



VILNIUS GEDIMINAS TECHNICAL UNIVERSITY

FACULTY OF MECHANICS

DEPARTMENT OF MECHANICAL AND MATERIAL ENGINEERING

Ali Arghoon Afzali

**IMPROVEMENT OF PRODUCT INNOVATION DEVELOPMENT IN
HEALTHCARE**

Master's degree Thesis

Industrial Engineering and Innovation Management study programme, state code 6211EX056

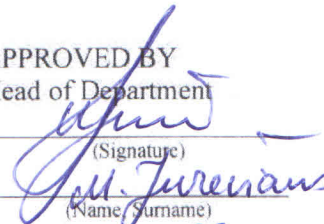
Industrial Enterprises Management Specialization

Production and Manufacturing Engineering study field

Vilnius, 2020

VILNIUS GEDIMINAS TECHNICAL UNIVERSITY
FACULTY OF MECHANICS
DEPARTMENT OF MECHANICAL AND MATERIAL ENGINEERING

APPROVED BY
Head of Department


(Signature)

(Name, Surname)

2020-05-02

(Date)

Ali Arghoon Afzali

**IMPROVEMENT OF PRODUCT INNOVATION DEVELOPMENT IN
HEALTHCARE**

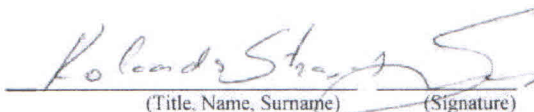
Master's degree Thesis

Industrial Engineering and Innovation Management study programme, state code 6211EX056

Industrial Enterprises Management Specialization

Production and Manufacturing Engineering study field

Supervisor


(Title, Name, Surname)

(Signature)

20200527
(Date)

Consultant

(Title, Name, Surname)

(Signature)

(Date)

Consultant

(Title, Name, Surname)

(Signature)

(Date)

VILNIUS GEDIMINAS TECHNICAL UNIVERSITY
FACULTY OF MECHANICS
DEPARTMENT OF MECHANICAL AND MATERIAL ENGINEERING

Production and Manufacturing Engineering study field

Industrial Engineering and Innovation Management study programme, state
code 6211EX056

APPROVED BY
Head of Department

(Signature)
Prof. Dr. Mindaugas Jurevičius
(Name, Surname)

(Date)

OBJECTIVES FOR MASTER THESIS

.....No.
Vilnius

For student : Ali Arghoon Afzali

Master Thesis title: Improvement of Product Innovation Development in Healthcare

Approved on 17, June, 2019 by Dean's decree No. 292me

The Final work has to be completed by May 25th, 2020

THE OBJECTIVES:

1. To analyse literature of problem in product development in healthcare, innovation and innovation models used for product development;
2. To conduct an empirical research on relevancy of different innovation models in product development in healthcare, common problems and trends in product development in healthcare;
3. To develop an improved innovation model for product development in healthcare.

Consultants of the Master Thesis:

.....
Academic Supervisor  (Title, Name, Surname)
(Signature)

Prof. Rolandas Strazdas
(Title, Name, Surname)

Objectives accepted as a guidance for my Master Thesis

.....
(Student's signature)
Ali Arghoon Afzali
(Student's name and surname)

(Date)

Vilnius Gediminas Technical University
Faculty of Mechanics
Department of Mechanical and Material Engineering

ISBN ISSN
Copies No.
Date-....-....

Master degree studies: **Industrial Engineering and Innovation Management** study programme Master graduation thesis 4
Title: **Improvement of Product Innovation Development in Healthcare**
Author: **Ali Arghoon Afzali**
Academic supervisor: **Prof. Rolandas Strazdas**

Thesis language

☒ English
☐ Lithuanian

Annotation

This study demonstrates a methodology for product innovation development in healthcare. At first, literature review of problems in product development in healthcare, the term innovation and innovation in healthcare. Subsequently, the analysis of 4 innovation models; Stage-gate model, Open innovation, Obeya and Design thinking model. Afterwards, the study presents a quantitative survey to assess the relevance of the aforementioned innovation models in product development in healthcare and also presents a qualitative survey in which the most common problems in product development in healthcare and recommendations on innovation trends were determined by specialists. Also, a real-world case study is applied in which a simple product innovation development model is conducted and reviewed. Lastly, an improved innovation model for product development in healthcare is demonstrated. The main findings of the study are: Identification of the most relevant innovation model in product development in healthcare; determination of the most common problems faced with product innovation development in healthcare; Demonstration of an improved innovation model for product development in healthcare.

Keywords: product innovation development, open innovation, internal and external knowledge, rapid prototyping and 3D printing, Standardization and certification, stages, steps and gates.

Vilniaus Gedimino Technikos Universitetas
Mechanikos fakultetas
Mechanikos ir medžiagų inžinerijos katedra

ISBN ISSN
Egz. sk.
Data-....-....

Antrosios pakopos studiju: **Pramonės inžinerijos ir inovacijų vadybos studijų programos Magistro baigiamasis darbas 4**
Pavadinimas: **Produktų inovacijų plėtojimo tobulinimas sveikatos priežiūros srityje**
Autorius: **Ali Arghoon Afzali**
Vadovas: **Prof. Rolandas Strazdas**

Kalba

☒ X Anglu
☐

Anotacija

Šis tyrimas analizuoja produktų inovacijų plėtrą sveikatos priežiūros srityje. Pirmiausia, literatūroje apžvelgiamos sveikatos priežiūros produktų kūrimo problemos, inovacijų ir naujovių terminas sveikatos priežiūros srityje. Vėliau analizuojami 4 inovacijų modeliai: *Stage-gate* modelis, Atvira inovacija, „Obeya“ ir Dizaino mąstymo modelis. Vėliau tyrime pristatomas kiekybinis tyrimas, siekiant įvertinti minėtų inovacijų modelių tinkamumą kuriant gaminius sveikatos priežiūros įstaigose, taip pat pateikiama kokybinė apklausa, kurioje specialistai nustatė dažniausiai pasitaikančias gaminių tobulinimo sveikatos priežiūros srityje problemas ir rekomendacijas dėl inovacijų tendencijų. Taip pat taikomas atvejo tyrimas, kuriame atliekamas ir peržiūrimas paprastas produkto inovacijų kūrimo modelis. Galiausiai pademonstruotas patobulintas inovacijų modelis kuriant sveikatos priežiūros produktus. Pagrindinės tyrimo išvados yra šios: nustatyti tinkamiausią inovacijų modelį kuriant sveikatos priežiūros produktus; nustatyti problemas, su kuriomis susiduriama kuriant produktų naujoves sveikatos priežiūros įstaigose; Patobulinto inovacijų modelio demonstravimas kuriant sveikatos priežiūros produktus.

Prasminiai žodžiai: inovacinių produktų plėtra, atviros inovacijos, vidinės ir išorinės žinios, greitas prototipų sudarymas ir 3D spausdinimas, standartizavimas ir sertifikavimas, etapai, žingsniai ir vartai.

(the document of Declaration of Authorship in the Final Degree Paper)

VILNIUS GEDIMINAS TECHNICAL UNIVERSITY

Ali Arghoon Afzali, 20142175

(Student's given name, family name, certificate number)

Faculty of Mechanics

(Faculty)

Industrial Engineering and Innovation Management, PIVfmuc18

(Study programme, academic group no.)

**DECLARATION OF AUTHORSHIP
IN THE FINAL DEGREE PAPER**

June 3, 2020

I declare that my Final Degree Paper entitled „Improvement of Product Innovation Development in Healthcare“ is entirely my own work. The title was confirmed on April 22, 2020 by Faculty Dean's order No. 65me. I have clearly signalled the presence of quoted or paraphrased material and referenced all sources.

I have acknowledged appropriately any assistance I have received by the following professionals/advisers:
Prof Doctor Rolandas Strazdas.

The academic supervisor of my Final Degree Paper is Prof Doctor Rolandas Strazdas.

No contribution of any other person was obtained, nor did I buy my Final Degree Paper.



(Signature)

Ali Arghoon Afzali

(Given name, family name)

Contents

LIST OF FIGURES	8
LIST OF TABLES	9
LIST OF APPENDICES	10
INTRODUCTION	11
1. THEORETICAL ASPECTS ANALYSIS IN HEALTHCARE PRODUCT DEVELOPMENT	14
1.1. Problems in product development in healthcare	14
1.2. Innovation understanding analysis	15
1.3. Innovation in healthcare	18
1.4. Analysis of innovation models in product development	19
2. EMPIRICAL RESEARCH ON PRODUCT INNOVATION DEVELOPMENT MODELS IN HEALTHCARE	30
2.1. Methodology	31
2.2. Survey analysis of innovation models relevancy in product development in healthcare ..	31
2.3. Qualitative research (Open-ended question survey) on product innovation development problems and innovation trends	37
2.4. Case Study	39
3. PRODUCT INNOVATION DEVELOPMENT MODEL IN HEALTHCARE	50
3.1. Improved product innovation development model in healthcare	50
CONCLUSION AND RECOMMENDATIONS	67
REFERENCES	70
APPENDICES	73

LIST OF FIGURES

Figure 1. Radical vs Incremental Innovation	16
Figure 2. Stage Gate Processes	21
Figure 3. Different rooms of Obeya.....	24
Figure 4. Design thinking: A 5 stage process	25
Figure 5. Open Innovation's relevancy to product development in healthcare.....	34
Figure 6. Stage-gate's relevancy to product development in healthcare.....	34
Figure 7. Obeya's relevancy to product development in healthcare	35
Figure 8. Design thinking model's relevancy to product development in healthcare	35
Figure 9. Graphic results of most relevant innovation models in product development in healthcare	36
Figure 10. Cortex cast.....	42
Figure 11. Osteoid Cast.....	43
Figure 12. Potential Customer Segmentation	44
Figure 13. Sense 3D Scanner.....	45
Figure 14. 3D Printed Cast.....	46
Figure 15. 3D Printing Process.	48
Figure 16. Product development model for healthcare	51

LIST OF TABLES

Table 1. Disruptive innovation	17
Table 2. Closed and open innovation principles	20
Table 3. Demographic information of Participants.....	33
Table 4. Results of qualitative research (by author).	37
Table 5. Available 3D Casts analysis	41
Table 6. ISO Standards in Healthcare.....	61

LIST OF APPENDICES

Appendix 1. Quantitative survey form of relevancy of innovation models in healthcare

Appendix 2. Quantitative survey's table of results

Appendix 3. Qualitative survey – Open-ended questions on problems in product development in healthcare and innovation trends in product development

Appendix 4. Qualitative survey's answers

Appendix 5. Young scientists' conference paper

INTRODUCTION

Healthcare has changed drastically in the last 30-40 years and this change has played a significant role in society in many ways. During this period of enhanced change, huge developments and great advances have been made to both invention of new medical equipment and products and to patient care. The focus of healthcare industry was mostly on improving the health of the patients and focusing on medical methodologies and ways to find significant improvements with them but that has changed and healthcare has become a great part of our society's economy.

Being a product development engineer has always been difficult in healthcare and this will continue to become more effortful and arduous. In order to succeed, such engineers will need to put more effort into their work and do much more than the past and will need to understand all the aspects of business of product development in healthcare. Successful healthcare protective gears have very long commercial lifecycles some of which can top 30 years in contrast to the short five to six years of 4 decades ago. The life of the product is directly connected with all the decisions made in early development phases by the development engineers. This includes the sales and costs, manufacturing and producing, marketing, inventory and etc for a product with more than 20 years of potential commercial lifecycle. In order to develop a successful product technically as well as financially, the development team must consider a variety of essential factors such as design emphasis, assessment of the viability of the design, also financial viability to optimize all aspects of the product development.

With the increasing pressure of the problems faced in healthcare such as rise of costs, the expectations and requirements for the development team to develop a new product and optimize the essential aspects of the development process such as commercial aspects will keep on getting more discouraging. The development team will have to assess the projects with greater details in order to identify what a successful product is and how to develop it. Further involvement of the financial department will be necessary to simulate various options to acquire detailed knowledge on the influence of design considerations and innovations on financial viability of the product over its predicted 20 or more-year lifecycle. This is just one of many tools that can be applied in product development projects.

Problem

In today's modern world, our everyday lives have become very fast and the society has become very competitive as a whole. Such competitiveness needs us to adapt to its pace which leads to the problem of this study which is product innovation development in Healthcare. Innovation has been the key towards breakthroughs and it has become a global term used in all industries from Manufacturing to Banking and etc. In order to be able to live up the expectation of today's society and keep up with the pace of the society, we need to have an innovation model that would help with Product development in Healthcare and in order to do that, we must find a combination of the available models to find the most suitable model that could be used most effectively while implementing all the essential tools.

Research objectives

Innovation is a very general and vast term and does not belong to only a single industry which makes the use of its models very difficult since a big variety of such models are available and have been used in a vast majority of industries so for this purpose, 4 different innovation models will be investigated and compared.

Research aim

This study is conducted in order to develop a model for product innovation development in healthcare.

Tasks

The list of tasks that will be performed during this study is listed below:

1. To analyse literature of problem in product development in healthcare, innovation and innovation models used for product development;
2. To conduct an empirical research on relevancy of different innovation models in product development in healthcare, common problems and trends in product development in healthcare;
3. To develop an improved innovation model for product development in healthcare.

Research methodology

In order to achieve the aim and find a key innovation model for product development in healthcare, the following methodology was created:

Literature review, this part of the study is based on seeking information from professional sources which consists of journal articles, books and book sections, internet websites. Many articles and journals were taken from 'Science direct' and 'ResearchGate' which are valuable sources for a big variety of articles and journals.

Empirical research, which consists of implementing a real-life case analysis of a '3D Printed Cast' and conducting a survey questionnaire which was answered by experts of familiar background with innovation. A questionnaire is a simple but very effective way of gathering information necessary to help understand the problem more effectively. The purpose of the questionnaire was to find the relevancy of different innovation models in product development in healthcare and compare them directly in order to find a solution. Both quantitative and qualitative methods were undertaken in this study. As previously mentioned, as for quantitative method, a survey questionnaire was fulfilled by experts and its data were analysed, on the other hand, as for qualitative method, an interview was made with an innovation consultant from Lithuanian Innovation Centre which helped us gather more information from the practical point of view regarding innovation models in healthcare.

Structure of the Thesis

This study consists of three sections, literature review, empirical research and solutions.

In the first section of the study, a variety of journals, books, websites and etc were reviewed to conceive information on innovation and innovation models which are trendy nowadays. Firstly, the term innovation, innovation types, R&D in innovation and innovation in healthcare were investigated. Then, 4 different models of innovation were analysed, this part consists of open innovation, Stage-gate model, Obeya and design thinking model.

The second part of the study consists of an empirical research which includes a case analysis, a survey questionnaire and an interview with an innovation consultant. Both quantitative method and qualitative methods were used in order to achieve a closer and more detailed view on innovation trends.

Lastly, the third and last part of the study, consists of a solution represented and implemented in the aforementioned case study in which the enhanced innovation model was used and the advantages were showed.

1 THEORETICAL ASPECTS ANALYSIS IN HEALTHCARE PRODUCT DEVELOPMENT

1.1 Problems in product development in healthcare

The continued growth of chronic diseases we can see the constant increase in healthcare costs. However, a variety of diagnostic services for patient treatment has been provided by many different firms and businesses. These firms and businesses must understand the according environment deeply in order to be able to offer better products and services. However, a critical problem faced in this process is that clever technologies are not enough anymore to solve problems of higher importance in healthcare. These companies must understand the essential need which their diagnostic device addresses and solve. A vast variety of users and individuals have different needs in healthcare and to be able to create products that satisfy them with their needs is essential.

Another crucial factor in product development in healthcare which is often forgotten is experiencing the real world. Many companies or scientific firms have the ability to have both scientific knowledge and all the essential engineering tools but they lack the understanding of ecosystem in which their product is supposed to be used in. They need a proper understanding of such ecosystem and they must get involved with customers and spend a lot of time with them.

Product development in healthcare requires a thorough understanding of all the fundamental regulatory requirements and certifications. The development of evidence required for such regulatory approval depends on the type of the product and disease (Peter Juhn, 2009). A risk-based classification system is used to establish standards and evaluate device safety and effectiveness. Majority of healthcare product developers understand such regulations and work according to them but some forget to conduct a proper research and fail to meet the requirement of the regulations and this eventually leads to project failure and a huge amount of money wasted. In the 2012 KPMG Pharmaceutical Outlook Survey, conducted in May 2012, 60 percent of executives said regulatory and legislative pressures are the most significant barrier to their company's growth over the next year (news-releases/pharma-execs-continue-looking-for-growth-opportunities-in-spite-of-increasing-regulatory-challenges-kpmg-survey, 2012). It was also mentioned by the executives that one of the main concerns about their company's future is increasing regulations and enforcement.

It is predicted that the future of healthcare products will be proactive and reactive and will be leading towards more integration of IT into healthcare and more remote patient monitoring and will become common. Such healthcare solutions face barriers most of which are related to long product development cycles. Based on Ralph Hugeneck's article on Jabil (Hugeneck, 2018), a survey was conducted and Almost half of the Jabil survey participants reported that the connected healthcare product development cycle takes from 18 to 36 months. Large companies especially struggle to complete a cycle in a year or less.

As a result of literature analysis on problems in product development in healthcare, we can list the problem as shown below:

- Lack of properly understanding of problems and needs in healthcare;
- Lack of accurate understanding of products and tools ecosystem and lack of involvement with customers and users;
- Fundamental regulatory requirements and problems faced fulfilling those requirements;
- Long product development cycles.

1.2 Innovation understanding analysis

Innovation is a term which means doing something differently. Nowadays, this word is used in every industry from manufacturing to banking and etc. Innovation is an important part of today's business world and can mean a new idea or a new product or novelty of any service, which help businesses sustain and create value.

According to (boer, 2001), Innovation is the creation of a new product-market-technology-organization combination which suggests that there are three key elements in innovation:

- Innovation is a process and should be managed as a process;
- The result must be a new product-market-technology-organization element;
- Innovation may vary from incremental to radical or quantum leap and etc.

As can be seen based on the thirds key element of Harry Boer, there are a variety of innovation types and they are used based on the objectives of the innovation and have different categories. Some examples of innovation types are discussed in this study.

Incremental and Radical Innovation

Innovation can be categorized based on its objectives, for example it can be strategic, social, political, philosophical, process and etc. Also, the classification can be different based on the purpose of its use. Two main types of innovation are Incremental and Radical and based on (Donald A. Norman, 2014) the definition of these innovation types is:

- Incremental Innovation: Improvements within a given frame of solutions (i.e., “doing better than we have already done”);
- Radical Innovation: A new frame (i.e., “doing something we had never done before”).

Incremental innovation is focused on the current technologies and processes and the step by step improvement of such processes in order to make them better, faster and cheaper while Radical innovation refers to some type of breakthrough in the market, some technology, product or service with maximum novelty that could change the world.

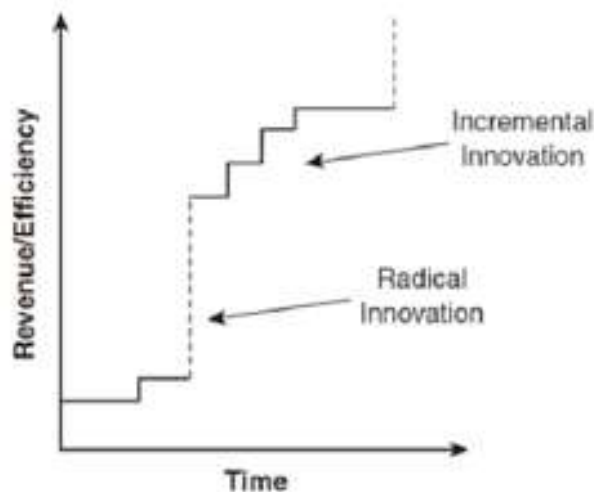


Figure 1. Radical vs Incremental Innovation

(Gardner, 2017)

Disruptive innovation

Disruptive innovation is not your usual breakthrough innovation where continuous improvement of products or process are discovered and a good product is made better for certain target customers with certain abilities and financial power but it has a very specific definition of transformation of a product or process which was originally so expensive and complicated which only a specific target group had access to it, a disruptive innovation makes this product or process much more affordable or accessible to a much larger population has access to it (Christensen, 2012).

Some examples of disruptive innovation include:

Table 1. Disruptive innovation

Disruptor	Disruptee
Personal computers	Mainframe and mini computers
Mini mills	Integrated steel mills
Cellular phones	Fixed line telephony
Community colleges	Four-year colleges

Source: (disruptive-innovation, 2012)

Research and Development in Innovation

A major part in innovation comes from Research and Development, this means that in order to imply innovation, research and development is a major step of the process. Innovation does not come from nowhere and it is gained through experiences and thoughts with which research and development can be extremely helpful. A great way of gaining experience and enhancing your thoughts and become more productive is implementing research and development in any innovation projects.

