investigate the possible influences of a pictogram-incorporated medication label on **understanding** and **dosing accuracy** among children’s caregivers.
• To assess **preferences** for two types of label design (text-only versus pictogram-incorporated).
Methods (1)

- A pilot study, designed as a two-arm, randomized controlled trial.
- Conducted in the Satellite II and Outpatient Pharmacy, HSB throughout the first 6 months in 2014.
- Inclusion criteria:
  - Caregivers of infants and children in the age range from 1 month to 8 years.
  - Presenting to pharmacy with a prescription containing a short-course antibiotic (≤ 14 days) in liquid form.
- Exclusion criteria:
  - Caregivers who did not actively involve in medication administration to children.
  - Unable to communicate in the Malay language.
Methods (2)

- Sample size: 30-40 participants per group for a pilot study that aims to provide preliminary information.\(^6\)
- Block randomization
  - Sealed envelopes in blocks of six, three for each arm.

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Control

Text-only label
(English version)

Intervention

Pictogram-incorporated label
(English version)
Important Information Illustrated by Using Pictograms

1. To highlight volume to measure
2. Food intake
3. Storage condition
4. The need for shaking before use
5. Four-time point dosing interval

Data Collection

Screened for eligibility (n=75)

Eligible caregivers (n=66)

Consented to participate in study (n=63)

Randomization

Control (n=31)

Text-only label + verbal education

Intervention (n=32)

Pictogram-incorporated label + verbal education

*By three pharmacists.

*Non-response rate = 4.5%.
### Assessment and Statistical Analysis

<table>
<thead>
<tr>
<th>No.</th>
<th>Endpoints</th>
<th>Assessment</th>
<th>Statistical Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Dosing accuracy</td>
<td>- Direct observation. &lt;br&gt;- Using a 10mL-syringe. &lt;br&gt;- “Correct” or “incorrect” (deviation &gt;20% from prescribed dose).&lt;sup&gt;6&lt;/sup&gt;</td>
<td>- Unadjusted odds ratio.</td>
</tr>
<tr>
<td>2.</td>
<td>Understanding</td>
<td>- Structured interview. &lt;br&gt;- Tested areas: <strong>frequency, duration of treatment, storage condition, the need for shaking, shelf-life.</strong> &lt;br&gt;- “Correct” or “incorrect”; judged by pharmacists.</td>
<td>Chi-square/Fisher’s exact tests</td>
</tr>
<tr>
<td>3.</td>
<td>Preferences</td>
<td>- Structured interview. &lt;br&gt;- Two labels were shown to caregivers at the end of assessment.</td>
<td>Chi-square/Fisher’s exact tests</td>
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</tbody>
</table>
Results and Discussion (1)

Sociodemographic Characteristics of Caregivers (n=63)

<table>
<thead>
<tr>
<th></th>
<th>Pictogram-incorporated label (n=32)</th>
<th>Text-only label (n=31)</th>
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</thead>
<tbody>
<tr>
<td>Gender, female (%)</td>
<td>14 (43.8)</td>
<td>9 (29.0)</td>
</tr>
<tr>
<td>Mean age (months) ± SD</td>
<td>39.13 ± 23.15</td>
<td>36.26 ± 31.85</td>
</tr>
<tr>
<td>Relationship (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parents</td>
<td>32 (100)</td>
<td>31 (100)</td>
</tr>
<tr>
<td>Extended family members</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of medication ± SD</td>
<td>1.81 ± 0.97</td>
<td>1.87 ± 1.02</td>
</tr>
<tr>
<td>Liquid medication received (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pnenoxyemethylpenicillin 125mg/5mL</td>
<td>21 (65.6)</td>
<td>12 (38.7)</td>
</tr>
<tr>
<td>Cefuroxime axetil 125mg/5mL</td>
<td>2 (6.2)</td>
<td>11 (35.5)</td>
</tr>
<tr>
<td>Others</td>
<td>9 (28.1)</td>
<td>8 (25.8)</td>
</tr>
</tbody>
</table>
# Results and Discussion (2)

<table>
<thead>
<tr>
<th></th>
<th>Pictogram-incorporated label (n=32)</th>
<th>Text-only label (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Marital status (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>30 (93.8)</td>
<td>29 (93.5)</td>
</tr>
<tr>
<td>Single</td>
<td>2 (6.2)</td>
<td>2 (6.5)</td>
</tr>
<tr>
<td><strong>Educational level, secondary or below (%)</strong></td>
<td>26 (81.2)</td>
<td>28 (90.3)</td>
</tr>
<tr>
<td><strong>Ethnicity (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malay</td>
<td>30 (93.8)</td>
<td>29 (93.5)</td>
</tr>
<tr>
<td>Chinese</td>
<td>2 (6.2)</td>
<td>2 (6.5)</td>
</tr>
<tr>
<td><strong>Employment status (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>20 (62.5)</td>
<td>12 (38.7)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>5 (15.6)</td>
<td>11 (35.5)</td>
</tr>
<tr>
<td>Housewife</td>
<td>7 (21.9)</td>
<td>8 (25.8)</td>
</tr>
<tr>
<td><strong>Number of children ± SD</strong></td>
<td>2.77 ± 1.52</td>
<td>2.72 ± 1.25</td>
</tr>
</tbody>
</table>
Results and Discussion (3)

• Endpoint 1: Dosing errors (deviation >20%)

- Intervention: 6.2%
- Control: 25.8%

Unadjusted OR: 0.192 (95% CI: 0.037, 0.990)
Results and Discussion (4)

- **Endpoint 2: Understanding**

  - **Shelf-life**
    - Intervention: -10.5% (p=0.365)
    - Control: -16.7% (p=0.135)

  - **Need for shaking**
    - Intervention: -26.1% (p=0.013)
    - Control: -29.3% (p=0.004)

  - **Storage condition**
    - Intervention: -26.1% (p=0.013)
    - Control: -29.3% (p=0.004)

  - **Duration of treatment**
    - Intervention: -0.3% (p>0.95)
    - Control: -0.3% (p>0.95)

  - **Frequency**
    - Intervention: -0.3% (p>0.95)
    - Control: -0.3% (p>0.95)
Results and Discussion (5)

• Endpoint 3: Preferences

- Pictogram-incorporated label 58.7%
- Text-only label 41.3%
Results and Discussion (6)

- **Educational level** is associated with the preferences for pictogram-incorporated label, highlighting the helpfulness of pictorial aids for those with limited health literacy.⁴

Results and Discussion (7)

• Strengths of this study:
  - Findings add to the existing literature by suggesting the use of pictograms in labeling of pediatric liquid medications. Previous studies mainly focused on the use of pictograms in patient instruction sheets.\(^4\)
  - Implemented in a hospital that has been using e-Hospital Information System (e-HIS) to facilitate medication dispensing, whereby the newly-designed label has the potential to be incorporated into labeling practices among hospitals that use the same system.

Limitations of this study:

- Multivariable analyses were not conducted due to the relatively small sample size (a pilot project).
- Follow-up assessment on the dosing accuracy and understanding was not conducted, highlighting the need for an investigation on the long-term effects of the new label.
- This was an open label trial, as it is almost impossible to blind both the researchers and participants.
Conclusions

- This study suggests that the pictogram-incorporated label has the potential to decrease dosing errors and improve understanding of medication instructions among children's caregivers.
- It was especially well accepted among caregivers with lower educational levels.
- A subsequent multicenter study involving a larger sample size is needed to substantiate these findings.
THANK YOU