The Evidence Basis of Recommendations for Decisions in Health Policy

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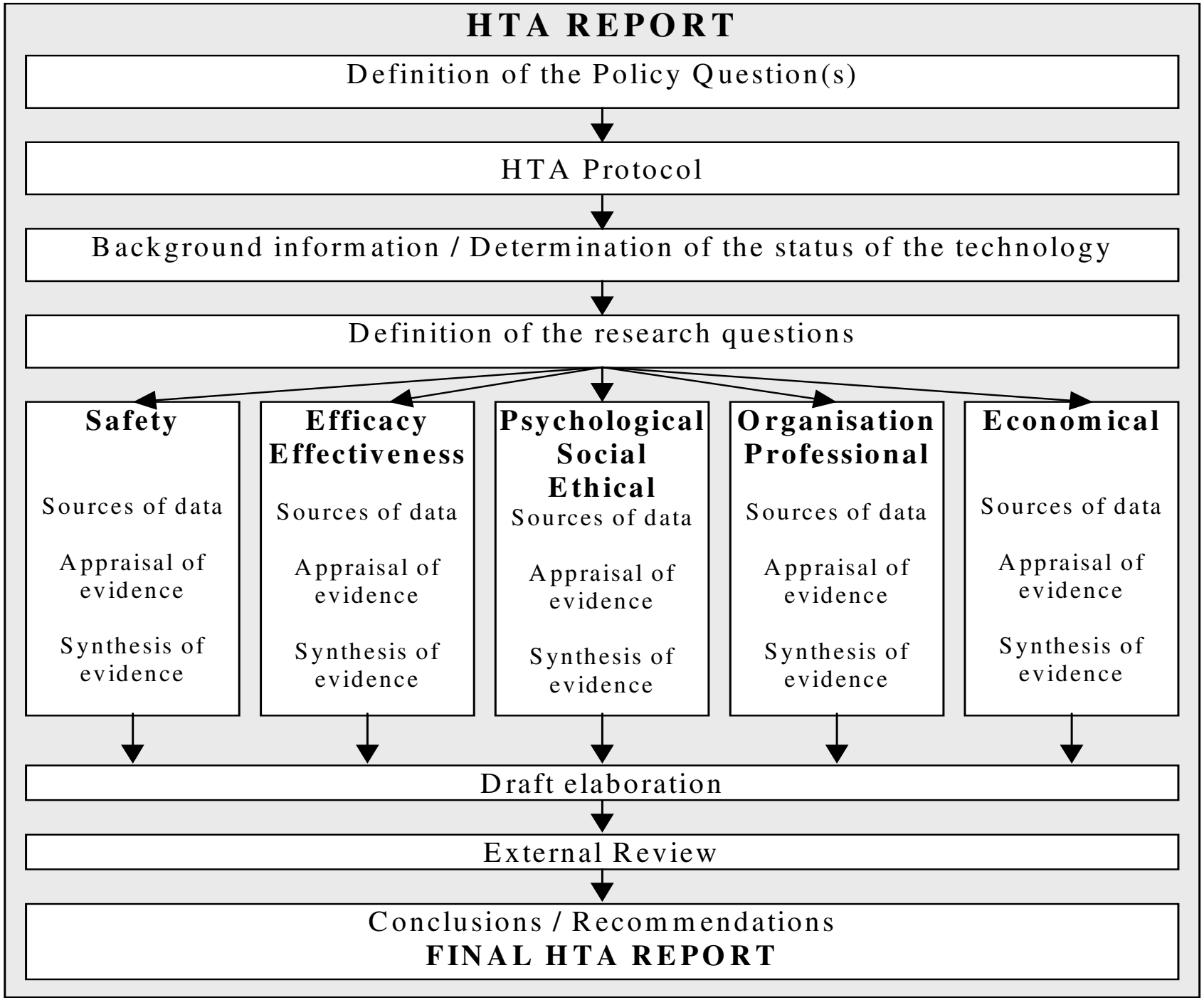
Section 1.
Health Technology Assessment – supporting decision makers

Busse R, Orvain J, Velasco M, Perleth M et al. (2002):
Best practice in undertaking and reporting HTA.
Int J Technol Assess Health Care 18(2): 361-422

Table 1. Aspects included in the policy question (Busse et al. 2002)

