# Supplementary Table 5b: Extraction of methodological documents of medical device evaluation (primarily) developed for external stakeholders

| **HAS (Methodological Choices for the Clinical Development of Medical Devices, 2013 (17))[[1]](#endnote-1)** | **DACEHTA (Introduction to mini-HTA - a management and decision support tool for the hospital services, 2005 (16))[[2]](#endnote-2)** | **LBI (Evaluation diagnostischer Technologien - Hintergrund, Probleme, Methoden, 2010 (20))[[3]](#endnote-3)** |
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| **1. Assessment elements** | | |
| **a) Which elements of the technology are evaluated?** | | |
| Efficacy assessment for new treatment: presents methods potentially available when randomisation and/or blinding are impossible to implement as well as limitations (from literature search)  Regarding the ideal assessment process: second phase consists of the in-depth assessment (safety and efficacy) of emerging technologies. | Clinical efficacy, safety, social aspects, organisational aspects, cost evaluation | Evaluation of diagnostic technologies according to six level of the model developed by Fryback and Thornbury, (e.g. technical quality; p.19 gives an overview). |
| **b) Are there methodological approaches specified for each aspect/element?** | | |
| No information (focus only on specific methods) | Yes, the tool entails domains of questions regarding patients, technology, organisation and economy | Yes, guidance follows the 6 levels of the model developed by Fryback and Thornbury. |
| **2. Evidence procurement and selection** | | |
| **a) Is the assessment based on submissions or on internally conducted research?** | | |
| No information (focus only on specific methods) | Systematic literature search (refers to the general method paper of the institution) | Not applicable (see purpose of the document)  Systematic Review proposed. |
| **b) What types of evidence are admissible for the assessment?** | | |
| RCTs whenever possible to be performed.  Whenever a methodology other than a RCT is chosen, it must be scientifically justified.  Main focus: HAS present other types of experimental designs to use when conventional RCTs may be difficult to implement in practice.  Comparative non-randomised observational studies admissible if it is impossible to conduct a randomised controlled trial. Presents types of comp. observational studies but the choice of an observational study should remain the exception. | Most qualified literature, prioritized in accordance with the scientific quality of the articles. | Preferred study designs per level: e.g. level 4 ‚therapeutic impact‘: RCTs, before/after studies (see table on p. 53 for more information)  For studies regarding diagnostic accuracy: systematic reviews= highest evidence level  RCTs best study design  Direct evidence preferred  Due to specific requirements linked evidence is often not an option to assess the effectiveness of diagnostic tests and even if so, its use must be reasonably justified. |
| **c) What sources are used to identify the evidence (databases, registries, specific websites, grey literature)?** | | |
| No information (focus only on specific methods) | No information on sources. Systematic but limited (time constraint) literature search referring to DECEHTA's general methods. | No specific information (described only for the search to reveal the information presented in this document) |
| **d) Are there specific requirements as to the endpoints included for assessment?** | | |
| Endpoint (defined as part of feasibility study) must be clinically relevant (e.g. mortality). The use of an intermediate endpoint be justified and validated in previous studies. | No information | General: patient-relevant endpoints.  Primarily clinical parameters (e.g. life expectancy, functionality, pain).  Additionally, parameters for diagnostic accuracy, such as sensitivity, specificity. |
| **e) Are there specifications as to the comparators to be included?** | | |
| Discuss choice of comparator.  Show off circumstances where placebo may be considered ethically acceptable (according to an international council directive).  From an ethical point of view, it is difficult to offer patients an invasive sham procedure.  Not ethical to administer a placebo in place of a standard treatment with demonstrated efficacy  Give examples for MD placebos from the literature: Similar prosthesis which does not provide the therapeutic effect (e.g. without producing heat) | No information | Studies on diagnostic accuracy studies: New test (=indextest) compared to the best available diagnostic test (=reference standard).  Linked evidence: Requirements include that the population of both, the diagnostic accuracy study and the treatment effectiveness study, are comparable or that a validated reference standard exists. |
| **3. Evidence Appraisal** | | |
| **Is the evidence critically appraised before conclusions are drawn? If so, are there specific tools used?** | | |
