THE PROCESS OF HT

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Thoughts on structures and processes in HTA

PROCESS OF HTA

Most HTA activity involves some form of the following basic steps.

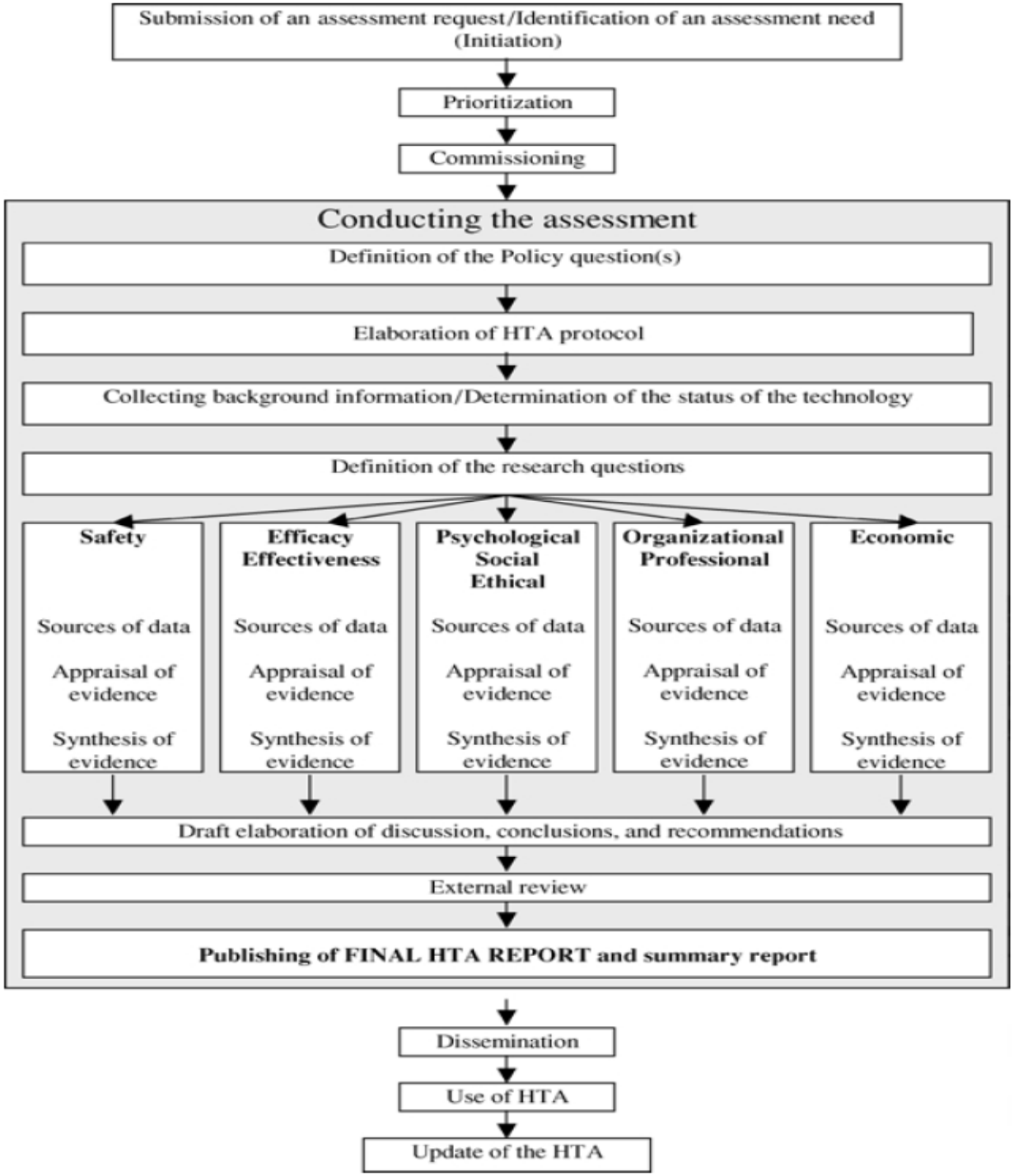
1. Identify assessment topics
2. Specify the assessment problem
3. Determine locus of assessment
4. Retrieve evidence
5. Collect new primary data (as appropriate)
6. Appraise/interpret evidence
7. Integrate/synthesize evidence
8. Formulate findings and recommendations
9. Disseminate findings and recommendations
10. Monitor impact

PROCESS OF HTA

- Scoping
- Assessment
  - Systematic Review on Safety and Efficacy of Technology
  - Economic Evaluation
- Appraisal
  - Accessibility, Affordability
  - Acceptability, Preference, Compliance
  - Feasibility
- Technology Impact assessment
  - Equity Concerns
  - Organizational Issues
  - Economic Impact Assessment
  - Health Impact Assessment

EUROPEAN COLLABORATION FOR HTA (BUSSE 2002)

- Submission of an assessment request/identification of an assessment need
- Prioritization
- Commissioning
- Conducting the assessment
  - Definition of policy question(s)
  - Elaboration of HTA protocol
  - Collecting background information/determination of the status of the technology
  - Definition of the research questions
  - Sources of data, appraisal of evidence, and synthesis of evidence for each of:
    - Safety
    - Efficacy/effectiveness
    - Psychological, social, ethical
    - Organizational, professional
    - Economic
  - Draft elaboration of discussion, conclusions, and recommendations
  - External review
  - Publishing of final HTA report and summary report
- Dissemination
- Use of HTA
- Update of the HTA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POLICY QUESTIONS

