MASTER THESIS

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Designing a service for the management and prevention of periprosthetic joint infection cases

ZIMMER BIOMET

TU Delft

Designing a service for the management and prevention of periprosthetic joint infection cases

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“The art of simplicity is a puzzle of complexity.”

- Douglas Horton

Thanks

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GLOSSARY

C

CDA

Clinical Document Architecture: "a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients." ("HL7 CDA Product Brief", n.d.)

D

DAIR

Debridement, Antibiotics and Implant Retention: a procedure during which the prosthesis is not replaced, and sometimes the liner (or: spacer) is. During this procedure, debridement (removing affected tissue) and lavage (cleaning affected area) is performed. After everything is cleaned up, the patient will be stitched up again, and the surgeons will at a later time evaluate if the infection is succesfully treated.

E

EBJIS

European Bone and Joint Infection Society: a medical society who's aim is "to promote the knowledge of all infections affecting the musculoskeletal system (bone and joint infections), and to promote the prevention and treatment of these infections." ("Aims", 2018)

EHR

Electronic Health Record: "systematized collection of patient and population electronically-stored health information in a digital format." (Gunter, Terry, 2005)

F

FHIR

Fast Healthcare Interoperability Resources: "...a next generation communication standards framework [...] that combines the best features of [previous communication standard product lines]", includes latest web standards and focusses on implementability. ("HL7 FHIR Product Brief", n.d.)

H

HIS

Hospital Information System: A system that manages all operations of a hospital, including administrative, clinical, legal and financial aspects. It allows health care providers and doctors to have access to necessary information and to track patient health information.

HL7

Health Level Seven International: An organisation that develops communication standards and are dedicated to "providing a comprehensive framework [...] for the exchange, integration, sharing and retrieval of electronic health information". ("Homepage | HL7 International", n.d.)

I

ICM

International Consensus Meeting: In August 2013, the first International Consensus Meeting on PJI was held in Philadelphia. More than 400 experts from 52 countries and representatives from over 130 societies convened. This meeting has resulted in consensus guidelines. In July 2018, the second International Consensus Meeting on PJI was held again. The resulting guidelines were created by 869 delegates from all around the world. During the meeting itself - which lasted three days -, even far more people were present.

IDSA

Infectious Diseases Society of America: a medical society who's purpose is "to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases." ("About IDSA", 2018)

L

LIS

Laboratory Information System: Software-based system in the clinical market that supports the exchange of laboratory data in a hospital.

M

MDT

Multidisciplinary team: a team comprised of physicians from different disciplines, that share expertise to decide on optimal treatment methods for patients.

MSIS

Musculoskeletal Infection Society: "a multidisciplinary educational and scientific forum for the advancement of knowledge in the field of musculoskeletal infection, for the education of the patient, the clinician and the researcher, and for the promotion of professional standards to guide patient care." ("About MSIS", 2018)

O

OR

Operating room: Also called operating theatre, this facility is used to perform surgical operations. Within the room, an aseptic environment is demarcated.

P

PACS

Picture Archiving and Communication System: A medical imaging system that provides convenient access to images from, amongst others, the radiology department. It furthermore facilitates the processing, archiving and spreading of these images.

PJI

(Peri)prosthetic Joint Infection: A complication that can follow total joint replacement.

R

RIS

Radiology Information System: A system that manages data of the radiology department. It links the data to the correct patients and controls the workflow of the department.

S

SAML

Security Assertion Markup Language: A communication protocol among digital systems that allows the exchange of data to happen in a safe way, by facilitating safe authentication of users.

SOSSID

Swiss Orthopedics and Swiss Society of Infectious Diseases: A medical society that has proposed diagnostic criteria and guidelines for PJI, that EBJIS has adopted.

SSI

Surgical Site Infection: An infection incurred by a patient, which appears to have been caused during surgery.

T

THA

Total Hip Arthroplasty: The surgical replacement of a hip joint with a prosthetic implant.

TJA

Total Joint Arthroplasty: The surgical replacement of a joint with a prosthetic implant.

TKA

Total Knee Arthroplasty: The surgical replacement of the articular surfaces of the knee with prosthetic implants.

Z

ZB

Zimmer Biomet: The leading manufacturer for orthopaedic medical devices and joint prostheses. Also the company for which this project is executed.

**The author of this report will be referred to as 'the designer', or when applicable 'the facilitator'.*

PROJECT OVERVIEW

Why this project?

What makes this thesis worth writing? Why is it necessary to design a service for the management and prevention of prosthetic joint infection cases? Why is the designer interested in these matters?

This project is initiated by Zimmer Biomet, the leading manufacturer for orthopaedic medical devices and joint prostheses. It is expected that providing services and tools that aid in the management and prevention of prosthetic joint infection (PJI) cases will become one of the future strategies of Zimmer Biomet. It is furthermore expected that this strategy can aid in decreasing the physical and financial burden that PJI has on patients and society.

PJI is a complication that follows total joint replacement and is devastating for the patient. The next chapter will elaborate on what this means in technical and medical terms, but this section will focus on the impact that this complication has and how this thesis may help reduce that impact. Firstly, PJI has an immense impact on the patient. Not only does it cause physical strain, but also its mental counterpart. The infection will always have a destructive effect on the mobility of a patient, this will never return to close what it was prior to the complication. The process of eliminating the infection and minimising the chances of its return is also intrusive and puts a heavy physical burden on the patient. Furthermore, that burden amplifies and becomes straining to the mental well-being of the patient as well. People that have suffered from PJI often experience mental problems caused by it.

Secondly, PJI lays a financial burden on hospitals and society. It is time-consuming to treat and it requires a large amount of effort by a large amount of people to eliminate. As big as this problem is currently, it is sadly the case that the occurrence and financial impact of PJI has been growing and is predicted to keep doing so. Aiding the relevant stakeholders in optimisation of management and prevention of PJI can decrease this burden. Allowing these stakeholders to be properly introduced to and regularly reminded of optimal methods of recognition, diagnosis, treatment, aftercare and prevention will aid in this improved management.

I want to counteract the rise of this awful complication. Also, I want to help people in managing cases of this infection, by providing them with (a) tool(s). This way, I aim to aid in the decrease of time, money and effort it requires to treat it. I furthermore want to help people in decreasing the occurrence of PJI, by aiding them in its prevention. In addition, I am interested in designing a service/tool that answers to a problem that is as complex as this one and originates from a sector that is new to me completely.

Finally, I believe that the development of a service that aids in the management and prevention of prosthetic joint infection cases can be profitable for Zimmer Biomet and is a wise strategic decision. I believe that the world is currently moving from a product-oriented economy towards a service-oriented economy. Zimmer Biomet offers a lot of high quality products and has a large share in the prosthetic joint market. The development of this tool helps the company to move in the direction of becoming more service-oriented. It can even be the ideal approach to establish itself as the market leader in services in their business.

Summary

This thesis describes the design process of a service/tool for the management and prevention of prosthetic joint infection cases. After an introduction to the subject, the assignment of this project is discussed and the approach the designer will take is described.

The analysis consists of a literature review and field research. Parts of the field research are interviews, OR visits and creative sessions with PJI experts, surgeons, OR staff and Zimmer Biomet employees. Analysis of the findings of this phase resulted in a conclusion.

It is concluded that a knowledge gap among medical staff is present and difficulty in decision-making can arise, both during diagnosis and treatment. Furthermore, be it between continents, countries, regions, hospitals or even surgeons, a lot of different approaches to the subject exist and there is no widespread global consensus on what the golden standard for infection prevention may be. Finally, even the best hospitals still experience infections, thus, space for reflection or improvement can always be found.

In the phase following analysis, the designer focusses on forming a vision and defining (areas for) opportunities. Creative sessions and individual analysis allow these views to be created. After validating opportunities that are deemed most interesting, a design brief is formed. This design brief includes a definition of the problem, the main stakeholders, the opportunity direction(s) and the design goal. A summarised version of the design goal is as follows: **"The goal is to *communicate* consensed *knowledge* to staff, make data easily *communicable* among them and *educate* them."**

The goal of the next phase of the process is to give substance to what is formulated in the design brief. An ideation process results in the presentation of three concepts. These concepts are evaluated and one is chosen to develop further, that concept is the 'MDT Dashboard'. The decision is made that the combination of all three presented concepts will offer the most added value to Zimmer Biomet. How this combination will work, and how it will be implemented is discussed in the chapter 'Strategy'. Also, the chosen concept is developped further and strategic considerations are thought out.

The aforementioned combination of concepts is coined 'PJI management system'. A strategy is developped for the beginning of the implementation of this system. The chapter 'Strategy' discusses the recommended strategy for Zimmer Biomet by formulating a vision, offering a visual explanation of the cohesion of the elements of the strategy and providing a roadmap. The latter includes technological, societal and medical developments as well as concrete solutions to stated solution directions that fit the defined strategy. Furthermore, recommendations for implementation and strategic approach are outlined.

At the same time, a digital prototype is developped of the MDT Dashboard in order for it to be tested by target users and for its value to be validated. The strategy and plan for implementation are also validated. This validation results in an extensive elaboration on the technical and organisational implementation of the dashboard. It is explained how the dashboard can be implemented into hospitals from a technical standpoint as well as an organisational standpoint. It furthermore sheds light on the acquisition process of a hospital for such a tool and it is discussed how the prototype's interface can be advanced and what elements of the strategy are adjusted. Finally, it gives concrete answers to the research questions posed at the beginning of analysis, as these are answered throughout the report. Together with all other steps of the process, the validation furthermore results in final recommendations.

A parallel line runs through the thesis. The designer's experiences during this project, and as a newcomer in the medical world, have resulted in guidelines on how to approach an innovation process in the medical world and how to acquire information to kickstart this process. These process guidelines will be mentioned throughout the report at the end of a chapter, when they are applicable to a specific phase. As a result, all guidelines will also be gathered in one corresponding chapter, at the end of this report.

CONTENTS

READING GUIDE

This thesis contains eight chapters that describe the journey of designing a service for the management and prevention of cases of PJI. All blue chapters are supportive to the thesis and as described in the summary, the chapter 'Process guidelines' discusses a result of this project, separate from the design process.

The guide below describes what these chapters discuss to guide the reader through this report.

At the end of the chapters 'Empathise' and 'Define', process guidelines that are intended to aid in the execution of an innovation process in the medical world are described.

At the end of the chapters 'Empathise', 'Define' and 'Ideation & Conceptualisation', aspects are discussed that have an implication on the final design and on the progress towards it.

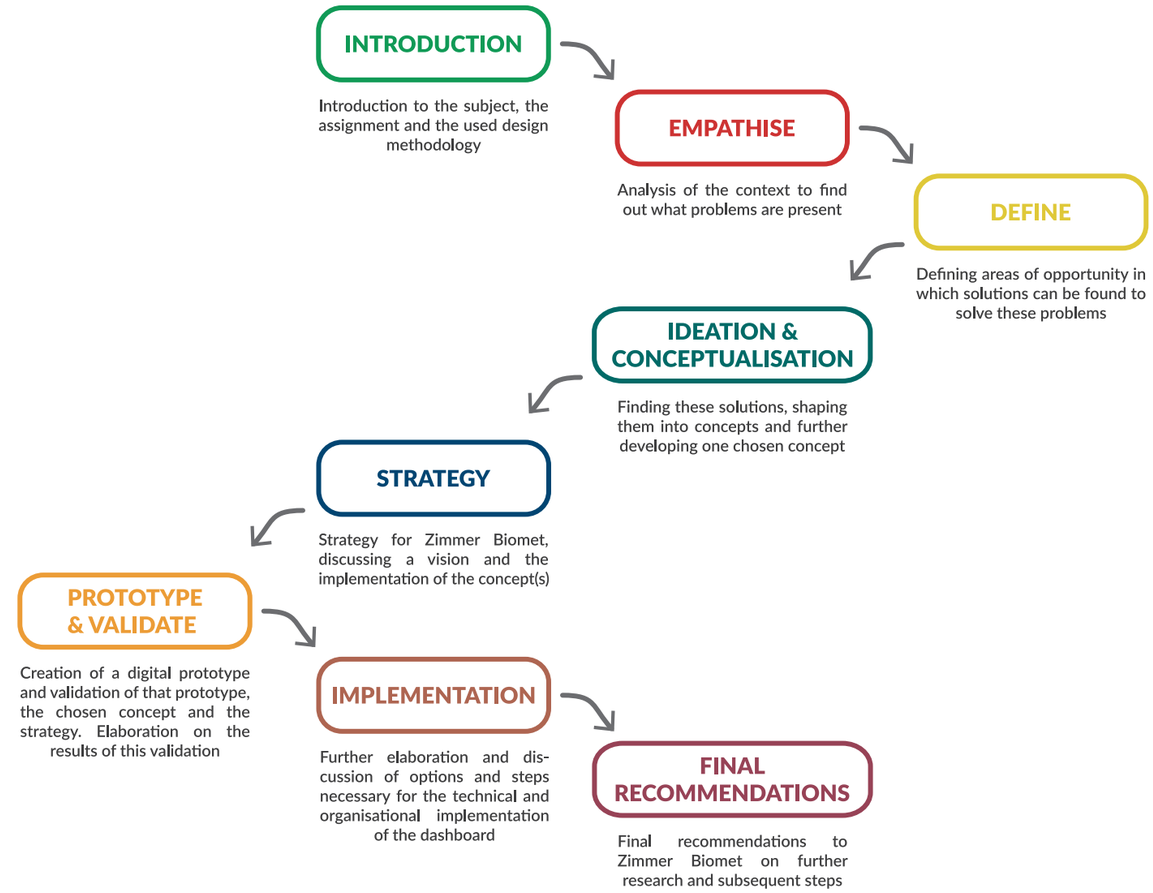


Figure 1. Reading guide

INTRODUCTION

In a human body, the total number of human cells is 30 trillion. The total number of bacteria cells is 38 trillion. (Sender et al, 2016) These cells, most of the time, live in harmony. Put differently, they live in a 'Cold War', where the parties are enemies, but no actual fight is taking place. (Zimmer Biomet Marketing director infection diagnostics, personal communication, April 4, 2018). However, when the activity of the bacteria surpasses the activity of the immune system, the balance is lost and an infection can arise, as is depicted in Figure 2.

Periprosthetic Joint Infection (PJI) is a complication that can follow total joint replacement and is devastating for the patient. These infections lead to excess mortality, they strain the patient with substantial morbidity and impose healthcare systems with an increasing financial burden. Managing these infections is a complex process and is mainly based on personal experience and the opinions of experts. (Springer, Parvizi, 2013)

Standardisation of approaching PJI falls short, this is due to a shortage of randomized controlled trials. (Zimmerli & Ochsner, 2013) Recently, clinical practice guidelines have been released by several expert societies, but clinicians still use varying methods to manage PJIs. (Osmon et al, 2012; Johannsson et al, 2010) Treatment methods guidelines have been previously followed. When they were, it yielded better outcomes for the patient. (Zimmerli & Ochsner, 2013; Betsch et al, 2008; Zimmerli, Trampuz & Ochsner, 2004)

The population increasingly wishes to maintain high physical functionality during the later phases of their lives, this has caused the amount of joint replacement surgeries to steadily rise in recent years. Infection is a complication that arises in 0.2% to 2% of joint replacement surgeries. (Otto-Lambertz et al, 2017) These numbers relate to primary joint replacement surgeries; for revision surgeries the numbers are much higher, ranging from 10% to 15%. Second (or higher) revision surgeries produce even higher numbers, as is depicted in Figure 3. (Company mentor, personal communication, February 2018) As stated before, because of high associated morbidity, it is of great importance to optimise therapeutic and diagnostic strategies that are relevant and to minimise factors that cause a risk for infection. (Otto-Lambertz et al, 2017)

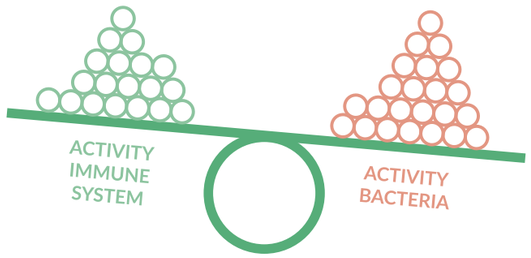


Figure 2. A loss of balance can cause an infection to arise

"Managing these infections is based on personal experience and the opinions of experts."

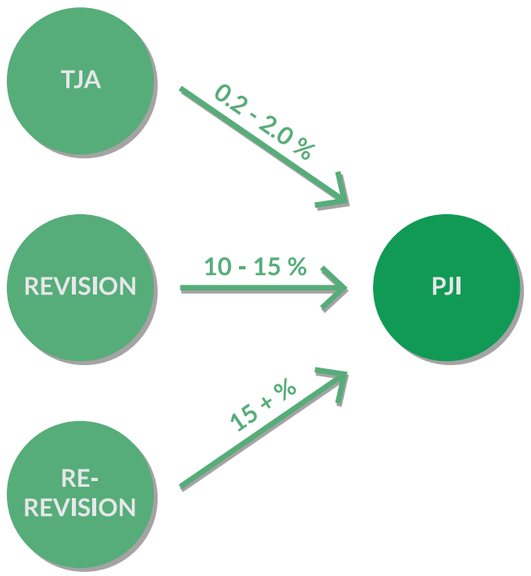


Figure 3. Chances of an infection arising after a primary, revision or re-revision total joint arthroplasty.

Infected Joint Journey

This project builds on the vision of a dedicated team at Zimmer Biomet (ZB), which states that the company should position itself as the industry leader for the prevention, diagnosis and treatment of orthopaedic infections. An opportunity is present to (gain and) grow valuable connections with clients, synchronise existing infection control products and service across business units, improve brand image, provide Zimmer Biomet with a long term leadership in PJI, create structural product outlets and become the preferred supplier. In order to execute this vision, a process of acquiring insights and understanding the problem is started. The analysis phase of this process is now coming to an end, with the step of adding data of patients and treatments being one of the last - this is an element that is outside of the scope of this graduation project. The next phase is to commercialise the service, which consists of designing and introducing it. This graduation project will aid in the beneficial progression of this phase. Its position is visualised in Figure 4.

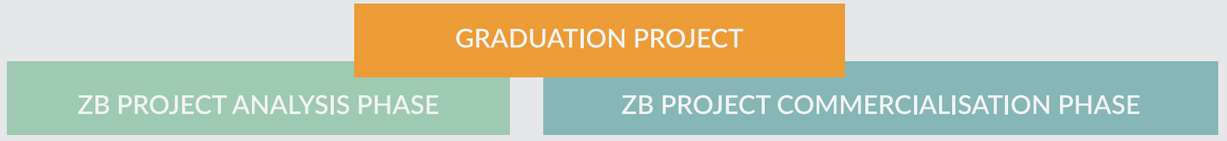


Figure 4. Position of graduation project in relation to Zimmer Biomet project

One main element that has been the result of the prior phases that the Zimmer Biomet project has gone through is the "Infected Joint Journey" (IJJ). This is an interactive map that depicts the possible processes of a case of an infected joint. Within this map a lot of information is given on possible steps that can be taken during such a case. The journey covers three phases: Presentation, Assessment (divided into Diagnosis and Decision) and Treatment. Within these phases substeps are covered for different possible processes. The journey is also viewed from three standpoints: the process, the organisational structure that is involved/necessary and the Zimmer Biomet products that are relevant to a specific phase. An overview of this map is shown as an abstract visualisation in Figure 6, on the next page.

Not only are all the steps covered in this interactive map, they are also clickable to discover more information on the exact step and in some cases advice on steps to take. Within the screens that appear when expanding a step, products of Zimmer Biomet and their use are shown and explained, whenever relevant. For instance, the screen that is shown in Figure 5 is what pops up when you click the 'Multi-Disciplinary Team Decision' tile, located in the 'Decision' phase of the 'Process' column (depicted in Figure 6 as the diamond outlined in red). A take-out from the Infected Joint Journey is shown in Figure 7 (depicted in Figure 6 as the circles outlined in red).

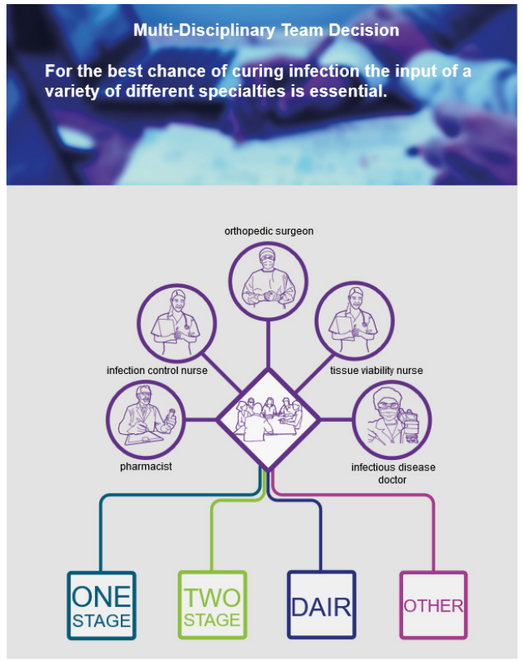


Figure 5. More information on the step 'Multi-Disciplinary Team Decision'. At this point a team decides on the treatment plan. For more information on this decision, you are referred to page 24.

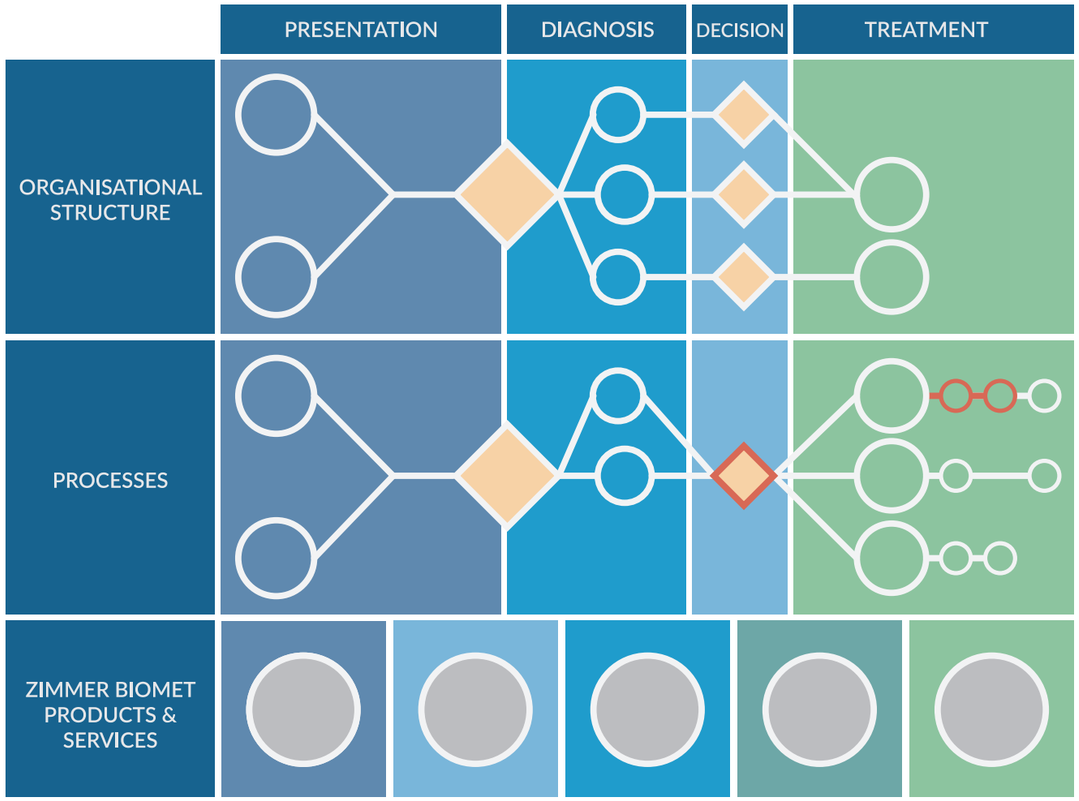


Figure 6. Abstract visualisation of the interactive map “Infected Joint Journey”

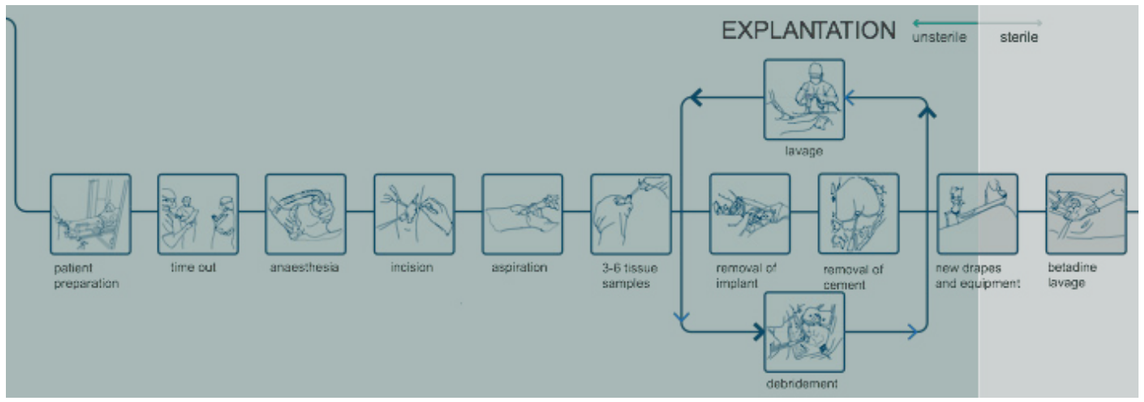


Figure 7. Take-out from Infected Joint Journey showing a part of the process for a one-stage surgery, as shown in the Processes: Treatment section (depicted in Figure 6 as the circles outlined in red). For more information on what a one-stage surgery entails, you are reffered to page 24.

Assignment

The “Infected Joint Journey”, as shown in the previous section, is an interactive map depicting the possible processes of a case of an infected joint. It is seen as a means, not an end, and this assignment takes this map as one of its starting points.

The assignment and end goal for Zimmer Biomet is to commercialise a service/tool that helps relevant stakeholders with managing a case of PJI, processing it more time- and cost-efficiently, making the process more comfortable for the patient and (indirectly) decreasing the occurrence of PJI. The first part of the assignment is to analyse the context and define several elements: the scope of the service, the targeted stakeholders, the design problem and design goal and the overall form of the service/tool. Later parts of this assignment include the development of ideas and concepts of the service, as well as prototyping, validation, strategy and implementation.

The context of the service/tool is a broad one. A lot of stakeholders are present and need to be taken into account when defining the aforementioned elements. The broadness of the context becomes clear when viewing the mindmap shown in Figure 8. The mindmap shows an array of stakeholders, which are categorised and for (some of) which examples are given. It has formed itself over the first ~6 weeks of this project and also clarifies the complexity of the project. To see the mindmap in more detail, and with practical examples of the named stakeholders, see Appendix A.

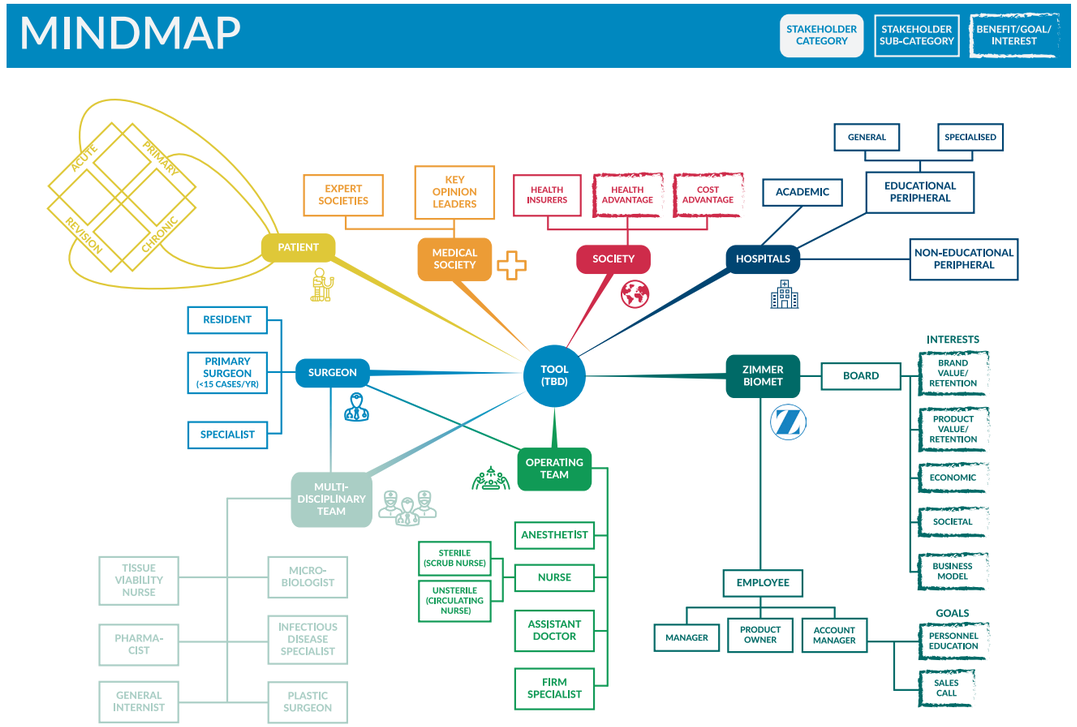


Figure 8. Mindmap of the necessary relations in the graduation project concerning prosthetic joint infections.

Approach

The design approach used is service design, which is split up into five phases: Empathise, Define, Ideate, Prototype and Test. One of the powers of service design is that it is co-creative; the expertise of different stakeholders is used to achieve the best result, while at the same time creating support – for the service being developed – among these stakeholders.

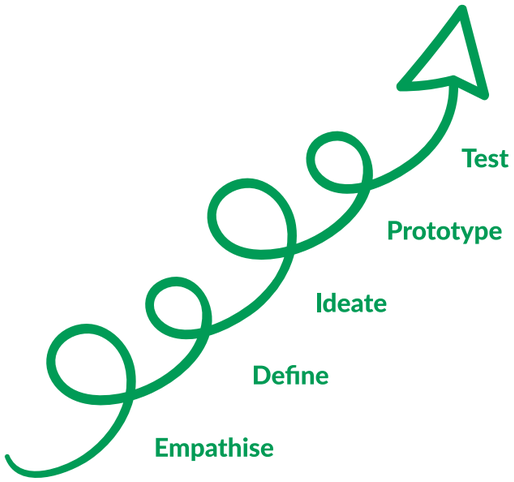


Figure 9. The iterative process of service design (adapted from "Koos Service Design", 2018)

Service design

Prior to the explanation of how service design will be applied in this project, some background information on what it entails is provided. Service design exists to help businesses innovate in such a way that answers to what the end-users of their service want and need. These may be things that that user is unaware of him- or herself. Explorative research methods are used to uncover these (latent) needs, after which a variety of methods can be used to communicate the findings in a meaningful way that conveys those needs clearly and convinces internal stakeholders to move forward with the insights. (Stickdorn, 2018) At this point already, co-creation starts to play an important role, since it helps greatly with finding the right insights by using the expertise of internal stakeholders. It also plays a helpful role in making those stakeholders the owners of the insights, by involving them in the process

and thus increases the chances of buy-in from these stakeholders. An ideation phase follows, which again builds greatly on co-creation, though definitely not less so on the skills of the involved designers. A strong belief in service design is that assumptions are gravely dangerous; a designer may think he is doing what the user wants, but the only true way to make a customer-centred design is by validating it with its users. For this reason the following phase involves rapidly prototyping your design and testing it. Valuable lessons will be learned from these tests with users, which can immediately be implemented into the design. After having tested a lot of big - and smaller - assumptions that have been made, the design can be finalised for a design proposal that the client can implement.

The process of service design is an iterative one, the steps almost always flow together and earlier steps can recur at a later time in the process.

Empathise

This first phase will be split up into empathising with the context and empathising with the end-user of the tool. The context will be explored by speaking with experts (i.e. surgeons, PJI experts, Zimmer Biomet employees and project mentors). A literature review on relevant medical subjects and thorough understanding of the tool as it stands will be executed. Furthermore, a broader and deeper understanding of service design will be gained by reviewing literature. This is to set a solid base for the project and give clear explanations of the (research) methods used. Throughout the project, experts will be continued to be spoken to; either by visits in the relevant context or via video conference.

Empathy for the end-user will be formed next. By interviewing the end-user (surgeons, supporting staff/ multi-disciplinary team/OR team, Zimmer Biomet employees), their needs will be found, in the context of using the tool. These can also be latent needs, which will be found through the use of generative interivewing techniques, including participatory design tools, like timelines and customer journey maps. (Stickdorn, 2018) You can read more about these interviewing techniques in the next chapter.

Define

By analysing and structuring the end-user's needs, findings can be translated using tools as journey mapping, morphological tensions (originating from the morphological psychology theory, developed in the 1960s by Wilhelm Salber), needs-based profiles, research insights, experience mapping and more. (Salber, 1965; Salbr 1969) Co-creative sessions can take place in this phase, to utilise expertise and start coming to a common understanding of multi-stakeholder needs.

Ideate

Following the research phase, co-creative ideation sessions will be organised to iterate on the 'insights journey'. These sessions allow the expertise of different stakeholders to be utilised and will at the same time create understanding of and support for the tool within the organisation. Following the ideation sessions, more sessions will be organised to keep stakeholders in the loop of progress, to continue using their expertise as an advantage and to build on the ideas – shaping them into actionable elements.

Prototyping & testing

Quickly prototyping the actionable elements – which were defined during the co-creative sessions and refined afterwards – will be done with the help of design tools as paper prototyping, interactive click modelling and perhaps, in the case of a digital prototype, wireframing and computer programs as Sketch and Marvel. By quickly prototyping these elements, their value can be validated by testing them with the future users of the tool. These tests are performed to avoid the pitfall of counting on assumptions. If the opportunity arises, these user tests can be live-streamed, so that stakeholders can view along as the end user is operating the tool. This phase of prototyping and testing will be executed in one-week (Google) design sprints. (Knapp, 2016)

Creating support

A desired goal is that support for the tool is created throughout the organisation. The method of service design is very suitable to this goal, since it offers a lot of involvement to the stakeholders, provides plenty of feedback moments throughout the process and makes stakeholders 'owners' or 'ambassadors' of the final tool through interaction.

Tool implementation

To ensure a wide implementation, support of the tool by stakeholders and users is essential. This support is created by factors elaborated on in the previous paragraph, as well as strong and clear visual communication of the tool, its working, and its interaction with the end user, which is part of the provided approach. Recommendations on implementation are given and a roadmap for implementation is provided.

EMPATHISE

Introduction

This chapter describes the methods, process and outcomes of building empathy with the context and the possible stakeholders for the service. After drawing up research questions, the methods, their processes and their participants are discussed. Subsequently, the insights, abstractions and conclusions drawn from them are shared.

Research questions

In order to find out what direction this project should move in, it is important to ask a couple of questions. The overarching question to be asked is: "How can Zimmer Biomet optimally design a service that aids in the management of a case of PJI?"

To make this problem practical and divide it into bits that can be tackled, this question is translated into the following research questions:

"What problems are most prominent in managing a case of PJI?"

"What sort of approach should the service take: informative, advisory, educational, connective, reflective, ...?"

"What stakeholders should the service focus on?"

"What are the needs and goals of these stakeholders?"

Methods

To find the answers to these questions, several methods have been used. To make these methods more succesful, participatory design tools have sometimes been used as part of them. Examples are the use of timelines and customer journey mapping. (Stickdorn, 2018) Together, these methods will bring insights and answers to the questions asked. How this is attempted to be achieved, will be explained per method.

Literature review

Prior to this project, the designer had very limited knowledge of subjects concerning medical care, let alone periprosthetic joint infection. A literature review was therefore more than desirable. It has been executed by reading research papers, review articles, website articles, books and more. This firstly resulted in an improved general understanding of medical themes. Furthermore, it shed light on what PJI entails, the weight of the problem, how it arises, what variables cause it, what shapes it can take, how it may be treated and how it may be prevented.

For a more elaborate explanation of what the concrete results of the literature review were, you are directed to Appendix C.

Interviews

Interviews with several stakeholders have been held. For these interviews, interview guides have been created to serve as a guideline both in preparation to the interview as well as during the interview. These interview guides are not supposed to be stuck to word per word, but serve as support or inspiration during the interview, when there needs to be any. (Raffalli, 2018) The interview guides are specific to stakeholders and are split up into:

- Medical expert
- Surgeon
- Zimmer Biomet employee
- Multi-disciplinary team
- Operating room staff
- Patient

All interview guides can be found in Appendices D-I.

These interviews are firstly intended to let experts on the topic share their expertise with the designer. Much like the literature review, this will broaden the understanding of the designer and provide insights. They are also intended to let experts and other stakeholders share their ideas about managing a case of PJI, by finding out what they feel are current problems, necessary goals and possible solutions. Finally, and most importantly, the interviews are intended to find out the (latent) needs and goals of all stakeholders specifically, in order to answer to these needs and goals in the final design. (Sanders, Stappers, 2012) In order to achieve finding latent needs, generative interviewing techniques will be used. These techniques include rules on how to formulate questions, like using a lot of questions that include the word "How", or avoiding leading questions*. (Harris, 1973; Hayes, 2002; Loftus, 1975)

> **A leading question is a question that contains bias and suggestion. Qualitative and explorative researchers aim to avoid these kind of questions as to not obstruct the goal of their research: finding out the need of the interviewee, without projecting your own assumptions onto him/her. An example of a leading question is: "Do you think this handlebar is uncomfortable?" This question forces the interview to think of the handlebar and of its comfortability. It also contains judgement, by calling the handlebar uncomfortable. A question that solves these issues would be: "What do you think of this bike?" After hearing out the interviewee, you may conclude he/she has nothing to say about the comfortability of the handlebar - or even the handlebar at all - and that he/she finds a lot of different things more important. Ofcourse if you first let the interviewee speak his/her mind, later in the interview you may ask: "What do you think of the handlebar?" and after hearing out the interviewee, you might even consider asking: "What do you think of the comfortability of the handlebar?".*

Other techniques include not sticking to a question list too much, but letting the conversation flow naturally (Raffalli, 2018) or laddering, which is a technique often used during explorative interviews to discover latent needs. (Reynolds, Gutman, 1988) It is furthermore advised to allow silences to be present in the conversation. This allows the interviewee to think freely and explore his/her thoughts, instead of the thinking process being interrupted by the interviewer's next question. (Stickdorn, 2018) For a more elaborate explanation of how the interviews were executed and what the concrete results were per interview, you are directed to Appendix J.

OR visits

Through the help of the company mentor and other employees, surgeons and affiliates, the designer has been able to visit several surgeries. These visits to the operating theatre/operating room (OR) have been eye-opening experiences, during which a formerly completely unknown world (to the designer) opened itself up. These visits have been important, since they have allowed the designer to be submerged into practical examples of the goings of treating cases of PJI. This offered the designer more than a taste of what the patient, surgeon and OR team experience during treatment, which is essential to involve in the development of the final design. It also offered the designer an extra channel to interview relevant stakeholders, that were present during these surgeries, allowing more insights to be shaped.

For a more elaborate description of what the concrete results were per OR visit, you are directed to Appendix K.

Creative sessions

Creative sessions have been organised to utilise the expertise of participants. These participants bring their knowledge on (a specific element of) the subject to a session that may last between 1 - 5 hours. During this session the facilitator leads them trough a creative process that will trigger their minds and result in valuable insights. These sessions are very helpful since there are plenty of people with a lot of experience on the subject and they are the experts of their own experience (Stickdorn, 2018): during these sessions, this experience is being utilised. It furthermore gives the participants a feeling of ownership over the solution that is in development. This results in internal support.

For a more elaborate explanation of how the creative sessions were performed and what the concrete results were per session, you are directed to Appendix L.

All of these methods together, have gradually shaped the knowledge and insights on the subject. Where the literature review has shaped the knowledge on what PJI entails, the interviews, OR visits and creative sessions have together provided insights on the subject, the problems and opportunities. After each executed interview, OR visit and creative session, the insights grew and knowledge to be gained decreased. This is visualised in Figure 10 on page 20.

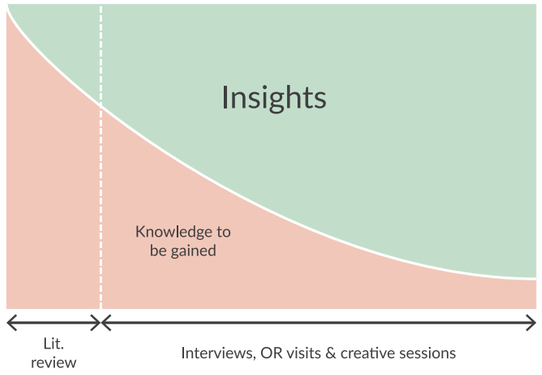


Figure 10. Process of knowledge and insights gained over time, due to the application of several methods

Participants

Interviews

The problem of managing a case of PJI is complex, it involves a lot of different stakeholders that have a role in the management or a stake in the quickest/ cheapest/healthiest completion of a case as possible. The stakeholders are numbered, to be referred to in the paragraph “Creative sessions”.

People that are seen as experts on the subject (1) are interviewed, to firstly find out more about PJI in general. Secondly, the goal is to find out what they feel is going wrong, what is going right, what their needs are during managing a case of PJI, where things can be improved and what they feel may be possible solutions. At a later phase of the project, experts are interviewed to validate the presented concept and certain aspects of it.

Surgeons (2) are interviewed to find out how they experience managing a case of PJI. These are the people that are most involved, they experience nearly every element of this management. What is sought after is how they experience each step of the process, where they might require help, where they feel progress can be made and what their (latent) needs are.

Patients (3) have not been interviewed. It is, however, desirable to interview them after this project to find out how they experience getting an infection and having it treated. There might be opportunities to help the patient with understanding or coping with the situation or to advise him/her as to improve the outcome. For future analysis into aiding the patient, interviews with patients are recommended.

Members of the OR team (4) are interviewed to firstly find out what their roles are in managing a case of PJI. Secondly, more importantly so, their first-hand experiences and (latent) needs for improvement are being sought after. The fact that they experience this subject up close, makes their views on where problems and opportunities lie very valuable.

Members of the MD team (5) have not been interviewed. Despite multiple efforts to arrange these interviews, it did not succeed. It would have been desirable to interview them since they are (together with the surgeon) largely in control of the diagnosis and treatment decision. Their experiences on how these steps in the process expire, where improvements are possible and their (latent) needs are valuable elements to find out.

Zimmer Biomet employees (6) have been interviewed for several reasons. Firstly, their experience in the medical world and with PJI can provide valuable insights. Secondly, some of them have spent a lot of time in operating theaters (and still do). Some of these employees can therefore also be seen as members of the OR team (4). Lastly, their visions on how the service can be of value to the company, society and all other stakeholders are valuable as well.

General practitioners (7) have not been interviewed. These interviews could have been interesting to find out if there lies an opportunity with providing a service/ tool to GP’s, in order to improve recognition of PJI, so to improve its management altogether. Interviewing general practitioners is recommended for future analysis.

OR visits

OR visits have been made to several hospitals. The goal of these visits is firstly to immerse oneself into the environment, as to better understand the dealings of an operating theatre. (IDEO, 2015) Secondly, the visits provide an excellent opportunity to speak to all people present, as to find out their views, experiences and needs concering the subject. Finally, the visits are crucial to experience how surgeons and the OR team treat a patient, how treatments differ and what all the elements of a treatment entail. The visits have been made to various hospitals, as to create a wider image of the sought after insights as described before.

Creative sessions

The creative sessions have been held with stakeholder groups 1, 2 and 6. The expertise and knowledge of these stakeholders allows them to be taken through a creative process from which valuable insights and ideas arise.

It would have been desirable to execute more creative sessions in which more and different stakeholders participated. Each of the stakeholders described under the section ‘Interviews’, has important insights and needs to share. These creative sessions uncover more and/or different insights and latent needs of these stakeholders, which is valuable to incorporate in the analysis. (Stickdorn, 2018) It would have been especially valuable to include groups 4 and 5. It is recommended to execute creative sessions with these groups during future analysis.

Insights

The methods (and participants) described in the previous section have provided insights that will be elaborated on in this section. For further explanation on how these insights were gathered and what they are based on, you are referred to Appendices B-L. Firstly, concrete insights will be discussed; afterwards, implicit deductions (or: abstractions) are discussed.

Current process & workflow

To give a clear understanding of what the workflow looks like for the stakeholders and what the progression and medical treatment of PJI looks like, a visual representation is shown in Figure 13 on page 22. More information is given on page 22.

Concrete insights

Incidence & impact

From research can be conluded that when a patient undergoes surgery to have a joint replaced by a prosthesis, there is a chance that an infection will arise. These operations often occur for hips and knees, which are named, respectively, Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). When the surgery concerns a revision, meaning that the patient’s current prosthesis needs to be replaced, the chance of infection is drastically higher (as is depicted in the chapter “Introduction” in Figure 3).

The amount of THAs and TKAs is growing rapidly, which consequently means that the number of PJIs is as well. Figure 11 shows a visual representation of this, based on a review article. (Kurtz et al, 2012)

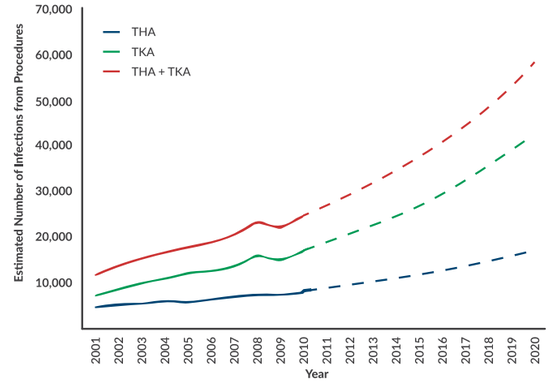


Figure 11. Historical and projected number of infections with THA, TKA and combined THA and TKA procedures within the USA between 2001 and 2020. (adapted from Kurtz et al, 2012)

The increasing occurrence of PJI, also causes the economic impact to grow. The cost of revision cases caused by PJI is shown in Figure 12 and will exceed $1.62 billion in 2020, in the United States alone. (Kurtz et al, 2012) (Tande, Patel, 2014)

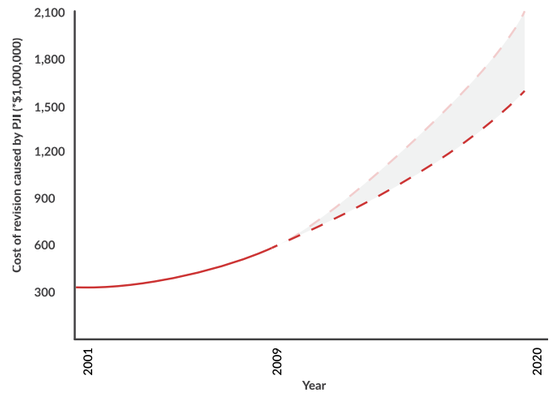


Figure 12. Cost of revision cases caused by PJI, in the United States. (based on Kurtz et al, 2012)

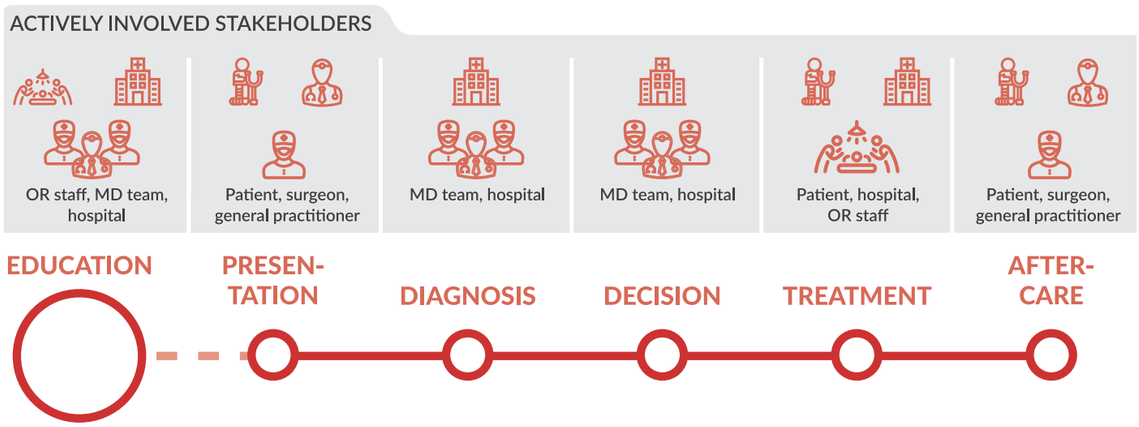


Figure 13. Visual representation of the current process & workflow

In Figure 13, the stakeholders that are actively involved are displayed per phase, using the same visual language as in the mindmap. The surgeon is part of the MD team and the OR staff.

As stated in this visualisation, education currently takes place in classes and by learning from experienced surgeons during surgery. Optionally, staff members educate themselves individually. (Senior house officer (ANIOS), personal communcation, July 2018)

Decisions for treatment method and all relevant treatment variables can be made by a multidisciplinary team, in consultation, or individually, by a surgeon. This differs per country and area. (Zimmer Biomet marketing director, personal communication, October 2018)

No clear standard

From literature can be concluded that a lot of differences exist in how PJI is defined. (Tande, Patel, 2014) Inequalities arise in definition of recognition, timing, diagnosis and risk factors. For instance, the timing of PJI is defined by some as 'acute' or 'chronic', while others define it as 'early', 'delayed' and 'late'. (Gehrke, Parvizi, 2014; Gbejuade, Lovering, Webb, 2015) Next to the difference in definition, big differences in protocol and treatment exist as well. (Orthopaedic surgeon & renowned PJI expert, personal communication, March 2018; Zimmer Biomet account manager, personal communication, April 2018) These arise in defining preoperative and intraoperative risk factors, diagnosis, decision of treatment, treatment itself and prevention. For example, the criteria that are used to determine whether or not a patient has a

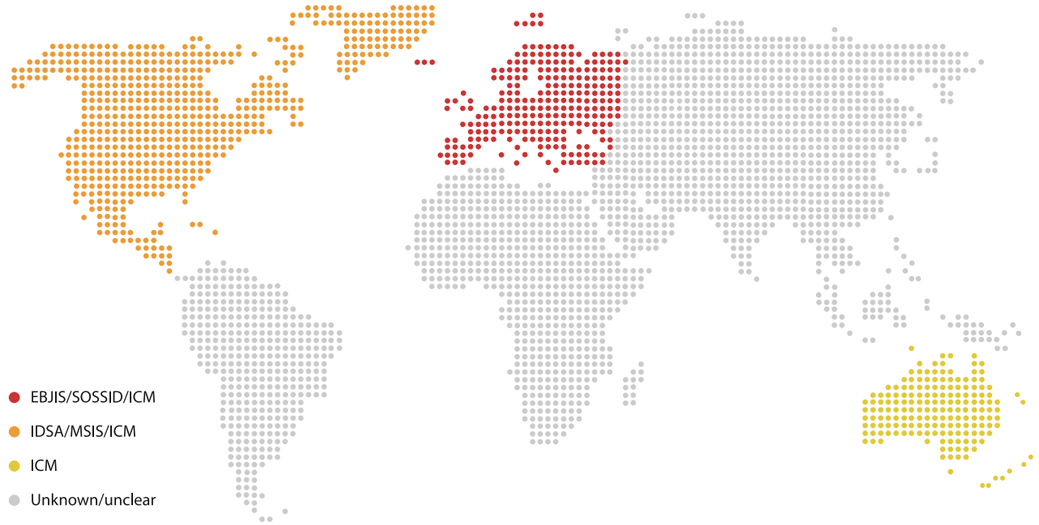


Figure 14. Visual representation of which expert society guideline is used where in the world. Much is still unclear, similar to the knowledge and available help on managing a PJI case.

prosthetic joint infection, differ per area/hospital/surgeon. (Tande, Patel, 2014)

Several expert societies exist that define guidelines on the subject of PJI. They base these guidelines on research papers, review articles and expert opinion. These guidelines comprise the whole process, being: definition, diagnosis, decision-making, treatment and prevention. Clinics and surgeons from different areas in the world adopt different guidelines, resulting in no clear consensus. Which surgeons or hospitals use which guideline exactly, is also often unclear. (Orthopaedic surgeon & renowned PJI expert, personal communication, March 2018; Zimmer Biomet account manager, personal communication, April 2018) A visual representation of how divided these views are and how unclear it even is in other areas, is shown in Figure 14. In August 2013, the International Consensus Meeting on PJI was held in Philadelphia. This meeting has resulted in consensus guidelines, though far from all surgeons adopt these guidelines. In July 2018 a new ICM was held, with many more participants from all over the world, resulting in extensively documented guidelines. (Parvizi, Gehrke, Mont & Callaghan, 2018) More information on this can be found in Appendix B.

Risk factors

A lot of risk factors for the occurrence of PJI exist. These can be divided into preoperative, intraoperative and postoperative risk factors.

Preoperative risk factors consist of patient conditions as diabetes, depression and rheumatoid arthritis. (Del Gaizo et al, 2014; Shahi, Parvizi, 2015) It is crucial for surgeons to know what patient conditions apply as risk factors and knowing their respective hazard ratio (how risky is this condition) is important as well.