| No information (focus only on specific methods) | Mini-HTA is reviewed critically by other impartial professionals within – and maybe also outside – the organisation. | QUADAS checklist  Cochrane Collaboration: ‘Handbook for Systematic Reviews of Diagnostic Accuracy’  STARD initiative (Standards for Reporting of Diagnostic Accuracy)  Based on a systematic review, additionally 90 different instruments have been identified for evaluation of the diagnostic accuracy (see Appendix 8.4) |
| **4. Review Process & Transparency** | | |
| **a) Are stakeholders directly involved in the production process?** | | |
| No information (focus only on specific methods) | Yes: During the process professionals from other occupational groups that will be affected by the new proposal will be involved (interdisciplinary work). | Not applicable (see purpose of document) |
| **b) Are (other) specific measures taken to ensure transparency of results?** | | |
| No information (focus only on specific methods)  . | Only found: Limitations regarding elucidation due to limited timeframe should be reported and rendered visible in the mini-HTA so that the basis for the assessment and any recommendations is completely unambiguous. High credibility is ensured through openness and transparency. | Not applicable (see purpose of document) |
| **5. Reassessment** | | |
| **Are there specific intervals/ conditions set for reassessment (fixed time/ new indication)?** | | |
| Regarding an ideal assessment process: Phase three of HTA process (monitoring phase) involves surveillance and regular re-assessment of the use of a technology in practice | No information | Not applicable (see purpose of document) |
| **6. Knowledge Exchange and Transferability** | | |
| **a) Does the agency use data and/or reports from other HTA institutions?** | | |
| No information (focus only on specific methods) | No information | Yes, for the development of this document |
| **b) Are there specific processes in place to ensure transferability of results?** | | |
| No information (focus only on specific methods) | No information | Generalisability: precise definition of research question and in- and exclusion criteria (PICO scheme etc.) |
| **7. Cost and Economic Evaluation** | | |
| **a) If cost or cost-effectiveness information is considered, what methods of evaluation are allowed?** | | |
| No information (focus only on specific methods) | No information | Cost and economic evaluation (according to level 6 by the model of Fryback and Thornbury) |
| **b) If cost or cost-effectiveness information is considered, what types of analyses are allowed/recommended?** | | |
| No information (focus only on specific methods) | No information | According to level 6: Cost-benefit analysis, Cost-effectiveness analysis, cost-utility analysis |
| **c) If cost-effectiveness information is considered, what kind of perspective must be used for the cost-effectiveness assessment?** | | |
| No information (focus only on specific methods) | No information | Societal perspective |
| **d) If cost-effectiveness information is considered, is estimation of uncertainty mandatory (e.g. confidence intervals)?** | | |
| No information (focus only on specific methods) | No information | Sensitivity analyses |
| **e) If cost-effectiveness information is considered, are threshold used to determine whether technology is cost-effective?** | | |
| No information (focus only on specific methods) | No information | No information |
| **8. Other aspects** | | |
| Emphasize that some methodological principles may be more difficult to apply when assessing medical devices and health technologies (e.g. timing, blinding, randomisation, choice of control or comparator group). Discuss also factors related to operator experience (learning curve, volume of activity). | - | Tabular overview given of methods used by other institutions (e.g. IQWiG, MSAC).  Development of a list of questions to estimate the evidence base of diagnostic procedures including links to relevant sections in the document (intended as a support tool for decision makers).  Emphasize existing research lacks (e.g. reference standard). |

1. Focuses on aspects of the clinical efficacy assessment for a new medical device or a new health technology from development on-wards, following feasibility studies. It aims to identify the methods and conditions that allow a high-quality clinical assessment of a medical device to be made. It is intended for manufacturers, research organizations and project developers. [↑](#endnote-ref-1)
2. Developed collectively by DACEHTA and the HTA units of the university hospitals in Aarhus, Copenhagen and Odense. Its goal was to create a flexible tool that is easily available and understandable for health professionals as well as health care managers. [↑](#endnote-ref-2)
3. The report describes the assessment methods of diagnostic technologies used by selected institutions, derived recommendations based on the assessment approaches and develops a list of questions (with links to the relevant sections in the document) as a support tool for decision makers when assessing diagnostic procedures. [↑](#endnote-ref-3)