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Institute for Innovation & Valuation in Health Care

"VALUE & VALUATION OF HEALTH TECHNOLOGIES"

Institut für Innovation & Evaluation im Gesundheitswesen

SWISS HTA CONSENSUS

GUIDING PRINCIPLES

Objectives

Scope

A Broad Technology Focus
HTA at the National Level

Stakeholder Involvement

Governance and Process Development
Technology Assessments

Evaluation Criteria

Beyond Clinical Efficacy:
A Prior Normative Commitment
Social Preferences
Swiss "WZW" Criteria

Evidence of Clinical Effectiveness

Reasonable Evidence Expectations:
Expected Level of Evidence
Grading of Clinical Evidence

Economic Viability

Budgetary Impact
Technical and Allocative Efficiency
Setting Limits
Managing Uncertainty

Evolutionary Options

Research Needs
Methods Development

FMH Verbindung der Schweizer Ärztinnen und Ärzte Fédération des médecins suisses Federazione dei medici svizzeri Swiss Medical Association
interpharma:ph
SCIENTIAE MEDICINALI ET SOCIETATI
santésuisse Die Schweizer Krankenversicherer Les assureurs-maladie suisses Gli assicuratori malattia svizzeri

GUIDING PRINCIPLES

The **Swiss HTA Consensus Project** (hereafter, briefly "*Swiss HTA Consensus*") was initiated jointly by santésuisse and Interpharma. Both parties believed, and continue to do so, that Switzerland should more effectively use the potential of Health Technology Assessments (HTAs) as a tool to continuously improve quality and efficiency of health care provision within the system of compulsory health insurance.

Primary objectives of the Swiss HTA Consensus Project were to complement the existing but fragmented Swiss HTA initiatives currently in place, notably by the Federal Office of Public Health (for new technologies in the context of reimbursement and pricing decisions), as well as the more recent initiative of the Zurich Medical Board (primarily assessing established technologies), and to contribute to the development of a refined and integrated approach at the national level.

The project was set up in an **inclusive** manner, i.e., santésuisse and Interpharma broadly invited participation of further HTA stakeholder groups. The offer was accepted by the Swiss Medical Association (FMH), the Swiss Academy of Medical Sciences (SAMS/*SAMW*), and by the Federal Office of Public Health (FOPH/*BAG*, with observer status). The parties involved collaborated constructively under the Chatham House Rule in an atmosphere of mutual trust. Despite heterogeneous perspectives and differing vested interests of the various stakeholders, it was possible to reach a consensus on the future use of HTA as an integral element of the Swiss Statutory health insurance system. The Swiss consensus covers principles, objectives, evaluation criteria, methods, processes, and implementation.

Four **documents** were issued by the project team on October 19, 2011:

1. *"Schweizer HTA-Konsensus-Projekt: Eckpunkte für die Weiterentwicklung in der Schweiz"* (30 pages)
   English translation:
   "Swiss HTA Consensus Project: Cornerstones for the Future Development of HTA in Switzerland" (30 pages);
2. Appendix to document 1, above:
   "Schweizer HTA-Konsensus-Projekt: Eckpunkte für die Weiterentwicklung in der Schweiz – Anhang" (30 pages);

3. *"Schweizer HTA-Konsensus-Projekt: Konsentierte Thesen, Gliederung des Referenzdokuments (Foliensatz)"* (13 pages), referring to document 4, below;

4. "*Bewertung medizinischer Interventionen in der sozialen Krankenversicherung. Dokumentation zum Thesenpapier (Eckpunkte des Schweizer Konsensus)*" (222 pages), supplementary documentation.

The following sections highlight major aspects of *Swiss HTA Consensus*, emphasizing those "**Guiding Principles**" that distinguish it from approaches to HTA adopted in other jurisdictions.