Intraoperative risk factors all relate to one goal: minimising the number of bacteria in the surgical wound and in the operating theatre. Examples are amount of OR traffic, use of sterile equipment and washing the skin of the patient. (Lee et al, 2006; Prokuski, 2008; Shahi, Parvizi, 2015) It is very important for surgeons and OR staff to understand that these and other measures are crucial to minimising the possibility of infection. The method of implementing these measures is currently done by counting on prior knowledge and protocol. The rise of new or improved knowledge on the subject is carried out by educating staff in lectures or session. Relevant staff is educated on certain specific actions in

training centers. (Senior house officer (ANIOS), personal communication, June 20, 2018)

Postoperative risk factors are, amongst others, hematogenous spreading and subsequent surgical procedures. (Springer, Parvizi, 2013) Here lies an opportunity for informing and/or educating patients as well as electronic health records (EHR), though the issues surrounding that phenomenon yield restraint.

Diagnosis

From research can be concluded that providing a correct diagnosis of periprosthetic joint infection after a patient has undergone arthroplasty can be difficult. When diagnosing the presence of prosthetic joint infection, there is no universally accepted definition available for the team. Furthermore, a lot of tests exist, which are still being optimised, and new tests arise. (Springer, Parvizi, 2013)

"No universally accepted definition is available"

Furthermore, performing a diagnosis of PJI is very complicated and difficult: several fields of expertise are necessary and the problems are almost always quite fluid and elastic. Current existing guidelines lack depth (and are dissimilar).

Finally, it is important to note that the diagnosis does not stop before treatment begins. Intraoperative tests are executed to uncover details about the infection important for further treatment.

Decision

From literature and interviews can be concluded that during the choice of treatment there are multiple variables to be taken into consideration, as depth of infection and quality of host. (Springer, Parvizi, 2013; Orthopaedic surgeon, personal communication, March 2018) The multidisciplinary team in charge of diagnosing the case and deciding on the treatment, also needs to choose the approach of the operation. This can be split up into six options, shown in Figure 15 (in order of severity to patient). The first treatment option, without surgery, includes using antibiotic suppression. Since there are no sources to define the severity of the treatment exactly, the designer has made an abstraction based on the length and physical intrusiveness of the treatment. The bars in Figure 15 are slanted, because the severity of a single treatment can also vary.

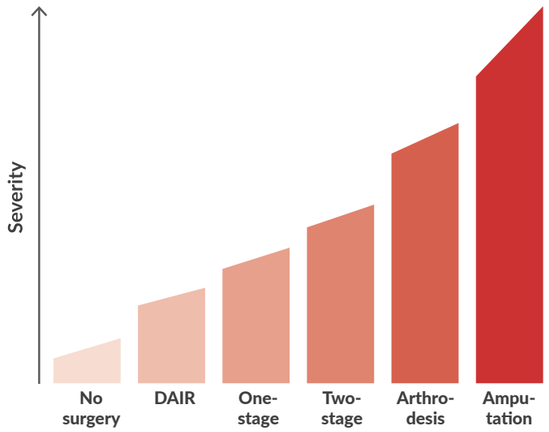


Figure 15. Treatment options, in order of severity to patient

Treatment options

For this project the focus lies on DAIR (see the text box on page 25) and one- and two-stage revision. During a one-stage revision, the removal of the infected hardware and the implantation of the replacing prosthesis, as shown in Figure 16, happen during the same session. Between these two events, the surrounding infected tissue is thoroughly debrided. With a two-stage approach, the infected hardware is removed and the patient is aggressively treated with antibiotics in the first session. A spacer is then implanted, a spacer is in this case a temporary 'prosthesis', that is intended to fill the space of where the actual prosthesis is to be placed. The term spacer is sometimes used as instead of 'liner': a part of the actual prosthesis, as shown in Figure 16. After implantation of the spacer, the patient has to wait for (commonly) 6 weeks. During a second surgery, new hardware is placed in the host. This approach allows time to identify the organisms causing the infection and sterilisation of the joint space before placing the new hardware.

DAIR (debridement, antibiotics and implant retention) procedure, is a treatment during which the prosthesis is not replaced, and sometimes the liner (or: spacer) is. During this procedure, the idea is to perform debridement (remove affected tissue) and clean the affected area using lavage. During lavage, a device (Zimmer Biomet offers this device: Pulsavac Lavage) pulses a liquid (often saline or betadine) onto the affected area, which cleans it. At the same time, that liquid and the debris is being sucked away. An amount of 6 litres of liquid is no exception. After everything is cleaned up, the patient will be stitched up again, and the surgeons will at a later time evaluate if the infection is succesfully treated.

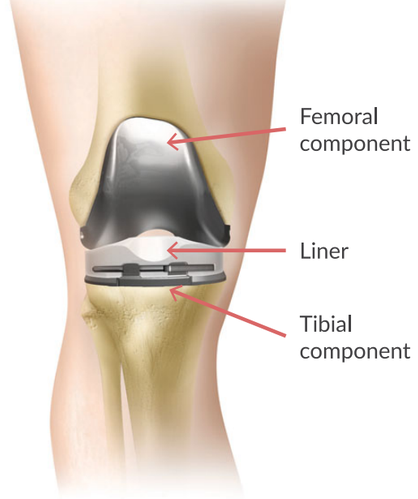


Figure 16. Parts of a primary total knee prostheses

Decision trees & tools

Some decision trees for MD teams currently exist, but receive the same critique as the guidelines: lacking in depth. This is not surprising since the upside to superficiality is speed and simplicity. The considerations that have to be made between depth and completeness as opposed to speed and simplicity are difficult and sensitive. The right balance has yet to be found. Some decision trees are also designed as (digital) tools, to help the medical staff. These tools are discussed in Appendix C.

Finally, it is again important to note that the decision phase does not stop before treatment begins. Some decisions can only be made during the operation and not in advance. These decisions often require expertise and experience of the surgeon. The reason they can only be made intraoperatively is that the required information for the decision is only available then - like amount of affected tissue, degree of bone degradation, etc. (Springer, Parvizi, 2013) For this reason, a lot of tools (of which much is provided by Zimmer Biomet) are present in the OR.

Treatment

From interviews can be concluded that protocols and traditions differ per hospital/area/country. Where in one hospital it may be normal to have zero door openings during surgery, OR staff wears protective suits and the area of laminar flow is respected at all times, another hospital may have 10+ door openings during one surgery, OR staff doesn't even wear surgical masks and laminar flow is believed to have no effect on sterility. (Firm specialist, personal communication, March 2018) Educating widely and connecting surgeons from all over the world may be helpful in improving this situation.

Prevention

From research can be concluded that there are a lot of measures that can be taken to (partially) prevent the occurrence of PJI. In essence, the knowledge for optimal prevention measures exists. (Froimson et al, 2014; Mauerhan et al; 1994 Meehan et al, 2009; Shahi, Parvizi, 2015; Tanner et al, 2011) The problem, however, exists of several elements. The first is finding out how to convey these measures to as much surgeons and involved staff as possible, and how to teach and ensure the implementation of the measures. Secondly, universal

consensus needs to be found on what measures are actually truly preventive. The ICM 2018 will help with this. Thirdly, discoveries of new and improved measures and development of current measures will take place. How can these developments be propagated? Finally, as stated before, not every OR team/hospital carries out preventive measures equally strict.

Patient care

Currently, little is done about providing patients with information on how to properly take care of themselves after having had surgery. Furthermore, patients that undergo a two-stage procedure, experience a long waiting period in between the stages.

Abstractions

Mental health

From interviews can be concluded that PJI is an intrusive illness, the majority of patients that experience it, have their lives ruined, become depressed and/or will never return to their old (physical, but at times also mental) self. (Resident surgeon, personal communication, May 2018; senior house officer (ANIOS), personal communcation July 2018) These patients report a loss of independence and a negative mental outlook. (Perry et al, 2012)

Lack of data

Research and interviews show that there is a shortage of data when it comes down to properly designing, developing and continuously improving guidelines, methods and decision trees. (Orthopaedic surgeon, general secretary joint infection society & renowned PJI expert, personal communication, March 2018; Orthopaedic surgeon & renowned PJI expert, personal communication, April 2018)

Reflection

From interviews and literature can be concluded that even the 'best' hospitals, still experience infections. (Zimmer Biomet account manager, personal communication, April 2018) The hospitals that report the best numbers on incidence of PJI do not report a number of 0.0%. A lot of hospitals obviously also exist that report far worse numbers than these hospitals. This problem may be caused by the fact that hospitals lack in opportunities for reflection.

"Even the 'best' hospitals still experience infections"

Knowledge gap

Interviews have shown that quite some surgeons exist that have a large amount of expertise on the subject of PJI. However, there are far more surgeons that lack the proper knowledge to optimally diagnose and treat patients suffering from PJI. (Orthopaedic surgeon, general secretary joint infection society & renowned PJI expert, personal communication, March 2018; Orthopaedic surgeon & renowned PJI expert, personal communication, April 2018) It is not the case that they know little, they could however profit from having more knowledge on the subject.

Rare problem

PJI, though increasing in occurrence and very intrusive to the patient, is still a relatively rare problem. (Orthopaedic surgeon, personal communication, March 2018) This in itself is also part of the reason for some of the problems that are mentioned, as lack of knowledge, lack of data, methods still being in development, etc.

Own experience

Interviews have clarified that next to the presence of guidelines, decision trees and other tools, a lot of surgeons trust most on their own experience: they often base their decisions primarily off of it. (Zimmer Biomet employees, personal communication, April 2018)

Recognition

When the patient first presents itself with this problem (though he/she probably does not know at that moment that an infection is present), a surgeon or general practitioner will assess the patient. At this point, it is crucial that surgeons, but also GPs, are aware of the criteria necessary to properly diagnose the patient and are able to recognize PJI.

Conclusion

Prosthetic joint infection is a complication that is devastating for the patient. It strains the patient and puts a large financial burden on the healthcare system. People's lives are ruined by these infections, they become depressed and their physical state never returns to even close to what it once was. The number of infections is predicted to grow, which also means that the economic impact will only rise.

In the current situation, surgeons often base their decisions on personal experience. Decisions are also made based on the opinions of experts, however, clear differences exist between those opinions. There is, thus, no clear global consensus. This results in surgeons taking a lot of different paths to manage a case of PJI, as visualised in Figure 17. Because of all these different paths, the outcomes may vary as well, but don't necessarily have to.

PJI is a complex phenomenon for which a lot of risk factors exist. These risk factors may be preoperative, intraoperative and postoperative or can be classified in several other categories. Knowledge on these risk factors is ever growing, though plenty of doctors throughout the world unfortunately come short on this knowledge.

Apart from risk factors, the complexity of PJI expresses itself in diagnosis, for which multiple routes exist and keep developing. Widespread knowledge lacks here as well, and no single clear guideline exists. The same goes for decision-making, where guidelines differ and do not always build on eachother, but move into separate directions.

Furthermore, the treatment of PJI may be the most complex phase of all. Doctors miss tools that help them reflect on their own surgeries as well as tools that help them learn from other surgeons around the world.

Finally, prevention is a crucial topic. The global society is still learning a lot on how to prevent PJI properly, and even the 'best' institutions report a number for the incidence of PJI higher than 0%. Broad knowledge on prevention sometimes lacks and there are little ways for doctors to learn from one another and themselves.

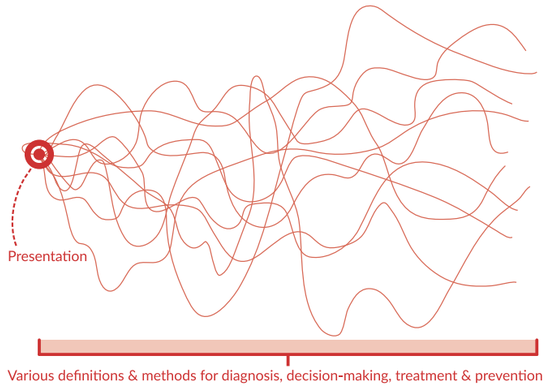


Figure 17. Surgeons' pathways to manage a case of PJI differ throughout the world, and the outcomes may vary

Surgeons, resident surgeons, nurses, firm specialists, Zimmer Biomet employees, PJI experts and the designer seem to agree on several main problematic themes:

- Knowledge gap
- Difficulty in decision-making
- The best hospitals still experience infections
- Different pathways, methods, terminology, etc.

DESIGN IMPLICATIONS

This chapter has certain implications on the final design and the process towards it. These implications are summarised below.

Educate

Experts on PJI exist throughout the world. However, most of the surgeons are not experts on PJI. Offering a tool that allows surgeons, residents, nurses and other relevant personnel to be educated on all elements of PJI would improve the overall management of cases of PJI greatly.

Advise

Because of the complexity of PJI, it is limited to experts on the field to be able to make all decisions correctly, based on their own knowledge. Therefore, it is crucial to offer all surgeons a tool that advises them on the proper decision, fitting the particular case.

The International Consensus Meeting of July 2018, has brought forward an extensive document that holds recommendations as to how to manage a case of PJI. These recommendations have been shaped by many experts on the subject from all over the world. The contents of that extensive document should be used in a user-friendly tool that advises its users on diagnosis, decision-making and treatment.

Connect

Whereas the content of the tool may start off based on the outcomes of ICM 2018, the knowledge on this subject is still far from complete. Diagnosis and treatment methods shall be improved, risk factors and prevention measures will be researched further, redefined or defined more precisely. In order for this knowledge not to go to waste, and the pathways of surgeons all across the world not to deviate from each other, a tool can be offered that allows these surgeons to connect with each other, share findings and collectively build towards optimal PJI management.

Per country, per hospital and even per surgeon, the preferred way to manage PJI differs. Roughly all contacted stakeholders believe that connecting doctors from all over the world can not only aid in allowing them to be on the same page, but can also - perhaps more importantly so - facilitate an optimal development of solutions to the problem at hand.

Reflect

Even though most patients experience TJA without a resulting infection, it unfortunately still occurs. Offering surgeons the capability of not only building on the experiences of other doctors around the world, but also learning from their own experiences, can help them improve greatly on how they manage a case of PJI. Giving surgeons a tool that allows them to learn from their mistakes and build on what they do right, can improve their outcomes.

PROCESS GUIDELINES

These guidelines are intended to aid in the execution of an innovation process in the medical world. They can be applied by anyone who is executing such a process. The guidelines are primarily created for students, but can also be applied by, for instance, an academic researcher or a business.

Contact

When trying to establish contact with stakeholders, for instance to acquire information on a subject, to pick their brain to acquire insights or to hear their views on some of your thoughts, it's important to consider a few things. Medical staff, and surgeons in particular, are extremely busy. Their days are filled with surgeries from 8 am till 6 pm, after which they often still have meetings to attend or other work to finish. It is therefore crucial to keep your request as a researcher as concise as possible, and be very flexible in your suggestions on meeting. Another aspect that is important in this regard, is that your request is convincing enough for the other party to accept, and give you part of their time. To achieve this, it is important to create goodwill: you either have to have something to offer that provides them with an advantage, you have to be able to help them progress, or your proposal has to be on a subject that is particularly interesting to the other party. It either has their interest greatly, or they are convinced by the added value of your suggestion. This means that your message needs to be specific enough to enthuse the stakeholder, yet concise enough to retain their focus. To convey your message in a convincing way, it is recommended to use visuals that explain the situation and trigger the recipient.

If, for some reason, you lose contact, you should not take it too personally. It is possible that political and hierarchical relations have caused this, and it is futile to try to fix this. Available time can be another factor to cause it. Subtle reminders can be sent, but more than once or twice will not aid your image and your attention is better aimed elsewhere.

Working culture

The medical world is a hierarchical one, which allows experience to play a crucial role in caring for patients. The experience of medical staff is vital to providing the optimal care that patients require. It is also very important in diagnosing, treating and making decisions. A lot of the decisions made are based on years and years of experience. The aforementioned hierarchy is important to take into account in all matters of your innovation process. Professors and surgeons are looked up to and they (will) have the last word in a lot of scenarios. This is crucial to consider when making contact, maintaining contact, having conversations and meetings, visiting the OR, facilitating sessions and designing products and services.

DEFINE

Introduction

This phase has already slightly started during emphasis; you automatically create an image in your mind of what needs to be done. Furthermore, the creative sessions that have been held include elements that are part of the 'Empathise' phase, but also (more) elements that belong to the 'Define' phase.

This chapter discusses opportunities that are deduced from the insights shared in the previous chapter. Afterwards, a design brief is coined that defines the scope: the problem, relevant stakeholders, solution direction, design goal and added value. Subsequently, several elements of the design goal are researched and ideated on further. Finally, validation of these and other elements of the design brief is discussed.

Opportunities

To define opportunities an 'analysis on the wall' (Stickdorn) has been performed, the results of which will be discussed here. For more information on this process, you are referred to Appendix T.

The analysis on the wall has firstly resulted in a map that shows insights, problems and opportunities. It furthermore shows relevant stakeholders and themes (which have been decided on during the process itself) as well as links between all elements. This map is visualised in Figure 18.

Schools of thought

It appears that it would be wise to adopt the guidelines resulting from ICM 2018, as the content for the service/tool, if applicable.

The guidelines from the meeting would be a terrific starting point. However, since current methods develop and new and improved methods may arise, it is important to provide a medium that allows the guidelines to be constantly optimised.

"A connecting medium allows guidelines to be constantly optimised and consensus to be reached"

Providing a connecting medium that allows this, also offers the possibility of connecting surgeons all over the world; resulting in quicker improvement of methods, possible movement in the direction of consensus and wide belief in and implementation of this consensus.

Intraoperative measures

The implementation of these measures differs greatly per area, providing much space for improvement.

"There is much space for improvement concerning the implementation of preventive intraoperative measures"

Recognition

It is crucial that surgeons, but also GPs, are aware of the criteria necessary to properly diagnose the patient and are able to recognize PJI. Educating surgeons and, more importantly so, GPs with this goal in mind can be very helpful.

Treatment

An opportunity is present for a system to be present during treatment. This could be a system that informs the OR staff on what measures to execute. This can be interpreted/executed in two ways: firstly, the system may take the shape of a roadmap/pathway that guides the OR staff through the process of TJA. Secondly, the system may take the shape of a checklist/guideline that informs the OR staff on preventive measures at the moment they are relevant.

Prevention

Allowing surgeons and involved staff to easily keep up with developments of current preventive measures and/or aid to them, is highly desirable.

Providing hospitals with a tool that enforces and ensures the use of preventive measures is desirable. This should be done in a way that does not restrict, but rather help

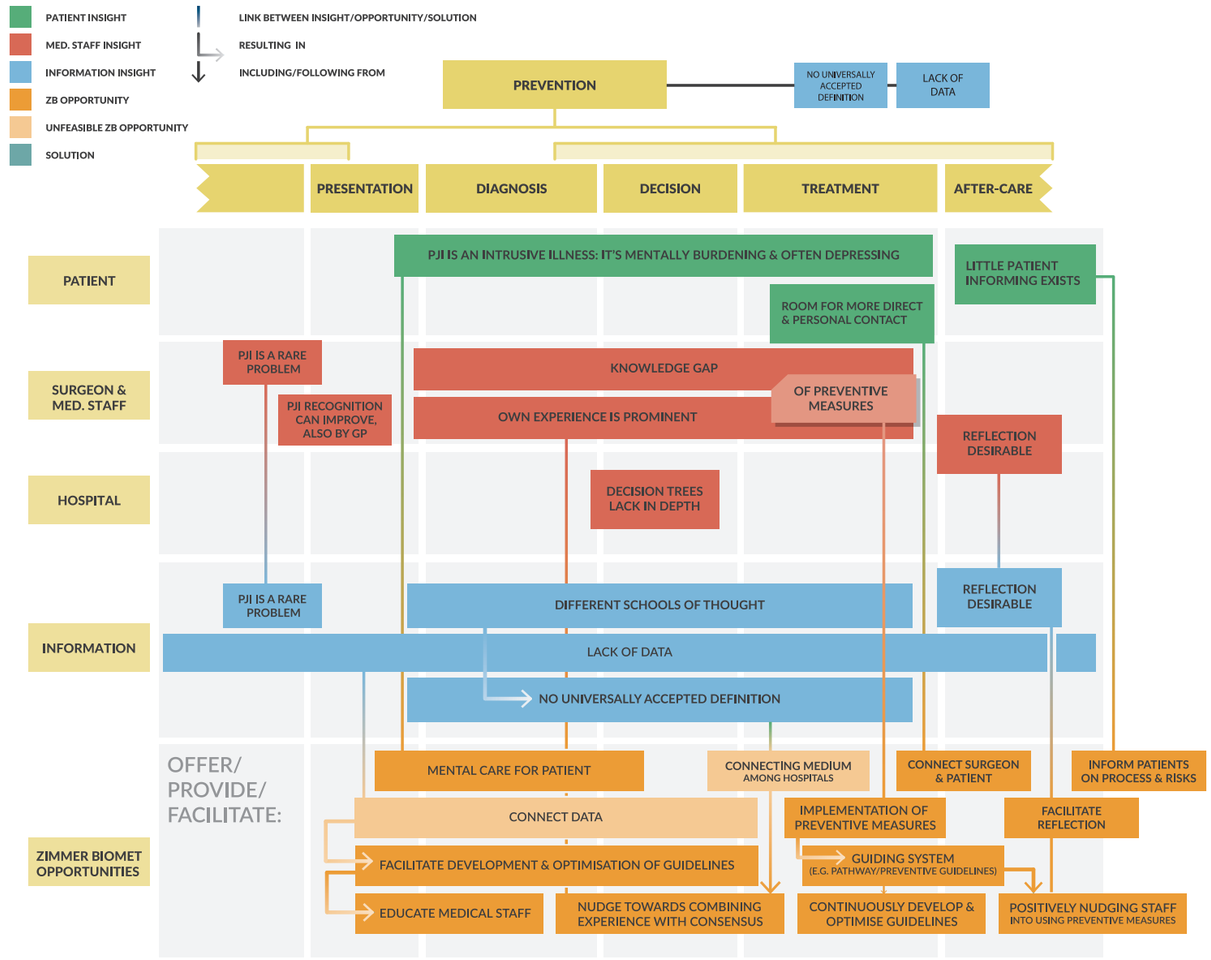


Figure 18. Result of analysis on the wall, including insights, problems, opportunites, relevant stakeholders and themes and the links between them

the OR team in positively nudging them into using the preventive measures.

"Providing hospitals with a tool that positively nudges the OR staff into using preventive measures is valuable"

Patient care

An opportunity presents itself for providing personal care and information (or even, education) to patients. After patients have had surgery, it is advantageous for them to be informed about how to take care of themselves and what to do in the future (e.g.: inform surgeon/dentist that you've had a total joint arthroplasty and/or what your antibiotic programme was).

Another opportunity arises that concerns the mental well-being of patients that have an infected joint. First of all, patients that undergo a two-stage procedure (for more information on what a two-stage procedure entails, you are referred to the 'Treatment options' section on page 24), experience a long waiting period in between the stages. Providing a connection during this period between surgeon and patient would be advantageous for both parties (Orthopaedic surgeon, personal communication, March 2018): the surgeon can more easily and directly track the patient's progress, the patient can be informed on his/her progress and what is happening in the process and both parties lose less time. Secondly, providing a platform of which the main goal is to keep the patient mentally healthy is desirable. PJI is not only physically, but also mentally very intrusive. (Perry et al, 2012) Patients that experience it, do not return to the physical state they were in before and often also have trouble with recovering mentally. A medium that aims to counteract this degradation of mental health can be very helpful.

"Providing a platform of which the main goal is to keep the patient mentally healthy is desirable"

Lack of data

An opportunity is present for a system to answer to the lack of data: by connecting surgeons all over the world, combined they can build on and develop optimal methods for the management and prevention of PJI.

Reflection

Providing a service that allows for reflection, may offer a way to detect areas of improvement and thus decrease the occurrence of infections.

Lack of knowledge

An opportunity is present to improve the management and decrease the occurrence of PJI by informing and/or educating these surgeons, resident surgeons, assistant doctors and supporting staff. The use of guidelines and decision trees can be applicable here as well.

Own experience

An opportunity is present for a shift towards combining this experience with trusting and using a collectively formed consensus (on diagnosis, decision, treatment and prevention). An appropriate way to achieve this is by positively nudging* surgeons and relevant staff into changing this habit. This will probably be no easy feat, though the results can be very impactful.

Nudging is a term for altering people's behaviour, in order to help reach a certain goal. Nudging does not enforce something on a person, nor does it give you only one option. Placing (healthy) food at eye-level is a good example of (positively) nudging. (Thaler, Sunstein, 2008)

Business model

In the service to be designed, there is room for products to be pushed to users of the service. It can also be a channel for 'free' feedback on other products of the company. Users of the service may be persuaded to vouch for those products to their superiors. It is unlikely that the end-users of the service will be responsible for making such purchase decisions, however, those who are do consult these end-users (on their experiences). (Zimmer Biomet sales manager, personal communication, June 2018) A possible way to set forth the business model is by offering it for free, though with the promise that the customer exclusively buys their products from Zimmer Biomet (exclusive supplier agreement). More information on this aspect is given in the chapter 'Validation' on page 83.

Validation

Validation with several stakeholders (N = 5) has offered valuable views on the insights of the designer. Constructive dialogues have led to a more concrete view of a possible solution in the designer's mind.

Connecting data

This chapter has several times mentioned opportunities to connect surgeons around the world, provide a connecting medium and connect data. Since the designers deems this solution direction intereseting, it has been validated thoroughly, which will be discussed in the following section.

It is important that correlation (and if possible causation) can be found between risk factors, preventive measures and diagnostic values and the occurrence of PJI. To achieve this it is crucial to gather data and reflect on it. This is something that can be done a lot more, but for which reluctance is present. (Senior house officer (ANIOS), personal communicaton, June 2018) This reluctance is understandable, since gathering this data would mean adding extra administrative tasks to the work schedule of an already busy surgeon/assistant doctor. Making this action as easy and quick as possible is therefore crucial. It is also very important to convey the value of performing the action: it needs to be clear and agreed with that executing these tasks will significantly aid in the optimisation of managing a case of PJI, and its decrease in occurrence.

Each surgeon will respond differently to this idea of gathering data, but all will consider its value on three elements, between which there needs to be a balance: time (input), effort (input) and added value (outcome). (Zimmer Biomet sales manager, personal communication, June 2018) This is depicted in Figure 19.

