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Medication errors • Cough in children • Immunisation

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Health professionals are human too: Making mistakes in general practice

The underlying philosophy of "to err is human" is that everyone is capable of making an error. It is not a human failing but human nature. Academic qualifications, experience, judgement and knowledge do not exempt a person from being human. We can, however, take steps to minimise the impact that errors may have, and the frequency with which they occur.

Perhaps one of the most important aspects of minimising medical errors is questioning things that do not seem right. Practitioners should feel encouraged to question a colleague if an error is suspected, rather than feeling embarrassed or awkward in the face of authority or reputation. Questions from patients and their families about medical care, prescribing or dispensing should be welcomed rather than dismissed or discouraged.

What is medical error?

Defining an error is a challenge as every event will be perceived and interpreted differently by each person involved. Often it is easy to disown an error or shift responsibility – "that was not my fault, it was a problem with the system" or "if my information system was up to date, I would not have prescribed the wrong medicine". Errors usually have multiple causes with several people or systems involved in a cascading chain of events. The responsibility for error prevention is collective and collaborative rather than resting on the shoulders of an individual.

Definition of error

Errors are events in your practice that made you conclude; "That was a threat to patient well-being and should not have happened. I do not want it to happen again." Such an event potentially affects the quality of care you give your patients. Errors might be large or small, administrative or clinical, or actions taken or not taken. Errors might or might not have discernable effects. Errors are anything you identify as something wrong, to be avoided in the future. **– Rosser et al**, 2005[1]

Medication errors

Medication errors are the most common type of medical error that occur in primary care. A medication error can be defined as; "failure of the treatment process that leads to, or has the potential to, harm the patient".[2]

Medication errors may occur during the following processes:[2]

- Choosing the medicine and dose – prescribing faults (irrational, inappropriate, ineffective prescribing, under or over-prescribing)
- Writing the prescription – prescription errors, illegibility
- Dispensing the medicine – wrong drug, formulation or label

- Manufacture or preparation of the medicine – wrong strength, contaminants
- Administering or taking the medicine – wrong dose, drug, route, frequency or duration
- Monitoring – failure to alter a treatment when indicated, erroneous alteration

Methods to minimise error

Most healthcare professionals are likely to have had some experience of medical errors, including near misses and errors that occur but are undetected. So what can be done in primary care to reduce medication errors and improve patient safety?

1. Review medication errors with practice colleagues and peers – discus what went wrong (including near misses) and consider factors that could be put in place to prevent future events.
2. Introduce a culture of openness, no blame and collective responsibility – many error incidents are not single acts but result from a chain of events. GPs, pharmacists, practice nurses and other primary care practitioners all have a role and responsibility in selecting, delivering, receiving and administering medicines correctly.
3. Involve patients in their own safety – collective responsibility for error prevention extends to patients as well. Patients and their families should be informed about the medicines they are receiving and encouraged to act on their suspicions if they feel something is not right.
4. Be extra vigilant with high risk medicines and situations – some factors increase the risk of an error occurring. Patients who have been recently discharged from hospital are especially vulnerable to error due to factors such as confusion over medicine changes, poor information transfer and lack of follow-up. High-risk medicines such as warfarin and opioids, polypharmacy and prescribing to very old or very young people, may also warrant closer attention to prevent errors.
5. Report errors and patient safety incidents – decide individually or as a practice what method should be used.

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2. Aronson JK. Medication errors: what they are, how they happen, and how to avoid them. QJM 2009;102(8):513-21.

The bpac^{nz} Patient Safety Incident Reporting System

Designed for people working in primary care to report and review patient safety incidents.

The system is:

- Completely anonymous, no identifying information is collected or recorded
- Focused on systems or processes rather than individuals
- Independent and non-punitive

The primary purpose of the bpac^{nz} Patient Safety Incident Reporting System is to improve safety by identifying the factors that commonly contribute to incidents in primary care, and sharing solutions to prevent these incidents from occurring again.

The online review facility includes the ability to comment on reports and view comments and observations made by peers on an incident. By submitting a report you are making an important contribution to the safety of your patients and colleagues.

How do I make a report?

Submit your report online on the bpac^{nz} website:

www.bpac.org.nz/safety

Patient safety incident reporting in **general practice**

Associate Professor Susan Dovey, Department of General Practice and Rural Health, Dunedin School of Medicine, University of Otago, reviews the bpac^{nz} Patient Safety Incident Reporting System.

Until about ten years ago, it was an anathema to suggest that patients could be unsafe in the care of their health systems. That myth was blown out of the water in late 1999 when the US Institute of Medicine released its report *To Err is Human*,[1] horrifying many with the statistic that 98,000 Americans died unnecessarily every year because of what happened to them while they were in hospitals. The consequent flurry of public activity created many things, including systems for reporting unsafe incidents, which concentrated on hospitals as unsafe healthcare settings. A focus on patient safety as a leading healthcare issue spread rapidly throughout the Northern Hemisphere. Australia had its own patient safety revolution in the 1990s and was well positioned to advise emergent patient safety "experts" in Europe and the Americas. At the 55th World Health Assembly in 2002 the World Health Organisation (WHO) passed a resolution "recognising the need to promote patient safety as a fundamental principle of all health systems" and in 2004 WHO launched its Patient Safety programme. National reporting systems are now operational or planned throughout Europe but only the UK, Denmark and Ireland have health system-wide, comprehensive reporting.[2] Formal analyses to highlight learning points are part of the more mature patient safety incident reporting systems of only the US and Australia so far.

New Zealand, usually at the international forefront of healthcare reform, did not initially show leadership in this area. However we do now have a process for reporting "serious and sentinel" incidents in hospitals and a draft policy for managing patient safety incidents.[3] Confirmation of this policy was due in April 2010 but has not yet been announced. The policy proposes a system that closely mirrors patient safety incident reporting in Australia, incorporating features associated with superior systems, such as root cause analysis. It is intended to apply to all New Zealand health delivery organisations, large or small, across the health sector. Unfortunately for the policy's implementation in primary care, many of New Zealand's general practices have limited experience in root cause analysis, less time to learn these skills and a lack of enthusiasm for engaging in the process of deciding whether an "incident" warrants a REB (Reportable Event Brief) or should be assigned a SAC (Severity Assessment Code) 1, 2, or 3.

Drawing on the international patient safety incident reporting research, bpac^{nz} has designed a beautifully simple, yet sophisticated, primary care safety incident reporting system. It is not just for reports. It is for learning. It is completely anonymous, with web-based entries being moderated to ensure absolute anonymity before it is released to the public. It is also completely public: anyone can access it through the bpac^{nz} website. Behind the scenes, the WHO international classification of patient safety incidents is applied to each report. Reports are made in plain English (or GP English!) without the need for any acronyms or jargon you would not use every day. Complicated reporting hierarchies are by-passed.

As of early July, 2010 25 reports had been made. Summaries of the main learning opportunities from these reports will regularly be published in *Best Practice Journal*. Both the reports themselves and the comments on the reports (which again can be made by anyone but are moderated by bpac^{nz}) have learning points. For example, of the 16 current reports about incidents involving medicines, two are about warfarin brand mix-ups. The lesson comes succinctly from a commentator, who writes from experience with similar problems: "Our practice is to only prescribe 1 mg tablets if at all possible." Table 1 summarises other reports. The bpac^{nz} Patient Safety Incident Reporting System is an excellent resource for New Zealand primary care practitioners: it is for you, by you and about you. Its value will increase as you use it.

Table 1: A summary of bpac[nz] Patient Safety Incident reports, July 2010

Incident class	Type of problem	Learning points*
Clinical process or procedure (7 reports)	Misdiagnosis of temporal arteritis Misdiagnosis of paroxysmal atrial fibrillation Documentation problems – eye checks for patient with diabetes, immunisations for patient with splenectomy Immunisation delivery problem Failure to deliver care indicated by positive lab test Referral lost in hospital system	Handover of patient information from GPs to and from other providers (hospitals, Healthline, labs, nurses, other GPs) is a high-risk situation: **a priority sort-out challenge**.
Medications (16 reports)	Prescribed contraindicated drug: ▪ Trimethoprim prescribed to pregnant woman ▪ Drug interaction between sotalol and norfloxacin ▪ Ocular steroids without fluorescein staining Prescribed wrong dose: ▪ Levothyroxine prescribed at 1000x indicated dose: computer software not updated ▪ Discharged on 80 mg daily PPI instead of 20 mg ▪ Computer generated repeat prescription for 40 mg Lipitor instead of 10 mg ▪ Computer generated PenG vials for injection instead of PenV capsules ▪ Computer generated M-Enalapril instead of M-Eslon Dispensed wrong drug: ▪ Adrenaline instead of vitamin B12 ▪ Atrovent inhaler dispensed instead of atrovent nasal spray ▪ Inhibace 2.5 mg dispensed instead of Inhibace Plus ▪ Dispensed wrong dose ▪ 250 µg flixotide dispensed instead of 25 µg ▪ 15 mg/5 mL midazolam dispensed instead of 5 mg/5 mL ▪ Patient dispensed 3 mg warfarin when was instructed to take four pills (supposed to be four x 1 mg) ▪ Warfarin 3 mg labelled as 1 mg Adverse reaction (no error): ▪ Neutropenia with clozapine	Watch the computer – it doesn't always deliver what you intended Mistakes can slip in all along the prescribing pathway
Medical device and equipment (2 reports)	Patient slipped on pathway leading to the practice Patient tripped over poorly lit step	Scan your physical environment for potential hazards

* More personally applicable lessons will be found by reading and contributing to the reports

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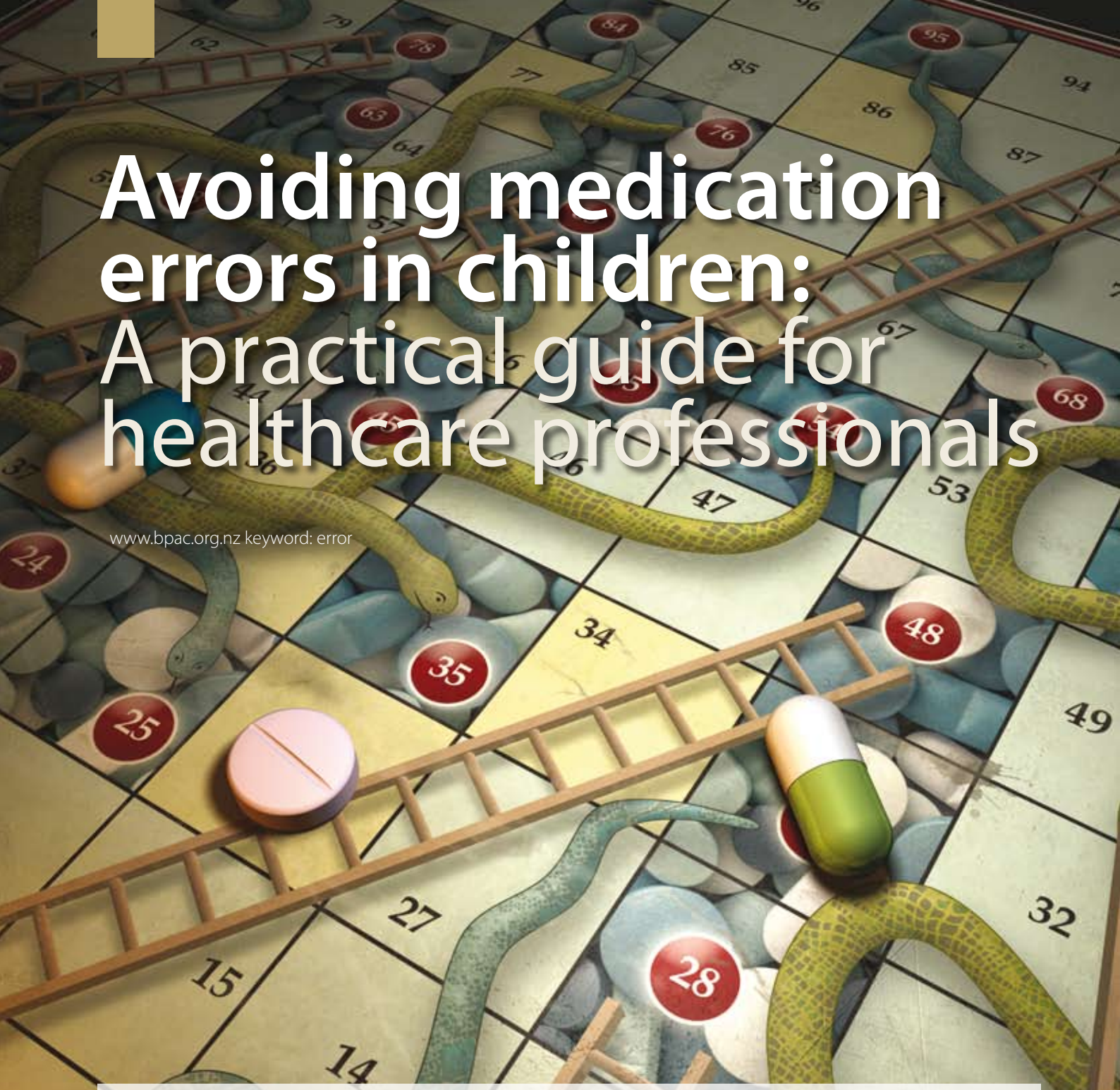
Avoiding medication errors in children: A practical guide for healthcare professionals

www.bpac.org.nz keyword: error



Key concepts:

Strategies for reducing medication errors in children include:

