Original Article

Evaluation of Guidance Provided on Labels of Paediatric Oral Liquid Medications Dispensed by Community Pharmacies

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Abstract

Effective understanding of medicine labels by caregivers is essential to ensure safe and optimal health outcomes for children. This study aimed to examine how instructions on oral liquid medicines dispensed in community pharmacies to children were presented, with a focus on variations in elements that may affect comprehension. A retrospective audit was conducted on the labeling of oral liquid medicines provided to children aged fourteen years and younger by community pharmacies in Aotearoa, New Zealand. The analysis considered how dose and dosing frequency were presented, the stated indication, treatment duration, and the use of special characters. Ethical approval was obtained from the Auckland Health Research Ethics Committee (Reference no: AH23844), and the study adhered to the Declaration of Helsinki. A total of 2,637 oral liquid medicine labels for 745 children, dispensed from 194 community pharmacies, were reviewed. Dosages were expressed in words (31.0%), numbers (40.3%), or a combination of both (28.7%). Most labels (58.1%) specified the number of doses per day without indicating the exact time or interval between doses. Explicit instructions regarding the time of day were present in only 4.8% of labels, while dosing intervals in hours were included in 31.1% of cases. There was substantial variation in label elements that can affect caregiver comprehension. Further investigation is required to identify the most effective label format and to assess whether Aotearoa New Zealand would benefit from its own guidelines for best practice in dispensing medicine labels.

Keywords: Prescription drug labels, Comprehension, Pharmacy, Aotearoa New Zealand, Pharmaceutical preparations, Patient-centred labels

Introduction

Safe and effective use of medicines is essential to optimise health outcomes and minimise potential harm to patients. When a patient consults a prescriber—such as a doctor, nurse, or dentist—information about the medicine and how to administer it is often provided verbally. Similarly, community pharmacists provide verbal guidance on medicine use as part of the dispensing service. However, research indicates that between 14% and 60% of orally provided information is either forgotten or inaccurately recalled [1, 2].

Health literacy is a complex and evolving concept encompassing both the individual and their broader health environment. It has been defined as "a dynamic state of knowledge, skills, and cognitive space relative to need" [3]. A recent review of health literacy definitions identified three key components: knowledge of health and the health system, the ability to interpret and apply health information, and the capacity to self-manage health in collaboration with healthcare providers [4]. In the context of pediatric medicines, evidence suggests that children with chronic conditions whose parents have greater health literacy needs tend to experience poorer health outcomes [5]. Therefore, ensuring that medicine labels are understandable is crucial to support caregivers in interpreting instructions and using medicines safely.

Prescribers include instructions on prescriptions, which pharmacy staff then transcribe onto the dispensed medicine label for the patient. The label, affixed to the medicine container, is intended to remain with the medicine until it is finished. Given the limitations of verbal instruction retention, these printed labels are a vital tool to ensure drugs are administered as intended by the prescriber. This is especially

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Received: 12 May 2025; **Accepted:** 16 August 2025

How to cite this article: Watts A, Snodin DJ, Easton V. Evaluation of Guidance Provided on Labels of Paediatric Oral Liquid Medications Dispensed by Community Pharmacies. Arch Pharm Pract. 2025;15(3):35-40. https://doi.org/10.51847/pfVsUKg6Qy

important when multiple caregivers may administer the medicine, but only one receives verbal guidance from the health professional. This scenario frequently occurs for children, where medicine labels provide essential information to parents, whānau (family), and caregivers in early learning centres and schools, supporting safe administration. Variations, ambiguities, and inconsistencies in label instructions can create comprehension barriers for caregivers, making it difficult to determine how, when, and for how long medicines should be administered [6, 7]. Such challenges may increase the risk of dosing errors or non-adherence [8]. Children are particularly vulnerable to medication risks due to their changing body weight, surface area, pharmacokinetics, and pharmacodynamics, and liquid formulations require precise dose calculations [9].

