ISPOR Abstract

A Formal System for Using Real-World Evidence to Revisit the HTA Decision: More Trouble Than It's Worth?

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Issue

Many European health technology assessment (HTA) processes make decisions for pharmacological therapies based on short-term randomised controlled trial (RCT) evidence, which is assumed to be generalisable to real-world settings and extrapolated under uncertainty to provide long-term estimates. The increasing availability of real-world evidence (RWE) provides opportunities to use such evidence to test these assumptions and uncertainties in a formal post-adoption HTA process, yet currently RWE collected post-adoption rarely informs subsequent HTAs – the Cancer Drugs Fund in England potentially being one example exception. A world can be imagined where RWE is routinely utilised to inform formal post-adoption HTA, to confirm initial decisions taken under uncertainty or in other ways (for example to inform dynamic adjustment of value-based prices). However, questions remain over the desirability, structure and practicality of such processes, and stakeholders may have divergent views on the merits, opportunities and challenges of moving to a formal system of post-adoption HTA based on RWE. With RWE representing one of ISPOR's top 10 HEOR trends, now is the time for this discussion.

Overview

Craig Brooks-Rooney will moderate discussion and challenge the panellists to discuss whether HTA processes should be adjusted to formally use RWE for post-adoption re-appraisal and present their vision for how such a system might look. Adrian Towse will provide an academic perspective, outlining the theoretical pros and cons of a formal system of post-adoption HTA informed by RWE in the context of the European HTA paradigm that includes national HTA bodies and EUnetHTA. Jeanette Kusel and Anna Halliday will provide the HTA and industry perspective, respectively, on the desirability of such a system, the opportunities offered and the practical and political barriers to its implementation. Following presentations, audience members will have opportunity to vote on the issue panel title question and put their questions to the panellists.

Please e-mail craig.brooks-rooney@costellomedical.com for a copy of the slides presented.