Supplementary Table 1: Categorization of methods of development-focused Health Technology Assessment from the academic literature

| Methods from review articles | Methods useful in DF-HTA | Notes |
| --- | --- | --- |
| Methods from Markiewicz et al (2014) |  |  |
| *Qualitative* |  |  |
| Literature review/analysis | **Literature review** | Included |
| Peer review |  | Excluded as relevance not clear |
| User profiles building | **Stakeholder consultation** | Included as qualitative method of stakeholder consultation |
| Focus groups |  | Included as qualitative method of stakeholder consultation |
| Interviews (eg. experts) |  | Included as qualitative method of stakeholder consultation |
| Informal discussions |  | Included as qualitative method of stakeholder consultation |
| Qualitative weighing of relevant factors |  | Excluded as unclear what method involves |
| Use cases writing |  | Included as qualitative method of stakeholder consultation |
| Key informant interviews |  | Included as qualitative method of stakeholder consultation |
| Strategic planning methods: PEST, SWOT |  | Excluded – as strategic planning is primarily a commercial activity although these methods may be useful to structure qualitative method of stakeholder consultation. |
| Soft-systems methodology |  | Excluded - research and development process |
| Expert panels/elicitation |  | Included as quantitative method of stakeholder consultation |
| Technology profiling/uncertainty profile and evidence profile) |  | Excluded - research and development process |
| Workshops |  | Included as qualitative method of stakeholder consultation |
| Surveys |  | Included as qualitative method of stakeholder consultation |
| Research and development portfolio management |  | Excluded - other commercial activities |
| Brainstorming sessions |  | Excluded - research and development process |
| Users-producers seminars |  | Included as qualitative method of stakeholder consultation |
| Usability tests |  | Excluded - research and development process |
| Users feedbacks |  | Excluded - research and development process |
| Clinical trials |  | Excluded - research and development process |
| Choice-based conjoint analysis (Discrete choice modelling) |  | Included as quantitative method of stakeholder consultation |
| Horizon-scanning |  | Excluded – horizon scanning is a process using methods such as literature review and stakeholder consultation to identify emerging technologies. It may be useful in DF-HTA to identify barriers to diffusion and relevant comparators for economic evaluation. |
| Preliminary market research |  | Excluded - other commercial activities |
| Bench studies |  | Excluded - research and development process |
| *Quantitative* |  |  |
| Headroom analysis | **Decision Analytic Modelling** | Included under Decision Analytic Modelling |
| Cost-effectiveness analysis |  | Included under Decision Analytic Modelling |
| Probabilistic sensitivity analysis |  | Included under Decision Analytic Modelling |
| Potential years of life lost |  | Included under Decision Analytic Modelling |
| Cost-benefit analysis |  | Included under Decision Analytic Modelling |
| Cost-utility analysis |  | Included under Decision Analytic Modelling |
| Opportunity costs (used as indicators to which relative weights are assigned) |  | Excluded as relevance not clear |
| Road-mapping process (Multi-path Mapping) |  | Excluded - research and development process |
| Scenarios building |  | Included under Decision Analytic Modelling |
| Return on investment |  | Excluded - other commercial activities. Headroom estimates from Decision Analytic Modelling can inform return on investment calculations. |
| Technological forecasting based on epidemiological data |  | Excluded - other commercial activities |
| Rudimental analysis of costs |  | Included as cost-minimisation analysis under Decision Analytic Modelling |
| Multi-criteria Decision Analysis (Analytic Hierarchy Process) |  | Included under quantitative methods of stakeholder consultation |
| Expected value of perfect information |  | Included under Decision Analytic Modelling |
| Bayesian modelling/statistics (data pooling, random effects analysis) |  | Included under Decision Analytic Modelling |