Objectives

According to Swiss HTA Consensus, HTA in Switzerland should provide effective support to health care decision makers in charge of reimbursement and pricing of interventions within the national system of compulsory health insurance (*Obligatorische Krankenpflege-versicherung*, OKP) and regular reevaluation of any such decisions. The objectives of HTA further include the identification of evidence gaps and research needs, and the provision of information supporting policies to ensure fair access of the Swiss population to high quality, effective and efficient health care interventions.

[=> 1.2]

Scope

In the context of *Swiss HTA Consensus*, "health technology" is understood as a comprehensive concept including (without any claim to being an exhaustive list) all interventions proposed and performed by health professionals and aiming at the improvement of the health of individuals and populations, e.g., medicines, medical devices, diagnostic measures, medical and surgical procedures, complex clinical care pathways and organizational and administrative settings.

[=> 2.1]

1. A Broad Technology Focus

HTAs should address both new and established (existing) technologies. New technologies are covered by a rapid-HTA process ("**rHTA**"). A particularly high potential for efficiency

and quality improvement can be expected among existing technologies. These are covered by a special complete HTA program ("**cHTA**"). Topics for evaluation by means of cHTA should be selected following a transparent process according to criteria including (but not limited to) 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.

[=> 2.2ff.; 2.2.2; 2.4ff.; 2.4.1; 2.4.2]

2. HTA at the National Level

HTAs should not only contribute to improved efficiency of health care delivery but be an efficient use of resources themselves. *Swiss HTA Consensus* thus recommends that HTAs be conducted at the national level. This should further help to avoid regional differences in patient access to health care services due to diverging technology assessments at multiple levels.

[=> 4.1]

Stakeholder Involvement

Swiss HTA Consensus does neither endorse nor require a particular **institutional arrangement** for the implementation of formal HTA processes in Switzerland, although it is recognized that one option might be an integrated "Swiss Institute for Technology Evaluation and Quality in Health Care". More importantly, *Swiss HTA Consensus* recommends a central process established at the federal level, with assessments and appraisals being informed by stakeholders throughout the whole process. Decisions based on these HTA activities will have to be taken independently (i.e., at the federal level).

[=> 4.1]

According to *Swiss HTA Consensus*, expertise and perspectives of stakeholders should predominantly be used at two distinct levels:

[=> 4.2.1]

1. Governance and Process Development

Support to and participation in **governance** of formal HTAs; oversight of implementation and further process development should be provided by way of expert input (or *Wissenschaft-*

licher Beirat of an official Institute) and by political representation (e.g., Supervisory Body or *Institutsrat* of the Institute) of stakeholders.

Furthermore, stakeholders should be offered opportunities to participate in the selection of technologies for evaluation (cf. below, "cHTA").

[=> 2.4.2.2; 4.1.3; 4.1.3.1; 4.1.3.3]

2. Technology Assessments

The actual **conduct** of Health Technology Assessments should be enhanced by formalized opportunities for stakeholders to provide input throughout the process, namely

(for "rapid-HTAs" [rHTAs]) exchange of information during optional early consultations, opportunities to offer comments on Dossier Assessment Reports and Appraisal Recommendations, if and when applicable, negotiation with the ultimate decision-maker (proposed by *Swiss HTA Consensus* to be the BAG, or another institution at the federal level), and defined options for lodging an appeal under certain restrictive conditions;

(for "complete-HTAs" [cHTAs]) participation in the selection process of technologies for cHTA ("assignments"), scoping of cHTAs, submission of information mandatory to be reviewed during assessment, comments on Draft Appraisals.

[=> 2.4.1ff.; 2.4.2ff.; 4.1.3.4; 4.2.2; 4.2.3]

Stakeholder participation will be supported by full **transparency** of the Swiss HTA processes and evaluation criteria. Accordingly, timelines and key documents pertaining to HTAs (such as key documents of assessments, appraisals, and decisions including their rationales) will be made available to the public.

