Assessment – APPRAISAL – Decision

(Good) Practice examples and recommendations

Working Paper

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Health Technology Assessment
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Contents

List of figures

List of tables

1 Introduction

Health Technology Assessment/HTA has in many countries become an integral part of health policy decision-making: the collection and synthesis of evidence is a research-based, objective activity with the intention to provide the scientific basis for decisions for efficient and appropriate use of resources [1]. HTA is based on a stringent methodology giving special importance to the traceability of the results and to equi-distance to interest groups in order to avoid undue influence.[1]

assessment = collection and synthesis of evidence = method with focus on traceability/replicability of the results

In some, but not all instances scientific evidence of sufficiently high quality that can directly lead to clear-cut policy decisions is lacking [2]. In addition uncertainty and social values need to be addressed [3]. As a result the need for an additional value based activity, for a "reality check" of evidence arises. Contextualizing the evidence and framing recommendations is carried out in an appraisal of the evidence that was before synthesized during the assessment step [1].

appraisal = contextualizing evidence and formulation of recommendations

The figure below illustrates the knowledge value chain in the health care sector and highlights the domains covered by HTA as well as the multistep process from assessment to appraisal and to health policy decision-making. These steps however are not distinct from each other: There will often be interaction between the steps of assessment, appraisal and decision-making, e.g. the framing of research questions may already be driven by interests.

multistep process: assessment – appraisal – decision-making

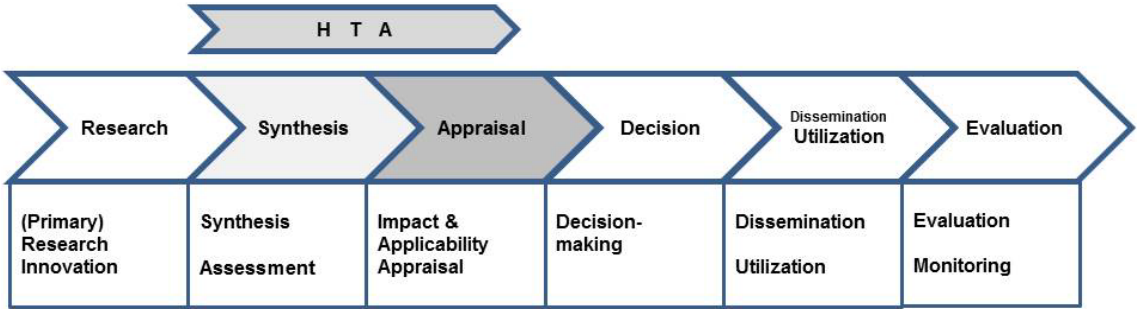

Figure 1: Knowledge value chain in the health sector. Source: developed from Garrido (2008)[4]
Abbreviation: HTA ... Health Technology Assessment

The focus of this report is on the process and the guiding principles of appraising evidence. There is not one „right" way to appraise evidence. An appraisal committee – sometimes also called policy committee – acts like a jury: a jury must above all be seen as credible and respected by those affected by the recommendations. The term jury underlines the subjective nature of formulating recommendations. Experts making up an appraisal committee should therefore demonstrably bring multiple perspectives to the table, they should be fair and unbiased, using a transparent process [1].

focus of this report is on process and guiding principles of appraising evidence

[1] http://hta.lbg.ac.at/page/about-us

appraisal committee ≠ clinical expert group ≠ stakeholder panel

This design distinguishes appraisal committees from mono-discipline and interest-driven expert committees (eminence-based) deciding on their recommendations behind closed doors. It also gives appraisal committees a role that is different from merely consulting stakeholders.

policy makers navigate between competing needs, political imperatives, patient and professional preferences, a societal macro perspective and fiscal constraints

Historically HTA evolved somewhat distant from the complexities of real world health systems' needs. Often policy makers are navigating between competing needs, political imperatives, patient and professional preferences on the micro level, the societal macro-perspective and the reality of fiscal constraints. Policy makers have therefore at times not found HTA alone relevant to their needs [2]. Appraisal committees operate at this complex interface between science and policy, where many mistakes and misunderstandings lie in wait. An appraisal committee discussing the potential impact of health technologies from various perspectives, taking into account various interests and tasked with drawing up contextualized and applicable recommendations is one way to bridge the divide between ivory tower HTA and policy making [5] and for research to better inform public services. An appraisal committee can make the life of policy makers easier. It can first serve to translate policy issues into research questions (which is not the focus of this working paper), and then help 'digest' and "translate" results and present them to policymakers in a concise way. Typically the appraisal committee will draw different scenarios and provide arguments and counter-arguments. Appraisal committees, however, do NOT replace those who are politically accountable. Another important aspect when assessing and appraising evidence is the factor time. Timeliness is almost always paramount in the policy world. Some pragmatic trade-off in favor of timeliness at the expense of depth of analysis is therefore suggested [6].

appraisal committees "digest" and "translate" research results ...

