The Swiss Health Technology Assessment (HTA) Consensus: Guiding Principles

Michael Schlander[1-3], Christian Affolter[4], Heiner Sandmeier[5], Thomas Cueni[5], Pius Gyger[6], Ansgar Hebborn[7], Daniel Herren[8], Stefan Kaufmann[4], Esther Kraft[8], Peter Suter[9]

[1]Institute for Innovation & Valuation in Health Care (INNOVAL[HC]), Wiesbaden (Germany);
[2]University of Heidelberg (Germany), Mannheim Medical Faculty, Department of Public Health, Social and Preventive Medicine; [3]University of Applied Economic Sciences Ludwigshafen (Germany);
[4]santésuisse, Solothurn (Switzerland); [5]Interpharma, Basel (Switzerland); [6]Helsana, Zurich (Switzerland); [7]Roche, Basel (Switzerland);
[8]Swiss Medical Association (FMH), Bern (Switzerland); [9]Swiss Academy of Medical Sciences (SAMW), Basel (Switzerland)

A Multi-Stakeholder Approach

Project Team	Scientific Steering Committee
Christian Affolter (santésuisse) Thomas Cueni (Interpharma) Andreas Faller[1] (BAG) Pius Gyger (Helsana) Ansgar Hebborn / Claude Cao (Roche) Daniel Herren[2] (FMH) Stefan Kaufmann (santésuisse) Heiner Sandmeier (Interpharma) Michael Schlander (U of Heidelberg) Peter Suter (SAMW)	Prof. Dr. Robert E. Leu (University of Bern, Switzerland) Prof. Dr. Gérard de Pouvourville (ESSEC, Paris, France) Prof. Dr. Michael Schlander (University of Heidelberg, Germany & InnoVal[HC], Wiesbaden, Germany) associated: Prof. Dr. Urs Brügger (ZHAW & WIG Winterthur, Switzerland) [1]Government representative, observer status [2]as of May 2011

Three Public Workshops

Retraite 1 (Muerren, Januar 27/28, 2011)
Retraite 2 (Hinterzarten, Februar 24/25, 2011)
Retraite 3 (Bern, April 26, 2011)
Retraite 4 (Brunnen, May 31 / June 01, 2011)
Retraite 5 (Solothurn, July 13, 2011)
Scientific Steering Committee (Wiesbaden, July 29, 2011)
Retraite 6 (Bern, August 19 /September 02, 2011)
Retraite 7 (Bern, October 19, 2011)

Deliberation by Project Team

Kartause Ittingen
November 05/06, 2010

Brunnen / Vierwaldstättersee
May 31 / June 01, 2011

Swiss Workshop 2: *Discussion of Interim Results with Stakeholders*

Expert Workshop 1: *Public Expectations & Societal Preferences; International Experience; Health Economic Evaluation Methods*

Luzern / Vierwaldstättersee
September 28/29, 2011

Swiss Workshop 2:
Discussion of Consensus Draft with Stakeholders

Scope and Objectives

HTA in Switzerland should

- provide effective support to health care decision makers in charge of reimbursement and pricing of interventions;
- regular reevaluation of any such decisions;
- identification of evidence gaps and research needs;
- provision of information supporting policies to ensure fair access of the Swiss population to high quality, effective and efficient health care interventions.

Scope:

- both new and established (existing) technologies;
- selected following a transparent process according to criteria including cost of illness and budgetary impact, prevalence and burden of disease, ongoing controversy regarding effectiveness, or the wish to inform the imminent development of clinical guidelines in a specific field;
- HTAs should be conducted at the national level.

Evaluation Criteria

1. **A Prior Normative Commitment,**
   determining boundaries for a federal HTA framework
   derived from constitutional provisions as well as the principled, rights-based legal tradition of Switzerland (non-discrimination, including that of persons with disabilities, special protection of the autonomy and the development opportunities of children, and procedural justice, have all been part of that tradition);
2. **Social Preferences of the Swiss Population,**
   a major input to an externally valid HTA framework;
   beyond pure efficiency goals, these include fairness objectives and equal access, preferences for reciprocity and altruistic motives (this best corresponds to the proposed concept of an "empirical ethics" with health care resource allocation being directed to best meet the expectations and the needs of the insured, which are believed to specifically include a priority for those worst off and for fair chances of access to effective health care, including access to innovative interventions);
3. **Swiss "WZW" Criteria,**
   with explicit recognition of multiple criteria for decision making: W (**Wirksamkeit**: "*effectiveness*"), Z (**Zweckmässigkeit**: "*appropriateness*", i.e., "*social desirability*"), constrained by the prior normative commitment; W (**Wirtschaftlichkeit**: "*economic viability*")