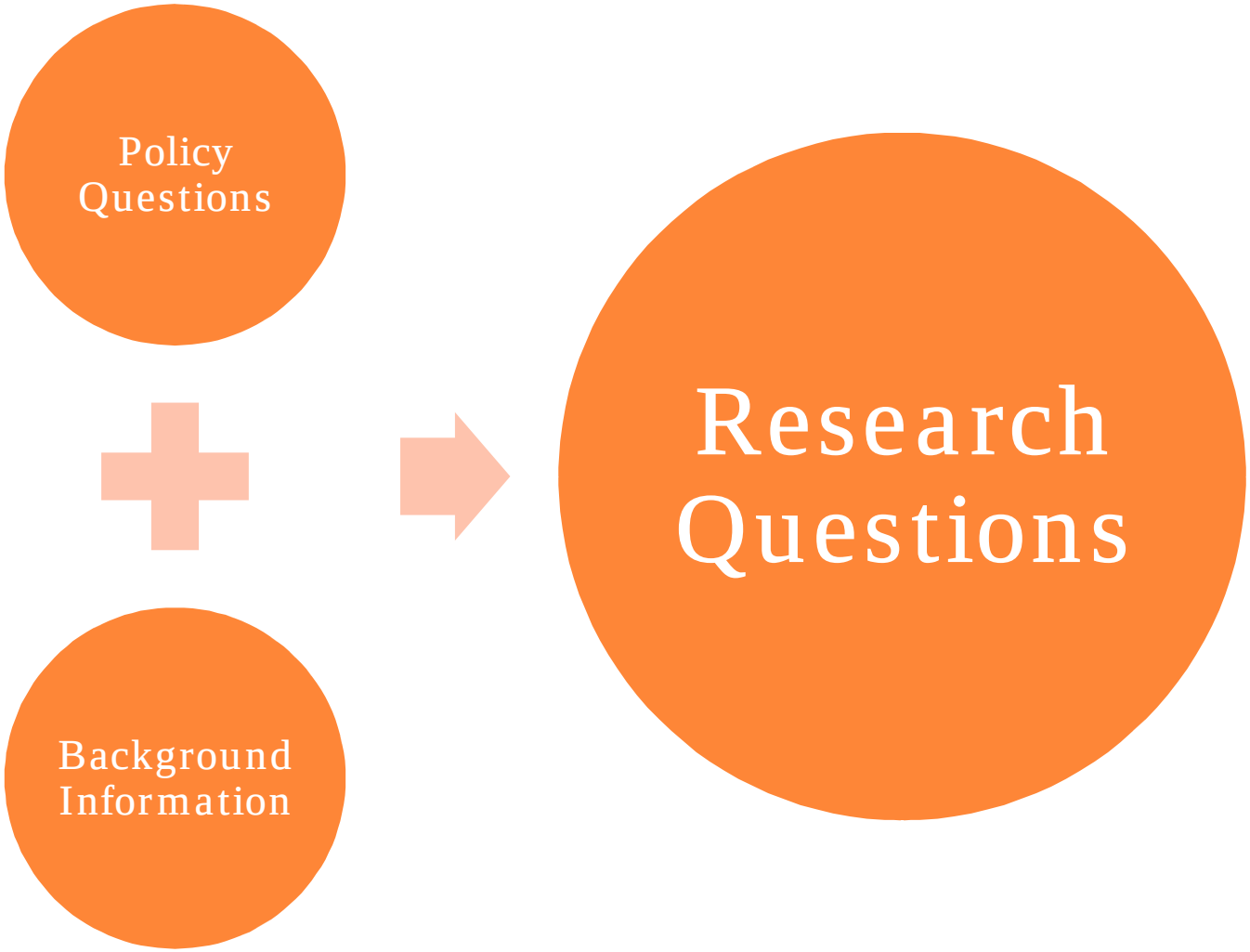
- HTA is policy-driven research, the commissioners' scope of the problem has to be clearly documented in the report.
- The policy questions, should be worded with close cooperation between the commissioners and the researchers.
- The policy question should be clearly stated in the HTA protocol as well as in the technical report (i.e., the detailed document), and the scientific summary report.

ASPECTS INCLUDED IN THE POLICY QUESTION

Question	Examples
Who initiated the report?	Policy makers Healthcare providers Third-party payers Patients' advocate
Who commissioned it?	
Why is an assessment needed right now?	New technology Changes in old technology New indications for old technology New findings Structural/organizational changes Safety concerns Ethical concerns Economic concerns
Which decision is it going to support?	Investment decisions Market licensure Inclusion in/exclusion from benefits catalogue Planning of capacities Guidance on best practice Investment in further research
Who represents the primary target audience for the report?	Political decision makers Third-party payers Hospital managers/administrators Clinicians Citizens/patients

HTA PROTOCOL= PROJECT PLAN

- the problem will be stated
- the way of gathering the background information will be defined
- the research questions will be posed
- Then the protocol should be completed by stating:
  - Which aspects of the problem are going to be assessed;
  - How each aspect will be addressed, i.e., which and how data sources will be searched and used;
  - Which methodology for the appraisal will be followed; and
  - What kind of synthesis of evidence is planned.


Policy Questions
Background Information
Research Questions

BACKGROUND INFORMATION

Key steps and sources of data:

1. Search for and record information on the:
   - Condition
   - Target Group
   - Technology status
2. Sources:
   - Research literature (search strategies targeting “reviews,” “prevalence,” “incidence,” etc.);
   - Routinely collected data (on utilization, costs, etc.);
   - Guidelines;
   - Special sources (disease registers, organizations of affected people, experts, manufacturers; some
   - of those sources are accessible through the internet);
   - Other HTA reports (searchable in INAHTA Database, or in the websites of HTA agencies)

QUESTIONS TO BE ADDRESSED AS BACKGROUND INFORMATION ON CONDITION AND TARGET GROUP

Questions	Example
Condition(s)	Health problem Disease
What are the mechanisms of disease?	Causes Pathology
What is the course and prognosis of the condition?	Clinical presentation Stages Time course
What are the consequences? (outcomes)	Physically disabling Psychological consequences Death
Treatment alternatives and current practice	Drugs Surgery Current service provision
Target group(s) (*epidemiology*, *burden of disease*)	Patients Healthy subjects (for prevention)
How many people are affected?	Incidence Prevalence
Who is affected?	Age Gender Social factors Risk factors

