

MASTER

New product development within a SME the development of a hand hygiene management system

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Eindhoven, April 2009

**New Product Development
within a SME; The Development
of a Hand Hygiene Management
System**

by
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in partial fulfilment of the requirements for the degree of

**Master of Science
in Innovation Management**

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Voorwoord

Voor u ligt de afstudeerscriptie van Michiel Ubink. Deze scriptie vormt het einde van mijn Master studie Innovatie Management die ik de afgelopen 3,5 jaar heb gevolgd aan de technische universiteit Eindhoven. Deze scriptie beschrijft het afstudeer onderzoek dat ik de afgelopen 7 maanden heb uitgevoerd bij Miscea.

Tijdens mijn eerste studie - Vliegtuig Operatie - die ik gevolgd heb aan de hogeschool van Amsterdam, ben ik geïnteresseerd geraakt in het ontwikkelen van nieuwe producten. Met name tijdens mijn afstudeerstage bij Crea-tech, een bedrijf dat machines ontwikkelt, produceert en vermarkt binnen de tuinbouw sector, ben ik geïnteresseerd geraakt in de vraag hoe je succesvolle nieuwe producten kunt ontwikkelen. Het werd me toen wel duidelijk dat het ontwikkelen van succesvolle nieuwe producten niet alleen een “technische” maar zeker ook een “commerciële” en een “bedrijfskundige” dimensie heeft. Tijdens mijn studie Vliegtuig Operatie heb ik mezelf op een basis niveau technisch ontwikkeld. In een mogelijke vervolgopleiding wilde ik mijn technische kennis met commerciële en bedrijfskundige kennis complementeren. Kortom ik wilde me niet alleen technisch maar ook op commercieel en bedrijfskundig vakgebied ontwikkelen. Een vrij logische keuze was daarom ook de studie Innovatie Management aan de technische universiteit Eindhoven.

Tijdens mijn studie Innovatie Management heb ik enorm veel geleerd over de bedrijfskundige aspecten die te maken hebben met het managen van innovatie binnen organisaties. Tijdens mijn studie heb ik met name een belangstelling ontwikkeld voor nieuwe product ontwikkelings processen en management, marketing, strategie management en technisch ondernemerschap. Daarnaast heb ik me tijdens de studie op persoonlijk gebied enorm ontwikkeld. De gemotiveerde en ambitieuze medestudenten, de gedreven en inspirerende universitair docenten, de uitdagende lesstof, en uiteraard de gezellige studentenstad Eindhoven hebben bijgedragen aan het feit dat mijn periode op de TU/e enorm leerzaam en bovendien plezierig is geweest. Daarnaast heb ik via de TU/e de mogelijkheid gehad om een semester in Zuid Korea te studeren, een periode die eveneens enorm leerzaam en inspirerend was.

Na mijn buitenlandse semester in Korea ben ik begonnen met mijn afstudeeronderzoek. Dit onderzoek heb ik uitgevoerd bij Miscea, en had betrekking op het ontwikkelen van een technische systeem voor de gezondheidszorg. Binnen dit onderzoek kwam de hamvraag waarvoor ik deze studie ben gaan volgen wederom terug, te weten: “hoe ontwikkel je succesvolle nieuwe producten?” Binnen dit onderzoek kwamen vrijwel alle kennisaspecten die de afgelopen 3.5 jaar binnen mijn studie aan bot zijn gekomen weer terug. Het onderzoek gaf me de mogelijkheid om de theoretische kennis die ik heb opgedaan tijdens mijn studie in de praktijk te brengen. Tijdens mijn studie heb ik veel kennis en ervaring opgedaan als het gaat om het “managen” van innovatie. Ik ben ervan overtuigd dat deze kennis en ervaringen een goede basis vormen om na mijn vakantie in Australië te starten met mijn eerste baan.

Graag zou ik een groot aantal mensen willen bedanken voor hun medewerking aan dit onderzoek. In de eerste plaats mijn eerste begeleidster op de TU/e, mevrouw Reymen, voor het delen van haar vaktechnische kennis en ervaring en haar tomeloze inzet om dit onderzoek een zoveel mogelijke academisch karakter te geven. Ook zou ik de heer van der Schaaf, mijn tweede afstudeerbegeleider op de TU/e, willen bedanken voor het delen van zijn praktische inzichten m.b.t. patiënten veiligheid en de gezondheidszorg in zijn algemeenheid. Daarnaast wil ik al mijn collega's bij Miscea en met name de heer Talsma bedanken voor de mogelijkheid die Miscea mij heeft geboden om dit onderzoek uit te voeren. De heer Talsma is een “echte” ondernemer, waarvan ik deze periode enorm veel geleerd heb. Daarnaast wil ik graag alle ziekenhuis hygiënisten, microbiologen en de hand hygiëne onderzoekers van het Erasmus MC bedanken voor hun medewerking aan dit onderzoek. Ik wil met name de heren Kluytmans en Timmermans, beide arts microbioloog, bedanken voor het delen van hun inzichten met betrekking tot hand hygiëne non-compliance, het opwerpen van suggesties over hoe deze problematiek zou kunnen worden opgelost door middel van een technisch systeem, en het verschaffen

van inzichten over hoe een dergelijk systeem er dan uit zou moeten komen te zien. Daarnaast wil ik ook de technische RTLS experts van onder andere TNO, het Telematica instituut en het RFID kenniscentrum bedanken voor het delen van hun technische kennis. Naast de technische experts zou ik ook graag de marketing managers van onder andere Imtech, Medica, en Schulke&Meyr willen bedanken voor het delen van hun marktkennis met betrekking tot de infectie preventie industrie en de ziekenhuismarkt. Daarnaast wil ik mijn vriendin, Khanh Nguyen bedanken voor de steun die ze mij heeft gegeven tijdens dit project en uiteraard voor het nakijken van al mijn rapporten. Ook wil ik graag de rest van mijn familie en vrienden bedanken voor het geduld dat ze konden opbrengen als ik weer eens een paar uur over hand hygiëne, patiënten veiligheid, nieuwe product ontwikkeling en de “potentiële” mogelijkheden van RTLS systemen aan het praten was. Tot slot wil ik uiteraard mijn ouders, Cees en Therese Ubink bedanken, voor de steun die zij mij hebben gegeven tijdens mijn gehele studieperiode.

Ik wens u veel plezier met het lezen van deze afstudeer scriptie. Ik hoop dat u net zoveel plezier beleeft aan het lezen van deze scriptie als ik heb gehad in de tot stand koming daarvan.

List of abbreviations

AHR	Alcohol based hand rub
APICE	Association for Professionals in Infection Control and Epidemiology
DECT	Digital Enhanced Cordless Telecommunications
DSP	Digital signal processing
ECDC	European Centre for Disease Prevention and Control
EMI	Electromagnetic interference
FFE	Fuzzy front end
HAI	Healthcare-associated infection
HCW	Healthcare worker
HH	Hand hygiene
HHMS	Hand hygiene management system
IC	Intensive care
ICP	Infection control practitioner
IPR	Intellectual property rights
IPS	Indoor positioning system
LAN	Local area network
MRSA	Methicilline Resistente Staphylococcus Aureus
NHS	National Health Service
NPD	New product development
PCB	Printed circuit board
PDMA	Product Development and Management Association
R&D	Research and Development
RFI	Radio frequency interference
RTLS	Real time locating system
SARS	Severe Acute Respiratory Syndrome
SME	Small- to medium sized enterprise
WHO	World Health Organisation
WLAN	Wireless local area network

Management summary

Healthcare-associated infections (HAIs) represent an important public health problem today as a major cause of high morbidity, mortality and economic consequences in hospitalized patients (Yalcin, 2003). Failure to comply with hand hygiene (HH) recommendations by healthcare workers (HCWs) is considered the leading cause of HAIs. Although HH has been intensively promoted as the most important means of preventing HAIs, numerous studies have demonstrated that compliance with HH recommendations among HCWs is poor (Sladek et al., 2007). In order to support infection control practitioners (ICPs) in improving HH compliance, Miscea is considering to develop the MISCEA hand hygiene management system (HHMS). The MISCEA HHMS is a system that consists of a combination of sensor-activated non-touch faucets and standalone dispensers. By coupling the MISCEA faucets and standalone dispensers to a wireless data network, and by integrating an identification registration system within the faucets and dispensers, a system will be developed that is able to monitor how many times a faucet or dispenser is used, when, how, and by whom. By giving HCWs ID cards, and by placing identification receivers in the faucets and dispensers, the MISCEA HHMS will be able to monitor individual HH behaviour. The MISCEA HHMS will be able to give ICPs detailed information concerning (individual) HH behaviour within their facilities.

This Master thesis research will analyse the technical as well as commercial viability of the new HHMS. Based on this analysis, Miscea will make a decision with regard to the continuation, and thereby corporate investment in, this new product development (NPD) project. The research question this Master thesis project will attempt to answer is:

RQ1: Should Miscea invest in the development of the proposed new hand hygiene management system?

A good strategy is a path of action that, when a company is developing a new product concept, answers the following question: “Are we doing the right things, when developing this idea, to create value for desired customers and to capture value for our firm” (Kahn, 2005). This Master thesis research attempts to answer the strategic question outlined above for the MISCEA HHMS. In order to answer this question, this study will deal with the fuzzy front end (FFE) of Coopers generic five-stage five-gate model. The FFE consists of all predevelopment or strategy-making work and includes the first three stages of Coopers’ model: (1) initial idea screen, (2) preliminary market and technical assessment, and (3) building the business case.

In the first phase (initial screening) of this NPD project, the researcher analysed the problem of HAIs, HH compliance and what could be done to improve HH compliance. Based on the strategy-making work performed in the first stage of this Master thesis research, the following conclusions can be drawn: (1) HAIs are an enormous problem, (2) around 1/3 of all HAIs can be prevented, (3) implementation of evidence-based HAI prevention interventions should be a high priority for all healthcare facilities to reduce preventable HAIs to the greatest extent possible. High mortality rates and economic expenses, which HAIs represent, emphasize the justification for measures of control, (4) proper HH is the most effective measure in preventing HAIs, (5) until now, few interventions have proved to be successful in sustainably improving HH compliance, (6) in order to improve compliance the interdependence of individual factors, environmental constraints and organisational climate play a key role in the success of behavioural interventions (7) within this respect a behavioural modification program (providing feedback) is most effective. Based on the understanding that was obtained about the problem in question, the researcher setup an initial concept design for the new system.

The second stage (preliminary market and technical assessment) in this NPD project contained a preliminary investigation on the commercial and technical viability of the proposed new system and consisted of a preliminary market and technical assessment. Based on the preliminary market assessment the following conclusions can be drawn: (1) the MISCEA HHMS could – in theory – help ICPs in improving HH compliance. Prof. Dr. J.A.J.W Kluytmans a Microbiologist and an expert on

the subject of HAIs supports this conclusion. Prof. Dr. Kluytmans has the hypothesis that a hospital management system that is able to provide ICPs with detailed personalized HH behaviour data could indeed help ICPs to achieve sustained improvements in HH compliance. Prof. Dr. Kluytmans intends to setup a large-scale clinical trial in five different IC units, in order to test the clinical effect of the MISCEA HHMS on HH compliance and thereby HAIs.

In addition to the preliminary market assessment, the second stage also included a preliminary technical assessment. Based on the understanding that was obtained in the former stages product and system specifications had been setup. After that, the researcher performed a technical research related to which technologies were best suitable for our application. By means of the technical research performed in this study, Miscea gained a handle on the development feasibility of the proposed new system. The analysis determined that it is technically feasible to develop the system.

The third phase (building the business case) consisted of a detailed investigation of the NPD project in question and consisting of a detailed market study, setting up marketing and commercialisation plans, setting up operational NPD plans, and completing a business and financial analysis. The project plan encompasses the whole process of developing the system, from specifying user requirements, developing the system, and building a prototype, to testing the prototype in the Miscea test centre in Stockholm and in a pilot study in the food industry. The project plan details the time frame needed to develop, test and install the system within the five IC units. Next to that, the plan provides a deeper understanding about the development costs needed to develop, manufacture and install the HHMS within the five participating IC units. The overall development project will take approximately 16 months. The total costs estimated from the standpoint of developing the system, manufacturing the system, installing the system in five IC units and providing after-sales support are approximately 300.000 Euros. The overall clinical research will take approximately 3 years and will cost (according to Prof. Dr. Kluytmans) around 1.3 million Euros.

Based on the strategy-making work performed in the third stage of this Master thesis research, the following conclusions can be drawn: (1) the infection control and prevention market is one of the most attractive and profitable in all of commerce, (2) the trends in the market are positive, as in today's rapidly changing healthcare industries, providers of care face unyielding pressure to improve quality, maintaining operating margins and lower costs, (3) reaching these goals requires a relentless focus on making healthcare safer and more productive, (4) patient safety and thereby HAIs, is high on the EU, US, UK and other EU member states policy agendas, (5) Miscea will be able to protect its innovation from being easily copied by competitors, thereby ensuring that, if the system becomes a success, Miscea will be able to appropriate value from its investment in this innovation, (6) Miscea will have the operational capability to actually develop the system, (7) Miscea will be able to develop the system, within a new platform development effort in collaboration with suppliers and end-customers, (8) The NPD project fits with Miscea's overall corporate strategy, (9) the NPD project complement the firm's available resources and existing innovation portfolio, (10) the NPD project matches its organisational structure and culture, (11) the innovation outcomes will be predictable and will not require financial investment from Miscea as the NPD project may be financed by means of subsidies, and (12) thus the NPD project can be setup with limited financial and organisational risks.

Based on the strategy-making study performed within this Master thesis project, the conclusion can be drawn, that Miscea should develop the MISCEA HHMS, if the development of the system can be financed by means of subsidies. The clinical trial that will be setup will result in a clear understanding about the impact of monitoring individual HH behaviour on HH compliance within a clinical setting. In this scenario, Miscea can develop the system without having to take financial risks, but indeed has an opportunity to develop a customized system for the clinical trial. If the VUmc researchers conclude that the MISCEA HHMS indeed improves HH compliance, and that the effect of improved HH compliance results in a statistically significant reduction of HAIs within the IC units over a three-year period, Miscea should setup targeted and effective marketing plans, and invest in executing the marketing plans as setup in this phase of commercialization.

The MISCEA HHMS may disrupt the position of established firms and open up opportunities for Miscea to enter the market and overtake incumbents. The MISCEA HHMS NPD effort will enable Miscea to build the technological base of the firm, develop its capabilities, improve its processes, and add to its reputation and brands. If the clinical trial shows good results in improving HH compliance, Miscea developed a product that improves the competitiveness of the firm by adding value to what they do.

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1. Problem definition

Healthcare-associated infections (HAIs) represent an important public health problem today as a major cause of high morbidity, mortality and economic consequences in hospitalized patients (Yalcin, 2003). Failure to comply with hand hygiene (HH) recommendations by healthcare workers (HCWs) is considered the leading cause of HAIs. Although HH has been intensively promoted as the most important means of preventing HAIs, numerous studies have demonstrated that compliance with HH recommendations among HCWs is poor (Sladek et al., 2007). In order to improve HH compliance, Miscea (appendix I) is considering to develop a new HH management system. Miscea's initial idea is to couple the advantages of the MISCEA dispenser system (appendix I) with an identification registration system. Miscea intends to bring to market a system that improves HH compliance dramatically and thereby reduces HAIs substantially.

This Master thesis research will analyse the technical as well as commercial viability of the new hand hygiene management system (HHMS). Based on this analysis, Miscea will make a decision with regards to the continuation of this new product development (NPD) project. The research question this Master thesis project will attempt to answer is:

RQ1: Should Miscea invest in the development of the new hand hygiene management system?

This Master thesis project can be seen as a feasibility study. The study does not only try to answer the question if monitoring HH behaviour on a personal level will –in theory- improve HH compliance, it also tries to answer the question if Miscea would be able to build a good business around its development. While new products hold the promise of greater profitability, the process from start to finish is costly, time-consuming, and fraught with technological, market and competitive uncertainties (Loch and Kavadias, 2008). The decision regarding which product concepts to develop and launch is no longer driven by technological feasibility concerns alone (Kahn, 2005). Questions related to technological and development feasibility must be answered alongside questions related to customer needs, market attractiveness, market trends, the competitive situation and the extent to which innovation outcomes are (un) predictable, costly, and appropriate.

Based on the analyses performed in this Master thesis research, a clear understanding about the (commercial) viability of the new HHMS will be obtained. Based on this understanding, a decision will be made with regard to the continuation, and thereby corporate investment in, this NPD project. This choice should be linked to anticipated economic benefits and the ability to appropriate returns from innovation. The management team of Miscea will look at operational, technical, marketing and financial aspects of the proposal to assess potential risks and rewards. The final decision needs to fit with overall corporate strategy, deciding whether or not the NPD project complements the firms' available resources and existing innovation portfolio and, whether ambitions match its organisational structure and culture.

This Master thesis research contributes to strengthening Misceas' knowledge about its (potential) customers and markets, science and technology, regulations, competition, suppliers, and available finance. This knowledge in itself helps to improve awareness of what can and what cannot be embraced and underpins the innovative capabilities that shape and guide the formulation of Misceas' innovation strategy and the selection and use of appropriate innovation processes. This will ensure that sufficient resources and capabilities are collected, organized, and deployed in a timely manner in order to succeed in bringing new products onto the market.

This research can be described as being an action-based research. The viability study can be seen as a case study about the initiation and strategy-making phases of a NPD project. This research can give important insights into the first predevelopment stages of the NPD process of a radical innovation, aimed at developing a product based on latent performance dimensions, within a small innovative company.

2. Theoretical perspective

According to Kahn (2005) product innovation – the development of new and improved products – is crucial to the survival and prosperity of the modern company. Firms compete successfully when they offer new, better, and/or cheaper products and services, which their customers can use to advantage, and which their competitors cannot provide. Of all the challenges faced by managers today, the management of technological innovation is one of the most demanding. Get it right and firms create value and profit, develop sustainable competitiveness, and become vibrant, fun places to work, attracting and retaining the most productive and creative staff (Dodgson et al., 2008).

While new products hold the promise of greater profitability, the process from start to finish is costly, time-consuming, and fraught with technological, market and competitive uncertainties (Loch and Kavadias, 2008). Technological innovation involves addressing a wide range of issues and activities that compound the challenges in managing it, add to its risk and uncertainty, and making it difficult to develop generic recipes for its success (Dodgson et al., 2008). Understanding why new products succeed and why some businesses are so much better at NPD is central to effective NPD management; it provides insights for managing NPD projects (Kahn, 2005).

This chapter starts (2.1) by describing why innovation and NPD are so crucial for modern-day corporations. Section (2.2) describes how companies can differentiate themselves by developing products that are based on latent performance dimensions. Section (2.3) will discuss the “nature” of new product development. Section (2.4) outlines the role of innovation strategy in guiding decisions related to NPD projects. After that, the formation and deployment of an innovation strategy is discussed (2.5). Section (2.6) describes the NPD process and provides an overview of methodologies that can be used to structure NPD projects.

2.1 Innovation and new product development

We live in turbulent times. Technology advances at an ever-increasing pace, customer and market needs are constantly changing, competition moves at lightning speed, and globalisation brings new players and opportunities into the game (Kahn, 2005). Because of this, the industrialised world has seen a shift from labour- and capital- intensive industries to knowledge- and technology- based economies. As competition has increased in markets throughout the world, technology has emerged as a significant business factor and a primary commodity. Knowledge transformed into know-how or technology has become a major asset within corporations (Trott, 2005).

According to Kahn (2005) product innovation – the development of new and improved products – is crucial to the survival and prosperity of the modern company. Firms compete successfully when they offer new, better, and/or cheaper products and services, which their customers can use to advantage, and which their competitors cannot provide. Competitive advantage therefore derives from the ability to operate and produce more efficiently than competitors, or to create new and unique value adding products and services (Dodgson et al., 2008). Manufactures all over the world are trying to gain a lead in product development. They bring different capabilities to the market and use different approaches, but they are all seeking to reduce development lead time and enter the market with the right product at the right time (Loch and Kavadias, 2008).

Innovation is intimately linked to the capacity of the firm to deliver value (Dodgson et al., 2008). Well-chosen new products and services deliver value, build the technological base of the firm, develop its capabilities, improve its processes, and add to its reputation and brands (Dodgson et al., 2008). The benefits of new product innovation include: providing rich financial rewards such as improved return on investment, higher margins, expanded sales volumes, increased value-added, lower costs, and improved productivity. According to Dodgson et al. (2008), technological innovation

allows firms to fulfil their overall purpose, be it profit generation, growth, better quality and range of delivery, greater market share, or increased employee remuneration, job security, or satisfaction.

Innovations can create many benefits for society, firms, and individuals – building wealth, increasing the quality of life, and even sustaining personal happiness. An innovation commonly produces wider social contributions beyond the value captured by the innovator (Dodgson et al., 2008). Successful innovations diffuse widely across society. A virtuous circle can develop between an innovation and its diffusion. As an innovation is launched onto the market, its purchase or consumption by others stimulates new demand. This allows the producer of the innovation to make more of the product or service, lowering its cost for subsequent users (Dodgson et al., 2008).

In summary, the ultimate aim of managing technological innovation is to improve the competitiveness of firms by adding value to what they do. Of all the challenges faced by managers today, the management of technological innovation is one of the most demanding. Get it right and firms create value and profit, develop sustainable competitiveness, and become vibrant, fun places to work, attracting and retaining the most productive and creative staff (Dodgson et al., 2008).

2.2 Differentiation based on latent performance dimensions

Understanding customers and markets and their needs and requirements has long been recognized as critical to the success of a NPD effort. For new products to be successful in the market they need to be perceived as beneficial by prospective buyers. The benefit needs to stand out, to be distinctive and attractive (Trott, 2005). According to Kahn (2005) the most successful product development efforts match a set of fully understood customer problems to a cost-competitive solution to these problems. Kahn concludes that superior and differentiated products – ones that deliver unique benefits and superior value to the customer – is the number one driver of success and new product profitability. Firms that are best performers at NPD are much stronger in terms of offering important benefits, a superior value proposition, and better value for the customer in their new products (Kahn, 2005).

A firm's product strategy expresses how the organization seeks to differentiate itself, and distance itself, from the competition. Product positioning refers to the perceptions customers have about the product. It is a relative term that describes customer perceptions of the product's position in the market relative to rival products (Trott, 2005). Understanding the set of benefits that consumers seek in a given category and determining how current offerings by different firms deliver on those benefits, is often used to identify new product positioning opportunities. Firms can achieve competitive advantages, not only through producing what customers want, but also, on occasion, through producing what they do not yet know they want (Dodgson et al., 2008).

Early in the process of deciding where to position a new product, a firm determines the attributes or dimensions relevant for consumer choice. Beyond mapping the set of attributes and features that are present in current offerings, a firm may also scout for new dimensions or features that have been ignored. These new dimensions may have become relevant due to new available technologies, developments in related categories, or shifts in consumer tastes (Loch and Kavadias, 2008). Often a customer request focuses on improvement along a primary performance dimension of the product, i.e., one that is embodied in current products and is highly valued by mainstream customers. The request may also focus on secondary performance dimensions, which is one firms are competing over even though it may not yet be offered on the market. The term latent dimension is used to describe dimensions that are altogether new, or that have so far been only dormant dimensions of competition (Loch and Kavadias, 2008).

