HEALTH INTERVENTION AND TECHNOLOGY ASSESSMENT PROGRAM (HITAP)

Health Technology Assessment Process Guidelines

March 2012

About this document:

This document describes the health technology assessment (HTA) process guidelines for use at the Health Intervention and Technology Assessment Program (HITAP). The document is also expected to guide other organizations conducting HTA research for the National List of Essential Medicines in Thailand.

HITAP welcomes feedback from stakeholders on the guidelines.

For additional information, please visit www.hitap.net/en

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Contents

1. The organization

Health technology assessment (HTA) is internationally acknowledged as a pivotal tool in resource allocation for all health administrators and practitioners to solve a country's health problems. However, at present Thailand is lacking the favourable factors to substantially and effectively utilize the results of HTA. There are many reasons for this:

• Lack of mechanisms to manage the knowledge base for policymaking and implementation.

• Very few HTA researchers, often driven by self-interest or the need of the funding institutions. Consequently, research results cannot satisfy the country's needs.

• Lack of networks between researchers from different groups; as a result, national-level research cannot be jointly conducted.

• Lack of knowledge and understanding of HTA so that concerned parties are unfamiliar with or cannot properly use HTA results.

As a consequence of the abovementioned situation, the Health Intervention and Technology Assessment Program (HITAP) was established in 2007 as a semiautonomous non-profit organization. Its main responsibility is to assess health technologies, including pharmaceuticals, medical devices, procedures, health promotion and disease prevention, as well as social health policy.

HITAP receives its main funding support from four public institutions; namely, the Thai Health Promotion Foundation, the Health Systems Research Institute, the National Health Security Office and the Bureau of Policy and Strategy, Ministry of Public Health. HITAP also receives specific funding from other non-profit organizations, such as the World Bank and the World Health Organization.

However, in order to assure neutrality and avoid conflict of interest, HITAP does not directly or indirectly receive any grant or support from profit-making organizations or institutes funded by profit-making organizations.

Vision:

Appropriate health interventions and technologies for Thai society.

Mission:

• To assess health technologies efficiently and transparently by using internationally accepted research methodologies;

• To develop systems and mechanisms to promote the optimal selection, procurement and management of health technology as well as health policy determination; and

• To distribute research findings and educate the public in order to make the best use of HTA results.

2. The development of the guidelines

Although HITAP strictly follows national HTA methodological guidelines, questions over the good governance of research arose from a lack of formal process guidelines. Therefore, HITAP embarked on the development of HTA process guidelines in 2011.

International guidelines were reviewed in order to develop a conceptual framework with the aim of connecting the principles of good governance with particular steps of HTA processes through specific mechanisms (see Figure). Several staff and external stakeholder meetings were convened to validate and refine both the principles and mechanisms encompassed in the framework.

Both the framework and stakeholder involvement proved useful in developing fit-for-purpose guidelines.

The major HTA processes were streamlined into (a) topic priority setting, (b) assessment and preliminary appraisal of health technologies, (c) dissemination of results and recommendations, and (d) monitoring and evaluation of the organization.

Meanwhile, the relevant process principles were considered to be (a) transparency, (b) accountability, (c) inclusiveness, (d) timeliness, (e) quality, (f) consistency, and (g) contestability.