According to Frascati Manual (2015), research and experimental development (R&D) comprise creative and systematic work undertaken in order to stock knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge.

For an activity to be an R&D activity, it must satisfy five core criteria:

- Novel;
- Creative;
- Uncertain;
- Systematic;
- Transferable and/or reproducible.

The term R&D covers three types of activity: basic research, applied research and experimental development. Basic research is gain knowledge through experiments and theories and facts. Applied research mostly refers to acquiring knowledge through practice and

investigation of a case. Experimental development is basically performing practices and experiments on the currently available knowledge in order to produce more thorough and additional knowledge.

Having analysed the term innovation, innovation types and R&D in innovation, we can conclude that all innovation types mentioned here are applicable in product development in healthcare and the importance of R&D to gain external knowledge is crucial. The type of innovation used in a model depends on the according field in healthcare and the type of product, for example, incremental innovation can be implemented in producing higher quality surgical instruments by modifying or simplifying the existing ones. On the other hand, radical innovation can be implemented in a breakthrough product development such as smart inhalers or robotic surgeries. R&D is one of the most important if not the most important factor in innovation in healthcare and can be implemented in all innovation models.

1.3 Innovation in healthcare

(Fariborz Demanpour, 1984) define innovation as those changes that help organizations cope with ‘environmental changes and uncertainties not only by applying new technology, but also by successfully integrating technical or administrative changes into their organizational structure that improve the level of achievement of their goals’. Innovation in healthcare refer to many aspects which all focus on one main principle which is enhancing the safety and outcomes for patients. This means helping healthcare professionals with their work, tools, products and help them work more efficiently, faster, more cost effectively and etc.

Innovation is a vast topic which does not end. A big step forward towards easier and more comfortable future has been innovation in healthcare. Nowadays, innovation in healthcare is directly relate to implementation of information technology and information systems and the level of success depends on how successful the healthcare industry is in implementing information technology and information systems. The major step in implementation of IT/IS is understanding the usefulness of it which is the leading step of technology adoption in healthcare. Such adoption can be used not only in-patient treatment but a major role of IT/IS would be realization of the need of new tools and products in healthcare which would need the help of innovators and designers to create those tools and products with the help of medical experts.

Based on (Ramendra Thakur, 2010), organizational culture is an internal factor whereas competition is an example of an external factor that encourages an organization to adopt

innovative ideas. This tells us that the success of the organizations depends on both factors which are internal and external. Internal factors can be sources of strategy planning to observe where efficiency is lacking and what could be improved while external factors can be sources of external, novel and effective knowledge which could be implied in organization to enhance the quality of life in this organization such as quality of healthcare and the focus on patient treatment. If a new tool or product is needed or wanted in the healthcare industry, the need for external factors is major since designing, prototyping and producing such tools need professionals of their own fields that can only be reached from external sources of knowledge.

To summarize, the main focus of innovation in healthcare is on safety and treatment of patients which is proven to be more comfortable with the implementation of information technology and information systems in healthcare. Moreover, use of both internal and external sources of knowledge is important to enhance the management and strategy within the firm and find places to be improved while enhancing the quality of healthcare product by focusing on major factors such designing, prototyping and producing.

1.4 Analysis of innovation models in product development

Innovation in product development has significantly improved and widened with a variety of innovation models that have been introduced over the last few decades. These innovation models have been introduced by different innovators or firms to enhance the quality, efficiency, productivity and results of their projects. Some examples of different innovation models have been reviewed in this study;

- Open innovation;
- Stage-gate process;
- Obeya;
- Design thinking.

1.4.1 Open Innovation

Open innovation refers to an open system where there are no boundaries for exchange of information among innovative companies, people or organization. In an open innovation model, innovators tend to gain external knowledge from different sources to enhance the level of knowledge within the organization and not limit themselves to only what they know. Open innovation is basically the opposite of closed innovation and closed innovation is a model which is based on working with the knowledge available within the boundaries of the of the

firm and all the processes from development to marketing and business is limited only within the firm's knowledge.

According to (Sjödin, 2010), Adapting open innovation principles requires proficiency in several different activities. Such activities include: seeking opportunities, evaluating each opportunity, recruiting potential partners, value-capturing through commercialization, and extending the innovation offering, which means that a lot of changes would be necessary internally and not always such internal changes are welcome. Also, such changes would mean big costs and involvement of external collaborators in the project which can sometimes result in conflicts and disagreements among team members.

Overall, open innovation is most effective if the boundaries are set accordingly and plan is well organized.

The table below shows the differences between open innovation and closed innovation:

Table 2. Closed and open innovation principles

Closed innovation principle	Open innovation principles
Most of the smart people in our field work for us	Not all the smart people work for us, so we must find and tap into the knowledge and expertise of bright individuals outside our company
To profit from R&D, we must discover, develop, and ship ourselves	External R&D can create significant value; internal R&D is needed to claim some portion of that value
If we discover it, we will get it to market first	We do not have to originate the research in order to be able to make profit from it
If we are the first to commercialize it, we will win	Building a better business model is better than getting to market first
If we create the most and the best ideas in the industry, we will win	If we make the best use of internal and external ideas, we will win

Source: (Vanhaverbeke, 2014)

1.4.2 Stage Gate Process

Stage-gate process is an innovation model which is based on creating new and winning products based on a business model that evaluates risk and produces new ideas some of which or chosen to be better than the others.

This model consists of a series of stages where the necessary activities and steps are carried out. Every stage is accompanied by an according gate which evaluates all the achievement of that stage and in order to move on to the next stage of the process, the achievements must pass the gates and start their activities in the next phase. Based on (Sjödin, 2010), The gates function as stop/go and prioritization points where decisions for the future of the project are made. The gates are typically manned by a cross functional group of senior managers, called gatekeepers, who evaluate projects on the idea of quality of execution, business rationale, and the quality of the action plan. In other words, gates are used to cancel projects or redefine them which works based on what is delivered, the criteria chosen by the gate keepers and the outputs.

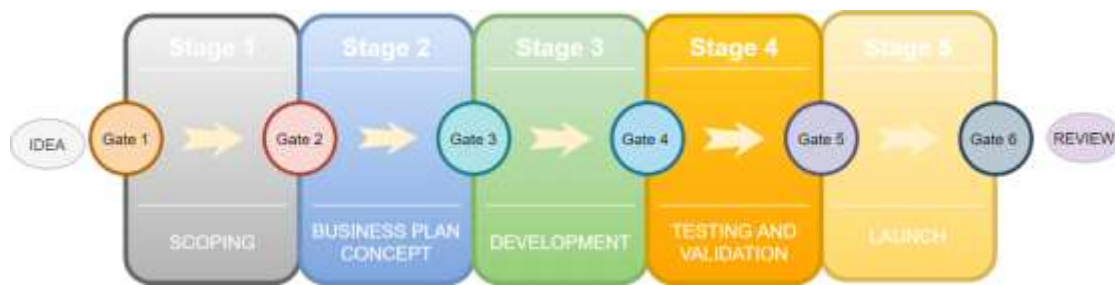


Figure 2. Stage Gate Processes

Source: (Mulder) – Designed by author

As previously mentioned, this model is comprised of a number of stages which are connected two each other by gates. The gates are used to evaluate the results of each stage. A variety of stage-gate processes are available in today's market based on the needs and wants of the firm. An example of a stage-gate model is represented below which is based on Figure 2.

- Stage 0: Ideation;
- Stage 1: Scoping;
- Stage 2: Business plan concept;
- Stage 3: Development;
- Stage 4: Testing and validation;
- Stage 5: Launch and implementation.

Stage 0: Ideation

The first stage of the process focusses on brainstorming ideas and generating as many ideas as possible to find a project which then the company would carry out. This stage includes work and ideas from a variety of sources depending on the principles of the firm. If the firm works within its boundaries only, then only managers and employees take part in these brainstorming sessions. If open innovation is used in this stage, the firm can focus on receiving ideas from external factors such as customers and suppliers.

Stage 1: Scoping

Scoping means evaluating your product and find the best possible market for it while doing a SWOT (Strength, weakness, opportunities, threats) analysis in order to find the advantages and disadvantages of this product. This stage clarifies if the product is going to be produced or not and the gate evaluates that and based on the decision of the gatekeeper, the project could be cancelled or proceeded to the next stage.

Stage 2: Business plan concept

If the product reaches this stage, a business plan must be developed in order to develop the product. A business plan must consist of determining the value of your product by conducting surveys and interviews and also analysis of the product. Such business plan must acquire all the preliminary legal requirements. Also, it needs to create a plan that indicates the responsibilities of all members in the development stage.

When a business plan is made, this plan is evaluated by different departments to check the feasibility of its success and when all departments have positive evaluation of the plan, then the plan is transformed into development.

Stage 3: Development

In this stage of the process, the previously made plan is carried out in order to develop the product. All the responsible people are directed towards their duties, the timeline is created and regularly revised and the prototype of the product is eventually made which is tested in the next stage of the process.

Stage 4: Testing and validation

As can be seen from the title of this stage, this stage includes testing and validation of the product previously prototyped. This means testing of the manufacturing process and market testing of the product.

Stage 5: Launch and implementation

During this stage of the Stage Gate process, marketing strategy is essential. All the preparations for the product are ready and it is ready for launch. This process requires a great

amount of hype in a variety of methods such as advertising campaigns, interviews and etc. An estimation about the sales of product is made and all the essential production policies such as inventory, distribution, warehousing, necessary tool and etc, is set up. The sales team are the responsible individuals for ensuring the smooth process in this stage.

1.4.3 Obeya

Obeya is a Japanese term which means ‘large room’. This term was originally created by Toyota in the 90’s and was used as a component of lean manufacturing which helped them with the production of Prius.

The idea behind this model is that all individuals who are a part of a project, meet in one common place which is often a large room to enhance the speed of communication and decision-making. It is a tool which brings team members closer and creates a better team.

Objectives behind Obeya

Obeya provides all the necessary information to all team members in a condensed format which helps them improve their decision making and save time.

One of the main objectives of Obeya is to save time and reduce time waste of projects. This is achieved by reducing the time needed for rework. When reworking a project after making a mistake or hitting a dead end, consultations, information and research is necessary and that is what Obeya offers at all times. This helps save time and manage planning the project more effectively.

Another way of saving time with Obeya is reducing the number of unnecessary discussions which always happens when team members do not have access to the information they need. When everybody has access to the same information at the same time, all the relevant individuals know their roles and tasks and there is no need of repeated discussions.

Different rooms and perspectives of an Obeya

Obeya can be understood in terms of its different aspects which could be considered as a variety of different rooms with different purposes which are combined to be called Obeya. Based on (Aasland, 2012), Obeya is a collage of different types of cooperation rooms relevant to the Obeya, which shows different functionality and different properties. Some examples of these rooms are war room, work room, meeting room, discovery room, sharing room, workflow room and visual management room which are shown in Figure 3.

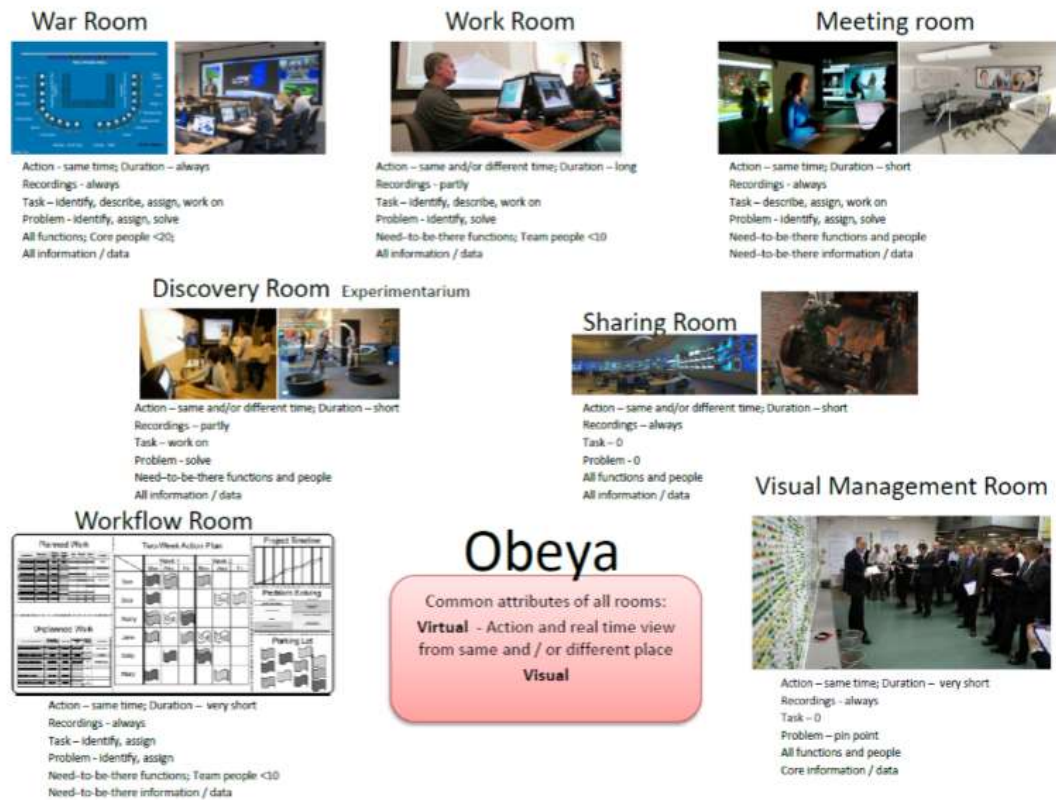


Figure 3. Different rooms of Obeya

Source: (Aasland, 2012)

It is important to understand that in today's world, the physical presence of an individual in a team work is not a must since the modern technology allows us the participate meeting virtually without being present. That means a project can consist of team members who are in different places with having access to all rooms.

On the other hand, being present in these rooms can enhance the quality of work done since visual perception can help us understand complex relations between many factors in a project by observing graphs, pictures, colours and object. Such graphs, colours, pictures and objects give us direct and clear information which can be understood easily and used more effectively.

1.4.4 Design thinking

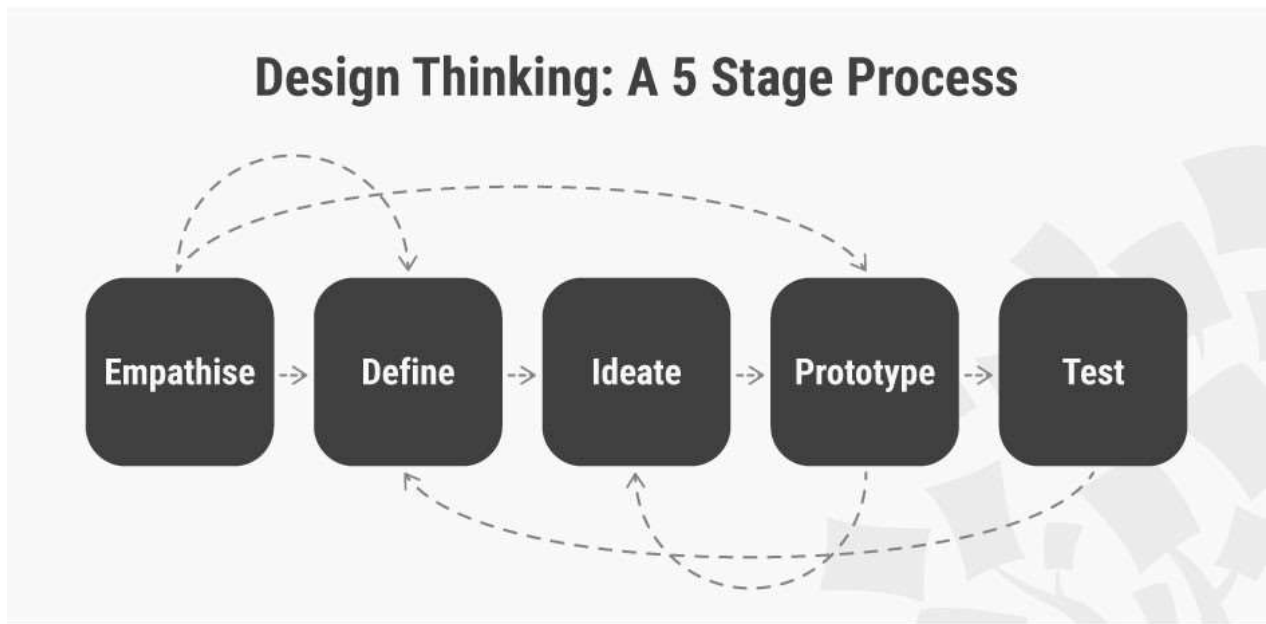


Figure 4. Design thinking: A 5 stage process

Source: (TEO, 2020)

Design thinking is process in which you study based on a mindset of understanding the needs of humans and tackling issues with a solution-based approach. This means empathising with the needs and wants of the humans, and to reframe and deeply understand them. When a problem is deeply understood, you can define the problem and this helps getting closer to those people and get to the core of the problem. When you reach the core of them problem with both internal and external help, you manage to co-design or ideate and innovate through diversity. Later this ideation leads to prototyping and testing.

Here we will take a look at the Design thinking model represented by the Hasso-Plattner Institute of Design at Stanford. The five stages of Design Thinking according to the school are as follows:

- Empathise;
- Define;
- Ideate;
- Prototype;
- Test.

Empathise

This stage is focused on understanding people and their needs on a deeper level. It is important to show empathy and answer the questions such as why, how and what is meaningful to them. Generally speaking, the problems are often not your own and they are related to a specific group of people who do not have the answer and seek for external help and in order to be able to solve those problems and design for them, their empathy must be acquired and they must be understood.

In order to empathize, the users and their behavior in their daily life must be understood. This can be done not in a stalking manner but by conducting interviews or regular surveys. This can help us achieve information which never could be found if not asked or observed. Also, having conversations just to get involved with the users is a useful method of empathy which could easily answer many 'Whys' that are not answered. Such engagements with users can be done by conducting short and random conversations or scheduled meetings for longer conversations. Another method of empathy would be observation, in simple words, to watch and to listen. In order to gain more information, ask someone to show you or to explain to you the way they do things or they complete a task and observe everything they do or say. This would help understand their methods and what goes through their mind.

Define

In this stage of Design Thinking, you uncover the needs and wants that was previously sought for. Define stage of the design process is defining the needs and making sense of the information gained from those needs. When you finish answering those questions of why, how and what, and after observing the people about their needs and gaining information on how they think and what their methods and ways of doing things are, a limited amount of those needs must be selected by their importance to the project and process. After selecting those needs, they must be analysed and a final problem statement must be made in order to proceed the rest of the design process.

Ideate

Ideate is basically brainstorming sessions of idea generation. This means that based on the problem statement created previously, we must present a variety of ideas that would help solve the problem stated.

To ideate you must brainstorm and use your thoughts and mind alongside your imagination. You must create ideas by observing facts, looking up materials, asking questions, adding constraints and thinking about the problem.

Prototype

Based on (TEO, 2020), the Prototype mode is the iterative generation of artifacts intended to answer questions that get you closer to your final solution. Prototyping is a method of reaching practical solutions and risk analysis of the process which is often done in quick and cheap methods to avoid big expenses. As more questions are answered and as ideas are refined with time, prototypes become more necessary and their production become key.

In order to prototype, you must understand the mindset of prototyping which (McElroy, 2017) translates as it is not a checkbox that you complete once on the way to finishing a project. It is a mindset where you are comfortable with testing unfinished ideas in order to make the best result possible. In the process of prototyping, you must not get too attached to your prototype as the chance of its failure is there and it is not a complete model. Furthermore, although it may seem contradictory, a detailed representation need not to be precise (Michel Beaudouin-Lafon). This is an important characteristic of prototypes which leads onto a more open discussion of the unprecise details and opens doors for further exploration of the prototype and potential solutions.

Test

In this mode of Design thinking model, the focus is on the prototypes and validating them based on the previous needs observed and discussed and to evaluate the level of its success with the help of your users. This is another chance to learn more about the users and understand them better. You can proceed to engage with users more in order to find potential solutions after testing of the prototypes. When a test is conducted, it is done without informing the user, for example the prototype is given to the user and their reaction, experience and feedback is observed and collected. If more than one prototype is done, a comparison among those prototypes must be made by the user to understand to what extent do these prototypes satisfy the users and find potential risks and problems in order to manage better solutions in the future.