Several organizations, including the Institute of Medicine in the United States and the Australian Commission on Safety and Quality in Health Care, have published guidelines aimed at enhancing the clarity and consistency of health information, including medicine labels [10, 11]. However, no specific guidelines currently exist in Aotearoa, New Zealand. Adopting overseas guidance may be problematic, as dispensing software, label dimensions, regulations, and prescriber and patient expectations vary between countries. Although anecdotal reports suggest that health professionals are concerned about label instruction variability, no comprehensive studies in Aotearoa New Zealand have examined how instructions are presented on dispensed medicine labels or the rationale behind pharmacy staff's formatting decisions. Before developing local labeling guidelines, it is essential to understand current practices. This study sought to address this gap by quantifying variations in how oral liquid medicine instructions were written for a sample of children receiving medicines from community pharmacies in Aotearoa, New Zealand.

Materials and Methods

Study Design

A retrospective review of dispensed medicine labels from community pharmacies in the Northland and Auckland regions of Aotearoa, New Zealand, was undertaken. Data were sourced from TestSafe (healthAlliance, Penrose, AK, NZ), an electronic health record system accessible to healthcare professionals, which stores details of medications dispensed. Following completion of data security training, researchers gained access via the Counties Manukau Health Intelligence and Informatics Department to records of patients aged 14 years or younger who were admitted to Kidz First Hospital between June and August 2021. For each patient, the dispensing history was examined in TestSafe, and information on the five most recent oral liquid medicines was extracted. If fewer than five oral liquid medicines had been dispensed, all available records were included. Extracted data comprised patient ethnicity, date of birth, the medication dispensed, and the instructions (limited to a maximum of 200 characters, including spaces, due to TestSafe storage constraints). No personally identifiable information was collected. Each child and dispensing pharmacy was assigned a unique code for data tracking.

Outcome Measures

Analysis focused on various attributes of the label instructions, conducted using Python version 3.11.5 (packaged by Anaconda [Anaconda Inc., Austin, TX, USA]) and Jupyter Notebook version 6.5.4 (Project Jupyter) [12]. The selection of instruction features to evaluate was guided by previous literature on patient-friendly, comprehensible medicine labelling **(Table 1)** [10, 11, 13-15]. Compliance with the Australian National Standard for Labelling Dispensed Medicines (Australian Standard) [11] was assessed by examining: Standard 6 (numerical representation of doses, except for fractions), Standard 7 (clear and unambiguous dosing instructions), Standard 8 (inclusion of the medicine's indication where feasible), and Standard 9 (presence of the maximum dose). For this study, only the presence of a maximum dose was recorded, while evaluation of the other standards was limited by the TestSafe dataset.

Table 1. Characteristics of medicine label instructions selected for analysis based on patient-centered label guidelines.

Label characteristic	Patient-centered label guideline	Definition applied in label analysis
Dose units	Use 'L' instead of 'l' to avoid confusion with the number '1'	Representation of dose units as MLS, mls, mLs, ML, ml, mL, MILS, drops, or sachets. Dose quantities in mg or mcg were also noted.
Dose quantity	Numbers should be written numerically (e.g., '2') except for fractions, avoiding capitalized text like 'two' [10, 11, 13]	The number before dose units is expressed as numerical, alphabetical (text), or alphanumerical (both).
Dose frequency	Standardized timing terms like morning, midday, and evening should be used [10, 11, 13]	Defined as a specific number of times per day (e.g., 'twice daily'), an explicit hourly interval between doses, or particular times like 'morning' or 'with breakfast.'

Duration of use	Clear duration information should be included [11, 13]	Indicated by the number of days, weeks, or months to take the medicine, or the phrase 'until finished.' Labels noting medicine taken 'when necessary' were also identified.
Indication or drug class	Include the reason for medicine use when privacy is not a concern [10, 11, 13]	Any reference to the indication (e.g., 'for infection') or medication class (e.g., 'antibiotic').
Action-oriented language	Use active verbs like 'give' instead of passive phrases like 'to be given' [11, 14]	Use of active verbs such as 'give,' 'take,' or 'drink' in instructions.
Maximum daily dosage	Specify the maximum dose when relevant [11]	Inclusion of a maximum daily dose (appropriateness of inclusion was not evaluated).

The study measured several aspects of the label instructions, including the use of directive, action-oriented phrasing (e.g., 'give' rather than 'to be given'), how doses and administration frequency were communicated, whether instructions included the intended duration or purpose of the medicine, and the presence of capital letters or other symbols. Information provided separately within Aotearoa New Zealand as warning labels [16] was not examined, as supplementary labels affixed to containers are not recorded in the TestSafe database.

