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# Probability Elicitation to Inform Early Health Economic Evaluations of New Medical Technologies: A Case Study in Heart Failure Disease Management

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## ABSTRACT

**Objectives:** Early estimates of the commercial headroom available to a new medical device can assist producers of health technology in making appropriate product investment decisions. The purpose of this study was to illustrate how this quantity can be captured probabilistically by combining probability elicitation with early health economic modeling. The technology considered was a novel point-of-care testing device in heart failure disease management. **Methods:** First, we developed a continuous-time Markov model to represent the patients' disease progression under the current care setting. Next, we identified the model parameters that are likely to change after the introduction of the new device and interviewed three cardiologists to capture the probability distributions of these parameters. Finally, we obtained the probability distribution of the commercial headroom available per measurement by propagating the uncertainty in the model inputs to uncertainty in modeled outcomes. **Results:** For a willingness-to-pay value of €10,000 per life-year, the median headroom available per

measurement was €1.64 (interquartile range €0.05–€3.16) when the measurement frequency was assumed to be daily. In the subsequently conducted sensitivity analysis, this median value increased to a maximum of €57.70 for different combinations of the willingness-to-pay threshold and the measurement frequency. **Conclusions:** Probability elicitation can successfully be combined with early health economic modeling to obtain the probability distribution of the headroom available to a new medical technology. Subsequently feeding this distribution into a product investment evaluation method enables stakeholders to make more informed decisions regarding to which markets a currently available product prototype should be targeted.

**Keywords:** early health economic modeling, headroom analysis, heart failure disease management, probability elicitation.

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## Introduction

Investment in the research and development of new medical technology typically results in several promising product concepts. There is usually, however, insufficient funding to further develop each of these concepts into concrete products that can be brought to the market. This forces producers of medical technology and other stakeholders, such as venture capitalists and funding agencies, to already decide early during the product development process which of these concepts to abandon and which of them to push forward for further development [1–5].

In the current practice of product investment decision making, such decisions often seem to be based on potentially arbitrary representations of the expected improvements in outcomes and costs resulting from the use of the new technology. A factual representation of the current care situation and the specific changes that are likely to occur after the new technology has been fully adopted is generally not elaborated. Thus, decisions regarding the selection of suitable target markets for a currently available prototype technology are reached in a

similarly arbitrary way. Early-stage health economic modeling has recently been suggested as a tool for supporting product investment decision making in a more formal way as it can provide insight into the maximum additional cost at which the intended clinical use of the new technology in a selected target market is still deemed cost-effective [3]. This upper bound on the technology's maximum cost, also known as the commercial headroom available [4,6], can then be fed into an appropriate product investment evaluation method to determine whether further development of the prototype technology is likely to yield sufficient return on investment [7,8].

In early-stage health economic evaluations, there is usually only a limited amount of data available with regard to the performance of the new technology, leading to high uncertainty in the values of some of the model inputs [9]. Expert judgment therefore needs to be relied on to obtain initial estimates of those parameters for which sufficient clinical evidence is not yet available. Probability elicitation (PE) refers to a set of techniques for formulating one or more experts' beliefs about the unknown parameters into a probability distribution of those parameters

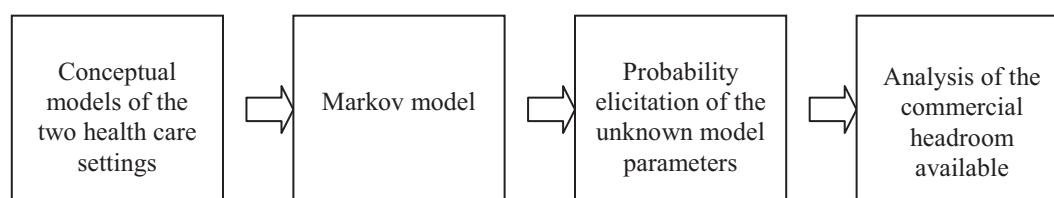
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**Fig. 1 – Schematic representation of the approach used in this article.**

[10,11]. Previous work already described how PE can be applied to handle parameter uncertainty in health economic models [12–14]. In this article, we take the use of this approach one step further by illustrating how PE can be combined with early health economic modeling to obtain the probability distribution of the commercial headroom available to a novel point-of-care testing (POCT) device, which is defined as laboratory testing at or near the patient, in the disease management of patients with heart failure (HF).