- Reducing dose calculation errors
- Focusing on safe use of medicines that are commonly associated with error including: analgesics, antibiotics, antiepileptic agents, asthma and allergy agents, vaccines and insulin products
- Improving access to specialised prescribing information e.g. BNF for Children
- Improving communication with parents
- Promoting error reporting systems to allow open discussion, for the benefit of healthcare professionals and patients

Minimising medication errors in children

Medication errors may never be completely eliminated, but strategies can be put in place to reduce the likelihood of error occurring. Practitioners are encouraged to identify and respond to signs that an error in prescribing or calculation may have occurred, so that harm can be prevented or reduced. It is also important to recognise circumstances in which errors are more likely to occur, e.g. care of unfamiliar patients, dealing with unusual or unfamiliar medicines, having an unusually heavy workload.[1]

Tips for healthcare professionals to minimise medication errors in children:

1. Take an accurate patient history - confirm that the child's weight is correct and current (record the weight in kilograms), check for drug allergies and adverse drug reactions, and enquire about any changes at each encounter.
2. Ensure full details appear on the prescription, including where appropriate:
    - Weight in kg (include the date the weight was measured)
    - Basis of dose i.e. mg/kg dose (ensure that weight-based dose does not exceed the recommended adult dose)
    - Indication for medicine e.g. on prescriptions for paracetamol state "only for use in pain or fever"
    - Specific instructions (avoid vague instructions such as "take as directed" or "when required")

    Avoid the use of abbreviations and symbols e.g. HCT is used for both hydrocortisone and hydrochlorothiazide, O.D can be mistaken for Q.I.D or BD ( For more information see Safe and Quality Use of Medicines Medication Alert 4, 2007 available from: **www.safeuseofmedicines.co.nz**)
3. For high-alert medicines (Page 12), comprehensive prescription details (as above) are even more important. Any complex calculations should be included as this facilitates independent double checking by other health professionals.
4. In pharmacies and practice medicine supplies, store paediatric products separately from adult preparations. Store look-alike and sound-alike medicines separate from one another.
5. Ensure that parents/carers understand medicine administration information, especially when multiple medicines are prescribed. Encourage use of oral syringes to improve the accuracy of dose measurement and administration of oral liquids. Inform parents of what to expect in terms of a response to the medicine and possible adverse effects. It can be helpful to ask the parent or carer to repeat back their understanding of the medicine and how it is to be administered.
6. Act on any feelings of uncertainty or questions raised by other health care professionals or parents/carers. Verify any unusual volumes or doses when questioned about a medicine or dose.
7. Make a final check of the prescription once it has been printed off. Do not just "click and sign", always look at the form and double check that the correct medicine has been prescribed to the correct patient at the correct dose.
8. Report medication errors so that other healthcare professionals can also learn from them.

Medication errors occur across the entire health sector

Medication errors can occur across the entire health sector, including at the interface between healthcare settings (e.g. hospital admission and discharge). They involve all routes of administration and all provider groups, and can occur in patients of all ages.[2]

A medication error has been defined as:

> "Any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures and systems including: prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."[3]

Much of what is known about medication errors in children is based on research undertaken in the hospital setting. There is very little research from primary care. Medication errors can occur with any medicine, but most commonly occur with frequently prescribed medicines such as paracetamol.[4] Medicine classes most commonly associated with error in primary care include analgesics, antibiotics, antiepileptic agents, asthma and allergy agents, vaccines and insulin products.[5,6]

A primary care based study found that approximately 15% of children were dispensed a medicine with a potential dosing error (8% were potential overdoses and 7% were potential underdoses).[5] Medicine administration errors by parents are also common.[7]

A New Zealand study in a paediatric inpatient setting found that medication errors occurred at a rate of 12 per 100 items prescribed. While most of these errors resulted in no harm, two per 100 items had the potential for harm, and one in 100 resulted in actual patient harm. Dosing errors were most commonly implicated in the harmful or potentially harmful errors, particularly during the prescribing stage and with use of antibacterial agents and analgesics.[8]

Medication error rates in children are similar to the overall error rates in adults, but children are more at risk of harm from these errors.[9]

Some important factors contributing to medication errors in children include:

- Individualised dosing - the doses of most medicines used in children are calculated individually, based on the child's age, weight and their clinical condition, leading to increased opportunities for error.
- Small dose volumes – children often require a small dose of a medicine, therefore precise dose measurement is important, particularly for high alert medicines.
- Monitoring difficulties – children are often unable to communicate about adverse effects they may experience, making the monitoring of the safety of a medicine difficult.[5]

Common causes of dosing errors in children

Dosing errors are the most common type of medication error in children in both primary and secondary care[10] and therefore are the best target for prevention strategies.

Inaccurate patient information

It is important to ask about, accurately record and frequently update all patient information. This includes history of allergies and adverse drug reactions and a medicines list including over-the-counter (OTC) products.

Ask parents open-ended questions such as "what medicines do you give your child?", rather than closed questions such as "do you give your child paracetamol?" For example, some parents may not realise that Pamol is the same medicine as paracetamol, and that Fenpaed is the same medicine as ibuprofen.

Medicine doses in children and infants are often based on dose per kilogram of body weight. Incorrectly measured or recorded weight or failure to update records following periods of rapid growth, are common causes of dosing errors.

Equipment should be maintained and frequently checked for accuracy. Take an up-to-date and accurate body weight measurement whenever possible e.g. at times of vaccination. It is good practice to record the child's weight on any prescription as this allows the pharmacist to check the dose as an extra safety precaution.

The calculated dose should not normally exceed the maximum recommended dose for an adult. **As a general guide, dosing on a mg/kg basis should stop once the weight for a child reaches 40 kg.** At that point the regular adult dose can be prescribed. In the hospital setting clinicians may base dose calculations on body surface area e.g. for chemotherapy agents, however this is not usually required in general practice.

Lack of paediatric drug Information

There is a lack of prescribing information for children in general. Product information commonly offers no paediatric guidance, due to lack of clinical trial evidence on safe levels of use. As a result, many medicines are used "off-label" in children, e.g. fluoxetine, omeprazole, beta-blockers.[11,12] This is more common in a hospital setting.

Prescribing information can be unclear or unspecific and contribute to confusion. For example, some prescribing guides state that a child aged between one and five years (10 – 18 kg) may be prescribed 120 – 250 mg of paracetamol, four times per day. Depending on how this is interpreted, the child may be prescribed a daily dose of between 27 and 100 mg/kg.[12]

A paracetamol dose calculator for children is available on the bpac website: **www.bpac.org.nz** Keyword: **calculator**.

World Health Organisation formulary for children

The World Health Organisation (WHO) has recently released a model formulary for prescribing medicines to children aged up to 12 years. The guidance covers 240 "essential medicines" and provides information on standard doses, adverse effects and contraindications.

The formulary is designed for use in resource limited settings and is based on international evidence and prescribing. It is not specific to New Zealand based practice, but can provide general guidance.

Visit the WHO website for further information and to access the formulary: **www.who.int/mediacentre/news/releases/2010/medicines_children_20100618/en/**

The use of out of date references may also contribute to dosing errors. In the absence of a New Zealand specific guide, the British National Formulary for Children (BNFC) is recommended. This is available electronically via subscription or can be purchased in hardcopy at medical bookshops and online.

Manufacturers datasheets for individual medicines are available online from the Medsafe website: **www.medsafe.govt.nz/profs/datasheet/dsform.asp**

Calculation errors

Miscalculations can occur during prescribing, dispensing and administration.

Some common errors include:[13]

- Misplacement of the decimal point
- Lack of a leading zero e.g. writing .5 mg instead of 0.5 mg – which can easily be misread as five milligrams rather than half a milligram
- Use of trailing zeroes e.g. writing 5.0 mg instead of 5 mg – which can easily be misread as fifty milligrams rather than five milligrams
- Incorrect expression of the dosage regimen
- Incorrect units e.g. milligrams instead of micrograms or millilitres

Errors are more likely to occur with more difficult calculations. For example, a study demonstrated that a significantly greater number of incorrect dose calculations occurred for a 23 kg child compared to a 10 kg child, reflecting the more complex calculation required.[4]

"As required" prescribing

"As required" (prn) prescribing is prone to error.[4] Errors are commonly associated with prn administration based on a minimum dosage interval, without guidance about the maximum dosage frequency (as often occurs with paracetamol prescribing). This may result in the total daily dose being exceeded. It has been suggested that one in five children receiving a ''prn'' medicine are potentially receiving an incorrect dose.[5]

If a medicine is prescribed prn, make sure that clear instructions are given about both the minimum time frame between doses and the maximum amount of doses to be given per day. An example of clear instructions for paracetamol 120 mg/5 mL would be:

"5 mL to be given, every four hours, as required for pain or fever, maximum of four doses per day."

High-alert medicines

High-alert medicines are associated with a greater risk of causing significant harm if used in error. Although mistakes are not necessarily more common with these medicines, the consequences of an error are more serious to the child. Therefore it is particularly important that calculations are correct and that an accurate dose measurement is obtained. For oral liquids, recommend that parents/carers use an oral syringe or measuring device, not a teaspoon.

Be wary when prescribing promethazine

Promethazine (Promethazine Winthrop Elixir, Phenergan) is often used in children, but is also often associated with adverse events. Although it is a sedating antihistamine, it can cause paradoxical CNS stimulation reactions in some children, resulting in hyperactivity. Promethazine should not be given to children aged under two years, as its use has been linked to sudden infant death syndrome. It should also be used with caution in children with epilepsy as it may precipitate seizures.[14]

High-alert medicines and high-alert situations

Examples of paediatric high-alert medicines used in primary care include antiepileptics (e.g. phenytoin), insulin and digoxin. These medicines are generally initiated in secondary care but GPs may be involved in follow-up care and repeat prescribing.

Some medicines, e.g. frusemide and ranitidine are not high-alert medicines, but represent a high-alert situation – they are prescribed rarely, therefore their use is unfamiliar which increases the potential for errors to occur.

Another potentially high-alert situation is the use of medicines in emergencies e.g. adrenaline and steroids. It is good practice to have a range of paediatric doses calculated and easily accessible e.g. attached to the box containing adrenaline ampoules.

Labelling, packaging and formulation of products

Dispensing label errors are common and were found to be involved in one in 20 paediatric medication errors reported in the UK.[6]

Product packaging can also contribute to errors. Look-alike and sound-alike medicines are easy to confuse e.g. penicillin and penicillamine. Adult and paediatric preparations can also be mistaken.

Most medicines are packaged and designed for use in adults. Only a few medicines are commercially available in suitable dosage forms or the correct strength for children. As a result, complex calculations and dilutions may be required to get the appropriate formulation and dose for children.[4, 13]

There is no consistency in the way the strength of a mixture is expressed, i.e. mg/mL, mg/5 mL or mg/10 mL. For example, paracetamol oral liquid is available in strengths

Medication error involving multiple factors

A diagnosis of bacterial conjunctivitis was made in a child and the GP decided to prescribe fusidic acid eye drops. The GP explained to the mother that she would receive a small tube of medicine and that she should place a small drop into the child's eyes, twice daily, until the infection cleared.

When completing the electronic prescription, in error the GP selected fusidic acid ointment, rather than eye drops, and wrote on the script for it to be used twice daily.

The pharmacist dispensed fusidic acid ointment (which is indicated for treatment of skin infections). The mother tried using the ointment in her child's eyes but gave up after a few days as it was nearly impossible to apply.

Three errors were made by the doctor:

- Incorrect formulation prescribed
- Prescription did not contain specific instructions, e.g. "apply to the eyes twice daily", that may have helped alert the pharmacist to a potential prescribing error
- The prescription was not checked before it was signed

The mother realised that the packaging and administration was not as had been described to her but she did not feel confident enough to talk to the doctor or pharmacist about her concerns.

Parents/carers should be encouraged to express any questions or concerns they may have, including after they leave the surgery.

of 50 mg/mL (Pamol Infant Drops available OTC), 120 mg/5 mL or 250 mg/5 mL. It is therefore, important that careful explanation is given to parents when different formulations of the same medicine are prescribed.

Uncertainty and misunderstanding by parents

It is essential that parents/carers receive adequate information about their child's medicine and understand how it should be administered.

Parents should know the name, strength and dose of the medicine, understand the label instructions and know the correct dosing interval. They must be able to accurately administer the dose using an oral syringe or other suitable measuring device (available from a pharmacy), rather than a household teaspoon that is less accurate and could lead to large dose variations.

A study found that even when literacy is not considered an issue, dispensing label instructions are misunderstood by more than one third of patients.[15] Rates of misunderstanding are even higher among patients with marginal and low literacy (including those with English as a second language) or when multiple medicines are required. Although this study tested patient understanding, this also applies to parents who must understand the labels in order to administer the medicine to their child.

Reinforcement and further explanation of the doctor's instructions by the pharmacist and other members of the healthcare team improves understanding.

The New Zealand Pharmacovigilance Centre

The New Zealand Pharmacovigilance Centre (NZPhvC) has recently been awarded a Ministry of Health grant to pilot a national medication error reporting and prevention system.

The NZPhvC has always received small numbers of medication error reports however, it is hoped that development of this system will serve to provide comprehensive surveillance for medication errors originating in primary care. Alongside traditional adverse drug reaction surveillance, this will allow the best learning opportunities to improve patient safety. The system will operate on principles of anonymity under the umbrella of the NZPhvC.

Healthcare professionals are therefore encouraged to report any medication-related events (i.e. medication errors and adverse drug reactions) to the Centre for Adverse Reactions Monitoring (CARM). Reports can be made online and reporting forms downloaded by visiting: **http://carm.otago.ac.nz/reporting.asp**

Reporting medication errors

Without reporting, opportunities for learning are diminished. Organisations that do not encourage reporting of incidents, where few medication errors are reported, may be at greater risk of causing medicine related harm to patients as there is less opportunity to learn and improve systems.[7]

Patient Safety Incident Reporting

Primary care health professionals can now report incidents to the bpac[nz] Patient Safety Incident Reporting System. This is an anonymous service aimed at improving patient safety by identifying the factors that commonly contribute to incidents and sharing solutions to prevent these incidents from occurring again. Reports can be submitted online or by completing a paper-based form.

