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SPECIAL FOODS

Infant formula • Nutrition in Coeliac Disease, Diabetes, COPD and Elderly People • Vitamins and Minerals • The Folic Acid Debate

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INTRODUCTION

IN THIS EDITION OF BPJ we explore the issues of nutrition from a number of perspectives. GPs may be involved with the care of patients receiving nutritional supplements and tube feeding formulations, however most would admit to gaps in their knowledge about indications, access and problems associated with administration.

Many groups require nutritional support or total replacement (for example with enteral tube feeding), and the reasons are numerous, ranging from substitution for breast milk to nutritional support in the very elderly. Allergies or food intolerance may dictate the use of specific preparations and metabolic deficiencies or chronic diseases may require special foods to sustain life.

These preparations are covered in the nutrition section of MIMS and the Special Foods section of the Pharmaceutical Schedule. There are a large number of preparations available (there are around 100 supplemental and enteral nutrition products and around 40 infant formula listed on MIMS) and it is often difficult to know when and what preparations should be considered. Furthermore, a number of these preparations (or very similar products) are also available in supermarkets.

Generally, the funded special foods that are available on the Pharmaceutical Schedule can only be initiated on the prescription of relevant specialist and most have to be obtained from a hospital pharmacy. However, a GP may be in the front-line when it comes to questions about changes in nutritional status and problems with access or administration.

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What side is your bread buttered on?

Mandatory fortification of bread with folic acid: the debate

In 2007 the New Zealand Food Safety Authority authorised the fortification of bread with folic acid with the primary purpose of decreasing the number of pregnancies affected by neural tube defects.[1] Bread manufacturers were given a transition time for implementation within two years, with full compliance expected by September 2009, with the exception of organically made bread. The level of fortification was set at 80–180 micrograms folic acid per 100g of bread.

The facts

- The last National Nutrition survey in 1997 showed that the median daily folate intake from food for New Zealand women aged 25–44 years was 213 micrograms. This is below the 400 micrograms per day recommended for women planning a pregnancy and 600 micrograms per day for pregnant women.[2]
- In addition to dietary intake, women planning pregnancy or who are in the early stages of pregnancy, are recommended to take a 800 micrograms folic acid tablet daily for at least four weeks before, and 12 weeks after conception.[3] Supplementation during this period is still necessary even if folic acid fortified bread is consumed. Also see page 34: folic acid supplements
- Not all cases of neural tube defects can be prevented. A daily intake of 400 micrograms of folic acid reduces the risk of neural tube defects by about 70%.
- The proposed level of fortification is expected to increase average daily folic acid intakes among women of childbearing age by 140 micrograms per day.[4] This would meet about 25% of the recommended intake and is estimated to result in a reduction of between four to 14 neural tube defect affected pregnancies in New Zealand each year.

The debate

The case against: Bread should not be fortified with folic acid because there is doubt that women would eat enough bread to have a significant effect on folate levels, there are safety concerns for some groups of people and freedom of consumer choice is compromised.

Professor David Smith, summarises his views as follows:

> "Are the benefits to a few outweighed by possible harm to some of the many exposed?
>
> Increased folic acid intake leads to elevated blood concentrations of naturally occurring folates and unmetabolised folic acid. Unmetabolised folic acid may be related to decreased natural killer cell cytotoxicity, and increased folate may reduce the response to antifolate drugs used for malaria, rheumatoid arthritis, psoriasis and cancer. In elderly people, high folate levels in combination with a vitamin B12 deficiency, may be associated with an increased risk of cognitive impairment and anaemia. Folate protects against cancer initiation but facilitates progression and growth of pre-cancerous cells and subclinical cancers.
>
> Nations considering fortification should be cautious. Further research is needed to identify the effects, good and bad, caused by

a high intake of folic acid. Only then can authorities develop the right strategies for the population as a whole."

— **David Smith**, Professor of Pharmacology, Department of Physiology, Anatomy and Genetics, University of Oxford, UK.

One of the primary concerns surrounding mandatory folic acid fortification is the possible negative effect on the incidence of cancer.[5, 6] Although folate could prevent cancer in healthy people, an accumulating body of evidence suggests that it might also promote the progression of pre-malignant and malignant lesions.[6, 7]

There is also concern about potential adverse effects of circulating blood levels of "free" or unmetabolised folic acid. Evidence indicates that moderate intakes of folic acid supplements may exceed the body's capacity to convert folic acid to the forms of folate that are used for metabolism. This leads to "spillover" and the appearance of unmetabolised folic acid in plasma.[8, 9] The consequences of this are unknown but could, theoretically, be detrimental as the interaction of folic acid with folate receptors and folate binding proteins differs from natural food folates. For example, in a cross-sectional study of post-menopausal women, unmetabolised folic acid from dietary sources and supplements compromised natural killer cell cytotoxicity – a potential first line defense against cancer.[10]

Associate Professor Mark Lawrence says:

"Mandatory folic acid fortification is associated with many scientific uncertainties and ethical dilemmas. By their own calculations Food Standards Australia New Zealand have estimated that this policy will prevent just 8% of neural tube defect cases in Australia and New Zealand - in other words 92% of cases will NOT be prevented with this policy. It has been reported that other approaches such as promoting folic acid supplement use may be more effective, unfortunately there has been little sustained investment in such alternative approaches.

There are a number of potential risks associated with raising the population's exposure to folic acid. These potential risks include the masking of the clinical symptoms of vitamin B12 deficiency, particularly among older adults, and a possible relationship with promoting the progression of bowel cancer. In addition, mandatory folic acid fortification will compromise consumer choice and unless they choose organic bread, all children, teenagers, adults and elderly people who consume bread will be exposed to raised levels of synthetic folic acid. The most critical issue now is for adequate and timely monitoring and surveillance mechanisms to be put in place, so that the potential risks and benefits associated with mandatory folic acid fortification can be evaluated into the future."

— **Mark Lawrence**, Associate Professor of Public Health and Nutrition, School of Exercise and Nutrition Science, Deakin University, Australia.

Professor Jim Mann says:

"The risks of fortification are small but so is the evidence for benefit in a country like New Zealand. If fortification is introduced, then monitoring is essential."

— **Jim Mann**, Professor of Human Nutrition and Medicine, University of Otago, New Zealand.

The case for: Bread should be fortified with folic acid to reduce the incidence of neural tube defects. This is a good way to ensure that women of child bearing age have satisfactory levels of folate, should they become pregnant.

Professor Max Kamien has long been an advocate for the fortification of staple foods to eliminate deficiency diseases. He says:

"Despite evidence of the beneficial effects of fortification, any attempt to improve the public's health by "tampering" with their food or water

invariably provokes a predictable and repetitive pattern of opposition. Opponents of fortification ask if it is ethical to medicate a conscious and mentally competent adult without obtaining their informed consent – they do not ask if it is ethical to deny potential benefits to populations and socioeconomic classes at risk.

In the case of folic acid, the problem with public education campaigns is that the information has to reach the public, they have to act on it and women have to know when they wish to fall pregnant. There is a persisting fear that folic acid fortification will mask the development of pernicious anaemia in elderly people and therefore lead to neurological damage. However experience in 50 countries that have mandatory fortification with folic acid has not shown any apparent increase in neurological disorder."

— **Max Kamien**, Emeritus Professor of General Practice, University of Western Australia.

Evidence shows that mandatory folic acid fortification programmes in other countries have significantly reduced the incidence of neural tube defects in infants. In addition, concerns that folic acid supplementation could mask pernicious anaemia and cause cancer have not been substantiated to date. There have been no reports of population level adverse effects from more than 50 countries with mandatory fortification programmes.

A mandatory folic acid fortification programme introduced in the United States and Canada over ten years ago has resulted in significant increases in dietary intakes and blood measurements of folate in the general population.[11] Marked reductions in rates of neural tube defects (19–49%) have occurred across North America.[12-14] A recent population study from Canada found that the prevalence of neural tube defects decreased from 1.58 per 1000 births before fortification to 0.86 per 1000 births post-fortification.[12]

A substantial proportion of women remain unaware of the need to take folic acid during the periconceptional period, and an even higher proportion is not implementing the recommendations despite sufficient knowledge.[15]

Professor Murray Skeaff offers the last word:

"Should we have folic acid fortification of bread? Yes! But it must be accompanied with a systematic programme to promote folic acid supplement use by women of child bearing age inasmuch as supplement use – even if only for planned pregnancies – will prevent more neural tube defects than fortification. Supplement use delivers the right dose at the right time but only to women who take them – therein lies the rub. Fortification reaches all women but delivers considerably less than the optimal dose. Folic acid fortification will prevent some neural tube defects, however, there is considerable uncertainty about how many neural tube defects will be prevented in New Zealand. The prediction is seven each year, however, it may be as low as four or as high as 14."

— **Murray Skeaff**, Professor of Human Nutrition, Head of Department Human Nutrition, University of Otago, New Zealand.

The verdict: Discuss with your colleagues, have a practice debate. Let us know your verdict.

Email **rebecca@bpac.org.nz**

See page 32 to read more about "Vitamins and minerals: dietary sources, supplements and deficiencies".

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Dr Lisa Houghton is a lecturer at the Department of Human Nutrition, University of Otago, New Zealand.

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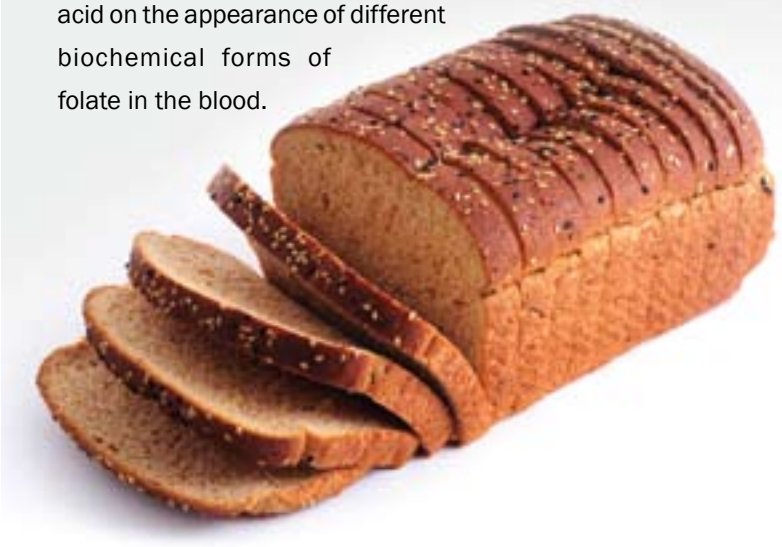
Monitoring the folic acid fortification programme

As part of the fortification programme, the Food Safety Authority of New Zealand will implement a monitoring strategy to "maintain a watching brief on any scientific developments which may potentially alter the understanding of risk to public health and safety".[4] However there is currently a lack of baseline data on the folate status of the New Zealand population.

Research has begun at the Human Nutrition department of the University of Otago to measure the increase in plasma and red blood cell folate concentrations in New Zealand women. This will enable a more accurate prediction of neural tube defects that will be prevented. It will also provide a baseline assessment of folate status against which to measure the effects of fortification. A secondary objective is to determine the effects of folic acid on the appearance of different biochemical forms of folate in the blood.



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Strategies to improve nutrition in **elderly people**

Key Reviewers: **Professor Tim Wilkinson**, Associate Dean, Christchurch School of Medicine and Health Sciences, University of Otago

Dr Sandy Macleod, Medical Director, Nurse Maude Hospice, Christchurch

www.bpac.org.nz keyword: elderlynutrition

Defining malnutrition

Malnutrition is both a "cause and a consequence of ill-health".[1] The term malnutrition can apply to various states – under-nutrition, over-nutrition or deficiencies of specific nutrients. This article will concentrate on under-nutrition and the term malnutrition when used will refer to this state.

Key concepts

- The best option for treating malnutrition is to enhance normal eating and drinking
- Routine use of oral nutritional supplements is not recommended
- Nutritional support is recommended for use in people who are malnourished and who are unable to maintain body weight with a normal balanced diet

Causes of under-nutrition

The "anorexia of ageing"[2,3]

Appetite and food intake often decline with ageing. Older people tend to be consistently less hungry than younger people, eat smaller meals, have fewer snacks between meals and also eat more slowly.[2] Between the ages of 20 and 80 there is on average, a decrease in energy intake of approximately 30%. When this decline in energy intake is more than the decrease in energy use that is also normal with ageing, then there is loss of weight.[2]

Most people lose weight as they age, but the amount lost is variable and those that are already lean, also lose weight. The problem with this weight loss is that it is not only unwanted adipose tissue that is lost but lean skeletal muscle.[4] The loss of lean tissue is associated with reductions in muscle function, bone mass and cognitive function, anaemia, dysfunction of the immune system, slow wound healing and recovery from surgery, and consequentially an increase in both morbidity and mortality.[2,4] Although lean muscle can be regained in younger people this is often not so for elderly people.

This means that being underweight, becomes more of a health problem in older age, than being overweight. Early nutritional intervention in elderly people who are at risk is recommended.

Increasing age has several effects on gastrointestinal function. Secretion of gastric acid, intrinsic factor and pepsin is decreased, which then reduces the absorption of vitamin B6, B12, folate, iron and calcium. Other gastrointestinal problems such as gastritis and gastrointestinal cancers can reduce nutritional status.[10]

A hypermetabolic state where there is increased resting energy use can be caused by acute respiratory or urinary infections, sepsis, cirrhosis of the liver, hyperthyroidism and the hyperactive state found in some people with dementia or Parkinson's.[10] COPD can cause anorexia and physical problems related to shortness of breath.

In addition to the "anorexia of ageing", there are physical, social, cultural, environmental and financial reasons for an inadequate diet.[1,2]

Prevalence of under-nutrition

Table 1. Estimates of prevalence of under-nutrition in elderly people

Prevalence	Type of population
5–10%	Non-institutionalised elderly people[1,5]
10–40%	Hospitalised for acute illness[6,7]
10–60%	Long care units or nursing homes[1,8,9]

These multiple reasons can be grouped under four headings:[1]

Impaired intake

Poor appetite: illness, pain or nausea when eating; depression or anxiety; social isolation or living alone; bereavement or other significant life event; food aversion; resistance to change; lack of understanding linking diet and health; beliefs regarding dietary restrictions; alcoholism; reduced sense of taste or smell; smoking.

Inability to eat: confusion, diminished consciousness; dementia; weakness or arthritis in the arms or hands; dysphagia; vomiting; COPD; painful mouth conditions, poor oral hygiene or dentition; restrictions imposed by surgery or investigations; lack of assistance with eating for those in hospitals and rest homes.

Lack of food: poverty, poor quality diet (home, hospital or rest home); problems with shopping and cooking; ethnic preferences not catered for particularly in hospitals and rest homes.

Medications: Many medications alter nutritional status in numerous ways (e.g. anorexia, decreased or altered taste, dry mouth, confusion, gastrointestinal upsets including nausea, vomiting, diarrhoea, constipation, dyspepsia). Incorrect use of medications may also cause problems (e.g. hypermetabolism with thyroxine and theophylline).[10]

Impaired digestion and/or absorption

Medical and surgical problems affecting stomach, intestine, pancreas and liver, cancer, infection, alcoholism.

Altered requirements

Increased or changed metabolic demands related to illness, surgery, organ dysfunction or treatment.

Excess nutrient losses

Vomiting, diarrhoea, fistulae, stomas, losses from nasogastric tube and other drains.

How do we detect under-nutrition?

The onset of nutritional problems is often gradual and therefore hard to detect. However there are features found in the history and examination that may help identify those at risk. Generally people don't present complaining of malnutrition. It is more likely that they will present with a variety of problems that may be vague or non-specific.

