INNOVAL HC
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"VALUE & VALUATION OF HEALTH TECHNOLOGIES"

SWISS HTA CONSENSUS PROJECT

CORNERSTONES FOR FURTHER DEVELOPMENT IN SWITZERLAND

Health Technology Assessment (HTA):
Systematic evaluation of medical interventions in the social health insurance

Note:
The figures in [square] brackets refer to the decimal structure of the detailed document (slide set)
*"**Propositions (Swiss Consensus)**" Final Version ("FV") of 19 October 2011 (=> corresponding slides).*

Submitted on 19 October 2011 for **FMH**, **Interpharma**, **SAMS** and **santésuisse**
with the participation of the **FOPH**

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SOCIETATI SCIENTIAE MEDICINALI ET
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Summary

With this document, the Swiss Medical Association (FMH), Interpharma, the Swiss Academy of Medical Sciences (SAMS) and santésuisse set forth a framework, with the involvement of the Federal Office of Public Health, showing how Health Technology Assessments (HTAs) can in future support the management of all services provided under compulsory health insurance (OKP) in keeping with objectives.

The scope of HTAs therefore covers both new and already established (existing) technologies; for the selection of products and procedures to be evaluated in the context of HTAs, a transparent process is presented with clear selection criteria.

Implementation is in principle not dependent on a particular type of organization, if and as long as there are guarantees in place to ensure that there is uniform process leadership for HTAs at federal level, the people responsible for implementation are independent and sufficient funds are provided. Just one of several conceivable options is the formation of a *Swiss Institute for Technology Evaluation and Quality in the Health Service* ("SITEQ"), which could allow a meaningful link-up with the quality strategy of the federal authorities.

Essential features of the consensus on the new Swiss HTA process include in particular:

1. Clear separation of assessment, appraisal and decision-making;
2. Transparency of process, criteria and decisions, including their underlying reasons, with defined timelines and broad stakeholder involvement, for new and existing technologies;
3. Operationalization and consistent systematization of the criteria of the Swiss health insurance act (KVG) for efficacy, suitability and cost-effectiveness;
4. Practice-oriented application of the principles of evidence-based medicine taking into account the relevance and scale of clinical therapeutic effects, the degree of trust in the existing data based on the available level of evidence in relation to the best level of evidence to be expected in the given context and the quality of the existing studies;
5. Focus on the expectations ("social preferences") of insured people within the limits of normative standards in the sense of Swiss legal tradition;
6. Assessment of cost-effectiveness without normatively problematic reductionist simplifications, such as threshold values for acceptable cost-effectiveness regardless of context;
7. Setting of limits at several levels (added benefit, suitability, cost-effectiveness) without being detrimental to innovation;
8. Consideration of further development opportunities in the future.

The likely cost of the new HTA processes at around CHF 15 million p.a. – which should be borne equally by technology providers / users, insurers and the public purse – contrasts with a substantially greater potential for increasing efficiency.

Background

[=> 0.4; 0.4.1; 0.4.3]

The management of services covered by compulsory health insurance in Switzerland poses a major health policy challenge. This is true both of unrestricted benefits in "open catalogues" (medical and chiropractic services, provided these are not the subject of controversy) and of explicitly defined benefit catalogues (paramedical services, medicines, analyses, equipment and appliances, and also medical preventive measures). The sub-objective of a health system that is financially sustainable and insurance premiums that do not go sky high – a system that is thus cost-effective – is faced with further sub-objectives of ensuring fair access to effective and high-quality healthcare for insured people. These sub-objectives complement each other in some ways, but in other ways they work in opposite directions, so a certain balance must be achieved.

In addition, the landscape is shaped by the interests of the stakeholders involved – from service and advance service providers on the one hand through *policy makers* and payers (FOPH, insurers) to patients and people covered by compulsory insurance on the other. In some respects these interests are mutually consistent and in other, not unimportant, respects they are mutually opposed to each other.

Against this background, the Federal Court was concerned with service-related questions concerning medicines in 2010 and 2011. In an initial ruling on a high-price product for the treatment of a very rare disease, the Federal Court confirmed that "*The judiciary has to some extent attempted to judge the cost/benefit relationship instead of the criteria hitherto undefined at the political level.*" In a second ruling, the Federal Court commented on the suitability of a treatment.

Both cases highlight an urgent need for operationalization of the criteria of efficacy, suitability and cost-effectiveness set forth in the health insurance act (KVG), which was already called for by the Parliamentary Administrative Control body (PVK, report of 2008) and the Business Review Commission of the National Council (GPK-N, recommendations of 2009).

Health Technology Assessments (HTAs)

[=> 0.2; 0.2.1.1-3; 0.2.2]

Operationalized criteria of efficacy, suitability and cost-effectiveness are the point of departure and at the same time serve as the crucial target criterion for an assessment of elements in the range of services

covered by the compulsory health insurance. For the systematic evaluation of medical interventions, the system of Health Technology Assessments (HTAs) is a recognized instrument of scientifically based political support that has largely established itself internationally based on the *Office of Technology Assessment* of the US American Congress (OTA, as from 1975).

HTAs that differ in the details of their form and function have since been used in numerous countries to evaluate the medical, social, economic and ethical implications of medical procedures and products in a way that is systematic, transparent and robust. The anticipated effects include in particular an improvement in quality and an increase in the cost-effectiveness of medical care. Possible instruments used for this are the recommendation of effective and economical services and conversely also the exclusion of services that offer no adequate evidence of benefit and / or no cost-effectiveness, as well as the development of binding guidelines on use.

Different definitions were proposed for HTAs, whose common features consist primarily in the multidisciplinary approach and in the systematic evaluation of the benefit of interventions, whereas the consideration of costs and cost/benefit relations differs considerably in some cases.

For a successful implementation of HTA results, a direct association of HTAs with defined political decision-making processes is crucial. At the same time, factors of major importance are the reputation (credibility and independence) of the institution(s) responsible for HTAs, the transparency of processes and criteria and the integration of stakeholders, as well as the quality and timely availability of HTA reports.

HTA in Switzerland

[=> 0.3; 0.3.1; 0.4.1; 0.4.2; and also 1.3.1, 1.3.2]

The implementation of Health Technology Assessments (HTAs) in Switzerland is inconsistent in terms of the nature, scope, criteria of assessment used and the degree of obligation (implementation of recommendations and decisions) and, in view of the current fragmentation alone, there is room for optimization.

