UTILIZATION AND EVALUATION OF DELPHI PANELS IN GERMAN AMNOG ASSESSMENTS

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BACKGROUND

- Expert advice/opinion is a valuable source of information, especially if reliable evidence is not available or sparse, like in rare or unexplored diseases.
- In those cases, a Delphi panel is a suitable tool to investigate expert opinion on specific topics to generate such missing evidence.
- A Delphi panel is a structured, consensus-driven approach utilizing the expertise of various experts and collecting their advice or opinion on a specific subject.[1]
- In accordance with the procedural rules by the German Federal Joint Committee (G-BA) during the Pharmaceuticals Market Reorganization Act (AMNOG), expert advice achieved by consensus, in principle, is accepted as a component of the regulatory dossier.[2]

OBJECTIVE

- The aim of this study was to examine how Delphi panels are integrated in German AMNOG assessments and how they are evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG) and the G-BA.

METHODS

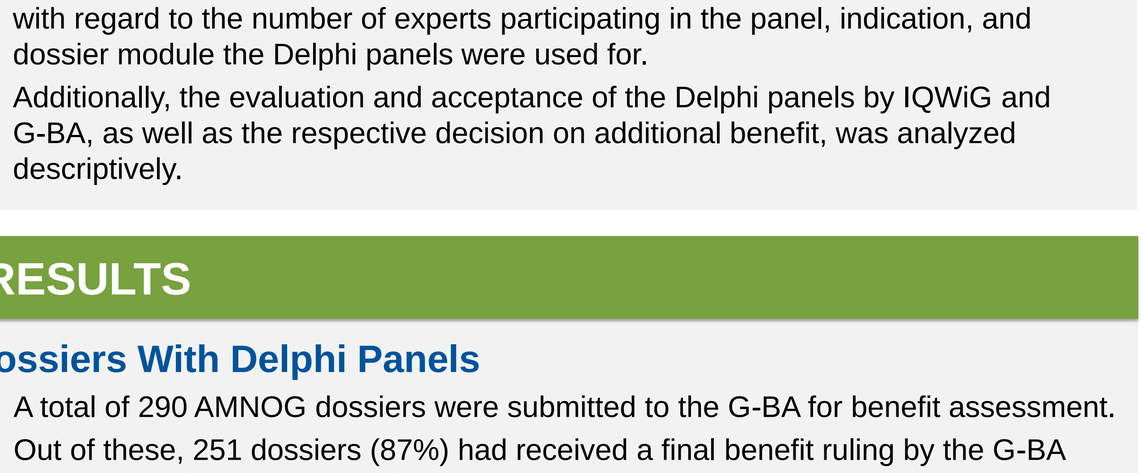
- All available AMNOG processes with a completed benefit assessment by the G-BA up until the end of June 2017 were included in the analysis.
- In the first step, all modules of the included dossiers, as well as the assessments by IQWiG and the final benefit assessments by G-BA, were screened with respect to the utilization of surveys or panels in which various experts participated. The following predefined search terms were used in the PDF search: “Delphi Panel” (English: Delphi panel), “Konsens” (English: consensus), “Experten” (English: experts).
- In the second step, all identified expert surveys and panels were reviewed in order to verify Delphi panel methods such as the integration of multiple experts, use of a consensus-driven approach, and the performance of more than 1 panel round.
- In the third step, all identified Delphi panels in the AMNOG dossiers were screened with regard to the number of experts participating in the panel, indication, and dossier module the Delphi panels were used for.
- Additionally, the evaluation and acceptance of the Delphi panels by IQWiG and G-BA, as well as the respective decision on additional benefit, was analyzed descriptively.

RESULTS

Dossiers With Delphi Panels

- A total of 290 AMNOG dossiers were submitted to the G-BA for benefit assessment.
- Out of these, 251 dossiers (87%) had received a final benefit ruling by the G-BA and were included in the analysis.
- Delphi panels were utilized in 4.4% (n=11) of the included dossiers (**Figure 1**).
- On average, 10.8 experts were included in the exercise (min=3, max=30 experts).

