

23 September 2021

Technical annex: Sensitivity analyses

Objective

This technical annex aims to support the preparation of applications to the Danish Health Technology Council with respect to enquiries regarding the use of health technology, including medical devices, but also other types of diagnostic devices, as well as treatments, rehabilitation, prevention, and types of organisation and collaboration in the provision of healthcare services. In the following, 'health technology' is used as an umbrella term for all of these.

This technical annex deals with the of sensitivity analyses in relation to the economic analysis. In collaboration with the Danish Health Technology Council secretariat, the expert committee may set specific requirements for the sensitivity analyses to be prepared in relation to the economic analysis intended to be part of the application. If an applicant is to draw up a best case/worst case scenario analysis and/or probabilistic sensitivity analysis, the sensitivity analyses should be carried out on the basis of the approaches described in this annex.

The design of the economic analysis will always reflect the health technology under examination, including its core outcome and the context in which it is to be used. The analysis design will never be more comprehensive than the expert committee considers necessary.

The approaches and methods set out in this technical annex should be considered as guidelines and therefore it is recommended that they be applied as the basis for drafting applications to the Danish Health Technology Council. However, the Danish Health Technology Council is aware that there may be situations in which it makes sense to deviate from the recommendations in this document. In such cases, the applicant should account for the reasons.

For further information concerning sensitivity analyses, see other texts [1–3]. See also the Danish Health Technology Council's [Process guide](#) and [Methods guide](#) for further information on applications to the Danish Health Technology Council. The Danish Health Technology Council's methods guide is subject to regular updating, so make sure to check out www.behandlingsraadet.dk for any recent updates. If there are further queries about specific areas, these may be clarified in dialogue with the Danish Health Technology Council secretariat after publication of the evaluation design.

1. Best case/worst case scenario analysis

The approach below should be followed when an applicant is to prepare a best case/worst case scenario analysis. Applicants may also submit this analysis at their own initiative. The purpose of the best case/worst case scenario analysis is to show the outcome of the economic analysis under extreme assumptions about the input parameters.

The best case/worst case scenario analysis illustrates the results of the economic analysis in two scenarios:

1. A scenario in which the intervention appears best possible (best case) relative to its comparator(s) within reasonable limits
2. A scenario in which the intervention appears worst possible (worst case) relative to its comparator(s) within reasonable limits

In the best-case scenario, all parameters for the intervention are set at the most favourable values within their plausible intervals (e.g. the lowest risk of adverse effects, lowest costs, highest health-related quality of life, lowest mortality, etc. relative to the confidence or uncertainty ranges applied). Correspondingly, all parameters for the comparator(s) are set at the least favourable values for the comparator(s) within their plausible intervals (e.g. the highest risk of adverse effects, highest costs, lowest health-related quality of life, highest mortality, etc. relative to the confidence or uncertainty ranges applied).

In the worst-case scenario, all parameters for the intervention are set at the least favourable values for the intervention within their plausible intervals (e.g. the highest risk of adverse effects, highest costs, lowest health-related quality of life, highest mortality, etc. relative to the confidence or uncertainty ranges applied). Correspondingly all parameters for the comparator(s) are set at the most favourable values for the comparator(s) within their plausible intervals (e.g. the lowest risk of adverse effects, lowest costs, highest health-related quality of life, lowest mortality, etc. relative to the confidence or uncertainty ranges applied).

Note that the best case/worst case scenario analysis does not indicate the probability of these scenarios occurring. The analysis is based on probable inputs, but there is no information on whether it is realistic that all the parameters take these values at the same time. As such, the best case/worst case analysis shows extreme scenarios with no certainty that they will ever arise.

2. Probabilistic sensitivity analysis

Preparation of a probabilistic sensitivity analysis is not standard in reporting on the economic analyses submitted to the Danish Health Technology Council. However, the expert committee may state in the evaluation design that the applicant is to prepare a probabilistic sensitivity analysis. Applicants may also submit a probabilistic sensitivity analysis with the economic analysis, at their own initiative, if they consider this informative.

As far as possible, the applicant should base the probability distributions in the probabilistic sensitivity analysis on the data basis available to the applicant. If the applicant does not have empirical data on the likely uncertainty of the parameters used in the model, the input parameters should nevertheless be ascribed a probability distribution to reflect that the average values of the parameters are probably not exact. If the applicant has ascribed probability distributions to the parameters without being able to draw on empirical evidence, the applicant should account for how uncertainty has been estimated. The applicant should account for the rationale behind the probability distributions ascribed to each model input, irrespective of whether it is based on empirical data or theory [1].

The following applies for reporting the probabilistic sensitivity analysis:

- If the economic analysis consists of a cost-effectiveness analysis or a cost-utility analysis, it is recommended that the applicant presents the results of the probabilistic sensitivity analysis in the form of a scatter plot and a cost-effectiveness acceptability curve.
 - If the economic analysis includes two interventions (the health technology under examination and one comparator), the applicant should present the probabilistic sensitivity analysis in an incremental cost-effectiveness scatter plot and a cost-effectiveness acceptability curve.
 - If more than two interventions are included, the applicant should present the probabilistic sensitivity analysis in a cost-effectiveness scatter plot and a cost-effectiveness acceptability curve.
- If the economic analysis consists of a cost analysis, the applicant may present the results of the probabilistic sensitivity analysis in the form of a histogram.
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3. References

1. A. Briggs, M.J. Schulpher, K. Claxton, Decision Modelling for Health Economic Evaluation, 1st ed., Oxford University Press, Oxford, 2006.
2. M. Drummond, M.J. Schulpher, K. Claxton, G.L. Stoddart, G.W. Torrance, Methods for the Economic Evaluation of Health Care Programmes, 4th ed., Oxford University Press, Oxford, 2015.
3. J. Fox-Rushby, J. Cairns, Economic Evaluation, Open University Press, 2005.