Federal Office of Public Health (FOPH)

At the Federal Office of Public Health (FOPH) there are different procedures and responsibilities (three commissions: ELGK, EAMGK, EAK) for different sectors (service providers and services, equipment and appliances, analyses, packaged medicines, extemporaneous preparations; since 1996). The processes currently established at the FOPH are heavily focused on new products and procedures (including their routine reevaluation) and with regard to the criteria of efficacy, suitability and cost-effectiveness are most intensively elaborated for the pharmaceutical sector and the activity of the Federal Medicines Commission (EAK) concerning this sector.

The identified potential for improvement of the official HTA activities of the FOPH includes the following: consistent separation of assessment, appraisal and decision-making; the greatest possible transparency of process, criteria, recommendations, decisions (and appeals, where applicable) and their underlying reasons; identification of evidence gaps and initiation of measures to plug these gaps, including their enforcement; implementation of HTA results in guidelines for use and quality assurance; innovative "m*anaged entry*" strategies for rapid market access without surrendering the demand for evidence; rigorous evaluation of existing technologies including selection criteria for HTA issues and their application.

Medical Board

A much heeded initiative for HTAs in Switzerland came from the Medical Board, initially (as from 2008) supported by Canton Zurich, and since 2011 supported by the GDK, FMH and SAMS. It was launched by the Health Department of Zurich as a pilot project "to help ensure [...] the efficacy, suitability and cost-effectiveness of medical treatments". At the heart of the method adopted by the Medical Board is the assessment of cost-effectiveness relations by means of a (lower and upper) threshold value, the definition of which requires a "social empirical and consensus finding process" and which reflects the "sense of solidarity" or the willingness to pay for a so-called *Quality-Adjusted Life Year* (QALY). The Medical Board has so far (as at 15 October 2011) presented five HTA reports.

The identified potential for improvement of the HTA activities of the Medical Board include the following: stronger integration of stakeholders (in terms of both the HTA process itself and its further development); greater consideration of the existing experiences of international HTA institutions and in-depth reference to the status of international developments in the relevant disciplines (including health economics); focus on expectations ("social preferences") of the insured members (instead of a primary reference to a quasi-utilitarian concept of assessment); consideration of the interactions between the principles of assessment in the context of HTAs and the criteria of efficacy, suitability and cost-effectiveness (and operationalization of these criteria to lend them concrete shape); standards for a differentiated evaluation of new and existing technologies; criteria for the selection of technologies for HTAs and their practical implementation.

Swiss Network for Health Technology Assessment (SNHTA)

Since 1999 the *Swiss Network for Health Technology Assessment* (SNHTA), which has set itself the goal of promoting the use of HTAs in Switzerland, has served as an association of Swiss stakeholders.

The "Swiss HTA" project

[=> 0.1; 0.5]

These incentives are being taken up and developed further with this project

- in an inclusive process open to Swiss HTA stakeholders;
- taking into account existing experiences with formal HTAs in other countries;
- with explicit reference to the status of international development in the relevant scientific disciplines, including health economics;
- focusing on the expectations (i.e. the "social preferences") of the Swiss population;
- taking into account the implications for operationalizing the criteria of the KVG for efficacy, suitability and cost-effectiveness;
- with clear standards for a differentiated evaluation of new and existing technologies.

Structuring of the project

[=> 0.5.1; 0.7; 0.8]

The Swiss HTA project was initiated by representatives of santésuisse, Helsana, Interpharma and Roche jointly with Professor Michael Schlander (University of Heidelberg) at a meeting in Zurich on 12 July 2010 after intensive preliminary discussions during the first half of 2010. The agreed framework and the project objectives were put in writing in a working paper entitled "*Objectives of the project – 'Assessment of medical interventions in social health insurance: development of a Swiss consensus'*" dated 21 July 2010 (see Annex 3).

On this basis, santésuisse and Interpharma invited interested Swiss stakeholders to collaborate. This led to a project team made up of Christian Affolter (for santésuisse), Thomas Cueni (Interpharma), Pius Gyger (Helsana), Ansgar Hebborn / Claude Cao (Roche), Daniel Herren (FMH), Stefan Kaufmann (santésuisse), Heiner Sandmeier (Interpharma), Michael Schlander (University of Heidelberg) Peter Suter (SAMS) and Andreas Faller (for the FOPH with observer status). The Chatham House Rule was agreed on as the basis for collaboration in the project team built on trust.

The project work received scientific support from a Scientific Steering Committee, consisting of Michael Schlander along with health economics Professor Robert Leu (University of Berne) and Professor Gérard de Pouvourville (ESSEC, Paris).

The path to consensus: milestones

[=> 0.5; 0.6]

The core of the project work was formed by two workshops and seven retreats of the project team, which were primarily devoted to addressing the following themes:

- **Workshop 1**
  (Ittingen Charterhouse, 5/6 November 2010):

  Scientifically based preparation of consensus development; objectives of HTAs, normative frameworks, empirical data on the expectations of insured people, overview of international experiences with HTAs, current standard evaluation methods with the focus on measuring benefits and evaluating costs versus benefits.

- **Retreat 1** of Project Team
  (Mürren, 27/28 January 2011):

  Matching of expectations; annotated synopsis of propositions by santésuisse, Helsana, Interpharma, Roche and corresponding solutions of HTA institutions and international guidelines

- **Retreat 2** of Project Team
  (Hinterzarten, 24/25 February 2011):

  Normative and legal framework of HTAs, target criteria for evaluations and the need for and possibility of a revision of the criteria of efficacy, suitability and cost-effectiveness; Swiss context / existing processes; view of the FOPH; structuring of the anticipated Output project and stakeholder comments on a preliminary draft

- **Retreat 3** of Project Team
  (Berne, 26 April 2011):

  Operationalization of objectives, rapid and complete HTA process, benefit dimensions and their assessment, including exploratory study of plausibility and feasibility, essential HTA conditions from the view of the health insurer, alternative criteria of health economics for setting limits, basic institutional conditions

- **Retreat 4** of extended Project Team
  together with the Scientific Steering Committee
  (Brunnen, 31 May / 1 June 2011):

  Presentation and discussion of the interim results achieved; operationalization of criteria of efficacy, suitability and cost-effectiveness, rapid and complete HTA, approaches for a systematic assessment of benefits, setting of limits and assessments of costs versus benefits; current developments in France, embedding of project in the political processes at federal level

- **Retreat 5** of the Project Team
  (Solothurn, 13 July 2011):

  Discussion of inputs after Retreat 4; rHTA and cHTA process, categories of benefit assessment, ELGK proposals for operationalized criteria of efficacy, suitability and cost-effectiveness, setting of limits and current developments in UK, structure of a consensus paper

- **Retreat 6** of the Project Team
  (Berne, 19 August and 2 September 2011):

  Rights of appeal and appeal procedures, funding proposals, addressing and provisional adoption of cornerstone paper and supplementary detailed slide set (V5.01) by the project team

- **Workshop 2** (extended Project Team)
  (Lucerne, 28/29 September 2011):

  Presentation and discussion of draft consensus by project team with focus on complex and potentially controversial aspects: view of stakeholders,

Potential for improvement of HTAs in Switzerland, process-related and content-based project objectives, proposed assessment of benefits, selection of technologies for cHTAs, best evidence that can be expected in the given context and evidence development / managed entry strategies for new technologies, setting of limits in the project

¬ **Retreat 7** of the Project Team
(Berne, 19 October 2011):

Review of workshop 2; final version of the consensus cornerstones, decision by the project team, release for ratification by the associations involved and planned communication of results achieved.