1.4.5 Analysis of innovation models in relation with product development in healthcare

Based on the analysis made on the aforementioned innovation models, it can be seen that each innovation model has a unique structure with specific tools that help with product development. Open innovation is a major model which works on the principle of acquiring external knowledge in order to enhance the quality of the organization and the products it develops, hence, the application of such model in product development in healthcare would be extremely useful. Furthermore, Stage-gate model is analysed which works based on the principles of managing a product development project in a well-organized manner using a stage

and gate process in which gates are designed to evaluate the according stage and make decision regarding passing or failing the project. This would be essential in any product development innovation model since the model is well-organized and has a clear structure. The third model analysed was Obeya which is a model developed and used by Toyota. This model gives any product development project a clear understanding of where all the information is or can be reached and it a major tool which helps with time management and communication issues. Therefore, the implementation of such model in a product development model in healthcare would be appropriate and helpful. Lastly, design thinking model was analysed in which the idea of solution-based approach to problems is discussed. Understanding the customer and patients' problems and needs can enhance the quality of ideas generated in product development in healthcare therefore, the implementation of this model can enhance the level of ideas generated.

Table 3 shows all the advantage and shortcoming of the previously mentioned innovation models in product development in healthcare;

Table 3. Advantages and Disadvantages of innovation models in product development in healthcare

Innovation Model	Advantages	Disadvantages
Open Innovation	• Helps gather essential external knowledge from healthcare experts. • Enhances the level of ideas created by deeper understanding of problems and needs in healthcare • Reduces levels of risk • Lowers costs of R&D	• Might expose ideas and plans generated within the firm • Extra costs generated • Dependence on external knowledge • Loss of control over intellectual property
Stage-gate model	• Efficient method of ideation • Enhances the quality of project with an organized system • High levels of risk management and risk evaluation	• Can result in low morale of team members who may feel that the project might fail • High chances of gate-keepers having to close projects
Obeya	• Enhances the level of communication • Better time management and increase in overall efficiency • Better collaboration among team members.	• Obeyas fail in technical areas where products and services need to appear in details • Physical Obeyas are not manageable and reachable by all members of a team
Design thinking	• Helps with deeper understanding of problems and needs in healthcare • Strong engagement of users and broader understanding of challenges • Increases the level of innovation culture within the company	• Requires involvement of users and their contribution which requires availability of time and resources • The methodology could clash with the restriction available in products and systems already in use

Source: (By author)

2 EMPIRICAL RESEARCH ON PRODUCT INNOVATION DEVELOPMENT MODELS IN HEALTHCARE

Empirical researches are based on ‘Empiricism’ which means knowledge gained by observation and ‘Rationalism’ which means reaching a conclusion through logic. It is all about gaining real and factual data which have been gained through actual experience and not only from theory. In order to conceive accurate information, both quantitative and qualitative research methods will be used in this study.

Quantitative research methods are based on statistics from numerical data. The results from such researches often answer ‘how’ and ‘why’ questions and describe relationships among the variables given. This method is based on gathering a certain amount of data that would help conceive, analyse and compare the gathered data which is often done by answering closed questions which are presented in forms of multiple-choice questions. In this study, a survey questionnaire was used in order to obtain information on the relevancy of different innovation models in Product development in healthcare. The survey consists of two sections, the first section includes the demographic information of the respondents and the second section of the questionnaire focuses on the relevancy of 4 innovation models (Open innovation, Stage-gate model, Obeya and Design thinking) from a scale of one to five in which one means not relevant and 5 means very relevant. This survey questionnaire was answered by experts from different industries such as Industrial engineers, Mechanical engineers, Service managers, prototypers and etc.

Qualitative research methods are used to obtain non-numerical data and the data analysis is not based on theory or the researcher’s bias notions but the researcher lets the data speak for itself. A common example of such research method is a recorded interview in which the person being interviewed answers a number of open questions. In this study, an alternative method of qualitative research was conducted. A survey questionnaire of two open-ended questions was filled in by professionals in the field of Mechanical engineering and product development in order to obtain the essential information that would eventually help acquire external knowledge in order to manage a reasonable solution.

2.1 Methodology

This study is focused on product innovation development in healthcare; It consists of three parts:

1. Quantitative research (Multiple-choice survey questionnaire)
2. Qualitative research (Open-ended questions' survey)
3. Case study

A quantitative research method is conducted to compare the aforementioned innovation models' relevancy to product innovation development in healthcare which can help us find a reasonable innovation model that could be implemented in product development in healthcare. Also, a qualitative research method is used to gather non-numerical data from an expert who answers questions in regards with innovation trends in 2020. Moreover, a case study is conducted and analysed and a simple innovation model is used to describe different steps of this product innovation and the results are discussed. Overall, the main objectives of this empirical research are:

- To find the most relevant innovation models in product development in healthcare;
- To find the most common problems in product development in healthcare and gain information on innovation trends in product development in healthcare;
- To perform a case analysis using an innovation model and analyse the results.

2.2 Survey analysis of innovation models relevancy in product development in healthcare

In this part of the study, a survey was fulfilled to compare the relevancy of different innovation models that can be used in Product development in Healthcare. The survey was designed according to preliminary review of the literature which is the Innovation Models. This survey questionnaire was answered by 19 professionals in the field of Engineering who are in fields of innovation, industrial engineering and mechanical engineering and etc. In order to be able to prepare the questionnaire in a consistent sequence and for the easy of understanding the matter, the questionnaire is divided into two sections. The first section is focused on the demographic information of the participants such as gender, age, degree of education, and years of experience in the field of innovation while the second section is directed towards the relevancy of each innovation model in product development in Healthcare. The relevancy scale was from 1-5 in which 1 – not relevant to 5 – very relevant. This survey is an electronic

questionnaire which was distributed to the participants via email and Facebook and a total of 19 professionals have answered the questionnaire.

As can be seen on table. 3, the majority of respondents are male managers, taking 52.6% of the total and 21.1% of them are product prototypers. It can also be seen that the majority of participants are between ages of 18-30 and almost 50% of the respondent have 1-3 years of experience. Moreover, 52.6% of the participants are have a postgraduate degree while 42.1% of them have a master's degree which indicates their academic level and knowledge. Observing the number of participants and the data represented on table. 3, it has been concluded that 19 respondents are adequate to be able to conceive the essential data from the questionnaire and be able to analyse and compare them to extract a solution.

Table 4. Demographic information of Participants

		Number	Percentage
Sex	Male	15	78.9%
	Female	4	21.1%
Age	18-30	16	84.2%
	31-50	3	15.8%
	>50	0	0%
Degree of education	Undergraduate	0	0%
	Graduate	1	5.3%
	Postgraduate	10	52.6%
	Master	8	42.1%
	PHD	0	0%
Years of experience	<1	1	5.3%
	1-3	9	47.4%
	4-6	6	31.6%
	7-10	1	5.3%
	>10	2	10.5%
Occupation	Manager	10	52.6%
	Designer	2	10.5%
	Researcher	2	10.5%
	Innovation consultant	1	5.3%
	Prototype Specialist	4	21.1%

Source: (By author)

Based on figure below, it can be seen that 63% of the respondents have voted Open innovation as very relevant (5) to product development in healthcare and the other 37% have voted the level of relevancy as 4 which is also very high. This indicates the fact that most of our participants find this innovation model relevant and useful in healthcare industry and product development in healthcare. This can help us analyze this model more thoroughly and come up with further implementation of it in product development in healthcare.

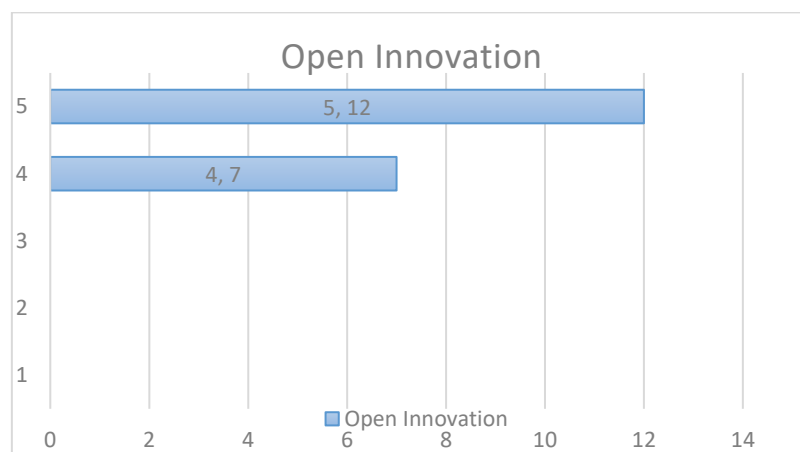


Figure 5. Open Innovation's relevancy to product development in healthcare

Source: (By author)

Stage-gate model was not considered as relevant as open innovation with having 53% of the participants vote 3 and 37% vote 2 as the level of relevancy which indicates that this model is a general innovation model and it is not directly relevant to product development in Healthcare.

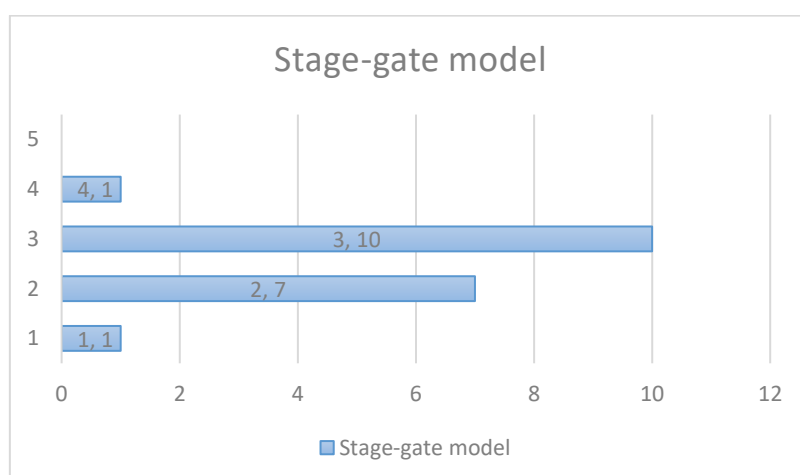


Figure 6. Stage-gate's relevancy to product development in healthcare

Source: (By author)

Obeya is a term which means a ‘large room’ and it was firstly used by Toyota. It is a component of lean manufacturing and it has become popular over the last two decades. As can be seen in figure below, our participants find Obeya, a relevant solution to product development in healthcare with 53% of votes for level 4 of relevancy, 26% for level 5 of relevancy and 16% for level 3 of relevancy. These numbers indicate the fact that our experts believe in the use of Obeya in product development in healthcare and this can be showcased in our case analysis and further solutions.

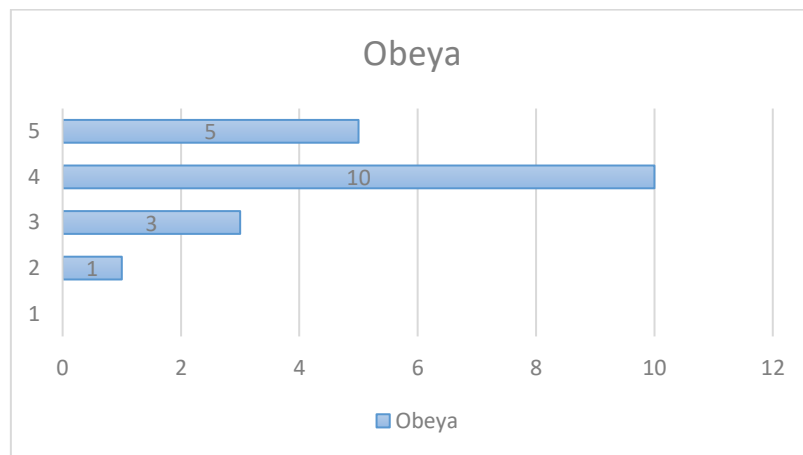


Figure 7. Obeya's relevancy to product development in healthcare

Source: (By author)

Design thinking is a common innovation tool used in many industries. The figure below shows that our participants think that this model is moderately relevant with product development in healthcare with 42% of respondent voted 3 and 37% of them voted 4.

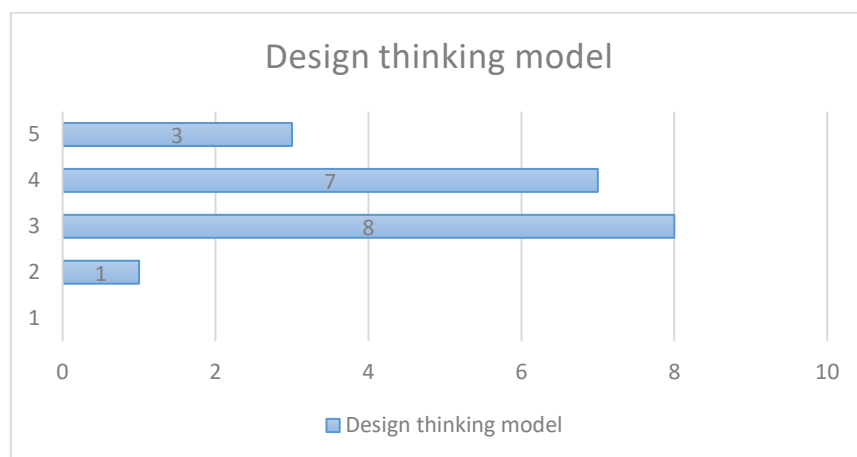


Figure 8. Design thinking model's relevancy to product development in healthcare

Source: (By author)

To sum up the results found in this research, we can see that open innovation has been voted as the most relevant innovation model in product development in healthcare with 63% of respondents having voted the level of relevancy 5/5 and 37% voted 4/5. This was expected since development of products in healthcare require an extensive amount of external knowledge which is gained using the concept of open innovation. Following open innovation, Obeya was voted as the second most relevant model with 53% votes to 4/5 level of relevancy and 26% votes to 5/5 level of relevancy. The third most relevant model in this study is design thinking with 37% of votes going to 4/5 level of relevancy and 42% of votes going to 3/5 level of relevancy. And lastly, stage-gate model was voted the least relevant in this study with 53% of participants' votes going to 3/5 level of relevancy and 37% to 2/5 level of relevancy.

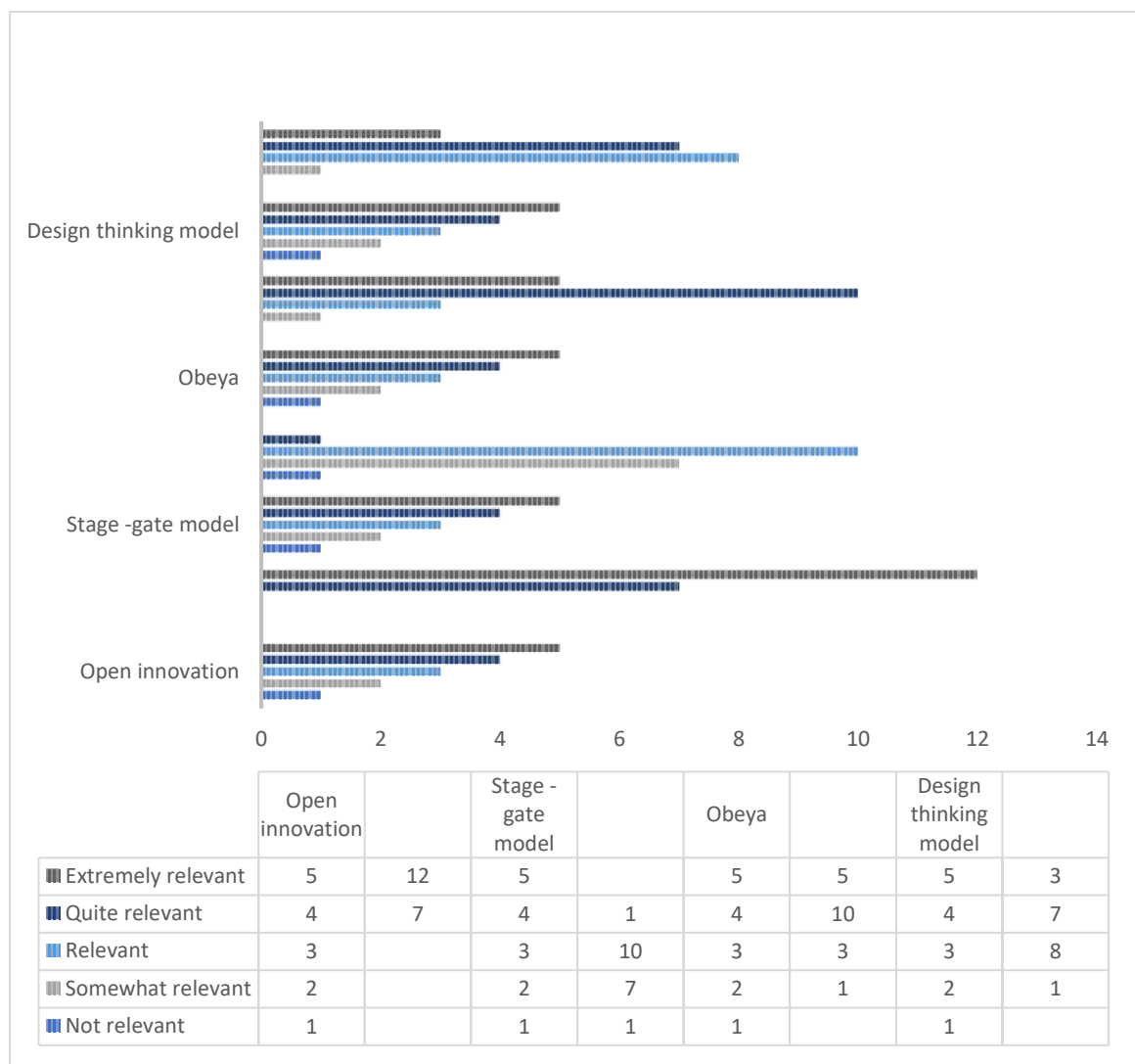


Figure 9. Graphic results of most relevant innovation models in product development in healthcare

Source: (By author)

Figure 9 shows the summarized results of the study. Based on these results, all innovation models which were a part of this study were voted as relevant to product development in healthcare. Open innovation was rated as the most relevant, then Obeya, design thinking and lastly stage-gate model.

2.3 Qualitative research (Open-ended question survey) on product innovation development problems and innovation trends

In this part of the study, a qualitative study was conducted in order to acquire knowledge on the most commonly known problems in product innovation development nowadays and find what are some innovation trends. This method of research consists of two open-ended questions and was answered by a group of diversified audience including a mechanical engineer, innovation consultants and a 3D printing specialist who have experience with the topic of product development. The results of the interview are shown in table below:

Table 5. Results of qualitative research.

Respondents	Problems faced with product innovation development	Innovation trends
1	• Time management • Lack of simple and precise methods • Difficulty with ownership	• Prototyping • Using different methods of Prototyping
2	• Lack of knowledge of tech specialists in healthcare • Lack of available communication with healthcare specialists	• Product development using sensors which track and measure and to control the sensors and extract data. • Use of artificial intelligence and machine learning
3	• Rise of competition and lack of motivation in product development due to the difficult market penetration • Having information only in one field	• Bottom up innovation • Rapid prototyping

Source: (By author)

As can be seen on Table 4, a variety of problems are stated by our participants, some of which are very significant in the product innovation development, especially in product innovation development in healthcare. One of the first problems stated was time management; Time management is a crucial factor in any product development process. A product development project never succeeds if the plan does not indicate a deadline and even with a deadline available, if the plan passes the deadline and the members of the project do not manage to finish the project within the previously anticipated period. Another problem mentioned is lack of simple and precise innovation process which indicates the difficulty of organizing processes of a product development project. Such project would never experience success because the process of its development was never indicated or was never clear to the team members hence it would eventually collapse and get cancelled.

One of the main issues in today's product development in healthcare was mentioned by the second participants which is the lack of knowledge of tech specialist in healthcare. This means that designers, innovators, product developer and etc, would never manage to properly innovate and develop product in healthcare due to not having enough or any knowledge in that field. The healthcare sector is huge and needs an immense amount of information in order to understand the needs of it and meet their expectations. On the other hand, there is lack of communication with healthcare specialists which leads to no information and hence no results. Moreover, the difficulty of market penetration was mentioned which can be a factor in demotivating product innovators and developers. And this issue of demotivation is elevated with not enough information in the healthcare industry.

This research also helped us gather some information regarding innovation trends nowadays. Two participants mentioned the idea of prototyping as an innovation trend. Rapid prototyping has become a major part in many product development projects, it enhances the speed of the projects while decreasing its risks and providing more practical information. Another innovation trend that was mentioned was the idea of using sensors in new product developments. Sensors allow users track and measure data which could later be controlled and collected by the users.

One of the very interesting trends mentioned by our third participant was the bottom-up innovation trends. This innovation method is used by company leaders who look for employees who are motivated, smart and are willing to use their motivation and passion in order to achieve greatness with the company. These employees initiate ideas regarding product development and share those ideas with bigger positions such as managers and directors of the company. This innovation trends are based on creativity and proper management.

