Acupuncture and ACC: therapeutic regulation and funding in New Zealand

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A report was recently published in the Journal which identified marketing materials (websites) which make therapeutic claims that may breach Section 58(1)(a) of the Medicines Act. Though the focus of the study was acupuncture, the report is timely with respect to issues it raises in the New Zealand therapeutics environment. This letter explores some of these issues through the lens provided by the study.

With regards to the therapeutic effectiveness of acupuncture, Ryan reports that many providers claim therapeutic efficacy without adequate evidence and that the funding of acupuncture by ACC is not evidence-based policy. Ryan presents a simple method for identifying these claims on publicly accessible websites. This is relevant to the readers of the Journal, as 50% of ACC-funded acupuncture providers are medical professionals.

Ryan laments the lack of evidence for the initial decision to fund acupuncture and cites the costs to ACC - NZD $30M in 2015–16 with 15% growth over that year. These costs are not contextualised by the costs of alternate interventions and therefore it’s not possible to determine the comparative magnitude of the “problem”. Indeed, we do not know how ACC’s decision to fund acupuncture has affected health outcomes for New Zealanders.

With regards to acupuncture, the report description seems to conflate multiple techniques under the term “acupuncture” and the omission of the keyword “dry needling” is notable. Ryan mainly refers to acupuncture as a single therapeutic intervention although within the discussion, Ryan reflects on ACC reports that showed “little effectiveness other than some positive evidence for chronic neck and shoulder pain” and also references inconclusive evidence of a positive effect for nausea and vomiting.

One of the over-riding principles of therapeutic regulation is to “manage the risk of avoidable harm”. These assessments are based on the intended, specific therapeutic use (which Medsafe refers to as “therapeutic purpose”) and are usually made separately to economic assessments such as cost-effectiveness analyses. For medicines, this regulatory-funder split is reflected in Medsafe’s role being medicines regulator and PHARMAC being the main public funding decision-maker. Particularly in the context that acupuncture seems to be used for such a wide range of conditions, the efficacy of acupuncture should be assessed for each therapeutic purpose—eg, for chronic neck pain—rather than as a single meta-group. Funding decisions should equally flow on this and so it is equally inconsistent with the principles of therapeutic regulation that ACC eschewed this convention in making their original funding decision.

Ryan cites that acupuncture has a placebo effect. Ideally therapies should not only be compared with placebo or a suitable sham-equivalent, but they should also be compared with other accepted interventions, for instance in chronic neck pain, pain medicines. Other than the potential for economic harm, which would not usually be considered by the regulator, Ryan fails to cite evidence that the placebo effect yielded by some uses of acupuncture are outweighed by potential harms. Furthermore, Ryan’s conclusion that acupuncture as a whole is ineffective, is inconsistent with the comments that it does yield a placebo effect, and with the principles of therapeutic regulation in that he acknowledges that evidence exists for specific therapeutic purposes. Evidence of a placebo effect is not evidence that a therapy is ineffective or harmful.
Despite these inconsistencies, Ryan’s article draws attention to some important public policy issues, particularly in light of the ongoing review of the therapeutic products regulatory regime, the drafting of the Therapeutic Products Bill and decisions made by public funders. In the rush to introduce new, exciting and promising therapies, often in response to consumer-demand, the medical profession has in the past done harm. To quote Prasad and Cifu, “A sizeable proportion of what doctors have done has turned out to be wrong—not wrong in retrospect but unfounded when they were doing it”. Therapies have been approved, only to be later withdrawn due to safety concerns—known as “medical reversal”; therapies have been funded, despite lack of evidence for cost-effectiveness.

Attention is often given to the ineffectiveness of complementary and alternative therapies, and yet arguably the largest source of harm has been from medical and surgical therapies. Indeed, management of adverse effects of therapies is a routine part of medical and surgical practice. Well-known examples of medical-reversal are oestrogen-replacement therapy and the withdrawal of Vioxx (rofecoxib) from the global market. In the surgical realm, a current example is the use of mesh repairs for urinary incontinence—with recent NICE and TGA reports recommending market withdrawal. Though some of these are unlikely to be marketed in the public sector, “marketing” in the private sector is often more ambient and socially-mediated, and efforts need to be made to identify and prevent misleading statements being made about the risk-harm balance of medical and surgical therapies in New Zealand.

So in conclusion, Ryan’s report should draw attention to why and how therapeutics are approved and funded in New Zealand. The report’s conclusion that there is insufficient evidence for the effectiveness of acupuncture is not, if somewhat semantically, supported by the assertion that there is evidence of efficacy for particular purposes. Efforts need to be made to identify and remove similarly misleading statements about medical and surgical interventions.

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