1. Objectives

[=> 1.2.1]

Rational decisions are only possible when there is clarity on the objectives pursued in these decisions, the alternatives available, the assessment criteria and processes to be applied and the information available.

Objectives of Health Technology Assessments (HTAs) in Switzerland

[=> 0.1.1; 0.2.2; 1.1]

HTA in Switzerland should serve two overriding objectives in particular, namely

1. the comprehensive systematic comparative evaluation of the individual and social benefit, cost implications and cost/benefit relationship of "medical technologies"; and
2. the management of services covered by compulsory health insurance.

HTA is expected to be useful in helping to increase efficiency (for example, by eliminating ineffective and / or uneconomical services) and to improve the quality of healthcare (for example, through the development of binding evidence-based guidelines for use based on HTA results) within the limits covered by compulsory health insurance.

The limits of the project (interfaces of the HTA process) arise partly from the marketability of a technology, in many cases thus from a prior regulatory approval (the activities of swissmedic do not fall within the

scope of this project).

At the same time, HTAs should provide useful information for associated decisions for the proper use of the technologies evaluated; however, the decisions themselves fall within the remit of the FOPH.

HTA as decision support

[=> 1.2]

HTAs should support decisions in keeping with objectives for a healthcare that meets the criteria of efficacy, suitability and cost-effectiveness within the limits covered by compulsory health insurance:

1. Reimbursement and price decisions within the limits of the provisions set forth for services covered by compulsory health insurance (e.g. maximum prices for medicines ["Specialties List"] and analyses ["Analyses List"] and maximum reimbursements e.g. for equipment and appliances "Equipments and Appliances List", etc.);
2. Regular reviews of the range of services for conformity with the criteria of efficacy, suitability and cost-effectiveness;
3. Identification of research needs: proper closure of evidence gaps;
4. Fair access to effective and efficient medical care at a high level of quality.

Focus on key objectives of solidarity-based healthcare

[=> 1.2.3; 1.2.4; 1.2.5]

Objectives conflicting with the solidarity principle (in particular financial sustainability and the wish of citizens for limitation of taxes and insurance contributions; the economic correlates of this are the elementary concepts of "scarcity" and "opportunity costs") require the setting of priorities in the definition of services covered by compulsory health insurance.

In this context the following hierarchy of objectives is considered:

1. ***Primary normative postulate:***
   [=> 1.2.5.1; 1.2.5.2; 1.2.5.3]

   Paramount focus on a rights-based concept of personality, integrity and autonomy of the individual and an understanding of health as a "conditional good", without a minimum of which it is not possible to achieve self-determined life plans ("facilitation character" of health), within the meaning of Swiss legal tradition (cf. in particular the Federal Constitution, the basic principle of equal rights, protection of children and youths, right to assistance in emergency situations and other norms), which urges desisting from primarily utilitarian approaches and is rather informed to a substantial degree by the principle of solidarity ;

2. ***Expectation of insured people ("social preferences")***
   [=> 1.2.5.4; 1.2.5.5]

   within the meaning of the concept of "empirical ethics": with a glance at the above normative premises and in view of existing Swiss studies and surveys, as well as international economic and socioeconomic studies, the following social preferences are postulated – in the sense of a working hypothesis.

   a. Priority for interventions in especially acute and/or especially severe disorders (*criterion of urgency and severity*),
   b. Special consideration of interventions for young people (who have not yet had any chance of independently realizing their individual life plans; *criterion of a "fair innings"*),
   c. A fair chance of access to effective medical care even in the case of rare diseases and / or high costs of intervention (*criterion of fairness*),
   d. Subordination of interventions for only minor disorders and / or in cases where self-financing by the insured person may be reasonably expected (*criterion of "bagatelles"*),
   e. As far as possible unhindered general and prompt access to new interventions that offer demonstrable added benefit (*criterion of innovations*).

For this there is an express need for further research (with regard to validation, ranking and relative weighting of criteria; cf. below, "Evaluation methods, criterion of suitability").

These target requirements are operationalized by lending concrete shape to the criteria of efficacy, suitability and cost-effectiveness:

Operationalization of the criteria of the KVG for efficacy, suitability and cost-effectiveness

[=> 1.3; 1.3.3]

The Swiss health insurance act (KVG) requires evidence of efficacy, suitability and cost-effectiveness and the periodic review of these criteria for all services covered by the basic (compulsory) insurance.

With the criteria of efficacy, suitability and cost-effectiveness, objectives are stipulated, the attainment of which is to be supported by HTAs. To meet both central normative premises and also the expectations of insured people, these criteria are operationalized with reference to the following standards:

1. ***Efficacy***

   [=> 1.3.3.1]

   a. Starting point (1):
      Relevant added benefit (always) compared with relevant alternatives; degree of confidence in the existing evidence
   b. Starting point (2):
      Consideration of the best available evidence, the relevance of which should be clear for the reality of Swiss healthcare

2. ***Suitability (appropriateness to purpose and objectives)***

   [=> 1.3.3.2]

   a. Starting point (3):
      Primary normative postulate within the meaning of Swiss legal tradition (see above)
   b. Starting point (4):
      Empirically demonstrable "social preferences" of insured persons (see above)

3. ***Cost-effectiveness***

   [=> 1.3.3.3]

   a. Starting point (5):
      Cost implications
   b. Starting point (6):
      Efficiency; relation of (added) benefits to (added) costs

The underlying classification consists in the logical assignment of the individual benefits perspective to (1), the social benefits perspective to (2) and the cost perspective to (3).

This classification is an essential prerequisite for a potential seamless further development of the method with a view to possible future setting of limits justified by health economics (cf. below, under "Further development potential", and Annex 2).

2. Evaluation processes

[=> 1.2.5.3; 2.4.1.7; 2.4.2.6; 2.5; 4.2; 4.4; 4.4.2.2; 4.4.4]

Contemporary Swiss thinking on the constitution is committed not only to a focus on the rights already mentioned, but also to the idea of procedural justice. From this follows the demand for broad involvement of all those affected (stakeholders) and their interests, as well as a careful weighing of different aspects on a case-by-case basis.

