A Framework to Manage the Early Value Proposition of Emerging Healthcare Technologies

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ABSTRACT

Health service managers and industry face significant challenges in implementing and delivering innovations for healthcare; shrinking budgets mean there is a need to understand more clearly the value of innovations.

An articulation of the value proposition, that is the value created for users by technology, is the key starting point for current thinking on open and innovative business models. The aim of this research is to develop a framework for 'valuing' a new medical device at the concept stage that balances benefit to the healthcare provider against commercial costs. This paper proposes that appropriate evidence-gathering activities such as determination of the clinical value proposition and early health economic tools such as the 'headroom method' can be utilised as part of the development process to contribute to the early stage estimates of value beneficial to both the health service and industry decision makers.

Key Words: innovation; emerging technology; open business model; health technology assessment; value proposition

INTRODUCTION

Healthcare accounts for a significant proportion of the global economy and managing rising healthcare costs is of major concern for all governments, particularly in times of slow economic growth and limited funding. Each year health-related spending grows

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often outpacing spending on other goods and services, meaning that the size of that slice increases. These cost increases have a significant effect on households, businesses and government programmes (Kaiser, 2007). Historically, the advancement of healthcare has been synonymous with the innovation of new medical devices and technologies. Medical devices are a significant and growing industry with a global market size of over US$100 billion (Frost & Sullivan, 2008). For almost 50 years, spending on healthcare has grown by 2 percentage points in excess of gross domestic product growth across all Organisation for Economic Co-Operation and Development (OECD) countries (Drouin et al., 2008). In the United States (US) spending on healthcare accounts for a significantly large proportion of the economy: the US spends about $7,400 per person on healthcare each year. Sixteen per cent of the US economy is devoted to healthcare (Kaiser, 2011). By 2018, national healthcare expenditures in the US are expected to reach $4.4 trillion, which is more than double 2007 spending (Siska, 2009).

The medical device sector today is one of the most innovative sectors, improving and saving lives every day by providing innovative solutions for diagnosis, prevention and treatments (Eucomed, 2010). The largest single healthcare market for new medical devices is in the US, where sales are expected to exceed US$100 billion by the end of 2010 (Frost & Sullivan, 2008). European medical technology sales are estimated to be worth over €72 billion (Wilkinson, 2009). The United Kingdom (UK) accounts for around 11 per cent of the European market and 3 per cent of the global market. Until the economic downturn in mid-2008 the growth rate in the European market was estimated as 5–6 per cent per annum. Some overseas markets have experienced significantly higher growth rates than Europe in recent years, with the Chinese market recording growth close to 11 per cent per annum until 2008 (Quotec, 2009).

Critical to the continued success of healthcare systems in developed nations is managing the adoption of innovative new technologies and medical devices. Doctors today are able to perform operations and procedures that they would not have deemed possible even a decade ago. Future developments in the fields of micromechanical systems, stem cell research, nanotechnology and remote medical informatics have the potential to dramatically change the accepted clinical patient care pathways. As well as this technology push, because of widespread internet access by the public, the patient who visits their doctor or general practitioner today is generally much better informed about their treatment options, which results in a patient pull for innovations that may be at least five to ten years from market as a result of necessary and rigorous regulatory hurdles.

Additionally, many national healthcare budgets are being reduced and healthcare systems are being faced with the possibility of major restructuring. Such is the case with proposals for healthcare reform of the National Health Service (NHS) by the government in the UK; this is currently receiving fierce objections from healthcare professionals. The Royal College of General Practitioners in a recent report raised concerns about charging for healthcare and issues relating to market forces and competition in healthcare (Royal College of General Practitioners, 2011).

There is, therefore, a need now more than ever to research methodologies to determine the early value proposition of new and emerging healthcare technologies. This paper explores the concept of the value proposition from a business model perspective and attempts to illustrate how early health economic approaches such as the headroom method can be applied to value innovative medical technologies in the early stages of development.

LITERATURE REVIEW

The rate of progress of innovations in healthcare in recent times has been most remarkable and the ability to innovate effectively is increasingly viewed as the single most important factor in developing and sustaining competitive advantage (Tidd et al., 2009). Indeed, innovation has become the mantra of organisations looking for economic growth in recent times (Malaviya and Wadhwa, 2005). Mulgan and Albury (2003), in their report on innovation in the public sector, state that bright ideas well implemented can lead to valued new services and the efficient delivery of existing ones at a time when the pressure on national purse strings is becoming even tighter.

Health innovation consists of complex bundles of new medical technologies and clinical services emerging from a highly distributed competence base. Health innovation systems are driven by the combination of institutionally bound interactions or 'gateways' of innovation and history-dependent trajectories of change often referred to as 'pathways' of innovation (Consoli and Mina, 2009).

Significant investment is often needed before a new medical device can enter even the first stage of clinical investigation and in many cases new healthcare technologies take decades to progress from concept to a product on the market as a result of intense and, in some cases, poorly understood regulatory requirements. Faulkner (2009) states that in the emerging area of tissue engineering technological innovation is conventionally seen as outpacing regulation – regulation usually 'lags behind' innovation. New regulatory arrangements are seen as responses to the composition and material qualities of novel technologies and practices. In more prosaic terms, regulation is seen as surveillance, policing, approving or disapproving, accrediting and so on. Thus regulation is not only seen as following innovation, but it is also seen as a socio-political force that is external to technological innovation and acts on it from a socio-political and non-technological realm of society. This adds to the challenges for innovators in the healthcare arena. Unlike the pharmaceutical sector, which has a well-defined route to market, it is generally accepted that the medical device industry has a less cohesive approach to new product development (Dixon et al., 2006).

Innovative Business Models

The need to examine the implicit and explicit business models within an organisation is essential in understanding how innovation actually takes place. History shows that the companies that continue to invest in their innovative capabilities during tough economic times are those that fare best when growth returns (Chesbrough and Garman, 2009). The

cross-disciplinary study of innovation is emerging as a new scientific field which has worldwide impact. There does not seem to be a slowdown in the societal interest for the innovation phenomenon (Fagerberg and Verspagen, 2009). Companies achieve competitive advantage through acts of innovation. They approach innovation in its broadest sense, including new technologies and new ways of doing things (Porter, 1990). Radical, breakthrough innovations create not only great industrial possibilities but also great social uncertainties. When a breakthrough medical technology is discovered the question arises as to whether to accept the possible risks involved or to defer implementing the innovation until more data are available, and, specifically, until others have taken up the innovation and demonstrated its efficacy, relative safety and market acceptance (Baba and Walsh, 2010).

Managers need a framework to help them understand what their organisations are capable of accomplishing (Christensen and Overdorf, 2000). An open business model, when used holistically, forces managers to consider the integrative nature of their business activity from an open innovation perspective.

A business model's great strength as a planning tool is that it focuses attention on how the elements of the system fit into a working practice as a whole, especially in terms of how perceived value is created. Innovation challenges differ from firm to firm and often some firms follow advice that can be wasteful and in some instances even harmful if applied to the wrong situations, but if solutions are tailored to address the right problems the innovation value chain can become a strong asset (Hansen and Birkshaw, 2007).

A business model performs two important functions: it creates value and it captures a portion of that value. A business model captures value by establishing a unique resource, asset or position within that series of activities where the firm enjoys competitive advantage. Open models create value by leveraging many more ideas, due to their inclusion of a variety of external concepts. A successful open business model creates heuristic logic that connects technical potential with the realisation of economic value (Chesbrough, 2006). The economic value of a technology remains latent until it is commercialised in some way. The same idea or technology taken to market through two different business models will yield two different economic outcomes and it can be said that a mediocre technology pursued within a great business model may be more valuable than a great technology exploited via a mediocre business model (Chesbrough, 2010).

Investigation of the elements of a business model is valuable in terms of translating business plans into business processes (Osterwalder and Pigneur, 2009). Chesbrough (2006) identifies six essential functions of a business model:

1. Articulating the value proposition – that is, the value created for users by the offering
2. Identifying a market segment – that is, the users to whom the offering and its purpose are useful
3. Defining the structure of the value chain required by the firm to create and distribute the offering, and determining the complementary assets needed to support the firm's position in this chain

4. Specifying the revenue generation mechanisms for the firm, and estimating the cost structure and profit potential of producing the offering, given the value proposition and value-chain structure chosen
5. Describing the position of the firm within the value network, linking suppliers and customers, including identifying potential complementors and competitors
6. Formulating the competitive strategy by which the innovating firm will gain and hold an advantage over rivals

In a recent paper on innovation in small high-tech medical device firms (Davey et al., 2011) one company stated that even though their technology has proven to be effective in an area that is of high priority to the health service at present they are finding difficulty in getting the necessary regulatory approval that will enable it to be adopted across the NHS because it acts in a different way to other technologies already approved for use. This indicates that having a unique product or technology is not enough to guarantee success within the healthcare sector; the innovative medical device must be shown to have a significantly high perception of value to all stakeholders to be adopted by policy makers in the health service. This is supported by the work of Vallejo-Torres et al. (2008) who state that the rapidly increasing range and expense of new medical devices has created a growing need to demonstrate that a new product is superior to an existing one in terms of value.

Value Propositions in Business and Healthcare

With ever tighter healthcare budgets there is an increasing need to demonstrate value in healthcare. Chesbrough (2006) simply describes the value proposition as the value created for users by the offering.

From a business perspective a value proposition can be understood as the statements of benefits that are delivered by the firm to its external constituencies. Modelling and mapping value propositions helps better understanding of the value a company wants to offer its customers and makes it communicable between various stakeholders. A formal approach to modelling a value proposition allows managers to seize mental models, understand and communicate value propositions, improve their implementation, compare them to the competition and eventually foster innovation (Osterwalder and Pigneur, 2002). The value proposition element of a business model gives an aggregated view of the value a company offers its customers. It can be further decomposed into its set of elementary value propositions. An elementary value proposition is a part of an overall value proposition; it is characterised by its attributes. These attributes capture the analysis of the value proposition and the reasoning as to why it could be valuable to the customer. Not withstanding economic value, at this point social value is created either through use (e.g. driving a car), reduction of the customer's risk (e.g. car insurance) or by making his/her life easier through reduction of his/her efforts (e.g. home delivery of groceries). These attributes – namely use, reduction of risk and reduction of effort – may translate to time or cost savings, which could be beneficial social parameters in which to consider the value of new technologies in the healthcare arena.

As a basis for understanding the challenges that the changing nature of healthcare presents for accurate valuations it is helpful to briefly reflect on certain principles of valuation theory. Economic theory holds that the value of a firm is equal to the present value of the expected future cash flows the company will generate (Damodaran, 2002). Assumptions about the expected future cash flows and the uncertainties of those cash flows, however, often vary among investors. Consequently, the notion of value to whom and under what circumstances becomes important.

Valuations of healthcare companies are largely driven by the quality of the organisation's technology portfolio and management team; however, it is critical to note that good science does not necessarily equate to a viable business proposition and elegant technical solutions are not in themselves sufficient to drive investment (Anderson and Hill, 2006; Cosh et al., 2007). The ultimate success of a technology is its usefulness (Boer, 1999). The clinical problem solved by the technology and its degree of innovation are critical considerations in evaluating the quality of a healthcare technology. It is useful to consider whether the technology improves upon an existing solution or provides a new solution altogether, and the extent to which the technology disrupts current practice.

Specification of Research Purpose

Earlier research within the healthcare technology sector has shown that for new technologies that have not yet been adopted by the health service companies often have difficulty determining the clinical value proposition for their technology in relation to its advantages over existing treatment options (Davey et al., 2010).

Indeed for managers operating within a resource constrained healthcare system, determining the value of new innovations that have the potential to contribute to improvements in the quality of care while also providing cost reductions is undoubtedly becoming increasingly important.

In a finite resource healthcare system the cost effectiveness of a technology can be compelling evidence for its adoption. Purchasing and reimbursement decisions in healthcare systems with finite resources are increasingly influenced by formal health economic analysis. The opportunity cost of a technology is based on its incremental cost effectiveness, i.e. the cost associated with the benefits achieved from a technology compared to the next best alternative. Cost effectiveness assessments are made from the perspective of the healthcare provider using current UK norms for the value of a 'quality adjusted life year' (QALY) (Girling et al., 2007). The National Institute for Health and Clinical Excellence (NICE), for example, uses this approach for appraisal of potential new treatments for the NHS in England. NICE medical technologies guidance, although mandatory only in England, are reviewed and often applied to other areas of the UK (National Institute for Health and Clinical Excellence, 2011). Cosh et al. (2007) describe an approach to this problem of conducting health economic analysis under circumstances where effectiveness is necessarily conjectural and they state that if the problem is not ruled out by strategic considerations then the investigation should move to the next stage with a study of the clinical problem.

This paper uses a case-based approach to explore the methods for determining the early value proposition of emerging healthcare technology and how these methods link with the elemental business model approach for technology adoption by healthcare companies and organisations. The first case study demonstrates how determining the clinical problem definition at an early stage in the design of an innovation can provide insight to guide investment decisions for a technology that improves upon an existing solution in the field of cardiology. The second case study provides the reader with an illustration of how fundamental health economic principles encapsulated in the 'headroom method' can be utilised to give an estimate of the potential value of a technology that provides a new solution altogether in the emerging field of tissue engineering. The implications for the research are discussed in terms of how methodologies to determine the value proposition of an innovation can influence an organisation's business model and the case for adoption by decision makers.

METHODOLOGY

This research uses a case-based approach to describe the operation of two different but complimentary methods to determine the early stage value proposition of an emerging healthcare technology. The use of a case-based approach has been shown to be a suitable method to test and build theory (Voss and Voss, 2000). Previous authors (Lindahl and Nordin, 2010) have regarded case study illustrations as a useful research approach to explore the interplay of two different disciplines in new product development and evaluation and to develop models to show how previously disparate methodologies can be coordinated.

With the aim of developing systems and frameworks to manage and understand the early value proposition of emerging healthcare technologies two different technologies were chosen. The first case study technology was an improvement on an existing medical device in the well-established field of stenting for vascular disease. Field research was carried out to determine the opinion of expert clinicians in relation to the value of this innovation.

The second case study technology explains the terminology and application of the 'headroom method' to exemplify the potential value of a technology that provides a new solution altogether in the field of tissue engineering. In this case secondary data was utilised previously gathered from a survey of experts as it was difficult to get accurate valuations of the potential benefit of a technology for a procedure of which healthcare professionals had no prior knowledge or experience.

FINDINGS

Clinical Problem Definition

In some circumstances the decision to invest in a technology can be made without recourse to any formal method of evaluation. If an unmet clinical need can be identified and resolved, such as curing a common, chronic disease at low cost, then the decision makes itself. In 1895, when Roentgen's wife was persuaded to interpose her hand between his x-ray source

and a photographic plate he did not need a health economist to tell him he was onto a winner. These blockbuster discoveries come along only seldom and the cost effectiveness of most proposed new technologies is much more difficult to predict (Cosh et al., 2007). However, there is undoubtedly benefit in determining the potential clinical value of a new device of technology at an early stage in the development. The following mini-case-study on a new technology stent for peripheral vascular disease attempts to illustrate this.

Mini-Case 1: Initial Assessment of the Value Proposition for a Revolutionary Design, ArtiStent
A company had developed a new design stent that has the potential to benefit patients with peripheral vascular or arterial disease. In order to make a case to attract investment to fund a clinical trial with the technology it was necessary to determine the clinical value proposition. The 'ArtiStent' technology consists of multiple stent segments that interlock once crimped into a single balloon, but completely disengage from each other during balloon expansion so that each stent segment can articulate independently within the vessel to provide a biomechanically stable solution to the challenges of stenting in peripheral vessels. Stenting in these regions in the past has proven to be problematic with good short-term results but generally poor long-term results. Peripheral arteries are, generally, highly flexible vessels which undergo various bending, twisting and torsion modes in multiple planes.

In order to determine the potential clinical value proposition for this device, taking into account the positive and negative attributes, target clinicians who were likely to benefit from this technology were identified and meetings were held with a number of leading consultants from both the vascular surgery and interventional radiology departments in the Belfast Health and Social Care Trust and the South Eastern Health and Social Care Trust. The clinicians were asked a series of questions about:

- Clinical treatment routes
- Disease context
- Current treatments
- Challenges with current stent designs

This enabled the drivers for the clinical success of the ArtiStent to be identified and adoption issues to be clarified.

A potential *clinical value proposition* of the ArtiStent design was qualified as follows:

- A bespoke solution that gives 'better fit' to blood vessels, improving the outcome for patients
- Has the possibility to be used in vessels where there is branching, reducing the need for bypass surgery and saving hospital costs
- Challenging areas where there is a large degree of movement of the vessels (e.g. around the inguinal ligament) could now be stented due to increased flexibility of design

This qualitative work on determining the clinical value proposition proved to be beneficial for the company developing this technology and has confirmed the potential for an innovative device in the treatment of peripheral arterial disease and the requirement for future investment in this area.

Early Health Economics: Headroom Method

When modelling, cost effectiveness parameter estimates are typically obtained from direct studies, ideally from large randomised controlled trials. However, in the case of a technology yet to be developed, or in the early stages of development, the very nature of the product is uncertain.

The headroom method simply looks at the potential of a clinically defined market. Instead of asking, 'How cost effective will the technology be?' – the question for conventional cost effectiveness analysis of a technology already developed – it can be useful to ask, 'Would it be cost effective if it works as well as one would hope?' In other words, optimistic assumptions are made about the incremental effectiveness of the proposed treatment over the best alternative.

It is then possible to calculate the incremental cost of the technology where it could still be cost effective; this is called the 'headroom'. The headroom method can lower the risk of embarking on an investment that is doomed from the outset (McAteer et al., 2007).

Cost effectiveness analysis aims to quantify the incremental cost effectiveness ratio (ICER), specifically the extra cost per unit of benefit when comparing one treatment, technology or programme against another. This incremental health benefit is expressed in QALYs (life years weighted by 'quality of life' (QoL), where 1 signifies perfect QoL and 0 represents death). The total incremental QALY gain for such a technology is a function of improvement in QoL (ΔQoL) and the duration over which this improvement is sustained:

$$\text{Equation 1:} \quad \Delta QALY = (1 - \Delta QoL) \times \text{time in years}$$

Incremental QALYs are converted into monetary terms to offset the financial costs of the treatment to arrive at a 'net health benefit' for each treatment (Ades et al., 2004). If the societal willingness to pay is assumed to be an ICER of £30,000 (€45,000 or $60,000) per QALY (Devlin and Parkin, 2004), the headroom can be calculated as follows:

$$\text{Equation 2:} \quad \Delta Cost \text{ (headroom)} = \Delta QALY \times £30{,}000$$

Where maxΔCost is the headroom – the maximum additional cost of the new treatment over the comparator for the new treatment to be deemed cost effective.

It can be said that if there is little or no chance that the technology could be marketed at a price that would keep the maxΔCost below the cost effectiveness threshold, then the technology should not attract further investment (Cosh et al., 2007).

Mini-Case 2: Headroom for Engineered Bladder

A tissue engineered bladder substitute could be used as an alternative to the use of bowel tissue in substitution cystoplasty after resection for cancer.

Information regarding quality of life after cystoplasty is sparse, and those studies that do exist are not easily translatable into QALYs (Venn et al., 1998). In the light of this and the complex nature of the medical conditions involved in cystoplasty, an estimate of the disutility of this procedure was made via a survey of urologists. The median utility value found was 0.95. The mean age of the presentation of this condition is 72 years (Sangar et al., 2005) and, while reported survival rates vary widely, we may assume that patients suitable for a tissue-engineered solution will have a better than average five year survival and will also be younger than average. Therefore, we assume a mean of ten years of life among this group.

These estimates give a ΔQALY of $10 \times (1 - 0.95) = 0.5$, which in turn suggests a headroom of £30,000 × 0.5 = £15,000.

The above calculation does not take into account savings of £1,000 per patient by avoiding bowel surgery. Headroom is hence £16,000 per patient treated, resulting in the potential equivalent cost savings to the health service.

Following the methods outlined the investor can make an intuitive decision to invest based on the outcome of the clinical problem definition and headroom method or they can perform a more formal valuation of investment analysis; either way, the additional information gleaned enables a more robust value proposition to be developed within the business model context.

The Relationship between Methodologies for Estimating the Early Value Proposition and the Business Model

The two mini-cases outlined in this paper have shown the benefit of assessing clinical opinion on a new technology at an early phase in its development. The key to successful assessment of the early value proposition of a new healthcare technology is knowing what methodologies to use and when.

Determination of the clinical value proposition can be extremely beneficial to innovating companies when the device or intervention being developed is an improvement on an existing solution. Defining and evaluating the clinically relevant perceptions on the value of an innovation can enable the developing company to enhance marketing of the attributes of the technology that are likely to provide greatest clinical benefit, thus benefiting the company's marketing strategy as a result of a greater knowledge of the target market. Additionally, a greater understanding of the clinical problem definition can enable improvement in linkages in the value chain and value network by strengthening the relationships an organisation has with the users of the technology.

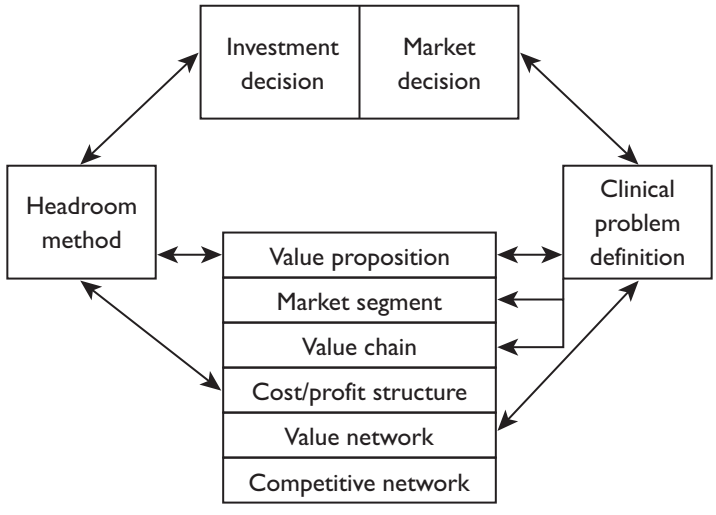
The value proposition is key to a company's business model and Figure 1 shows the role of the methods in relation to the six-element business model proposed by Chesbrough (2006).

By understanding the headroom method – that is the additional value or 'headroom' that an emerging innovation can provide compared to existing treatments – an organisation is likely to be able to stay ahead of the game and will be willing to invest in innovations that are radical but have the potential to provide great healthcare solutions at reduced costs.

Specifically, the headroom method can benefit early estimates of the likely cost or profits for an innovation, providing valuable information to help guide investment decisions.

The model in Figure 1 aims to illuminate the conceptualisation of these linkages, providing potential beneficiaries of an innovation with knowledge of its benefits while the innovation is still in the development phase.

Figure 1: Conceptualisation of the Methods to Determine the 'Early Value Proposition' of Healthcare Technologies with a Business Model Framework



As shown in Figure 1, determining the early value proposition within the context of an elemental business model can provide a framework for investment decisions which can illuminate a situation that may otherwise appear hard to fathom for healthcare decision makers.

DISCUSSION

In the face of scarce resources when the budget for new healthcare technologies is ever limited, methodologies to assess the early value proposition for prioritising the most beneficial healthcare development likely to succeed is indisputably valuable.

As development proceeds, it is important to revisit the clinical problem and economic data with new information regarding the likely effectiveness of the technology as it becomes available. Mina et al. (2007) discuss the mechanisms through which medical knowledge emerges, grows and transforms itself. This is a process that is distributed across time, space and epistemic domains. It involves the development of correlated understandings about the nature of medical problems and the search for solutions to these problems. It entails a shift from the exploratory undertaking of inquisitive individuals to the more systemic

interactions of dispersed groups of practitioners competing and cooperating to solve scientific and technical puzzles in a variety of institutional settings and different incentive structures.

A headroom analysis is primarily useful as a barrier to misguidedly investing in those devices that can never be cost effective. As research progresses, estimates of costs and effectiveness can be updated.

It should be noted that the value of applying these methods at the supply side is dependent on the planned technologies being aimed at the third-party payer market. The value that consumers and/or patients place on a technology will undoubtedly be different to health technology assessment agencies and the health service in terms of willingness to pay. For instance, the National Institute for Health and Clinical Excellence in the UK has developed formal methods of economic evaluation that explicitly set funding norms, one effect of which is to moderate acceptable prices for drugs and devices. Meanwhile, from a vendor's perspective, this changing terrain will affect the choice of product to invest in and the level of investment that is warranted, given the price a particular product may attract in the marketplace. This places considerable pressure upon early stage decisions. However, much of the long-term impact of a given device will be shaped by such decisions, which are often made quickly and with limited evidence (Girling et al., 2010).

The process of innovation in medical devices is often one of continuous incremental improvements in close interaction with the users of the technology (Siebert et al., 2002). Therefore, interaction between all stakeholders as early as possible in the development cycle is extremely beneficial. Medical device users are an extremely heterogeneous group and for any one device they may include not only healthcare professionals but also the patients who may use the device themselves or receive treatment using the device and, in some cases, carers who are relatives and friends. There are a number of factors that make capturing user requirements for medical device development challenging, including the ethical and research governance involved with studying users, as well as the inevitable time and financial constraints. Investment in user requirements research benefits the developer as well as the user and the healthcare sector. The increasing recognition, among healthcare purchasers and regulators, of the links between good design and patient safety, clinical and general efficiency and satisfaction has led to formal requirements for user research by funders of development work on medical devices (Martin et al., 2006).

When making early-stage valuations, it seems that value is enhanced when the outlook is uncertain – uncertain cash flows appear to be more valuable than certain cash flows. It does not amount to risk preference; nor is it an invitation to wilfully overstate the degree of uncertainty involved. Uncertainty is advantageous only in a certain sense. In the commercial situation the option to proceed with the product while bypassing the development phase is not available, since the development phase is essential for the realisation of a product concept. Thus it is not the value of the development information that should inform the investment decision, but the full early valuation of the product (Girling et al., 2010). Additionally, the long-term perspective has been adopted by Mina et al. (2007), which stresses another important, and nevertheless often forgotten, feature of the process of emergence,

growth and transformation of a radically new understanding and treatment of diseases: its characteristically irregular tempo. The pace of innovation is uneven through time and the benefits that are now associated with successful new techniques are nowhere to be found in the performance of their first applications. The most relevant gains were usually obtained well after the original insights (and devices) were conceived and only in combination with other developments that were not at all foreseeable in the first place. Technologies that in the long run have proven remarkably successful initially grew, and often did so for several years, in conditions of uncertainty with regard to their relative efficiency but on the basis of an increasingly collective vision of their potential benefits. Mina et al. (2007) go on to state that in the case of statins diversified incremental change through shared practice, and not the genius of pioneers alone, was the key to their long-term affirmation.

CONCLUSIONS AND IMPLICATIONS

Incorporation of available evidence from both clinicians and users into the value proposition helps companies to develop more informed business models and improve their target market knowledge and competitive strategy. There would be clear benefits to the enhanced study of frameworks and models of innovation capable of studying interactions between service providers, patients and policy makers, and how these complex interactions determine the timing, direction and success of innovations in the public sector (Windrum and García-Goñi, 2008).

Implications for Practice

For virtually any organisation the ability to raise capital is critical to success. A reasonably accurate valuation is, in turn, critical to capital creation from investors in terms of decisions relating to future cash flow streams. The extremely dynamic nature of healthcare organisations will make application of the traditional approaches to valuation more difficult in the coming years. In addition, Carden et al. (2010) state that the combination of greater volatility in cash flows and less accurate valuation of those flows may increase the cost of capital for these enterprises, thereby changing the economic fundamentals of the business. They warn that the unintended consequences of making radical changes to lower the cost of healthcare, only to find that those changes have increased its costs by making the cost of capital higher, would serve to exacerbate the already almost intractable problem of national healthcare cost. The development of a framework which incorporates evidence-gathering activities such as determination of the clinical value proposition and early health economic tools at the conception or development phase of an innovation, therefore, is likely to be highly beneficial. By utilising the most appropriate method for evaluating an early stage technology or intervention companies are likely to be able to reduce the time to first patient with minimal financial risk. Also, enhancing potential customers' knowledge of the attributes and benefits of an innovation while the innovation is still in the development phase is likely to nurture their interest and desire for the technology at an early stage. This is applicable to other high technology innovative sectors such as aerospace engineering, information technology and, in particular, smart consumer devices such as the iPhone.

Future Research

The need for methods to determine the early value proposition of innovative healthcare technologies to all stakeholders, including patients, clinicians, industry, health service organisations and governments, is likely to increase in the near future as a result of limited budgets. Michael Scanlan (2010), who at the time was Secretary General of the Department of Health and Children (now the Department of Health) in Ireland, stated that technology, affordability and choices will always be issues for policy makers:

> Many potential investments can be shown to provide value for money but affordability is a major factor which is clearer now in the current economic situation (Scanlan, 2010).

Future research is required to develop interdisciplinary methodologies for measuring the value of innovative medical technologies in the early stages of development to allow improvements in healthcare to be made without immeasurable increases in the cost of care.

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