

Payers' Use of Independent Reports in Decision Making – Will There Be an ICER Effect?

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KEY POINTS . . .

US payer feedback indicates that ICER assessments are likely to have an important impact on formulary decision making processes in the United States.

The potential impact of ICER assessments outside the US is less certain, but the preliminary impressions suggest that they may be useful to decision makers in some European countries and in Latin America.

Globally (outside the United States), the main challenge will be in transferring and applying the results to local jurisdictions with their different health care systems.



The use of economic analysis to assist reimbursement decision making is not new. For more than 10 years, the National Institute for Health and Care Excellence (NICE) in the UK, the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, the Canadian Agency for Drugs and Technologies in Health (CADTH), and other health technology assessment (HTA) organizations have released reports documenting reimbursement recommendations. Typically, the manufacturer produces a dossier, which is then scrutinized by the HTA organization concerned, often assisted by an independent review group. The key feature of this process is the development of a value assessment framework, in terms of added clinical value and/or cost effectiveness.

To date, the use of economic analysis in formulary decision making in the United States has been sparse, or variable at best. One of the main reasons is that payers have not had access to independent assessments of the value of new drugs. However, in the past 2 years, value assessments have been produced by the Institute for Clinical and Economic Review (ICER) and clinical societies, such as the American Society of Clinical Oncology (ASCO). Publication of the ICER reports [1] and other value assessments represents a shift in the widespread availability of independent evidence, often with an economic component, shortly after product approval by the US Food and Drug Administration (FDA). These reports have the potential to contribute to the US debate surrounding necessary trade-offs between clinical benefit and the cost of care.

What remains unknown is how the ICER reports will impact reimbursement and value assessment trends in the United States and elsewhere. It is not certain whether formulary decision makers in the United States will use the reports. In addition, the reports might be valuable outside the United States since FDA authorization and formulary listing in the United States often precedes regulatory and reimbursement

approval in many other countries. In order to address these questions, this article, produced following an issue panel held at the ISPOR Annual Meeting in Washington, DC, discusses the following issues: 1) How will US payers utilize these new resources and will they impact price negotiations with pharmaceutical companies? 2) Does the timing of these reports mean they have the potential to create a global ripple effect? 3) Will the reports assist countries with limited HTA capacity in undertaking value assessments? and 4) Will there be greater harmonization in reimbursement decisions across jurisdictions?

Use of ICER Reports by Formulary Decision Makers in the US

Two surveys of US payers' use of ICER reports have been conducted by Dymaxium Inc., using the AMCP eDossier System, which includes more than 1400 decision makers in managed care, pharmacy benefit management organizations, hospitals, etc. The initial survey, conducted in September/October 2015, shortly after the release of the first 3 ICER reports, had 100 respondents (7% of all registered users) and explored their *intended* use and perceived limitations of ICER reports. The second survey, conducted in May 2016, had 99 respondents and asked about their *actual* use of the ICER assessments in their drug evaluation and coverage policy development process. Full details of the survey can be obtained from info@dymaxium.com.

In the initial survey, 46% of respondents indicated that they intended to use ICER reports as part of their evaluation process. In the second survey, 59% of the 99 respondents indicated that they, or their organization, had used the reports; only 17% were unaware of the existence of the reports (Fig. 1).

The second survey also explored more detailed aspects of the use of the ICER reports by those respondents who responded positively to the initial question (N=55). In Figure 2, the *timing* of the use of the reports is shown. It can be seen that a

considerable proportion of the use was in the early stages of the formulary decision-making process. Figure 3 shows that the reports were used in several ways, the main ones being: as an evidence source for making P&T recommendations, to inform or validate the respondents' own analysis, to assist in determining product availability, and to develop prior authorization criteria.

Figure 4 outlines the limitations in the use of the ICER reports, as determined by the respondents in the second survey. The most striking result is that, even though the reports were released shortly after the launch of the products concerned, 49% of respondents still felt that timeliness was an issue. This finding accords with the findings of an earlier Dymaxium survey of 100 decision makers [2] that found that many initiate their review process well in advance of FDA approval of the products concerned.

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Discussions with ICER leadership have indicated that the timeliness limitation will be addressed in future reports, as their goal is to have draft reports available 2 months before the Prescription Drug User Fee Act (PDUFA) date, and revised evidence reports with value-based price benchmarks approximately 3 weeks before PDUFA.