Results and Discussion

A total of 2,637 medicine labels for 745 children, dispensed across 194 community pharmacies, were analysed. The demographic characteristics of the sample are presented in **Table 2**. The majority of labels were for paracetamol (n = 967; World Health Organization [WHO] anatomical therapeutic chemical [ATC] classification index N), followed by amoxicillin (n = 302; WHO ATC index J) and ibuprofen (n = 194; WHO ATC index M).

Table 2. Summary of children, medicines, and their labels evaluated in the audit

Parameter	Data reported (n unless otherwise specified)
Total children included in audit (n)	745
Median age (range) in years at first dispensing	1.5 (0, 14.7)
Total dispensed medicines audited (n)	2637
Median (range) number of medicines per child	4 (1, 5)
Age in years of children at first dispensing	0: 273, 1: 154, 2: 69, 3: 42, 4: 41, 5: 29, 6: 22, 7: 22, 8: 16, 9: 15, 10: 23, 11: 22, 12: 9, 13: 5, 14: 3
Recorded ethnicity [a] of children included	Māori: 197, European: 111, Pacific Peoples: 311, Asian: 114, Middle Eastern, Latin American, African: 8, Other Ethnicity: 2, Not Recorded: 2
WHO ATC classification of dispensed medicines	A Alimentary Tract and Metabolism: 328, B Blood and Blood Forming Organs: 82, C Cardiovascular System: 8, D Dermatologicals: 0, G Genito Urinary System and Sex Hormones: 1, H Systemic Hormone Preparations (Excluding Sex Hormones and Insulins): 119, L Antineoplastic and Immunomodulating Agents: 3, J Anti-infectives for Systemic Use: 659, M Musculoskeletal System: 196, N Nervous System: 1010, P Antiparasitic Products, Insecticides, and Repellents: 1, R Respiratory System: 177, S Sensory Organs: 0, V Various: 53

The median length of instructions was 91 characters (range: 13–167) when spaces were excluded, and 112 characters (range: 15–200) when spaces were counted. For 30 labels, the maximum capacity of two hundred characters was reached. The proportion of text using capital letters (excluding spaces and special symbols) ranged widely, from 1.1%—where only the first word of the sentence was capitalized—to 97.3%, where nearly all non-numerical text was in uppercase. The median capitalization across labels was 15.1%, typically involving partial capitalization, such as numbers written as words.

Action-oriented language appeared on almost all labels (98.5%), consistent with Australian Standard 7 for clear and

explicit instructions. In our sample, 2,452 labels (93.0%) used the term 'give,' which aligns with the median age at first dispensing of eighteen months **(Table 1)**. In contrast, 108 labels (4.1%) used 'take' instead of 'give,' of which 86 were intended for children under 10 years old.

Approximately two-thirds of the 2,637 labels (64.5%) included either a therapeutic indication (e.g., 'for infection') or medication class (e.g., 'antibiotic').

Presentation of Dose Information

Among the 2,434 labels specifying a dose in millilitres, only 238 (9.8%) adhered to the recommended SI unit notation 'mL,' with the most common alternatives being 'ml' (n = 1,595; 65.5%) and 'mls' (n = 573; 23.5%). Doses were presented in various formats **(Table 3)**. Australian Standard 6 recommends using numerals rather than words for dose quantities, except for fractions; only 428 labels (17.6%) fully complied with this guidance. An additional 25.4% of labels presented doses as decimals, although Standard 6 advises against this.

Among labels with non-integer doses (n = 930), most fractional amounts were written either numerically as decimals (e.g., 'give 2.5 mL…') or alphabetically as fractions (e.g., 'Give TWO and a HALF mL…'). In 26.7% of these cases, doses were expressed alphanumerically, including decimals written in words (6.2%, e.g., 'give FIVE point EIGHT mL (5.8 mL) …') or fractions combined with decimal notation (20.4%, e.g., 'give THREE and a HALF mls (3.5 mls) …'). Some fractional doses were provided to two decimal places, such as 4.33 mL, 5.28 mL, and 6.25 mL, which could be challenging to measure accurately using standard home dosing devices.