The information obtained from this research demonstrates the importance of external knowledge specially knowledge and information from healthcare experts. As a result of analysis of this research, we can summarize that lack of knowledge in healthcare and lack of communication with healthcare specialists are two of the most relevant problems on today's product development in healthcare. On the other hand, some common innovation trends were identified; Prototyping and rapid prototyping have been mentioned by our respondents as innovation trends. According to the level of standards and difficulty of market penetration, prototyping is a must be done stage of most product development models. Also, bottom up innovation tool was proposed which is a method of internal innovation in which the firm acquires ideas from employees. To sum up, we have identified key problems in product development in healthcare and gathered some innovation trends which could help with the development of innovation model further in this study.

2.4 Case Study

This case study is conducted to overview a simple innovation model which later is analysed and based on the results, a final conclusion is stated. This helps our study find potential problems and areas which could be improved in process of product development in healthcare. This innovation model has 3 main steps which are listed below:

1. Ideation;
2. Validations;
3. Development.

Ideation

The underlying way to deal with throwing requires a careful evaluation of the skin, neurovascular status, delicate tissues, and hard structures to precisely survey and analyze the injury. When the requirement for immobilization has been resolved, the doctor must conclude whether to apply a brace or a cast.

Throws and braces serve to immobilize orthopedic wounds:

- They advance mending;
- Maintain bone arrangement;
- Diminish torment;
- Protect the injury;
- Help make up for encompassing solid shortcoming.

Inappropriate or drawn out application can build the danger of difficulties from immobilization. Nearby such danger of blunders, wrapping the cast and its strategy could have awful results if not done appropriately. For instance, if during this system, the arm moves and the cast was wrapped somewhat off, it could cause the inaccurate setting of bones and even odds of consumes of the delicate tissue where the cast is applied.

Mortar gauzes and supports are made by impregnating crinoline with mortar of paris $[\text{CaSO}_4]2\text{H}_2\text{O}$. At the point when this material is plunged into water, the fine mortar of paris is changed into a strong crystalline type of gypsum. The measure of warmth emitted is dictated by the measure of mortar applied and the temperature of the water. The more mortar and the more sweltering the water, the more warmth is produced. The interlocking of the precious stones framed is basic to the quality and unbending nature of the cast.

Analysis of existing casts

Advantages Plaster of Paris

- It is modest;
- It is effectively accessible;
- It is agreeable;
- It is anything but difficult to form;
- It is solid and light;
- It is anything but difficult to expel;
- It is penetrable to radiography;

As of late, various organizations have created materials to supplant mortar of paris as a cast. A large portion of these are a fiberglass texture impregnated with polyurethane pitch. The prepolymer is methylene bisphenyl diisocyanate, which changes over to a nontoxic polymeric urea substitute. The exothermic response doesn't put the patient's skin in danger for warm injury. These materials are favored for most orthopedic applications aside from in intense cracks in which decrease upkeep is basic. Fiberglass throws don't give higher skin pressure when contrasted with mortar throws when appropriately applied.

Focal points

- These materials are solid, lightweight, and oppose breakdown in water; they are likewise accessible in various hues and examples
- Impediments
- They are harder to form than Plaster of Paris;

- The polyurethane may aggravate the skin;
- Fiberglass is harder to apply, despite the fact that the fresher inclination stretch material is an improvement.

In light of research by clinical specialists, a cast could influence patient's life in different manners. A couple of them are; driving, showering, working, composing, cooking, smell, weight, irritated, consideration drawing, and so on. The mending time would diminish if patient's psychological circumstance would be typical during the recuperating procedure and the recuperation rate would increment.

Validation

This stage of our innovation model is to test and check the feasibility of the idea chosen in this study. In order to validate the idea, a study on two available 3D printed cast was conducted and also a potential target customer analysis was done.

3D Casts Analysis

An assortment of 3D Printed Casts have been acquainted with the business sectors in the course of the most recent decade. These throws have indicated the benefits of 3D Printed Casts and its potential later on. In this investigation, two 3D printed throws were breaking down.

Table 6. Available 3D Casts analysis

Casts	Description	Advantages
Cortex Cast	The Cortex Cast was one of the earliest developments in 3D printed casts. The cast is designed using X-rays and 3D scans of a patient's fracture.	• Light • Ventilated • Shower friendly
Osteoid Medical Cast	With daily 20-minute sessions with the stimulator system, a patient can actually speed up the healing process.	• Water friendly • Light • Ventilated • Stable support

Source: (By author)

Cortex Cast

One of the absolute first 3D printed throws acquainted with the market was the Cortex thrown. The Cortex Cast was probably the most punctual advancement in 3D printed throws.

In 2013, Jake and Ollie Evill planned the Cortex Cast to move past the conventional mortar cast framework. The Cortex cast includes a confined emotionally supportive network that is light, ventilated and shower neighborly.

The cast is structured utilizing X-beams and 3D outputs of a patient's break. The subsequent 3D printable cast has ideal help for the most powerless zones while giving an ideal fit to basic help. The cast can without much of a stretch be worn by snap fitting two parts together, which forestalls dismantling.



Figure 10. Cortex cast

Source: (Evill, 2012)

Osteoid Medical Cast

The Osteoid clinical cast was planned by Deniz Karasahin in 2014 as a major aspect of the A'Design Award and Competition. Deniz won the gold honor winning plan for his cast. Notwithstanding offering stable help, being agreeable, water-accommodating, light-weight and ventilated, the cast can likewise be joined with a reciprocal low-force beat ultrasound (LIPUS) bone trigger framework.

As far as anyone knows, with day by day 20-minute meetings with the trigger framework, a patient can really accelerate the mending procedure. This sort of extra LIPUS framework can just work related to a 3D printed plan, as the ultrasound tests should be in

contact with the skin at the site of injury, which would not be conceivable with a conventional cast.

Nonetheless, proof for LIPUS as a proposed treatment for mending bones is faulty and uncertain. An investigation in 2018 announced entire cerebrum LIPUS treatment improved psychological capacity in mice so the valuable utilization of this innovation presently can't seem to be resolved. By and by, the 3D printed cast takes into account the joining of advancements like LIPUS while conventional throws don't.

This cast is also not commercially available.



Figure 11. Osteoid Cast

Source: (Zhang, 2014)

Target Customers

In such study, categorizing and pre-selecting the target customer is a rather essential part of the process. A potential target segmentation analysis was conducted here:

Psychographic

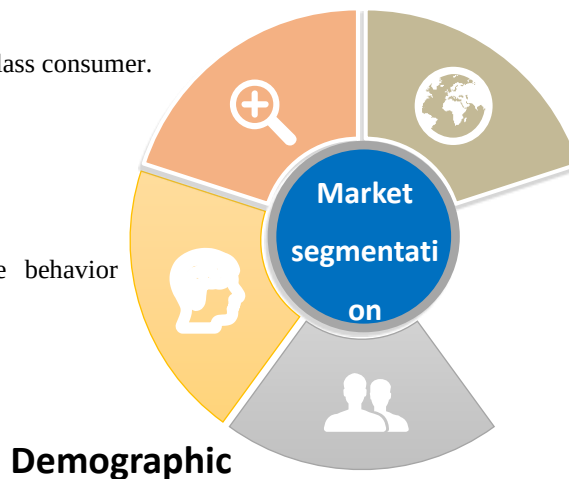
Middle class and upper-class consumer.

Behavioral

Our customer purchase behavior would be random.

Geographic

Our geographic segmentation is for now limited to Lithuania and might cover United Arab Emirates in the future.



Demographic

Demographic segmentation would comprise of all genders and all ages including kids and elderly.

Figure 12. Potential Customer Segmentation

Source: (By author)

Geographic segmentation: Our geographic segmentation is for now limited to Lithuania and might cover United Arab Emirates in the future.

Demographic segmentation: Demographic segmentation would comprise of all genders and all ages including kids and elderly.

Psychographic segmentation: Middle class and upper class are chosen as our social class consumers. This refers to people who can afford paying for private medical expenses.

Behavioral Segmentation: Our customer purchase behavior would be random. Customers are predicted to contact the service any time of the year regardless of seasons or months.

Development

In this stage of the process, the idea selection is finalized and the development of the '3D Printed Cast' begins. This development process consists of 3 main stages listed below:

- Scan
- Design
- 3D Print (Prototype)

Scan

Scanning is one of the most essential steps of the development process. In order to manage to design and 3D print a cast, the scanning process must be extremely accurate and no mistakes are tolerable since the casts are patient specific. A variety of 3D scanners are available nowadays some of which help us scan in a matter of minutes.

The scanning process was done by a former 3D printing specialist using a Sense scanner. The procedure was done twice to make sure the accuracy of the scan is high. This process was handled in a matter of 3 days. The first part of the process was to find a place to perform scanning, then the scanning process was done in about 10-15 minutes. After the scanning process was done, it took another day to prepare the necessary step. format of the scanned file. After receiving the scanned file, the design step was initiated.



Figure 13. Sense 3D Scanner

Source: (store/printer-accessories/3d-systems-sense-scanner, 2015)

Design

The design process of the development stage is based on a few main criteria, such as comfort, strength and stability, aesthetics and price. In this process, three innovation ideas were listed to enhance the criteria mentioned above.

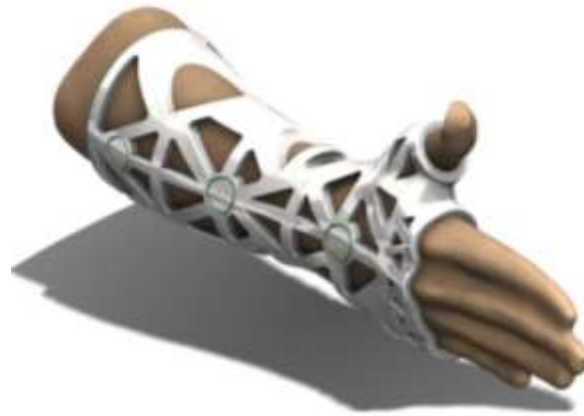


Figure 14. 3D Printed Cast

Source: (By author)

Innovation Ideas

As can be seen based on the available competition, there are not many producers of 3D Printed Cast available in the market today which increases the field of ideas for innovation with 3D printed cast.

- **Comfort:** One of the most important features of a 3D printed cast is the level of comfort it delivers to the customers. This means that material selection is one of the most essential steps in a 3D printed cast development. In this study, thermoplastic is used as the material for 3D printing and also in addition to the material, the surface finishing and the end quality of the cast would be emphasized on.
- **Design:** It is very important for a patient to obtain a beautiful and appealing cast on their arm/hand since they carry this cast with them between 2 to 6 weeks or even more. It is decided to provide a few designs which could catch the attention of patients of different ages.
- **Price:** Another important factor is the price of a 3D printed cast. In order to keep the prices low but the quality of the cast high, we have decided to keep the material as thermoplastic as mentioned before and focus on using cheaper 3D printers which results in slower 3D printing but could be dealt with.

The '3D Printed Cast' was designed and modelled in a span of 5 weeks. A variety of models were generated, different types of joining mechanisms were analysed but lastly, the final cast was developed and is presented in Figure 12.

The pattern is based on triangle structures which give the cast better strength and rigidity. A stronger cast could be obtained by increasing the thickness of the cast. That perspective of designing would increase the material usage which means the price of the cast would increase and additionally the printing time would increase as well.

Aside from the strength and attractiveness, the joint mechanism of the cast is a major part of the design. A joint mechanism can firstly affect the comfort of the patient, it has major effects on rigidity and beauty of the cast as well. The joining mechanism chosen for this cast consists of six rubber bands placed in the printed hollows made for them. This mechanism gives extra tolerance to the cast which are extra essential in case of swollen arm/hand. As for the alignment of the cast, after the printing procedure, 6 small holes of 1 mm wide are drilled on each part of the cast on the joining mechanism and connected with small pins and special glue.

The first software used to design this cast was blender, but due to lack of experience and knowledge with this software, the designer (author) decided to design the cast using Solidworks 2018. The initial step of the design was to decrease the number of surfaces created by the scanned file and this process was very time consuming since the designer did not have access to software capable of doing that. Having decreased the number of surfaces, the designer experimented a variety of models to finally achieve what is presented in Figure 14. After the design process was finalized, the model was ready to be 3D printed.

3D Print (Prototype)

Final step of the development process was the 3D print the finalized cast. This process was conducted by the help of a small 3D Printing company who use FDM (filament-based technology) printing as their main method of 3D printing.

Due to the size limit of the 3D printers available, the model was divided into 4 parts and printed separately. The printing bed was preheated and this is a routine to make sure the quality is good and the structure is strong. Zortrax m200 was used to 3D print the parts which used 80° Celsius bed temperature and the layer height was 0.19mm.

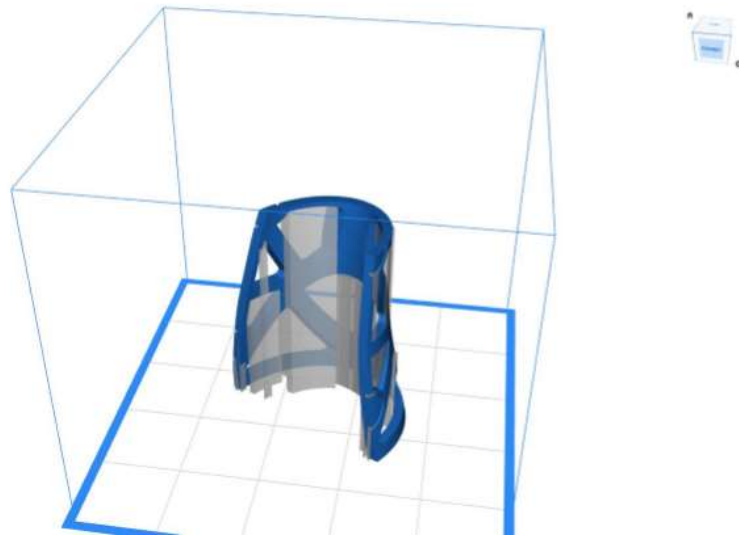


Figure 15. 3D Printing Process

Source: (By author)

The amount of time consumed on 3D printing all four parts equalled to 36 hours and also another. But the overall time used to find the 3D printing company, placing an order, and their delivery was about a week.

The overall process of the product innovation development model used in this case analysis was a moderate success. The simple model presented a three-stage innovation model. To sum up the case study analysis, advantages and disadvantages of the innovation model used in this study are mentioned below:

Advantages:

- Simple and easy to follow structure;
- Internal flow of information to keep the novelty of project safe;
- Use of real-life prototype to analyze the results and risks of the project.

Disadvantages:

- No external sources of knowledge and lack of communication with healthcare experts;
- High chance of failure due to low risk analysis and lack of thorough evaluation;
- No sources of medical standards and certification which can lead to failure of the product;
- Lack of proper preparation which led to a massive amount of time waste.

Having mentioned all the above information, the main findings of the empirical research are:

- Not all innovation models were equally found relevant to product development in healthcare by our respondents;
- 63% of the participants voted 5 as the level of relevancy of open innovation in product innovation development in healthcare while 37% voted 4 as the level of relevancy which concludes open innovation as the most relevant innovation model in product innovation development in healthcare;
- The majority of high relevancy votes were directed to Open innovation and Obeya but Stage-gate model and Design thinking were also voted as moderately relevant which indicates that all the mentioned innovation models can somehow be relevant to product development in healthcare;
- Among all the problems mentioned in this study, the biggest problem stated was lack of knowledge of tech specialist in healthcare and also lack of communication with healthcare specialists which limit the ideas and the information needed for a product innovation development project;
- One of the main trends in today's product innovation is prototyping or rapid prototyping;
- Use of bottom-up innovation can help a company or firm enhance the level of their creativity and organize better team management systems;
- Case study shows that even an organized product innovation development model is not always enough to find the best results;
- The amount of time used in the development stages of the product could be shortened if use of Obeya was implemented in the case analysis;
- The feasibility of the quality of the 3D Printed Cast is unknown due to no communication with healthcare specialists and no external flow of information from potential users;
- 3D printing quality and time management could be enhanced if a more suitable 3D Printer was used with the help of 3D printing experts.

3 PRODUCT INNOVATION DEVELOPMENT MODEL IN HEALTHCARE

3.1 Improved product innovation development model in healthcare

Innovation is a term which is globally used in all industries and it has no boundaries. This makes the availability of innovation models much simpler than before, but it conversely makes it more difficult to find the most appropriate innovation model in your own industry. Many innovation models have been introduced and they were primarily used only in one industry but over time, that changed and those innovation models were used in a vast variety of industries. Based on the literature review of 4 innovation models (Open innovation, Stage-gate model, Obeya and Design thinking) and the results concluded from the empirical research, an improved innovation model was created which includes all four innovation models mentioned in this study combined alongside a few sub-models and tools that help these models function more effectively with product development in healthcare.

The general understanding of the improved model in this practice would be choosing Stage-gate model as the framework for product development in healthcare. This means that the structure of the models is based on the structure of the Stage-gate model which is comprised of a few stages, gates and gate keepers (People who review the project). Having chosen the structure of the model, in order to enhance the rate of its success and in order to manage better results, we implement the first three stages of design thinking model which are Empathise, define and ideate. These three stages focus on the preliminary stages of idea generation and they help us answers many questions such as why we are doing this or for whom and then clarifies the processes of idea generation for us and help us expand the levels of creativity and possibilities. After implementation of these two models as the structure of the model in this study, we use Open innovation in every stage and gate of the structure. Open innovation simply expands possibilities, knowledge and hence the rate of success in product innovation development. In this manner, Open innovation can be named as an essential tool which assists every stage of our innovation model and would enhance their effectiveness. Lastly, Obeya which means a ‘large room’ will be the place where all the product development takes place and in accordance with the availability of people and sources, there would be physical or virtual places where every team member can interact and have access to all the necessary information.

The improved innovation model was designed using draw.io and is shown below:

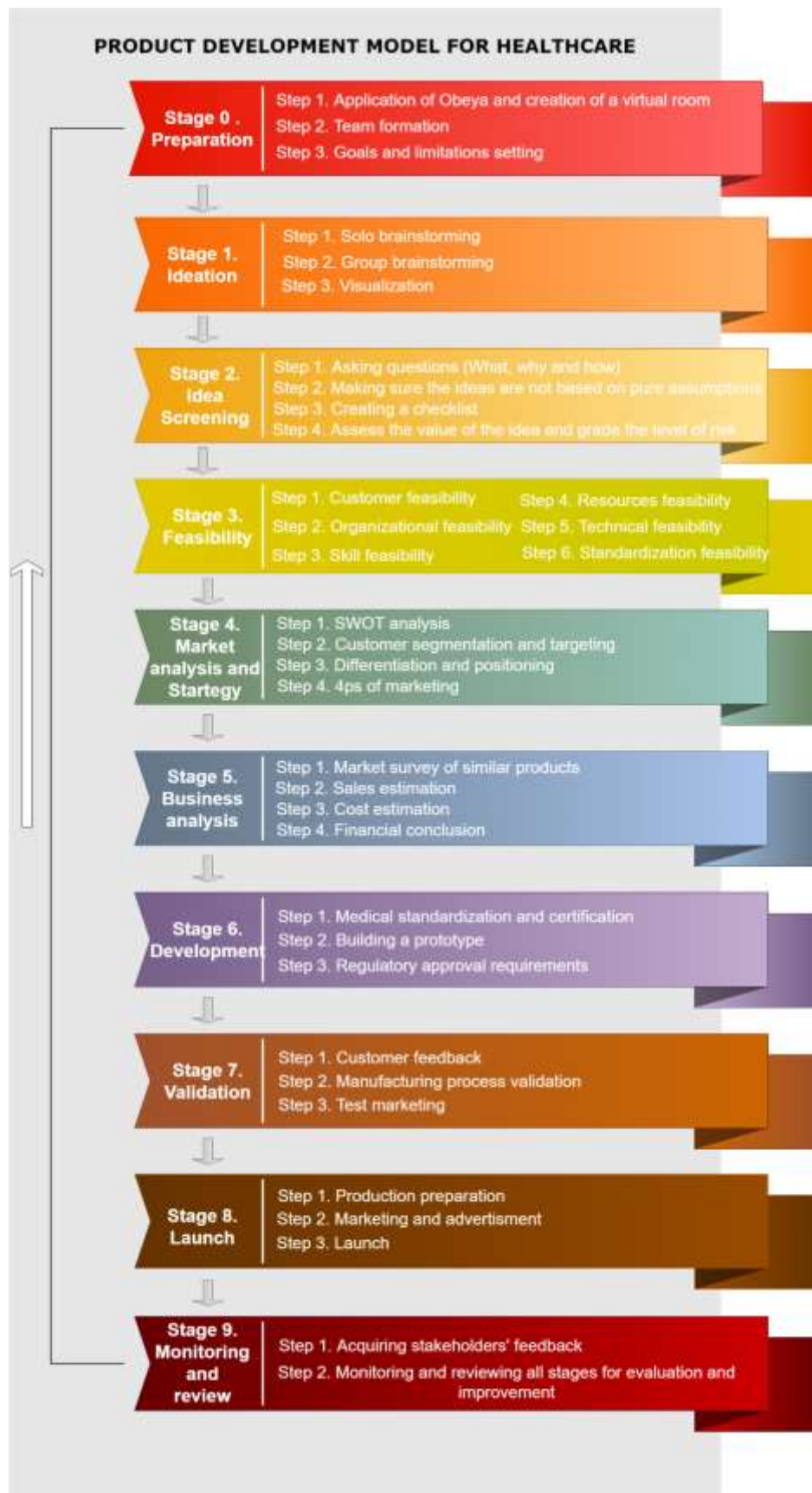


Figure 16. Product development model for healthcare

Source: (By author)

Stage 0. Preparation

This stage consists of preliminary steps into the product development model in which the responsible parties set goals such as financial goals, budget limits and time limits, also they determine the initiative team of the project and their responsibilities accordingly. This stage consists of 3 main steps which are listed below:

1. Application of Obeya and creation of virtual room
2. Team formation
3. Set Goals and limitation

Step 1. Application of Obeya and creation of virtual room

In the first step of the first stage, Obeya model is implemented. Obeya is a Japanese term which means a 'Large room' and is an Innovation tool created by Toyota which works based on information access and availability to all members of the project. Obeya is implemented in this model to:

- Enhance the level of communication among all team members;
- Manage time better and eliminate time waste;
- Minimizes risk of project failure.