Potential Impact of ICER Reports in Europe

Western Europe is fairly advanced in its use of economic analysis in formulary decisions. Several HTA bodies in the larger countries, such as NICE in the UK, the Haute Autorité de la Santé (HAS) in France and the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany, have an extensive infrastructure for assessing the value of new medicines, either in terms of cost effectiveness (NICE) or added clinical value (HAS, IQWiG). These countries have considerable resources to undertake their own assessments, but always conduct a review of the existing literature as part of that process, and are likely to locate the ICER reports if these exist for the medicines under consideration.

Figure 1: Did you or your organization use any of the drug assessment reports that ICER released in the last year as part of the drug evaluation/coverage policy development process? (N= 99)

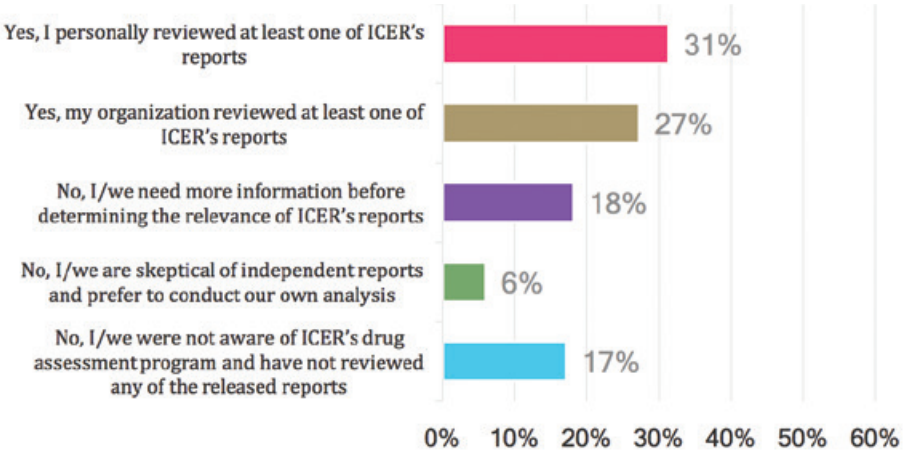
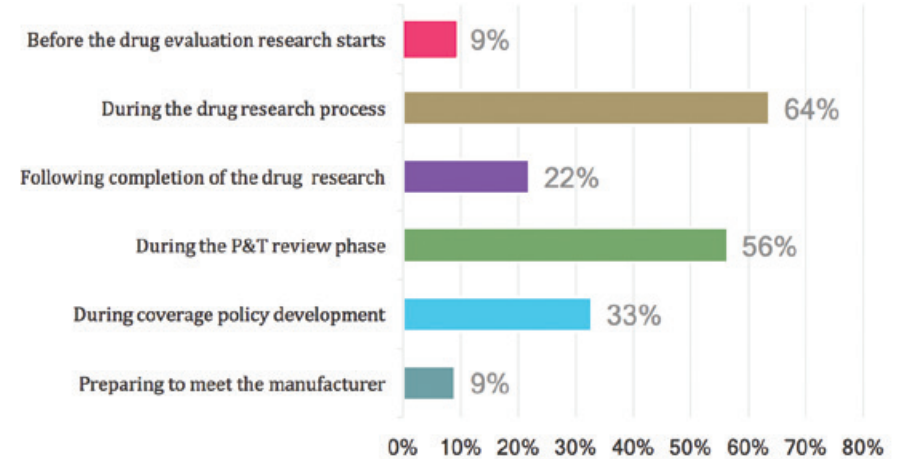
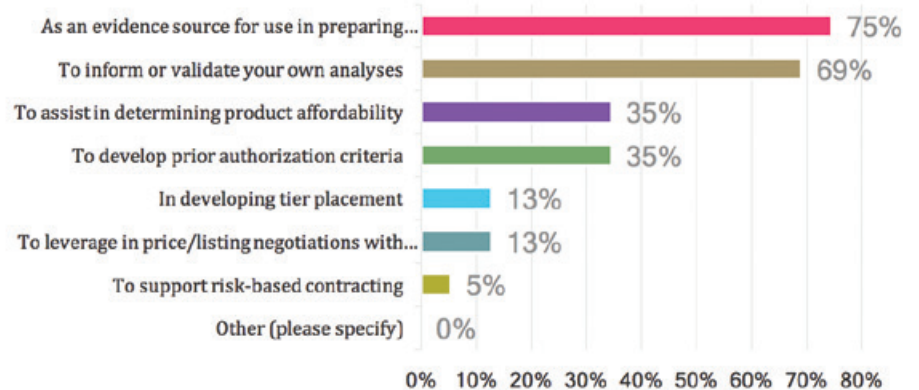


Figure 2. During which phase of the drug evaluation/coverage policy development process did you or your organization review the ICER reports? (Select all that apply) (N= 55)



P&T indicates pharmacy and therapeutics committee.