[=> 2.5]

Evaluation Criteria

Rational decision-making requires systematic evaluation of alternative ways to achieve defined objectives. Given the condition of "scarcity" or, more generally, resource constraints, these objectives determine the appropriate evaluation criteria.

These criteria exceed the traditional set of medical parameters, usually centered on clinical efficacy, safety, and quality:

[=> 1.2.1; 1.2.2; 1.2.3]

1. **A Prior Normative Commitment,**
   determining boundaries for a federal HTA framework

   Empirical preferences (neither individual nor social ones, see below) alone do not form a sufficient basis for decision-making; *Swiss HTA Consensus* states they need to be embedded in the context of a prior normative commitment. This commitment is 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. Equal access to appropriate health care, effectively maintaining or restoring health-related quality of life, functioning and capabilities, should primarily protect individuals' normal range of opportunities to pursue their plans of life in autonomy. The Swiss health care legislation has been dominated by a focus on solidarity and the provision of support for those in greatest need.

   [=> 1.2.5.1; 1.2.5.2; 1.2.5.3]

2. **Social Preferences,**
   a major input to an externally valid HTA framework

   Within the boundaries of the prior normative commitment, the expectations ("social preferences") of the Swiss population for a specific allocation of jointly funded health care resources should guide the decision-making process. Beyond pure efficiency goals, these generally 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.

Swiss HTA Consensus recognizes the need for, and hence encourages, the conduct of further research and methods development in this respect.

[=> 1.2.5.4; 1.2.5.5; 1.2.6ff.]

3. Swiss "WZW" Criteria,
explicit recognition of multiple criteria for decision making

Decisions about the allocation of health care resources in Switzerland have to comply with the so called **"WZW" criteria** stipulated by the Swiss Health Insurance Act (*Krankenversicherungsgesetz*, KVG). In line with the aforementioned considerations, *Swiss HTA Consensus* proposes a revised interpretation of these criteria as follows:

1. W (**Wirksamkeit**: "*effectiveness*"), as the additional health related benefits conferred by a technology in comparison to the existing standard of care in Switzerland, which especially in case of subsequent economic evaluation may also comprise valuation (e.g., "*utility*") from an individual perspective;

   [=> 1.3.3; 1.3.3.1]

2. Z (**Zweckmässigkeit**: "*appropriateness*"), as the ability of a technology to promote the purpose and objectives of the Swiss statutory health insurance system as defined by the social preferences of the Swiss population (i.e., "*social desirability*"), constrained by the prior normative commitment;

   [=> 1.3.3; 1.3.3.2]

3. W (**Wirtschaftlichkeit**: "*economic viability*"), as the economic impact of funding a health technology within the Swiss statutory health insurance system (opportunity cost; budget impact; efficiency).

   [=> 1.3.3; 1.3.3.3]

Evidence of Clinical Effectiveness

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 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.

[=> 3.1.1ff.; 3.1.1.4; 3.1.1.6]

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.

[=> 3.1.1.5]

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.

[=> 3.1.1.7]

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.

[=> 3.1.1.4; 3.1.1.8]

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.

[=> 3.3.3; 3.3.4]

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. As a starting point of any economic evaluation, *Swiss HTA Consensus* therefore suggests using the results of **budgetary impact analyses** (actual and / or projected costs associated with the use of a technology, applying the scenario analysis technique including a conceivable range of unit prices, i.e., acquisition costs from the perspective of Swiss health insurance).[1]

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 (including the compulsory health insurance, patients, and society as a whole).

[=> 3.2.1]

Formal **cost benefit evaluations** (comparative health economic analyses of "efficiency") 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.

[=> 3.2.1.3]

2. 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,

[1] Consistent with this line of thought, *Swiss HTA Consensus* recommends budgetary impact (or opportunity cost from a system's perspective) as the most important criterion for the selection of technologies to undergo cHTAs. [=> 2.2.2]

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**".

[=> 3.2.3ff.]