The proposed processes are also inspired by a concept of "accountability for reasonableness" modified with a view to its practical feasibility, underpinned by the following principles: maximum possible transparency, relevance in the sense of evidence-based aspects and fairness (cf. in the concept criteria for individual and social benefits), rights of appeal (cf. below; supplemented in the concept by broad stakeholder involvement) and commitment (cf. in the concept implementation, enforcement of decisions and quality assurance).

Scope and balance of the HTA process

[=> 2.1; 2.1.1]

Health Technology is a comprehensive concept and includes (without any claim to being an exhaustive list) medicines, medical devices, diagnostic measures, medical and surgical procedures, complex clinical care pathways and organizational and administrative settings.

With the exception of medical services reimbursed in an "open benefit catalogue", new technologies are usually not included in a benefit catalogueof the compulsory health insurance until after an assessment (=> "**rHTA**", see below) and are thus automatically subject to a Health Technology Assessment.

But particularly high potential for efficiency and quality improvement can be realized in the area of existing technologies. To take this into account, a special program should be defined for the systematic evaluation of existing technologies (=> "**cHTA**", see below), the scope of which must be measurable on the basis of defined quantifiable target criteria. To ensure there is a degree of balance in this respect, a minimum of 12 to 18 completed cHTAs per annum is proposed as a target parameter.

Criteria for the selection of technologies for HTAs

[=> 2.2; 2.2.2]

Robust HTAs are not only qualitatively challenging and complex in their implementation, but also need to satisfy the criterion for efficiency themselves. So not all conceivable services covered by the compulsory health insurance should undergo an HTA. The following are therefore proposed as criteria for the selection of HTA issues:

1. New technologies (products and procedures) before a decision on their inclusion in a positive list and / or in the event of predictably high costs (budgetary relevance) and / or in the case of a specific dispute
2. Established technologies (products and procedures) based on their system relevance:
   a. Budgetary burden (/opportunity costs);
   b. Prevalence and / or burden of disease;
   c. (also) in the case of a dispute with unclear evidence;
   d. in particular (also) when clinical (or other use) guidelines are to be developed for a group of indications
3. Reevaluation of technologies usually after three years (in individual cases also after between two and five years, adapted according to the situation concerned)

Separation of assessment, appraisal, decision

[=> 2.3]

The responsibility for HTAs could be assigned to a **Swiss "HTA Institute"** or, if need be, in the context of the federal quality initiative, also to a Swiss institute for technology evaluation and quality in healthcare ("SITEQ", cf. below – 4. –: => "*Institutional integration*").

1. ***Assessment:***
   Task: rigorous formal synthesis of available evidence as target-oriented support for the following => *Appraisal*

2. ***Appraisal:***
   Task: comprehensive evaluation, identification of evidence gaps, and recommendations based on the assessment as a basis for => *Decisions*

Decisions on reimbursement, prices and other decisions are not a part of the actual HTA process, which establishes the essential basis of information for this (primarily through allocation to evidence-based benefit categories and, beyond this, the determination of cost implications and cost/benefit relations):

Decisions consequently remain the responsibility of the Federal Department of Home Affairs (FDHA) and the FOPH**:**
- Decisions on reimbursement and prices,
- Research conditions and their implementation,
- Quality-assured medical care: development of guidelines on use and clinical guidelines (with the medical societies) including monitoring of an implementation.

Rapid (r)HTA and Complete (c)HTA process

[=> 2.4ff.; 4.1.4]

To guarantee a proper, differentiated process for the evaluation both of new and of existing technologies along with standardized criteria of assessment at the same time, two separate sub-processes will be introduced:

Process:	primarily for new technologies: **Rapid (rHTA) process**	primarily for **existing** technologies: **Complete (cHTA) process**
Primary objectives:		Management of services
	Systematic review of available evidence and its quality	Systematic review of available evidence and its quality
	Definition of research needs	Definition of research needs
	Basic principles for decisions on reimbursability and maximum prices	Basic principles for the development of *binding* guidelines for use *and* if need be a review of reimbursability and maximum prices

Process:	**rHTA**	**cHTA**
Responsibility:	Applicant's dossier Review by HTA institute / academic review group (*Dossier Assessment Group*, DAG)	Academic institution (*Academic Assessment Group*, AAG; commissioned by HTA institute)
Phases:	*Early consultation* (HTA institute, *optional*) *Dossier submission / triage* (FOPH): => Bypass, fast track or standard rHTA *Assessment* (HTA institute; DAG) *Appraisal* (HTA institute; commissions) *Decision* (FOPH)	*Assignment* (FOPH; consolidated proposals from HTA institute) *Scoping* (HTA institute) *Assessment* (HTA institute; AAG) *Appraisal* (HTA institute; commissions) *Decision* (FOPH)
Funding:	Applicant (fees)	Mixed funding: equally through compulsory health insurance (contributions); confederation; fees

Rapid (r)HTA process

[=> 2.4.1ff.; especially 2.4.1.3; 2.4.1.5; 2.4.1.6]

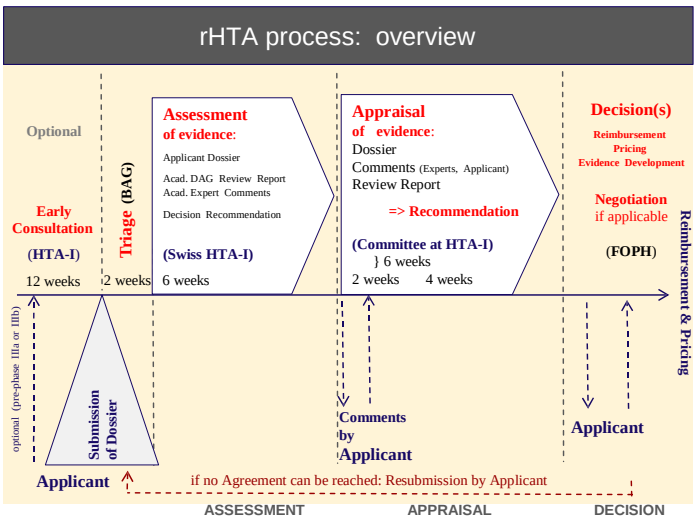

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***Figure 1**: Overview of rHTA process (cf. => 2.4.1.1)*

The special features of the rHTA process include a range (that can be seen by the applicants as an option) of "early consultations" (subject to a fee), which serve as an exchange of information with the institute that will be responsible later on for implementing an rHTA. The objects of an early consultation arise primarily from the consulting needs of the technology developer.