## Methods

The approach that we used for combining PE with early health economic modeling is summarized in Figure 1. First, conceptual models of the current care setting (e.g., the health care setting in which the conventional disease management strategies are applied) and the new care setting (e.g., the health care setting in which the novel POCT device is introduced) were developed. Then, a continuous-time Markov model that appropriately reflects the disease progression in patients under the current care setting was developed. Next, the model parameters that are likely to change under the new care setting were identified. These served as the unknown Parameter(s) of Interest (uPoI) for which PE was subsequently conducted. Finally, the commercial headroom available was calculated and its uncertainty was captured probabilistically by propagating the uPoI distributions.

### Conceptual Models of the Two Health Care Settings

The current care comparator depends on the clinical setting in which the POCT device will be applied after it has been brought to the market. As this device could potentially be used in different clinical settings (e.g., outpatient clinic, home setting), we used semi-structured interviews to learn from the clinical experts in which setting the introduction of the POCT device was likely to generate the highest clinical impact. As none of the cardiologists could see any value in the use of this device in the outpatient setting, we decided to focus the early health economic assessment around the introduction of the POCT device in the home setting. More detailed assumptions on how the device would affect the care pathway when introduced in this setting were subsequently elicited from the same experts. Based on the results of these interviews, the current and new care settings were defined as follows:

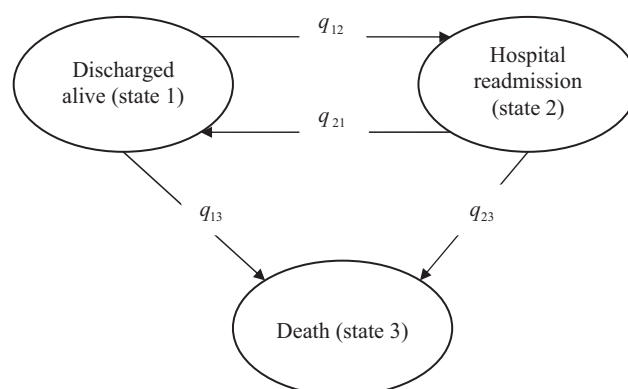
- The current care setting consisted of several follow-up visits to the cardiologist and of additional support provided by nurses with special education and training in HF management. During the first 4 months after discharge, patients on average have one visit to the cardiologist and four visits to one of the HF nurses. After this initial period, the number of outpatient visits reduces to a yearly follow-up visit to the cardiologist. After an HF-related readmission, the above visiting frequency was repeated.
- The new care setting consisted of the introduction of the novel POCT device in the home setting to allow for more efficient monitoring of an HF patient's disease progression. The home measuring itself was not expected to change the outpatient visiting frequency.

### Markov Model

To estimate the expected health outcomes and costs under the current care setting, we developed a continuous-time Markov model with three health states (Fig. 2): discharged alive from hospital, HF-related hospital readmission, and death. For practical purposes, the transition intensities were assumed to be constant over time and independent of patient-related risk factors. We used the data collected during the Coordinating Study Evaluating Outcomes of Advising and Counseling in Heart Failure (COACH), one of the largest multicenter, randomized controlled trials of nurse-led disease management programs in HF [15,16], to estimate the current care model parameters. To be consistent with our description of the current care setting, we included all patients from COACH who received additional basic or intensive support from a nurse specialized in the disease management of patients with HF. This resulted in a total sample size of 684. To make the model of the current care setting probabilistic, simple random sampling with replacement was conducted to obtain 10,000 resamples of equal size to the original sample. For each bootstrap resample, the current care transition intensities were subsequently estimated by using the msm package for R [17], resulting in 10,000 realizations from the joint probability distribution of the current care transition intensities. Unit costs for outpatient visits and HF-related hospitalization were taken from Postmus et al. [18] and set to be equal to €110/visit and €769/d, respectively.

### Probability Elicitation of the Unknown Model Parameters

The transition intensities of the continuous-time Markov model were identified as the uPoI for the new care setting. The same three cardiologists who assisted in developing the conceptual models of the two health care settings were invited to take part in the face-to-face PE interviews. We took the suggestions from Soares et al. [13] and expressed the uPoI in terms of more directly observable quantities for which the experts' beliefs were elicited. In particular, let  $T_i$  denote the amount of time spent in health state  $i$ , let  $F_i(t_i)$  denote the proportion of patients who have left health state  $i$  by time  $t_i$ , and let  $P_{ij}$  denote the probability that



**Fig. 2 – Structure of the continuous-time Markov model.**

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