Visit **www.bpac.org.nz/safety** to submit a report or read and comment on reports from colleagues.

ACKNOWLEDGMENT Thank you to **Dr Desiree Kunac**, New Zealand Pharmacovigilance Centre, Department of Preventive and Social Medicine, University of Otago for expert guidance in developing this article.

Medication errors with vaccines

Vaccines are frequently associated with medication incident reports. Vaccines may be mistakenly administered when they are contraindicated, when they have previously been administered and where parental consent has been refused. Poor systems for documentation of vaccination records are often implicated.[6]

Error example: A child was due to receive a pre-school immunisation booster, which included MMR vaccine. The child's mother had previously stated that she did not wish her child to receive the MMR vaccine. The child was brought to the appointment by her grandmother, with the child's record book and in error the child was given the MMR vaccine with the DPT/Polio vaccine.[6]

Another common vaccine error is an "extra dose" error where two siblings attend for vaccination and one child receives two doses and the other child none.

Common errors when prescribing simple analgesics to children

The most likely error that occurs when analgesics are prescribed is overdose.[5] This is of particular concern as most of these medicines have a high likelihood of serious adverse events. One of the reasons that analgesics are associated with dosing error is that they are often prescribed "prn" which increases the potential for overdose.

Paracetamol

Paracetamol is the preferred first-line analgesic for children for fever and mild to moderate pain. It has few adverse effects when dosed correctly, however serious, and sometimes even fatal, liver toxicity can occur with acute and chronic overdose.

The weight-based dose for paracetamol in children is generally 10–15 mg/kg, every four to six hours (maximum of four doses in 24 hours).[11, 12]

The BNF for children states:[11]

Paracetamol 120 mg/5 mL

- Infants 1–3 months: 30–60 mg, eight hourly (maximum 60 mg/kg/day in divided doses)
- Infants 3–12 months: 60–120 mg every 4–6 hours (maximum 4 doses/24 hours)
- Children 1–5 years: 120–250 mg every 4–6 hours (maximum 4 doses/24 hours)

Paracetamol 250 mg/5 mL

- Children 6–12 years: 250–500 mg every 4–6 hours (maximum 4 doses/24 hours)

Lack of awareness of the strengths of different paediatric formulations e.g. 120 mg/5 mL or 250 mg/5 mL, and use of more than one preparation containing paracetamol, may lead to dosage errors and toxicity.

Error example: A mother is used to giving her five-year-old child 10 mL of paracetamol 120 mg/5 mL. When her child is then prescribed a higher strength formulation (i.e. 250 mg/5 mL), the change in dosing instructions was not carefully explained to her, she does not read the label and gives the usual 10 mL.

Error example: A child presents to the practice with symptoms of a respiratory infection. The GP diagnoses viral upper respiratory infection and explains that antibiotics are not necessary and that cough and cold preparations are not recommended. The GP writes a prescription for paracetamol 120 mg/5 mL, 5 mL, four times per day.

The mother returns with the child the next day, concerned because he is lethargic and sweaty. She reveals that she gave the child the paracetamol as instructed, but also had some "Pamol" at home and gave that too. In addition, as she was advised against giving "cough mixture" she made the child a warm "Lemsip" drink. The mother was not aware that all of these products contained paracetamol.

Over the past 24 hours the child had four 5 mL doses of paracetamol 120 mg/5 mL, four 5 mL doses of Pamol (paracetamol 250 mg/5 mL) and one sachet of Lemsip (paracetamol 500 mg). In total this is 1980 mg of paracetamol, giving a dose of 198 mg/kg in the 10 kg child.

The child was referred to secondary care with suspected paracetamol toxicity. Although the mother herself made many errors, this example highlights the importance of carefully explaining medicines to parents, including generic and trade names they might know them by. Also instruct parents how to read labels of over-the-counter medicine preparations and know what medicines they contain.

Ibuprofen

Ibuprofen is an alternative to paracetamol for the management of pain (e.g. musculoskeletal pain) and fever. It is associated with an increased risk of gastrointestinal bleeding. There have also been reports of renal toxicity and aspirin-like sensitivity reactions.[14] Ibuprofen should not be used if the child is dehydrated or has acute renal failure.

All NSAIDs have the potential to worsen asthma, either acutely or as a gradual worsening of symptoms.[11] Therefore children with asthma should preferably use paracetamol.

Dose recommendations:

Always use the lowest effective dose, for the shortest possible duration, and preferably administer after food. For infants and children the usual oral dose is 20 mg/kg/day, in divided doses (if over 7 kg and a severe condition, this can be up to 30 mg/kg/day). In children weighing less than 30 kg, the total daily dose should not exceed 500 mg.[11]

The BNF for children states:[11]

Ibuprofen 100 mg/5 mL:

- Infants 1–6 months: 5 mg/kg, three to four times daily
- Infants 6–12 months 50 mg, three times daily
- Children 1–2 years 50 mg, three to four times daily
- Children 2–7 years 100 mg, three to four times daily
- Children 7–18 years 200 mg, three to four times daily

Error example: A 10-year old child is prescribed 200 mg ibuprofen (100 mg/5 mL), with the instruction "use as required". The doctor is running late and does not weigh the child. The child is of lean build and weighs 27 kg. The child's parents give her five doses of medicine during the day (every four hours), equalling a total dose of 1000 mg.

Errors made:

- The doctor did not weigh the child for a more accurate dose
- The doctor did not provide clear dose instructions, with dosing intervals and maximum daily dose
- The pharmacist did not double-check the dose and explain the dosing instructions to the parents
- The maximum recommended daily dose of 500 mg in a child weighing less than 30 kg was exceeded.

Aspirin

Aspirin should not be used in children aged less than 12 years, although some countries, including the UK, do not recommend use under age 16 years. Although it is a well-documented analgesic, anti-inflammatory and antipyretic, aspirin is associated with Reye's syndrome in children.[14]

Given that other effective analgesics are available, it is usually not necessary to prescribe aspirin to a child of any age for pain relief in general practice.

See Correspondence "Aspirin in children", BPJ 17 (Oct, 2008) and BPJ 27 Quiz Feedback "What is Reye's syndrome" for further information.

Department of General Practice
Dunedin School of Medicine, University of Otago

Ethics in General Practice

GENX 824

Semester Two, 2010 – 15 points

Offered by distance learning and can be credited towards the Postgraduate Diploma in General Practice (PGDipGP)

This paper looks at ethical issues inherent in modern medicine and explores ways of thinking about them, and of dealing with them.

The particular focus lies on the ethical challenges that are relevant to general practice, which include informed consent, confidentiality, patient autonomy, rights and duties, rationing of health care resources, the ethics of screening and genetic testing, and end of life dilemmas.

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Adverse Drug Reaction Reporting

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Cough in children

www.bpac.org.nz keyword: cough

Key concepts

- The cause of cough in children is often different than for adults and management reflects this
- The majority of children with acute cough will have a viral upper respiratory tract infection
- An accurate diagnosis, guided by history and examination, should be made whenever possible to allow successful management of the cough
- Management of chronic cough depends on the underlying diagnosis
- In children without symptoms and signs of a specific serious underlying disease process, the recommended approach is to watch, wait and review

CHILDREN WHO COUGH are frequently seen in general practice. Determining what is "normal" cough from that which is abnormal can be challenging for both parents and primary care teams. Cough is a protective reflex and children who have no evidence of illness may cough an average of 11 times over a day.[1]

Children are not small adults and the causes of cough in children may be different to the causes in adults.[2,3]

The assessment of children with cough, particularly when the cough is chronic, should be carried out in a systematic way. This should assist with the formation of an accurate diagnosis whenever possible and then allow successful management of the cough.

In New Zealand, bronchiectasis and pertussis continue to be prevalent, especially in the upper North Island. This is despite the fact that worldwide the incidence of these diseases is declining. Factors such as over-crowding, a lower socio-economic environment and late presentation to healthcare facilities are thought to play a significant role in the continuing prevalence of these diseases in New Zealand.

History and examination guide diagnosis

Acute cough is likely to be caused by a viral upper respiratory tract infection

The majority of children with acute cough will have a viral upper respiratory tract infection (URTI) and cough will be just one of the several ubiquitous symptoms. In these children, a clinical diagnosis of a viral URTI can be made and the role of symptomatic management outlined to the parents.

It is important however, not to overlook any symptoms that may suggest a more serious but less common cause for the cough. Also plan a review if the child deteriorates or the cough persists. Asking a question such as "Can you tell me about the cough?" will often help reveal other information that may point to red flags in the history (see sidebar "Detecting serious illness in children").

Listen to the concerns of parents

Cough in children, regardless of the underlying reason, can cause significant distress, disruption of daily activities and a lack of sleep for both the child and the parents. Ask open questions following the standard "FIFE" format such as:

- **F**eelings: What are your concerns?
- **I**deas: What do you think is the cause of the cough?
- **F**unction: How is the cough affecting your child and yourself?
- **E**xpectations: What do you think is needed to help resolve the cough?

Responses to these questions should help uncover parental concerns, suggest areas requiring further direct questioning and guide the type and range of advice given. In many cases the answers may also reveal the likely diagnosis.

Consider personal, family history and environmental factors

Aspects of the child's personal, family and social history may provide clues to the underlying reason for a cough. Ask about:

- The child's personal medical history e.g. a history of atopy, recurrent infections, poor growth
- The family history (particularly a history of any respiratory conditions)
- Any exposure to environmental factors e.g. cigarette smoke, pets, damp living conditions
- The immunisation status of the child and others in the family
- Tuberculosis (TB) if the family is from a high risk country or if there is any history of contact with a person with TB

This information may not always be required e.g. in a child with a likely URTI or the information may already be known e.g. a patient who regularly consults the same GP at a practice. Take the opportunity to measure height and weight, to check on overdue recalls, to provide advice about a smoke-free home or to check oral health.

Ask key questions if the cause of the cough is not clear

Determining the cause of a cough may not always be straight forward, particularly if the cough becomes chronic (persisting for more than four to six weeks). If the responses to initial open questions have raised concerns then further direct questioning is required.

There are several key considerations that may be useful to help make an accurate diagnosis in children with

Detecting serious illness in children[4,5]

It is estimated that less than 1% of children presenting to general practice will have a serious illness. The role of the GP is therefore to detect and diagnose these very ill children while also appropriately reassuring parents of children who are less unwell. Complicating this further is that the initial consultation may be at an early stage in an illness when the diagnosis is not clear and there is little indication of the potential severity. Time can be a useful diagnostic tool in general practice. Provide a "safety net", particularly if a diagnosis has not been reached.[6] This may include verbal, or preferably written, information for parents that outlines symptoms or signs of worsening illness, instructions on how to access after hours care and a clear plan for follow-up.

Although the majority of children with an acute cough are likely to have a viral URTI the possibility of a more serious problem should be considered. History and examination may reveal the presence of red flags that can help to determine which children require further investigation or referral.

Red flags in children who cough:[7]

- Neonatal onset of cough
- Cough during feeding
- Sudden onset of cough or a history of choking that may suggest foreign body inhalation
- Chronic, wet cough with sputum production
- Continuous, unremitting or worsening cough
- Presence of associated features such as shortness of breath, hypoxia or cyanosis, rapid breathing, stridor, night sweats, weight loss or haemoptysis
- Signs of chronic lung disease e.g. chest wall deformity, digital clubbing, poor growth
- Parental concern that persists despite reassurance
- Clinician's instinct

For guidance on assessing a child with fever see "Identifying the risk of serious illness in children with fever" Page 30.

cough. These include:

1. How long has the child been coughing for?
2. What does the cough sound like?
3. Is the cough wet or dry?
4. Does the child cough at night?
5. What is the age of the child?
6. Are there any associated symptoms?
7. What triggers the cough?

How long has the child been coughing for?

Cough in children can be categorised as:

- Acute cough – lasting for less than two weeks
- Sub-acute or persistent cough – lasting two to four weeks
- Chronic cough – lasting for more than four weeks

Acute and sub-acute cough in children is usually due to a viral respiratory tract infection that will spontaneously resolve within one to three weeks in 90% of children.[8]

Other serious causes of acute cough e.g. pneumonia, pertussis, foreign body inhalation should however, be considered and excluded if possible. The acute cough may also indicate the start of a chronic cough condition. In some cases, chronic cough lasting more than four weeks is caused by recurrent viral infections over winter, each incompletely resolving before the next infection. A careful history should distinguish this from true chronic cough. Children with chronic cough are likely to require review as the underlying cause of the cough may not initially be clear and the type of cough may change over time.

It is also important to ask about the onset of the cough. A cough associated with a very sudden onset or a history of choking may suggest inhalation of a foreign body, particularly in younger children.

What does the cough sound like?

The character or the quality of the cough may in some cases suggest a specific cause, termed as classically recognised cough (Table 1). However, in practice this may have limited value. Unless the child is coughing in the waiting or consulting room, the GP is dependent on a description of the cough from the parents.

