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The effect of traffic lights and regulatory statements on the choice between complementary and conventional medicines in Australia: Results from a discrete choice experiment

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ABSTRACT

It has been suggested that complementary medicines are currently 'under-regulated' in some countries due to their potential for harm as a direct result from side-effects or interactions; from delaying more effective care; or from the economic cost of purchasing an ineffective or inappropriate treatment. The requirement of additional labelling on complementary medicine products has been suggested in Australia and may provide additional information to consumers at the point of purchase. This paper details a unique way of testing the potential effects on consumer behaviour of including either a traffic light logo or regulatory statement on labels. Using a discrete choice experiment, data were collected in 2012 in a sample of 521 Australians with either type 2 diabetes or cardiovascular disease. We find that additional labelling can affect consumer behaviour, but in unpredictable ways. The results of this experiment are informative to further the dialogue concerning possible regulatory mechanisms.

1. Introduction

The World Health Organization estimates that global spending on complementary or 'traditional' medicines was in excess of US$83 billion in 2008 and growing exponentially (World Health Organization, 2011). Estimates of the prevalence of use vary from country to country reflecting different uptake rates as well as the definitions used. For example, it is estimated that over 17% of all adults in the US have taken a non-vitamin, non-mineral, natural product (such as fish oil) in the previous year (Barnes et al., 2008); a comparable figure of 10% of Canadians have used herbal preparations (Esmail, 2007). When this definition was extended to include vitamins and minerals (excluding those prescribed by a doctor), more than 50% of Australians (MacLennan et al., 2006) and 65% of South Koreans (Ock et al., 2009) reported use in the previous year.

This popularity is in contrast with the lack of high-level evidence of efficacy for most complementary medicine (CM) (Ernst, 1999) and poses a challenge for health policy makers. On one hand, CM is obviously viewed by many as a legitimate option in their suite of health care choices (Astin, 1998). CM is purchased almost without exception as an out-of-pocket expense and whilst this may be viewed as inequitable (for effective treatments), it is arguably of little concern to tax-payers. On the other hand, there are ongoing safety concerns over CM use, either directly as a result of side effects or interactions with other medicines (Ernst, 2001; Izzo and Ernst, 2009) or as a result of delaying more effective care (Ernst, 1997; Greenlee and Ernst, 2012). Institutional responses to this uncertainty by way of regulation vary between countries (Bodeker and Burford, 2007), however, there have been calls for greater levels of intervention (Avorn, 2000; Bollen and Whicker, 2009; Briggs, 2008; Harvey, 2009; Hunt and Ernst, 2010; Smith, 2012). Where increased regulation is the chosen path, it can be difficult to find the right balance between allowing individual choice, protecting public safety and limiting the chance of economic harm – the opportunity cost to a consumer of purchasing an ineffective or inappropriate product (Ramsay, 2010).

There is a large body of evidence detailing reasons why consumers use CM. Particular health conditions, especially chronic conditions such as arthritis (Fautrel et al., 2002), cardiovascular disease (Yeh et al., 2006), cancer (Girgis et al., 2005) and mental health conditions (Kessler et al., 2001) are strongly linked with CM use. For others, CM is part of a preventive paradigm and products are used to promote 'general health and wellbeing' (Kraft, 2009).

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Slimming and diet products (Pittler and Ernst, 2004) and 'sports supplements' (Sobal and Marquart, 1994) are used to reduce body weight or improve performance. Prior use or experience with CM will often inform future use (Williamson et al., 2008). Other less tangible reasons are also relevant. Views on empowerment, control and the degree of self-efficacy are linked with the choice of CM and health care more generally (Lorig and Holman, 2003). Risk preferences (Furnham and Lovett, 2001; Sturm, 2000), beliefs and 'worldview' (Astin, 1998; Bishop et al., 2007; MacLennan et al., 2002) and even personality traits (Honda and Jacobson, 2005; Owens et al., 1999) may also be important.

The choice of CM may be viewed as a two-step process – the decision to use, followed by the process of product selection and purchase. Unlike pharmaceutical or 'conventional' medicines which require a prescription and which are subject to strict supply rules in most high income countries, CM medicines are freely available in supermarkets, health food stores and online. As a consequence, consumers may not have the opportunity to access advice from a qualified health professional before purchase and may instead be led by recommendations from family and friends (Williamson et al., 2008). Increasingly, consumers access information via the internet and are faced with the difficult task of appraising content of variable quality (Sagaram et al., 2002; Williamson et al., 2008). To complicate matters further, CM products are generally not subject to the same regulations as conventional medicines with regard to promotion, and advertising and celebrity endorsement are powerful drivers of use (Ernst and Pittler, 2006). Individual heterogeneity with respect to health literacy (Nutbeam, 2008) and cognitive processing limits are important here (Capon and Davis, 1984) and simplified decision rules or heuristics may be used to make mental short-cuts through the dizzying array of available information (Hibbard and Peters, 2003). These factors, together with the expanding range of CM treatment alternatives, increasing availability, and increasing competition in the market make the choice between competing CMs highly complex. As a consequence, market failure due to imperfect and asymmetric information is highly likely.