Implementation of physical Obeya has always proved to be challenging due to some factors as workplace limitation or budget, hence, the idea of virtual Obeya would be implemented in this study in which all team members of an innovation project would have access to an online room where all the necessary information is shared and in such room, everybody can ask, answer and discuss questions of all varieties. This would reduce time waste and also there won't be any need of repeating questions as all the data, graphics, numbers, questions and etc would be available at all times.

Implementation of open innovation without Obeya would be very costly and time consuming. Every stage of product innovation development model in healthcare requires consultations with healthcare experts and since the developers and healthcare experts do not share a workplace, the process of communication between them becomes very time consuming and difficult. Obeya allows this communication in a more organized manner in which all stakeholders of the project are aware of all the information and have access to all the project schedules, hence, time waste is reduced to minimum and project cost is reduced.

Step 2. Team formation

The second step in the first stage focuses on formation of a team who will be responsible for the product development project. This step consists of calling up experts of different departments such as designers, technicians, sales managers, purchasing managers, researchers and etc, and appointing responsibilities to them accordingly. Team formation must consist of team members from various business units, different ages, with different areas of expertise and a variety of different cultural backgrounds. This enhances the creativity necessary for future stages.

Step 3. Goals and limitations setting

In this step, the vision and values for the enterprise are defined. The last step of the preparation stage is to set the essential goals and limitations before working on a product development project.

Goals:

- Financial
- Technical
- Sales

Limitations:

- Project budget
- Project deadline

Stage 1. Ideation

In this stage of the model, which is the preliminary stage, many ideas are generated and discussed. These ideas can be generated by:

- Random thoughts
- Problem solutions
- Customer feedbacks
- Straight up innovation

Every innovative project begins with an idea, a novel idea, a bright idea or any normal idea which later can lead to success. Ideas are generated by a variety of sources, some of which can be internal or external. In order to enhance this step of the innovation model, the design thinking model is implemented in this stage and open innovation is applied to gain external knowledge. Furthermore, the ideation stage consists of 3 steps which are mentioned below:

1. Solo brainstorming;
2. Group brainstorming;
3. Visualization.

Step 1. Solo brainstorming

Solo brainstorming step is to focus on generating as many ideas as possible for the according product development project. This step of ideation is done with implementation of design thinking model and practice of emotional design. The process of solo brainstorming helps us conduct a preliminary evaluation on the ideas generated individually by sketching or drawing some ideas or keeping them in journals. This step is flexible and can be done in different ways depending on the interest of the individuals.

Design thinking model in Solo brainstorming

Design thinking model is an innovation model used to tackle complex problems. Based on Hasso-Plattner Institute of Design at Stanford (school), this model consists of 5 stage, Empathise, Define, Ideate, Prototype and Test. In our model, we implement the first three stages of this model into our first stage which is Ideation. This would enhance the quality of the ideas we propose into our model.

As previously discussed in the theoretical part of the study, Design thinking model is commonly used as a solution-based problem-solving method and is used to answer complex problems. This means, the ideas generated in this model are based on deeply understanding the problem, clarifying the problem, its analysis and reformulation. Then such problem is observed, preliminary target group is characterized, customer needs are described. After managing the first two steps, we begin idea generation using solution-based method which means using creativity to generate ideas related to the problems defined in previous steps.

Emotional design

Emotional design is the concept of Donald Norman (Norman, 2004). Emotions can have deep effects on how humans perceive certain things around them hence, consumers find it more effective to purchase or use goods that are aesthetically appealing.

In order to develop a product that would satisfy all senses of consumers and users, we would need a great amount of knowledge covering all aspects of a product, from major aspects which are quality and price to details such as colour, weights and etc. Emotional design focus on satisfying the users in three different levels. The first level would be the short-term and a sudden level where only appearance, touch and feel matter, the second level would be mostly connected to the experience of the user with the product and lastly, the third level would be connected with long-term satisfaction of the user with the product. In order to achieve user

satisfaction in all three levels, the product must be perfect in all aspects in. Open innovation as discussed before can utilize information of all levels from different sources and combine them so that the projects of product developments can achieve maximum results and satisfaction of all parties.

Step 2. Group brainstorming

In this step of the ideation stage, the focus is on generating ideas with the help of all members of the team and also help from external sources of information and knowledge such as healthcare experts and other specialists. Also, application of environmental design as an additional tool is presented in this step.

Internal sources of ideas

A company or firm can always generate ideas within the boundaries of their own company. This means they can generate ideas using internal sources. Some of which are mentioned below:

- Research and development team;
- Innovation group meetings with all members of the project's team;
- Bottom up innovation model (Using employee's ideas).

When a company uses only internal sources to generated ideas, they limit their knowledge and boundaries which is a big disadvantage in product innovation development. In order to overcome such boundaries, external sources of ideas are needed which is explained further.

Open innovation in Stage 1 (external sources of ideas)

Understanding of today's most common problems and needs in healthcare is one of the most crucial knowledge needed in order to innovate products in this industry. If no communication exists among professionals who understand those needs and professionals in the product development field, there will be no appropriate solution. Open innovation allows us to understand the needs and problems of today's healthcare and be able to come up with innovative ideas accordingly using all the external knowledge that can be gained by communicating with healthcare professionals and experts. Some external sources of idea generation would be:

- Healthcare experts;
- Analysis of existing products;
- Competition analysis;
- Market research in healthcare;

Environmental design

Environmental design is often connected to engineering and industrial design. In order to be able to produce a product which can satisfy the customers' needs from all perspectives would be to connect engineering staff, designers and professionals in Healthcare. This would enhance the innovativeness of a product by introducing the relevancy of a variety of perspectives into a product innovation.

For instance, the professional in Healthcare would specify the need for a product which would then require a certain design and would need a serious amount of attention in pricing, structure, quality, safety and etc. A diversified team of professionals from different fields would be able to introduce a more innovative product than a team which is focused in one field.

Step 3. Visualization

In this step of the first stage, all the ideas generated by brainstorming sessions are visualized using a variety of methods such as workflow diagrams, post notes, drawings and other methods based on the interest of the individual. The purpose of this step is to be able to transform our ideas into persistent objects to which discussions always return.

Stage 2. Idea screening

In this stage of the innovation model, all the ideas generated previously are going to be narrowed down to just the ideas with the biggest potential and lowest risks. This stage is developed in order to make sure that poor product ideas are not passed since poor ideas lead to waste of money and effort in all stages of a product innovation model and eventually gets cancelled.

Idea screening is done in 4 steps demonstrated below:

1. Asking questions (what, why and how);
2. Making sure the ideas are not based on pure assumptions;
3. Creating a checklist;
4. Assess the value of the idea and grade the level of risk.

Step 1. Asking questions

The first step of idea screening is to make sure the idea is practical and applicable by asking certain questions such as 'Why would our customers buy this product', 'What are the competitions', 'How big is the market for this product' and etc.

Step 2. Making sure the ideas are not based on pure assumptions

In order to avoid complications and manage time, the ideas generated are checked for validity. This step helps us eliminate ideas which were created based on pure assumptions and have no real practical value to the organization.

Step 3. Creating a checklist

Creating a checklist allows us to determine the ideas relevancy and limits within the organization's goals and standards. It also evaluates the level of constraints such as resources and budget.

Step 4. Assess the value of the idea and grade the level of risk

The final step of the idea screening stage is to assess the value of the idea. To have approximate assumptions of the level of profit it can bring to the organization and also evaluate the level of risk by conducting researches.

Idea screening is a stage which is often done within the company's boundaries since most companies do not want to share the ideas with others. But idea screening is better done if some external sources of knowledge assist us, such as, consultation with experts of healthcare who can assess certain potential and risks more effectively than developers.

Stage 3. Feasibility

After narrowing down our ideas, we run a feasibility test in which we question our ideas in details and look for faults and potential risks while making sure that they are workable and results are reachable. The process of idea screening is a preliminary step of testing ideas while feasibility is to assess those ideas chosen in details.

In product development in healthcare, the steps running a feasibility test are:

1. Customer feasibility;
2. Organizational feasibility;
3. Skill feasibility;
4. Resources feasibility;
5. Technical feasibility;
6. Standardization feasibility.

Step 1. Customer feasibility

This step is conducted in order to assess the availability of target customers, do research on different segmentations and cross out ideas in which no potential customer segmentation is available.

Step 2. Organizational feasibility

Similar to previously mentioned checklist in the screening process, this feasibility test is done to measure the capabilities and limits of the firm in details. This determines if the idea is applicable within the capabilities of the firm.

Step 3. Skill feasibility

After narrowing down ideas to which can be applicable based on the organization's limits, the level of skills needed of this product idea is evaluated. This helps us assume possible needed workforce and establish essential teams.

Step 4. Resource feasibility

This step is to check for the level of budget and resources available.

Step 5. Technical feasibility

In order to assess the complexity of the idea and technical uncertainty, a technical feasibility is run in this step. We need to make sure that this product is producible within the limits of our production, whether its tools or machines, we must determine the possibilities.

Step 6. Standardization feasibility

Lastly, to make sure the standards are available and reachable, standardization feasibility test is conducted in which, the essential standards and certifications necessary are analysed and the availability of them are checked.

To run a complete feasibility test, both internal and external knowledge is necessary. For example, to assess both organizational and resources feasibility, internal knowledge and communication is needed which is done by team meetings among all the related departments from management to financial and sales. External knowledge would be necessary with customer feasibility and standardization feasibility, in which open innovation is implemented. An assessment of customer target is done by gathering external and internal knowledge from different sources to make sure that the idea has enough potential customers. Also, this stage must ensure the level of standardization necessary according to the product idea since healthcare industry is heavily standardized.

Stage 4. Market analysis and strategy

In this stage of the model, we implement a SWOT analysis (strengths, weaknesses, opportunities and threats) and also a customer-driven marketing strategy. Moreover, implementation of a marketing mix analysis using 4ps of marketing tool (product, place, price and promotion). Marketing strategy is done on ideas which have passed the previous stages and have the biggest potentials. Such analysis helps us evaluate the idea properly market wise and if the marketing strategy fails, that idea is also eliminated and the project is stopped. The steps in this stage are presented below:

1. SWOT analysis;
2. Customer segmentation and targeting;
3. Differentiation and positioning;
4. 4ps of marketing.

Step 1. SWOT analysis

In order to manage the marketing function of an organization, the initial step is to analyse the company's situation in complete. SWOT analysis evaluates a company's internal and external situation. Strength and Weaknesses are assessed in order to show the internal situation of the company while Opportunities and Threats are used to evaluate the external situation of the firm.

Step 2. Customer segmentation and targeting

In this step of the market analysis, we divide the potential market into segmentation and select the segments to enter based on our product.

Step 3. Differentiation and positioning

In order to create superior customer value, the marketing offerings are differentiated in this step and later positioned in the mind of selected target customer.

Step 4. 4ps of marketing

In the 4th step of market analysis and strategy state, we use a marketing mix concept in which four factors, product, price, place and promotion are analysed both internally and externally. This concept enhances the quality of marketing in the product development model.

Implementing marketing strategy tools such as SWOT analysis and 4ps of marketing cannot be done without external knowledge and information. Open innovation helps us with:

- Consultation with healthcare market specialists;
- Gain knowledge on healthcare market segments;
- Assess the growth in healthcare market;
- Understand the potential healthcare market growth;
- Better understanding of places where certain healthcare products are sold;
- Better understanding of product pricing systems in healthcare;
- Better understanding of how the healthcare industry attracts consumers to certain products.

Stage 5. Business analysis

In this stage of the product innovation model, business attractiveness of the proposed product is assessed. This is done by reviewing potential sales, costs and profit in order to evaluate if the product meets the objectives of the organization. The steps taken in this stage are:

1. Market survey of similar products;
2. Sales estimation;
3. Cost estimation;
4. Financial conclusion.

Step 1. Market survey of similar product

The initial business analysis step is to conduct market survey of similar product to acquire estimation of sales and costs which is used to measure the level of risk.

Step 2. Sales estimation

After acquiring knowledge on sales history of similar products, we estimate the prices of the product and potential number of future sales.

Step 3. Cost estimation

Having estimated the potential sales, the firm must estimate the expected costs of the product.

Step 4. Financial conclusion

After gathering all the above information, the sales forecast is prepared, the expected costs are estimated and an approximate figure of profit is assessed. All the information gathered is then used to analyse the financial attractiveness of the product and assess whether its ready for development or not.

Stage 6. Development

This stage of the model consists of developing an actual physical concept of the product. This is done to explore the target market further, identify what further features and attributes can be added to the product, to find the most practical method of producing the product and finalizing the price of the product and the cost of production. The development stage in this model consisted of two steps:

1. Medical standardization and certification;
2. Building a prototype;
3. Regulatory approval requirements.

Step 1. Medical standardization and certification

Development stage of new product in healthcare is a time-consuming and expensive stage. Product in healthcare have to pass a variety of medical standards according to the medical field in which the product is related to. Some of such medical standards taken from the ISO (International Organization for Standardization) manual is shown below:

Table 7. ISO Standards in Healthcare.

Standard	Explanation
ISO/TC 210	Quality management and corresponding general aspects for medical devices.
ISO/TC 194	Biological and clinical evaluation of medical devices.
ISO/TC 198	Sterilization of healthcare products.
ISO/TC 172	Optics and photonics.
ISO/TC 106	Dentistry, a major sector in ISO is healthcare technology.
ISO/TC 150	Implants for surgery.
ISO/TC 170	Surgical instruments
ISO/TC 173	Assistive products

Source: (ISO and health, 2019)

Step 2. Building a prototype

Research and development department is in charge of creating the prototype based on the required standards and previously set features. This process can be very time consuming based on the product, it can take days, weeks, months or even years.

One recommended method of prototyping in healthcare is the usage of 3D printing:

3D printing

In order to be able to maintain the quality and functionality of a product while keeping the price reasonable, it is suggested to enhance the relevancy of 3D printing in Healthcare. 3D printing was introduced a few decades ago and after years of improving, professionals in healthcare welcomed the use of 3D printing for a variety of products.

3D printing is a method of rapid prototyping operations which is based on quickly manufacturing parts and assembly units using three-dimensional Computer-Aided-Design (CAD) data sources. The process consists of a few stages:

- 3D modelling of the product using a CAD software (Solidworks, Autocad, Autodesk Inventor, Blender and etc.);
- Conversion of the model into a STL. file which is a format used by 3D printing software;
- Automatic printing; this usually takes several hours but the length of printing varies depending on the model and type of the printer used;
- Post printing processes; often the products which are 3D printed must be cleaned, polished, painted or some surface treatment processes are required.

Advantages of 3D printing in Healthcare:

- It can be used for device testing, physician training and surgical planning;
- With the help of scanners, transplanting can be more accurate than ever;
- With the help of scanners, patient-specific protective gears can be produced with maximum accuracy;
- The choices of filaments used for 3D printing of products have widely expanded and because of the sudden increase of popularity of 3D printing in Healthcare, an explicit category of filaments is being produced with the purpose of being used mainly in Healthcare. Such filaments are produced with the focus on the use of the products which can vary from simple casts to body parts.

3D printing requires knowledge of experts who are familiar with the process of 3D printing, variety of 3D printers, materials used in 3D printers and etc, which makes it more difficult for innovators to be able to apply this technology in their projects. Here is where the idea of Open innovation models helps us seek knowledge from experts of this industry who can co-operate on product development project in the healthcare sector and help us find solutions together which would save a massive amount of time and enhance the quality of the projects. Also, knowledge of the required standards can only be gained by communicating with experts in healthcare and analysing different types of standards and providing a prototype based on those standards to the consumers and to the market.

Step 3. Regulatory approval requirements

An essential factor in development stage of a product before the validation stage is to gather enough evidence for regulatory approval of the product. Regulatory approval stands for licenses, registrations and authorization of the product or device. The developed product or prototype needs an approval application before entering the market or test marketing. This depends on the level of risk it poses. There are three levels of risk talking about medical devices

and products: Low level risk, medium-level risk and high-level risk. The approval of regulations and acquiring of the approval depends on geographical location of the company. For instance, in the USA, the Food and Drug administration (FDA) is responsible for this approval according to section 510(k) of FDA cosmetic act. Low-level risk devices and product are exempt from the premarketing review by FDA but medium-level and high-level risk products and devices are reviewed and approved based on the cosmetic act.

Stage 7. Validation

In this stage of the model, the prototype or the prototypes created are tested and validated based on all the requirements necessary, from all the medical standards required to the design and aesthetic testing of the product. The process of validation is done in 3 steps.

1. Customer feedback;
2. Manufacturing process validation;
3. Test marketing.

Step 1. Customer feedback

The first step taken after the development of the prototypes is making the prototypes available to customers to acquire practical information on the prototypes' design, price, targeted customers and etc.

Step 2. Manufacturing process validation

When theoretical and practical knowledge are gathered, the proper and finalized manufacturing process is determined and validated based on the regulations of the project. In this process, the use of which machine, tool and methods for production of the product is determined.

Step 3. Test marketing

In this step of the validation stage, the product is tested in realistic markets to assess the potential of the product before its final release. The entire marketing programme is tested in this step and the final decision whether this product is ready to be launched or not is made.

Stage 8. Launch

The validation stage gives all the essential information needed to make a final decision which is to launch the product or to cancel the project. If the product has passed the validation stage, the company or firm decided to launch the product and this is the stage which costs the most. A variety of costs, such as all the facilities needed for production, promotion costs, marketing and advertisement costs and etc. Steps taken in this stage are:

1. Production preparation;
2. Marketing and advertisement;
3. Launch.

Step 1. Production preparation

The initial step of launch stage is to rent or build a manufacturing facility and provide all the necessary equipment. This step depends on the organization's current situation.

Step 2. Marketing and advertisement

When the production site is determined, the release of the new product requires a big amount of hype and attention in order to have successful sales. This can be done by advertising campaigns on TV, social media, radio, banners and etc.

Step 3. Launch

When all preparation is done, the introduction place and timing is determined. The place in which the product will be launched and also questions such 'Will it be launched in one place or in different regions, or in the international market' must be taken into consideration.

Stage 9. Monitoring and review

The final stage of this innovation model is applied to ensure the long-term success of the model. It can help with demonstration of accountability to developers and project stakeholders. This stage consists of 2 steps.

1. Acquiring stakeholders' feedback;
2. Monitoring and reviewing all stages for evaluation and improvement.

Step 1. Acquiring stakeholder's feedback

The initial step in monitoring and review stage is to focus on the feedback gained by stakeholders of the project. The feedback gained can help amend the product development model in the future.

Step 2. Monitoring and reviewing all stages for evaluation and improvement

When monitoring all stages of the model, we can identify problems that slowed down the process or suspended projects and find further and more suitable solutions. This step enables the developers and project team members to improve the process of product development continuously learning from mistakes, facing unexpected problems and improvising solutions.