Who initiated the assessment?/ Who commissioned it?	• Policy makers • Health care providers • Third party payers • Patients' advocate
Why is an assessment needed right now?	• New technology • Changes in old technology • New indications for old technology • New findings • Structural / organisational changes • Safety concerns • Ethical concerns • Economic concerns
Which decision is it going to support?	• Investment decisions • Market licensure • Inclusion in / exclusion from benefit 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 REPORT
Definition of the Policy Question(s)
HTA Protocol
Background information / Determination of the status of the technology
Definition of the research questions
Safety
Sources of data
Appraisal of evidence
Synthesis of evidence
Efficacy Effectiveness
Sources of data
Appraisal of evidence
Synthesis of evidence
Psychological Social Ethical
Sources of data
Appraisal of evidence
Synthesis of evidence
Organisation Professional
Sources of data
Appraisal of evidence
Synthesis of evidence
Economical
Sources of data
Appraisal of evidence
Synthesis of evidence
Draft elaboration
External Review
Conclusions / Recommendations
FINAL HTA REPORT

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 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
Psychological/ Social/ Ethical	• Compliance • Acceptance • Satisfaction • Demand • Preferences • Information/advice requirements
Organisational/ Professional	• Change in length of hospital stay • Change in personnel and e.g. hospital beds required • Training requirements • Utilisation of service
Economical	• Costs and changes in cost compared to current practice • Cost-effectiveness, cost-utility, cost-benefit

Differences between "Executive Summary" and "Scientific Summary Report"	
Executive Summary	**Scientific Summary Report**
• Addressed to local decision makers ("executives")	• Addressed to the HTA and Scientific Community
• Focuses on recommendations and conclusions	• Stresses the context of the HTA and methodological aspects, beside conclusions and recommendations
• Written in agencies'/institutions' official tongue(s)	• Available in English
• Allows to quickly inform decisions	• Allows critical appraisal of relevance, quality, and main findings

Section 2. What is the “evidence” in an assessment?

“Evidence” is understood as the product of systematic observation or experiment and it is inseparable from the notion of data.

The idea to base decisions on the “best availableevidence” implies a “hierarchy” of the evidence.

Figure 1. Hierarchy of research designs to base health policy decisions upon (based mainly on internal validity)

