

## Regulatory and government funding agency consideration of monetary costs to the cancer patient

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### Abstract

The Australian healthcare system aims to provide accessible healthcare to all citizens, and on a global scale it appears to achieve good health outcomes, with relative efficiency. However, the system is complex and despite various public funding programs, numerous out-of-pocket expenses to patients remain; in cancer patients these are estimated to be significant. The types of costs associated with healthcare are described here, as are the main public healthcare funding schemes in Australia. Decision-makers for these schemes do request information regarding patient costs in economic analyses, however the extent to which cost data are available is limited. Generally and primarily for the practical reasons – but sometimes with a philosophical consideration – only limited information on patient healthcare-related costs will have been considered before a funding recommendation is made. There is a concern that without increased consideration of patient costs, the existing network of public funding schemes in Australia may not adequately ensure the affordability of healthcare.

Few people in Australia understand the true cost of the healthcare services and products they utilise, nor who is responsible for funding the different aspects of their healthcare. The 'healthcare system' comprises individual community service providers – including general practitioners, specialists, community nurses, pharmacists, other allied health professionals and large institutions – mainly public and private hospitals. It is a complex, multi-faceted system, concurrently run by federal and state governments, and regulated private industry. The intention is that the resultant 'web' of health services and structures gives all Australians access to adequate, affordable health care, irrespective of their personal circumstances.<sup>1,2</sup> A number of indicators suggest that despite, or perhaps because of the complexity, the overall system works reasonably well - compared to other OECD countries, Australian life expectancy is relatively high and our health expenditure is relatively low.<sup>3</sup>

Success at improving health across the population over the last century has, ironically, resulted in an increase in cancers because of increased life expectancy, and in turn, investment and research has yielded many new, often expensive, treatment options. Unsurprisingly, providing greater healthcare services to increasing numbers of patients has resulted in rapidly growing cancer healthcare expenditure. The Australian Institute of Health and Welfare estimated annual health system expenditure on cancer increased from approximately \$2.9 billion in 2001 to over \$4.5 billion in 2009 in real terms based on 2009 prices,<sup>4</sup> however those direct health system expenditures may represent less than half of the overall financial costs of cancer, with patient households incurring a similar magnitude of cancer-related costs as the government; average financial costs were estimated to be in excess of \$47,000 per cancer patient in 2005.<sup>5</sup> These figures clearly identify that patient costs need to be an important consideration in government funding decisions and regulation of the healthcare system, if affordable healthcare is to remain the intention of public policy.

At the patient level, the web of different systems can result in confusion and uncertainty; depending on what part of the system is accessed, patient out-of-pocket costs vary greatly.<sup>6,7</sup> Even for a simple service such as a blood test, out-of-pocket costs to a patient depend on: whether the person is admitted to hospital or uses a service as an 'outpatient' and if so, whether that is a public or private hospital outpatient, or not associated with a hospital; whether their doctor bulk-bills or charges a gap; whether the specific type of test required is listed on the government schedule; and whether or not they hold a health care card.

The following review describes decision-making for government funding of healthcare in Australia. It also examines the extent to which individual patient costs are considered by regulatory bodies and funding schemes when making decisions about new policy and healthcare services or products.

## What are the different types of costs?

In this review, the costs described relate only to monetary costs. This is consistent with terminology used in the regulatory and funding space. Non-monetary costs, such as life or 'human suffering', whether physical or emotional, are not overlooked, but are considered separately as 'health outcomes', which are not the subject of this paper.

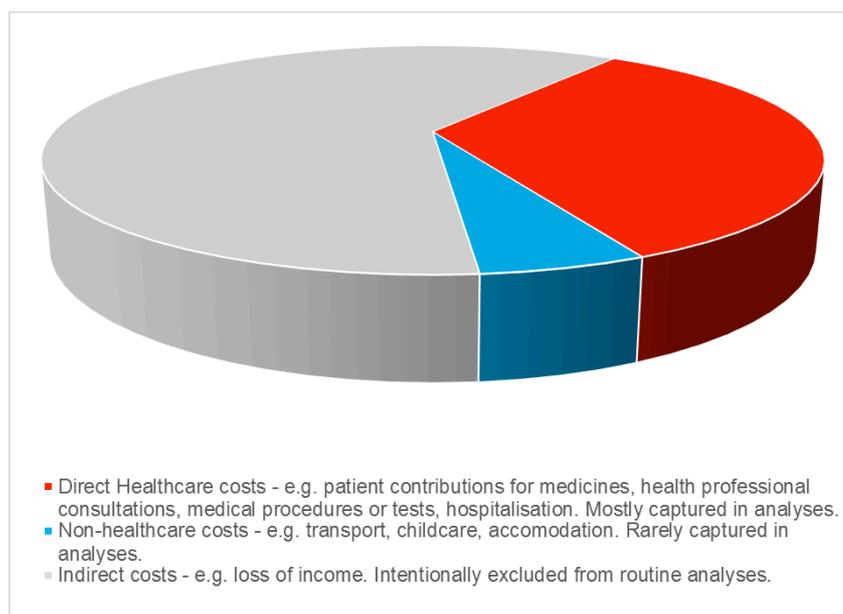
Monetary costs associated with cancer may be categorised as healthcare or non-healthcare related costs. Direct healthcare costs, for example the medicines, investigations and medical consultations, are relatively easy to identify and are routinely considered by regulatory or administrative bodies associated with funding decisions. In addition, the capital and maintenance costs of medical equipment and facilities are also generally considered if relevant. Less obvious, and much more likely to be overlooked - but acutely felt by patients - are direct non-healthcare costs such as transport, parking or child-care associated with hospital visits to receive chemotherapy.