Other causes should not be excluded on this basis alone e.g. a "pertussis-like" paroxysmal cough may be due to *Bordetella pertussis* but could also be caused by a

Table 1: Classically recognised cough and underlying causes (adapted from Chang at al, 2006[8])

Cough type	Suggested underlying disease process
Barking, brassy or croupy cough	Acute or spasmodic croup, tracheomalacia (tracheal collapse), habit cough (psychogenic)
Honking cough (usually absent during sleep)	Habit cough
Paroxysmal (with or without inspiratory "whoop")	Pertussis*
Staccato cough in infants	Chlamydia infection
Chronic wet cough in mornings only	Suppurative lung disease
Cough associated with wheeze and breathlessness	Consider asthma

* Any child with a cough, especially sub-acute or chronic, may have pertussis. Typical symptoms are uncommon and not diagnostic. It may be overlooked when cases are sporadic and over diagnosed during an epidemic. Immunisation is the best strategy.

viral infection such as adenovirus, parainfluenza virus, respiratory syncytial virus (RSV) or mycoplasma.

The age of the child may also alter the character of cough e.g. infants aged under six months with pertussis do not usually "whoop".

Is the cough dry or wet?

Determining whether the cough is dry and irritating or wet and "rattly" may help to diagnose the cause, particularly if the cough is chronic. A chronic cough with purulent sputum in a child requires further assessment as it always indicates underlying disease.[9]

A wet cough in older children and adults is often called a "productive" cough, but this term has limited value for many younger children as they tend to swallow sputum rather than cough it up, often resulting in vomiting. It may be more useful to ask if the child has vomited.

Research has shown that subjective reporting of a wet cough by parents is consistent with findings of airway secretions at bronchoscopy.[10] A wet cough was shown to be always associated with an increase in airways secretions, however a dry cough did not always signify an absence of secretions. In addition, a dry cough may be reported early in an illness and then evolve into a wet cough as secretions increase.[10] Parents should be made aware of when it is appropriate to bring the child back for review and also advised about signs that may suggest worsening illness (see Page 27 for guidance on information that can be given to parents).

Does the child cough at night?

Sleep generally suppresses "normal" and habit cough (see sidebar "Habit cough syndrome") and although nocturnal cough is often associated with asthma, this is less likely for children in the absence of any other associated symptoms such as wheeze.

Nocturnal cough is often a reason for presentation for medical attention because the cough may cause significant anxiety for the parents, be more noticeable and disturb sleep for the whole family. Although nocturnal cough may

Table 2: Neonatal causes of chronic cough[9]

Diagnosis	Features
Aspiration (usually milk)	A moist cough that follows feeding Irritability, arching or choking after feeds. Usually in a child with an underlying congenital cause such as tracheo-oesophageal fistula or laryngeal cleft. Only rarely in a child with normal anatomy and development.
Congenital malformation: compression of airway or tracheobronchomalacia	Stridor, wheeze, cough Recurrent respiratory infections
Cystic fibrosis	Varied presentation - respiratory symptoms (often cough), gastrointestinal complications (intestinal and pancreatic), failure to thrive
Primary cilial dyskinesia	Chronic, persistent rhinitis since birth
Lung infection in utero or in the perinatal period	Chlamydia, cytomegalovirus, respiratory syncytial virus

be the symptom that drives the parent to bring the child to the GP, evidence suggests that parental reporting of nocturnal cough can be subjective.[11]

How old is the child?

The age of the child when the cough started may be important in helping determine the diagnosis. Any unexplained persistent cough that begins in the neonatal period (the first 28 days of life) requires investigation and usually indicates significant disease (Table 2).[7] Discussion with, or referral to, a paediatrician is usually recommended.

Foreign body inhalation

Once children are old enough to put small objects in their mouths, the possibility of aspiration of a foreign body should be considered. Most cases of foreign body aspiration occur in children aged less than four years. Ask parents about the potential for foreign body aspiration, such as access to any small object or consumption of small, smooth foods (e.g. peanuts, raisins, grapes). If foreign body inhalation is suspected then the child should be referred to secondary care for further investigations.

Are there any associated symptoms?

Does the child only have a cough or are there other symptoms? The presence of any associated symptoms may help determine the underlying cause of a cough. Examples may include:

- A cough associated with runny or blocked nose, sore ears or throat, fever or irritability suggests viral infection
- A cough that started after an episode of choking strongly suggests foreign body inhalation
- A cough that is associated with wheezing and breathlessness may suggest asthma
- A history of night sweats and haemoptysis in a "high-risk" child could suggest tuberculosis

Habit cough syndrome[7,9,12,13]

Habit (psychogenic) cough is estimated to be the cause of persistent cough in children in 3–10% of cases. Diagnosis should only be made after other causes have been excluded, such as a transient or chronic tic disorder or Tourette's syndrome. The typical characteristics which may suggest this diagnosis include:

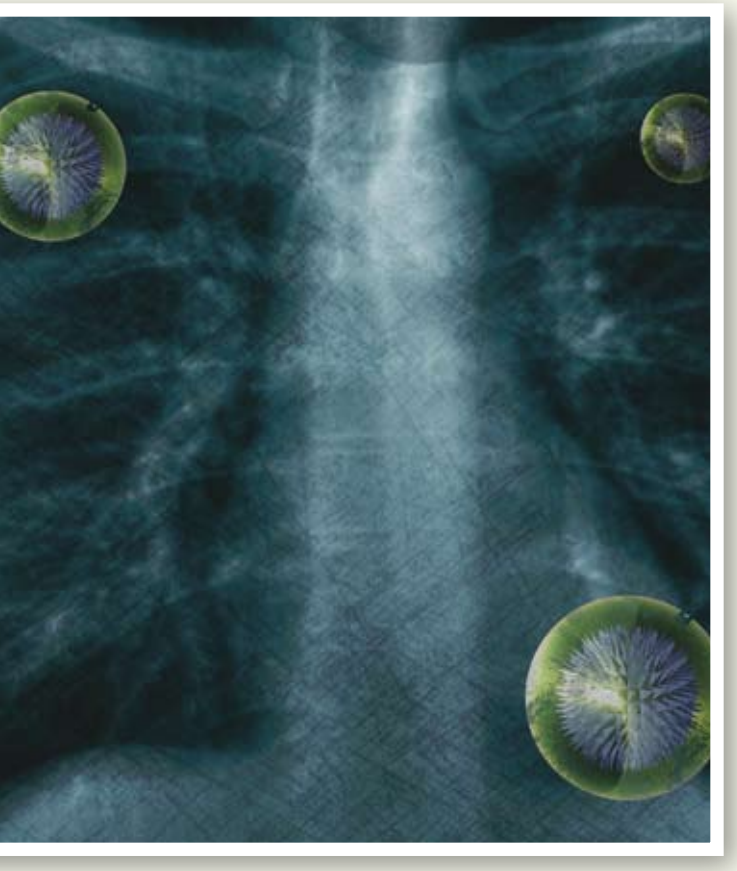
- A dry, harsh, often honking, repetitive cough. In some cases however, it may be more a "clearing of the throat"
- An initial association with an upper respiratory tract infection
- A cough that tends to decrease during enjoyable activities and be absent during sleep
- A cough that may occur before speaking and at times of stress and increases in the presence of parents and teachers
- The cough may be disruptive to others while the child appears indifferent to it
- The cough is usually able to be reproduced upon request
- There may be secondary gain from the cough such as increased parental attention or absence from school
- A history of psychosocial problems such as abuse, anxiety, school phobia or depression

Management includes identification of, and assistance with, any problems at home or school, behavioural intervention and speech-language therapy.

Normal respiratory and heart rates vary with age

An assessment of respiratory and heart rate can give good information about how unwell a child is. The table below gives a range of normal values that are appropriate at varying ages during childhood.

Age (years)	Respiratory rate (breaths/min)	Heart rate (beats/min)
<1	30–60	100–160
1–2	24–40	90–150
2–5	22–34	80–140
6–12	18–30	70–120
>12	12–16	60–100



What triggers the cough?

Ask about any factors that may trigger the cough e.g. exercise, excitement or cold air. Also ask about environmental factors e.g.:

- Is the house smoke-free?
- Are there family pets?
- Is the house damp?

Cough that only appears in specific situations e.g. before speaking, with stress, at school, that disappears at night and that is reproducible upon request may be a habit cough (see sidebar “Habit cough syndrome”).

Examination

The clinical examination of a child who presents with cough should include:

- An assessment of how “well” the child is
- Temperature, hydration, pulse rate and respiratory rate (see sidebar “Normal respiratory and heart rates vary with age)
- Height and weight
- Ear/nose/throat examination – primarily checking for signs consistent with upper respiratory tract infection. N.B. Cough can be triggered in some people by an irritation of the auricular branch of the vagal nerve e.g. by wax or a foreign body in the auditory canal.
- A check for clinical signs suggestive of allergy e.g. allergic “shiners” (dark circles under the eyes), nasal speech, eczema
- Chest examination including observation e.g. accessory muscle use, indrawing, chest deformity and chest auscultation for localised or generalised chest signs
- A check for digital clubbing

Best practice tip – In some young children it can be difficult to get them to take breaths that are deep enough to give reliable findings on auscultation. Asking children to "pant like a big dog" with their mouth open or to "huff" (breathe out forcibly) may reveal chest signs that are not apparent with normal shallower breaths and also may stimulate a cough which enables the quality (dry or wet) to be heard.

Investigations for cough

Investigations are not required for children with acute cough who are likely to have a diagnosis of a viral URTI.

Sputum

Sputum culture may be indicated in an older child with a chronic, wet cough. Most young children swallow their sputum and are unable to produce a sample that is of sufficient quality to provide useful results.

Spirometry

Spirometry is indicated for children with chronic, dry cough who are old enough to master the technique (usually school-age children).[13] Spirometry may give information about airway obstruction and responsiveness to a bronchodilator. N.B. If the child is asymptomatic and normal results are obtained, this does not exclude a diagnosis of asthma.[14] Peak flow is generally not used as a diagnostic tool for asthma as it has not been validated for this use and results are not repeatable.

Radiography

A chest x-ray should be considered if a child has a:

- Chronic cough of unknown aetiology
- History of aspiration (acute onset of cough, choking episode)
- Persistent signs on chest examination (deformity, focal findings on auscultation)

N.B. A normal chest x-ray does not exclude the presence of an inhaled foreign body.

Management of acute cough in children

The majority of children who present to general practice with acute cough will have a viral URTI. In children without symptoms and signs of a specific serious underlying disease process, the recommended approach is to watch, wait and review. Investigations are not usually required and treatment should be aimed at providing symptomatic relief (see "Do cough and cold medicines work in children" Page 32).

Parents should be given information that enables them to make an informed decision about if and when to bring the child back for review. This may include information on:

- The symptoms to expect
- The duration of these symptoms
- Symptoms and signs of worsening illness
- The plan for follow up
- The potential hazards and ineffectiveness of cough and cold medicines

Among the many children who present with acute cough, it is important to identify the child who may have a predominantly lower respiratory infection and be unwell, with fever, tachypnoea, decreased oxygen saturation and chest signs. Antibiotics may be indicated depending on the diagnosis and a follow up appointment should be arranged to check for clinical improvement and resolution of chest signs. If the child is very unwell, referral for further assessment, chest x-ray and treatment in a secondary care setting may be required.

Management of chronic cough in children

Management of chronic cough depends on the underlying diagnosis. If symptoms and signs found in the history and examination suggest there is a specific underlying disease causing the cough, then treatment should be aimed at this condition. In some cases, the child may need further investigations before a diagnosis can be made.

Bronchiectasis is still common in New Zealand

The incidence of bronchiectasis has declined in most developed countries in the world due to improved living conditions and increased vaccination rates, but this illness still persists in New Zealand. It is most prevalent in Māori and Pacific children, especially those living in the lowest socioeconomic areas of the country e.g. Northland.[15]

Bronchiectasis is a "chronic, wet cough", defined as irreversible widening of the bronchi in the lungs. It is characterised by inflammation, destruction of bronchial walls and chronic bacterial infection. Severe or recurrent respiratory infections such as pneumonia, tuberculosis or pertussis often result in bronchiectasis, especially if access to care or treatment is delayed.

A New Zealand based study found that the prevalence of bronchiectasis among children in Auckland was approximately one in 6000, with a disproportionately higher rate among Pacific and Māori children.[15] An alarming finding was that the level of bronchiectasis seen in these children was severe, with bilateral lung destruction and a wide range of co-morbidities and underlying disease processes.[15] Although bronchiectasis is usually most prevalent in pre-school children, the median age of children with bronchiectasis in Auckland was eight years.[15]

Early recognition of children with a "chronic, wet cough", especially those with recurrent respiratory infections, is critical in reducing the incidence of bronchiectasis in New Zealand.[15] Practices also need to consider culturally appropriate ways of communicating this disease risk and expressing the importance of seeking early treatment. Consider supplying information in other languages and involving Māori and Pacific health providers.

Causes of chronic cough in children include:[7]

- Persistent respiratory infection including post viral cough, chronic bronchitis, bronchiectasis, cystic fibrosis, pertussis and tuberculosis
- Passive exposure to cigarette smoke
- Asthma
- Recurrent aspiration e.g. secondary to reflux, congenital abnormality
- Habit cough
- Upper airway cough syndrome
- Gastro-oesophageal reflux
- Cardiac causes e.g. congestive heart failure, congenital heart disease
- Medication e.g. rarely ACE inhibitors

Indications for referral

Referral indications for a child with cough include:

- Cough that does not resolve despite simple management
- Suspected foreign body aspiration
- Haemoptysis
- Recurrent pneumonia (or chest signs that do not resolve)
- Suppurative lung disease
- Congenital lung lesions or disease
- Immunodeficiency states
- Cardiac abnormalities

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ADULT DEPRESSION

Adult Depression is activated for patients over the age of 18 years when the Depression module is opened.

The module has targeted screening questions for common mental health disorders. If the patient wants assistance the module offers additional assessments such as PHQ9 or K-10 and suicide assessment. These assist in the diagnosis of depression.