... draw up different scenarios ...

thereby making the life of policy decision takers easier

(good) practice examples of assessing evidence ... from different sectors of health care system ... distilled into 7 recommendations

In the following chapter examples for (good) practice of appraisal committees supporting decisions in different sectors of the health care system (e.g. centralized screening or technology uptake decisions; regional hospitals investment decisions etc.) from the United Kingdom, Canada, the Netherlands, the United States, Australia, Switzerland and Germany are presented. Chapter 3 presents a Canadian (good) practice example from Ontario in more detail. The final chapter 4 distills possible lessons from the international experience into seven recommendations.

method: web search, experts contacted through professional networks, resulting overview not comprehensive

An initial hand search of institutional websites for procedural descriptions of the work of appraisal committees yielded only little officially published material. Experts known to the authors from professional networks were contacted next and asked to provide further information. Hence the resulting here presented selection of 11 appraisal committees is selective, the underlying materials are by no means comprehensive.

2 Appraisal committees internationally

In this chapter information on the following 11 appraisal committees from 7 countries is presented.

11 appraisal committees from 7 countries:

- **United Kingdom (England):** Technology Appraisal Committee: Advisory Committee to the Board of the National Institute for Health and Clinical Excellence (NICE)
- **United Kingdom (England):** National Screening Committee (UK NSC): Advisory Committee to the Ministry of Health and the National Health Service
- **United Kingdom (Scotland):** Scottish Intercollegiate Guidelines Network (SIGN) for National Health Service (NHS) Scotland

UK: NICE+ UK NSC + SIGN

- **Canada (Ontario):** Ontario Health Technology Advisory Committee (OHTAC) for Health Quality Ontario
- **Canada (Quebec):** Policy Committee of McGill University Health Centre – Technology Assessment Unit

CA: OHTAC + McGill

- **The Netherlands:** Appraisal Committee at the National Health Care Institute – *Zorginstituut Nederland* (ZIN) and The Health Council of the Netherlands – *De Gezondheidsraad* (GR) – Advisory Committee to the Ministry of Health

NL: ZIN + GR

- **Unites States of America:** United States Preventive Services Task Force (USPSTF)

USA: USPSTF

- **Australia:** National Health and Medical Research Council (NHMRC) inter alia approves guidelines, responsible to the Ministry of Health

AU: NHMRC

- **Switzerland:** Swiss Federal Services Policy Commission – *Eidgenössische Kommission für allgemeine Leistungen und Grundsatzfragen (ELGK)*, Advisory Committee to Ministry of Interior, incorporating the Federal Office of Public Health – *Eidgenössisches Departement des Innern/ Bundesamt für Gesundheit*

CH: ELGK

- **Germany:** Subcommittee – *themenbezogene Arbeitsgruppe* – appraises evidence for the Federal Joint Committee – *Gemeinsamer Bundesausschuss* (G-BA)

GER: G-BA

Not all of the presented committees officially call themselves "Appraisal Committee". All are, though, juries of evidence, putting systematically synthesized evidence into a political context. In this chapter information on committee remit/terms of reference, on the composition of committee membership, on the appraisal criteria used and on the rules for the process of appraising evidence is presented.

appraisal committees are "juries of evidence": putting the available evidence into context

Remit/terms of refercence

The remit/terms of reference of the presented appraisal committees vary, as does their respective statutory nature and the financial resources at their disposition. Both Germany's G-BA – advised by the relevant subcommittee – and Switzerland's ELGK have a direct say in the determination of social insurance coverage of a service. The Scottish Intercollegiate Guidelines Network SIGN, as the name suggests, draws up national treatment guidelines. The hospital-based HTA produced by the Technology Assessment Unit of McGill University Health Centre in Canada is appraised by their Policy Committee in light of the needs of this individual tertiary hospital. While the appraisal of HTA

depending on statutory nature:

binding or non-binding recommendations

support to local, regional or national decision-making

is only a small part of what Australia's National Health and Medical Research Council NHMRC does, the United States Preventive Services Task Force US-PSTF deals exclusively with evidence appraisal, confined to preventive services.

Composition

individuals nominated as representatives of professional bodies and the narrower and wider public

broad range of size: 9-39 members

public access to information

The size of membership lies between 9 in the Netherland's Health Council and 39 in Scotland's SIGN. Representing a professional body or a wider public constituency forms the basis for nominations of individual members: Professional groups (clinicians and other health care providers), academics (from different disciplines: public health, economics, ethics, social sciences etc.) and administrators (managers, payers), government representatives, lay members (citizens, insurees, patients) and, like in the case of Germany's G-BA, corporatist representatives (physicians, hospitals, sickness funds) or, in UK's NICE, representatives from industry make up these diverse bodies. Sometimes a set of members are only observers and have no voting right (e.g. UK's NSC). Limits on the duration of an appointment are sometimes in place (e.g. Ontario's OHTAC for Chair and Vice-Chair). All committees put a list with the names and affiliations of their members online. (In Germany only the names of the members of the G-BA plenum are published, names and positions of sub-committee members are confidential.)

Appraisal criteria

criteria most often: general in nature, rarely operationalized

Many, though not all, committees lay down transparent appraisal criteria in considerable detail (e.g. Ontario's OHTAC, UK's NSC, Netherland's National Health Care Institute). The Appendix presents two sets of appraisal criteria in detail. Sometimes criteria are general in nature (Germany's G-BA), some committees strive towards operationalization (Switzerland's ELGK). How criteria are weighted against each other is only rarely addressed explicitly, and if, like at US PSTF, only cursory.

Process of appraising evidence

(transparent) policies or procedures to deal with:

public availability of conflict of interest, involvement of public, processing of comments, documentation of consensus and dissent, reasons for deviating from evidence, dissemination of recommendations, possibility of appeal, impact evaluation

All bodies require a declaration of conflicts of interests (CoI). Some bodies make the declaration of interest of each member publicly available (e.g. UK's NICE, Health Council of the Netherlands [7], Switzerland's ELGK). Information on how appraisal committees deal with explicit CoI (e.g. NICE or US-PSTF exclusion from voting for a particular recommendation) is more rarely available. Many committees post their agenda and minutes online (e.g. UK's NICE, UK's NSC, Australia's NHMRC). Some committees have a long tradition of involving the wider public in the deliberative process (e.g. UK's NICE), most have a policy for that and for systematically dealing with comments in place (e.g. Scotland's SIGN). Some committees put a particular emphasis on distributional effects of recommendations (e.g. Australia's NHMRC). Some appraisal processes allow for appeal (e.g. UK's NICE), some don't (Switzerland's ELGK). Procedural arrangements for some appraisal committees include following-up on how the addressee of the recommendations dealt with them, e.g. Health Council of the Netherlands [7]. There, following every report, the minister of health officially briefs parliament on her/his actions taken or not. This is also published online. Some appraisal committees evaluate their own impact: e.g. Ontario's OHTAC focuses on assuring ongoing relevance, on quality and on improving overall performance in its periodic self-evaluations.

The table below offers more detailed information in these four areas.

Table 5.1-1: Examples of appraisal committee practice

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
UK	National Institute for Health and Clinical Excellence NICE www.nice.org.uk	❁ Technology Appraisals Committee operates as a standing Advisory Committee of the Board of NICE ❁ It receives, considers and interprets evidence on the clinical effectiveness and cost effectiveness of health technologies referred to it ❁ It develops guidance for the National Health System NHS in accordance with the published methods and processes of Health Technology Appraisal ❁ It submits its recommendations to NICE's Guidance Executive, which acts under delegated powers of the Board in considering and approving the guidance for publication	Technology Appraisal Committee divided into four branch committees (A-D) ❁ Chair and members appointed for a period of 3 years, extension up to 10 years ❁ Drawn from ❁ National Health Service NHS ❁ Patient and carer organizations ❁ Academia ❁ Pharmaceutical and medical devices industries Committee A currently has 31 members. List of members available online	NICE publishes a detailed guide to the methods of technology appraisal (available at: www.nice.org.uk/article/PMG9/chapter/Foreword) Broad criteria: ❁ The broad balance between the benefits and costs of providing health services or social care ❁ The degree of need of people for health services or social care ❁ The desirability of promoting innovation in providing health services or social care Narrower criteria: ❁ clinical effectiveness and health-related factors ❁ appropriateness and relevance of comparator technologies ❁ cost effectiveness ❁ non-health factors ❁ impact on broader social considerations ❁ costs/savings/benefits outside the health sector	❁ Monthly meetings ❁ Attendance of at least 50% of meetings mandated ❁ Open to public and press ❁ Agenda published online at least 20 working days prior ❁ Decisions normally by consensus of members present ❁ Anonymous voting ❁ Simple majority ❁ Principle of collective responsibility: no speaking out against recommendations in public ❁ Petitions to be made formally to secretariat, not directly to Committee or to individual members Structure of the meeting: ❁ Part 1 (public session) ❁ Members of the Committee and individuals having direct input into the discussions (including clinical specialists, commissioning experts, patient experts and NICE staff) declare their interests, which are recorded in the minutes ❁ Part 2 (closed session) ❁ During the closed session, the Committee considers 'commercial in confidence' information and agrees on the recommendations. Members of the public and press are asked to leave the meeting before this discussion takes place ❁ Unconfirmed minutes online within 15 working days ❁ Confirmed minutes online within 6 weeks Consultee organizations (right of appeal against final recommendations) ❁ National groups representing patients and carers

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
					✿ Bodies representing health professionals ✿ Manufacturer(s) or sponsor(s) of the technology in development ✿ Department of Health ✿ Primary care trusts and local health boards Commentator organizations (no right of appeal against final recommendations) ✿ Manufacturers of comparator technologies ✿ Research groups working in the area
UK	UK National Screening Committee UK NSC www.screening.nhs.uk	✿ It advises ministers and the National Health System NHS about: ✿ The case for implementing new population screening programs not presently provided by the NHS ✿ Screening technologies of proven effectiveness but which require controlled and well-managed introduction ✿ The case for continuing, modifying or withdrawing existing population screening programs. In particular, programs inadequately evaluated or of doubtful effectiveness, quality, or value ✿ Generic issues relating to screening programs and policy ✿ It calls on sound evidence to inform its advice and recommendations ✿ It agrees standards for the new programs, which can be used as a basis for discussion by the standard setting bodies ✿ It advises on their implementation in the NHS	Advisory Committee Currently 19 Members ✿ Deputy Chief Medical Officer, England (Chair) ✿ 2 General practitioners ✿ 3 Hospital physicians ✿ Obstetrician ✿ Community Child Health ✿ Genetics ✿ 1 Consumer Representative ✿ 2 User Representatives ✿ 2 Academia ✿ School of Law, King's College London ✿ Health Economics Research Group, Brunel University ✿ 1 Department of Health, Social Services and Public Safety Northern Ireland ✿ 1 Scottish Government ✿ 1 Welsh Government ✿ 1 Joint Director of Public Health, National Health Service Borders ✿ 1 Public Health Agency Northern Ireland ✿ 1 Screening Division, Public Health Wales ✿ 1 UK National Screening Committee ✿ 1 UK NSC Screening Programs Director	22 program appraisal criteria [8], see Appendix	✿ 3 meetings per year ✿ Draft minutes and summary of key decisions published 4 weeks later ✿ Recommendations first to ministers before sharing them more widely 3 month consultation period for evidence report ✿ Pre-defined criteria for who qualifies as stakeholder: comments by others „considered more circumspectly" ✿ Incorporation of stakeholder views ✿ If particularly controversial: stakeholder workshop ✿ Public availability for comment on website UK NSC's role, terms of reference and membership are reviewed every three years

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
			Observers • National Cancer Screening Service, Republic of Ireland • National Coordinating Centre for HTA • Medical Research Council List of members available online		

UK	Scottish Intercollegiate Guidelines Network SIGN
	www.sign.ac.uk
		SIGN develops evidence based clinical practice guidelines for the National Health Service (NHS) in Scotland [9].
		[To improve the quality of health care for patients in Scotland
		• by reducing variation in practice and outcome]
		• through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence
		SIGN makes a "considered judgment"
			Membership, currently 39, comprised of all the medical specialties
			• Nursing
			• Pharmacy
			• Dentistry
			• Professions allied to medicine
			• Patients
			• Health service managers
			• Social services
			• Researchers
			List of members available online
				• Quality of evidence for guidelines:
				  • Volume of evidence
				  • Applicability
				  • Generalisability
				  • Consistency
				  • Clinical impact
				  • Resource implications
				  • Other factors (open category)
				• Recommendations
				  • Potential harms associated with implementation of a recommendation
				  • Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
				  • Implementability, i.e. how practical it would be to implement the recommendation)
					• Difference of opinion recorded and reason for dissent noted
					• Peer review process evaluates clarity of guideline recommendations and usefulness as working tool
					• „National Open Meeting": widely publicized, 150-300 participants – draft guidelines available online prior for 1 month
					• Comments documented: each point addressed, resulting changes noted, if no change made, reasons recorded
					• Pilot testing of guidelines as part of local implementation process instead of in one isolated pilot site, as feasibility of implementation in one environment may not be applicable to another

CAN
Ontario
	Ontario Health Technology Advisory Committee OHTAC
	www.hqontario.ca
		• To review, investigate, and advise on the uptake, diffusion, and distribution of new health technologies and the replacement and/or removal of obsolete or old health technologies [10]
		• It makes recommendations to the Health Quality Ontario Board on the best evidence about the best health care services and medical devices
			Board of Health Quality Ontario HQO appoints members for renewable 2-year terms
			Chair and Vice-Chair serve for a maximum of 5 years
			12 members minimum, 30 maximum (currently 28)
			• Representatives from hospital, community and long-term care sectors
			• Nursing and medical professions
			• Ontario Hospital Association
			• Ontario Medical Association
			• Council of Academic Hospitals of Ontario
			• Local Health Integration Networks
				4 appraisal decision criteria and 9 sub-criteria [11], see Appendix	• 10 meetings a year
					• OHTAC creates and implements mechanisms to involve general public
					• OHTAC invites public engagement in reaching recommendations
					• Decisions by consensus
					• If not possible: simple majority of members present (significant objections noted)
					• OHTAC tracks and reports on the implementation of recommendations
					  • Diffusion of technology in the health care system
					  • Performance of the technology once diffused
					  • Impact on the health care system