Swiss HTA Consensus recognizes that the pursuit of "**allocative efficiency**" – as defined by currently widely applied evaluation techniques (using either maximum individual willingness-to-pay or quality-adjusted life years (QALYs) as the measure of "value" or of individual "utility") – does imply a contentious normative dimension insofar as it is concerned with interpersonal comparisons. The results of such assessments can be positively unethical when examined against the prior normative commitment (as delineated earlier) and the social preferences of the Swiss population, and hence threaten the "external validity" of the HTA framework.

Therefore, *Swiss HTA Consensus* rejects the idea of uniform cost per QALY benchmarks.

[=> 3.2.4ff.]

3. Setting Limits

This notwithstanding, *Swiss HTA Consensus* fully acknowledges the need for setting limits within the framework of the statutory health insurance system. For the time being, *Swiss HTA Consensus* proposes to decide on limits based upon comparative clinical effectiveness, evidence of added health-related benefits (including the degree of confidence in the available evidence, budgetary impact (or opportunity cost from a system's perspective), and technical efficiency.

[=> 3.3ff.]

4. Managing Uncertainty

Swiss HTA Consensus distinguishes between clinical and economic evidence that cannot be reasonably expected in a given context, and evidence gaps that might have been avoided. Evidence gaps create uncertainty, which will be dealt with by means of modeling techniques and by managed entry schemes, including "coverage with mandatory evidence development" agreements and subsequent reviews of data. Thus, *Swiss HTA Consensus* offers strong dynamic incentives for technology providers to produce evidence.

[=> 3.4ff.]

IV

Evolutionary Options

Research Needs and Methods Development

The recommendations by *Swiss HTA Consensus* have been developed with an open mind regarding further development options.

Research needs identified by *Swiss HTA Consensus* include

1. high-level empirical studies of the "social preferences" of the Swiss population with regard to health care resource allocation decisions;
2. development of improved economic evaluation methods that enable capturing these "social preferences".

[=> 3.3.4ff. (Appendix); 4.4ff.]

Implementation of the proposals forwarded by *Swiss HTA Consensus* will provide options for seamless evolution of methods and processes, in line with relevant scientific theory and debate as well as international practical experience in the field.

Swiss HTA Consensus firmly believes that the results achieved to date provide a basis for, and encourage, continued strong stakeholder involvement in the implementation and further evolution of HTA in Switzerland at the federal level. The *Swiss HTA Consensus* Group is prepared to actively contribute to this process.

Glossary

BAG	*Bundesamt für Gesundheit* within the *Eidgenössisches Departement des Inneren* (EDI): Federal Office of Public Health within the Federal Department of Home Affairs
cHTA	complete HTA process, primarily designed to assess existing technologies and complex clinical pathways
KVG	*Krankenversicherungsgesetz*: Swiss Health Insurance Act
OKP	*Obligatorische Krankenpflegeversicherung*: Swiss compulsory health (and long term care) insurance
rHTA	rapid HTA process, primarily designed to assess new technologies
WZW	*Wirksamkeit*, *Zweckmaessigkeit*, *Wirtschaftlichkeit*: effectiveness, appropriateness, economic viability, criteria for the evaluation of health technologies stipulated by the Swiss Health Insurance Act (=> KVG)

This document should be referenced as follows:

M. Schlander, C. Affolter, H. Sandmeier, U. Brügger, C. Cao, T. Cueni, E. Kraft, G. de Pouvourville, A. Faller, P. Gyger, A. Hebborn, D. Herren, S. Kaufmann, R. Leu, P. Suter:
Swiss HTA Consensus Project: Guiding Principles.
Basel, Bern, Solothurn and Wiesbaden, March 13, 2012.
Available for download at www.swisshta.org.

Cross-references [in brackets] refer to document no. 4 mentioned above, i.e., the supplementary documentation "*Bewertung medizinischer Interventionen in der sozialen Krankenversicherung. Dokumentation zum Thesenpapier (Eckpunkte des Schweizer Konsensus)*"