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Technical annex. Health-related quality of life

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.

In collaboration with the Danish Health Technology Council secretariat, the expert committee may set specific requirements in the evaluation design as to how the significance of the intervention for health-related quality of life (HRQoL) is to be described in relation to the application, for example when using patient-reported outcomes (PRO) data. This annex deals with handling data on outcomes evaluated in the form of the impact on HRQoL, including the types of data that the Danish Health Technology Council recommends that the applicant uses in analyses (when this is assessed relevant in the evaluation design). Specifications of the degree to which and how the significance for HRQoL is to be described will always reflect the characteristics of 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 general information concerning HRQoL, see other texts [1–4]. 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. Instruments to measure health-related quality of life

HRQoL can be measured through generic and disease-specific instruments that focus on the overall and disease-specific elements likely to be significant for HRQoL. Generic instruments typically focus on general conditions such as pain level, ability to carry out normal activities, energy level, etc. while disease-specific instruments focus on aspects related to the specific disease being studied,

usually with respect to symptoms and treatment. As different instruments focus on different aspects of HRQoL, they do not necessarily give the same estimate of HRQoL.

The technology's core outcome, the context and the purpose of the evaluation, determine which instrument is optimal to examine how a given health technology affects patient HRQoL.

If, in an application, an applicant has to draw up a cost-utility analysis, the Danish Health Technology Council generally recommends that applicants use data collected through the generic EuroQoL-5Dimensions-5Levels (EQ-5D-5L) questionnaire when estimating quality-adjusted life years (see also the technical annex on health economic modelling) To ensure coherence between data on patient HRQoL (and across applications) and data included in the economic analysis, the Danish Health Technology Council therefore recommends that applicants apply EQ-5D-5L data to assess HRQoL if this is possible.

However, there may be reasons for using other instruments than the EQ-5D-5L questionnaire when estimating how the technology affects HRQoL: including the availability of data. Therefore, the Danish Health Technology Council also accepts other instruments to assess HRQoL, provided there are validation studies of these. As different instruments have different strengths and weaknesses, applicants should account for the appropriateness of the instrument(s) used to estimate patient HRQoL in a given evaluation when the EQ-5D-5L questionnaire is not used. These instruments may include generic questionnaires and disease-specific questionnaires (such as Short Form (SF)-36 and Cystic Fibrosis Quality of Life (CFQoL)). In the evaluation design, the expert committee may specify which instrument is to be used to estimate patient HRQoL.

2. Use of literature-based data on health-related quality of life

If the applicant's estimates of the effect on HRQoL of the health technology under examination are literature-based, the applicant should handle these estimates as described in section 6.4 of the methods guide from the Danish Health Technology Council.
If the applicant reports data from international studies in which foreign preference weights are used when reporting EQ-5D-5L data, for example, the applicant should report these as described in section 3.2.

In cases where the applicant has several studies on how the health technology under examination affects HRQoL, and in which different instruments have been applied, the Danish Health Technology Council will generally give priority to studies in which generic instruments have been applied to measure the HRQoL. Of the generic instruments, the Danish Health Technology Council gives the highest priority on the EQ-5D-5L questionnaire, however taking into account the core outcome of the health technology under examination, the quality of the studies, representativeness for the study population, etc., as well as any specifications the expert committee may have.

3. Use of empirical data on health-related quality of life

If the applicant has empirical data on how the health technology under examination affects patient HRQoL, the applicant should describe the points below in the report. This applies, irrespective of the instrument used to investigate how the technology affects patient HRQoL.

- Description of the number and the percentage of patients for whom HRQoL data is available on different follow-up times during the study period.

- Description and analysis of non-response to the questionnaire (missingness) and any trends or correlation in this.
- Description of the imputation method used if data is imputed. The description should include how missing data is dealt with, given expectations regarding missingness. The applicant should provide a full description of the methods applied.
- Description of the statistical models applied, including a full description of assumptions in the models as well as the co-variables used. The applicant should also describe any differences in the baseline HRQoL between the interventions included.

For an elaboration on managing missing data for HRQoL, including identification of the type of missingness and any imputation, etc., see the article by Faria et al. [5].

3.1 Use of EQ-5D-5L data

As the Danish Health Technology Council generally recommends estimating HRQoL on the basis of EQ-5D-5L data, the process of estimating HRQoL is briefly summarised here for the EQ-5D-5L questionnaire.

The process for estimating HRQoL using the EQ-5D-5L questionnaire is divided into two steps:

1. Patients whose HRQoL is to be identified complete the questionnaire, for example in relation to a clinical study.
2. HRQoL is estimated on the basis of the patient responses to the EQ-5D-5L questionnaire. This is done by attributing an index value to the health state based on the Danish preference weights (see below).

When the applicant has EQ-5D-5L questionnaire responses available, the Danish Health Technology Council recommends that the applicant use weights that represent preferences for a representative cross section of the Danish adult population to estimate patient HRQoL. The Danish preference weights are stated in the article by Jensen et al. [6].

2. Use of foreign preference weights and weights for sub-populations

If foreign preference weights are used to estimate HRQoL, the applicant should describe how the foreign preference weights differ from the Danish in general as well as how the applicant believes this affects the results. The applicant should also provide a summary of the method applied to derive the preference weights used. This includes a description of the study population applied and the elicitation and statistical methods used.

Similarly, if the applicant applies preference weights for a specific patient population and not for the general population, the applicant should describe how these differ from preference weights obtained for the general population, as well as how this is likely to influence the results. This is because the preference weights may differ, depending on whether they have been taken for a specific patient population or the general population, and depending on which population has been used. The perception of different states of health may vary, depending on whether subjects have experienced a certain condition themselves or have no experience of it, and depending on the surrounding society. For this reason, it is important to state for which population group preferences have been found.

4 References

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