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
		✿ Board then takes its advice into account when formulating its recommendations to health care organizations and to other entities regarding standards of care, and to the minister regarding the funding, for health care services and medical devices	✿ Ministry of Health and Long-Term Care ✿ Human factors engineers ✿ Academia (health economics, ethics, and technology assessment) ✿ Industry List of members available online		✿ OHTAC conducts periodic objective evaluations of its work ✿ Assuring ongoing relevance ✿ Quality ✿ Improving overall performance ✿ Results of this evaluation are made public ✿ Members are not to engage in any activity or provide any service to any other persons or organizations where such service creates an actual, potential, or perceived conflict of interest without prior written consent of the Chair
CAN Quebec	Policy Committee of McGill University Health Centre – Technology Assessment Unit www.mcgill.ca/tau/	Advises the hospital in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments and a transparent, fair decision-making process.	Members (currently 11) chosen by their peers ✿ Nurses ✿ Allied health-care workers ✿ Patients ✿ Administrators ✿ Doctors List of members available online	n/a	Local involvement: committee is supplemented for each report by representatives of discipline most affected ✿ They provide subject expertise ✿ They greatly influence acceptance Transparency: Policy recommendations distributed together with the data and the reasoning behind them Communication: reports and policy recommendations ✿ Submitted to the hospital authorities ✿ Made public to the hospital community ✿ Made available to organizations and hospitals for which the topic might be relevant ✿ Posted on the TAU website Evaluation: regular follow-up of each policy recommendation to document impact on hospital policy
NL	National Health Care Institute – *Zorginstituut Nederland* www.zorginstituutnederland.nl	✿ Advises board of directors on societal implications ✿ Appraisal Committee laid down by national law	Appraisal Committee 9 members ✿ 3 members from the board of directors ✿ 6 appointed by minister of health with expertise in ✿ HTA ✿ Medical ethics ✿ Medical practice and decision making	✿ Necessity ✿ Efficacy ✿ Cost-effectiveness ✿ Feasibility	✿ Open to public and press ✿ Agenda published online ✿ Stakeholders are given the opportunity to briefly state their case, provided they have requested to do so in advance ✿ Decisions normally by consensus of members present

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
	http://bit.ly/1CVlVfl		◦ Long term care ◦ Patient's perspective List of members and conflict of interest statements available online: http://bit.ly/1tAYP79 (in Dutch)		◦ Operated in tandem with „Assessment Committee" (evidence issues)
USA	United States Preventive Services Task Force – USPSTF www.uspreventiveservicestaskforce.org	◦ Conducts scientific evidence reviews of a broad range of clinical preventive health care services (such as screening, counseling, and preventive medications) [12] ◦ Develops recommendations for primary care clinicians and health systems ◦ Strives to make accurate, up-to-date, and relevant recommendations about preventive services in primary care „Assessing evidence is job of Task Force"	◦ Up to 16 members (currently 16) ◦ Members from fields of preventive medicine, evidence-based medicine and primary care ◦ Internal medicine ◦ Family medicine ◦ Pediatrics ◦ Behavioral health ◦ Obstetrics and gynecology ◦ Nursing Online form to nominate members List of members available online	◦ Health benefits and harms are the outcomes that matter most in weighing the evidence and making recommendations ◦ Economic costs (direct and indirect), both to individuals and to society, warrant consideration in making recommendations but are not the first priority	◦ Feasibility and public expectations may take precedence over narrower scientific evidence in clinical practice and in public policy ◦ Preliminary recommendations posted online for public comment for 4 weeks ◦ Final recommendation statements include "Response to Public Comments" section, summarizing how the Task Force addressed comments received
AUS	National Health and Medical Research Council – NHMRC www.nhmrc.gov.au	◦ Statutory responsibilities to ◦ [raise the standard of individual and public health throughout Australia] ◦ foster the development of consistent health standards [13] ◦ It encourages the development of evidence-based guidelines and its duties include approving guidelines ◦ Brings together within a single national organization the functions of research funding and development of advice ◦ [CEO is directly responsible to the Minister for Health and Minister for Sport]	Members of the Council ◦ Part-time appointees ◦ Appointment up to 3 years ◦ Reappointment possible Composition of Council (currently 23): ◦ Chair ◦ Chief medical officer for the Commonwealth ◦ Chief medical officer for each State and Territory ◦ Person with expertise in the health needs of Aboriginal persons and Torres Strait Islanders ◦ Person with expertise in consumer issues ◦ Person with expertise in business ◦ At least 6, but no more than 11, persons with expertise in one or more of the following: ◦ Health care training ◦ Professional medical standards	n/a	◦ Council meets in full session on several occasions each year ◦ Proceedings of each session made available online Guideline development ◦ Public consultation required ◦ 30 days ◦ Notice published in at least 1 major national daily newspaper ◦ Use of socio-economic evidence focusing on differences mandated ◦ After 5 years: recommendation to NHMRC's CEO if guidelines need to be reviewed ◦ After 10 years: all guidelines either reviewed and evidence updated, or revoked

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
			✿ Medical profession and post graduate medical training ✿ Nursing profession ✿ Public health research and medical research issues ✿ Public health ✿ Ethics relating to research involving humans List of members available online		
CH	Swiss Federal Services Policy Commission – *Eidgenoessische Leistungs- und Grundsatz-kommission* ELGK at the Federal Office of Public Health – *Bundesamt für Gesundheit* BAG www.bag.admin.ch	Recommends for or against coverage by social health insurance	✿ Currently 18 members ✿ Nominated by government (*Bundesrat*) List of interests/institutional ties (Interessensbindungen) of each member available online List of members available online	Effectiveness *(Wirksamkeit)* operationalized as [14]: ✿ Are reproducible studies on effectiveness available? ✿ What is their quality? ✿ Are the results relevant outcomes? ✿ Are the results of multiple studies consistent? ✿ Are the results transferable to Switzerland? Appropriateness (*Zweckmäßigkeit*) operationalized as [14]: ✿ Relevant/necessary ✿ Net benefit in relation to comparator(s) ✿ Is there a more cost effective alternative? ✿ Is there risk of inappropriate utilization? Economic *(Wirtschaftlichkeit)* operationalized as [14]: ✿ Economical (cost-effectiveness) ✿ Plausibility of cost and price calculation ✿ Cost impact	Appraisal check-list under development Proceedings and minutes are confidential Process in case of conflict of interests detailed Positive recommendations often include restrictions ✿ Particular patient group ✿ Particular service provider ✿ Provisional limited funding pending evaluation Negative recommendations include justification No appeal possible

