Key principles and related questions for HTA bodies.

Key principle	Questions
Principle 1 The goal and remit of the HTA should be explicit and relevant to its use.	• Is the remit for the HTA organisation clearly defined? • Is an initial (scoping) document drawn up prior to an HTA that contains information on the specific decision problem to be addressed, the relevant patient **P**opulations to be considered, the **I**ntervention of interest, the relevant alternatives (**C**omparators), and the **O**utcomes to be assessed (PICOs)? *PICOs = Patient problem/population (P) – Intervention (I) – Comparison(C) – Outcome(s) (O)*
Principle 2 HTA should be an unbiased and transparent exercise.	• Is the HTA organisation independent of the body making the reimbursement or coverage decision? • Are the recommendations of the HTA organisation made by an independent expert advisory committee? • Are any conflicts of interest of committee members documented and made public? • Are the meetings of the committee held in public? • Is the supporting information and the basis of the recommendations made publicly available? • Does the organisation normally commission outside groups to undertake the HTA? • Are the reports produced subjected to independent peer-review prior to final determination? • Are the draft conclusions subject to review by stakeholders and the public, with rationale underlying final determinations of contentious issues?
Principle 3 HTA should include all relevant technologies.	• Are all types of technologies (e.g. medicines, devices, diagnostics, procedures, behavioural modification) considered? • Within each category, are both new and existing technologies considered? • In assessments of new technologies, are all relevant alternatives considered?
Principle 4 A clear system for setting priorities for HTA should exist.	• Does a formal system for prioritising and selecting topics exist? • Is the priority-setting approach clear and transparent?
Principle 5 HTA should incorporate appropriate methods for assessing costs and benefits.	• Does the HTA organisation consider costs as well as benefits and harms? • Does the HTA organisation have published methods or guidelines for assessing the benefits, harms and costs of health technologies? • Is a full systematic review of clinical evidence required as a basis for economic modelling? • Does the team undertaking HTAs on behalf of the organisation include individuals with skills in epidemiology/biostatistics, health services research and economics?

Principle 6 HTAs should consider a wide range of evidence and outcomes.	• Does the relevant clinical evidence include observational and non-randomised studies, as well as randomised controlled trials? • Does the HTA consider impacts on quality of life and other patient-reported outcomes, as well as clinical events? • Does the HTA consider relevant sub-groups of the patient population (e.g. by baseline risk)?
Principle 7 A full societal perspective should be considered when undertaking HTAs.	• Does the HTA only consider the impact on a specific budget, for example for medicines? • Does the HTA consider all healthcare costs? • Can other costs be included as extra information? • Are productivity gains and losses (such as indirect costs and benefits) considered when relevant? • Are costs for informal care included when relevant? • Are costs in added years of life included in the cost-effectiveness ratio?
Principle 8 HTAs should explicitly characterise uncertainty surrounding estimates.	• Does the HTA include a sensitivity analysis? • Are confidence intervals presented for key estimates? • Have the key deficiencies in available data been identified and discussed? • Is an agenda for key future research proposed?
Principle 9 HTAs should consider and address issues of generalisability and transferability.	• Does the HTA organisation have methods or guidance for dealing with transferability issues when using data or analyses from other jurisdictions? • Does the HTA organisation consider the generalisability of the results of its studies to other patient populations, healthcare delivery systems or practice settings that are relevant for its jurisdiction?
Principle 10 Those conducting HTAs should actively engage all key stakeholder groups (e.g., professional bodies, patient organisations, manufacturers).	• Is the HTA organisation formally required to engage stakeholders in its activities? • Does the HTA organisation involve stakeholders in the formulation (scoping) of HTAs? • Does the HTA organisation have a mechanism for identifying the relevant stakeholders? • Does the organisation encourage or require submissions of evidence from stakeholders? • Does the organisation allow stakeholders to comment on reports at the draft stage? • Does the organisation allow stakeholders to appeal against recommendations and decisions? • Do the organisation's committees include stakeholders' representation (for example, patient groups, technology manufacturers, clinical specialists)?
Principle 11 Those undertaking HTAs should actively seek all available data.	• Does the systematic review of clinical evidence include the grey literature (academic literature not formally published) and other unpublished data? • Does the HTA organisation have processes for handling confidential data from manufacturers?

Principle 12 The implementation of HTA findings needs to be monitored.	• Does the HTA organisation develop an implementation plan for its HTAs? • Does the HTA organisation monitor the impact of its recommendations?
Principle 13 HTA should be timely.	• Does the HTA organisation have a defined time period for conducting HTAs and producing recommendations? • Does the HTA organisation adhere to the agreed timelines? • Does the organisation have a mechanism to update its HTAs and recommendations within a given time period?
Principle 14 HTA findings need to be communicated appropriately to different decision-makers.	• Does the HTA organisation develop a communications plan for its recommendations and decisions? • Are separate versions of reports produced for different audiences (e.g. health professionals, decision-makers, general public)? • Is the effectiveness of communication monitored and evaluated?
Principle 15 The link between HTA findings and decision-making processes needs to be transparent and clearly defined.	• Does the organisation distinguish between the scientific assessment of the evidence and the appraisal decision? • Does the organisation have an explicit decision rule for acceptance/non-acceptance of health technologies? • Does the organisation have a transparent approach for weighing various considerations (e.g. cost-effectiveness, equity)? • Does the organisation recommend, or operate, conditional reimbursement/special coverage for participation in developing clinical trials? • Does the organisation distinguish between identifiable sub-groups of the patient population when making decisions?

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