Health Economic Model For Novel In Vitro Diagnostic Kit For Infective Endocarditis

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Introduction

The presented economic model estimated costs and benefits of a novel in vitro diagnostic kit for infective endocarditis (IE), developed by Hutman Diagnostics AG (Basel, Switzerland). This new product applies molecular diagnostics to detect bacteria in cardiac tissue faster (see Fig. 1).

The focus of the model is set on the diagnostic procedures of Endocardi-Gene® Tissue (Fig. 1) and of the gold standard procedure as benchmark i.e. is microbial culturing (MC), with respect to cost relevant parameters. Based on these parameters the model describes the expected areas of cost-saving potentials for the diagnostic and therapeutic procedure with respect to the aetiopathology of IE and estimates expected savings for an individual patient in a standard hospital and scales these numbers up for Switzerland (CH), Germany (GER) and the United Kingdom (UK).

In a bottom-up approach initial results are derived for one patient and three development scenarios potentially occurring during aetiopathology of IE in a standard hospital. Hereby country-specific cost structures were taken into considerations. Based on these results and annual statistical data for the expected number of treated patients estimates for the annual costs and potential savings for all three countries are derived.

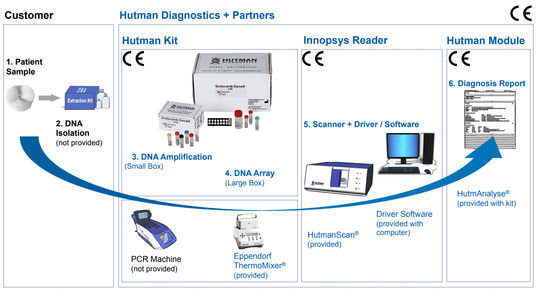

Fig.1: Steps of the novel in vitro diagnostic kit for infective endocarditis by Hutman Diagnostics AG.

Methods

Decision tree for aetiopathology of IE

As the novel kit provides results within 4-6 hours after sampling instead of 2-3 days by MCs, the following three main outcome scenarios (S) for aetiopathology of IE were investigated by establishing a decision tree:

S1 - Adjusted hospitalisation and treatment: Decreased average hospitalisation and earlier specific antibiotic treatment due to quicker diagnosis.
S2 - Reoperation: Reduction of reoperation frequency.
S3 - Influence on mortality of recurrent and uncontrolled IE: Reduction of mortality due to fistula formation.

Statistics for decision tree

The quantitative model uses statistical data for the decision tree from literature and interviews with clinical experts.

Assumptions for Switzerland:

- Incidence of IE cases of 3.1/100'000 population and year [10]
- Implication of required surgery in about 50% of all IE patients [1-3, 5, 9, 11]
- Pathogen identification before surgery in about 80% of all cardio-surgery patients [6]
- average operative mortality of 10% [4]

In conclusion, for CH these assumptions lead for **S1** to 67.1 patients on average per year with definitive IE but without diagnosis for a specific pathogen after cardiosurgery by assuming Respective figures for GER and the UK and cases in **S2** and **S3** are depicted in Table 1.

Table 1: Average incidence for IE and potential cases without specific diagnosis after cardiosurgery of Switzerland, Germany and UK [7, 8, 10]

	CH	GER	UK
Average incidence of IE [cases per 100'000 population and year]	3.1	3	6.5
Relevant population (EC, 2013)	8'039'060	80'523'746	63'890'710
S 1 [cases/country and year]	67.1	694.5	1'448.7
S 2 [cases/country and year]	6.5	68.7	154
S 3 [cases/country and year]	0.4	7.1	9.5

These basic data allow estimating potential cost savings comparing the two diagnostic procedures for the three countries.

Economic parameters

Parameters quantified for both diagnostic procedures were following:

- **Capital costs:** includes additional equipment needed
- **Diagnostics:** includes labour costs, costs for the related diagnostic method and specific required (e.g. DNA isolation)
- **Reoperation:** costs for cardiac surgery
- **Antibiotics:** difference in costs for empiric and specific antibiotics
- **Hospitalisation:** difference in duration of hospitalisation
- **Productivity losses:** costs due to absence at patients' working places
- **Productivity losses YLL:** costs due to premature death of patients and the years of life lost (YLL)

The outcome spectra and their economic performance were transferred into potential savings due to Endocardi-Gene® Tissue.

Results

The potential savings per patient and country for each scenario are presented in Table 2 in national currency as well as in Euros.

Table 2: Potential savings in main outcome scenarios per patient, year and country due to the application of Endocardi-Gene Tissue®.

Country	Switzerland		Germany	United Kingdom	
Currency	[CHF/p]	[€/p]	[€/p]	[£/p]	[€/p]
S1	4'104	3'367	1'533	741	916
S2	275'831	226'254	144'424	93'961	116'038
S3	2'173'175	1'782'573	946'476	687'641	849'211

The highest savings per patient could be generated in Switzerland for all three scenarios, followed by Germany and UK.

In **S1** the relevant cost parameter for the savings due to Endocardi-Gene® Tissue is the shorter hospitalisation. The main cost saving factors for all investigated countries in **S2** are also mitigation of productivity losses YLL, shorter hospitalisation and avoidance of reoperation. **S3** could potentially provide the highest savings due to the avoidance of premature mortality and the related productivity losses due YLL.

Potential financial and economic cost savings of up to almost 29 Mio £ (35 Mio €) in UK, 22 Mio € in GER and 3.9 Mio CHF (3.2 Mio €) in CH per year could be realised by using Endocardi-Gene® Tissue as diagnostic procedure instead or together with the standard procedure of microbiological culture as summarized in Table 3.

These savings are estimated based on the total amount of all three scenarios: 74 patients in CH, 770 patients in GER and about 1'612 patients in UK per year.

Table 3: Potential savings and related cost parameters per year and country due to the application of Endocardi-Gene Tissue®.

Cost parameters	CH [CHF/a]	GER [€/a]	UK [£/a]
Capital costs	21	184	342
Diagnostics	-9'901	-97'739	-162'999
Antibiotics	50'667	1'944'596	348'075
Reoperation	225'835	131'491	3'583'640
Hospitalisation	474'450	3'245'375	1'779'075
Productivity losses	58'087	276'352	442'640
Productivity losses YLL	3'091'358	16'709'722	22'607'794
Total	**3'890'518**	**22'209'980**	**28'598'567**

Conclusions

Due to current clinical reality and according to Duke's criteria it is assumed that Endocardi-Gene® Tissue would not replace microbiological culturing completely, but could complement the standard diagnostic procedure and display its advantages in speed.

in CH main contributing cost factors relevant for potential savings are in the same order as follows: the mitigation of productivity losses YLL, shortage of hospitalisation and avoidance of reoperation.
In GER the same order is shown for cost parameters. Furthermore, productivity losses and adapted antibiotic treatment have a financial impact yet in GER with a shared amount of about 400'000 €/a.
In the UK reduction in productivity losses YLL also accounts the most for potential savings. But following avoidance of reoperation contributes the second most before shorter lengths of stay in hospital due to lower relative costs per hospital day and patient in an average UK hospital compared to GER and CH.

Additional economic benefits from earlier and more targeted treatment for different complications of IE (e.g. risk for systemic embolism) can be expected and are not taken into account in this study. Furthermore, operation and maintenance costs in more diverse outcome scenarios as well as the influence on long-term mortality could contribute to a higher level of detail and exactness.

Therefore, it is recommended to verify the assumptions and estimated potentials supplementing this study with additional data and information from pilot studies and clinical trials with Endocardi-Gene® Tissue.

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