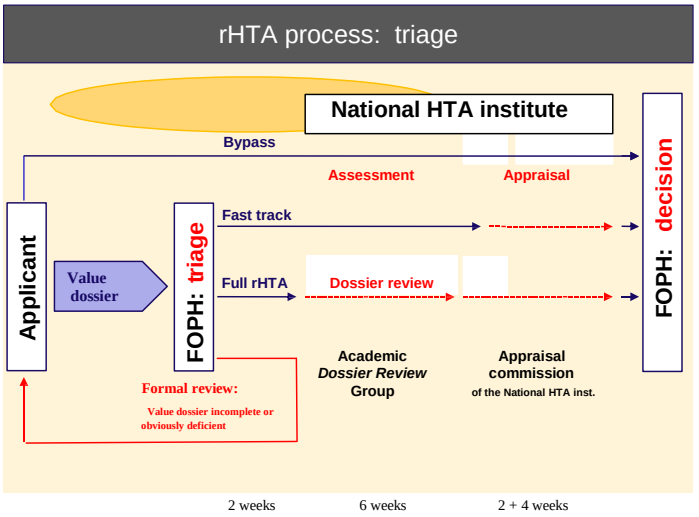

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***Figure 2**: Triage in the rHTA process (cf. => 2.4.1.4)*

Furthermore, a "triage" of the dossier submitted (to the FOPH) at the start of the rHTA process ensures that the evaluation process can be conducted as quickly and efficiently as possible. Dossiers shown in a formal preliminary review to be incomplete or deficient are returned to the applicant within two weeks for revision and possible resubmission. Based on transparent criteria the options of a bypass and a fast-track process remain.

The envisaged co-determination options for stakeholders – beyond stakeholder representation on the Appraisal Committees – are sketched out in Figures 1 and 11. Key stakeholders (represented in each case by their associations at federal level) are basically patients, the medical profession and other service providers, health insurers and also technology providers (the latter also individually when directly concerned) [cf. => 4.2.1]. Other stakeholders are, for example, scientists, HTA experts and health policy makers.

Complete (c)HTA process

[=> 2.4.2ff.; especially 2.4.2.2; 2.4.2.3]

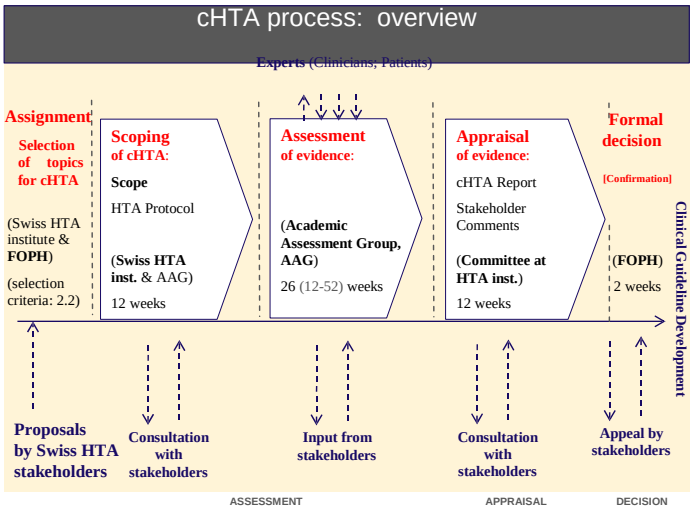

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***Figure 3**: Overview of cHTA process (cf. => 2.4.2.1)*

The cHTA process begins with a structured collection of issues at the FOPH, which are assessed by an expert committee of the HTA institute according to the defined criteria for selection (see above) and submitted to the FOPH in a consolidated list of proposals for a decision. On this basis, the FOPH commissions the HTA institute to carry out cHTAs (Assignment).

On completion of the assignment, the HTA institute initiates the evaluation process, starting with an operationalization of the issue with the participation of stakeholders and experts (Scoping) with regard to e.g. comparators, sub-group analyses and the nature, perspective and timetable of analyses (=> Assessment Protocol).

The cHTA process envisages clearly defined co-determination options for stakeholders during the phases of assessment and appraisal (=> cf. Figures 3 and 12).

Rights of appeal (appeals process)

[=> 2.4.3; 2.4.3.1; 2.4.3.2]

The appeals process must be safeguarded against possible misuse by representatives of particular interests. Therefore appeals do not in principle have any suspensive effect on decisions.

Appeals are only permitted after a decision has been made.

Rights of appeal against (positive *and* negative) decisions are (only) granted to those materially or economically affected; this includes manufacturers and their associations, as well as - at federal level - the national associations of insurers, of service providers and of patients. Appeals may be lodged against formal errors and against flawed decision-making frameworks (*assessments*, *appraisals*). They are dealt with before one of the Appraisal Committees and the Appeal Committee, which is independent of the decision makers, and on this basis a decision is quickly reached (within not more than three months).

From a legal point of view, it has to be borne in mind, amongst other things, that it may be necessary for a general contestability to be anchored in law. Consequently, this would always require the issuing of decrees instead of ordinances. It may be enshrined in the health insurance act (KVG) that, based on the result of an HTA process, decisions can be taken further by means of an appeal within 30 days to the appropriate Appeal Committee (independent authority for appeals). Any right of appeal for associations would likewise have to be enshrined in law.

Transparency

[=> 2.5]

Within the meaning of the Swiss law on transparency in administration (BGÖ) of 2004 and internationally recognized standards for "Good HTA Practice" – and taking account also of the criteria for "Accountability for Reasonableness" – the greatest possible transparency is sought in the HTA process. This entails publication of the evaluation criteria and methods, as well as all HTA process-related standards; publication of process-related information; publication of the key documents of assessments and appraisals; preservation of the confidentiality of all personal information with disclosure of potential conflicts of interest of those involved in the HTA process at the same time.

3. Evaluation methods

Assessment of benefits

[=> 3.1.1; 3.1.1.4; 3.1.1.7]

In principle, assessments should always be made with reference to the present *Standard of Care* in Switzerland.

The potential (added) benefit of interventions should be comprehensively evaluated; this includes not only clinical/therapeutic effects and quality of life from the *individual* (patient) *perspective*, but also benefits from the individual perspective of third parties (involved / uninvolved: "public health benefits", for example with vaccinations; the latter should in principle be restrictively interpreted).

Socio-economic benefits (including "indirect" consequences for the economy) are included in the evaluation under the criterion of cost-effectiveness (analyses of cost implications and possibly also analyses of efficiency– see below).

