The Health of Innovation: Why Open Business Models Can Benefit the Healthcare Sector

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ABSTRACT

Innovation is central to the healthcare industry; future developments in nano-, bio- and information technology have the potential to dramatically change the accepted clinical patient care pathways. The public are often well informed about these matters, which results in a patient pull for innovations that are years from market. Companies operating in this environment today face huge challenges in terms of realising the latent economic potential from new innovations. By developing open business models, healthcare companies can manage the multifaceted ideas of scientists, engineers, clinicians and indeed patients at an earlier stage, allowing the good and necessary technologies to reach the health service more promptly. This study uses a qualitative approach to research the explicit and implicit business models within healthcare technology companies of a range of sizes and organisational structures and provides a useful contribution to understanding the management of innovation in the healthcare environment.

Key Words: healthcare technology; innovation; medical device; open business model

INTRODUCTION

The ability to innovate effectively is increasingly viewed as the single most important factor in developing and sustaining competitive advantage (Tidd et al., 2009) and has consistently been found to be the most important characteristic associated with success (Statistics Canada, 2006). As early as 1934, Schumpeter had defined innovation as being at the heart of the entrepreneurial role: the creation of a linkage between new ideas and markets; innovation includes the production or adoption of useful ideas and idea implementation (Van

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de Ven, 1986). Firms care about their ability to innovate, on which their future allegedly depends (Christensen, 1997; Christensen and Raynor, 2003), and the study of innovation, viewed as cross-disciplinary, is emerging as a new scientific field which has worldwide impact (Fagerberg and Verspagen, 2009). They approach innovation in its broadest sense, including new technologies and new ways of doing things (Porter, 1990). Indeed, innovation has become the mantra of organisations looking for economic growth in recent times (Malaviya and Wadhwa, 2005). Albury (2004), in his report on innovation in the public sector, states 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.

This is particularly true for the area of healthcare, where the rate of progress of innovations over the last century has been most remarkable. Health innovation consists of complex bundles of new medical technologies and clinical services emerging from a highly distributed competence base. In many cases new healthcare technologies take decades to progress from concept to a product on the market as a result of regulatory and clinical hurdles. Significant investment is often needed before a new medical device can enter even the first stage of a clinical investigation. Given these challenges, there is a need to better understand how innovations are managed within technology-based healthcare companies, developed, nurtured and brought to the patient. Of particular interest is researching how companies can best work together to improve their own competitiveness and the strength of the healthcare sector as a whole.

The adoption of open innovation, which means that companies should make much greater use of external ideas in their own business while letting their unused ideas be used by other companies (Chesbrough, 2006) within the medical devices sector, may provide for a more effective route to market for many new technologies and offers the opportunity to share some of the risks involved. The use of open business models within the healthcare technology base offers the possibility to engage scientists, engineers, clinicians and indeed patients at earlier stages of the process, thus allowing viable technologies to reach the market more quickly in a way that is evidence-focused. However, the effective realisation of this approach requires knowledge of the actual business models being operated in the sector.

This research hypothesises that an open business model approach can enable companies involved in the development and delivery of healthcare to work more effectively together and hence reduce the time to first patient for a new medical innovation. This paper aims to explore how innovation takes place in companies that are operating within the medical devices sector who are involved in the development and production of technologically led products to improve, diagnose or monitor patient health. The study uses an open business model framework as a technique for making explicit how innovative activity is undertaken by such firms from the perspective of an open innovation paradigm.

Innovation in Healthcare

Historically, the advancement of healthcare has been synonymous with the innovation of new medical devices and technologies. Healthcare accounts for a significant proportion of the global economy and managing rising healthcare costs is of major concern for all governments, particularly in the context of the ageing economy. Each year health-related spending grows – often outpacing spending on other goods and services. These increased costs create significant challenges and opportunities for businesses (Kaiser, 2007).

