

Decision-making tools for medical device development

New products development is vital for company survival in the medical device market. Sukhvinder Johal and Hywel Williams report on techniques to aid selection of which products to focus on.

New products are crucial for the growth and prosperity of any company, especially in the rapidly changing medical device market. Companies must innovate to be successful but this invariably carries some risk and uncertainty. Here we present and discuss three such techniques that the medical device industry might consider adopting to improve early decision-making on new product development.

Unlike the pharmaceutical industry, which is dominated by a few industrial giants with well-defined product development and commercialisation pathways, the medical device industry is far more heterogenous in terms of types of product, potential health gain and risks, size and type of company, and product development processes. Financial returns for a product are therefore much more difficult to predict.

Managers of new medical device projects are faced with the tricky dilemma of whether or not to commit funds and resources to a new product development (NPD) project. The concept screening stage is often the most critical point for investment, and it is here that decision tools can play a part.

Medical device companies use a range of methods to decide on which new products are likely to result in good financial returns, including discounted cash flow through to less tangible approaches such as 'gut feeling' based on experience in the marketplace. Quite often they are used simply because 'that's the way it has been done in the past'.

In a consultation exercise conducted by the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) with senior managers of six industrial partners, five companies said

that they used discounted cash flow (DCF) methods such as net present value, for the economic evaluation of their products.

These techniques take into account the time value of money and discount future costs/returns to the present using an appropriate discount rate, which is set to reflect the perceived risk of the project.

Surprisingly (or perhaps not), the 'simple' payback period method, a method that evaluates projects based on how long it takes to recover the amount of money invested into the project, was used by all of these five companies.

However, most companies said that the techniques do not account for the flexibility and changes within a project lifecycle and they assumed a single line of development for a product.

Companies also used other techniques to assess projects, which were not necessarily based on cash flow analysis including very simple, informal techniques, such as an unstructured peer review, scoring checklists or more complex methods such as decision tree analysis (one company only).

Other major industry sectors have, over the years, faced similar difficulties in dealing with uncertainty in early decision making, yet they have moved on and have used other techniques that have proven to provide better insights into technology values and also to better predict the drivers of the value of such technology.

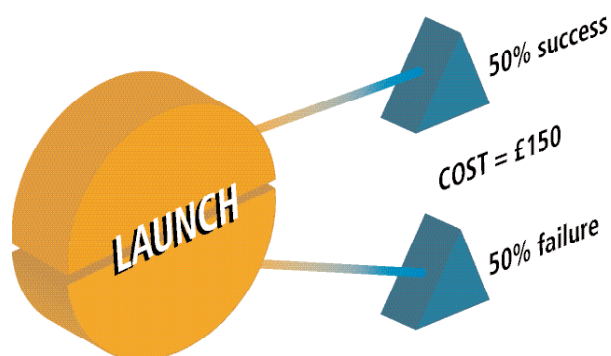
Decision-making tools

The three techniques discussed here generally fall into two categories; strategic and financial valuation of projects (real options) and weighting and scoring of products and product criteria (analytic hierarchy process and conjoint analysis). A third category, not discussed here, includes methods that attempt to mimic human decision-making (fuzzy logic and expert systems).

Real options

Prediction of the profitability and future cash flows quite often drives an initial

Figure 1 (below):
Traditional 'static' valuation



	Revenue	Profit	x	Prob	Expected Profit
←	£400	£250	x	0.5	£125
←	£0	-£150	x	0.5	-£75
Expected Value					£50

business plan, and provides senior management with a quantitative prediction for a product's success even though this is complicated by the inherent subjectivity involved in attempting to predict the future.

A number of financial tools such as discounted cash flow already exist to assist in making decisions about financial returns.

However, these techniques ignore an important business reality – projects rarely proceed as planned and management frequently has to adapt and revise future decisions as new information becomes available or as uncertainties are resolved.

An alternative method to traditional financial valuation techniques, which is increasingly being used in sectors such as pharmaceuticals and oil and gas exploration, is real options analysis (ROA). ROA is based on the theory of option pricing in the financial sector and aims to capture the value of management flexibility.

A financial option provides the holder with the right, but not obligation to buy or sell a specified asset at a specified price in the future.

Similarly, new product development can be thought of as being made up of a sequential nature of investments (opportunities) analogous to options evaluation; there is an opportunity, but not an obligation, to go ahead with that opportunity.

For example, a real option could occur in a research and development process that enables a company to launch a new product in to the market giving the stakeholders the 'right, but not the obligation' to do so. Even if the R&D phase is successful, the market may not yet be favourable for the launch of the new product.

Other examples of options that can be modelled as real options include options to delay, expand, contract,

switch uses, outsource or abandon projects and to license technology.

Consider a simple example in which a firm is assessing whether to launch a new medical device product on to the market. Figure 1 depicts the scenario, with a traditional 'DCF mindset', in which it is assumed that the product will be launched and that it is a yes or no decision. There is a 50% chance of success because of uncertainty relating to the technology and market.