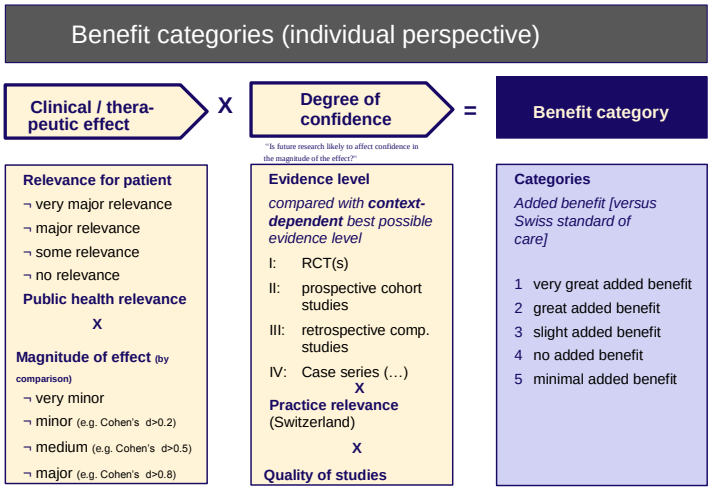

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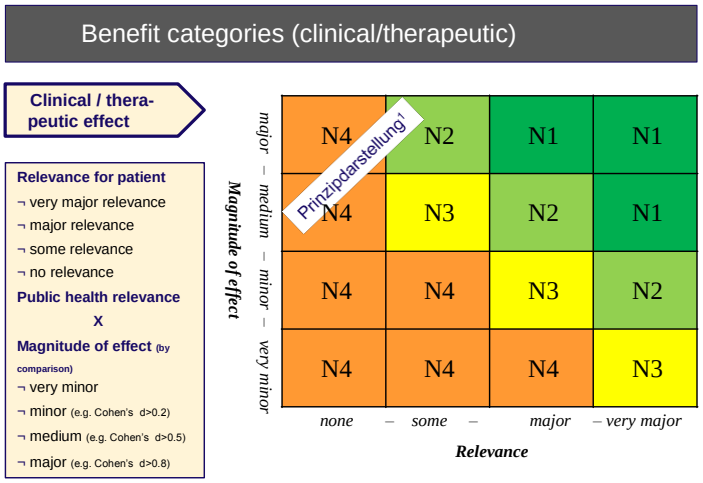
***Figure 4**: Benefit categories from an individual perspective (cf. => 3.1.1.4)*



Reference: => 117

***Figure 5**: Clinical/therapeutic effects: magnitude of effect and relevance (cf. => 3.1.1.6)*

Clinical therapeutic effects (including improvements in quality of life) are assessed in relation to their relevance and their magnitude; in addition, the available level of evidence relative to the best level of evidence that can be expected under the circumstances, the practical relevance with regard to the Swiss health system and the quality of the existing studies are also taken into account. This serves to determine the degree of confidence as to whether (and, if so, to what extent) future research is likely to alter the observed effects.

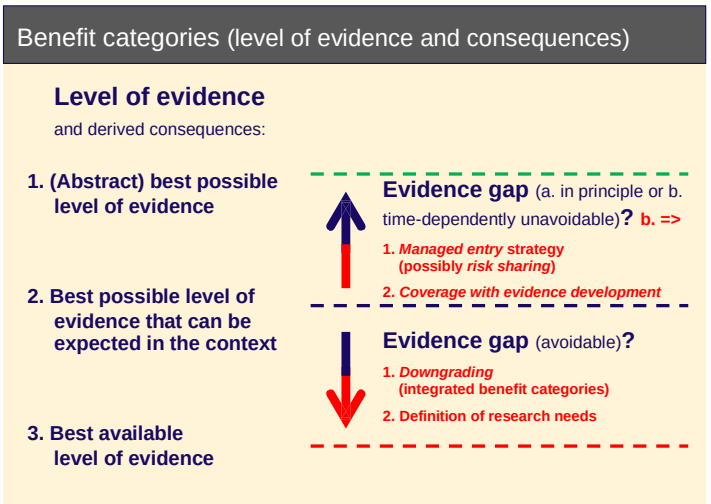


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***Figure 6**: Best possible level of evidence to be expected under the circumstances (cf. => 3.1.1.5b)*

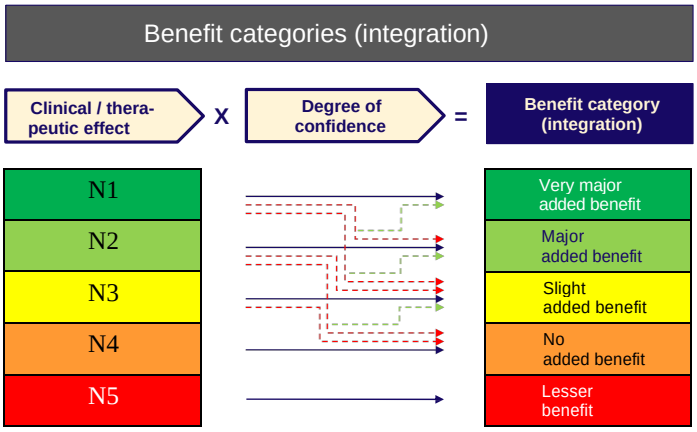
If the outcome of the assessment falls below the (possible) level of evidence to be expected and/or the relevance and/or the quality of the study, this leads to a *downgrading* of the intervention in the comparative benefit rating.

The intervention may be downgraded by up to two notches, one if

a) the documented formal level of evidence is lower than the context-related, best possible level of evidence to be expected; and one if

b) the quality of the data is not sufficiently persuasive, either because of methodological deficiencies in the studies or because of the limitations of the empirical data available.

In exceptional cases, a downgrading may be compensated by up to one notch if very major positive effects of an intervention have been observed, if there is an unequivocal dose-response relationship, and if all conceivable sources of bias have been attenuated by the observed effect.



Reference: => 124

***Figure 7**: Integrative assessment of benefits from an individual perspective (cf. => 3.1.1.8)*

The (added) benefit assessed integratively and categorically from an individual perspective (cf. Figure 7) in this way is a basis not only for assessing the suitability and cost-effectiveness of the intervention, but also – together with the latter – for the subsequent decisions of the FOPH on reimbursement and maximum price.

Assessment of suitability

[=> 3.1.2; 3.1.2.1; 3.1.2.2]

The assessment of suitability adds a *social perspective* to the individual perspective of the cost-effectiveness assessment. It consists of an examination for conformity with the priority objectives of solidarity-based healthcare within the limits covered by compulsory health insurance. Essential elements for this are not only normative premises, but also empirically demonstrable expectations, including the willingness of Swiss insurers to accept *trade-offs* (so-called social preferences); for this there is further need for research (see above, "Operationalization of criteria of efficacy, suitability and cost-effectiveness"), especially with regard to the offered validation of the assumptions made on the basis of national and international studies concerning the objectives of a jointly financed healthcare and thus the criteria for suitability, including their ranking and weighting.

