

# Too much information?

**Grant Gillett** MBChB, D.Phil (Oxon), FRS NZ, FRACs; **Donald Saville-Cook** BSc, PGDip.HealSci (Otago), D.E.T.C.C.

A number of recent cases have raised the issue of the risks that are posed both by everyday medicines and by alternatives to standard medical interventions, an aspect of practice that has been made especially significant by the recent NZ Medical Council advice about fringe medicine<sup>1</sup> and from the tendencies in contemporary medical literature and social policy to favour what can be referred to as 'marketing-based medicine' masquerading as evidence-based medicine.<sup>2</sup>

The partial and selective information provided by the medical establishment raises questions about how many risks we should unwittingly run or be allowed to run by our medical advisors. The answer to this question must, however, be balanced against two other considerations in the area of information and disclosure.

- i. An ordinary consulting doctor, within the constraints of a clinical practice, cannot be expected to run through all the potentially relevant information relating to a condition and its management as part of a normal consultation with a patient, although there must be some required level of diligence.

- ii. Although the doctor has a legally well-established duty to answer a patient's questions truthfully and to the best of their ability, the patient should not have to play a macabre game of 20 questions to find out about aspects of their condition and its treatment that they might regard as significant.

The problem of information and what is required to satisfy rights 5 and 6 of the New Zealand Code of Health and Disability Services Consumers' Rights<sup>3</sup> is made pressing by two possibilities. The first is the existence of potentially very serious but systematically downplayed or concealed side effects from heavily marketed and promoted medications (such as statins) and the second is the existence of unorthodox or fringe regimens for diseases with a standard therapeutic profile (such as psychiatric syndromes or cardiovascular disease).

## A case study

Statin therapy has been associated with some serious and poorly documented side effects in that there is a link between not only myalgia but also rhabdomyolysis and statins.<sup>4,5</sup> Various reports in sources ranging from *The American Journal of*

*Medicine to The New York Times* have listed multiple neuromuscular conditions associated with statins, although this evidence, by its very nature, may be under-reported because of its varying severity. A number of patients may well not be told of this association and its potentially life-affecting consequences, despite the fact that it is alluded to in the drug information, in part, because of the lack of emphasis on this aspect of the drugs in the literature and the widely publicised prophylactic benefits of statins. The importance of prevention of heart attacks and strokes (and the attendant mortality and morbidity) makes us very ready to swallow the industry message (not to say the pills). Therefore, even if patients have a right to know about such problems, it is not clear to what extent a doctor should foreground them (despite the clear warnings on the Medsafe website) nor to what extent s/he could be the subject of complaints that potentially debilitating side effects were not mentioned. Given that patients often take their cue from the doctor about what is relevant to discuss in a clinic appointment, the omission could be serious in certain cases.

The second problem is posed by the recent NZ Medical Council advice in its

## CORRESPONDENCE TO: Grant Gillett

Professor of Medical Ethics,  
Otago Bioethics Centre,  
University of Otago Medical  
School, PO Box 913,  
Dunedin, New Zealand  
grant.gillett@otago.ac.nz

The **ETHICS** column explores issues around practising ethically in primary health care and aims to encourage thoughtfulness about ethical dilemmas that we may face.

**THIS ISSUE:** Grant Gillett, Professor of Medical Ethics from Otago, and his colleague, Donald Saville-Cook, address the issue of how much information needs to be given to patients, firstly about serious and potentially life-threatening adverse effects of commonly-prescribed medications (such as statins) and, secondly, our duty to raise the options of radical or fringe treatments, and then explain why risk might outweigh benefit.

*Ethics 101* column.<sup>6</sup> The tone of the piece is to equate all non-orthodox practices with quackery or fraud and to dismiss them out of hand. But the idea that our biomedical theories are fully adequate to the intractable bestiary of 'medicine in the (urban) jungle' is a gross simplification. In reality, a complex nexus of socio-economic variables, genetic dispositions, patterns of referral and categorisation, market-based selection of disseminated medical information, and so on,<sup>2</sup> and the rise of the psycho-neuro-humero-immunological concepts of human health and disease muddy the waters.<sup>7</sup> What, given this mish-mash and the lack of undistorted and scientific evidence relating to wide swathes of medical practice such as primary care, community psychiatry, and everyday unwellness, ought one to say and do?

The problem is intensified when we consider cases such as the following: an 18-year-old male underwent cognitive behavioural therapy for severe obsessive compulsive disorder (OCD) and depression which had the effect of mitigating it from severe to moderate. He then underwent an 'ABAB, (n of 1)' trial of a nutritional formula during which 'his mood stabilised, his anxiety reduced, and his obsessions were in remission'.<sup>8</sup> A return to normal diet provoked a relapse in his symptoms. This single case study may never be supported by any 'robust clinical evidence' considering patterns of research funding, publication and promulgation in contemporary medicine,<sup>9</sup> quite apart from the reality of the situation. Nevertheless it is the kind of case behind the major damages awarded to Truehope as a result of a class 1 withdrawal of drugs required by Health Canada.<sup>10</sup>