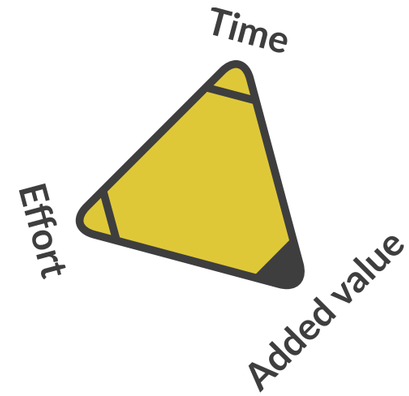


Figure 19. Balance between time, effort and utitlity, concerning reflection on data.

Allowing such a connecting system to indeed require as little effort and time as possible can be achieved by linking it to an already existing system that surgeons (are required to) use. Two feasible options (in the Netherlands) are linking it to the patient record, which the surgeon is required to update after a surgery, and linking it to the LROI, which is a mandatory registry for all orthopaedic implants.

Furthermore, if such a system is not imposed on surgeons/hospitals, it is very likely to be seen as too big a (time- and cost)investment. Therefore it is valuable to have it be enforced by government/law. To achieve this, several parties are required to be convinced. Firstly government, since it is to impose this system on orthopaedic departments and surgeons - the Dutch Health Care Inspectorate would be a good candidate. (Zimmer Biomet sales manager, personal communication, June 2018) However, government will only be convinced if hospitals and surgeons vouch for the idea and see its value. Therefore, hospitals (Boards of Directors) need to be convinced as well (also since they are to impose the system on its surgeons). Finally, as stated, surgeons need to be convinced, also since they are to partake in the system firsthand.

Setting this all up with merely the promise of value, will be impossible. It is therefore imperative that the previously mentioned parties can be convinced by a (or several) practical example(s). It is thus necessary to find a (group of) hospital(s) that sees the value of this idea and

is willing to partake. In time, the system will demonstrate its value and more and more hospitals will be willing to join.

The direction explained in this section will be able to provide value to hospitals individually. If and when a growing group of hospitals is partaking in the system, a new opportunity arises: The exact same system can now be used to link the datasets of the hospitals (which all consist of the same datapoints). Linking them into one large database provides countless opportunities to deduce conclusions that will aid in the optimisation of guidelines and decision trees concerning diagnosis, treatment and prevention. Examples of correlations that can be found are patient groups with higher risk for infection, added value of certain preventive measures and efficacy of diagnostic methods. The system can shed light on a lot of current uncertainties. It can also determine what methods used are best and conclude international discussions. Finally, it can function as a feedback loop and over time continue to optimise guidelines as new improved methods are being introduced and used.

Different surgeons will respond differently to this endeavour. There will be surgeons that are eager to aid in shaping an optimised consensus, by providing their stake. There will also be surgeons that may want to hold on to their data or believe that their experience is more valuable and want to do it themselves. This second group is to be persuaded by the optimised consensus that the first group is working on. For all surgeons, it is yet again important that there is balance between time, effort and added value, as previously shown in Figure 19.

It is paramount that the data within this system is exclusively used to aid the goal of optimally managing cases of PJI and decreasing its occurrence, and not for other (commercial) goals. The European law called GDPR would obligate Zimmer Biomet to mention these goals to users. Such secondary (commercial) goals will deter necessary users.

Validation with Zimmer Biomet employees has resulted in the conclusion that this second endeavour of linking data of hospitals is feasibe only to a limited extent. (Zimmer Biomet Senior Managers, personal communication, June 2018) Linking data between hospitals has been a problem for a longer time and requires a lot of time and steps to solve. This goal is certainly desired to be reached, however, does not fit the timeframe of the scope of this project. The term for this endeavour to be succesful is closer to 20 years than 5 years. (Zimmer Biomet Senior Manager, personal communication, June 2018) It is therefore decided to no longer pursue the solution direction of connecting data between hospitals.

Communicating knowledge

The communication of knowledge has to be executed with consideration. In order for the knowledge to be accepted into the current goings of the process, it needs to be presented in such a way that fits that current process. It is crucial that it does not feel as though the knowledge is imposed onto the staff, rather that it complements their current process. This validation is supported by a Zimmer Biomet team that works on the progress of this project internally.

Implementation

In order to have the implementation of the design be succesful, it needs to be performed in a top-down fashion. Firstly, the responsible hospital organisational body (e.g. Board of Directors) needs to be convinced of the added value, after which the department responsible for implementation and the surgeon partnership need to be convinced. Finally, all members of staff that will be using the tool will be convinced through education, information and support from higher up. Again, this validation has been supported by a Zimmer Biomet sales manager and marketing director and other ZB staff part of an internal team dedicated to developping a service to aid in the management of PJI.

Recommendations

Aiding the patient can be done in several ways. Firstly, the patient can be helped during aftercare: by providing patients with knowledge of properly taking care of themselves, the chance of a re-introduction or new presentation of infection can be minimised. The medical rehabilitation process can furthermore be made less impactful. Seccondly, the mental well-being of the patient is under a lot of pressure during the entire process. Helping the patient in coping with the situation and informing the patient in order to better understand and process the mental impact of this infection, can help greatly. It is recommended that more research in this field is done by interviewing patients and testing concepts with them.

Design brief

The following page shows the design brief that is formed out of the analyses and their validation.

DEFINE

DESIGN BRIEF

Introduction

This design brief defines what needs to be designed to aid in the management and decrease of occurrence of PJI. This is done by concisely giving an overview of the problem at hand, defining the stakeholders for which the design is meant, offering a solution direction and defining the overall design goal.

Problem definition

To summarize and bring focus to the core problem abstracted from all insights, this section will bring a concise definition.

Due to newly available consensed knowledge and a lack of data, a variety in treating PJI and a knowledge gap among medical staff exists. This lack of data, on its turn, is due to a lack of opportunity for data reflection and inter-hospital connection of data. This is visualised in Figure 20.

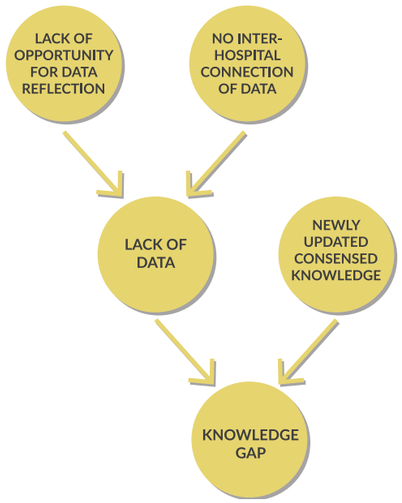


Figure 20. Causative relation between the levels of the main problem concerning the management and prevention of PJI

Main stakeholders

The main stakeholders that are troubled by this problem are the patient, surgeon, MD team, OR team and hospital. The solution direction that is defined in this design brief, offers direct help to the surgeon, MD team and OR team, as depicted in Figure 21.

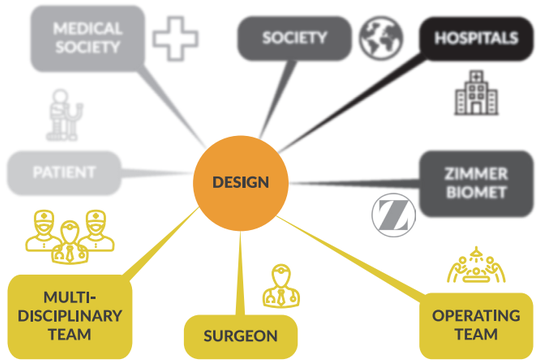


Figure 21. Stakeholders to which the solution will offer direct help.

Solution direction

Offering knowledge by offering opportunity for data communication and offering education, based on consensus. This education is at the same time being optimised by participants, by connecting data and experience of a (group of) hospital(s).

A barrier that may arise during this endeavour is the willingness to cooperate of surgeons and hospitals. Another difficulty that presents itself is how to design this solution in such a way that the users don't feel as if the knowledge is imposed on them, but rather that it feels natural, fits within the process and allows for combination of own experience and this knowledge.

Goal

To design and implement the above-mentioned solution in such a way that ensures extensive participation. The aim is to design a solution that is intuitive and fits the medical world. The goal is to find a way to valuably communicate the knowledge and to implement the system in such a way that ensures adaptation. The design needs to fit within the care and working processes and needs to be able to be implemented. Positively nudging users into using the presented knowledge is aimed for. The relationship between problem, solution direction and design goal is visualised in Figure 22, in which three main solution directions are proposed. Of these directions, the first one: offering data connection, is out of this graduation project's scope. For this reason, the direction is not elaborated on, nor is there a design

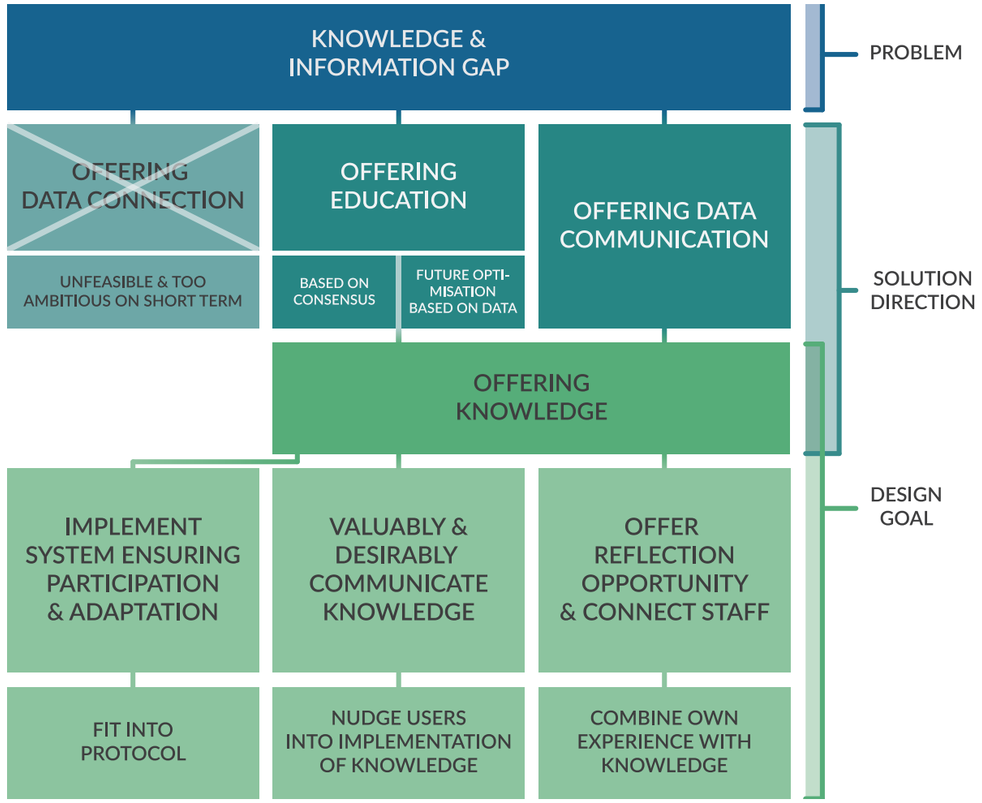


Figure 22. Relationship between problem, solution direction and design goal

goal that is linked to it. Things to find out for the chosen direction are how to:

- Communicate knowledge
- Connect medical staff
- Offer reflection opportunity
- Educate medical staff
- Fit into protocol

Added value

The design will help surgeons and other medical staff all over the world to better educate themselves on how to manage and prevent a case of PJI. Guidelines, preventive measures, decision trees and more can be continuously optimised by analysing data.

Zimmer Biomet will provide a service to numbers of (new) clients that tackles a big societal and hospital-internal problem. Providing this service is desired to boost the brand image and customer retention and make Zimmer Biomet the preferred supplier. It will furthermore allow space for product placement, provide a network to test and push products and give way to the possibility to act as a feedback channel for the company. Zimmer Biomet can offer the service with an exclusive supplier agreement. (Tang, 1999)

DESIGN IMPLICATIONS

This past chapter also has certain implications on the final design. These build on the implications from the previous chapter and demonstrate the progress of the design process towards the final design. These implications are summarised below.

Knowledge

A knowledge gap concerning optimal management, treatment and prevention of PJI exists. This gap exists between what is known by a small portion of surgeons & experts and a large remaining segment of surgeons and relevant staff. It is key that the solution aims to bridge this gap.

Communication

Communication is a principal element to consider for the development of the design. Firstly, it is important to ensure fluent communication among staff members. Secondly, it is important to ensure fluent communication between staff members and designed concepts. Finally, it is important to ensure fluid communication between staff members and the knowledge that needs to be communicated. For this last matter, it is firstly crucial that the users of the concept understand the knowledge that is provided to them. It is furthermore essential that this knowledge is presented to the users in such a way that they will not be averse to it.

Adaptation

To ensure adaptation of the concept by the users and to achieve their maximum participation, several factors need to be considered when developing the concepts. First of all, the design needs to fit within the care and working processes and needs to be able to be implemented. Furthermore, it is vital that the presented knowledge can be combined with the staff's own experience. A lot of decisions are based on this experience, thus presenting the knowledge in a compatible way that allows for combined use of these elements is highly desirable. Lastly, it is advantageous if the designed concept nudges the users to apply the knowledge, in contrast to the knowledge feeling like it is being imposed on them.

PROCESS GUIDELINES

These guidelines are specifically intended to aid in creative facilitation in the medical world. This is an important element of an innovation process. (Stickdorn, 2018) The guidelines are primarily created for students, but can also be applied by, for instance, an academic researcher or a business.

Creative facilitation

When following an innovation process, you are very likely to organise sessions that include the stakeholders of your assignment. During the preparation and execution of these sessions it is important to consider a couple of matters. You should know who will be attending and what their roles are: the hierarchical relations are important during such a session. Keep in mind that the participants are likely to have a more practical approach than you're used to: count on less 'out of the box' thinking, more existing solutions and substantiations. Try to find a way to cut through this. You can, for example, let people attend of whom you know they are creative thinkers, to trigger the other participants. Also, the participants may need more guidance: give examples, push them into directions, help them, 'pull' the ideas out of them. You might need to speak more than you are accustomed to. Furthermore, the course of the sessions can be approximately split up into two scenarios. These scenarios and their corresponding guidelines are outlined below.

Introvert and/or passive participants

- Give little pushes in the right direction: 'tease' directions to ideate in
- Devise analogies
- Simplify used methods
- Give more elaborate explanations
- Take participants by the hand
- Ask a lot of questions
- Use methods to further expand on presented ideas and to think of variations
- First to last resort: nudge participants towards solution directions already thought of
- Last resort: nudge participants towards ideas already thought of

Active participants bring innovative ideas

- Speak less
- Let participants be more in control themselves
- Use creative methods
- Let creativity flow: accomodate their creativity
- Go along with presented ideas and ask questions
- Challenge the participants
- Use methods to generate large quantities of ideas
- Use methods to further expand on presented ideas and to think of variations

On the following page, the design goal is repeated in a summarized manner, in order for it to be as clear as possible and to ensure it is top of mind as we move into the next chapter, 'Ideate'.

DESIGN GOAL

The goal is to *communicate* consensed *knowledge* to staff, make data easy to *communicate* among them and *educate* them.

IDEATION & CONCEPTUALISATION

Introduction

This chapter discusses the creation of ideas based on the validated solution directions of the previous chapter. It furthermore presents three concepts, discusses the evaluation of these concepts, the decision of which concept to develop further and this further development.

As stated in the previous chapter, the direction in which solutions will be sought for is offering knowledge. The design goal that needs to be tackled consists of: how to communicate this knowledge; how to nudge users into implementation of this knowledge; how to combine own eperience with this knowledge; and how to implement the system ensuring participation and adaptation. A difficulty that presents itself is how to design the solution in such a way that the users don't feel as if the knowledge is imposed on them, but rather that it feels natural, fits within the process and allows for combination of own experience and this knowledge.

Goal

To design and implement the above-mentioned solution in such a way that ensures extensive participation. The aim is to design a solution that is intuitive and fits the medical world. The design needs to fit within the care process and needs to be able to be implemented. Positively nudging users into using the presented knowledge is aimed for. The goal is to communicate knowledge to staff, make data easily communicable among them and educate them.

Methods

To find practical and implementable solutions that answer to the design goal, several methods are used. More extensive information on methods used can be found in Appendix L and U.

Ideation session

The first methods that are used took place in an ideation session with multiple participants. During this session the participants used the 'How To?' method (Stickdorn, 2018) and the '10 plus 10' method (Stickdorn, 2018) to come up with ideas. The participants were stakeholders of the project. A more extensive description of the session can be found in Appendix L.

Analysis on the wall

The 'analysis on the wall' (Stickdorn, 2018) that has been used in a previous state of the project, is used again at this point. It has resulted in solutions which have been found by utilising the overview that the map brings. These results are also linked to the problem, insight and opportunity they are meant to resolve. This can be seen in Figure 23. This method has been the most fruitful of all, yielding the most results.

Other

Other methods that have been used to spark creativity include comparing the situation to different sectors and approaching the ideation through a relevant theme, like 'communication', 'information', or 'culture/routine'. The designer has also applied the method "Who, What, Where, When, Why and How" (Curedale, 2012; Van Boeijen et al, 2014) This method created a deeper understanding of what the locations are where specific problems occur and how this relates to the respective phase of the care pathway during which that problem occurs. For instance, a lot of the problems that occur in the treatment phase, can not only be solved in the treatment phase, but also at an earlier stage. Besides, when a problem could be solved in multiple phases, it's interesting to compare the value that each solution can bring in relation to the time and effort (and money) it costs to execute and/or implement that solution. Dr. Justin Barad for example states that much smaller investments in global training programs result in a much larger impact on patient outcomes, than much larger investments in prosthesis optimisation. (LaWell, 2018) Next to these, the method also provided insights into why the problem is present and why no (complete) solution is yet present. More information on this method can be found in Appendix U.

Expert discussions

With the new-found information, opportunities and ideas, discussions with experts are again very helpful. Experts give their view on the directions in which solutions are being sought after and how these can be tweaked. Furthermore, they are triggered by the solution directions thought of by the designer, which causes them to provide concrete feedback on which the designer can act. Finally, hearing the ideas and solutions the designer has come up with so far, primes them to think along, give feedback and share their opinion and views on how to further develop these ideas.

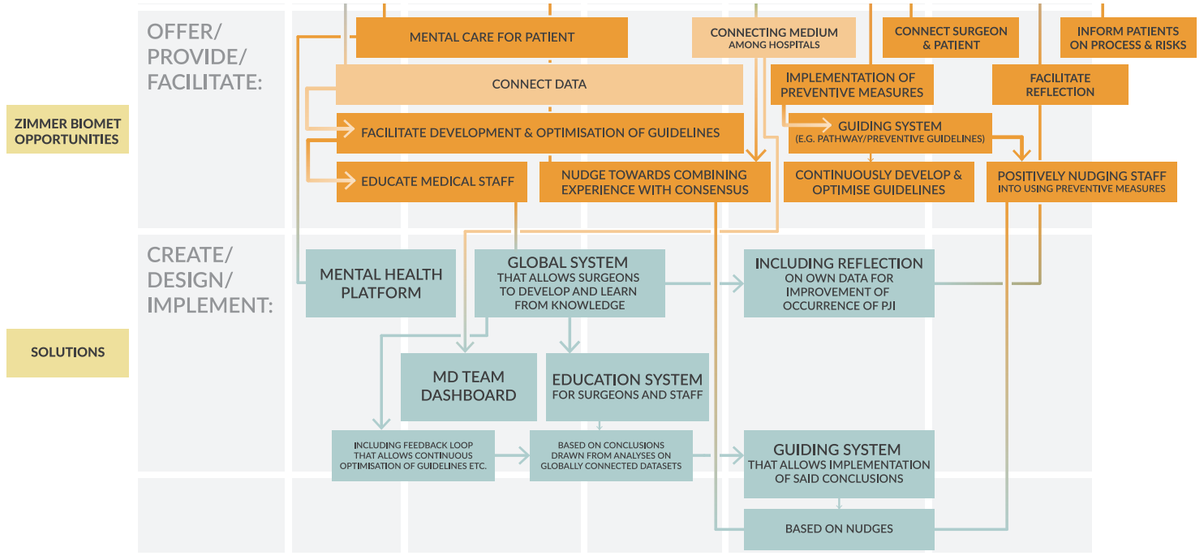


Figure 23. Result of analysis on the wall, including opportunites, the solutions deemed most valuable and the links between them. To see the rest of the analysis including the insights, problems and the relevant stakeholders, you are referred to Figure 18

These discussions resulted in several insights. Zimmer Biomet employees stated that it is important to categorise the results of the ICM 2018, in order for them to be used in one of the suggested systems. It is furthermore important that for each country/area, optimal treatment differs. It is vital to make advice on treatment adaptable to a certain area. The optimal way to achieve this, is by co-developing such systems with end-users of the area you are aiming to implement it in. (Zimmer Biomet associate director, marketing director and senior manager, personal communication, June 2018).

Another discussion with an assistant surgeon resulted in the conclusion that the highest chance of adaptation will be achieved when the solution can act as a protocol or can be implemented into current protocol. The approach that should be taken to pitch the solution is top-down: starting with the institution that defines strategy, moving to department heads and finally reaching entire departments and end-users. (Senior house officer (ANIOS), personal communication, July 2018)

A discussion with an MSc Biomedical Engineering gave rise to the idea of informing the user of the chance of infection and/or during what step or phase that chance is present. Further research into the possibility of detecting certain bacteria is also recommended. (MSc Biomedical Engineering, personal communication, July 2018) Later research has shown that developments are being made in this area and devices that approximate this goal are close to implementation. (LaWell, 2018) Furthermore, the idea is posed to offer patients with self-test packages subsequent to surgery to detect arising infections. (MSc Biomedical Engineering, personal communication, July 2018)

Concepts

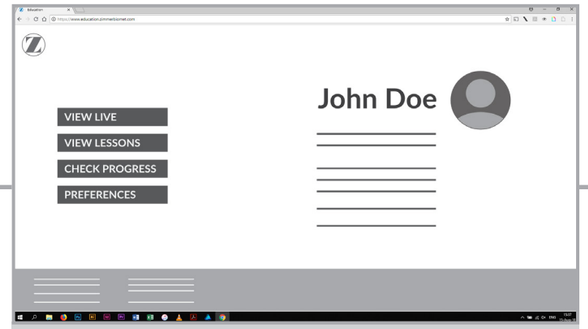
On the following pages, the concepts that have been deemed most valuable by the designer and the people that have given feedback are presented on concept sheets. The PJI care process, as introduced in Figure 13 on page 22, is shown in the top bar of each concept sheet. The phase during which the presented concept will be used, is highlighted. Subsequently, the concepts are submitted to an evaluation. This evaluation is based on the opinions of the designer, his mentors and several others such as an assistant surgeon, ZB employees and a student graduating for his BioMedical Engineering degree. It is also based on literature and other sources.

VR EDUCATION PLATFORM

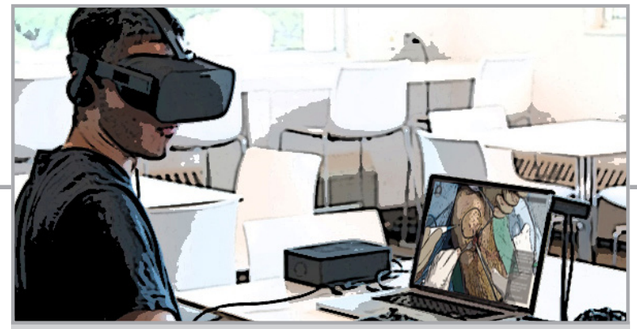
EDUCATION — PRESEN-TATION — DIAGNOSIS — DECISION — TREATMENT — AFTER-CARE

CONCEPT SHEET

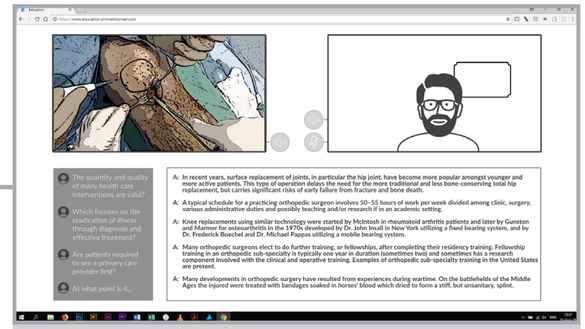
Being present in an OR during a surgery is the best way to learn for a (aspiring) surgeon. However, this is a time- and cost-consuming endeavour, so...



...this platform allows surgeons from all over the world to learn from experts on treatment and prevention of PJI. The surgeries can be viewed live, or can be re-watched at a later time.



The learning surgeon is immersed into the OR where the surgery is taking/has taken place, through the use of VR glasses. Virtual reality functionalities allow the learning surgeon to pratice instrument handling while watching, mimicking the actions of the teacher.



Students can ask questions during the session, the expert will take time after the session to answer questions. This will be recorded and made available for playback as well.

LEARNING FROM 'PRACTICE' DESIRABLE

This platform offers the 'next best' solution to learning in practice during OR visits

POV IMMERSION

Point of view cameras and virtual reality functionalities make this experience feel as close to 'the real thing' as possible

INTEGRAL PLATFORM

This teaching platform will go over all different kinds of treatment, infection, cause and levels of difficulty and complexity

TIME- & COST-EFFICIENT

Its usage requires a minimal amount of time-investment of both 'teacher' and 'student'

EXPERT TEACHERS WORLDWIDE

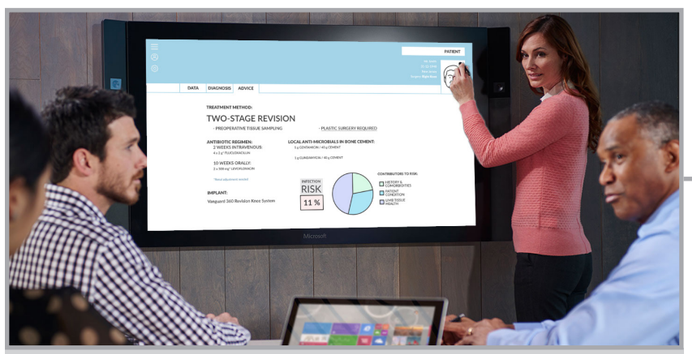
The platform allows experts from all over the world to share their specific expertise

A cooperation with Osso VR ("Osso VR", 2018) can benefit the development of this concept. The company shares the mindset of providing efficient education, or: "bridging the course-to-case gap". (LaWell, 2018) Virtual reality functionalities are well developed within the company and can help this concept to reach it's full potential.