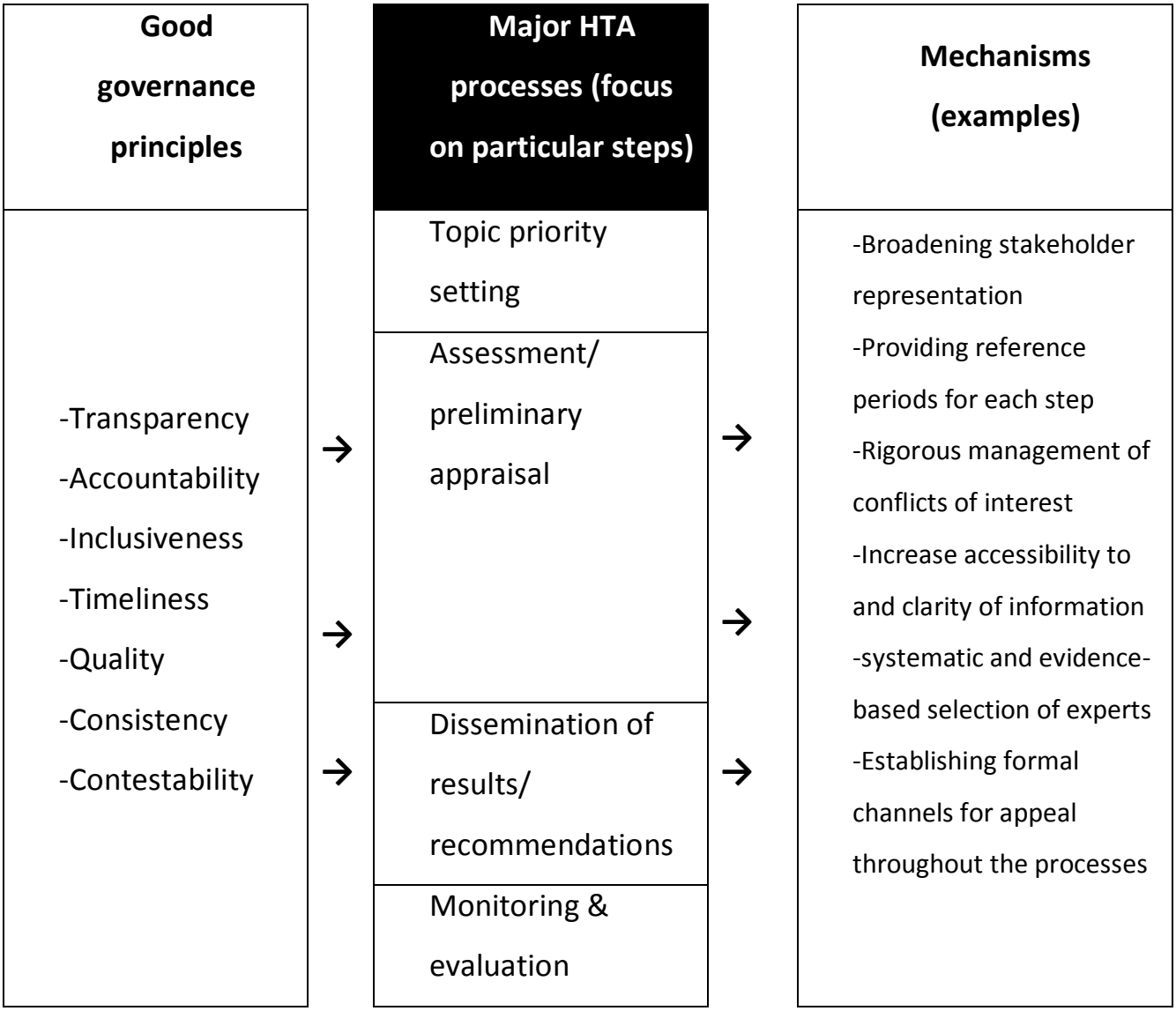
The mechanisms on which stakeholders placed special emphasis were (a) broadening stakeholder representation, (b) providing reference periods, (c) the rigorous management of conflicts of interest, (d) increasing accessibility to and clarity of information, (e) systematic and evidence-based selection of experts, and (f) establishing formal channels for appeal throughout the processes.

Finally, the wide dissemination of the guidelines is planned through both printed and electronic media and targeting a broad range of stakeholders (e.g., policymakers, healthcare insurers and professionals).

Process guidelines for conducting research, including HTA, have become increasingly important, especially in countries where evidence-informed policy is supported. Whilst meeting international governance standards, these guidelines strive to be context-specific by including stakeholders' views and expectations. However, decision-making and implementation processes are not covered because these are issues over which HITAP has no authority. To achieve a significant impact, the need for mechanisms to motivate user adherence to the guidelines is recognized. Furthermore, performance indicators are necessary to audit the processes annually.

To conclude, these guidelines are expected to provide both internal and external benefits ranging from a better understanding of and trust in the organization to efficiency improvements and greater consistency. They may also be helpful for researchers and policymakers from other organizations in Thailand and in other settings interested in establishing HTA systems.

Figure: Conceptual framework covering principles applied to HTA processes and mechanisms to meet the principles



3. The principles of good HTA governance

Good HTA governance:
Processes need to exist for a successful project, program or body. HTA institutions in Europe and North America generally set the standards for comparison.

HTA process:
"Operation or work process internal to an organization, intended to produce specific outputs (e.g., products or services). Processes are the primary link in the chain through which outcomes are achieved". There are two types of processes: generic management processes and processes specific to HTA, which are the focus of these guidelines.[1]

Note: principles that need to be carried out continuously for more than one month are considered processes for the purpose of these guidelines. Some principles are considered to have both an inherent and an instrumental value. In other words, they can be thought of as a condition for meeting another principle (e.g., transparency is necessary for accountability, but not sufficient).

Principle 1: Transparency

"Environment in which objectives of policy, its legal, institutional, and economic framework, policy decisions and their rationale, data and information related to monetary and financial policies, and the terms of agencies' accountability are provided to the public in a comprehensible, accessible, and timely manner".[2]

Principle 2: Inclusiveness

"Inclusion of a wide range of relevant stakeholders….Decisions are fundamentally value judgments – and value judgments will inevitably vary between individuals and groups within society. As such,…the decision-making process is more likely to be legitimate if it enables different interests to contribute via participation….In particular, those who come out of a decision less well than others may feel better able to accept it if they have at least had their voices heard. Greater legitimacy in this respect may also promote trust in decision-makers".[3]

Principle 3: Accountability

"Managers are held responsible for carrying out a defined set of duties and for conforming with rules and standards applicable to their posts…[because they have been delegated] greater flexibility and autonomy…as a means of improving efficiency and effectiveness of their operations….Greater power to make decisions [brings about] much greater emphasis on accountability as a means of balancing and checking exercise of power.

[1] Wanke M, Juzwishin D, Thornley R, Chan L (2006) An exploratory review of evaluations of health technology assessment agencies. Edmonton, CA: Alberta Heritage Foundation for Medical Research.

[2] Organization for Economic Cooperation and Development (2007) OECD glossary of statistical terms. Paris, FR: Organization for Economic Cooperation and Development.

[3] Clark S, Weale A (2011) Social values in health priority setting. London, UK: University College London.