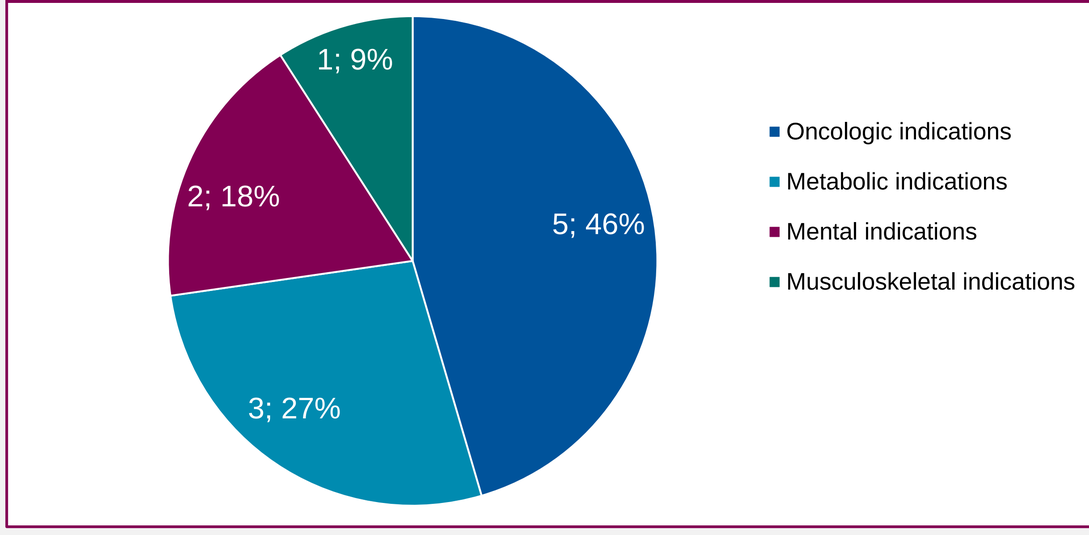
Figure 1. AMNOG Dossiers Stratified by Status of Benefit Assessment and Utilization of Delphi Panels



Disease Areas and Topics

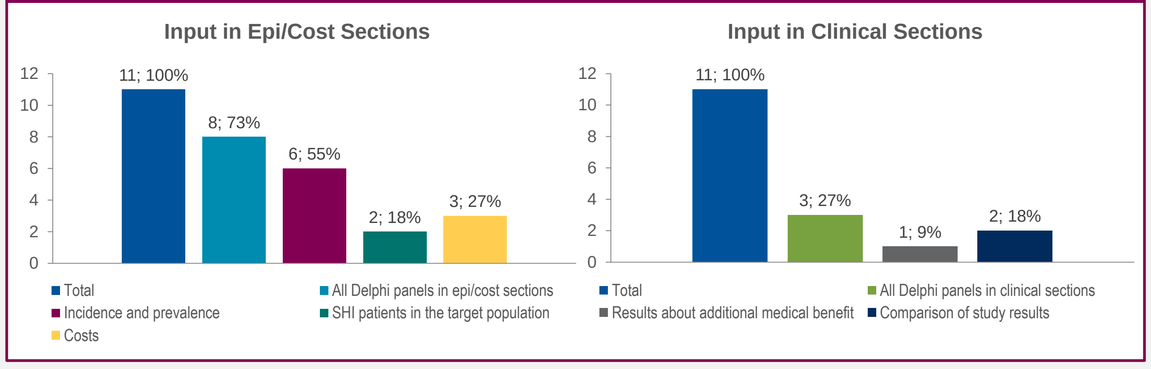
- Nearly half of the Delphi panels (n=5; 46%) were used to address evidence needs in oncologic indications, 27% (n=3) in metabolic indications, 18% (n=2) in mental indications, and 9% (n=1) in musculoskeletal indications (**Figure 2**).

Figure 2. AMNOG Dossiers With Delphi Panels Stratified by Indication



- Results from Delphi panels were mainly used in epidemiological sections (n=8; 73%) to describe the incidence and prevalence of the respective disease and the proportion of patients covered by statutory health insurance (SHI) in the target population (**Figure 3**).
- Furthermore, 3 (27%) dossiers also used the Delphi panels to describe economic impacts regarding costs of therapy for the SHI and the costs of best supportive care.
- In clinical sections of the dossier (n=3; 27%), the Delphi panel findings were compared to the results of other studies and used to add information about the additional medical benefit.

Figure 3. AMNOG Dossiers With Delphi Panels Stratified by Dossier Modules and Investigated Research Topics



Acceptance and Additional Benefit Assessment

- The IQWiG assessment was mainly positive, as no identified Delphi panel was rejected.
- However, 4 (36%) Delphi panels were criticized by IQWiG for methodological reasons.
- In 2 (18%) cases, the criticism focused on the number of experts included in the panel. One of these Delphi panels included 3 experts and the other Delphi panel included 8 experts. Besides the small number of experts, IQWiG also criticized the fact that no inpatient clinicians were included in 1 study.
- In another 2 (18%) Delphi panels, IQWiG requested a more detailed discussion of the limitations and the transfer of results to the target population.
- As a consequence, IQWiG was not able to validate the indicated findings of these 4 dossiers due to the previously mentioned criticisms.
- G-BA granted an additional benefit to 4 dossiers (out of 11; 36%), with 1 of these receiving a significant additional benefit.

CONCLUSIONS

- Despite the fact that many times, only sparse information is available in various areas relevant for the regulatory assessment, Delphi panels are rarely used within the German AMNOG process.
- A potential reason for this might lie in the fact that this type of analysis takes some time to conduct from the development stage to final execution (3 to 6 months).
- Besides supporting the evidence on prevalence and incidence of a respective indication and the target population, Delphi panels can also be implemented to describe further topics such as costs, medical benefit, and best supportive care.
- As the acceptance by IQWiG and G-BA seems to be very high, the application of Delphi panels offers a viable option to address or minimize evidence gaps in an AMNOG assessment.

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