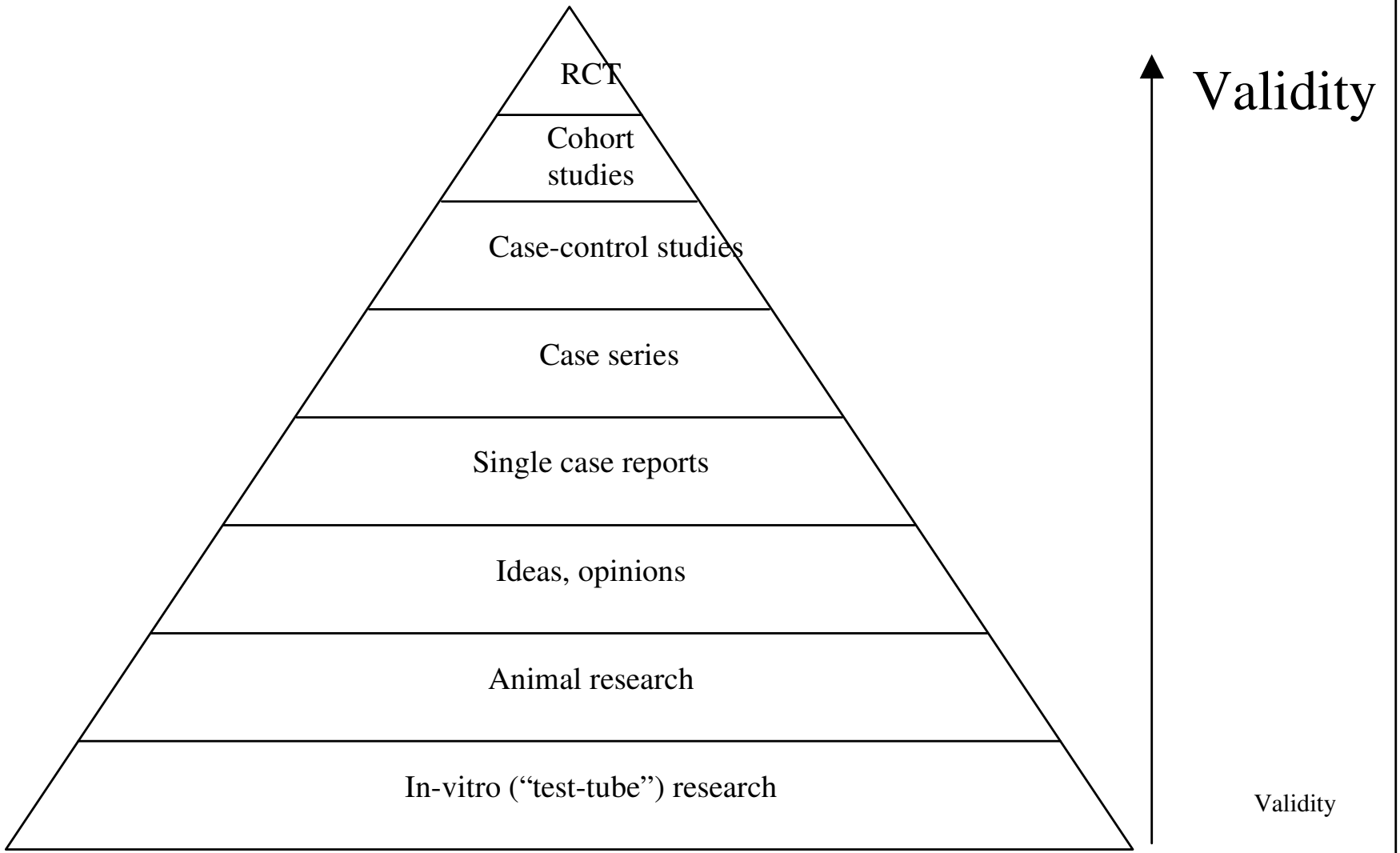


Figure 2. Algorithm of Study Design and Levels of Suitability (adapted from Briss et al 2000)

