The Value of Expert Opinion

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Expert Opinion to inform decisions on cost effectiveness and affordability of new medicines has become an important part of the overall reimbursement process in Ireland. Those who are charged with assessing whether a new medicine should be reimbursed or not, need to have a thorough understanding of the local clinical context and perspective of the Irish Health Care Professionals (HCP's) who provide care to patients with the particular disease or condition. Information on the care pathway, specific clinical guidelines in use, and current treatments provide key insights as to where a new therapy option fits in the overall treatment paradigm and will ultimately, benefit Irish patients.

Expert opinion provided by HCP's can be viewed as a qualitative expression of an individual's view, or a quantitative expression of judgement on key clinical assumptions. Insights from Clinicians, Clinical Nurse Specialists and Pharmacists are relevant and potentially, hugely valuable.

Where Is Expert Opinion Used?

For each medicine holding a new marketing authorisation and seeking reimbursement on one of the community or hospital drug schemes in Ireland, a Rapid Review Dossier must be submitted to the Health Service Executive for assessment by the National Centre for Pharmacotherapy (NCPE). Within the Rapid Review template are three sections where insights from HCP's with expertise in the particular disease area should be gathered to establish local practice. These sections relate to the current standard of care, the anticipated place in therapy for the new medicine and the comparators which are used in routine clinical practice in Ireland.

For those medicines where a full Health Technology Assessment (HTA) is required following the NCPE's assessment of a submitted Rapid Review, additional opportunities exist to integrate local Expert Opinion into the modelling and corresponding dossier reporting the clinical and economic benefits of the new medicine. The majority of HTA's conducted in Ireland are for rare, orphan medicinal products (OMP's) or oncology drugs initiated by specialists in the acute hospital setting so this is where Expert Opinion becomes extremely important.

Populating cost effectiveness models in an HTA submission for an OMP or an oncology drug is often complex, requiring an increasingly diverse range of data sources to be applied. Insights from local experts can be used effectively to validate key modelling assumptions, help identity the appropriate patient population and associated costs as well as the frequency of patient- related outcomes, disease progression rates and rare adverse events.

How To Gather Expert Opinion

There are several ways in which Expert Opinion can be successfully obtained for the purposes of a pending reimbursement submission in Ireland. Advisory boards, focus groups, in depth interviews and delphi panels are all well established mechanisms to elicit key and pertinent clinical insights. However, there are Pros and Cons to each option with some affording better opportunities than others to harness Expert Opinion. Advisory boards with HCP's have the advantage of being relatively easy to organise, are usually well attended events which permit clinical or modelling data to be shared with attendees allowing insights to be harnessed over a few hours of a day or an evening meeting. However, they can have limited value if not all those who attend the meeting contribute evenly to the discussions and as with any group meeting, an experienced facilitator is a must to steer the discussion topics and ensure full participation. Collating the feedback on discussions threads from advisory boards can be challenging even when an experienced medical writer is in attendance with differences in views harder to capture.

Focus Groups are an alternative option to advisory boards and allow smaller groups of 6-8 participants to contribute knowledge and insights on particular topics. This medium tends to work well for meetings with clinical nurse specialists, pharmacists or patient groups but is less frequently used to gather clinician insights. Potential exists here too for a small number of participants to give the most feedback.

The nature of in-depth interviews (IDI's) with clinicians typically results in very good quality insights from the various participants which can then be aggregated and collated into a written report. However, conducting face to face IDI's is quite time consuming both to organise and conduct and reporting the output on IDI's requires a thematic analysis to be conducted on major discussion items.

Delphi panels offer a very robust medium for expert elicitation but require specific expertise from an external, independent agency to ensure they are conducted correctly. Requiring multiple rounds of questionnaires, an iterative approach is used with interim summaries provided to participants so that at the end of this highly structured process, a clear consensus on the topics discussed is available for use.