A malnourished state is defined as any of the following: [1]

- BMI < 18.5kg/m^2
- Unintentional weight loss > 10% within the last 3–6 months
- BMI < 20kg/m^2 and unintentional weight loss > 5% within the last three to six months

Assessment tools

Clinical judgment is usually sufficient to diagnose under-nutrition in most cases. However, not everyone who is malnourished is thin. Special assessment tools are necessary when the diagnosis is uncertain.[6]

The UK National Institute of Clinical Excellence (NICE) guidelines rely on the Malnutrition Universal Screening Tool (MUST) which includes BMI, unintentional weight loss (over three to six months) and an acute illness or lack of adequate food for more than five days.[1,11]

Laboratory testing

Laboratory testing is not useful for diagnosis, however some tests may be required to detect specific deficiencies such as iron, folate and vitamin B12.[1,10] Albumin has been suggested in the past as a marker of nutritional status but it is now regarded as unhelpful.[12] However if tested, haemoglobin, albumin, lymphocytes and cholesterol can often be low in those who are malnourished.[6]

Table 2: Ways to optimise oral nutrition in elderly people[10,13]

Problem	Solution
Loss of appetite	Check medications; select favourite foods; provision of a variety of foods; provision of culturally acceptable foods; small energy rich meals; more frequent meals and snacks; improve ambiance surrounding mealtimes – company, quietness, comfortable seating, avoid interruptions or rushing; avoid strong unpleasant smells; avoid naps around mealtimes; keep active; take medications in middle or at end of meal
Chewing problems	Adequate dental and mouth care; food of correct texture and consistency; meat cuts chosen and prepared well
Swallowing difficulties	Speech therapy; alter consistency of foods
Difficulties obtaining or preparing food	Enlist family and carer support; physiotherapy; occupational therapy; provision of ready to eat meals
Mobility problems	Physiotherapy; occupational therapy; family, friends or carers to assist with feeding
Chronic pain	Find and treat cause where possible; check analgesic use
Depression	Check medication use; counselling; support from family, friends and support groups
Social isolation	Meals on wheels; family, friends and social services

What can we do to improve nutrition?

The best option is to enhance normal eating and drinking (see side bar). Referral to a dietitian may be required. Ways to help elderly people maintain adequate oral nutrition are summarised in Table 2.

Indications for nutritional support

Nutritional support is recommended for use in people who are malnourished and who are unable to maintain body weight with a normal balanced diet.

In addition, nutritional support may also be considered in those who have:[1]

- Eaten little or nothing for more than five days or are likely to eat little or nothing for the next five days or longer
- A poor absorptive capacity or high nutrient losses or increased nutritional needs from causes such as breakdown of muscle

Oral nutritional supplements

There is a lack of consensus regarding the benefits of oral nutritional supplements for elderly people. A Cochrane Review in 2006 of 55 trials concluded that there was little evidence of effectiveness in improving nutrition in elderly people living in the community.[14] There was some evidence of improvement for hospital and rest home patients but the reviewers noted that the data was limited and of poor quality.

The success of oral nutritional supplement use can be limited by a lack of compliance often due to low palatability, adverse effects (e.g. nausea and diarrhoea) and by cost.[15] Some studies have shown that there can be a decrease in the consumption of normal foods when oral nutritional supplements are given.[15,16] Wastage of up to 35% of these products is also reported.[17]

Best results are seen when people are offered a variety of different flavours and consistencies and also when

Practical food suggestions for people who are malnourished

In normal circumstances GPs promote low fat and low sugar food choices. For patients who are malnourished or losing weight unintentionally, these concepts may need to be reversed. The best options may be foods which are high in fat and sugar, although this advice may not be suitable for people with diabetes or high cholesterol.

General suggestions may include:

- Three small meals and three in-between snacks every day
- Two courses for each of the three meals
- Add oils, butter, margarine, cream, cheese, salad dressing, honey or sugar to meals to increase calorie intake
- Drink 7–8 glasses of fluid a day but choosing milky drinks, soups, fruit juices or products such as Complan or Vitaplan instead of water or tea
- Make dessert a regular option rather than a treat

Specific food suggestions could include:

- Breakfast: porridge with milk and sugar or honey, followed by scrambled eggs with bacon or cheese
- Light meal: sandwiches with meat, egg, cheese fillings or a baked potato with butter and cheese and a salad with dressing
- Main meal: meat, fish or eggs and include potato, rice or pasta, vegetables or salad complete with butter and dressings
- Dessert: custard or ice cream with fruit, milk based desserts or baked desserts such as rice pudding with cream
- Snacks: milky drinks or fruit juices accompanied by cake, biscuits, pastries, scones, cheese or nuts

Which oral nutritional supplement for malnutrition should be used?

There are a range of oral nutritional supplements available on prescription (initiated by a specialist) subsidised for up to 500ml a day. Examples include Ensure, Fortisip and Fortijuice (suitable for those who do not like milky drinks). They are usually dispensed from a hospital pharmacy although some community pharmacies have a special foods contract. These supplements can also be purchased from pharmacies without a prescription but are often not kept in stock and need to be ordered for individual patients. Powdered products such as Complan and Vitaplan can also be used to supplement the diet and are available in most supermarkets.

the temperature at which the products are consumed is varied.[15] Oral nutritional supplements should be given between meals, not at meal times. They are not a food replacement but a supplement.*

Oral nutrition supplements for malnourished elderly people have to be initiated by a specialist. GPs are able to renew prescriptions provided the treatment remains appropriate and the patient is benefiting from the treatment.

Considerations may include:

- Is the patient gaining weight?
- Could the patient be encouraged to adopt a diet that meets their energy needs, through the use of supermarket products or prepared meals?
- Is there a plan in place to gradually replace use of the supplement with a regular diet?
- Is the patient using the supplement? Is there any wastage?

* occasional use as a complete food

Enteral tube feeding

Enteral nutrition is a method of providing food via a tube placed in the nose (nasogastric), the stomach (gastrostomy) or the small intestine (percutaneous endoscopic gastrostomy, PEG).[15]

Tube feeding can be considered when people cannot maintain an adequate diet from normal food and fluids or oral supplements, or in people who cannot eat and drink safely. The most common indication is for people with dysphagia following stroke.

If tube feeding is likely to be required for more than four weeks, then insertion of a PEG tube may be required.[15] The main benefit of a PEG tube over a nasogastric tube is patient comfort. It is also less likely to be displaced and can be hidden under clothes.[1] However a PEG is invasive and the risk of aspiration remains with both nasogastric and PEG feeding.[18,19]

Tube feeding should be stopped if adequate oral intake is re-established.[1]

The use of tube feeding in people who are chronically unwell is controversial, especially when used for people with dementia. The debate focuses on the selection of who will benefit from this form of nutritional supplementation.[20] Both oral supplements and tube feeding can improve the nutritional state of people with dementia. European Society Parenteral and Enteral Nutrition (ESPEN) guidelines recommend that its use be considered in early and moderate dementia, however not in terminal dementia.**

The decision regarding the use of tube feeding must always be made on an individual basis with input from relatives, caregivers, GP, therapists and if required, legal representation.[15]

Considerations for the use of long term tube feeding may include:[15]

- Does the patient suffer from a condition likely to benefit from enteral feeding?
- Will nutritional support improve outcome and/or accelerate recovery?
- Does the patient suffer from an incurable disease, but one in which quality of life and wellbeing can be maintained or improved by enteral nutrition?
- Does the anticipated benefit outweigh the potential risks?
- Does the use of enteral nutrition agree with the expressed or presumed will of the patient or in the case of incompetent patients of his/her legal representative?
- Are there sufficient resources available to manage enteral nutrition properly? If long term enteral nutrition implies a different living situation (e.g. home vs institution) will the change benefit the patient overall?

** terminal dementia is irreversible, the patient is immobile, unable to communicate, completely dependent and has a lack of physical resources

! Caution Medicines and enteral feeds should not be mixed. Temporarily stop the tube feed to give medicines and flush the tube before and after.

Parenteral nutrition

Parenteral nutrition is a method of providing nutrition directly into the venous system, usually via a central line therefore avoiding the digestive system. It is referred to as total parenteral nutrition (TPN) and in general is used in a hospital setting. Its use in the community is mainly reserved for people with severe Crohn's disease, those with vascular damage to the bowel and some people with cancer.[21] Home parenteral nutrition is expensive and requires careful patient selection and training. It is not widely used in New Zealand.

Further reading

For further information on assessment tools for malnutrition the following websites may be useful;

The British Association for Parental and Enteral Nutrition website includes a guide to the use of "MUST", BMI charts, weight loss tables and instructions for alternative measurements when measurements of height and weight are unable to be done to calculate BMI.

www.bapen.org.uk/pdfs/must/must_full.pdf

The Mini Nutritional Assessment (MNA) was developed specifically to assess the risk of malnutrition in elderly people and is widely used in the United States. The MNA includes 18 items covering anthropometry, a global assessment of lifestyle, medication and mobility and a dietary history. A short form version for screening uses the first six questions and takes approximately four minutes to complete.

www.mna-elderly.com

High energy/high protein food ideas:

Energy boosters:

Milk, fruit juice, yoghurt, sour cream, cream cheese, ice cream, butter, vegetable oils, jam, syrup, honey, museli with dried fruit.

Protein boosters:

Eat plenty of cheese, eggs, meat, fish, poultry, beans and legumes. Add skim milk powder to regular milk to create high protein milk. Add soy or whey protein powder to milkshakes or soups. Eat plenty of nuts and seeds including butters e.g. peanut butter, tahini (sesame butter). Add tofu to soups, stews or stir fry.

High energy/high protein snacks:

Crackers and cheese, scones with butter, jam and cream, museli bars, corn chips and avocado dip, cakes, biscuits, hot chocolate.

Non-solid food options:

Milkshakes, cream soups, buttermilk, porridge, yoghurt smoothies, mashed potatoes, scrambled eggs.

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Special circumstances can alter nutritional needs

Surgery

The metabolic changes caused by surgery, the increased demands required for successful healing, sepsis and the stress of the surgical procedure itself, all increase energy needs.[22] To supply this energy, protein stored as muscle is broken down and amino acids released. A septic state will increase this muscle breakdown further. Nutritional requirements must meet these increased needs. Furthermore, patients may already be malnourished due to the illness that led to their surgery.

Once discharged, there will be ongoing higher nutritional needs during the recovery phase, although muscle lost may never be regained. Oral nutritional supplements may be useful during the recovery period.

Cancer

People with cancer are often malnourished. Physical and metabolic changes can be compounded by social and psychological problems.[23] Cancer may result in cachexic syndrome which is a state of complex metabolic changes associated with anorexia, progressive weight loss and depletion of reserves of adipose tissue and skeletal muscle.[15]

Nutritional advice tailored on an individual basis should be given at an early stage to help prevent nutritional deficiencies.[24] High energy, high protein foods are ideal for maintaining strength and wellbeing (see previous sidebar). Loss of appetite, pain, nausea and vomiting all contribute to poor oral intake. Prednisone is used to stimulate appetite, but its effect tends to be short lived.[25]

Oral nutritional supplements can be beneficial when a normal balanced diet cannot be tolerated. These supplements help prevent malnutrition but eventually cannot halt the cachexic state associated with many end-stage cancers.

Chronic renal failure

Nutritional requirements for people with chronic renal failure vary widely.[15] In general, they require a diet that promotes adequate nutrition, minimises uraemic toxicity and delays the progression of renal disease.

The requirements therefore are for a low protein diet with high energy content. The diet should be low in phosphorus which means limiting foods of animal origin that are rich in phosphorus (such as dairy, egg yolks and meat). In addition, supplementation of water soluble vitamins may be required (e.g. thiamine, riboflavin, pyridoxine and ascorbic acid). The fat soluble vitamins A, E & K do not need to be supplemented, however vitamin D does.

Those requiring haemodialysis have some differing needs – they require additional protein, low potassium and phosphate and high energy but low volume supplements.

There are specialised protein reduced nutritional supplements available on the pharmaceutical schedule that can be initiated by a specialist. These include Renilon and Nepro.

www.bpac.org.nz keyword: copdweightloss

The Nutritional Management of **Weight Loss in COPD**

Key Reviewer: **Dr Lisa Houghton**, Lecturer: Department of Human Nutrition, University of Otago

Weight loss is common in people with COPD

In people with chronic obstructive pulmonary disease (COPD), energy requirements have been reported to be 15–20% above normal needs due to the increased energy required for breathing. People with COPD are generally underweight and have reduced muscle mass.[1] One UK based study showed that 23% of subjects with COPD were classified as malnourished. The malnourished subjects had lower lung function measurements, suffered more dietary problems and had lower nutritional intake compared with the adequately nourished subjects.[2]

Careful balancing of caloric intake is required. One study showed that a total caloric intake in excess of 50% above need was associated with poorer outcomes, while caloric intake of 30% above need was beneficial.[3]

Referral to a dietitian is recommended to establish an appropriate diet for a person with COPD who is malnourished.

Key concepts:

- Weight loss is common in people with COPD and nutritional management plays an important role.
- Weight loss is related to decreased exercise capacity, health status and increased morbidity.
- Opportunities for dietary and nutritional interventions in COPD management should be explored, aiming at early detection and early treatment of involuntary weight loss.

Eating small, frequent meals may help to reduce dyspnoea

As COPD progresses, many people find that breathing becomes more difficult if they eat a heavy meal, so in this situation, eating frequent, small and nutritious (high energy, high protein) meals is best (see “High energy, high protein food ideas” on page 14). If people with COPD are not managing to keep their weight above a desired level they may require dietary assistance.[4]

Evidence for nutritional support is limited

Evidence supporting the use of nutritional supplements for people with COPD is limited. A 2005 Cochrane systematic review found no evidence that nutritional supplementation makes a significant difference to weight gain or health outcomes in people with COPD.[5]

Despite this lack of evidence, the UK National Institute for Clinical Excellence guidelines for the management of COPD in adults, suggest that nutritional supplements may be considered for people with a BMI less than 20 kg/m^2

and these patients should also be encouraged to exercise regularly to build muscle mass.[6]

The American Thoracic Society also recommends considering nutritional supplementation for people with COPD who have involuntary weight loss of more than 10% in the last six months or more than 5% in the past month.[7]

Nutritional management of patients with severe COPD is challenging and interventions should be extended to the early detection and further prevention of weight loss before patients become malnourished.

Hypercapnia

A late manifestation of COPD is hypercapnia. It is caused by a reduction in ventilatory drive and is a feature of severe COPD.

In theory, under ideal conditions, dietary fat utilisation produces less CO_2 per O_2 molecule consumed than carbohydrate. However, most studies indicate that consuming excess calories is a more important contributor to increased CO_2 production than the fat composition of the food.[3]

Higher fat supplements have been found to delay gastric emptying. This may be important in determining patient tolerance of these formulas as a delay in gastric emptying can lead to extended periods of abdominal distention.

Pulmocare is a high fat, low carbohydrate formula designed to minimise CO_2 retention in chronic or acute respiratory insufficiency. Pulmocare is the only COPD specific product available in New Zealand.

Subsidy for Pulmocare (which contains 1.5kcal/mL in 237mL cans) is available from a relevant specialist for patients who have COPD and have hypercapnia and need the supplement as part of, or as a complete, diet.

GPs role in the nutritional care of people with COPD

Encourage patients with COPD to make and maintain dietary changes such as eating a high energy, high protein diet or eating small, frequent meals, to minimise involuntary weight loss and nutritional depletion.

Advise people with COPD who become breathless when eating to eat frequent small meals.

Consider oral nutritional supplements for patients with a low BMI, significant involuntary weight loss or those who develop hypercapnia. For more information on oral supplements see page 12.