Summary of innovation model

In this study, an improved model of product innovation development was introduced and described. This improved model is a combination of 4 different product innovation development models: Stage-gate model, Open innovation, Obeya and Design thinking. The model is based on a stage and gate process in which 10 different subsequent stages are provided. Each stage consists of steps which sequence and give structure to the stage. Also, each stage consists of a gate in which the according gate-keeper(s) is in charge of evaluating the stage and making decisions regarding proceeding with the content of the gate or cancelling and eliminating the project. The stages of this model are not a novelty since a variety of scientists and researchers have used similar models however, the methods used are acknowledged very commonly which make this model very coherent and apprehensive. This model is adjusted with product development in healthcare; hence, stages consist of some steps content which help with specific knowledge and demand with product innovation development in healthcare. Number of innovation models and tool used in this industry are limited in order to make sure that the model is applicable in all product innovation development projects in healthcare. A simplified understanding of the model conclusion is listed below:

- The improved model consists of 4 well-known models combined which are commonly used in a variety of sectors thus, developer and innovators of all fields can use this model for their healthcare product innovation development projects.
- Most common problems of product innovation development in healthcare which is lack of knowledge in healthcare is easily solved with this model implementing open innovation to gain external knowledge;
- Every stage of the model has already been used in different innovation models and case studies hence the structure is understandable to all;
- A few sub-stage tools such as emotional design, environmental design and 3D printing are used in this model in order to enhance the quality of each stage and make this model more adaptable in healthcare;
- In order to achieve external communication and knowledge while having an excellent time management system, Obeya is implemented which provides different virtual rooms for product innovation development team to communicate with each other, ask questions, discuss topics and have access to all the necessary information in forms of graphs, numerical data, pictures, diagrams and etc.

Having mentioned all the above information, we can assume that this model is simple but complete product innovation development model which has clear stages which consist of a variety of well-known tools hence, some advantages of this model are:

- Easy to read structure with stage and gate processes;
- Stages and gates are simple to be guided by and they function coherently;
- The framework is a combination of well-known innovation models which make it easy to understand and implement;
- The model solves the biggest problem in product innovation development in healthcare which is lack of knowledge in healthcare;
- The model solves lack of understanding of problems and needs in healthcare by implementation of Design-thinking model.
- With a little adjustment, this innovation model could be implemented in different fields further;

CONCLUSION AND RECOMMENDATIONS

1. In this study, literature of the problems in healthcare, the term innovation and its function in healthcare was described and the functionality and importance of innovation in healthcare was analysed. The finding of the theoretical aspects analysis is listed below:
 - The most common problems in healthcare are: “Lack of properly understanding of problems and needs in healthcare; Lack of accurate understanding of products and tools ecosystem and lack of involvement with customers and users; Fundamental regulatory requirements and problems faced fulfilling those requirements; Long product development cycles”.
 - Different types of innovation such as incremental, radical and disruptive were presented and compared.
 - The main focus of innovation in healthcare is on safety and treatment of patients which is proven to be more comfortable with the implementation of information technology and information systems in healthcare using internal and external sources of knowledge.
 - Based on the analysis made on the aforementioned innovation models, it can be seen that each innovation model has a unique structure with specific tools that help with product development; “Open innovation will enhance the level of knowledge by acquiring knowledge from external sources; Stage-gate model reduces risk of project failure while it enhances the quality of a product development project with an organized system; Obeya increases efficiency by creating better time management and better communication; Design-thinking model helps with deeper understanding of problems and needs in healthcare and also strong engagement of users in product development process”.
2. Moreover, an empirical research was conducted on product innovation development including three steps. A quantitative research, a qualitative research and a case study analysis. The main findings of the empirical research are:
 - 63% of the participants voted 5 as the level of relevancy of open innovation in product innovation development in healthcare while 37% voted 4 as the level of relevancy which concludes open innovation as the most relevant innovation model in product innovation development in healthcare;

- The majority of high relevancy votes were directed to Open innovation and Obeya but Stage-gate model and Design thinking were also voted as moderately relevant which indicates that all the mentioned innovation models can somehow be relevant to product development in healthcare;
- Among all the problems mentioned in this study, the biggest problem stated was lack of knowledge of tech specialist in healthcare and also lack of communication with healthcare specialists which limit the ideas and the information needed for a product innovation development project;
- One of the main trends in today's product innovation is prototyping or rapid prototyping;
- Case study shows that even an organized product innovation development model is not always enough to find the best results;
- The amount of time used in the development stages of the product could be shortened if use of Obeya was implemented in the case analysis;
- The feasibility of the quality of the 3D Printed Cast is unknown due to no communication with healthcare specialists and no external flow of information from potential users;
- 3D printing quality and time management could be enhanced if a more suitable 3D Printer was used with the help of 3D printing experts.

3. Lastly, a model for product innovation development in healthcare was presented.

The model presented is based on the review of literature of innovation in healthcare and innovation models and also the data and knowledge gathered from the empirical research on product innovation development in healthcare.

- The improved model consists of 4 well-known models combined which are commonly used in a variety of sectors thus, developer and innovators of all fields can use this model for their healthcare product innovation development projects;
- Most common problems of product innovation development in healthcare which is lack of knowledge in healthcare is easily solved with this model implementing open innovation to gain external knowledge;
- Every stage of the model has already been used in different innovation models and case studies hence the structure is understandable to all;
- A few sub-stage tools such as emotional design, environmental design and 3D printing are used in this model in order to enhance the quality of each stage and make this model more adaptable in healthcare;

- In order to achieve external communication and knowledge while having an excellent time management system, Obeya is implemented which provides different virtual rooms for product innovation development team to communicate with each other, ask questions, discuss topics and have access to all the necessary information in forms of graphs, numerical data, pictures, diagrams and etc.

Future work recommendations

- To better understand the implications of these results, future studies could address additional tools that could be implemented in different steps of every stage.
- An understanding of a specific healthcare sector such as dentistry or orthopedics can help develop a model more specific and simplified according to their standards and the most common problems and needs.



REFERENCES

- Aasland, K. E. (2012). *An analysis of the uses and properties of the Obeya*.
- boer, H. (2001). Innovatio, What Innovation? A Comparison between product, process, and organizational innovation. . *International Journal of Technology Management*.
- Brenda Helen Sheingold, J. A. (2014). The history of healthcare quality: The first 100 years 1860–1960. *International Journal of Africa Nursing Sciences*.
- Brian Stretcher, S. K. (2004). Organizational Improvement and Accountability . In H. B. Kirby, *Toyota Production System/Lean Manufacturing* (p. 17). Rand Corporation.
- Christensen, C. (2012, March 30). Disruptive Innovation explained.
- Communities, O. a. (2018). *Oslo Manual 2018*. Oslo.
- Disruptive-innovation*. (2012). Retrieved from <http://usdynamics.com/http://usdynamics.com/disruptive-innovation/>
- Donald A. Norman, R. V. (2014). *Incremental and Radical Innovation: Design Research vs Technology and Meaning Change*. Massachusetts Institute of Technology.
- Evill, J. (2012). *cortex*. Retrieved from [evilldesign.com: https://www.evilldesign.com/cortex](http://www.evilldesign.com/cortex)
- Fariborz Demanpour, W. M. (1984). Organizational Innovation and Performance: The Problem of "Organizational Lag". 393.
- Gardner, D. (2017, November 14). *Radical vs. Incremental Innovation: The Right Approach For The Right Time*. Retrieved from marumatchbox.com/https://marumatchbox.com/radical-vs-incremental-innovation-the-right-approach-for-the-right-time/
- Guedim, Z. (2019, October 09). *5-industries-3d-printing-is-changing*. Retrieved from [edgy.app: https://edgy.app/https://edgy.app/5-industries-3d-printing-is-changing](https://edgy.app/https://edgy.app/5-industries-3d-printing-is-changing)
- Halling, B. (2013). Lean Implementation: The Significance of People and Dualism.
- Hugeneck, R. (2018). *healthcare-product-development-cycle*. Retrieved from [www.jabil.com: https://www.jabil.com/blog/healthcare-product-development-cycle.html](http://www.jabil.com/https://www.jabil.com/blog/healthcare-product-development-cycle.html)
- Hui Lin, L. S. (2016). A rapid and intelligent designing technique for patient-specific and 3D-printed cast. 10.
- Inkton. (n.d.). *3d-printing-know-its-advantages-and-disadvantages/*. Retrieved from [blog.inktonerstore.com: https://blog.inktonerstore.com/3d-printing-know-its-advantages-and-disadvantages/](https://blog.inktonerstore.com/https://blog.inktonerstore.com/3d-printing-know-its-advantages-and-disadvantages/)
- (2019). *ISO and health*. Geneva: ISO Central Secretariat Chemin de Blandonnet 8 CP 401 .
- Laal, M. (2012). Innovation in medicine; health information technology.

- Magid, H. A. (2010). Lean process management implementation. *Journal of Industrial Engineering and Management*, 47.
- Manual, F. (2015). *Guidelines for Collecting and Reporting Data on Research and Experimental Development*. OECD.
- McElroy, K. (2017). Prototyping for Designers. *Developing the Best Digital and Physical Products*, 17-25.
- Michel Beaudouin-Lafon, W. E. (n.d.). Prototyping Tools and Techniques. Chapter 52.
- Mulder, P. (n.d.). Stage Gate Process by Robert Cooper.
- News-releases/pharma-execs-continue-looking-for-growth-opportunities-in-spite-of-increasing-regulatory-challenges-kpmg-survey*. (2012, June 22). Retrieved from [www.prnewswire.com: https://www.prnewswire.com/news-releases/pharma-execs-continue-looking-for-growth-opportunities-in-spite-of-increasing-regulatory-challenges-kpmg-survey-159993345.html](https://www.prnewswire.com/news-releases/pharma-execs-continue-looking-for-growth-opportunities-in-spite-of-increasing-regulatory-challenges-kpmg-survey-159993345.html)
- Norman, D. (2004). *Emotional Design*.
- Obeya. (2020). Retrieved from wikipedia: <https://en.wikipedia.org/wiki/Obeya>
- Parvaiz K. Ahmad, D. C. (2010). *Innovation Management*. Prentice Hall.
- Peter Juhn, J. &. (2009). *Leadership Commitments to Improve Value in Healthcare: Finding Common Ground: Workshop Summary*. National Academy of Sciences.
- Plattner, H. (n.d.). *An Introduction to Design Thinking*. Institute of Design at Stanford .
- Ramendra Thakur, S. H. (2010). Innovation in healthcare: Issues and future trends. *Journal of Business Research*, 563-568.
- Sites/johncgoodman*. (2016, July 25). Retrieved from [forbes.com: https://www.forbes.com/sites/johngoodman/2016/07/25/best-kept-secret-in-washington-dc-the-future-of-medicare/#357542591045](https://www.forbes.com/sites/johngoodman/2016/07/25/best-kept-secret-in-washington-dc-the-future-of-medicare/#357542591045)
- Sjödin, D. (2010). *Open Innovation and Stage Gate process: A Revised Model for New Product Development*. California.
- Store/printer-accessories/3d-systems-sense-scanner*. (2015). Retrieved from [matterhackers.com: https://www.matterhackers.com/store/printer-accessories/3d-systems-sense-scanner](https://www.matterhackers.com/store/printer-accessories/3d-systems-sense-scanner)
- TEO, R. F. (2020, March). *5 Stages in the Design Thinking Process*. Retrieved from [https://www.interaction-design.org/:](https://www.interaction-design.org/literature/article/5-stages-in-the-design-thinking-process) <https://www.interaction-design.org/literature/article/5-stages-in-the-design-thinking-process>
- Vanhaverbeke, W. (2014). *Open Innovation*.

- Yan-Jun Chen, H. L. (2017). Application of 3D–printed and patient-specific cast for the treatment of distal radius fractures: initial experience. 9.
- Young, C. J. (2017). Promoting innovation in healthcare. *Future Healthcare Journal* .
- YUSUF, S. O. (1999). Rapid prototyping technology: applications and benefits for rapid product development. *Journal of Intelligent Manufacturing* , 301-311.
- Zhang, J. (2014, April 23). *deniz-karashin-osteoid-cast*. Retrieved from mymodernmet.com: <https://mymodernmet.com/deniz-karashin-osteoid-cast/>

APPENDICES

Product Innovation development in Healthcare (Experts)

My name is Ali Arghoon Afzali. I am conducting this research for my Master's Thesis.

The purpose of this survey is to obtain information regarding Innovation model comparison from experts who are familiar with Open innovation, Stage gate process, Obeya and Design thinking model.

The questionnaire asks about some personal information and about your opinion on relevancy of these models in product development in healthcare.

Your participation is entirely voluntary.

Thank you for your cooperation!

*Required

1. Sex *

Mark only one oval.

☐ Female

☐ Male

☐ Prefer not to say

☐ Other: _____

2. Age *

Mark only one oval.

☐ 18-30

☐ 31-50

☐ >50

3. Education *

Mark only one oval.

- ☐ Undergraduate
- ☐ Graduate
- ☐ Postgraduate
- ☐ Master
- ☐ PHD

4. Years of experience *

Mark only one oval.

- ☐ <1
- ☐ 1-3
- ☐ 4-6
- ☐ 7-10
- ☐ >10

5. Occupation *

Mark only one oval.

- ☐ Manager
- ☐ Designer/Model designer
- ☐ Researcher
- ☐ Innovation consultant
- ☐ Product design prototyper
- ☐ Other: _____

Innovation Model Comparison

6. How relevant is Open innovation in product development in Healthcare? *

Mark only one oval.

	1	2	3	4	5	
Not relevant	☐	☐	☐	☐	☐	Very relevant

7. How relevant is Stage gate model in product development in Healthcare? *

Mark only one oval.

	1	2	3	4	5	
Not relevant	☐	☐	☐	☐	☐	Very relevant

8. How relevant is Obeya in product development in Healthcare? *

Mark only one oval.

	1	2	3	4	5	
Not relevant	☐	☐	☐	☐	☐	Very relevant

9. How relevant is Design thinking model in product development in Healthcare? *

Mark only one oval.

	1	2	3	4	5	
Not relevant	☐	☐	☐	☐	☐	Very relevant

This content is neither created nor endorsed by Google.

Google Forms

Table of answers

Section 1					Section 2			
Sex	Age	Education	Years of experience	Occupation	Open innovation	Stage-gate	Obeya	Design thinking
Male	18-30	Master	1-3	Manager	5	3	4	4
Male	18-30	Master	<1	Manager	4	4	3	4
Male	18-30	Graduate	1-3	Manager	4	3	2	5
Female	18-30	Master	1-3	Manager	4	3	4	2
Male	18-30	Postgraduate	1-3	Product design prototyper	5	3	4	4
Female	18-30	Postgraduate	1-3	Product design prototyper	4	2	4	3
Male	31-50	Master	7-10	Manager	5	2	4	5
Male	31-50	Postgraduate	>10	Manager	5	3	3	3
Male	18-30	Master	4-6	Researcher	5	3	4	4
Female	18-30	Postgraduate	1-3	Researcher	4	1	4	3
Male	18-30	Postgraduate	4-6	Innovation consultant	5	2	4	3
Female	18-30	Master	4-6	Product design prototyper	4	3	3	4
Male	18-30	Master	4-6	Designer/Model designer	5	2	5	3
Male	18-30	Postgraduate	1-3	Designer/Model designer	5	2	5	4
Male	31-50	Postgraduate	>10	Manager	5	3	5	5
Male	18-30	Postgraduate	4-6	Manager	5	3	4	4
Male	18-30	Postgraduate	1-3	Manager	5	2	5	3
Male	18-30	Master	4-6	Manager	5	2	4	3
Male	18-30	Postgraduate	1-3	Product design prototyper	4	3	5	3

Improvement of Product Innovation Development in Healthcare – Questionnaire

My name is Ali Arghoon Afzali. I am conducting this research for my Master's Thesis.

This questionnaire is provided to identify common problems in product development in healthcare and understand common trends in product development innovation.

Respondent's name:

Occupation:

-
- 1. What are some common problems faced with product innovation development in healthcare?**

-
- 2. What are the innovation trends in product development and product development in healthcare today?**

Improvement of Product Innovation Development in Healthcare – Questionnaire

My name is Ali Arghoon Afzali. I am conducting this research for my Master's Thesis.

This questionnaire is provided to identify common problems in product development in healthcare and understand common trends in product development innovation.

Respondent's name: Arunn Prasshad Baskaran

Occupation: Master's degree student (Industrial Engineering and Innovation Management)

1. What are some common problems faced with product innovation development in healthcare?

One of the main issues in product innovation development today is time management. It takes too long to product and market a new product in this sector. Moreover, there are not enough simple and precise methods to product development in healthcare and lastly, it is difficult to gain patent and ownership of product in healthcare.

2. What are the innovation trends in product development and product development in healthcare today?

In today's product development, prototyping using different methods is the most common trend.

Improvement of Product Innovation Development in Healthcare – Questionnaire

My name is Ali Arghoon Afzali. I am conducting this research for my Master's Thesis.

This questionnaire is provided to identify common problems in product development in healthcare and understand common trends in product development innovation.

Respondent's name: Mantas Vyšniauskas

Occupation: Mechanical engineer

1. What are some common problems faced with product innovation development in healthcare?

Lack of knowledge of tech people in healthcare field. Also lack of easily available communication with doctors and other specialists. Tech people also don't have enough knowledge in devices that would be useful for specialists, if they can't communicate what they need.

2. What are the innovation trends in product development and product development in healthcare today?

Nowadays trends in product development appears using different sensors and applying to different spheres, which can track and measure things which wasn't available before. Also, to control sensors and work with data needs Apps, so a lot of innovation appears here. Artificial intelligence and machine learning are huge innovation trends in product development today.

Improvement of Product Innovation Development in Healthcare – Questionnaire

My name is Ali Arghoon Afzali. I am conducting this research for my Master's Thesis.

This questionnaire is provided to identify common problems in product development in healthcare and understand common trends in product development innovation.

Respondent's name: Abdullah Sharafi

Occupation: Designer/Developer – 3D printing specialist

1. What are some common problems faced with product innovation development in healthcare?

Since the market in healthcare industry has become very competitive, lack of motivation in product development in healthcare has risen due to difficult market penetration. Also, information regarding different sectors in healthcare is limited to developers and designers.

2. What are the innovation trends in product development and product development in healthcare today?

In today's product innovation, the ideas generated for a new product does not come from high position managers only but the process of idea generation includes all the employees who are interested. This trend is known as bottom-up innovation. Also, rapid prototyping such as 3D printing is a big and common trend in many healthcare fields today.

IMPROVEMENT OF PRODUCT INNOVATION DEVELOPMENT IN HEALTHCARE

Ali Arghoon Afzali

Department of Mechanics and Materials Engineering, Vilnius Gediminas Technical University, Vilnius, Lithuania
Ali Arghoon Afzali, email: ali-arghoun.afzali@stud.vgtu.lt

received 23rd April 2020; accepted 24th April 2020

Abstract. This paper demonstrates a methodology for product innovation development in healthcare. At first, literature review of the term innovation and innovation in healthcare. Subsequently, the analysis of 4 innovation models; Stage-gate model, Open innovation, Obeya and Design thinking model. Afterwards, the study presents a quantitative survey to assess the relevance of the aforementioned innovation models in product development in healthcare and also presents a qualitative survey in which the most common problems in product development in healthcare and recommendations on innovation trends were determined by specialists. Lastly, a real-world case study is applied in which a simple product innovation development model is conducted and reviewed. The main findings of the study are: Identification of the most relevant innovation model in product development in healthcare; determination of the most common problems faced with product innovation development in healthcare; Demonstration of an innovation model for product development in healthcare.

Keywords: product innovation development, open innovation, internal and external knowledge, rapid prototyping and 3D printing, Standardization and certification, stages, steps and gates.

Introduction

Healthcare has changed drastically in the last 30-40 years and this change has played a significant role in society in many ways. During this period of enhanced change, huge developments and great advances have been made to both invention of new medical equipment and products and to patient care. The focus of healthcare industry was mostly on improving the health of the patients and focusing on medical methodologies and ways to find significant improvements with them but that has changed and healthcare has become a great part of our society's economy.

Being a product development engineer has always been difficult in healthcare and this will continue to become more effortful and arduous. In order to succeed, such engineers will need to put more effort into their work and do much more than the past and will need to understand all the aspects of business of product development in healthcare. Successful healthcare protective gears have very long commercial lifecycles some of which can top 30 years in contrast to the short five to six years of 4 decades ago. The life of the product is directly connected with all the decisions made in early development phases by the development engineers. This includes the sales and costs, manufacturing and producing, marketing, inventory and etc for a product with more than 20 years of potential commercial lifecycle. In order to develop a successful product technically as well as financially, the development team must consider a variety of essential factors such as design emphasis, assessment of the viability of the design, also financial viability to optimize all aspects of the product development.

With the increasing pressure of the problems faced in healthcare such as rise of costs, the expectations and requirements for the development team to develop a new product and optimize the essential aspects of the

development process such as commercial aspects will keep on getting more discouraging. The development team will have to assess the projects with greater details in order to identify what a successful product is and how to develop it. Further involvement of the financial department will be necessary to simulate various options to acquire detailed knowledge on the influence of design considerations and innovations on financial viability of the product over its predicted 20 or more-year lifecycle. This is just one of many tools that can be applied in product development projects.

Innovation is a term which means doing something differently. Nowadays, this word is used in every industry from manufacturing to banking and etc. Innovation is an important part of today's business world and can mean a new idea or a new product or novelty of any service, which help businesses sustain and create value. (Fariborz Demanpour, 1984) define innovation as those changes that help organizations cope with 'environmental changes and uncertainties not only by applying new technology, but also by successfully integrating technical or administrative changes into their organizational structure that improve the level of achievement of their goals'. Innovation in healthcare refer to many aspects which all focus on one main principle which is enhancing the safety and outcomes for patients. This means helping healthcare professionals with their work, tools, products and help them work more efficiently, faster, more cost effectively and etc.