- Internal, to a higher level of management, in which managers are assessed on a regular basis on the way in which they have carried out the tasks set out in their job descriptions.
- External, to parliament, the public or central agencies…for their own performance (and in the case of senior officials, for the performance of the organisation which they manage)".[2]

Principle 4: Quality

"The quality characteristics of most importance depend on user perspectives, needs and priorities, which vary across groups of users….Quality is viewed in terms of seven dimensions…: a) relevance, b) accuracy, c) credibility, d) timeliness, e) accessibility, f) interpretability, and g) coherence".[2]

Principle 5: Timeliness

"Speed of dissemination of the data, i.e., the lapse of time between the end of a reference period (or a reference date) and dissemination of the data".[2]

Principle 6: Consistency

"Logical…coherence [across processes, criteria and rationales]".[2]

Principle 7: Contestability

"Ability to call into question and take an active stand against".[4]

[4] http://www.thefreedictionary.com/contest

4. The priority-setting process guidelines

In order to comply with the organization's governance principles, the following steps should be taken for each procedure included in the process of research topic priority setting:

4.1. Preparatory work (stakeholder selection)

Transparency:

A register of proposed and selected stakeholder candidates should be kept as well as the pertinent information (conflict of interest disclosures, minutes, etc.). The register should be made available online.

Inclusiveness:

The composition of the stakeholder groups should be multidisciplinary and balanced. It should include all relevant groups such as government, civil society, health professionals, health managers, healthcare insurers, academics, patients and the private sector.

Accountability:

By written disclosure, stakeholders considered must state all interests and activities potentially resulting in conflicts of interest with priority setting.

Disclosure by stakeholders should reflect all current and planned commercial, non-commercial, intellectual, institutional, and patient/public activities (including those of close family members).

The conflict of interest disclosures should be discussed by the topic selection secretariat. Whenever possible, stakeholders should not have conflicts of interest, and if so, those stakeholders with conflicts of interest should be a minority. The chair or co-chair should not have a conflict of interest.

Stakeholders should follow the organization's code of conduct.

Quality:

Selection of stakeholders should be conducted following agreed-upon criteria.

The process should include key clinical and public health stakeholders, experts, and patient groups with varied and relevant perspectives and experiences.

A systematic and balanced method to identify key stakeholders should be followed (e.g., brainstorming, interviews, electronic search).

Timeliness:

Selection of stakeholders should be well planned in advance so that it allows room for replacement. The process should be carried out in two months.

The register of stakeholders should be posted online at least one month before the topic selection meeting as well as the criteria for selection.

Comments and complaints about the selection of stakeholders should be made two weeks after the register is posted online. Responses should be posted in a reasonable time.

Consistency:

Criteria for selecting stakeholders should be consistent between priority-setting channels and replicable in time, although allowing for improvement.

Contestability:

Comments and complaints about the selection of stakeholders should be made though an online feedback system to allow the public to submit their comments and also to receive the organization's response.

4.2. Topic submission

Transparency:

All identified, relevant stakeholders should receive invitation letters in writing explaining the mission of the organization as well as purposes of the priority setting.

The submission form should include the prioritization criteria to be employed in order to help stakeholders decide.

A formal database of suggested topics, their evolution and outcome should be maintained so that topics can be consulted if they become candidates for reassessment.

Inclusiveness:

Non-applicable.

Accountability:

The importance of the topic should be explained in writing in the submission form as well as the expected benefit of conducting such research.

Quality:

Attempts should be made to ensure a systematic and comprehensive listing of all relevant research options.

Timeliness:

Stakeholders should be given at least one month to prepare and submit topics.

Prioritization criteria should be made available online two months before the topic selection meeting.

Consistency:

Non-applicable.

Contestability:

Non-applicable at this stage, but will be after the preliminary assessment of topics.

4.3. Preliminary assessment of topics

Transparency:

HTA research staff assesses the eligible topics according to agreed-upon criteria.

Inclusiveness:

Non-applicable.

Accountability:

By written disclosure, research staff and experts must declare all interests and activities potentially resulting in conflicts of interest with the topic under review.

Disclosure by research staff and experts should state all current and planned commercial, non-commercial, intellectual, institutional and patient/public activities (including those of their close family members).[5]

Reviewers must not have conflicts of interest and must follow the organization's code of conduct.

Quality:

Rapid literature review and internal discussion should be the methods used for selecting topics.

If research staff need to clarify any aspect of the submitted topics, they should get in contact with the proponent organization.

[5] Institute of Medicine (2011) Clinical practice guidelines we can trust. Washington DC, US: Institute of Medicine.

When possible, the best available experts should be engaged to compile evidence to inform the process. This would ensure that the evidence being used for the priority-setting process is high quality, trustworthy and relevant.

Timeliness:

HTA research staff should conduct all preliminary assessments within one month.

Complaints should be submitted within two weeks of the completion of the preliminary assessments.

Consistency:

Topics should be filtered out under these circumstances:

a) if they have been researched in Thailand or proposed previously in the last five years,
b) if they are under the scope of another organization, and
c) if they are not under the scope of the organization or health research.

Contestability:

Complaints about the administration of the priority-setting process should be made in writing and submitted to the organization. However, agreed-upon criteria are excluded from complaint.