Country	Organization/ Source of Information	Remit/ Terms of Reference	Composition	Appraisal Criteria	Process
GER	Federal Joint Committee – *Gemeinsamer Bundes-ausschuss* G-BA www.g-ba.de	✿ [Is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds] ✿ Issues directives for the benefit catalogue of the statutory health insurance funds and thus specifies which services in medical care are reimbursed ✿ Subcommittee (*themenbezogene Arbeitsgruppe*) appraises evidence gathered during external assessment ✿ [Specifies measures for quality assurance in inpatient and outpatient areas]	Appointment for 6 year term 13 (voting) members ✿ 1 impartial chair and 2 impartial members (salaried) ✿ 5 members appointed by National Association of Health Insurance Funds ✿ 2 members appointed by German Hospital Federation ✿ 2 members appointed by National Association of Statutory Health Insurance Physicians ✿ 1 member appointed by National Association of Statutory Health Insurance Dentists These patient and self-help organizations are currently entitled to appoint (non-voting) patient representatives: ✿ German Council of People with Disabilities ✿ Federal Syndicate of Patient Interest Groups ✿ German Syndicate of Self-Help Groups ✿ Federation of German Consumer Organizations List of members available online	✿ Benefit ✿ Necessity ✿ Cost-effectiveness in light of care for insured population that is sufficient (*ausreichend*), appropriate (*zweckmäßig*) and economic (*wirtschaftlich*) These criteria are further detailed in the rules of procedure *(Verfahrensordnung):* www.g-ba.de/informationen/richtlinien/42	✿ Detailed rules of procedures available online [15] ✿ The plenary assembly meets once or twice a month in public session. Sub-committee meetings are not open to the public. ✿ Plenary assembly resolution passed if at least 7 votes in favor ✿ Subcommittee (*themenbezogene Arbeitsgruppe*) appraises evidence gathered during external assessment 1. Subcommittee determines in a first step the patient-relevant benefit of technology as compared to the current standard (independent of intra- or extramural delivery of service) 2. Subcommittee determines in a second step if the technology is to be provided in the intramural sector only or in the extramural sector as well, whether there are sufficient qualified service providers etc. ✿ Hearing required when interests of third parties affected ✿ Results of hearing evaluated by subcommittee ✿ Detailed final report summarizing proceedings and content of consultations accessible online

3 A (good) practice example: Ontario's OHTAC

Health Quality Ontario (HQO) Evidence Review Process: transparent from assessment to appraisal to decision

Ontario is Canada's most populous province with almost 13 Mio. inhabitants. In 2003 Ontario started to develop a single provincial portal for the uptake and diffusion of health technologies based on an approach that is evidentiary, bottom-up, transparent, accountable and open to appeal [2]. The figure below illustrates Health Quality Ontario's (HQO) Evidence Review Process.

multi-step process:

step 1: framing the policy questions

step 2: HTA

step 3: recommendations by HTA

step 4: appraisal + recommendations

step 5: processing of appraisal recommendations

step 6: publication of results

step 7: possible need for further evidence generation or piloting

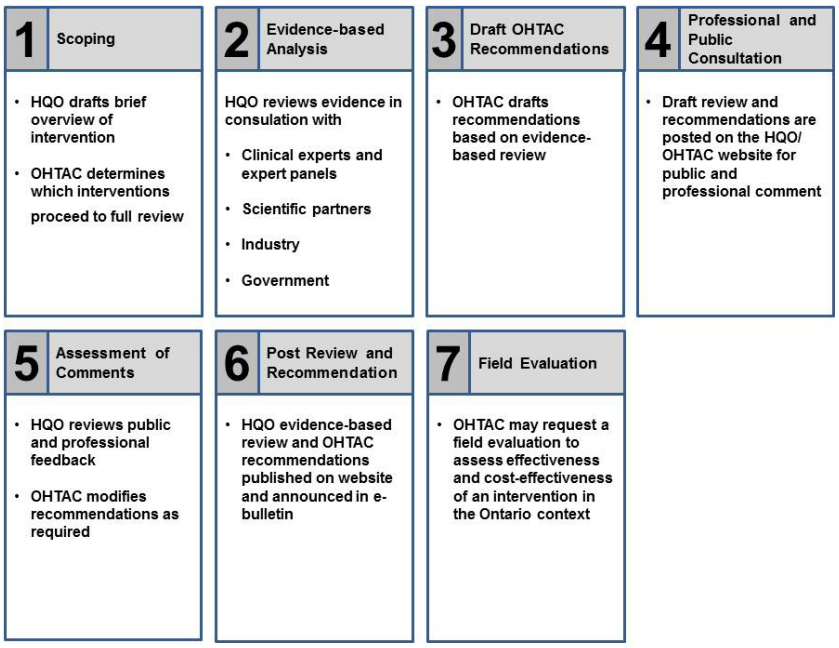

Figure 2: Ontario Evidence Review Process. Source: [16]
Abbreviations: HQO ... Health Quality Ontario, OHTAC ... Ontario Health Technology Advisory Committee

