

## Curing cancer — child's play

**TO THE EDITOR:** Last week, a close friend began chemotherapy for breast cancer, and this week, my husband is having a radical prostatectomy for prostate cancer. Hardly surprising, given our age and that these are the commonest cancers of women and men. However, it is surprising that despite them both being treated by the best oncology specialists, neither is enrolled in a clinical trial.

It seems that clinical trials in these diseases are more common for recurrent or metastatic disease and are usually drug company trials aimed at marketing new and expensive drugs for patients with incurable cancer. Indeed, the availability of targeted therapies has transformed many incurable cancers into chronic diseases, but the costs threaten to break the health budget.

A simple way to reduce these costs is to cure patients when they present with *de novo* disease. Improving the cure rate is achieved by enrolling patients in clinical trials. Until cancer has 100% cure without toxicity, there is always a question to be asked by means of a randomised controlled trial. These trials may or may not include new drugs and interactions with industry (at arm's length to avoid any real or perceived conflicts of interest).

I am describing embedded clinical research in all cancer treatment centres aimed at continual improvement in outcomes. Research in such centres is performed by committed oncologists (including surgeons, radiation oncologists and the entire multidisciplinary team) setting aside the time to take part in cooperative group trials. The cooperative groups require minimal funding, as most of the costs of cancer treatment are being incurred whether or not the patient is in a trial. However, they do need government commitment and hospital administrative support for

data management and statistical analysis.

To see an example of how this system works in practice, look no further than the paediatric oncologists who have worked collaboratively for half a century, enrolling patients in embedded clinical trials, and are now curing over 80% of children with cancer.<sup>1,2</sup>

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## Knowing when to stop antibiotic therapy

**TO THE EDITOR:** The recent article by Gilbert usefully drew attention to the the harms that can arise from unnecessarily long courses of antibiotics.<sup>1</sup> It was of particular interest that she highlighted the misconception that resistance will emerge if a course of treatment is not completed.

Australian health professionals commonly advise patients verbally to complete antibiotic courses, and professional guidance for pharmacists specifically recommends annotating dispensing labels with the words "until all used" or "until all taken".<sup>2</sup> This recommendation appears to be widely implemented based on our analysis of de-identified dispensing records collected as part of the PROMISE III trial.<sup>3</sup>

This dataset contains over 11 000 dispensings for the two most widely prescribed antibiotics in Australia, cephalexin and amoxicillin.<sup>4</sup> Dispensing directions



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included a reference to completing the course in 87.9% and 91.7% of prescriptions for these two drugs, respectively.

The impact of advice to complete antibiotic courses is likely to be magnified in Australia by two further system factors, namely the poor alignment of pack sizes with clinically appropriate course durations and the widespread practice of prescribing antibiotics with repeat prescriptions.<sup>5</sup>

A significant change in both professional practice and the arrangements under the Pharmaceutical Benefits Scheme will therefore be necessary if we are to avoid perpetuating current habits, which may be contrary to efforts now being made to improve antimicrobial stewardship.

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**IN REPLY:** Thompson and colleagues make an important point: contradicting dogma about the need to complete an antibiotic course is risky and potentially confusing.

My article<sup>1</sup> was not written for patients, but it attracted media interest and public comment.<sup>2,3</sup> I did not suggest that patients stop taking antibiotics as soon as they feel better, as some assumed<sup>2</sup> — although I suspect many do.

Clearly whether they can do so safely, depends on the indication. It would be reasonable for a patient to ask, if the doctor has not explained, whether completing the course is necessary. If, as I suspect is still common, the antibiotic was prescribed for an acute respiratory infection, it is certainly sensible to stop when symptoms improve — albeit better not to have started.

Even when there is a good indication for taking antibiotics, pack sizes often do not correspond with recommended course durations,<sup>4</sup> and both are often based on limited evidence. Shorter courses are likely to be just as effective for many infections.<sup>5</sup> We need more evidence and more common sense, because unnecessary or unnecessarily long antibiotic courses promote resistance.<sup>6</sup>

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## Antenatal care for asylum seekers

**TO THE EDITOR:** We read with interest the recent perspective written by doctors from International Health and Medical Services (IHMS).<sup>1</sup> They state that regular visits to Nauru by specialists, including paediatricians, deliver care “commensurate with that in Australian communities”. The IHMS doctors also state that “We encourage informed commentary and debate among the public and the medical profession”. As specialist paediatricians who recently visited Nauru for IHMS, we disagree with both these statements.