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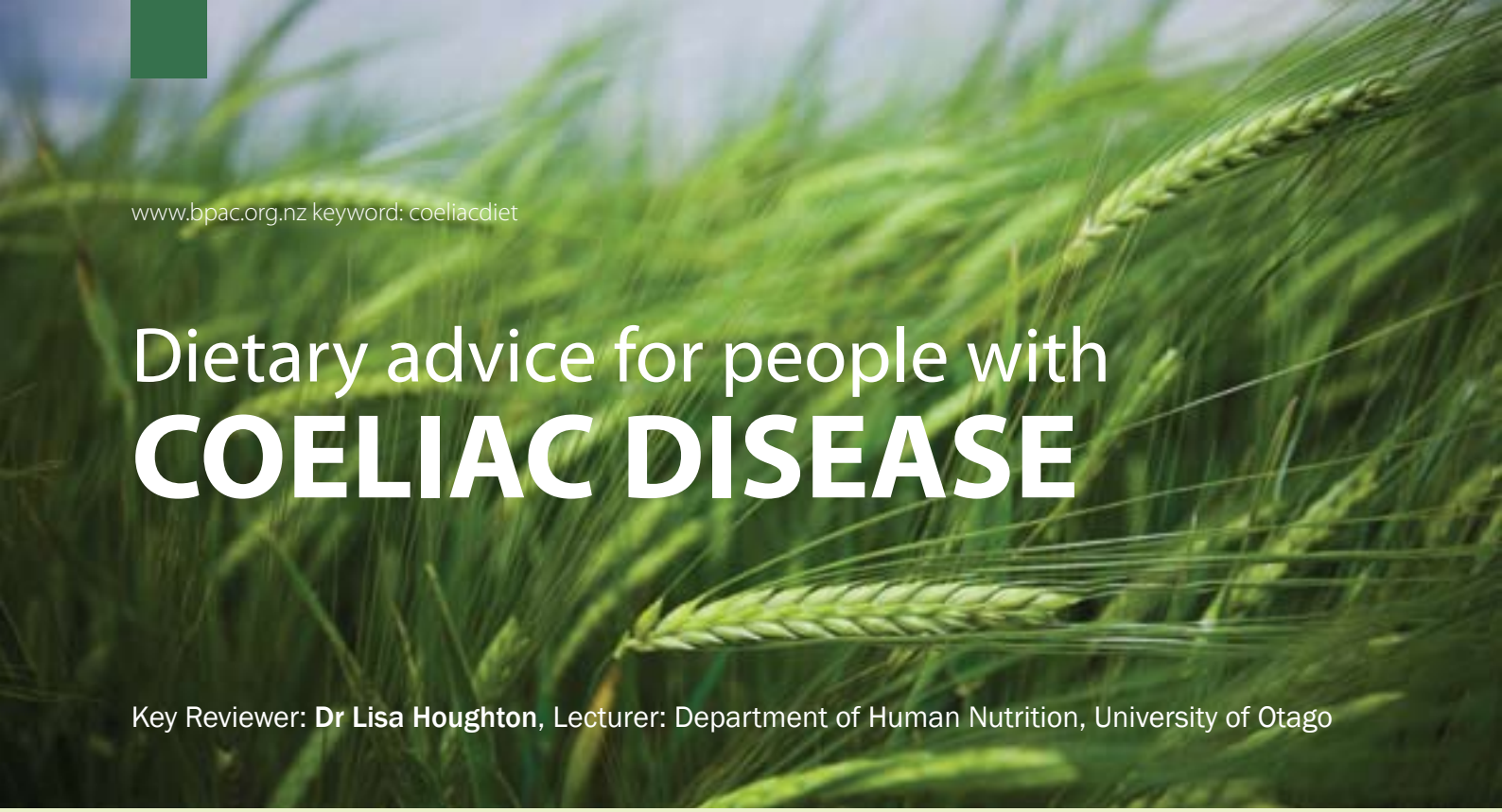

www.bpac.org.nz keyword: coeliacdiet

Dietary advice for people with COELIAC DISEASE

Key Reviewer: **Dr Lisa Houghton**, Lecturer: Department of Human Nutrition, University of Otago

Key concepts

- A gluten free diet is first line treatment for coeliac disease.
- A wide range of gluten free foods are now available in supermarkets, however it is important to read labels.
- There is a limited range of gluten free foods available partly subsidised on prescription. The only advantage of obtaining these foods on prescription is a possible reduction in cost for the patient.
- Gluten free foods on prescription are not different from, and not necessarily cheaper than supermarket equivalents, when taking into account consultation and other fees.

Nutritional status of newly diagnosed people

At the time of diagnosis, some patients with coeliac disease present with substantial weight loss, anaemia and evidence of vitamin and mineral deficiencies. Nutritional status depends on the severity of GI tract damage and the length of time that the person has lived with the active disease. Malabsorption of iron, folate, calcium and fat-soluble vitamins are common.

When people with coeliac disease eliminate foods containing gluten from their diet, normal absorption of nutrients is usually restored within a few months but may take up to two years in older adults. Recommended repletion doses of vitamin and minerals are individually based, however many people with coeliac disease benefit from a calcium and vitamin D supplement.[1]

Calcium and vitamin D malabsorption dramatically increases the risk of osteoporosis and osteomalacia in people with gluten-sensitive enteropathy. Most people with coeliac disease have some degree of osteopenia or osteoporosis. People who develop osteoporosis at a young age are usually advised to be tested for coeliac disease. Fortunately, calcium and vitamin D supplementation coupled with a strict gluten-free diet, usually results in remineralisation of the skeleton.[2, 3]

Uncontaminated oats are ok for people with coeliac disease[5]

Oats, as part of a gluten free diet, have been the subject of controversy for a number of years. Recently the Canadian Coeliac Association, supported by Health Canada, has published a position statement on the use of pure and uncontaminated oats by people with coeliac disease.

They concluded that the majority of adults with coeliac disease could safely consume 50 to 70 grams of pure uncontaminated oats per day (half to three quarters cup dry rolled oats) and children could safely consume 20 to 25 grams per day (one quarter cup of dry rolled oats). Studies included in their analysis demonstrated safety over five years. However, the studies involved a small number of patients, the oats were pure, free of gluten contamination and the amount allowed per day was limited.

In New Zealand no oats can be guaranteed to be completely gluten free. Cross contamination with very small amounts of gluten may occur during the planting, harvesting, transport and processing of oats therefore it can be very difficult to avoid.

Some adults with coeliac disease can tolerate small amounts of gluten but if oats were introduced to the diet monitoring would be required to ensure tolerance.

General remission diet

People with coeliac disease must follow a lifelong gluten free diet by excluding wheat, rye, barley and their derivatives. This means they cannot eat most breads, cereals, biscuits, pastas and processed foods. For some people adherence to a gluten free diet is difficult. However eating gluten containing foods often results in an immediate return of gastrointestinal symptoms and increases the risk of long-term health issues including osteoporosis, anaemia and autoimmune disorders.

People following a gluten-free diet can eat all non-carbohydrate food normally, however it is important to read food labels as processed food, coatings, sauces and dressings may contain gluten. Safe carbohydrate choices include potato, kumara, pumpkin, parsnips, yams, corn/maize, beans, pulses and rice.

Most supermarkets and health food shops now sell a wide range of gluten free products including non-wheat based flours, potato flour, rice flour and maize flour.

There is some concern about the level of gluten contamination in gluten free products and whether trace amounts of gluten are acceptable for people with coeliac disease. A low gluten diet may be tolerated by some adults with coeliac disease. Low gluten foods must have less than 20 mg of gluten per 100 g of the food. One study found that the residual gluten in gluten-free products is at a safe limit at usual consumption levels for adults with coeliac disease.[4] A zero gluten diet is recommended for children with coeliac disease, although consumption of commercially prepared gluten free foods is considered safe.

Gluten free diets generally should not be trialled without confirmation of the diagnosis of coeliac disease.

Special foods

A small range of gluten free foods, including flour, bread mix and pasta, is available partially subsidised on the New Zealand pharmaceutical schedule. Initial application must

be made by a specialist for those diagnosed by biopsy with gluten enteropathy or those with dermatitis herpetiformis (caused by allergy to gluten).

Partially subsidised gluten free foods

The price of prescription gluten free foods varies between pharmacies depending on their mark-up. Average costs* to the patient are:

- $4.04 for Healtheries gluten free baking mix 1000g
- $7.25 for Bakels gluten free bread mix 1000g
- $4.83 for NZB low gluten bread mix 1000g
- $7.66 for Horleys gluten free bread mix 1000g
- $12.83 for Horleys gluten free flour 2000g
- $1.09 –s $2.07 for Orgran gluten free pasta 250g

* Estimated charge based on pharmacy mark-up plus GST. Wholesaler and pharmacy mark-ups may vary. This does not include prescription charges.

The only advantage of obtaining gluten free foods on prescription is a possible reduction in cost for the patient. However, there is not always an advantage once other costs of obtaining a prescription are taken into account. As special foods are only dispensed by a limited number of pharmacies (usually hospital pharmacies) access may be an issue also.

Further resources

The Manufactured Foods Database, compiled by Auckland City Hospital on behalf of the New Zealand Food Safety Authority, provides listings of manufactured foods available in New Zealand that are suitable for people with some common food allergies or intolerances including gluten intolerance:

www.mfd.co.nz

The Coeliac Society of New Zealand offers many resources on its website including a list of gluten-free cafes and restaurants throughout New Zealand (click on “Eating by region”).

www.colourcards.com/coeliac/

See BPJ 9 “Coeliac disease” for further information on diagnosis, treatment and management.

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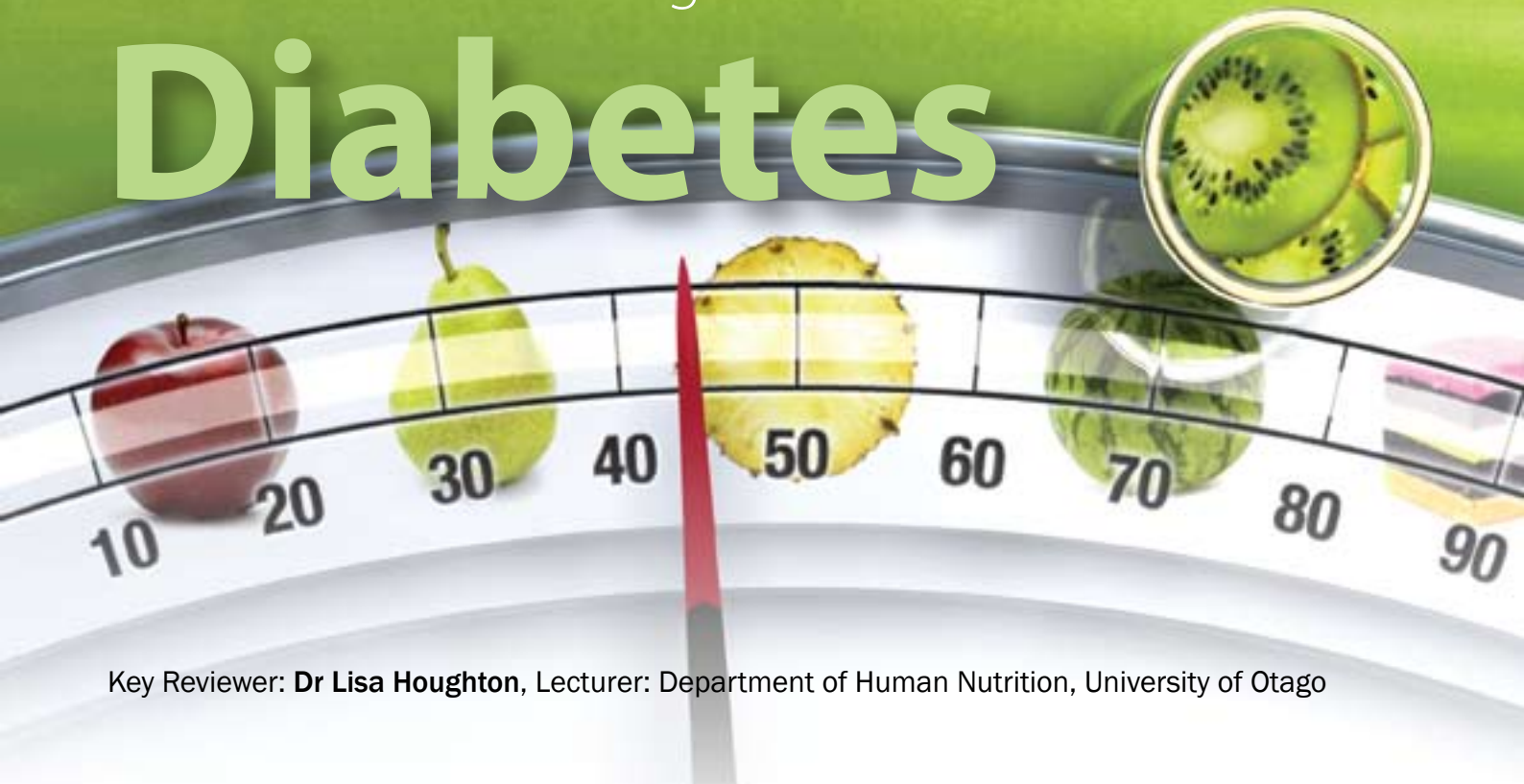
The Nutritional Management of Diabetes



Key Reviewer: **Dr Lisa Houghton**, Lecturer: Department of Human Nutrition, University of Otago

Nutritional management plays an important role in preventing diabetes, managing existing diabetes, and slowing the rate of development of diabetic complications.

Key concepts:

- Managing diet is a priority for overall health and wellbeing for people with diabetes
- Glycaemic index and glycaemic load are useful measures for making good food choices
- Including soluble fibre in the diet can help to maintain glycaemic control
- The purchase of special "diabetic" foods is unnecessary. It is more important to be able to understand food labels

What constitutes good food for people with diabetes?

The goals of nutritional management for people with diabetes or pre-diabetes (those with impaired fasting glycaemia or impaired glucose tolerance) are:

- Achievement and maintenance of blood glucose levels and blood pressure levels that are as close to normal as possible.
- Achievement and maintenance of a lipid profile that reduces cardiovascular risk.
- Delaying or preventing diabetic complications.
- Achievement and maintenance of healthy body weight goals with an emphasis on regular and consistent physical activity as appropriate.
- Addressing individual nutritional needs taking into account personal and cultural preferences.
- Maintaining the pleasure of eating.

For people with diabetes, managing diet and glucose intake becomes a priority for overall health and wellbeing.

Some topics that people with diabetes may ask you about include:

- Glycaemic index
- Dietary fibre
- Carbohydrate counting
- Diabetic foods
- Artificial sweeteners
- Prescription special foods

Glycaemic index and glycaemic load

The glycaemic index (GI) of a food is based on the rate at which glucose is released into the bloodstream following ingestion. High GI foods (e.g. white bread) are rapidly digested and absorbed, resulting in a greater rise in blood glucose levels.

It has not yet been determined whether choosing low GI foods in place of high GI foods has a clinically useful effect on overall glycaemic control in people with diabetes. Some research has shown a benefit that is similar to that achieved by pharmacological agents,[1] while other research has failed to show this.[2,3]

A limitation of the glycaemic index is that it does not take into account the amount of carbohydrate consumed (i.e. portion size), which is an important determinant of glycaemic response.

Both the type and amount of carbohydrate in the diet is important to achieve optimal glycaemic control. Glycaemic load (GL) takes into account how much carbohydrate a serving of food contains as well as its GI. This may be a more useful measure for managing glycaemic control.

For example, watermelon has a high GI (around 72) due to its sugar content, but only contains five grams of carbohydrate per one hundred grams, therefore it has a minimal glycaemic effect. The GL of watermelon is around 3.6 which takes both GI and carbohydrate amount into consideration. This is compared to a bread roll which also has a high GI (around 95), but its higher GL (around 48) than watermelon reflects the amount of carbohydrate in the portion size (fifty grams of carbohydrate per one hundred grams).

Knowing the GI and GL of foods can be useful in assisting people with diabetes to make good food choices.

Glycaemic Index	
Low <55	Oats, barley, legumes, pasta, pumpernickel (coarse rye) bread, apples, oranges, milk, yogurt.
Medium 55–69	Pineapple, beetroot, melon, new potato, white rice
High 70–99	White bread, watermelon, baked potato, parsnip
100	Pure glucose

Glycaemic Load	
Low <10	Carrots, apples, watermelon, pineapple, pear, peanuts, kidney beans, chick peas, lentils, pop corn, wheat bread
Medium 10–19	Banana, new potato, kumara, apple juice, orange juice
High >20	Pasta, cous cous, white rice

GL = [carbohydrate (g) x GI]/100

Dietary fibre

There are two types of fibre that occur in foods – soluble and insoluble. Only soluble fibre which is found in fruit, vegetables, legumes and oats affects glycaemic control. Adding soluble fibre to a meal increases the viscosity and the stomach and bowel take longer to empty, therefore increasing the feeling of satiety. In addition the fibre forms a thin film on the intestinal surface which causes glucose to be absorbed more slowly. Including soluble fibre with a high glucose food can decrease the expected rise in glucose levels.

High fibre diets have been shown to be associated with lower blood glucose levels and to significantly lower total cholesterol. There is, however, inconclusive evidence that increasing dietary fibre above recommended levels will influence glycaemic control in people with diabetes.[4] The adequate intake for dietary fibre is set at 25 g/d for adult women and 30 g/d for adult men.