Over recent months with the Coronavirus pandemic, it has not been possible for any face to face meetings or advisory boards to take place and with social distancing set to become the new norm, there is likely to be a significant reduction in all non-essential, work related, face to face or group advisory board meetings over the foreseeable future. However, this does not mean that Expert Opinion cannot still be successfully obtained and a rise in the number of virtual engagement meetings using various software platforms can be expected. Many of the multinational pharmaceutical companies have been piloting virtual advisory boards and delphi panels for global projects over the past 18 months.

In our own organisation, we have made the switch to "virtual" and we now conduct expert elicitation with the help of an online engagement platform where meetings can occur in either a "real time "or "over time" context. The benefits of going the virtual route for us has been immediate with significantly higher levels of engagement from participants, yielding better quality data and a lowering of the logistical hurdles and costs associated with "live" meetings.

How To Present Expert Opinion?

The NCPE have outlined 12 specific criteria on how Expert Opinion in an HTA submission should be described and these are outlined in the table shown. These are important criteria to address when collating the output to any research conducted with experts in Ireland.

A key emphasis is placed by the NCPE on reporting Expert Opinion information in a clear, transparent and unbiased format where its use is well justified. These criteria are similar to those used in other countries and reflect the expectations from the authorities to integrate expert opinion into reimbursement applications using robust and well-developed methodologies.

NCPE criteria* for Reviewing Submitted Expert Opinion
Description of the criteria used for selecting the experts.
Numbers of experts approached
Details of experts who participated.
Dates on which the expert opinion was obtained.
Declaration of potential conflicts of interest from each expert whose opinion was sought.
Background information provided to the experts on the study and its consistency with the evidence provided in the submission.
Detailed method used to collect opinions e.g. either individually or through a meeting.
Medium used to collect opinions e.g. direct interview, questionnaire, telephone.
Questions asked (including a copy of the questionnaire or outline of the interview).
Numbers of responses received for each question.
Responses received for each question.
The analytic approach used to collate the opinion, including the variability in opinion.

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In terms of clinicians identified to provide Expert Opinion, HTA agencies overall have a preference for a representative group of specialists to be involved. If the prescribing community for a new medicine is expected to be large, it would not be acceptable to have Expert Opinion derived from a small group of clinicians as this would not represent the full prescribing community.

It is imperative too that a signed declaration of conflicts is obtained from all participants.

The way in which questions are asked of experts is particularly important as this could result in a potential bias. Assessors will look closely at each question to see how it was phrased, whether neutral or biased and whether open ended or closed. It is therefore essential when collating the findings of the expert elicitation undertaken to include a copy of the full questionnaire and describe how the questions were developed including any piloting undertaken before wider dissemination.

The NCPE will want to see the level of responsiveness to the questions to assess whether the degree of any non-response to particular questions might diminish the representativeness of the overall opinion. It is critical that any difference in opinions expressed be captured with particulars on the actual number agreeing or disagreeing on qualitative aspects captured. It would be unusual amongst a group of 10 clinical experts for there not to be some differing views so rather than ignoring this, it is preferable to record it and if possible, state the reasons for why opinions differed on a particular issue.

Role of Field Based Personnel

Field as well as office-based personnel including Medical Science Liaisons, Medical Affairs Managers and Hospital Representatives have an important role to play in helping to identify the key specialists in Ireland who are treating particular medical conditions.

Field teams know their customer base extremely well and over time, will have developed a deep understanding as to the areas of expertise of the various specialists they call to as part of their regular work. In advance of any formal approaches to clinicians to attend a delphi panel, advisory board or partake in an IDI, informal conversations can be had by field based teams. This facilitates an understanding of the main issues to managing the care of patients with a particular condition for example, the numbers of patients with a rare disease or any geographical differences observed which may be important to capture. If this information is properly collated, it can be very useful for third party agencies to create both pilot and final questionnaires to elicit Expert Opinion.

In summary, Expert Opinion can play a very important role in contributing key insights to help the Irish authorities determine the overall value of a new pharmaceutical medicine. However, when used to inform reimbursement submissions, companies must ensure rigorous standards are applied both in gathering the information and reporting on the Expert Opinion that was provided.

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