Assessment of cost-effectiveness

[=> 3.2ff.; cf. 3.2.4; 3.2.4.1]

Analyses of the cost implications for the starting point for any assessment of cost-effectiveness in the context of the HTA process. The aim of these analyses is to establish transparency on the short, medium and long-term consequences of a decision for all payers (including the compulsory health insurance and patients) and, where applicable, for costs to the economy. They include (amongst other things) scenarios with different price assumptions.

If critical budget sums are exceeded for the compulsory health insurance (projected within the subsequent five years in the case of new interventions, actual or projected in the case of existing technologies) formal efficiency analyses are necessary.

Theoretical background (excursus):

The scientific concept of (welfare-related) economic efficiency is *not* identical to the everyday understanding of cost-effectiveness. Both assessment constructs, which are theoretically correct from a health economics point of view (on the one hand individual willingness to pay for "health" [according to the neoclassically oriented school of "welfarism"] and on the other the assumption of a universal social willingness to pay for a "produced" quality-adjusted life year [QALY; according to the school of "extra-welfarism"]), can lead to recommendations that contradict the criteria for suitability defined above. This essentially has its origins in a utilitarian concept of ethics that is not primarily based on rights.

Against this background efficiency analyses are – provisionally – confined to analyses of technical and productive efficiency, i.e. there are explicitly no economic comparisons across patient groups initially. In practice, this implies an express rejection of the idea of a universally valid, context-related limit (or a "benchmark") for maximum acceptable costs per QALY as a measure of the efficiency of an intervention.

Such a universal benchmark would also be only theoretically conceivable if the hypothesis were true that the primary objective of jointly financed healthcare was to maximize the number of QALYs "produced" with a given allocation of resources. From today's perspective, it has to be seen as empirically false for this assumption (the "QALY maximization hypothesis") to be squared with the social preferences of the insured person.

According to the principle of a pluralism of methods the economic method of evaluation that should be selected in the HTA process is the one most suitable for a meaningful differentiation of the evaluated intervention(s) in the individual case. This gives rise at the same time to the need for => *Early Consultations* (in the rHTA process) and => *Scoping* (in the *cHTA process*).

Need for setting limits

[=> 3.2.2; 3.3.3]

The need for setting limits is acknowledged. The limits are derived from the operationalized criteria of efficacy, suitability and cost-effectiveness and include the following:

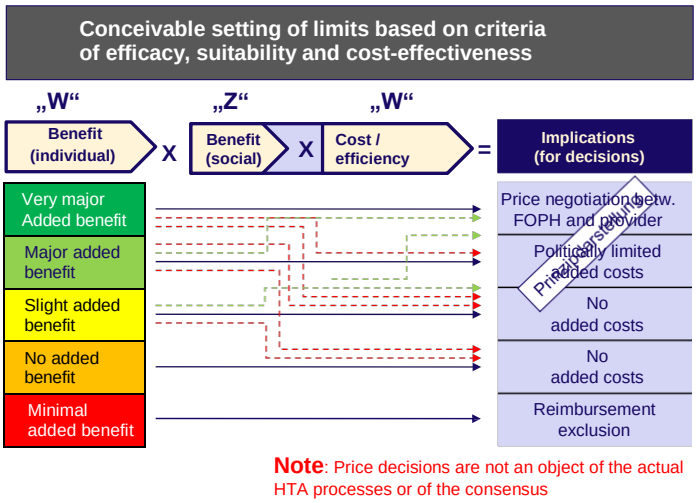
(a) with regard to the criteria of efficacy, the demand for a demonstrable added benefit, the relevance and magnitude of effects, the level and quality of the existing evidence,

(b) with regard to the criteria of suitability, the exclusion of "bagatelles" (based on the triviality of the disorder or the self-financing that can be reasonably expected of the insured person; basis of judgment: analysis of cost implications from insured person's perspective) from the services covered by compulsory health insurance

(c) with regard to the criteria for cost-effectiveness, the possible influence of all cost implications (scale of program) on appropriate decisions regarding reimbursement and prices

and

(d) the exclusion (or adequate cost reduction) of technically and productively inefficient technologies.



Reference: => 146

***Figure 8**: Conceivable setting of limits based on criteria of efficacy, suitability and cost-effectiveness (cf. => 3.3.3)*

Potential for further development of method

[=> 3.2.4.2; 3.3.4; Appendix 1: 3.2.4.2a-e; Appendix 2: 3.3.4.1-4]

Building on the agreed principles, there is potential for a targeted further development of the limit-setting method by the addition of an efficiency criterion, which meets the needs of suitability. In this context, promising options appear to be

(a) [in the sense of an approximation] variable cost/QALY benchmarks as a function of the severity and frequency of a disorder

and

(b) [prospectively] direct methods of measuring relative social willingness to pay.

From today's viewpoint, further research and development are needed for this. Concrete proposals for the next steps will be submitted (cf. => Appendix 2, 3.3.4.1-4 and Annex 2).

Dealing with uncertainty

[3.4]

HTAs do not eliminate uncertainty, but identify and characterize uncertainty and lack of evidence. A distinction is to be drawn here between clinical and economic evidence that is in principle not (yet) available and evidence that has not been generated but can be expected. Dealing with uncertainty includes the use of modeling techniques (without probative value), including scenario and sensitivity analyses, on the one hand, and of managed entry strategies (fixed-term conditioned reimbursement and reevaluation, *coverage with evidence development* and *risk sharing* agreements) on the other.

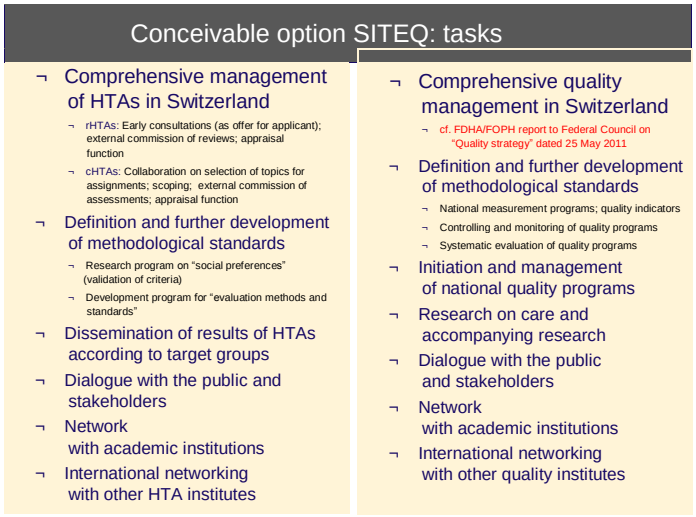
4. Implementation

Institutional integration

[=> 4.1ff.]