At any stage, options are available to assist in step-wise management based on the severity of depression. This provides management options that are the least intensive to achieve clinical change for your patient.

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Identifying the risk of **serious illness** in **children with fever**

1. **Identify any immediately life-threatening features including compromise of the airway, breathing or circulation and decreased level of consciousness.**
2. **Use the "traffic light system" to predict risk of serious illness**

CLINICAL CONDITION	Low risk	Intermediate risk	High risk
Skin appearance	Normal colour of skin, lips and tongue	Pallor reported by parent/carer	Pale, mottled, ashen, blue
Responsiveness	▪ Responds normally to social cues ▪ Content/smiles ▪ Stays awake or awakens quickly ▪ Strong normal cry or not crying	▪ Not responding normally to social cues ▪ Wakes only with prolonged stimulation ▪ Decreased activity ▪ No smile	▪ No response to social cues ▪ Appears ill to a healthcare professional ▪ Does not wake or if roused does not stay awake ▪ Weak, high pitched or continuous cry
Respiratory	Normal	▪ Nasal flaring ▪ Tachypnoea: 6–12 months RR > 50 breaths/minute >12 months RR > 40 breaths/minute ▪ Oxygen saturation ≤ 95% in air ▪ Crackles/chest signs	▪ Grunting ▪ Tachypnoea: RR > 60 breaths/minute ▪ Moderate or severe chest indrawing
Hydration	▪ Normal skin and eyes ▪ Moist mucous membranes	▪ Dry mucous membranes ▪ Poor feeding in infants ▪ Capillary refill time (CRT) ≥ 3 seconds ▪ Reduced urine output	▪ Reduced skin turgor
Other	▪ None of the amber or red symptoms or signs	▪ Fever for ≥ 5 days ▪ Swelling of a limb or joint ▪ Non-weight bearing, not using an extremity ▪ A new lump > 2 cm ▪ None of the red symptoms or signs	▪ Age 0 – 3 months, temperature ≥ 38°C ▪ Age 3 – 6 months, temperature ≥ 39°C ▪ Non-blanching rash ▪ Bulging fontanelle ▪ Neck stiffness ▪ Status epilepticus ▪ Focal neurological signs ▪ Focal seizures ▪ Bile-stained vomiting
ACTION	**Reassure**	**Review**	**Refer**

3. **Refer:** ANY of the symptoms or signs in the red column
   - Immediately life-threatening illness – call ambulance
   - All other situations – to be assessed in secondary care within two hours

   Review: ANY of the symptoms or signs in the amber column, but NONE in the red column
   - Diagnosis made – treat accordingly
   - No diagnosis – provide parent/carer with verbal and written information on warning symptoms and ensure that they know how to access further healthcare after hours. Arrange an appointment for follow-up.

   Reassure: ANY of the symptoms and signs in the green column, but NONE in the amber or red columns
   - Provide parent/carer with advice on symptomatic management and when to seek further attention from healthcare services.

4. **Advice for care at home:**

Managing child's temperature	Care at home	When to seek further help
DO ▪ Use paracetamol if the child appears distressed or unwell ▪ Use ibuprofen if there is no response to paracetamol **DO NOT** ▪ Routinely use paracetamol and ibuprofen together ▪ Use paracetamol for the specific purpose of preventing febrile convulsion ▪ Under-dress or over-wrap the child ▪ Sponge the child (i.e. "tepid sponging")	▪ Keep up regular fluids (breast milk if breast feeding) ▪ Look for signs of dehydration: sunken fontanelle, dry mouth, sunken eyes, absence of tears, decreased urine output, overall unwell appearance ▪ Look for signs of a non-blanching rash ▪ Check the child regularly overnight ▪ Keep child away from day-care or school while the fever persists (notify them of illness)	▪ The child has a fit ▪ The child develops a non-blanching rash ▪ The fever is persistent ▪ The parent/carer feels that the child's condition is worsening rather than improving ▪ The parent/carer is more worried than when they previously sought advice ▪ The parent/carer is distressed or concerned that they are unable to look after the child

Adapted from:

National Institute of Clinical Excellence (NICE). Feverish illness in children. NICE Clinical Guideline 47. NICE, London, 2007. Available from: www.nice.org.uk (Accessed July, 2010).

www.bpac.org.nz keyword: cold

Key concepts:

- There is little evidence of clinical effectiveness of cough and cold preparations in children
- Most cough and cold preparations contain medicines that are not recommended for use in children aged under six years
- Simple analgesics such as paracetamol can be considered for symptomatic treatment of the pain or fever associated with cough and cold
- Saline spray or drops may be effective for nasal congestion in younger children
- Environmental factors such as a warm, dry, smokefree home, warm clothing, adequate nutrition and good hygiene are important

The short answer is…no

There is little evidence that cough and cold preparations containing antitussives, mucolytics, expectorants, decongestants or antihistamines, have any clinically significant effect on reducing the symptoms or duration of the common cold in children.

In addition, Medsafe recommends that cough and cold preparations containing certain medicines (Box 1) should not be used in children aged under six years.[1] This decision was made based on the balance of benefit, which is low, versus risk – there is a significant potential for adverse effects and risk of toxicity in overdose.

Box 1. Cough and cold preparations containing the following medicines should not be used in children aged under six years:[1]

- The antihistamines brompheniramine, chlorpheniramine, diphenhydramine, doxylamine, promethazine or triprolidine
- The antitussives (cough suppressants) dextromethorphan or pholcodine
- The expectorants guaifenesin or ipecacuanha
- The decongestants phenylephrine or pseudoephedrine

Cough and cold preparations are now required to be labelled as such, although some companies may still be phasing in new product packaging.

A list of cough and cold preparations available in New Zealand that are affected by these restrictions is available from: **www.medsafe.govt.nz/hot/alerts/coughandcold/affectedmedicinesoct2009.asp**

Sales restrictions on cough and cold preparations for children aged under 12 years

Medsafe has recently announced that cough and cold preparations containing dextromethorphan, phenylephrine and ipecacuanha will now be required to be re-labelled for use in adults and children aged over 12 years, when sold in supermarkets. These products will still be available for sale to children aged between six and 12 years at pharmacies, where parents can receive professional advice on their use and safety.[2]

This restriction does not apply to cough and cold preparations containing ingredients such as glycerol, honey, lemon and other natural substances. These products will remain for general sale in supermarkets.[2]

N.B. Medsafe advises that preparations containing only bromhexine (mucolytic) or intranasal decongestants such as oxymetazoline and xylometazoline remain restricted to use in children aged over two years.[1]

Cough and cold preparations

Cough and cold preparations are designed to provide relief from the symptoms of viral respiratory infections.

Cough and cold preparations commonly contain:

- Mucolytics/expectorants which aim to loosen phlegm from the respiratory tract, making it easier to expel e.g. bromhexine, guaifenisin
- Antitussives which aim to decrease the urge to cough e.g. pholcodine, dextromethorphan
- Nasal decongestants which aim to reduce the amount of fluid reaching the nose and reduce swelling inside the nose e.g. phenylephrine, pseudoephedrine
- Antihistamines which are used based on the premise that they reduce similar types of symptoms in allergies (rhinitis, sneezing) e.g. promethazine, diphenhydramine

Limited evidence of effectiveness in children

Although widely used, cough and cold preparations containing any of these medicines, or combinations, are not particularly effective at reducing symptoms in children. Infection with the common cold affects children and adults differently, therefore products which may be effective for adults do not necessarily work in the same way for children. It is acknowledged that the placebo effect may play a significant role in the anecdotal success and popularity of using cough and cold preparations.

A recent review of over-the-counter cough preparations in children found that antitussives, antihistamines, antihistamine/decongestant combinations and antitussive/bronchodilator combinations were no more effective than placebo in alleviating symptoms of cough and cold. There was insufficient evidence to evaluate expectorants or mucolytics.[3]

There is no evidence to support the use of beta-2 antagonists e.g. salbutamol in children with acute cough with no airflow obstruction. They do not reduce the incidence or severity of cough.[4]

Harmful effects

Most cough and cold preparations contain either a CNS depressant (e.g. promethazine) leading to possible sedation, psychomotor impairment, dizziness and hallucinations or a CNS stimulant (e.g. phenylephrine) leading to possible insomnia, tremor, hallucinations and palpitations. Combination products increase the risk of CNS effects, resulting in additive drowsiness or paradoxical CNS stimulation. It is recommended that the use of CNS-acting medicines in children is avoided unless there is a clear need and benefit.

There is some suggestion that cough suppressants may cause retention of sputum. This can be harmful as the retained sputum then becomes a site for bacterial infection e.g. as in bronchiectasis.[5]

Other treatments for cough and cold

As parents begin to accept that cough and cold medicines may not be appropriate or effective for their child, other treatments are likely to be sought.

Consider paracetamol or ibuprofen

Paracetamol can be considered first-line for the treatment of pain and fever associated with cough and cold. **Ibuprofen** may also be significantly effective for associated headache, earache, muscle and joint pain, and could be considered for children as a second-line alternative to paracetamol.[6]

Saline

Saline drops or spray may be used as a nasal decongestant, particularly in younger children and infants. Commercial products are available (sodium chloride 0.9%). Alternatively a home-made salt water solution could be used: mix ¼ tsp salt with two cups of cooled, boiled water and administer using a small spray bottle, nasal dropper or syringe.

Honey

Honey is often suggested as a suitable treatment for cough and cold, largely due to its demulcent properties, which act to soothe the throat and mucous membranes. Honey* can be administered directly on a teaspoon or given as a warm honey and lemon drink. Lozenges are not recommended due to the risk of choking. Honey is not recommended in children aged under one year due to its rare association with infant botulism.[7]

A systematic review of the clinical effectiveness of honey for cough and cold symptoms, found that there was insufficient evidence to advise for or against its use.[8]

Honey was more effective in reducing frequency of cough and bothersome cough and improving sleep quality of the child, compared to no treatment. However, there was no difference between honey and no treatment, in reducing the severity of cough or the sleep quality of parents.[8]

Despite the lack of clinical evidence, honey can still be regarded as a safe treatment to trial for a child, aged over one year with cough and cold.

Aromatic inhalations and decongestants

Aromatic compounds such as menthol and eucalyptus oils can be added to warm water to create a vapour, which is inhaled to relieve congestion and ease breathing. This encourages inspiration of warm, moist air which can also provide comfort.[5]

A systematic review of steam inhalation used for the common cold in adults concluded that there was insufficient evidence to determine whether there was any beneficial clinical effect. For some people, the steam inhalation worsened the symptoms of congestion.[9]

*Any type of honey may be used

Table 1: Evidence of effectiveness of non-pharmacological treatments for cough and cold

Intervention	Study population	Conclusions
Echinacea	Adults and children receiving echinacea for prevention or treatment of the common cold, compared to placebo and other treatments	There is no evidence that echinacea prevents occurrences of cold. There was mixed evidence of echinacea as a treatment for cold, however overall no beneficial effect was shown. Echinacea medicines differ greatly (by species, parts of the plant used and manufacturing methods). There is some evidence that medicines based on the aerial parts of *E. purpurea* might be more effective than other medicines in adults.[11]
Garlic	Adults receiving either garlic supplement (180 mg allicin) or placebo daily for 12 weeks	A single trial suggested that garlic may prevent occurrences of cold, but does not reduce duration. More studies are needed to validate this finding.[12]
Vitamin C	Adults and children receiving ≥ 0.2 g vitamin C per day as prophylaxis or therapy after symptom onset for the common cold	There was some evidence that prophylactic vitamin C modestly reduced the duration and severity of cold symptoms. This effect was slightly greater in children (duration of cold reduced by 13% compared with 8% in adults). There was no evidence that therapeutic vitamin C reduced the duration of cold or alleviated symptoms. Routine prophylaxis or therapeutic use of vitamin C is not justified.[13]

If this treatment is to be trialled for a child, it is important not to use boiling water due to the risk of scalding. In addition, accidental ingestion of aromatic oils, even in small amounts, is associated with a significant risk of CNS depression (due to toxicity) and aspiration (due to volatility). Remind parents that aromatic oils and inhalation solutions should be stored out of reach of children.

Aromatic decongestant rubs (e.g. Vicks VapoRub) are also used to provide comfort. They may be applied directly onto the throat, chest or back or onto a pillow or clothing for children with sensitive skin. Aromatic rubs are not recommended for use in children aged less than three months.[5] Care must be taken to avoid ingestion due to the toxic nature of these products. There is no evidence that aromatic rubs have any clinically significant effect on cough and cold symptoms.

Ivy leaf extract

"Bronchial syrups" containing ivy leaf extract (*Hedera helix*) are commonly used throughout Europe for the treatment of cough and cold, and are gaining popularity in New Zealand. As this product is classified as a dietary supplement, there are no associated age restrictions for its use.

There is currently little evidence of clinical effectiveness of ivy leaf extract for treatment of cough and cold. A review of randomised controlled trials, testing the efficacy of ivy leaf extract in children with bronchial asthma, concluded that ivy leaf preparations have some effect on improving respiratory function, but there is insufficient evidence to make any recommendations for their use.[10]

Alternative remedies for cold prophylaxis and treatment

There is little evidence of effectiveness of products such as vitamin C, echinacea and garlic, which are commonly used for prevention and treatment of cough and cold (Table 1). These products are not recommended in children based on their lack of proven benefit.

Advice for parents

So if cough and cold preparations are not suitable for children and most alternative remedies lack evidence of effectiveness, what can parents actually do?