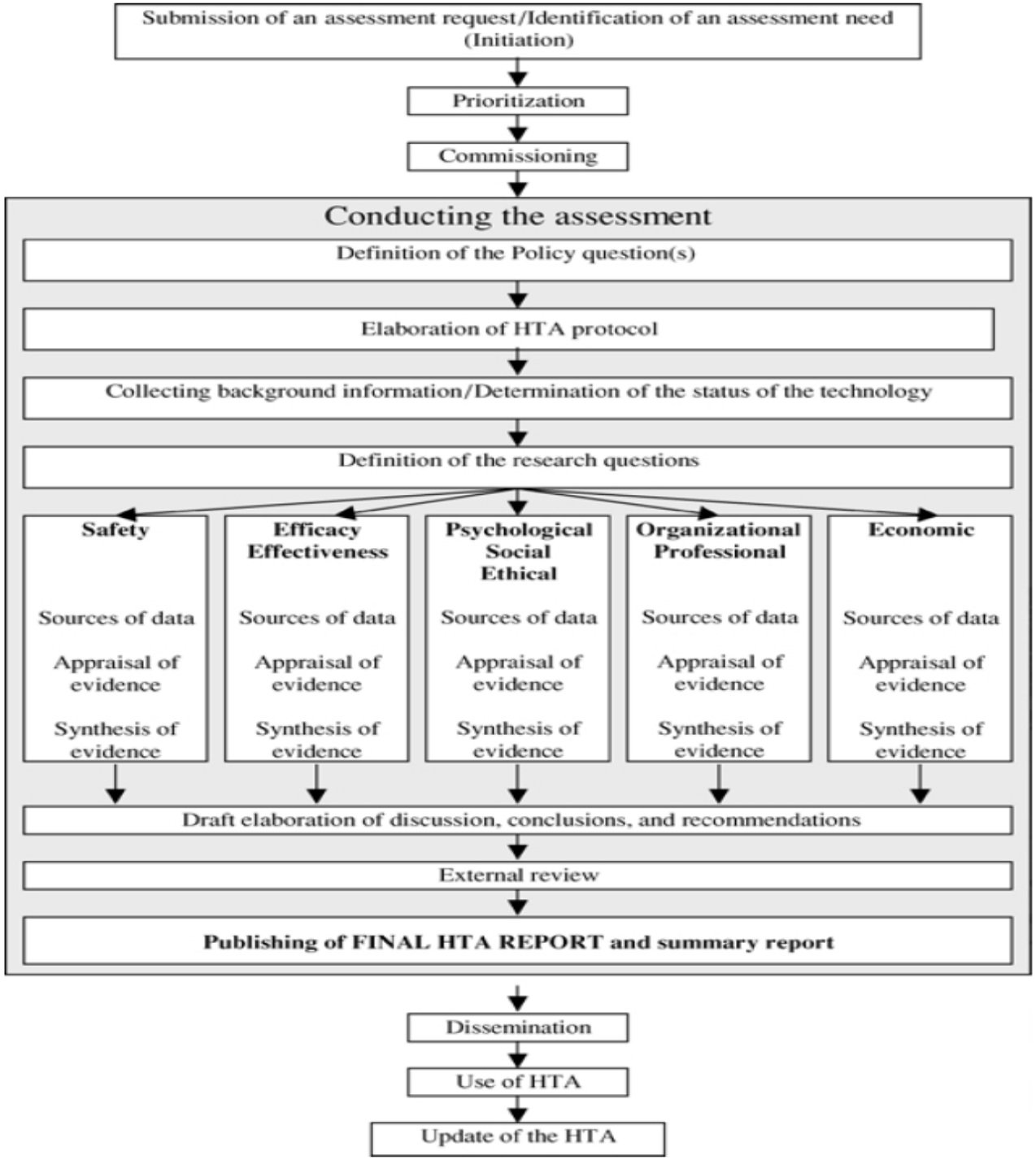
QUESTIONS TO BE ADDRESSED AS BACKGROUND INFORMATION ON THE TECHNOLOGY

Question	Aspects/examples
How does it work? What kind of intervention is it?	If a device, explain technical characteristics, functioning If a community/system-related intervention, explain its crucial features
What are the requirements for its use?	Setting for use/implementation Special measures needed for use/implementation Qualification required Maintenance
What is the status of the technology?	Diffusion/distribution Patterns of use Current indications for use Current utilization Costs Regulatory status Manufacturers and market shares

RESEARCH QUESTION(S)

- Formulating the research question(s) means specifying the policy question in terms of safety, efficacy, effectiveness, psychological, social, ethical, organizational, professional, and economic aspects.
- The formulation of the research questions also implies defining the outcomes of interest for the assessment.

Research Questions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CHARACTERISTICS OF RESEARCH QUESTIONS

- Clearly worded;
- Answerable;
- Limited in number;
- Address meaningful outcomes; and
- Address other relevant treatment alternatives.

EXAMPLES OF OUTCOMES FOR DIFFERENT ASPECTS OF HTA

Aspect of assessment	Outcomes
Safety	Mortality directly related to the use of technology
	Morbidity/disability directly related to the use of technology
Efficacy/effectiveness	Change in overall/condition-specific mortality
	Change in morbidity/disability/disease-free interval
	Change in quality of life
	Change in quality-/disability-adjusted life-years (QALYs/DALYs)
Psychological/social/ethical	Compliance
	Acceptance
	Satisfaction
	Demand
	Preferences
	Information/patient advice requirements
Organizational/professional	Utilization of service
	Change in the treatment location
	Change in length of hospital stay
	Change in required personnel, material inputs (e.g., hospital beds) and organizational structure
	Training requirements
Economic	Costs and changes in cost compared to current practice (if applicable)
	Cost-effectiveness, cost-utility, cost-benefit

ANSWERING THE QUESTIONS /GENERAL METHODOLOGY

1) Searching for sources of information;
2) Selecting and evaluating information (application of inclusion and exclusion criteria)/appraising the evidence; and
3) Synthesizing the obtained data.