We agree with our fellow Australian general paediatricians<sup>2</sup> and the Australian Medical Association:<sup>3</sup> mandatory immigration detention of children is child abuse. This view is supported by the numerous specific instances of child abuse meticulously documented in the Australian Human Rights



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Commission’s report of the National Inquiry into Children in Immigration Detention<sup>4</sup> and corroborated in the Australian Government Department of Immigration and Border Control’s own Moss Review.<sup>5</sup> The Royal Australasian College of Physicians and 14 other colleges and health organisations have called for the immediate release of children from prolonged immigration detention.<sup>6</sup>

As long as asylum seekers are in detention on remote islands, IHMS cannot provide paediatric and obstetric care commensurate with that in Australian communities. However, IHMS doctors can claim that they are trying to provide the best health care possible by working within the system. Unlike the Red Cross, which eschews political involvement, IHMS, a private company, has a significant conflict of interest: its contractual obligation to the Department of Immigration and Border Control.

IHMS required us to sign a contract that included clauses forbidding media comment or “any public statement that concerns or is related to or which might reasonably be expected to affect the Department [of Immigration and Border Control] or IHMS”. IHMS cannot forbid transparency and then claim to encourage informed commentary and debate.

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## Communicating the health effects of air pollution

**TO THE EDITOR:** Air pollution causes 3000 deaths each year in Australia.<sup>1</sup> To put this in perspective: the national road toll in 2014 was 1153. Deaths from air pollution are due to both acute and chronic effects, and the principal diagnoses are of cardiac and respiratory disease. Reform of Australia's national air quality standards and regulatory mechanisms is currently underway, with the federal government calling for public consultation in the revision of the National Environmental Protection Measure (Ambient Air Quality) for particulates. Engagement in this consultation process requires that the risks be communicated in a way

that the public can understand.

A large published cohort study can be of assistance.<sup>2</sup> The mortality impacts of both particulate air pollution less than 2.5 µm in diameter (PM<sub>2.5</sub>) and of cigarette smoking for a large American cohort were followed up for 16 years. The relative risk of all-cause mortality associated with smoking 22 cigarettes a day was 2.58, while the relative risk associated with each 10 µg/m<sup>3</sup> of PM<sub>2.5</sub> exposure was 1.04 (95% CI, 1.01–1.08), making smoking 24 times as risky to survival (relative risks combine exponentially; 1.04 raised to the power of 24 = 2.58). Assuming that the effects are linear, breathing air including 10 µg/m<sup>3</sup> PM<sub>2.5</sub> is equivalent in mortality terms to smoking 22/24 of a cigarette each day. The Australian ambient air quality standard for PM<sub>2.5</sub> exposure is set at an annual average of 8 µg/m<sup>3</sup>, which in this metric would be equivalent to 0.73 cigarettes a day. This calculation is based on mortality alone, and says nothing about the amount of particulate matter in cigarette smoke. In 2013, the New South Wales Environmental Protection Authority monitor at Beresfield, near the coal corridor to Newcastle, recorded annual average PM<sub>2.5</sub> exposure of 8.3 µg/m<sup>3</sup>, so every adult and child in that district is exposed to this risk.

Debate continues as to whether there is a safe PM<sub>2.5</sub> level, below which there is no health effect. Using the smoking analogy again, we cannot point to a cohort study

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Air pollution causes 3000 deaths each year in Australia

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showing health damage from smoking one cigarette a day, but no one would suggest that this level of smoking is safe.

There are many opportunities to improve air quality in Australia, such as restricting the mining and transport of coal in close proximity to residential areas, phasing out wood-burning heaters, shifting the electricity supply away from coal, and enforcing Australian emissions standards on ships in port. These improvements will not eventuate unless the public demands them, and better risk communication allows public participation in this technically complex area.

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## Imported gluten-free foods: free of gluten?

**TO THE EDITOR:** The recent hepatitis A outbreak associated with imported berries has brought the problem of imported food quality acutely into the public spotlight. By contrast, the serious adverse effects for many people with coeliac disease of non-compliant imported foods being labelled “gluten-free” (GF) is more insidious and less easily assessed.

Concern has previously been expressed about proposals to raise



the amount of gluten permitted in GF foods.<sup>1</sup> In Australia, the current standard for claiming that a food is “gluten-free” is that it contains “no detectable gluten”<sup>2</sup> on the basis of the limits of current laboratory test sensitivity, this equates to less than 3 parts per million (ppm).

Closely aligned with this concern is the fact that imported food labelled “GF” may comply with standards in the country of manufacture but not with tighter Australian standards. For example, “GF” in Europe and North America indicates gluten levels of less than 20 ppm; accordingly, GF-labelled foods imported from these regions may contain detectable gluten. Further, gluten-level testing of GF-labelled foods is not mandatory in the United States;<sup>3</sup> in one report, 20% of US foods labelled “GF” did not comply with the Food and Drug Administration standard.<sup>4</sup>

Governance of food regulation in Australia is unfortunately complex. Food Standards Australia New Zealand set food standards federally; individual states set laws based on the federal standards; local government health officials implement state laws and monitor compliance. The Australian Competition and Consumer Commission, responsible for consumer law, has also contributed to food regulation and compliance. Further, the federal Department of Agriculture has responsibility for regulating imported foods. Local importers and retailers should also facilitate food safety.

