Endorsed by
ROYAL PHARMACEUTICAL SOCIETY

NPPG
Neonatal & Paediatric Pharmacy Group

Position statement

Labelling of Dispensed Oral Medicines for Children

Executive Summary

- Oral medicines are widely prescribed and dispensed for neonates and children.
- Parents, carers and patients are often reliant on dosing instructions provided on the dispensing label to ensure that the medicine is given correctly.
- The wording used to communicate dosing information on dispensing labels is known to be highly variable. This lack of consistency increases the potential for confusion and dosing error; such errors have been associated with patient harm, including death.
- There is limited evidence to inform the optimum approach, but continued variation is not in the interests of patient safety.
- To increase consistency and thus reduce the likelihood of error, it is recommended that when preparing dispensing labels for ***oral liquid*** medicines:
    1. **The dose** must be expressed numerically by volume ***only***, usually in millilitres, e.g. "give 5mL once daily". Expressing doses in terms of "spoonfuls" is also acceptable, provided that the volume of the spoon is also stated "e.g. "...one 5mL spoonful", as is stating a number of drops where the product is designed to be dosed in this way e.g. "....two drops".
    2. The dosing **frequency** must be expressed in words as the number of times "a day" the medicine should be taken, rather than the number of times "daily" the medicine should be taken, e.g.: "once a day", "twice a day" "three times a day" or "four times a day".
- Standardisation of the wording used to describe dosing of solid dosage forms, e.g. tablets and capsules, is also a patient safety priority. A collaborative effort by a wide range of organisations is required to achieve this goal.

Additional Key Safe Practice Measures for Oral Liquid Medicines

In addition to following the labelling guidance above, the dispenser must also:

1. Ensure that the volume specified can be measured with the administration device provided.
2. Check the concentration of oral liquid supplied previously if the patient has had this medicine before. Ideally, continue with the same concentration, but if it must be altered the change in concentration and the volume needed to give the correct dose must be clearly explained to the parent/caregiver.

Background

Regulatory requirements specify the information to be included on a dispensing label, but there are no recommendations as to how dosing instructions should be best worded to maximise clarity for patients and caregivers. As a result, practice is highly variable. Given that it is known that misunderstanding of medication instructions is common, the current inconsistency is likely to increase the potential for confusion and dosing error.

Evidence to inform the optimum approach regarding communication of doses is limited. However, continued variation is not in the interests of patient safety. The following standards aim to reduce the risk of harm by encouraging consistent practice when labelling oral liquid medicines for children, or where tablets/capsule contents are to be dispersed in water. Although much needed, no recommendations are made regarding the labelling of solid dosage forms ***swallowed whole***; this requires consensus agreement between paediatric and adult practice.

Recommendations

Dosing Instructions for Oral Liquid Medicines:

1) The dose must be expressed numerically in millilitres ***only***. Expressing doses in terms of "spoonfuls" is also acceptable, provided that the volume of the spoon is also stated.

a) The dose should not be expressed in mass or biological units (e.g. mg, micrograms, International Units).

b) The dispenser must ensure that the specified dose volume can be measured with the administration device provided.

c) It may be necessary for the dispenser to round the dose volume to allow accurate measurement with the administration device provided. In general, dose volumes less than 1mL must be rounded to a maximum of two decimal places and dose volumes greater than 1mL should be rounded to a maximum of one decimal place. Where doses volumes are rounded to enable accurate measurement, this should ideally be noted in the patient's records so that a consistent approach is used each time the medicine is dispensed.

d) In the rare cases where a liquid medicine is designed to be dosed in terms of drops, and the prescribed dose can be administered in this way, the labelled dose can be expressed as a number of drops e.g. "….two drops".

2) Frequency must be expressed in words, as the number of times "a day" the medicine should be taken rather than the number of times "daily", e.g.: "once a day", "twice" a day, "three times a day" or "four times a day". In rare situations where more precise timing is needed, the time must also be expressed in words, e.g. "Every six hours" or "Every four to six hours".

Examples:

150mL Chlorphenamine 2mg/5mL solution

Take 2.5mL four times a day when required

A Child 15/12/2025

Keep out of reach and sight of children

XYZ Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

200mL Lactulose solution

Take 10mL twice a day

A Child 15/12/2025

Keep out of reach and sight of children

XYZ Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

100mL Amoxicillin 250mg/5mL suspension

Take one 5mL spoonful three times a day

A Child 15/12/2025

Keep out of reach and sight of children

XYZ Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

10mL Alfacalcidol 2microgram/mL drops

Take two drops once daily

A Child 15/12/2025

Keep out of reach and sight of children

XYZ Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

Dosing Instructions for Tablets and Capsules, where the tablet is to be **crushed and/or dispersed in water**, or the capsule contents are to be mixed with water.

1) The volume of water in which the tablet or capsule contents are to be dispersed should be expressed on the label. A standardised volume of 5mL is suitable in most cases and should be used wherever practical.

2) If the required dose is less than the total tablet/capsule content, the volume of the prepared suspension/solution to be given should also be included on the label.

3) The **frequency** must be expressed as described under oral liquid dosing above.

Examples:

28 Amlodipine 5mg tablets

Crush and disperse one tablet in 5mL water and take 4mL once a day

A Child 15/12/2025

Keep out of reach and sight of children

XYZ Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

100 Gabapentin 300mg capsules

Empty and disperse the contents of two capsules in 5mL water and take 4mL three times a day

A Child 15/12/2025

Keep out of reach and sight of children

XYZ Pharmacy, A Town, AB1 CD2. Tel: 020 123 4567

Supporting Information

Dispensing of oral liquid medicines (OLMs) to children can be complex. Associated challenges include selecting an appropriate administration device, a need to round doses so that the volume to be given is measurable and the need to clearly communicate often complex dosing instructions[1,2,3]. Children rely on parents/caregivers to administer medicines to them. Caregivers misreading or misinterpreting dosing instructions is frequently cited as contributing to paediatric dosing errors[4,5].