Carbohydrate counting

Carbohydrate counting is a process increasingly used for younger people with type 1 diabetes. Carbohydrate counting allows an increased variety of food and more flexibility in meals and snacks.

There are two levels of carbohydrate counting; basic and advanced.

Basic carbohydrate counting matches insulin doses to servings of carbohydrate. One carbohydrate serving is equal to 15g of carbohydrate (e.g. one slice of bread, one small piece of fruit, half a cup of fruit juice, one cup of non-fat milk or two small cookies).

This form of carbohydrate counting allows increased flexibility in meal planning while keeping the amount of carbohydrate consistent from day to day. It is most often used for patients on fixed doses of insulin.

The number of carbohydrate servings at each meal can be planned. For example a typical carbohydrate meal plan may be:

Breakfast: three carbohydrate servings (45g)

Lunch: three carbohydrate servings (45g)

Dinner: four carbohydrate servings (60g)

Snack: one carbohydrate serving (15g)

Total carbohydrates for the day: 165g

Advanced carbohydrate counting is where the number of grams of carbohydrate at a meal is calculated and the insulin dose adjusted to cover this amount of carbohydrate and bring glucose levels back to target ranges. An insulin-to-carbohydrate ratio is used to calculate this amount of insulin.

An insulin-to-carbohydrate ratio is determined by calculating, for each individual patient, how many grams of carbohydrate one unit of insulin covers. For example, if someone consumes 75g of carbohydrate and requires five units of insulin to return glucose to baseline levels, then the insulin-to-carbohydrate ratio is one unit of insulin/15g of carbohydrate.

Basic mathematic skills are required for carbohydrate counting and the ability to read food labels and weigh and measure portions of home-prepared foods.

"Diabetic" or low sugar foods

It is not necessary for people with diabetes to buy special foods, it is more important to be able to understand product labels.

- Be aware that diabetic or sugar free foods may still be high in kilojoules (energy) and fat.
- "No added sugar" does not mean that the product does not contain sugar, natural sugar from fruit or berries may be present.
- Sugar free foods may still affect blood glucose levels, depending on the other ingredients they contain.

Fructose is a sugar alternative that is often added to diabetic or low sugar foods. It is found naturally in fruits and berries and some foods including honey and some root vegetables. It has the same energy value as sugar but a lower glycaemic index (19 compared to 61 for sucrose). Fructose requires less insulin than sucrose for metabolism.

In moderation, fructose containing foods are considered as healthy choices, but in excess, fructose may affect triglycerides and LDL cholesterol.[5] This is a particular problem when in the form of high fructose corn syrup (roughly half fructose and half glucose), which is added

to soft drinks, canned fruits, deserts and processed food products. In this form it is linked with complications of insulin resistance syndrome and may be associated with the development of non-alcoholic fatty liver disease.[6]

Using honey in preference to sugar does not provide any advantage for people with diabetes. The glycaemic index of honey is around 55 as compared to 61 for table sugar.

Artificial sweeteners

Sorbitol, a polyol (sugar alcohol), is a nutritive sweetener and found in many diabetic or low kilojoule food products. It is about 60% as sweet as sucrose with one-third fewer kilojoules. Sorbitol is only partially and more slowly absorbed than sugar and produces lower blood glucose levels. Other polyols commonly used in New Zealand include mannitol, xylitol, lacitol and isomalt. Polyols may cause bloating, flatulence or diarrhoea if consumed in large quantities.

In New Zealand there are five common non-nutritive sweeteners (providing no kilojoules or energy).

Aspartame (Equal) is around 200 times sweeter than sugar but is used in very small amounts so the energy content is almost zero. People with phenylketonuria cannot use aspartame. Despite many myths otherwise, aspartame is considered to be safe and not associated with any adverse health effects. Many foods such as milk, meat, fruit and vegetables contain aspartic acid which is one of the two amino acids which make up aspartame. An adult would need to consume around 14 cans of aspartame sweetened drink to exceed the recommended daily intake.

Saccharin (Sucaryl and Surgromax) is around 300 to 500 times sweeter than sugar and withstands heat, so can be used in baking. Saccharin is not recommended for use in children aged under two years or pregnant women.

Sucralose (Splenda) is made from sugar but is around 600 times sweeter. It does not affect blood glucose levels. It can also be used for baking.

Cyclamate is 30 to 50 times sweeter than sugar. It is often used in soft drinks, dairy products and chocolate. The UK Food Standards Agency advises parents not to give children aged up to four years more than 180 ml of cyclamate containing drinks per day as this would exceed the recommended daily allowance. In New Zealand, cyclamate is not recommended for use in children aged under two years or pregnant women.

Acesulfame-K is 180 to 200 times sweeter than sugar and is often blended with other sweeteners such as aspartame and sucralose.

None of these artificial sweeteners contribute to dental caries, so are appropriate for use in chewing gum and sweets. Aspartame and sucralose are the only sweeteners recommended during pregnancy.

Prescription special foods

People with diabetes do not require prescriptions for special foods unless they become significantly malnourished and cannot gain adequate energy and nutrients from diet alone.

Products currently available in New Zealand on the pharmaceutical schedule for malnutrition in people with diabetes are:

- Oral feed 1 kcal/mL (Resource Diabetic, Diasip, Glucerna)
- Enteral feed 1 kcal/mL (Diason RTH, Glucerna RTH, Resource Diabetic TF RTH)

These products are for use as a supplement or as a complete diet. Prescriptions must be initiated by a specialist. When renewing a prescription for these items, GPs should consider whether the treatment is still appropriate, whether the product is being used, whether the patient is benefitting from the product and whether there are any other suitable alternatives.

Resources

"Diabetes and healthy food choices". Available from Diabetes New Zealand. Phone 0800 DIABETES (0800 342 238) or email info@diabetes.org.nz

Diabetes New Zealand website:

www.diabetes.org.nz

Glycaemic index and glycaemic load of foods:

www.mendosa.com/gilists.htm

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Infant formula

Key Reviewer: **Barbara Cormack**, Paediatric Dietitian, Auckland City Hospital

While it is recognised that breastfeeding is the best option for mother and baby, some mothers cannot or choose not to breastfeed. General practitioners, practice nurses and other health professionals should have knowledge of infant formula so they can provide guidance for these mothers.

Exclusive breastfeeding for around six months is ideal, at which time complementary foods can be introduced with continued breastfeeding until the infant is aged at least one year.[1] All efforts should be made to encourage breastfeeding for as long as possible.

Key concepts

- Breastfeeding is best
- Cows' milk based formula is recommended if breastfeeding does not occur
- Soy formula is rarely indicated and is not recommended for cows' milk allergy
- Hydrolysed cows' milk formula can be used for infants with cows' milk allergy

Important considerations when infant formula is used:[1]

- Encourage the maintenance of breastfeeding if possible
- Choose an appropriate formula for the infant's age
- Cows' milk-based formula is routinely recommended for feeding an infant who is not breastfed
- Soy based infant formula should not be used routinely
- At six months of age, if an infant is thriving on regular or standard infant formula and complementary foods, there is generally no advantage to changing to a follow-on formula
- Formula should be made up as close as possible to feeding time and needs to be handled and stored carefully

How does breast milk differ from formula milk?

Breast milk is a complex nutritional food that contains antibodies, enzymes and hormones, all of which have significant health benefits. While the composition of formula milk is modelled on breast milk it cannot replicate it exactly.[2]

Breast is best

Breast milk is the preferred food for all infants. It is a nutritionally complete food and is all that is required for a baby's first six months of life. It has many beneficial effects for both mother and infant. See Table 1 for examples.

There are very few reasons not to breastfeed

There are only a few situations where breastfeeding is contraindicated such as infants with galactosemia, mothers receiving chemotherapy or mothers with HIV or uncontrolled tuberculosis.

Prescribing for breastfeeding mothers[2]

Maternal drug therapy should rarely constitute a reason to avoid breastfeeding.

Caution should be used with the following drugs and the infant monitored:

Antiepileptics	Lithium	Sedatives
Antipsychotics	Diuretics	Codeine*

*The amount of codeine present in breast milk is usually too small to be harmful however mothers vary considerably in their capacity to metabolise codeine. One case of fatal morphine toxicity has been reported.

Monitor the infant for evidence of adverse effects e.g. sedation, altered bowel habit.

Useful reference sources:

Ministry of Health:

www.moh.govt.nz/breastfeeding

UK Drugs in Lactation Advisory Service:

www.ukmicentral.nhs.uk/drugpreg/guide.htm

Drugs and Lactation Database (LactMed):

http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT

In New Zealand, the rates of breastfeeding do not reflect the vital role breastfeeding plays in an infant's development. Overall only 66% of infants are breastfed at six weeks and this decreases to only 25% by six months.[1]

Table 1: Beneficial effects of breast feeding for mother and infant[1, 2]

Beneficial effects for infant	Beneficial effects for mother
Provides optimum nutrition	Encourages contraction of the uterus after birth
Reduced incidence and severity of infectious disease (e.g. gastrointestinal or respiratory infection, otitis media)	May reduce the risk of ovarian and breast cancer
Associated with decreased risk of chronic disease later in life (e.g. high blood pressure, obesity, diabetes)	May help the mother return to her pre-pregnancy weight
Assists with physical and emotional development	May reduce risk of other conditions (e.g. type 2 diabetes, postnatal depression, osteoporosis)

Breastfeeding rates and use of infant formula among Māori[1]

In 2006*, the rate of exclusive breastfeeding for Māori infants at six weeks of age was 59% compared with 66% of infants across all ethnic groups (70% for European infants, 55% for Asian infants and 57% for Pacific infants).

Information from 2005* shows that the rates of infant formula use was highest for Māori infants across all age groups (25% at six weeks, 37% at three months and 49% at six months).

> "Whanau have the biggest influence on whether a mother breastfeeds or not, and provide the best support for the breastfeeding mother. The best way to improving breastfeeding statistics is through whanau, hapu and iwi development."
>
> — **Raeleen de Joux**, Maori Educator, New Zealand Breastfeeding Authority. Te Karaka 2008, Issue 39.

*Rates from Plunket representing approximately 90% of all births

Infant feeding definitions

Infant formula – Formula intended as a substitute to breast milk for infants from birth to six months old.

Follow-on formula – Formula that is marketed for infants aged from six months to 12 months.

Complementary feeding – Foods fed to infants from around six months to complement breastfeeding or formula feeding.

Types of formula

In New Zealand, infant formula and follow-on formula must comply with the requirements of the Australia New Zealand Food Standards Code.[3] This code contains standards for the composition of infant formulas so they meet the nutritional needs of a growing infant.

Infant formulas differ depending on where the protein in the formula is derived. Infant formulas available in New Zealand are based on cows' milk, goats' milk and soy protein.

Cows' milk-based formula is routinely recommended for feeding an infant who is not breastfed

Cows' milk-based formula is recommended as the first choice for feeding healthy infants who are not fully breastfed.[4]

The protein in cows' milk-based formula is derived from cows' milk. The carbohydrate component is generally provided by lactose, corn syrup solids and corn maltodextrin. Vegetable oil blends usually provide the fat component.

Whey and casein are the two types of protein present in breast milk and cows' milk. Breast milk contains more whey than casein and this ratio changes over the course of lactation.[1] Infant formulas vary in their composition and may be whey or casein dominant.

There are many different commercially available cows' milk based formulas which are readily available from supermarkets and pharmacies. Some examples are S-26, Nurture Starter, Novalac 1, Nan 1 Gold Protect and Karicare Gold 1. Cows' milk formulas appropriate for infants aged up to six months often have "1" or "starter" in their name.

Regular cows' milk is not suitable for infants aged less than one year

Soy-based formula should not be used routinely

There are only a few indications for the use of soy-based infant formula in place of cows' milk-based formula. These indications are: infants with galactosaemia, a rare inherited condition where infants are unable to metabolise galactose to glucose, or vegan infants who are not breastfed.

The protein in soy-based infant formula is derived from refined soy protein isolate. Soy-based formula is free of lactose and cows' milk protein.[1] However soy-based formula is not recommended for cows' milk allergy as 10-14% of infants with allergy to cows' milk protein will also have a soy protein allergy (see hydrolysed formula for recommendations).[2, 4]

Soy-based formula is not designed for or recommended for pre-term infants.[14]

Soy-based formula needs to meet defined standards for infant formula and requires fortification with the amino acid methionine. Soy-based formulas contain high concentrations of phytate, aluminium and phytoestrogens, for which the long term effects are unknown.[4] Examples of soy-based formula are S-26 Soy and Karicare Soya.

Goats' milk-based formula

Goats' milk formula is not suitable for infants with lactose intolerance, galactosaemia or allergy to cows' milk protein.[1] It contains lactose and has cross-reactivity with cows' milk protein, which means that infants allergic to cows milk are also likely to be allergic to goats milk. The likelihood of cross-reactivity between cow and goat milk is approximately 90%.[5]

Specialised formula and additional ingredients

Hydrolysed formula for cows' milk protein allergy

Partially or extensively hydrolysed formula contains cows' milk protein that has been broken down into peptides. In general, the more extensive the hydrolysis of the protein, the less likely it is to cause an allergic response.[1] Extensively hydrolysed formula (e.g. Pepti Junior) should be used for the treatment of children who have diagnosed cows' milk allergy.[6] If allergic symptoms persist a free amino acid formula (e.g. Neocate) is recommended.[4,7]

There is some evidence for the use of hydrolysed formula for high risk infants (infants with at least one first-degree relative – parent or sibling – with diagnosed allergic disease) to prevent or delay the development of atopic dermatitis. Extensively hydrolysed formula may be more effective in preventing allergies than partially hydrolysed formula.[1,7] The recently published German Infant Nutritional Intervention study confirms a preventive effect of hydrolysed infant formula persists until age six years.[8] More research is needed into whether these benefits extend into late childhood and beyond.

Hydrolysed formula carries a significant cost and referral to a paediatrician or allergy specialist is advised to obtain funding for them under special authority.

Probiotics, prebiotics and long chain polyunsaturated fatty acids

Probiotics, prebiotics and long chain polyunsaturated fatty acids are added to infant formula to make them more closely resemble breast milk.

Probiotics are live bacteria that colonise the gastrointestinal tract. When administered in adequate amounts they may improve gut barrier function and host immune response. There are many different strains of probiotics but the most common are *Bifidobacterium* or *Lactobacillus* species. Breastfed infants have been shown to have more Lactobacilli and Bifidobacteria in their intestines than formula fed infants.

Prebiotics are food ingredients (usually oligosaccharides) that are resistant to digestion in the small intestine. They are fermented by beneficial bacteria in the large intestine selectively stimulating the growth of non-pathogenic bacteria in the colon such as *Lactobacilli* and *Bifidobacteria*. Breast milk contains oligosaccharides which have been shown to demonstrate a prebiotic effect in infants.[9]

Two systematic reviews in 2007 found that there was insufficient evidence to recommend the use of probiotics or prebiotics in infant formula for the prevention of allergic disease or food reactions.[10 11]

Long chain polyunsaturated fatty acids (LCPUFAs) are present in breast milk. LCPUFAs are important components of the phospholipids present in the retina and the brain and are also integral structural components of all cells in the body. Almost half the high lipid content of the brain is LCPUFAs. Since the mid 1990s LCPUFAs, have been the focus of much research. Early research suggested that infants fed a continuous supply of LCPUFAs, from either breast milk or a supplemented formula, may have improved visual functioning.[12] For this reason LCPUFAs are now added to some infant formula. Although LCPUFA-supplemented infant formula seems safe, a 2007 Cochrane Systematic Review found that the results of most of the well conducted randomised controlled trials, have not shown beneficial effects of LCPUFA supplementation on the physical, visual and neurodevelopmental outcomes of infants born at term.[13]

Indications for switching formula

Generally there is limited evidence for switching formula when infants experience symptoms such as vomiting, spilling, crying, diarrhoea or constipation.

