Clinical Opinion in Rapid Review: How much value does it add to Positive Reimbursement Decisions? Retrospective analysis of outcomes from Rapid Reviews developed by AXIS Consulting

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01. Introduction

The Health Service Executive (HSE) is responsible for decisions regarding the reimbursement of new drug technologies in Ireland. The National Centre for Pharmacoeconomics (NCPE) performs health technology assessments (HTAs) of pharmaceutical products to support this process.

A Rapid Review (RR) serves as a preliminary step in the drug reimbursement process in Ireland, a process which all medicines must undergo. The NCPE RR assessment takes approximately four weeks. An Applicant may submit an RR once a positive opinion is granted by the Committee for Medicinal Products for Humas Use (CHMP).

The outcome of RR is a recommendation to the HSE on reimbursement, rejection at the submitted price or the need full HTA. Not all medicines are recommended to progress to a formal HTA, particularly in cases where there are no significant uncertainties relating to comparative clinical efficacy or value for money for the HSE.

In the context of HTA, a clinical opinion (CO) refers to expert input provided by clinician(s) or other health professionals based on their experience or knowledge of a specific medical condition, treatment or intervention.

Local expert CO is frequently used to inform and support reimbursement submissions to the NCPE. Expert CO is a valuable source of information for RRs and HTAs. Input from clinician's aids in understanding real-world clinical practice, the potential role and place in therapy of a new treatment and to the selection of appropriate comparators.

Local expert CO can address minor uncertainties or questions raised by the NCPE during the assessment process.

The purpose of this research is to assess the value of incorporating CO into RR Dossiers (RRDs) and seek to understand the impact on the reimbursement decisions in Ireland.

02. Clinical Opinion

When seeking expert CO, different methods such as surveys, in-depth interviews, and advisory boards can be used to gather specialised insights. Each method has unique features, advantages, and challenges that make them suited for specific contexts within clinical settings. The NCPE require a detailed report of how CO is obtained for RRDs or HTAs.

Surveys are structured questionnaires designed to gather data from a broader or more defined audience, including experts in clinical fields. They allow for consistency in questions, enabling the comparison of responses across a wide group of experts.

In-depth interviews (IDIs) are qualitative, one-on-one conversations designed to extract detailed insights from individual experts. IDIs allow the exploration of expert opinions on complex medical issues, such as treatment choices, diagnostic challenges, or emerging therapies, in a more nuanced and thorough manner, enabling clinicians to explain their reasoning in detail, providing richer insights into clinical decision-making processes.

Advisory boards are groups of clinical experts convened to provide ongoing or periodic advice and guidance on specific medical issues, new and innovative treatments, or policies. Advisory boards leverage the collective knowledge and experience of multiple clinicians, often from different specialties, creating a platform for interdisciplinary collaboration.

NCPE Guidance on the use of clinical opinion as supporting evidence in a submission

The NCPE require details of the process used to obtain CO for a submission which include the following elements:

1. A description of the criteria used for selecting the experts.
2. The number of experts approached.
3. The details of experts who participated.
4. The date(s) on which the opinion was obtained.
5. A declaration of potential conflict of interest from each experts whose opinion was sought.
6. The background information that was provided to the experts on the study and its consistency with the evidence provided in the submission.
7. Detailed methods used to collect opinions
8. The medium used to collect opinions.
9. The questions asked, and the responses received for each question.
10. The analytic approach to collate the opinion, including variability in opinion. This is of particular importance where quantitative expert opinion has been used to inform a model input parameter, in which case all the data used to derive the parameter in addition to a description of the mathematical method or process used to aggregate the data is required.

03. Methods

A retrospective analysis was carried out on RRDs developed by AXIS Healthcare Consulting, a leading market access consultancy operating in Ireland & the UK, between 2021 and 2023. The analysis aimed to assess the impact of incorporating CO on reimbursement outcomes.

The RRDs were categorised into two distinct groups based on the inclusion or exclusion of CO. In the dossiers where CO was included, three specific formats were analysed:

1. Surveys
2. IDIs
3. Advisory boards

Data Sources

The data for this analysis were drawn from multiple sources to ensure a comprehensive understanding of outcomes. These sources included:

- Internal consultancy records
- Payer feedback
- Secondary literature

Analysis

The primary focus of the analysis was to compare the reimbursement outcomes between the two groups. This involved examining the extent to which the inclusion of CO influenced the likelihood of receiving a positive reimbursement decision. Key factors considered during the comparison included the type of CO used, the complexity of the case, and the nature of payer feedback.

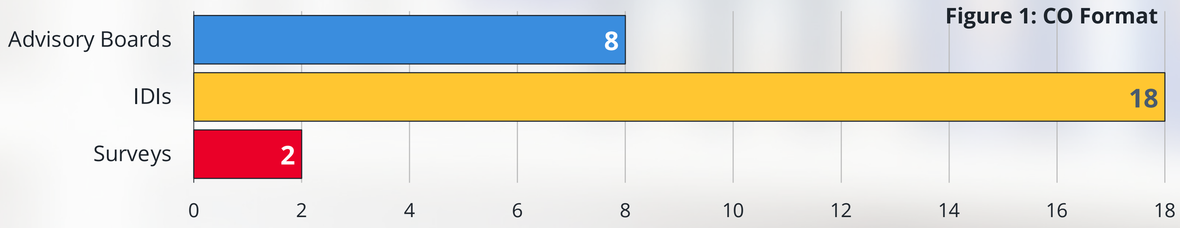
04. Results

A total of 38 RRDs developed between 2021 and 2023 were included in the analysis.

Among these, 28 RRDs (73.7%) incorporated CO, obtained through three formats: surveys, IDIs, and advisory boards.

