



## NICE rationing of specialised health care services for South Africa?

Although public funds in post-apartheid South Africa have increasingly been used to broaden and strengthen primary health care services, secondary and tertiary care remains a critical component of our country's national health care system.<sup>1</sup> Nonetheless, given the expense relating to such specialist-based services, as well as the inflationary pressures resulting from the so-called 'enhanced capabilities of medicine' that are often introduced at this level of care, related budgets are continuously under scrutiny, in both the public and the private sectors. In South Africa, this is particularly pronounced, given the mounting pressures on primary care services as a result of the HIV epidemic, burgeoning lifestyle-related diseases and unabated traumatic injuries, as well as the government's constitutional obligation to facilitate every citizen's right to access to reasonable health care. There is a common view that primary care services are as a rule more cost-effective and therefore most likely to maximise the health benefits for the nation served. As such, budgets for specialist-based care are unlikely to grow in real terms in the foreseeable future. This poses many challenges for those tasked with managing associated expenditure, one of which relates to the influx of new drugs and cutting-edge technology that has the potential to extend or save lives, albeit in most instances at extra cost to the health care system.

In a bid *inter alia* to prioritise specialist-advised and so-called tertiary services with the aim of achieving a more appropriate and sustainable national health care system in South Africa, Kenyon *et al.*<sup>2</sup> in this edition of the Journal propose the establishment of a central structure similar to the National Institute for Health and Clinical Excellence (NICE) in the UK, and the Pharmaceutical Benefits Scheme (PBS) in Australia. It is argued that in order to maximise benefits for the population served, health-related activities should be favoured on the basis of cost-effectiveness. For reasons of practicality, the proposed establishment should in the first instance be tasked with evaluating new drugs and technologies; this would include an assessment of their incremental cost-effectiveness ratio (ICER) against a nationally defined ICER threshold that is defined in cost per additional quality-adjusted life-year (QALY). (ICER refers to the ratio of the change in costs of a therapeutic intervention, compared with the alternative such as doing nothing or using the current standard of care, to the change in effects relating to the proposed intervention.) Where such a ratio compares favourably, it is deemed appropriate to include a new intervention within the offering of a health care package offered by a third-party funder.

Although such an approach has merit, with widespread support among health policy-makers, its usefulness in the

actual decision-making process of resource allocation has been challenged.

From an ethical point of view, it assumes a utilitarian standard of distributive justice; that is, it accepts that finite community funds are best spent if they can purchase the greatest health gains ('the biggest bang for the buck'). Unfortunately, such a quest for pure efficiency ignores other moral views regarding the fair allocation of limited resources. Most egalitarians would show some special concern for those who are sickest in order not to increase the already unjustified disadvantage they suffer due to their ill-health. Some may also argue that QALYs at various stages of one's life should be weighted differently, with a year of life extension in a child being prioritised over that in an elderly person (assuming no difference in the quality of the year of life extension). Furthermore, they are likely to preferentially choose treatment for those who are likely to benefit the most, i.e. they would favour treating a smaller group of patients who would gain significantly from treatment, over treating a larger group of less seriously ill individuals who would only improve their health status marginally by any given intervention.<sup>3</sup> The instinctively wrong decisions that may be derived from a blinkered utility approach were evidenced by the Oregon draft of prioritisation whereby tooth-capping was ranked above emergency surgery for both acute appendicitis and ectopic pregnancy. Based on considerations of comparative cost-effectiveness, inclusion of treatment for a relatively cheap disorder which can cause highly variable levels of suffering and where pain may resolve even without treatment, was deemed more appropriate for inclusion in a minimum package than highly effective, life-saving treatment of conditions that commonly affect otherwise young and healthy individuals.<sup>4</sup>

Among health economists, sceptics have referred to the ICER in the context of resource allocation as 'Information Created to Evade the decision-maker's Reality'.<sup>5</sup> First and foremost, the approach of including all interventions within a given efficiency threshold distracts from the reality of fixed budgets and instead assumes limitless expansion of health care budgets. Although the ICER indicates what the average cost of additional health gains is, it is silent on the quantity of QALYs that must be purchased to achieve such efficiency. It also provides no information on the additional funds that would have to be invested to achieve associated health care gains (or, more realistically, that would have to be re-allocated from other areas of the health care budget). The fact that it ignores opportunity costs has been one of the major criticisms of NICE guidance, which has been legally binding since January 2005 yet has not been supported by appropriate increases



in funding, or with associated formal exclusion of existing services. The resultant haphazard withdrawal of care following a positive recommendation by NICE – and as such the undermining of health gain maximisation – was highlighted by UK doctors after the approval of Herceptin for early breast cancer.<sup>6</sup>

Furthermore, the additional cost per unit QALY estimated for a particular intervention is an average value, with an implicit assumption that it is constant. However, where the theoretical assumptions of a mathematical model do not apply (e.g. because a target patient population responds somewhat differently to treatment than the research population), efficiency can no longer be guaranteed. Indeed, estimated QALYs are highly context-specific, and it is this consideration that makes national pharmaco-economic assessment for purposes of prioritisation problematic, given that factors such as *inter alia* standard of care, disease profiles of the population served, clinical expertise, referral systems and service acquisition prices are not homogeneous. This is particularly so in the South African system where the provision and cost of care is highly variable across the public and private sectors, as well as geographical regions.

Another concern relating to the 'threshold' ICER approach is the fact that 'cut-off' values against which cost-efficiency is adjudicated are regarded as somewhat arbitrary. It has been noted that there is no applied research literature, or indeed sound theoretical argument, substantiating why certain levels are chosen. There is also an underlying assumption that willingness-to-pay per QALY is constant over a wide range of QALYs. This is contrary to what one would expect – namely, that it diminishes with the size of their production.<sup>7</sup>

From a purely practical perspective, the construct of sound economic models is not only restricted by a lack of real-life practice and cost data, but the clinical trial information from which effectiveness of interventions is extrapolated is fraught with difficulties, e.g. choice of clinical comparators is often inappropriate, negative findings are often not in the public domain, and study populations do not reflect the types of patient who would receive an intervention in real life. There is as a rule significant uncertainty in the results produced.

Cost-utility analyses are therefore not the panacea for allocation of scarce resources as often claimed. As much as some countries have adopted these in their centralised decision-making process, other nations such as Germany have rejected their use.<sup>8</sup> It is argued that distribution of resources on the basis of aggregated QALYs is not accepted by the population, as it neither distributes resources equitably nor reduces existing inequalities. With this, it is contrary to the country's social values that support equity of accessibility and allocation. Nevertheless, the reservations about QALYs in prioritisation of scarce resources should not detract from their value in informing price negotiations between funders and manufacturers of drugs and technologies. Instead of estimated ICERs being used by manufacturers of new technology to justify inclusion of the latter in government-subsidised or mandated health care packages, they should provide a basis on which funders (supported by doctors) adjudicate the appropriateness of pricing of novel interventions.

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