

Influencing ICER: A Review of Manufacturer Involvement in ICER Assessments

Atkinson M,¹ Allen G,² Morten P²

¹Costello Medical, London, UK; ²Costello Medical, Cambridge, UK

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Objectives

- To review the level of manufacturer engagement with the Institute for Clinical and Economic Review (ICER) and determine whether this input has led to meaningful changes in their Final Evidence Report (FER) in previously conducted assessments.

Background

- ICER is an independent organization that objectively evaluates the clinical and economic value of healthcare interventions in the US.
- The assessment process involves opportunities for manufacturer engagement at multiple stages (Figure 1A).¹

Methods

- The ICER website was searched in November 2018 and completed assessments with public comments on the Draft Scoping Document (DSD) and responses to comments on the Draft Evidence Report (DER) were reviewed.
- Manufacturer comments on these documents were categorized as concerning 'Comparative Clinical Effectiveness' (CCE), 'Comparative Value' (CV), the 'Process or Methods of the ICER Assessment' or 'Other' topics.
- Whether manufacturer comments on the DER led to a 'meaningful change' in the approach, content or interpretation of the FER was also assessed.
- To evaluate the possibility of passively influencing ICER before the assessment process, DSD bibliographies were also reviewed for economic models published by manufacturers involved in the assessment.

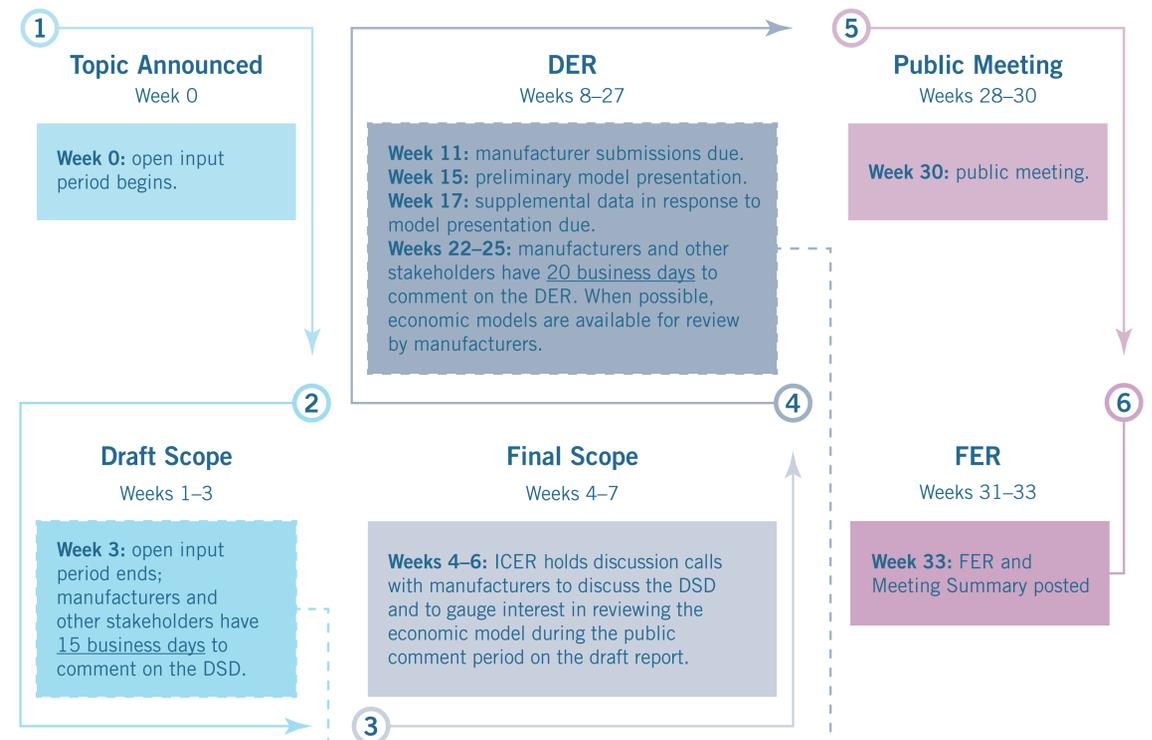
Results

Summary of manufacturer comments during the ICER process

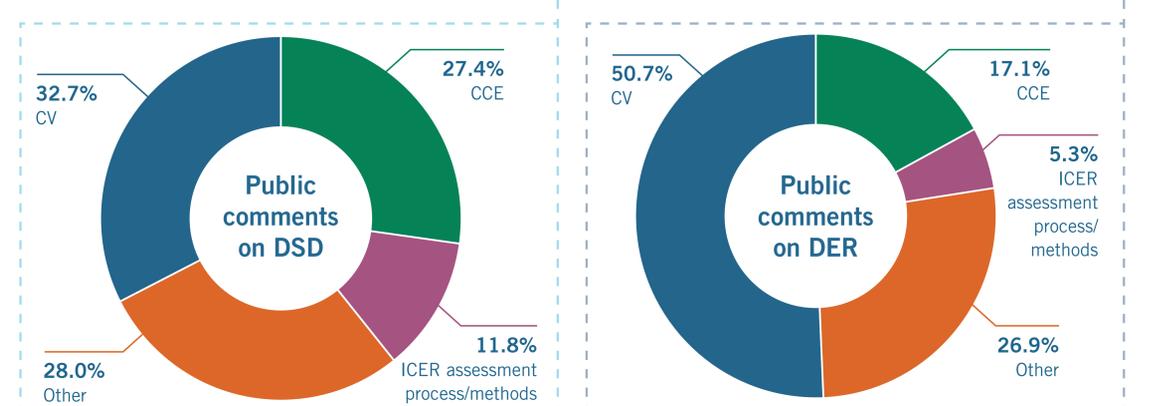
- Fourteen assessments were reviewed, representing a total of 54 manufacturers.
- In 6 (42.9%) assessments, at least 1 manufacturer did not provide comments at any stage. Overall, 46 (85.2%) manufacturers commented at least once.
- On average, manufacturers made 7 and 13 comments on the DSD and DER, respectively, with the largest proportion of comments concerning 'CV' in both cases (Figure 1B).
- At both the DSD and DER stages, comments relating to 'Other' topics were most commonly related to factual inaccuracies or wording of the document (31.1% of 'Other' comments for the DSD and 87.2% of 'Other' comments for the DER). 'Other' comments relating to the comparators or patient population were more often raised at the DSD stage (26.7% of 'Other' comments each), compared to the DER stage (5.4% and 0.7%, respectively).