MDT DASHBOARD

EDUCATION · PRESEN-TATION · DIAGNOSIS · DECISION · TREATMENT · AFTER-CARE

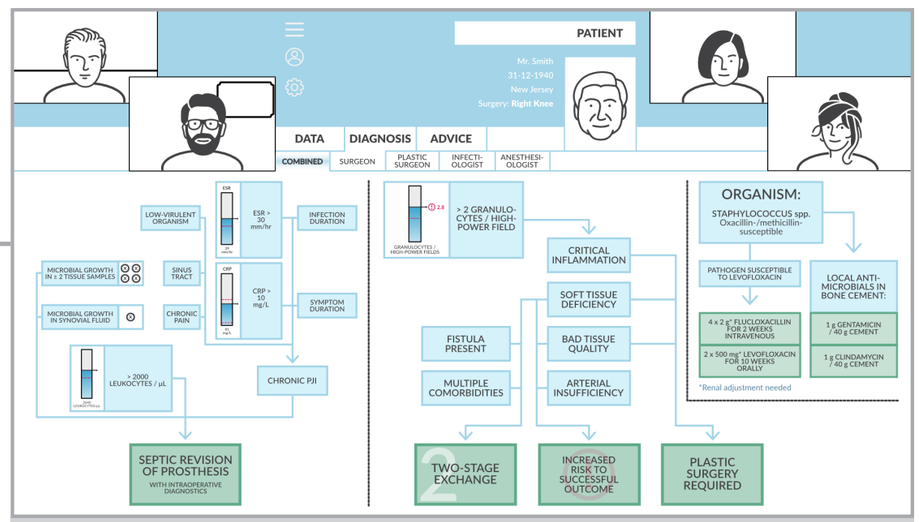
CONCEPT SHEET



The multi-disciplinary team (MDT) dashboard is usable prior to and during the MDT meeting. During the meeting, It improves mutual communication and supports the final decision that needs to be made for each case.

Each member has a dedicated interface, on which they can review data relevent to their expertise, prior to the meeting. They receive an advice concerning their discipline.

Algorithms based on ICM 2018 guidelines and relevant guidelines of each discipline, allow a diagnosis to be executed of all necessary data. This diagnosis results in both discipline-specific advice, as well as one final combined advice.



The dashboard provides visual aids to communicate the diagnosis, the advice and the data that substantiates it. It furthermore provides the option to let the meeting take place remotely.

MAKES DATA UNDERSTANDABLE

Visual aids help all members understand the substantiation that each member uses for their advice

USABLE PRIOR TO & DURING MEETING

Prior to the meeting, data and discipline-specific diagnoses can be reviewed. During the meeting, all data, (combined) diagnoses and advice can be consulted

IMPROVES MUTUAL COMMUNICATION

The dashboard helps in communicating arguments and substantiation and ensures that every element is discussed

TIME- & COST-EFFICIENT

Next to the improved communication, the fact that meetings can take place remotely saves a lot of time and thus cost

DATA > ALGORITHM > ADVICE

Data is linked from other hospital-specific data entry systems. With this data, algorithms based on relevant guidelines execute a diagnosis that results in a non-binding advice

A cooperation with ChipSoft ("ChipSoft", 2018) can benefit the development of this concept. The company controls ~70% of the Dutch market of hospital information systems (van Eekeren & van Zuilen, 2018) and allows the dashboard to be implemented and linked to all systems that contain necessary data for diagnoses.

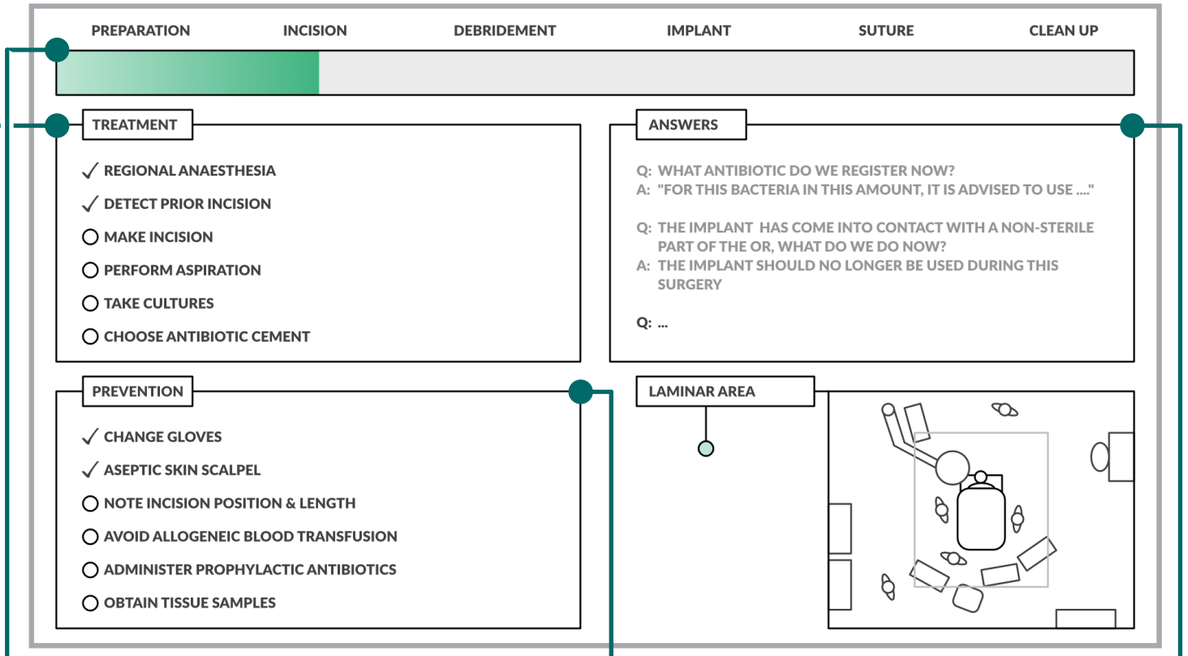
GUIDING SYSTEM

EDUCATION · PRESEN-TATION · DIAGNOSIS · DECISION · **TREATMENT** · AFTER-CARE

CONCEPT SHEET

During treatment, OR staff has to remember a lot of information and knowledge on their own. They can count on each other, if deliberation takes place. Newly taught protocols, methods and measures, also need to be remembered by heart.

The guiding system helps the OR team to follow the progress of the surgery, know what to do next, make decisions, remember important preventive measures and more.



DECISION-MAKING SUPPORT SYSTEM

This system's functionalities aid the OR staff in making the right decisions concerning treatment and prevention

SAFE & EFFICIENT SURGERIES

The system's reminders and support during surgery, allow it to transpire in a safe and effcient manner.

A cooperation with ChipSoft ("ChipSoft", 2018), or a competinghospital information system manufacturer, like Epic ("Epic", 2018), can benefit the development of this concept. It can facilitate the implementation of the system and allow it to be linked to patient data and other systems in the hospital

PROGRESS BAR

A progress bar at the top of the screen shows the phase the surgery is currently in

PREVENTION MEASURES

To achieve their optimal application, SSI and PJI prevention measures are listed in the relevant phase. This list scrolls along and checks measures that have been performed

TREATMENT PROGRESS TRACKER

The treatment progress is tracked in more detail, by checking the steps that have taken place and listing the steps that are to be executed next. This list scrolls along with the real-time progress of the surgery

VOICE-CONTROLLED Q&A

Based on voice-assistance technology - similar to Google Home - and the systems (ICM) database, questions about treatment steps and prevention measures can be asked, orally. Answers are then communicated, either orally or written

Concept evaluation

Each concept will be evaluated on its feasibility, viability and desirability as well as how well it scores on the three most important factors of the design goal: knowledge, communication and education. This evaluation is an abstraction and combination of opinions of the designer, his mentors and several others such as an assistant surgeon, ZB employees and a student graduating for his BioMedical Engineering degree. It is furthermore substantiated by literature and other sources.

VR Education platform

Feasibility

Zimmer Biomet already provides educational support, be it in a different form. (Zimmer Biomet Senior Manager, personal communication, June 2018) The required technology for this concept exists and is easily implementable (“Samsung Gear VR”, 2018; “360fly”, 2018), Oculus is even supplying their product for educational use. (Oculus VR, 2018) The creation of an online platform would be necessary, but this will not be a difficult task. (“Live Virtual Reality (VR) & 360 Degree Streaming Software”, 2018) One challenge to be considered is that the experts teaching the classes may need financial incentives to make time for Q&A sessions. (Zimmer Biomet sales manager, personal communication, August 2018)

Viability

The development and implementation of this concept requires a relatively small amount of effort and money. Similar systems with comparable goals exist and are in demand. (LaWell, 2018; “Osso VR”, 2018) The added value that it brings is relatively large: being in the OR will always be the best way of learning, this is however a close second that is far more time- and cost-efficient. This education program can replace other current methods of education which makes it valuable to spend money on. (Senior house officer (ANIOS), personal communication, August 2018; MSc Biomedical Engineering, personal communication, August 2018)

Desirability

Positive reactions have been given to this concept, by an assistant surgeon, a Zimmer Biomet marketing director, a Biomedical Engineering graduate and the mentors of this project. The platform can bring an added value that previously did not exist. Immersing yourself into the OR, while being able to not have to travel or occupy space in that OR and seeing everything from the surgeon’s point of view while receiving explanations is very opportune. (Senior house officer (ANIOS), personal communication, August 2018) It is furthermore noted by experts that “in the face of work-hour restrictions and greater accountability for patient-centric value, the need for efficient surgical education has taken center stage. [It] is ripe for a makeover as our professions must train specialists faster and better.” (Beard et al, 2016)

Knowledge

The main focus of this concept is bringing more knowledge to its users. This is, evidently, done in the form education, though it still very much supports this pillar.

Communication

The way that this concept communicates the knowledge and gives shape to the education is done in a way that is beneficial to the users, though communication is not its primary strength. However, it is the communicative element of this concept that makes it an accessible form of education. (Senior house officer (ANIOS), personal communication, August 2018; MSc Biomedical Engineer, personal communication, August 2018)

Education

As stated before, the main focus of this concept is bringing more knowledge to its users in the form of education. The role of the platform is to facilitate education in such a way that makes it accessible and as easy as possible

to comprehend. The immersive experience it brings will achieve fulfilling this role and will optimise education as well as make it accessible.

MDT Dashboard

Feasibility

Most elements of this concept are quite easy to be developed. One challenge that arises is to ensure the proper adaptation of the guidelines that allow the system to provide the correct diagnosis and advice. (Zimmer Biomet marketing director, personal communication, October 2018) Linking this dashboard to current information systems is also an important element that requires further research. (Zimmer Biomet marketing director, personal communication, October 2018; project mentors, personal communication, September 2018). The chapter ‘Validation’ elaborates on this subject.

Viability

This system will provide great added value to the current way that MDT meetings are being prepared and executed. (MSc Biomedical Engineering, personal communication, August 2018; Zimmer Biomet marketing director, personal communication, October 2018) Making data easily communicable, giving each member the tools to properly convey their diagnosis and supporting the final decision (of the surgeon) are selling points that give this system value to hospitals. This system can also be sold through a bundle contract. (Zimmer Biomet associate director, marketing director and senior manager, personal communication, June 2018).

Desirability

This concept has received one mixed response, with the question if this is new to the world for its specific medical field. (Senior policy advisor, academic hospital, personal communication, October 2018) It can be concluded that comparable systems exist and are in use on the Dutch market, though not focussed on PJI. However, in a lot of other countries this system can bring much benefit to the diagnosis phase of medical cases (of PJI). (Zimmer Biomet marketing director, personal communication, October 2018) Furthermore, those comparable systems are not focused on PJI and therefore lack specific value that this system does bring. The concept has also received positive reactions and is thought to be helpful to its final users. (Zimmer Biomet marketing director, personal communication, October 2018; Senior house officer (ANIOS), personal communication, August 2018; MSc Biomedical Engineering, personal communication, August 2018; Project mentors, personal communication, August 2018) Another expert on PJI sees great opportunity in offering help to the multidisciplinary team in executing the diagnosis and making the decision. (Orthopaedic surgeon, general secretary joint infection society & renowned PJI expert, personal communication, March 2018) Finally, clinical decision support tools like this dashboard are being called for on a broad scale, or as a Chief Medical Officer at a hospital states: “The amount of information we need to understand is getting so untenable that it’s unreasonable to expect the average clinician to integrate all of it into their decision-making effectively and reliably. If we really want to make sure every human being gets great care, then you have to make sure that you’re assisted by technology.” (Bresnick, 2018)

Knowledge

The dashboard holds a lot of knowledge that can be shared if any member of the team requires so. Merely by linking the data required for a proper, complete diagnosis from other information systems, the system can execute the diagnosis based on the guidelines that are included in its database.

Communication

This concept’s primary focus is ensuring proper communication between members of the multi-disciplinary team. This is done by making data understandable, giving each member the tools to present their diagnoses, providing an aid to make each meeting as constructive and succesful as possible and by facilitating

these meetings in a time- and cost-efficient manner. These benefits are recgonised by several reviewers of this concept. (Zimmer Biomet marketing director, personal communication, October 2018; Senior house officer (ANIOS), personal communication, August 2018)

Education

Similar to the previous concept, education is not this concept's main goal. However, by offering an advice based on the entered data, the system can teach users what the recommended form of treatment and prevention is for all different elements relevant to the diagnosis.

Guiding system

Feasibility

The technological aspects of this concept are feasible at this moment. Bacteria detection and localisation in the OR itself was a part of the concept at first, but is not technically poosible. In fact, that will probably not be available in a similar fashion in the near future. This conclusion was drawn after validation with people that are knowledgeable on the subject. (Consultant healthcare accomodation, personal communication, August 2018; Company mentor, personal communication, August 2018) Voice-controlled assistance and machine learning is developed enough for this system to work as designed. (Van der Velde, 2018) Linking the system to existing information systems in hospitals is an element that requires further research. The chapter 'Validation' elaborates on this subject.

Viability

Similar products have succeeded in the past. (Inter Visual Systems, 2018) The added value that this system brings will persuade hospitals to pay a fair amount. The system can be sold at a very low price, or even offered for free (including updates), when acquired under an exclusive supplier agreement. The implementation of this concept will be supported if development happens in cooperation with a hospital information system manufacturer, like ChipSoft. (Construction cost expert, personal communication, October 2018; Project mentor, personal communication, October 2018)

Desirability

Positive responses have been given to this idea. (MSc Biomedical Engineering, personal communication, August 2018; Project mentor, personal communication, August 2018; Zimmer Biomet marketing director, personal communication, October 2018) A point of critique is that information is preferrably taught in advance. (Senior house officer (ANIOS), personal communication, August 2018) This may still be possible, where this system then works as a reminder that supports decision-making and allows for more efficient and safe surgeries.

Knowledge

This concept offers a lot of knowledge to its users, during a surgery. The users are informed on optimal treatment progress and on important preventive measures. Furthermore, a database of knowledge is available for the users to tap into, at any given moment.

Communication

The fact that the concept offers knowledge is one thing, but the power lies in how it is offered. During the surgery the system offers a lot of guidance. Any insecurity can be eliminated and it will be hard to forget important elements. OR staff can ask questions easily - verbally - and will receive their answers quickly. This value is supported by several reviewers of this concept. (Senior house officer (ANIOS), personal communication, August 2018; Zimmer Biomet marketing director, personal communication, October 2018).

Education

Though the concept is not primarily focussed on educating OR staff members, it is possible for it to do so. Through the method of working as a tool that reminds and guides OR staff, the system can eventually teach elements about treatment steps/decisions, preventive measures and other relevant information.

Conclusion

After an evaluation and validation of these concepts, it has become clear that the most value can be obtained by offering a system that combines all of these concepts (and perhaps more). Providing a combination of education, applying that education in diagnosis & treament and giving desirable reminders of the knowledge during execution is what offers the most value to the end-users, the hospitals, society and Zimmer Biomet. (Senior house officer (ANIOS), personal communication, August 2018; Project mentor, personal communication, August 2018; Company mentor, personal communication, August 2018) How this combination can work, be developed and be implemented is elaborated upon in the chapter 'Strategy'.

Though this combination works best and developing each concept would be most favorable, for this project one concept is chosen to be optimised and considered further. One of these concepts is deemed to provide the most added value and answers to the goal most directly. It furthermore is considered to be the best choice to be implemented as the primary element of the complete system. That concept is the MDT Dashboard.

Concept development

This section describes further development of the operation of the MDT Dashboard. The MDT Dashboard is a system that gathers data from other information systems present in the hospital. The gathered data runs through algorithms that perform diagnoses. These result in a non-binding advice. The data, diagnosis and advice are presented in the dashboard in such ways that allow the members of the team to use them as substantiation for their personal diagnosis and advice. The algorithms are created based on guidelines that are relevant to the diagnosis of PJI. The following paragraphs will elaborate on these - and other - matters. For a better understanding of the context that the dashboard functions in, the visualisation in Figure 24 shows the process of case diagnosis and treatment decision. The figure furthermore visualises which medical stakeholders are active during each phase, Finally, it is emphasised during what parts of the process the dashboard supports the staff. The figure is based on communications the designer has had with various hospital staff member, such as a Chief Medical Information Officer (personal communication, October 2018)

Communication

This concept's first and most significant strength is communication. Literature shows that communication does not always occur properly: organisational and relational structures cause lack of communication which contributes to detrimental outcomes. (Sutcliff, Lewton & Rosenthal, 2004) During a contemporary multi-disciplinary meeting it can be difficult for each member of the team to make sure that their thoughts and considerations are heard. (Resident surgeon, personal communication, May 2018; Zimmer Biomet senior manager, June 2018) Each member makes their own diagnosis, relevant to their specialty, with data they have collected themselves, from the patient or from an information system. The MDT dashboard provides each member of the team with visual aids to present their diagnosis in a convincing manner. The data that their diagnosis is based on can be shown in an understable manner as well. Finally, each MDT member's individual advice, based on their expertise, can be presented with the necessary substantiation: they can easily refer to their data or their diagnosis to convince other members of their point. Examples of how these visual aids can look are depicted in Figure 25 and Appendix V. During the meeting itself, a screen is present that each member can refer to; they can go to each tab to show any necessary substantiation or conclusion of the diagnoses. This way, the combined advice is achieved by optimally considering all elements and supporting the team in making their decision.

Effective communication is commonly counteracted by the presence of hierarchy. (Jablin, 1987; Sutcliff, Lewton & Rosenthal, 2004) The dashboard aims to circumvent this and to aid in facilitating this effective communnication, which helps prevent errors. (O'Daniel & Rosenstein, 2008) It does so by giving all members of the team a platform to share their opinion. The dashboard is a tool that structurises the process of hearing everyone's view, increasing the likeliness of them being shared. Multiple sources of literature substantiate that "because of the complexity of medical care, [...] it is critically important that clinicians have standardized communication tools and create an environment in which individuals can speak

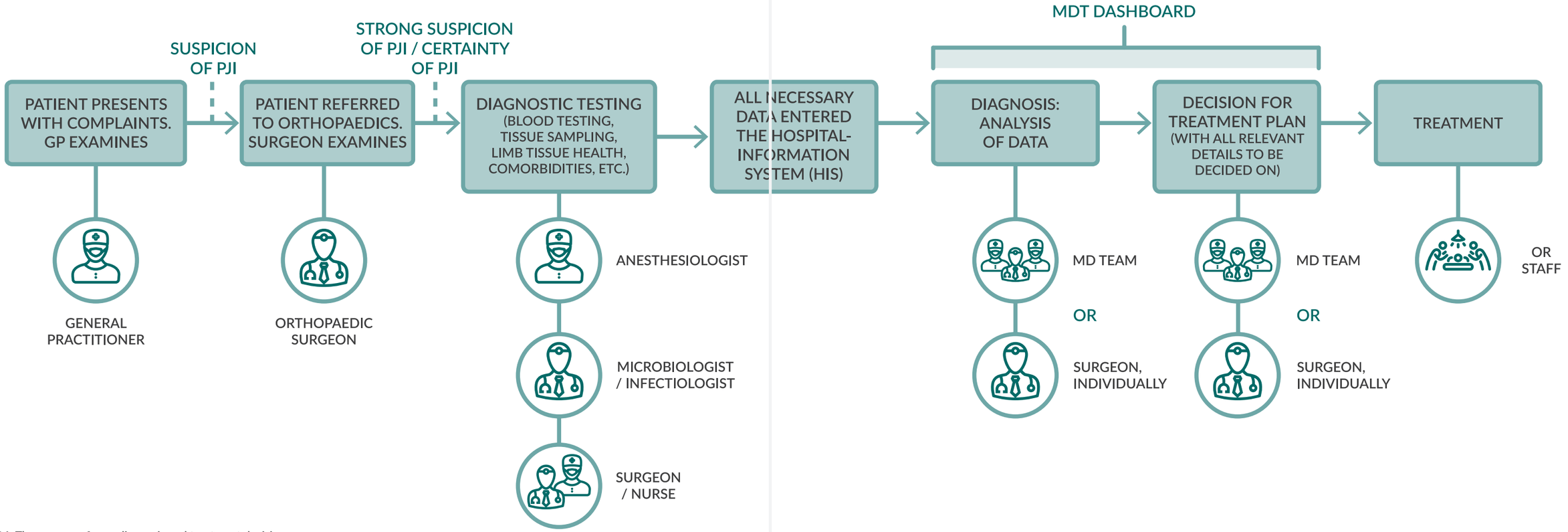


Figure 24. The process of case diagnosis and treatment decision.

IDEATION & CONCEPTUALISATION

up and express concerns." (O'Daniel & Rosenstein, 2008) The MDT Dashboard does just that: providing the multi-disciplinary team with a tool that facilitates structured communication. When complex information needs to be communicated in a short period of time, such tools are helpful to ensure accuracy and minimise medical errors. (O'Daniel & Rosenstein, 2008)

Another advantage that this concept's strength in communication brings, is that the aforementioned decision can be made more time- and cost-efficiently. First of all, the advantages mentioned in the previous paragraph allow the decision-making process to be executed more efficiently. Secondly, next to the fact that the meeting can be more streamlined when held in person, it can be carried out even more efficiently by utilising the option to let the meeting take place remotely. This option allows the members to carry out the meeting from their own offices/homes. The option thus also allows the team to be flexible in its composition. A certain case may require an expert on a specific matter: letting the meeting take place remotely simplifies this possibility immensely. Experts from all around the world can remotely join an MDT meeting and give their diagnosis and advice on specifically difficult cases. During the remote meeting the functionalities of the system work as good, if not better, as during a physical meeting. Each member can coordinate through the system, while the meeting is taking place. Therefore, members can easily refer to elements of the diagnosis, while the other members can view along. Just as with a normal video conference, the members have the option to show and view themselves and others via webcam.

Knowledge

Another strength of this concept revolves around knowledge. The reason that the dashboard can perform a diagnosis and provide advice based on the data entered by the team, is that it includes a database of knowledge. This database is comprised out of the guidelines of the ICM 2018, as well as guidelines for prevention of SSI and guidelines relevant to anesthesia, microbiology and (plastic) surgery. The data entered into the system moves through algorithms, resulting in an advice. This advice should at all times be seen as non-binding, it is merely meant to support the team in making their decision. The thing is, each case is different and exceptional. The guidelines are modelled to approximate the overall best decision. The experience, knowledge and deductive strength of the team is crucial to the diagnosis and should at all times be used to make the final call. The system can be used by the team to substantiate that final call, help them in making it and to expedite the process.

The knowledge provided by the database of guidelines is intended to be updated regularly. Whenever new knowledge on a subject emerges and consensus on that knowledge has arrived, the guidelines are updated.

The algorithms can be developed by firstly researching the guidelines and preparing those for adaptation to the algorithms. This should be done by letting experts on PJI cooperate with algorithm developers and members of multidisciplinary teams. The role of the experts can be filled by people who have previously aided in the development of this project, or by other PJI experts. Algorithm development can be outsourced to different companies, or freelancers can be hired. ("Algorithm Design and Development", 2018; "Algorithm Development", 2018; "Data Science - TMC", 2018) Validation of this element of the concept has resulted in further elaboration: more information on the development of these algorithms can be found in the chapters 'Strategy', 'Validation' and 'Implementation'.

Interface

In Figure 25 on page 57 you can see designs of what the different screens of the interface can look like. These are interfaces dedicated to each member of the team and for usage during meetings. All designed screens can be viewed in more detail in Appendix V. Note: the values depicted in these designs are merely intended to build a picture of the system and its working. These designs are meant to be viewed as examples of what the dashboard may look like. The variables described in the screens are based primarily on the Proceedings of the International Consensus Meeting on PJI 2018 (Parvizi, Gehrke, Mont & Callaghan, 2018), as well as on the Infected Joint Journey (Komen, 2017) and the Pocket Guide to Diagnostics & Treatment of PJI. (Renz & Trampuz, 2017) A further description of the operations of the dashboard, is explained from page 59 forward, supported by interface examples.