When a healthcare or non-healthcare related direct cost is incurred, there is an immediate financial impact for either, or both the patient and the funding body, and the monetary value can generally be estimated by a receipt. Collectively, all of the direct costs associated with cancer would be expected to make up the total 'financial costs', as described in the introductory paragraphs.

However, there are also indirect costs with monetary impact, for example the inability to work and earn income that would have otherwise be earned had cancer not occurred. Indirect costs, often associated with loss of productivity, may be very relevant at the individual and household level, but are hard to estimate with certainty, and often not apparent to administrators.<sup>5,6</sup>

While all these costs – direct healthcare and non-healthcare costs, and indirect costs – are broadly acknowledged in the study or practice of health economics, the extent to which they are explicitly considered in analyses for regulatory bodies or funding schemes varies. A depiction of the approximate relative sizes of the various types of costs as identified in cancer patients, and a summary of the extent of their inclusion in routine government analyses is shown in figure 1.

**Figure 1:** Types of monetary costs associated with cancer and extent to which they are routinely considered by Australian regulatory agencies.



\* Relative sizes are approximate, based on data from Access Economics Pty Limited. Cost of Cancer in NSW.<sup>5</sup>

## Key government regulatory bodies and funding schemes

In Australia, various regulatory and/or funding bodies and committees are involved in providing access to publicly funded healthcare services. The two predominant funding schemes for healthcare, and therefore cancer care, at the national level in Australia are the Medicare Benefits Scheme, which facilitates and funds provision of medical services, except those undertaken by public hospitals, and the Pharmaceutical Benefits Scheme, which subsidises medicines. Newly available cancer treatments - services or medicines - that have not previously been listed on the Medical Benefits Scheme or Pharmaceutical Benefits Scheme, or have a listing restricted to specific cancer types or circumstances, but are now considered useful in other types of cancer patients, need to be considered and recommended by the relevant funding scheme's decision-making committee; the Medical Services Advisory Committee (MSAC) or the Pharmaceutical Benefits Advisory Committee (PBAC), before the service or treatment can be publicly funded on these schemes.

Cancer-related healthcare services are generally included under the broader healthcare umbrella and decisions about funding cancer-related healthcare are generally managed by the same funding bodies, and in the same manner, as decisions about funding healthcare in other therapeutic areas. This differs from the UK, for example, where a specific Cancer Drugs Fund exists, with an explicit budget allocation for cancer drugs.<sup>8</sup> The Cancer Drugs Fund is outside of the broader National Health System budget and unregulated by the National Institute of Clinical Excellence, which advises on other drug funding. Multiple arguments exist regarding both the merits and concerns of allocating a public funding body specifically to supply cancer agents outside of the broader healthcare regulatory and funding agency, such as the claim that cancer-specific expertise improves the quality of decisions, but the questionable fairness in providing some patients unequal claim to collective public resources.<sup>9-11</sup>

To initiate consideration of public funding of a service or treatment in Australia, a sponsor – often a pharmaceutical or device company – is required to make a detailed submission of evidence and analyses, including an economic evaluation considering costs to the relevant committee. The submission receives extensive scrutiny and evaluation by independent experts, after which a committee decision is made regarding whether the new item is deemed sufficiently effective and cost-effective to be recommended to the Minister of Health for listing and public funding. In the case of a medical service, an applicant can request that the department organise for an assessment report to be prepared by an independent group.

Other regulatory and funding bodies relevant to Australian healthcare include: the Therapeutic Goods Administration; the arm of the Australian Department of Health responsible for regulation of therapeutic goods, and various additional state or territory government departments and committees that make decisions related to funding of interventions through public hospitals.<sup>12</sup> The Therapeutic Goods Administration licenses products and manufacturers and seeks to ensure acceptable product safety, but does not investigate affordability or consider public funding. Decisions made by the body may indirectly impact patient costs. For example, registering a new medicine that is not funded may increase the likelihood that the treatment is recommended, and determining that a medicine may be purchased over the counter may reduce costs associated with obtaining a doctor's prescription. However, the need for access is a secondary consideration in the decision-making of this body and there is little information to suggest patient costs are considered.<sup>13</sup> Further, at the state government and public hospital decision-making level, there is little information available as to the extent to which patient costs are considered.