UK legal requirements govern the information which should be included on the dispensing label of a dispensed medicine. These include a need to provide "directions for use" [6,7]. However, there are no agreed standards on the wording of dosing instructions and considerable variation is seen in practice. This publication provides clear guidance on how dosing instructions should be written for oral liquid medicines, with a view to drive standardisation. Standardisation is also needed for solid dosage forms, but wider stakeholder engagement and a clear implementation strategy is needed to achieve this.

Variability in the Wording of Dosing Instructions

A 2022 survey asked UK hospital pharmacy staff to indicate the dosing instructions they would include on the label for 8 simulated prescriptions[8]. For each prescription, dosing instructions were worded in an average of 90 different ways. For solid dosage forms, 86.7% expressed the dose amount in words (e.g. one capsule), rather than numerals (e.g., 1 capsule). For OLMs, 65.7% expressed the dose in terms of 'mL', 30.1% as 'mL (mg)', and 4.3% as 'mg', 'mg (mL)', or 'mL (mL)' (e.g., 2 mL (two mL)). The amount of water suggested to enable "part-tablet" dosing from a 75 mg aspirin tablet ranged from 3 - 75mL.

Another 2022 study analysed dosing instructions on 210 medicines dispensed in 70 different community pharmacies [9]. Twelve (5.7%) dosing instructions were considered ambiguous due to use of generic instructions (e.g. "as directed"); use of Latin dosing frequency abbreviations; or the absence of a dose quantity or unit of measurement. Nine (4.3%) dose instructions expressed the amount to give only in "mg" or 'mcg". Of the 129 OLM labels analysed, 55.8% expressed the dose as "…mL", 13.2% as "…mL (…mg)", 13.2% as "…mg (…mL)", and 11.6% as "…spoonful(s)".

Standardisation of the Wording of Dosing Instructions Oral Medicines

Published evidence to inform how dosing instructions should be worded for optimal understanding is limited. It is unlikely that there is a single best approach for all patients, parents and carers, but the current level of variability is far from ideal. Standardising labelling, largely irrespective of the exact approach taken is likely to aid understanding and improve patient safety, even more so in individuals with lower literacy levels, a lower level of educational achievement and/or of non-white ethnicity, all of whom are more prone to misinterpreting dosing instructions[4].

Although not specific to paediatric practice, in 2021 the Australian Commission on Safety and Quality in Health Care published national labelling standards for dispensed medicines[10]. For oral liquids, it is advised the dose volume is displayed in numbers that relate to markings on the oral syringe, e.g. "0.5mL". A 2024 UK survey explored parent/carer preferences for OLM dose expression[11]. 72.8% of the respondents without a healthcare background preferred "...mL", while 23.8% preferred "...mL (...mg)". Overall, 98.8%, 96.3% and 74.5% of the respondents marked syringe images correctly when OLM doses were expressed as "…mL" , "…mL (…mg)" and "…mg (…mL)", respectively.

For solid dosage forms, the Australian standards state that the dosing quantity should be expressed numerically, except in the case of fractions[10]. The 2024 UK caregiver survey findings align with this, with a greater proportion of respondents from non-healthcare backgrounds preferring "1 tablet" to "one tablet" (59.6% vs 33.3%)[11]. Regarding dose frequency expression, 51.6% of caregivers preferred "Give 5mL twice a day" to "Give 5mL in the morning, Give 5mL in the evening", "Give 5mL in the morning and evening", or "Give 5mL two times a day"[11].

Importance of Ensuring Parent/Carer Understanding

In addition to use of clear, standardised wording on dispensing labels, it is critical that patients, parents and/or carers are given verbal instructions as to how the medicine should be used. The dispenser should ensure patient, parent/carer understanding of the information given, including providing support with/demonstration of the use of administration devices[6]. Provision of an appropriate administration device coupled with appropriate support decreases the risk of medication error[12,13]

Provision of an Appropriate Administration Device for OLMs

Domestic teaspoons or measuring devices should not be used to administer OLMs due to a lack of consistent calibration of these products[1]. A 5mL medicine spoon or a 5mL oral/enteral syringe should be used to measure dose volumes which are 5mL or whole multiples of 5mL, the choice of device taking into account patient and parent/carer preferences[1]. Where the dose volume is not 5mL or a whole multiple of 5mL, an appropriate oral/enteral syringe should be used. Where the dose volume is less than 1mL, a 1mL syringe should be used to minimise dosing inaccuracy. Use of larger syringes to measure volumes less than 1mL results in greater inaccuracy and variability, even if the required volume corresponds with available graduations[3].

In some cases, it may be necessary to round the required dose volume to enable accurate measurement. For low-risk medicines, clinically acceptable dosing variance is generally considered to be up to 10% of the intended dose; for high-risk drugs, a variance up to 5% of is acceptable[14]. Where doses volumes are rounded to enable accurate measurement, this should ideally be noted in the patient's records so that a consistent approach is used each time the medicine is dispensed.

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Disclaimer

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Key changes from Version 1 (published June 2025):

- Removal of recommendations for the labelling of solid dosage forms swallowed whole.
- Addition of statement that standardisation of dosing instruction wording for solid dosage forms remains important, and requires a collaborative approach between a range of organisations.

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