4.4. Topic selection

Transparency:

Presentation of topics including all relevant information should be made by proponents in the topic selection meeting.

The agreed-upon criteria for prioritization should be employed by the priority-setting panels.

An explicit (quantitative) method to determine a candidate topic's priority ranking should be used, complemented by deliberations.

Social value judgments employed as reasons for prioritization should be made explicit if they are not included in the agreed-upon criteria.

A written record of the selection should be kept to ensure transparency and traceability.

Membership (by invitation only) of the consideration panels, minutes and other information relating to decisions made and the priority-setting process policies should be made available online.

Inclusiveness:

Stakeholder deliberation should be encouraged that allows for equal opportunity and constructive discussion.
Special support for disabled persons should be provided.

Accountability:

Non-applicable since stakeholders should have disclosed their conflicts of interest at the selection stage.

Quality:

Criteria for priority setting should be revised and updated, as well as quantitative methods if necessary, while taking practical issues into account.

Timeliness:

Candidate topic briefs should be forwarded to stakeholders at least two weeks in advance for their consideration.

Topic selection should be carried out in a one-day session.

Minutes and other information should be made available online within one month.

Consistency:

The topic selection secretariat should ensure that there is consistency among topics selected and propose mechanisms to minimize inconsistent prioritization.

Contestability:

Stakeholders should be able to appeal decisions based on emerging issues or arguments. Revisions should be made explicit in the pertinent report.

5. The assessment and preliminary appraisal process guidelines

In order to comply with the organization's governance principles, the following steps should be taken for each procedure included in the process of assessment and preliminary appraisal of health technologies:

5.1. Background review

Transparency:

Online announcement of the start of the background review and invitation to experts to submit information electronically should be made.

Results from the background review should be presented to relevant stakeholders in the scoping meeting, including a list of references used and search date.

Background reviews should be made available online.

Inclusiveness:

When appropriate, relevant experts should be engaged (by invitation only).

Relevant documents may be provided by the experts.

Accountability:

The research team should be formed at this stage, including topic proponents and relevant experts identified through systematic and balanced methods (e.g., literature review, brainstorming, etc.).

Conflict of interest disclosure should be sought in this stage.

Quality:

A preliminary literature search for relevant papers on the technology/health problem in question should be conducted using appropriate databases. Sometimes, field visits to settings where the technology is used may also be helpful.

Timeliness:

Information by experts should be submitted within two weeks of announcement of the start of the background review.

The background review should be conducted within six weeks, or in any case, should be concluded at least one week before the start of the scoping meeting.

The briefing should be sent electronically at least one week in advance of the scoping meeting.

Consistency:

Background reviews should follow a standard template and take into account the results from the preliminary assessment for topic selection, and if discrepancies are found, this should be clarified with the previous reviewer(s) and topic proponent(s) and documented.

Contestability:

Non-applicable at this stage since this step is for researchers to explore and understand the issues surrounding the research topic.

5.2. Scoping/definitions of questions

Transparency:

A scoping meeting should be convened among all relevant stakeholders.

Invitation letters in writing explaining the topic to be assessed, the meeting agenda, the meeting chair and the expected role of the stakeholder should be sent.

A register of expert collaborators should be built progressively.

Prior to starting the formulation of the research questions, policy questions should be clarified among stakeholders.

Meeting minutes of the scoping consultation should be distributed among stakeholders and posted in the organization's website.

Inclusiveness:

Key stakeholders should be identified through systematic and balanced methods (e.g., literature review, brainstorming, etc.).

All stakeholders should be encouraged to express their views on the policy questions and invited to define the research questions.

Accountability:

All stakeholders should disclose conflicts of interest.

Creative commons licenses should be negotiated with research funders at an early stage, if necessary, in order to make freely available the contents of research.

Quality:

HTA questions should be tailored to clearly address the information needs of decision-makers or target groups. They should be answerable and manageable in quantity.

Timeliness:

The scoping meeting should be held in half-day sessions.

If new questions arise along the assessment process, priority should be given to the initially agreed-upon questions, and the new questions subsequently supplemented.

Scoping meeting minutes should be distributed among stakeholders within two weeks of the consultation and also posted online.

Consistency:

Research questions should be consistent with the policy questions prioritized (except when all stakeholders agree to change them).

Contestability:

Stakeholders are allowed to propose new research questions in the scoping meeting, given that proposals try to fill a closely related knowledge gap. However, acceptance of the new research questions should depend on the project leader.

5.3. Elaboration of protocol

Transparency:

A detailed protocol of the research should be developed before starting the assessment phase.

The link with decision-making should be clearly stated.

The protocol (available online) should provide these essential elements:
a) introduction; b) objectives; c) methodology; d) dissemination plan; e) project organization; and f) timeline.

Information included in the research protocols should be submitted electronically to any relevant register of the WHO or ICMJE-approved registries (for interventional studies, including clinical trials) (http://www.who.int/ictrp/trial_reg/en/index1.html) or PROSPERO (for systematic reviews) (http://www.crd.york.ac.uk/prospero/).

In addition, for these and other types of research, protocols should be available in the organization's website. The protocol should also be electronically distributed among stakeholders once completed.

Modifications requested for the protocols should be addressed and documented.

Inclusiveness:

The protocol should be prepared in close cooperation with the persons participating in the project, including external experts.