Compare this with Figure 2, which represents a 'real options mindset' applied to the same problem. In this case the senior manager in charge of the launch of new products may choose to launch a pilot study of the product among a few key customers such as a sample of NHS primary care trusts.

Depending on the results of this pilot study, the company is in a better position to decide whether to have a full scale launch or abandon the project.

Although this example is very artificial it demonstrates that RO analysis quantifies the value to decision-makers of additional information in reducing uncertainty.

Not all funding is committed up front and decisions are made as and when new data becomes available. This may well happen informally in practice anyway but traditional valuation techniques tend not to capture the value of a 'wait and see' approach, which can result in the under-valuation of projects.

In this simplified example the extra value created by staging the investment and waiting for further information is £33. Thus real options analysis provides an approach to handling uncertainty in economic evaluation and not only serves as a financial valuation tool but also as a strategic planning tool.

useful in making complex decisions based on a balance of quantitative data (data from the various variables) and qualitative data (judgements about the variables from decision-makers).

In AHP a complex decision problem is first broken down into a hierarchical structure of factors or elements. Generally, the hierarchy has at least three levels: the goal, the criteria, and the alternatives.

In this way the decision problem can be broken down into units of smaller sets of decisions.

For example, a company facing the dilemma of which medical device to develop out of a number of concepts or ideas may set the goal as 'select the best device to invest in'. The criteria could be clinical value, barriers to entry, and market size.

The alternatives are the different project proposals. Figure 3 depicts the hierarchy in this example.

Once the structure has been established, criteria and alternatives are then compared a pair at a time, using a nine point scale, to obtain relative weights indicating the extent to which elements of one level have influence over those of a succeeding level.

These relative weights would be determined by key personnel working on the project, possibly in a brainstorming session. Finally the relative importance of each alternative in meeting the goal is computed.

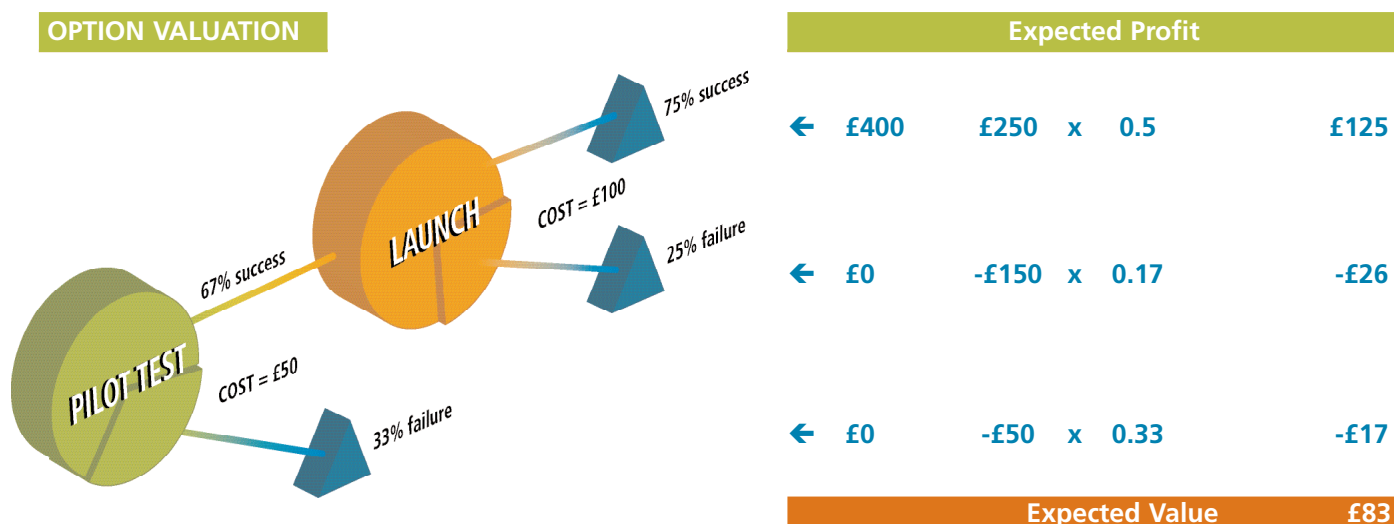
The AHP is relatively simple and cheap to implement by managers to rank projects. Commercial software tools that incorporate the mathematical procedures of the AHP are readily available.

The AHP accommodates uncertain and subjective information and is a systematic methodology that can force decision-makers to make consistent and logical judgments when screening new products.

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"Such tools force decision makers to systematically consider all the factors"

Figure 2 (below):
Capturing the value of management flexibility



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Conjoint analysis

Like AHP, conjoint analysis (CA) has been developed for measuring human perceptions and preferences. Conjoint analysis is sometimes referred to as 'trade-off' analysis because respondents in a conjoint study are forced to make trade-offs or choices between product features.