- Lactose intolerance – lactose-free (e.g. De-lact, S-26 LF) and reduced lactose cows' milk formula (e.g. Novalac AC or AD) can be used when the elimination or reduction of lactose from the diet is required. However lactose intolerance is likely to be dose dependent and only rarely does lactose need to be totally eliminated from the diet. Therefore the use of lactose-free soy-based formula for this indication should be restricted.[14]
- Diagnosed cows' milk protein allergy – An extensively hydrolysed protein formula (see previous page) should be used for infants with cows' milk protein allergy. Soy-based formula is not recommended in infants with allergy to cows' milk protein.[14]
- Acute gastroenteritis – most previously well infants can be managed after initial rehydration with continued use of breast milk or standard cows' milk formula.
- Colic, regurgitation or prolonged crying – Counselling parents about the cause and duration of colic may have more value than switching formula. There is no evidence for soy-based formula for the prevention or management of infantile colic, regurgitation or prolonged crying.[4]
- Prevention of allergies – There is some evidence for using hydrolysed formula for preventing allergies.[8] Routine use of soy-based formula has no proven value in the prevention of atopic disease in healthy or high-risk infants.

Follow-on formula

Follow-on formula is designed for infants from 6–12 months. It is fortified with additional nutrients such as iron. However if an infant is thriving on the standard infant formula and eating a well-balanced complementary diet, switching to this formula is not usually necessary.[2]

Regular cows' milk is not suitable for infants aged less than one year. For infants weaned from breastfeeding after they are six months old and before 12 months old a follow-on formula may be an appropriate choice.

When to refer to a paediatrician

- If special authority for prescription is required
- If the infant is failing to thrive
- If you suspect a serious adverse reaction to a formula
- If you are unsure of the diagnosis

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Vitamins and minerals: dietary sources, supplements and deficiencies

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The New Zealand National Nutrition Survey in 1997 indicated that half of adults consumed a vitamin or mineral supplement in the past year, with 28% doing so regularly and 23% occasionally.[1]

Key concepts

- In most cases, nutrient needs should be met primarily through consuming a well balanced diet.
- When a nutrient is unable to be consumed through diet in recommended amounts, fortified foods can provide an alternative source.
- Supplements may be appropriate only when nutrients cannot be derived from any other source or in cases where nutrient needs are higher than normal.

In the US in 2006, it was reported that the highest users of multivitamin supplements were women, elderly people, those who are better educated, wealthier, have a healthier lifestyle, disease survivors, chronic disease sufferers and people with lower BMI. Smokers, African Americans, Hispanics and Native Americans used the least.*

The quality of clinical trials for most vitamin and mineral supplements is poor. There is presently no conclusive evidence that supplementation of a single nutrient or combination of nutrients is significantly effective in reducing the risk of cancer, cardiovascular disease or neurological syndromes. Some in fact may increase risk.

The following article focuses on the necessity for use of four common vitamins and minerals.

* NIH (National Institutes of Health) State-of-the-Science Conference on Multivitamin/Mineral Supplements and Chronic Disease Prevention', Bethesda, MD, 2006. Panel chair: J. Michael McGinnis

Folate

- Folate is especially important during pregnancy. A folic acid supplement of 800 mcg/day is recommended for at least four weeks before and 12 weeks after conception.
- Some medications can affect folate metabolism, supplementation can be considered.
- Folate deficiency is often accompanied by vitamin B12 deficiency. If folate deficiency is suspected in a person aged over 50 years, vitamin B12 status should also be checked.

What is it?

Folate is a term which includes naturally occurring food folate and synthetic folic acid, which is used in supplements and fortified foods. The human body requires folate for cell division, especially during foetal development and infancy. Folate is also required to make new red blood cells and prevent anaemia.[2 3]

Who needs it?

Most people who eat a balanced diet consume an adequate amount of folate for their needs. However, there are some situations where people require more.

Medical conditions that increase the need for folate or result in increased excretion of folate include:[3]

- Pregnancy and lactation
- Alcohol abuse
- Malabsorption
- Kidney dialysis
- Liver disease
- Anaemia
- Smoking

The role of folate and B vitamins in cardiovascular disease

Some observational studies have reported that raised homocysteine levels are directly associated with an increase in cardiovascular risk. Daily supplementation with folic acid, vitamin B6, vitamin B12, or a combination can reduce homocysteine levels. Based on this, several randomised trials were designed to test the hypothesis that supplementation with folic acid, B vitamins or both would prevent cardiovascular disease. However, published trials on patients with pre-existing vascular disease have not demonstrated a benefit of folic acid or B vitamins on cardiovascular risk.[6]

This strongly suggests that homocysteine is not an instigator but merely an indicator of cardiovascular disease.[7]

Medications that reduce the availability of folate include:[3]

- Methotrexate
- Anticonvulsants
- Metformin
- Sulphasalazine
- Some other chemotherapeutic agents

Folate deficiency

One of the most critical times for adequate folate intake is during pregnancy and lactation, because deficiency results in a greater risk of giving birth to a premature or low birth weight infant, or an infant with neural tube defects (spina bifida, anencephaly). Research shows that these risks are reduced with the use of folic acid supplements, in conjunction with a healthy diet, both before and after conception.[4]

Signs of folate deficiency may include diarrhoea, loss of appetite, weight loss, weakness, tiredness, sore tongue, headaches, heart palpitations, irritability, forgetfulness and behavioural disorders.[5] In infants and children, folate deficiency can slow overall growth rate.

Folate and vitamin B12 deficiency

Certain processes in the body are dependent on the presence of both folate (substrate) and vitamin B12 (coenzyme). Older people with low levels of folate have a greater risk of also having a vitamin B12 deficiency. It is important that adults do not exceed the recommended upper level of intake of 1000 mcg/day of folic acid because if there is a concurrent untreated vitamin B12 deficiency, irreparable damage to the nervous system can occur.[2, 3]

If folate deficiency is suspected in a person aged over 50 years, also check their B12 status.

Adverse effects of excess folate

No adverse effects have been reported from consuming foods naturally rich in folate. With the exception of concurrent vitamin B12 deficiency, the risk of adverse effects from folic acid supplements and fortified foods is also low, although this is the subject of current debate.

Tests for folate status

Symptoms of folate deficiency are general and can also result from a variety of other medical conditions. Other causes should be considered.

Serum folate is generally regarded as the primary indicator of folate deficiency. Red cell folate is theoretically a more accurate measure of folate, but this test is time consuming, has poorer precision and is not offered by all laboratories.

Dietary sources and supplements

Good sources of folate include leafy green vegetables (e.g. spinach), citrus fruits and juices, dried beans and peas. As well as the recent requirement for fortification of bread with folic acid, many juices, cereals and cereal products (e.g. biscuits, cereal flours and pasta) are enriched with folic acid. Cows' milk can aid the absorption of folate derived from foods.[2]

Folic acid supplements

Folic acid supplements should be considered for people using **methotrexate**. Supplements could also be considered for people with medical conditions or using other medications that increase their need for folate. Vitamin B12 levels should be checked before beginning folic acid treatment.[8]

Folic acid supplements taken prior to and during **pregnancy** can reduce the occurrence and recurrence of neural tube defects. In New Zealand the Ministry of Health recommends that all women planning pregnancy and those who are in the early stages of pregnancy take 800 mcg folic acid daily for at least four weeks before, and twelve weeks after, conception.

Supplementation with 400 mcg is sufficient to reduce the risk of neural tube defects, but folic acid tablets currently available as registered medicines in New Zealand contain either 800 mcg or 5 mg.[9] Women with a higher risk of giving birth to infants with neural tube defects are usually advised to take 5 mg folic acid tablets. This includes women using anticonvulsants who may become pregnant.

Both 800 mcg and 5 mg folic acid tablets are available funded on the pharmaceutical schedule.

Also see page 4 "What side is your bread buttered on?".

Iodine

- Many people in New Zealand have low iodine levels.
- Dietary sources of iodine include dairy products and iodised salt.
- Supplements are not generally recommended, although women who are planning a pregnancy, are pregnant or are lactating, may require supplementation.

What is it?

Iodine is an essential nutrient that plays an important role in thyroid hormone production. Thyroid hormones maintain metabolic state and support normal growth and development.[10]

Who needs it?

Everybody needs a small amount of iodine in their diet to maintain normal growth and metabolism, however iodine is especially important for pregnant and breastfeeding mothers. Pregnancy alters thyroid function due to an increase in hormone requirements, beginning in the first trimester.[11]

Iodine deficiency

Most table salt in New Zealand is fortified with 25–65 mg/kg iodine. However, recent evidence shows that many New Zealanders have low iodine levels. A study in 2005 found that babies who had been breastfed had lower levels of iodine (due to the low concentration of iodine in their mother's milk) than babies who had been bottle fed.[12] The 2002 Children's Nutrition Survey found that most New Zealand children aged 5–14 years had mild iodine deficiency (assessed by urinary iodine excretion).[13]

The re-emergence of iodine deficiency is thought be to due to:[10]

- Increased consumption of commercially prepared foods which are manufactured with non-iodised salt
- Declining use of iodine sanitisers (iodophores) in the dairy industry (opportunistic source of iodine)
- Less salt being used due to healthy eating messages
- Increased use of non-iodised sea salt or rock salt

Symptoms of iodine deficiency

Iodine deficiency causes thyroid dysfunction, resulting in stunted growth, developmental brain damage and adverse effects on hearing, motor and cognitive function.[10]

Iodine deficiency during pregnancy can cause impaired mental development of the foetus and in severe cases may result in miscarriage, still birth or congenital abnormalities.[14]

Adverse effects of excess iodine

The primary adverse effect of excess iodine is inhibition of thyroid hormone production. Adverse effects have been observed at iodine levels of 1700 mcg/day but people with thyroid disorders or a long history of iodine deficiency may experience adverse effects at lower levels.[14]

Tests for iodine status

Laboratory testing of iodine status on an individual basis is not usually indicated when iodine deficiency is suspected.

A normal TSH level may be used as a "rule out" test for hypothyroidism caused by iodine deficiency.

Dietary sources and supplements

Dairy products are the main source of iodine in the typical New Zealand diet. Iodised salt should be used in preference to non-iodised salt, however overall consumption of salt should not be increased. It is difficult to obtain adequate iodine from a normal diet. Good dietary sources of iodine include seafood (fish, shellfish, seaweed), seameal custard, milk and eggs.

The iodine content in New Zealand soil is low, therefore plants grown locally are not a good source of iodine. Brassica vegetables (cabbage, broccoli, brussel sprouts), kumara, cassava and lima beans can impair iodine absorption. The iodine content of foods can also be depleted by cooking.[10, 14]

Iodine supplements

The World Health Authority and other researchers recommend that women who are considering a pregnancy, are pregnant or are lactating, consume a supplement of potassium iodide, 150 mcg/day.[15, 16] Prenatal vitamin supplements usually contain potassium iodide.

Routine use of iodine supplements is not indicated for other groups of people. Iodine supplements such as kelp tablets are not recommended as the iodine content is variable and not subject to control.

Fortification

In March 2008 a proposal to recommend the use of iodised salt in all bread making in New Zealand was accepted (excluding organic breads). The bread making industry has been given 18 months to prepare for iodine fortification. The standard will become enforceable in September 2009. This also coincides with the implementation date for mandatory fortification of bread with folic acid.

See www.nzfsa.govt.nz for more information.

Iron

- Many New Zealand children may be iron deficient.
- Most people can derive enough iron from a healthy, well-balanced diet.
- Supplements may be appropriate for some groups of people. They are not necessary in the absence of iron deficiency.
- Short-acting supplements given in divided doses may be most appropriate.

What is it?

Iron is a component of many important proteins in the body including haemoglobin, myoglobin, cytochromes and enzymes. It is essential for oxygen transport and cell function.

Who needs it?

Everyone needs iron, however requirements are higher during phases of rapid growth and development in early childhood, adolescence and during pregnancy. Adult men and post-menopausal women have the lowest risk of iron deficiency.

- Medical conditions which increase the risk of iron deficiency include kidney failure, chronic malabsorption, gastrointestinal disorders and menorrhagia.
- People who engage in regular, intense exercise may also have a greater need for iron, especially female, vegetarian or endurance athletes.[17]
- Frequent blood donation may also increase risk, especially in women of child-bearing age.

Iron deficiency

The 2002 Children's Nutrition Survey found that the prevalence of iron deficiency in school-age New Zealand children was 1.6% and iron deficiency anaemia 0.3%.

The highest prevalence was found in females aged 11–14 years and Māori and Pacific peoples – 11% of Māori females aged 11–14 years were iron deficient.[13]

Other studies in New Zealand have reported rates of iron deficiency in children aged 6–24 months ranging from 8% to 14%.[18 19] Prevalence appears to vary with ethnicity (non-Europeans had serum ferritin levels 30% lower than Europeans) but not with socioeconomic status.

Less iron is absorbed from a vegetarian diet, so dietary intake of iron needs to be 80% higher than non-vegetarians who can derive their iron from meat.[20]

Healthy, full term babies are born with a supply of iron that lasts for 4–6 months. Lactating women do not need additional iron requirements as it is assumed that menstruation does not resume until after six months of exclusive breast feeding.

Symptoms of iron deficiency

Iron deficiency develops gradually and may eventually result in iron deficiency anaemia. Symptoms of iron deficiency anaemia include reduced physical work capacity, fatigue, light headedness, weakness, breathlessness, impaired cognitive function, difficulty maintaining body temperature, impaired immunity, adverse pregnancy outcomes and delayed psychomotor development in infants.[17 20] Less severe iron deficiency has been associated with fatigue, poorer learning and memory.

Adverse effects of excessive iron

Adverse effects of excessive iron range from gastrointestinal irritation to systemic toxicity. Iron is potentially dangerous if taken in overdose, especially in children, therefore it should be stored safely.

Iron overload can occur when excess iron in the blood is stored in the liver and heart. Up to 0.5% of the population of Northern European descent is homozygous for hereditary **haemochromatosis** and therefore particularly susceptible to iron overload, even with normal dietary intake. These people should avoid supplements and excessive use of iron fortified foods.

People with blood disorders that require frequent transfusions are also at risk of iron overload.[20]

Tests for iron status

Many people with iron deficiency will present with tiredness as the predominant symptom. Serum ferritin and complete blood count are the most appropriate tests for iron deficiency. Note that a normal ferritin level in a patient with inflammation or infection does not rule out iron deficiency (ferritin is raised during this time).

Dietary sources and supplements

Dietary iron

There are two types of dietary iron – haem and non-haem. Haem iron is more easily absorbed and can also increase the absorption of non-haem iron.

Haem iron is found in foods that originally contained haemoglobin and myoglobin such as red meat, fish and poultry.

Non-haem iron is found in plant based foods such as beans, lentils, nuts, whole grain cereals and some vegetables and fruits. This is also the type of iron that is added to fortified foods such as breakfast cereals. Absorption of non-haem iron is influenced by other dietary factors.

- Vitamin C, citric, lactic or malic acid (apples) can increase the absorption of iron.
- Calcium, zinc, tannin (tea) and phytates (legumes, rice, grains, seeds and nuts) can inhibit iron absorption.
- Conversely, high iron intakes can affect the absorption of other nutrients such as zinc and calcium.

People who have diets low in iron, vegetarian diets, at times of iron loss (e.g. heavy menstruation) or when iron

Iron	Strength	Approximate elemental iron	Additional ingredient	Trade name
Ferrous fumarate	200 mg	65 mg		Ferro-tab
Ferrous fumarate	310 mg	100 mg	Folic acid 350 mcg	Ferro-F-Tabs
Ferrous gluconate	170 mg	20 mg	Ascorbic acid 40 mg	Healtheries
Ferrous sulphate	150mg/5ml	30 mg/5ml		Ferodan
Ferrous sulphate*	325 mg	105 mg		Ferro-gradumet
Ferrous sulphate*	325mg	105 mg	Folic acid 350 mcg	Ferrograd-Folic

* not fully subsidised, long-acting tablets

requirements are high (e.g. pregnancy) should ensure that foods which enhance iron absorption are consumed with meals (e.g. vitamin C) and that tea is not consumed with meals.[17, 20]

Iron supplements

Most people are able to achieve an adequate iron intake with a healthy, balanced diet. Iron supplementation in the absence of deficiency should be avoided.

However, there are three groups of people who may require supplementation:[17]

- Those with a greater need for iron e.g. pregnant women, teenage girls
- Those who lose more iron than normal e.g. heavy menstruation
- Those who do not absorb iron normally e.g. renal failure, malabsorption

The iron supplements (see table) are available on the medicines schedule in New Zealand. There is no particular advantage of one ferrous salt type over another, provided adequate elemental iron is given, so choice of medicine is dependent on the incidence of side effects and cost.

