Appendix 7
Checklist for assessing the quality of trialbased health economic studies

REVISION 2017

The SBU checklist for trialbased health economic studies is based on previous checklists [1–3] but has been revised and complemented to suit the SBU work.

Few health economic analyses meet all the checklist requirements. Studies that fail to meet requirements are of course still useful for some purposes. However, the deficiencies should be born in mind when interpreting the results. The overall assessment of study transferability and quality is summarised below, after the respective checklist items have been assessed.

Reviewer, date: _____

Author: _____ Year: _____ Article number: _____

	High	Moderate	Low	Insufficient	Comments
Assessment of the transferability of the study's economic results (Section 2):	❑	❑	❑	❑	
Assessment of the study quality with respect to economic aspects (Sections 3 and 4):	❑	❑	❑	❑	
Assessment of the study quality with respect to the effects and side effects of the intervention (assessed by the project experts):	❑	❑	❑	❑	

1. Study relevance (PICO) in relation to the project research questions For the study to be included, these questions must be answered by "yes"	**Yes**	**No**	**Unclear**	**Not applicable**	**Comments**
For the study to be included, these questions must be answered by "yes"					
a) Is the study population relevant?	❑	❑	❑	❑	
b) Is the intervention relevant?	❑	❑	❑	❑	
c) Is the comparator relevant?	❑	❑	❑	❑	
d) Is the outcome measure relevant?	❑	❑	❑	❑	
2. Transferability of the study's economic results	**Yes**	**No**	**Unclear**	**Not applicable**	**Comments**
a) Are both costs and effects studied (or are the effects assumed to be equal)?	❑	❑	❑	❑	
b) Is the intervention implemented in a sector or by an organisation (e.g. hospital care or a local social service office) that is relevant to the current Swedish context?	❑	❑	❑	❑	
c) Are the unit costs used in the study relevant to the current Swedish context? [1]	❑	❑	❑	❑	
d) Does the extent and type of care or intervention delivered to study participants correspond to what patients/users receive in the current Swedish context?	❑	❑	❑	❑	
e) Do the study have a societal perspective?	❑	❑	❑	❑	
3. Potential conflicts of interest	**Yes**	**No**	**Unclear**	**Not applicable**	**Comments**
a) Is there a low risk that the conflicts of interest declared by the authors may have influenced the study results?	❑	❑	❑	❑	
b) Is there a low risk that a sponsor with an economic interest in the outcome may have influenced the study results?	❑	❑	❑	❑	
c) Is there a low risk of conflict of interest from other sources (e.g. the authors have developed the intervention)?	❑	❑	❑	❑	
4. Quality of the economic analysis	**Yes**	**No**	**Unclear**	**Not applicable**	**Comments**
4.1 Choice of analysis and reporting of results					
a) Is the type of economic analysis justified in relation to the research questions?	❑	❑	❑	❑	
b) Was an incremental analysis of both costs and outcomes performed (or is it possible to calculate)?	❑	❑	❑	❑	
c) Are appropriate statistical methods used?	❑	❑	❑	❑	
d) Are the conclusions consistent with the reported results?	❑	❑	❑	❑	
e) Is the time horizon sufficient to reflect all important differences in costs and effects?	❑	❑	❑	❑	

Continued	Yes	No	Unclear	Not applicable	Comments
4.2 Costs and effects					
a) Is the difference in outcomes between the alternatives statistically significant?	❑	❑	❑	❑	
b) Has the study considered compliance? [2]	❑	❑	❑	❑	
c) Is the proportion of missing data (costs and outcomes) acceptable? [3]	❑	❑	❑	❑	
d) Have all relevant outcomes been identified (including side effects)?	❑	❑	❑	❑	
e) Are the outcomes quantified appropriately?	❑	❑	❑	❑	
f) If the outcome measure is QALYs, are the quality-of-life weights valued appropriately? [4]	❑	❑	❑	❑	
g) Given the perspective of the analysis, have all relevant costs been identified (including those due to side effects)?	❑	❑	❑	❑	
h) Is the resource use quantified appropriately in physical units (e.g. number of social worker visits, number of hospital care days)?	❑	❑	❑	❑	
i) Are the unit costs valued appropriately?	❑	❑	❑	❑	
4.3 Sensitivity analysis					
a) Are all important variables explored in sensitivity analyses? [5]	❑	❑	❑	❑	
b) Is the uncertainty in the result explored using probabilistic sensitivity analysis?	❑	❑	❑	❑	
c) Is the result insensitive to changes in examined variables? [6]	❑	❑	❑	❑	
4.4 Discounting (for studies with a time horizon exceeding 1 year) [7]					
a) Are costs discounted appropriately?	❑	❑	❑	❑	
b) Are outcomes discounted appropriately?	❑	❑	❑	❑	

[1] Provided that that they, if necessary, are converted to Swedish krona [SEK], and adjusted to the current price year according to purchasing power parity (PPP). The following cost converter is used: http://eppi.ioe.ac.uk/costconversion/default.aspx

[2] Has the study considered compliance, possibly supplemented with information on whether analyses were performed according to intention-to-treat (ITT)? Do patients/users and care providers employ the intervention as intended (e.g. the number of sessions in a treatment programme)?

[3] The extent of missing data on costs and quality-of-life might be different from the extent of missing clinical data. A high rate of attrition, differences in attrition rates between groups and, most importantly, differences in reasons for the attrition increase the risk of bias. Here, attrition refers to individuals dropping out after randomization.

Missing data should never be assumed to occur randomly. Attrition bias is less problematic when the characteristics of the individuals in the drop out group are similar to those that remain in the study. The following examples can serve as crude benchmarks of attrition: small (<10%), moderate (10–19%), large (20–29%) and very large (≥30%). When the level of missing data exceeds 30%, the study is often considered to contain no informative value, which might indicate a reason for exclusion.

[4] For example: which tariff was used to elicit the weights for the quality-adjusted life-years (quality-of-life weights)?

[5] Concerns variables containing uncertainty that may influence the results of the analysis. If extrapolations are made from empirical data, it may be important to explore different methods of extrapolating.

[6] Concerns the robustness of the results, i.e. that the sensitivity analyses do not alter the overall conclusions about cost-effectiveness (regarding both one-way and probabilistic sensitivity analysis).

[7] Is the selected approach justified? Different countries have different recommendations. Future costs should be discounted (but the discount rate may vary). For future outcomes, there are arguments both for and against discounting. In Sweden, the Dental and Pharmaceutical Benefits Agency recommends a discount rate of 3% for both costs and effects, but also requires sensitivity analyses with rates of 0 and 5%.

References

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2. Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods for the economic evaluation of health care programmes, 3rd edition. Oxford: Oxford University Press, 2005.

3. Evers S, Gossen M, de Vet H, van Tulder M, Ament A. Criteria list for assessment of methodological quality of economic evaluations: Consensus on health economic criteria. Int J Technol Assess Health Care 2005; 21(2):240-5.