This is a classical example of fringe medicine (contra the Medical Council document,<sup>3</sup> rationally and scientifically reported and assessed) but should the option it reports be offered or even

mentioned to patients with OCD or depression? We seem to be on notice by the Medical Council of NZ that if that were done they would not regard the practice as ethical, but the HDC code Right 6(a) demands of providers 'an explanation of the options available'<sup>3</sup> (of which more anon). Suppose the patient found prescribed alternatives distressing or to have unwanted side effects (like weight gain)? The well-intentioned and patient-centred doctor is likely to be in a quandary in such a case, particularly if the patient is one in whom untoward events might be predicted. One might want to mention the possibility of something a bit 'fringe' but what is the ethical stance to doing so? It seems that the patient is entitled to a fair representation of current medical opinion and

answer problematic. There obviously needs to be some kind of weighting of advice about risks, but how should that be done. The language of material risk—the kind of risk a reasonable person would take into account in making a decision—that is often used does not tell us how well established those risks should be. A risk of rhabdomyolysis or polyneuropathy is likely to be material to anyone even though it is rare, and common problems like myalgia are plausibly material in that the kind of group who take statins might find their physical activity significantly compromised by such a side effect. But these may not be foregrounded in the information available to the average practitioner, so that the question arises as to what constitutes due diligence in

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one should probably position the advice being given against that framework in any consultation.<sup>11</sup>

A number of further questions arise from these problems about the ethics of medical information and the responsibilities of doctors in their advice to patients.

#### **To what extent are patients entitled to information about risks of their treatment?**

A number of blanket statements state that a patient is entitled to know of any significant risks associated with a proposed course of treatment (as in Right 6.1(b) of the code) but the existence of contested or unusual risks makes that

accessing the relevant information, a problem compounded by the abundance of medical information of varying quality on the Internet.

#### **How should doctors deal with risks that a patient has found about from the Internet and other sites?**

Here one faces the nightmare scenario of the patient who 'cannot see the wood for the trees'. There are in every practice patients who will make a major issue out of a possibility that most people would not be overly concerned about to the point where they might make bad decisions from a faulty appraisal of the evidence available. The idea of truly patient-centred medicine takes us a certain way in that the doc-

tor should assess the patient and the ways in which the patient is likely to distort or misinterpret evidence in the light of idiosyncratic personality factors so as to form a harmful or prejudicial opinion about their illness and its management. But one can imagine pitfalls aplenty in certain cases. Perhaps all that one can say is that the doctor should be a trustworthy guide and partner in the information sharing required for effective treatment, a role that is hard to specify but that is a key element of good clinical practice.

### **What options should a doctor or health care professional provide the patient with information about?**

This question raises the issue of what is 'reasonable medical care' or 'a reasonable body of medical opinion' (both terms are often used in disciplinary hearings). The concept becomes difficult to interpret when there are options available that may or may not be regarded as standard treatment in the context of the doctor's practice. That problem became pressing in a NZ surgical case where a patient found out, via the Internet, about a radical approach to the treatment of brain tumours and took that option. Subsequently a complaint was made that he had not been told of the possibility as part of his clinical management. The Health and Disability Commissioner's opinion was that the advice given to the patient should have indicated the controversial possibility of more radical treatment than that which was offered.

It was held that the neurosurgeon should have taken the time to discuss the option of further surgery. Although it would not be reasonable to expect him to offer to perform a procedure that he did not believe was a viable option, he needed to raise the option of further surgery (which was available elsewhere in New Zealand and in Australia) and explain

why he thought the risks outweighed any potential benefit. The surgeon was found in breach of Right 6(1)(b).

The more radical surgical option was commented on by other neurosurgeons who wrote to the Commissioner in the following terms: 'whether or not a doubtful procedure should be advised to an anxious patient who will clutch at any straw is indeed arguable'; 'Dr [X] gave advice to the patient and his family in keeping with standard... opinion'; 'it is difficult to see why a surgeon should apologise for a management plan that was correct.' These remarks express what many feel is sound and sensible when doctors are giving recommendations to patients about treatments. Nevertheless, the finding is in keeping with the Medical Council recommendation that a patient is entitled to know how the advice s/he has received compares with a range of clinical opinion in the area concerned. This is probably sound advice also in the light of the controversies surrounding complementary and alternative medicines (CAM) and 'fringe' or 'natural' therapies.

### **Should patients be encouraged to do their own homework?**

The ethical response to this question follows from the arguments above. In general, a patient should be encouraged to be an active participant in the problem-solving partnership that is a clinical relationship. In that context, a negotiated mix of spontaneous disclosure (conveying a more or less standard medical opinion about the patient's problem) and a responsive disclosure (about matters raised by the patient) is likely to be the best that a well-intentioned doctor can do. The scope of information that gets into that conversation is potentially broad but should have the effect of helping the patient find his/her way around in the strange land that is Clinicum<sup>11</sup> with its often

poorly understood hazards and variably well-understood therapeutic responses to those hazards and where a great deal of the guidance that one gets in the normal course of practice is both interested and promotional.

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