SAFETY

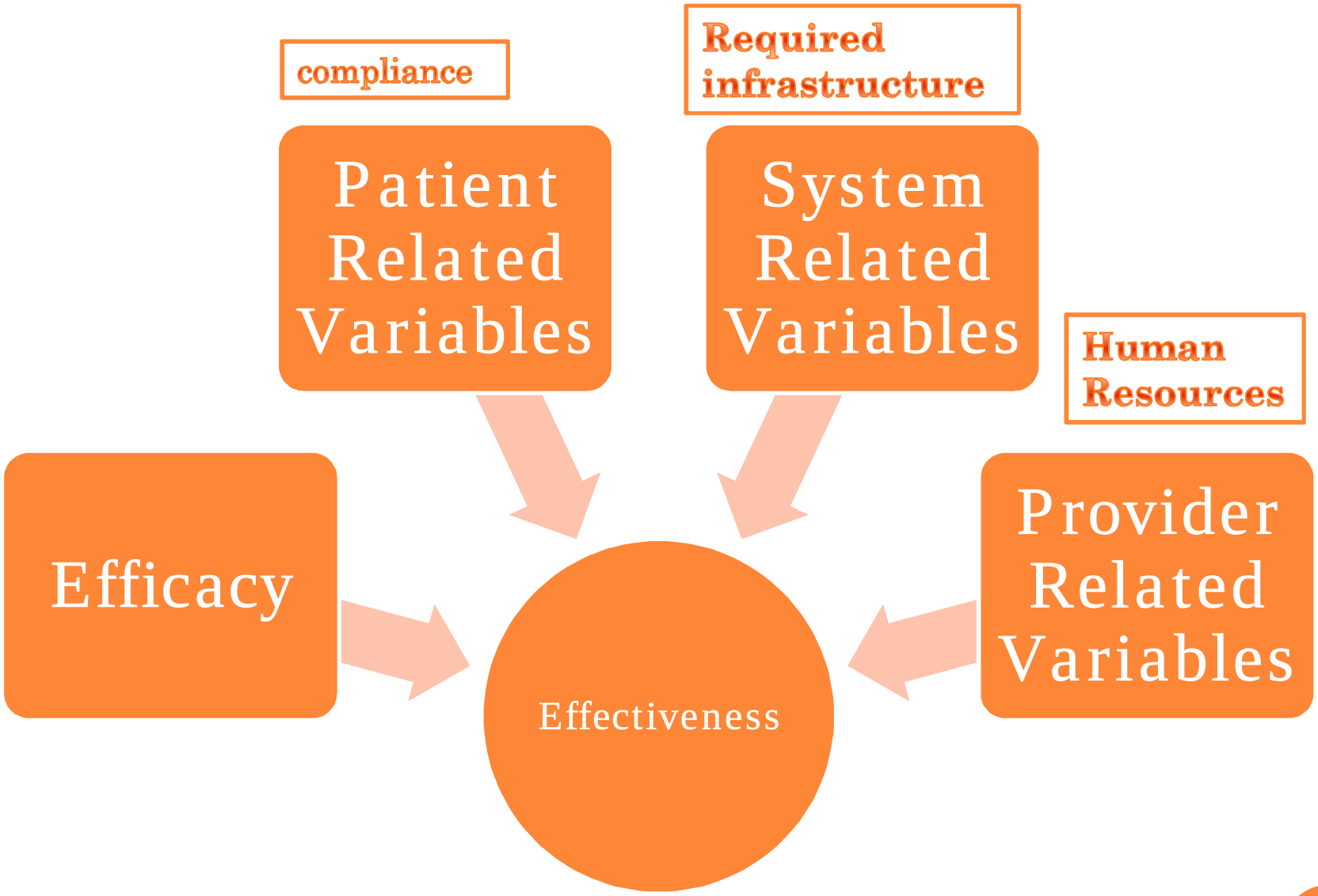
- The different sources of data on safety should be documented, taking into consideration their quality and validity.
- Safety can be summarized as frequency of adverse effects, relative risk, or as the number needed to treat to produce one episode of harm (NNH)

SAFETY

- Classification of adverse effects like:
  - Device-dependent or related to the application of the technology.
  - Operator- or setting-dependent
  - Timing (short-term, long-term) and severity of adverse effects
  - Identification of differences in risk among different groups of patients
  - When possible, quantification of harm into QALYs or DALYs

EFFICACY AND EFFECTIVENESS

Efficacy	Effectiveness	Source
The ability of a particular medical action in altering the natural history of a particular disease for the better under ideal conditions.	The ability of a particular medical action in altering the natural history of a particular disease for the better under actual conditions of practice and use	Cochrane (9)
The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal circumstances of use.	The benefit of a technology under average conditions of use	U.S. Congress (59)
Maximum achievable benefit	Achieved benefit	Williamson (61)
Can it work? Does the maneuver, procedure, or service do more good than harm to people who fully comply with the associated recommendations or treatment?	Does it work? Does the maneuver, procedure, or service do more good than harm to those people to whom it is offered?	Sackett (54)
What works under carefully controlled conditions, such as RCTs	What works in day-to-day clinical practice	Rettig (51)


compliance
Required infrastructure
Patient Related Variables
System Related Variables
Human Resources
Efficacy
Provider Related Variables
Effectiveness

PSYCHOLOGICAL, SOCIAL, AND ETHICAL CONSIDERATIONS

- Psychological effects:
  - fear,
  - anxiety,
  - feeling labeled, and
  - satisfaction
- social effects:
  - changes in equity or access to care produced by the implementation of a technology
- ethical implications:
  - exploration of all possible effects of technology on values (e.g., the use of a technology may foster judgments; for example, discrimination of handicapped life through the use of prenatal diagnostic tests).