- Supplementation is usually required for less than three months.
- The amount of iron absorbed from tablets decreases with increasing doses, therefore it may be beneficial for people to take an iron supplement, in two or three equally spaced doses per day.
- Taking iron supplements with food may help to minimise gastrointestinal side effects.
- Enteric coated or delayed release preparations have fewer side effects, however they are not as well absorbed and are not usually recommended.[17]
- Ferodan is the only option available for children if tablets are unable to be swallowed.

Prophylaxis or mild iron deficiency:

65–130 mg elemental iron per day for adults and children aged over 12 years.

Moderate iron deficiency or iron deficiency anaemia:

100–200 mg elemental iron per day for adults and children aged over 12 years.

Children:

30–120 mg elemental iron per day for children aged 6–12 years.

< 30 mg elemental iron per day for children aged 2–6 years.

Iron supplements should only be given to children aged under two years on specialist advice.

"Over the counter" supplements

There are many iron supplements available over the counter. People should be cautious about unwarranted use and carefully read labels for iron content and consider whether dietary iron may be a better alternative.

Vitamin B12

- Elderly people and people with gastrointestinal disorders or anaemia have a higher risk of vitamin B12 deficiency.
- Unexplained neurological symptoms in people at higher risk of vitamin B12 deficiency would warrant testing of vitamin B12 status. Supplementation may then be required.
- Vitamin B12 status could be checked in people who have taken a PPI or H_2RA medication for more than three years.

What is it?

Vitamin B12 refers to the group of cobalamins including hydroxycobalamin and cyanocobalamin. It is required for the synthesis of DNA and the formation of red blood cells and is also essential for neurological function.

Who needs it?

The most common cause of vitamin B12 deficiency is pernicious anaemia.

Elderly people also have an increased risk of vitamin B12 deficiency due to a higher incidence of atrophic gastritis and reduced gastric acid secretion. Vitamin B12 requires gastric acid and pepsin to release it from food.

People with coeliac disease, Crohn's disease or other stomach and small intestine disorders may be unable to absorb enough vitamin B12 from a normal diet.

Higher dietary levels of vitamin B12 are required throughout pregnancy and breast feeding. Breastfed infants receive their daily intake of vitamin B12 through breast milk, dependent on the mother's intake.

Some drugs are associated with a higher risk of vitamin B12 deficiency:

- Metformin due to its effect on calcium metabolism which is required for vitamin B12 absorption.[21, 22]
- Long term use of H_2RA's (e.g. ranitidine) or PPIs (e.g. omeprazole) due to reduced gastric acid secretion (See BPJ 5, May 2007 "Can proton pump inhibitors cause vitamin B12 deficiency")

Vitamin B12 levels take approximately two years to deplete so deficiency is unlikely to result from short term changes in diet. Long term strict vegetarian or vegan diets (i.e. no animal products) are associated with a higher risk of vitamin B12 deficiency.[23, 24]

Women taking oral contraceptives may have falsely low vitamin B12 levels, possibly as a result of low vitamin B12 binding proteins in serum. This is not associated with other markers of impaired B12 status and treatment is unwarranted.[25]

Vitamin B12 deficiency

Vitamin B12 deficiency can produce haematological, neurological or gastrointestinal symptoms.

Signs and symptoms are those generally associated with anaemia – skin pallor, low energy and exercise tolerance, fatigue, shortness of breath, palpitations and sore mouth or tongue.

Neurological symptoms include peripheral neuropathy, motor disturbance, cognitive changes ranging from memory loss to dementia, mood change, visual disturbances and depression.

Gastrointestinal symptoms include constipation, loss of appetite, weight loss, impaired bladder and bowel control.

Signs of vitamin B12 deficiency in an infant include failure to thrive, movement disorders, delayed development and megaloblastic anaemia.[23, 24]

Adverse effects of excessive vitamin B12

No adverse effects have been reported with excess vitamin B12 intake from food or supplementation in healthy individuals. It is thought that the body is able to decrease absorption in response to high intakes.[23]

Tests for vitamin B12 status

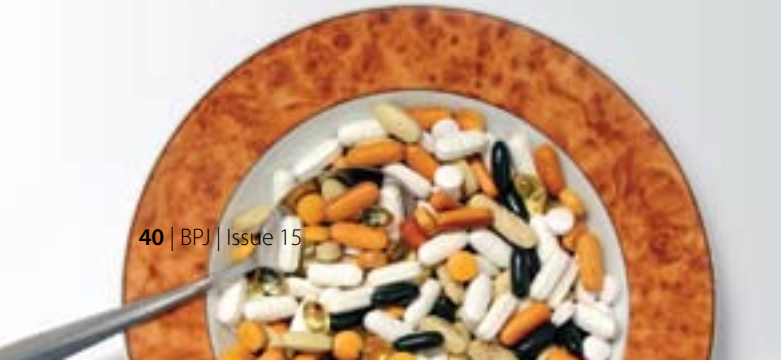
The presence of unexplained symptoms in a person at greater risk of vitamin B12 deficiency would indicate that testing was required. Vitamin B12 could also be checked in older people with poor nutrition.

Vitamin B12 status may be checked in people who have been taking PPIs or H_2RAs for more than three or four years, especially if there are any signs and symptoms, or if the patient is older.

Complete blood count should be performed first followed by serum vitamin B12 if the results are suggestive of deficiency. Low vitamin B12 levels reflect a long-term deficiency or chronic low intake, as serum B12 has low sensitivity and often remains normal for weeks or months after a negative balance has occurred.

Multivitamin and mineral supplements

Multivitamin and mineral supplements do not correct poor diets, do not contain calories, proteins, essential fatty acids or fibre and often do not contain enough essential vitamins and minerals. People who take these supplements are at higher risk of nutrient drug interactions and toxicity. There is insufficient evidence of their benefit and safety. Encouraging people to concentrate on eating nutrient-dense healthy meals, and improving access to reliable evidence based nutrition advice, is a much better approach to health and wellbeing.[26]



Normal serum B12 levels do not necessarily exclude deficiency and low levels do not necessarily indicate deficiency. Low levels without deficiency may particularly be seen in pregnancy. However, the lower the level, the greater the likelihood of a true B12 deficiency. It is important to interpret results in the clinical context and specialist advice may be needed to guide further investigation in situations where the diagnosis is not clear.

Dietary sources and supplements

Dietary vitamin B12

Natural sources of vitamin B12 include red meat, seafood, poultry, milk and dairy products. Spirulina, seaweed and soy products may contain vitamin B12 but are not a reliable source. Many other foods, especially vegan foods, contain vitamin B12 as an additive.

Vitamin B12 supplements

Vitamin B12 supplements are usually not necessary in healthy adults and children, however it is important to maintain recommended daily intakes through diet or fortified food products.

- People with pernicious anaemia require parenteral injections of vitamin B12, three times a week for two weeks, then once every two to three months.[8]
- People with gastrointestinal disorders and older adults (over 50 years) who cannot obtain enough vitamin B12 in the diet or through fortified foods may also require supplementation. If the deficiency is due to diet, twice yearly injections of vitamin B12 can be given. Treatment can be stopped when vitamin B12 levels have corrected and if the diet has been improved.[8]
- People with a vegan diet may need vitamin B12 supplementation. This is especially important throughout pregnancy and lactation.

Metformin and vitamin B12 deficiency

Calcium is essential for the absorption of vitamin B12. Metformin is known to affect calcium metabolism, therefore some people who use metformin may have reduced vitamin

B12 absorption, leading to megaloblastic anaemia. A small study found that 1200 mg/day calcium carbonate limited the negative effect of metformin on vitamin B12 levels.[22] However, a more recent study concluded that while vitamin B12 levels are depleted in people taking metformin (the greater the dose, the larger the deficiency), calcium supplements are not necessary. There was no evidence that calcium reduced the prevalence of vitamin B12 deficiency.[27]

In light of conflicting evidence, best practice would be to monitor vitamin B12 status once per year in people taking continuous metformin, especially older people and those who have taken metformin for several years. Vitamin B12 supplements could be considered in the presence of deficiency.

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Educational programme on the use of

ANTIPSYCHOTICS for symptoms associated with DEMENTIA

Bpac is launching an educational programme to promote the safe and rational use of antipsychotic drugs for behavioural and psychological symptoms of dementia (BPSD).

BPSD refers to the often distressing non-cognitive symptoms of dementia and includes agitation and aggressive behaviour.

Recent research has indicated that both typical (e.g. haloperidol) and atypical (e.g. risperidone) antipsychotics are associated with an increased risk of stroke, mortality and morbidity in people with dementia. Antipsychotics can also cause adverse effects such as constipation, hypotension and CNS depression that can increase the likelihood of adverse events, especially in the elderly.

Furthermore, these drugs are not clinically effective for most BPSD and research shows that they tend to be used at excessive doses for prolonged periods, without review.

Two recent international communications, an All Party Parliamentary Report from the UK and a directive from the Food and Drug Administration in the USA, have corroborated the need to review prescribing practices for these drugs. Both reports emphasise the limited value of antipsychotic drugs for BPSD and the requirement for a careful benefit: risk analysis before prescribing.[1,2]

The bpac programme consists of a Best Practice Guide to the use of antipsychotics for BPSD, and a prescribing audit for residential care facilities. The audit is intended to analyse the prescribing process rather than audit individual practitioners. Results of this audit will be fed back to general practitioners involved in the care of patients in residential care. This will provide the opportunity for interdisciplinary discussion and education about strategies to optimise patient care.

The resource is based on the clinical recommendations published by the Royal Australian and New Zealand College of Psychiatrists; “The Use of Antipsychotics in Residential Aged Care” which is also available from the bpac web site.

For more details about the programme please visit

www.bpac.org.nz/a4d

Safe and rational use of antipsychotic drugs for BPSD

Key concepts

- Most BPSD are transient and respond to non-pharmacological treatment which should be trialed before drug treatment is considered.
- Antipsychotics are only indicated as a "last resort" if aggression, agitation or psychotic symptoms cause severe distress or an immediate risk of harm to the patient or others. Even for these indications they are only moderately effective.
- All antipsychotics are associated with increased morbidity and mortality in people with dementia.
- Antipsychotics should only be prescribed for specific problem behaviours and the response to treatment should be closely monitored.
- The risks and benefits of antipsychotic treatment should be assessed on an individual basis. Drug treatment should be reviewed regularly and stopped as soon as symptoms resolve.

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Improving Māori Health – Increased awareness of issues

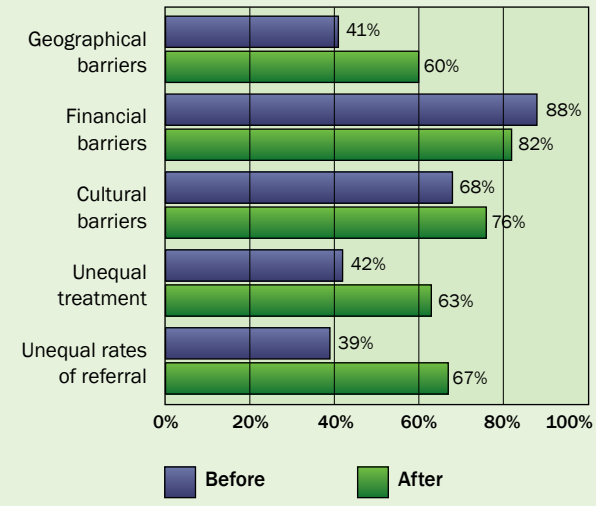
In May 2008, bpac published an issue of Best Practice Journal focused on improving Māori health. A randomly selected group of GPs was invited to complete a survey on their knowledge of Māori health issues, before and after the publication.

GPs were asked whether they believed there were significant issues for Māori compared to non-Māori in their location, in regards to specific aspects of healthcare. Following the publication of BPJ 13 awareness of these issues had increased (Figure 1).

Following publication of BPJ 13 there was also an increase in the proportion of GPs who said they would ask patients about their use of Rongoā Māori. There was an increase in knowledge of the prevalence of gout in Māori and inequalities in treatment of childhood asthma.

Interestingly, the survey results showed that GPs confidence in handling Māori health issues decreased, following the publication, which may reflect a greater awareness of the issues that are faced.

Figure 1. Proportion of GPs who believed there were issues for Māori in selected aspects of healthcare.



Using nebulisers safely

Nebulisers are used to deliver bronchodilators to people with asthma or COPD or antibiotics to those with bronchiectasis.

There is now substantial evidence that the use of a metered dose inhaler (MDI) with a spacer is just as effective as a nebuliser, even in acute asthma.

Indications for nebuliser use

For acute deteriorations in asthma or COPD

- If the patient is unable to use a MDI and spacer e.g. very young children, intellectual disability, anxiety.
- If the episode is so severe that the rate of breathing is above 30 per minute at rest (in an adult), and the patient is unable to inhale from a spacer properly.
- The patient has a condition e.g. rheumatoid arthritis, which impairs use of the MDI or spacer.
- If the patient has a history of "crashing" or life-threatening asthma.

For chronic asthma or COPD

- For a patient with COPD whose lung function is so poor that they cannot inhale properly from any hand held delivery device.
- For a patient with asthma or COPD with another disability which prevents them using a MDI and spacer.

For cystic fibrosis or bronchiectasis

- For delivery of prophylactic antibiotics.
- For delivery of hypertonic saline.
- For delivery of DNA-ase.

What are the potential harmful effects of nebuliser therapy?

Regular nebulised bronchodilator therapy (i.e. for more than a few days) should be avoided. The risk of adverse effects is based on the following:

- The delivered dose using a nebuliser is high. The dose in a single nebule may be equivalent to either 25 or even 50 puffs of bronchodilator from a MDI.
- Beta-agonists have a pro-inflammatory effect when given at high doses.
- Beta-agonists result in an increase in airway hyper-responsiveness (AHR) when given regularly or at high doses.
- In some patients the increase in AHR is associated with rebound bronchconstriction at the end of the dosing interval. Therefore, a vicious circle develops in some patients because with increased inflammation and AHR, symptoms worsen and there is a perception that even more "reliever" is required.

There are other pitfalls. Using a nebuliser may create a false sense of security, especially during an acute episode of asthma. The temporary relief from a high dose of nebulised bronchodilator may result in a delay in starting steroid therapy – or in ringing the ambulance. Also, the "rush" which occurs with nebulised beta-agonist - often associated with a fast heart rate or tremor – is enjoyable for some people. "Reliever" beta-agonists are modified forms of adrenaline and, because the delivered dose of nebulised beta-agonist is so high, it affects not only the airways but other organs also. The "adrenaline rush" is therefore real, and psychological dependence may occur.

The Asthma and Respiratory Foundation of New Zealand (Inc.)
Te Taumatua Huango, Mate Ha o Aotearoa

These problems may be encountered in people with COPD just as much as in people with asthma, although the evidence is less clear cut. In people with predominantly emphysema, there is an additional problem – the smooth muscle relaxation which occurs with nebulised bronchodilator may actually cause "floppy" airways to collapse. Paradoxically the patient gets worse, not better. Some patients may benefit from beta-agonist withdrawal.

Psychological dependence on beta-agonists is a recognised problem. One of the ways of identifying psychological dependence is to measure peak flow at times when the patient feels the need to use the nebuliser and then afterwards. If there is no fall in peak flow associated with symptoms, or no increase with bronchodilator, then it may be that symptoms are not due to bronchospasm but something else, including vocal cord dysfunction or anxiety hyper-ventilation. This scenario may not apply to patients with COPD in whom the relationship between airway spasm and symptoms is less clear.

A very carefully constructed plan of action to wean someone off excessive beta-agonist therapy may be required. Sometimes it even requires admission to hospital for 3–4 days so that the patient can be weaned off safely. If this situation arises, consultation with a respiratory specialist is advised.

Professor D. Robin Taylor,

Medical Adviser,

Asthma and Respiratory Foundation of New Zealand.

July, 2008

Nau Mai – Te Ao Māori [6]

Nau mai e ngā hua e hora nei
I haere mai nā koe
I whakatupua nuku, i whakatupua rangi
Tāwhia ki a Rehua ki te ao mārama
Kia whakairia ki runga
Kia tina!
TINA!
Hui e!
TAIKI E!

Prayer – Acknowledging The Māori World
We acknowledge these fruits laid before us
Which have come from you
Descended from our ancestral parents
Into the world of light
Let it be elevated above
So that it has certainty
And is maintained
And it will be secure.