Accountability:

Conflicts of interest of researchers should be disclosed in the protocol.

Researchers and external experts acting as principal investigators should follow the code of conduct.

A detailed explanation of the contributions of each research team member should be agreed upon at the start of the project and included in the protocol.

Lists of funders should be disclosed as well as aiming to obtain the Ministry of Public Health's ethics approval and informed consent of human subjects, if appropriate.

Quality:

The protocol should provide detailed information in each of the essential sections and reviewed both internally and externally (by experts participating in the project or in the project scoping).

Timeliness:

The protocol should be completed and electronically available within two months.

Experts should send comments back within two weeks.

Consistency:

There should be consistency across research protocols, which should follow a standard template/checklist, with the exception of non-research projects for which a concept note will suffice.

Contestability:

Experts should be allowed to suggest modifications to the protocol. For intervention studies and systematic reviews, modifications will not be possible once they have been registered online unless there are reasonable and necessary changes.

5.4. Conduct of research

Transparency:

The research team should update the status of the work on the organization's website.

Inclusiveness:

Relevant experts (e.g., with track records of relevant publications or demonstrated expertise) should be invited to participate in the assessments.

Accountability:

Conflicts of interest of researchers should be disclosed in the preliminary report.

A detailed explanation of the contributions of each research team member should be disclosed.

Lists of funders should be disclosed.

Quality:

The preliminary report should follow the most updated version of the Thai HTA methods guidelines.[6]

For research types that are not covered by the HTA guidelines in detail, e.g., systematic reviews or Health Policy and Systems Research (HPSR), internationally accepted guidelines should be followed, such as the *Cochrane Handbook for systematic reviews of interventions* [7] or those on the *WHO Alliance on HPSR resources* website.[8]

Timeliness:

Time frame for evidence reviews should be dependent on the following:

a) type of review: Meta-analysis > systematic review > rapid review > systematic search and review > systematized review > overview > scoping review
b) topic: pharmaceuticals < diagnostic/screening tests/medical devices < public health interventions (e.g., health promotion) < policy and organizational questions
c) volume of the literature (expected number of citations), need for translations, volume of the grey literature
d) scope: number of questions to be addressed
e) concreteness/abstractness of the question(s)
f) the extent of the search

-Average time for "rapid reviews/literature scans" (systematic with limits≤10 most relevant papers selected for appraisal): 1-1.5 months

-Average time for "update of systematic reviews" (systematic limited to additional studies only): 3 months

-Average times for "systematic reviews": ~ 6 – 7 months (with meta-analysis), full-time (range: 1.5 – 15.5 months)

Number of researchers: minimum 2 per each key question addressed

Time frame for economic evaluations:

A full report typically may include an evidence review, an economic model and a budget impact analysis. If the evidence review is systematic, the time frame will be longer than if the review is non-systematic.

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[6] Tangcharoensathien V, Wibulpolprasert S, Kamolratanakul P (editors) (2008) Health Technology Assessment Guideline J Med Assoc Thai 91 (Suppl 2), 1-88.

[7] Higgins JPT, Green S (editors) (2009) Cochrane handbook for systematic reviews of interventions. Version 5.0.2 [updated September 2009]. The Cochrane Collaboration. www.cochrane-handbook.org

[8] WHO Alliance on Health Policy and Systems Research (2011) HPSR Resources. http://www.who.int/alliance-hpsr/resources/training/alliancehpsr_trainingresourcesFeb2011.pdf

Depending on complexity (i.e., number of citations included in the review, static versus dynamic model): 9-12 months

Number of researchers: minimum 2

An economic evaluation alongside clinical trial will be typically longer and depend on the clinical trial duration.

Time frame for guidelines:

Clinical practice guidelines: 18-24 months

Public health guidance: 26–64 weeks

Number of researchers: 2 per each key question addressed

Time frame for quantitative primary studies:

This should depend on the type of study, the type of patient studied (e.g., for a rare disease, they may be difficult to recruit) and the intervention that is going to be evaluated (e.g., non-pharmaceutical interventions may need longer follow-up times to detect an outcome). The timeline should reflect the number of subjects to be recruited and the data collection method. In economic evaluations alongside clinical trials, the study may need to be longer when evaluating high-cost technologies.

Time frame for qualitative primary studies:

Variable and dependent on methods used and whether retrospective or prospective.

Consistency:

There should be consistency across preliminary reports, which should follow a standard template, with the exception of non-research projects.

Contestability:

Non-applicable at this stage, but will be in the next step.

5.5. Validation of results/formulation of recommendations/preparation of final report

Transparency:

Preliminary results should be presented to relevant stakeholders.

Reports should be forwarded electronically to stakeholders in advance.

Meeting minutes of the validation meeting, including a description and explanation of any differences of opinion regarding the recommendations made, should be published.

Inclusiveness:

At least all relevant stakeholders who attended the scoping meeting should be invited.

Additional stakeholders who may have been identified during the assessment and who may provide valuable recommendations in light of the results may be invited.

Strategies such as training in evidence appraisal to enhance the successful participation of stakeholders, especially of patient and citizen representatives, should be adopted.

Accountability:

New stakeholders (who did not attend the scoping meeting) should disclose conflicts of interest.

Conflicts of interest of researchers should be disclosed in the final report.