Figure 3: How did you or your organization use the ICER reports in the drug evaluation/coverage policy development process? (N=55)

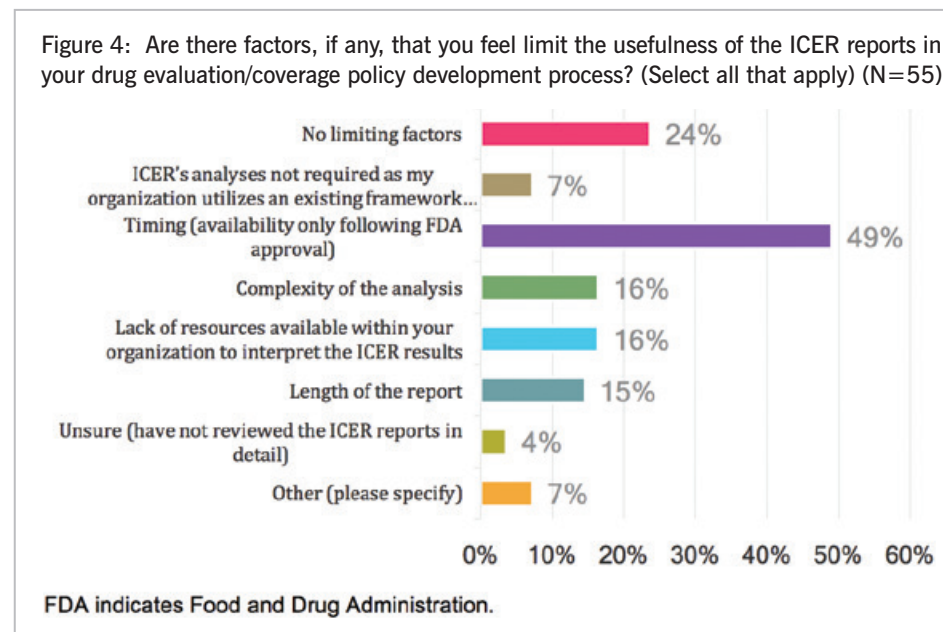


In addition, there are several smaller countries, mainly in Northern and Eastern Europe, that have a strong interest in the use of cost-effectiveness in formulary decisions, most notably Finland, the Netherlands, Sweden, Belgium, Slovakia, Croatia, Hungary, and Poland. These countries might find assessments from the US, conducted early in the launch process, particularly useful if they lack resources to conduct thorough assessments of all the medicines of interest.

Ireland is another country with a strong interest in the use of cost effectiveness and has established a National Centre for Pharmacoeconomics (NCPE) to conduct assessments on behalf of the Health Services Executive (HSE). The number of assessments produced has been substantial in relation to the resources available, with 60 or more products being reviewed in both 2014 and 2015, and more than 30 being reviewed in the first half of 2016.

The evaluation methodology used in Ireland is to estimate the incremental cost per quality-adjusted life year (QALY) gained from the adoption of the new medicine, as compared with current care. This is one of the most common approaches followed in Europe [3] and is consistent with the approach used by ICER in its assessments. The ICER reports also address budget impact. This is not required in all European countries. However, following the recent agreement between the HSE and the Irish Pharmaceutical Healthcare Association (IPHA), the importance of budget impact in reimbursement decisions has been emphasized. When pharmaceutical companies submit their economic dossiers to the NCPE, a budget impact assessment must accompany the cost-effectiveness estimate. This reflects the importance of affordability in the Irish Healthcare setting where 46 cost-containment measures have been introduced since 2006.

In considering the ICER reports specifically, a major concern in Ireland and possibly other European countries with a publicly funded health care system, is that the reports are completely independent and that ICER is not unduly influenced by any party. The most useful parts of the reports are the assessments of clinical and cost effectiveness, with the recognition that costs would need to be adjusted to be relevant to the local context. The NPCE already consults reports from NICE, the Scottish Medicines Consortium



(SMC) and EUnetHTA, when these are available for the drugs of interest.

