






PRESCRIBING FOR CHILDREN

SUMMARY

-  **Many factors must be considered when prescribing for children including formulations available, routes available, acceptability, taste and excipient content.**
-  **Most paediatric doses are calculated on a weight basis. Information should be obtained from a paediatric formulary.**
-  **Good communication with the parent/carer will help to increase compliance and reduce the risk of medication error.**

INTRODUCTION

Children represent one of the largest patient groups that attend General Practitioners (GPs). Paediatric prescribing is much more complicated than prescribing for adults, with many factors to consider, including the limitations of commercially available dosage formulations, and a relative lack of information about drug use in children.¹ Rational drug treatment for infants and children requires an understanding of the wide variability in drug handling and response in the early years of life.² Recently, there has been a change in the definition of age and agreement has now been reached internationally.³ (Table 1).

Table 1: Definitions of Age³

Preterm newborn	<37 weeks gestation
Term newborn	0-27 days
Infants and toddlers	28 days to 23 months
Children	2 to 11 years
Adolescents	12 to 16-18 years

CONSIDERATIONS WHEN PRESCRIBING FOR CHILDREN

The decision to use medications requires accurate diagnosis and a clear understanding of the risks and benefits of the planned treatment. It is especially important to avoid “treating” the carer rather than the infant or child.⁴ In addition, there are limited studies of the risks and benefits of specific treatments in children. Finally, the long-term effects of particular therapies may not be fully elucidated and this may be of particular concern in the treatment of chronic conditions, e.g. long-term corticosteroid use.¹

If possible, it should be explained to a child why they are taking a medicine and how they should take it. It is important that the child is comforted and reassured so that they are not left with an impression that being given medicine is a punishment for being sick.⁵

Which route and what formulation?

For children, the choice of formulation is highly important. Ease of administration, routes available, acceptability, taste, and excipient content are all important considerations, in addition to, the cost and safety of many formulations.¹

Oral Formulations: The taste, smell, appearance, texture, and aftertaste of medications are major determinants in the acceptability of medicines to children.⁷

- Liquid preparations - Most children aged 5 years or more will successfully take solid preparations.^{2,5} The child's ability to take a solid dosage form can usually be ascertained from the parent/carer. Oral syringes should be used for the administration of liquids where the dose required is less than 5ml. This avoids dilution, and helps to ensure greater accuracy in dosing. Parents should also be reminded to shake liquid preparations before administering them. Where no commercial liquid preparation exists, a number of methods can be employed to overcome this problem. If information is available regarding stability, some tablets can be crushed and dispersed in water or added to a suspending agent, e.g. xanthan gum (Keltrol®). There are also a number of parenteral preparations which can be administered orally, e.g. phytomenadione (Konaktion MM®). It is important to inform parents when it is not appropriate to crush a solid dosage form, e.g. modified release preparations, as the stability or release profile of a preparation may be compromised.
- Palatability - Sugar-free preparations are recommended where available. A variety of alternative sweetening agents including aspartame (e.g. Augmentin® suspension, Singulair Paediatric®, Fybogel®) or sorbitol, are used in place of sucrose to enhance palatability, although these in turn can cause problems in some patients. Aspartame should be used cautiously in children with phenylketonuria due to the phenylalanine content, and diarrhoea has been reported following sorbitol administration. Some liquid preparations still contain sucrose. The long-term use of medicines containing sucrose increases the incidence of tooth caries and gingivitis. If these preparations must be used, the teeth should be brushed after each dose.^{2,5}
- Excipients are often considered unimportant, inactive components of medications yet they can be responsible for a number of clinically significant allergic reactions. These include solvents such as arachis (peanut) oil e.g. Polytar® preparations.^{1,7}
- Parents should not mix medicines with essential food items such as milk or formula feeds. Interactions may occur with milk feeds in particular, and if the entire feed is not taken, a proportion of the dose will be lost. In addition, there is the possibility that the child may develop an aversion to the food item involved.^{6,8}

Parenteral: The intramuscular (IM) route is extremely painful, due to a child's small muscle mass and should only be employed if absolutely necessary e.g. for vaccine administration or initial antibiotic therapy. The "smallest" appropriate needle should be used to help minimise pain.

Topical: Some common conditions encountered in primary care require topical administration, e.g. eczema. Systemic adverse effects have occurred through increased absorption, especially if the cream, ointment or gel is applied to the groin or face. Inflammation also increases the amount of drug absorbed, as does occlusion.^{3,9}

- Creams may cause irritation often as a result of the stabiliser content, e.g. propylene glycol, but ointments are more occlusive.¹⁰
- Parents are often unsure as to the correct amount of cream, ointment or gel, particularly of corticosteroids, to be applied. They should be shown the fingertip unit i.e. the amount of cream required to cover the index finger of an adult from the tip to the crease of the first joint. This measurement can be used to calculate the amount of cream/ointment required to treat a particular area of the body. (Table 2)

Table 2: Number of Fingertip units required for different body areas¹¹

Age	Face & Neck	Arm & Hand	Leg & Foot	Trunk (Front)	Trunk (Back) & Buttocks
3-6 months	1	1	1.5	1	1.5
1-2 years	1.5	1.5	2	2	3
3-5 years	1.5	2	3	3	3.5
6-10 years	2	2.5	4.5	3.5	5