Tikanga relating to food[1]

The following basic Māori practices rely on an understanding of tapu and noa – key concepts that underpin many practices, Tapu and noa are entirely consistent with a logical Māori view of hygiene and align with good health and safety practices.

- Food should never be passed over the head.
- Fridges/freezers used to store food or medication for human consumption should be clearly marked and not used for any other purpose.
- Tea towels should only be used for the purpose of drying dishes and washed separately from all other soiled linen.
- Anything that comes into contact with the body or body fluids must be kept separate from food and should not be placed on surfaces where food is placed.
- Receptacles used for drinking water should be solely used for that purpose.
- Staff should not sit on tables or workbenches and particularly on surfaces used for food or medication.
- Food or drink should never be taken into a room containing a tūpāpaku

Healthy kai

It is important to be aware of Māori lifestyles, including diet. Providers should be aware and become familiar with the specific cultural preferences and foods of their patients because they have an important role in their health.[2]

Dietary changes, while recommended for an individual, often need to be adopted by the whole whānau to be successful, because preparing separate meals is unrealistic. The person requiring the change in diet may not be responsible for shopping or cooking family meals, and expectations need to be realistic and culturally acceptable.

Some foods have special meaning and can be an important part of cultural preferences. Rather than advocating their complete removal from a diet, it may be more practical to discuss how they can be prepared to minimise the salt and fat content.

For example, healthier boil up:[3]
Use pre-trimmed meat or trim fat off meat.
Half way through boiling the meat pour off the fatty water, refill the pot, boil and continue to simmer the meat.
Add lots of vegetables then boil and simmer until they are cooked. Leave skin on potatoes and kumara. Add onions, garlic and herbs instead of salt for extra flavour.

Further reading:
Te Hotu Manawa Māori

www.tehotumanawa.org.nz

Tirohanga Māori by Mason Durie available from Te Iho – Māori Mental Health Training Programme website

www.teiho.org/MaoriHealthPerspectives/TirohangaMaoriByMasonDurie.aspx

Glossary:

Kai – Food, to eat

Manaakitanga – protection, blessings, show respect or kindness to.

Mana – prestige, respect, authority

Mihimihi – to greet

Noa – free from tapu

Pōwhiri – welcome

Tapu – sacred, restricted

Tikanga – rule, customs, protocol, lore

Tūpāpaku – body of the deceased

Whānau – family group, give birth

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Manaakitanga

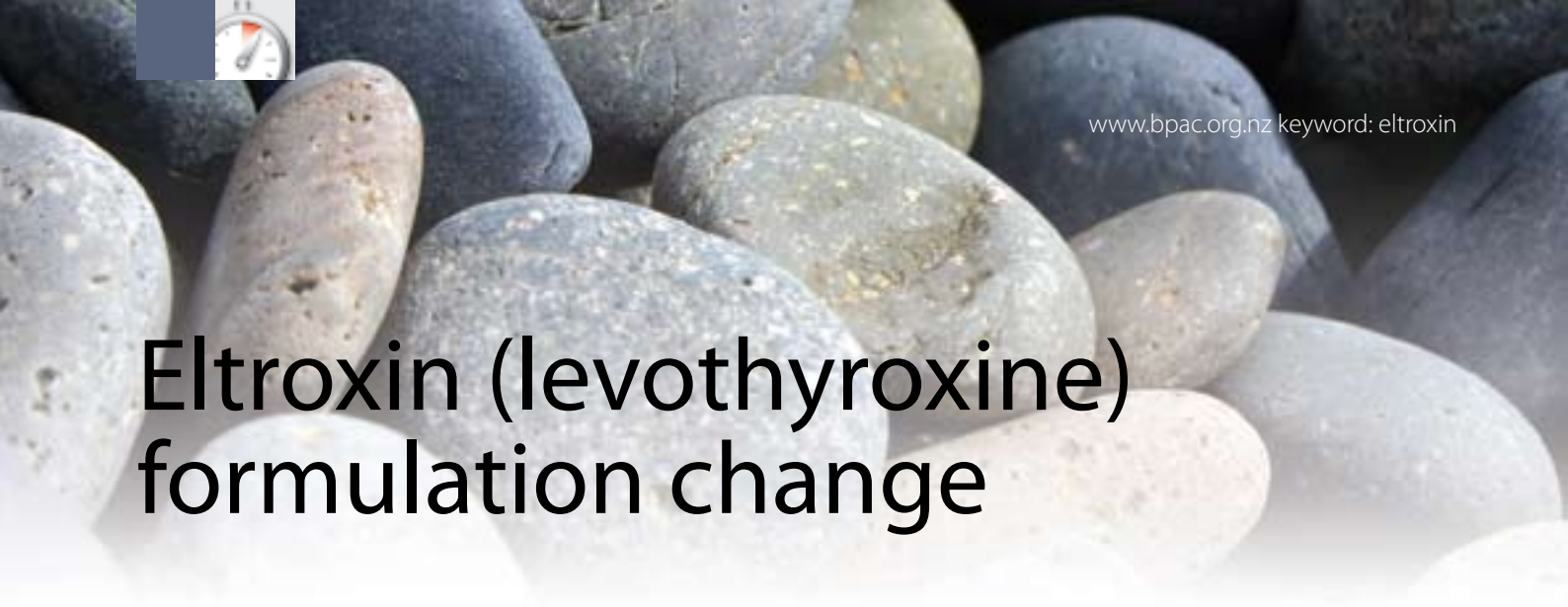
Manaakitanga – nurturing relationships, looking after people and being very careful about how others are treated is a key component of Māori culture. The principles and values attached to it underpin all tikanga Māori. Manaakitanga is always considered important, no matter what the circumstances.

Manaakitanga focuses on positive human behaviour and encourages people to rise above their personal attitudes and feelings towards others. The aim is to nurture relationships and to respect the mana of other people no matter what their standing in society may be. Being hospitable and looking after visitors is given high priority.[4]

When visiting Māori on a marae or at home, it is important to allow sufficient time for any welcome and refreshments that may be offered. While health professionals do work under considerable time pressures it is considered impolite to not partake in this aspect. To socialise even briefly will greatly assist in developing rapport and building an effective therapeutic relationship. A whānau hui involving proper rituals of engagement and closure can be invaluable in developing rapport and partnership with patients and their families.

Health professionals are held in high esteem and so it is important to acknowledge the welcome. Often, in the clinical context, a more informal process of welcome is undertaken with some of the essential elements of the pōwhiri and some of the more informal aspects of the mihimihi. This may include speeches and waiata. Knowledge of these rituals is important in whānau meetings and in meetings with the local Māori community and providers.[5]

Rituals can vary, so be guided by your hosts about what is appropriate. If you are not sure of the correct process, it is better to ask than to risk causing offence.



Eltroxin (levothyroxine) formulation change

New formulation of Eltroxin

Since July 2007, Glaxo Smith Kline has distributed a new formulation of Eltroxin 50 microgram and 100 microgram. The tablets have changed in size and colour and the score line has been removed. The excipients in the new formulation are also different but are commonly used in medicines.

Since then, there has been an increase in the number of adverse reaction reports involving Eltroxin, received by the Centre for Adverse Reactions Monitoring (CARM) – see side bar.

Medsafe review of Eltroxin

In response to the increase in adverse reaction reports received by CARM, Medsafe reassessed the change in formulation and confirmed that all international criteria for quality, safety, and bioequivalence were satisfactorily met.

A review of the adverse reaction reports has suggested that there is evidence of a decreased therapeutic effect in some cases. Causes of a decreased therapeutic effect may include reduced patient compliance, lack of or inappropriate blood monitoring, or quality problems with the product.

Following consultation with specialist endocrinologists, Medsafe issued advice to all healthcare professionals, emphasising the importance of thyroid function monitoring, patient compliance and how to adjust the dose of Eltroxin if necessary.

Medsafe has also initiated independent testing of the changed formulation to assess whether the presence of contaminants, or the supply of a poor quality product, could be a factor in the reactions observed. Unfortunately it will be several weeks before the results of the product testing are available.

Bioequivalence issues

Any brand or formulation change can affect the bioequivalence of a medicine. While bioequivalence is assessed using international standards before a product or formulation is approved, it is possible that up to 5% of patients may experience either an increased or decreased therapeutic effect, even when the product has been judged to be bioequivalent with the product previously available. This is why the manufacturer issued advice to all healthcare professionals, describing the change in formulation, prior to its distribution to pharmacies.

Definition of bioequivalence

Two medicines are said to be bioequivalent if the 90% confidence intervals for the ratios of the geometric means of the AUC and Cmax fall between 0.8 and 0.125 (80% and 125%). However in practice, manufacturers attempt to have this as close to 1.0 as possible.

See BPJ Special Edition March 2007 for information about bioequivalence.

Treatment of thyroid dysfunction is subject to significant inter-patient variability. Small changes in dosing of levothyroxine can affect serum thyroid hormone levels.[1]

Analysis of Eltroxin adverse reaction reports received by CARM

Approximately 70,000 patients are being prescribed Eltroxin in New Zealand.

CARM received the first report of a problem attributed to the new formulation on October 8 2007. As of August 4 2008 CARM had received 462 reports, of which 419 were received following media coverage describing patient concerns and adverse reactions in mid-June 2008. Prior to October 2007 CARM had received a total of 14 reports where thyroxine was the suspected agent.

Typical adverse reactions in the reports received by CARM include:

- Symptoms that may be attributed to thyroid dysfunction such as weight gain, lethargy, alopecia, insomnia and palpitations
- Symptoms thought unrelated to thyroid dysfunction such as eye pain, conjunctivitis, headache, visual disturbance and acute upper gastrointestinal effects
- Hypersensitivity type reactions such as angioedema, rash and facial oedema.

The onset of symptoms varies greatly in the reports. As expected, hypersensitivity reactions typically had a shorter duration of onset (days). The non-specific symptoms such as eye pain and visual disturbance also tended to have a shorter duration of onset (within the first month) whereas symptoms related to thyroid dysfunction occurred, on average, 1–2 months after conversion to the new formulation.

Details of dechallenge improvement and recurrence on rechallenge in some instances have added weight in support of a causal association with the new Eltroxin formulation.

A breakdown of reports received by CARM shows that the source of over 40% of Eltroxin adverse reaction reports were from the public, versus 29% from GPs, and 22% from pharmacists. The high proportion of reports received by the public is unusual unless a specific issue is highlighted in the media.

Possible causes of changes in therapeutic effect of Eltroxin

Slight changes in bioavailability may be an issue for patients at the upper or lower limits of the normal range.

Where TSH levels lie in the reference range, may predict how likely someone is to experience adverse effects, from a change in bioavailability.

For patients whose TSH has been adjusted to the mid-normal range, a 15% to 20% rise or fall in effective levothyroxine dose would be unlikely to result in a TSH level outside the normal range, therefore they would be unlikely to experience adverse effects.

However, a patient whose TSH level is nearer the upper or lower limits of the normal range, may be at greater risk of adverse effects with the same change, as this would be more likely to push the TSH levels outside the normal range.[2]

Patient compliance may be affected by the change in dosing instructions.

Compliance may be affected by the need to take Eltroxin tablets on an empty stomach, or the need for alternate day dosing in some patients.[1]

See Table 1 for dosing and administration recommendations from GSK.

Table 1: Dosing and administration recommendations.

Daily dose	Dosing regimen
25 microgram	One 50 microgram tablet on alternate days
50 microgram	One 50 microgram tablet daily
75 microgram	One 50 microgram tablet daily and one additional 50 microgram tablet on alternate days
100 microgram	One 100 microgram tablet daily
125 microgram	One 100 microgram tablet daily and one additional 50 microgram tablet on alternate days

Advice to prescribers

Check dosing and administration of Eltroxin[3]

1. Eltroxin tablets should be taken on an empty stomach preferably 30 minutes before breakfast.
2. Eltroxin tablets should be swallowed whole and taken with a full glass of water.
3. Doses requiring 25 microgram increments should be administered using alternate day dosing of 50 microgram tablets.

Monitor thyroid function in patients on Eltroxin[3]

Thyroid function should be monitored, particularly for patients who have noticed symptoms since changing to the new formulation.[1]

- TSH levels are the best indicator of thyroid function.
- Thyroid function tests do not have to be performed at a particular time of the day.
- Due to the long half life of levothyroxine (5–7 days) thyroid function tests should be performed no earlier than 4–6 weeks after a change in dose, or change in formulation.
- If testing is required in this first six weeks of treatment due to particular concerns about thyroid function, free T4 and free T3 levels can be monitored.

Dose adjustments in response to TSH levels should not usually exceed 50 micrograms per day. Dose adjustments in elderly people, in those with pre-existing heart disease or diabetes, should not exceed 50 micrograms on alternate days.

Report adverse reactions to Eltroxin

Adverse reactions should be reported to CARM. If possible include:

- Pre- and post- formulation change thyroid function tests (and previous dosage stability generally)
- Information on whether the patient has changed the timing of their dosage (i.e. did they take the previous formulation before or after food; and are they taking the new formulation before or after food?)
- Confirmation the patient is not halving the tablet
- When the patient was changed to the new formulation
- Whether symptoms are seemingly hyper- or hypo-thyroidism
- If any acute management was necessary

Acknowledgment:
Thank you to **Chris James**, Clinical Risk Management Team, Medsafe, for contribution to this article.

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Advice from Medsafe: Access to alternative levothyroxine tablets

Eltroxin is the only brand of levothyroxine tablets that has approval for distribution in New Zealand. Currently Medsafe does not have any applications for alternative brands of levothyroxine tablets from other pharmaceutical companies.

Although Medsafe is working to encourage another brand of levothyroxine to be supplied in New Zealand, the decision to market in New Zealand is not within Medsafe's control.

Any alternative brand of levothyroxine can only be supplied as an unapproved medicine. Unapproved medicines can be supplied under provisions in the Medicines Act (Sections 25 & 29) that allows an authorised prescriber to request or obtain the medicine for a specific patient under their care. Further information on the use of unapproved medicines and the obligations of the prescriber can be viewed at http://www.medsafe.govt.nz/regulatory/unapproved.asp.

The use of unapproved medicines would not usually be advocated. This is a last resort measure for people who experience significant adverse effects with Eltroxin and are unable to tolerate it. Unapproved medicines should not be routinely used in other circumstances.

Medsafe understands that Health Support Ltd is supplying an alternative brand of levothyroxine tablets using the Section 29 exemption of the Medicines Act 1981.

Medsafe has not assessed other brands or formulations of levothyroxine for quality, safety or bioequivalence. Transfer to another brand should only be considered in patients:

- With hypersensitivity or intolerance type reactions
- Exhibiting hypothyroid type symptoms that have not responded to dose adjustment.

Patients transferred to another brand of levothyroxine will require ongoing monitoring in the same way as the current GSK product.

It's time to get your patients ready for a change

Brand change notification – Losec and Omezol brands change to Dr Reddy's Omeprazole.

PHARMAC has reached an agreement with a new supplier of omeprazole. Because of this agreement only Dr Reddy's Omeprazole will be funded by PHARMAC from 1 May 2009.

This means that you have nearly 1 year to review your patient's medication.

There are a few important dates to note.

This changeover will take place over the next few months as the funding for Losec and Omezol is reduced, consequently costs may increase for Losec or Omezol, particularly if requested after these dates;

- From 1 July 2008 the cost of Omezol may go up.
- From 1 January 2009 the cost of Losec may go up.

Reference material and brand switch information about the change can be found on the PHARMAC website, www.pharmac.govt.nz.

We encourage your feedback on this brand change in a short survey accessible on **www.pharmac.govt.nz**. Follow the brand switch link found on the home page.

BrandSwitch

PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Evidence That Counts

Clinical presentation of coeliac disease in children

Journal Watch, Vol. 28, No. 5, March 1, 2008

The realisation that coeliac disease is far more common than once thought makes understanding its clinical presentation more important. Investigators from the Children's Hospital of Wisconsin reviewed the medical records of all 143 patients (age range 1–17 years) who received coeliac disease diagnoses over a 17-year period.

The number of cases diagnosed rose significantly year by year, from one in 1986 to 93 in 2003, as did mean patient age from 5.3 years before 1995 to 8.7 years after 1995. The most common non-gastrointestinal conditions associated with coeliac disease were type 1 diabetes (n=56), thyroiditis (n=15), short stature (n=13), Down syndrome (n=11), family history of coeliac disease (n=10) and iron deficiency (n=9). GI conditions that led to the diagnosis included diarrhoea (n=40), failure to thrive (n=36), abdominal pain (n=32), bloating (n=17) and constipation (n=8).