- Simple analgesia, such as paracetamol or ibuprofen, may be given as required for general aches and pains, fever and headache associated with cough and cold.
- For nasal congestion, a saline spray or drops can be effective and is well tolerated, without adverse effects. This is especially helpful in young children and infants.
- Honey (straight or added to a drink) may be trialled in children aged over one year, for the purpose of providing comfort.
- Provide general care such as encouraging rest, ensuring adequate fluid intake and keeping warm.

Cough and cold preparations are not recommended, but if they are used in children aged over six years, advise parents to follow dose instructions carefully. Do not give more than one type of medicine at a time and do not use for longer than five days.

Focus on environmental factors

One of the most important things that parents can do for their child with cough and cold, is to provide a "healthy home" environment.

Encourage parents to make their home smoke free. Children exposed to cigarette smoke are more likely to develop asthma, chest infections e.g. bronchiolitis, ear infections and many other health problems.[14]

Make sure the house is warm and dry. Heat pumps, wood pellet burners and flued gas appliances are preferable to multi-fuel or coal burners, electric heaters and unflued gas heaters, which are associated with the release of moisture, nitrogen dioxide and emissions into the internal environment. The New Zealand Healthy Homes study demonstrated that there was a significant improvement in the self-reported respiratory health of families who received retro-fitting of insulation in their homes.[15]

A "healthy home" environment also means that children are provided with warm clothing and good nutrition. Good hygiene practices e.g. hand washing, covering the mouth and nose with a tissue when coughing or sneezing, should also be encouraged to help prevent transmission of cough and cold to others in the household.

The Energy Efficiency and Conservation Authority (EECA) provides funding to assist people in insulating their homes and installing clean and efficient heating. Homeowners with houses built before 2000 are eligible. People in rental homes should speak to their landlords.

Local providers can be located on the EECA website: **www.energywise.govt.nz**

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DEPRESSION in Young People

Depression in Young People is activated for patients under the age of 18 years when the Depression module is opened.

Structured clinical assessment is the key to identifying both problems and protective factors in young people.

It is desirable to offer opportunities for the young person to speak alone to the GP.

Differentiating abnormal from normal behaviour

The following criteria can be used to help distinguish normal variations in behaviour from more serious mental health problems:

- **Safety**: there is a perceived risk
- **Duration**: problems last more than a few weeks
- **Intensity**: symptoms are severe and fixed, with a loss of normal fluctuations in mood and behaviour
- **Impact**: problems impact significantly on school work, interpersonal relations, home and leisure activities
- **Hypomanic episodes**: these may indicate bipolar disorder
- **Profound hopelessness**

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Immunisation in CHILDREN by age two years

PHO PERFORMANCE PROGRAMME

www.bpac.org.nz keyword: immunisation

Targets for immunisation in children aged two years and under

The PHO Performance Programme (PPP) was established to improve the health outcomes of people enrolled in general practice and to reduce inequalities, especially in high needs populations (Māori, Pacific peoples and those living in lower socioeconomic areas).

An important focus of the PPP for younger patients is to ensure that they are receiving their necessary immunisations, by the recommended age milestones.

It is imperative that the majority of children are immunised against selected serious diseases in order to ensure that re-emergence of these diseases does not occur. As well as achieving immunisation coverage, it is equally important that children are vaccinated on time. Delay in receiving the first infant vaccinations (at age six weeks) is associated with subsequent non-completion of the immunisation schedule.[1] Delays also increase the risk of contracting disease, e.g. one study found that children who had their pertussis vaccination delayed were four to six times more likely to be hospitalised for pertussis than those who received the vaccination on time.[2]

The PPP goal is for 85% or more of a PHOs enrolled population to have received their complete set of age appropriate vaccinations by their 2nd birthday.

The overall national immunisation goal set by the Ministry of Health is for 95% of children in New Zealand to be fully immunised by age two years.

Key concepts:

- An important focus of the PHO Performance Programme is for children to have received their necessary immunisations by the recommended age milestones
- A small minority of children are still not receiving these vaccinations and the reasons for this must be identified and addressed in order to reduce this disparity
- Barriers to vaccination include healthcare system factors e.g. access to appropriate services, healthcare provider factors e.g. inadequate communication and parent/carer factors e.g. fears and misconceptions
- Target interventions for people in the high needs group (Māori, Pacific peoples and those living in lower socioeconomic areas) in order not to increase disparities
- Effective communication and balanced information are essential to allay any fears and misconceptions

Immunisation rates reach 85% in 2010

Immunisation rates among children in New Zealand have been increasing over recent years. Latest data from the Ministry of Health shows that 85% of children in New Zealand that turned two between January and March 2010, had completed their age appropriate immunisations. Rates varied by DHB region, from 72% in Northland to 94% in Otago.

Immunisation rates by age two years also increased compared to previous years for the high needs population – Māori 80%, Pacific 87% and people living in Deprivation Level 9–10 (greatest level of deprivation) 82%.[3]

Although this data is encouraging, ongoing improvement in overall coverage rates is necessary and disparities are still apparent between population groups. Timeliness of vaccines also needs to be improved. Only 67% of children aged six months had completed their age appropriate immunisations (72% European, 53% Māori, 64% Pacific, 58% Deprivation Level 9–10, Figures 1 & 2) in March 2010.[3]

Identifying and addressing barriers to meeting immunisation targets

The development of vaccines has been one of the greatest advancements in modern medicine. Rates of childhood illness have decreased substantially, morbidity and mortality has reduced and disease epidemics have become rare. Diseases such as smallpox have been eradicated (except in laboratory settings) and others such as polio and measles are likely to disappear over the next few decades. The chance of surviving childhood today is considerably greater than even fifty years ago.

Despite this, a small number of parents still refrain from having their child immunised. The reasons for this can be grouped into three main categories:[4]

- Systems barriers e.g. access to services, appropriateness of services, cost
- Healthcare provider barriers e.g. inadequate knowledge about vaccines, lack of risk communication skills
- Parent barriers e.g. fears, misconceptions

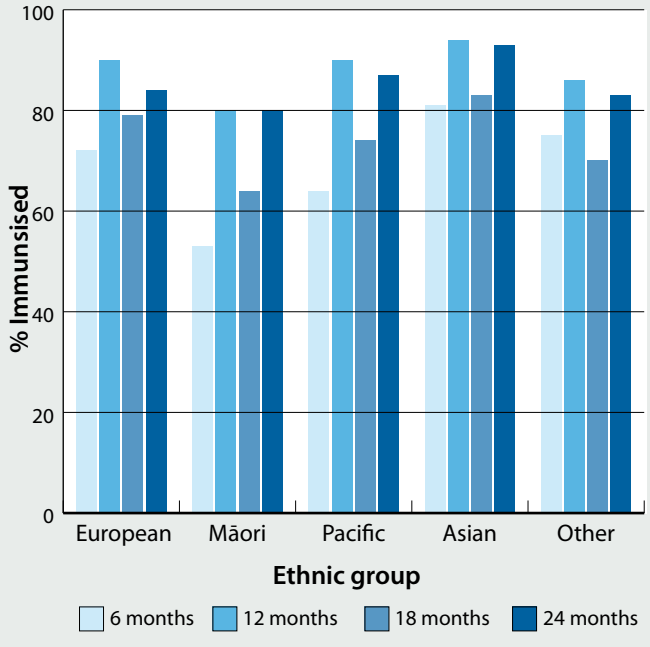

Figure 1: Immunisation coverage in New Zealand between January and March 2010, by ethnicity. [3]

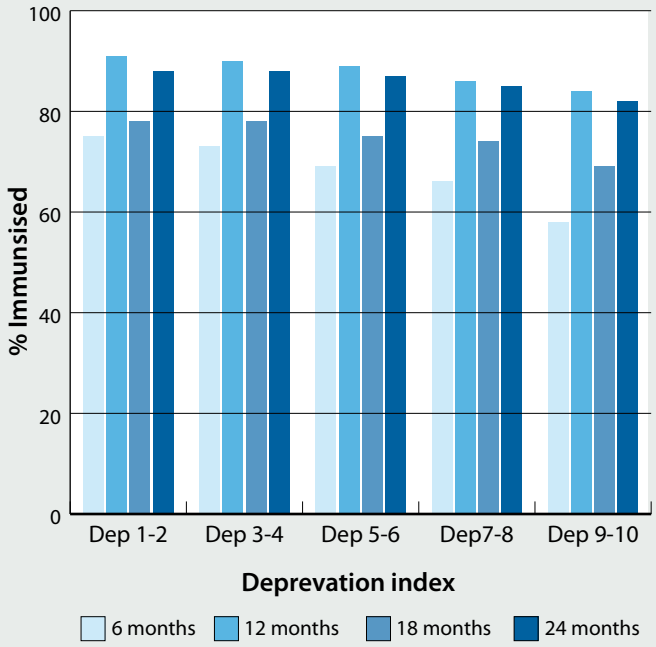

Figure 2: Immunisation coverage in New Zealand between January and March 2010, by deprivation level (Dep 1–2 = least deprived, Dep 9–10 = most deprived).[3]

Being aware of these barriers is a good first step, but awareness alone is not sufficient to overcome a barrier. Planning at a practice level is necessary to address issues and disparities. Key strategies include:

- Assess immunisation rates in your practice
- Develop approaches to increase rates of immunisation
- Educate families about the benefits and risks of immunisation
- Educate yourself about current routine and high risk schedule vaccine recommendations, non-schedule vaccines that are available, contraindications and adverse effects
- Educate yourself about the risks of diseases being vaccinated against

Addressing system barriers

High coverage rates for child immunisation relies on the premise that parents are aware of; the threat of illness, that vaccinations exist, that their child needs to be immunised and that they can access appropriate services. This is not always the case.

Even if the parent is aware that immunisation is necessary, not knowing where to go, inconvenient clinic hours, long waiting times and lack of personally appropriate services may all be barriers to receiving care. Immunisation schedules may be difficult to understand for some parents and they may be unclear as to what vaccines are necessary and at what time.

Also consider that new immigrants may not always be aware that vaccinations are necessary as all vaccines are not routine in all countries. They may require assistance with understanding the healthcare system and the New Zealand immunisation schedule, which can be further complicated by language barriers.

Cost is frequently a barrier to accessing services, especially in the high needs population. Visits to general practice for enrolled children under six may be subsidised or free in some practices, and vaccinations on the national immunisation schedule are funded. However, other costs may be incurred such as transport costs in getting to the practice, childcare costs and wages lost due to taking time off work. This may mean that taking a child for their vaccinations can become a low priority.

Target the high needs population to avoid increasing disparities

Although immunisation rates among the high needs population are increasing at an encouraging rate, they are still lower than the total population in many areas and there is still progress to be made. Specifically targeting initiatives to Māori, Pacific people and those living in lower socioeconomic areas, helps to avoid increasing disparities.

- Use your Patient Management System (PMS) to identify children aged under two years who have not been immunised or who are overdue for immunisations (including past-due for follow-up vaccines)
- Check the National Immunisation Register (see sidebar over page) to see if immunisation has been given by another provider or if there is a contraindication or decline recorded
- Send an invitation to attend the practice for immunisation
- Place an alert on the patient record to discuss with the parents next time they attend
- Consider approaches unique to your practice population

Try to avoid viewing people as “hard to reach”, think of them instead as hard to find, unconvinced, uninformed, undecided or under-immunised.

Consider ways in which your practice may be viewed as “hard to use” and ways in which these barriers can be addressed. Do you offer flexible clinic hours? Is your service child-friendly? Do you provide information in different languages?

The National Immunisation Register

The National Immunisation Register is an electronic record of immunisation details of children in New Zealand. It was launched in 2004/2005 so data covers immunisations for children born from the launch date in their area onwards. It can be used by authorised health professionals to determine what vaccines a child has been given and when. This is especially useful if the child sees multiple providers or has moved.

The register also records medical or personal reasons for not receiving a particular vaccine. Children are automatically enrolled at birth, but parents have the option of removing them from the register.

Providers can access records from the register through their PMS or by phone. Vaccination information can be provided back to the register via the PMS or a paper-based system.

Community outreach programmes

If a practice is unable to make contact with a child's parents after repeated attempts, it may be possible that they will respond to a community outreach programme. However it should be clear that this is a "last resort" option as it is important that all efforts are made to get the child and their family re-engaged with general practice.

A range of outreach services are available to increase immunisation rates among people who may have encountered barriers in accessing mainstream services. Services may be provided in community settings or in people's homes.

 Contact your local immunisation co-ordinator, DHB or PHO for details of these services.

Fragmented care and incomplete immunisation records

Information about immunisations may be delivered by a variety of providers including midwives, Plunket, Māori and Pacific Well Child nurses, practice nurses, GPs, hospital vaccinators and outreach services. This may mean that parents are well targeted with information and opportunities to vaccinate their child, but it can also lead to fragmented care, contradictory information, delayed and missed immunisations.

The number of different providers that may be involved in a young child's care also increases the likelihood of incomplete immunisation records. It may be unclear as to who takes responsibility for providing recalls, following-up missed immunisations and ensuring that children are not "lost in the system".

Keep immunisation records up-to-date

As the quality of data in the National Immunisation Register is dependent on the quality of data received from providers, ensure that an accurate record of immunisation is recorded in the PMS, including any adverse reactions. Also record any reasons for vaccination refusal. Aim for uniformity in data entry within a practice.

Parents receive a "Well Child" book for newborns, usually from the Plunket nurse. This contains information about the New Zealand immunisation schedule and a written record of vaccines that the child has received. It is important to encourage parents to use this book and to keep it up to date.

Enrol young patients early

The way in which maternity care is organised in New Zealand makes its difficult for general practices to sometimes even be aware that a patient has had a new baby. Often the first contact is when the parent brings the child in for their six-week old health check.