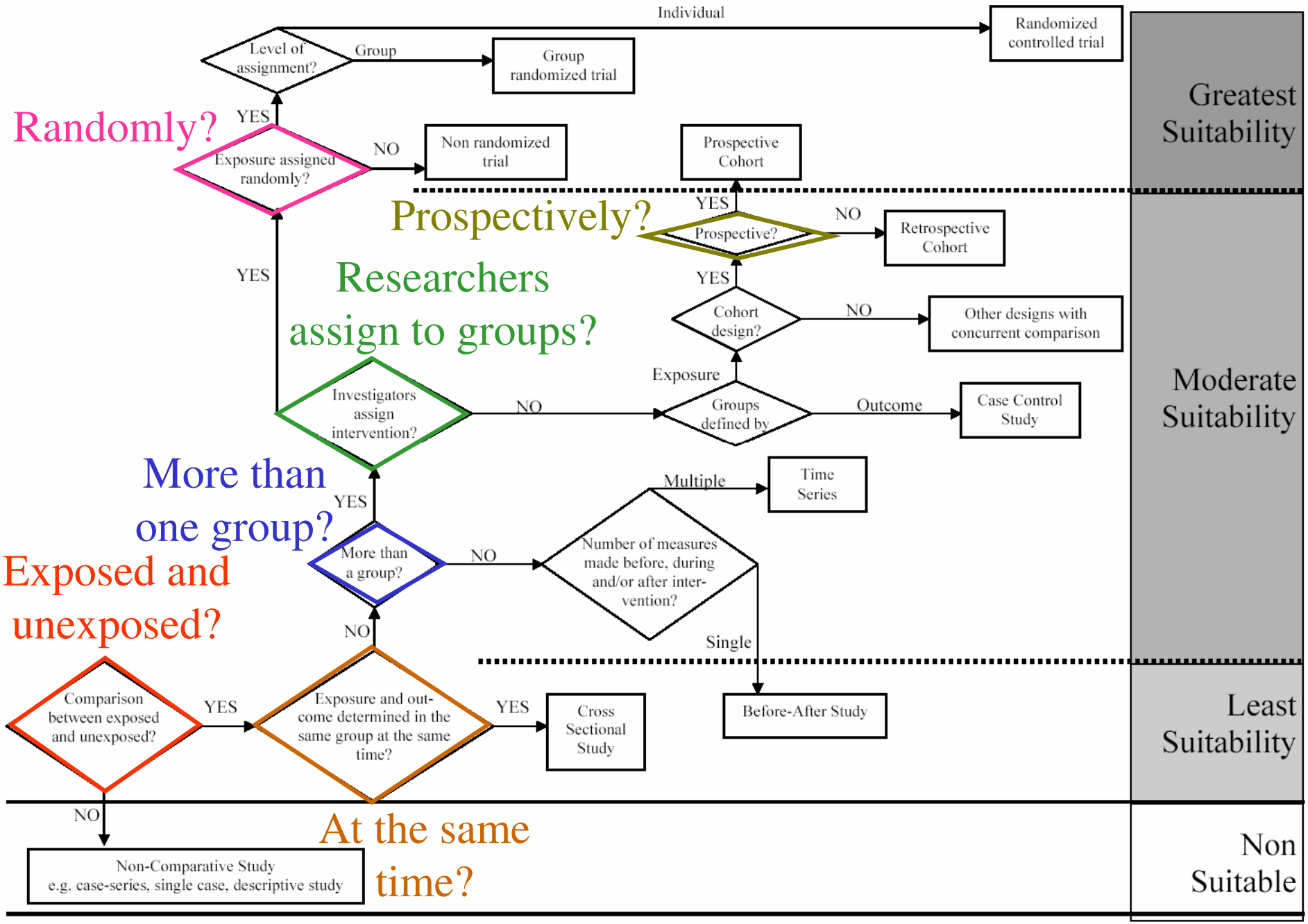
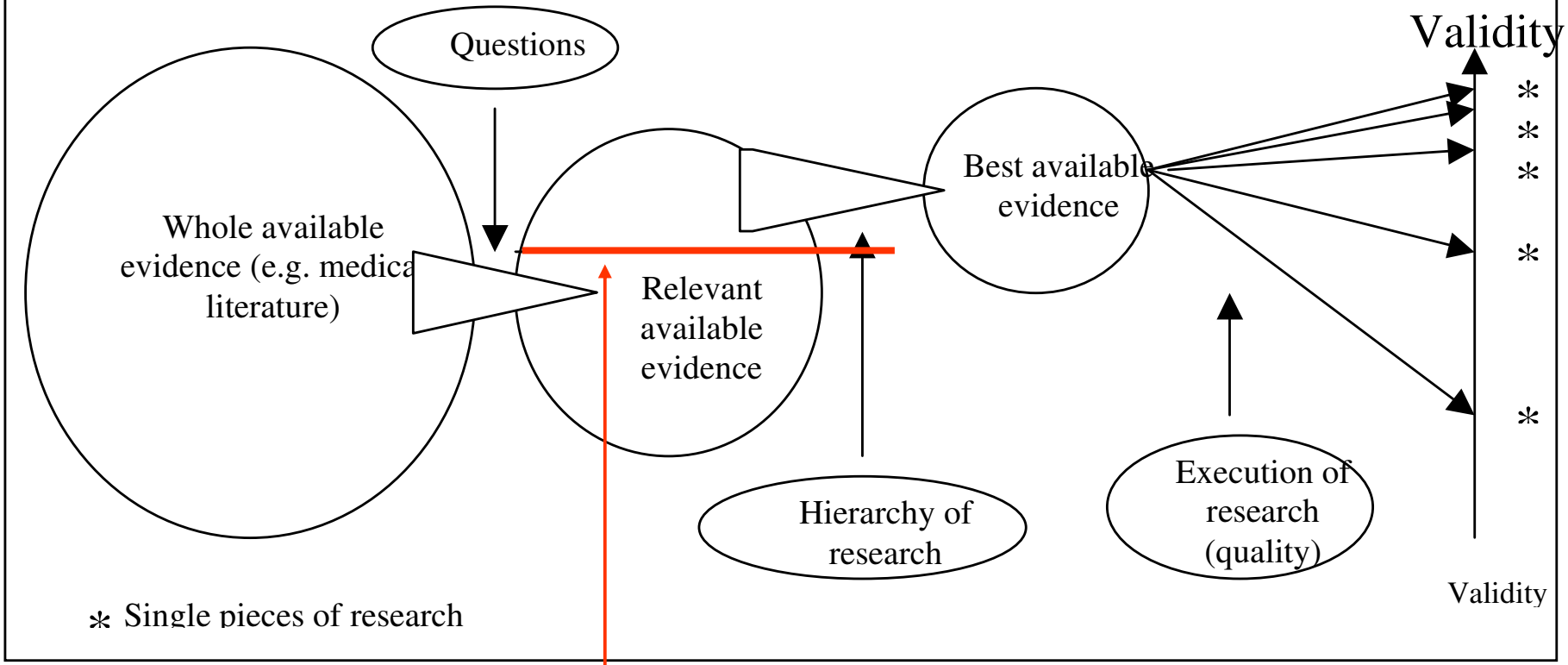


Figure 3. Simplified process of selection and organisation of the evidence.