A detailed explanation of the contributions of each research team member should be disclosed.

Lists of funders should be stated.

Since the organization is accountable to the whole society, in-house publications should be freely available at no charge (with the exception of the Thai version of the HTA methodological guidelines book).

Quality:

HTA reports should be balanced, transparent, logical, precise and detailed.

The report should be clearly dated, and an update can be proposed with enough evidence support through topic priority setting after five years.

Methodological limitations should be stated and their significance for the soundness of the results discussed.

Prior to an HTA report from an internal or external project team being disseminated, at least one independent and anonymous expert should assess the manuscript and give suggestions for improvement. For in-house reports, external peer review should be conducted.
For mixed internally/externally-produced reports, the organization's staff should not be involved. For external reports, the organization's staff should be able to peer review.
A database of potential peer reviewers should be constructed from literature review or previous collaboration with experts.[9]

A checklist should be used in the peer review of HTA reports.

[9] European network for Health Technology Assessment (EUnetHTA) (2008) Handbook on HTA capacity building. Barcelona, ES: Catalan Agency for Health Technology Assessment and Research.

Authorship of peer reviewers should be kept confidential unless they waive that protection.

Timeliness:

The validation meeting should be convened within one month of the completion of the study.

Peer review of the final reports should be completed within one month.

Validation meeting minutes should be available online within one month.

Final reports including the recommendations elaborated by the validation panel should be available online three months after the validation meeting and distributed electronically among stakeholders.

Consistency:

Recommendations and conclusions should be based on results and not over-interpreted. Each recommendation should be accompanied by its underlying reasons: potential benefits and harms, evidence base and the role of values, opinions, theory, and experience in eliciting the recommendation.[10]

Contestability:

Stakeholders are allowed to suggest modifications to the final recommendations within one week of its distribution among stakeholders.

6. The dissemination process guidelines

In order to comply with the organization's governance principles, the following steps should be taken for each procedure included in the process of dissemination of research results and recommendations:

6.1. Preparation of policy briefs/presentation to decision-makers

Transparency:

Policy briefs should be prepared for each policy-oriented project.

The policy brief should follow a standardized template, be clearly dated and should be available online.

Formal presentation to the target decision-makers should be made. The presentation should briefly include all important features of the study, including limitations and uncertainties, and the recommendations formulated in the validation meeting.

[10] Institute of Medicine (2011) Clinical practice guidelines we can trust. Washington DC, US: Institute of Medicine.

Inclusiveness:

All relevant decision-makers should be targeted.

Policy briefs and presentations should be adapted to the particular decision-makers.

Accountability:

A brief section at the end of the policy brief or presentation should list the funders of research.

Quality:

The policy brief should follow a standardized template and be succinct, only include directly relevant results and recommendations to the target group, and highlight the importance of the issues in question.

Presentations should follow a similar structure to the policy brief, as appropriate.

Timeliness:

Policy briefs should be prepared alongside the final report and distributed as soon as the final report is completed.

On some occasions, preliminary policy briefs may need to be completed and distributed to inform policy beforehand.

Presentations should be prepared at least one week before the policy forum or presentation meeting.

Consistency:

Policy briefs, presentations and final reports should be consistent in content but flexible with regard to results and recommendations, which may need to be targeted to specific decision-makers.

Contestability:

Non-applicable at this stage since this step refers to the communication between researchers and decision-makers.

6.2. Dissemination to the public (health professionals, research community, patients)

Transparency:

Dissemination of products should be adapted to each target audience, for instance, following the NHS *Toolkit for producing patient information*.[11]

The product should be dated.

At the beginning of the research protocol elaboration, the target audience should be clearly identified, e.g., policymakers and administrators, health professionals, academics, citizens, the healthcare industry, and the media (general or specialized press).

Inclusiveness:

For each type of document, different versions should be produced to ensure its adaptation to the target population for which it is intended (considering disabilities as well).

The structure and format of these different versions should be standardized.

They should have a structure similar to that of a scientific article for healthcare professionals or be adapted to the recommended guidelines for citizens.

Accountability:

A brief section at the end of the dissemination document should disclose lists of funders.

Since the organization is accountable to the whole society, open access journal publishing or publishing in leading journals in their respective areas should be sought.

Quality:

State-of-the-art dissemination strategies should be adopted, for example, systematic publication in leading journals, magazines or other media, both general or specialised publication of a newsletter, both nationally and internationally, and creation of discussion groups, distribution lists, and news alert systems.[12]

Timeliness:

The dissemination products should be produced and disseminated as appropriate unless there is a fixed schedule such as in the case of newsletters or conferences.

[11] National Health Service (2003) Toolkit for producing patient information. Version 2.0. London, UK: Department of Health.

[12] Hermosilla Gago T, the AETSA group of experts (2007) [Guidelines to produce citizen-friendly health technology assessment reports]. Seville, ES: AETSA.

Consistency:

Information contained in the dissemination documents should be consistent with previous versions.

The terminologies of policy briefs, reports and journal articles should be standardised through a common glossary.

Methodological or support documents that enable users of research to acquire more knowledge of the HTA functioning and principles should be made available online.

Contestability:

Feedback should be encouraged in the different dissemination products by providing a contact person's details and a feedback system on the organization's website.