Figure 1 | Manufacturer involvement in the ICER assessment process

A) The ICER assessment process



B) Comments on the DSD or DER by Topic



Adapted from the ICER Manufacturer Engagement Guide.¹

CCE: comparative clinical effectiveness; CV: comparative value; DER: draft evidence report; DSD: draft scoping document; FER: final evidence report; ICER: Institute for Clinical and Economic Review.

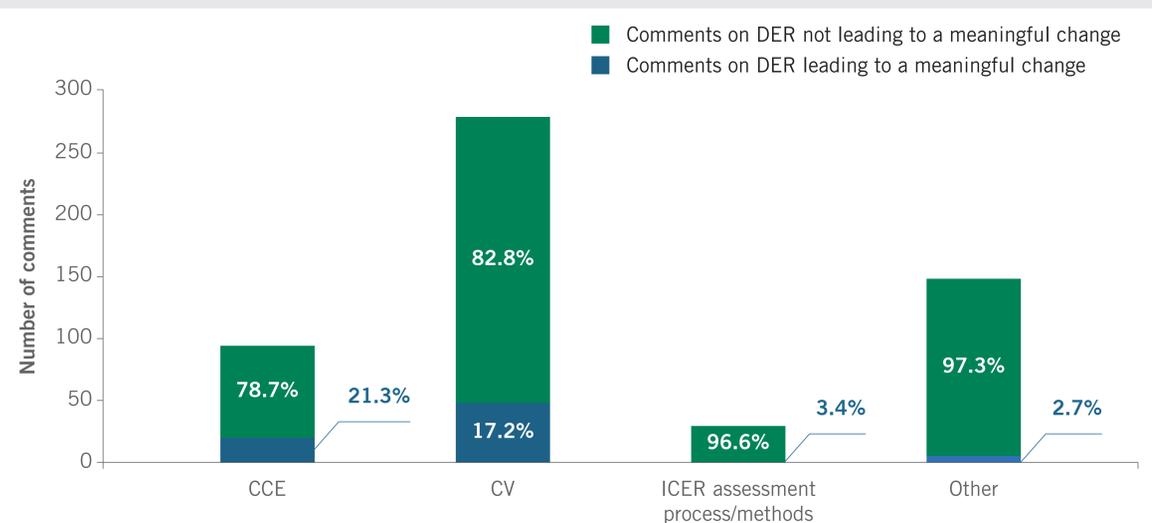
- Across all categories, only 13.3% comments on the DER were deemed to lead to meaningful changes in the FER, ranging from 2.7% of 'Other' comments to 21.3% of 'CCE' comments (Figure 2).

Published manufacturer models used by ICER

- Of the citations listed in the DSDs, only 1 published economic model was identified for which author affiliations included a relevant manufacturer (Batty *et al.* 2013; chronic migraine assessment).²

- This published cost-effectiveness model was used by ICER to inform the model structure and time horizon. However, the ICER model also deviated from published models in a number of respects, as described by ICER in the 'Model validation' section of the FER.

Figure 2 | Comments on the DER leading to meaningful changes^a



^aA 'meaningful' change was defined as ICER making substantial changes to the economic model or FER, likely in response to manufacturer input. Examples of such changes are the inclusion or modification of model inputs or analyses, or presenting large amounts of additional data or justification in the FER that would aid interpretation of the evidence presented. Changes that were deemed unlikely to affect the assessment outcome, such as minor amendments to model inputs or document wording, were not viewed to be 'meaningful' within the scope of this review.

CCE: comparative clinical effectiveness; CV: comparative value; DER: draft evidence report; FER: final evidence report; ICER: Institute for Clinical and Economic Review.

Conclusions

- Manufacturers actively participate in ICER assessments.
- Most manufacturer comments on the DER do not seem to lead to meaningful changes, although those regarding 'CCE' appear more likely to be accepted than comments elsewhere.
- Based on this review, there is little evidence that published manufacturer models have been used by ICER as part of the development of the DSD, but this may not preclude the use of published models to inform ICER's assessment of 'CV'.

References

- ICER. ICER Manufacturer Engagement Guide. Available at: https://icer-review.org/methodology/stakeholder-engagement/icer_mfr_engagement_guide_080216/ [Last accessed: April 01, 2019];
 - Batty AJ, Hansen RN, Bloudek LM, *et al.* The cost-effectiveness of onabotulinumtoxinA for the prophylaxis of headache in adults with chronic migraine in the UK. *J Med Econ* 2013;16:877-87.
- ICER assessment documents were accessed from: <https://icer-review.org/topics/#past-topics> [Last accessed: April 01, 2019].

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