THE WAY TO APPROACH THESE ISSUES IN HTA

- Present medical literature(search proper databanks with optimal strategy e.g.,PsycINFO, Sociological Abstracts)
- no evidence from the literature: primary research in order to include the patient perspective when assessing a technology. With methods like, participant observation, individual interviews, focus group discussions, Delphi method, or future workshops.
- Time and financial constraints: other sources of information such as patient organization websites to gain knowledge about the perspective of the patients or make some assumptions about the possible psychological/social implications and the ethical considerations of a technology.

- In summary, assessment of psychological, social, and ethical considerations refers to the inclusion of the public perspective in a structured way in HTA.
- These aspects determine public preferences about technologies, and thus their assessment could also be considered a tool of HTA.

Organizational and Professional Implications: examples

- Utilization of service (for example, if the introduction of a pharmaceutical therapy reduces or even replaces surgical interventions);
- Change in the treatment location (for example, if a traditional inpatient treatment, by means of the new technology, can be performed as an outpatient procedure);
- Training/qualification requirements (for example, if the application of a health technology—in contrast to its alternatives—presupposes the skills of a special medical expert);
- Channels of cooperation/communication (for example, if the effective use of a health technology presupposes extra communication between hospital and general practice); and
- Job satisfaction (for example, if a new procedure presupposes such a high throughput that the physicians have insufficient time for following the patients' progress).

THE WAY TO APPROACH THESE ISSUES IN HTA

- Determine stakeholders and their interests
- critical survey of literature,
- collect data from the organization by using:
  - Questionnaires,
  - Focus group interviews,
  - Structured group processes such as future workshops or the Delphi method, especially when trying to identify and evaluate future changes of organizational structure and processes or when trying to predict reactions of people involved in the implementation.

ECONOMIC ISSUES

1. Collecting information on resource consumption from the use of the technology (costs)
2. conduct an analysis comparing costs to other outcomes, such as efficacy or effectiveness

TYPES OF COSTS IN AN ECONOMIC ANALYSIS

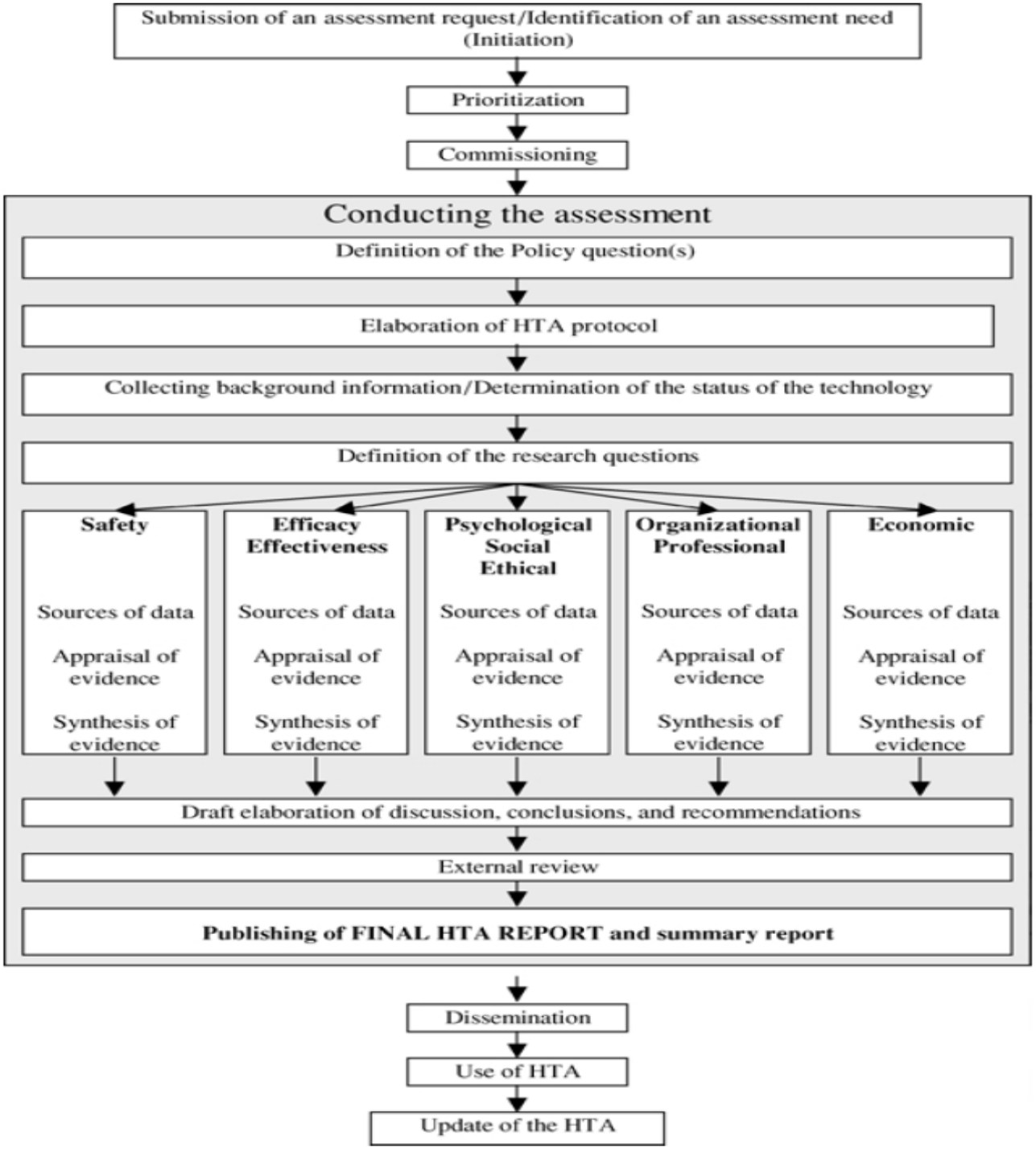
Perspectives	Types of costs	Examples
Healthcare payer		
Hospital	Direct costs	Healthcare staff, medicine, tests, capital costs (equipment and buildings), inpatient stay (hotel), outpatient visits, overhead costs (e.g., food, light, heat), possibly research, and education
Ambulatory care	Direct costs	Visits with general practitioner, ambulatory specialist, physiotherapist, etc., prescription drugs (the share paid by the healthcare payer), screening programs
Societal perspective		
	Direct costs (possibly in other sectors)	Rehabilitation, home care and nursing care at home, social arrangements
	Direct costs (for the patient and family)	User payment (medicine, dentist), cost for traveling, time costs due to patient's time used for the treatment, family or friends' (unpaid) use of time of the patient
	Lost production in society	The patient's temporary absence from work due to illness, reduced working capacity due to illness and disablement, or lost production due to an early death
	Future healthcare costs	Future unrelated healthcare costs caused by curing the patient with the present treatment

Source: Modified from Kristenson et al. (37).

