Volume 12 • Number 2 • 2009
VALUE IN HEALTH

Who Does the Numbers? The Role of Third-Party Technology Assessment to Inform Health Systems' Decision-Making about the Funding of Health Technologies

Marco Barbieri, MSc,[1] Neil Hawkins, PhD,[2] Mark Sculpher, PhD[2]

[1]Universitat Pompeu Fabra, Barcelona, Spain; [2]Centre for Health Economics, University of York, York, UK

ABSTRACT

Background: There is an increasing number of health-care systems using economic evaluations to inform decisions about the reimbursement of health technologies. There are usually two separate elements of this process: assembling relevant evidence and undertaking analyses (technology assessment), and decision-making. In most systems, technology assessment is undertaken by the manufacturer of the technology. In a few, "third-party" assessment is used.

Methods: In the United Kingdom, the National Institute for Health and Clinical Excellence used a combination of third-party and manufacturer assessments between 1999 and 2005. After this point, a Single Technology Appraisal program (using manufacturer-based assessment) was instituted for some technologies. Here the role of third-party assessment is considered in this from of decision-making. The article reviews the requirements of economic evaluation to support decision-making, and considers the extent to which each type of assessment is likely to meet these requirements. It also attempts to address whether the two forms of assessment differ in their impact on decision-making using a comparison of the decisions made by National Institute for Health and Clinical Excellence (NICE) (under its multiple-technology appraisal system) and the Scottish Medicines Consortium (SMC), which relies on manufacturer assessment.

Results: The comparison is limited by the small number of technologies considered by both bodies. Nevertheless, it suggests that there are potentially important differences between the two bodies, with NICE generally placing more restrictions of the use of technologies.

Conclusions: The article concludes that there are potential advantages to third-party assessment, but its cost and timing may preclude its use for all new technologies. A hybrid arrangement is suggested where third-party assessment is used in particular circumstances.

Keywords: cost-effectiveness analysis, decision models, health economics methods, priority setting, UK NHS.

Introduction

Many health-care systems now require economic evaluations as a key input into a formal decision-making process about whether to reimburse/fund/cover new health technologies [1,2]. There are two distinct components to this use of economic evaluation. The first is the technology assessment process which, here, is understood as the process by which relevant evidence is identified, assembled, and synthesized to provide the basis for a clinical review and cost-effectiveness modeling. The second is decision-making, into which technology assessment is an important input. In most systems, the technology assessments are undertaken by the manufacturer, although they are usually critically reviewed by experts within the system or a third party. In a small subset of systems, however, there is a role for third-party organizations (usually academic groups) to undertake the assessments, usually in addition to assessments submitted by the relevant manufacturers. The use of such third-party assessments exists, for example, with National Institute for Health and Clinical Excellence (NICE) in the United Kingdom and the Medical Services Advisory Committee, which considers nonpharmaceutical technologies for the Australian health-care system.

The role of third-party technology assessment in this form of decision-making has recently been brought to the fore following NICE's decision to limit its use in their technology appraisal process. From its advent in 1999 until the end of 2005, NICE's standard process involved a third-party academic group undertaking a technology assessment report (TAR) to input, together with manufacturer and professional evidence and analyses, into the Appraisal Committee's deliberations. The TAR consists of a review of relevant clinical and economic evidence, a critical assessment of one or more manufacturer submissions (which includes the manufacturers' own reviews and models), and, usually, the development of a cost-effectiveness model. These arrangements still exist for some technologies as part of NICE's multiple-technology appraisal (MTA) process. Nevertheless, since 2006, many technologies (particularly newly licensed pharmaceuticals) enter a new single-technology appraisal (STA) process [3]. These arrangements are similar to those in many systems internationally in that the only reviews and analyses informing decision-making are undertaken by the manufacturer, although, as in some other systems, these are accompanied by critical review of the latter's submission by a third-party evidence review group.

This article considers the role of third-party technology assessments and their potential strengths and weaknesses. The aim is to inform the important policy question of whether health-care systems should use third-party technology assessment when developing new decision-making processes. It can also inform the specific debate in the United Kingdom about the balance between the MTA and STA processes at NICE.

A key issue to consider in addressing this question is the evidence regarding whether third-party assessment makes a difference to decisions—that is, are decision-making authorities more or less likely to support the use of a technology if they have access to a third-party assessment? Given the limited number of examples of third-party assessment internationally and the differences between decision-making processes in different systems, which hampers comparison, there is a dearth of such evidence. In time, some potentially valuable evidence will be provided by studying the decisions of the NICE Appraisal Committee and comparing those made under the MTA system with those from

Address correspondence to: Mark Sculpher, Centre for Health Economics, University of York, York YO10 5DD, UK. E-mail: mjs23:@york.ac.uk
10.1111/j.1524-4733.2008.00441.x

© 2008, International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

STAs. Nevertheless, such a comparison will inevitably be constrained by the fact that different technologies have been considered under the two sets of arrangements. Such a comparison is provided here for those technologies and indications considered by both organizations, and this updates and extends the comparison undertaken by Cairns [4].

To assess different assessment arrangements, the next part of the article describes the required features of economic evaluation to inform decision-making about health-care technologies and considers the possible strengths and weaknesses of third-party assessment for the achievement of these required features. The section called "Does Third-Party Assessment Make a Difference to Decisions" presents the comparison of NICE (MTA) and SMC decisions for a range of technologies. The last section provides a discussion that considers implications for health-care systems internationally.