The core elements of this consensus are not dependent on the selected form of organizational implementation.

HTA processes could in principle be placed with the FOPH, in a national HTA institute or in a Swiss institute for technology evaluation and quality in the health service (SITEQ).



Reference: => 162

***Figure 9**: Tasks of a possible Swiss institute for technology evaluation and quality in the health service (SITEQ, cf. => 4.1.4.1)*

The latter variant would permit a very useful-looking integration of the HTA initiative and the current quality initiative of the confederation.

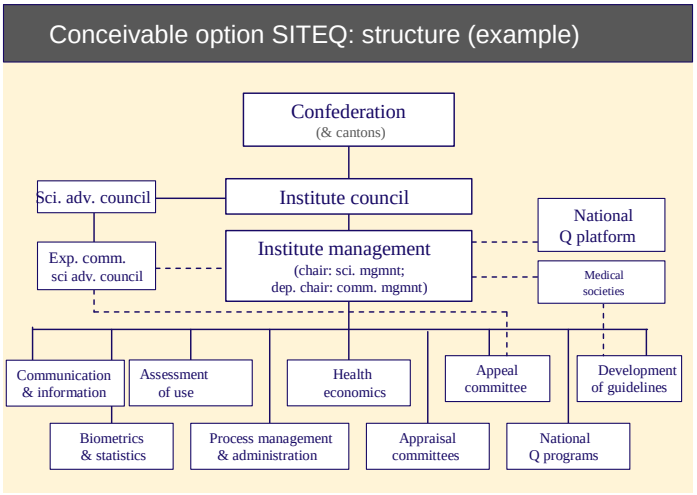


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***Figure 10**: Structure a possible Swiss institute for technology evaluation and quality in the health service (cf. => 4.1.4.2)*

Critical success factors are – regardless of the specific organizational arrangement – the concentration of responsibility for HTAs in one place, associated with central process leadership, and in each case adequate human and material resources, long-term financial security and independence of HTAs from political influence.

Funding

[=> 4.1.4; 4.1.5; 4.1.5.5a,b]

According to provisional estimates, an annual funding requirement in the order of about CHF 15 million is assumed.

rHTAs should be financed by the applicants through cost-covering fees; equally shared funding of the HTA activities of an institute through fees paid by the technology providers, through the public purse (the federal authorities) and through compulsory health insurance (contributions) would amount to a contribution share per insured person per year of about 63 centimes; in addition, there would be an

approximately equal share per Swiss citizen raised through (federal) taxes.

The cost of HTA in Switzerland is offset by potential savings that, even on very conservative assumptions, can be expected to amount to ten times the likely costs in terms of falling expenditure in the compulsory health insurance. The introduction of improved HTA processes in Switzerland can thus be described as efficient under the proposed conditions.

Implementation

[=> 4.3]

The results of HTAs serve as a basis for FOPH decisions on reimbursement and prices, in *managed entry* strategies (*coverage with evidence development*; *risk sharing agreements*) for new technologies, binding agreements for closing evidence gaps, for the development of clinical guidelines (with the participation of the medical societies), and also for monitoring of their implementation (follow-up based on measurable target criteria defined *ex ante*).

Also crucial for the desired impact of HTAs are the binding nature of agreements to close evidence gaps and of guidelines for use, the monitoring of their implementation and effective sanction options and the actual imposition of such sanctions if necessary.

Moreover, the acceptance of HTAs, as mentioned at the beginning, depends on the reputation of the institution(s) charged with carrying them out, on the perceived legitimacy of the processes (cf. the principles of an "a*ccountability for reasonableness*") and thus also on broad stakeholder involvement.

Integration of stakeholders

[=> 4.1.3ff.; 4.2; 4.2.1; 4.2.2; 4.2.3]

Comprehensive opportunities for participation by Swiss stakeholders are proposed both at institutional level (primarily political representation on the institute council and primarily expert representation on the scientific advisory council, and also representation on the appraisal committees of the HTA institute; cf. Figure 10) and also at the process-related level (cf. Figures 11 and 12).

Stakeholder involvement: rHTA

Key stakeholders (applicants = always those directly affected; others economically and/or materially affected):

¬ Early consultation
¬ Comment on dossier assessment report
¬ Comment on appraisal recommendation
¬ Negotiation with the FOPH, if necessary
¬ Right of appeal

Stakeholders:

¬ (if necessary) inclusion for early consultation by HTA institute
¬ (if necessary) inclusion for dossier review by HTA institute; comment on applicant dossier
¬ Comment on dossier assessment report

Reference: => 173

***Figure 11**: Proposed stakeholder involvement in the rHTA process (=> 4.2.2)*

Stakeholder involvement: cHTA

Key stakeholders (economically and/or materially affected):

¬ Consultation by HTA institute during scoping
¬ Assessment: optional submission of evidence ("Value dossiers" that must be considered)
¬ Appraisal: Comment on draft appraisal
¬ Right of appeal
¬ (if necessary) expert input on development of guidelines for use

Stakeholders:

¬ Proposal of topics for HTAs
¬ (if necessary) consultation by HTA institute during scoping
¬ Assessment: (if necessary) submission of statements
¬ Appraisal: Comment on assessment report and draft appraisal

Reference: => 174

***Figure 12**: Proposed stakeholder involvement in the cHTA process (=> 4.2.3)*

Quality assurance

[=> 4.4; 4.4.1-4; Appendix 3]

The HTA processes are subject to quality assurance measures

(a) before their implementation in terms of target validation and target conformity, an alignment of processes with internationally accepted standards for the implementation of HTAs,

and

(b) continuously with regard to compliance with key requirements, implementation of identified potential for improvement and defined measures for further development as well as measurable process and results-related targets (including *key performance indicators*).

Suggested method of citation

M. Schlander, C. Affolter, H. Sandmeier, U. Brügger, C. Cao, T. Cueni, G. de Pouvourville, A. Faller, P. Gyger, A. Hebborn, D. Herren, S. Kaufmann, R. Leu, P. Suter:
Schweizer HTA-Konsensus-Projekt: Eckpunkte für die Weiterentwicklung in der Schweiz.
Basel, Bern, Solothurn und Wiesbaden, 19 October 2011.
Available as download from www.swisshta.org

Annexes

Annex 1:
Glossary

Annex 2:
Further development options (in German only)

Annex 3: *Working paper on "Objectives of project – 'Evaluation of medical interventions in social health insurance: Development of a Swiss consensus'" Zurich, 21 July 2010 (in German only)*

Reference materials

*Slide set **"Propositions (Swiss consensus)"** FV of 19 October 2011(in German only)*
***Overview: Structure of propositions** FV of 19 October 2011(in German only)*