Medical devices are a significant and growing industry with a market size of US$75 billion and US$1.5 billion in venture capital invested (AdvaMed, 2004). In the United States (US), spending on healthcare accounts for a significantly large proportion of the economy with national health spending expected to reach US$2.5 trillion in 2009, accounting for 17.6 per cent of gross domestic product (GDP). By 2018, national healthcare expenditure in the US is expected to reach US$4.4 trillion, which is more than double 2007 spending (Siska, 2009).

In order to remain competitive in the global marketplace that characterises the healthcare technology sector, companies must be able to benefit from the introduction of new product innovations and understand market need at an early stage. 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). Unlike the pharmaceutical sector, which has a well-defined route to market, it is generally accepted that the medical devices industry has a less cohesive approach to new product development (Dixon et al., 2006).

The demonstration of safety and efficacy for a new medical device is a long, arduous and expensive development path from early concept to introduction into clinical practice (Kaplan et al., 2004; Maisel, 2004; Martin et al., 2006). In a finite resource healthcare system, the cost-effectiveness of a technology can be compelling evidence for its adoption. The 'opportunity' cost of a technology is based on its incremental cost effectiveness, i.e. the cost associated with the benefits achieved from the technology compared to the next best alternative. The National Institute for Health and Clinical Excellence (NICE), for example, uses this approach for appraisal of potential new treatments for the United Kingdom (UK) National Health Service (NHS). It therefore makes sense for a firm developing a new technology to assess its potential cost effectiveness as early as possible in the new product development cycle. This will inform investment decisions and indicate which products and markets may prove most fruitful (Cosh et al., 2007).

It is often the case that breakthrough medical technologies have difficulty finding their way through the transition path from promising solutions in the research laboratory to economically viable healthcare products in the marketplace. Revolutionary advances in the interfaces between the previously separate fields of science and technology have the potential to create transforming tools available for improving human health. The term 'convergent technologies' has emerged from the synergistic combination of four major domains, namely nanotechnology–biotechnology–informatics–cognitive sciences (NBIC). While each creates new opportunities in its own right, the interface between two or more

of these domains offers truly new to-market opportunities (Roco and Bainbridge, 2003). Realising the benefits of this 'new convergence' paradigm is of interest to governments and national agencies and it has received considerable funding in recent times (European Commission, 2009; Fuller, 2009).

The medical devices market is reportedly one that can never reach stagnation, as it inherently develops in parallel with advancements in medical practice (Frost & Sullivan, 2008). Given these market dynamics, there is a real need to carry out research into the means to overcome these challenges. It is interesting to note that in the healthcare technology sector doctors are not only the primary customers for medical devices but are often innovators as well. These user innovations, which can arise from patients as well as healthcare professionals, are an important source of ideas for incumbent firms and new entrants (Chatterji, 2009). In this respect, Bernstein and Singh (2006) also cite technology push, which can be described as a situation where an emerging technology forces change in an as yet undeveloped market, as one of the reasons why a more comprehensive and integrated model for innovation processes within biotechnology firms is needed. This paper aims to address the need for a better understanding of the business models used in healthcare technology organisations.

Innovative Business Models

The necessity to examine the implicit and explicit business model within a company is essential in understanding how innovation actually happens within organisations. Innovation challenges differ from firm to firm and often followed advice can be wasteful, even harmful if applied to the wrong situations, but if solutions are tailored to the right problems a weak link in the innovation value chain can become a strong one (Hansen and Birkshaw, 2007). The study reported in this paper therefore attempts to uncover the innovative activity used by companies operating within the medical devices arena, taking account of the fact that the sector is highly fragmentary, constantly changing, heavily regulated and global in nature.

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. Economic exchange, intellectual organisation and geographical constraints can all be considered as different dynamics that interact in the complex system that constitutes a knowledge-based economy (Leydesdorff and Meyer, 2003).

A business model performs two important functions: it creates value and it captures a portion of that value. The 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, and the same technology commercialised in two different ways will yield different returns. Investigation of the elements of a business model is valuable in terms of translating business plans into business processes (Osterwalder and Pigneur, 2009).

