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EDITORIAL

Challenges in Using MCDA for Reimbursement Decisions on New Medicines?

Multicriteria decision analysis (MCDA) is attracting considerable interest as a tool to assist decision makers faced with the challenge of considering a range of relevant factors when making their decision. The Scottish Medicines Consortium (SMC) is a long-established national health technology assessment (HTA) agency providing guidance to the health service on all new medicines. The stated criterion includes clinical effectiveness and cost-effectiveness but allows other factors to play a role. "Cost per quality-adjusted life-year (QALY)" is important but is not the only factor—if it were, as one SMC Chairman remarked, the committee could just chat over lunch while the economists made the decisions.

What might the SMC make of the ISPOR Task Force report on emerging good practice in MCDA? The starting point would be to consider what MCDA is. The report refers to "methods that help deliberative discussions using explicitly defined criteria, but without quantitative modeling." How does the SMC include other factors now? There are three possibilities.

Committee Discussion

During discussions by the committee, any relevant issue can be raised by members, or (in writing) by patient groups and clinical experts. Certain topics are considered as "outside remit," such as affordability, the robustness of the licensing decision, and potential off-label use, but any other factor can be considered.

"Modifiers" [1]

When a medicine has a cost per QALY that would be judged too high, criteria can be applied to change or modify the decision (hence "modifiers"). There are six criteria including evidence of substantial improvements in life expectancy and/or quality of life, and absence of other therapeutic options of proven benefit. In the committee discussion, the Chair proposes which of these criteria apply in this particular case and invites members to take these into account when voting.

Patient and Clinician Engagement [2]

Since 2014 the SMC process has included an additional stage available to medicines for rare diseases or for "end-of-life" situations. The pharmaceutical company initiating the review can ask for a meeting of potential prescribers and patients to be convened by the SMC to discuss the benefits of the medicine, especially those not captured by the QALY, and how the medicine will be used in practice. The SMC prepares a consensus statement that is discussed at the committee meeting.

These changes are referred to as Patient and Clinician Engagement (PACE) and also include an adapted submission form for medicines with "ultra-orphan" status (prevalence <1 in 50,000) where the pharmaceutical company in its evidence submission can submit evidence under headings such as "nature of the condition" and "impact beyond direct health benefits."

"Modifiers" and "PACE" (at least the ultra-orphan framework) have some features of MCDA, although they do not involve scoring the evidence, weighting the criteria, or producing an aggregated score. In practice, the SMC uses modifiers in a binary fashion (it is proposed a medicine does or does not meet a criterion) and members are not guided on what weight to attach.

Thus, the existing SMC system can include multiple criteria and explicitly prompts debate about these points, so it meets the Task Force's general definition. The current SMC system is not what the Task Force refers to as value measurement, leaving open the question of whether the system is MCDA or not.

To include more MCDA thinking, and assuming a value measurement approach, the performance of a new medicine against each modifier criterion would be scored and weights attached. This comes at some resource cost to the HTA agency in terms of collecting evidence, consulting, scoring, and quality checking, as well as adding to meeting papers that already run into thousands of pages. But what this would add? One possibility is that the current system makes decisions that are "wrong" (however this may be judged), by either not considering a relevant factor or by giving a factor an inappropriate weight. Another possible problem with the existing process is one of perception; that is, the current SMC system may be perceived as not taking account of some factors (even if they are actually considered).

Some stakeholders, notably patient groups, often think a particular SMC decision is wrong, but this is exclusively when the decision is not to recommend the therapy concerned. Would they be less unhappy if the "no" resulted from a more explicit MCDA approach? It seems unlikely. If the way of gaining more acceptability is simply to turn "no" decisions into "yes" decisions, it can be achieved much more simply.

The issue of perceptions is not trivial, however. The SMC is accountable through its umbrella National Health Service organization to the Scottish government and to Parliament; the PACE

Conflict of interest: A. Walker has acted as an adviser to the SMC. However, the views expressed are entirely personal and are not necessarily those of the SMC.

changes were in response to politicians' concerns that too many medicines for rare diseases and end of life were not recommended. Therefore, MCDA could form a useful way for the SMC to demonstrate the quality and rigor of its work to others.

However, could there be unintended consequences for the SMC of adopting an MCDA approach? The scoring and weighting of factors is intended to stimulate debate, but it could also shut it down, while giving more power to the people preparing the scoring and weighting. A key issue for an HTA agency is to balance the preparation of evidence for a committee to the extent that is helpful, without simply channeling debate and asking members to rubber-stamp a decision effectively made by the agency's support staff. Also, although intended to promote greater consistency, an explicit scoring system might give critics additional opportunities to question why a weighted points score of *x* seemed to have more weight in one situation than in another.

The final issue is that even if a change to a formal MCDA approach were beneficial on balance, this may not be the SMC's priority for reform. The toughest issue the SMC currently faces is how to interpret flawed and uncertain clinical evidence, such as what survival benefit will patients get if this interim disease marker is achieved, what faith can we have in a flawed indirect comparison, how do we interpret a single-arm study compared with a historical control? The second most important current concern is, irrespective of how the various factors are weighed, how to give reasonable access to new medicines balanced against the opportunity cost of each decision to accept them, in terms of reduced funding for other services. Therefore, although an MCDA does have some merits, it seems a solution to a problem that is a long way from the top of the SMC's agenda.

A possible way to experiment with more use of MCDA at the SMC could be in the context of "ultra-orphan" medicines, where the importance of, and the weight given to, the various considerations is more problematic. It is not yet clear whether the framework introduced through PACE will lead to more positive decisions for medicines such as eculizumab or elosulfase alfa, but were the system be judged to fall short of political expectations, this could be the area in which ideas for change to an MCDA approach might be most actively considered.

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