7. The monitoring and evaluation process guidelines

In order to comply with the organization's governance principles, the following steps should be taken for each procedure included in the process of monitoring and evaluation of the organization:

7.1. External evaluation

Transparency:

A report including the results and recommendations from the external evaluators should be made publicly accessible.

The report should also be submitted to the funders of the organization, if appropriate.

Inclusiveness:

The views of both staff and relevant stakeholders should be sought by the evaluation team. Stakeholders should be selected following agreed-upon criteria.

Accountability:

Conflicts of interest of evaluators should be disclosed before the start of the evaluation and published in the evaluation report.

A detailed explanation of the contributions of each evaluator should be disclosed.

Lists of funders of the evaluation should be disclosed.

Quality:

Leading national and international experts in public health, HPSR and HTA should be invited to conduct the organization's evaluation.

Evaluators should follow state-of-the-art evaluation methods.

The organization should develop performance indicators to assist external evaluators in auditing these guidelines, if appropriate.

Timeliness:

The evaluation should be conducted within six months, every two years.

Consistency:

The evaluation should be consistent with previous evaluations to allow comparison in time (similar framework and team characteristics). However, new dimensions for evaluation may be introduced if they are justified.

Contestability:

The evaluation results should be peer reviewed by leading national or international experts. In addition, the organization's senior staff should be allowed to contest the results and recommendations.

8. Selected bibliography

Governance of HTA agencies:

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Littlejohns P, Rawlins M (2010) Patients, the public and the priorities in health care. Milton Keynes, UK: Radcliffe Publishing. http://books.google.com/books?id=PKby3r0RUm0C&source=gbs_similarbooks_r&cad=2

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Canadian Agency for Drugs and Technologies in Health (2003) Guidelines for authors of CADTH health technology assessment reports. Ottawa, CA: CADTH. http://cadth.ca/products/methods-and- guidelines

Kristensen FB, Sigmund H (eds); Danish Centre for Health Technology Assessment (2008) Health technology assessment handbook 2007. Copenhagen, DK: DACEHTA. http://www.sst.dk/publ/Publ2008/MTV/Metode/HTA_Handbook_net_final.pdf

Priority setting guidance:

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National Institute for Health and Clinical Excellence (2008) Topic selection programme process manual. London, UK: NICE. http://www.nice.org.uk/media/96A/B2/TopicSelectionProcessManualv25.pdf

Viergever RF, Olifson S, Ghaffar A, Terry RF (2010) A checklist for health research priority setting: nine common themes of good practice. Health Res Policy Syst 8:36. http://www.health-policy-systems.com/content/pdf/1478-4505-8-36.pdf

Technology assessment guidance:

Tangcharoensathien V, Wibulpolprasert S, Kamolratanakul P (editors) (2008) Health Technology Assessment Guideline J Med Assoc Thai 91(Suppl 2), 1-88. http://www.ispor.org/PEguidelines/source/Thailand-Health-Technology-Assessment-Guidelines.pdf

Guidelines development guidance:

Scottish Intercollegiate Guidelines Network (2008) A guideline developer's handbook. Edinburgh, UK: SIGN. http://www.sign.ac.uk/pdf/sign50.pdf

World Health Organization (2008) WHO Handbook for guideline development. Geneva, CH: WHO. http://www.searo.who.int/LinkFiles/RPC_Handbook_Guideline_Development.pdf

National Institute for Health and Clinical Excellence (2009) The guidelines manual. London, UK: NICE. http://www.nice.org.uk/media/5F2/44/The_guidelines_manual_2009_-_All_chapters.pdf

Institute of Medicine (2011) Clinical practice guidelines we can trust. Washington DC, US: Institute of Medicine.http://www.iom.edu/~/media/Files/Report%20Files/2011/Clinical-Practice-Guidelines-We-Can-Trust/Clinical%20Practice%20Guidelines%202011%20Insert.pdf

Bosch-Capblanch (ed); World Health Organization, Swiss Centre for International Health (2011) Handbook for supporting the development of health system guidance. Basel, CH: Swiss Centre for International Health. http://www.swisstph.ch/fileadmin/user_upload/Pdfs/SCIH/WHOHSG_Handbook_v03b.secure.pdf

Systematic review guidance:

Armstrong R, Waters E, Jackson N, Oliver S, Popay J, Shepherd J, et al. (2007) Guidelines for systematic reviews of health promotion and public health interventions. Version 2. Melbourne, AU: Melbourne University. http://ph.cochrane.org/sites/ph.cochrane.org/files/uploads/Guidelines%20HP_PH%20reviews.pdf

Institute of Medicine (2011) Finding what works in health care: standards for systematic reviews. Washington DC, US: Institute of Medicine. http://www.iom.edu/~/media/Files/Report%20Files/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards%20for%20Systematic%20Review%202010%20Insert.pdf

Technology appraisal guidance:

National Institute for Health and Clinical Excellence (2009) Guide to the single technology appraisal process. London, UK: NICE. http://www.nice.org.uk/media/913/06/Guide_to_the_STA-proof_6-26-10-09.pdf

National Institute for Health and Clinical Excellence (2009) Guide to the multiple technology appraisal process. London, UK: NICE. http://www.nice.org.uk/media/42D/8C/MTAGuideLRFINAL.pdf

Dissemination guidance:

National Health Service (2003) Toolkit for producing patient information. Version 2.0. London, UK: Department of Health.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasse t/dh_4068462.pdf

Lavis JN, Permanand G, Oxman AD, Lewin S, Fretheim A (2009) SUPPORT Tools for evidence-informed health Policymaking (STP) 13: Preparing and using policy briefs to support evidence-informed policymaking. Health Res Policy Syst. 16;7 Suppl 1:S13.
http://www.health-policy- systems.com/content/pdf/1478-4505-7-S1-S13.pdf

9. Templates/checklists

External review template for research report

Note:

1. The Health Intervention and Technology Assessment Program (HITAP) applies valuable comments and suggestions from external reviewers in order to publish research reports of full-quality standards.
2. Please feel free to make comments and suggestions based on your expertise.
3. Comments and suggestions can be in Thai or English.

1. Project title

2. Principal investigator

3. Abstract

3.1 Correctness

3.2 Comprehension

4. Introduction

4.1 Problem(s) and situation

4.2 Background rationale

4.3 Reference(s)

5. Content

5.1 Methodology

1) Inclusiveness and correctness
2) Appropriate illustrations (box, table and figure)
3) Study design
4) Population and sample
5) Variables, data collection and tools
6) Data analysis
7) Ethical issue(s)

5.2 Results

1) Inclusiveness and correctness
2) Appropriate illustrations (box, table and figure)
3) Address of research question
4) Compatibility with research methodology

5.3 Discussion and recommendations

1) Inclusiveness and correctness
2) Compatibility with research context
3) Limitations
4) Appropriate recommendation(s)

6. Comprehensiveness, up-to-date information, correctness of reference(s)

7. Overall content

7.1 Language

7.2 Sequence

7.4 Coherence

7.5 Academic content

7.6 Reasonableness

7.7 Usefulness

8. Suggestion

The research report should

☐ have a major revision

☐ have a minor revision

☐ be accepted for publishing as is

9. Other comments

……
……
……
……

10. Would you like to disclose your name as an external reviewer of this research study?

☐ Yes ☐ No

Signature ……..……..

(…….....……)

Date ……...…/……/……

Protocol template

Introduction

Background and rationale

Research question

Objectives

Conceptual framework (if any)

Methodology

Items	Qualitative study	Quantitative study	Economic Evaluation
Study design	✓	✓	✓
Study population	✓	✓	✓
Study samples -inclusion criteria -exclusion criteria	 ✓ ✓	 ✓ ✓	 ✓ ✓
Sample size	✓	✓	+/-
Comparator		+/-	✓
Perspective			✓
Time horizon and cycle length			✓
Discounting rate			✓
Model structure			✓
Model parameters		✓	✓
Data collection (e.g., data collection tools, study sites and data collection method)	✓	✓	✓
Ethical approval	✓	✓	+/-
Data analysis	✓	✓	✓
Uncertainty analysis/triangulation	✓	+/-	✓

Expected outcomes

Study timeframe

Budget (if required)

Funders

Collaborating research organizations

Detailed contribution of researchers

Research dissemination plan

Conflict of interest

References

Final report template (economic evaluation study)

Acknowledgments (including research project funders)

Abstract (Thai and English)

Table of contents (including tables and figures)

Introduction

- Background
- Expected outcome
- Background of health problem and health intervention
- Literature review
- Research question(s)

Objectives (including general and specific objectives)

Methodology

- Study design
- Perspective
- Time frame for modelling
- Discounting
- Model development
- Parameters
  - A) Parameters input (for systematic review)
    - Selection criteria and critical appraisal
    - Data search
  - B) Parameters input (for primary research)
    - Population and sample
    - Selection criteria
    - Data collection
    - Others (depending on research methodology)
    - Ethics review approval for research involving human subjects

Data analysis

- Variable analysis
- Cost-effectiveness analysis
- Probabilistic sensitivity analysis
- Budget impact analysis (if any)

Results

- Cost-effectiveness analysis
- Probabilistic sensitivity analysis
- Budget impact analysis (if any)

Discussion

- Limitations
- Usefulness and generalization
- Impact on health system
- Knowledge gaps and recommendations for future research

Policy recommendations

Description of contribution of researchers

Conflicts of interest

Reference(s)

Appendix

Final report template (generic)

Month/year of the completed research report

Acknowledgments (including research project funders and external reviewers)

Abstract (Thai and English)

Table of contents (including tables and figures)

Introduction

- Background
- Expected outcome
- Background of health problem and health intervention
- Literature review
- Research question(s)

Objectives (including general and specific objectives)

Conceptual framework (if any)

Methodology

- Study design
- Data collection
- Data analysis
- Ethics review approval for research involving human subjects

Results

Discussion

- Limitations
- Usefulness and generalization
- Impact on health system
- Knowledge gaps and recommendations for future research

Policy recommendations

Description of contribution of researchers

Conflicts of interest

Reference(s)

Appendix

Abstract template (not more than 1 A4) (Thai and English)

Introduction

Objectives

Methodology

Results

Discussion and conclusion

Keywords

Policy brief template (not more than 1 A4) (Thai only)

Project title

Researcher(s) and affiliation(s)

Financial disclosure

Introduction (including research objectives and methodology)

Results and summary (including research limitations and uncertainties)

Policy recommendation(s)