The Requirements of Economic Evaluation to Support Decision-Making and the Role of Third-Party Technology Assessment

The advent of economic evaluation studies to inform explicit decisions about the use of health-care technologies in particular populations by specific decision-makers at a point in time has raised a number of distinct issues about analytical methods. Various artcles have suggested some general requirements of economic evaluation in this context [5,6]. Some of these are particularly relevant to the consideration of the role of third-party assessment to inform decision-making, and are discussed below.

Appropriate specification of the decision problem. Any economic analysis informing decisions needs to be clear about which patient population(s) and indications are being considered. Once this is clear, all relevant options need to be defined—that is, the technologies of interest together with the full list of comparators. The latter should include not just the "mostly widely used" or "the most effective," but all relevant options that can be used in the system. The definition of "alternative options" may well extend to include the specification of alternative sequences of interventions or diagnostic tests and different stopping and starting rules for treatments.

It is generally accepted that research questions should be explicitly defined before the research is commenced. Consistent with this, in the context of decision-making about new technologies, the decision problem should be specified in advance and be explicit in any analysis. In many systems, this is left to the manufacturer to define within their economic analysis. Although, in the case of pharmaceuticals, the license defines the relevant patient population, there is considerable flexibility for the manufacturer in specifying their decision problem even if they are made aware of the principles.

There seems to be a strong case, however, for the health system having control of the specification of the decision problem. First, the system should be able to form a view on how a new technology would be used based on its license, together with clinical guidelines and advice in that system. Second, the system should have the best information about the existing ways of managing the particular patient group (i.e., the comparators).

What implications does this have for the assessment process? There is some evidence that economic evaluations of technologies undertaken (or funded) by the manufacturers may indicate better cost-effectiveness compared with other studies [7–9]. Although there are a number of potential reasons for this, one possible explanation is that in making choices between methods approaches in general, the manufacturer may tend to select those that show their product in the best light. Although there may be no intention to bias the results intentionally, decision-makers will be aware of the potential conflicts of interest a manufacturer faces in making such judgments and may, as a consequence, be skeptical about some aspects of a submission. Therefore, it is arguable that with manufacturer assessment, given freedom to specify the decision problem, some manufacturers may select comparators that reflect (or are perceived to reflect) favorably on their product. Of course, this can be countered with an effective review process that correctly identifies a potentially misleading analysis on the basis of an inappropriate decision question. The risk of misleading analysis can be further reduced by the system clearly specifying the appropriate decision problem at the outset and only accepting analyses from the manufacturer that are consistent with it. In principal, this can be achieved with manufacturer assessment. The only situation where there may be a case for third-party assessment in this context is when the manufacturer is unwilling to accept the system's definition of the decision problem. Of course, those undertaking third-party assessment may possess conflicts of interest, but, in most systems, if these are considered a risk to the independence of the research, they will not be permitted to participate in the assessment.

All relevant evidence. To inform decisions about resource allocation, the available relevant evidence base needs to be identified and synthesized in a systematic manner. There will always be issues about how intensive and comprehensive this review process can be given time and resource constraints, but the inclusion of only a selected subset of evidence represents a partial analysis with potentially misleading results —this is true for any evidence-based decisions [10].

The appropriate evidence base for an economic evaluation cannot be specified before the work is undertaken, as it is an inextricable feature of the research itself. Therefore, there is inevitably some scope for judgment on the part of those undertaking the assessment regarding the identification, extraction, and synthesis of the evidence. Again, the manufacturer may have an interest in selecting evidence that when incorporated into a model, is likely to bolster the cost-effectiveness of their product. Nevertheless, this risk can be ameliorated in two ways that fall short of third-party assessment. The first is by the decision-maker, through its methods guidelines, providing a clear statement of the principles relating to the evidence—namely, the need for a transparent and reproducible systematic review of all evidence, and an explicit synthesis. The second is for the decision-maker to undertake or commission a rigorous review of all aspects of the manufacturer's assessment, including their evidence base, and to identify research that falls short in implementing the principles outlined in the methods guidelines.

There may, however, be a case that unless the decision-maker is able to commission a third-party assessment, it will never know with certainty whether the manufacturer's evidence base is reliable. There is perhaps a more compelling argument for third-party assessment in the context of identifying and synthesizing the relevant evidence base. For some assessments, more than one new technology will be included in the comparison. This might be the case, for example, if two or more new pharmaceuticals within a class are licensed for the same patient group contemporaneously. In this situation, it is very likely that the full extent of the evidence base relating to the new technologies is not in the public domain. In which case, the manufacturer is the only source of this unpublished evidence, but only for its own product. In other words, in the case of two new technologies, neither manufacturer has access to the full extent of the relevant

دریافت فوری ← متن کامل مقاله

ISIArticles
مرجع مقالات تخصصی ایران

✓ امکان دانلود نسخه تمام متن مقالات انگلیسی
✓ امکان دانلود نسخه ترجمه شده مقالات
✓ پذیرش سفارش ترجمه تخصصی
✓ امکان جستجو در آرشیو جامعی از صدها موضوع و هزاران مقاله
✓ امکان دانلود رایگان ۲ صفحه اول هر مقاله
✓ امکان پرداخت اینترنتی با کلیه کارت های عضو شتاب
✓ دانلود فوری مقاله پس از پرداخت آنلاین
✓ پشتیبانی کامل خرید با بهره مندی از سیستم هوشمند رهگیری سفارشات