Table 3. Formats used for presenting dose instructions on labels where a dose was specified (n = 2,434)

Dose format	Alphabetical	Numerical	Alphanumerical
Overall	754 (31.0%)	981 (40.3%)[a]	699 (28.7%)
Decimal	0	617 (25.4%)	58 (2.4%)
Fraction	64 (2.6%)[a]	0	0
Numerical decimal combined with alphabetical fraction	–	–	190 (7.8%)

[a] Recommended formats according to the Australian Commission for Safety and Quality in Health Care [11].

A minimal number of labels (32, 1.2%) included both the volume of the liquid dose and the corresponding quantity in milligrams ('mg') or micrograms ('mcg').

Dosing Frequency Details

Only 127 labels (4.8%) specified the exact timing for medicine administration, using terms such as 'with breakfast' or 'at night.' An interval expressed in hours appeared on 819 labels (31.1%), for example, 'every four to six hours,' which is consistent with Australian Standard 7 that recommends unambiguous instructions. Despite this, most labels (1,533, 58.1%) listed only the number of doses per day, without indicating specific times or intervals.

Regarding the duration for which the medicine should be taken, 621 labels (23.5%) instructed caregivers to continue 'until finished,' whereas 222 labels (8.4%) provided a defined duration, such as 'for 4 days' or 'for one month.' Among the labels, 659 (approximately 25%) were for medications classified under the WHO ATC index J – anti-infectives for systemic use. Of these, 599 labels (90.9%) used the phrase 'until finished,' and 44 labels (6.7%) specified a specific period, for instance, 'for 7 days.'

An unusual observation was that five antibiotic labels, from different pharmacies and patients, instructed that the medicine be taken 'as required.' Upon review, it appeared the instructions were incorrect: they mirrored those for paracetamol despite the medication being an antibiotic. One example included a cefalexin 250 mg/5 mL label stating: 'ANTIBIOTIC shake well and give TEN mL FOUR times daily when required for pain or fever. Maximum of FOUR doses in 24 hours.'

In total, 1,287 labels (48.8%) indicated the medicine could be administered 'as required.' Aside from the five antibiotic labels noted above, these instructions were only present on labels for paracetamol, ibuprofen, and loratadine.

Compliance with the Australian National Standard for Labelling Dispensed Medicines

Based on the criteria that could be assessed from the data, four of the Australian labelling standards were examined. At the same time, many labels incorporated one or more of the recommended elements; only a small fraction—315 of 2,434 labels containing dose instructions (12.9%)—fulfilled all four standards **(Figure 1)**.

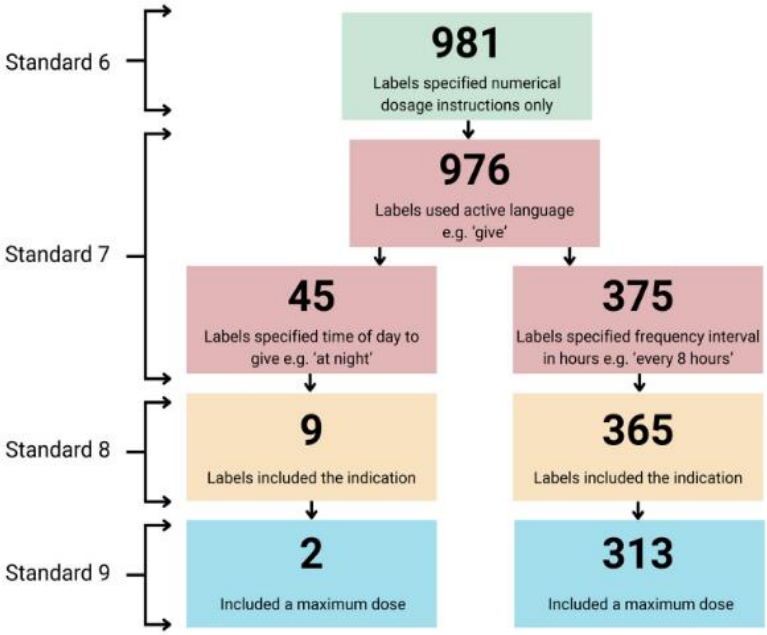

Figure 1. Number of label instructions complying with Standards 6 to 9 of the Australian National Standard for Labelling Dispensed Medicines [11]. Only labels meeting the previous standard were included in the evaluation for each subsequent standard.