When faced with information problems, we might expect any opportunity to provide consumers with additional, reliable and readily understood evidence-based information prior to purchase to be a worthwhile policy intervention. Mandatory labelling is one such way of providing this information – a strategy already implemented in Canada (Boon, 2003; Boon and Kachan, 2007). Australia is now considering changes to CM labelling as part of a range of measures. A report for the Commonwealth (National) Government (Parliamentary Secretary) by an Expert Committee (Expert Committee on Complementary Medicines in the Health System, 2003), provides recommendations for enhancements to the current framework of existing policies and regulations with regard to CMs, including labelling requirements. This had led to some debate as to the merits of mandatory labelling as well as specific suggestions for content (Harvey et al., 2008a,b). There is, however, a risk that adding information will simply add complexity and that this additional information may trigger simplifying heuristics rather than evidence-based decision-making (Spinks, 2014).

2. Availability and regulation of complementary medicines in Australia

In Australia, CMs are available for self-selection at a variety of retail outlets including supermarkets, 'health food stores', and community pharmacies. They may also be sold by naturopaths, who receive vocational or university-based training, but who are not registered as health professionals on a national basis. Pharmacists may be accessed for advice by consumers, however this is not a requirement for sale. What this means for consumers is that, by and large, they rely on information from sources such as family and friends, the internet, advertising and information contained in the product label to make their purchasing decisions (Williamson et al., 2008).

The Therapeutic Goods Administration (TGA) is the government body responsible for the regulation of all pharmaceutical medicines as well as CMs in Australia. The TGA adopts a risk-based approach to the regulation of medicines (Therapeutic Goods Administration, 2013). Substances deemed to be higher risk, including all prescription medicines, are required to be assessed for the 'Registered' medicines list. This requires evidence of efficacy, usually in the form of randomised, controlled trial evidence, which is rigorously assessed prior to registration. However, substances deemed to be lower risk, including most CMs, need only to apply for inclusion on the 'Listed' register and 'traditional use' may be used to make a claim for efficacy. For these products, although the sponsor (manufacturer) is required to hold substantive evidence for any therapeutic claim made, this evidence is not necessarily assessed by the TGA at the time of listing. Indications for use are limited to health maintenance or health enhancement, or for minor health complaints (Expert Committee on Complementary Medicines in the Health System, 2003). Further, the type of evidence required by the TGA is not currently specified. One option under the new proposal is for CM manufacturers to pay to have their product assessed for efficacy by an independent body. Under such a scheme, the level of evidence, the treatment claims and the consumer product information would all be assessed and awarded a recognisable symbol as a means of providing readily accessible information to consumers if the standard was met. It was also proffered that a disclaimer could be added to all CMs, to make it clear to consumers that the TGA itself had not assessed the product for efficacy. The proposed wording of the disclaimer is: "*This medicine has not been evaluated by Australian Health Authorities for efficacy*" (Harvey, 2009). The reason being that although CMs are generally subject to far less scrutiny from regulatory agencies, there is evidence to suggest that consumers are unaware of this (Boon and Kachan, 2007; MacLennan et al., 2006; Williamson et al., 2008). A less wordy version of this statement has also been proposed – simply the word "*Untested*" (Tippet, 2011). We were also interested as to how a positive endorsement might be perceived: "*This medicine has been evaluated by Australian Health Authorities for efficacy*".

There are many parallels with nutritional labelling initiatives designed to provide consumers more readily available information about fat and sugar content (Balcombe et al., 2010). 'Traffic light' logos have been implemented in the United Kingdom (UK) and Europe as one way of conveying a summary of the overall 'healthiness' of food choices (Balcombe et al., 2010; Sacks et al., 2009). In the same way, we propose that a 'traffic light' system might also be considered, alongside the aforementioned regulatory statements, as an alternative way of providing reliable and accessible information to consumers at the point of purchase.

3. Study purpose

It is difficult to evaluate in advance what effect, if any, the proposed labelling changes may have on consumer choice. This information is important not only to policy makers, but also to CM manufacturers and consumer groups. Ideally, we would want to know the relative effect labelling might have compared to the other factors known to affect the decision to use CM discussed above, for example, price, availability and the source of recommendation. Discrete choice experiments (DCEs) are increasingly used in health care (de Bekker-Grob et al., 2012; Lancsar and Louviere, 2008; Viney et al., 2002) and offer a flexible way of collecting such