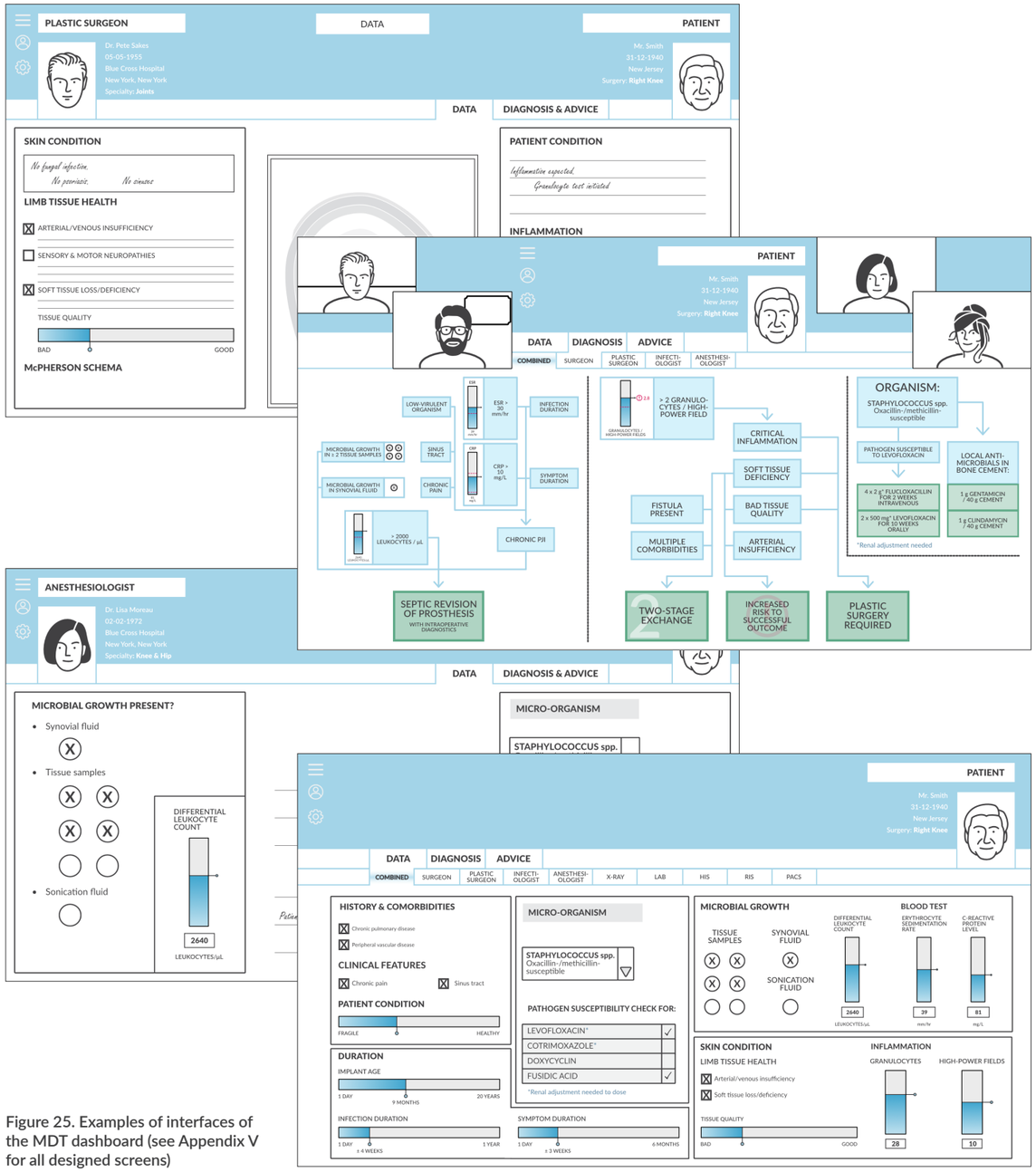


Figure 25. Examples of interfaces of the MDT dashboard (see Appendix V for all designed screens)

Information systems

In hospitals, various information systems exist. Not all hospitals use the same system, nor do all departments within one hospital (group). Among others, there are lab systems, OR systems, HIS (Hospital Information System), RIS (Radiology Information System) and PACS (Picture Archiving and Communication System). Already in 1991, the need for a connecting interface was emphasised. (Bakker, 1991) The MDT dashboard will function as a connecting interface. It will be able to connect with the information systems that are necessary for the diagnosis of PJI. It will allow the team members to view any data they may need for the diagnosis from these systems in the MDT dashboard. They will also be able to view the diagnosis (the decision tree) and the resulting advice. The dashboard functions as an overview system that puts the data of these information systems into one system. Together with software developers, functionalities will be developed that allow the information from the other systems to be imported into the dashboard. Again, validation of this element has resulted in further elaboration, which can be found in the following chapters.

Strategic value

Implementing the MDT dashboard as the primary element of a PJI management system - that acts on a broader scale than this concept on its own - provides strategic value that will be discussed in the chapter 'Strategy'.

This concept optimally supports the surgeon and multi-disciplinary team in their decision-making process. It connects members of the team and supports them in their communication, providing tools to aid them in their substantiation and reach the optimal conclusion.

The dashboard functions as an overview system for other information systems, putting all the data necessary for diagnosis in one place, making it as clear as possible.

Since it is the first system to provide the functionalities that it does, it offers help within a hospital that is unprecedented up to now. This concept leads the way for Zimmer Biomet to make a name for itself as the leading service provider in its field. That will give Zimmer Biomet opportunities to expand its portfolio in the form of services. The dashboard will furthermore lay the groundwork for all other expansions to be added onto the system.

Implementation

The strategic considerations to be made during the implementation of this and other elements of the entire PJI management system will be discussed in the chapter 'Strategy'. Therefore, this section will mostly discuss matters pertaining to technology.

For the system to work with existing information systems, it is important that their workings are understood and that links between those systems and the dashboard are facilitated. All information needs to be made adaptable to variables used in the dashboard. Input and output parameters need to be streamlined along the entire spectrum of systems and the connection between them and the dashboard needs to be facilitated. This should be done in such a way that hospitals and their staff do not have to solve any of these problems themselves. It is furthermore desirable for the dashboard to be customisable to some extent. Seeing that not every hospital operates in the exact same way, some customisation according to the existing protocols in a hospital should be made possible, in consultation, during or shortly prior to installation. More information on how this will be done can be found in the chapter 'Validation'.

The database is comprised out of guidelines concerning PJI, SSI, anesthesia, microbiology and (plastic) surgery. Next to the guidelines from ICM 2018, it is important that guidelines for the other categories are carefully considered. It is furthermore key that they are adapted to the system. Finally, the guidelines should be updated to newly emerged knowledge on the subject.

To ensure that the guidelines can provide their desired function to the system, it is essential that algorithms are written. These algorithms contain the values, decision trees, parameters and other elements to execute the system's diagnosis. It is important that firstly it is researched what all necessary variables are for the diagnosis, also the variables that relate to the specific expertise of each team member. Consequently, this is linked to all available data in the guidelines that will be used for the system. Only if a guideline is available, should the variable be included in the dashboard. Weightings should be appointed to the variables, to allow the system to make the correct decisions for its advice if elements of the diagnoses are conflicting. Finally, the algorithms can be created, based on the guidelines. An algorithm also has to be written for the calculation of infection risk. Inspiration for this risk calculator can be gathered from the PJI risk calculator resulting from the ICM 2018 (Nicholson & Penna, 2018) and its substantiating journal article. (Tan et al, 2018)

IDEATION & CONCEPTUALISATION

Dashboard operations

The following pages describe how the dashboard operates, supported by interface examples.

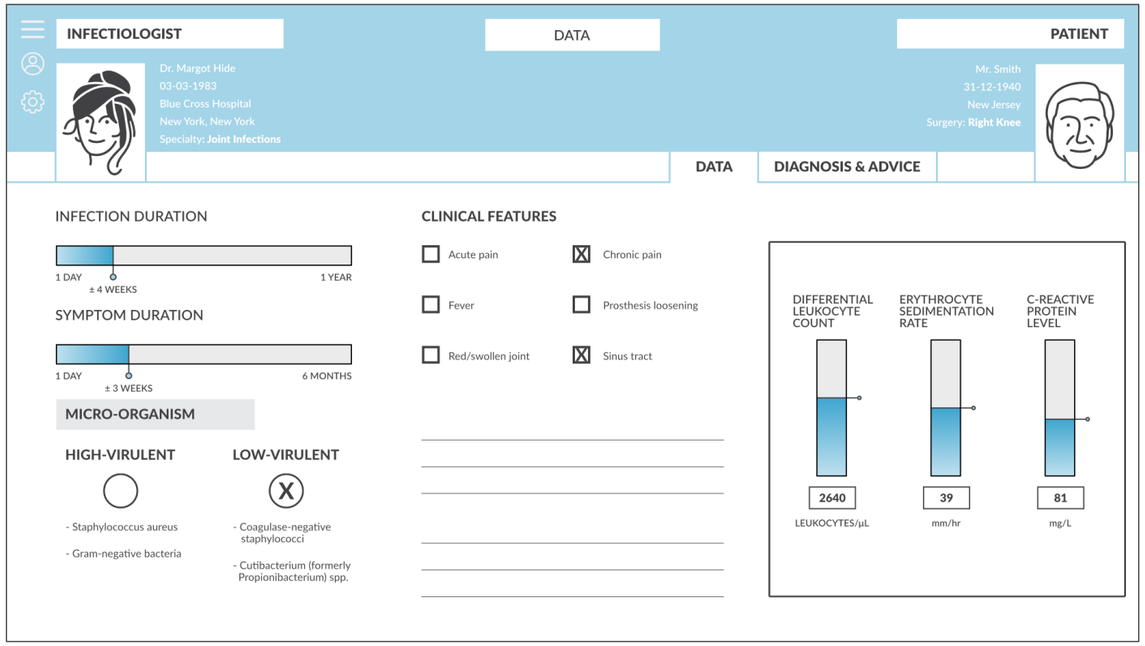


Figure 26. Data directly relevant to the diagnosis of the infectiologist

Figure 26 shows that patient data has entered the dashboard and can be systematically reviewed by each MDT member. For this example, we take the infectiologist who sees data that is directly relevant to the diagnosis of her discipline.

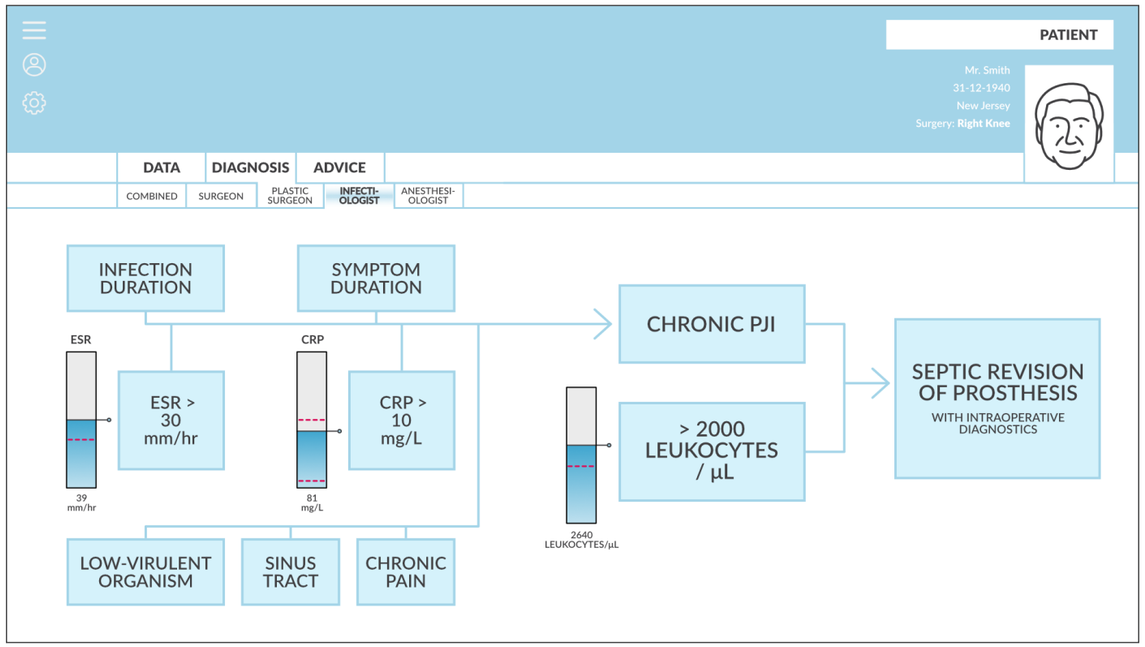


Figure 27. Diagnosis based on the data relevant to the infectiologist

When the infectiologist clicks on 'Diagnosis & Advice' she'll see a visual representation of the diagnosis that the dashboard has made, based on the data relevant to her discipline.

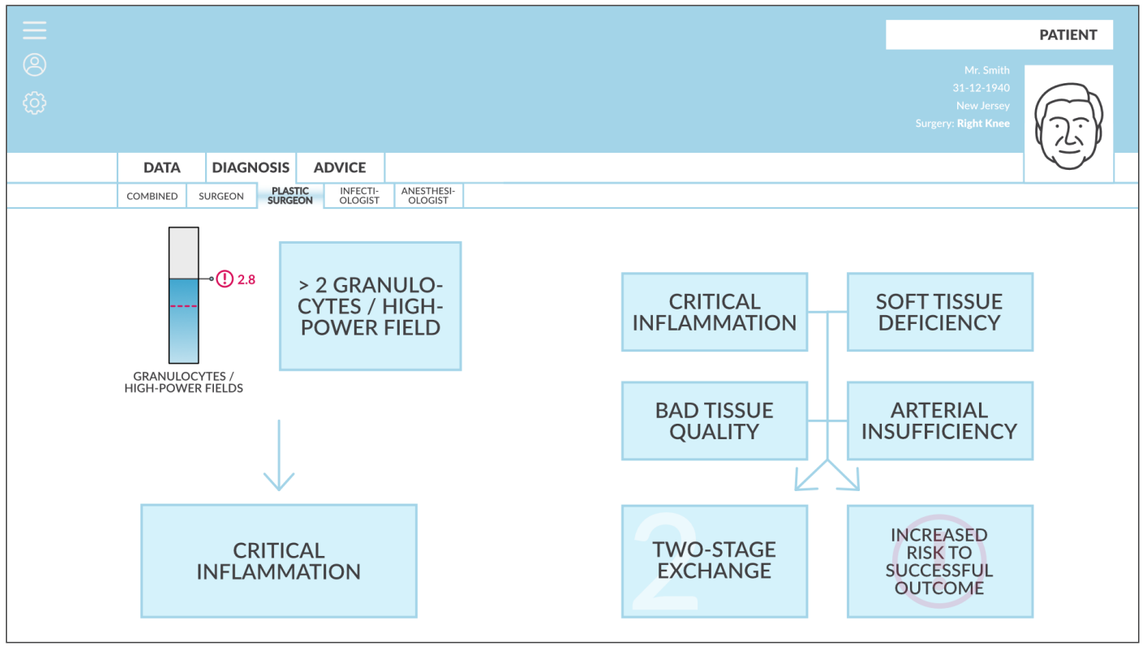


Figure 28. Diagnosis based on the data relevant to the plastic surgeon

Next to her own diagnosis, she can also review the diagnoses relevant to each discipline separately. Just as the previous screens (and the next), this screen can be viewed both prior to (individually) and during the meeting.

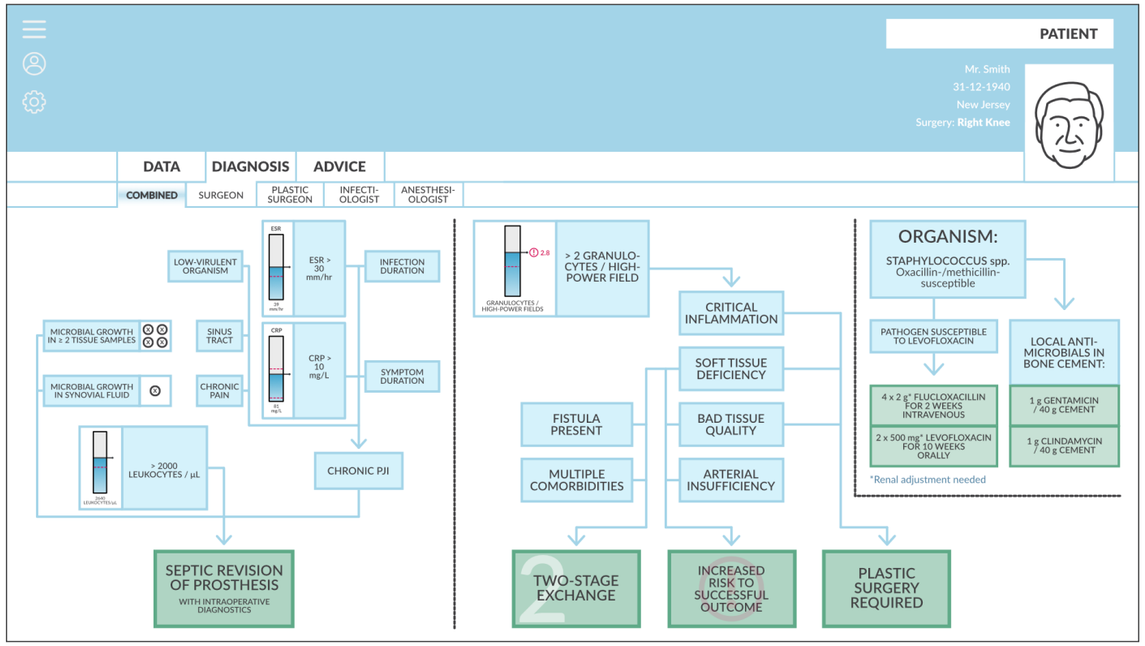


Figure 29. Combined diagnosis of all input/patient data

Each MDT member can not only review the diagnoses separately, but also combined, seeing a full overview of the total diagnosis made by the dashboard.

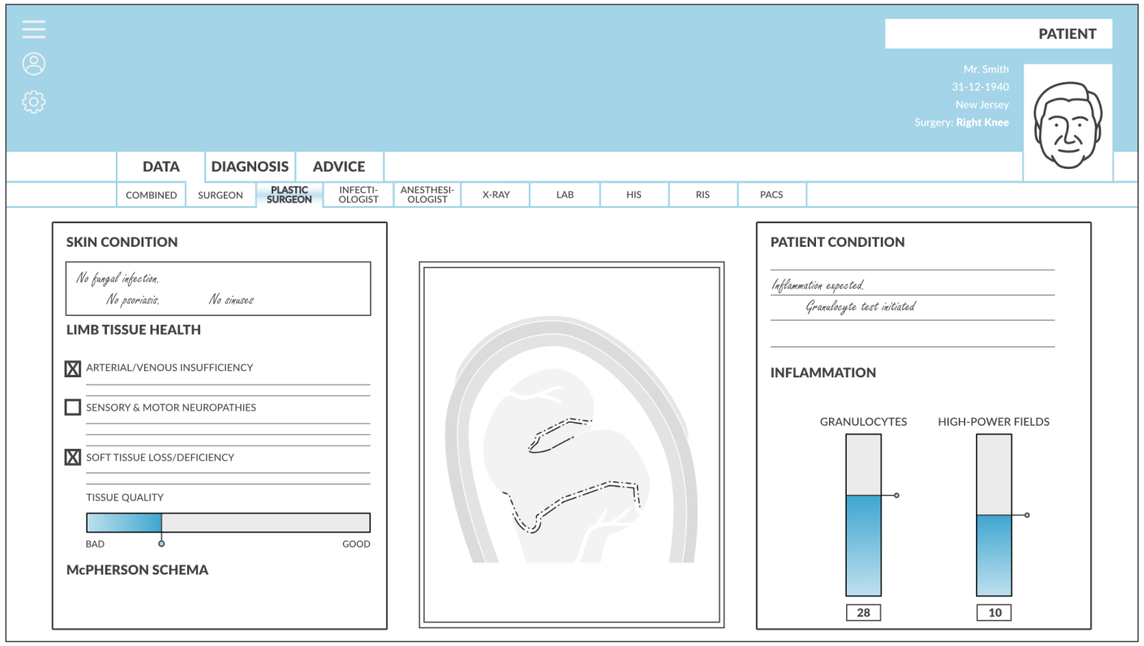


Figure 30. Data directly relevant to the diagnosis of the plastic surgeon

It is furthermore possible to review the patient data relevant to each discipline's diagnosis, separately. In this screen, for instance, you see the input data of the plastic surgeon.

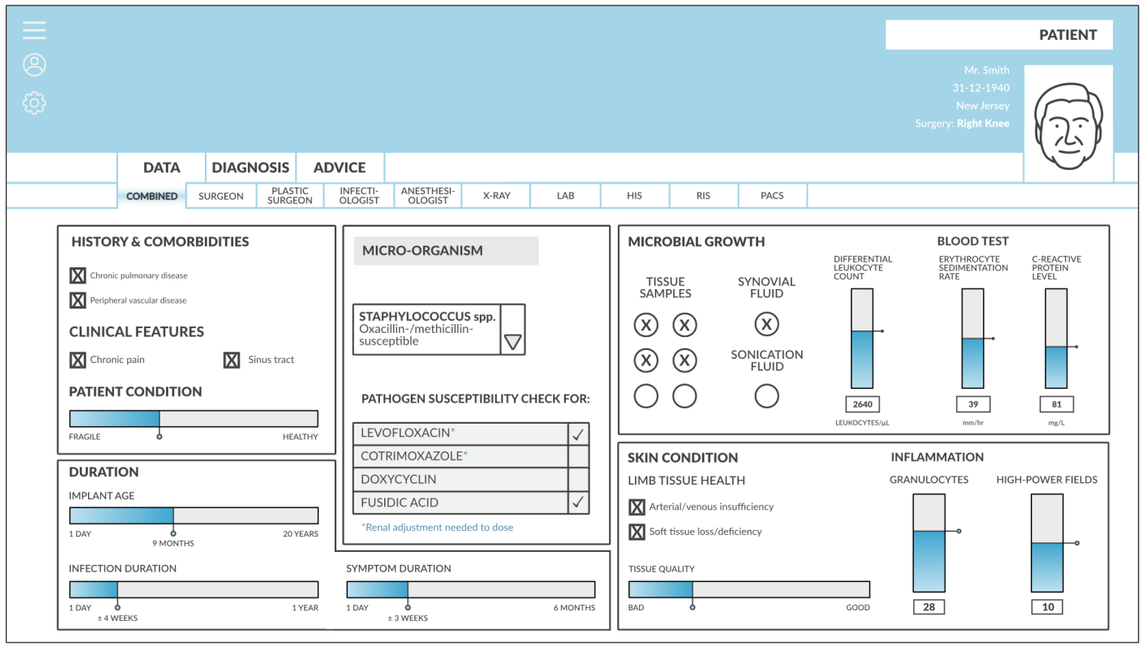


Figure 31. All patient/input data, divided per category

Next to reviewing the data per discipline, the dashboard also visualises all data combined, divided per category.

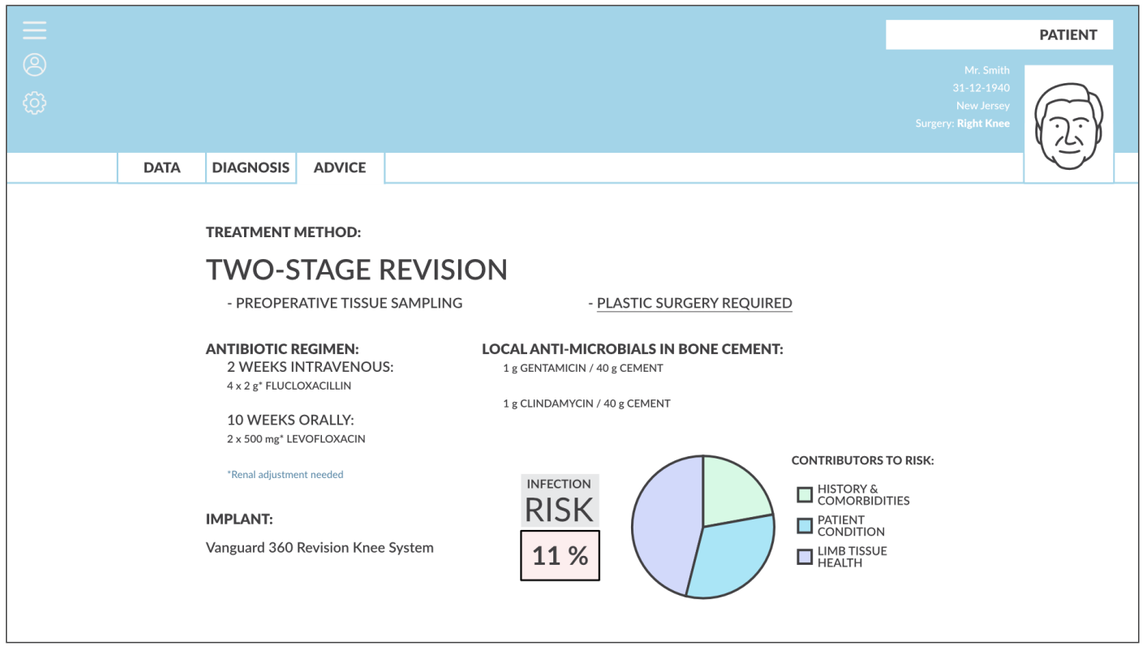


Figure 32. Non-binding advice, resulting from the diagnosis made by the dashboard

The combined patient data that runs through the algorithms to allow the dashboard to perform its diagnosis, results in a non-binding advice. This advice discusses all necessary aspects of the treatment method to be decided on.

Figure 33. Physician reviewing all patient data prior to the MDT meeting

The overview of all data and the communication of optimal treatment methods by visualising the diagnosis and providing a non-binding advice, allow the MDT members to better shape and substantiate their own diagnosis and advice.

IDEATION & CONCEPTUALISATION

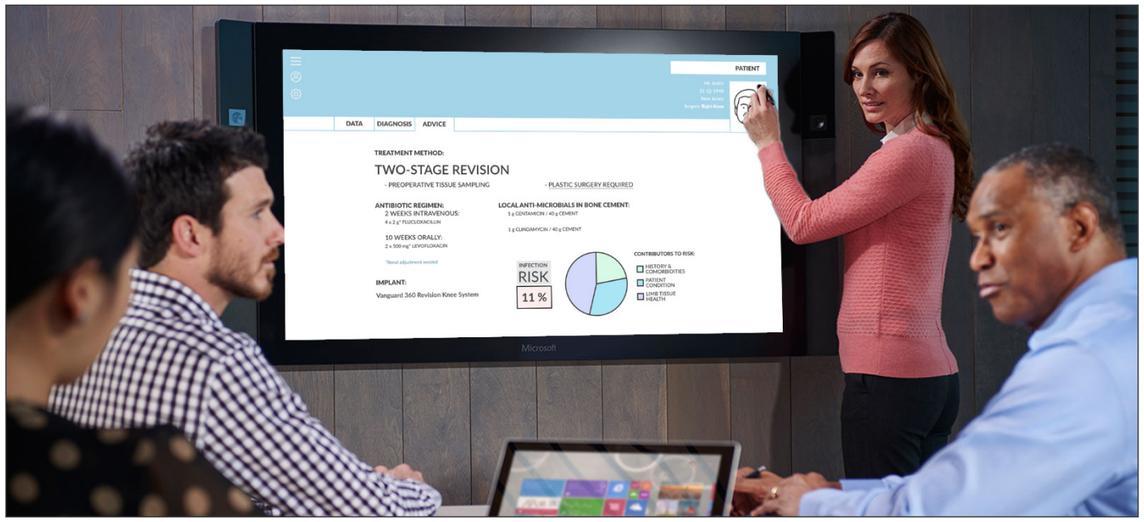


Figure 34. MDT members discussing a case of PJI during the MDT meeting

During the meeting, all data, diagnoses and advice can be consulted. This can be done per discipline, which ensures that every element is discussed. The dashboard's visual aids help in communicating arguments and substantiation.

Cost of the system

A full financial analysis of this dashboard, its development and the profits arising from an exclusive supplier agreement is to be made. More elaboration on this aspect is given in the chapter 'Validation'.

Reduction of infection (and cost)

This paragraph answers how the dashboard aids in the management of cases of PJI, thus resulting in a lower burden of time and cost, and in its prevention, thus decreasing its occurrence.