If others outside a firm providing a technologically driven product uncover a better business model, they may realise more value than that obtained by the firm that originally discovered the technology. Chesbrough (2006) identifies six essential functions of a business model:

1. Articulate the value proposition, that is, the value created for users by the offering
2. Identify a market segment, that is, the users to whom the offering and its purpose are useful
3. Define the structure of the value chain required by the firm to create and distribute the offering, and determine the complementary assets needed to support the firm's position in this chain
4. Specify the revenue generation mechanisms for the firm, and estimate the cost structure and profit potential of producing the offering, given the value proposition and value chain structure chosen
5. Describe the position of the firm within the value network, linking suppliers and customers, including identification of potential complementors and competitors
6. Formulate the competitive strategy by which the innovating firm will gain and hold an advantage over rivals

The value proposition has become one of the most widely used terms in business in recent years (Anderson et al., 2006). At the heart of any strategy is a unique value proposition, a set of needs a company can meet for its chosen customers that others cannot (Kaplan and Norton, 2000; Osterwalder and Pigneur, 2002; Porter and Kramer, 2006). In his paper on creating high-performance organisations, Lawler (2005) states that the value proposition must be designed to fit with the business strategy of an organisation. The value proposition is also important when considering outsourcing and dealing with client organisations (Levina and Ross, 2003).

The benefits of defining a market segment for a new technology have been evident since the 1970s (Johnson, 1971; Young et al., 1978). A little more recently, Grover and Srinivasan (1987) defined a market segment to be a group of customers homogeneous in terms of the probabilities of choosing the different brands in a product class. Choosing the right market segment is one of the difficulties firms face in commercialising new technologies today and there is debate as to how to modify the initial marketing approach that was successful with early adopters of the product so that mainstream customers will also embrace the new technology (Slater and Mohr, 2006).

Value chain management has been shown to deliver major economic benefits to a diverse range of businesses (Horvath, 2001), however, the understanding of the value chain is changing: global competition, changing markets and new technologies are opening up qualitatively new ways of creating value. In so volatile a competitive environment,

increasingly successful companies do not just add value, they reinvent it (Normann and Ramirez, 1993). Hansen and Birkshaw (2007) argue that to improve innovation, executives need to view the process of transforming ideas into commercial outputs as an integrated flow or value chain for transforming raw materials into finished goods.

Christensen and Rosenbloom (1995) state that the value network – the context within which a firm competes and solves customers' problems – is an important factor affecting whether incumbent or entrant firms will most successfully innovate.

A firm's competitive strategy is related to performance (Baum et al., 2001) and in today's hypercompetitive markets executives desperately need new tools to help them systematically analyse their own and other players' competitive positions (D'Aveni, 2007).

These six elements or functions within the business model have been used to formulate the structured engagement with the company executives interviewed for this study. The objective of this paper is to investigate how the six elements of the open business model proposed by Chesbrough (2006) operate in healthcare companies of various sizes and how the range in the perceptions of innovation can impact the adoption of a healthcare technology.

RESEARCH METHODOLOGY

The research undertaken here used a multiple case study-based approach (Yin, 2003; Stake, 2005) to investigate the implicit and explicit business models in the healthcare industry to research how innovation is considered within organisations and delivered to the patient.

In-depth, structured interviews were carried out with four companies as summarised in Table 1. The location of the companies covered an area ranging from the north of Scotland

Table 1: Summary of Case Study Companies and Business Role of Interviewees

Company	Strategic Business Type	Technology Focus	Role of Key Informant		
			Research & Development	Product Specialist	Sales or Marketing
Company A	SME	Diagnosis/analysis equipment manufacturer	✓	✓	✓
Company B	Medium-sized	Anesthetics and gas delivery	✓		
Company C	Multinational	Multiple business sectors			✓
Company D	SME	Diagnosis/analysis equipment manufacturer		✓	

to Devon in England and also Ireland. This ensured that the companies were marketing their technologies to a number of different health and social care authorities.

A summary of each of the case study companies presented in this paper is outlined as follows:

Company A is primarily concerned with the manufacture and development of technology for the early assessment of patients with burns.