Testing of imported foods labelled “GF” is ad hoc, lacking coordination across multiple jurisdictions, and is hampered by financial constraints. There is a tendency for organisations to suggest that the responsibility for compliance lies elsewhere. Enhanced transparency of laboratory food testing outcomes is required, for there are scant published data that assure the consumer about food code compliance for foods labelled “GF”. It is to be hoped that some good will come of the hepatitis

A food contamination incident, by providing the impetus for significant change in the governance of Australian food safety.

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## Medical negligence system must change

**TO THE EDITOR:** A recent medical negligence decision of the Queensland Court of Appeal in a case involving damages of \$6.7 million<sup>1</sup> further supports the suggestion that Australia should follow the example of six other nations and switch to a no-fault medical indemnity/insurance system.<sup>2</sup> The case concerned a 49-year-old woman who became severely disabled (blind and deaf) as the result of cryptococcal meningitis. Key clinical questions that the Court of Appeal judges needed to decide included the subtleties of distinguishing



Governance of food regulation in Australia is unfortunately complex



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a no-fault system of medical indemnity ... is necessary and inevitable



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neck stiffness suggestive of meningitis from that due to cervical spondylosis; recognition by a general practitioner of other symptoms suggesting the gradual onset of this rare type of meningitis; and the timeliness of their referring the patient to a specialist. This case illustrates the weaknesses of the fault-based medical negligence system, which focuses on assigning blame rather than promptly assisting the catastrophically injured. This approach usually involves inordinate delays, the lottery of the court process, and the waste of valuable resources.

The patient has already waited an unacceptable 7 years for a final decision. The woman’s illness occurred in 2008, but the first court decision (which went against her) was made in 2014, and the appeal decision was delivered in February 2015 (a decision that may be appealed further). To date, the complex medical evidence has been considered by four senior judges, with two finding for and two against the patient, suggesting some randomness and uncertainty in the decision-making processes. The \$6.7 million awarded will not be all available to support the difficult life that lies ahead for the patient, as estimates of legal costs are typically in the vicinity of 50% of the awarded sum.<sup>2</sup> To that waste of resources can be added the costs to the public purse incurred by the conduct of two court hearings.

We sympathise with the judges concerned, as it must be extremely difficult to make decisions on complex and contested clinical issues without specialist medical knowledge or clinical experience. In no-fault systems in other countries, such adverse outcomes — were causation or responsibility subject to dispute — would be determined by expert medical panels. Where questions about the professional performance of a doctor arise, they are referred to the relevant authority.

The Queensland decision makes very interesting reading for

doctors. Those who study it should be moved to add their voices to a demand that a no-fault system of medical indemnity be carefully considered by our governments, and sooner rather than later. Such a system is necessary and inevitable — and was first recommended for Australia in 1974.<sup>2</sup>

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## Death due to intravenous use of $\alpha$ -pyrrolidinopentio-phenone

**TO THE EDITOR:** Sellors and colleagues report a fatality where

urine drug testing (UDT) failed to detect the drug of overdose detected on the coronial blood assay.<sup>1</sup> This highlights how clinical care may be handicapped by older testing technology.

Historically, UDT was used for forensic and occupational safety testing. Medicare subsidises UDT that relies on an immunoassay and on standards designed for forensic and occupational safety purposes. The target substances and cut-off values are potentially inappropriate for contemporary use. When prescribing opioid analgesia for chronic pain,<sup>2</sup> palliative care or emergency care, physicians need to know whether psychoactive substance use is complicating presentations or whether there may be drug diversion.<sup>3</sup> Limitations of UDT include failure to detect buprenorphine, fentanyl, oxycodone (except at very high levels), anabolic steroids, synthetic cannabinoids and most designer and emerging drugs.<sup>1,2</sup>

Clinicians who wish to test for the presence of specific substances using refined and state-of-the-art technology such as mass spectrophotometry may find that laboratories are unwilling to assist because of the high cost of infrastructure, including highly trained personnel and expensive equipment. Where available, the effort and costs associated with the detection of novel substances is



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prohibitively expensive. Currently, these confirmatory tests are not subsidised by Medicare. Thus the costs of these tests may be passed on to consumers, who may be unwilling to pay for them.

The case described by Sellors et al presents a timely opportunity for a review of the UDT Medicare subsidy so that it can adequately support diagnosis and improve clinical outcomes.

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