This study revealed considerable variability in how instructions were presented on oral medication labels dispensed for children by community pharmacies. These variations occurred in elements known to affect readability and comprehension [17, 18]. Providing clear and accessible written information is crucial for both patients and caregivers responsible for administering medicines. Patient-focused labels enhance autonomy by making instructions easier to follow, thereby supporting correct medication use and reducing reliance on memory for verbal instructions from healthcare professionals. A recent U.S. study using prescription fill data indicated that patient-centered labels can improve adherence to certain medications [19].

The New Zealand Ministry of Health's Health Literacy Framework emphasizes the creation of a health-literate system, placing responsibility on healthcare providers to employ evidence-based communication strategies to reduce the literacy demands on patients [20]. Likewise, organizations such as the U.S. Agency for Healthcare Research and Quality recommend the Universal Precautions Approach, which structures health information to minimize misunderstanding [21]. Applied to dispensed medicine labels, this approach means prioritizing essential information, presenting it clearly and consistently, and confirming that the patient or caregiver understands it [21].

In this audit, label instructions were assessed against the Australian standards. While many labels partially complied with these standards, fewer than 15% fully met all four criteria. Some labels, although not strictly adhering to a standard, were still potentially suitable. For instance, Standard 6 recommends using fractions to avoid dosing errors [11], but not all doses (e.g., 6.3 mL) are ideal for this format. Standard 9 advises including a maximum dose where relevant. In this study, labels were evaluated for the presence of a maximum dose, but the appropriateness of its inclusion was not assessed. Consequently, 59 labels met Standards 6–8 but did not specify a maximum dose, which may have been clinically appropriate.

The way instructions are presented can impact health outcomes for children, potentially contributing to poorer or inequitable results. Some instructions were written primarily in capital letters, which reduces legibility [15]. Variations were also observed in the representation of measurement units—for example, 89% of labels used a lowercase 'l' for millilitres rather than 'L,' which increases the risk of misreading it as the number '1' [22]. Certain label features added unnecessary complexity. Some labels reported doses in both milligrams and millilitres, while others specified fractional volumes to two decimal places, making accurate administration with household tools challenging. Additionally, discrepancies between the instructions and the medicine on the label were noted, highlighting the potential for harm and the importance of careful prescription verification before dispensing.

Future Research

Future studies will focus on populations in Aotearoa New Zealand with poorer child health outcomes, including Māori, Pacific peoples, and those living in areas of high socioeconomic disadvantage [23]. Collaborations with these communities will explore preferences for and comprehension

of different label formats and typographical features with parents, whānau, and caregivers. Findings will inform whether there is a need for Aotearoa New Zealand-specific guidelines for pharmacy labeling practices, or if existing international standards can be adapted for local use.

Strengths and Limitations

A key strength of this study was the large number of individual label instructions analyzed from numerous pharmacies, which is greater than in previous studies that relied on manually collected physical labels. This approach also eliminated any burden on caregivers, children, or pharmacy staff to gather labels, and it minimized potential selection bias or behavioral changes that might have occurred if pharmacies had known their labels were being evaluated. The most frequently represented medicines in the audit—paracetamol, amoxicillin, and ibuprofen—are consistent with prior reports identifying them as the most commonly dispensed medications for children in Aotearoa New Zealand [24].

However, there are limitations. Most labels came from pharmacies within a single region, which may limit the generalizability of the findings. Additionally, this method could not capture certain typographical features present on the physical labels, such as bold text, font size, text alignment, arrangement of information, or the use of white space, all of which can influence readability [17]. As a result, only four of the Australian standards could be applied for comparison. It should also be noted that these Australian standards are not officially promoted in Aotearoa, New Zealand. Furthermore, the dispensed medicine data analyzed are over four years old, although no known national guidance has been introduced in that period that would have affected labeling practices.

Conclusion

This study demonstrates that there is notable variation in how medicines for children are labelled in Aotearoa New Zealand. Further research is required to assess how these variations influence understandability within local communities and to determine whether a dedicated guideline for dispensed medicine labelling specific to Aotearoa New Zealand would be beneficial.

ACKNOWLEDGMENTS: None
CONFLICT OF INTEREST: None
FINANCIAL SUPPORT: None
ETHICS STATEMENT: This study received ethical approval from the Auckland Health Research Ethics Committee (Reference no: AH23844) and was conducted in accordance with the Declaration of Helsinki.

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