appraisal committee of OHTAC contextualizes evidence based on:

current clinical practice, cost-benefit aspects (= clinical benefit and value for money), organizational feasibility + usability, human resources, acceptance, societal values, ethical implications

Based on the available evidence the Ontario Health Technology Advisory Committee (OHTAC) – a standing advisory committee appointed by HQO's Board – makes recommendations about the uptake, diffusion, distribution or removal of health interventions. Its members include representatives from the hospital, community and long-term care sector, nursing and medical professions, Ontario Hospital Association, Ontario Medical Association, Council of Academic Hospitals of Ontario, Local Health Integration Networks, Ministry of Health and Long-Term Care, academia (health economics, ethics and technology assessment) and industry. A list of OHTAC's current members is available online. OHTAC considers existing clinical practice, economic issues, human resource issues, societal values, regulatory implications and ethical issues in its recommendations. OHTAC's Decision Determinants Subcommittee currently develops a decision determinants framework that considers the clinical benefit offered by a health intervention in addition to value for money, societal and ethical considerations and economic and organizational feasibility. OHTAC facilitates broad stakeholder engagement via its professional and public consultation process, in which its recommendations are open for com-

ment for 21 days. Using OHTAC's recommendations and advice, the Health Quality Ontario Board formulates final recommendations to the health care system and the Minister of Health and Long-Term Care [10].

recommendations include: increasing funding or access to intervention; no funding; disinvestment; limitation to specific patient groups

Common recommendations include increasing funding or access to an intervention, recommending against the use of an intervention in Ontario or recommending access to an intervention for only certain patient groups or clinical indications. When there is insufficient evidence on the safety, effectiveness and/or cost-effectiveness of a health intervention, a field evaluation may be recommended and commissioned. The value of these evaluations strongly depends on the study design. Thereby Ontario funds and evaluates promising health interventions in real-time clinical settings. The program is designed to inform policy and funding decisions prior to making long-term commitments and is the largest of its kind in the world. It represents a conditional funding model for promising technologies. Field evaluation partners are research institutes focused on multi-centered clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies [3, 10].

field evaluation and piloting under conditional coverage

transition from traditional static HTA reports to dynamic responses to policy questions

Ontario's evidence review process has changed the way policy makers view and use health technology analyses. Instead of the traditional static report that does not address the needs of decision makers the Ontario process is more relevant, responsive and dynamic [3].

4 Recommendations for appraisal committees

HTA as part of evidence-informed decision making: process requires transparency and inclusiveness

appraisal committees are essential mosaic stone in evidence-informed decision making

HTA has the potential to form an integral part of a comprehensive continuum for evidence-informed decision making. This process requires transparency and inclusiveness [2]. Recommendations stemming from an appraisal process that are well supported by good evidence and clear reasoning can carry considerable weight. Making them public makes it even harder for decision makers not to consider them [1]. In case a recommendation departs from available evidence, clear arguments for this deviation have to be put forth. This is a departure from traditional ways in which policy decisions are made by administrators behind closed doors [1]. Realistically, what is necessary to achieve the translation from evidence to policy deployment, is a mosaic of programs [2]. Appraisal committees informed by good practice are one such mosaic stone. This final chapter suggests seven recommendations to consider when establishing an appraisal committee. These recommendations are drawn from the international experience presented in the chapters above.

clearly stated remit: decision support ...

... on investment and disinvestment

1. The remit of the appraisal committee should be clearly stated. It should not only address new technologies but also encompass the evaluation of existing ones in view of disinvestment decisions (e.g. Switzerland's ELGK). The appraisal committee's terms of reference should also include scoping of issues, follow-up evaluation of a technology (e.g. Canada's OHTAC monitors the diffusion of the technology in the health care system, its performance once diffused and its impact on the health care system) and the periodic update of recommendations (e.g. Australia's NHMRC).

documented procedural rules incl. appraisal criteria available to the public

2. The procedural rules governing the appraisal committee's work should be documented and available to the general public (e.g. UK's NICE, Germany's G-BA). These should include the set of criteria used for the appraisal, ideally operationalized (e.g. UK's NSC). Information on whether and how criteria are weighed against each other is desirable but not yet found in practice.

