Evidence

Swiss HTA Consensus defines "levels of evidence" in line with the principles of evidence-based medicine, with randomized controlled clinical trials ranking highest, followed by prospective cohort studies, retrospective studies, case series, and – at the lower end of the scale – expert opinion (consensus).

Reasonable Evidence Expectations

Swiss HTA Consensus provides strong incentives for the provider of a given health technology to produce evidence to the extent and quality that can "reasonably" be expected given the specifics of a technology in a given phase of its life cycle:

1. "Expected Level of Evidence"

Swiss HTA Consensus fully endorses the principles of evidence-based medicine. The rigorous application of these principles should be pragmatic in order to appropriately accommodate situational aspects inevitably influencing the level and quality of evidence of effectiveness that can be reasonably expected from a provider of a technology at a given time in the technology life cycle.

The full range of demonstrated health-related benefits will be evaluated from an individual's perspective. Outcomes will be rated based on relevance and magnitude of the effects observed.

Judgments on the degree of confidence in the health-related benefits found in studies will primarily depend on the available level of evidence. As a reference level for grading, Swiss HTA Consensus defines the best possible level of evidence that can be expected in a given context (which includes consideration of the technology life cycle). This expectation may differ from the (abstract) best possible level of evidence.

2. Grading of Clinical Evidence

Avoidable evidence gaps (either concerning the level of evidence or related to the quality of available data according to a set of pre-defined criteria) will lead to a formal downgrading. In exceptional cases, such downgrading may be compensated. This will be possible if and when large effects of an intervention have been observed consistently, if a dose-response gradient is clearly present, and/or if all plausible causes of bias would decrease the magnitude of the observed effects.

On the basis of an assessment integrating the aspects mentioned, as well as taking account of differences between the available evidence and the current Swiss standard of care (if and when deemed relevant), health technologies may be assigned to one out of five benefit categories.

In combination with a systematic assessment according to the second and third of the WZW criteria, the proposed assessment methodology for health-related benefits might then provide a solid basis for subsequent decisions, which may be concerned with reimbursement and pricing, restrictions of use, and clinical guideline development.