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Social values and health priority setting in Australia: An analysis applied to the context of health technology assessment

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ABSTRACT

Objective: To describe the role of social values in priority setting related to health technology assessment processes and decision-making in Australia.

Approach: The processes and decision criteria of the Pharmaceutical and Medical Benefits Advisory Committees are described based on literature and policy sources, and analysed using a framework for identifying social values in priority-setting.

Findings: Transparency and accountability of processes are apparent. Participation balances inclusiveness and effectiveness of decision-making, but presents an opportunity to enhance priority setting processes. Clinical and cost-effectiveness are important content considerations. Social values related to justice/equity are considered, without quantification of criteria weights for equity relative to other factors. HTA processes support solidarity through subsidising approved technologies for all Australians, whilst retaining autonomy by permitting non-subsidised technologies to be accessed privately, leading to possible tension between the values of solidarity, autonomy and equity.

Conclusions: Priority setting related to health technology subsidy incorporates a range of inter-related social values in the processes and content of decision-making. Participation in decision-making could arguably be improved if a patient and public engagement policy were to be formulated alongside more widespread changes across processes to assess social values using approaches such as the Citizens' Jury.

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1. Introduction

Priority-setting in healthcare decision-making is a necessity. Limited health resources, a steady growth in health expenditure combined with an ageing population,

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and technological advances, have contributed to this pressure. Perhaps the most prominent examples of prioritysetting processes have been those related to health technologies. Many countries now have a specific and accountable process in place to make recommendations around the availability and public funding of new (and continued use of existing) health technologies, based on the principles of procedural justice [1–3]. Health technology assessment (HTA) has been defined as "a multidisciplinary field of policy analysis" which "studies the *medical, social, ethical, and economic implications* of development, diffusion, and use of health technology" (emphasis added) [4]. Much of the focus

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of HTA during its establishment has been on the medical and economic implications of decisions around technologies. However, there is an increasing recognition of the importance of the social and ethical implications of health technology decision-making for society.

Historically, Australia has been at the forefront of the establishment of priority-setting processes globally; particularly those related to HTA and decision-making [5]. Australia has a two stage process for assessing health technologies. The first stage relates to marketing approval; this has been undertaken since the 1970s by the Therapeutic Good Administration (TGA) [5], based on an appraisal of the safety, efficacy and quality of pharmaceuticals and medical devices. After TGA approval, a pharmaceutical or medical device can be marketed in Australia and supplied as a private prescription or service, but is not yet subsidised by the Government. Separate processes make recommendations around Government subsidy. The Pharmaceutical Benefits Advisory Committee (PBAC) was established in 1954 to make recommendations to the Minister for Health and Ageing (now the Minister for Health) on which pharmaceuticals should be subsidised under the Pharmaceutical Benefits Scheme (PBS) [6]. Non-pharmaceutical technologies have been assessed by a range of Committees, most notably The National Health Technology Advisory Panel, which was established in 1982, and later subsumed by the Australian Health Technology Advisory Committee (in 1990) and then by the Medical Services Advisory Committee (MSAC) since 1998. Whilst these marketing and subsidy stages were historically sequential, recent changes have supported concurrent assessment by the TGA and either the PBAC or MSAC, to reduce any delays in the time to subsidy [7].

The PBAC in Australia was the first HTA process to consider evidence on cost-effectiveness in its recommendations when this became a mandatory requirement in 1993 [5,8,9]. In 1998, the creation of a parallel HTA process for new medical services required evidence of sufficient cost-effectiveness alongside safety and effectiveness to support recommendations by the MSAC [10], and many countries now similarly use economic evaluation methods to assess the value of health care interventions [11]. A value-based pricing approach, now being implemented in the United Kingdom (UK) [12], has formed the basis of reference-based pharmaceutical pricing policy in Australia for many years. It is clear that clinical and economic evidence is carefully considered in decision-making around the subsidy of health technologies in Australia [13–16]. However, what constitutes value is likely to extend beyond the measures of clinical benefit that are conventionally assessed in clinical trials [17] and included in an economic evaluation; exactly what characteristics of a technology should be considered when assessing value is a normative decision for societal consideration [1]. It is much less clear whether, and to what extent, desirable characteristics of a health technology other than clinical and cost-effectiveness might be considered in assessing the overall societal value that might be associated with a new technology.

Several recent policy reviews in Australia have placed an explicit focus on the importance of engaging the general

public and patients and considering their preferences in healthcare priority-setting. In 2008, the Prime Minister and Minister for Health and Ageing established a National Health and Hospitals Reform Commission: their remit was to develop a longterm health reform plan [18]. Their final report made 123 reform recommendations and reaffirmed the need for the publically funded health system to "deliver the best health outcomes, while reflecting the values and priorities of the community" (Recommendation 2) [18]. The Commission highlighted the need for a "systematic mechanism to formulating health care priorities that incorporates clinical, economic and community perspectives through vehicles like citizen juries" (Recommendation 93). At a similar time, the Australian Government Department of Health and Ageing, now known as the Department of Health (DoH) reviewed HTA processes in Australia, and emphasised the importance of "encouraging a consumer and patient focus without increasing regulatory burden" [19]. Thus, social values are considered to be an important consideration for priority-setting in Australia.

In 2012, a themed issue of the Journal of Health Organisation and Management focussed on social values and healthcare priority-setting. One of the key papers in this journal was Clark and Weale's conceptual framework for the analysis of social values relating to the process and content of priority-setting decisions [20]. This framework has been used to review the association between social values and health technology decision-making in Thailand [21], Korea [22], China [23], England [24], Germany [25], the USA [26] and Latin America [27]. However, despite Australia's early involvement and relative prominence in the establishment of priority setting processes globally, only limited attention has been given to the application of social values in health priority setting decisions in Australia [11,28].

This paper describes the role of social values in priority setting in Australia, as they relate to health technology assessment (HTA) processes and decision-making. We use Clark and Weale's conceptual framework to describe the values of decision-making in Australia [20]. Other frameworks promoting fair priority setting processes are available, the most widely known being Daniels and Sabin's Accountability for Reasonableness Framework [2,3]. Clark and Weales' Framework considered Daniels and Sabin's Framework in its development [20], and is applied here as it has an explicit focus on social values that extends to the content as well as the process of decision-making.

2. Methods and approach

The processes and decision criteria of the PBAC and MSAC are described and analysed against Clark and Weale's framework for identifying social values in priority-setting. As the State and Territory Governments are principally responsible for the provision of public hospital and health services, priority setting related to HTA also occurs at a state level. However, much less is generally known about these processes [5] and there is potential variability between states. Therefore, this descriptive analysis will focus on the more substantial national level processes of the PBAC and MSAC.

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