Company B has recently developed a home-use anaesthetic device and their research and development (R&D) manager stated that the company is keen to develop a business model that will enable it to develop a foothold in the medical devices market.

Company C is a large multinational company with over 300,000 employees worldwide. The interview focused on one specific business segment of the company: the challenges of telemedicine, which can be described as the provision of clinical and health monitoring solutions in a non-hospital or remote environment and the adoption of new technologies in a home-based setting.

Company D is a small company in a peripheral location that develops probes for analysis and medical applications.

In the interviews, business development executives responsible for bringing new technological applications to the marketplace were asked a series of questions based on Chesbrough's (2006) business model framework. The executives interviewed were responsible for the development of the technology and planning of its route to the market. Between one and three executives were interviewed in each of the case study companies because in some cases it was deemed necessary to talk to more that one person in order to gain a full understanding of the company's current business practices and innovation strategies.

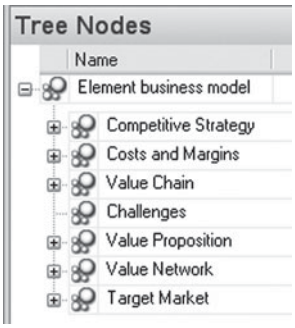
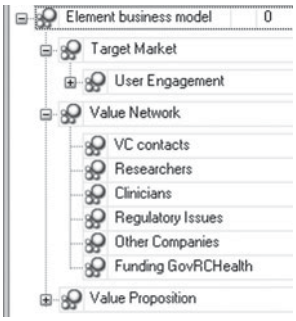
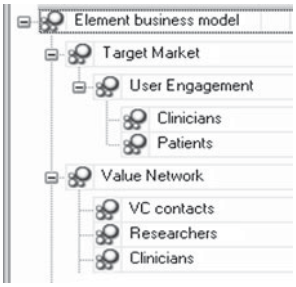
The questions in the interviews were phrased in such a manner to allow the elicitation of information on each company business model based on the Chesbrough (2006) framework. Questions were asked on value proposition, target market, value chain, costs/margins, value network (e.g. What is your relationship to other organisations?) and competitive strategy (e.g. Do you monitor your competitor's activities?), and a question was also asked on business challenges in the current environment. An overview of the coding methodology is detailed in Table 2.

The interviews were all digitally recorded and transcribed. Analysis was then carried out on the text line by line using QSR NVivo©, which is a powerful qualitative research software valuable for organisation and analysis of qualitative data. Key themes were coded using the method of three-phase coding proposed by Bandara (2006) and Gibbs (2002), as outlined in Table 2. This method of coding enabled each of the six business model elements to be analysed independently and any sub-constructs that emerged from the interview transcripts to be explored, giving additional useful qualitative insight into the research.

RESULTS

The timeframe for the interviews with the company executives was from December 2008 to April 2009. This was found to be beneficial to ensure that the wider economic conditions could be comparable for each of the companies studied. The results of the in-depth

Table 2: Overview of Coding Methodology for Healthcare Company Case Study Interviews

Phase	Description
Phase 1: Mapping of constructs to prior, which was based on an earlier theory-derived model	This phase populated the nodes created with the 6 a priori constructs (based on Chesbrough's proposed open business model elements (Chesbrough, 2006)). When potential new constructs were identified, new nodes were created and data coded. 
Phase 2: Analysing the coded constructs	The data coded under each node was re-analysed to make sure that they did belong to the coded node. Furthermore, the coded data was then further coded to investigate the existence of constructs that had not been mapped in the original priori. 
Phase 3: In-vivo coding phase conducted	Once the data which belonged to the overall constructs had been extracted, in-vivo coding (coding with the key words identified within the text) was conducted to tease out the potential sub-constructs that are considered to be measurable in the analysis. 

interviews were analysed and the company focus and business challenge for each of the cases is described.

Case Company Comparison

Company A describes its technology for application in the burns market to be fairly unique, it has spent many years developing the technology and meeting the regulatory requirements that enable them to market it in Europe and the US. It engages directly with the clinical community and is having difficulty proving the value of its technology to the health service even though it has been proven to be beneficial to patients.