In Cochrane reviews usually RCTs

CAVE: „No evidence“ then only means „no RCTs“

Table 3. Strength of evidence of the Canadian Task Force on Preventive Health Care (1979)

Strength of Evidence	*Description*
I	Evidence from at least one 1 properly randomized controlled trial
II-1	Evidence from well-designed controlled trials without randomization
II-2	Evidence from well-designed cohort or case-control analytic studies, preferably from than 1 center or research group
II-3	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
III	Opinions of respected authorities, based on clinical experiences, descriptive studies or reports of expert committees.

Table 4. Grades of Recommendation of the Canadian Task Force on Preventive Health Care (1979)

Grade of recommendation	*Description*
A	Good evidence to support the recommendation that the condition be specifically considered in a Periodical Health Examination.
B	Fair evidence to support the recommendation that the condition be specifically considered in a Periodical Health Examination.
C	Poor evidence regarding inclusion or exclusion of a condition in a Periodical Health Examination, but recommendations may be made on other grounds.
D	Fair evidence to support the recommendation that the condition be specifically excluded from consideration in a Periodical Health Examination.
E	Good evidence to support the recommendation that the condition be specifically excluded from consideration in a Periodical Health Examination.

Table 5. Levels of Evidence and recommendations from the Oxford Centre for Evidence Based Medicine (www.eboncall.co.uk/content/levels.html, accessed May 2003)

Grade of Recommendation	*Strength of Evidence*	*Description*
A	1a	Systematic Review of Randomised Controlled Trials (with homogeneity)
	1b	Individual Randomised Controlled Trial (with narrow confidence interval)
	1c	All or none (i.e. spectacles to correct myopia)
B	2a	Systematic Review of cohort studies
	2b	Individual cohort study / low quality randomised controlled trial
	2c	"Outcomes" research/Ecological studies
	3a	Systematic review of case-control studies
	3b	Individual case-control study
C	4	Case-series, poor quality cohort and case-control studies
D	5	Expert opinion without explicit critical appraisal, or results from animal experiments, etc.

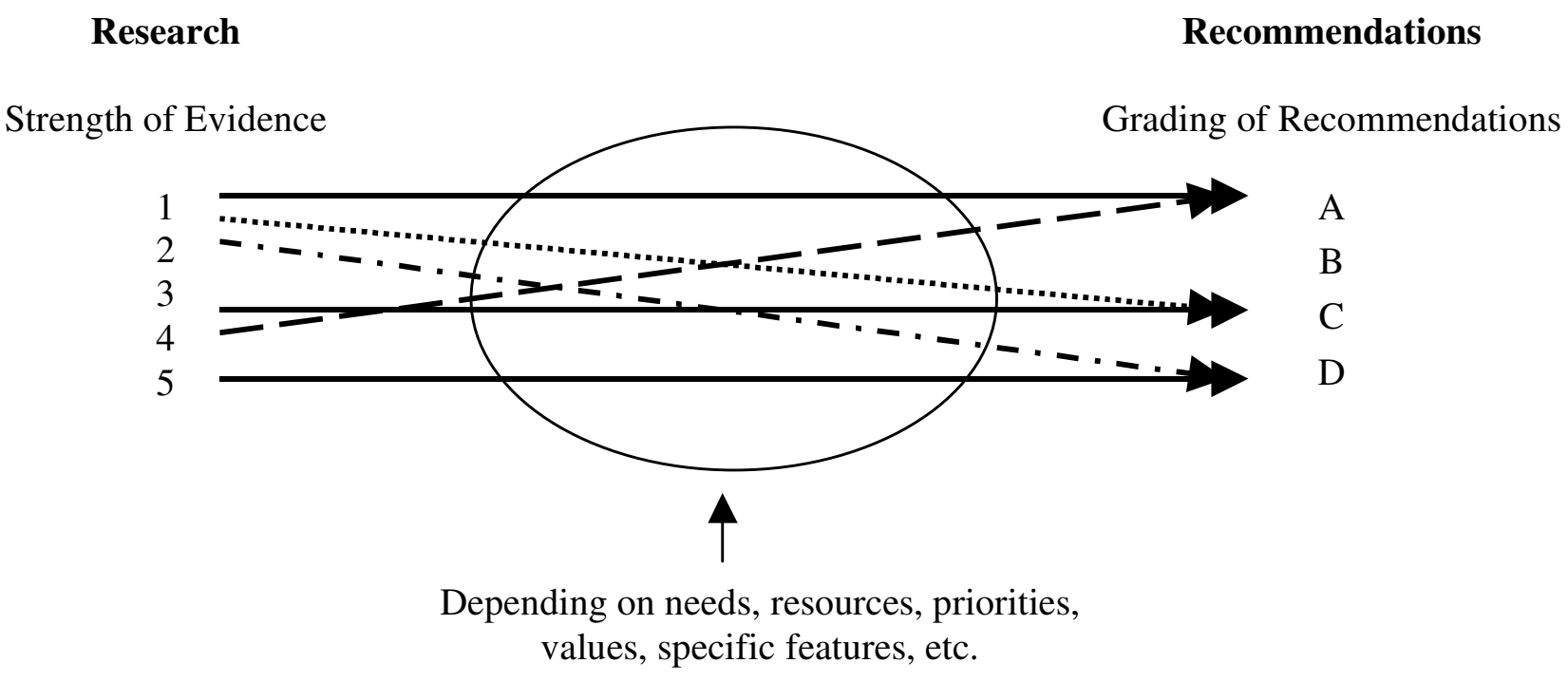
Table 6. Strength of evidence and Strength of Recommendations (Briss et al. 2000)