Innovation is a vast topic which does not end. A big step forward towards easier and more comfortable future has been innovation in healthcare. Nowadays, innovation in healthcare is directly relate to implementation of information technology and information systems and the level of success depends

on how successful the healthcare industry is in implementing information technology and information systems. The major step in implementation of IT/IS is understanding the usefulness of it which is the leading step of technology adoption in healthcare. Such adoption can be used not only in-patient treatment but a major role of IT/IS would be realization of the need of new tools and products in healthcare which would need the help of innovators and designers to create those tools and products with the help of medical experts. Based on (Ramendra Thakur, 2010), organizational culture is an internal factor whereas competition is an example of an external factor that encourages an organization to adopt innovative ideas. This tells us that the success of the organizations depends on both factors which are internal and external. Internal factors can be sources of strategy planning to observe where efficiency is lacking and what could be improved while external factors can be sources of external, novel and effective knowledge which could be implied in organization to enhance the quality of life in this organization such as quality of healthcare and the focus on patient treatment. If a new tool or product is needed or wanted in the healthcare industry, the need for external factors is major since designing, prototyping and producing such tools need professionals of their own fields that can only be reached from external sources of knowledge.

Methodology

This study is conducted in order to develop a model for product innovation development in healthcare. In order to achieve the aim and find a key innovation model for product development in healthcare, literature review was done on analysis of information provided by experts of innovation and product innovation development models which is mostly based on articles and journals were taken from 'Science direct' and 'ResearchGate' which are valuable sources for a big variety of articles and journals.

The research was done in healthcare so the product innovation development model demonstrated in this study is adapted in all product development projects in the healthcare sector.

Literature background

The methodical review of the literature anticipates the analysis of 4 innovation models: Open innovation, Stage-gate process, Obeya and Design thinking model.

Open innovation

Open innovation refers to an open system where there are no boundaries for exchange of information among innovative companies, people or organization. In an

open innovation model, innovators tend to gain external knowledge from different sources to enhance the level of knowledge within the organization and not limit themselves to only what they know. Open innovation is basically the opposite of closed innovation and closed innovation is a model which is based on working with the knowledge available within the boundaries of the of the firm and all the processes from development to marketing and business is limited only within the firm's knowledge.

According to (Sjödin, 2010), Adapting open innovation principles requires proficiency in several different activities. Such activities include: seeking opportunities, evaluating each opportunity, recruiting potential partners, value-capturing through commercialization, and extending the innovation offering, which means that a lot of changes would be necessary internally and not always such internal changes are welcome. Also, such changes would mean big costs and involvement of external collaborators in the project which can sometimes results in conflicts and disagreements among team members.

Table 1. Closed and open innovation principles

Closed innovation principle	Open innovation principles
Most of the smart people in our field work for us	Not all the smart people work for us, so we must find and tap into the knowledge and expertise of bright individuals outside our company
To profit from R&D, we must discover, develop, and ship ourselves	External R&D can create significant value; internal R&D is needed to claim some portion of that value
If we discover it, we will get it to market first	We do not have to originate the research in order to be able to make profit from it
If we are the first to commercialize it, we will win	Building a better business model is better than getting to market first
If we create the most and the best ideas in the industry, we will win	If we make the best use of internal and external ideas, we will win
We should control our IPR so that our competitors do not profit from our ideas	We should profit from others' use of IPR, and we should buy others' IPR whenever it advances our own business model

Source: (Vanhaverbeke, 2014)

Stage-gate process

This model consists of a series of stages where the necessary activities and steps are carried out. Every stage is accompanied by an according gate which evaluates all the achievement of that stage and in order to move on to the next stage of the process, the achievements must pass the gates and start their activities in the next phase. Based on (Sjödin, 2010), The gates function as stop/go and prioritization points where decisions for the future of the project are made. The gates are typically manned by a cross functional group of senior managers, called gatekeepers, who evaluate projects on the basis of quality of execution, business rationale, and the quality of the action plan. In other words, gates are used to cancel projects or redefine them which works based on what is delivered, the criteria chosen by the gate keepers and the outputs.

An example of a stage-gate model is represented below which is based on Figure 1.

- Stage 0: Ideation;
- Stage 1: Scoping;
- Stage 2: Business plan concept;
- Stage 3: Development;
- Stage 4: Testing and validation;
- Stage 5: Launch and implementation.

Stage 0: Ideation. The first stage of the process focusses on brainstorming ideas and generating as many ideas as possible to find a project which then the company would carry out.

Stage 1: Scoping. Scoping means evaluating your product and find the best possible market for it while doing a SWOT (Strength, weakness, opportunities, threats) analysis in order to find the advantages and

disadvantages of this product. This stage clarifies if the product is going to be produced or not and the gate evaluates that and based on the decision of the gatekeeper, the project could be cancelled or proceeded to the next stage.

Stage 2: Business plan concept. If the product reaches this stage, a business plan must be developed in order to develop the product. A business plan must consist of determining the value of your product by conducting surveys and interviews and also analysis of the product. Such business plan must acquire all the preliminary legal requirements. Also, it needs to create a plan that indicates the responsibilities of all members in the development stage.

Stage 3: Development. In this stage of the process, the previously made plan is carried out in order to develop the product. All the responsible people are directed towards their duties, the timeline is created and regularly revised and the prototype of the product is eventually made which is tested in the next stage of the

Stage 4: Testing and validation. as can be seen from the title of this stage; this stage includes testing and validation of the product previously prototyped. This means testing of the manufacturing process and market testing of the product.

Stage 5: Launch and implementation. During this stage of the Stage Gate process, marketing strategy is essential. All the preparations for the product is ready and it is ready for launch. This process requires a great amount of hype in a variety of methods such as advertising campaigns, interviews and etc. An estimation about the sales of product is made and all the essential production policies such as inventory, distribution, warehousing, necessary tool and etc is set up. The sales team are the responsible individuals for ensuring the smooth process in this stage.

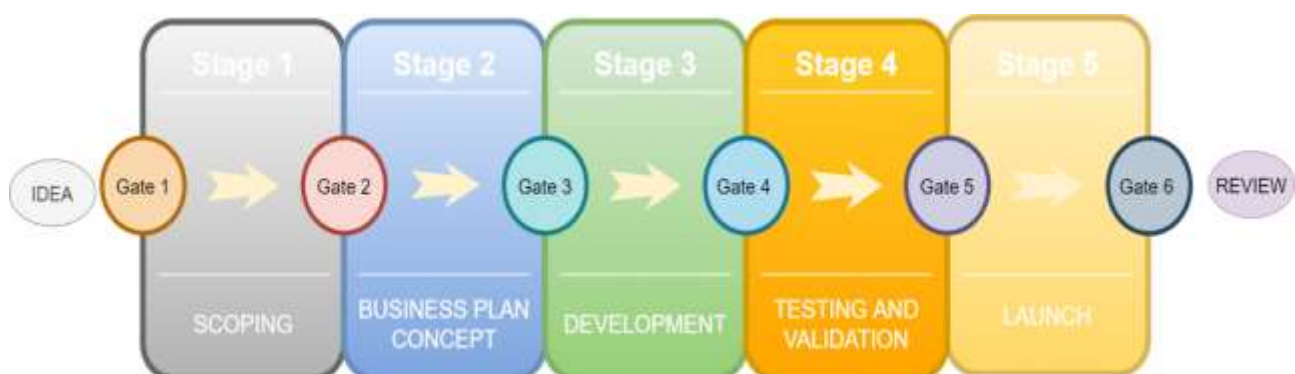


Figure 1. Stage Gate Processes

Source: (Mulder) – Designed by author

Obeya

Obeya is a Japanese term which means 'large room'. This term was originally created by Toyota in the 90's and was used as a component of lean manufacturing which helped them with the production of Prius. The idea behind this model is that all individuals who are a part of a project, meet in one common place which is often a large room to enhance the speed of communication and decision-making. It is a tool which brings team members closer and creates a better team. Obeya provides all the necessary information to all team members in a condensed format which helps them improve their decision making and save time. One of the main objectives of Obeya is to save time and reduce time waste of projects. This is achieved by reducing the time needed for rework. When reworking a project after making a mistake or hitting a dead end, consultations, information and research is necessary and that is what Obeya offers at all times. This helps save time and manage planning the project more effectively. Another way of saving time with Obeya is reducing the number of unnecessary discussions which always happens when team members do not have access to the information they need. When everybody has access to the same information at the same time, all the relevant individuals know their roles and tasks and there is no need of repeated discussions.

It is important to understand that in today's world, the physical presence of an individual in a team work is not a must since the modern technology allows us the participate meeting virtually without being present. That means a project can consist of team members who are in different places with having access to all rooms. On the other hand, being present in these rooms can enhance the quality of work done since visual perception can help us understand complex relations between many factors in a project by observing graphs, pictures, colours and object. Such graphs, colours, pictures and objects give us direct and clear information which can be understood easily and used more effectively.

Design thinking

Design thinking is process in which you study based on a mindset of understanding the needs of humans and tackling issues with a solution-based approach. This means empathising with the needs and wants of the humans, and to reframe and deeply understand them. When a problem is deeply understood, you can define the problem and this helps getting closer to those people and get to the core of the problem. When you reach the core of them problem with both internal and external help, you manage to co-design or ideate and innovate through diversity. Later this ideation leads to prototyping and testing.

Here we will take a look at the Design thinking model represented by the Hasso-Plattner Institute of Design

at Stanford. The five stages of Design Thinking according to the school are as follows:

- Empathise;
- Define;
- Ideate;
- Prototype;
- Test.

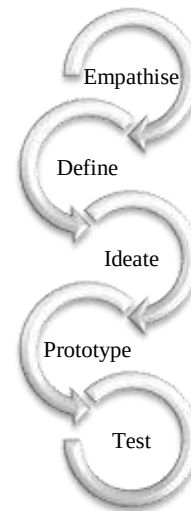


Figure 2. Design thinking: A 5 stage process

Source: (By author)

Based on the analysis made on the aforementioned innovation models, it can be seen that each innovation model has a unique structure with specific tools that help with product development. Open innovation is a major model which works on the principle of acquiring external knowledge in order to enhance the quality of the organization and the products it develops, hence, the application of such model in product development in healthcare would be extremely useful. Furthermore, Stage-gate model is analysed which works based on the principles of managing a product development project in a well-organized manner using a stage and gate process in which gates are designed to evaluate the according stage and make decision regarding passing or failing the project. This would be essential in any product development innovation model since the model is well-organized and has a clear structure. The third model analysed was Obeya which is a model developed and used by Toyota. This model gives any product development project a clear understanding of where all the information is or can be reached and it a major tool which helps with time management and communication issues. Therefore, the implementation of such model in a product development model in healthcare would be appropriate and helpful. Lastly, design thinking model was analysed in which the idea of solution-based approach to problems is discussed. Understanding the customer and patients' problems and needs can enhance the quality of ideas generated in product development in healthcare therefore, the implementation of this model can enhance the level of ideas generated.

Empirical study

This study is focused on product innovation development in healthcare; A quantitative research method is conducted to compare the aforementioned innovation models' relevancy to product innovation development in healthcare which can help us find a reasonable innovation model that could be implemented in product development in healthcare. Also, a qualitative research method is used to gather non-numerical data from an expert who answers questions in regards with innovation trends in 2020. Moreover, a case study is conducted and analysed and a simple innovation model is used to describe different steps of this product innovation and the results are discussed.

Survey analysis with experts

In this part of the study, a survey was fulfilled to compare the relevancy of different innovation models that can be used in Product development in Healthcare. The survey was designed according to preliminary review of the literature which is the Innovation Models. This survey questionnaire was answered by 19 professionals in the field of Engineering who are in fields of innovation, industrial engineering and mechanical engineering and etc. In order to be able to prepare the questionnaire in a consistent sequence and for the easy of understanding the matter, the questionnaire is divided into two sections. The first section is focused on the demographic information of the participants such as gender, age, degree of education, and years of experience in the field of innovation while the second section is directed towards the relevancy of each innovation model in product development in Healthcare. The relevancy scale was from 1-5 in which 1 – not relevant to 5 – very relevant. This survey is an electronic questionnaire which was distributed to the participants via email and Facebook and a total of 19 professionals have answered the questionnaire.

As can be seen on table. 3, the majority of respondents are male managers, taking 52.6% of the total and 21.1% of them are product prototypers. It can also be seen that the majority of participants are between ages of 18-30 and almost 50% of the respondent have 1-3 years of experience. Moreover, 52.6% of the participants are have a postgraduate degree while 42.1% of them have a master's degree which indicates their academic level and knowledge. Observing the number of participants and the data represented on table. 3, it has been concluded that 19 respondents are adequate to be able to conceive the essential data from the questionnaire and be able to analyse and compare them to extract a solution.

Table 2. Demographic information of Participants

		Number	Percentage
Sex	Male	15	78.9%
	Female	4	21.1%
Age	18-30	16	84.2%
	31-50	3	15.8%
	>50	0	0%
Degree of education	Undergraduate	0	0%
	Graduate	1	5.3%
	Postgraduate	10	52.6%
	Master	8	42.1%
	PHD	0	0%
Years of experience	<1	1	5.3%
	1-3	9	47.4%
	4-6	6	31.6%
	7-10	1	5.3%
	>10	2	10.5%
Occupation	Manager	10	52.6%
	Designer	2	10.5%
	Researcher	2	10.5%
	Innovation consultant	1	5.3%
	Prototype Specialist	4	21.1%

Source: (By author)

To sum up the results found in this research, we can see on Figure 3 that open innovation has been voted as the most relevant innovation model in product development in healthcare with 63% of respondents having voted the level of relevancy 5/5 and 37% voted 4/5. This was expected since development of products in healthcare require an extensive amount of external knowledge which is gained using the concept of open innovation. Following open innovation, Obeya was voted as the second most relevant model with 53% votes to 4/5 level of relevancy and 26% votes to 5/5 level of relevancy. The third most relevant model in this study is design thinking with 37% of votes going to 4/5 level of relevancy and 42% of votes going to 3/5 level of relevancy. And lastly, stage-gate model was voted the least relevant in this study with 53% of participants' votes going to 3/5 level of relevancy and 37% to 2/5 level of relevancy.

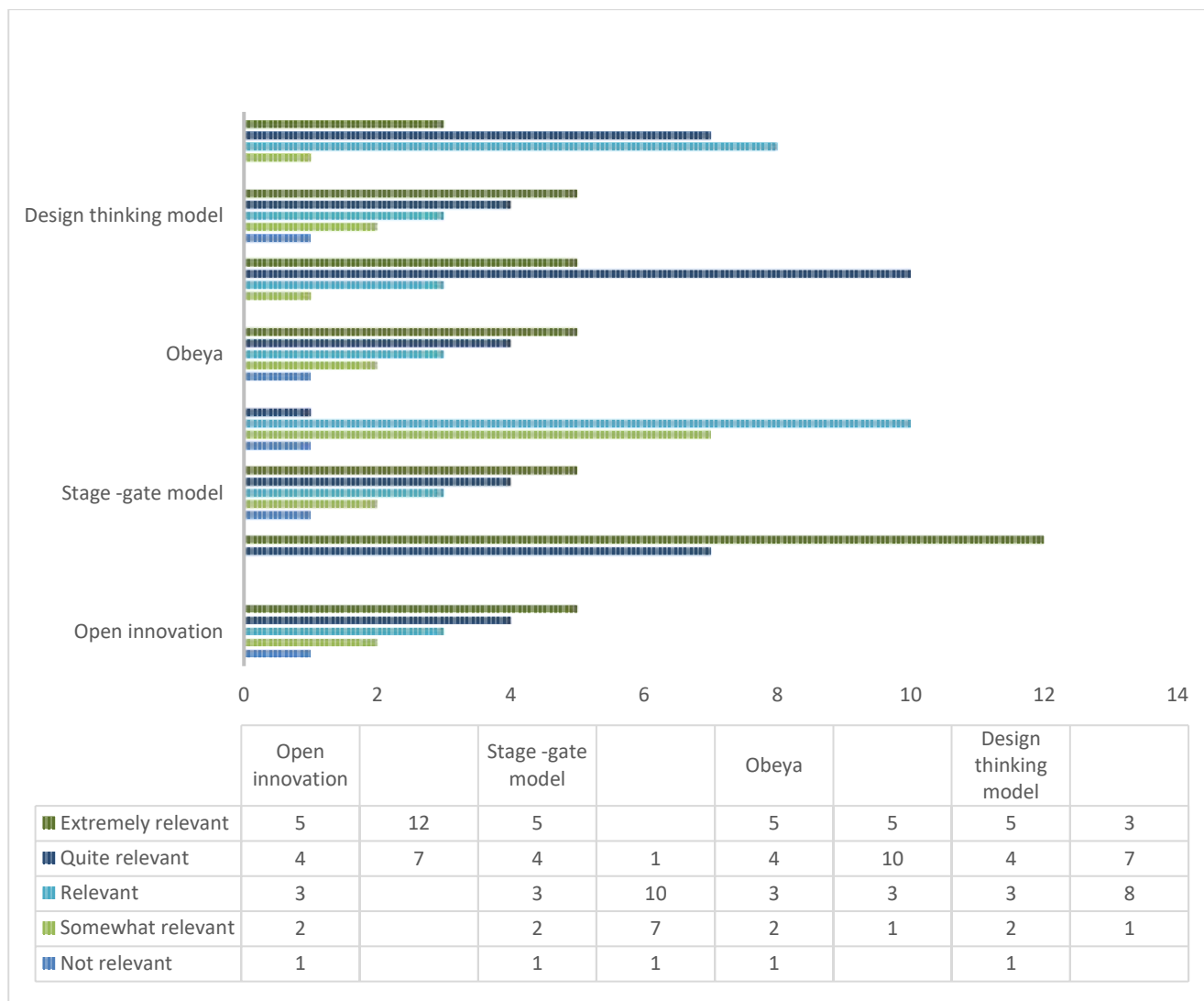


Figure 3. Graphic results of most relevant innovation models in product development in healthcare

Source: (By author)

Figure 3 shows the summarized results of the study. Based on these results, all innovation models which were a part of this study were voted as relevant to product development in healthcare. Open innovation was rated as the most relevant, then Obeya, design thinking and lastly stage-gate model. Understanding of the expert's point of view on the relevancy of these models help with the prioritizing of the final model creation and the necessity of implementation of the models accordingly.

Qualitative research (Open-ended questions)

a qualitative study was conducted in order to acquire knowledge on the most commonly known problems in product innovation development nowadays and find what are some innovation trends. This method of research consists of two open-ended questions and was answered by a group of diversified audience including a mechanical engineer, innovation consultants and a 3D

printing specialist who have experience with the topic of product development. The results of the interview are shown in table below:

As can be seen on Table 3, a variety of problems are stated by our participants, some of which are very significant in the product innovation development, especially in product innovation development in healthcare. One of the first problems stated was time management; Time management is a crucial factor in any product development process. A product development project never succeeds if the plan does not indicate a deadline and even with a deadline available, if the plan passes the deadline and the members of the project do not manage to finish the project within the previously anticipated period. Another problem mentioned is lack of simple and precise innovation process which indicates the difficulty of organizing processes of a product development project. Such project would never experience success because the process of its development was never indicated or was never clear

to the team members hence it would eventually collapse and get cancelled.

One of the main issues in today's product development in healthcare was mentioned by the second participants which is the lack of knowledge of tech specialist in healthcare. This means that designers, innovators, product developer and etc, would never manage to properly innovate and develop product in healthcare due to not having enough or any knowledge in that field. The healthcare sector is huge and needs an immense amount of information in order to understand the needs of it and meet their expectations. On the other hand, there is lack of communication with healthcare specialists which leads to no information and hence no results. Moreover, the difficulty of market penetration was mentioned which can be a factor in demotivating product innovators and developers. And this issue of demotivation is elevated with not enough information in the healthcare industry.

This research also helped us gather some information regarding innovation trends nowadays. Two participants mentioned the idea of prototyping as an innovation trend. Rapid prototyping has become a major part in many product development projects, it enhances the speed of the projects while decreasing its risks and providing more practical information. Another innovation trend that was mentioned was the idea of using sensors in new product developments. Sensors allow users track and measure data which could later be controlled and collected by the users.

One of the very interesting trends mentioned by our third participant was the bottom-up innovation trends. This innovation method is used by company leaders who look for employees who are motivated, smart and are willing to use their motivation and passion in order to achieve greatness with the company. These employees initiate ideas regarding product development and share those ideas with bigger positions such as managers and directors of the company. This innovation trends are based on creativity and proper management.