Company B is an established player in the gas delivery market for clinical use including anaesthetics but a new entrant in the medical devices sector. It is aiming to sell medical devices to customers to whom it already supplies other products. However, with a small R&D team it is struggling to find the resources to develop and market this innovative technology.

Company C is a global company that operates in a number of core business areas but has stated that telemedicine, or the provision of clinical and health monitoring solutions in a non-hospital or remote environment, is the area with the greatest challenges at present. Its product is fully developed, however there are huge challenges in terms of marketing a healthcare technology for a home-based setting and the company is looking at options for pricing strategies in terms of who pays.

Company D has managed to establish a business developing probes for medical research; it secured funding from government agencies to develop the technology. The company says that sales and marketing is its biggest challenge, and also being able to educate people on the benefits of its technology.

The overview of the four case companies analysed shows that while all the companies in this study are involved in the development or manufacture of healthcare technologies, the focus of the companies in relation to the technology and user varies, as will be discussed in the following section in relation to the business model framework.

Business Model Element Analysis

NVivo analysis enabled each of the six elements of the open innovation business model to be explored fully and themes that emerged from interviews to be mapped to better understand the companies' business and innovation strategies.

Table 3 provides an overview of the issues that were discussed in the interviews with the healthcare companies and which issues were referenced most often by the individual cases.

Companies most often referred to their competitive strategy, followed by their costs and margins. The third issue that they gave the greatest volume of information on was their organisation's value chain, followed by value proposition, followed by value network and then the target market for their technology. Each of these elements of the business model is now discussed in the order in which they were given most weighting by the companies.

Table 3: Analysis of Business Model from Six Perspectives on Healthcare Companies

Construct	Sub-Construct	Number of Informants (Cases)	Number of References by Cases
Element Business Model	**Tree Node**		
Competitive Strategy		*6*	*20*
	Website	2	4
	Academic collaboration	4	5
	Conferences and exhibitions	4	7
	Number of competitors	5	9
Costs and Margins		*6*	*19*
	Lease	4	4
	Selling price	6	9
Value Chain		*6*	*16*
	Outsourcing	4	4
	Intellectual property	6	8
	Timescales	6	9
	In-house	6	9
Value Proposition		*6*	*9*
	Unique	4	9
Value Network		*5*	*8*
	Researchers	3	4
	Venture capital contacts	4	5
	Clinicians	4	5
	Regulatory issues	4	6
	Other companies	5	8
	Funding from government research council or health authorities	6	8
Target Market		*5*	*6*
	User engagement	5	11
	Patients	4	9
	Clinicians	5	7

Competitive Strategy

An analysis of the ways in which companies monitor their competitors' activities shows that there is variation in the activities a company engages in.

It was found that the small to medium enterprises (SMEs) in this study tended to rely heavily on their competitors' websites to finds out information for strategic advantage:

> We try to find out information about our competitors. We look at their website; we look at are they reacting to changing conditions in science and decide the answer is no, because we can't see their websites change. (Company A)

> All the time we monitor them, I wouldn't say daily but almost every other day we go on their website and talk to people who are using their systems so to find out if there is anything new. Their website is usually more immediate. (Company D)

It was interesting to note that the multinational company rated the importance of academic collaboration in their competitive strategy:

> The benefit to the academics of working with us is that we can give them total freedom to publish; what we are looking for is rights to commercialise so we can get what we want out of the agreement without too much conflict. From the academic side they want lots of publications. (Company C)

In comparison, the SMEs in this study generally do not fund academic research directly but instead rely on conferences and exhibitions to find out about new developments and other companies' technologies:

> I go to Medtec [the leading exhibition and conference for the medical devices manufacturing industry] every year and look around about what's on show, exhibit there where all of the other kind of respiratory people are. (Company B)

The small companies in this study also had a good knowledge of the number of competitors in their sector and where their competitors were located. This shows that meeting competitors at events can be beneficial in terms of marketing a technology and also in terms of gaining intelligence for competitive advantage. This research also shows the emerging importance of the internet in the high-tech medical sector for business scanning and intelligence.