Most hospitals and maternity facilities will inform a patient's GP in writing, when she has a baby (if a GP is nominated). Consider using receipt of this letter as an opportunity to invite the mother to enrol the baby in the practice and provide information about immunisation. It is important to be aware if an infant is on a high risk immunisation schedule and requires extra protection from pneumococcal disease or is at risk of tuberculosis, e.g. a child with a medical problem or born to a mother who is hepatitis B positive.

If a mother presents to the practice while pregnant, make sure immunisation is discussed and create an expectation that the child will be enrolled in the practice when born.

A New Zealand study identified that children who are registered with their general practice at a younger age are more likely to subsequently complete the immunisation schedule.[1]

How to catch up if immunisations are missed

Firstly establish which immunisations have been given and when (use the National Immunisation Register if necessary). A catch-up regimen can then be commenced based on the current age of the child.

Immunisation catch-up schedules can be found in the 2008 National Immunisation Schedule Health Provider Booklet (Page 50).

If a child has come from another country, find out what the immunisation schedule is for that country and check they have received those vaccines. It is important to check by antigen rather than vaccine, e.g. some countries use single measles and rubella vaccines therefore a child would need MMR as a catch up to provide mumps protection.

If the child does not have a valid record of immunisation, start an age-appropriate catch-up programme based on vaccines on the New Zealand Immunisation Schedule.

For details of immunisation schedules of other countries, contact your local immunisation co-ordinator/ facilitator, medical officer of health or the Immunisation Advisory Centre (IMAC).

Addressing healthcare provider barriers

Missed opportunities and lack of time

In the course of a busy consultation it can be difficult to find time for preventive healthcare. Immunisation status is more likely to be checked at a well-child visit than a sick-child visit.

Asking about immunisation status and actively following-up on children who are have missed immunisations takes time, and is not always prioritised.

Even if immunisation is discussed, there is often not enough time in one consultation to provide the level of information and reassurance needed in order for some parents to understand and realise the importance of immunisation and feel comfortable with the decision.

Take every opportunity to ask about and encourage immunisation.

Patients rely on information about vaccines from their general practice. When a young child attends for any reason, take the opportunity to check whether they have been immunised and discuss the reasons why, if they have not been.

A – Ask

B – Briefly advise

C – Communicate effectively

Validate a parents decision to immunise their child, emphasise both personal and community benefits and encourage them to encourage others.

Knowledge gaps and communication difficulties

Some clinicians may find it difficult to stay current with the national immunisation schedule and newly available vaccines. Vaccinators are expected to be knowledgeable about indications, contraindications and adverse effects, as well as the risks of the diseases being vaccinated against.

The benefits of vaccination must be explained, while acknowledging the rare chance of adverse effects.[5] This can be endorsed with written resources e.g. brochures from the Ministry of Health.

There are only a few contraindications to vaccinations in young children (Table 1).[6]

There are also a few precautions to administering vaccines in young children (Table 2).[6]

There are also many **false** contraindications to vaccinations in young children, including:[6]

- Minor infections, without significant fever
- Asthma, hay fever, eczema
- Severe allergy to foods or medications unrelated to the vaccine (N.B. egg allergy is not a contraindication to MMR)
- Treatment with antibiotics or locally acting steroids (i.e. topical or inhaled)
- The child being over the usual age for immunisation
- The child's mother being pregnant
- Neonatal jaundice
- Prematurity in an otherwise well infant
- A child who is breast feeding
- Low weight in an otherwise healthy child
- Established neurological conditions such as cerebral palsy or Down syndrome

Table 1: Contraindications to vaccinations in young children [6]

Vaccine	Contraindications
All Vaccines	▪ Anaphylactic type reaction to a previous dose of that vaccine, or to any vaccine component
Pertussis-containing vaccines	▪ Encephalopathy within seven days after a previous pertussis-containing vaccine ▪ Evolving (undiagnosed) neurological problem*
Measles, mumps, rubella, MMR, varicella, yellow fever, oral polio	▪ Immunosuppression (e.g. cancer treatment, high-dose systemic steroids†) ▪ Receipt of blood, plasma or immunoglobulin in the last 11 months‡
Influenza, yellow fever	▪ Anaphylactic reaction to chickens, including eggs, egg protein, feathers.

* To avoid any implication of the vaccine in brain damage

† Exact dose of steroid is not well defined but in general a daily dose > 2 mg/kg or > 20 mg, taken for >14 days is a contraindication to live vaccines and may reduce the immune response to other vaccines[7]

‡ To avoid a suboptimal immune response

- Family history of vaccine reactions, seizures or Sudden Infant Death Syndrome
- Contact with an infectious disease
- Clinical history of pertussis, measles, mumps or rubella (clinical history without laboratory confirmation can not be taken as proof of immunity)

Addressing parent barriers

Many of the serious diseases, for which vaccines exist, have now reduced in occurrence to the point where most people have no experience of their impact. When media coverage focuses on rare adverse effects and hypothesised negative health associations of vaccines, it makes it more difficult to justify their use to some parents.[5]

Anti-vaccine lobby groups campaign strongly and can easily convince parents who lack balanced information, not to immunise their child. These groups claim that vaccines do not eradicate or significantly reduce disease (it is simply a coincidence) or that vaccines themselves cause disease (e.g. autism). Many of these groups also advocate homeopathic "vaccines" (water containing the "memory" of molecules), dangerously compromising the health of children.

Overcome barriers through effective communication

To effectively communicate the benefits and risks of immunisation to parents, it must first be established what factors are affecting the parents acceptance and perception of these benefits and risks.[5]

Listen to, and acknowledge, parents concerns about immunisation, provide clear and balanced information, respectfully correct any misinformation and build a trusting relationship. It may take several appointments before some parents are convinced or ready for their child to be immunised. Let parents take the time to feel prepared, do not rush them, encourage questions, let them have time to absorb the information.

Not knowing what to expect

Parents may be unsure about how vaccinations are given and fear that it will cause undue pain and suffering for

Table 2: Precautions when administering vaccines in young children [6]

Precaution	Explanation
Giving a live vaccine less than four weeks after another live vaccine (unless given on the same day)	There is a theoretical risk that administering a live virus vaccine (e.g. MMR, varicella) within four weeks of another live virus vaccine, will result in a suboptimal immune response. This does not apply to live vaccines administered on the same day, which is acceptable.
Allergy to vaccine components	Provided there is no history of anaphylaxis, allergies to vaccine components, e.g. asthma following exposure to feathers, or a rash following consumption of eggs, should be treated as a precaution only. A longer period of observation following immunisation is recommended.
Thrombocytopenia or history of thrombocytopenic purpura and MMR	In most circumstances, the benefits of vaccination are greater than the potential risks and giving MMR is justified, particularly in view of the even greater risk of thrombocytopenia following measles or rubella.
Haemophilia and related bleeding disorders	Children with haemophilia and related bleeding disorders should be immunised. In some cases of severe haemophilia the vaccine can be given subcutaneously rather than intramuscularly. Prophylaxis should be given on the same day as the vaccine. Consult a haematologist for advice if required.

New Zealand immunisation schedule for children

The National Immunisation Schedule is now reviewed every three years by an expert advisory committee and changes are made as new, effective vaccines become available. The next schedule review is due in 2011.

The National Immunisation Schedule	
Age	Diseases covered and Vaccines
6 weeks	Diphtheria / Tetanus / Pertussis / Polio / Hepatitis B / Haemophilus influenzae type b **- 1 injection (INFANRIX®- *hexa*)** Pneumococcal **- 1 injection (Prevenar®)**
3 months	Diphtheria / Tetanus / Pertussis / Polio / Hepatitis B / Haemophilus influenzae type b **-** **1 injection (INFANRIX®- *hexa*)** Pneumococcal **1 injection (Prevenar®)**
5 months	Diphtheria / Tetanus / Pertussis / Polio / Hepatitis B / Haemophilus influenzae type b **- 1 injection (INFANRIX®- *hexa*)** Pneumococcal **- 1 injection (Prevenar®)**
15 months	Haemophilus influenzae type b **- 1 injection (Hiberix™)** Measles / Mumps / Rubella **- 1 injection (M-M-R® II)** Pneumococcal **- 1 injection (Prevenar®)**
4 years	Diphtheria / Tetanus / Pertussis / Polio - **1 injection (INFANRIX-IPV™)** Measles / Mumps / Rubella **- 1 injection (M-M-R® II)**
11 years	Diphtheria / Tetanus / Pertussis **1 injection (Boostrix™)**
12 years girls only	Human Papillomavirus **** - 3 doses given over 6 months (GARDASIL™)**
Hepatitis B and Human normal immunoglobin at birth if mother hepatitis B positive BCG vaccine if assessed at risk for tuberculosis if under six months or Mantoux test if assessed at risk between six months and five years prior to BCG vaccine Extra pneumococcal protection for high risk under fives at age two and three to five years of age Annual influenza protection from age six months if high risk	

their child. Parents should be fully informed and involved in the vaccination process. Uncertainties and negative experiences shared with whānau and friends can cause this barrier to become widespread.

To allay fears about vaccine administration show parents the needles and equipment for vaccination, explain what will happen and tell them they are welcome to bring a support person if they are likely to be upset by the vaccination procedure for their child.

Parents often like to hold their child in the "cuddle" position during vaccination. Mothers may wish to breastfeed immediately afterwards and they should be supported to do so. Some parents prefer not to hold their child during vaccination, so if possible arrange an appointment when another practice staff member is able to assist.

Explain that adverse effects are usually mild and transitory (Table 3). Make sure the parent knows that they will be required to wait at the surgery for at least 20 minutes after the vaccination for observation to ensure there is no severe allergic reaction.

In the past some practitioners would use paracetamol prophylactically at the time of vaccination, however research now suggests that this may lessen the effectiveness of the vaccine.[8] Therefore paracetamol is only recommended after vaccinations if distress from fever, pain or irritability occurs.

See BPJ 25 (Dec, 2009). "Reconsider paracetamol use post-vaccination" for further information.

Table 3: Adverse effects of vaccine administration

Common	Rare
Redness, swelling, soreness at injection site Fever and irritability	Allergic reactions to components (e.g. egg, yeast, gelatine, neomycin) Febrile seizures Sterile abscesses

Common fears and misconceptions

One of the main barriers to vaccination for some parents is the fear that the vaccine itself will cause harm to the child. This is despite the fact that the risk of adverse effects from vaccination is extremely low compared to the risks to the child if they contract the disease.

A common fear is that vaccine administration causes the onset of neurological conditions such as autism. There is no evidence that there is a causative association between vaccinations and autism. Signs and symptoms of autism-spectrum disorders often become apparent at a similar time in the child's life to when they are receiving vaccines, therefore an association is assumed.[5]

Thiomersal (ethyl-mercury, also known as thimerosal) was used as a preservative in some older vaccines. There was concern expressed that the mercury exposure associated with receiving a thiomersal containing vaccine, would result in the development of autism. Multiple epidemiological studies have found no association between thiomersal and autistic-spectrum disorders. Modern vaccines contain either no thiomersal or only minute traces.[5] All vaccines on the current New Zealand immunisation schedule are thiomersal free.

Another misconception is that vaccination is linked to the development in later life of chronic diseases such as asthma, diabetes or multiple sclerosis. Again, there is no evidence of these associations.[5]

Fear of weakening the immune system

Some parents believe that administering too many vaccines at once weakens the immune system because it is "overloaded" with antigens. In actual fact, modern vaccines now contain lesser amounts of antigens. There are only about 50 antigens in the current, combined children's vaccines compared to 3000 in the one whole cell pertussis vaccine, which is no longer used. In addition, the burden to the immune system of contracting any one of the diseases being vaccinated against is much greater.[5]

The danger of association

In early 2010, the Lancet withdrew a 1998 observational study of eight children by Dr Andrew Wakefield and colleagues. The results of the study raised the hypothesis that there was a connection between the Measles, Mumps and Rubella (MMR) vaccine and autism and inflammatory bowel disease. Many subsequent studies on hundreds of thousands of children by other researchers failed to replicate the results. It was later determined that Wakefield had serious conflicts of interest and had allegedly "fixed" the results of the study, however by this time serious consequences had already occurred. Media attention from Dr Wakefield's original hypothesis resulted in a significant decline in vaccination rates and a rise in the cases of measles among children in the United Kingdom, including at least four deaths.

Religious objections

Some people may have religious objections to using vaccines, e.g. concerns over the original viruses for some vaccines being grown in cell lines from aborted foetal tissues (single antigen rubella vaccine, MMR vaccine, single antigen chickenpox vaccine and Hepatitis A vaccines). However most religious leaders are of the view that the source of the cell line was not the choice of the parents and that the only viable option to protect their child and the community from these diseases is to use the vaccine.[9] Parents should be encouraged to discuss any concerns with their religious leaders.

Cultural beliefs

For some cultures, visits to healthcare providers do not occur until there are symptoms, therefore protecting against a possible future occurrence of disease is not considered. Many also believe that prevention can be achieved through maintaining a good diet, achieving good spiritual balance and using traditional remedies that promote health. It is important to be respectful of cultural beliefs, but also to provide a balanced viewpoint on the importance and necessity of vaccination. Consider seeking the assistance of culturally specific healthcare providers.

Misconception that natural immunity from disease exposure is superior

Some parents believe that vaccines are not natural and that it is much better for a child to contract a disease and subsequently become immune (e.g. chicken pox "parties"). Others may believe that they are able to control their child's exposure to disease through environmental factors, therefore immunisation is unnecessary.

Parents can justify the choice not to immunise the child by believing that if the child becomes ill from an adverse reaction to a vaccination, it is their fault but if they become ill from a disease, it is an act of nature and therefore they are not to blame.[5]

A child who is not vaccinated is being placed at undue risk of contracting a virus which can cause serious harm or even death. In addition, contracting a virus does not necessarily infer that the child will become immune.

