IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

Involvement of people affected in the production of reports on benefit assessments[1]

[1] Translation of the document *Beteiligung von Betroffenen bei der Erstellung von Berichten zur Nutzenbewertung* (Version 1.1; Status: 04 October 2017). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Table of contents

List of figures

List of abbreviations

Abbreviation	Meaning
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
SGB	Sozialgesetzbuch (Social Code Book)

1 Background

The production of reports on the benefit assessment of drug and non-drug interventions is performed on the basis of a single commission by the Federal Joint Committee (G-BA) or the Federal Ministry of Health. The basis for this are the Institute's tasks described in §139a Social Code Book (SGB) V.

The Institute is commissioned by the G-BA within an assessment procedure initiated at the G-BA by application of the supporting organizations, non-partisan members or patient representatives. After the **award of the commission**, the research question is formulated within the production process of the **report plan** (protocol). In this context, people affected[2] as a rule are involved by means of a consultation. The report plan is then produced. It includes the outcome criteria (i.e., primarily patient-relevant outcomes), the inclusion and exclusion criteria for the information to be used in the assessment, as well as the presentation of the project-specific methodology for the retrieval and assessment of this information. The report plan is published on the Institute's website and the public is given the **opportunity to submit written comments (hearing)**. The comments are evaluated and published for the purpose of documentation of the hearing. If it is necessary to adapt the project-specific methodology a revised report plan is published on the Institute's website, together with the documentation of the hearing on the report plan. The report plan forms the basis for the production of the preliminary report. The results of the information retrieval and the scientific assessment are presented in the **preliminary report**. This report contains the preliminary recommendation to the G-BA. It is also published on the Institute's website and the public is given the **opportunity to submit written comments (hearing)**. Optionally, an oral scientific debate including persons submitting comments may be held. The **final report** represents the concluding product of report production. It builds on the preliminary report and contains the assessment of the scientific evidence, under consideration of the results of the hearing on the preliminary report. The final report and the documentation of the hearing on the preliminary report are also published on the Institute's website. Following the assessment by the Institute, the consultation is continued in the committees of the G-BA and is concluded with the resolution in the plenum.

Throughout the entire procedure patient organizations have the right to be involved, including active contributions. At the G-BA this applies in particular to the opportunity to submit applications, as well as to contribute to the work in the different committees. Which organizations predominantly represent the interests of people affected at the G-BA is regulated in the Regulation on Patient Involvement. Beyond the legal obligation according to §139a (5) SGB V, which specifies that patient representatives must be given the opportunity to submit comments, it is particularly important for IQWiG to ensure the involvement of people affected so that the patient perspective can be considered in the assessment. This is

[2] "People affected" can in particular be patients (if necessary, represented by their parents or other relatives) as well as potential participants in preventive measures.

ensured by involving these people in the production of reports (see Figure 1). The following text refers only to their involvement in IQWiG's reports on benefit assessments.

In addition to reports, the Institute also produces so-called rapid reports. They are particularly intended for recommendations at short notice, for which, from the point of view of the contracting agency, no (renewed) hearings by the Institute are required. Many rapid reports serve to update earlier reports, in which people affected were already involved. They are thus not normally involved in rapid reports.