It is now widely recognized that improving a product's performance along primary performance dimensions is an obvious path for any player in an industry, and therefore the competition in this arena will be intense. Since all players recognize the importance of primary performance dimensions, this type of improvement is likely to soon become an order qualifier, rather than an order winning

criterion, forcing players further up market. Pursuing established performance dimensions that are the focus of all players in the industry is a necessary rat race. Pursuing latent dimensions can be a subtler and less predictable way to compete (Loch and Kavadias, 2008).

Despite the greater uncertainties involved (at least from the consumer adoption standpoint), there can be huge advantages to position along a new dimension. The firm can brand itself in relation to the new dimension; thereby creating a first mover advantage around being the initial firm to significantly offer the benefit. Such a strategy may be particularly attractive for new entrants to a market. Existing firms have likely built equities around the ability to deliver reliable performance on the established attributes. Hence providing a new dimension may help overcome a disadvantage with respect to existing equities along the established product dimensions (Loch and Kavadias, 2008). If it turns out that the primary dimensions of performance are not compromised when latent dimensions are added on, and the latent dimensions resonate deeply with the mainstream market, then the firm has the potential to develop a mass-market product with greater appeal to all customers (Loch and Kavadias, 2008).

2.3 The nature of new product development

The management of technological innovation often involves managing in circumstances where there is a high degree of ambiguity, uncertainty, and risk (Dodgson et al., 2008). Market risks, competitive risks, technological risks, organisational risks, operational risks and financial risks are all risks associated with NPD projects. While there are many incentives to innovate, there are considerable obstacles to success. Understanding why new products succeed and why some businesses are so much better at NPD is central to effective NPD management; it provides insights for managing NPD projects (Kahn, 2005).

According to Loch and Kavadias (2008) firms that intend to develop new products first need to have an understanding of what market opportunity exists in terms of which end users can be targeted and with what specific benefits. Second, the firm needs to have a handle on the development feasibility of any proposed new product aimed at addressing a given market opportunity. These two aspects of new product strategy introduce market and technical uncertainty, respectively, into NPD decision-making. Market uncertainty reflects the fact that before a new product is actually launched, there exists some degree of doubt as to whether consumers perceive the benefits that the new product can provide to be large enough to offset any adoption obstacles, such as switching costs and risk of product failure. Technical uncertainty reflects the fact that development challenges may be difficult to overcome, resulting in more R&D investment than initially expected or a delay in the timing of introduction. Technical uncertainty may also be associated with having to forecast the variable manufacturing costs the new product will entail (Loch and Kavadias, 2008). As a firm navigates through these sources of uncertainty, yet a third factor must be reckoned with, namely, competition. In the context of developing new products, the presence, or in some case the potential threat of rivals can have considerable implications for which opportunities a firm ultimately chooses to pursue (Loch and Kavadias, 2008).

Thus, while new products hold the promise of greater profitability, the process from start to finish is costly, time-consuming, and fraught with technological, market and competitive uncertainties (Loch and Kavadias, 2008). The decision regarding which product concepts to develop and launch is no longer driven by technological feasibility concerns alone. Increasingly, firms must consider how to position new products to maximize commercial viability in the face of competition. A thorough understanding of customers' needs and wants, the competitive situation, and the nature of the market is an essential component of new product success (Kahn, 2005). Ultimately, those firms that are able to anticipate and manage the confluence of market, technical and competitive pressures on a systematic basis – conducting the analysis with fresh eyes upon each successive generation by using input on customer tastes, technology advances, and rivals' expected actions – will be the ones most likely to repeatedly succeed in positioning new products (Loch and Kavadias, 2008).

Managing technological innovation includes the ways managers create and deliver value from innovation strategy, R&D, innovation in products, services, operations, and processes, and commercialization, within innovation networks and communities. The challenges of managing technological innovation can be seen to include far more than technological issues. Decisions on strategy, organisation, finance, marketing and location of business are alongside those related to research, design, and operations. The challenge for business is to make effective decisions in each of these different areas, often at the same time. They include managing organisational, financial, human resource, marketing, and collaboration issues. They also encompass major strategic issues, concerning the business models used to deliver value (Dodgson et al., 2008). Managing innovation involves making choices about product development projects in uncertain and ambiguous circumstances (Dodgson et al., 2008). These activities can be complex, involving technological and organisational integration, and risky, with high levels of uncertainty, concern to control costs, and manage appropriability (Dodgson et al., 2008).

All these features point to the complexity of technological innovation, and hence to the challenge of managing it. Technological innovation involves addressing a wide range of issues and activities that compound the challenges in managing it, add to its risk and uncertainty, and making it difficult to develop generic recipes for its success. It is the very difficulty of managing technological innovation that makes it such a source of competitive advantage. If every firm could do it successfully, it would not provide a source of relative competitive advantage (Dodgson et al., 2008).

2.4 Innovation strategy

Firms can be very good at the various activities involved in managing technological innovation, such as R&D or operations, but these count for little unless they are supported by a well-grounded innovation strategy that guides firms' choices, prioritizations, and sequences (Dodgson et al., 2008). It is important to distinguish between process performance (how efficient the firm is at developing new products) and product effectiveness (is the firm producing the right products) (Dodgson et al., 2008). A good strategy is a path of action that, when a company is developing a new product concept, answers the following question: "Are we doing the right things, when developing this idea, to create value for desired customers and to capture value for our firm (Kahn, 2005). There is little value in being highly efficient in developing or delivering new products and services if they are the wrong products and services for the firm and its markets. The question one needs to answer is; "Are we doing the right thing?" and, after that; "are we doing it right?" An innovation strategy helps firms to decide on the right things to do; their innovation processes help them do things in the right way (Dodgson et al., 2008).

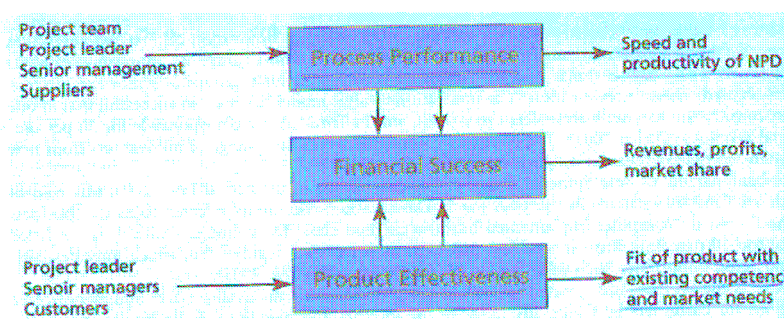


Fig. 1 New product development strategy and innovation process

Tactical issues relate to how firms manage R&D activities, develop new products and services, and improve operations. At a higher level, strategic matters include analysis of the firm's competitive and technological environment, and assessment of its external challenges and opportunities. Innovation

strategy helps to focus attention on how resources, capabilities, and processes are best developed and deployed to meet a firm's objectives for innovation and thereby deliver value and build competitive advantage (Dodgson et al., 2008).

An innovation strategy identifies the technologies and markets the firm should best develop and exploit to create and capture value. Innovation strategy gives an as accurate as possible understanding of market trends and technological and competitive circumstances and their impact on innovation positions. Wider analysis of market, technological, and sectoral trends are essential ingredient of innovation strategy (Dodgson et al., 2008). Choices should be linked to anticipated economic benefits and the ability to appropriate returns from innovation. They need to fit with overall corporate strategy, deciding whether or not innovation targets complement the firm's available resources and existing innovation portfolio and, whether ambitions match its organisational structure and culture. The choices made should also include attention to issues of timing; whether for example, a firm aims to be a productive innovator or to be a reactive follower. These decisions help prioritize resource allocation, providing a focus for marshalling and integrating different components of innovation processes and guiding them towards specific markets and customers within the competitive environment (Dodgson et al., 2008).

New product development has become a strategic agenda item for firms in many industries (Loch and Kavadias, 2008). Globalisation of technology and markets, with many potential new customers, suppliers, partners, and competitors in different parts of the world, requires companies to take a strategic approach to their innovation activities to provide focus within an ever-expanding set of opportunities and threats. The formation of an innovation strategy guides the way in complex, risky, and expensive activities, such as R&D, product innovation design, operations, networking, and collaboration. These activities can hamper a firm's competitive position and may result in piecemeal, short-term focused, and potentially conflicting outcomes unless they are guided by choices that build synergies and grow expertise cumulatively. In addition, firms that identify innovation as a strategic activity are more likely to attract creative workers in search of exciting opportunities in the 'war over talent'. More than ever, businesses need a product innovation and technology strategy to help chart the way (Kahn, 2005).

2.5 Innovation strategy formation and deployment

Innovation strategy development and use can vary markedly depending upon whether the firm is new or well established, large or small, centralized or dispersed in its organisation, deals in simple or complex products, operates within well-defined or uncertain technological and market circumstances, with a major or minor impact on society, safety, and the environment. It also varies according to the characteristics of the sectors and innovation systems in which it operates (Dodgson et al., 2008).

Innovation strategy is different to mainstream business strategy because it needs to comprehensively accommodate uncertainty. Some uncertainty is always present in strategic management of incremental innovation, but it is a major strategic factor in radical innovation (Dodgson et al., 2008). According to Dodgson et al. (2008) it is generally useful for managers to assess the level of uncertainty surrounding their decision-making so they can tailor strategy accordingly. Conventional strategy analysis tools such as Porter's five forces industry analysis are useful for low levels of uncertainty but as uncertainty increases the key elements of successful strategy become search and responsiveness, helping firms to react to unforeseen events. Under conditions of high uncertainty, the use of many common strategy tools can be misleading and, in some cases, even dangerous (Dodgson et al., 2008). Strategies that are less specific and more emergent are more commonplace in rapidly changing or emerging sectors and markets, in the context of radical innovation, or in the early stages of a product life cycle where there is a high degree of uncertainty (Dodgson et al., 2008).

Thus, in practice the process of formulating and implementing an innovation strategy are often iterative and dynamic, drawing on evidence from the external environment and appraisal of the

opportunities, constraints, and limitations of internal resources, capabilities, and processes. Making decisions about which creative ideas to pursue involves trade-offs which shape the direction of the firm and outcomes from particular investments. They involve choices about which technology paths to pursue and which customers to target, what is offered to these customers by way of solutions and value propositions, tasks to be performed by the business and those to be outsourced, and configuration of resources to perform these tasks to create, capture, and retain value (Dodgson et al., 2008).

The formulation and implementation of strategy is intimately connected and informed by learning (Dodgson et al., 2008). Innovations do not just occur through the heroic efforts of individuals; they almost commonly result from the combined activities of groups of people and organisations building upon each other’s knowledge and experience (Dodgson et al., 2008). The innovation process often requires ways of integrating knowledge from many different parts of the firm and working with various actors outside the firm, including consultants, customers, suppliers, and universities (Dodgson et al., 2008). Such processes require managerial capabilities to build relationships with and absorb knowledge from external sources, and to bring together knowledge from inside the firm, combining experiences and ideas from different departments, divisions, and disciplines (Dodgson et al., 2008).

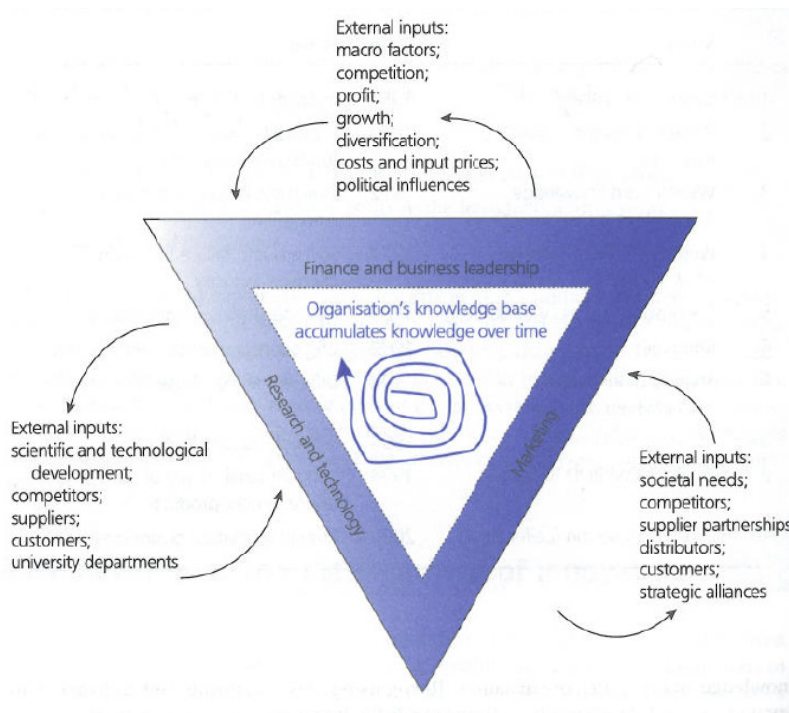


Fig. 2 Iterative new product development (Trott, 2005)

Forward-thinking firms welcome any information, guidance, or advice on likely future developments or scenarios in their areas of science and technology, and on the trajectories their technology is likely to follow (Dodgson et al., 2008). The process of searching for and acquiring technical information is a necessary activity for organisations in order to maintain their knowledge base thereby enabling them to create innovations. This can be effectively achieved by scanning the technological environment, either through the scientific literature or through interactions with other people (Trott, 2005). Thus, innovation within firms is a process of know-how accumulation based on a complementary mix of in-house R&D and R&D performed elsewhere, obtaining via the process of technology scanning (Trott, 2005). External scanning without a full understanding of the organisation’s capabilities and future requirements is likely to produce much ‘noise’ along with the ‘signal’. Tuned scanning’, achieved through the internal assimilation of an organisation’s activities, as opposed to ‘untuned scanning’ will produce a higher ‘signal-to-noise’ ratio (Trott, 2005).

The inward technology transfer process involves more than identifying interesting technology; it is necessary to match technology with a market need in order to produce a potential opportunity for the business. The scanning process needs to incorporate commercial scanning as well as technology scanning so that technological opportunities may be matched with market needs (Trott, 2005). Innovative capabilities include the way firms select technologies that will provide the future basis of market competitiveness. The selection of new technologies entails choosing which technologies are core to the firm, where it needs a proprietary position, and which are related and complementary. Choices need to be made on which technologies to concentrate on, which to develop internally, and which to access externally, through purchase or collaboration (Dodgson et al., 2008).

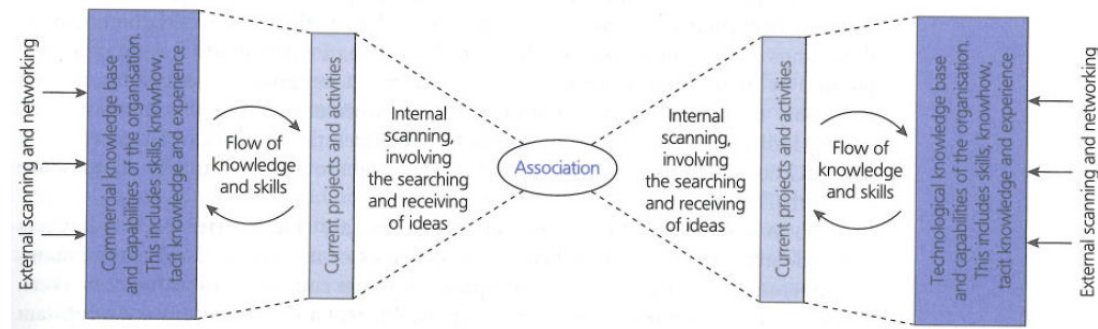


Fig. 3 The inward technology transfer process (Trott, 2005)

The final stage in the inward technology transfer process is the application of the business opportunity for competitive advantage. In this stage the organisation brings about commercial benefits from the launch of a new product or an improved product or manufacturing process (Trott, 2005).

2.6 New product development process

According to Sloane (2006), most organizations find that generating ideas is easier than evaluating or implementing them. Once a firm generates many promising ideas, these ideas need to be evaluated. In larger organizations with a rich flow of promising ideas a formalized and disciplined approach is called for. According to a best-practices study performed by the Product Development & Management Association (PDMA), 68% of leading U.S. product developers now use some type of gating process to progress and evaluate innovations from conception of the idea through to full launch of a new product.

Ideas from all sources flow in at the top of the funnel. Promising new product ideas go through a series of stages and gates. In Cooper's (2001) generic five-stage five-gate model (figure 3) there are five key stages: (i) preliminary investigation, (ii) detailed investigation, (iii) development, (iv) testing and validation, and (v) full production and market launch. The gating process determines which ideas carry on to the next round and which do not.



Fig. 4 Five-stage five-gate model (Cooper, 2001)

One of the most widespread and well-accepted conceptual descriptions of the NPD process is developed by Iansiti & Kosnik (1999). The funnel concept (figure 4) illustrates how customer needs and technological possibilities influence concept generation and selection. Furthermore, it shows how projects then evolve through the subsequent steps of product design, prototyping and testing, and pilot production to end up in manufacturing ramp-up and release. These steps are all taking place under decreasing levels of uncertainty - which simultaneously means reduced flexibility - as the development phases unfold over time. Thus, the opportunity to influence the design reduces over time. Path dependency sets in and projects become locked-in to particular sets of solutions (Dodgson et al., 2008). In the figure, the definition phase of the NPD process illustrates the time the firm spends before the freezing of specifications where the objective is to minimize the market and technological uncertainty, while the testing and integration phase is the part of the NPD process where the objective of the firm is to minimize the unit variable cost of manufacturing (Loch and Kavadias, 2008).

The innovation process may be divided into three (interconnected) parts; the fuzzy front end (FFE), the new product development (NPD) portion, and commercialization. The FFE is defined by those activities that come before the more formal and well-structured NPD process. The FFE consists of all the predevelopment or strategy-making work (Kahn, 2005). Strategy-making work consists of a conscientious completion of six tasks before starting with the physical design and development of the innovation. The first task is conducting a screening of product concepts for exploiting a new product opportunity. The second step is the completion of a preliminary study of the marketplace for the product concept. The third task is a quick technical appraisal of possible development work. After that, an introductory marketing research study describing potential customers' wants, needs, and willingness to buy a product developed from the concept has to be completed. In addition, possible competitive products must be identified. Finally, a preliminary business and financial analysis of the new product has to be prepared based on what is known at this point (Kahn, 2005).

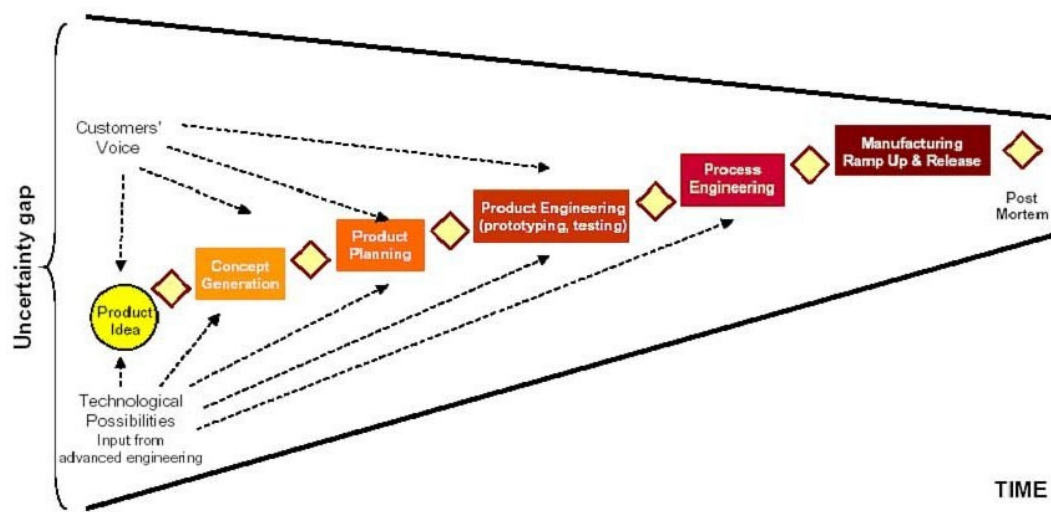


Fig. 5 Innovation funnel (Iansiti, 1999)

3. Research methodology and approach

In order to improve HH compliance within hospitals, Miscea is considering to develop a new HH management system. Misceas’ initial idea is to couple the advantages of the MISCEA dispenser system with an identification registration system. This Master thesis research will analyse the technical as well as commercial viability of the new HHMS. Based on this analysis, Miscea will make a decision with regards to the continuation of this NPD project. The research question this Master thesis project will attempt to answer is:

RQ1: Should Miscea invest in the development of the proposed new hand hygiene management system?

As already pointed out, a good strategy is a path of action that, when a company is developing a new product concept, answers the following question: “Are we doing the right things, when developing this idea, to create value for desired customers and to capture value for our firm (Kahn, 2005). This Master thesis research attempts to answer the strategic question outlined above for the MISCEA HHMS. In order to properly answer this question, the firm needs to have a handle on the market, technical and competitive uncertainty related to the NPD project in question. In order to answer the research question outlined above, this study will deal with the FFE of Coopers model (figure 4). The FFE is defined by those activities that come before the more formal and well-structured physical NPD portion. The FFE consists of all the predevelopment or strategy-making work (Kahn, 2005). Many companies consider the FFE to include the first three stages of the five-stage five-gate model and be completed at gate 3 with business and financial analyses and detailed project management plans. This Master thesis research will provide Miscea with a clear understanding about the viability of the proposed new HHMS. Based on this understanding, a decision will be made with regards to the continuation, and thereby corporate investment in, the NPD project.

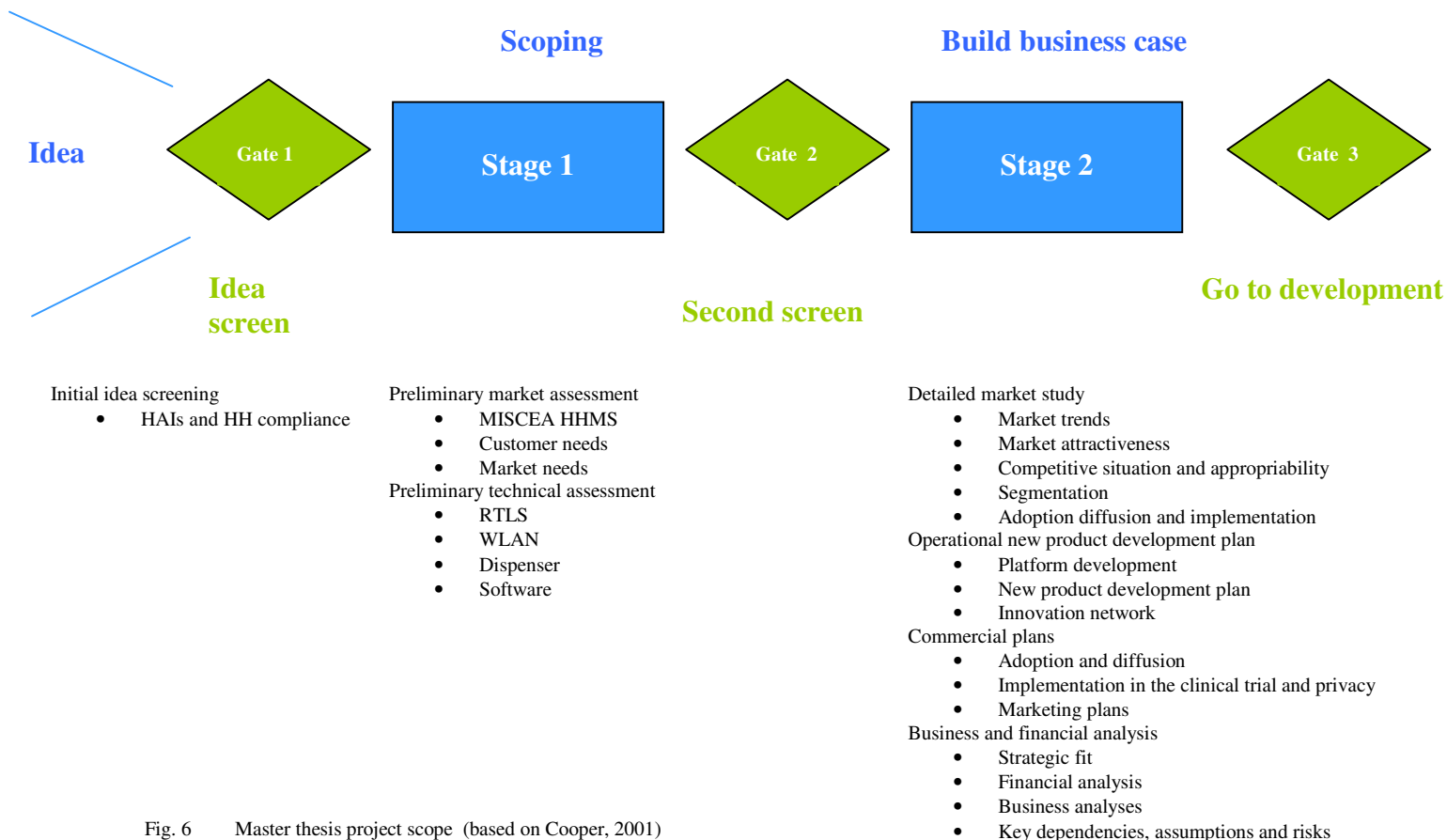


Fig. 6 Master thesis project scope (based on Cooper, 2001)

In the first phase (initial idea screen) of this research project, the problem of HAIs and HH non-compliance was examined. The aim of this research phase was to determine if a system that provides ICPs with individualized HH behaviour data could help in improving hand hygiene compliance. Next to that, this research phase tried to answer the question of how such a system should look like. This was done by means of a literature research in the form of analysis of documents, materials and scientific papers, visiting an academic conference about HH in Dutch hospital at the Erasmus MC in Rotterdam, doing a contextual research in the form of direct observations in the Elisabeth hospital in Leiderdorp and by arranging in-depth interviews with ICPs. Based on the understanding that was obtained in this research stage, an initial concept design for the proposed new system had been setup.

The second stage in this NPD project (preliminary market and technical assessment) contained a preliminary investigation on the commercial and technical viability of the proposed new system. In order to determine if there is a market need for the proposed new system, a primary market research involving original field research (e.g. focus groups and interviews) has been setup. In order to determine if there is a market need among ICPs for a system that provides individual HH behaviour data, the researcher setup different interviews and discussions with a number of ICPs.

Based on the understanding that was obtained in the former NPD stages product and system specifications were setup in cooperation with leading ICPs. After that, the researcher performed a technical research related to which technologies were best suitable for our application. First an expensive literature research was performed; in addition the researcher had different meetings with RTLS and WLAN specialists. After an extensive research a number of RTLS and WLAN technologies were identified, which are able to fulfil the market requirements. After this was clear, different meetings with suppliers of systems that are based on these different technologies were arranged. Based on meeting with sales representatives of the different RTLS and WLAN suppliers, the team gained a deeper understanding about which technology would best suit our requirements in the market place.

In the third stage of this NPD project (building the business case) a detailed market study, examining the market trends, the attractiveness of the market and the competitive situation in the market has been completed. This has been done by means of an extensive literature research related to the infection control and prevention market, visiting the Health and Technology (HAT) congress in Arnhem, and by different meetings with sales and marketing directors from Miscea, Schulke-Meyer, Imtech and Medica. Based on NPD literature the researcher setup operational NPD plans and an adoption and commercialisation plan. Next to that, business and financial analyses were completed. In the end of this research the risks associated with this NPD project were examined.

The three phases that have been completed are extensively described in three separate additional “phase reports” that complement this Master thesis. All the literature used in this project can be found in the references. All interviews, meetings, congresses and symposiums that have been setup/visited can also be found at the end of this report.

Each gate within this NPD project consisted of a corporate meeting determining whether or not the project moved on to the next phase of development. Each gate involved team activity. A cross-functional management team examined the project using key parameters and gathered information in order to make the decision as to whether the project advanced to the next stage or not. The team looked at operational, technical, marketing and financial aspects of the proposal to assess potential risk and reward. The proposal had to clear the hurdles in the gate before proceeding to the next; each stage involves more financial commitment and development than the previous. The idea is to kill off those projects that do not meet the gating criteria. As project passed through the gates it was better understood, there was consequently less risk and more financial and marketing resources could be devoted to them (based on Sloane, 2006). The decision regarding the continuation of this NPD project is governed by (a) how uncertain Miscea is about the rewards related to the project (b) how uncertain

the project is from the standpoint of developing the technology, (c) which paths (potential) competitors will be taking, (d) and the initial industry position of Miscea (based on Loch and Kavadias, 2008).

This research can be described as being a qualitative action-based case study. Rather than using samples and following a rigid protocol to examine a limited number of variables, qualitative case study methods involve an in-depth, longitudinal examination of a single instance or event: a case. Reason and colleagues (2007) define action research as a participatory, democratic process concerned with developing practical knowing in the pursuit of worthwhile human purposes, grounded in participatory worldview, which they believe is emerging at this historical moment. It seeks to bring together action and reflection, theory and practice, in participation with others, in the pursuit of practical solutions to issues of pressing concern to people, and more generally the flourishing of individual persons and their communities. The viability study can be seen as a case study about the initiation and strategy-making phases of a NPD project within a SME. This research can give important insights into the first three stages of the NPD process of a radical innovation, aimed at developing a product based on latent performance dimensions, within a small innovative company. Action research is about working towards practical outcomes, and also about creating new forms of understanding, since action without reflection and understanding is blind, just as theory without action is meaningless (Reason and Bradbury, 2007). Action research is an emancipatory, evolving process of coming to know rooted in everyday experience. This means action research cannot be programmatic and cannot be defined in terms of hard and fast methods (Reason and Bradbury, 2007).

4. Initial idea screen

This chapter deals with the first stage of Cooper's (2001) generic five-stage five-gate model. The first stage is an initial screening of the (commercial) viability of the new product idea. Based on the analysis presented in this chapter a basic understanding about the viability of the proposed new project idea was obtained.

“Modern healthcare has brought unprecedented benefits to generations of patients and their families. Lives can be saved, diseases can be cured, survival can be prolonged and quality of life can be enhanced, all on a scale that could not have been foreseen over 50 years ago. Today's healthcare, though, brings risks as well as benefits. No risk is more fundamental than the risk of infection” (Department of Health, 2000).

“In the 19th century, hospitals were hazardous environments. Until the latter part of that century there was no understanding of the mode of transmission of infectious diseases. So there was little application of the principles of hygiene to prevent patients acquiring infection during surgery or childbirth. As a result in-hospital mortality rates were high. The situation improved dramatically with increased understanding of the link between basic hygiene and infection. In 1860 Florence Nightingale published ‘Notes on Nursing’, in her book she placed great emphasis on the importance of hygiene, cleanliness and standards of care. She dramatically cut the death rates from infection in a military hospital in the Crimean war. Further improvements came about with the discovery of the value of antisepsis during surgery. However HAIs made a resurgence during the last three decades of the 20th century and is now a major problem for healthcare systems around the world” (Department of Health, 2005).

Healthcare-associated infections represent an important public health problem today as a major cause of high morbidity, mortality and economic consequences in hospitalized patients (Yalcin, 2003). Healthcare-associated infections are infections, which are a result of treatment in a hospital or a healthcare service unit, but secondary to the patient's original condition. Infections are considered a HAI if they first appear 48 hours or more after hospital admission or within 30 days after discharge. This type of infection is also known as a hospital-acquired infection or nosocomial infection (WHO, 2005).

“Infections acquired in healthcare settings are among the major causes of death and increased morbidity in hospitalized patients. Healthcare-associated infections represent a significant burden for both the patient and his or her family and for public health. Healthcare-associated infections affect hundreds of millions of patients worldwide every year. As an unintended result of seeking care, these infections lead to more serious illness, prolong hospital stays, and induce long-term disability. Not only do they inflict unexpected high costs on patients and their families, they also lead to a massive additional financial burden on the healthcare system and — last but not least — contribute to unnecessary patient deaths” (WHO, 2005).

According to the World Health Organization (WHO), over 8.6 million people worldwide suffer from infectious complications associated with healthcare. In developed countries, about 5–10% of patients admitted to acute care hospitals acquire an infection that was not present or incubating on admission. Healthcare-associated infections add to the morbidity, mortality and costs that would be expected from the patient's underlying disease alone. In the USA, one in 136 hospital patients becomes seriously ill as a result of acquiring an infection while being hospitalized. This is equivalent to 2.000.000 cases a year and tragically about 80.000 deaths annually. The European Centre for Disease Prevention and Control (ECDC) has calculated that the yearly number of patients in the EU with at least one HAI can be estimated at 4.1 million patients, this is equivalent to one in twenty patients. Since patients sometimes acquire more than one infection during the same hospitalisation, the yearly number of acquired infections is estimated to be 4.5 million. Every year, approximately 37,000 deaths

are thought to be caused *directly* by HAIs; an additional 110,000 deaths yearly occur in which such infections have contributed to death (EU, 2008). When a patient acquires a HAI it is extremely distressing for them, their family and the healthcare staff treating them.

Estimated prevalence of healthcare associated infection			
• USA	5-10%	• Denmark	8%
• Australia	6%	• France	6-10%
• Norway	7%	• Netherlands	7%
• England	9%	• Spain	8%

Source: Thames Valley University, Richard Wells Research Centre and other expert sources

Fig. 7 Estimated Prevalence of HAIs

Added to the considerable human misery caused by HAIs is their economic impact. Infections are very costly. On average, HAIs add three to ten days onto a patient's length of stay in hospital. According to a calculation performed by the European Union, the resulting extra healthcare cost caused by HAIs for the EU can be estimated conservatively at € 5.28 billion per year. In the USA, the risks of acquiring a HAI have risen steadily over the last decades with accompanying extra costs estimated at \$4.5 billion to \$11 billion a year. In the UK, HAIs are estimated to cost £1000 million annually to the National Health Service (NHS). The costs of HAIs vary from country to country, but are substantial everywhere (WHO, 2005).

In a report written in 2005, the WHO states that most patient deaths and suffering that are attributable to HAIs can be prevented. Different studies have shown that at least one third of all HAIs are preventable. The WHO (2008) considers HH to be the primary measure to reduce HAIs. Although HH has been intensively promoted as the most important means of preventing HAIs, numerous studies have demonstrated that compliance with HH recommendations is poor (Gould et al., 2008). The mean baseline rate among HCWs has been reported as 40%, ranging from 5% to 81% in 51 different studies published between 1981 and 2004 (Sladek et al., 2007). As failure to comply with HH recommendations is considered the leading cause of HAIs, focusing on the improvement of HH behaviour will be most effective in reducing HAIs. The WHO states in a 2005 report that improving HH compliance has the potential to save millions of lives and to halt the diversion of a significant amount of resources from other more productive uses.

Although HH is frequently advocated as “the single most important practice to reduce the transmission of infectious agents in healthcare settings”, compliance with HH protocols is poor. In an attempt to understand this, the Association for Professionals in Infection Control and Epidemiology (APICE) setup a survey to determine barriers HCWs experience when it comes to HH compliance. A survey performed by Gina Rollins (2008) among a sample of 3.227 infection control specialists shows the following results. Major challenges to HH compliance reported by participants include: staff not thinking about it (43 percent), being too busy (25 percent), having patient needs take priority (25 percent) and not having a role model (24 percent). Other studies (Backman et al., 2008) (Pittet et al., 2000) (WHO, 2005) show the same results. The barriers can be divided in four categories: (1) forgetfulness, (2) lack of time, (3) inconvenience and (4) lack of knowledge.

According to Jarvis (2007) implementation of evidence-based HAI prevention interventions should be a high priority for all healthcare facilities to reduce preventable HAIs to the greatest extent possible. High mortality rates and economic expenses, which HAIs represent, emphasize the justification for measures of control (Yalcin, 2003). The research literature describes a lot of interventions and research programs that have been tried to improve HH compliance and their effects on infection rates (Rollins, 2008) (Pittet, 2001) (Gould et al, 2008) (Institute for Healthcare Improvement, 2008).

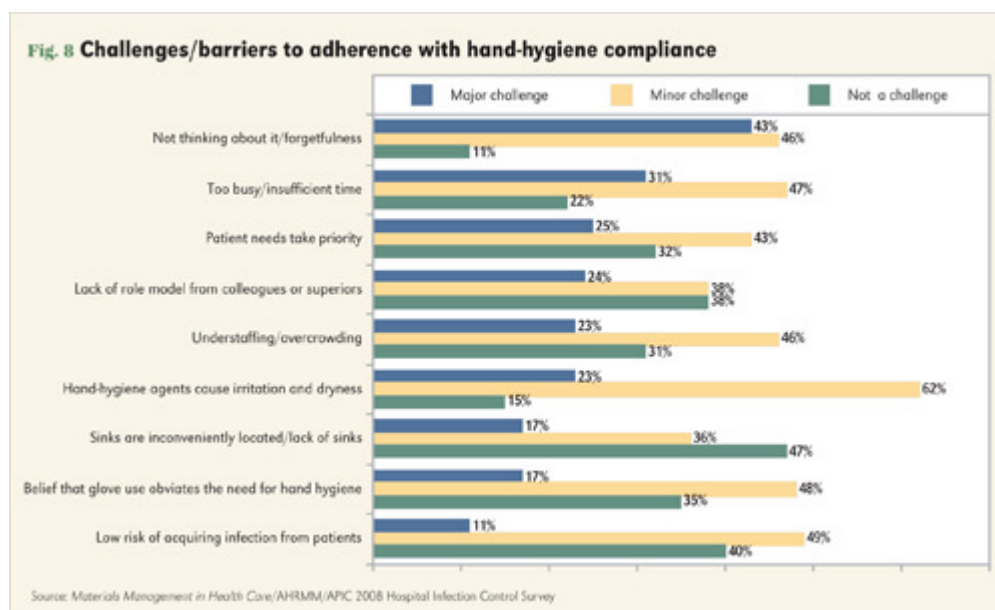


Fig. 8 Barriers to HH compliance

According to a review article written by Backman et al. (2008), it is very difficult to identify specific HH interventions that were clearly associated with significant reductions in the incidence of HAIs. According to this review article it is very difficult to isolate the specific effects of the different HH interventions on HH compliance and related HAIs. This is consistent with a review paper written by Gould et al. (2008), according to them the relative contribution of each intervention is difficult to measure. Gould et al. state that there is a dearth of methodologically robust studies to explore the effectiveness of single interventions to improve HH compliance.

According to a number of scholars and research institutions alike, the interdependence of individual factors (eg, knowledge, attitudes), environmental constraints (eg, access to washing facilities) and organisational climate (eg feedback, positive reinforcement) may play a key role in the success of behavioural interventions. Due to the complexity of the process of behavioural change, and the wide diversity of organisation life, multimodal strategies to improve HH compliance are necessary to reduce the occurrence of HAIs (Pittet, 2001). The United Kingdom, Australia, and Switzerland, among other countries are in agreement that a multimodal strategy to improve HH compliance is necessary to reduce the occurrence of HAIs. This is consistent with review papers written by Naikoba (2001) and Gould et al. (2008) who conclude that multifaceted approaches promoted HH compliance more effectively than single interventions. These global consensus guidelines reinforce the need for multidimensional strategies as the most effective approach to improve HH compliance.

In the field there are three widely known multimodal programs that have resulted in improved HH compliance. Two major programs, Washington (Pittet et al., 2000) and Geneva (Larson, 1999), have demonstrated interventions that have induced sustained improvements in HH compliance. Both programs consisted of making alcohol-based hand rubs (AHRs) widely available, and by continuously assessing the stage of behavioural change and providing HCWs feedback on the stage of behavioural change. The introduction of AHR in combination with a short education program has also been reported to improve compliance. Whitby et al. (2008) tried to examine the effects of the three programs on sustained HH compliance by HCWs. In order to do so the researchers setup a two-year study to determine the sustained improvements of the three different programs on HH compliance. The paper concludes that the Washington program as well as the Geneva program were effective in achieving sustained improvements in HH compliance. Introduction of AHR without an associated behavioural modification program proved ineffective. The two multimodal HH improvement programs that proved to be successful in the long run both had repeated monitoring of compliance and routine performance feedback as key elements. The importance of monitoring and performance

feedback cannot be underestimated in the successful, long-term implementation of the Geneva and the Washington program.

Feedback is the way to guide, coach and educate employees to improve or sustain performance (Forte, 2008). According to Mesch et al. (1994) feedback may serve as an important motivational tool for managing group performance. It has been frequently observed that managers who demand high performance from their subordinates often achieve better performance than those who expect less. Imposing high standards in the form of negative feedback increases performance in part through its effect on group goals and group effort (Mesch et al., 1994). This is consistent with Forte (2008) who states that feedback is one of the most powerful tools a manager has to influence performance. A planned, matter-of-fact process for delivering information about performance helps people know where they stand and what's expected of them — and creates a consistent opportunity for praise (Kislik, 2007). Feedback is recognized as a key determinant of individual performance in organizations because it provides employees with information regarding the effectiveness of their behaviours (Brutus and Greguras, 2008).

Although few studies have examined the direct role of monitoring and feedback on HH compliance, four research papers (Clifton, 2008) (Jefferson et al., 2005) (Venkatesh et al., 2008) and (Chou, 2008) further support the conclusion that monitoring and feedback could improve HH compliance in a sustained fashion. All four papers were not included in the review papers of Gould et al. (2008) and Backman et al. (2008). Programs that have tried to influence compliance by monitoring HH behaviour, and providing feedback based on this behavioural data - as part of a multimodal program or as a single intervention - are among the only studies that have seen a sustainable increase in compliance. This is consistent with the conclusions drawn based on the Geneva research. The Geneva researchers concluded that the most effective measure in their program had been routine observation and feedback (Pittet, 2001). According to Pittet (2001) improvement in infection control practices requires, continuous assessment of the stage of behavioural change and providing HCWs feedback on the stage of behavioural change. Based on this understanding, direct surveillance to determine HH compliance has become a routine activity for ICPs; however, such projects are time consuming, labour intensive and may be prone to significant bias.

Economic concerns have taken on increasing importance in infection control since the mid 1970s. The economic impact of HAIs is high. The studies that made an assessment of the cost of HH control programs to reduce infection rates versus benefits shows major savings can be achieved. Good data are available from the United States. They show that the costs of maintaining one hospital bed for a year would support a full hospital infection control program in a 250-bedded hospital. The results of a study performed in the UK suggest that, if the incidence of HAIs observed could be reduced nationally with 10 percent, resources to the value of £ 93.1 million might be released. This would be equivalent to 364056 bed-days or 47902 consultant episodes (Department of Health, 2003). These findings are consistent with research papers written by Jarvis (2007) and Macartney et al. (2000). Both research papers conclude that even minimally effective infection control programs are cost-effective. Both researchers state that increased support should be given to infection control programs so that preventable HAIs and their associated expenditures can be averted. Next to that, two research articles briefly discussed the cost-effectiveness of their HH compliance improvement interventions. Both articles concluded that their program was cost-effective from a societal perspective (Pittet et al., 2000). Kristine et al. even conclude that their program saved about \$6 on every dollar spend on infection control interventions (Kristine et al., 2000).

In summary, improving HCWs HH compliance and thereby reducing HAIs may be one of the only proven methods for reducing resource utilization while improving patient care (Yalcin, 2003).

5. Scoping

This chapter deals with the second stage of Cooper's (2001) generic five-stage five-gate model. The second stage is a preliminary investigation on the commercial and technical viability of the new HHMS. The preliminary investigation consists of a preliminary market assessment (5.1) and a preliminary technical assessment (5.2).

5.1 Preliminary market assessment

This chapter starts by describing the MISCEA HHMS (5.1.1). This section will also outline the user advantages of the system. This section ends with outlining the market needs study performed as part of this NPD project (5.1.2).

5.1.1 The MISCEA hand hygiene management system

In order to support ICPs in improving overall HH and HH compliance, Miscea is considering to develop the MISCEA HHMS. The MISCEA HHMS is a system that consists of a combination of sensor-activated non-touch faucets (figure 9) and standalone dispensers (figure 10). The MISCEA faucet, delivers water and a maximum of two other liquids, depending on the situation: soap, lotion, disinfectant or detergent. The MISCEA faucet consists of two parts: a faucet and a systembox. The non-touch faucet is mounted on the washbasin. The systembox is installed under the washbasin. All hard and software of the MISCEA faucet are placed in the systembox. Water, electricity and the non-refillable packages containing HH agent are connected to the MISCEA via the systembox. The MISCEA standalone dispensers are sensor-activated battery-powered dispensers that can be used to deliver different types of HH agent, in a hospital facility this will most often be soap or disinfectant but this can also be hand lotion. If a hospital purchases a total system, including faucets and stand-alone dispensers, the dispensers will -most of the time- contain disinfectant and will be made available near the point of care, in order to facilitate easy access to disinfectant. The MISCEA HHMS makes use of a patented refill system, the MISCEA packaging system. The MISCEA packaging system is a vacuum, closed system.



Fig. 9 MISCEA Faucet



Fig. 10 MISCEA dispenser

The usage of the MISCEA faucets and stand-alone dispensers is completely touch-free, which prevents the risks of cross contamination. The MISCEA faucets and dispensers are quick and easy to use and have an attractive modern design. In addition, the MISCEA faucet is easy to clean, especially in comparison to a situation in which you have a faucet and two separate dispensers. As the MISCEA

faucet is placed on a washbasin, there is no dripping of dispenser fluid outside the washbasin. Additionally, the MISCEA faucet is equipped with a flush function program that guards against Legionella bacteria.

The MISCEA packaging system is a closed, vacuum, non-refillable system that makes use of peristaltic pumps; this ensures a high level of hygiene. As the MISCEA packaging system is a vacuum system, the MISCEA always dispenses an exact dosage of soap and disinfectant thereby ensuring that the hands of HCWs are always washed or disinfected with the correct amount of product. As the MISCEA system makes use of a patented refill system; HH product packages cannot be refilled. The HH agent product packages are transparent and can be easily replaced. Additionally, the patented refill system also makes it possible for MISCEA to select which suppliers may provide refill products. This guarantees a high and stable quality of product.

The MISCEA HHMS can improve the environmental conditions under which HCWs work in order to facilitate HCWs to adhere to HH recommendations more easily. By making HH facilities touch free, more easily accessible, quick and easy to use, and by providing HCWs with (the correct amount of) effective and skin-friendly HH products, the HHMS will make it easier and more convenient for HCWs to perform HH. In addition to improving the environmental conditions under which HCWs work, the HHMS will be able to provide ICPs with detailed information concerning (individual) HH behaviour within their facilities. By coupling the MISCEA faucets and standalone dispensers to a wireless data network, and by integrating an identification registration system within the faucets and dispensers, a system will be developed that will be able to monitor how many times a faucet or dispenser is used, when, how, and by whom. By giving HCWs id-cards, and by placing id-receivers in the faucets and dispensers, the MISCEA HHMS will be able to monitor individual HH behaviour. As already mentioned, direct surveillance to determine HH compliance is time consuming, labour intensive (and thereby very expensive) and may be prone to significant bias. The HHMS will be able to monitor individual HH behaviour in a cost-effective and non-biased way.

A distinction between monitoring HH behaviour, and determining HH compliance must be made. The MISCEA HHMS will be able to monitor (absolute) HH behaviour and thereby give an indication of HH compliance. By coupling the HH behaviour data, to the number of patients and statistical data relating to the average number of patient contacts and thus HH action opportunities, an indication of HH compliance can be given. The system will only give an indication of HH compliance. If a HCW for instance transfuses blood he or she is expected to perform HH with soap and water before and after patient contact. The HHMS will not be able to tell if a HCW is compliant with these HH recommendations. These types of organisation-wide compliance data can only be gained by monitoring all HCWs within the total organisation, all day long, at all time. Although in theory this might lead to 100% reliable compliance data, in real-life this is practically impossible to achieve.

The MISCEA HHMS has the following user advantages:

1. Individualized hand hygiene behaviour management information

It is often said that you can't manage what you can't measure. Knowledge is power, and without truly understanding what is happening inside your facility at any given time, it is difficult to identify and correct problems and take action to improve business processes. Due to the complexity of the process of (behavioural) change, and the wide diversity of organisation life, hospitals that want to improve HH compliance first need to analyse the root causes of HH non-compliance within their own organisation (based on van der Schaaf, 2005). The factors that may cause HH non-compliance are multiple and may differ for every department, team, individual, ward, room or even bedside. Analysing and determining root causes of HH non-compliance is not as easy as one might expect. As a matter affect it is extremely difficult. The fact that only limited data related to HCW HH behaviour is available to ICPs does not make the challenge any easier. Currently ICPs have to analyse the complex problem of HH non-compliance by means of random observational test samples that are not

only time consuming and labour intensive to execute, but are also incomplete and are prone to significant bias.

With the support of the MISCEA HHMS, ICPs can gain a deeper understanding about HH behaviour within their own organisation. Based on this understanding, ICPs can analyse the problem of HH non-compliance in more detail. Grounded on the data provided by the system and by complementary analyses - that might consist of direct observations, interviews, surveys and discussions with HCWs - different technical as well as organisational interventions to improve HH compliance can be initiated, designed and finally implemented (Appendix III). The analyses performed will provide ICPs with a more realistic view of how the system is actually working, as well as contribute to the creation of more focussed and therefore more (cost) effective and sustainable interventions.

After interventions are developed and implemented, the system will be able to monitor the interventions efficacy in improving HH behaviour. The system will give the hospital a tool to monitor how efficient their interventions are in achieving their aim. If the eventual aim is not met, the hospital can analyse the problem further, and based on this, initiate and develop new interventions. This cycle continues until a point is reached in which HH behaviour is deemed sufficient. When a sufficient level of HH behaviour is reached, it is important to maintain this state of affairs. As the system will be in place for a longer period of time, ICPs will be notified if there are indications of declines in compliance rates. If compliance rates decline over time, the whole analysis, design and intervention cycle can be initiated again, if deemed necessary.

In addition to providing ICPs with a tool to monitor HH behaviour, the HHMS in itself will most probably induce behavioural change already. As HCWs know that their behaviour is being monitored, awareness will grow, and compliance will increase as a result of that. Additionally, providing HCWs feedback on the stage of behaviour change is an effective measure in itself to induce sustained improvements in compliance. The HH behaviour data provided by the system, would enable ICPs to detect HCWs that might be non-compliant with HH recommendations. Based on this information ICPs can communicate more effectively with these (potentially) non-compliant HCWs and give them more meaningful feedback in order to improve their compliance with HH procedures.

As already mentioned, feedback may serve as an important motivational tool for managing group performance (Mesch et al., 1994). Kislik (2007) concludes in his research paper that a planned, matter-of-fact process for delivering information about performance helps people know where they stand and what is expected of them — and creates a consistent opportunity for praise. Brutus and Greguras (2008) state that feedback is recognized as a key determinant of individual performance in organizations because it provides employees with information regarding the effectiveness of their behaviours. This is consistent with Forte (2008) who concludes that feedback is one of the most powerful tools a manager has to influence performance.

Effective performance feedback has rules to ensure its effectiveness because, done poorly, it can do damage to the manager/employee relationship (Cleveland, 1991). Employees don't want to be told what to do or to be scolded. They want meaningful information to help them improve (Forte, 2008). Change is always hard; typically, a performance change requires change in both ideas and behaviors. To create the changed idea, you start by giving the employee evidence or descriptions of the demonstrated behavior, both the more desirable behavior and the gaps or variances between the two. It can help to explain why the demonstrated behavior isn't considered successful and the negative impact it creates on others, on the subject herself, or on the organization overall. Explaining why the desired behavior is preferable helps the subject convince herself that there is a value to trying to make the change. This sense of value and purpose is crucial to generating and sustaining the new behavior (Kislik, 2007). Criticizing performance without giving suggestions for improvement is a common feedback mistake, therefore it's important to develop a progress plan (Lindenberger, 2005). It is important to work with the employees to suggest options that would improve a negative event or keep a good event going (Forte, 2008). Additionally, it is important to be clear about the specific changes

in behaviour that is expected in a specific period of time, and follow up as scheduled (Lindenberger, 2005). In this way, well-structured performance feedback creates both an opportunity for change and a road map for change (Kislik, 2007).

Feedback has an impact on emotions and subsequently on work attitudes and behavioural intentions. Feedback affects recipients' emotions and such emotional reactions can mediate the relationship between feedback and counterproductive behaviour, turnover intentions, citizenship, and affective commitment (Belschak, 2009). According to Forte (2008) it is very important to show respect and understanding. In this respect, giving negative feedback in public is highly discouraged. Giving and receiving clear and constructive feedback requires courage and skill. It is essential to build good relationships with employees, motivating peak performance from the team in question (Lindenberger, 2005).

If the employee's performance does not change, does not improve, then you may have to shift from developmental feedback to corrective action, a more stringent and rule-based form of discussion, meant to let the employee know that she's approaching serious consequences (Kislik, 2007). Previous research on the effects of feedback sign on goal setting and performance at the individual level suggests that individuals who receive negative feedback perform at higher levels and set higher goals than individuals who receive positive feedback (Mesch et al., 1994). A study by Mesch et al. (1994) suggests that, in the short term, negative feedback may have a positive effect on goal setting and performance. The results of this study also indicate that negative feedback leads to higher levels of dissatisfaction among group members, which has been known in the literature to be positively correlated with employee turnover and absenteeism and to be negatively correlated with organisational citizenship behaviours. As a result, there may be a point where using negative feedback to increase performance becomes detrimental rather than beneficial (Mesch et al., 1994). It may be that the critical variable in determining whether or not negative feedback is advantageous or detrimental may be the manner in which feedback is given. If managers provide feedback in a specific, non-evaluative way, where the group perceives the feedback to challenge them to strive for attainable goals, then negative feedback may lead to higher group performance. If, on the other hand, negative feedback is presented in a punishing, evaluative manner, Mesch and his colleagues (1994) expect unfavourable outcomes.

2. Touch-free

The usage of the MISCEA faucets and dispensers is completely touch-free, which prevents the risks of cross contamination. If a faucet is manually operated, a towel must be used to turn of the spigot. If HH procedures are not followed up, thus the contaminated spigot is used to turn off the faucet without using a towel, HH becomes less effective. Touch-free systems make HH procedures easier and therefore make HH efficacy more consistent organization-wide. A research paper written by Montville et al. (2001) shows that conventional hand washing systems caused a small increase in contamination compared to touch-free systems. In a study performed by Larson (1991), the impact of automated sinks on HH practice and attitude of staff were examined. The researchers conclude that hands were washed significantly better with the help of automated sinks. The benefits of touch-free systems are being widely acknowledged. In 2006, Germany introduced new guidelines on HH procedures in medical environments. The new guidelines dictate that faucets and dispensers should be operated touch-free. In the UK a faucet or a dispenser should be touch-free as well, either being elbow, knee or sensor operated.

3. Easily accesible

Research has shown that making HH facilities more easily accesible increases HH complaine (Pittet, 2001). The value of easy access to HH supplies, whether sink, soap, medicated detergent, or waterless AHRs solution, is self-explanatory. Asking HCWs to walk away from the patient bed to reach a washbasin or a hand antiseptis solution invites non-compliance with HH recommendations. Pittet

(2001) concludes that easy and timely access to HH facilities appears to be a necessary prerequisite for appropriate HH behaviour (Pittet, 2001). Alcohol-based hand rubs are very well suited for hygienic hand disinfection. Alcohol-based hand rubs have two major advantages compared to washing with water and soap. First of all, no washbasin is needed to perform hygienic hand disinfection, thereby making it easier to make AHRs available at the bedside. Second of all, as AHRs have an excellent spreading quality and evaporate rapidly, hygienic hand disinfection can be performed relatively fast (Pittet, 2001). Research shows that placing AHR dispensers near the point of care has been associated with increased HH compliance (Institute for Healthcare Improvement, 2008). The MISCEA stand-alone dispensers can be placed near the point of care, thereby facilitating easy access to AHR.

4. Ease of use

Research has shown that HH compliance falls during periods of high workloads. The workload HCWs currently experience is very high, and will most likely increase in the future (Clements et al., 2008). By simplifying HH procedures, workloads can be lowered. As the MISCEA standalone dispensers can be placed near the point of care, and are quick and easy to use, HCWs do not see HH as interfering with their work, and/or increase their workloads.

5. Effective and skin-friendly HH agents

Using effective and skinfriendly HH agents is very important in healthcare settings. The efficacy as well as the irritation potential of the HH agents is very critical in this respect. In addition to the efficacy and the skin friendliness of the individual HH products, it is important to ensure that the selected HH agents are chemically compatible; that the individual HH products don't deteriorate each other's effectiveness; and that they minimize skin reaction from the exposure to a variety of chemicals (Bush et al., 2007). As skin irritation caused by hand washing is an impediment to HH compliance, healthcare organizations should make sure that they provide HH agents that cause minimum harm to the skin. Additionally, they should provide skin care products that reduce skin irritation (like hand lotions). As the MISCEA faucets and dispensers make use of a patented refill system, MISCEA can select providers of HH products. This ensures that the products provided are efficacious, skin friendly and are chemically compatible. Additionally, the MISCEA could also be used to provide skin care products like hand lotion.

Next to that, mixing two HH agents together can deteriorate the efficacy of the HH agent used. The MISCEA system can ensure that packages cannot be refilled. The MISCEA packaging system ensures that only non-refillable disposable vacuum packages can be used in the system. The benefits of non-refillable disposable packages have been widely acknowledged. In 2006 Germany introduced new guidelines on HH procedures in medical environments. The new guidelines dictate that HH agents used must be made available in a non-refillable disposable vacuum package. In the UK, the Department of Health also states that disinfectants of soap and disinfectant should not be refillable, but be of a disposable single-cartridge design.

6. Correct amount of product

It is important that dispensers provide the correct amount of product (Institute for Healthcare Improvement, 2008). As the MISCEA packaging system is a vacuum system, the MISCEA faucets and dispensers will always dispense an exact dosage of soap and disinfectant thereby ensuring that the hands of HCWs are always washed or disinfected with the correct amount of product.

7. HH facilities as a reminder

Staff not thinking about HH is reported by many HCWs as a major challenge to compliance (Rollins, 2008). Hand hygiene facilities act as visual cues for HH behaviour (Bush et al., 2007). By placing the

MISCEA, an eye catcher due to its attractive modern design, in healthcare facilities this challenge could be overcome.

Next to that, hospitals can improve on their image. Last few years have seen an increase in media attention and public concern relating to overall hygiene in healthcare facilities. This is very alarming for hospitals as patients and the general public tends to use cleanliness as a proxy for general quality (Department of Health, 2008). Touch-free sanitation has been known to portray an upscale image that resonates with end-users. People often believe that facilities that use touch-free dispensers and faucets are more modern and user friendly (Mollenkamp, 2006). By installing the MISCEA, that has an attractive modern touch-free design, hospitals can improve on their image.

8. Easy to clean

For a person to be infected while in hospital, a simple process has to occur. There has to be a reservoir or source of the virus, bacteria, or other organism that can cause the infection and there has to be a means or vector of transmission. In order to reduce reservoirs cleaning is very important. The sensor-operated MISCEA faucets and dispensers stay cleaner in the first place as the faucets and dispensers can be operated without physical contact. Additionally, the MISCEA faucet is easy to clean, especially compared to a situation in which you have a faucet and two separate dispensers. As the MISCEA faucet is placed on a washbasin, there is no dripping of dispenser fluid outside the washbasin. The MISCEA system reduces waste, such as soap build-up below a manual dispenser or water pooling around faucets.

9. Refilling

It is essential to keep HH product dispensers correctly filled at all times as an empty dispenser frustrates a HCWs intention to perform HH (Bush et al., 2007). In a situation in which a hospital wants to make HH facilities more easily accessible (thereby increasing the amount of dispensers), and if HH compliance rates increase, the number of product dispensers to be refilled rises dramatically as well as the number of times each dispenser has to be refilled. This can present a formidable challenge to the housekeeping department or other groups responsible for refilling product dispensers (Bush et al., 2007). As product packages of 1 to 2 litres can be used in the MISCEA system, product packages have to be replaced less frequently. Additionally, the replacement of the empty pouch is easy and done within an instant. Next to that, the MISCEA management system consists of a never empty system, in which housekeeping receives an electronic alert (for instance a text message or an email) if a dispenser is (almost) empty, thereby ensuring that dispensers are correctly filled at all times.

10. Green and economical

Compared to a manually operated faucet the MISCEA faucet saves up to 70% water. Additionally, the MISCEA faucets and dispensers always dispense an exact and correct dosage of soap and disinfectant, thereby minimizing HH product waste. Reducing water and HH product waste leads to an economic advantage that can be realized by the system. The reduction in time needed to clean the faucet and the worktop - no separate dispensers, no dripping - and the efficient refill system - pouches up to 2 litres - also increases the economic advantage that can be achieved by means of the system. In addition to providing HH behaviour data, coupling the MISCEA faucets and standalone dispensers to a wireless data network gives hospital management exact data on the amount and type of HH product being used within their organisation. Based on these data the hospital can pay their HH supply bills accordingly.

By implementing the MISCEA HHMS, most of the barriers HCWs experience in complying with HH recommendations will be diminished. The HH system will make it quicker, easier (easy access to washing facilities, ease of use) and more convenient (touch free, providing low irritation potential HH agent and providing lotion) for HCWs to perform HH, thereby removing the barriers related to having lack of time and inconvenience. Next to that, as HH faucets and dispenser will be placed throughout

the facility, HCWs will be constantly reminded of the importance of proper HH, this can partly remove the barrier related to forgetfulness.

The Miscea HHMS will provide ICPs with detailed management information. This information can be used to analyse the problem of HH non-compliance and to provide HCWs with individualized HH behaviour feedback. The system will enable ICPs to monitor and analyse individual HH behaviour. ICPs can use this data to determine the individual factors, environmental constraints as well as organisational climate variables that inhibit or could facilitate HH compliance and setup focused and thereby (cost) effective measures to improve on the current situation in a sustainable fashion. After interventions are developed and implemented, the system will be able to monitor the interventions efficacy in improving HH behaviour. The system will give the hospital a tool to monitor how efficient their interventions are in achieving their aim. If the eventual aim is not met, the hospital can analyse the problem further, and based on this, initiate and develop new interventions. This cycle continues until a point is reached in which HH behaviour is deemed sufficient.

Next to that, the management information provided by the system will make it possible for ICPs or hospital managers to provide HCWs with individualized feedback on the stage of behaviour change. As already mentioned, feedback may serve as an important motivational tool for managing group performance (Mesch et al., 1994). According to Kislik (2007) it will be critically important to give HCWs evidence or descriptions of the demonstrated behavior, both the more desirable behavior and the gaps or variances between the two. This can be achieved by setting up education and training sessions outlining the importance of HH recommendations, how to properly perform HH and how to use the MISCEA HH system. In addition, as top management decides to invest in the system, HCWs know HH is a top management priority, thereby reinforcing the importance of complying with HH recommendations. This in turn could diminish the barrier “lack of knowledge” HCWs experience when it comes to complying with HH recommendations.

After that, ICPs in cooperation with HCWs must determine the “cap” between the current and the desired behaviour. According to Kislik (2007) it will be critically important to give HCWs evidence or descriptions of the demonstrated behavior, both the more desirable behavior and the gaps or variances between the two. Once the “cap” is determined, the ICP in cooperation with the HCW must develop a progress plan in order to improve performance. According to Forte (2008) and Lindenberger (2005) it is important to work with the HCW to suggest options that would improve HH compliance. According to Lindenberger (2005) it is important to be clear about the specific changes in behaviour that is expected in a specific period of time, and follow up regularly with performance feedback afterwards. The MISCEA HHMS will provide the ICP with detailed information related to the HH behaviour of the HCW in question. The information provided by the system can be used to provide HCWs with meaningful information to help them improve their performance. The planned, matter-of-fact process for delivering information about performance will help HCWs know where they stand and what is expected of them — and creates a consistent opportunity for praise. The information provided by the system will provide HCWs with information regarding the effectiveness of their behaviours. In this way, the system will make it possible to provide HCWs with well-structured performance feedback, this in turn will create both an opportunity for change and a road map for change (Kislik, 2007).

If the MISCEA HHMS improves HH compliance and thereby reduces HAIs, the system will result in improved patient safety, higher quality of care, and reduced costs. The MISCEA system can reduce staff inefficiencies, missed reimbursements, lost customers/sales, reduce waste and improve the reputation and image of the healthcare facility. The MISCEA HHMS can be seen as an innovation that improves the quality of care as well as reduce overall healthcare costs. The MISCEA HHMS will make healthcare safer and more productive

With regard to the user advantages as described above there is always a certain degree of market uncertainty. Market uncertainty reflects the fact that before a new product is actually launched, there

exists some degree of doubt as to whether consumers perceive the benefits that the new product can provide to be large enough to offset any adoption obstacles, such as switching costs and risk of product failure (Dogson, 2008).

5.1.2 Market needs

In a carefully constructed literature study about HAIs and HH compliance, which was completed as part of the first phase of this NPD project (phase report 1), the conclusion is drawn – based on state of the art literature - that the MISCEA HHMS could, in theory, improve HH and HH compliance and therefore benefit healthcare systems around the world in reducing HAIs. In order to validate the conclusions drawn in the literature study, and to gain a deeper understanding about the needs of ICPs working within healthcare organisations, different ICPs have been interviewed. Based on these interviews, the (preliminary) conclusion was drawn that there is indeed a market need (from the perspective of ICPs working within a hospital) for a system that is able to provide ICPs with detailed personalized data related to HH behaviour. Most ICPs emphasized though, that although they believe that the system could help them in improving HH compliance, they expect that it will be difficult to implement the innovation (thus get the innovation accepted by HCWs). Within discussions with mainly hygienists, the researcher asked which members within their peer group were regarded as opinion leaders. The hygienists gave the name of Prof. Dr. Kluytmans and Prof. Dr. Vos. The NPD team came into contact with Prof. Dr. Kluytmans

The conclusions drawn in the literature study (as part of phase 1) are supported by Prof. Dr. J.A.J.W Kluytmans. Professor Jan Kluytmans MD PhD works at the Amphia Hospital, and since 1996, has been Professor of medical microbiology and infection prevention at the VUmc university medical center, in Amsterdam. Prof. Dr. Kluytmans is a specialist in medical microbiology and infection prevention, in particular the epidemiology of nosocomial infections. Prof. dr. Kluytmans is involved in many guidelines on infection control, especially those dealing with MRSA control, and has over 100 papers published in peer-reviewed journals. Prof. dr. Kluytmans is an authority in the Netherlands (and internationally) on the subject of HAIs.

Prof. Dr. Kluytmans has the hypothesis that a hospital management system that provides ICPs with detailed personalized HH behaviour data could indeed help ICPs to achieve sustained improvements in HH compliance. Prof. Dr. Kluytmans intends to setup a large-scale clinical trial, in order to test the clinical effect of the MISCEA HHMS on HH compliance and thereby HAIs. The pivotal trial is designed to clearly demonstrate product efficacy through a large-scale, multicenter, double blind trial. The large-scale clinical trial will be setup in five different IC units in (academic) hospitals in the Netherlands. In a large-scale study the effect of the MISCEA HHMS on HH compliance will be determined. The results of the study will be published in peer-reviewed journals.

The conclusion is drawn - based on a literature research; discussions with ICPs; the content and discussions with ICPs on an academic conference about HH in Dutch hospitals; and the fact that Prof. Dr. Kluytmans intends to setup a large-scale clinical trial - that there is indeed a market need for a system that is able to provide management information related to individual HH behaviour in order to improve HH compliance.

5.2 Preliminary technical assessment

This chapter contains a preliminary technical assessment into the technologies that will be needed to setup the system and into the possible development work that have to be done in order to develop the new system. This section aims to verify the technical viability of the new system and thereby the overall NPD project.

In NPD projects, the market needs of the new product needs to be taken into account, i.e., the specification of the product have to be matched as closely as possible to the needs of the market, market needs are elicited either through market research or from the understanding of the NPD team of market needs (Loch and Kavadias, 2008). Based on the understanding that was gained by means of the literature research, direct observations, interviews with different ICPs and in-depth discussions with Prof. Dr. Kluytmans, product and system specification were setup. As the first system will be installed in the VUmc, the system specifications were setup in close collaboration with Prof. Dr. Kluytmans. After the specifications for the system were setup, the Researcher performed a technical research related to which RTLS system and which WLAN technologies were best suitable for our application. First an expensive literature research was performed, in addition the researcher had different meetings with RTLS specialist (amongst them researchers from TNO, the Telematica Instituut, the RFID kenniscentrum and multiple RTLS engineering firms).

In order to develop the system, a low cost plug-and-play touch-free dispenser must be developed (5.2.1). Next to that, the data collected by the registration system must be made available to the principle in need for HH behaviour data. In order to send the HH behaviour data to the end user's computer, a wireless local area network (WLAN) will be needed (5.2.2). Next to that, the MISCEA faucets and dispensers must be coupled to a real time location system (RTLS) in order to identify the user of the MISCEA hardware (5.2.3). Next to that, a HHMS software package must be developed that present the HH behaviour data in a clear, ordered, and understandable way, which is easily comprehended by the end user of the data (5.2.4).

5.2.1 Standalone dispenser

In order to develop the total system, Miscea is going to develop a low cost, plug-and-play touch-free dispenser. The MISCEA non-touch standalone dispensers can be used to make AHR more easily available at the point of care, in most cases at the bedside. The MISCEA stand-alone dispenser will be designed according to plug-and-play design principles. The dispensers are battery-powered, with batteries that have an extended battery life (at least a year). As the dispensers are battery operated, the dispensers do not have to be connected to the electricity grid. In addition, the dispensers are low in volume and weight and are flexible to install. This ensures that the dispensers can be rapidly adopted by hospitals as virtually no data or power cables are pulled when installing the dispensers -- making installation simple, fast, scalable, and minimizing infection control issues. Additionally, the dispensers will have to be easy and intuitive to install to gain support in the distribution channel from installation partners. The dispensers will have an attractive, robust, and easy to clean design, therefore reducing reservoirs of infection. Next to that, the high quality dispensers are low in maintenance and can be used very intuitively. The design should be made to allow ease of manufacturing and assembly. Larger purchase volume of key components needs to bring the cost price to the level where the system as a whole can be priced competitively in the retail market.

5.2.2 Wireless local area network

The data collected by the registration system must be made available to the principle in need for HH behaviour data. In the case of a hospital; the principle would be a microbiologist, a hygienist or a hospital manager. In order to send the HH behaviour data to the end user's computer, a wireless local area network (WLAN) is needed. Different types of technological solutions can be used to setup a WLAN, among them: WiFi (2.4 GHz 802.11b and 80s.11g), DECT, Bluetooth, Zigbee, Wibree, Wireless USB (Ultrawide-band radio communication protocol, 3.1 to 10.6 GHz) and different other types of radio communication links (like 868 MHz frequency hopping datanetwork protocols). As in most hospitals there is already a DECT network available, Miscea can piggyback on the wireless data network already available. DECT devices are low in power consumption. This is a big advantage as this extends the battery-life of the battery-powered stand-alone dispensers. The MISCEA faucets and dispensers will be equipped with a data memory card. This enables HH behaviour data to be stored

within the faucets and dispensers. By sending the HH data in a batch at the end of the day, week or month the battery life of the dispensers can be extended.

5.2.3 Real time location system

In addition to coupling the MISCEA faucets and standalone dispensers to a wireless data network, the faucets and dispensers must be coupled to a real time location system (RTLS). By giving HCWs id-cards, and by placing id-receivers in the faucets and dispensers, the MISCEA HHMS will be able to monitor individual HH behaviour. The RTLS technology chosen must fulfil some basic requirements. Most important of all, the RTLS technology chosen may not cause any electromagnetic interference within other medical equipment. Electromagnetic interference (or EMI, also called radio frequency interference or RFI) is an unwanted disturbance that affects an electrical circuit due to electromagnetic radiation emitted from an external source. The disturbance may interrupt, obstruct, or otherwise degrade or limit the effective performance of the circuit. The source may be any object, artificial or natural, that carries rapidly changing electrical currents, such as an electronic circuit (Wahle and Blokhuis, 2007). The RTLS technology and infrastructure may not have any effect on the performance of medical equipment. It is of great importance that the equipment used in highly complex and technical environments like operating theatres, intensive care departments and blood transfusion labs is not affected in any way by the application of this new technology, so that it remains completely safe for patients (Jansen and Stegwee, 2006).

The MISCEA HHMS must be easy and intuitively to use for HCWs. The system must be able to identify the HCW using a faucet or dispenser without the HCW having to perform an extra action in order for him or her to be identified. This means that the RTLS technology chosen should be able to read id-cards at a distance of about 1.5 meters from the faucet or dispenser and within the time-frame that the HCW is within reach of the reader. The RTLS technology chosen must be able to identify the HCW if the HCW wears the tag on his or her body, or if a HCW (for instance) has the id-card in the pocket of his or her pants. Additionally, the id-cards of the HCWs should have a long battery-life so that HCWs do not have to recharge or change their id-cards very often.

One of the key factors for enabling the use of hand wash monitoring is the unit variable cost of the equipment. In order to market and commercialize the system in the nearby future, the unit variable cost of the hardware equipment must be relatively low. Next to that, the power consumption of the receivers should be low, as the stand-alone dispensers are battery-operated and Miscea is aiming to design stand-alone dispensers that have a battery life of at least a year. The receivers should be low in volume and weight, as the receivers have to be built into the systembox of the faucets, and into the stand-alone dispensers.

The RTLS chosen must be fast and inexpensive to deploy, must retrofit easily into existing buildings without patient care disruption and must allow for easy changes and updates to accommodate the ever-changing hospital physical plant. Most importantly, they must co-exist with other hospital infrastructure technologies, such as LAN's, WLAN's (Wi-Fi), and the growing variety of network-enabled and wireless medical equipment. The RTLS technology that will be chosen must be: safe, reliable, low in volume and weight, economically achievable, and have low power consumption. After an extensive research the following RTLS technologies are identified, that are able to fulfil the requirements as set out by Miscea, in cooperation with the VUmc: (i) Semi-passive RFID, (ii) Ultrasound, (iii) Bluetooth and (iv) Zigbee.

After this was clear, different meetings with suppliers of systems that are based on the four different technologies were arranged. Based on meeting with sales representatives of the different RTLS suppliers, a deeper understanding about which technology would best suit the requirements as been set out was gained. Based on the literature research, discussions with RTLS experts and meetings with sales representatives of component suppliers, ultrasound was identified as best suiting the requirements that will fulfil the customer needs in the market place. Ultrasounds systems are

(relatively) low in costs, highly reliable, and low in power consumption. Next to that, ultrasound indoor positioning systems (IPS) are able to detect HCWs in front of a dispenser or faucet at a normal range (1.5 meters), and in a minimum amount of time (msec). Last but not least, ultrasound will not cause any electromagnetic interference (EMI) problems within other (critical) hospital equipment.

Sonitor, a small high-tech company from Norway is the only company in the world that brings IPSs based on ultrasound on the market. The Sonitor IPS uses tags and receivers. The Sonitor IPS tags are battery powered wireless devices attached to movable objects or people. When moving and/or at predefined intervals, the tag will transmit its own id number via ultrasound waves. The nearest Sonitor IPS detector, which is actually a microphone, receives the signal. The receivers, that use Sonitor patented Digital Signal Processing (DSP) algorithms, picks up the signal and transmits it via an existing LAN/Wi-Fi network to a central computer that stores the information about the tag's room-location and the time of receipt of the signal. The low quantity of data transmitted from the tags requires minimal LAN bandwidth so existing wired or wireless LAN can easily be leveraged. Existing PC's can be leveraged as tag signal receivers, eliminating the need for other RTLS hardware then tags attached to the objects to be located or tracked. Sonitor Technologies' RTLS technology is designed for seamless integration with third party applications software and integration solutions.

The Sonitor system uses ultrasound as its means of communications. Ultrasound waves are mechanical waves, and therefore are immune to interference. They do not interfere with sensitive equipment that might otherwise be disturbed by electromagnetic waves (Griffioen and Wybenga, 2007). Next to that the security of an ultrasound system is very high, making it virtually impossible to eavesdrop on the communications link from outside the premises of the installation.

The built-in microphones of the Sonitor high definition receiver can resolve multiple location zones within a room. A single high definition receiver unit can be configured to resolve from one to three sub-zones within the same room. Through future firmware upgrades this zoning capability can be extended to inch level 3D resolution. Rotating turret microphones with wave-guides (optional) can be used to create defined sub-room location zones, such as patient beds or sanitizing stations. The Sonitor system is very precise in determining the exact position of a tag. The accuracy of the system is truly remarkable; the position of the tags can be determined with an accuracy of centimetres. It is because of this that the Sonitor ultrasound system is very reliable in identifying tags, which are within the vicinity of a dispenser or faucet. Ultrasound does not require line of sight between the tag and the microphone, making it possible to track objects that are hidden or located in drawers or filing cabinets. The Sonitor system will be able to register HCWs that are within the vicinity of the dispenser regardless if they wear the tag on their body or within the pocket of their pants

One of the key factors for enabling the use of hand wash monitoring is the unit cost of the equipment. The unit variable costs of the Sonitor hardware are low. This makes it possible to provide location detection per unique location area (in our case a faucet or dispenser) at relatively low cost. Next to that, the Sonitor system has very low infrastructure maintenance requirements, thereby reducing the total cost of ownership.

As the Sonitor microphones make use of a protocol that transmit 28 bits every 0.5 seconds, the Sonitor receivers are low in power consumption (2.5 milliampere per second). Next to that, the system does not need a high-speed tag read, as the person will be at the dispenser for a few seconds at least. Therefore it would be possible to only switch on the Sonitor receivers when a faucet or dispenser has been activated. If a faucet or dispenser is being used, thus the device signals a user by means of the infrared sensors; the PCB will activate the Sonitor receiver. In this way the receiver will not draw any power until the dispenser is being used, then the system will switch on the receiver, the receiver confirms the persons ID and then goes back to sleep. This is an important design element as the stand-alone dispensers are battery-operated and Miscea is aiming to design stand-alone dispensers that have a battery life of at least a year.

The Sonitor IPS P-Tag has been designed using feedback from hospital personnel, specifically to be worn by patients and personnel. The unique construction consists of a reusable electronics core and a disposable, single use (and waterproof) outer shell, which eliminates the risk of cross contamination. The small footprint tags have optional communication buttons for custom configuration. Additionally, the Sonitor tags have a long battery life and are inexpensive to buy. The Sonitor tags are safe, comfortable and inexpensive.

5.2.4 Hand hygiene management system software

The Sonitor IP system uses receivers and tags that are linked to a digital file containing all vital statistics and information about the item or person being monitored. In order for the end user to understand the delivered data, a HHMS software package must be developed that present the HH behaviour data in a clear, ordered, and understandable way, which is easily comprehended by the end user of the data.

6. Building the business case

This chapter deals with the third stage of Cooper's (2001) generic five-stage five-gate model. In the second stage of this project, the technical viability of the new system has been determined. Next to that, the preliminary market assessment shows that there is a market need for the MISCEA HHMS. The third phase consists of a detailed investigation of the NPD project consisting of a detailed market study (6.1), setting up marketing and commercialisation plans (6.2), setting up operational NPD plans (6.3), and completing a business and financial analysis (6.4).

6.1 Detailed market study

In NPD market attractiveness is an important strategic variable (Kahn, 2005). To properly evaluate the potential for new product success, it is necessary to understand the market. This market understanding should clarify how the product will benefit both the customer and the company (Mital et al., 2008). Close analysis of the present situation in the market is fundamental, along with speculations about how it might progress in the future (Kahn, 2005). In order to gain basic market understanding, an extensive literature research related to the infection control and prevention market has been completed. In addition to the literature research, the researcher visited the congress Health and Technology and had different meetings with sales and marketing directors from Miscea, Schulke-Meyer, Imtech and Medica.

Based on the literature research, the congress, and the meetings, market trends (6.1.1) and attractiveness of the market (6.1.2) were determined. In addition, a competitive product and (potential) competitor analysis was setup. The research also tries to appropriately answer the question in regards to appropriability. In other words, how can Miscea protect its innovation from being easily copied by competitors in the future (6.1.3)?

6.1.1 Market trends

In the Netherlands the total expenditure on health per capital (Intl \$, 2005) was 3.187. The total expenditure on health as a percentage of GDP (2005) was 9.2 %¹. The healthcare market is enormous and growing as the world's populations are aging and older people consume considerably more healthcare than younger people. The ageing trend is a megatrend that will have enormous influence on healthcare in the future as people not only live longer but expect to be well for longer too. Next to that, healthcare expenditure is growing steadily; this is not only caused by aging populations, but also by the progression of medical technology, more and more (quality) conscious patients, and economic prosperity. This results in the fact that the costs of healthcare and thereby health insurance is rising every year. In the Netherlands, there is a growing concern that healthcare expenditure is rising steadily; healthcare insurance companies are becoming increasingly worried about the affordability of high quality healthcare in the near by future². Next to that, countries in the developed world face a slowly growing shortfall of nurses.

People can find on the Internet a wealth of information about diseases, diagnoses, and treatment options; next to that, consumers can gain information about the quality of care delivered in different hospital organisations within their service area. Consumers, all over the developed world, are demanding a much greater role in decisions involving their healthcare. This move towards more individual control over healthcare decisions and healthcare spending is part of a global movement towards healthcare consumerism. It is projected that this will lead to cut throat competition in medical centres including medical tourism in the nearby future. As hospital organisations are increasingly subjected to free market forces, they have an increased economic incentive to improve the quality of

¹ Source: WHO

² Source: Presentation Nederlandse zorgautoriteit

care delivered within their facilities in order to attract and retain customers. Next to that, last few years have seen an increase in media attention and public concern relating to overall quality of healthcare facilities. According to the Department of Health (2008) there is a growing concern about the fact that patients and the general public are losing confidence in their healthcare systems. In addition, lawsuits are on the rise (especially in the US).



Fig. 10 Continuous growth on healthcare expenditure (presentation Philips Healthcare)

Thus, in today’s rapidly changing healthcare industry, providers of care face unyielding pressure to improve quality, maintaining operating margins and lower costs (Burns, 2005). In order to provide future generations with high quality and affordable healthcare, hospital organisation around the world have to improve the efficiency of their operations, as well as improve the quality of the care delivered within their facilities as they are forced to operate in a free market. In order to solve this problem one needs to look at the value chain and cost continuum of care. As a patient progresses through this continuum (diagnosis, work-up, treatment), expenses from labour fees and stay climb. The economic factors are forceful. Procedures and medical personnel are extraordinarily expensive (Burns, 2005). By emphasising prevention, healthcare costs can be reduced; workloads can be lowered and last but not least clinical care can be improved. The Dutch society of healthcare insurance companies also stresses the need to prevent instead of cure. Healthcare systems can be improved dramatically, by implementing innovations that not only improve the safety and quality of care but also lower overall healthcare costs.

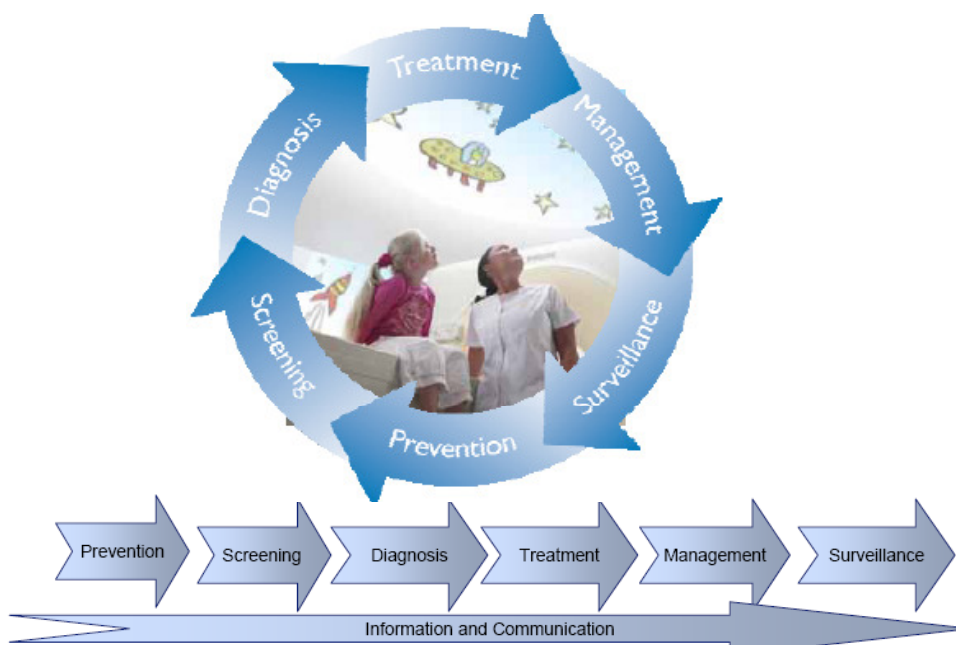


Fig. 6 Driving new care delivery models (Porter and Teisberg, 2006)

As already mentioned healthcare providers face unyielding pressure to improve quality, maintaining operating margins and lower costs (Burns, 2005). Reaching these goals requires a relentless focus on making healthcare safer and more productive. This brings us to the point of patient safety. Patient safety, defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare, is an issue of increasing concern all over the world. It is estimated that in EU Member States between 8% and 12% of patients admitted to hospitals suffer from adverse events whilst receiving healthcare³. Frequently occurring adverse events include HAIs that affect an estimated one in twenty hospital patients on average every year. Reducing HAIs may be one of the only proven methods for reducing resource utilization while improving patient care (Yalcin, 2003). Patient safety is high on the EU, US, UK and other EU member states policy agendas.

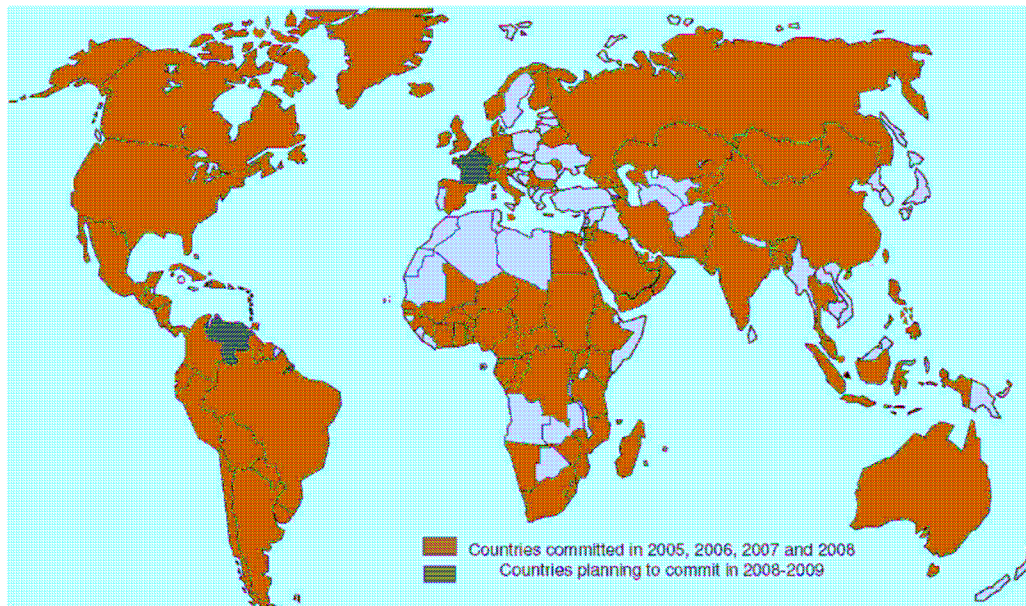


Fig. 11 Countries committed to address HAIs (WHO, 2008)

6.1.2 Market attractiveness

The healthcare market is an interesting market to focus on for a number of reasons. “The medical device sector is by any measure one of the most attractive and profitable in all of commerce. A cottage industry a few decades ago, the sector has consistently grown at mid-to high single digit rates to reach over \$165 billion in worldwide revenues in 2003. This total is divided between medical devices, accounting for approximately \$90 billion in revenues, and commodity supplies at \$75 billion. The medical device sector has a higher and more consistent rate of growth than nearly every other industry sector. Yet it is on the measure of profitability that the medical device sector truly stands out” (Burns, 2005).

In the Netherlands the total expenditure on health per capital (Intl \$, 2005) was 3.187. The total expenditure on health as a percentage of GDP (2005) was 9.2 %⁴. Within the Netherlands, forty-three percent of this money is spend on hospitals. In the Netherlands alone, there are over 140 hospital locations⁵. Healthcare supplies (e.g., drugs, medical devices, etc.) account for 19 percent of a hospitals total expenditure. If one includes the costs of handling and distributing these supplies internally, as well as the cost of all services contracted from outside, the percentage of hospital expenditures may reach as high as 30 percent (Burns, 2005).

³ Source: Public health portal European Union

⁴ Source: WHO

⁵ Source: Presentation Nederlandse zorgautoriteit

According to a recently published report by the Freedonia Group, the US infection prevention products and services industry will exceed US\$11 billion in revenues by 2010. US demand for infection prevention products and services will grow by 4.0% annually to reach US\$16.8 billion in 2011. The industry research company reports that growth will reflect increasing government and private pressures on the medical community to alleviate the problem of HAIs. Mandatory state reporting requirements along with recommendations developed by the AORN, CDC, FDA, OSHA and JCAHO will lead to a widespread upgrading of infection prevention safeguards throughout the healthcare and life science sectors. Demand for infection-prevention equipment will advance slowly over the next several years. A slight decline in the number of hospitals and slowing growth in the number of other healthcare facilities will weaken sales prospects for new placements⁶. Disinfectants consumed by healthcare and life science facilities will comprise a \$2.8 billion market in 2011. Pressures on healthcare facilities to adopt stricter staff hygiene and facility cleaning and disinfection practices will bolster gains.

An important feature of the medical device sector is that, in contrast to most markets or industries, medical products are not purchased by consumers. Instead they are purchased by a limited number of physicians that use the products in treating patients. Thus it is a concentrated and therefore efficient market. The concentration of buyers/customers and the associated channel efficiencies have implications for the business models of participating companies. Targeted (focused) selling campaigns, primarily carried out by direct sales forces, are relatively inexpensive and quite effective (Burns, 2005).

An economic feature of medical technology is the fact that consumers of the products and the parties that buy and pay for these products are three distinctly different constituencies. The parties are either completely separate or only loosely affiliated; incentives are certainly not aligned. Physicians make the clinical decision to perform a procedure, as well as the purchase decision to order the specific product and equipment needed for a procedure. The principal decision maker, the physician, does not pay for the procedure and in many cases has virtually no comprehension of the product costs involved. The patient, as a consumer of the products and services, has little say in the decision to perform the procedures and even less say in the brand and type of hardware used. That brings us to the payer: the private insurance company or the federal payment system. The fact that these parties are separated from the buyers/consumers and customers and have motivations that are not only unaligned but are often directly opposed, has profound implications on the marketing tactics and price behaviour of the firms operating in the medical device sector. In short this separation between buyers/consumers, consumers and payers allow a degree of pricing freedom that is truly unusual. It is for this and other reasons that competitive pricing is a rare exception. Practitioners are motivated to provide the best care for patients and are therefore driven to select the best performing products irrespective of price. Thereby medical devices are by their nature heterogeneous and resistant to administered prices. Thus, demand for medical technology is exceedingly inelastic. This aspect of the medical device sector produces several uncommon economic benefits, including favourable pricing and efficient channels both of which result in high profitability (Burns, 2005).

“Devices play an important role in the value chain and cost continuum of care. As a patient progresses through this continuum (diagnosis, work-up, treatment), expenses from labour fees and stay climb. This situation allows medical device makers to arrive at prices that are associated with the savings they generate or the outcomes they produce rather than a cost basis. Companies that market products on a performance basis, unshackled from cost-based pricing, can enjoy high gross margins and above average profits. The economic factors are forceful. Procedures and medical personnel are extraordinary expensive. When a device can force a change in practice, save time, or reduce repeat procedures, it unleashes economic value at the critical site, the centre of the cost-producing activity, and is paid accordingly” (Burns, 2005).

⁶ Source: Freedonia Group

Exhibit 1.1 Health Care Value Chain

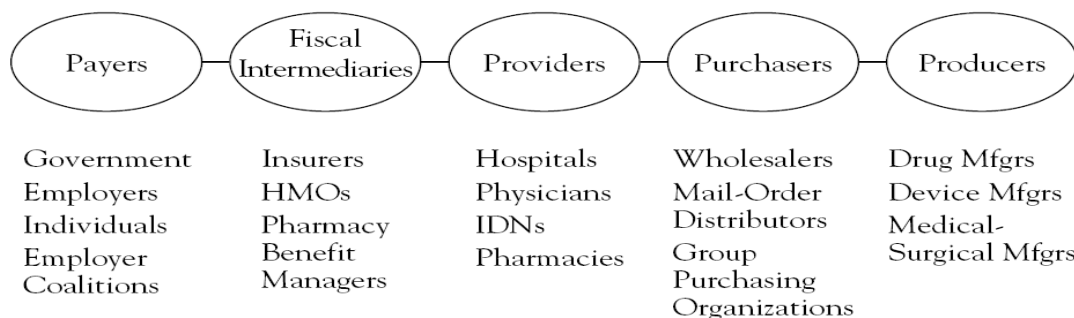


Fig. 12 Health Care Value Chain (Burns, 2001)

According to Burns (2005), the medical device sector has had, and continues to have an important role in the delivery of healthcare around the world. The medical device sector appears to be as vibrant, healthy, and full of promise as ever. Many developments flow from venture-backed start-up and small, single product public companies. Profitability is maintained at above-average rates due to manufacturing scale efficiencies, evolutionary (not revolutionary) product changes, and well-developed marketing and selling channels” (Burns, 2005). According to Burns (2005) there is a tremendous need for medical products if these products fulfil a clinical need and serve as useful tools that enable physicians to produce important clinical outcomes. When medical products are developed that “add value” within the clinical setting by saving time, changing outcomes, providing safety, and increasing utility, then those products will be demanded and successful business enterprises can be built around them.

6.1.3 The competitive situation and appropriability

All firms have to consider the market in which they are competing, the nature of competition and how their capabilities will enable their products to be successful (Trott, 2005). Next to that, firms have to conduct a competitive product analysis (competitive benchmarking) in order to determine competitive product strengths and weaknesses, and to identify competitive strategies (Kahn, 2005). Good ideas travel fast and can be seen so obvious after they have been found. Hence, in selecting the optimal new product location, a firm would be advised to anticipate competitive reactions (Loch and Kavadias, 2008). In many cases, the introduction of a product will make the existing brands worse off. Hence, in selecting the optimal new product location, a firm would be advised to anticipate competitive reactions (Loch and Kavadias, 2008). Innovations provide only temporary monopolies. There are many fast followers: skilled competitors able to overcome leaders by copying or by drawing on assets those first to market do not have. The capture of value from an innovation is a competitive and uncertain activity, requiring awareness of the dangers of opportunistic behaviour by others (Dodgson et al., 2008). Appropriating value from firms’ investments in technological innovation is a central element in effective innovation management and involves consideration of intellectual property rights (IPRs), licensing, the creation of technological standards, speed, and secrecy, and the ownership of ‘complementary assets’ (Dodgson et al., 2008).

Within this Master thesis research, a competitive product analysis is performed (see report phase 3). At this moment there are no companies that have a similar product like the MISCEA. A traditional sensor operated non-touch faucet combined with two other non-touch sensor operated dispensers can deliver the same functionality as the MISCEA. There are a lot of chemical companies, supplying healthcare facilities with medical soap, disinfectant, detergent and lotion. Most of these companies also provide total HH solutions, including HH supplies, dispensers, and other products and consulting services related to infection control and prevention. In addition, there are companies that are specialised in providing products and services aimed at reducing infections and improving HH compliance. Based on the analysis completed the conclusion can be drawn that the MISCEA HHMS

is totally unique. At the moment there are no (infection control and prevention) companies that bring a system on the market that is able to provide ICPs with detailed management information related to individual HH behaviour.

Appropriability regimes are set up to facilitate the erection of barriers to imitation. Appropriability regimes are the environmental factors that govern an innovator's ability to capture profits generated by an innovation. Given the character of technology, it is possible to apply for and gain effective and enforceable IPRs (Dodgson et al., 2008). Miscea GmbH filed a patent application for the MISCEA HHMS. The written patent application contains a claim on the technological capability to couple an identification registration system to a network of faucets and dispensers in order to log the use of faucets and dispensers on a personal level. According to the patent advocate of Miscea in Augsburg Germany, Miscea has a very high chance of getting granted the patent as being filed in March 2009.

In addition, Miscea can benefit from more informal methods of protection. By partnering with Sonitor, a leading provider of RTLS systems based on ultrasound, Miscea can gain a competitive advantage in relation to future competitors. In phase 2 of this NPD project, Ultrasound was identified as the most suitable and in the nearby future most promising technology for tracking and tracing personnel and equipment with the help of an IPS within hospitals. At the moment Sonitor is the only company in the world that brings IPSs based on ultrasound on the market. By setting up a trusting and long-lasting partnership in addition to an exclusivity agreement with Sonitor, Miscea can ensure that only Miscea is able to use an ultrasound IPS to log the use of faucets and dispensers. As Sonitor's ultrasound technology is identified as the preferred RTLS technology, this will lead to a competitive advantage compared to future competitors. Partnering with Sonitor has benefits as well as risks. If Zigbee becomes more and more attractive, for instance because it becomes less expensive to use Zigbee as a way to track and trace personnel within a hospital, Miscea is locked to Sonitor and future competitors can try to bring HH management systems on the market based on Zigbee technology.

Next to that, a clinical trial is also a substantial barrier to entry. However the high cost of clinical trials and the potential for application rejection has important and direct implications for a company's business model and product cost economics, which can often make the risk too high (Burns, 2005). Miscea will also benefit from other more informal methods of protection, such as leveraging first mover advantages. Nevertheless, there are two obvious drawbacks to being the first mover: cost and risk.

6.2 Commercialisation and marketing plans

All sectors in the medical technology world face the same dual challenge: the invention of new technology and assuring its long-term clinical adoption by customers (Burns, 2005). Getting a new innovation adopted, even when it has obvious advantages, is difficult. Many medical innovations require a lengthy period of many years from the time when they become available to the time when they are widely adopted (De Miranda et al., 2005). In order for a firm to be successful in bringing innovations to the market, an understanding of potential customers and the factors influencing their adoption decision is important. Research on the adoption and diffusion of innovations offers significant contributions to such understanding (Rogers, 1995).

Innovators often fail to reap the returns from their innovative efforts. Therefore it is needed to setup clear and detailed marketing and commercialisation plans, answering the question of how to commercialize the MISCEA HHMS. This section outlines a short commercialisation and adoption research, answering the questions of how to get the innovation adopted by ICPs (6.2.1), and how to commercialise the eventual system within the healthcare market (6.2.2). Section (6.2.3) describes how the innovation could be implemented within the clinical trial especially in relation to privacy issues

6.2.1 Adoption and diffusion

The clinical trial can be seen as the first step in the commercialization process of the HHMS. Prof. Dr. Kluytmans and thereby the VUmc and the other participating hospitals (IC wards) can be characterised as innovators or launching customers of the MISCEA HHMS. In order to convince the healthcare sector to start using the MISCEA system it is essential to show the clinical efficacy of the system. This will be achieved by setting up a clinical trial. The clinical trial will be designed to demonstrate product efficacy through a large-scale, multicenter, double blind trial. In a large-scale scientific study the effect of the MISCEA HHMS on HH compliance will be determined. The system would gain a lot of credibility within the market place if the clinical trial, (that will be executed by objective neutral scientific researchers) shows good results in improving HH compliance.

The results of the clinical study will be published in peer-reviewed journals. This will enable the competitive advantage of the innovation to be communicated to the target buyers and thereby reduce uncertainty about the advantages and disadvantages of the system. The relative advantage of the innovation will be disseminated using scientific means, within the target audience (ICPs) of the MISCEA system. While mass media and other impersonal channels, such as scientific journals, may create awareness of an innovation, interpersonal influence through social networks is the most dominant mechanism for diffusion (Rogers, 2003). Prof. Dr. Kluytmans is an authority in the Netherlands on the subject of HAIs, and serves as an opinion leader within the social network of ICPs. Influential persons can lead in the spread of new ideas, and thereby facilitate adoption.

By winning over (lead) users to the HHMS, it may be possible to create a community of early users. Early users may be attracted to products not simply because they perform a particular function, but because they are part of a community movement. Many contributors are driven by the desire to gain status and the urge to solve problems (Dodgson et al., 2008). In addition, as the firm is developing products and systems in cooperation with leading hospital organisations, Miscea as well as its products will gain credibility in the market place (also in for instance the dental market).

6.2.2 Marketing plans

For the MISCEA HHMS that will be developed, different market segments can be identified: (i) healthcare, (ii) food service, and (iii) facility management. All customer groups are not equal in their needs, behaviours, and profitability. Improving a company's focus on the most profitable customers can provide enormous returns (Kahn, 2005). Based on the analyses performed in this Master thesis project, the Miscea NPD team decided to focus attention on developing (and eventually commercialising) HH systems for the healthcare market. This decision was based on two arguments. (1) As HAIs represent an important public health problem today as a major cause of high morbidity, mortality and economic consequences in hospitalized patients, and as failure to comply with HH recommendations is considered the leading cause of HAIs, the Miscea NPD team believes that there is a tremendous need for systems that can improve HH behaviour within the healthcare facilities and especially within hospitals. (2) Next to that, the infection control and prevention sector is by any measure one of the most attractive and profitable in all of commerce.

The clinical trial that will be setup will result in a clear understanding about the impact of monitoring individual HH behaviour on HH compliance within a clinical setting. If the MISCEA HHMS improves HH compliance and thereby reduces HAIs, the system will result in improved patient safety, higher quality standards of care, and reduced costs. In that case, the MISCEA system can reduce staff inefficiencies, missed reimbursements, lost customers/sales, reduce waste and improve the reputation and image of the healthcare facility in question. The MISCEA HHMS can be seen as an innovation that improves the quality of care delivered within a hospital. In addition the system will reduce overall healthcare costs. In summary, the MISCEA HHMS will make healthcare safer and more productive.

Miscea aims to provide quality products and cost containment solutions to healthcare providers while enhancing the quality of patient care. The Miscea systems will be based on the principle of providing simple, low cost, high impact solutions to improve HH and HH compliance. The MISCEA HH systems must be made very customizable in order to facilitate adoption. Hospital organisations must be able to purchase a wide variety of different systems based on the products and systems developed within the NPD project. If a hospital (for instance) wants to purchase a HHMS, but does not want to purchase MISCEA faucets (for instance because they believe the user interface of the faucets is too difficult for patients) it must be relatively easy to customize a HHMS that will only consist of dispensers.

In the beginning of commercialisation, the MISCEA HHMS will most likely not be purchased by entire hospital organisations but will most likely be purchased by (individual) wards that expect to benefit most from improved HH compliance, for instance IC wards. In addition, the Miscea NPD team feels that private hospitals would be willing to invest in a system that improves patient safety, reduces costs and most importantly improves the image of the hospital as being a facility that delivers the highest standard of clinical care (and is paid accordingly). Next to that, if a private hospital has an outbreak of, lets say MRSA, the Norovirus or other RN viruses (SARS, influenza, hepatitis C.), this will lead to a massive increase in extra costs (that must be accounted for), wards or even total hospital breakdowns, increased patients suffering and mortality, media attention, and as a result of that deterioration of the image and reputation of the private hospital as being a facility that offers the highest standard of clinical care. In addition, Miscea should try to sell systems to hospitals that are going to construct new, or renovate current hospital facilities. The difference for a total hospital organization (compared to a situation in which a hospital purchases “normal” faucets and dispensers) would approximate € 200.000.

It can be estimated that around 1/3 of all HAIs are preventable. The WHO (2005) states that improvements in HH compliance are most effective in reducing HAIs. According to the WHO, it can be conservatively estimated that around 25 percent of all infections are preventable if HH recommendations are followed up. If a hospital has around 20.000 patient intakes a year, and around 1 in 10 patients acquires an infection, approximately 500 patients, within this hospital, within one year would acquire an infection. If the researchers performing the clinical trial conclude that the MISCEA HHMS resulted (within their research setting) in a reduction of HAIs by only 10 percent (as a result of improved levels of HH compliance) this would mean that the system, within this hospital, could prevent 200 patients from acquiring an infection, every year. The costs of handling an infection vary widely (between different patients and types of infections), but can be conservatively estimated to cost around € 1.000 (literature \$2.500-\$20.000). The HHMS would result in a cost reduction for the hospital in the ongoing operations amounting ($€ 1.000 * 200$) = € 200.000. Thus in addition to improving patient safety (and thereby lowering patient morbidity and mortality), lowering HCW workloads and improving the image and reputation of the hospital organisation, the HHMS would result in a significant reduction of hospital expenditure on ongoing operations. Based on the calculations performed in this research, the system would have a payback time of approximately 1.5 year.

Cooperating with suppliers of HH products can lower the overall investment of a hospital in a HHMS. By partnering with Miscea, these firms can differentiate themselves from their competitors. Suppliers of HH products can co-finance a part of the HH infrastructure (for instance pay for the dispensers) in order to win a supply contract. As the Miscea makes use of a patented connector system, only HH supplies of the partner organisation can be used in the MISCEA system. Miscea should consider partnering up with big infection prevention and control companies like Ecolab, in the commercialisation phase of the HH systems.

6.2.3 Implementation in the clinical trial and privacy issues

Although the implementation of the MISCEA system within the IC wards will be the responsibility of the VUmc researchers, report three of this Master thesis research, gives some suggestions on how the HHMS could be implemented within the IC wards of the participating hospitals (especially in relation to privacy issues). There are two types of organizational adoption decisions that can be identified, i.e. the decision made by an organization and the decision made by an individual within an organization. Implementation has been defined as “the early usage activities that often follow the adoption decision”. Adoption of innovations in an organization implies that adoption also occurs within the organization, at the individual level. Frambach and Schillewaert (2002) refer to this as intra-organizational acceptance. Organizational innovations that have to be incorporated in the work processes of an organization are of little value if they are not used or complied with. Hence, it is important to examine the acceptance of innovations within organizations because, if there is no acceptance among the target group, the desired consequences cannot be realized and the organization may eventually discontinue the intended adoption (Frambach and Schillewaert, 2002). When introducing innovations to healthcare, it is important to gain insights into determinants that may facilitate or impede the introduction, in order to design an appropriate strategy for introducing the innovation (Fleuren et al., 2004).

RTL systems may be seen as a threat to privacy, if applied to persons, either directly or parasitically. The requirement therefore is to describe the purpose and the conditions of operation to those affected and to advertise for expressed agreement. Recent adjustment of jurisdiction leads to more careful assessment of needs and options. The newly declared human right of informational self-determination, i.e. to prevent one's identity and personal data from disclosure to others, covers disclosure of locality as well. Base of discussion is very similar to disclosure of personal data for passing immigration at US airports: balancing threat and burden (Beugelsdijk, 2006). Simply looking at locating as a threat is the first impulse, and emotions will drive this attitude to steadiness. However, getting located in daily business life may be regarded as a chance to balance burdens. The work share in organizations always needs re-balancing, and the individual does not serve this need by hiding oneself (Schermer, 2006).

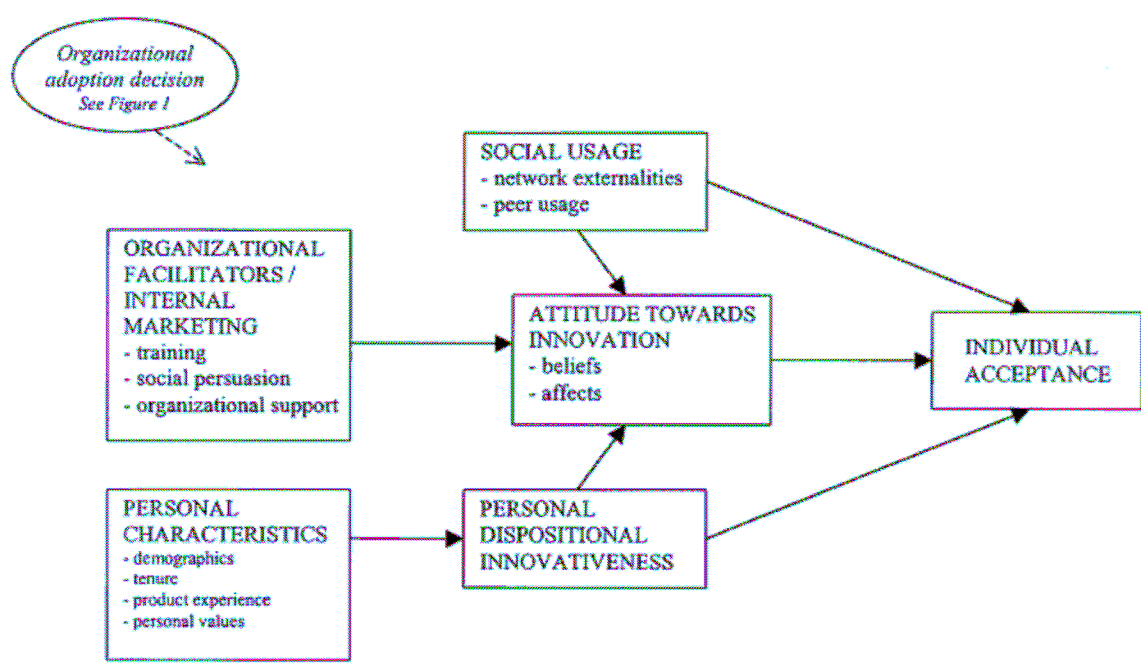


Fig. 13 A conceptual framework of individual innovation acceptance within in organisations

6.3 Operational new product development plan

This section contains an operational project plan for the development of the new HHMS. Based on the investigations performed in the first two stages, a clear understanding about what was needed to develop the system was obtained. In order to share design elements and development resources across products and systems; reduce development costs; manage complexity; and offer product variety while ensuring high levels of product performance the new HHMS will be developed within a new platform development effort that will create the basic architecture for a whole new ‘family’ of next generation products (6.3.1). After this was clear, a NPD project plan has been setup. The project plan is aimed at developing a system that can test the clinical effect of monitoring individual HH behaviour on compliance rates (6.3.2). In order for Miscea to develop the HHMS, different types of technologies, products and systems must be designed, developed and integrated in the Miscea faucets and dispensers. After a short analysis of what could be done internally, the Miscea management team came to the conclusion that the system must be developed in a network of partners. Based on a literature research and meetings with different companies, the NPD team setup an NPD network. The MISCEA HHMS will be developed in a network of international technology partners in which Miscea will lead the overall project. Next to that, the system will be developed in close collaboration with healthcare professionals working in the field (6.3.3).

6.3.1 Platform development

Firms in many industries are experiencing the need to offer increasing levels of product variety. Due to the increasing technological complexity of products the cost of developing and offering products has been rising sharply, while the length of the product lifecycle during which profits can be earned is becoming shorter due to intense competition and rapid technological advances. As a consequence of these trends, the ability to share design elements and development resources across products has become important for such firms to reduce costs and to benefit from product variety. In the quest to manage the complexity and costs of product variety while ensuring high levels of product performance, some firms have begun exploring the use of a product family-based approach to development. The products in a family are developed in an integrated manner as much as possible before detailed differences necessitate a more dedicated effort (Loch and Kavadias, 2008).

The HHMS will be developed within a new platform development effort that will create the basic architecture for a whole new ‘family’ of next generation products. Within this new platform development project, three different HH systems will be developed that can improve overall HH and HH compliance; the MISCEA HH system, the MISCEA HH data system, and the MISCEA HHMS (see report phase 3). The MISCEA HH system is a system that only consists of faucets and dispensers. The MISCEA HH data system is a system that consists of faucets and dispensers coupled to a WLAN.

The HHMS will be developed within a platform development effort in order to share design elements and development resources across products and systems; reduce development costs; manage complexity; offer product variety while ensuring high levels of product performance; be more flexible to adapt to changing customer requirements; reduce the fixed costs of developing individual product variants; and use the platforms greater degree of reuse. This will result in better architecture, tighter integration of components and lower unit variable costs (due to higher volume usage). The new platform development project will require a multi-market, multi-product plan, which will share common architecture and have common systems and interfaces.

The systems within the new platform development project will have a modular ‘architecture’. The HHMS will consist of the following modules: MISCEA faucets, MISCEA dispensers, DECT network parts, and the ultrasound RTLS parts. All components will have standardized interfaces, and will be coupled loosely such that it will be relatively easy to separate and recombine the system’s components. Modularity enables the development sequence of the NPD work to be executed in parallel. Partly parallel processes shorten overall development times, enable closer coordination

between stages and allows better controlling of development costs (Sanchez and Perez, 2003). In addition, modularity enables it to distribute development responsibilities to third party component suppliers of modules that will be integrated in the final system, such as the ultrasound receivers developed by Sonitor (Sanchez and Perez, 2003).

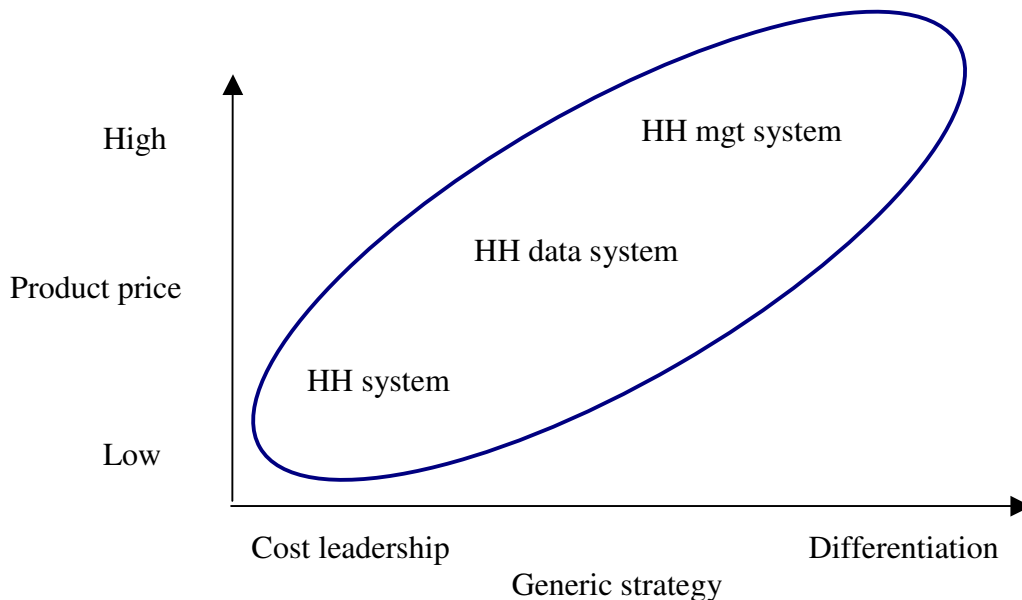


Fig. 14 Miscea new platform development project

6.3.2 New product development plan

In order to develop the new HHMS, a project plan has been setup. The project plan is aimed at developing a system that can test the clinical effect of monitoring individual HH behaviour on compliance rates. The system developed in this phase does not have to be the final design (that is ready to be commercialized), but must have the necessary functionality to make the clinical trial a success. The project plan encompasses the whole process of developing the system, from specifying user requirements, developing the system, and building a prototype, to testing the prototype in the Miscea test centre in Stockholm. The project plan details the time frame needed to develop, test, and install the system within the five participating IC units.

Once Miscea developed the HHMS, and integrated the WLAN and RTLS system in the MISCEA dispensers and faucets, a prototype can be built. This prototype of the system must be fully tested by Miscea engineers. In addition, Miscea will setup a pilot test in the food industry before the system will be implemented in the clinical trial. Before Miscea starts with the clinical trial all technological reliability problems within the new system must be solved. The success of the clinical trial as setup in the five participating IC wards will be crucial for the (commercial) success of the HHMS. Therefore technological problems with the system must be solved at all cost before the system will be implemented in the IC units.

The clinical trail will be executed in a project team in which Miscea will deliver the MISCEA HH system (with integrated hardware for the HHMS) and HH management software. Next to that, Miscea will be responsible for technical support, software, and training. The technical support given by Miscea and the technological reliability of the MISCEA system will be critically important in arriving at a successful clinical trial. During the implementation of the MISCEA system, Miscea in cooperation with the VUmc researcher will determine how the final design of the system will look like. Software engineers in cooperation with Prof Dr. Kluytmans will determine the final specifications of the software package. In this stage Miscea in cooperation with the VUmc will

iteratively and experimentally determine which data are needed by ICPs to improve HH compliance. Miscea must collect user feedback and engineering data in order to improve the system. The feedback provided from the end users in the clinical trial must be incorporated in the final design that will be commercialised in the healthcare sector.

A project overview can be found in report 3. The overall development project will take approximately 16 months. It cannot be emphasized enough that it is critically important to install a system that is technically reliable; restoring, reworking, fixing or improving the system once it is installed within an IC ward is practically impossible. Next to that, adoption and acceptance of the system by HCWs will be hampered if the system does not (always) work. The technical reliability of the system is critically important in setting up a successful clinical trial.

6.3.3 Innovation network

Based on the investigations performed in the first two stages of this NPD project, a clear understanding about what was needed to develop the system was obtained. In order for Miscea to develop the HHMS, different types of technologies, products and systems must be designed, developed and integrated in the Miscea faucets and dispensers. After a short analysis of what could be done internally, the NPD team came to the conclusion that the system must be developed in a network of partners. Based on a literature research and meetings with different companies, the NPD team setup an innovation network. The MISCEA HHMS will be developed in a network of international technology partners (6.3.3.1) in which Miscea will lead the overall project. Next to that, the system will be developed in close collaboration with healthcare professionals in the field (6.3.3.2). Within this network, the component suppliers of the dispenser, the DECT network and the ultrasound IPS system are responsible for their part of the NPD work. Miscea will be the “system integrator”. Miscea will coordinate the overall design process. Miscea will choose components and technologies; will specify the interfaces between different systems; and will combine new components with different vintages of technology.

6.3.3.1 Supplier involvement

Miscea GmbH is a privately held company, which designs manufactures and commercializes state of the art dispensing systems. Miscea has resources, competencies, and experience in developing and designing high-tech dispensing solutions. Miscea does not have any competencies and experience in developing information management systems. In order to develop the HHMS, WLAN and RTLS systems need to be integrated in the MISCEA faucets and dispensers. Miscea does not have any competencies or experience in integrating WLAN hardware in the faucets and dispensers and setting up a wireless data network, nor does Miscea have any experience in setting up and utilizing RTLS systems to identify users of the Miscea hardware. The cost of building and sustaining the necessary technical expertise and specialised equipment in both areas is too high for Miscea. As Miscea does not have the necessary competencies to develop the HHMS, Miscea needs to find partners to co-develop the system with. In phase two of this NPD project, locations and resources best suited for specific components/activities were identified. The market was scanned proactively for available talent and centres of excellence. The market was scanned with focus on the skills needed today as well as tomorrow.

The MISCEA HHMS will be developed in close collaboration with suppliers. The companies within this network will share their resources and expertise to develop new products, achieve economies of scale, and gain access to new technologies and markets. Working within a supplier network in order to develop products will lead to: improved access to capital and new business, shared risk and liability, better relationship with strategic partners, technology transfer benefits, reduced R&D costs, use of distribution skills, access to marketing strengths, and access to technology and management skills. In addition, early involvement of suppliers in NPD is instrumental in reducing lead-time and avoiding production problems downstream.

First of all, Miscea needs to design and develop a non-touch stand-alone dispenser. Miscea will design, develop and manufacture the dispenser in cooperation with Dittrich-co, a German company specialised in high-tech plastics injection moulding. For the development of the HH data system and the HHMS, thus integrating the DECT system within the faucets and dispensers Miscea will cooperate with Ascom, a Danish supplier of DECT wireless data systems. In addition, Miscea has to integrate the ultrasound microphones and the Sonitor infrastructure in the faucets and dispensers. Miscea will cooperate with Sonitor to design and develop the total system as well as integrate the ultrasound technology in the Miscea hardware. The component suppliers are expected to manage their own costs in R&D and not to expect reimbursement for these costs except for the price per piece of goods shipped (long) after the R&D was done.

Emeritor Software Development will develop the MISCEA hand hygiene management software. Emeritor is specialized in developing management information software. Emeritor build 'INCONTO e-Procurement' an e-procurement web-based software application. Miscea will co-develop the system with its electronics partner in Sweden, ICU Scandinavia. ICU Scandinavia is a Swedish leading supplier of automated systems for logging, monitoring and quality assurance of data in laboratories, restaurants and other food production companies. ICU will integrate the DECT and the ultrasound microphones in the faucets and dispensers. ICU will also setup the wireless data network, as well as implement the management information software needed. Next to that, ICU will perform the first test phase. Blidor will produce the MISCEA hand hygiene systems in Switzerland. The new systems will require more time to assemble, but it will not be necessary to setup, and invest in, new production facilities. Next to that, the output of the production capacity can be easily scaled up.

Miscea will cooperate with Imtech in the development phase and potentially in the commercialisation phase of the new systems. Imtech N.V. is a European technical services provider in the fields of electrical engineering, ICT and mechanical engineering. Imtech is already active in numerous hospitals, nursing institutions and homes for the elderly in the Netherlands. As Imtech is familiar with data communication and ICT services within hospitals, and because Imtech knows about the environmental conditions, requirements and regulations within healthcare facilities, it is very advantageous for Miscea to work in close collaboration with Imtech. Next to that, Imtech has a lot of experience in setting up big R&D projects, has management and technological capabilities in ICT and datacommunication and is able to install the HHMSs within the IC units that are going to participate in the clinical trial. This will enable Miscea to develop a management information system that can be seamlessly lined up with the primary care process within the participating hospitals.

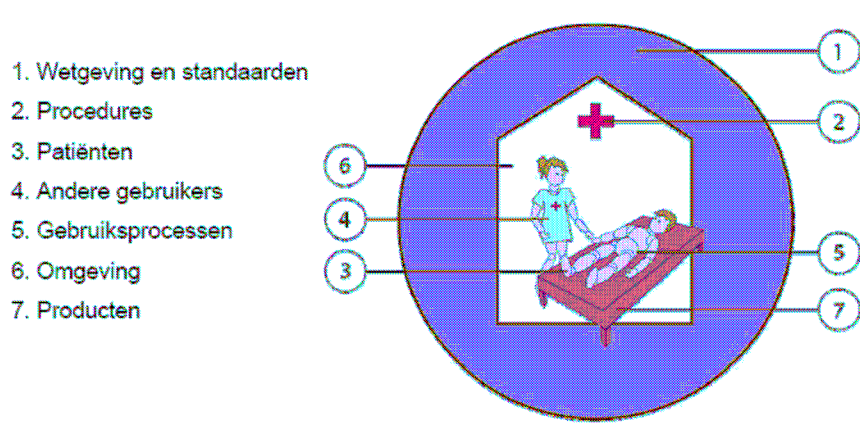


Fig. 15 Designing medical equipment⁷

⁷ Source: presentation Indes

6.3.3.2 Customer involvement

Successful innovative firms have a strong market orientation, with an emphasis on satisfying customer needs (Dodgson et al., 2008). Good quality information from the market is essential for understanding customer needs. Innovative companies interact with customers extensively to obtain necessary input for their NPD projects. Customer input is needed to overcome the inherent risks associated with NPD, to develop a product that fulfils customer needs better than competitors do, and to manage the overall innovation process and outcome better (Kahn, 2005). It is important that customer needs are monitored throughout the course of the NPD project, because they rarely remain completely static. An iterative problem-solving approach to interaction is needed because it provides the opportunity to challenge, question, and clarify customer input and requirements until they make sense (Trott, 2005). According to Loch and Kavadias (2008) the benefits of involving customers in the NPD process are: superior and differentiated new products, reduced time-to-market, reduced time-to-acceptance and building up long-term relationships.

Miscea will design, develop and test the HHMS in co-operation with the VUmc. The VUmc can be characterised as being a lead user or launching customer that will be involved in the NPD process early, iteratively and in-depth in order to provide the NPD team with the opportunity to clarify customer inputs and requirements. The VUmc will be able to provide the NPD team with positive and critical feedback on user needs, incorporating the needs of microbiologists, hospital managers, the purchasing department, the technical department and individual HCWs. Next to that, Miscea is looking for healthcare organizations that want to partner in the development of a stand-alone dispenser that can be used to make AHR available near the point of care. According to Erasmus MC HH (compliance) experts, one of the measures that should be taken to improve HH compliance is to make HH supplies more easily available to HCWs in order to facilitate the adherence to HH recommendations. The Erasmus MC researchers are currently looking for ways to develop an automatic hand pump that can be placed near the hospital bed and will dispense AHR. Miscea should consider developing a stand-alone non-touch dispenser in co-operation with the Erasmus MC. Contacts with regards to this (potential) co-development project are under way.

6.4 Business and financial analysis

This section contains detailed business and financial analyses. First the strategic fit between this NPD project en Misceas' overall corporate strategy is examined (6.4.1). Section (6.4.2) will outline the business and financial analysis. This section ends with outlining the key dependencies, assumptions and risks associated with this NPD project (6.4.3).

6.4.1 Strategic fit

Miscea is a new technology-based firm. New technology-based firms are those small to medium sized enterprises (SMEs) whose business is based on new technologies. Niche strategy, technology-based firms are those firms that use technology as the basis for their competitiveness (Dodgson et al., 2008). Miscea can be characterized as being a prospector, seeking out innovative new products, and looking for new opportunities and ways of responding to emerging market needs. Miscea is a company that follows a proactive, innovation strategy; pursuing technological and market leadership based on (radical) innovation, in-house development, and a strong research orientation. Firms following a proactive innovation strategy are prepared to take big bets and participate in high-risk projects executed in collaboration with technology leaders and demanding lead customers.

With the development of the MISCEA HHMS, Miscea is following a feature leadership design strategy, a strategy that is aimed at introducing leading-edge products emphasizing new features. Miscea is focussing on delivering on latent performance dimensions, in this case the provision of

management information related to individualised HH behaviour. This strategy involves pursuing new solutions and often pushing the frontier in terms of applying or developing technology (Kahn, 2005).

With the development of the MISCEA HHMS, a system will be developed that, for the first time in history, will create a network of “smart” faucets and dispensers that can communicate with each other, with the end-user as well as with the operator of the system (Appendix IV). The MISCEA HHMS can be described as a “real” innovation. The system is completely new to the firm, industry, and world. Schumpeter (1934) describes how the fundamental character of the search for innovation requires firms to find and carry out ‘new combinations’ among technologies, knowledge, and markets. The fusion of different technologies is more than a combination of different technologies. It is the creation of a new technology where the whole is greater than the sum of the parts. Each fusion creates new markets and new growth opportunities for the innovation (Dodgson et al., 2008). The MISCEA HHMS is a system that combines non-touch dispensers, non-touch faucets with integrated dispensers, and a non-refillable single-cartridge disposable packaging system. In addition, the MISCEA system makes use of wireless local area network (WLAN) technology, real time location system (RTLS) technology, and information technology (IT).

The new platform development project aligns with Miscea’s strategy and mission to become a strong brand that is recognized by its customers as a new standard in the conservative market of sanitation and dispensers. In addition, the new platform development project leverages Miscea’s core competencies. Although the new platform development effort leverages Miscea’s core competencies in marketing, technology and manufacturing, the project will take Miscea in unfamiliar territories both in terms of: a product category that is new to the firm; new customers and unfamiliar needs to be served; unfamiliar technologies; a new sales force, channels, and servicing requirements; and an unfamiliar manufacturing process. According to the research literature in innovation management it is sometimes necessary to venture into new and unfamiliar markets, technologies, or manufacturing processes (Kahn, 2005).

The MISCEA HHMS will have to be superior to competing products in terms of meeting users’ needs, offer unique features not available on competitive products, and solve the problems that customers have with competitive products (or solutions) they currently use (or could use) to monitor (individual) HH behaviour.

6.4.2 Business and financial analysis

The last step in this research was a financial analysis, answering the question of how much Miscea has to invest in order to develop the system and a financial and business analysis detailing if it is likely that Miscea will make a return of innovation effort. The project plan (that can be found in report 3) provides a deeper understanding about the development costs needed to develop, manufacture and install the HHMS within the five participating IC units.

Report three outlines the total costs of developing, manufacturing, assembling, and installing the MISCEA HHMS. In addition, Miscea will provide after sales support. Report 3 outlines the costs - from the standpoint of Miscea – for setting up the clinical trial, including development and hardware costs. The clinical trial will be held in five IC units and will last for 3 years. Imtech will install the equipment in the different IC units. Miscea will provide after sales support. The development work will be outsourced to ICU (€ 115,000). Software development will be outsourced (€ 35,000) to Emeritor. Miscea will develop the stand-alone dispenser in cooperation with Dittrich-co (€ 30,000). Dittrich-co will co-finance the development of the dispenser. Next to that, Miscea will redesign the current faucet systembox (€ 15,000). ICU will be responsible for integrating the DECT data network, the Sonitor IP system, the Miscea hardware and the Miscea software. ICU will be responsible for the end result.

The overall clinical research will take approximately 3 years and will cost (according to Prof. Dr.

Kluytmans) around 1.3 million Euros. The total costs estimated from the standpoint of developing the system, manufacturing the system, installing the system in the five IC units and providing after-sales support are approximately 300.000 Euros. The overall research project must be financed by means of subsidies. At this moment, Miscea in cooperation with the VUmc, are investigating the possibilities of getting the project financed.

Normally if a company starts a NPD project, the company needs to invest in R&D, manufacturing and marketing. If the new product is a success, the company sells the product profitably and the firm achieves a return on innovation investment. In the Miscea new platform development project, the development portion of the project will be paid for by the launching customers of the system, in this case the VUmc and the 4 other participating hospitals (out of subsidies that are granted to setup the clinical trial). This situation allows Miscea to develop customized systems that are consistent with customer needs and that will involve (from the standpoint of Miscea) limited financial risks.

Within the financial envelope that is granted for the development of the MISCEA HHMS, Miscea can develop a stand-alone dispenser, redesign the current systembox, and develop the MISCEA hand hygiene data system. The clinical trial that will be setup will result in a clear understanding about the impact of monitoring individual HH behaviour on HH compliance within a clinical setting. If the VUmc researchers conclude that the MISCEA HHMS indeed improves HH compliance, and that the effect of improved HH compliance results in a statistically significant reduction of HAIs within the IC units over a three-year period, Miscea should setup targeted and effective marketing plans, and invest in executing the marketing plans as setup in this phase of commercialization.

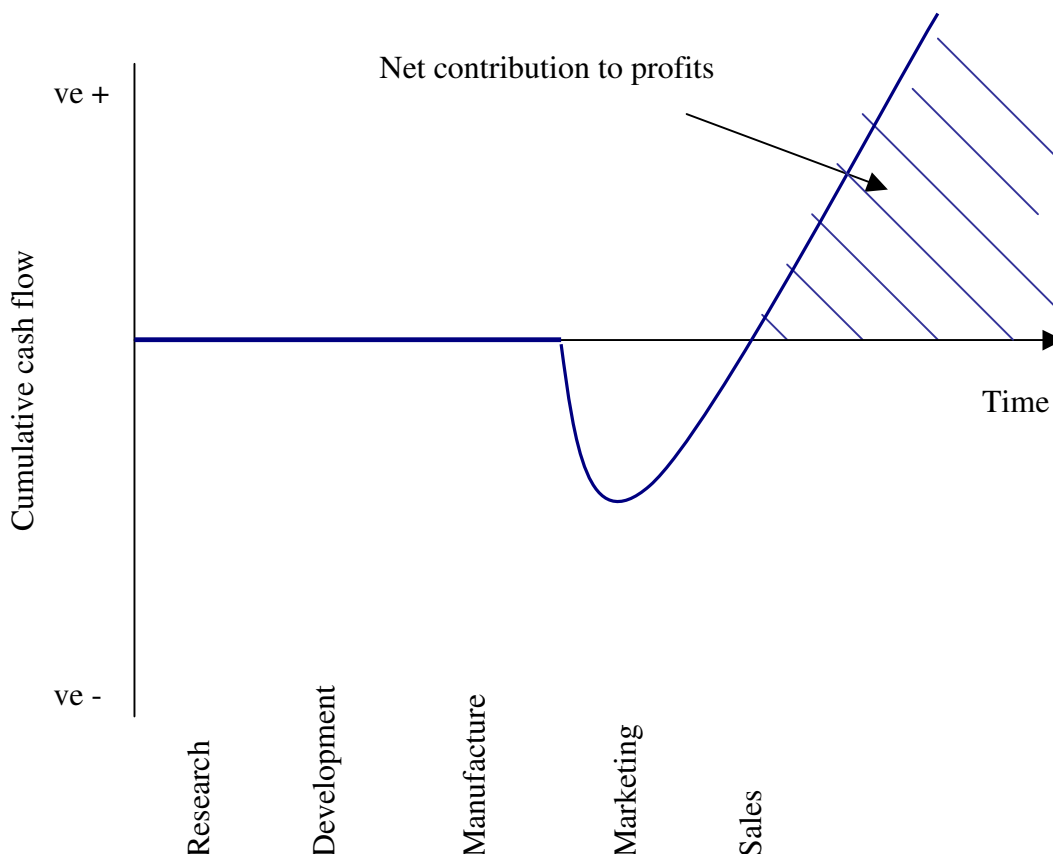


Fig. 16 Cash flow new platform development project

The MISCEA HHMS will have a razor and blades commercial business model. As the MISCEA system makes use of patented refill system, only MISCEA product packages can be used in the

MISCEA system. Miscea will sell product packages to HH agent manufacturers. Once Miscea realized a large installed base, Miscea can make a profit on the product packages that are being sold to HH agent manufacturers. A medium sized hospital (500 beds), purchases for around € 75.500 of soap and for around € 16.600 of AHRs. One litre of soap costs € 3.50, a litre of AHR costs € 4.50⁸. Within a total hospital organisation this would mean that there are 25.000 one-litre product packages sold to this particular hospital within a period of a year. Miscea sells the product packages to HH agent manufacturers for € 1,00 and has a gross profit of € 0.5 for every product package being sold. For this hospital, this would mean an additional cash flow of around € 25.000 and a gross profit over this additional operation amounting € 12.500 yearly. Once a hospital organisation installed the Miscea system, the switching costs are extremely high. The technical lifetime, the total time period [during which] an asset/machine can technically perform/function before it must be replaced, can be conservatively estimated to approximate 15 years. This results in additional profits out of the installed base amounting $(15 * € 12.500) = € 187.500$.

In addition, Miscea should try and sell service contract to customers that bought a MISCEA system. Next to that, Miscea should consider charging a yearly license fee for the software package. Miscea should also consider bringing HH improvement consulting services to the market in cooperation with healthcare professionals (especially microbiologists and organisation psychologists).

6.4.3 Key dependencies, assumptions and risks

The innovative activities of firms are confronted by general business uncertainty; technological uncertainty, and market uncertainty about the commercial viability of new products (Dodgson et al., 2008). Most of the healthcare sectors are characterized by high risk. Small firms account for much of the innovation across these sectors, and firm survival rates are notoriously low (Burns, 2005).

At this moment, there are four fundamental risks for this new platform development project:

1. Can the clinical trial be financed by means of subsidies?
2. Will HCWs working within the IC wards, accept the fact that their HH behaviour is being monitored and analysed, thus will HCWs accept the innovation?
3. Will the HHMS, thus monitoring individual HH behaviour, result in improved levels of HH compliance and coinciding reductions in HAIs?
4. If the HHMS results in improved HH compliance, are hospital organisations willing to invest in such a system?

On Monday the 20th of April, Conside a subsidy consultancy firm, applied for a subsidy at the Dutch ministry of Health, Welfare and Sport. Jeroen van Beugen, a subsidy consultant with 15 years of experience in applying for subsidies, believes that the research consortium that has been setup will have a high change of getting granted a subsidy for setting up the research project in question. In the first phase of the application process, an initial research description has been setup that will be assessed by the ministry as part of a preliminary subsidy assessment. In the second phase of the application process a more detailed description of the research project, including a description of the research in relation to patient safety has to be setup. This research proposal should describe very clearly how the new system will improve hand hygiene compliance and thereby improve overall patient safety within the participating facilities. Thus, the proposal should modulate the effect of the system on patient safety outcomes.

If the consortium does not get a subsidy from the ministry of Health, Welfare and Sport, the consortium should investigate other possibilities of getting the project financed. There are different other options open for getting the project financed, amongst them: getting the project financed by healthcare insurance companies, getting the project financed by the participating hospitals themselves, getting a subsidy from ZonMw, and getting the project subsidised by means of the EU Health

⁸ Source Medica Europe

programme 2008-2013. In this scenario, the team should also consider setting up a small-scale research project, for instance in one instead of five IC wards.

Getting the research project accepted by HCWs is also identified as a possible risk associated with the project. In order to diminish this risk, an in-depth research into the implementation including how the innovation could be made operational within the IC wards (for instance how to give HCWs effective feedback) has to be setup. This research can possibly be done as part of a Master thesis research, in cooperation with healthcare professionals working within the VUmc, and the patient safety research group at the university of Hasselt.

7. Conclusion, discussion and future research directions

This Master thesis research analysed the technical as well as commercial viability of the new hand hygiene management system. Based on this analysis, Miscea will make a decision with regards to the continuation of this new product development (NPD) project. The research question this Master thesis project attempts to answer is:

RQ1: Should Miscea invest in the development of the proposed new hand hygiene management system?

In order to answer this question, this study dealt with the FFE of the HHMS NPD project. The FFE consists of all the predevelopment or strategy-making work. Based on a preliminary analysis, a critical elements diagram has been setup. The critical elements diagram shows the variables that influence the technical as well as commercial viability of the new HHMS. As part of the strategy-making work, all variables have been examined. The strategy-making work consisted of operational, technical, marketing and financial aspects related to this NPD project. The strategy-making work that is completed, gives a clear understanding about the overall viability of the new HHMS. Based on this understanding, a decision will be made with regards to the continuation, and thereby corporate investment in, the “physical” development of the MISCEA HHMS. This choice will be linked to anticipated economic benefits and the ability to appropriate returns from innovation. If Miscea decides to continue with the project, the project will go into fourth stage of the NPD process, the actual “physical” development of the system. The fourth stage of the NPD project will involve more financial commitment and development than the first three.

Section (7.1) will outline the conclusions that can be drawn based on this research. After that, section (7.2) outlines a discussion about new product development within SMEs. This report ends (7.3) with a few suggestions for future research.

7.1 Conclusions

Based on the strategy-making work performed in the first stage of this Master thesis research (initial screening), the following conclusions can be drawn: (1) HAIs are an enormous problem, (2) around 1/3 of all HAIs can be prevented, (3) implementation of evidence-based HAI prevention interventions should be a high priority for all healthcare facilities to reduce preventable HAIs to the greatest extent possible. High mortality rates and economic expenses, which HAIs represent, emphasize the justification for measures of control, (4) proper HH is the most effective measure in preventing HAIs, (5) until now, few interventions have proved to be successful in sustainably improving HH compliance, (6) in order to improve compliance the interdependence of individual factors, environmental constraints and organisational climate play a key role in the success of behavioural interventions (7) within this respect a behavioural modification program (feedback) is most effective.

Based on the strategy-making work performed in the second stage of this Master thesis research (preliminary market and technical assessment), the following conclusions can be drawn: (1) the MISCEA HHMS could – in theory – help ICPs in improving HH compliance, (2) there is a market need amongst ICPs for the MISCEA HHMS concept idea, (3) it is technically viable to develop the new system.

Based on the strategy-making work performed in the third stage of this Master thesis research (building the business case), the following conclusions can be drawn: (1) the infection control and prevention market is one of the most attractive and profitable in all of commerce, (2) the trends in the market are positive, as in today’s rapidly changing healthcare industries, providers of care face unyielding pressure to improve quality, maintaining operating margins and lower costs, (3) reaching these goals requires a relentless focus on making healthcare safer and more productive, (4) patient

safety and thereby HAIs, is high on the EU, US, UK and other EU member states policy agendas, (5) Miscea will be able to protect its innovation from being easily copied by competitors, thereby ensuring that, if the system becomes a success, Miscea will be able to appropriate value from its investment in this innovation, (6) Miscea will have the operational capability to actually develop the system, (7) Miscea will be able to develop the system, within a new platform development effort in collaboration with suppliers and end-customers, (8) The NPD project fits with Miscea's overall corporate strategy, (9) the NPD project complement the firm's available resources and existing innovation portfolio, (10) the NPD project matches its organisational structure and culture, (11) the innovation outcomes are predictable and will not require financial investment from the firm as the NPD project will be financed by means of subsidies, (12) the NPD project can be setup with limited financial and organisational risks.

Based on the strategy-making study performed within this Master thesis project, the conclusion can be drawn, that Miscea should develop the MISCEA HHMS, if the program can be financed by means of subsidies. The clinical trial that will be setup will result in a clear understanding about the impact of monitoring individual HH behaviour on HH compliance within a clinical setting. The acceptance of the innovation by HCWs is the most critical factor in arriving at a successful clinical trial. If HCWs accept the new innovation, the clinical trial will show if the system has an impact on sustainably improving HH compliance. In this scenario, Miscea can develop the system without having to take financial risks, but indeed has an opportunity to develop a customized system for the clinical trial. If the VUmc researchers conclude that the MISCEA HHMS indeed improves HH compliance, and that the effect of improved HH compliance results in a statistically significant reduction of HAIs within the IC units over a three-year period, Miscea should setup targeted and effective marketing plans, and invest in executing the marketing plans as setup in this phase of commercialization. The MISCEA HHMS may disrupt the position of established firms and open up opportunities for Miscea to enter the market and overtake incumbents.

If the MISCEA HHMS improves HH compliance and thereby reduces HAIs, the system will result in improved patient safety, higher quality of care, and reduced costs. The MISCEA system can reduce staff inefficiencies, missed reimbursements, lost customers/sales, reduce waste and improve the reputation and image of the healthcare facility. The MISCEA HHMS can be seen as an innovation that improve the quality of care as well as reduce overall healthcare costs. The MISCEA HHMS will make healthcare safer and more productive

Within the financial envelope that will be granted for the development of the MISCEA HHMS, Miscea can develop a stand-alone dispenser, redesign the current systembox, and develop the MISCEA HH data system. The MISCEA HH systems will be very customizable as the systems have a modular product architecture. Hospital organisations can purchase a wide variety of different systems based on the products developed within the new platform development effort. Within the new platform development project end-customers are involved in the project early and in-depth. This will enable Miscea to develop products and systems that will create products advantages and will satisfy user needs. In addition, cooperation with leading, influential hospital organisations will give Miscea as well as its products not only credibility in the hospital market but also amongst (for instance) dentists.

The new platform development effort will enable Miscea to build the technological base of the firm, develop its capabilities, improve its processes, and add to its reputation and brands. If the clinical trail shows good results in improving HH compliance, Miscea developed products that deliver value, must probably provide rich financial rewards, and improve the competitiveness of the firm by adding value to what they do.

7.2 Discussion

Of all the challenges faced by managers today, the management of technological innovation is one of the most demanding. Get it right and firms create value and profit, develop sustainable competitiveness, and become vibrant, fun places to work, attracting and retaining the most productive and creative staff (Dodgson et al., 2008). Technological innovation involves addressing a wide range of issues and activities that compound the challenges in managing it, add to its risk and uncertainty, and making it difficult to develop generic recipes for its success (Dodgson et al., 2008). Understanding why new products succeed and why some businesses are so much better at NPD is central to effective NPD management; it provides insights for managing NPD projects (Kahn, 2005). It is because of this, that scientific research into NPD projects is critically important for businesses, research institutions and government organisations alike. This research can be described as being a qualitative case study about the initiation and strategy-making phases of a NPD project that intends to develop a new product within a small innovative company. This research can give important insights into the first three stages (of Coopers model) within a NPD process of a radical innovation, aimed at providing a product based on latent performance dimensions, within a small innovative company.

The conclusion can be drawn that the management literature related to NPD within a small technology company is sufficient to give direction and guidance in setting up a NPD project. The research literature in the field of innovation management and NPD provides valuable insights into the development of new (potentially) successful products. The conclusion can be drawn that especially Cooper's (2001) generic five-stage five-gate model is a NPD methodology that is very helpful in setting up a NPD project aimed at developing an innovation based on latent performance dimensions within a SME. Based on this study, the claim that innovations (within SMEs) do not just occur through the heroic efforts of individuals but almost commonly result from the combined activities of groups of people and organisations building upon each other's knowledge and experience can be supported. The claim that innovation development within this context requires ways of integrating knowledge from many different parts of the firm and working with various actors outside the firm, including consultants, customers, suppliers, and universities can also be supported based on this study. Based on the insights gained by means of this study, it can be concluded that the development of innovation within firms is a process of know-how accumulation based on a complementary mix of in-house R&D and R&D performed elsewhere, obtained via the process of technology scanning.

It can be concluded that research into the actual process of innovation and NPD is very hard. When this project started, there was a very high degree of market, technological as well as competitive uncertainty related to this NPD project. As there were high degrees of uncertainty, it was hard (or actually impossible if I look back at the project in retrospect) to write a Master thesis research proposal (for instance to describe how the proposed system will look like) or to setup detailed project plans. Formulating and implementing predevelopment or strategy-making work within this Master thesis research was an iterative and dynamic process. When you are in the process, you are not a passive researcher that aims to analyse, optimize or validate a certain business process; instead you are actively participating in the project aiming to "create" a business enterprise. Every day, you learn more about different aspects of the project. The insights gained in this report, support the model in figure 1. Based on this case study it can be concluded that the development and deployment of the first three phases of this NPD project was a dynamic, iterative process, that was intimately connected and informed by learning and that was characterized by a spirit of enterprise, creativity, curiosity, perseverance, external and internal communication, and analysing a wide variety of different aspects, that were often interconnected and that will all influence the successful development of the product or system in question. It can be concluded that developing new products is a risky, uncertain, and at times highly frustrating activity, anticipating and managing the confluence of market, technical and competitive pressures by using input on customer tastes, technology advances, and rivals' expected

actions in order to match technology with a market need in order to produce a potential opportunity for the business.

7.3 Future research directions

This research can be the starting point of a longitudinal research project aimed at gaining a deeper understanding about innovation development within a SME. By initiating a new (Master thesis) research project, in the development and test phases of this NPD project - in which a customized system will be developed for the healthcare sector in close collaboration with technology partners and healthcare professionals - a deeper understanding about the more structured and more formal phases of a NPD project can be gained. In addition, a Master thesis research project can be initiated at the VUmc. The research can give important insights into how hospital organisation can work together with industry in order to solve their problems by means of technical innovations. The process of working together with industry will include setting up customer needs (from the perspective of a wide variety of different stakeholders), making implementation plans and analysing the process of innovation implementation and acceptance among HCWs.

The management literature related to the adoption and diffusion of innovations is (almost) not included in the NPD literature. Nowadays, innovation diffusion and adoption is regarded as a marketing activity, I believe that it would be helpful for product developers to incorporate innovation adoption and diffusion knowledge and characteristics in the early phases of NPD in order for their innovations to be adopted and commercialised in later stages more easily. Next to that, the number of studies of innovation processes has increased greatly over the last 15 years, but little is known about the conditions for, or determinants of, the successful implementation of innovations to healthcare organizations. So far, most research on innovations in healthcare has focused on individual doctors working independently in small practices, such as general practitioners (GPs) working with guidelines. Less is known about the determinants of innovations in larger healthcare organizations, which may be different from those of innovations for individual healthcare professionals (Fleuren et al., 2004). As the MISCEA HHMS will affect all HCWs working within the participating IC wards, the longitudinal research can shed light into this unexplored field.

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List of interviews

Appendix I Miscea GmbH

Miscea

Miscea GmbH is a privately held company based in Augsburg, Germany, which designs manufactures and commercializes state of the art dispensing systems. Miscea products are designed to provide users with a durable product enabling higher standards of hygiene and efficiency. The history of Miscea GmbH dates back to 1999 when in Augsburg two engineers started the development of an improved dispensing system. In 2003 the development of the first generation of faucets was completed and sold in small amounts in different European countries. In May 2006, Miscea started the development of a second-generation faucet to improve the technological reliability and the user interface of the system. In 2007 the development of the improved faucet was completed, the Miscea was born.

Products

The Miscea is a sensor-activated non-touch dispenser-faucet. The Miscea delivers water and a maximum of two other liquids, depending on the situation: soap, lotion, disinfectant or detergent. As the Miscea makes use of a patented refill system, Miscea is in the position to select which packages can be attached to the Miscea. Miscea supplies the only non-refillable packages that can be attached to the Miscea. Miscea sells these packages to partners in the soap and disinfectant industry (community Miscea). Together with partners in Community Miscea, Miscea seeks to provide end users with a higher level of care with better-designed dispensers and refill products, which are friendly for both skin and environment. Next to that, Miscea is the exclusive distribution agent of the Mitsubishi JetTowel in ten European countries.

Business concept

The business concept of Miscea combines different elements. First of all Miscea develops, manufactures and markets multi-functional dispensing system. Next to that the patented refill system makes it possible for Miscea to determine which packages can be attached to the Miscea system. In order to profit from the installed base, Miscea supplies the only non-refillable packages that can be attached to the Miscea. In the future, when there is a large installed base of dispenser systems, Miscea intends to supply refill products for the Miscea as well.

Mission

The mission of Miscea is to sell and market the Miscea concept, multi-functional faucets and make Miscea a strong brand that is sold worldwide. Miscea must be recognized as a new standard in the conservative market of sanitation and dispensers. The mission of community Miscea is: setting a new standard in care by maintaining strict levels of product quality and following latest environmental standards.

Organization

Miscea is a small organization employing a staff of six. Miscea has a sales and marketing office in Nieuwkoop (Miscea BV), the Netherlands. The office in Nieuwkoop serves the Benelux as well as all other markets not yet served by national partners. Currently purchasing and administration are being done in Nieuwkoop as well. Miscea pursues a phased roll out of its sales function with national partners. Currently Miscea has sales offices in: Augsburg, serving the German and Austrian market, Langnau am Elbis, serving the Swiss market, Täby serving the Scandinavian market and Cannes serving the France market. The Miscea partners that serve the different markets are responsible for: marketing and sales, building up distribution, taking care of refill logistics and providing aftersales and other services to support the Miscea. Miscea BV is intensely involved with the national marketing and sales organizations.

The production of the Miscea dispenser system is outsourced to Blidor, a company based in Switzerland. Blidor is responsible for production, quality control and logistics. The installation of new dispenser systems by customers is being done by national technical service providers (like “uw rechterhand” in the Netherlands).

Three engineers are responsible for the engineering function of Miscea. One is occupational in Nieuwkoop, one in Eindhoven and one in Augsburg. Miscea works closely together with development partners to develop and design dispenser systems, non-refillable HH product packages, connector systems for packaging and technological parts (like mixer valves) incorporated in the Miscea system.

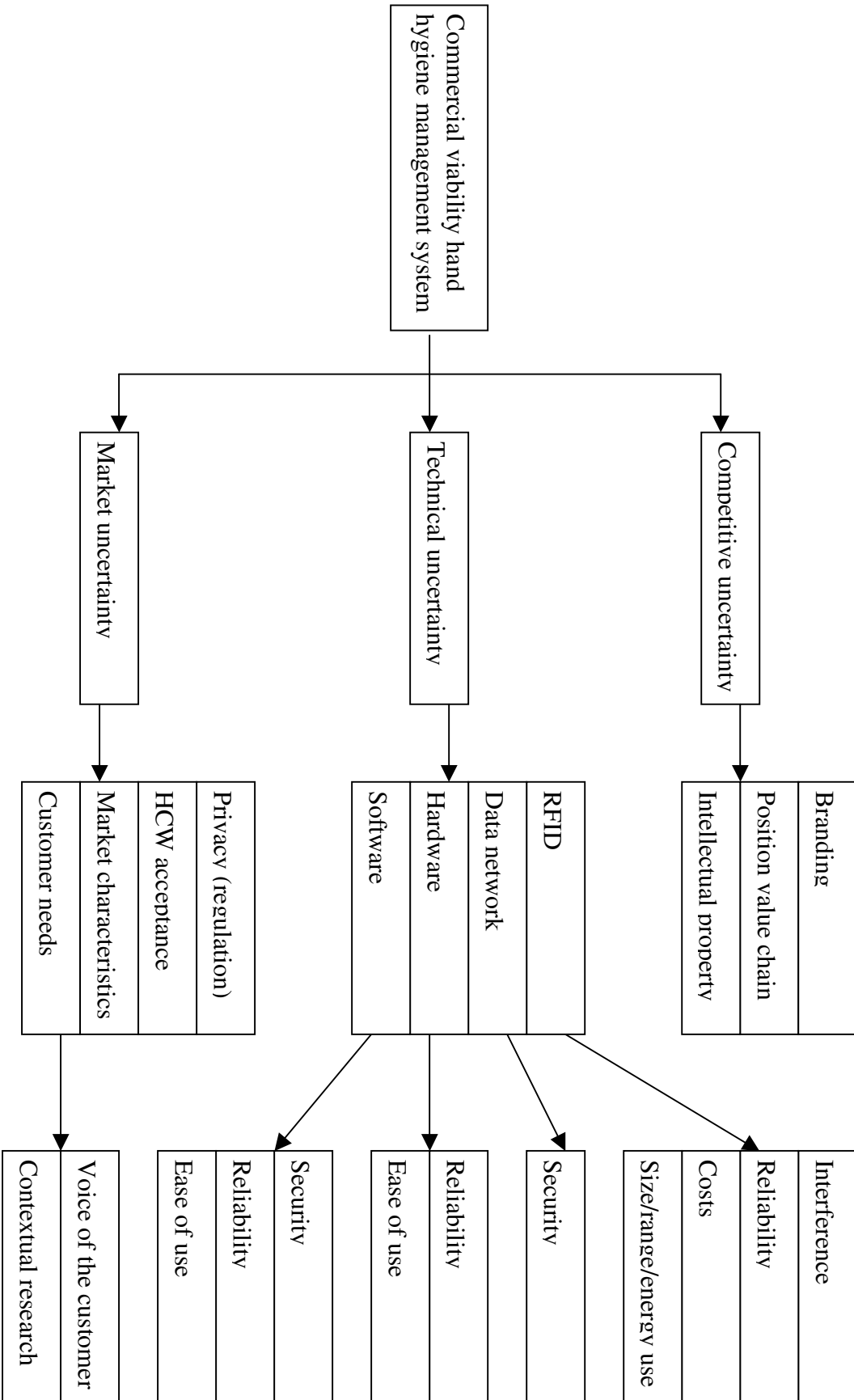
Customer groups

Miscea intends to sell its product to different customer groups. Customer groups can be divided in two segments: private and professional. The private segment is the home market (kitchens, bathrooms, toilets). The professional segment contains; the medical sector ranging from hospitals, dental practices, family doctors, pharmacies and veterinary surgeons; the food industry ranging from restaurants, catering and slaughterhouse; facility management ranging from hotels and offices; and industry ranging from clean rooms in pharmaceutical companies to the electronics industry. Currently the Miscea dispenser system appeals most to dental practices.

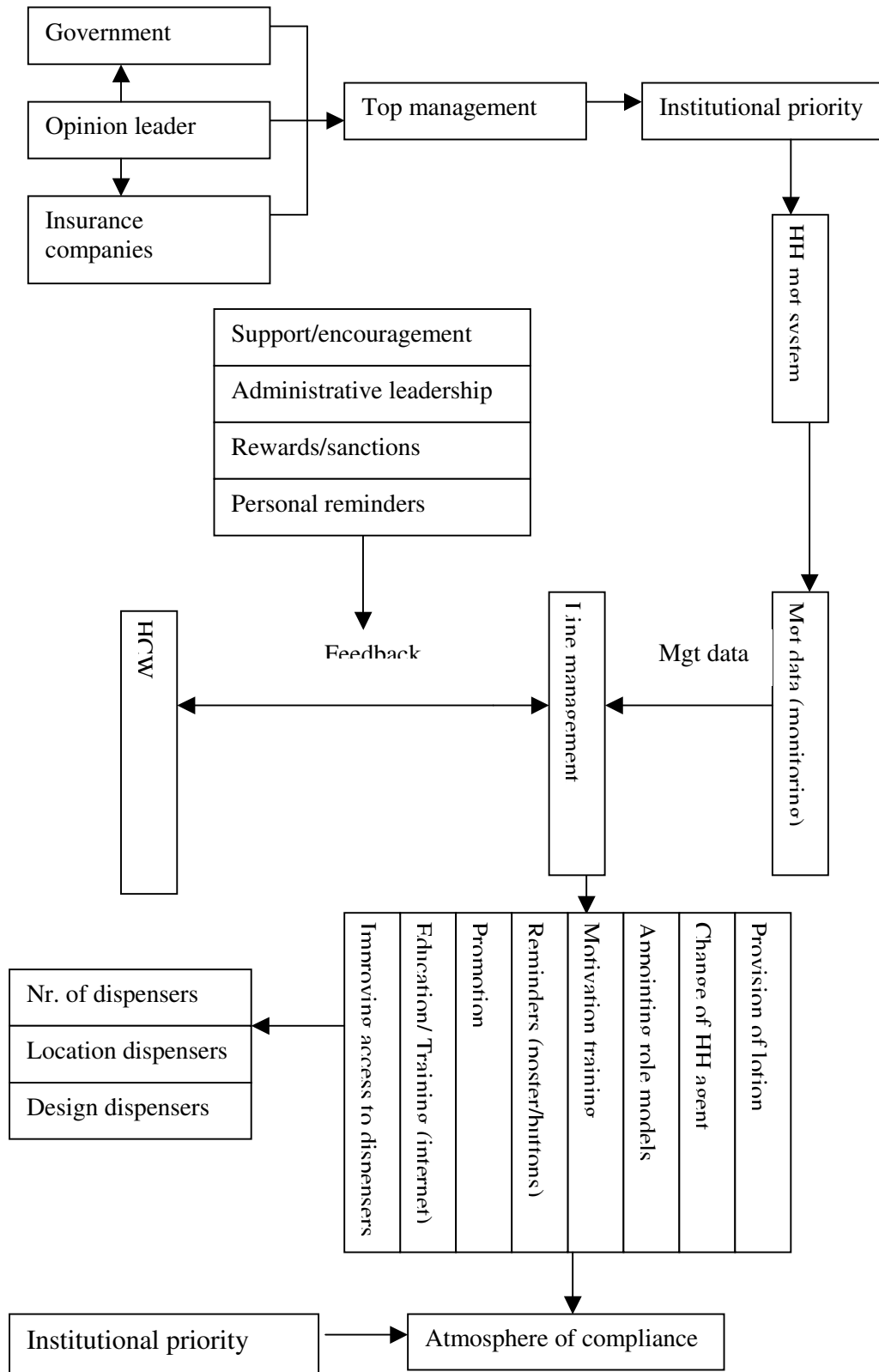
Main competitors

At the moment there are no companies that have a similar product like Miscea. Miscea is the only company that combines a faucet with two separate dispensers that can be operated non-touch in one product. A traditional sensor operated non-touch faucet combined with two other non-touch sensor operated dispensers can deliver the same functionality as the Miscea. There are a lot of companies around the world that supply either sensor operated faucets and/or dispensers. Examples of companies that commercialize sensor-operated faucets are: Hansgrohe, Silfra, Toto and Hansa to name a few. Companies that supply touch free dispensers are multiple as well. Companies that supply non-touch dispensers are Micronova, Smarthome, Touchfree concepts and Germstar. Germstar sells non-touch disinfectant dispensers to hospitals.

Appendix II Critical elements diagram



Appendix III Hand hygiene improvement diagram



Appendix IV Miscea hand hygiene mgt system