"Other children are immunised so mine does not have to be"

Parents may rely on the fact that the majority of other children are immunised to protect their own child. However, this simply increases the risk for everyone, by increasing the circulation of disease.

Herd immunity occurs when a certain proportion of the population is vaccinated against a disease, significantly reducing the spread of that disease and consequently providing protection to unvaccinated people. The exact proportion of people needed to be vaccinated for herd immunity to occur is different depending on the disease, but is usually around 95%. Only a small proportion of

people can remain unvaccinated to retain herd immunity in a population. This relies upon the majority of healthy individuals being vaccinated, thus protecting those who cannot receive vaccines due to serious medical conditions e.g. immune disorders and organ transplants are contraindications for live vaccines.

In New Zealand, there continue to be outbreaks of diseases such as measles and pertussis. This is because herd immunity of the population is not sufficient, due to lack of vaccination in some communities.

Non-schedule vaccines

There are several vaccines available that are not currently part of the National Immunisation Schedule, but are available for purchase by parents. Varicella (chicken pox) and rotavirus vaccines are not presently funded, but are used in many other countries schedules and are predicted to be part of the New Zealand immunisation schedule in the future (although they will not be on the next schedule change in 2011).

Meningococcal C vaccine, which is used in many other Western countries (as part of their immunisation schedules) is available for purchase in New Zealand. Travel vaccines such as hepatitis A may be given but check the age for licensure e.g. typhoid vaccine is not given under age two.

Varicella

Varicella zoster virus (human herpes virus type 3), otherwise known as chickenpox, affects an estimated 90% of children in New Zealand. It has a peak incidence between age five to nine years, although with more children attending pre-school and day care facilities, peak incidence may now be occurring at an even younger age. Varicella is highly infectious and can be transmitted to around 85% of those who have close contact with an infected person.[10]

Varicella causes fever, general unwellness and an itchy, full body rash lasting for one to two weeks. The disease is usually mild but it can cause serious illness and complications such as cerebellitis, aseptic meningitis and pneumonia in some children (even in previously healthy children). Varicella is usually more severe for adolescents, adults, people who are immunosupressed (including taking oral steroids), people with skin conditions or recent sunburn, people with asthma or other lung conditions and smokers/smoking households.[10]

Contracting varicella during pregnancy is associated with some significant risks to the foetus. Varicella during weeks eight to twenty of pregnancy is associated with a 0.7–2% risk of congenital varicella syndrome. This can result in scarring, blindness, growth

retardation, limb and cranial malformations, delayed development, mental retardation, spontaneous abortion or foetal death. If the mother has varicella during weeks 25 to 36 of pregnancy, there is a 0.8–1.7% risk of the child developing herpes zoster infection (shingles) during infancy. In addition, there is a 17–30% risk of serious disease for a newborn if the mother has varicella in the period ranging from five days before to two days after birth.[10]

Therefore, reasons to consider varicella vaccination include the potential risk of serious complications of the disease, and the subsequent risks to non-immune adults, particularly pregnant women and people who are immunocompromised.

Varicella vaccination may be administered in children aged nine months to 13 years (single dose), who have not previously had the illness. It may be given at the same time as other vaccines including MMR, DTaP, hepatitis B and meningococcal C conjugate. Children aged 14 years or older and adults receive two doses of the vaccine.

Immunocompromised children (e.g. undergoing treatment for cancer) cannot be given varicella vaccine as it is a live vaccine, however these children are at particularly high risk and it is important to offer vaccination to close contacts. As with all live vaccines, varicella vaccine is contraindicated during pregnancy and if not given simultaneously with other live vaccines e.g. MMR, it should be given at least four weeks apart.

The cost of the vaccine is approximately $90 per dose.

Tetravalent vaccines including measles, mumps, rubella and varicella (MMRV) are currently available overseas and are likely to be available in New Zealand within the next few years.

Rotavirus

Rotavirus infections are the most common cause of diarrhoea in children aged under two years. It is estimated that almost all children will be infected by age three years.[10]

Symptoms include watery diarrhoea, vomiting, fever and abdominal pain, lasting for up to eight days. Significant dehydration and metabolic acidosis occur in approximately 1–2% of infected children.[10]

Children do not become immune after infection with rotavirus, but subsequent infections are usually less severe. Most adults infected with rotavirus do not have any symptoms.[10]

Rotarix and RotaTeq are oral rotavirus vaccines currently available in New Zealand. The first dose is given between age six and fourteen weeks and the second dose given around four weeks later (but before age 24 weeks). The vaccine is administered orally, to the inside of the cheek, using an applicator. The dose may be repeated if the child spits or regurgitates most of the liquid. Rotavirus vaccine may be administered at the same time as DTaP, Hib, IPV, Hep B and pneumococcal conjugate (i.e. routine paediatric vaccines).

Rotavirus vaccine does not protect against non-rotaviral gastroenteritis or diarrhoea due to other causes.

The cost of the vaccine is approximately $140 per dose.

Resources

Immunisation Advisory Centre. Free phone: 0800 IMMUNE (0800 466863) or visit:
www.immune.org.nz

Paediatric Society of New Zealand: Kids health.
www.kidshealth.org.nz

Ministry of Health. Immunisation
www.moh.govt.nz/moh.nsf/indexmh/immunisation-diseasesandvaccines

World Health Organisation:
www.who.int/topics/immunization/en

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Donepezil to be funded on pharmaceutical schedule

PHARMAC recently announced that donepezil, a medicine used in the treatment of Alzheimer's disease, is to be funded on the pharmaceutical schedule. Donepezil (brand name Donepezil-Rex) will be available for prescription by any prescriber, and will not require Special Authority approval or specialist recommendation. The exact date of funding has not yet been determined.

Donepezil is a specific and reversible inhibitor of acetylcholinesterase, registered in New Zealand for the treatment of mild, moderate and severe Alzheimer's disease and vascular dementia (dementia associated with cardiovascular disease). However most international guidelines recommend that donepezil is used only for the symptomatic treatment of moderate Alzheimer's disease (rated by a MMSE* score of 10 – 20).

Efficacy of donepezil in Alzheimer's disease

Donepezil has been shown to have a modest beneficial effect in some people with mild to moderate Alzheimer's disease. Minor improvements in daily activity scores and cognition test results have been observed (e.g. an improvement of two to three points on the 70 point ADAS-cog† score and one to two points on the MMSE).

Trials that have compared donepezil with placebo have generally been of short duration (12 – 60 weeks) and long term benefits have not been shown. However, it is clear that in some patients donepezil provides modest improvements or delays in progression of Alzheimer's disease for up to six months or more.

Although not a requirement for funding, it is recommended that donepezil is only prescribed by practitioners experienced in the treatment of patients with dementia. It is important to obtain a baseline evaluation of cognition using ADAS-cog or MMSE and continue monitoring during treatment.

Dose

The starting dose of donepezil is 5 mg daily for the first month, increasing to 10 mg daily if necessary. The higher dose may be slightly more effective in some patients but dose related adverse effects may increase.

Adverse effects and drug interactions

In clinical trials, dropout rates for patients taking donepezil were significantly higher (about 30%) than those taking placebo. The most common adverse effects are nausea, vomiting and diarrhoea.

The hepatic metabolism of donepezil involves the enzymes CYP3A4 and possibly CYP2D6. Drugs that inhibit CYP3A4 such as erythromycin and fluoxetine may increase the plasma concentration of donepezil but the clinical significance of this is unknown. Donepezil may interfere with actions of anticholinergic drugs.

For more information refer to the medicine safety data sheet, available from: www.medsafe.govt.nz/Profs/Datasheet/DSForm.asp

Further information about donepezil and the pharmacological management of Alzheimer's disease will be covered in a future edition of Best Practice Journal.

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* Mini Mental State Examination

† Alzheimer's Disease Assessment Scale-cognitive subscale

Dextropropoxyphene - finding alternatives

From August 1, 2010 dextropropoxyphene (combined with paracetamol in Paradex and Capadex) will no longer be approved for use in New Zealand. Patients who continue to require treatment will need to be prescribed an alternative analgesic.

There is no robust evidence that dextropropoxyphene combined with paracetamol is any more effective than paracetamol alone, for either acute or chronic pain.

Review analgesic requirements

Review the patient's medical history and ascertain the type and severity of pain they are experiencing. If a recent review has not taken place, symptoms may have resolved or ameliorated. Most people taking dextropropoxyphene are likely to have mild to moderate pain which responds well to paracetamol, a weak opioid or low dose NSAIDs.

A recent time series analysis looked at the impact of the discontinuation of dextropropoxyphene containing products in the UK.[1] Over the two years following discontinuation, there was a significant increase in the number of prescriptions for paracetamol, codeine and paracetamol/codeine products, but not tramadol. These observations indicate that most patients can be successfully switched to regular full dose paracetamol (1 g, four times daily).

If paracetamol alone is not sufficient, a low dose NSAID (e.g. Ibuprofen 200 – 400 mg three times daily) can be added to, or used instead of paracetamol.[2] NSAIDs should be used at the lowest possible dose for the shortest possible time. If an NSAID is contraindicated or if there are safety concerns, a weak opioid such as codeine can be added to full dose paracetamol.[2] Preparations containing a combination of paracetamol with codeine can be tried initially, but the amount of codeine may be insufficient to add to the analgesic effects of paracetamol alone. A full dose of 30 – 60 mg codeine, up to four times daily, may be required.

It is not necessary to calculate opioid analgesic dose equivalents when switching from dextropropoxyphene.

For more information on the use of weak opioids for pain see "WHO analgesic ladder: which weak opioid to use at step two", BPJ 18 (Dec, 2008).

If these combinations are not effective in controlling pain, a strong opioid may be indicated. The strong opioid of choice is morphine. However, it is very unlikely that morphine will be required for anyone previously taking dextropropoxyphene.

A relatively small number of patients may need referral; to a pain clinic for complex pain syndromes, or to a drug and alcohol centre if dextropropoxyphene is being misused.

Tramadol and oxycodone - not logical alternatives

Tramadol and oxycodone should not be considered as first line alternatives to dextropropoxyphene. Although tramadol has recently been funded on the pharmaceutical schedule, it is NOT because it is intended to replace dextropropoxyphene. Tramadol is an alternative to first line weak opioids, such as codeine, if these are not tolerated or are contraindicated. Oxycodone is a strong opioid and is only recommended as an alternative to morphine for severe pain.

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Vitamin D, oral health and pregnancy

Dear bpac,

In your recent article "Common issues in paediatric oral health" (BPJ 27, April 2010), I was surprised that the importance of vitamin D in dental and gingival health was not mentioned.

I think doctors should be aware that vitamin D does not only affect bone health, but oral health too. It appears to be important in the brain of the developing foetus and may have a preventative effect against child autism and type 1 diabetes.

–Dr Richard Coleman, GP
Auckland

Oral health

The question of vitamin D and oral health is an interesting one. Historical research in the 1920s and 1930s suggested that sufficient nutritional intake of vitamin D was a factor in resistance to dental caries. However other research contradicted this finding and it was accepted that additional dietary factors (sugars, fermentable carbohydrates and fluoride) had a much greater impact on dental caries.

More recently (1989), researchers investigated the effect of ultraviolet light on the incidence of dental caries in Alberta, Canada. They found reduced incidence of caries in children exposed to full spectrum lighting in classrooms at school.[1] The hypothesised mechanism behind this is that salivary flow is increased in light compared to darkness, and therefore the increased classroom lighting increased the production of saliva, which is protective against dental caries. This study has not been replicated and remains to be corroborated by further research. However it is of interest in these days where sun exposure may be limited due to avoidance and sunscreen usage.

With respect to gingival health, several observational studies have found an association between low plasma concentrations of vitamin D and increased markers of periodontal disease such as gingival inflammation, bleeding and gum pocket depth.[2, 3] A recent cross sectional study indicated a trend towards better periodontal health in people taking vitamin D with calcium supplements.[4] Further studies are required to clarify the relationship between vitamin D status and oral health but it is reasonable to assume that low vitamin D status is associated with increased risk and severity of periodontal disease.

Good nutritional intake is necessary for general oral health. However, there is currently no evidence that supplementation of vitamin D, over and above normal dietary intake and exposure to sunlight, provides additional benefits in terms of oral health.

Pregnancy

It is well accepted that vitamin D is important for maternal and foetal health during pregnancy. Low levels of vitamin D may adversely affect foetal bone growth and accumulation of newborn vitamin D stores. Rickets is a clinical marker of poor pre- and post-natal bone health caused by vitamin D deficiency.

Current research and epidemiological studies are now looking into the possible association between low levels of maternal vitamin D at birth and later development of autoimmune disorders such as multiple sclerosis and diabetes. It has also been suggested that low vitamin D levels during pregnancy are a possible risk factor for autism. This hypothesis is based on the fact that vitamin D inhibits excessive cell proliferation in a number of tissues, including the brain and therefore an absence or deficiency of vitamin D would result in neuronal overgrowth, a suggested key feature of autism.[5] Further research is required to provide conclusive evidence for or against these hypotheses.

Although it remains to be seen if vitamin D deficiency will be implicated as a cause of illnesses such as type

1 diabetes and autism, maintaining adequate vitamin D levels during pregnancy, and in newborns, is important. The current recommendation of 200 IU of vitamin D per day during pregnancy is viewed by most experts as a gross underestimation of actual need. What this level of supplementation should be is still unclear but a large, multi-year, double-blinded, placebo controlled trial of supplementation up to 4000 IU per day is currently underway.

For more information about the vitamin D trial visit: **http://clinicaltrials.gov (Trial # R01HD 043921)**

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