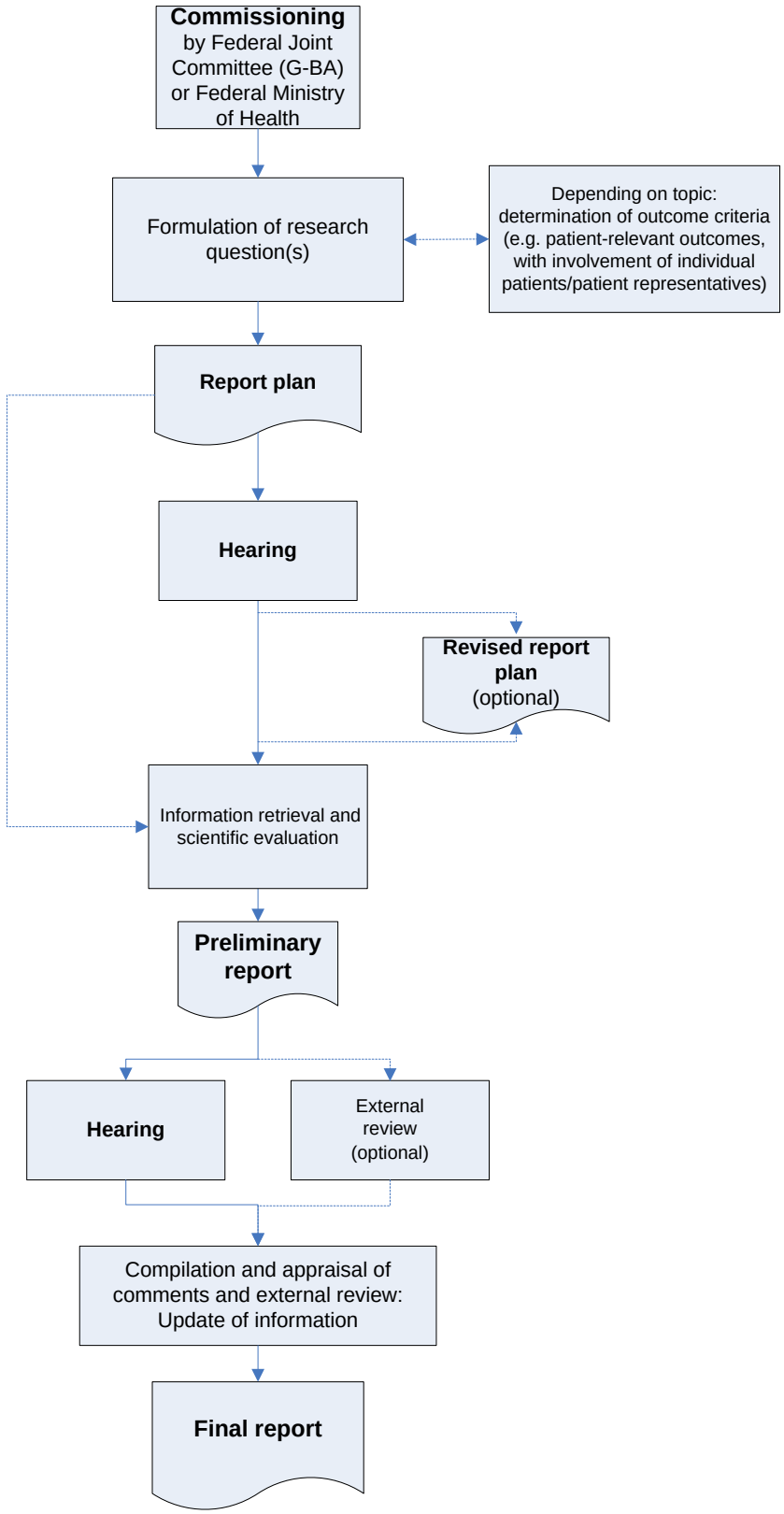

Figure 1: Production process of reports

2 Procedure of patient involvement at IQWiG

2.1 Consultation of people affected

People affected are consulted within the production process of the report plan. Consultations do not have to be conducted for each individual commission, but are usually conducted when a combination of the intervention and therapeutic indication was not already the subject of an earlier consultation.

The consultation takes place in a personal meeting on the premises of the Institute. About 1 to 2 hours are planned for this meeting. On behalf of the Institute, the Institute's Management, as well as the project manager, usually participate in the meeting. No minutes are taken.

2.1.1 Content of the consultation

The aim of the consultation is to exchange opinions on patient-relevant outcomes. People affected can also provide information on whether specific subgroups should be considered.

The regular agenda of the consultation starts with words of welcome from the moderator and introduction of the participants. If necessary, open issues on the *Form for the disclosure of conflicts of interest* (see below) are clarified and the Institute's mode of operation presented. Then the moderator or project manager presents general information on the commission (e.g. aim and methods) and on the report (e.g. project status, schedule), as well as information on the aims and relevance of the meeting.

The key component in the consultation and the actual participation of people affected is the exchange of opinions on patient-relevant outcomes and on relevant subgroups.

Within the context of this exchange of opinions on patient-relevant outcomes, before starting work on a project, the Institute would like to learn what is important for people affected (i.e. patients and their relatives), which problems and burdens are associated with the disease, and what they wish or expect from treatment. For instance, in patients with serious diseases such issues can be the occurrence of side effects or the quality of life. From these details, the Institute can infer important information for the determination of patient-relevant outcomes.