Multidisciplinary teams are not (yet) a common occurrence in all hospitals. However, there are movements towards implementing the use of these teams in more areas, since the added value of the combined decision-making is clear to many. (Zimmer Biomet marketing director, personal communication, October 2018) For instance: a result of the ICM 2018 was a unanimous vote that the engagement of multidisciplinary teams is beneficial for patients with PJIs. (Parvizi, Gehrke, Mont & Callaghan, 2018) Another example is a statement made in an article about multidisciplinary team meetings (in which most examples are of cancer treatment): "One resulting decision from a multidisciplinary discussion is more accurate and effective than the sum of all individual opinions." (Ruhstaller, Thürlimann, & Nicoll, 2006) Furthermore, MDTs aid in the prevention of PJI (Parvizi, Gehrke, Mont & Callaghan, 2018)

A multidisciplinary team is deemed to function effectively when the meeting takes place in an organised fashion. (Christopher, 2010) The dashboard helps the meeting to be organised by providing clear steps (tab pages) that the team can walk through, discussing all necessary topics. The dashboard also allows the team to vary in its composition and include experts on any subject from anywhere around the world.

Healthcare staff has a tendency to work in an autonomous fashion. (Coles, 1995) Providing tools to allow this staff to build on each others expertise, can help in the management of PJI cases and in enhancing clinical outcomes. As stated before, it is critically important that standardised communication tools exist to improve effective communication and minimise medical errors. (O'Daniel, Rosenstein, 2008) Using the dashboard will strengthen mutual communication among the team members as well as promote collaborative decision-making. These competencies are part of what makes a multidisciplinary team highly effective. (Nancarrow et al, 2013) Addressing the issue of communication and implementing tools that provide help on that matter, gives healthcare organisations the opportunity to greatly improve their clinical outcomes. (O'Daniel, Rosenstein, 2008)

The dashboard is built around the guidelines that expert surgeons from all over the world have created. Conventional approaches to guideline implementation leave a large gap between what the guidelines recommend and what is adopted and applied in practice. (McGlynn et al, 2013) Reasons for this gap include the length and complexity of the guidelines. (Mazza, Russell, 2001) The format and usability of a guideline are paramount indicators for its uptake. (Kastner et al, 2014) The dashboard aims to minimise the guidelines' complexity and format them in a clear and usable way. The dashboard furthermore focusses on offering the guidelines in a visual way, to aid in their application. Placement of visual elements and conveying recommendations with the use of graphs and flowcharts help promote the use of guidelines in practice. (Carlson, Glenton & Pope, 2007; Gagliardi et al, 2011) The dashboard does exactly that. These aspects of the dashboard will improve the application of the guidelines that are created to aid in the management and decrease the occurrence of PJI.

Clinical decision support systems - like the dashboard - from other medical fields have proven to improve clinical outcomes and decrease healthcare costs. (Anchala et al, 2015; Dalaba et al, 2015; O'Connor et al, 2012; Poley et al, 2007; Sperl-Hillen et al, 2018) A 2013 report of a renowned healthcare research firm shows that 79% of healthcare providers say that clinical decision support systems positively impact how well they are able to care for their patients. (KLAS Research, 2013)

IDEATION & CONCEPTUALISATION

DESIGN IMPLICATIONS

These implications on the final design have been taken into consideration to define the strategy and to execute the validation of both the strategy and the final design.

Combination

It has become clear that the most added value can be gained by combining the in this chapter presented concepts. Other additions to such a PJI management system can be useful as well. The combination of education and application of that knowledge during diagnosis and treatment as well as the improved communication of data and communication among staff is what makes it so valuable.

Implementation

Because of the fact that the combination of the concepts is deemed most valuable, it is vital to consider how and when the elements should be implemented. It is important to consider the necessary steps to be taken for each element to be implementable, to ensure technological feasibility and to find the right approach to obtain interest from clients.

Information systems

An important implication to the design of the MDT dashboard is that it needs to cooperate fluently with current information systems in use by hospitals. This requires research and development.

Updated guidelines for all disciplines

The MDT dashboard needs to be equipped with all guidelines that are necessary for each member of the team to be able to execute their diagnosis fully. Co-designing the system with members of MD teams can ensure that this goal is reached completely. Furthermore, these guidelines need to be updated whenever necessary: if new or improved knowledge emerges and consensus on it has been reached, it should be implemented in the system.

STRATEGY

Introduction

This chapter discusses the recommended strategy for Zimmer Biomet by formulating a vision, offering a visual explanation of the cohesion of the elements of the strategy and providing a roadmap. The latter includes technological, societal and medical developments as well as concrete solutions to stated solution directions that fit the defined strategy. Furthermore, recommendations for implementation and strategic approach are outlined.

Vision

The vision to be upheld during the execution of the strategic recommendations in this chapter, is as follows:

"Provide a system that allows easy communication of both data and consensed knowledge along the entire PJI care pathway as well as educate staff."

Pillars

This vision is built on three pillars, which will be a recurring theme during this chapter, the pillars are defined as follows:

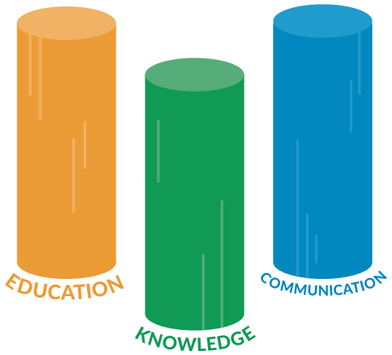


Figure 35. The pillars that visualise what the strategic vision is built on; knowledge, education and communication

These pillars are what the chosen concept is built on. Furthermore, the combination of the three presented concepts provides a strategic added value for Zimmer Biomet: in the future, they can cooperatively operate in one system and perfectly complement each other.

Cohesion

The realisation of a system that contains (among others) the three presented concepts ties in with the vision as well as the pillars. It is precisely the combination and integrality of the system that make it most valuable for clients (primarily, hospitals). At every moment during the care pathway, the system offers help to provide knowledge and education and facilitation of communication.

The synergy between the elements ensures an optimal result to the overall goal of this project: to improve the management, treatment and prevention of PJI. Firstly, education takes place: the knowledge developed by experts is being taught to relevant staff in a highly immersive manner, through the VR education platform.

Education currently takes places mostly in the form of a classroom. Another method is for someone to attend the OR. During the surgery, the operating surgeon will educate the visiting party. This more immersive method is preferred. The method proposed in this report will provide great added value: practice is as important as the medical and technical aspects of the guidelines in ensuring successful implementation. (Rogers, Shoemaker, 1971) For the system to adapt to this new method, not much intervention is necessary: users can use the method more time-efficiently and schedule it very flexibly.

The taught knowledge is then applied during diagnosis and decision-making, in a system that makes the knowledge available again and provides guidance. Furthermore, this system facilitates a desirable and helpful way of communicating data, diagnosis and advice among members of the multi-disciplinary team (MDT).

Because of this, it adds value both prior to and during the MDT meeting. During the meeting it offers a helpful tool to find connecting factors and to convey important conclusions clearly. The opportunity to save time is also present by having the meeting take place remotely, while the system eases communication and is being used as guidance.

The taught knowledge is furthermore applied in the OR, during treatment. To facilitate treatment and convey the knowledge again as a reminder, the system is present here as well: knowledge is being communicated desirably, support is offered during the process and the execution of steps, decisions and measures is being facilitated. The system's strategic cohesion and its added value is visualised in Figure 36, on the next page. The top part of this visualisation presents that strategic cohesion. The layer below presents the elements of the management system that bring the added value. The bottom part links these elements to the pathway that has been used to start the creation of insights. The elements are linked to the place within the pathway during which they are used.

Implementation roadmap

On page 74, the roadmap for implementation of the combined PJI management system and steps for its expansion is shown. The roadmap covers a 3-year strategic implementation plan as well as the vision and the pillars. The latter two are present for the staff to be reminded what they are aiming for. The roadmap is intended for internal use, in two ways. Firstly, it is intended as a presentation tool: it can be used as a means to explain the system, its cohesion and the implementation steps necessary. It can furthermore be used to persuade parties of the system's value. Secondly, it is intended as an internal tool for development and support. The roadmap can be provided to (Zimmer Biomet or other) staff that is working on the development of the project to support them in understanding steps to be taken. In addition, it allows them to keep the vision in mind and to remain on course.

When implementing new guidelines into a medical organisation, it is important to consider what the current workings of that organisation are and how the guidelines can be adapted to function properly. Besides, the strategic goals of a project and suggested guidelines need to fit with the organisational strategy of the institution they are being implemented in. (Sonnad, 1998) How this is achieved, is explained in the chapter 'Validation'. Further explanation of the roadmap and its elements will be given on the page following the roadmap.

STRATEGY

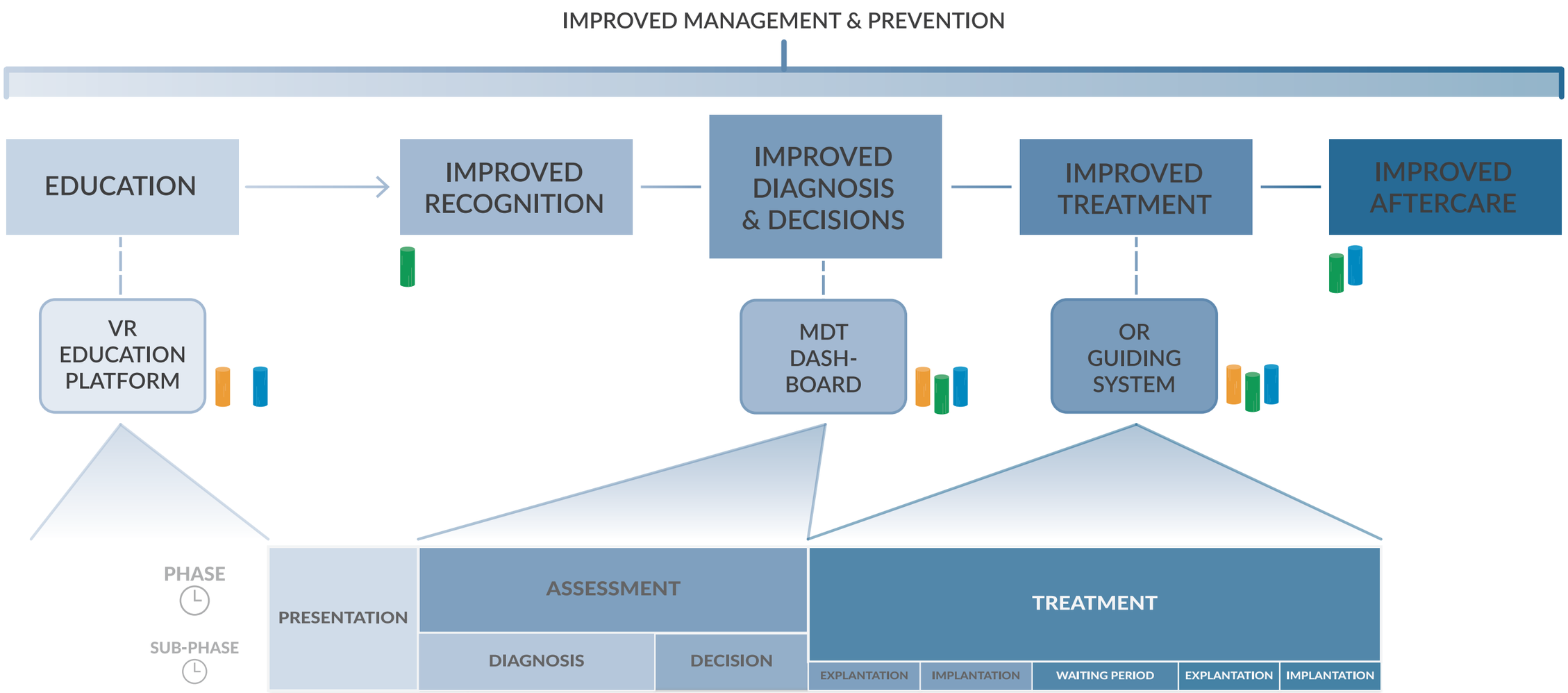


Figure 36. The cohesion between elements of the system that add value to the process, linked to the relevant pillars, and their position in the PJI care pathway during which those elements will be used.

IMPLEMENTATION ROADMAP

NOW

2018 | 2019 | 2020 | 2021 | FUTURE

MEDICAL DEVELOPMENT

EXTERNAL
INTERNAL
ICM 2018
PJI OCCURRENCE RISING
NEW ICM'S ON PJI AND OTHER RELEVANT SUBJECTS
DIAGNOSIS GUIDELINE RESEARCH
EXPERT SURGEON ACQUISITION
COOPERATE w/ ICM EXPERTS
TREATMENT GUIDELINE RESEARCH

IMPLEMENTATION STRATEGY

CLIENT ACQUISITION
CURRENT CLIENTS
BUNDLE CONTRACT SALES
MDT PROTOTYPE SYSTEM DEMOS
SURGEONS & MDT MEMBERS PITCHING
SERVER MANAGEMENT
VOICE ASSIST. ADAPTATION
GUIDELINE UPDATES
GUIDELINE ADAPTATION
GUIDELINE CONSIDERATION
INF. SYSTEM ADAPTATION

"Provide a system that allows easy communication of both data and consensed knowledge along the entire PJI care pathway as well as educate staff."

EDUCATION
KNOWLEDGE
COMMUNICATION

PJI MANAGEMENT SYSTEM

MDT DASHBOARD

VR EDUCATION PLATFORM

GUIDING SYSTEM

TECHNOLOGICAL DEVELOPMENT

GUIDELINE ALGORITHM DEVELOPMENT
DIAGNOSIS VARIABLE RESEARCH
LINK GUIDELINES TO VARIABLES
ALGORITHM DEVELOPMENT
TREATMENT GUIDELINE ADAPTATION
VIRTUAL REALITY IMPLEMENTATION
INTERNAL
INTERFACE DEVELOPMENT
EXTERNAL
VOICE-CONTROLLED ASSISTANCE
(REAL-TIME) BACTERIA DETECTION

Figure 37. Roadmap

Roadmap elements

The roadmap consists of several elements. Medical development is split up into external developments that happen in the (medical) world and internal developments that are necessary to finalise components of the system. Technological development is also split up into external developments that happen in the world that Zimmer Biomet can profit from and internal developments that need to be executed to achieve an optimal finished system. Next, the implementation strategy consists of methods for client aquisition and necessary steps to implement (components of) the system. Finally, all the aforementioned elements are linked to the component of the system it relates to, in order of development. After validation of these aspects, more elaborate explanations have been drawn up. These can be found in the chapter 'Validation'.

Medical development

External

Firstly, it is made clear in the roadmap that the occurrence of PJI is still rising and is predicted to keep doing so for the foreseeable future. This is to be remembered why the system is to be developed in the first place and why it is of importance to global society. The ICM 2018 has resulted in a vast amount of guidelines that contribute to all three components of the system, mostly so to the MDT dashboard and the guiding system. In the future new consensus meetings will take place, updating the information, knowledge and consensus of the current results. This will happen for the ICM on PJI, but also for other relevant guidelines.

Internal

For the MDT dashboard it is crucial that guideline algorithms are developed. For this development, it is important that the guidelines are researched in preparation of their adaptation. As stated before, this preparation should be executed by PJI experts in cooperation with algorithm developers. The VR education platform succeeds or fails with the acquisition of proper teachers. It is thus essential that experts on PJI, and specific sub-elements related to it, are found to cooperate with the program. A possible and helpful direction to acquire these teachers from would be cooperators to the development of the ICM 2018 guidelines. Prior to the launch of the VR education platform it is also necessary that several education videos have already been recorded. The acquired teachers will do this before the launch. These experts may be able to teach the guidelines best. Similar to the MDT dashboard, the guiding system also requires guideline research in preparation to their adaptation.

Technological development

External

As described earlier in this report, the bacteria detection element designed for the guiding system is currently not technologically feasible. Through research and development however, the time it takes to detect bacteria is becoming ever shorter. The bacteria detection element may at some point in the future be able to be added to the guiding system, with perhaps some modifications. Voice-controlled assistance is a technology that a lot of companies are developing and optimising (e.g. Google, Amazon) and is currently already in a state that is ready for use. The guiding system will utilise this developed technology.

Internal

Interface development is necessary for all three components included in the roadmap. Some preliminary interface design work has been executed by the designer, but this is mostly intended as a means of presentation and to convey the functions of the components. It is recommended that for future interface development an agency is hired. It is furthermore recommended that UX designers (from that agency) will work on the interface development. This will ensure that the components will answer the needs of its users best. Virtual reality systems and glasses are a technology that is developed and is widely available to use. It will be necessary to set up a virtual reality system that is implementable into the education platform. An external company can provide this service, which will not be very extensive. Oculus VR is currently even donating their systems to education programs. (Oculus VR, 2018) As stated before, it is crucial for the MDT dashboard that guideline algorithms are developed. Firstly, it is necessary to contact members of multidisciplinary teams to research what guidelines are necessary for PJI diagnosis, next to the guidelines of the IMC 2018. Examples are guidelines for prevention of SSI and guidelines relevant to anesthesia, microbiology and (plastic) surgery. Following the research of guidelines in preparation of their adaptation, it will be researched how the diagnosis variables can be adapted to be implemented into algorithms. Weightings will need to be appointed to the guidelines to allow for the right decisions to be made in case of conflicting diagnoses. Consequently, the guidelines and variables will be linked within the system. Finally, the algorithm will actually be developed in order for the dashboard to work as intended. An algorithmic developer should be hired to execute this job. Cooperation between the PJI experts working on this development and the algorithm developers and the members of multidisciplinary teams is crucial. (Bresnick, 2017) How the process of developing the algorithms will work is visualised in Figure 38, including the relevant members of the development team, per phase: when the dotted squares overlap, it means the roles are simultaneously and cooperatively working on the steps. The figure should be read from top to bottom. The guiding system requires less work when it comes to guideline preparation. The treatment guidelines need to be adapted to be able to be used within the system. They also need to be adapted in order to function together with the voice-controlled assistance, more on this in the following section.

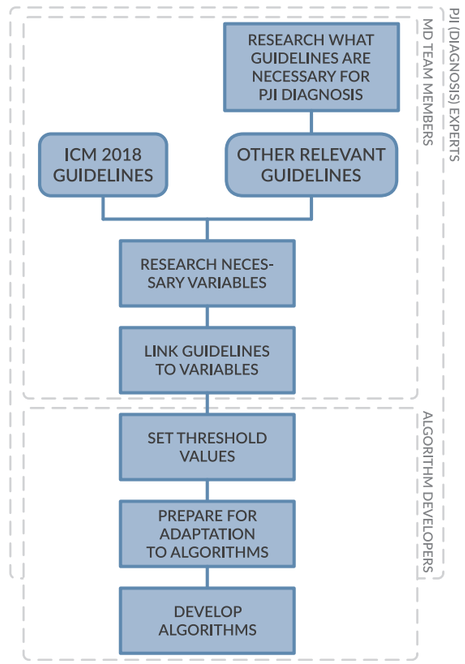


Figure 38. Visualisation of the steps necessary to develop the algorithms required for the MDT Dashboard.

Implementation strategy

The MDT dashboard functions best if it can cooperate with exisitng information systems in hospitals. It then even functions as an overview system. In order for this to be achieved, it is necessary that technological steps are taken for the dashboard to be able to cooperate with those information systems. As mentioned before, for both the MDT dashboard and the guiding system it is important to take the relevant guidelines for diagnosis and treatment into consideration. In cooperation with experts, it should be considered what guidelines can be implemented into the components. It should furthermore be investigated how the guidelines can be adapted to function in the components. Subsequently, this adaptation and implementation should take place. From the moment that a component launches, updates to guidelines should be kept in sight and implemented after review and reached consensus. Shortly prior to the launch of the PJI management system, servers should be up and running. Whether these servers are local, within hospitals, or external, has to be determinded. Guidelines, software systems, patient information, algorithms, educational videos and live-streaming of these videos are part of the data that needs to be managed. The technology for voice assistance is developed far enough to be used within the guiding system. However, it is still necessary for a system to be developed that utilises this technology. This software element of the guiding system will combinedly use the guidelines and the voice assistance technology to facilitate real-time Q&A.

Client acquisition

The system needs to be pitched to possible customers. Sales staff of Zimmer Biomet and other staff that communicates with current clients as hospitals, its boards, surgeons, members of multi-disciplinary teams and members of OR staff, can pitch the system. The system can be sold based on a one-time fee, though with future expansions in mind (as the education platform) a subscription model may be more apt. A different option, however, is to offer the system with an exclusive supplier agreement. This way, the customer would make Zimmer Biomet their exclusive supplier for joint prostheses and the corresponding tools, without paying for the system itself. A financial analysis is required to decide what business model works best for the system.

Acquiring clients will work best by implementing and approaching in a top-down fashion. (Zimmer Biomet sales manager, personal communication, June 2018;

Senior house officer (ANIOS), personal communication, June 2018; Zimmer Biomet marketing director, personal communication, June 2018) The higher ups need to be persuaded of the system's value, before moving down the ladder to convince other department heads and executive staff. It is important that the actual users of the product are convinced of its working, and starting at the top is deemed the best way to achieve this. This is also most realistic since these are the decision-makers and there is simply a too large amount of end-users to convince individually. Pitching to boards of directors and other department heads that make decisions concerning the acquisition and implementation of such systems, is thus instrumental. To gain a more widespread support of its value, it is recommended to perform demonstrations of the system, focussing on its strong points and emphasising the value it brings. That value consists of: managing cases of PJI more cost- and time-efficiently, optimising PJI diagnosis, treatment and prevention for optimal patient results and decreasing the occurrence of PJI. Finally, since word of mouth is the best advertising, it is recommended to make the system a conversation piece by convincing anyone possible of its value, which is also greatly a societal one. More information on acquisition is given in the chapter 'Validation'.

PJI Management System

As shown in the roadmap, three components of the management system are taken into consideration for their implementationd and launch strategy. The system will launch with the introduction of the MDT dashboard in three seasons from now (beginning Q3 2019). At the end of Q4 2019, it is aimed to launch the VR education platform. Three seasons later, in Q3 2020, the guiding system is to be added to the system. The expansion of the management system is not limited to the components presented in this roadmap. Further development is recommended to increase the amount of functionalities of the system. Though it is definitely not necesary, it would be beneficial if the system becomes a hub that replaces a large amount of different systems: all information would be available in one system and transferrable among functionalities.

A possible addition to the system that is not mentioned is the roadmap is to allow the management system to work as a reflective tool. When enough functionalities are part of the system, a lot of data will run through it. This allows the option to add a functionality that analyses this data and defines best practices. This way, a feedback loop can come into existence, optimising treatment results and minimising PJI occurrence.

PROTOTYPE & VALIDATE

Introduction

This chapter discusses the development of a prototype of the MDT dashboard. The validation of this prototype is also reviewed, as well as the validation of the presented strategy and various elements of implementation (N = 11). These various aspects of validation have resulted in adaptations and elaborations on the digital prototype, the strategy and some other aspects as privacy and cost. Most focus during the validation phase has been put on technical and organisational implementation. Insights concerning these aspects will be discussed in this chapter, after which more extensive elaboration on implementation steps will be discussed in the next chapter: 'Implementation'. Finally, the research questions posed at the beginning of this thesis will be validated.

Prototype development

The prototype is developed with several goals. The first goal is to present the concept and explain its functions, workings and added value. The second goal is to allow the (digital) prototype to be tested on its functionalities. The people that test the prototype are stakeholders of the project, or people who currently hold a position that is comparable to one of the project's stakeholders.

The prototype's interface development has occurred with the use of Adobe Photoshop, Adobe Illustrator and Affinity Designer. The screens were then implemented into a web application called InVision (App). This tool allows the interface to work as it would be imagined to work in a finalised design.

Digital prototype

The workings of the prototyped application can be depicted in a screen map/service flowchart, but a more hands-on method is for the digital prototype to be viewed by the reader. The screen map is for this reason omitted from the report, next to the fact that the amount of screens did not allow it to be visualised in a readable manner. The digital prototype can be examined and tested by following this link: https://invis.io/TPO3709SNC6. All screens can furthermore be viewed in Appendix V.

"All screens of the digital prototype can be viewed in Appendix V."

Validation methods

Prototype

The designer intended to validate the concept with feedback of the users that the dashboard is intended for. These are members of the multidisciplinary team, like surgeons, infectiologists, plastic surgeons, anesthesiologists, microbiologists etc. This has not occurred.

Instead, the method is adapted to the person that has participated in the validation. This is a Zimmer Biomet employee specialised in infection diagnostics, who has a lot of technical, medical and overall knowledge on the subject, but is not a member of a multi-disciplinary team.

What, why and how the dashboard is tested is summarized below. Subsequently, how the test is executed is elaborated on.

What is being tested: dashboard's functionalities.
Goal of validation: finding out if these are the right functionalities and/or if they are presented correctly.
How is it tested: describing scenarios that the participant executes using the digital prototype.

The validation session took place remotely, via video conference. The designer gave a presentation that includes a summary of the project and the design process that resulted in this concept. After presenting the added value - such as the aforementioned communication and time- and cost benefits - and functionalities of the concept, the designer explained what level of design is under scrutiny during the session: as depicted in Figure 39, the concept's aesthetics, functionalities and content can be validated. This validation session is intended to validate the concept's functionalities.

The participant will then go through three scenarios, which can be found in Appendix W. During the course of that process, the designer will ask for their feedback and thoughts in general. Next to their overall impression and critique on the concept, the designer is interested in the feasibility, viability and desirability of several elements of the concept. To receive feedback on this and attempt to make the validation as thorough as possible, a list of questions has been prepared. This list can be viewed, in its entirety, in Appendix W. A sampling of the questions is given on the following page.

- *Do you see the advantage of being able to let the meeting take place remotely?*
  - *Does this indeed provide such a time- and cost benefit as described?*
  - *How can it be improved?*
- *Do you see the advantage of visualising risk factors?*
  - *How can it be improved?*
- *How do you feel about the future strategic vision of letting this dashboard turn into the sole information entry system?*

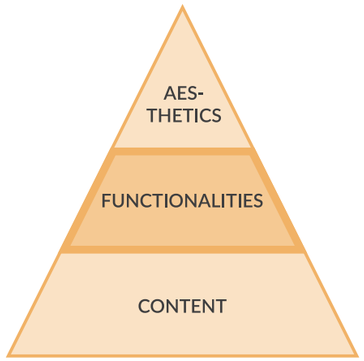


Figure 39. Levels of the concept that are possible to validate. Functionalities is emphasised, since that is the level for which validation is desired.

Strategy & implementation

Next to the validation of the concept, for which the digital prototype is used, the proposed strategy and implementation have also been validated.

The strategy and implementation have been validated during sessions during which the concept's digital prototype was not validated. During these sessions, the designer researched several aspects in more detail. These aspects include the organisational and technical implementation, organisational acquisition and cost, technical operations of hospital information systems and the technical feasibility of the concept.