Costs and Margins

The selling price of the technologies in this study varied from approximately GBP £120 to GBP £70,000. The selling price was something that demanded a great deal of consideration for SMEs, whereas the larger company was less concerned with the price of the technology.

The SMEs and the larger company had investigated options to lease the technology, and one company answered:

> About 1 per cent of clients rent and they only rent to test it. But very few universities will rent, I don't think we have ever had a rent system back. It always turns into a sale. (Company D)

The medium-sized company, which was a new entrant into the market, had not as yet investigated options such as leasing and was primarily concerned with reducing development costs to enable it to enter the market at a low selling price. This highlights the need for companies to fully consider all the options when deciding on the optimum method for realising profit from their technology. These findings also indicate that companies could benefit greatly by researching the selling price to the health service at a much earlier stage in the development cycle for an innovative healthcare technology.

Value Chain

The value chain highlights which activities a company does in-house and which it tends to outsource. It is interesting to note that the multinational company placed a high weighting on intellectual property as an asset and it rarely outsources any of its activities. In comparison, SMEs do a lot of outsourcing of their activities, possibly because they do not have the facilities so it is more cost-effective to outsource the manufacture of complex parts.

The development times for technology often tend to be longer for small companies that for larger companies. One SME stated that:

> The line scanner sat on the shelf for two years before it was included in the Millennium Dome exhibition and it was another six years after that before it got all the necessary approvals for clinical trial. (Company A)

Another, when asked about development times, answered:

> The development times are quite long – three to five years – because it has got to be built, commissioned, used, data gathered, improvement shown internally and it takes a long time before that knowledge comes into the public domain. (Company D)

On the other hand, when the larger company, Company C, was asked to give an example of typical timescales for development of a new device the respondent said that the company needs to push technologies out more quickly and in many cases aims to get its medical devices to market within two years:

> Ultrasound into GPs' surgeries, because of miniaturisation and ease of reading, to be honest we have expect it to take eighteen months to two years. (Company C)

This research indicated that there is a need within smaller firms to understand the regulatory and user need issues that will enable companies to improve their value chain and reduce the time to first patient for their technology.

Value Proposition

Questions were asked on the firms' value proposition in order to gain an insight into the perceived value of the technologies. It was found that the SMEs in this study generally viewed their technology to be more unique and valuable to their customer than the larger company did. It is interesting when you compare how the opinion on the uniqueness of the technology varied with the individual's role within the company, with the sales department often stressing that their product is more unique:

> Our technology is unique; we are the only people in the world selling it. (Sales and marketing manager, Company A)

The R&D team, on the other hand, often adopt a slightly more cautious approach to the uniqueness of new technologies:

> We are fairly unique, we are the only company that has an FDA [US Food and Drug Administration] approved technology for this application at this time. (R&D manager, Company A)

One recommendation we can give from this finding would be that research staff and development engineers should work more closely with the marketing and customer-facing departments, so that the value and market for ideas that are truly unique can be realised at an earlier stage. It must be noted, however, 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.

Value Network

When asked about how they worked with other organisations, there was a great deal of variation in the responses and a number of other issues were raised in response to this question. The results of the value network analysis are shown in Table 4.

The topics raised included regulatory hurdles, benefits of lobbing with other companies and the role of venture capital and government or research council funding.

It is interesting to note that one of the SMEs in this study often referred to the importance of funding from government agencies, research councils and healthcare organisations in the discussions:

> We are looking to try and extent the current funding; HTD [an NHS funding scheme] love us, they see us as being one of the better projects, so what they are telling us is 'apply for an extension'. (Company B)

Table 4: Matrix of Value Network by Company Size and Role in Company

	Company Size			Role in Company		
	SME	Medium-Sized	Multi-national	Research & Development	Product Specialist	Sales or Marketing
1. Value Network	5	1	2	3	3	2
2. Venture Capital Contacts	3	1	1	2	2	1
3. Researchers	2	1	2	3	0	2
4. Regulatory Issues	1	1	2	2	0	2
5. Other Companies	5	0	1	1	1	4
6. Funding from Government Research Council or Health Authorities	5	1	2	3	2	3

Note: The shadings relate to the relative importance of each of the elements in the table. Whereas 5 has high importance and has the darkest shading, 1 and 0 have low importance and hence light shading for illustration purposes.