| Probabilistic risk analysis |  | Excluded - research and development process |
| Real options analysis |  | Excluded - other commercial activities. Headroom estimates from Decision Analytic Modelling can be combined with a form of real options analysis. |
| Best-worst scaling |  | Included as quantitative form of stakeholder consultation |
| Decision tree analysis |  | Included under Decision Analytic Modelling |
| Methods from Ijzerman and Steuten (2011) |  |  |
| Payback from research analysis |  | Excluded - other commercial activities |
| Strategic business case |  | Excluded as umbrella term |
| Health impact assessment |  | Excluded as umbrella term |
| Multi-criteria Decision Analysis (Analytic Hierarchy Process) |  | Excluded as duplicate |
| Choice-based preference methods (discrete choice experiments and conjoint analysis) |  | Included as quantitative form of stakeholder consultation |
| Real options analysis |  | Excluded as duplicate |
| Health economic modelling |  | Included under Decision Analytic Modelling |
| Horizon-scanning systems |  | Excluded as duplicate |
| Clinical trial simulation |  | Excluded - research and development process. |
| Value of information analysis |  | Included under Decision Analytic Modelling |
| Methods from Redekop and Mikudina (2013) |  |  |
| Early health economic modelling |  | Included under Decision Analytic Modelling |
| Clinical trial simulation |  | Excluded as duplicate |
| Multi-criteria Decision Analysis |  | Excluded as duplicate |
| Headroom |  | Included under Decision Analytic Modelling |
| Bayesian analytical framework |  | Included under Decision Analytic Modelling |
| Value of Information analysis |  | Excluded as duplicate |
| Methods from Miller (2005) |  |  |
| Clinical Trial Simulation |  | Excluded as duplicate |
| Option Pricing |  | Excluded as synonymous with real option analysis |
| Investment Appraisal |  | Excluded as umbrella term |
| Threshold analysis |  | Included under Decision Analytic Modelling |
| Value of information analysis |  | Excluded as duplicate |
| Methods from Hartz and John (2008) |  |  |
| Early health economic modelling |  | Excluded as duplicate |
| The Bayesian Analytical Framework |  | Excluded as duplicate |
| Value of information analysis |  | Excluded as duplicate |
| Clinical trial simulation |  | Excluded as duplicate |
| Methods from Bartelmes (2009) |  |  |
| Analytic Hierarchy Process |  | Included as quantitative methods of stakeholder consultation (form of Multi-criteria decision analysis) |
| Stated-preference methods |  | Included as quantitative method of stakeholder consultation |
| Expert systems |  | Excluded - research and development process |
| Fuzzy logic |  | Excluded - other commercial activities |
| Bayesian methods |  | Excluded as duplicate |
| Decision analytic models (e.g. Markov models) |  | Excluded as duplicate |
| Pharmacokinetic and pharmacodynamic modelling |  | Excluded - research and development process |
| User-centred design |  | Excluded - research and development process |
| Failure and reliability analysis |  | Excluded - research and development process |
| Real-options analysis |  | Excluded as duplicate |
| Pre-protocol research |  | Excluded - research and development process |
| Tracker-trials |  | Excluded - research and development process |
| Constructive Technology Assessment |  | Excluded as umbrella term |
| Iterative economic evaluations |  | Included under Decision Analytic Modelling |
| Evaluation frameworks for information technologies |  | Excluded as not development-focused |
| Methods from Graziadio (2020) |  |  |
| Articulating value propositions |  | Included as Qualitative methods of stakeholder consultation |
| Care pathway analysis |  | Discussed as an outcome of literature review, stakeholder consultation and input to decision analytic modelling |
| Clinical validity studies |  | Excluded as research and development |
| Clinical utility studies |  | Excluded as research and development |
| Cost-effectiveness analysis |  | Included under Decision Analytic Modelling |
| Cost-consequences analysis |  | Included under Decision Analytic Modelling |
| Budget impact analysis |  | Included under Decision Analytic Modelling |