Clinical Effectiveness

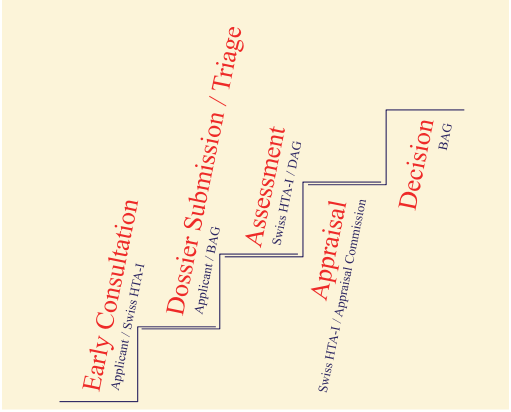
"**Levels of evidence**" defined in line with the principles of evidence-based medicine (EBM):

- **Reasonable Evidence Expectations**
  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;
- **Expected Level of Evidence**
  application of the principles of EBM 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;
- **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 and quality of evidence. As a **reference level for grading**, *Swiss HTA* defines the best possible level of evidence that can be expected in a given context.

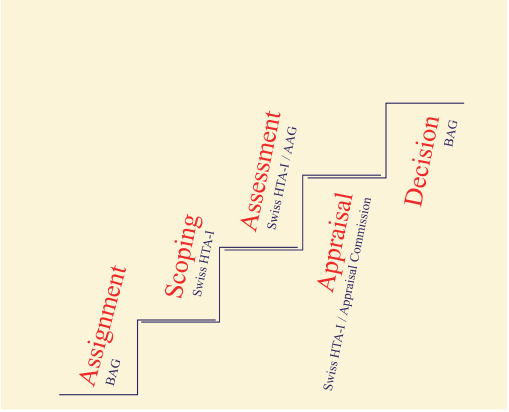
Economic Viability

1. **Budgetary Impact**
   Opportunity costs from a decision makers' perspective are defined by the overall budgetary impact of funding a specific health technology. The aim of these analyses is to establish transparency on the short, medium, and long term consequences of a decision from the perspective of payers.
2. **Cost Benefit Evaluations**
   are considered most useful for technologies with a high budgetary impact, especially when there is reason to believe that social benefits conferred by their use are small or moderate only.
3. **Technical and Allocative Efficiency**
   The evaluation of relative cost benefit ratios ("efficiency") should, for the time being, focus on issues of "*technical efficiency*", i.e., compare alternative ways to achieve the same clinical objective. Accordingly, the most appropriate evaluation method (cost minimization, cost effectiveness, cost utility analysis, etc., will depend on the specific research question. In other words, *Swiss HTA Consensus* recommends "*methodological pluralism*".
4. *SwissHTA* recognizes that the results of conventional cost benefit evaluations can be positively unethical when judged against the prior normative commitment.
   ***Swiss HTA* rejects the idea of uniform cost per QALY benchmarks.**

Rapid (r-)HTA Process



Complete (c-)HTA Process



Four Key Documents were issued by the project team on October 19, 2011:

- *Swiss HTA Consensus Project: Cornerstones for the Future Development of HTA in Switzerland* (30 pages)
- *Schweizer HTA-Konsensus-Projekt: Eckpunkte für die Weiterentwicklung in der Schweiz – Anhang"* (30 pages)
- *Schweizer HTA-Konsensus-Projekt: Konsentierte Thesen, Gliederung des Referenzdokuments (Foliensatz)* (13 pages)
- *Dokumentation zum Thesenpapier (Eck punkte des Schweizer Konsensus)* (222 pages)

Five Implementation Papers are underway in 2012.

INNOVAL HC
Institute for Innovation & Valuation in Health Care

Contact and address for correspondence:
michael.schlander@innoval-hc.com