CO Format

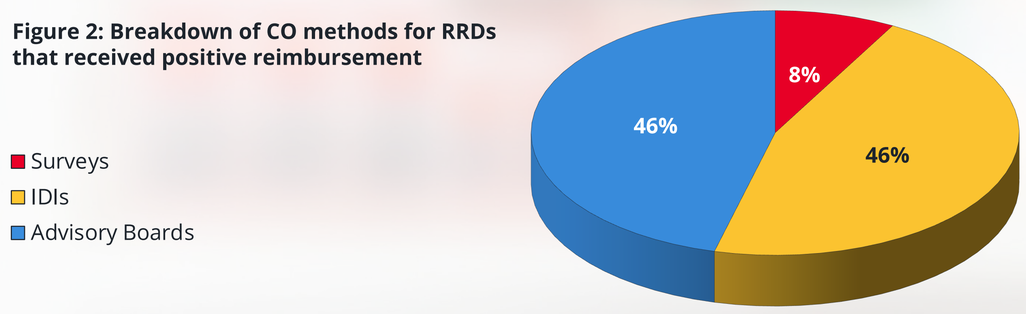
Figure 1: CO Format



Surveys were utilised in 2 RRDs (7.1% of CO-including dossiers). IDIs were the most frequently used CO format, included in 18 RRDs (64.3% of CO-including dossiers). Advisory boards were used in 8 RRDs (28.6% of CO-including dossiers).

Reimbursement Outcomes

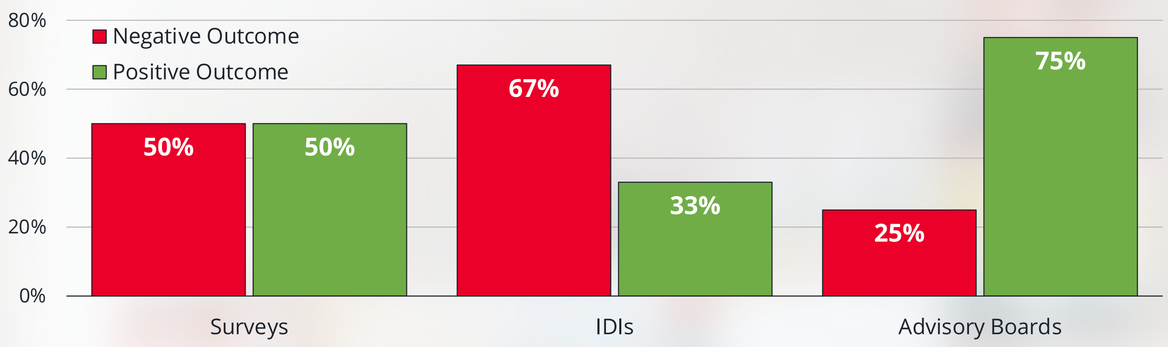
Figure 2: Breakdown of CO methods for RRDs that received positive reimbursement



In total, 13 RRDs out of 28 with CO included, received positive reimbursement recommendations at the rapid review stage.

CO format with positive and negative reimbursement outcomes

Figure 3: Breakdown of CO success rate with positive reimbursement



Discussion

Of the 8 dossiers that incorporated advisory boards, 6 of these (75%) resulted in positive reimbursement recommendations post RR. This suggests that advisory boards, which foster group discussions and consensus-building among clinical experts, may provide more comprehensive and persuasive input to support positive payer decisions.

Among the 18 dossiers that included IDIs, 6 of these (33.3%) received positive reimbursement recommendations. This relatively lower success rate suggests that while IDIs provide in-depth clinical insights, their contribution to positive decisions may be limited by other factors such as clinical uncertainty or payer priorities.

Surveys were used in 2 RRDs, with one (50%) receiving a positive reimbursement recommendation. While surveys offer structured feedback, their limited use and relatively neutral success rate suggest that they may be less impactful compared to more interactive formats such as advisory boards or IDIs.

The results of this retrospective analysis demonstrate a variable impact of CO on the reimbursement outcomes of RRDs submitted to the NCPE. Although CO was included in the majority of RRDs (73.7%), the analysis revealed that its overall influence on positive reimbursement outcomes was modest. The most successful format for CO was advisory boards, which resulted in a 75% success rate in receiving positive reimbursement recommendations. This may be attributed to the collaborative nature of advisory boards, which allow for comprehensive discussions and consensus-building among multiple clinical experts. IDIs and surveys yielded less substantial outcomes, with success rates of 33.3% and 50%, respectively.

05. Conclusion and Recommendations

Conclusion

This analysis suggests that incorporating CO into RRDs, particularly through advisory boards, enhances the likelihood of positive reimbursement recommendations. However, the overall impact of CO remains modest, and positive reimbursement decisions are influenced by multiple factors beyond expert opinion alone.

Limitations

Key limitations of this study include the small sample size and the focus on a single consultancy in Ireland. These factors may limit the generalisability of the findings. Future research should seek to include larger datasets, involve multiple consultancies, and explore additional factors contributing to reimbursement outcomes, such as payer feedback and real-world evidence.

Recommendations for future research

1. Expand the sample size to include more RRDs across different consultancies and healthcare settings.
2. Investigate the role of payer feedback and its interaction with CO in influencing reimbursement decisions.
3. Explore alternative formats for collecting CO, such as hybrid methods combining quantitative and qualitative approaches.
4. Conduct further analyses to assess the impact of CO in different therapeutic areas and on full HTAs.

By addressing these gaps, future studies can provide a more nuanced understanding of the role CO plays in reimbursement decisions and guide more effective submission strategies.

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