swiss medical board

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Methodical further development

A commentary by the executive committee of the sponsoring association

One of the main tasks of the sponsoring association of the Swiss Medical Board was first to establish and later to maintain the appropriate methodological standards for an HTA report. Appropriate standards did not exist in Switzerland. The methods that had proven themselves in leading countries for HTA were adopted or adapted. The comparison with the best from abroad remained an important task of the supporting association. This was the only way to maintain the high standard.

The discontinuation of the activities of the Swiss Medical Board had just been decided when we became aware that in leading HTA countries "Benefit Harm Assessment" was already being used as an additional tool in selected HTA reports. True to our credo of continuous improvement, it was then decided to apply this innovation to the last two HTA reports of the SMB.

The two reports have now been completed and the lessons learned from the additional focus on the benefit-harm balancehave proven to be worthwhile. We would therefore like to recommend to the stakeholders of future complex HTA reports to apply this additional tool and, if necessary, to initiate a discussion to create the preconditions for meaningful Benefit Harm Assessment (e.g. data quality).

What exactly Benefit Harm Assessment is about is described below by the two specialists from the Institute of Epidemiology, Biostatistics and Prevention at the University of Zurich:

Assessing the benefits and risks of therapies and technologies.

Why decision makers can benefit from this assessment as an additional element of Health Technology Assessments

Dominik Menges & Milo Puhan

The Swiss Medical Board conducted assessments of medical interventions and technologies from 2009 to 2022. These assessments are based on detailed analyses of available data from clinical trials and also take into account expert opinions, costs, and ethical considerations. The process follows high methodological standards and, after the precise definition of the research question, includes a detailed scientific assessment followed by an appraisal of the options for action by an interdisciplinary panel of experts. This procedure is common practice worldwide for so-called Health Technology Assessments and is intended to support decisions in the regulatory environment and in clinical practice as well as possible with findings from research.

There are decisions in medicine that are complex due to various factors and for which such Health Technology Assessments are particularly suitable. Medical treatments can have a number of different effects (outcomes) that are either positive or represent undesirable side effects. An example of this is cholesterol-lowering drugs, which have a positive reduction in the risk of heart attacks and strokes, but which also carry an increased risk of adverse outcomes such as muscle pain, diabetes, or cataracts. How should these positive and negative effects be balanced? Does the balance of positive and negative effects vary by age, sex, and risk for cardiovascular disease or risk for specific adverse events? And how does the balance of positive and negative effects change when people individually value the importance of outcomes such as heart attacks or side effects differently?

A conventional Health Technology Assessment answers this question of the balance of positive and negative effects of medical interventions and technologies only to a limited extent. The scientific assessment provides the expert panel with the best available data separately for the various positive and negative effects of a therapy. However, it typically does not provide an estimate of the balance of relevant positive and negative effects. Accordingly, the expert panel is confronted with the complex task of combining the various positive and negative effects into an overall assessment. This is cognitively demanding and hardly feasible in a systematic way. As a result, experts may disagree on whether the positive effects of a therapy outweigh the negative effects and whether the balance differs between patient groups. Often, due to a lack of transparency in the assessment, it also remains unclear why or on which points experts disagree.

This is where the so-called Benefit Harm Assessment comes into play. In a Benefit Harm Assessment, the positive and negative effects of a therapy are weighed in a systematic and transparent way and combined into an overall picture. In the most commonly used methods, the best available data are used to estimate how many patients have the positive and negative effects over a given period of time with the therapy. Different patient profiles and patient preferences for the positive and negative outcomes (i.e., how patients rate the outcomes) can also be taken into account. From the analysis, it is possible to infer whether the balance of positive and negative effects is in favor of or against a therapy and how this balance differs for different patient profiles and patient preferences. As a result, for many, often hundreds of patient groups, the balance of positive and negative effects of a therapy can be estimated in a systematic and transparent way and the formulation of recommendations can be supported with scientific data.

The Swiss Medical Board commissioned a Benefit Harm Assessment for two recent reports as a new innovative element of a Health Technology Assessment. Such a Benefit Harm Assessment is not always necessary. But it can support decision-making in complex decisions where benefits and side effects are close together or patient preferences play an important role. A decisive advantage of a Benefit Harm Assessment is that the data and assumptions used can be varied systematically and transparently and thus different opinions or also decision-making situations can be represented. Thus, Benefit Harm Assessment can represent a valuable bridge between the scientific assessment of the research question and the appraisal and formulation of recommendations by the interdisciplinary expert panel.