Comment:
This report, with all the limitations characteristic of case series, sheds light on the clinical presentation of coeliac disease, particularly the associated non-GI conditions. The authors suggest screening for coeliac disease in high-risk groups, including first-degree relatives of patients with coeliac disease and people with Down syndrome, Turner syndrome, type 1 diabetes, thyroiditis, Addison disease, short stature, persistent iron deficiency anaemia and unexplained elevation of aminotransferase levels.

— **Howard Bauchner**, MD

Telega G et al. Emerging new clinical patterns in the presentation of coeliac disease. Arch Pediatr Adolesc Med 2008 Feb; 162:164.

Early gluten exposure and risk for coeliac disease

Journal Watch Paediatrics and Adolescent Medicine July 25, 2005

Timing of introduction of gluten to diets of high-risk infants is associated with coeliac disease.

To assess whether the timing of introduction of gluten to infants' diets influences subsequent onset of coeliac disease autoimmunity, investigators in Colorado prospectively followed 1560 high-risk children (mean follow-up 4.8 years). Children at high risk for coeliac disease had either human leukocyte antigen (HLA)-DR3 or -DR4 alleles or a first-degree relative with type 1 diabetes (because these same alleles confer an increased risk for type 1 diabetes). Onset of coeliac disease autoimmunity was defined as two or more consecutive tests that showed positive antibodies for tissue transglutaminase (tTG). Children were tested at birth, at 9, 15, and 24 months, and annually thereafter. Clinical evaluation was conducted after two positive tTG tests. No dietary advice was provided to families.

Of the 51 children who developed coeliac disease autoimmunity, 34 underwent small-bowel biopsies (25 were coeliac disease autoimmunity-positive). The mean age at first positive tTG antibody test was 4.7 years. Three coeliac disease autoimmunity-positive children (6%) were exposed to wheat, barley and rye (gluten foods) by 3 months of age; 12 (23%) were exposed at 4–6 months, and 36 (71%) at or after age 7 months. Among HLA-DR3–positive children, introduction of gluten foods by age 3 months was associated with a fivefold increased risk for coeliac disease autoimmunity compared with exposure at age 4–6 months. Exposure at or after age 7 months was associated with a slightly increased risk for coeliac disease autoimmunity compared with exposure at 4–6 months. Coeliac disease autoimmunity risk was not influenced by breast-feeding

duration or age at exposure to oats, rice, or cow's milk. In analyses limited to children with the highest risk for coeliac disease (HLA-DR3–positive) children exposed to gluten foods during the first three months of life had a 40% risk for CDA by age 5.5 years.

Comment:
This report is the second by these investigators to show an association between early introduction of certain nutrients and subsequent autoimmunity in high-risk populations (see JW Pediatr Adolesc Med Nov 24 2003). We should caution families with a history of type 1 diabetes or coeliac disease about early exposure to wheat, barley or rye, as is recommended by the American Academy of Paediatrics. I would not specifically expose at-risk infants to gluten at age 4–6 months based solely on these data, but we should watch this literature carefully.

— **F. Bruder Stapleton**, MD

Norris JM et al. Risk of coeliac disease autoimmunity and timing of gluten introduction in the diet of infants at increased risk of disease. JAMA 2005 May 18; 293:2343-51.

The placebo effect and irritable bowel syndrome

Journal Watch, Vol. 28, No. 11, June 1, 2008

The placebo effect is a widely recognised phenomenon. However the mechanisms that engender the placebo effect are unclear. In this trial, investigators sought to determine whether the placebo effect can be broken down into three components — responses to clinician assessment and observation, placebo treatment and a supportive clinician–patient relationship — and whether combining these components enhances clinical improvement. Specifically, 262 adults with irritable bowel syndrome were randomised to clinical assessment and observation only, placebo acupuncture only or placebo acupuncture "augmented" by supportive clinician–patient relationships that were characterised by "warmth, attention, and confidence."

At three weeks, the percentages of patients who reported adequate pain relief were 28% in the observation-only group, 44% in the placebo acupuncture–only group and 62% in the augmented placebo acupuncture group — a significant trend ($P<0.001$). Similar results were found for scores on validated scales of global improvement, symptom severity and quality of life. Notably, improvement was significantly greater in the augmented group than in the placebo acupuncture–only group, for all outcomes. Results at six weeks were similar to those at three weeks.

Comment:
The placebo effect can be broken down into three components that, when combined, result in statistically and clinically important effects. Especially intriguing is how a supportive clinician–patient relationship augments the efficacy of placebo treatment. Because such a relationship is likely to enhance treatments that are biologically effective also, editorialists reasonably claim that "a good doctor–patient relationship can tangibly improve patients' responses to treatment, placebo or otherwise."

— **Paul S. Mueller**, MD, MPH, FACP

Kaptchuk TJ et al. Components of placebo effect: Randomised controlled trial in patients with irritable bowel syndrome. BMJ 2008 Apr 3; [e-pub ahead of print]. (http://dx.doi.org/10.1136/bmj.39524.439618.25)

Spiegel D and Harrington A. What is the placebo worth? BMJ 2008 Apr 3; [e-pub ahead of print]. (http://dx.doi.org/10.1136/bmj.39535.344201.BE)

Evidence That Counts

Statins and muscle disorders – be careful with the dose

Australian Adverse Drug Reactions Bulletin
Volume 27, Number 3, June 2008
http://www.tga.gov.au/adr/aadrb/aadr0806.htm

Muscle disorders are well known to be associated with the statins, with risk factors including age > 70 years, various disease states (diabetes, hypothyroidism, renal and hepatic disease), concurrent use of CYP3A4 inhibitors and, importantly, the dose of the statin.[1,2] The Australian Adverse Drug Reactions Advisory Committee (ADRAC) continues to receive reports describing myositis/rhabdomyolysis occurring in situations where statin therapy has been initiated at an inappropriately high dose. The following vignette is a case in point.

A 65 year old woman with a history of hypothyroidism (treated with replacement therapy), asthma, Meniere's disease and gastro-oesophageal reflux was started on simvastatin, 80 mg daily, for treatment of hypercholesterolaemia. After four months she noticed the onset of severe pain and weakness in her lower limbs, which required admission to hospital. She had myoglobinuria and grossly elevated serum creatine kinase (14,450 IU/L) establishing the diagnosis of rhabdomyolysis.

High dose simvastatin is a major risk factor and hypothyroidism, if under-treated, is also a risk factor for rhabdomyolysis.

By late 2007 the TGA (Therapeutic Goods Administration) had received 5,846 adverse reaction reports implicating a statin. Of these, almost one-third described muscle disorders such as myalgia, myopathy, myositis, or rhabdomyolysis (which, when severe were associated with myoglobinuria and, in extreme cases, renal failure).

Prescribers are reminded that statin treatment should commence with the lowest possible dose, which may then be titrated if necessary according to lipid levels, while monitoring for adverse reactions, especially any symptoms of muscle disorders.

References

1. Risk Factors for myopathy and rhabdomyolysis with the statins. Aust Adv Drug Reactions Bull 2004; 23(1): 14.
2. Ronaldson KJ, O'Shea JM, Boyd IW. Risk factors for rhabdomyolysis with simvastatin and atorvastatin. Drug Safety 2006; 29(11): 1061-1067.

Declining MI and cardiovascular risk factors

Journal Watch, Vol. 28, No. 7, April 1, 2008

Cardiovascular disease is the leading cause of death in the U.K., but the incidence of myocardial infarction has fallen in recent years. British Regional Heart Study investigators have examined whether this decline reflects changes in cardiovascular risk factors.

Among 7735 men who were followed for 25 years, the age-adjusted hazard for MI decreased by 3.8% annually, which corresponded to a 62% decline during the 25-year period. Beneficial trends were decreases in cigarette smoking, systolic blood pressure, and non–HDL cholesterol levels and increases in HDL cholesterol and physical activity levels. A potentially harmful trend was increased body-mass index. No significant changes in alcohol consumption were noted and diabetes was not assessed. Declines in cigarette smoking accounted for 23% of the reduction in MI incidence; improvement in blood pressure accounted for 13%; changes in HDL cholesterol levels for 12%; and reductions in non–HDL cholesterol levels for 10%. Physical activity and alcohol consumption had no significant effects.

Comment:

In this analysis, changes in four traditional risk factors (cigarette smoking, blood pressure, HDL cholesterol levels and non–HDL cholesterol levels) accounted for approximately half the reduction in MI incidence over time. The analysis did not distinguish between improvements that resulted from lifestyle changes and those that were related to medication. The good news is that even modest changes in risk factors can substantially lower risk for MI, but rising BMI (and presumably more diabetes) might counteract these otherwise favourable findings.

— **Kirsten E. Fleischmann**, MD, MPH

Hardoon SL et al. How much of the recent decline in the incidence of myocardial infarction in British men can be explained by changes in cardiovascular risk factors? Evidence from a prospective population-based study. Circulation 2008 Feb 5; 117:598.

Choice of antihypertensive agents for patients with metabolic syndrome: ALLHAT results

Journal Watch, Vol. 28, No. 7, April 1, 2008

Results from the largest antihypertensive trial to date — ALLHAT — suggested that diuretics should be the preferred initial drug for treating patients with hypertension. However, concern persists about thiazides because of their adverse effects on insulin sensitivity and onset of diabetes, particularly among people with diabetes risk factors. In a post hoc analysis, ALLHAT researchers assessed metabolic and cardiovascular outcomes in nondiabetic patients with or without metabolic syndrome who were assigned to a diuretic (chlorthalidone), a calcium channel blocker (CCB; amlodipine) or an angiotensin-converting-enzyme (ACE) inhibitor (lisinopril).

Among people with metabolic syndrome, diabetes incidence at four years was 17% in the chlorthalidone group, 16% in the amlodipine group, and 13% in the lisinopril group. Among people without metabolic syndrome, diabetes incidence was 7.7% in the chlorthalidone group, 4.2% in the amlodipine group, and 4.7% in the lisinopril group. However, risks for coronary heart disease, all-cause mortality, stroke and end-stage renal disease were not significantly different among treatment arms (regardless of metabolic syndrome status). The incidences of heart failure and combined cardiovascular diseases were significantly lower in patients with metabolic syndrome, who were assigned to chlorthalidone, than among similar patients who received lisinopril.

Comment:

Treatment with a diuretic, compared with a CCB or an ACE inhibitor, resulted in a higher incidence of diabetes among ALLHAT participants with or without metabolic syndrome. Nevertheless, the chlorthalidone group had clinical outcomes that were similar to (and, in some cases, better than) outcomes in the other groups, regardless of metabolic syndrome status. Given the relatively short duration of follow-up, the possibility that adverse events will accrue later cannot be excluded. However, as pointed out by the authors, long-term follow-up (14 years) in the Systolic Hypertension in the Elderly Program did not show excess risk for CVD mortality among participants who were assigned to a thiazide and who later developed diabetes (Am J Cardiol 2005; 95:29). Thiazides should remain a first line agent for most patients and, at a minimum, should be a component of any multidrug regimen.

— Jamaluddin Moloo, MD, MPH

Black HR et al. Metabolic and clinical outcomes in nondiabetic individuals with the metabolic syndrome assigned to chlorthalidone, amlodipine, or lisinopril as initial treatment for hypertension: A report from the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). Diabetes Care 2008 Feb; 31:353.

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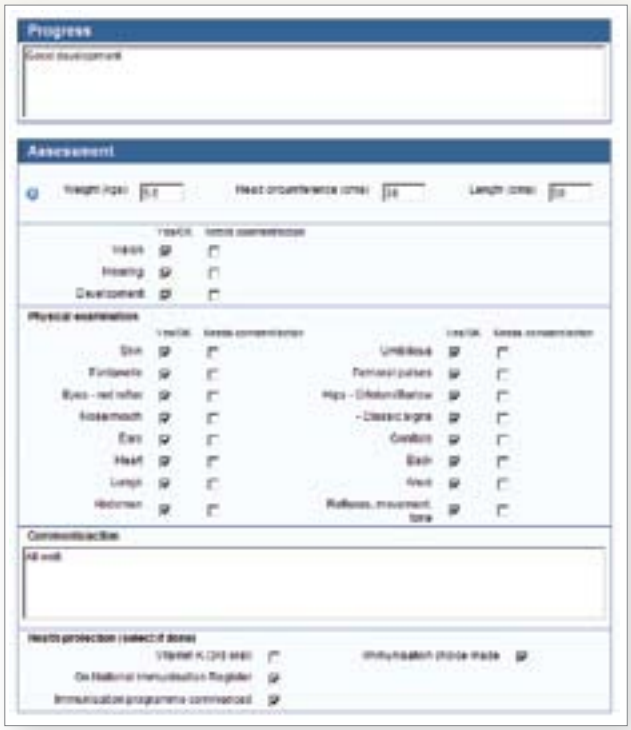
Well Child - Tamariki Ora



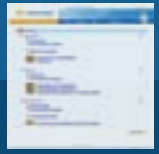
The ***Six Week Check*** module is designed to assist health professionals in completing a ***Six Week Well Child Assessment***. It does this by providing:

- A checklist of data required and physical examinations to perform.
- A facility for the storage of relevant information in the Practice Management System as an Outbox document for recording purposes and later reference.
- Plots of the recorded weight, height and head circumference measurements against the relevant growth percentile charts.
- Health promotion resources for babies and families.

*The screenshot to the left shows the form presented by the **Well Child - Six Week Check** module to gather the required information. This form doubles as a checklist for measurements and physical examinations required.*

These screenshots show some of the most popular of the currently available modules.


Diabetes

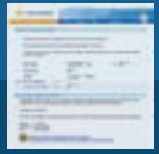

Nursing Management Guides

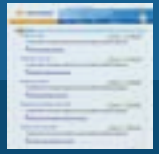

CVD


Chronic Kidney Disease


Atrial Fibrillation


Forms


Clinical Toolkit


Interactive Education


Healthy Children

Improving Māori Health

Dear bpac,
Thanks for the interesting BPJ on Improving Māori Health.

Working in a practice with a larger percentage of Māori/ Pacific peoples than Pakeha, I am beginning to believe that one of the most effective ways to improve health outcomes is to have free medication - especially for the older children.

Their parents may make poor economic decisions, but this should not mean the children do not get their medication because the caregiver has no money. We see it a few times per day. Even the adults often do not fill their scripts even though the rapport with staff is good. Their priorities are different.

By the way, has anyone ever asked the Māori/ Pacific communities if they actually want to increase their average life span or is it just another western model of feeling like we have achieved something?

GP, South Island

There are many reasons why patients do not fill prescriptions. While socioeconomic factors may be one barrier, effectiveness of communication between the health practitioner and patient can also be significant.

He Korowai Oranga, the National Māori Health Strategy, encourages Māori to determine their own aspirations and priorities for health and disability and provides mechanisms for ensuring these are taken into account in the planning and delivery of services. Published discourse about Maori aspirations show that Maori want more access to health care, more effective health care delivery, and better health outcomes. PHOs should consider establishing specific services to address the identified needs of the Māori or Pacific peoples among their enrolled population. We encourage you to raise this issue with your PHO and work with them to address it.

The evidence of disparities in health care is significant and the responsibility for achieving better outcomes is clearly shared broadly across society. Bpac will continue to contribute through education, analysis and advice, and we look forward to working with health practitioners who are similarly motivated to provide best practice health services to their patients.

Generic Prescribing

Dear bpac,
Whilst I welcome your article on generic prescribing and wholeheartedly support the practice I have come across an instance where it does not necessarily indicate "good prescribing practice."

The generic prescribing of oral contraceptives is confusing and causes the most problems especially with scripts written for ethinyloestradiol 30mcg and levonorgestrel 150mcg, which allows the dispensing of four different brands, two of which are subsidised and two of which bear differing part charges.

It would be decidedly helpful in these cases to have the brand specified as the odds of choosing the wrong one for new patients are quite high.

In a patients mind, dispensing Monofeme when they have used Levlen ED in the past is a dispensing error.

Yours generically,
Derek Lang FPS MNZCP

We value your feedback. Write to us at:
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