**Supplementary Table 2: Definitions of methods of development-focused Health Technology Assessment from the academic literature**

| **Method group** | **Underlying methods** | **Definition** | **Source of definition** |
| --- | --- | --- | --- |
| Literature review | Literature review | “Reviewing a body of text to come up with the critical points of current knowledge including substantive findings as well as theoretical and methodological contributions to a particular topic of interest in the medical device’s development.” “Topic, product or field of interest may refer to different parts of analysis and actions performed during the development of the medical devices, in the fields like: applications, patient populations, patients preferences, usability, cost-effectiveness, etc” | Markiewicz et al  2014 [11] |
| Stakeholder consultation | Qualitative methods of stakeholder consultation | Focus groups – “Method based on asking questions in an interactive group setting where participants are free to talk with other group members, in order to gather the information about perceptions, opinions, beliefs, and attitudes towards a topic/product of interest.” | Markiewicz et al  2014 [11] |
| Workshops – “a method based on creating a setting where participants can benefit from focused interaction with each other. The goal is to discuss and to exchange experiences on a range of relevant topics in medical devices development, during facilitated sessions.” | Markiewicz et al  2014 [11] |
| Interviews – “The qualitative research interview is performed to describe and understand the meanings of central themes in the medical devices development.” | Markiewicz et al  2014 [11] |
| Survey research – “The broad area of survey research encompasses any measurement procedures that involve asking questions of respondents (eg. a short paper and pencil feedback form to an intensive one-on-one in-depth interview) to get the user involvement in the development process.” | Markiewicz et al  2014 [11] |
| Expert opinion – “studies that aim to draw forth the opinions or beliefs of experts expressed in a qualitative format” | Iglesias et al  2016 [24] |
| Expert panels/elicitation (eg. Delphi method) – “A highly structured technique in which selected experts provide their assessment of likely future outcomes of implementing new medical device by responding to several rounds of questions.” | Iglesias et al  2016 [24] |
| Quantitative methods of stakeholder consultation | Multi-criteria decision analysis - “A series of techniques aimed at supporting decision makers faced with making numerous and sometimes conflicting evaluations. Multi-criteria decision analysis aims at highlighting these conflicts and deriving a way to come to a compromise in a transparent process.” | Ijzerman and Steuten, 2011 [7] |
| Discrete choice experiments - Choice-based conjoint analysis (Discrete Choice Modelling) – “Method based on the choice experiments: a test person is confronted with a small number of options sampled from a parameterized space and has to choose his preferred option.” | Markiewicz et al  2014 [11] |
| Structured expert elicitation – ‘formal methods to quantify experts’ beliefs’ | Soares et al  2018 [SM1] |
| Decision analytic modelling | Cost-effectiveness analysis  (cost utility analysis  cost consequence analysis  cost benefit analysis  cost minimisation analysis  estimation of headroom, budget impact analysis) | Cost-effectiveness analysis “compares the relative costs and outcomes (effects) of two or more courses of action to find the best alternative activity, process or intervention that minimises resource use to achieve the desired result”. | Markiewicz et al  2014 [11] |
| Cost-utility analysis – “a method aimed to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries.” | Markiewicz et al  2014 [11] |
| Cost-consequence analysis – “is a form of economic evaluation where disaggregated costs and a range of outcomes are presented to allow readers to form their own opinion on relevance and relative importance to their decision-making context” | Drummond et al  2015 [SM2] |
| Cost-benefit analysis – “a systematic process for calculating if a medical device development project is a sound investment/decision, and to provide a basis for comparing projects.” | Markiewicz et al  2014 [11] |
| Cost-minimisation analysis – “compares interventions based solely on their net cost” | Hunink et al  2014 [SM3] |
| Headroom “is a relatively simple threshold approach … that estimates the maximum amount that a technology could cost and yet still be considered cost-effective.” | Redekop and Mikudina, 2013 [10] |
| A budget impact analysis provides a measure of the affordability of adopting a medical device by  quantifying the effects on the budget of a healthcare provider. | Graziadio et al,  2020 [12] |
| Value of information analysis  (Expected value of perfect information, expected value of partial parameter information, expected value of sampling information) | Value of Information analysis (VOI) – “an analysis aimed at presenting the amount a decision maker would be willing to pay for information prior to making a decision during the medical device development to avoid uncertainty.” | Markiewicz et al  2014 [11] |
| Expected Value of Perfect Information (EVPI)... “reflects the discrepancy between the current information position and a position of no perfect information (no uncertainty)” “population EVPI can provide a measure of the maximum return of future research, placing an upper limit on the societal costs of it”. | Steuten et al  2013 [34] |
| Expected Value of Partial Parameter Information (EVPPI) – “informs us for which specific consequences of the technology (eg. impact on utilities, costs or health status) more information is needed to make a less uncertain decision in the future, again offset by the costs of collecting that further information.” | Steuten et al  2013 [34] |
| Expected Value of Sample Information (EVSI) – “estimates the expected VOI that could be gathered from a sample of a given size *n* within a particular study design, over a specified time period”. | Steuten et al  2013 [34] |

References for the sources of the definitions are included in the main manuscript with the exception of those additional references which are listed below.

[SM1] Soares MO, Sharples L, Morton A, Claxton K, Bojke L. Experiences of structured elicitation for model-based cost-effectiveness analyses. Value in Health. 2018 Jun 1;21(6):715-23.

[SM2] Drummond, M. F., Sculpher, M. J., Claxton, K., Stoddart, G. L. & Torrance, G. W. 2015. Methods for the economic evaluation of health care programmes, Oxford university press.

[SM3] Hunink, M.M., Weinstein, M.C., Wittenberg, E., Drummond, M.F., Pliskin, J.S., Wong, J.B. And Glasziou, P.P., 2014. Decision making in health and medicine: integrating evidence and values. Cambridge University Press.