## Health economic evaluation of costs associated with new technologies

Explicit guidance on the nature of the evidence and the economic and financial analyses that should be included in a submission to the respective Australian decision-making committee is available.<sup>14-16</sup> A proposed treatment or service needs to demonstrate that it is cost-effective to be recommended for funding through these schemes, but 'cost-effective' is not objectively defined. This allows the decision-making body discretion to interpret results of economic analyses in varying contexts which, arguably, is useful and reasonable given the unique needs of different patient groups and the complexities of our healthcare system, however is also frequently criticised as lacking transparency.<sup>17,18</sup>

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All assessments of cost-effectiveness require an explicit statement of perspective, as the conclusion of whether publicly funding a new service or medicine is cost-effective will frequently vary, depending on whether it is viewed in the terms of the funding body, broader society or the patient perspective.

The MSAC guidelines request economic analyses be conducted on three levels: a Medical Benefits Scheme or government funding agency level; a healthcare perspective including all healthcare costs, regardless of whether they are incurred by the government or patient or other body; and a societal perspective including all costs.<sup>14,15</sup> However, despite the guidelines suggesting that an analysis from a societal perspective is desirable, in reality to date, few societal assessments have been presented to the MSAC; most assessments represent the healthcare perspective. Likewise, the PBAC guidelines state that the base case economic analyses should consider all healthcare cost impacts and health outcomes associated with an intervention from a healthcare system perspective and suggest additional analyses from a societal perspective should be presented as a supplementary analysis where relevant.<sup>16</sup> Thus it would be fair to say most funding decisions in Australia have considered patient healthcare costs, but few consider broader patient costs that are not specifically healthcare related, even if they are incurred in the course of accessing healthcare services or treatments.

While the inclusion of patient healthcare costs is described as routine, in reality this is less simple. To standardise evaluations, the MSAC and PBAC guidelines assume that patient costs for healthcare services equate to the standard Medicare contribution. However, there is little regulation with respect to medical fees in Australia, and a significant number of medical services are charged to patients at prices far in excess of the Medicare scheduled fee.<sup>6</sup> This type of additional patient cost is likely to be highly concerning for patients – and may directly impact the accessibility and affordability of treatment, yet is rarely brought to the attention of government funding bodies and their decision-makers.

There are both practical and political reasons why the requirement that any societal economic evaluation presented to the MSAC or PBAC be presented distinctly from a healthcare perspective. On practical grounds, the monetary value of indirect costs such as income loss are potentially very significant, but are notoriously difficult to estimate and highly uncertain.<sup>19</sup> Thus routinely including productivity estimates reduces the likely accuracy of economic evaluations and the overall consistency and reliability of the decision-making process. However, perhaps more important, are the ethical implications; only treatments provided to potentially productive members of society will be associated with productivity loss. Including this indirect cost in economic analyses will implicitly favour such treatments and patient populations, relative to treatments that are predominantly used in patients who are not economically productive, including the elderly and severely disabled people. Given both the practical and philosophical concerns faced by public funding decision-makers if they include consideration of patient income loss, it is of little surprise that few public funding decisions are based on economic analyses including productivity.<sup>19,20</sup>

The Australian approach is similar to the approach taken by the National Institute of Clinical Excellence in the UK, and many European agencies, requiring evaluations be conducted from a healthcare perspective at a minimum, and in some cases considering societal perspectives,<sup>21</sup> but contrasts greatly with the United States, where the albeit limited public funding body of Medicare part-funds all drugs approved by regulators, without consideration of cost-effectiveness, nor costs to the government or patients.<sup>22</sup>

Irrespective of the funding body's stated request to be informed of expected societal costs, few economic analyses considered by Australian funding bodies identify patient costs other than immediate healthcare costs.<sup>6</sup> Again, there are practical considerations. It is very difficult to record all non-health costs associated with obtaining healthcare treatment. For some patients, there will be significant transport, childcare and even accommodation costs associated with obtaining cancer treatment, but these will vary greatly depending on the individual circumstances of each patient. To estimate the expected value across the entire Australian patient population would require large datasets that simply don't exist. But without such data, or an alternative approach to funding, some patients risk ongoing hidden cost burdens, or in some cases do not seek adequate care, due to the broader unaffordability of costs associated with obtaining healthcare.<sup>6</sup>

## Conclusion

Do Australian regulatory agencies and funding bodies consider patient costs? Invariably they do, and the economic analysis methods that are applied are of international standard. However, some health-related patient costs, and 'non-health' expenses, are often omitted and this may adversely impact on universal access and affordability for people receiving cancer treatment. Ongoing efforts are needed to improve the collection and incorporation of these additional costs and promote the societal perspective in regulatory and reimbursement decisions.

Note: this article expresses the views of the author and does not represent the official position of any government regulatory body.

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