



Health claims for functional foods

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one half of those in the intravenous group.³ Four trials have compared different intravenous antibiotics given for 7-14 days, with 3-4 days of intravenous and 4-14 days of oral therapy.² No differences in recurrence of urinary tract infection and renal parenchymal abnormality were found. So what do we conclude? Oral antibiotics, carefully chosen to cover local uropathogens, are as safe and effective as intravenous antibiotics in children with a clinical diagnosis of acute pyelonephritis. This is not surprising given the combination of high bioavailability and renal excretion of orally administered antibiotics. Intravenous treatment should be preserved for children who are seriously ill, or who fail oral treatment because of persistent vomiting. There is no evidence to support the practice of giving a single dose of parenteral antibiotics in addition to a standard course of orally administered antibiotics.⁵

Which antibiotic should be given? The five trials comparing different antibiotics are largely uninformative for routine clinical care because the antibiotics evaluated have limited availability and are not routinely used.² Choice of first line oral antibiotics will vary with local antibiotic resistance patterns, but trimethoprim alone or in combination with sulphamethoxazole, cephalixin or amoxicillin-clavulanic acid are standard first line agents. Given that *E coli* is the causative organism in 90% of cases and that β -lactamase production is present in at least 50%, amoxicillin alone should not be used.

If intravenous antibiotics are required, aminoglycosides or third generation cephalosporins are often given. Aminoglycosides are favoured because of their pharmacokinetic properties, efficacy, widespread availability, and low cost. Three trials, which compared a single daily dose with three times daily doses of aminoglycosides, have shown no differences in persisting bacteriuria, time to resolution of fever, recurrence of urinary tract infections, hearing impairment, or renal dysfunction.⁶⁻⁸ These results are similar to data from studies in adults, where toxicity tends to favour single dose treatment.⁹ Given the equivalence of the dosing regimens, the ease of administration, and reduced nursing time, once daily dosing seems preferable in general.

How long should antibiotics be given for? In children with urinary tract infection other than pyelonephritis, there is evidence that short course treatment (3-4 days) is as effective as standard course (7-10 days) treatment.¹⁰ However, none of the three trials examining duration of treatment in children with pyelonephritis have compared these clinically relevant alternatives.² Since children with acute pyelonephritis typically take 3-4 days to recover clinically, it seems prudent to continue antibiotic treatment for 7-10 days until further trials examining treatment duration are performed.

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Health claims for functional foods

Regulations vary between countries and often permit vague claims

Functional foods are foods that claim to improve wellbeing or health.¹ The health claim may be implicit ("rich in vitamin C"), or vague ("strengthens the body's defence system"), but invariably the product is presented with the suggestion of a benefit. Sales of such products are huge and growing. What ingredients do such foods contain—and who safeguards the truth of claims?

Many functional foods contain added vitamins, minerals, and other essential nutrients. Some of these added nutrients indeed promote health: folic acid reduces the risk of neural tube defects, table salt with potassium reduces blood pressure, and polyunsaturated fatty acids reduce the risk of heart disease. But other claims are more dubious—for example, that zinc

lozenges protect against colds or that drinks rich in vitamin C protect against cardiovascular disease.

Functional foods may also contain non-nutritive ingredients. Examples of effective non-nutritive ingredients are sugar alcohols in chewing gum, which reduce risk of dental caries; plant stanols and sterols, which lower low density lipoprotein cholesterol (although effects on heart disease remain to be shown); and probiotic bacteria, which may diminish rotavirus diarrhoea in infants. But other effects of probiotics are insufficiently substantiated, as are effects of phytoestrogens against breast cancer,² of oligosaccharides for "gut health," of flavonoids against heart disease, and of conjugated linoleic acid for weight loss. Herbs such as Kava, St John's wort, and echinacea can also be considered

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non-nutritive ingredients. They are sold as supplements and added to foods, but their efficacy is controversial and concern remains over potential harm.³

Functional foods are marketed directly to consumers, who are unable to assess the implied health claims. Consumers thus must rely on their governments to make sure that they are not misled. Unfortunately, current government regulations leave room for misleading claims. Deception is promoted by the fact that legislation of health claims for foods is layered: there are soft claims, which require soft evidence, and hard claims, which require harder evidence. For example, a draft regulation of the Codex Commission of the United Nations, which sets international food standards, recognises claims about nutrient content (“rich in calcium”) and disease reduction (“prevents osteoporosis”), as well as various intermediate categories. Manufacturers have therefore made the formulation of soft claims into a fine art, creating claims that imply health effects without actually naming a disease.

Regulations differ between countries. Japan was the first country to recognise functional foods as a separate category when in 1991 it introduced the FOSHU (Foods for Specific Health Use) system to evaluate health claims. This system has valuable aspects: it regulates both safety and health, and it demands that the food be analysed for the amount of effective component.⁴ But it is voluntary, and even though the evidence required has been reduced in recent years and is minimal by pharmaceutical standards, most manufacturers opt for softer categories of claims, which require little evidence. An example is the unproved but lawful statement that extra vitamins help to maintain healthy skin and mucosa. Watering down of regulations has also occurred in the United States, which once had a solid system for disease reduction claims for foods, which were allowed only if there was “significant scientific agreement” that the claim was valid.⁵ However, the Food and Drug Administration’s oversight over health claims has eroded, and the United States now allows “qualified health claims” for which there is hardly any evidence, as long as a disclaimer is included. In the European Union the safety of novel foods is thoroughly regulated but health claims are not—EU legislation for nutrition claims is complex, fragmented, and poorly enforced. Paradoxically, current EU regulations prohibit claims that a food ingredient prevents a disease even when the claim is true—for example, that folic acid prevents neural

tube defects. Finally, Canada, Australia, and New Zealand have introduced new systems to regulate health claims, but experience with these is still limited.

The lack of proper regulatory oversight has led to some functional foods that are no more than quackery, while at the same time other functional foods do promote health and prevent disease. The potential for effective functional foods is certainly there. Foods and food components could prevent or ameliorate many diseases,^{6,7} but not enough research is being done to identify effective ingredients and substantiate their efficacy and safety. Whether such research will be done depends to a large extent on proper regulation. Major food companies are eager to expand into health promoting foods, but there is no incentive to underpin such health effects with solid research when products can be successfully marketed on the basis of vague allusions alone. But there is hope. After more than 20 years of deliberations the European Commission recently agreed on new regulations that would prohibit vague claims and that would allow hard claims of disease reduction for foods if the evidence is solid.⁸ The commission even wants to grant companies seven years of exclusivity for truly novel claims backed up by solid data. If the European Parliament accepts these proposals it would be a step in the right direction.

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Suspension of doctors

The process is badly handled at present, and new guidance is welcome

For any employee to be excluded from work is a devastating blow, whatever the circumstances. In the case of doctors the safety of patients may be a justifiable reason, but the process that leads to that decision is not straightforward and in many cases the individuals concerned, their colleagues, and the patients feel confused and uninformed.

A recent report from the National Audit Office has confirmed what many suspected and some have

suffered at first hand—that the process of suspension has to date been haphazard and badly handled in many NHS organisations.¹ Following this report comes new guidance from the Department of Health, contained in a direction to NHS trusts that has to be applied to all suspensions.

The report from the National Audit Office is forthright about the expensive and damaging consequences that result when suspensions are performed badly. The