Therefore, the ICER reports are likely to be a useful addition and would be of help in the assessment processes carried out in Ireland. However, the particular reimbursement recommendations in the reports would probably be less relevant, as Ireland often looks to the experience in neighboring countries when making its reimbursement decisions.

Potential Impact of ICER Reports in Latin America and Asia

Middle income countries in Asia and Latin America also have a growing interest in economic assessments. Some, such as South Korea, Thailand, Taiwan, and Brazil, have an infrastructure to undertake assessments, but in general the interest in these assessments currently exceeds the local resources to conduct them [4]. Therefore, it is possible that assessments conducted in other countries, including the US, may be useful.

The first Latin America Health Policy Forum run by Health Technology Assessment International (HTAi) confirmed the growing interest in HTA in the region, with 18 decision makers from 10 countries attending (Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Peru, and Uruguay), along with 17 representatives from pharmaceutical and medical devices companies. A wide range of issues were discussed. All key HTA principles and methods were considered

relevant, but there was agreement that all need adaptation to each specific local context. Two points in particular were relevant to the potential use of ICER assessments. First, it was noted that, given the increasing demand for HTA in the region, the resources to conduct these assessments with enough rigor are likely to be stretched. Therefore, the existence of ICER reports would be a welcome addition to other currently available sources.

Secondly, there is already some significant use of reports from bodies such as NICE, CADTH and PBAC. One survey of decision makers suggested that in 76% of the instances when an HTA report was used in a decision-making process, the report was not from the Latin American jurisdiction concerned. Therefore, a major concern is how these assessments can be made transferable to the local context.

This issue was examined in a recent survey of decision makers in 12 middle-income countries in Asia, Eastern Europe, and Latin America that are frequent users of economic evaluations in their decision-making processes [4]. The main challenges mentioned by decision-makers in transferring studies or results from other countries were that: 1) other practice patterns, or the availability of facilities, are often different in my jurisdiction; 2) the current standard of care/ relevant comparator is often different in my jurisdiction; 3) studies are often conducted in countries with a higher GDP, so the results do not apply in my jurisdiction;

4) studies are often badly reported or not enough details are given; 5) it is often difficult or impossible to obtain an electronic copy of the model. Therefore, although the ICER assessments are potentially useful, efforts need to be made to address issues related to transferability.

Conclusions

It is clear from the evidence gathered to date that the existence of ICER assessments is likely to have an important impact on formulary decision-making processes in the US. That is, we do expect an 'ICER effect.' The current use of the assessment reports is high and decision-makers are using them in a number of different ways. The main limitation appears to be in the timeliness of the reports, since many decision makers begin their assessment process before the FDA approval of new medicines. However, it seems this will be addressed with future draft ICER reports being released before approval.

The potential impact of ICER assessments outside the US is less certain, but the

preliminary impressions suggest that they may be useful to decision makers in some European countries and in Latin America. Decision makers in these countries already use assessments from outside their jurisdiction, where these are available, and ICER's assessments are likely to be available earlier in the drug assessment process. However, outside the US, the main challenge will be in transferring the results to jurisdictions where the health care systems are often substantially different than that existing in the US.

References

- [1] Institute for Clinical and Economic Review (ICER). Available at: <https://icer-review.org/materials/>. [Accessed October 27, 2016]. [2] Dymaxium Inc. (2016) AMCP Science and Innovation Webinar: Using the AMCP eDossier System's New Features to Close the Information Gap Between Decision Makers and Manufacturers. June 29, 2016. Available at: http://www.amcp.org/Newsletter.aspx?id=20912&utm_content=bufferd9c98&utm_medium=social&utm_source=linkedin.com&utm_campaign=buffer. [Accessed November 15, 2016]. [3] International

Society for Pharmacoeconomics and Outcomes Research (ISPOR). Available at: <http://www.ispor.org/PEguidelines/index.asp>. [Accessed October 27, 2016]. [4] Drummond MF, Augustovski F, Kalo Z, et al. Challenges faced in transferring economic evaluations to middle income countries. *Int J Technol Assess Health Care*. 2016;31: 442-448. ■


Additional information:

The preceding article is based on an issue panel given at the ISPOR 21st Annual Meeting.

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