The information obtained from this research demonstrates the importance of external knowledge specially knowledge and information from healthcare experts. As a result of analysis of this research, we can summarize that lack of knowledge in healthcare and lack of communication with healthcare specialists are two of the most relevant problems on today's product development in healthcare. On the other hand, some common innovation trends were identified; Prototyping and rapid prototyping have been mentioned by our respondents as innovation trends. According to the level of standards and difficulty of market penetration, prototyping is a must be done stage of most product development models. Also, bottom up innovation tool was proposed which is a method of internal innovation in which the firm acquires ideas from employees. To sum up, we have identified key problems in product development in healthcare and gathered some

innovation trends which could help with the development of innovation model further in this study.

Table 3. Results of qualitative research

Respondents	Problems faced with product innovation development	Innovation trends
1	-Time management -Lack of simple and precise methods Difficulty with ownership	-Prototyping -Using different methods of Prototyping
2	-Lack of knowledge of tech specialists in healthcare -Lack of available communication with healthcare specialists	-Product development using sensors which track and measure and to control the sensors and extract data. -Use of artificial intelligence and machine learning
3	-Rise of competition and lack of motivation in product development due to the difficult market penetration -Having information only in one field	-Bottom up innovation -Rapid prototyping

Source: (By author)

Case study

This case study is conducted to overview a simple innovation model which later is analysed and based on the results, a final conclusion is stated. This helps our study find potential problems and areas which could be improved in process of product development in healthcare. This innovation model has 3 main steps which are listed below:

- Ideation;
- Validations;
- Development.

Ideation

In this process, a variety of ideas were analysed by the author and eventually, a '3D Printed Cast' was chosen as the theme of this innovation model. A '3D Printed Cast' is protective gear which is used on broken arms/legs in order to unable them from moving and keep them firm at all time to speed up the process of healing. This process includes a general understanding of medical casts and analysis of the existing casts today.

Medical casts: The initial approach to casting requires a thorough assessment of the skin, neurovascular status, soft tissues, and bony structures to accurately assess and diagnose the injury.

Once the need for immobilization has been determined, the physician must decide whether to

apply a splint or a cast. Casts and splints serve to immobilize orthopaedic injuries:

- They promote healing;
- Maintain bone alignment;
- Diminish pain;
- Protect the injury;
- Help compensate for surrounding muscular weakness.

In recent years, a number of companies have developed materials to replace plaster of paris as a cast. Most of these are a fiberglass fabric impregnated with polyurethane resin. The prepolymer is methylene bisphenyl diisocyanate, which converts to a nontoxic polymeric urea substitute. The exothermic reaction does not place the patient's skin at risk for thermal injury. These materials are preferred for most orthopedic applications except in acute fractures in which reduction maintenance is critical. Fiberglass casts do not provide higher skin pressure when compared to plaster casts when properly applied. Based on research by clinical experts, a cast could affect patient's life in various ways. A few of them are; driving, showering, working, typing, cooking, smell, weight, itchy, attention drawing, and etc. The healing time would decrease if patient's mental situation would be normal during the healing process and the recovery rate would increase.

Validation

This stage of our innovation model is to test and check the feasibility of the idea chosen in this study. In order to validate the idea, a study on two available 3D printed cast was conducted and also a potential target customer analysis was done.

3D Casts Analysis: A variety of 3D Printed Casts have been introduced to the markets over the last decade. These casts have shown the advantages of 3D Printed Casts and its potential in the future. In this analysis, two 3D printed casts were analysed.

Table 4. Available 3D Casts analysis

Casts	Description	Advantages
Cortex Cast	The cast is designed using X-rays and 3D scans of a patient's fracture.	-Light -Ventilated -Shower friendly
Osteoid Medical Cast	With daily 20-minute sessions with the stimulator system, a patient can actually speed up the healing process.	-Water friendly -Light -Ventilated -Stable support

Source: (By author)

Target Customers: In such study, categorizing and pre-selecting the target customer is a rather essential part of

the process. A potential target segmentation analysis was conducted here:



Figure 4. Potential Customer Segmentation

Source: (By author)

Development

In this stage of the process, the idea selection is finalized and the development of the '3D Printed Cast' begins. This development process consists of 3 main stages listed below:

- Scan
- Design
- 3D Print (Prototype)

Scan: Scanning is one of the most essential steps of the development process. In order to manage to design and 3D print a cast, the scanning process must be extremely accurate and no mistakes are tolerable since the casts are patient specific. A variety of 3D scanners are available nowadays some of which help us scan in a matter of minutes.

The scanning process was done by a former 3D printing specialist using a Sense scanner. The procedure was done twice to make sure the accuracy of the scan is high. This process was handled in a matter of 3 days. The first part of the process was to find a place to perform scanning, then the scanning process was done in about 10-15 minutes. After the scanning process was done, it took another day to prepare the necessary step. format of the scanned file. After receiving the scanned file, the design step was initiated.



Figure 5. Sense 3D Scanner

Source: (store/printer-accessories/3d-systems-sense-scanner, 2015)

Design: The design process of the development stage is based on a few main criteria, such as comfort, strength and stability, aesthetics and price. In this process, three innovation ideas were listed to enhance the criteria mentioned above.

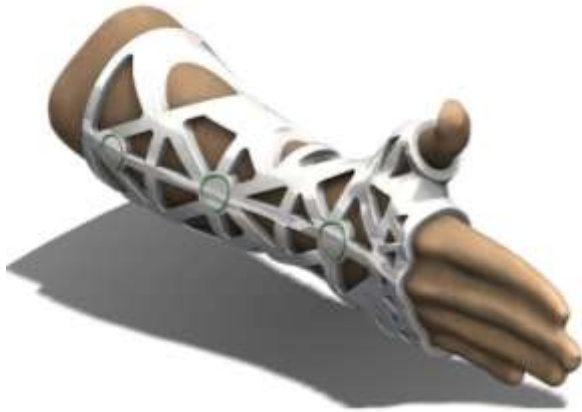


Figure 6. 3D Printed Cast Model

Source: (By author)

The '3D Printed Cast' was designed and modelled in a span of 5 weeks. A variety of models were generated, different types of joining mechanisms were analysed but lastly, the final cast was developed and is presented in Figure 12. The pattern is based on triangle structures which give the cast better strength and rigidity. A stronger cast could be obtained by increasing the thickness of the cast. That perspective of designing would increase the material usage which means the price of the cast would increase and additionally the printing time would increase as well.

Aside from the strength and attractiveness, the joint mechanism of the cast is a major part of the design. A joint mechanism can firstly affect the comfort of the patient, it has major effects on rigidity and beauty of the cast as well. The joining mechanism chosen for this cast consists of six rubber bands placed in the printed hollows made for them. This mechanism gives extra tolerance to the cast which is extra essential in case of swollen arm/hand. As for the alignment of the cast, after the printing procedure, 6 small holes of 1 mm wide are drilled on each part of the cast on the joining mechanism and connected with small pins and special glue.

The first software used to design this cast was Blender, but due to lack of experience and knowledge with this software, the designer (author) decided to design the cast using Solidworks 2018. The initial step of the design was to decrease the number of surfaces created by the scanned file and this process was very time consuming since the designer did not have access to software capable of doing that. Having decreased the number of surfaces, the designer experimented a variety of models to finally achieve what is presented in Figure 6. After the design process was finalized, the model was ready to be 3D printed.

3D Print (Prototype): Final step of the development process was the 3D print the finalized cast. This process was conducted by the help of a small 3D Printing company who use FDM (filament-based technology) printing as their main method of 3D printing. Due to the size limit of the 3D printers available, the model was divided into 4 parts and printed separately. The printing bed was preheated and this is a routine to make sure the quality is good and the structure is strong. Zortrax m200 was used to 3D print the parts which used 80° Celsius bed temperature and the layer height was 0.19mm.

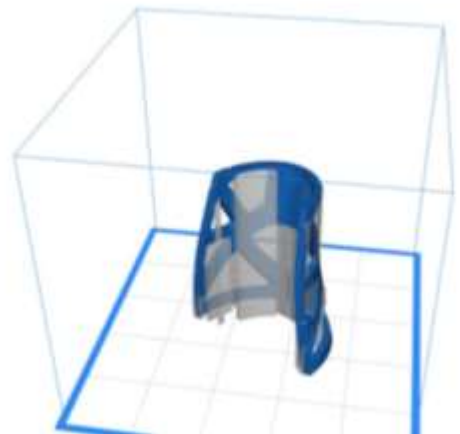


Figure 7. 3D Printing Process

Source: (By author)

The amount of time consumed on 3D printing all four parts equalled to 36 hours and also another. But the overall time used to find the 3D printing company, placing an order, and their delivery was about a week.

The overall process of the product innovation development model used in this case analysis was a moderate success. The simple model presented a three-stage innovation model. To sum up the case study analysis, advantages and disadvantages of the innovation model used in this study are mentioned below:

Advantages:

- Simple and easy to follow structure;
- Internal flow of information to keep the novelty of project safe;
- Use of real-life prototype to analyze the results and risks of the project.

Disadvantages:

- No external sources of knowledge and lack of communication with healthcare experts;
- High chance of failure due to low risk analysis and lack of thorough evaluation;
- No sources of medical standards and certification which can lead to failure of the product;
- Lack of proper preparation which led to a massive amount of time waste.

Innovation model development in product development in healthcare

Innovation is a term which is globally used in all industries and it has no boundaries. This makes the availability of innovation models much simpler than before, but it conversely makes it more difficult to find the most appropriate innovation model in your own industry. Many innovation models have been introduced and they were primarily used only in one industry but over time, that changed and those innovation models were used in a vast variety of industries. Based on the literature review of 4 innovation models (Open innovation, Stage-gate model, Obeya and Design thinking) and the results concluded from the empirical research, an improved innovation model was created which includes all four innovation models mentioned in this study combined alongside a few sub-models and tools that help these models function more effectively with product development in healthcare.

This improved model is a combination of 4 different product innovation development models: Stage-gate model, Open innovation, Obeya and Design thinking. The model is based on a stage and gate process in which 10 different subsequent stages are provided. Each stage consists of steps which sequence and give structure to the stage. Also, Each stage consists of a gate in which the according gate-keeper(s) is in charge of evaluating the stage and making decisions regarding proceeding with the content of the gate or cancelling and eliminating the project. The stages of this model are not a novelty since a variety of scientists and researchers have used similar models however, the methods used are acknowledged very commonly which make this model very coherent and apprehensive. This model is adjusted with product development in healthcare; hence, stages consist of some steps content which help with specific knowledge and demand with product innovation development in healthcare. Number of innovation models and tool used in this industry are limited in order to make sure that the model is applicable in all product innovation development projects in healthcare.



Figure 8. Product development model for healthcare

Source: (By author)

Stage 0. Preparation: This stage consists of preliminary steps into the product development model in which the responsible parties set goals such as financial goals, budget limits and time limits, also they determine the initiative team of the project and their responsibilities accordingly.

Stage 1. Ideation: In this stage of the model, which is the preliminary stage, many ideas are generated and discussed.

Stage 2. Idea screening In this stage of the innovation model, all the ideas generated previously are going to be narrowed down to just the ideas with the biggest potential and lowest risks. This stage is developed in order to make sure that poor product ideas are not passed since poor ideas lead to waste of money and effort in all stages of a product innovation model and eventually gets cancelled.

Stage 3. Feasibility After narrowing down our ideas, we run a feasibility test in which we question our ideas in details and look for faults and potential risks while

making sure that they are workable and results are reachable. The process of idea screening is a preliminary step of testing ideas while feasibility is to assess those ideas chosen in details.

Stage 4. Market analysis and strategy In this stage of the model, we implement a SWOT analysis (strengths, weaknesses, opportunities and threats) and also a customer-driven marketing strategy. Moreover, implementation of a marketing mix analysis using 4ps of marketing tool (product, place, price and promotion). Marketing strategy is done on ideas which have passed the previous stages and have the biggest potentials. Such analysis helps us evaluate the idea properly market wise and if the marketing strategy fails, that idea is also eliminated and the project is stopped.

Stage 5. Business analysis In this stage of the product innovation model, business attractiveness of the proposed product is assessed. This is done by reviewing potential sales, costs and profit in order to evaluate if the product meets the objectives of the organization.

Stage 6. Development This stage of the model consists of developing an actual physical concept of the product. This is done to explore the target market further, identify what further features and attributes can be added to the product, to find the most practical method of producing the product and finalizing the price of the product and the cost of production.

Stage 7. Validation In this stage of the model, the prototype or the prototypes created are tested and validated based on all the requirements necessary, from all the medical standards required to the design and aesthetic testing of the product.

Stage 8. Launch The validation stage gives all the essential information needed to make a final decision which is to launch the product or to cancel the project. If the product has passed the validation stage, the company or firm decided to launch the product and this is the stage which costs the most. A variety of costs, such as all the facilities needed for production, promotion costs, marketing and advertisement costs and etc.

Stage 9. Monitoring and review the final stage of this innovation model is applied to ensure the long-term success of the model. It can help with demonstration of accountability to developers and project stakeholders.

Conclusions and recommendations

Every industry aims to improve the level of creativity and innovation and one of the major industries in today's society is healthcare. The aim of healthcare is to use innovation to enhance the level of patient satisfaction and treatment. Moreover, product innovation development in healthcare has become very competitive and is classified as major market today. The process of product innovation development in healthcare is a complicated process in which many difficulties and problems are faced. Thus, a complete product innovation model is essential to give this process a structure that would provide the possibility of product development in healthcare for various fields and experts.

Moreover, 4 innovation models; Stage-gate model, Open innovation, Design thinking and Obeya with a summary of advantages and disadvantages were analysed and the potential of the implementation of the models was criticised.

An empirical research was conducted on product innovation development including three steps. A quantitative survey questionnaire was used to find the relevancy of the aforementioned innovation models in product development in healthcare. Hence, all innovation models which were a part of the study were voted as relevant to product development in healthcare. Open innovation was rated as the most relevant with 63% of votes going to 5/5 level of relevancy while 37% going to 4/5 level of relevancy. After open innovation, Obeya was voted as the second most relevant with 53% of votes for level 4 of relevancy, 26% for level 5 of relevancy and 16% for level 3 of relevancy. Then, design thinking model was found moderately relevant with product development in healthcare with 42% of respondent voted 3 and 37% of them voted 4. Lastly, stage gate model was voted with having 53% of the participants vote 3 and 37% vote 2 as the level of relevancy. Based on these results, all innovation models which were a part of this study were voted as relevant to product development in healthcare. Open innovation was rated as the most relevant, then Obeya, design thinking and lastly stage-gate model.

In addition, a qualitative research was conducted in which the information obtained demonstrated the importance of external knowledge specially knowledge and information from healthcare experts. As a result of analysis of this research, that lack of knowledge in healthcare and lack of communication with healthcare specialists are two of the most relevant problems on today's product development in healthcare. Moreover, Prototyping and rapid prototyping were recommended as innovation trends. Also, bottom up innovation tool was proposed which is a method of internal innovation in which the firm acquires ideas from employees.

Additionally, a case analysis was performed in which the overall process of the product innovation development model used was analyzed. The simple model presented a three-stage innovation model and the advantages and shortcoming of the model were presented.

At last, a new model for product innovation development in healthcare was presented. The model presented is based on the review of literature of innovation in healthcare and innovation models and also the data and knowledge gathered from the empirical research on product innovation development in healthcare. The improved model is a combination of 4 different product innovation development models: Stage-gate model, Open innovation, Obeya and Design thinking. The model is based on a stage and gate process in which 10 different subsequent stages are provided. Each stage

consists of steps which sequence and give structure to the stage. Also, each stage consists of a gate in which the according gate-keeper(s) is in charge of evaluating the stage and making decisions regarding proceeding with the content of the gate or cancelling and eliminating the project. The sequence of the stages demonstrates the importance of every stage and the steps necessary to pass that stage.

To better understand the implications of these results, future studies could address additional tools that could be implemented in different steps of every stage. Also, an understanding of a specific healthcare sector such as dentistry or orthopaedics can help develop a model more specific and simplified according to their standards and the most common problems and needs.

Acknowledgements

The author wishes to thank Professor Rolandas Strazdas for their guidance and valuable comments.

Funding

This work was supported by the author.

Disclosure Statement

The author does not have any competing financial, professional, or personal interests from other parties.

References

1. Aasland, K. E. (2012). An analysis of the uses and properties of the Obeya.
2. boer, H. (2001). Innovation, What Innovation? A Comparison between product, process, and organizational innovation. . International Journal of Technology Management.
3. Brenda Helen Sheingold, J. A. (2014). The history of healthcare quality: The first 100 years 1860–1960. International Journal of Africa Nursing Sciences.
4. Brian Stretcher, S. K. (2004). Organizational Improvement and Accountability. In H. B. Kirby, Toyota Production System/Lean Manufacturing (p. 17). Rand Corporation.
5. Christensen, C. (2012, March 30). Disruptive Innovation explained.
6. Communities, O. a. (2018). Oslo Manual 2018. Oslo.
7. disruptive-innovation. (2012). Retrieved from <http://usdynamics.com/>
8. Donald A. Norman, R. V. (2014). Incremental and Radical Innovation: Design Research vs Technology and Meaning Change. Massachusetts Institute of Technology.
9. Evill, J. (2012). cortex. Retrieved from [evilldesign.com: https://www.evilldesign.com/cortex](http://www.evilldesign.com/cortex)
10. Fariborz Demanpour, W. M. (1984). Organizational Innovation and Performance: The Problem of "Organizational Lag". 393.
11. Gardner, D. (2017, November 14). Radical vs. Incremental Innovation: The Right Approach For The Right Time. Retrieved from marumatchbox.com/: <https://marumatchbox.com/radical-vs-incremental-innovation-the-right-approach-forthe-right-time/>
12. Guedim, Z. (2019, October 09). 5-industries-3d-printing-is-changing. Retrieved from edgy.app: <https://edgy.app/5-industries-3d-printing-is-changing>
13. Halling, B. (2013). Lean Implementation: The Significance of People and Dualism.
14. Hui Lin, L. S. (2016). A rapid and intelligent designing technique for patient-specific and 3D-printed cast. 10.
15. Inkton. (n.d.). 3d-printing-know-its-advantages-and-disadvantages/. Retrieved from blog.inktonerstore.com: <https://blog.inktonerstore.com/3d-printing-know-itsadvantages-and-disadvantages/>
16. Laal, M. (2012). Innovation in medicine; health information technology.
17. Magid, H. A. (2010). Lean process management implementation. Journal of Industrial Engineering and Management, 47.
18. Manual, F. (2015). Guidelines for Collecting and Reporting Data on Research and Experimental Development. OECD.
19. McElroy, K. (2017). Prototyping for Designers. Developing the Best Digital and Physical Products, 17-25.
20. Michel Beaudouin-Lafon, W. E. (n.d.). Prototyping Tools and Techniques. Chapter 52.
21. Mulder, P. (n.d.). Stage Gate Process by Robert Cooper.
22. Norman, D. (2004). Emotional Design.
23. Obeya. (2020). Retrieved from [wikipedia: https://en.wikipedia.org/wiki/Obeya](http://wikipedia.org/wiki/Obeya)
24. Parvaiz K. Ahmad, D. C. (2010). Innovation Management. Prentice Hall.
25. plattner, H. (n.d.). An Introduction to Design Thinking. Institute of Design at Stanford
26. Ramendra Thakur, S. H. (2010). Innovation in healthcare: Issues and future trends. Journal of Business Research, 563-568.
27. sites/johncgoodman. (2016, July 25). Retrieved from forbes.com: <https://www.forbes.com/sites/johngoodman/2016/07/25/best-kept-secret-inwashington-dc-the-future-of-medicare/#357542591045>
28. Sjödin, D. (2010). Open Innovation and Stage Gate process: A Revised Model for New Product Development. California.
29. store/prINTER-accessories/3d-systems-sense-scanner. (2015). Retrieved from matterhackers.com: <https://www.matterhackers.com/store/prINTER-accessories/3dsystems-sense-scanner>
30. TEO, R. F. (2020, March). 5 Stages in the Design Thinking Process. Retrieved from

- <https://www.interaction-design.org/>:
<https://www.interactiondesign.org/literature/article/5-stages-in-the-design-thinking-process> 31.
- Vanhaverbeke, W. (2014). Open Innovation.
32. Yan-Jun Chen, H. L. (2017). Application of 3D-printed and patient-specific cast for the treatment of distal radius fractures: initial experience. 9.
33. Young, C. J. (2017). Promoting innovation in healthcare. Future Healthcare Journal .
34. YUSUF, S. O. (1999). Rapid prototyping technology: applications and benefits for rapid product development. Journal of Intelligent Manufacturing , 301-311.
35. Zhang, J. (2014, April 23). deniz-karashin-osteoid-cast. Retrieved from mymodernmet.com: <https://mymodernmet.com/deniz-karashin-osteoid-cast/>