> Yes we have had funding from a local enterprise agency, but we don't work with others in terms of commercial concerns unless they are very big. (Company D)

Regulatory issues were referred to as being of high importance for sales and marketing teams, particularly in the SMEs where one respondent from the sales department stated that the company's main challenges are with regulatory affairs issues. The multinational company in the study also referred to the role of researchers in its value chain. These results show that the value network differs considerably depending on the size of the organisation.

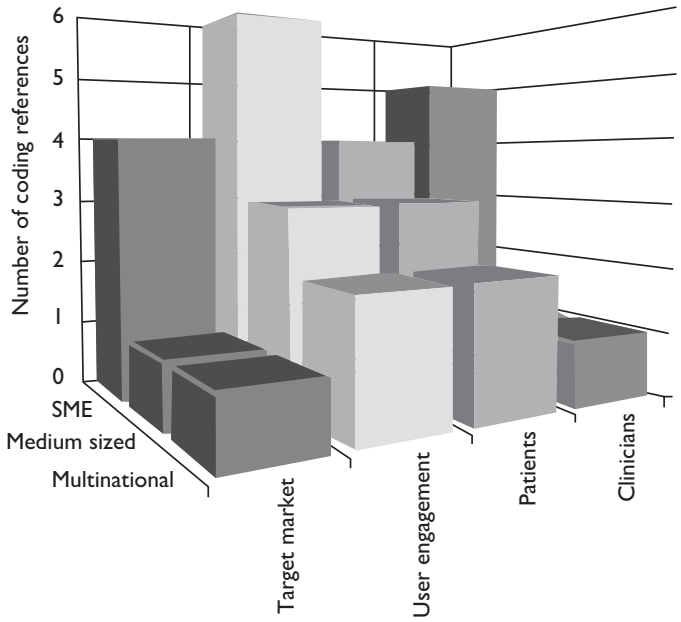
It is clear from this study that a number of issues and external organisations are of importance to the various medical devices companies' value chains. It is often challenging but necessary for the successful healthcare technology company to be aware of the operations of all of the key organisations in its value chain.

Target Market

Companies were asked about their target market and, in terms of developing and marketing the technology, which stakeholders are most important and what was the sequence of engagement with these users of the technology. Figure 1 shows the results of the number of coded references for each of the elements that are important in term of target market in relation to company size.

From Figure 1 it can be seen that the size of the company clearly does have a weighting on how the organisation values the necessity for user engagement in the development of the technology.

Figure 1: Results of Coding for Target Market in Comparison to Company Size



It was found that the small companies in this study often referred to the importance of patients and clinicians when discussing the development of their technology and the target market, and user engagement ranked very highly with SMEs.

The answers that individuals gave when asked about who is involved in the development of the technology can be associated with company size to a limited extent:

> Well, the patient certainly and we have got clinicians on the project team so they are there at the beginning. (Company B, medium-sized company)

> Well one of the interesting things is that the crux is the people getting the benefit are not the people paying; the people who are saving money are the NHS. (Company C, multinational)

This may perhaps be because the large companies are dealing directly with the health service organisations as opposed to the individual.

Open Business Model Themes and Challenges

Analysis of the results of the in-depth interviews enabled a number of key themes to be elicited and these identified specific innovation challenges for the medical devices companies.

The first issue that the majority of companies in this study were struggling with was technology uniqueness and the difficulties of marketing a new technology in a healthcare

market where trust and company credibility are of high importance. Emerging technologies can often struggle to find acceptance in the clinical arena and in many cases small firms do not have the deep pockets required to fund large-scale clinical trials and overcome regulatory hurdles.