Strength of Recommendation	*Strength of evidence*	*Quality of execution*	*Design suitability*	*Number of studies*	*Con-sistency*	*Effect Size*	*Expert Opinion*
Strongly Recommended (Discouraged, if harmful)	Strong	Good	Greatest	At least 2	Yes	Sufficient	Not used
		Good	Greatest or Moderate	At least 5	Yes	Sufficient	
		Good or Fair	Greatest	At least 5	Yes	Sufficient	
		Evidence meets criteria for "Sufficient" but effect is …				Large	
Recommended	Sufficient	Good	Greatest	1	NA	Sufficient	Not used
		Good or Fair	Greatest or Moderate	At least 3	Yes	Sufficient	
		Good or Fair	Greatest, Moderate or Least	At least 5	Yes	Sufficient	
Recommended based on expert opinion	Insufficient empirical information, supported by expert opinion	varies	varies	varies	varies	varies	Supports a recom-menda-tion
Available studies do not provide sufficient evidence to assess	Insufficient	A: Insufficient designs or execution		B: too few studies	C: incon-sistent	D: Small	Not used

Table 7. Factors used to judge the strength of evidence in three different systems

System	*Hierarchy of research design*	*Quality of execution*	*Number of studies*	*Consistency*	*Effect size*
CTFPHC	+	+/-	+	-	-
Oxford	+	+/-	+/-	+	-
TFCPS	+	+	+	+	+/-

Figure 4. Relation between Strength of Evidence and Grade of Recommendations (Council of Europe 2001).



Section 3. Evidence basis for two selected interventions

- Scenario 1.
  Prostate Cancer Screening
- Scenario 2.
  Nicotine Replacement Therapy

Scenario 1

- *Policy question: Should the health check-up in my community include PSA-testing for screening of all men for prostate cancer?*

Scenario 1

- *Research Questions:*
  - *Is PSA-testing an effective intervention?*
  - *Does it contribute to a reduction of mortality from prostate cancer?*
  - *Does it contribute to a reduction of overall mortality?*
  - *Does it contribute to improving the quality of life of men suffering from prostate cancer?*
  - *Besides effectiveness, which other issues should be taken into account to consider when deciding upon the inclusion of it?*

Scenario 1

- *Results: In the ten most recent reviews/ reports, there is no good evidence for its effectiveness (i.e. a reduction in mortality from prostate cancer) of PSA-screening of non-symptomatic men.*

  There is also no good evidence supporting its ineffectiveness.

Scenario 2

- *Policy question: Should we include nicotine replacement therapy in the benefit catalogue/ positive list of prescribable products?*
- *Research Questions:*
  o Is nicotine replacement therapy effective for increasing the rate of smoking cessation?
  o Is it a safe intervention?
- *Results: All six reports provide good/ strong evidence of the effectiveness of nicotine replacement therapy.*