diverse set of backgrounds for membership to accurately represent the public

conflict of interest policy

rules for re-appointments and maximum terms

3. Committee membership should encompass as diverse a set of backgrounds as possible to accurately represent the public in the interest of which a decision is recommended. The list of professions and areas of public life to be represented by committee members and the list of the actual nominated members should be available to the public (as is standard at all presented regional or national committees) alongside regulations on conflict of interest (e.g. UK's NICE, Switzerland's ELGK) and individual member's declarations. To offer the public the chance to suggest new members (e.g. United States PSTF) adds to the openness of the process. Rules for possible re-appointment (e.g. Australia's NHMRC) and a limit for the total period of appointment (e.g. Germany's G-BA or Canada's OHTAC for Chair and Vice-Chair) are recommended.

documentation of arguments for/against recommendations, of dissent and of reasons for deviation from evidence

4. Meeting agendas should be publicly advertised well in advance. The committee deliberations should allow, where possible, for at least partial openness to the public (e.g. UK's NICE). When reaching recommendations, difference of opinion between committee members should be documented and reasons for dissent noted (e.g. Scotland's SIGN). Minutes should be published online alongside the recommendations (e.g. Canada's OHTAC).

5. Public (e.g. UK's NICE) or stakeholder consultations (e.g. Germany's G-BA, the Netherland's National Health Care Institute) should be an integral part of the process, preferably both in the prior HTA evidence assessment and in the committee's appraisal. Stakeholder consultations should be considered as additional input used by the appraisal committee when formulating its recommendation, but does not replace the function of the appraisal committee itself. The formats of public outreach should be variable and appropriate for the respective relevant target group (e.g. UK's NSC or Scotland's SIGN). Comments should be documented, each point addressed, resulting changes noted and if no change ensues, reasons should be recorded (e.g. Scotland's SIGN). It should be clearly defined who qualifies as stakeholder in a specific technology deliberation (e.g. UK's NSC).

clear definition who qualifies as stakeholder

public involvement: public outreach appropriate for relevant target group, documentation of comments

6. Earmarked funding should make additional evidence collection through pilot testing, trials etc. possible, if needed (e.g. Canada's OHTAC, the Netherland's National Health Care Institute's coverage within the Evicence Development Program).

earmarked funding for additional evidence generation if needed

7. A process to appeal a recommendation may be made available (e.g. UK's NICE). The addressee of the recommendations, e.g. the federal health minister, should officially have to react to them to increase accountability (e.g. in the Netherland when the Health Council is consulted). Tracking and reporting on implementation of recommendations should be an integral part of the appraisal process (e.g. Canada's OHTAC). Finally a periodic evaluation of the impact of the appraisal committee's work (e.g. Canada's OHTAC) should be envisioned.

process of appeal may be considered, tracking and reporting on implementation of recommendations, evaluation of impact of the appraisal committee's work

5 Appendix: Examples of detailed appraisal criteria

In the previous chapter recommendation 2 for good-practice in appraisal committees prescribes the formulation of a set of criteria used for the appraisal. To illustrate this, a detailed example from the UK and one from Canada are presented in this appendix.

5.1 UK National Screening Committee

The UK National Screening Committee employs 22 criteria for appraising the viability, effectiveness and appropriateness of a screening program [8]. Ideally all the following criteria should be met before screening for a condition is initiated.

	No.	Criteria
The Condition	1.	The condition should be an important health problem
	2.	The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage.
	3.	All the cost-effective primary prevention interventions should have been implemented as far as practicable.
	4.	If the carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including the psychological implications.
The Test	5.	There should be a simple, safe, precise and validated screening test.
	6.	The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.
	7.	The test should be acceptable to the population.
	8.	There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.
	9.	If the test is for mutations the criteria used to select the subset of mutations to be covered by screening, if all possible mutations are not being tested, should be clearly set out.
The Treatment	10.	There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.
	11.	There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.
	12.	Clinical management of the condition and patient outcomes should be optimized in all health care providers prior to participation in a screening programme.
The Screening Programme	13.	There should be evidence from high quality Randomized Controlled Trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an "informed choice" (e.g. Down's syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.
	14.	There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/intervention) is clinically, socially and ethically acceptable to health professionals and the public.
	15.	The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

	No.	Criteria
The Screening Programme *(continued)*	16.	The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (i.e. value for money). Assessment against this criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource.
	17.	All other options for managing the condition should have been considered (e.g. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.
	18.	There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.
	19.	Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.
	20.	Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.
	21.	Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.
	22.	If screening is for a mutation the programme should be acceptable to people identified as carriers and to other family members.

5.2 Ontario Health Technology Advisory Committee

Ontario Health Technology Advisory Committee recommendations are guided by a decision determinants framework [11], that considers the clinical benefit offered by a health intervention, in addition to value for money, societal and ethical considerations; and economic and organizational feasibility. It encompasses the 4 decision criteria and 9 sub-criteria below. The framework is currently being reviewed and updated by the Decision Determinants Subcommittee.

No.	Decision Criteria	No.	Sub-Criteria
1.	Overall clinical benefit	1.	Effectiveness
		2.	Safety
		3.	Burden of illness
		4.	Need
2.	Consistency with expected societal and ethical values	5.	Expected Societal values
		6.	Expected Ethical values
3.	Value for Money	7.	Economic evaluation
4.	Feasibility of adoption into health system	8.	Economic feasibility
		9.	Organizational feasibility

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