TYPES OF ECONOMIC ANALYSIS

Type of economic analysis	When should the specific type of analysis be chosen?
Cost-minimization analysis	If the compared technologies are equally effective, then it is only necessary to collect data about costs
Cost-effectiveness analysis	If the effectiveness of the compared technologies are different (e.g., the difference in costs have to be weighted against the difference in effectiveness)
	If activities with the same aim and measure of effectiveness are compared
Cost-utility analysis	If health-related quality of life is an important health outcome
	If activities across specialties or departments in the healthcare sector are compared
Cost-benefit analysis	If non-health effects also are of importance (e.g., the treatment process itself, utility of information)
	If only one technology is assessed (net benefit)
	If individual lives are valued in monetary units
	If activities across society are compared

Source: Kristensen et al. (37).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DISCUSSION OF METHODS AND RESULTS

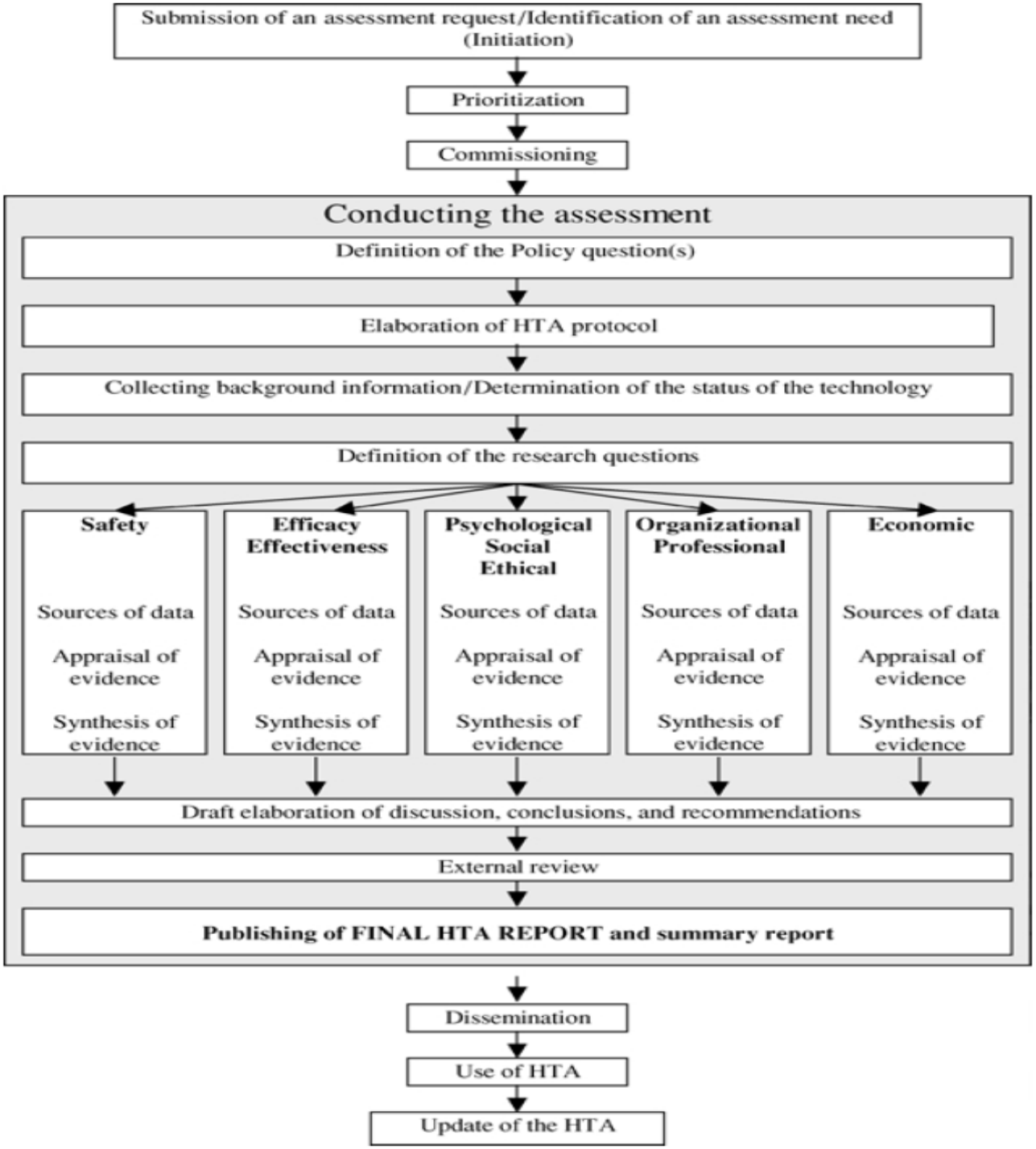
- a structured summary discussion should be always included in an assessment as a separate section, which should include the following:
  - Methodology of the assessment;
  - Evidence used (quality, validity, generalizability);
  - Assumptions made;
  - Discrepancies and uncertainties identified; and
  - Expected changes (in technology, in evidence).
- The discussion can be seen as a needed step before formulating conclusions and/or recommendations.