Inhalation: In the paediatric population, asthma is most frequently managed using the inhalation route of administration. The British Thoracic Society (BTS) recently published updated guidelines on the management of asthma. In young children (0-5 years) a metered dose inhaler (MDI) and spacer device are the preferred method of delivery of β_2 agonists or inhaled steroids. A face mask is required until the child can breathe reproducibly using the spacer mouthpiece. Where this is ineffective a nebuliser may be required. In children 5 years and older a MDI and spacer device was found to be as effective as any dry powder inhaler.¹²

The use of spacer devices, e.g. Babyhaler[®], Nebuhaler[®] removes the need for co-ordination between actuation of a pressurised MDI and inhalation. Children and their parents should be instructed as to the correct use and care of the spacer device (cleaned once a week by washing in mild detergent and then allowed to dry in the air). Spacer devices should be replaced every six to twelve months. The teaching of the correct technique, use of an appropriate device and regular review are essential for success.⁸

What Dose?

Paediatric dosing is much more complicated than the “one dose fits all” approach common in adults. The Summary of Product Characteristics (SPC) should be checked first as this will indicate if a preparation is licensed in Ireland for use in children. Paediatric reference texts such as Medicines for Children will provide further confirmation of the recommended dose. Prescribers should become familiar with the way the dose is stated in their paediatric formulary. Some texts state the total daily dose to be given whereas others state the divided dose to be given and the frequency at which it should be given. Paediatric doses should not be extrapolated from the adult dose. Most doses are calculated on an individual patient basis and are weight based. Ideally, it is best to weigh the child, but where this is not possible; the following table may be used as a guide (Table 3).

Table 3: Age-Mean Weight^{45,13}

Age	Mean Weight for Age (Kilograms)
Newborn	3.5
1 month	4.2
3 months	5.6
6 months	7.7
1 year	10
3 years	15
5 years	18
7 years	23
12 years	39

For treatment of chronic conditions, the dose of medication should be re-evaluated at regular intervals based on the child’s age and weight.

Compliance

Compliance is an important consideration in the administration of medicines to children. It is known that adults find it extremely difficult to comply and as parents are often responsible for the administration of medicines to their children, the compliance of both the parent and child must be considered. Barriers to compliance include⁸:

- Age; adolescents are less compliant than younger children
- Parental perception of the child’s illness
- Ease of administration and palatability
- Complexity of administration
- Poor understanding of directions and reasons for administration
- Socio-economic factors

Unlicensed or Off-label Use

In Ireland, many of the preparations commonly used in children may not in fact be licensed for such use. Prescribers must be aware of the licensed indications (this information is found in the product SPCs), as many manufacturers write disclaimers stating that their products should not be used in this patient group. It is the responsibility of the prescriber to ensure that adequate information exists to support the quality, efficacy, safety and intended use of a drug before prescribing it.⁶ This has led to medicines being used that have not been subjected to a licensing process (unlicensed) or medicines being used outside the license restrictions (off-label). A study published in 2000 showed

that almost 70% of children, in hospital, in Europe receive at least one unlicensed or off-label medicine during a hospital stay.¹⁴ This study highlighted the fact that there is a lack of suitable, licensed medicines for use in children largely due to the lack of clinical trials providing evidence to support such applications.³ The medicines that are most frequently used off-label include analgesics, antibiotics and bronchodilators.¹⁵ In some situations there may be a lack of a suitable preparation for children and a product may require extemporaneous preparation. Good communication between primary and secondary care is necessary to ensure continuity of supply as these therapies are often initiated in hospital, but GPs may be asked to continue prescribing. Informing parents of the risk-benefit decision in the off-label or unlicensed use of a medicine should be considered. The use of an unlicensed preparation can also have implications for availability and reimbursement under community drug schemes.

Medication Errors

Medication errors are a further concern in prescribing for children. The lack of suitable, licensed formulations for children can potentially lead to medication errors. These errors occur all too frequently in paediatric therapy and this is often a consequence of inappropriate drug administration.^{4,8} Ten-fold dosage errors are an especially important paediatric problem. These can be the result of calculation errors, misplaced decimal point errors or unit confusion.

- Always write a leading zero before a decimal point, i.e. 0.6 milligram, not .6 milligram
- Never write a trailing zero after a whole number, i.e. 8 milligram not 8.0 milligram
- Leave a space between the number and the unit to add clarity, i.e. 8 milligram not 8 milligram
- Units should always be written in full, i.e. microgram not mcg

Parents need to know the name of the drug, purpose for which it is being used and the amount of drug to be administered. Safe and effective administration requires the correct use of droppers, oral syringes, measuring cups, 5ml spoons etc. However, errors have been reported with all of these devices and parents should be instructed as to how to use such devices correctly. The potential for dispensing errors exists where more than one concentration of a medicine is available, and it is essential that the strength of a preparation is specified when a doctor is prescribing.⁸ The dose should be prescribed ideally as the number of milligrams/micrograms required and not just the number of millilitres to be given.

CONCLUSION

Prescribing for children can be a more complicated procedure than in adults. Factors such as individual dosing, formulation, taste, licensing etc. must be considered. GPs are encouraged to consult a paediatric formulary for information on dosing. In addition, the prescriber should strive for excellent communication with parents/carers to increase compliance and reduce the risk of error occurrence.

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CORRECTION: Current Pharmacotherapy of Rheumatoid Arthritis Vol.9, No.1, 2003

In the table of costs, it should be noted that infliximab is not reimbursable under the High Tech Drugs scheme.