It is widely used as a marketing research tool for consumer products as well as in pharmaceutical, transportation and service industries. CA attempts to break down a decision into its component parts.

Products or services are defined on a limited number of relevant attributes or characteristics each with a limited number of levels. Conjoint analysis combines these attributes and level descriptions into hypothetical alternative profiles and asks the relevant group of people to rate them.

Respondents are asked to make tradeoffs between the various levels of the different attributes. In a product development scenario, respondents could be the key decision-makers within a company.

A conjoint analysis can then be carried out to determine the 'key drivers' (product features) that would be essential for newly developed products to offer to potential customers.

The process also offers insight into how product development managers go about making investment decisions when selecting projects for financing.

There are various data collection procedures that have been implemented for CA. One method utilises the complete set of attributes by asking the respondents to rank, order, or score a set of cards according to preference.

The objective of CA is to find out what the preference contributions are for each separate attribute and level are and then to determine the relative importance of each attribute to the overall product development decision.

"Medical device companies use a range of methods to decide on new products, including 'gut feeling' based on market experience"

Figure 4 (below): Example of a CA full profile card

New Medical Device Concept 7

• Does the product meet an unmet clinical need?	No
• Level of regulatory hurdles?	Medium
• Any unique features of the product?	Yes
• Is there a patent to protect the product?	Yes
• Potential market share	Over 25%
• Educational capability (to overcome market ignorance)	Medium
• Level of competition rivalry?	Medium
• Expected product gross margin?	Over 50%

Rating

Rate this concept on a 0 to 100 scale
where 0 means "I would not develop this concept"
and 100 means "I would definitely develop this concept"

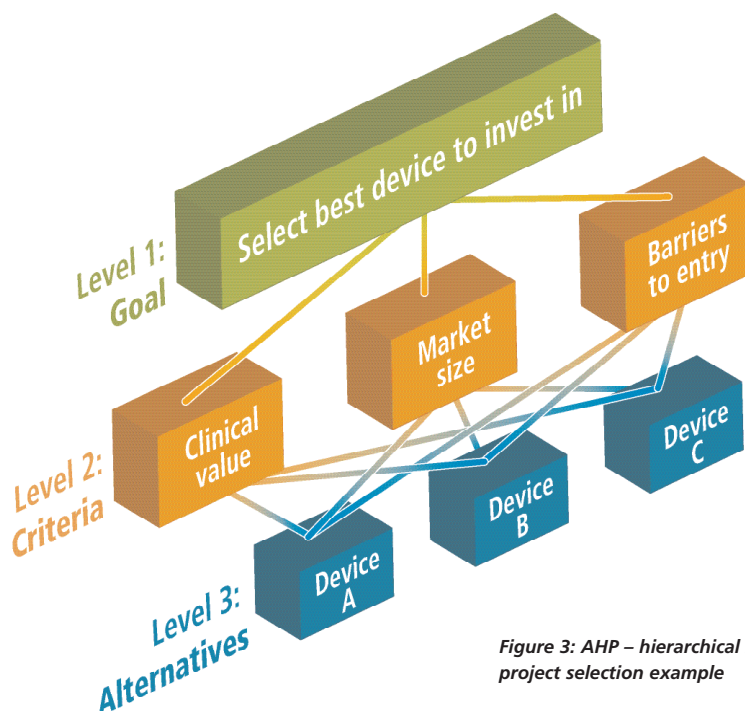


Figure 3: AHP – hierarchical structure of project selection example

Conjoint analysis represents a sophisticated method to elicit customer preferences and has been used extensively by industry to input the 'voice of the customer' into the decision-making process.

Conclusion

This article has presented three techniques that could help managers in the medical device industry in terms of screening concept projects, project valuation, product development and strategic planning.

Although other techniques have been studied for concept screening and new product development such as fuzzy logic, actuarial models, neural networks, technology road mapping and expert systems, the techniques described here have been used extensively and successfully in other industries.

There are, however, three major criticisms of using these or any other decision-making tools.

First, people can become overly focused on the numerical precision of the calculations and the sophistication of the model rather than on the quality or relevance of the data input into the model.

Second, many managers may feel a little intimidated by the complexity of the techniques, and third, such tools require extra resources and are hence a luxury that only 'large' organisations may be able to afford.

The main aim of a decision-making tool should not be just about getting a number or a valuation but should be to force practitioners to think hard about where the uncertainties exist and quantify them.

Also, such tools force decision makers to systematically consider all the

factors and attributes needed to make a good decision for project selection and development, as well as elucidating the interdependencies and interrelationships between the different factors, and to attempt to quantify them.

In terms of complexity and resource, a decision-making tool would probably require a 'decision champion' in an organisation to promote it and encourage its use.

Once implemented in the form of say a software application, should be relatively easy to apply practically to provide an effective input to the decision-making process of new project selection and development in the medical device sector.

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