Reviewer's report

Title: From accuracy to patient outcome and cost-effectiveness evaluations of diagnostic tests and biomarkers: an exemplary modelling study

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Reviewer: Ron Leonardus Hubertus Handels

Reviewer's report:

The manuscript represents a decision analytic model estimating the cost-effectiveness of TEE versus manual palpation and elaborate on the added value of modeling to RCT-based research. Although the analysis are solid and the advantages of using decision models to RCT-based research methods are clearly described I have several concerns:

MAJOR

1. I have trouble linking the introduction and discussion to the methods, results and conclusion. Attention is drawn to the added value of decision modeling to RCT-based research and it is also discussed extensively (e.g. it is “showed that model-based (cost-)effectiveness of diagnostics tests are feasible and can rapidly, at relatively low costs, provide insights into the value of the use or introduction of a new test or marker in terms of improved patient outcomes”). Therefore the aim seems twofold: estimate cost-effectiveness of TEE and showing the added value of modeling to RCT-based research. However, no methods are described to quantify or quality the added value of modeling to RCT-research.

2. I find it difficult to get through the introduction and distinguish side issues from main arguments. It might be shortened.

3. The aim is to “illustrate the use of such decision analytic modelling”. Have other studies tried to illustrate this and what is the added value of this study? 4. The discussion should elaborate more on the results of this study in relation to other studies with similar aim.

5. Table 1: Utility of the ‘No complications’ health state is estimated 1. This assumption is not described in the model assumptions paragraph. Besides, when measuring utility in a control group (e.g. with EQ-5D or VAS scale) it might be scored lower than 1. Perhaps a utility of the general population in similar age groups can be applied. Otherwise expert opinion might provide a best estimate and a confidence interval to include it in the probabilistic sensitivity analysis.

DISCRETIONARY

1. The discount rate for effects of 4% is stated in the table while in the text 1.5% is stated.

Table 2: besides life-years after surgery it would be interesting to add the QALY after surgery to the table for both strategies.
2. please rephrase: "Based on the combined sources of evidence, the long term course of hypothetical individuals can be while tracking risk factors, events, procedures, quality of life, and costs, to assess health impact, comparative effectiveness, and incremental cost-effectiveness of the use of a new diagnostic test, marker or strategy."

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests