

The lean healthcare entrepreneur

*Is the lean startup methodology applicable
when facing a healthcare challenge?*

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THE LEAN HEALTHCARE ENTREPRENEUR

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Approved 2014-05-15	Examiner Gunilla Ölundh Sandström	Supervisor Jens Hagman
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Abstract

Healthcare firms spend years developing a product uncertain whether it will work, if it will be safe and tolerated, or if anyone will invest in their efforts once the product reaches the market. At the same time the flow of new and improved products in the healthcare sector has escalated resulting in shorter life cycles for products. Although user driven innovation during the initial stage of product development in the healthcare sector has proved to enhance the chance to *hit the market with greater precision and gain better return on investment*, few studies have examined this field of research. The lean startup methodology encourage innovators to stay open-minded towards modifying their product or approaching a different customer segment, prior to having launched the final product and spent all of their venture capital. The methodology has mostly been applied by *high-tech startups* experimenting with web applications. Could the healthcare innovator also apply this lean methodology?

This investigation identified how the high-tech web-startup was different from a healthcare venture. Thereafter a framework inspired by Maurya's running lean and user driven methods was used to carry out the initial stage of a healthcare project entitled '*Motivation-driven Self-managed post-Stroke rehabilitation*'. The project set up to explore the problem area and conceptualise solutions for a personalised self-managed stroke-rehabilitation system.

While examining the case study it became clear that the two sectors are different, thus the framework was slightly modified. For example the lean *business* model approach was not applicable in the early stage of the project. Further, the healthcare sector is built around a wide range of different users and stakeholders whom all should take part in the development process. Thus the lean narrow and agile focus, often referred to as the product/market fit, was neither applicable.

The conclusion presents a conceptual framework and six recommended *conditions for success*, which can be used in future similar projects during the initial stage of product development, guiding the lean entrepreneur as he or she navigates through the precarious health care setting. These conditions are as follows: *Involve different types of users from start, Practice a both need-and business model-driven approach, Use users as a valuable source of information, Get out of the building, Employ a strategic push* and finally *Make use of multidisciplinary expertise*.



KTH Industriell teknik
och management

Examensarbete MMK 2014:07 MPI 01

Lean entreprenörskap inom hälsa- och sjukvård

Är det möjligt att applicera den metodik som förespråkas av 'the lean startup' för att möta en utmaning inom hälsa- och sjukvård?

Katarina Juréen

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Sammanfattning

Företag verksamma inom sjukvården ägnar ofta flera år för att utveckla en produkt osäkra på om den kommer att fungera, vara säker för användaren och accepteras av regelverket, eller om någon kommer att investera i deras ansträngningar när produkten väl når marknaden. Samtidigt escalerar flödet av nya och förbättrade produkter inom vårdsektorn vilket resulterar i kortare livscykler för dessa produkter. Trots att användardriven innovation under det initiala skedet av produktutvecklingen inom vårdsektorn har visat sig öka chansen att nå marknaden med större precision och få bättre avkastning på sin investering, har få studier undersökt detta forskningsområde. Teorierna om Lean-entreprenörskap uppmuntrar innovatörer att överväga möjligheten att ändra sin produkt eller närmar sig ett annat kundsegment, innan man lanserat den slutliga produkten och spenderat hela sitt riskkapital. Metodiken har främst tillämpats av högteknologiska startups som experimenterar med webbapplikationer. Kan sjukvårdens innovatör också applicera denna metodik ?

Denna undersökning har identifierat hur ett högteknologiska web-startup skiljer sig från ett företag inom sjukvården. Därefter har ett ramverk, inspirerat av Mauryas *Running lean* och användardrivna metoder, använts för att genomföra det initiala skedet av vård-projektet '*Motivations-driven egenrehabilitering efter stroke*'. Projektet inrättades för att undersöka problemområdet och konceptualisera lösningar för ett egenrehabiliterings-system för stroke patienter.

Genom undersökningen av fallstudien framkom det att de två sektorerna är olika och ramverket modifierades något. Till exempel bedömdes det fokus på en affärsmodell lean förespråkar inte var tillämpningsbart i det initiala skedet av projektet. Vidare består vårdsektorn av ett stort antal olika användare och intressenter som alla bör ta del av utvecklingsprocessen. Således ansågs det inte heller lämpligt att fokusera på en typ av användare eller lösning, vad som av lean metodiken brukar identifieras som en iterativ ansats för att identifiera en *product/market fit*.

Undersökningen resulterade i ett konceptuellt ramverk och sex rekommenderade förutsättningar för ett framgångsrikt projekt. Dessa rekommendationer skulle kunna vägleda entreprenören inför framtida liknande projekt inom sjukvårdssektorn. Villkor är som följer: *Engagera olika typer av användare från start*, *Applicera en både behovs- och affärsmodells-driven strategi*, *Involvera användare som en värdefull källa till information*, *Ta dig ut och testa i verkligheten*, *Mobilisera intressenter* och slutligen *Utnyttja tvärvetenskaplig expertis*.

PREFACE

It was almost exactly one year ago I first laid my hands on the book *The lean startup* by Eric Ries. Little did I know that Ries's words would come back to haunt me in my sleep for several months, but half a year later. The book was given to me by my mentors my first week working for a Singapore based startup called Flocations- which was bringing together a ridiculously large amount of local travel agencies' *travel experiences* online. The experience of working for a startup expanded my interest for conceptual development and entrepreneurship.

Half a year later, the words came back to me in a different manner. I was about to initiate the project leading up to this thesis, as part of the course MF211X which serves as the final examination of my Master in *Product Innovation Management* at the Royal Institute of Technology in Stockholm, Sweden.

It was with great pleasure I had accepted to assist my future mentor and entrepreneur, in his quest to apply the lean methodology in a different setting than the typical high-tech-web sector, namely *healthcare*. It was not until this point I started to grasp the intriguing concepts of the lean startup movement. However, researching and modifying the methodology to fit the scattered healthcare sector also exposed the difficulties developing radical innovation using a lean approach. Did hubris finally catch up with the lean startup movement? Withal, the lean way of building ventures still intrigues me and I honestly believe that design engineers ought to embrace the lean startup mindset to connect with today's consumers: who express a profound must-have-passion for new products and services yet quickly lose interest in their possessions.

I dedicate this thesis to the passionate entrepreneurs I have had the pleasure to work with, who have the guts to fail, and learn.

TACK!

Jens Hagman and Jenny Janhager Stier, for helping me to sort out my thoughts and build upon my ideas. The project manager and entrepreneur Niss Jonas Carlsson, for teaching me how to make faster decisions in order for the project to reach its goals. Carl Wadell for the numerous brilliant top-three-answers to all my questions regarding innovation in healthcare. Marcus Lithander, Fredrik Juréen, Bryan O'Regan, Nicole Ahne and Charlotte Hilding Shalin for your support, ideas and feedback while reading the first versions of this report.

TERMINOLOGY

A startup: *“...is an organization formed to search for a repeatable and scalable business model.”* Within this definition, a startup can be a new venture or it can be a new division or business unit in an existing company (Blank, 2010).

The lean startup: is an expression coined by Eric Ries in 2008, who defined a startup as *“an organization dedicated to creating something new under conditions of extreme uncertainty”* (Ries, The lean startup, 2008). The theories described by Ries were aimed at high-tech ventures in particular and in the beginning the theories were mostly applied by startups experimenting with web applications (Weintraub, 2014).

The healthcare sector: in Sweden is primary a public responsibility that is organized and managed on three levels; national, regional and local. There are 21 health care regions made up of county councils and regions. The majority of care is provided under the region’s own management and the remaining part is dealt with by private care providers (SLL, 2012).

Biomedical engineering: is the application of engineering principles and design concepts for healthcare purposes. It refers to medical technology, Information Communication Technology (ICT), pharmaceutical and biomedical products and services (Ask, 2013).

User driven Innovation: is defined as *“...the process of tapping users’ knowledge in order to develop new products, services and concepts. A user driven innovation process is based on an understanding of true user needs and a more systematic involvement of users.”* (Høgenhaven, 2008)

Stroke: is an obstruction of blood flow to the brain due to blockage or internal bleeding, causing a rapid loss of brain function. A stroke causes various permanent neurological damages depending on which part of the brain is affected and how widespread the damage is (KI, 2014).

Rehabilitation plan: refers to the action-plan that is constructed together with the patient prior to him/her being discharged from hospital. Stroke victims will be living with long-term disabilities in need of a life-long rehabilitation strategy. Three core themes in stroke rehabilitation are goal setting, using outcome measures and providing feedback (Mawson, 2013).

Personalised Self Managed rehabilitation System (PSMrS): translates current models of stroke rehabilitation and theories underpinning self-management and self-efficacy into an ICT-based system for home-based post-stroke rehabilitation (Mawson, 2013).

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1. GET OUT OF THE BUILDING

In December 2013 *The Lean Startup* movement made its first official attempt to break into the healthcare sector. Steve Blank, one of the contributors to the lean startup movement, launched *The Lean LaunchPad*. The goal was to teach researchers and clinicians how to move their technology from an academic lab or clinic into the commercial world. The life science class gathered drug developers, software engineers and medical device inventors, and encouraged them to test their ideas before launching them into a business (Weintraub, 2014).

Lean production strives to deliver high value with low waste. Although first employed in the manufacturing process by Toyota, thinking lean has grown to cover all sorts of process transformation activities, including how entrepreneurs should manage their startups in order to succeed (Ries, 2011). Ries, who coined the expression *The Lean Startup* in 2008, defines a startup as “*an organization dedicated to creating something new under conditions of extreme uncertainty*”. The methodology was aimed at *high-tech* ventures in particular and in the beginning the theories were mostly applied by *Startups* experimenting with web applications. However, three years later, the theory has been praised and adopted by various industries, firms and design methodologies - *the lean startup has gone mainstream* (Ries, preface to Cooper & Vlaskovits, 2013).

Similar to other industries, early-stage healthcare ventures need to reduce market, technological and regulatory risk. However the difference between a high-tech web-startup and healthcare venture is that the latter is often driven by a technology-push and hindered by regulations (Staalesen & Dybvik, 2009 and Suennen & Shaywitz, 2013). Technology driven projects as such have a very high market uncertainty (Herstatt & Lettl, 2004). Firms spend years developing a product uncertain whether it will work, if it will be safe and tolerated, or if anyone will invest in their efforts once the product reaches the market. Most of these product attributes are determined at an early stage. The challenge is to figure out what this product is and determine who might benefit the most from it (Suennen & Shaywitz, 2013). *The Lean LaunchPad* initiative seeks to encourage innovators to stay open-minded towards modifying their product or approaching a different customer segment, prior to having launched the final product and spent all of their venture capital (Weintraub, 2014). The innovators should ask themselves: ‘*Is the business model profitable, repeatable and scalable?*’ (Maurya, 2010)

However, this thesis focuses on the initial stage of product development, what the lean startup methodology refers to as the *product/solution fit* (Maurya, 2010). Can the healthcare innovator apply the lean method in the initial state of product development, to explore the problems and the needs of the user, before investing in costly development programmes?

1.1 Purpose and relevance

In the paper *Problems and promises of innovation*, Dixon-Woods et al. argues that the most important challenge that the healthcare industry is facing today is the need to *avoid unnecessary innovations and manage the transition for necessary innovations*.

The shift in the distribution of the population towards older ages and the increase in income demands for innovative solutions (Staalesen & Dybvik, 2009). However, the flow of new and improved products in the healthcare sector has escalated resulting in shorter life cycles for products (DECA, 2007). At the same time new products can only reach the market at the expense of existing solutions, thus have to provide sufficient evidence regarding safety, innovative potential and profitability (Ask et al., 2013). Furthermore, although user driven innovation during the initial stage of product development in the healthcare sector has proved to enhance the chance to hit the market with greater precision and gain better return on investment, few studies have examined this field of research (Staalesen & Dybvik, 2009 and Vinnova, 2014).

In 2013 *the National Forum for Swedish Biomedical Engineering* presented a study of the recent trends in the biomedical engineering field called *Medtech4Health*. The authors identified a need to study new process related initiatives in product development of biomedical engineering, and therefore a need to document, analyse and map different phases of product development (Ask et al., 2013). As of yet there is not enough evidence supporting the claim that the lean startup methodology is an applicable approach in the healthcare sector. However, in theory and judging from trends described in this section as well as at a later stage of this report, the lean approach could very well prove to be an ideal choice for tackling challenges in healthcare (Weintraub, 2014). The lean framework described by Maurya in 2010 provides a set of methods inspired by the lean startup theory. These methods could possibly be used in order to catch up with the current dynamic healthcare environment and this thesis will describe the process of investigating how.

1.2 Research question

This thesis will elaborate upon the intriguing challenges faced by future healthcare systems and the entrepreneurial climate which promotes the use of lean initiatives. One key-area of interest is a look into how users previously have been involved in the design process and what sort of methods and challenges these studies have identified as relevant during early stages of product development. However the main focus of this thesis is to investigate whether the running lean framework is applicable in a healthcare setting.

The main research question this thesis will seek answers to is:

Is the lean startup methodology applicable when facing a healthcare challenge?

The main research question was answered by conducting a literature review and implementing a case study. Three sub questions were articulated in order to guide the research:

- SQ1: What major differences can be seen when comparing the high-tech web-startup, commonly applying the lean methodology, and a healthcare venture?**
- SQ2: What parts of the lean framework, described by Ash Maurya, can be applied in the context of the case study?**
- SQ3: What additional user driven methods should be added to the framework?**

To carry out this investigation, a modified version inspired by the *Running lean* framework (Maurya, 2010) was used in the initial stage of a healthcare project entitled '*Motivation-driven self-managed post-stroke rehabilitation*'. This project was set up to explore the problem area and conceptualise solutions for a *Personalised Self-Managed rehabilitation System* (PSMrS) for stroke patients.

1.3 Context of the case study: Motivation-driven self-managed post-stroke rehabilitation

A stroke is an obstruction of blood flow to the brain due to blockage or internal bleeding, causing a rapid loss of brain function. A stroke causes various permanent neurological damages depending on which part of the brain is affected and how widespread the damage is. Stroke is one of the most significant causes of adult disability in Sweden. Every year more than 30,000 people suffer from their first stroke and more than 20% of these persons are younger than 65 years old. In cases with a non-lethal outcome the person is still left facing consequences that affect their physical and mental health, fundamentally challenging their ability as a functional and social individual (KI, 2014).

Due to the decrease in mortality and rise in morbidity, an increasing number of stroke victims will be living with long-term disabilities, in need of a life-long rehabilitation strategy (Mawson et al., 2013). Recent research has proven that the human brain is capable of re-learning functions of the motor memory, what usually is referred to as neuroplasticity (KI, 2014). However, Mawson with colleagues (2013) argue that even if stroke survivors are recommended hospital based treatment and rehabilitation until maximal recovery, they are eventually discharged from hospital and the supervised support is gradually withdrawn.

The major demographic changes described earlier on in this chapter will increase the demand on services and cause financial restraints. These changes will cause *a contextual shift in health care service delivery*. (Torsi et al., 2009). Future healthcare challenges will require radical solutions for a *self-managed and home-based rehabilitation system* (Mawson et al., 2013 and Torsi et al., 2009). Recent studies of future biomedical technologies state that the *patient's increased empowerment and participation in their own treatment offloads the healthcare sector* (Ask et al., 2013). Recent studies also advocates the importance of involving users in the design process at an early stage in order to succeed developing solutions as such (Staalesen & Dybvik, 2009, Torsi et al., 2009, Ask et al., 2013 and Mawson et al., 2013) However, with a self-managed system it is no longer the medical expert that is the primary user but the patient. This shift complicates the task of involving the primary user in the design process since patients are often impeded by their medical condition (Torsi et al., 2009 and Mawson et al., 2013).

SCOPE

The project was commenced by a non-profit organisation which initiates and supports various research and development projects focusing on encouraging physical activity. The main purpose of the foundation is to support the idea that physical activity will improve your muscle health, regardless of age or medical condition. One challenging area of interest is stroke rehabilitation. A project was therefore initiated and funded by a Swedish governmental innovation agency, *Vinnova*, within the category of *Challenge Driven Innovation* that supports projects during a *3-step-process*. During the first step Vinnova supports several different projects and based on the outcome of these projects only some of them move on to receiving funding for the next step (Vinnova, 2014).

During the initial stage of the project the aim was to mobilize partners and resources to both investigate how *self-managed post stroke rehabilitation* was managed today and develop a solution for a *Personalised Self-Managed rehabilitation System* (PSMrS). Similar ongoing studies in the UK had already demonstrated supporting evidence that this approach was of particular interest dealing with solutions for future stroke rehabilitation (Torsi et al., 2009 and Mawson, 2013).

A small team, consisting of the project manager and the project assistant, set up to investigate the problem area and solution space. The aim at this stage was to conceptualise solutions in collaboration with diverse partners from universities, healthcare institutions and high-tech firms and startups. The market hosts a wide range of new innovative solutions relevant to PSMrS such as medical devices, various treatments, high-tech solutions and new approaches in health informatics.

ICT (Information Communication Technology) has been identified as a particularly relevant approach when developing solutions for self-managed care. ICT solutions provide a new set of tools that may encourage patient empowerment, transparency and participation in care processes (Torsi et al., 2009, Mawson, 2013 and Vinnova, 2014). The question that arises is, *how can these creative minds and solutions work together?* Through a *lean and user driven approach* the objectives during the initial phase were to:

- Investigate the problem area
- Explore the solution space
- Conceptualise holistic solutions
- Mobilize various partners prior to moving on with a large scale project, developing and implementing solutions.

The last two objectives of this project was to report the results of the study to Vinnova, *and* to complete an additional application to request funding for step two.

1.4 Delimitations

This thesis describes the theory and the process of the first six months of conducting a project. The main objective during the initial state of the project was to complete stage 1 (*Problem/Solution fit*, Maurya, 2010), by partially adopting the *Running lean* framework: That is to say by validating the final concept qualitatively by involving and gaining insight from different types of relevant actors. This thesis focuses on describing this part of the framework, it should be noted however, that the concepts that emerged during this process can not be demonstrated due to confidentiality.

This study aim to explore a new approach for how to manage productdevelopment in the healthcare sector. Rather than offering an extensive literature review the theoretical framework uses a range of disciplinary perspectives on user involvement in the design process, lean entrepreneurship and challenges faced by healthcare. *How have previous users successfully been involved in the design process?* and *What are the key concepts and methods of the lean startup methodology?*

1.5 Structure of the report

Figure 1 demonstrates the structure of the report in four steps; build the theoretical framework, implement the case study, discuss the results and formulate recommendations.

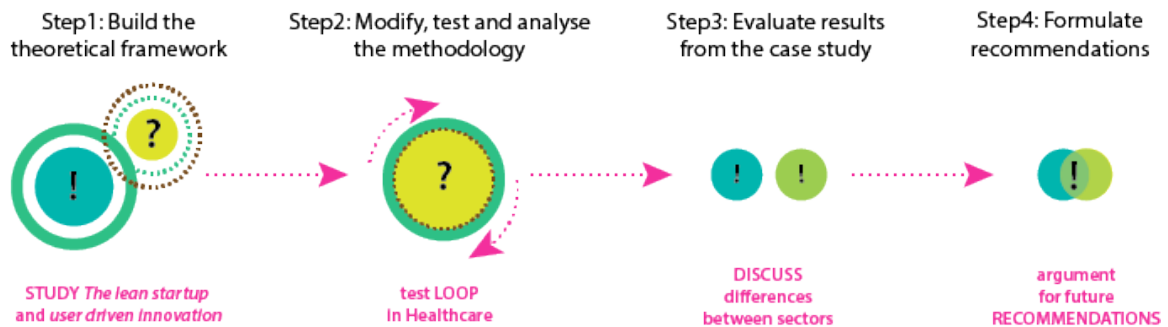


Figure 1: The structure of the report explained in four steps.

- 1. Step1: Construct a framework inspired by the theoretical background of the running lean framework and user driven innovation theories.**

Chapter 2 aims at giving the reader a thorough understanding of user involvement in product development and the theories of the lean startup. To give the reader a comprehensive understanding of the environment and context of the case study, chapter 4 summarizes the findings from the literature review. This chapter presents the key concepts of a typical high-tech web-startup commonly applying the lean startup methodology and the corresponding concepts of a healthcare venture.

- 2. Step 2: Investigate whether this approach is applicable in the healthcare sector using a specific case.**

The following chapter 4 presents the methodology and the final process of implementing the framework developed by the author.

- 3. Step 3: Compare the high-tech-web-startup, commonly applying the lean methodology, and the case study in order to see if and in what way the lean methodology was applicable.**

Chapter 5 summarizes the results from the case study referring to the theory presented in chapter 2 and the key concepts identified in chapter 3.

- 4. Step 4: Formulate recommendations for future similar projects based on these findings.**

Chapter 6 ends the thesis with recommended conditions for success, which can be used in future similar projects during the initial stage of product development, guiding the lean entrepreneur as he or she navigates through the precarious healthcare setting.

2. THEORETICAL FRAMEWORK: The lean startup tree

The running lean framework is based upon The lean startup methodology, which in turn is derived from three theories (Ries, 2011): Lean manufacturing- preserving value with less work, Discovery driven planning- iterating ideas through experimentation at lowest possible cost, and Customer development methodology by Blank, 2005- a scientific approach teaching entrepreneurs how to balance the relationship between developing a product and understanding the customer. Finally, the lean startup movement is influenced by Bootstrapping. Bootstrapping means funding with customer revenues, or the starting of a self-sustaining process void of any external input (Maurya, 2010). The concept of Bootstrapping appears to have originated as early as in the 19th century, as a metaphor for improving your situation through your own efforts (Entrepreneur, 2014). The timeline below (Figure 2) illustrating the milestones of the lean startup movement is shaped as a tree. The tree is a metaphor for how the movement has grown. Rooted in lean manufacturing and user centered design, it has grown through the trunk, which represents different approaches in user driven design and entrepreneurship, till becoming today's blooming crown inhabited by different approaches adapting the lean startup methodology (Weintraub, 2014). This chapter provides a glimpse into the lean movement and how previous users have been involved in the design process. In conclusion an introduction to the first part of the running lean framework is presented, the problem/solution fit (Maurya, 2010).

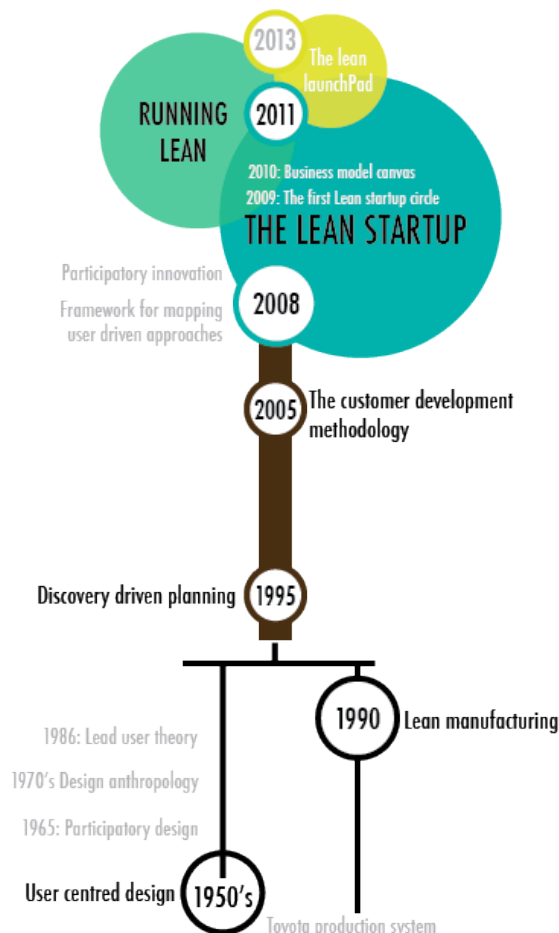


Figure 2: The lean startup tree is a metaphor for how the movement has grown and illustrates a timeline that highlights important milestones.

2.1 THE ROOTS: A shift from technology-push to customer-pull

During the 1950's Dreyfuss held a seminal study called *Designing for People* (Dreyfuss, 1955). His research laid ground for the user driven design methodologies of today, such as the *Customer Development methodology* (Blank, 2005). Dreyfuss' original theory combines *anthropology*- expose hidden assumptions through working and living together with the people being studied (Buur & Matthews, 2008) and *Sociology*- *The study of the development, organization, functioning and classification of human societies* (Collins, 2009). At the same time across the globe the Toyota Production System was being developed. Taiichi Ohno coined the expression *Genchi Genbutsu*- that means *go and see*. Toyotas key principle was based on their belief that in order to truly understand a situation one needs to *gemba, go to the real place*- where the work is being done. Taiichi Ohno is considered the precursor of *Lean manufacturing*, introduced in 1990 (Maurya, 2010).

The lean startup methodology is a business model driven-approach, yet pulled by the users' needs (Ries, 2011). Although there are several different perspectives on user centered design methods, all these theories employ a design process driven by a customer-pull. What differentiates this need-finding mindset from a traditional technology-push strategy, is that the latter is often driven by problem-solving. Further, a customer pull strategy applies a strategic focus on direct involvement of the user/customer and make use of multiple skills and perspectives, such as design anthropology. In comparison, a technology push strategy focus on research and development and is in general limited to technical and business perspectives. Lastly, a customer-pull strategy seeks to establish an open and collaborative development process and business environment, followed by revenue-enhancing activities by developing solutions that better meet consumer needs. In comparison a technology push strategy focuses on cost cutting activities and a closed development process (Staalesen & Dybvik, 2009)

2.2 THE TRUNK: Participatory innovation

In 2008 Wise and Høgehaven presented a framework that exposed two main directions for *user driven design methods* (Høgehaven & Wise, 2008).

- The user is *directly* involved in the design process as lead users and responsible for articulating their needs and for creating new ideas and solutions.
- Alternatively, the user is *indirectly* involved and thus considered more of a valuable source of information.

The same year that Wise and Høgehaven presented their new framework also marked the birth of the expression *The Lean Startup*, coined by entrepreneur Eric Ries on his blog *Startup Lessons Learned*. This theory was inspired by Ries personal experiences adapting *lean management principles* to the high-tech startup world (Ries, *The lean startup*, 2008).

USING USERS

Wise and Høgehaven (2008) constructed the *Innovation Wheel* (Figure 3), dividing the design process into two phases, the *WHY* and the *HOW* phase. The *WHY* refers to the process of understanding users acknowledged *and* unacknowledged needs (what people say they do and what they actually do in real life) and includes methods such as *Opportunity Identification*, *Data Collection*, *Pattern Recognition* and generating *Ideas*. The *HOW* phase consists of ways to *Conceptualize*, *Prototype*, *Test* and *Implement* the product considering market possibilities and technology.

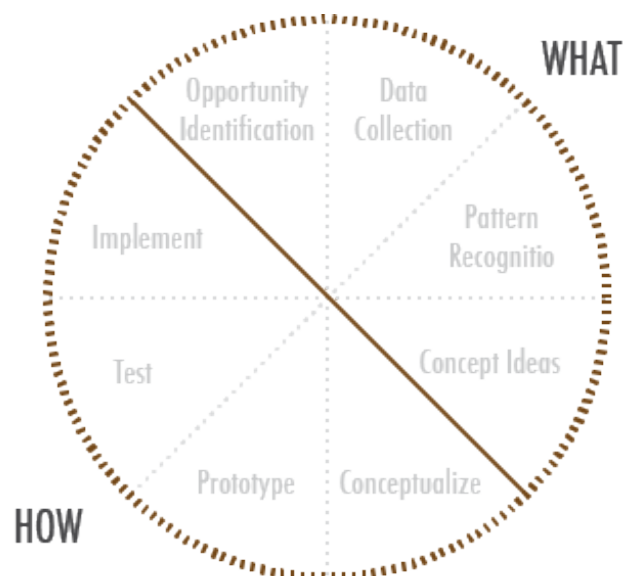


Figure 3: The innovation wheel (p.23, Høgehaven, 2008)

Wise and Høgehaven (2008) also introduced a *four quadrant framework* (Figure 4) for mapping different approaches of user driven innovation based on three different scenarios:

1. *Acknowledged* and *unacknowledged* needs
2. If the user is *directly* or *indirectly* involved in the design process
3. The *WHAT* and *HOW* phase.

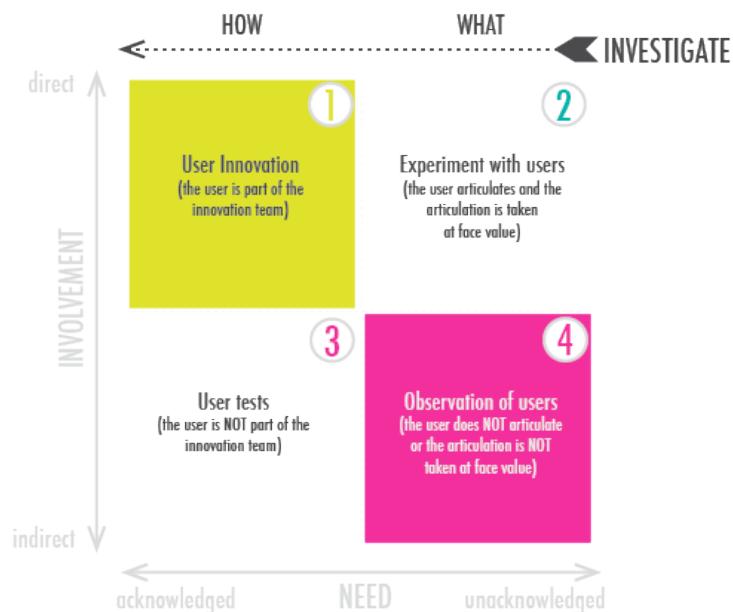


Figure 4: The four quadrant framework (p. 25, Høgehaven & Wise, 2008)

Inside quadrant 1 the user is directly involved- the other four quadrants ask, observe or experiment with users. The fourth quadrant separates the methods used to gain access without any articulation from users, from methods where the user is encouraged to articulate face value.

Regardless of which design approach the team choose to apply, the level of user involvement tends to vary throughout the process according to several or all quadrants in the figure (Staalesen & Dybvik, 2009).

The following sections describes the three different *approaches* in reference to the *four quadrant framework* and how these approaches have typically been applied.

USER AS LEAD USER

(Fig. 4, quadrant 1: User innovation, the user is part of the innovation team)

Von Hippel identified the lead user phenomena as when the ‘end-user becomes entangled with the process so as to sometimes take on outsourced assignments in order for the product to evolve’ (Von Hippel, 2005). In a healthcare context, the practitioner has often been referred to as the end user, despite the product’s main function. Previous successful cases of innovation in the healthcare sector have often derived from a lead user approach when collaboration with physicians have resulted in increasingly innovative products and services (Fabrizio & Chatterji, 2013). In fact, many successful products such as St.Jude’s Pacemaker, have emerged thanks to enthusiastic practitioners regardless of any strategic approach to solve a particular problem (St.Jude Medical, 2014).

THE USER AS A VALUABLE SOURCE OF INFORMATION

(Fig. 4, quadrant 3 and 4: User tests or Observations of users, the user is not part of the innovation team)

The design firm IDEO founded in 1991, typically implements its users as a *valuable source of information*. IDEO describes the User Centred Design process using the venn diagram illustrated in figure 5; the solutions should be desirable (human needs), feasible (business) and viable (technology). IDEO encourages this way of interacting with users and stresses the importance of studying not just what people *say*, but what they *do*, *think* and *feel*. IDEO supplies a set of tools that can be used to *Hear, Create and Deliver* (Staalesen & Dybvik, 2009).

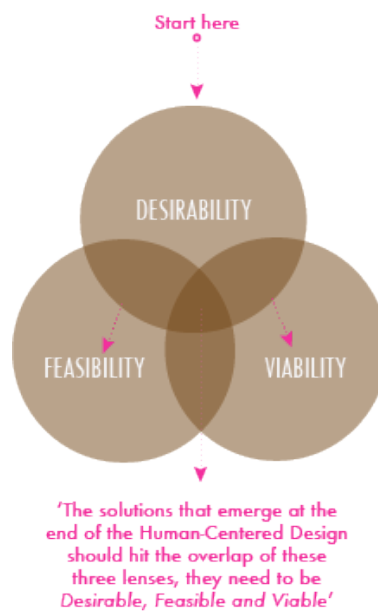


Figure 5: IDEO venn diagram (p.17 IDEO, 2009)

USER AS CO-CREATOR

(Fig. 4, quadrant 2: Experiment with users, the user articulates and their articulation is taken at face value)

Participatory Design, also called *Cooperative Design*, involves the participation of all the different stakeholders throughout the whole design process, from the initial exploration and problem definition, to generating ideas, developing solutions and evaluating proposed solutions (Buur & Matthews, 2008).

Buur and Matthews coined the expression Participatory Innovation; ‘...dynamic participation by all stakeholders’. Participatory Innovation aims to combine the strengths of Participatory Design and Design Anthropology, while expanding towards a market orientation. The concept includes a range of different types of activities and seeks to generate knowledge about users/customers whilst also generating business opportunities. “This has not been a focus of the participatory design community, who have rather investigated on how to best involve users in development processes, and how to ensure that user concerns

were not lost in the process, or trumped by engineering, marketing or production issues further downstream.”

Figure 6 demonstrates how Buur & Matthews mapped the three contemporary approaches; using users as lead users (1), co-creators (2) or source of information (3&4), according to their main focus (conditions for innovation or process of innovation), and their main orientation (market or society/culture).

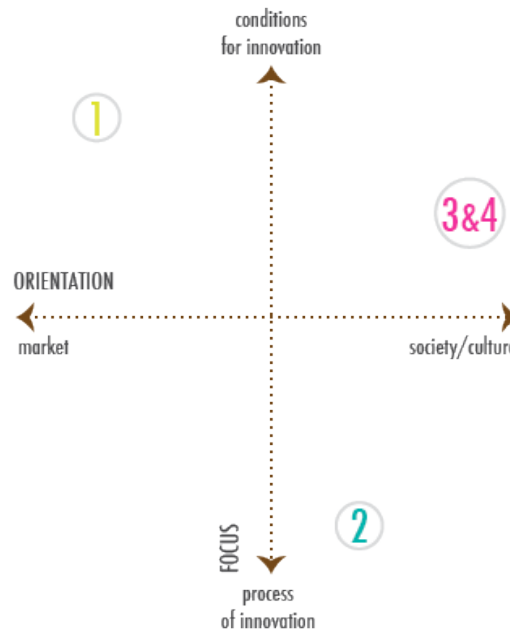


Figure 6: The Lead user-, co-creator- and source of information- theory, mapped according to their main focus and orientation' (page 261, Buur & Matthews, 2008)

USER AS EARLY ADOPTER

The theory of the Lean startup encourage entrepreneurs to directly involve users, by inviting *early adopters* (customers or trendsetters who adapt the product long before the market does) to partake in the design process as *co-creators*, however *not to lead* the process (Ries, 2011).

2.3 THE CROWN: The lean startup movement

The lean startup movement stresses the importance of getting out of the building and talking to your customer prior to developing the product. Only at this point should ideas be turned into products. It is also imperative to continue *measuring the customer's response, in order to learn whether to pivot or persevere* (*shift focus* or *stay focused* on the main market/customer/feature etc.). The lean startup is not about *launching a successful venture*, but rather about the *learning process* of building a *sustainable business*. This is managed through a three-step *feedback loop*; Build, Measure and Learn. (Ries, 2011) Another key activity is defining *the Minimal Viable Product (MVP)*, which is done by identifying the customer's most critical problem, the so called *must-have problem*, and *the features* needed to solve this problem.

The MVP is usually a set of conceptual wireframes or a prototype for a web application that the user can then interact with. The goal should be to launch the bare-bone product as soon as possible and allow useful feedback from early adopters (Maurya, 2010). Figure 7 illustrates the key elements of the lean feedback loop.

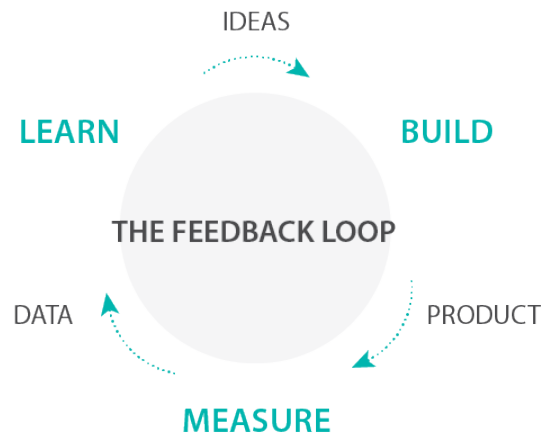


Figure 7: The Build-Measure-Learn feedback loop (Ries, 2011)

The online manual *Running Lean- A systematic process for iterating your web application Plan A to a plan that works* describes a *step-by-step workflow* for building web based software (Maurya, 2012). Maurya illustrates his teaching by using *the process of writing the book as a case example in the actual book*. He applies a set of experiments inspired by the methodology on his own work to test *why, what and how* he should write the book *Running Lean*. Maurya was inspired by Ries theories of a *Lean Startup* and the *Feedback Loop* and also referred to Blanks theories regarding *Customer Development*.

Furthermore, Maurya introduced *The Lean Canvas* based on the *Business Model Canvas* (Alexander Osterwalder Pigneur & al.). *The Lean Canvas* breaks down *the typical 50 pages business model* into nine interrelated components. See **Appendix 1** to learn more about the canvas. He also advocated the importance of *Bootstrapping; The Right Action at The Right Time* (Maurya, 2010).

INTRODUCTION TO THE RUNNING LEAN FRAMEWORK

In comparison to user centred design methods the Lean Startup entrepreneur *formulates a testable hypothesis* prior to observing and talking to the customer and *continues to systematically test the MVP* rather than launching a finished product. Figure 8 illustrates the four stages of the running lean framework. The first part of the process runs through two *feedback loops*; to understand the problem (1) and to validate the demo (2).

Following that, the solution is validated qualitatively getting to Product/Launch Fit (3) and finally the solution is verified quantitatively to reach Product/Market Fit (4). The objectives of these two last parts are to build something that people want and are willing to pay for, thus *simultaneously iterating on the product and searching for a profitable, repeatable and scalable business model*. Once you reach a product/market fit it is time to scale. At this point *both you and the investors are aligned on the same measure of progress – growth*, thus, if needed, it is a convenient time to raise additional funding (Maurya, 2010).

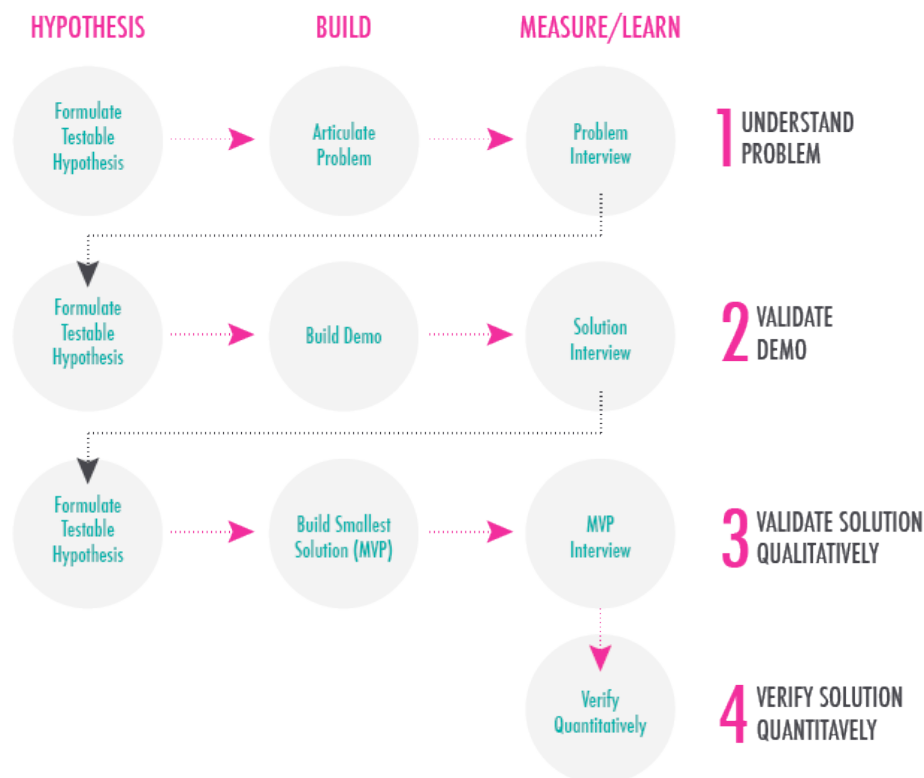


Figure 8: The four stages; understand problem, validate demo, validate solution qualitatively and verify solution quantitatively (Maurya, 2010)

The framework consist of three repeating steps:

1. **Formulate a testable hypothesis:** Identify the top three problems or solutions
2. **Build an experiment:** Conduct an interview or test your prototype by asking your customer to rank and validate your problems or solutions.
3. **Measure/learn based on customer insights:** Indentify your customer’s must-have problem/solution, and the features needed to solve this problem or implement the solution.

A brief overview of the different elements of the Running lean framework can be viewed in **Appendix 2**.

PART 1: PROBLEM/SOLUTION FIT

(Fig. 8 Stage 1. Understand problem and 2. Validate demo)

The aim during the first part is to identify the problem, the solution to the problem and decide if the problem is worth solving. The entrepreneur succeeds in doing this by asking three questions in particular:

1. Is it something customers want? (must-have/desirable)
2. Can it be solved? (feasible)
3. Will they pay for it? If not, who will? (viable)

The key activities during this part include; Document your Plan A by sketching multiple lean canvas, Get ready to interview customers by preparing the interview script and conduct The Problem- (test your hypothesis) and The Solution-interview (test your solution). Figure 9 illustrates the key activities during stage 1 and 2.

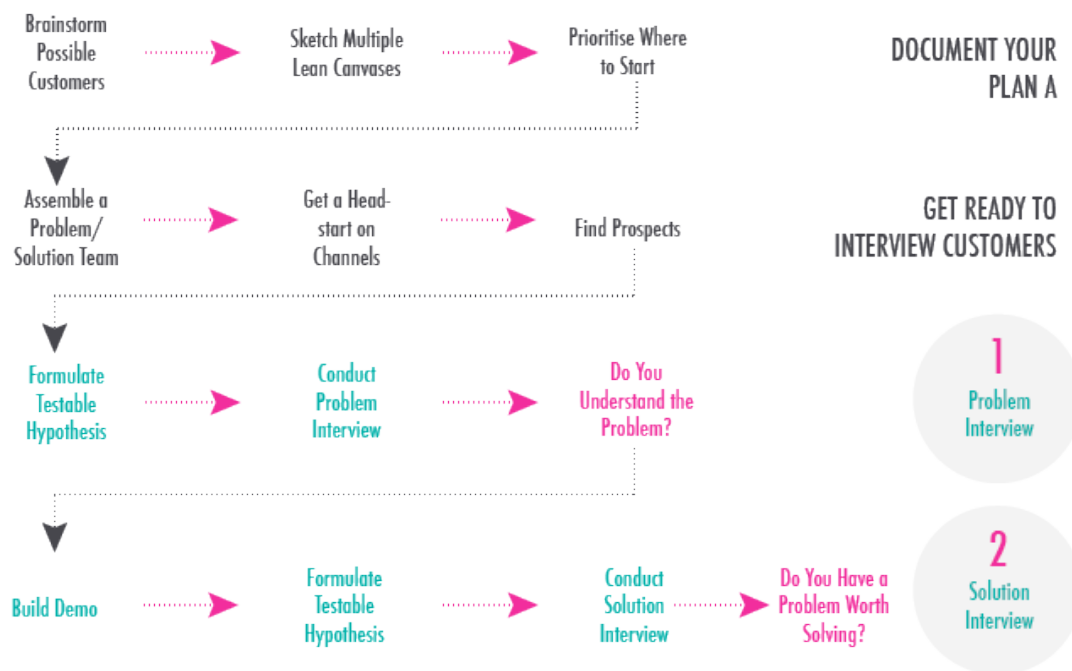


Figure 9: The problem/solution fit (Maurya, 2010)

In the beginning the lean startup theory was mostly put to use by startups consisting of web developers and business personalities who started to experiment with web applications. But during the three years that followed the theory was praised and adopted by various industries, firms and design methodologies. Last October (2013) Blank introduced *The Lean LaunchPad*, previously described in the introduction (Weintraub, 2014). One month earlier Shaywitz and Suennen had published the book *TechTonics*. The duo also elaborated on the subject of entrepreneurs' different approaches in healthcare: 'Can passionate entrepreneurs heal healthcare with technology' (Suennen & Shaywitz, 2013)?

3. THE SIX KEY CONCEPTS -Studying innovation while it is occurring

Ries once defined the Lean Entrepreneur as someone dedicated to navigate big change. Dixon-Woods et al. (2010) argues that the innovators should be ‘...studying the innovation at the same time it is occurring, not wait until the trial is complete before working out what is needed to adopt to implement the intervention in real life’ and finally ‘involve relevant stakeholders to mediate and adjudicate between the competing interests and demands’. The authors regard health reforms as *continuous experimental learnings*, and request *wise but courageous choices*, because *any medical system will eventually be discarded and replaced*. The Lean Startup approach shares some resemblance with the recommendations called for by Dixon-Woods et al., such as studying the innovation while it is occurring through *continuous experimentation*. The findings from the theoretical framework can be divided into six key concepts of The lean startup and are summarized below (Ries, 2011 and Maurya, 2010).

PRODUCT MARKET FIT: Narrow focus on one segment/niche/feature at a time, experiment with the MVP until you reach Product Market Fit (PMF).

THE LEAN CANVAS: Apply a business model driven approach using the reusable one page business model that breaks down all business models into nine interrelated components

USER AS EARLY ADOPTER: Identify your early adopters and invite them to partake in the design process.

BUILD-MEASURE-LEARN: Turn ideas into products, measure how customers respond and then learn weather to pivot or persevere.

BOOTSTRAPPING: Funding with customer revenues, decide when to conserve spending and when it is time to spend -based on the right action at the right time.

TECHNOLOGY & BUSINESS: The typical startup team develops web application and consists of developers and business expertise.

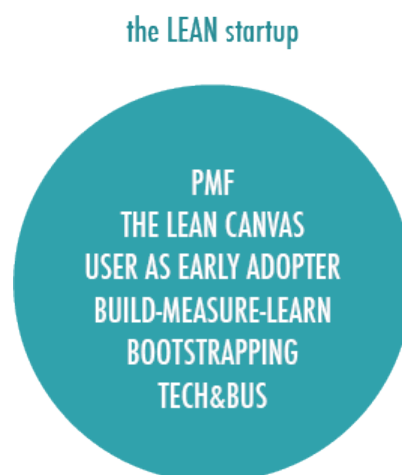


Figure 10: The key concepts of The lean startup

Nevertheless a *healthcare venture* often requires a great deal of time to launch a workable product and differs from the typical *high-tech web-startup* commonly applying the Lean Startup methodology (Nobel, 2011). In *what* particular ways these two startups differ will be answered next.

3.1 The six corresponding concepts in a healthcare venture

Guided by the above mentioned six key concepts the six corresponding concepts of a typical venture in a healthcare context were identified,

THE MULTI-SIDED MARKET: Dixon-Woods with colleagues (2010) argue that the complex organization of healthcare institutions and the broad spectrum of different users can cause major difficulties when managing changes or modifications of the system.

TECHNOLOGY DRIVEN: Most of the products relevant properties are determined at the early stage. Weintraub (2014) claims that the challenge is to figure out what this product is and determine who might benefit the most from it.

USER AS LEAD USER: Fabrizio & Chatterji (2013) reveal how previous successful cases of innovation in the healthcare sector have often derived from a lead user approach when collaboration with physicians have resulted in increasingly innovative products and services. Further, Staalesen & Dybvik (2009) argue that medical technology concepts are *not* successful usually when the user, i.e. the medical expert, patient or relative, is not involved in the actual development process. In some cases the user is involved, but only during the initial state of the process when his or her needs are identified. Fabrizio & Chatterji (2013) and Ask with colleagues (2013) determine that because of this the solution developed by an engineer or researcher fails to work in reality, lacking the approval of the user of the product

LONG TIME BEFORE REACHING THE MARKET: Innovators are obliged to go through expensive and time consuming procedures before their product reaches the market to ensure the patients safety. Products that have been launched prior to the evidence being firmly established, have on occasion lead to a catastrophic outcomes. One such example occurred in march 2010 when Sweden banned PIP implants because *'it was discovered that substandard silicone gel was causing an unusually high number of implants to burst.'* Nearly 2500 swedish women were urged to surgically remove their implants (TT/AFP/The Local, 2011). The PIP example illustrates the necessity of thorough vetting procedures for new biomedical products.

THE LEAN HEALTHCARE ENTREPRENEUR

- Is the lean startup methodology applicable when facing a healthcare challenge?

HIGH COSTS: The most apparent strategy in order to cope with the high costs is expanding into other application and market-areas or by outsourcing non-core activities. Another strategy is diversification into related product areas, also called spin offs. Williams & Hourd (2008) clarify how such strategies are managed through either a strategic partnership (establish a network and exploit their competencies and expertise), a vertical (such as sharing the costs for clinical trials), or a horizontal alliance (joint new product or prototype R&D). However according to Institute of Directors, smaller and more narrowly focused firms often have difficulties breaking into the healthcare space. Although they are *at a greater risk of failing, they are also most likely to create value (IoD, cited by Williams & Hourd, 2008)*. Thus, the government advertises various grants as means for innovators to cope with obstacles such as regulatory risks and expensive, time consuming development processes (Williams & Hourd, 2008 and Vinnova, 2014).

RESEARCH & DEVELOPMENT: Williams & Hourd (2008) emphasize that besides the common support from incubators such as governmental innovation agencies, the collaboration between universities and healthcare institutions is common and has generated a range of innovative products and systems.

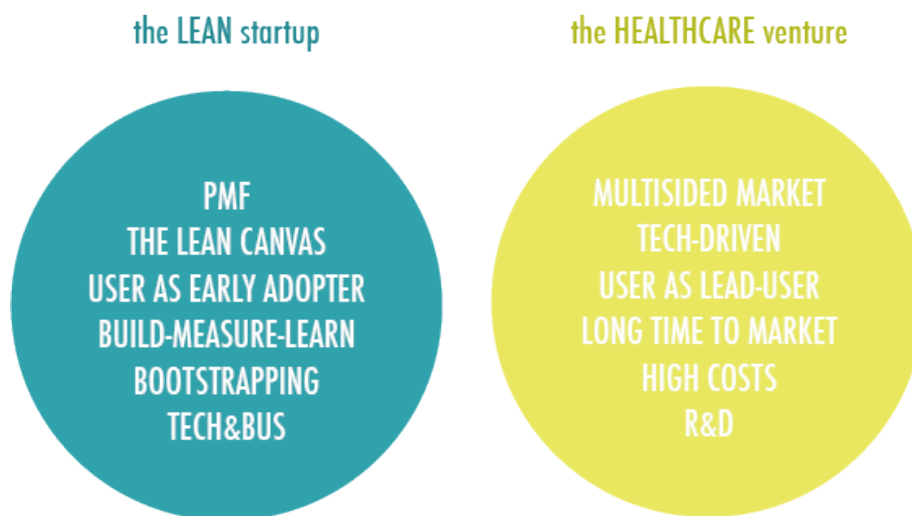


Figure 11: Comparing the lean startup with the healthcare venture

Based on these findings the case study sought to identify how the lean and user driven methods could and should be applied in the project and thus identifying crucial points for a successful project.

4. METHODOLOGY

The six key concepts of the lean startup and the six corresponding concepts of a startup in a healthcare context guided the work of constructing the conceptual framework prior to implementing the case study. Thereafter a slightly modified methodology inspired by the running lean framework was applied in the initial state of the project entitled *Motivation-driven self-managed post-stroke rehabilitation*. The conceptual framework will be explained in a later segment in this section entitled *Test framework examining a case study*, describing the project. Guided by the key concepts the case study sought to identify how the lean and user driven methods could be applied in the context of the case study and thus identifying crucial points for a successful project. Figure 12 demonstrates the implementation loop in three steps; modify, test and analyse the conceptual framework.

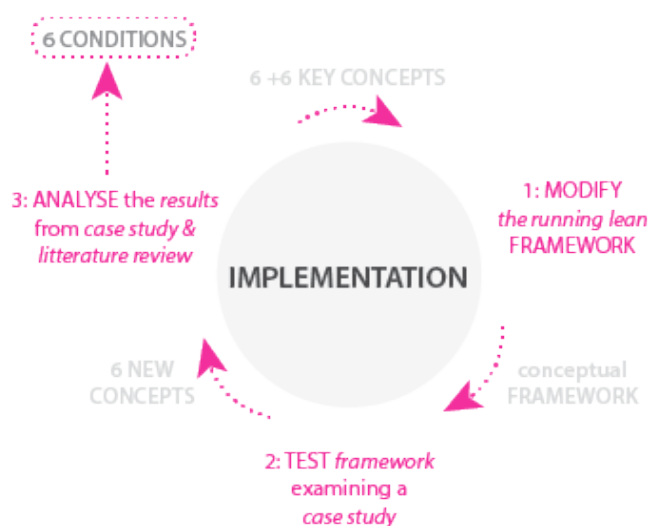


Figure 12: The implementation loop describes the process of this research study in three steps.

Firstly, the running lean framework was slightly modified.

Secondly, the conceptual framework was tested by examining a case study

And thirdly, the results were analyzed leading to the six conditions for success.

4.1 Approach

Since no previous research has been found studying a similar methodology applied in the healthcare sector this study is categorized as explorative. The primary data was collected by studying the outcome of the project, hence the approach is considered qualitative (Muaz, 2013). The case study approach was considered appropriate for this research study because, as Bell (1999) argued, “...a case study approach is particularly appropriate for individual researchers because it gives an opportunity for one aspect of a problem to be studied in some depth within a limited time scale”.

4.2 Modify the running lean framework

The healthcare venture differs from the typical high-tech web-startup commonly applying the lean startup methodology and thus the *lean framework* was slightly modified by deviating or replacing some of the key-steps and adding additional methods to the toolbox inspired by ideation methods (IDEO, 2009, and Plattner, 2011). The complete list of additional methods can be viewed in **Appendix 3, The Toolbox**, which also includes some techniques that were used to analyse data, present results and conceptualise ideas.

The main objective during the initial state of the project was to complete the first part described by the *Running Lean* framework: *To validate the Problem/Solution Fit qualitatively* by involving and gaining insight from different types of relevant actors. To do so the team adapted the *build-measure-learn* feedback loop, previously described in chapter 2. Other concepts such as *the lean canvas* and *bootstrapping* were deemed to have no relevance to the, previously defined, project objectives, at this stage of the process Figure 13 illustrates the findings from the literature review.

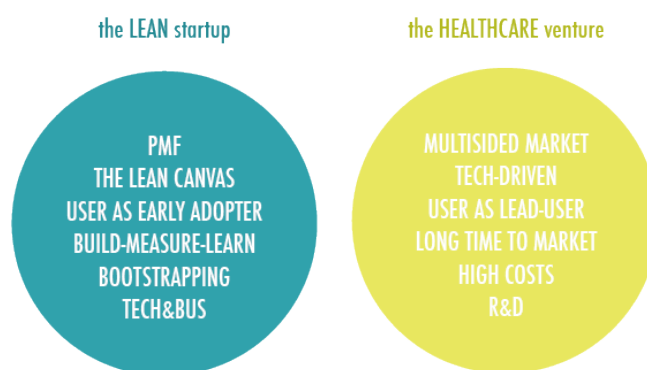


Figure 13: One main objective during the initial stage of the project was to adapt the fourth key-concept: Build-measure-learn, whilst other concepts such as the lean canvas were deviated.

The modifications were made iteratively, prior to implementing each new stage of the process. In order to ensure progress of the research, verify ongoing results and modify changes to the framework, the author continually conducted meetings with the project manager on a weekly basis.

A background study and explorative interviews were initially organized in order to grasp the subject and explore the existing solution space for post stroke rehabilitation. In conclusion the project differed from the typical healthcare venture and these differences also influenced the modification of the methodology and the implementation of the project. Rather than focusing on the typical technology-push or lead user approach the project team chose to apply a user driven approach. Additionally, instead of but involving scholars and engineers when developing solutions, the team consulted multidisciplinary expertise. In summary, three important conditions were considered prior to implementing the case study, which will be explained next; *consider the multisided market, consult multidisciplinary expertise and use user as a source.*

USING USERS IN HEALTHCARE -THE MULTI-SIDED MARKET

During the explorative interviews the project manager quickly realised that the project was facing a *multi-sided market*, more specifically five different types of *actors* were identified and categorized according to four different *user types* (Janhager, 2005).

- **Primary user:** "...a person who uses the product for its primary purpose".
- **Secondary user:** "...a person who uses the product, but not for its primary purpose".
- **Side user:** "...a person who is affected by the product, either negatively or positively, in daily life but without having decided to use the product."
- **Co-user:** "...a person who cooperates with a primary or secondary user in some way without using his or her product".

These actors were all relevant to the development of a PSMrS and in order to understand the problem area all five types were interviewed. *The primary user* of the system was identified as the patient suffering from a stroke. *The secondary user* was identified as the medical expert, whose main concern is that the patient must be motivated and open to accept the medical experts' assistance. This category included the persons responsible for medical and nursing plans and also involved people of other disciplines, such as experts in physiotherapy, nutrition, psychologists or neurologists. Experts promoting alternative means of PSMrS were also relevant and important actors to address. One *side user* was identified, the relative. The relative is often weighed down by the responsibility of caring for and supporting their loved ones, and is in need of better information on how to act and on what can be done for the stroke patient.

Finally, two *co-users* were identified, the volunteer and the decision maker. The volunteers are various people who support the patient or relative in different ways and is often part of a non-profit federation. The volunteer often possesses relevant knowledge but does not have access to channels where he or she can reach out to more stroke patients. The decision maker represents a big group of actors that include EU-, national and regional authority organs handling directives, restrictions, regulations and prescribing processes. The decision maker decides which products reach the market and who gets what, consequently influencing the process of establishing a new concept in healthcare. Figure 14 illustrates the different actors who took part in this study.

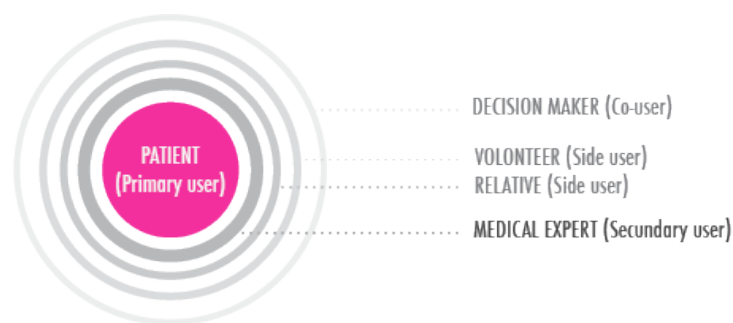


Figure 14: The five actors were categorised according to four different user types

CONSULT MULTIDISCIPLINARY EXPERTISE

Dixon-Woods with colleagues (2010) stressed that there is a need to implement user-centered, social-science methods, in order to ensure that all dimensions and stakeholders, at all different stages of product development and diffusion of new technologies, are considered and advised. The case study was managed by a small project team consisting of two people, however partners and collaborators from the private sector, both startups and established high-tech firms were also engaged from the beginning. The choice was made to involve a wide range of relevant stakeholders and cross-disciplinary competences early on in the design process. The decision was made with the supposition that a multidisciplinary expertise might open up the solution space.

The Venn Diagram below (Figure 15) presents a brief overview of the different relevant stakeholders and how they are entwined. The collaboration between the university and the healthcare institutions is a common phenomena in the healthcare sector (Institutions), as well as the support from incubators such as governmental innovation agencies (Agencies). Innovators are obliged to go through expensive and time consuming procedures before their product reaches the market (Authorities) and are often supported by governmental grants to cope with such expenses.



Figure 15: An overview of the relevant stakeholders.
A range of stakeholders representing decision makers, scholars, firms and startups were engaged from the beginning.

USING USERS TO UNDERSTAND THE PROBLEM AREA AND EVALUATE SOLUTIONS

As stated before, with a self managed system it is no longer the medical expert that is the *Primary User* but the patient. The project team decided to involve the patient as a valuable source of information rather than leading the design process. The patient posses valuable knowledge derived from their own experiences, or from knowing other people in similar situations. Thus, while conducting the study it was important to find appropriate methods that allowed the patients to be involved as observers. A few additional methods were added to the framework inspired by participatory innovation activities, IDEO’s and BOOTSTRAP BOOTLEG’s ideation tools (IDEO, 2009 and Plattner, 2011). These will be explained in the following chapter presenting the implementation of the project.

4.3 Test framework examining a case study

The project was conducted by the project manager and the project author over a period of six months. The implementation was managed through three *Stages*; *Understanding the problem*, *Validating concepts qualitatively* and *Refining final concept*. Each stage was represented by three *Key Activities*;

1. **Articulate hypothesis:** Identify the patient's most critical problems or solutions.
2. **Build something you are able to test against the user:** Conduct an interview or test the prototype by asking the participant to rank and validate the problems or solutions.
3. **Measure and learn from the user's feedback:** Focus on the patient's must-have problem or solution and the features needed to solve the problem or implement the solution.

COLLECTION OF DATA

A total of 53 semi-structured qualitative interviews were conducted during stage 1 and 2 (including explorative interviews and interviews with patients through Skype). The interviews lasted from 45 to 120 minutes and the script was tailored for the different types of actors and different stages. The interview session focused on four main topics; *Collect demographic information*, *Test hypothesis*, *Explore customer's worldview* and *Ask for referrals*. (An example of the script outline can be viewed in **Appendix 4**) During the second stage the interviewee was also instructed to try six different types of *equipment*.

A total of 22 stroke patients participated between the age of 32 to 75 years old and the majority of them were under 50 years old. 11 females/11 men shared their post stroke experiences from the past three months to 16 years (the majority falling into the time span of 2-6 years). In addition to the patients, 8 medical experts, 4 relatives/volunteers and 4 decision makers also participated in the study. Some of the participants were engaged during all three stages, others only took part during one or two stages.

The interviews were conducted by one or two project members. The interviews were documented through audio recordings, photographs and by taking notes. Debriefing sessions between project members were held at the beginning of each week.

During stage 2 one workshop, two field trips and one seminar were also organized. During the last stage the final concept was demonstrated during a workshop together with partners. The final concept was also verified against one of the previous participating stroke patients. The process of implementing the project will be presented next.

STAGE 1: Understanding the Problem

The first key activity during the initial stage is to document the plan A. This is typically done by sketching several *Lean canvases* (see **Appendix 1**) and getting a head start on channels. However the business model driven approach was deemed to have no relevance to the project, previously defined objectives, at this stage of the process. Instead, the different users and stakeholders were identified, as has been described in the previous section, and the problem area was investigated in order to formulate a testable hypothesis. During the problem interview three new methods were added that would encourage the participants to interact; *Draw journey map*, *Review symptoms* and *Card Sort Tool*, which will be explained in further detail later on in this chapter. Figure 16 illustrates the first stage of the conceptual framework.

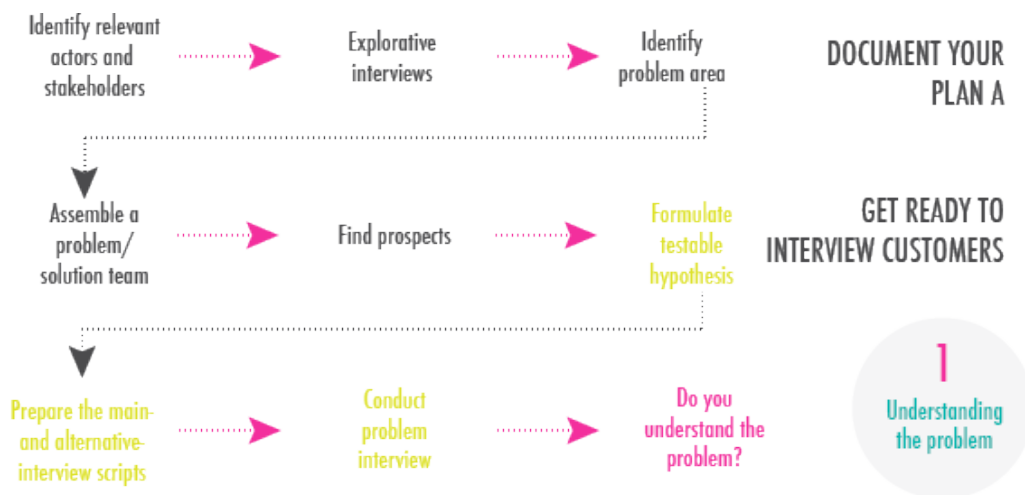


Figure 11: Stage 1, Understanding the problem

Formulate testable hypothesis: In order to formulate a testable hypothesis and prepare the interview script outline, a general but thorough background study was conducted covering three main topics:

- Identify general symptoms and treatment procedures post stroke.
- Explore existing solutions; new approaches for stroke treatment/rehabilitation, existing innovations and future technological possibilities relevant to stroke rehabilitation.
- Identify important factors that support successful self-managed rehabilitation post stroke.

These topics were investigated primarily by conducting a number of explorative interviews with patients, relatives and a stroke rehabilitation coordinator, and complemented by a literature review.

Build: The patient's attitude towards self responsibility when pursuing their rehabilitation is said to be highly influenced by *motivation* and *empowerment*; the opportunity to influence the rehabilitation plan (Torsi et al., 2009). Four additional influential factors were identified; Knowledge, Equipment, Support person and Measure/Visualize. The detailed definition of the influential factors is listed in **Appendix 5**.



Figure 12: The cards used during interviews to rank and validate the six influential factors.

From top left to bottom right: Empowerment, Knowledge, Equipment, Support person, Motivation and Measure/Visualize

The Problem interview was divided into two parts, the first part of the interview focused on the user's experience of stroke and instructed the patients to indicate which symptoms and effects they were being affected by. Subsequently, the participant were asked to visualise their own or their experience of a stroke patient's progress post stroke by drawing a curved timeline on a piece of paper. The x-axis represented their improvement and the y-axis demonstrated the time post discharged from hospital. This method was inspired by the *Draw It* (IDEO, 2009) and *Journey Map Tool* (Entrepreneur, 2014)., described in *The Toolbox* (**Appendix 3**). To encourage participants to visualize their experience through drawings and diagrams can be a good way to *debunk assumptions and reveal how people conceive of and order their activities*. The purpose of the journey map was to map out the details and steps of the rehabilitation process to illuminate areas of potential insights.

The second part encouraged the participant to firstly rank and thereafter validate six cards, each representing the influential factors. The factors were ranked as unimportant, important or very important. This method was inspired by the *Card Sort Tool*, also described in *The Toolbox*. This tool was used in order to expose the participant's expectations and priorities about the intended rehabilitation system. The patient was encouraged to add cards, which occurred in three cases and resulted in two new factors; location (rehabilitation at home or not at home) and communication (especially between the patient and his/her range of caretakers).

The majority of the questions during all three stages were referring to *the patient's situation*, regardless of which actor was being interviewed. For example, when *the medical expert* was asked to rank cards he/she was encouraged to do so in reference to what was most important to the patient. The main interview script was constructed for interviewing patients, for other actors some questions were excluded and some added. For example, the medical experts were asked an additional question regarding *How much exercise The patient could manage and if and why the frequency of rehabilitation varied amongst different patients*.

Another example is that the patient was instructed to look through a list of various symptoms and effects and indicate which ones they were being affected by, while as the medical expert only needed to answer which effects were *the most common*, the *most painful* and which ones he/she *treated mostly*. Halfway through the interviews the team decided to stop asking the patient to fill out the *list of symptoms* and instead encouraged them to describe their condition and focus on what they experienced as *the most painful effect*. This decision, to make a major change in the script halfway through, is a good example of a typical lean approach. The answers so far had shown that almost all patients were suffering from a variety of symptoms and effects, thus the solution had to meet all of these different symptom and effects. Furthermore, a common most painful effect was mental fatigue (severe tiredness), which is almost impossible to *treat* and had a negative effect on all the other disabilities. The discussions regarding tiredness lead to interesting insights and therefore it was decided that it was better to test how common this particular effect was and what insights other most painful symptoms could lead to.

Measure/learn: In conclusion, motivation was evaluated as *the most significant factor* affecting a PSMrS and the need of a rehabilitation plan was identified as the *must-have problem*.

STAGE 2: Validating Concepts Qualitatively

Stage 2 described in *running lean* focuses on investigating the price customers are willing to pay for your product as well as how you can build a business model around these figures. Again, these aspects were decided to be irrelevant at this stage. The team took inspiration from the *exit criteria* described by the original workflow, however chose to call this part of the process *objectives*. Two objectives were added during stage two; *to understand the Swedish healthcare management context and procedures better*, and *to gain a greater understanding of the solution space and identify potential future partners*. Also, the co-creation activity was implemented by hosting a workshop together with project partners, and a range of other methods were added as will be explained further on in this section. Figure 18 illustrates the second stage of the conceptual framework.

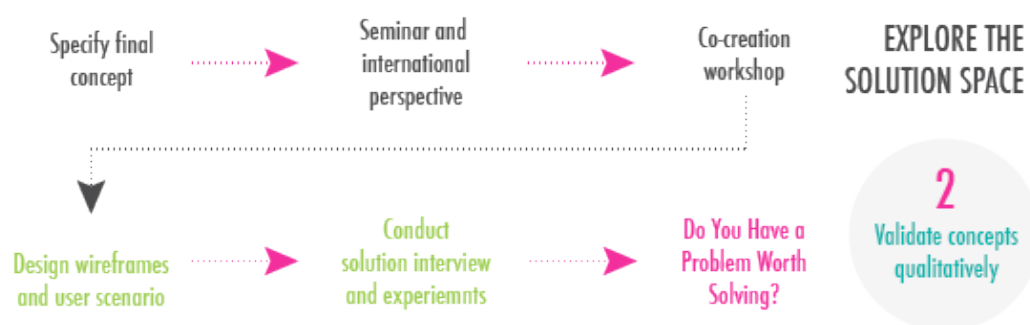


Figure 13: Stage 2, Validate concepts qualitatively

Formulate testable hypothesis: During Stage 2 one seminar, one workshop and two fieldtrips were organised.

The Foundation organized a seminar gathering about 50 leading scholars, physicians and product developers to discuss how to realise innovative ideas concerning future stroke rehabilitation. The project team was given a chance to present the outcome of the first interview phase and discuss some of the insights and paradoxes so far. The majority of partners and collaborators that were present shared glimpses into recent scientific innovation. These important stakeholders were then encouraged to learn more about eachothers ideas and gain hands on experience with some of the products relevant to the PSMrS project.

The outcome of the first interview phase was also presented in detail during a workshop held together with project partners representing experts from university (integrated product development, 2), research (health informatic, 2) and high-tech (mobile applications and optical solutions, 2). A summary of the results of the problem interviews was sent out to participants beforehand. After a brief presentation of the outcome from the first stage the group was introduced to four *Personas*. The personas summarized interesting observations into four specific, recognizable characters. The purpose of using personas was to create composite characters which the group could keep in mind when experimenting with possible solutions. The tool was inspired by the *Create composite character profiles tool* (Entrepreneur, 2014).

The participants formed two teams and brainstormed possible solutions which were later discussed and evaluated by the group. The workshop was inspired by the co-ideation method described by Buur & Matthews (2008) which encourage innovators to generate ideas based on the understanding of people's practices in collaboration with industry partners and the people studied. The complete list of additional methods can be viewed in **Appendix 3, The Toolbox**.

In addition to the ongoing collaboration with partners in Sweden the project sought to explore how PSMrS was thought of from an international perspective. Meetings were organized with leading scholars from England (*UK Stroke Forum, dec13*) and Canada (*Toronto Rehabilitation Institute, dec13*) related to stroke rehabilitation. The findings during these field trips lead to a deeper understanding of PSMrS and recent high-tech solutions for stroke rehabilitation equipment. Most importantly, the project manager was given the chance to discuss possible solutions and establish vital bonds for future collaboration.

Build : The ideas generated during the workshop resulted in one *main concept* and five smaller *related concepts*. The main concept resulted in a holistic approach for a new system network that would meet the demand for a *rehabilitation plan* and the gamification of the PSMrS. The five other concepts demonstrated examples of how the user could interact with the system by utilizing high-tech devices. These concepts also questioned the preferable environment for PSMrS: at home or outside of the home environment.

The project team outsourced the task of designing the five smaller concepts to a professional illustrator who created user scenarios. The specifications of the main concept was documented in a detailed report prior to generating conceptual wireframes. The final designs were presented in a joint proposal that was sent out to participating interviewees and partners prior to the second interview, the solution interview.

Measure/learn: The solution interview consisted of three parts. New interviewees were asked some additional demographic questions before the validation session could begin. During the introduction the interviewee was asked quick questions regarding their experience of using smart technology and by using which screens they preferred to interact with a PSMrS. Thereafter the main concept was presented using a tablet. The participants were asked to evaluate features and elaborate on their answers, occasionally raising additional concerns.

The second step focused on discussing the five related concepts and some additional props were brought to the scene to demonstrate different user scenarios. The improved possibilities to track, measure and receive feedback through high-tech solutions were the main topics. Lastly, the interviewee was instructed to try six different types of *equipment* mainly tied to the rehabilitation of physical disabilities. Most of these devices were also connected to some kind of interface and the interaction with such systems can trigger both cognitive functions and communication skills. The treatment and symptoms in focus were:

- **Rhythm therapy, that stems from the idea that the human brain is capable of re-learning functions of the motor memory and that music can help triggering such activity.**
- **Physical therapy, the most common treatment that promotes mobility, movement and functional ability through physical intervention.**
- **Muscle training accommodating concentric resistance while allowing for eccentric overload.**
- **Balance and visual impairment through gamified exercises and sensors.**
- **Motor skill exercises assisted by muscle strengthening technology.**
- **Fluency of movement, coordination and cognition training in virtual reality.**

Ranking and evaluation of features, concepts and equipment were performed with the help of printed cards illustrating the different *features (main concept)*, *user scenarios (related concepts)* and *photos* of the *equipment*.

The most significant features needed to accomplish self-managed rehabilitation were identified as: *a rehabilitation plan*, *inspiration*, and lastly *instructions* on how to pursue various exercises. The need for *constant feedback*, in order to be confident that the exercise is being performed in the correct manner, was evaluated as the patient's *must-have problem*.

STAGE 3: Refining the Final Concept

The last stage of the process took inspiration from only one of the key activities described by the original framework: *to verify the solution qualitatively*. This was done by organizing another workshop together with partners, as opposed to conducting more interviews with users.

Two important objectives were added; *To prepare the final report of the results*, and *to mobilize partners prior to the additional application*.

Before presenting the results to the partners and investors the *related concepts* were dropped and the *main concept* was *refined*. This decision was based on the simple fact that the *main concept*, a solution for a PSMrS, provided the *minimum properties and features* (a rehabilitation plan, inspiration, and instructions) needed to solve the *must-have problems* (constant feedback). Figure 19 illustrates the first stage of the conceptual framework.

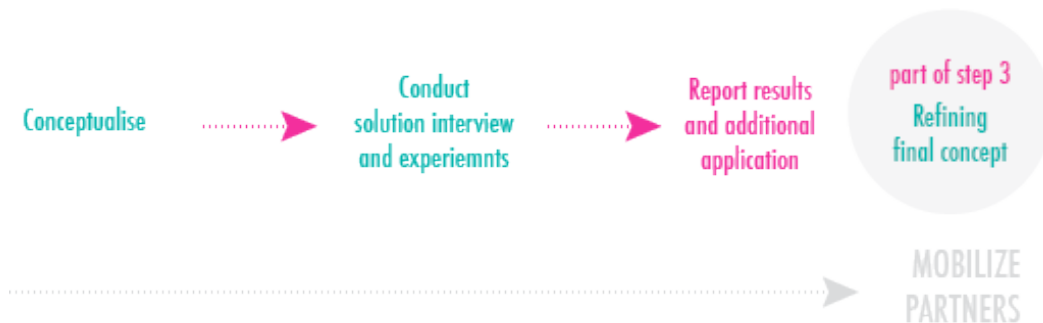


Figure 14: Stage 3, refine final concept

Formulate testable hypothesis: The project assistant used the principles of the P.O.I.N.T technique (*P = Problems, O = Obstacles, I = Insights, N =Needs and finally T = Themes,*) in order to structure the feedback given by users. (Appendix 3, *The Toolbox*) This was done through three iterations, ultimately dividing the insights into three categories; attractive features, insights/keywords and challenges. The project team discussed how to improve the most critical features and enhance the user experience based on what was gathered from the solution interviews. The analysis consisted of two parts:

- A specification covering details regarding features, content and experience.
- A moodboard, a user profile and a user scenario were designed to support the specification visually.

Build: The material obtained from the previous step of the process was later employed when outsourcing the work of designing the final concept to a professional user experience designer. The moodboard, a collage of pictures, was created to communicate the creative vision of the final concept and the user scenario was generated to demonstrate the typical product-user and how he/she would integrate with the system (Buur & Matthews, 2008). Both methods can be retrieved in Appendix 3, *The Toolbox*.

The prototype went through three iterations before it was complete and resulted in a range of wireframes demonstrating the key features through a typical user scenario. This prototype was only a visual demonstration and not functional.

The final concept investigated current ways of managing post-stroke rehabilitation and if these activities could be translated into an ICT-based system reinforced by theories of various treatments, self-management, behavioral change, support from carers and finally high-tech products. The result demonstrated a personalized system for self-managed rehabilitation, which has the potential to improve the existing rehabilitation plan by triggering the patient's motivation through goal setting, inspiration and constant feedback.

Measure/learn: The concept was demonstrated during a workshop together with partners representing experts from health informatic and high-tech research. The final concept was also verified against one of the previous participating stroke patients to gather some additional feedback prior to demonstrating the final results to the investors.

The initial phase of the project lead to an additional application to request funding for the next step of the *Challenge driven innovation 3-step-initiative*. The application engaged five universities and eight firms. Besides the main project, moving on with the solution for a PSMrS, nine possible, related projects were spawned. These projects described various initiatives to develop new products and to improve existing medical devices and exercises together with medical experts, scholars and high-tech firms. These projects would work as complementary solutions to enhance the main solution for a Personalised Self-managed rehabilitation System.

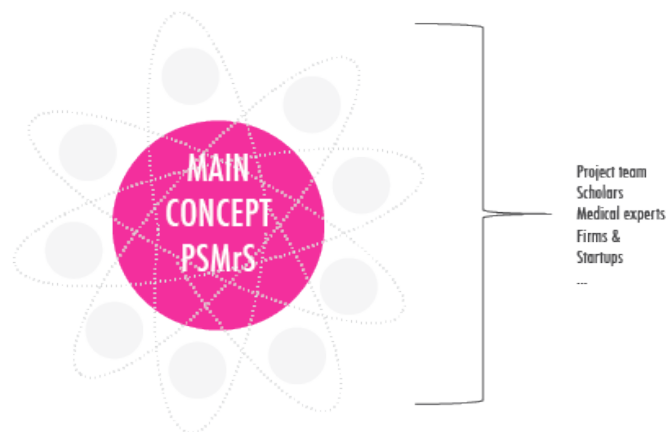


Figure 15: One main project and nine complementary projects

4.4 Analyse the results from case study and literature review

After analysing the findings from the project and the literature reviews, the final conceptual *framework* was created, *six new key concepts* had been formulated, and *six conditions for success* were identified. These conclusions were then refined during an evaluation session together with the project manager.

1. **The key activities, steps and methods used during each step of the process was mapped out iteratively and essentially composed in a spreadsheet describing the final process.**

The conceptual framework was constructed according to the lean framework and runs through the three key-activities; formulate testable hypothesis, build and measure/learn. The key activities are defined by their key steps and clarified by the methods used. Finally the range of objectives are noted in the last column. The project team systematically worked their way through the three loops, and added or deviated elements as the project proceeded. The next loop was initiated as soon as the current objectives were met, if these were still relevant. Figure 21, on the next page, illustrates an overview of the three feedback loops. The conceptual framework can be viewed in **Appendix 6**.

2. **Guided by the key concepts of a lean startup and a healthcare venture six new concepts representing the project were formulated.**
3. **In accordance to these six new concepts the project author was able to identify six recommended conditions for success which can be used in future similar projects during the initial stage of product development.**

4.5 Limitations and criticism of the source

Time constraints, as well as practical and financial reasons limited the depth and quantity of the collection of data. The research team recruited respondents primarily situated in Stockholm and the majority of patients interviewed were younger than 65 years old which only represents about 20% of the people suffering from stroke. Respondents were recruited through organizations cooperating with the research foundation. The recruitment process took more time than expected leading to fewer respondents participating, particularly during the third interview phase which was also interrupted because of a *pre-set deadline* to submit a report to the main investor, concluding the results from the first step.

The construction, implementation, verification of the conceptual framework was conducted in collaboration with the project manager, who had experience from applying the methodology during previous projects. Each step of the process was verified according to the pre-set aims. The project team managed to gain insights from various users, conceptualise solutions and verify one final concept. The process was validated simultaneously by the project team, resulting in minor changes to the framework. However, to verify the common usefulness of the methodology the conceptual framework should be implemented in future similar projects during the initial stage of product development.

In conclusion the study does not provide an objective analysis of the lean methodology. Such an analysis would have required a parallel comparison with a similar case study using a different methodology. Alternatively, interviews and a quantitative survey could have been conducted, querying different entrepreneurs about their previous experiences with a technology-push approach: *Did their approach lead to unexpected and expensive branching that could have been avoided by using lean and user centred methods at an earlier stage of product development?* Ultimately, however, it is at this stage impossible to predict what effect this initial approach will have on the project's future success.

Figure 21 illustrates an overview of the project's three feedback loops.

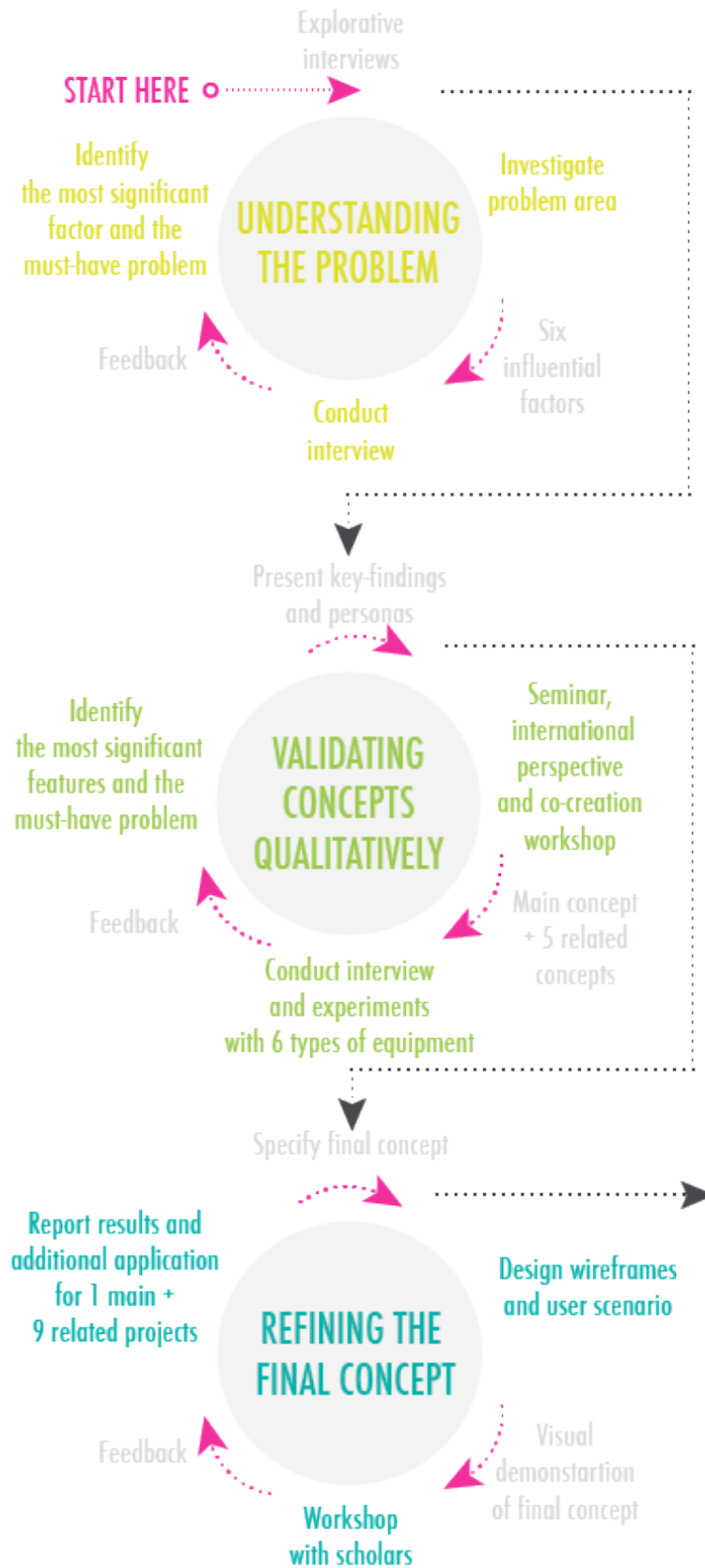


Figure 21: The three feedback loops

5. DISCUSSION

Is the lean startup methodology applicable when facing a healthcare challenge? The findings from the literature study showed how the high-tech lean-startup and the typical healthcare venture are different. The six key concepts of the lean startup and the six corresponding concepts of a startup in a healthcare context were identified, thus answering the first sub question: *What major differences can be seen when comparing the high-tech-web-startup, commonly applying the lean methodology, and a healthcare venture?* Figure 22 summarises the different concepts,

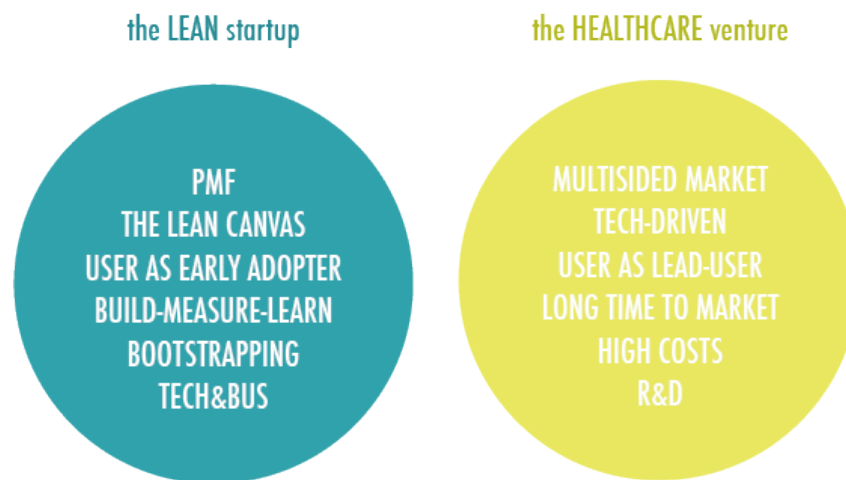


Figure 22: Comparing The lean startup with The healthcare venture

In turn, the project differed from the typical healthcare venture. These differences also influenced the modification of the methodology and the execution of the project, which answered the two remaining sub questions: *What parts of the lean framework, described by Ash Maurya, can be applied in the context of the case study?* and *What additional user driven methods should be added to the framework?* The six new concepts and how these are related to the theory and case study will be explained next.

THE MULTI-SIDED MARKET: In comparison to the lean narrow focus on PMF the healthcare venture needs to consider the complex organization of healthcare institutions and the broad spectrum of different users. Over the past decades the innovators' traditional technology-push approach in healthcare has shifted towards a customer oriented mindset. In turn, recent trends in the sector have demonstrated the need and success of a participatory approach that transforms the technology to grow in symbiosis with the user as well as the relevant stakeholders while also expanding towards a market oriented mindset (Buur & Matthews, 2008 and Dixon-Woods et al., 2010).

The project successfully managed to involve different users and stakeholders throughout the whole process. The patient, medical expert and relative/volunteer were involved in the process both as experts during the initial problem investigating stage (What) and as critics evaluating the final concepts (How). The decision makers offered valuable insights into the active role played by the public sector in healthcare policies. They expressed an interest for the concept of a PSMrS and concluded that the final concept might be considered a new type of treatment. If this is the case, this treatment creates a demand for a different set of prescribed equipment. However, the decision makers main concern was that before considering such an proposal, they required evidence of such an initiative being beneficial and safe for the patient. Further the different stakeholders, namely scholars, firms and entrepreneurs, who took part in the process of conceptualising ideas contributed with their experience and expertise in various fields. The figure below illustrates how and during what stage the different users and stakeholders were involved in the project. While as the traditional healthcare venture directly involved lead users to investigate *how* to solve problems, the lean startup focuses on involving co-users to investigate *what* the problem is. The project invited users to indirectly and stakeholders to directly be involved. The model (Figure 23) is inspired by the four quadrant figure described by Høgenhaven & Wise (2008).

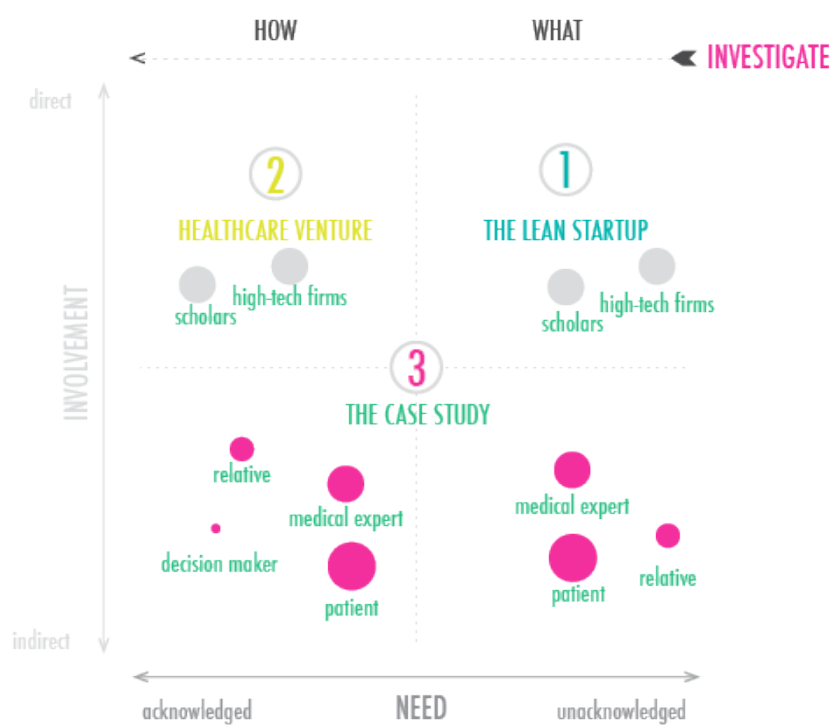


Figure 23: The involvement of different users and stakeholders during different stages.

The medical expert, patient and relative were indirectly involved, while as the scholar and high-tech firm were directly involved in the design process.

NEED DRIVEN: Due to the dynamic environment and *contextual shift in health care service delivery* there is a need for solutions that empower patients and encourage their participation in their own treatment. Thus the patient's acknowledged needs have to be taken into account when developing new products. (Staalesen & Dybvik, 2009) The fact that Swedish healthcare is a public responsibility means that it is less driven by a market force, which complicated the task to apply a lean business model approach. The project deviated these parts from the lean framework, such as the lean canvas and questions regarding feasibility. However, during interviews several of the stroke patients revealed that they had already invested or showed an interest in investing money to receive or self-manage complementary rehabilitation. Recent trends in the healthcare sector indicates that the market supports revenue enhancing activities instead of just cost cutting (Staalesen & Dybvik, 2009). In difference to how this particular project chose to approach a healthcare challenge, a lean business model-driven approach could possibly be applied earlier on in the development process.

Figure 24 maps out the three scenarios discussed in this thesis, inspired by Buur & Matthews's mapping of contemporary approaches in 2008. Firstly, the market oriented lean startup approach- which advocates an iterative process to find the right conditions for successful innovation. Secondly, the healthcare venture- driven by a technology push, where innovative solutions often has derived from a lead user approach. Thirdly, the case study- which demonstrates a participatory and need driven approach.

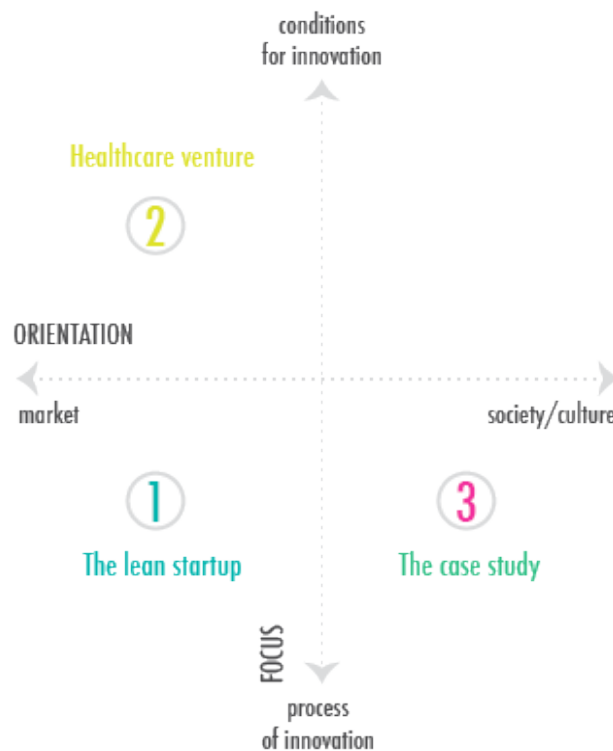


Figure 24: Mapping out the three scenarios; The lean startup, the healthcare venture and the case study

USER AS SOURCE: Similar to the lean methodology one main objective with the project was to ensure that the concepts developed during the process had been driven by the needs and concerns of the different users, in the context of a patient's life-long rehabilitation strategy. The range of user driven design methods that were added to support the lean approach proved useful in order to gain a deeper understanding of the different actors' needs and concerns. The *journey map* proved useful in order for the patient to remember and share their key moments, people and accomplishments. The *cards* facilitated the evaluation procedures and helped to ease the communication by concluding our *questions* or reminding them of the *equipment* they just experienced. These methods are useful for the successful interaction with people having cognitive disabilities.

Further, the proposal based on the first stage of the process, was sent out to the participants before the second interview, which gave rise to useful feedback from the different actors during the actual interview. Some stroke patients brought their notebooks to the next session to provide feedback, questions and even recommendations for how the concepts could be implemented.

Using users as observing experts rather than co-creators might be necessary in order to come up with radical and yet sustainable ideas. The project regarded the Swedish healthcare sector as a public body, where the patients are biased and harbor political interests as they push for more public funding. Thus, what the user wants may not be economically defensible or cost-effective. However, the patient proved to be a valuable source of information during the problem interview and when evaluating the concepts. The patient enlightened the project team on existing alternative treatments, goal setting and their perception of smart technology amongst other topics. The other types of users also provided valuable knowledge, the medical experts in particular, who could confirm or disagree with the patient's concerns and build upon the project teams' ideas.

CLOSING THE FEEDBACK LOOP: The lean methodology provided a structured work process that encouraged the project team to close the feedback loop with the different users by inviting them early and repeatedly to test and evaluate the conceptual ideas before moving on towards developing a finished product. In comparison to user centred design methods the lean approach encouraged the project team to formulate a testable hypothesis prior to observing and talking to the users, which proved useful in order to reach answers and decisions faster.

The interviewees had a tendency to share more than enough on the subject of stroke rehabilitation. The interview script was therefore constructed in a way that forced them to limit their focus on a few topics in particular. For example the interviewee had to focus on *the six* factors or *the four* features, rather than answering but open-ended questions, as is custom when applying a user driven approach. Further, on occasion the project team adopted the lean way of making minor pivots. Halfway through the interviews conducted during stage 1 the team decided to stop asking the patient to fill out the *list of symptoms* and instead encouraged them to describe their condition.

Another example is how the interviews during the last stage were interrupted because of the limited timeframe and because the results from the first and only interview proved little new knowledge in order to move forward. Instead the team continued to investigate how to improve the main concept during a second workshop with stakeholders.

Could it be possible to define clinical utility prior to have developed the final product? The most important lesson learned by conducting this case study might be the importance of establishing a feedback-loop with the different users. Thus, ensure your solution to their problem is desirable, viable and feasible. The next stage of the project, developing the actual PSMrS, will have to involve the primary users more frequently in order to expand the users' experiences with regards to their various disabilities.

HIGH COSTS: In comparison to the lean way of funding through customer revenue the healthcare venture is often obliged to invest in costly development programmes. The most apparent strategy in order to cope with the high costs in healthcare is expanding into other application and market-areas, outsourcing non-core activities or diversification into related product areas, also called spin offs (Williams & Hourd, 2008). Further, healthcare ventures must in most cases be supported by governmental aid, design solutions for international growth and involve devoted stakeholders (Vinnova, 2014).

The project collaborated with a governmental agency, a healthcare institution, scholars and sought to explore how PSMrS was thought of from an international perspective. Further, the project was also supported by a non-profit foundation. By the end of the last stage the collaborating partners had grown from a small group of four to involving a dozen different stakeholders. This group included a range of smaller firms and startups and few of these developed products that emphasised on stroke care. One of the high-tech entrepreneurs explained that the reason he was participating in the project was that his product would get promoted. He was very devoted to research and development and cared less about the process of implementing finished products. He was happy to 'share' the technology with entrepreneurs and scholars as long as they, themselves, managed the development process and he in turn could continue his own development projects.

In June last year (2013) representatives from the private and governmental sector gathered to discuss how innovation in healthcare is and should be managed in Sweden. Charlotte Brogren, *Director General, Vinnova* called for better conditions that would encourage entrepreneurs to insist to fail and learn. "*I'd rather have a bad idea managed by a good entrepreneur, than the other way around*"¹

In conclusion, the unbiased entrepreneur this project symbolises, proved useful in order to mobilize the best people with the most recent research and make use of their expertise in a productive way. This approach enabled the innovators to continue investigating *How* and the entrepreneurs to explore *What*.

¹ cited by Essen, C. V., 2013

MULTIDISCIPLINARY: A typical lean startup often combines high tech developers and business expertise. In a healthcare context, however, the need to ‘*involve relevant stakeholders to mediate and adjudicate between the competing interests and demands*’ is considered one of the main objectives for a successful project (Dixon-Woods et al., 2010).

The project involved relevant stakeholders to participate in the design process to generate sustainable ideas and possible business opportunities at a later stage of the project. The *co-ideation* activities did open up the solution space and ensured that solutions were developed with less bias due to the personal ambitions of the project team and their preconceptions. These activities also enabled solutions to grow in symbiosis with the system, the market and the different users.

An inspiring example of an initiative involving a multidisciplinary expertise is *rockhealth*² initiated by the United States government. This platform gathers partners from medical institutions, venture capital firms and corporate strategic partners, that *supports startups building the next generation of technologies transforming healthcare*.

The case study demonstrates a lean way of closing the feedback loop with the end users in healthcare by engaging a range of actors and stakeholders at an early stage of product development. At this point the project is able to gather feedback, iterate and explore interesting aspects or features based on the demonstrated users’ needs and in collaboration with multidisciplinary expertise. Figure 25 summarises the concepts of a lean startup compared with the findings from examining the case study,

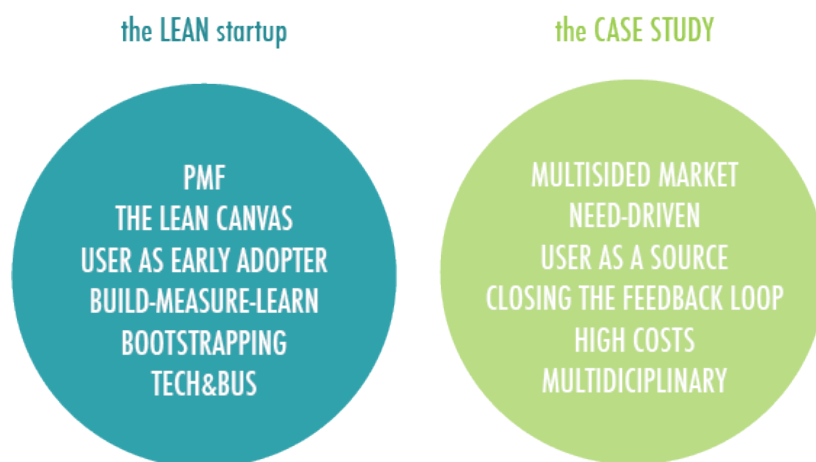


Figure 25: The lean startup and the Case study

² <http://rockhealth.com/>

6. RECOMMENDATIONS

The lean approach provides a set of agile methods that could be used to give developers an edge in the dynamic and fast paced healthcare sector. Through a lean and user driven approach the project sought to iteratively find solutions for how to optimize and improve patient care while at the same time promoting new ways of realising innovative ideas concerning future stroke rehabilitation. The conclusion presents six recommended *conditions for success*, which can be used in future similar projects during the initial stage of product development, guiding the lean entrepreneur as he or she navigates through the precarious health care setting.

1. INVOLVE DIFFERENT TYPES OF USERS FROM START

The process of developing solutions for future self managed care involves several different users and stakeholders. A healthcare startup striving to the market is obliged to consider these actors different needs and concerns.

2. PRACTICE A BOTH NEED- & BUSINESS MODEL- DRIVEN APPROACH

The approach should primarily be need-driven and integrated with health care realities, however recent trends indicates the possibility to apply a lean business model-driven approach.

3. USE USER AS A VALUABLE SOURCE OF INFORMATION

Involve the users early in the process, however not as leaders in the design process, but as experts used to evaluate the final concepts.

4. GET OUT OF THE BUILDING

Formulate a testable hypothesis and test your assumptions prior to have spent all of your millions of dollars in venture capital.

5. EMPLOY A STRATEGIC PUSH

It is vital to identify and engage relevant stakeholders early in the process, whose expertise will contribute to the design process and possibly generate additional funding later on.

6. MULTIDISCIPLINARY EXPERTISE

Transforms the technology to grow in symbiosis with the system, the market and the different users and stakeholders.

Figure 26 summarises the six conditions of success based on the concepts of a lean startup compared with the findings from examining the case study,

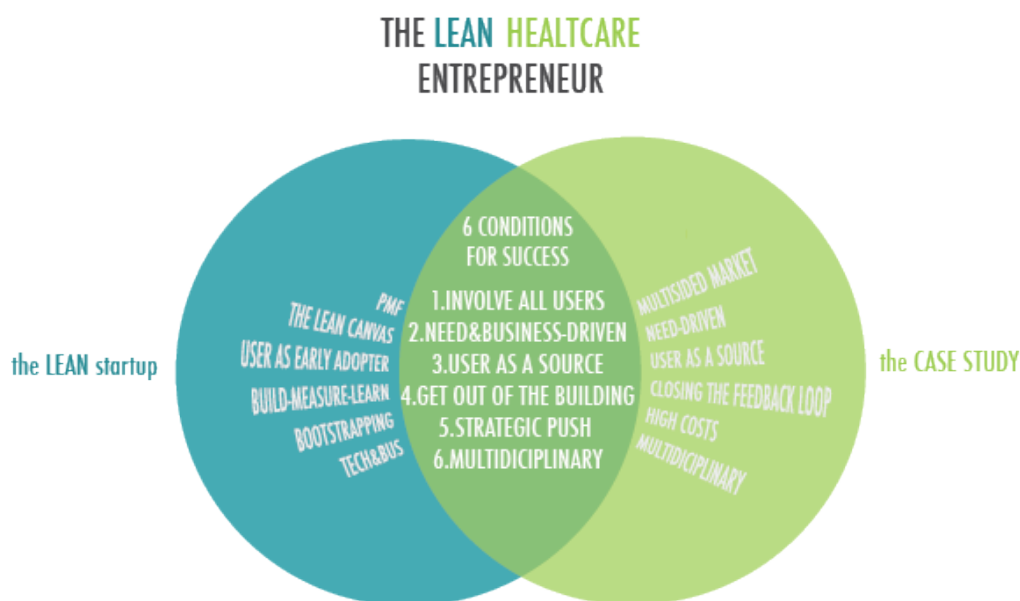


Figure 26: The six conditions for success

6.1 What's next?

One of the smaller firms collaborating with the project explained that the process of getting *one* product into the hands of *one* patient could take over a year. The medical device they were promoting was well thought of by medical experts and patients, however the product was not part of the original catalogue of products provided by the decision makers. In comparison to the procedure of labelling the device, the process of actually subscribing the product was described as a major management issue.

Promotion of the product was another concern and during interviews with decision makers it became clear that the recommended selection of products was rarely updated. Smaller firms experienced difficulties finding the appropriate channels to reach their customer, i.e. the practitioners or the patients.

Withal, current regulations hamper innovators from breaking into the market. The entrepreneur is left with two options, either you promote a commercially sustainable product or you rely on politics and regulations to support and prescribe your product. The decision makers partaking in the study confirmed that as soon as your product gains commercial traction, it is less likely to ever be thought of or accepted as a prescribed product.

This paradox lead to an interesting topic for future research, namely studying the process of creating the feedback loop in itself. Thus, investigate how the patient could be more involved in the participatory initiative currently promoted by the healthcare sector. By identifying channels to reach out to the patient at an early stage, their concerns and preconceptions of new concepts in general could reveal how the product should approach the market. *Is the concept a public responsibility or of market interest?*

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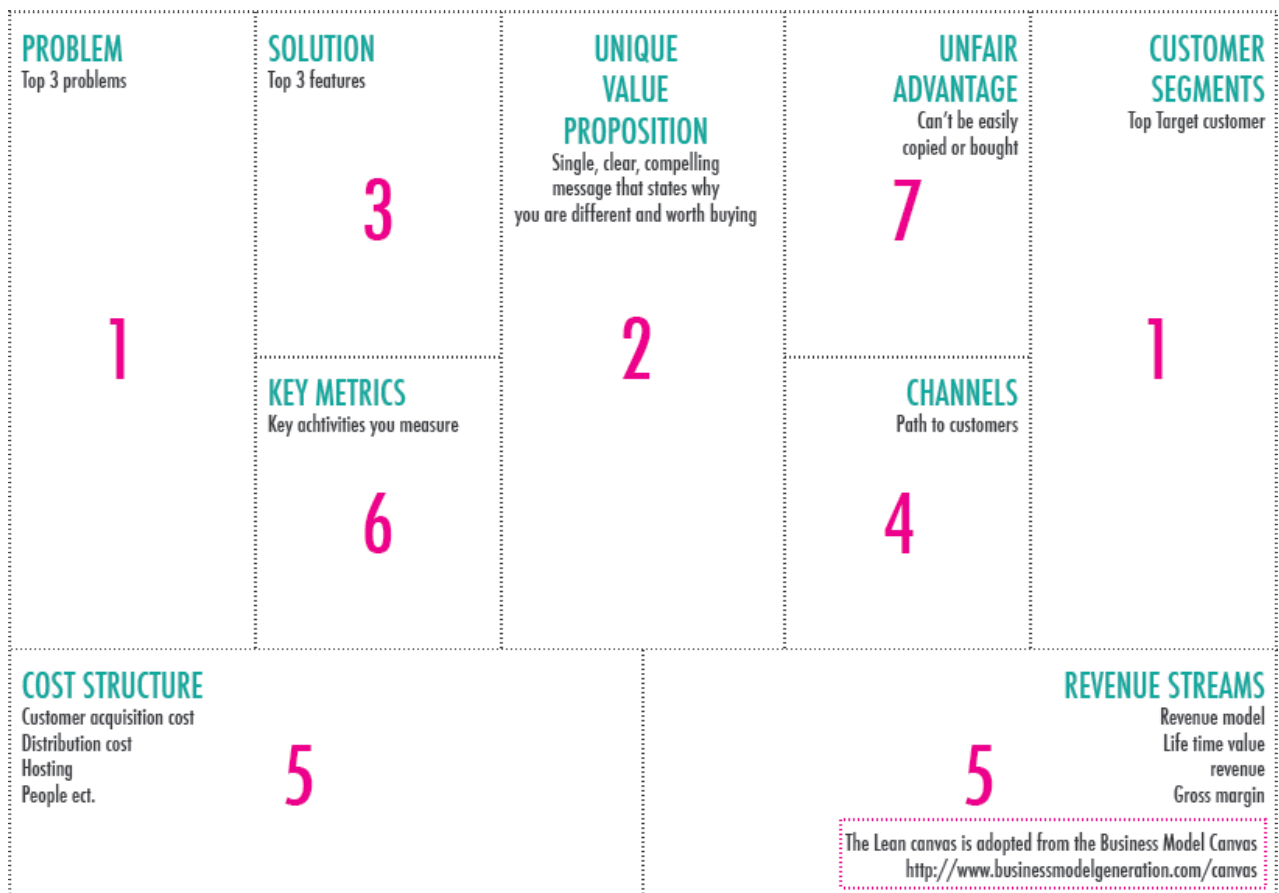
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APPENDIX 1: The lean canvas

Document your plan A by sketching multiple lean canvases

The lean canvas is a slightly modified version of the Business Model Canvas developed by Alexander Osterwalder Pigneur & al.in 2010 (Ash Maurya 2010, Running lean p.40) The canvas is a flexible and reusable one page business model that breaks down all business models into nine interrelated components. Firstly list the *Top 3 Problems* and identify the *Target Customer*. Then; formulate the *Unique Value Proposition*- why the product is different and worth buying (UVP), elaborate on the *Top 3 Features*, *Channels* to reach customers, the *Cost Structure*, the *Revenue Streams* and finally the *Key Metrics*- activities to measure if the plan works and your unfair advantage.



After the potential customers have been identified, the canvas should be used to brainstorm possible business models, making it easier to *prioritize where to start* and *formulate a testable hypothesis*. It is also often re-used throughout the process in order to keep track on ongoing learnings.

APPENDIX 2: The running lean framework

The matrix below describes the three stages and each loop's key- activities, -steps and exit criteria

STAGE	LOOP	O	KEY-ACTIVITY	KEY-STEP	EXIT CRITERIA	
SCALE	2: PRODUCT/MARKET FIT	4: VERIFY QUANTITATIVELY	Measure product/market fit	Focus on the "Right" Macro	...be able to clearly articulate your MVP	
			Don't be a feature pusher	Complete conversion dashboard	...be primed to sign-up for your service,	
			Prioritize feature backlog	Implement 80/20 rule	...accept your price model.	
			Experimentn with pivots	Constrain feature pipeline	...make it through your activation flow, and	
1: PROBLEM/SOLUTION FIT	3: VALIDATE SOLUTION QUALITATIVELY	Get ready to measure	The MVP interview	Formulate testable hypothesis	...retain 40% of your users,	
			Verify solution quantitatively	Conduct MVP interview: Are you ready to launch?	...pass the Sean Ellis test, and	
			Refine final concept and get ready to sell	Reduce down MVP	...get paid (added bonus: reach break-even)	
			The solution interview	Build a Demo	Formulate testable hypothesis	...can identify the demographics of an early adopter
Conduct Solution Interview: Do you have a problem worth solving?	Conduct Problem Interview: Do you understand the problem?	...have a must-have problem				
1: PROBLEM/SOLUTION FIT	1: UNDERSTAND PROBLEM	FORMULATE TESTABLE HYPOTHESIS	Document your plan A	Brainstorm possible customers	...can describe how customers solve this problem today	
			Get ready to interview customers	Sketch multiple lean canvases	...confidently identify the demographics of an early adopter	
			The problem interview	Prioritize where to start	Assemble a problem/solution team	...have a must-have problem
				Get a head start on channels	Find prospects	...can define the minimum features needed to solve this problem, and
2: VALIDATE DEMO	2: VALIDATE DEMO	BUILD MEASURE & LEARN	The problem interview	Formulate testable hypothesis	...have a price the customer is willing to pay	
				Articulate Problem	...that you can build a business around (using the back-of-the-envelope-calculation	
			The solution interview	Build a Demo	Formulate testable hypothesis	...confidently identify the demographics of an early adopter
				Conduct Solution Interview: Do you have a problem worth solving?	Conduct Problem Interview: Do you understand the problem?	...have a must-have problem

APPENDIX 3: The toolbox

The toolbox consists of two compartments; *Interact* and *Conceptualise*, each containing a set of useful methods.

INTERACT

Activate empathy

Draw it: The participants are asked to visualize their experience through drawings and diagrams. *This can be a good way to debunk assumptions and reveal how people conceive of and order their activities. (Bootstrap)*

Card Sort: The participants are asked to organize cards spatially, in ways that make sense to them. The cards can demonstrate possible features, functions, or design attributes. *This helps to expose people's mental models of a device or system. Their organization reveals expectations and priorities about the intended functions. (IDEO)*

CONCEPTUALISE

Analyse, Ideate and Share insights

P.O.I.N.T technique: This method is used to make sense of research data. The identified problems and needs are translated into insights. These insights are then split into five categories; *P = Problems, O = Obstacles, I = Insights, N = Needs and finally T = Themes. (IDEO)*

Co-ideation: Generate ideas based on the understanding of people's practices in collaboration with *Industry Partners* and *the people studied*. (PartInno)

User scenarios and moodboards: Generate user scenarios to demonstrate the typical product-user or customer. Use moodboards (a collage of pictures) to communicate the creative vision of the solution/product. (PartInno)

The journey map: Map out the details and steps of a certain process or experience to illuminate areas of potential insights. *Creating a journey map is an excellent way to systematically think about the steps or milestones of a process. A journey map can be used for your own empathy work, or to communicate your findings to others. (bootstrap)*

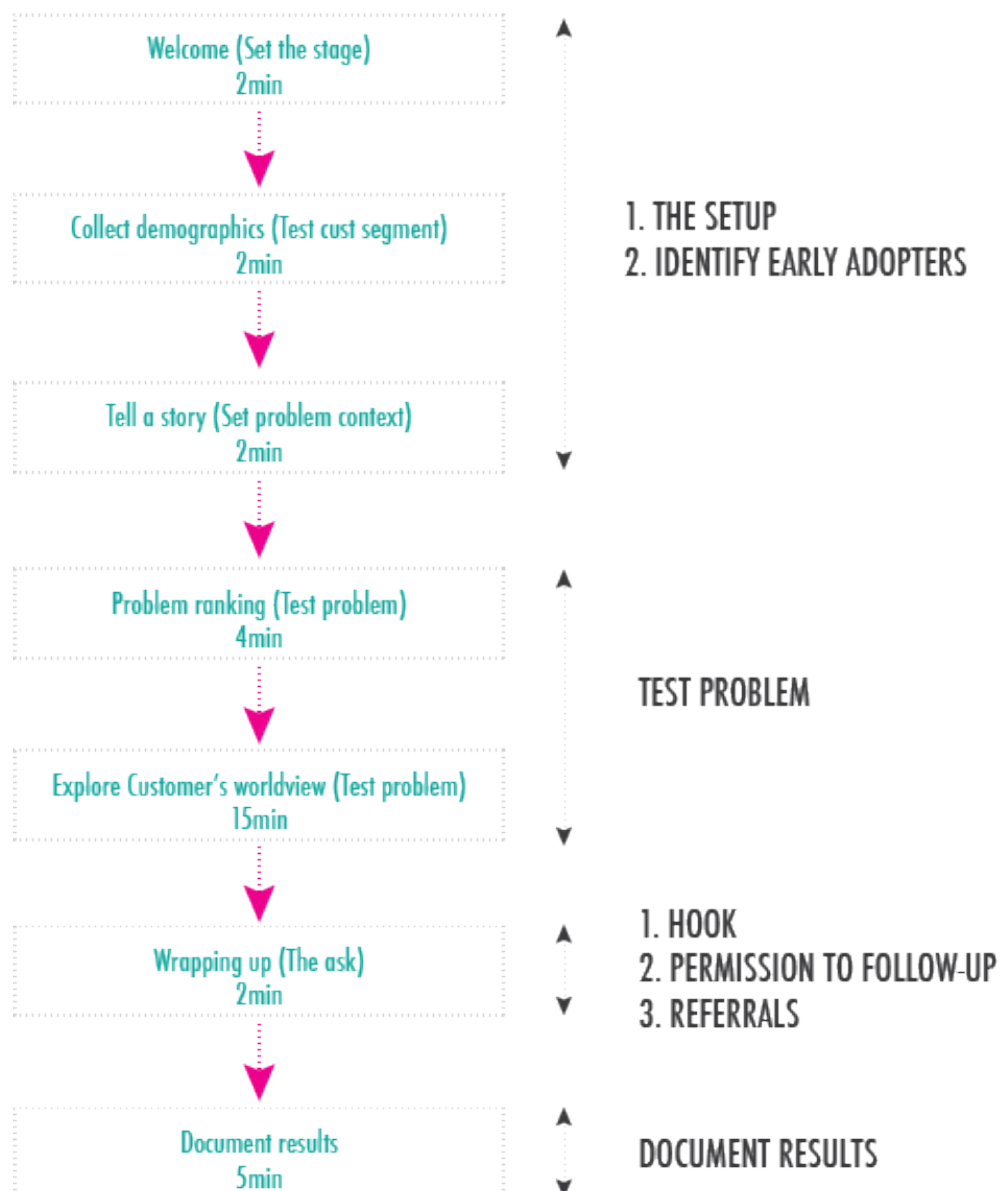
Create composite character profiles: Bucket interesting observations into one or several specific, recognizable characters. *Forming a composite character can be a great way to create a "guinea pig" to keep the team moving forward. (Bootstrap)*

APPENDIX 4: The running lean interview script

Interview script

The 30min-interview script outline consist of four parts; Setup (Welcome-Collect Demographics-Describe Problem), Test problem (Ranking-Validating-Discuss), Wrapping up and Document Results. During the Test part the top 3 problems are ranked and validated by the interviewee followed by a discussion on *how they solve these problems today*.

The results of the interviews should be reviewed weekly in order to make potential changes to the script such as: Adding or removing problems, focusing on early adopters and dropping segments that are the least favorable. When analysing the results it is important to understand the customers existing solutions and different paths to reach the early adopters. The script is slightly modified prior to each step, Each step is completed when at least ten people have been interviewed and the exit criteria are fulfilled.



APPENDIX 5: The six influential factors

F1 Empowerment: every patient is guaranteed a rehabilitation plan, however the patient might not feel that they have enough influence on what this plan should look like.

F2 Knowledge: the expression, and what it means, *self managed rehabilitation* is not yet established amongst professionals and patients, consequentially patients are not recommended to pursue such activities.

F3 Equipment: post-discharged from the hospital, a multidisciplinary team of experts assists the patient in their home environment. However, in between these supervised sessions the patient does not have access to the appropriate equipment to pursue the rehabilitation exercises on their own.

F4 Support person: for some patients the support from experts, family or similar is vital in order to perform any type of rehabilitation activity.

F5 Motivation: Despite knowledge of what and how to pursue with self managed rehabilitation, patients chose not to engage in self managed activities because of lack of motivation.

F6 Measure & Visualise the progress: the patients are not able to track their progress properly and as a result find it hard to gain knowledge of their own progress and to share their experiences with medical experts.

APPENDIX 6: The conceptual framework

FEEDBACK LOOP		STAGE	KEY-ACTIVITY	KEY-STEP	METHOD	EXIT CRITERIA
FORMULATE TESTABLE HYPOTHESIS	Identify customer pull	Document your plan A	Identify relevant stakeholders/actors/artifacts	stakeholder matrix	Identify the demographics of an early adopter. Understand stroke survivor	
			Identify problematic situation and articulate problem	semi-structured explorative interviews		
			Formulate testable hypothesis	literature review		
BUILD	Understand problem	Get ready to interview customers	assemble a problem/solution team	interview script	Identify the most critical factors that might influence their ability to pursue with self managed rehab post stroke. Identify additional factors and a must have problem.	
			find prospects	Go through organisations and clinics to find interviewees. Ask for referrals after each interview		
MEASURE & LEARN	Understand problem	The problem interview	Conduct problem interview	validate and rank hypothesis with cards	Identify stroke survivors alternative means of handling supervised and self managed rehabilitation, especially concerning above identified most	
			Do you understand the problem?	review symptoms draw journey map		
H	Explore solution space & generate ideas	The solution interview	Analyze data	extract insights, themes and qualitative data personas	Understand under what political conditions such solution can become sustainable Have a greater understanding of the technological possibilities, the solution space and potential partners	
			Plot out exciting solutions, research and development	Seminar		
B	Validate demo	Conceptualise solutions	Formulate testable hypothesis	International viewpoint workshop with panel of experts detailed description of refined concepts		
			Build a demo	design conceptual wireframes outsource illustration work Design of concept proposal interview script		
M&L	The solution interview	The solution interview	Conduct the solution interview	validate and rank with cards	Able to confidently identify the demographics of an early adopter Identified their must have problem Defined the minimum features needed to solve this problem	
			How do you solve their problem?	semi-experiments		
H	Review final concept	Build MVP	Analyze data	extract insights, themes and qualitative data	Able to clearly articulate the UVP to main investors Gathered relevant stakeholders that are interested in partnering or collaborating for future development and investment.	
			formulate testable hypothesis	Identify MVP moodboard user scenario		
B	Refine final concept	The validation interview	Refine final concept	design specification and brief outsource ux and design work workshop		
			Conduct the validation interview	semi structured interview		
M&L			What do you do next?			

PRODUCT/SOLUTION FIT

PRODUCT/MARKET FIT ...