EARLY STAGE ECONOMIC EVALUATION WITH A SMALL MEDICAL DEVICE START-UP COMPANY USING A MARKOV MODEL

Overview

- Common understanding of value between innovator and assessor is required to take new medical devices into adoption.
- Health technology assessment (HTA) bodies are asking medical device startups to justify economic value of their innovations at earlier stages of development.
- The experience of introducing a medical device start-up company to health economics methods is described.
- A basic Markov model is used to assess the potential cost-effectiveness of a wound healing innovation for treating diabetic foot ulcer.

Rationale

- In England and Wales the new Evaluation Pathway Programme for Medical Technologies of the National Health Service (NHS) National Institute for Health and Clinical Excellence (NICE) requires the manufacturer to submit an economic evaluation.
- Minimising uncertainty in early stage decision-making within development and adoption processes can be achieved by the use of formal methods, models and tools.
- This should foster mutual understanding of cost-effectiveness by suppliers, evaluators and buyers.

Process

Through discussion with the manufacturer of an electrical stimulation woundcare device, the main principles of an economic evaluation were highlighted:

- Elucidating the clinical pathway (a diabetic patient whose foot may incur wound)
- Articulating the change made by the innovation (improving healing rate)
- Constructing a decision tree to compare alternatives (versus standard care)
- Developing an economic model (in this case a Markov model)
- Gathering data (costs, probabilities, utilities)
- Assigning costs and benefit measures to the model based on plausible usage scenarios (hospital use, unsupervised home use, supervised home use)
- Dealing with uncertainty (sensitivity of the results to model data and parameters)
- Appreciating the limitations of an early stage model (e.g. no stratification)

Markov Model

![Markov state diagram alongside data from one of the modeled scenarios and one set of conditions (hospital setting, using electrical stimulation, 88% healing rate, low risk patients, mid-range parameters)]](image)

Conclusions

A short-run economic evaluation can benefit both the innovator and the healthcare provider, using modeling as employed by HTA bodies. For the startup innovator, the results provide an indication that the device is reimbursable and confidence of a return on investment if the device is adopted.

An early stage model is not expected to cover all of the nuances of a full model. On the other hand, whilst making clear what the limitations are, a plausible model can be constructed in a short time period (2 weeks) to estimate a measure of value for both the innovator and healthcare provider, one that may be revised post-adoptive if necessary.