An interesting theme to emerge from this research is the importance of competitor networks for small companies; it has been shown that meeting competitors at events can be beneficial in terms of marketing a technology and also in terms of gaining intelligence for competitive advantage. Recent open innovation literature (Chesbrough, 2009) has stated that making your own company's know-how and intellectual property (IP) work for you and others can be financially rewarding.

The main challenge that emerged when looking at costs and margins from an open innovation perspective with the case study companies is the need to look at pricing as a competitive strategy. Many companies are still looking at the production costs as a key input into the selling price, as opposed to a willingness to pay based on a potential improvement of patient quality of life, which is the health economic approach often utilised by purchasers in the health service.

DISCUSSION AND CONCLUDING COMMENTS

This study has shown that by analysing the six different elements of the open innovation business model from a number of different perspectives within healthcare companies there are significant variations in how the companies perceive each of the elements. These variations were not only dependent on the size and structure of the organisation, but also a degree of intra-organisational variation in outlook was observed between people in different departments within the one organisation. This supports the findings of McAdam et al. (2004), which highlight differences in how 'innovativeness' is incorporated into SMEs from small to larger companies.

A number of key business challenges have emerged in both the technical and social domain for healthcare companies and these issues and the possible open innovation solutions needed to bridge the gaps will now be discussed.

Companies often have difficulty determining the clinical value proposition for their technology in relation to its advantages over existing treatment options. In a situation such as this, Chesbrough (2009) suggests becoming a customer or supplier of your former internal projects and joining with others in or beyond your industry. He outlines the example of Eli Lilly, which began a project called Bounty Chem to improve its sourcing of external ideas for developing new drugs. The company quickly realised that the project would be more effective if it sourced ideas for many other companies too, and so InnoCentive (www.innocentive.com) began.

This would indicate that small companies could benefit by working with larger companies to bring ideas to market and larger companies should be actively looking to invest in IP that is generated by SMEs. One suggestion emanating from this research would be that a value proposition should be created alongside a technical specification for a new product. This value proposition should be dependent on the target market and should utilise the

opinions of knowledgeable patient and clinical groups. A study by Shah and Robinson (2006) shows that medical device users are not homogeneous but heterogeneous in several aspects, such as needs, skills and working environments. This is an important consideration for incorporating users' perspectives in medical device technologies. In terms of realising profit for a device, companies of all sizes are likely to benefit from utilising some form of cost-effectiveness analysis at the development phase of a technology that has potential clinical benefit (Lilford et al., 2007).

In a situation where there is a reduction in funding, such as may be the case in a future health service, it has been suggested that growing your ecosystem, even when you are not expanding as a company, will be advantageous in order to identify future opportunities (Chesbrough, 2009). If a company is continually engaging with its customers, collaborators, industry experts, trade associations and others to identify future opportunities then building on the ecosystem of potential innovation partners is likely to be beneficial in staying ahead of the game.

One cannot ignore the fact that medical device innovations will bring future benefits to patients; however, companies need to overcome business challenges in order for their innovations to be successful in the complex arena of healthcare.

This paper has aimed to highlight the challenges for companies operating in the healthcare arena; however, the authors believe that the business challenges identified, such as globalisation, technology differentiation and the increasing costs of research and regulation, are by no means unique to this sector. Therefore, the open innovation strategic solutions postulated could benefit other sectors such as communications, information technology and aviation.

Internal collaboration is almost universally viewed as good for an organisation, but, as stated by Hansen (2009), the challenge is to cultivate the right kind of collaboration so that companies can achieve things that are not possible when they work alone. This suggests that open innovation needs to be tailored based on a company's business model, and the strategy for engaging with open innovation within this business model will be unique for each company. This finding is useful for funding organisations, venture capitalists and policy makers as a one-size-fits-all solution in relation to assisting growth and development is unlikely to be appropriate for the medical devices sector.

This early research has shown that the development of an open innovation business model can be a key starting point for healthcare companies to allow organisations within the healthcare sector to work together, improving how new medical technologies are brought to the patient.

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