CONCLUSIONS AND RECOMMENDATIONS

- Conclusions should include the following points:
  - Related primarily to the research question(s);
  - Summarize quality/origin of the evidence;
  - Summarize evidence on all aspects assessed;
  - Give size of effect (benefit/adverse);
  - Highlight differences among groups of patients (if found);
  - Highlight variations of effect with varying characteristics of technology (if found);
  - Discuss applicability of evidence for national/local context and “community effectiveness”; and
  - Point out fields where further research is needed.

CONCLUSIONS AND RECOMMENDATIONS

- Recommendations must be consistent with the findings of the assessment and take into account the kind of evidence they rely on.
- The gradation of recommendations using hierarchies, which consider the quality of the underlying evidence, represents the best practice when giving recommendations.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REVIEW PROCESS

- The review process should assess the following:
  - Did the report undergo an expert review before publication?
  - Who reviewed the report (disciplines)?
  - Were there possible conflict(s) of interest?
  - Were the comments from reviewers incorporated into the final report? How?
  - How many comments were usable? How many were not usable?

UPDATING OF ASSESSMENT

- The need for an update:
  - *New evidence: Screening searches can be regularly made (e.g., annually if rapid change is expected)* to assess whether new evidence relevant to the problem has appeared;
  - *Controversy: If interested parties communicate disagreement with report after publication, revision* may be indicated; and
  - *Interest: If interest is communicated by the public, update may be undertaken.*

UPDATING OF ASSESSMENT

- Information about updating the HTA should include the following aspects:
  - Is an update planned?
  - How will the timing/the need for the update be assessed?
  - If an update need is identified, how should the update be conducted?
- If a standard institutional policy on updating exists, which is always the same, this does not necessarily need to always be reported, since it may be enough to refer to the source in which the process is described.

How to report HTA

1. Abstract;
2. Scientific summary report; and
3. Technical report.

DATA TO BE INCLUDED IN AN ENGLISH STRUCTURED ABSTRACT

- *Title: first title in English, then original title in brackets*
- *Author/s: according to Vancouver style*
- *Organization: organization commissioning the report*
- *Contact person: name and address*
- *Date: month and year of publication*
- *Language: language(s) of publication*
- *Abstract: specify whether summaries other than structured abstract are* included and their language (e.g., "patient information summary in Dutch")
- *Publication type: report, clinical practice guideline*
- *Pages*
- *References: number of references cited*
- *ISBN: International Standard Book Number.*
- *Technology type: e.g., screening, diagnostic, therapeutic, organizational*
- *Subject index terms: it is recommended to use terms from Index Medicus, indicating the major*
- *Objectives: general and specific objectives*
- *Methods*
- *Results: main results*
- *Recommendations: if given*
- *Peer review process: specify: Yes/No/Internal/External/Both*

Differences Between an Executive summary and a Scientific Summary Report

Executive summary	Scientific summary report
Addressed to local decision makers ("executives")	Addressed to the HTA and the scientific community
Focuses on recommendations and conclusions	Stresses the context of the HTA and methodologic aspects, in addition to conclusions and recommendations
Written in agencies'/institutions' official tongue(s)	Available in English
Quickly informs decisions	Allows for critical appraisal of relevance, quality, and main findings

TECHNICAL REPORT

- Title
- Authors
- Statement on conflict of interest
- Policy question
  - Who commissioned the assessment? Why? What decision(s) is it supporting?
- Methodology of the HTA report
  - HTA Protocol
  - Review process
  - Sources of data
  - Appraisal of data/studies (inclusion/exclusion criteria)
  - Method of synthesis
- Background information
  - Target condition, target group, outcomes of interest, technology aspects
- Research questions
- Results
  - Safety
  - Efficacy/effectiveness
  - Psychological/social/ethical considerations
  - Organizational/professional implications
  - Economic issues

TECHNICAL REPORT

- Discussion
  - Methodology of the assessment
  - Quality of evidence/types of evidence (studies/data)
  - Uncertainties/lack of information
  - Generalizability, applicability of findings
- Conclusions
- Recommendations
- Appendixes
  - Documentation of sources (search protocols, keywords used, etc.)
  - Selection process documentation
  - Tables of evidence for included studies (including study characteristics, quality, and results)
  - Excluded studies with reasons for exclusion
  - Reference lists (included, excluded, other references used)
  - Tables of evidence from other sources of data included (e.g., routine registers)
  - Appraisal tools used
  - Levels of evidence/grading of recommendations used
  - Glossary
  - Update plan

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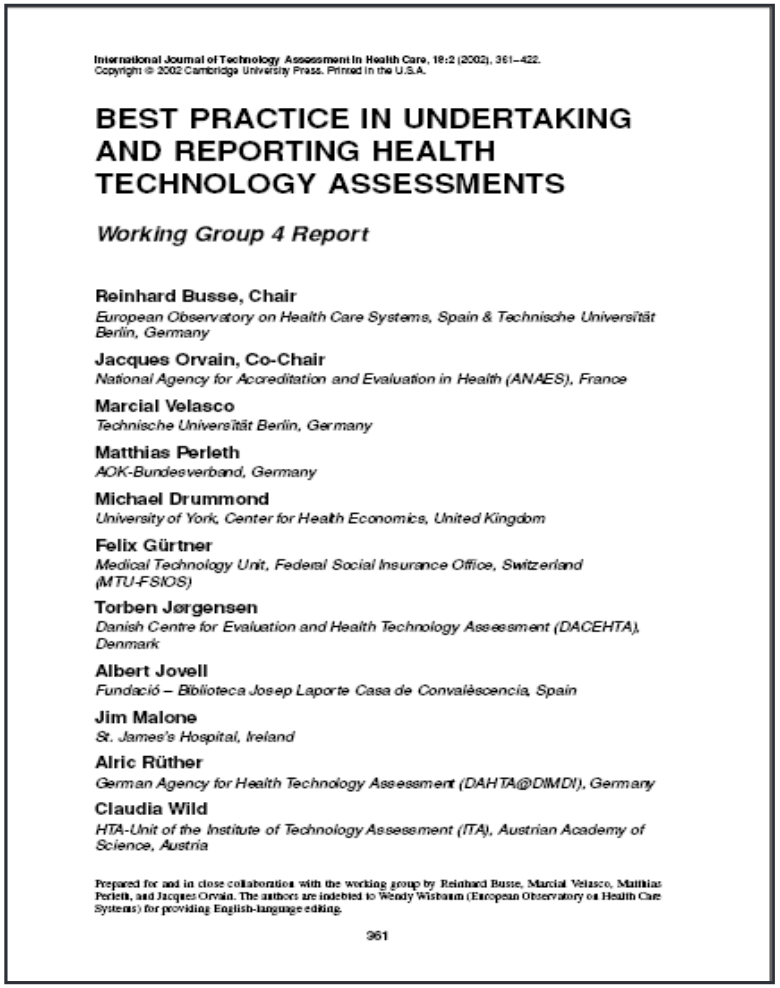

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BEST PRACTICE IN UNDERTAKING AND REPORTING HEALTH TECHNOLOGY ASSESSMENTS

Working Group 4 Report

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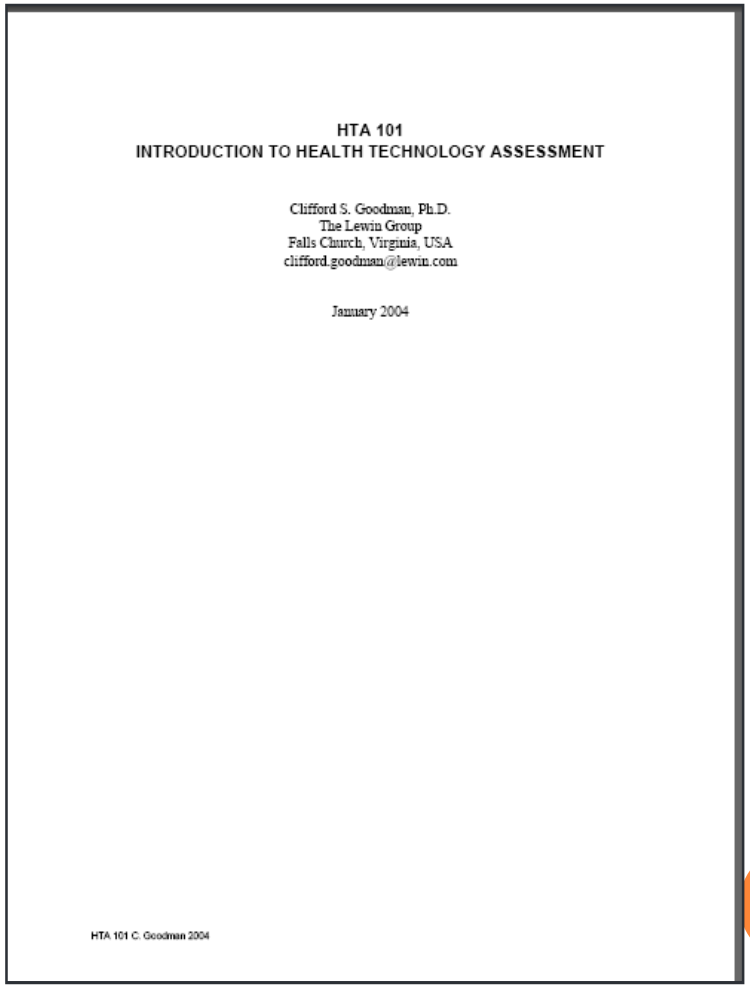

HTA 101
INTRODUCTION TO HEALTH TECHNOLOGY ASSESSMENT

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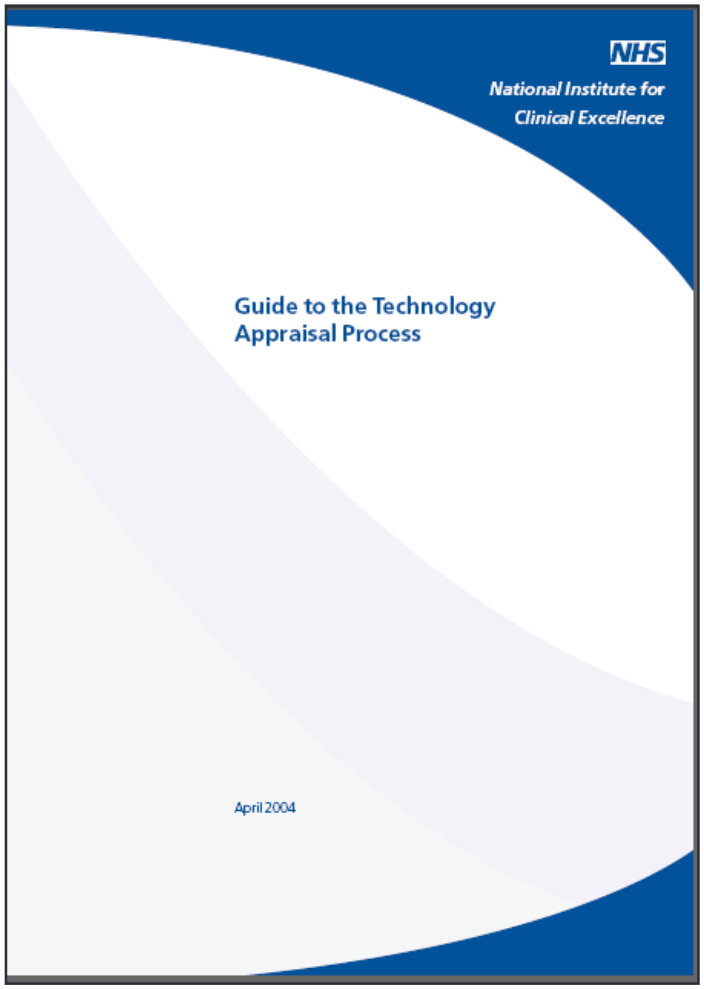
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