The exchange of opinions on relevant subgroups concerns the question as to which patient characteristics could potentially influence effects. Here the people affected can provide suggestions on whether, from their point of view, certain characteristics should be considered in the analyses (e.g. in relation to disease severity or specific factors).

The results are then summarized by the moderator and an outlook with regard to further project steps is provided, including the opportunity to submit comments.

The results of the consultation are considered in the production of the report plan.

2.1.2 Selection of people affected

People affected are primarily contacted via the speaker of the Coordinating Committee of the Patient Representatives in the G-BA, as he or she is responsible for the coordination of these patient representatives.[3] For this purpose, the speaker is contacted in writing and asked to name one or more contact persons suitable for dealing with the research question. The speaker forwards the request to the respective patient organizations and provides the Institute with the names of suitable contact persons. The Institute then sends written invitations to these persons and later also contacts them directly with regard to the coordination of meeting appointments.

In addition to those named by the speaker, further people affected can be directly contacted and invited by the Institute. In such a case, the speaker is informed about this.

2.1.3 Conflicts of interest

Only those persons can participate in the meeting who have sent the Institute beforehand a completed *Form for the disclosure of potential conflicts of interest*. For this purpose, the general conflicts of interest form is used that is also used for other Institute products.

The declared conflicts of interest are published together with the report plan. However, it is only stated whether or not there are conflicts of interest in the area covered by the question, i.e. only the answer "yes" or "no" is provided. No specific details on relationships or the amount of any remuneration received are published. The names of the people affected are not named in the report unless consent was submitted previously by a separate form.

2.1.4 Further aspects

No remuneration or financial expense allowance is paid for participation in the consultation. For those conferring with the Institute, the coverage of travel costs is in principle possible within the framework of the German Travel Expenses Act.

2.2 Opportunity for submission of comments (hearing)

In accordance with §139a (5) SGB V, the Institute must ensure that the following parties are given the opportunity to submit comments in all important phases of the assessment procedure: medical, pharmaceutical, and health economic experts (from research and practice), drug manufacturers, relevant organizations representing the interests of patients and self-help groups for the chronically ill and disabled, as well as the Federal Government Commissioner for Patients' Affairs. The comments must be considered in the decision. These legal requirements are taken into account by the fact that hearings are conducted on the report plan and preliminary report.

[3] In the G-BA only certain patient organizations have the right to participate in consultations or submit applications. In the Regulation on Patient Involvement it is specified that in particular the disclosure of funding of organizations, and thus proof that they work neutrally and independently, is required for this right to be granted.

2.2.1 Content of the hearings

The opportunity to submit written comments on the report plan refers in particular to the project-specific methodological approach applied to answer the research question. The research question itself is usually specified by the commission, and is not a subject of the commenting procedure.

The results of the retrieval and assessment of information presented in the preliminary report are in particular the subject of the commenting procedure on the preliminary report. Optionally, an oral scientific debate including those submitting comments may be held. This debate serves the potentially necessary clarification of aspects of the written comments and aims at improving the scientific quality of the final report.

2.2.2 Selection of people affected

The circle of people entitled to submit comments is not restricted.

2.2.3 Conflicts of interest

In order to avoid unreasonable delay in the Institute's work, the comments must fulfil certain formal requirements. Further information on the commenting procedure, including the conditions for participation in a scientific debate, can be found in a guideline published on the Institute's website.

Together with the formal evaluation of comments it is also checked whether an original version of the *Form for the disclosure of conflicts of interest* is available for each person submitting comments. If such a form is not available, it is requested from the person submitting comments within the formal evaluation process. If the original version of the form is still not available after this deadline, the person submitting comments cannot participate in the debate. The declared conflicts of interest are published in a general form, as described in Section 2.1.3.

2.2.4 Further aspects

After publication of the report plan and the preliminary report on the Institute's website, comments can be submitted for a period of at least 4 weeks.

Those comments fulfilling formal requirements are published on the Institute's website in a separate document (*Documentation of the hearing*). If a debate was held, the verbatim minutes are also published in this document.