The what, why and how of these validation sessions vary. Therefore, the table in Figure 40 on page 82 is used to clarify this. The abbreviations (P1, P2, ...) given to the participants are furthermore used from this point forward to make the necessary references: instead of reading "(Zimmer Biomet marketing director, personal communication, October 2018)", you will now read "(P1)".

Participants

In this paragraph, the participants' titles and/or roles are mentioned, and each participant is given a number. It is furthermore defined what aspect is validated with what participant. These aspects are divided into:

- Digital prototype
- Dashboard functionalities
- Technical aspects
- Organisational aspects

Technical aspects include technical implementation, operations of hospital information systems and technical feasibility of the dashboard. Organisational aspects include organisational implementation, acquisition and cost-effectiveness.

Below, all participants of validation sessions are listed (note: project mentors have not participated in validation sessions but have aided to the validation):

- **P1**: Zimmer Biomet marketing director
- **P2**: MSc Biomedical Engineering
- **P3**: Senior policy adviser at academic hospital
- **P4:** Chief Medical Information Officer at peripheral (see Appendix A) hospital
- **P5**: Information Architect at academic hospital
- **P6**: Manager Research & Development at hospital information system (HIS) manufacturer
- **P7**: Application specialist at peripheral hospital
- **P8**: Coordinator application management at peripheral hospital
- **P9**: Project manager data & analytics at academic hospital
- **P10**: Member board of directors at rehabilitation center
- **P11**: Sales & strategy consultant
- **P12**: Project mentor

The table in Figure 40 clarifies what aspect is validated with what participant.

Results

Digital prototype

Validation of the digital prototype has resulted in several remarks that changed the lay-out of the interface, as can be seen in Appendix V. For instance, the 'advice' tab used to include a percentage that stated the 'chance of success' of the surgery. The word 'success', however, is open to interpretation and can be sensitive to use. (P1). Risk is defined in the same tab, several people have conveyed their doubts about the technical feasibilty of this calculation. (P1; P2; P12) Further research has shown that a risk calculator for PJI is feasible and an example of it has in fact been created as a result of the ICM 2018. (Nicholson & Penna, 2018; Tan et al, 2018) Validation of the digital prototype has furthermore resulted in confirmation of the added value of the dashboard. It is noted that the dashboard brings a lot of transparency into the decision-making process, which is beneficial. It is furthermore noted that "the dashboard will help detection, treatment and prevention of infection, which will help decrease costs immensely, both to hospitals and to society." (P1)

"The dashboard will help detection, treatment and prevention of infection, which will help decrease costs immensely, both to hospitals and to society." (P1)

Strategy

Defining a future vision, that includes a strategic standpoint that states that in the future the dashboard can be aimed at becoming the sole information entry system is deemed desirable. "Everyone" is asking for a common data pool, where you can see the data of all systems in one system. (P1) The fact that it is desirable, however, does not mean it is also feasible. Further validation has resulted in the conclusion that the dashboard should not be a data-entry system. There is no need for an extra data-entry system, next to the ones currently in existence. (P4; P5) Furthermore, aiming to have the dashboard become the sole information entry system is too opportunistic and does not fit Zimmer Biomet: this paradigm shift should be fulfilled by other organisations.

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11
DIGITAL PROTOTYPE	✓										
DASHBOARD FUNCTIONALITIES	✓	✓	✓		✓	✓		✓	✓	✓	✓
TECHNICAL ASPECTS			✓	✓	✓	✓	✓	✓	✓		
ORGANISATIONAL ASPECTS		✓	✓	✓	✓	✓			✓	✓	✓

Figure 40. Table that clarifies what aspect is validated with what participant

Technical implementation

During validation, several questions arose about how the dashboard would be implemented into hospitals, how it is linked to current information systems and how the desired data enters the system, since these are crucial aspects for the dashboard to be able to execute its proposed functionalities. (P1; P12) To answer these questions, the designer has contacted several experts on the subject, ranging from staff at various hospitals to employees of various hospital information system manufacturers. These experts brought a lot of insights as to how the technical implementation of the dashboard can be achieved. These insights are gathered in the next chapter, where steps for implementation are outlined.

Organisational implementation

An interesting matter arose during the validation of the digital prototype. As common as multidisciplinary teams are in the Netherlands, they are not (yet) a common occurrence in all countries around the world, let alone Europe. However, there are movements towards implementing the use of these teams in more areas, since the added value of the combined decision-making is clear to many. The implementation of this dashboard may aid in the introduction of MDTs in areas where it is not yet common, thus improving the detection, treatment and prevention of infections. What's also important to consider regarding this matter, is that the term MDT, its meaning and the workings of such a team should be explained. (P1)

"Multidisciplinary teams are not (yet) a common occurrence in all countries around the world. However, the added value is clear to many."

Following on that point, it may be useful to consider thinking about and/or helping with the creation of multi-disciplinary teams. If the dashboard can help to make clear who has what responsibility and how the responsibility of decisions is shifting, the creation of these teams may transpire fluently.

Next to these insights, validation with experts has given more insights on how the organisational implementation of the dashboard can be achieved. Again, these insights are gathered in the next chapter, where steps for implementation are outlined.

Client acquisition & cost

Validation of the client acquisition strategy posed in the chapter 'Strategy' has yielded several results. For instance, the suggested top-down fashion of selling the system may not be the best approach. These and other results have directly influenced recommendations on how to acquire clients and are further discussed in the chapter 'Implementation'.

Cost

The cost of developping a clinical decision support tool like this dashboard, could not be validated with HIS manufacturers, clinical decision support system manufacturers or other experts. Questions asked about costs were given no response. Literature sources, however, have yielded an approximation of development costs. One development team spent 924.5 man hours at a cost of almost $50,000.- (almost €45,000.-) on developping a clinical decision support system for renal medication dosing. This team included all staff necessary for the development throughout the entire process, such as physicians, project coordinator, IT coordinator and computer programmers. (Field et al, 2008) Such a team composition is highly resemblant of the dashboard development team composition suggested in this report. Similar to the dashboard, this system is aimed at patient-specific advice and is added to a commercial HIS/EHR.

A development process of a decision support system at the University Hospital of São Paulo, which included its "conception, elaboration, construction and transition", resulted in direct labor costs of R$ 752,618.56 (just over €170,000.-). 72% of these costs related to wages for the IT consulting company. (Castilho et al, 2014)

Another clinical decision support system - for ordering blood test in primary care - costed €79,000. This investment was earned back within 6 months. It was hence concluded that providing the decision support "represented an economically promising concept." (Poley et al, 2007) Research into the return on investment of a hypothetical clinical decision support furthermore reports lucrative results and predicts a financial outcome beneficial to the hospital. (Rosenstein, 2000) The implementation of clinical decision support at an American academic medical center resulted in "significant cost savings." (Mazanec, 2016) More information, explanation and reports on the cost-effectiveness of a clinical decision support system are given in the subsection 'Reduction of infection (and cost)' on page 68. The research presented in this report suggests that the development of the dashboard will likely cost somewhere between €45,000.- and €170,000.-

Profit

As for the profit that the dashboard will create, several considerations are to be made. The dashboard can yield direct profit to Zimmer Biomet from selling the system. It can, however, also yield indirect advantages to the company, by empowering its current strategic position and creating new strategic opportunities. ZB currently primarily provides physical products; adding services like the dashboard (and in the future a PJI management system that aids staff on several levels) to their product range expands their position in the market: this combination of products and services is a beneficial extension to ZB's portfolio. Providing hospitals with a more complete package of solutions - instead of just parts of it - will give ZB a strategic advantage. Future considerations allow the company to expand on this unique selling point and extend this strategic advantage. (P11)

Privacy

Privcay matters pertaining to patient data should not be a concern. The proposed methods of implementation utilise the safe identification environment of the HIS itself, ensuring that only the necessary staff - who are under doctor-patient confidentiality - can view the patient data. (P4; P6; P9)

Research questions validation

The research questions posed at the beginning of the 'Empathise' chapter have been answered throughout this report. This is, however, done between the lines. Therefore, in conclusion, the questions will be concretely answered here.

- *"What problems are most prominent in managing a case of PJI?"*

The research from this thesis shows that the most prominent problem in managing a case of PJI is the presence of a knowledge gap between available knowledge on diagnosis, treatment and prevention and appliable knowledge by the average hospital staff.

- *"What sort of approach should the service take: informative, advisory, educational, connective, reflective, ...?"*

The developped service should (and does) take the role of informing and advising staff as well as promoting mutual communication, effectivity and efficiency. Other opportunities are present in providing education and reflection. Providing a connecting factor between hospitals has been deemed unfit for Zimmer Biomet to pursue.

- *"What stakeholders should the service focus on?"*

Research has shown that the service should (and does) focus on the stakeholders that are directly influenced by the stated problem. These are the surgeon, the OR team and the multidisciplinary team. There are opportunities to develop different services or tools that aid the patient.

- *"What are the needs and goals of these stakeholders?"*

The goals of these stakeholders are to manage cases of PJI as efficiently and effectively as possible and to prevent as much (re)occurences. Their needs are firstly to be able to apply the necessary knowledge and methods. Focussing on the multidisciplinary team: their needs are secondly to freely communicate their substantiation and address all necessary aspects to make the optimal decision.

PROTOTYPE & VALIDATE

Further user validation

Validation with intended users of the dashboard, such as microbiologists, anaesthesiologists, infectiologists, nurses and plastic surgeons is highly recommended. Due to limitations in possibilities of approaching these stakeholders and limitations pertaining to confidentiality, this validation has not taken place. It is highly recommended that this is executed to find out their specific needs and their exact requirements for the dashboard.

IMPLEMENTATION

Introduction

This chapter presents options and discusses steps necessary for the technical and organisational implementation of the dashboard. This includes elements such as implementation into hospital information systems, steps for guideline adaptation and algorithm creation, organisational aspects of hospital implementation and acquiring future clients for the dashboard.

Technical implementation

The dashboard can be implemented in several ways. One option implements the dashboard as a module of a hospital information system (HIS), also referred to as electronic health record (EHR) - also sometimes referred to as HIS/EHR. This is a system that manages all operations of a hospital, including administrative, clinical, legal and financial aspects. It allows health care providers and doctors to have access to necessary information and to track patient health information. Global market leaders in HISs are Cerner, Epic and InterSystems. (Lagemann & Christensen, 2017; Lagemann & Christensen, 2018) In the Netherlands, most hospitals use the HIS manufactured by Chipsoft. (van Eekeren & van Zuilen, 2018) This, however, does pertain to hospitals specifically. Nearly all medical rehabilitation centers in the Netherlands, for instance, use VIR. (Houben, Eurlings & van Dongen, 2017; P10) Since this project and the concept focusses on operations that take place in a hospital environment, and since most information and validation concerning information systems is gathered in the Netherlands, this chapter will take the HIS manufactured by ChipSoft, HiX, as an example. ("HiX", n.d.)

Implementing the dashboard as a module of a HIS, like that of Chipsoft (called HiX), requires Zimmer Biomet to enter into a close cooperation with ChipSoft. That also means sharing the profits of the dashboard. Furthermore, chances are that the HiX software can not execute the steps and calculations necessary for the diagnosis to be completed. (P6) The possibility exists that the algorithms can not be implemented into HiX. For these reasons, a different option is deemed more feasible and desirable by the designer. Implementing the dashboard as a module should however not be dismissed and can still be interesting to consider as an option and is therefore further elaborated on in Appendix X.

Dashboard as a stand-alone application

Another optional way to implement the dashboard is visualised in Figure 41. The burgundy-coloured square represents the hospital information system (HIS), which can be a HIS of any manufacturer that supports the viewing of web applications within the HIS (web-based view) - which, according to P6, is virtually each one. The HIS exchanges data with several healthcare institutions, such as the general practitioner and the pharmacy, as can be seen in the green tile. This data exchange is facilitated by a service that provides transmural support (in the case of HiX, this service is called 'Zorgplatform'). Transmural support/cooperation in healthcare assists in patient referrals, shared/cooperative care, remote care and more. ("Zorgplatform", 2018; P6; P8).

The teal tiles show examples of different kinds of data that originates from input systems. Some data is directly entered into the HIS itself, while other data enters the HIS via a message broker. A message broker 'translates' messages from the sending party's 'language' (type of file/document and used communication protocol) into a 'language' that the receiving party understands. (Apshankar et al, 2002; Kale, 2014) The sending party's 'language', differs per hospital, but in the Netherlands are almost alway messages of the HL7 communication standard, particularly HL7 Version 2. ("HL7 V2 Product Brief", n.d.; P8)

A HIS has modules - as can be seen in the other optional way of implementation in Appendix X in Figure 84 - but it also allows web-based applications to be visually integrated into the system. With this method of implementation, the MDT dashboard is not a module of the HIS, but a stand-alone application. This way, the downsides of the first option are eliminated: the operations that are necessary to let the dashboard come to an advice and the visual aids it provides - as shown in the red tile -, can be developped in an application external to the HIS. (P6) This furthermore means that Zimmer Biomet does not have to share the profits of the application.

The data necessary to execute the diagnosis enters the dashboard via a message broker. (P6) Validation of this way of implementation with P8 yielded the doubt if it was possible for the data that is entered into a HIS directly - 'Patient clinical features' in Figure 41 -, to enter the dashboard. Another validation step with P6, resulted in the conclusion that this is certainly possible: when a datapoint is adjusted in the HIS, a message (e.g. CDA-

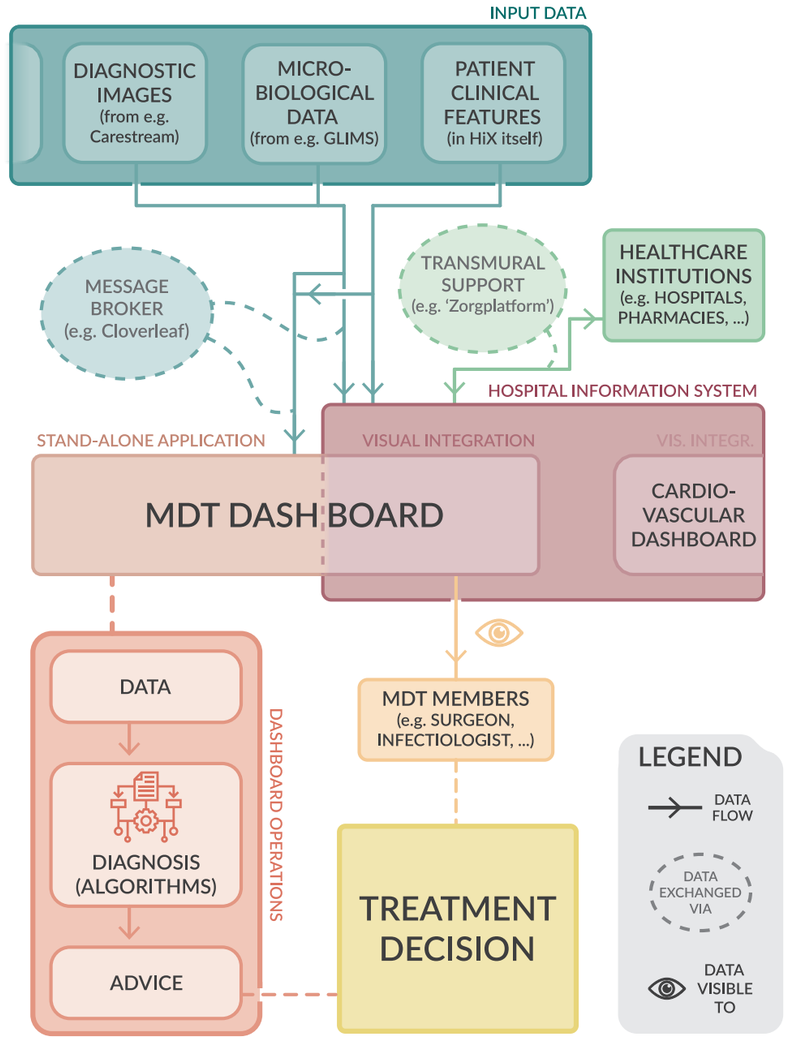


Figure 41. Optional way of implementation of MDT dashboard into hospital

document, see next paragraph) can be sent out via the message broker. This allows the dashboard to receive this (adjustment of) data.

As stated before, most data is sent via a message of the HL7 Version 2 communication standard. It is desirable for the dashboard to be developped based on next generation communication standards, like HL7 CDA and HL7 FHIR. As explained by P6: "these standards provide documents that contain more structured data, which will be helpful to the execution of the diagnosis performed by the dashboard." Furthermore, P8 explains that "CDA-documents (Clinical Document Architecture), for instance, provide data that is more structured, instead of being offered as plain text. This makes the data alot more suitable to analyse with a diagnosis algorithm in a clinical decision support tool." These explanations are confirmed on the respective web pages. ("HL7 CDA Product Brief", n.d.; "HL7 FHIR Product Brief", n.d.;)

In the red tile the operations of the dashboard are described. Data from the input systems runs through the algorithms based on guidelines, resulting in an advice. Furthermore, the input data, the diagnosis and the advice are presentend in such a way that they can be used as visual aids by members of the team. See Appendix V for examples of how this can be visualised.

The orange tile shows which staff members have access to the data, diagnosis and advice that is presented in the dashboard. These are the MDT members, such as a surgeon, infectiologist, plastic surgeon, microbiologist, anaesthesiologist or nurse.

The multidisciplinary team (re)views the data, diagnosis and advice shaped by the dashboard. They discuss these and synthesise it with their own experience. Combined, they allow the MD team to make an optimal decision for the treatment plan, depicted by the yellow tile.

The MDT dashboard and the cardiovascular dashboard are examples of web-based applications that are visible within the HIS via visual integration. These are applications of which the operations (and calculations, visualisations, etc.) take place outside of the HIS. The result of the calculations and software operations (such as the interface examples in Appendix V) can be viewed within the HIS. (P6) The cardiovascular dashboard mentioned in Figure 41 is just one example of such an application, as it is used in an academic hospital in the Netherlands. (P5)

This visual integration is possible because the HISs have a module that can integrate external web applications. The stand-alone application thus needs to have an interface viewable on the web. ("Koppelingen", 2018; P5) This integration also happens in a safe way, respecting of privacy matters, due to an SAML assertion. (P6) This is a form of authentication that does not require the user to sign in again and is safe. (Geyer, 2007)

This method of implementation also allows the dashboard to be viewed in not just one HIS it was developped for, but in any HIS of any manufcaturer that supports the visual integration of web applications. This facilitates implementation at a much broader scale and makes it financially more attractive to Zimmer Biomet.

"This method facilitates implementation at a broad scale."

This option furthermore makes it easier to execute the strategy proposed in the previous chapter: the OR guiding system can be added onto the existing stand-alone application. Besides, the education platform can be added onto it as well. When hospitals have already implemented the stand-alone application, the threshold for them to add an additional functionality to their portfolio is far lower. The proposed way of implementation in Figure 84 in Appendix X is preferred by hospital IT staff for the same reason: they don't have to implement new software. Offering the dashboard as a cloud-based service could eliminate this issue altogether. More information on this is given in the next chapter.

The method of implementation proposed in Figure 41 is deemed feasible and suitable to fit the strategy of a company like Zimmer Biomet. (P5, P6)

Other (future) options

As discussed in the previous section, it is recommended to develop the dashboard based on communication standards like HL7 CDA and HL7 FHIR. It is also recommended to allow the dashboard to understand various (other) 'languages', in order to be as widely implementable as possible. Validation with P8 has brought to light that there are movements present - in the Netherlands - to enforce wide use of the same communication standard. This standard is called health and care information models (HCIMs, also called ZIBs: Zorginformatiebouwstenen). Validation with the P6 furthermore yielded that comorbidities and other secondary diagnosis elements are part of the 'Basisgegevensset Zorg (BgZ)', which roughly translates to 'Basic Dataset for Healthcare'. The "BgZ" will become part of the new Dutch national standard and is an example of an application of HCIMs. (Smeele, 2018) These efforts are focussed on standardising communication, to enhance interoperability between hospitals, departments and applications. ("Interoperabiliteit", n.d.) Nictiz - which is a center of expertise on 'e-health': contributing to better heatlhcare through better information - defines five levels of interoperability that are important in healthcare, as is shown in Figure 42.

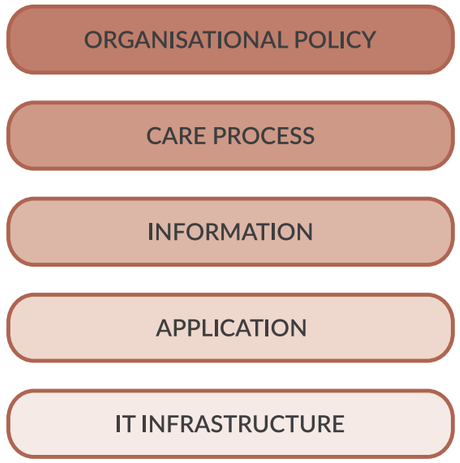


Figure 42. Five levels of interoperability in healthcare, as defined by Nictiz. (Adapted from "Interoperabiliteit", n.d.)

The dashboard itself also supports interoperability, mostly so on the levels of the care process and information. Interoperability on the level of the care process is about cooperation and interoperability on the level of information is about structure and content. ("Interoperabiliteit", n.d.) It is important to strive for interoperability on all defined levels: this means that during further development of the dashboard, interoperability should play an important role in the approach. Letting the dashboard understand multiple 'languages' is a way to achieve this. (P9)

As these movements towards new standards are in effect, but have not yet come to their conclusion, it is recommended to keep a close eye on their development and execute further research on implementing these standards, which also focus on cooperation with HL7 CDA and HL7 FHIR. (de Bel et al, 2017)

Guideline implementation

As described in the previous section, it is important to let the dashboard be able to understand the languages of the data/files that originate from the input systems. It is also important to know what variable is written in what format. As described previously, this requires research with a group of people. This should be a group with experts from different disciplines working together to arrive to the right conclusions, as efficiently as possible. Figure 38 on page 77 shows who these people are.

It is important to let this group pinpoint the exact variables that need to be gathered by the dashboard. This should be done by finding out what variables are required for the guidelines - by researching the proceedings of the ICM 2018 - and by finding out where these variables originate as data points in the hospital. Subsequently, the format/data type of each data point can be examined, and the necessary links and/or steps for 'translation' of the data can be outlined. (P8)

The necessary steps for development of the algorithms have been shown in Figure 38 on page 77. On the following page an example is given in Figure 43 of how these steps for development can look in practice. This practical example is based on guidelines taken from the proceedings of the ICM 2018. (Parvizi, Gehrke, Mont & Callaghan, 2018) The figure should be read from top to bottom. Another example is given in Appendix X. Note: the 'algorithms' shown in Figure 43 and Figure 85 are not created by an algorithm developer. They are merely intended to illustrate the entire process of developping the algorithms.

Organisational implementation

It is important to discuss how the dashboard can be implemented into hospitals on an organisational level. Validation with several experts has resulted in various

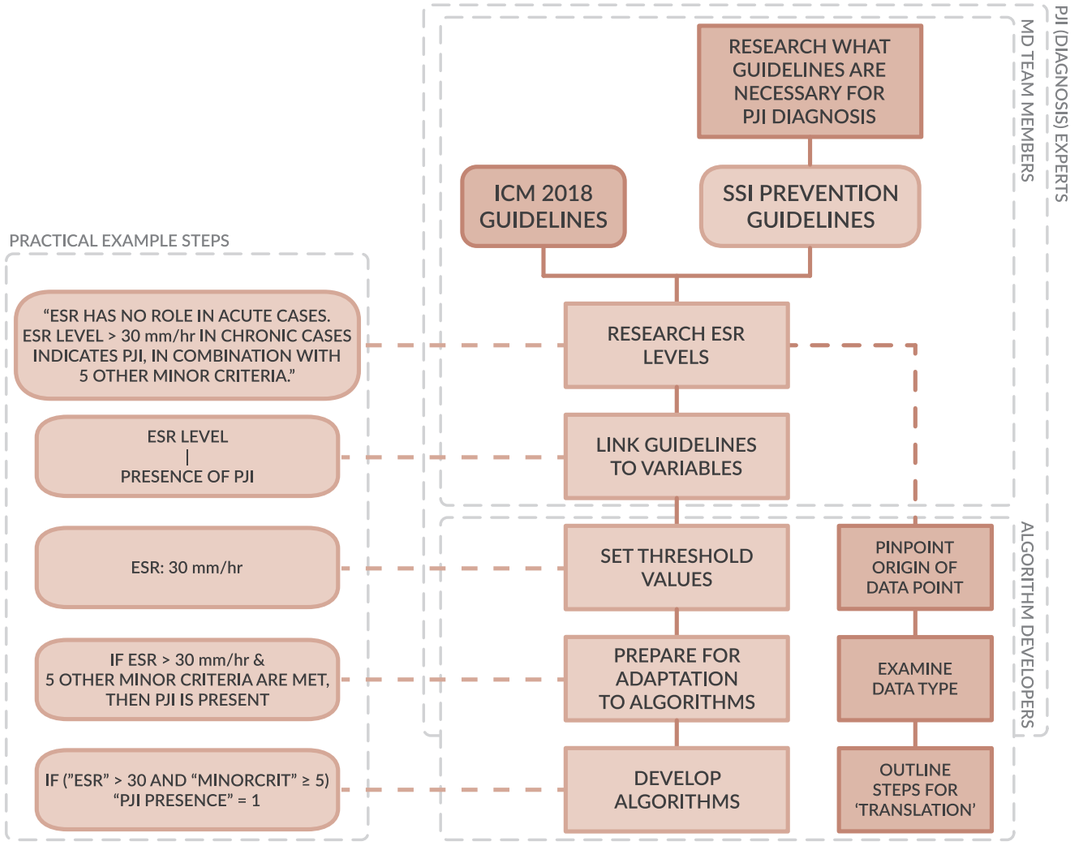


Figure 43. Practical example of steps necessary for development of algorithm (guideline content based on Parvizi, Gehrke, Mont & Callaghan, 2018)

insights. It is for instance important to consider that every hospital is different and everyone has their own care process. (P1) Cooperating with the hospital or team of intended users can, firstly, help to come to an operative multidisciplinary team. Secondly, for teams that are already in existence, this will support the quality and efficacy of the dashboard and will help produce optimal results. These considerations on how the system can be adaptable to various hospitals is discussed in the next paragraph.

Adaptibility per hospital

The system will be developed as described before: guidelines will be researched, algorithms will be written and the system uses the correct technology to receive the necessary data from other hospital (input) systems. To allow the system to be adaptable to the workings of particular hospitals, individually, and in order to fit within the care process, several elements are necessary to consider. First of all, as mentioned before, the system needs to understand mulitple 'languages' (HL7, FHIR, CDA documents, HCIM), in order to be able to be implemented in varying hospitals with systems built on varying communication standards. Secondly, not each

hospital uses the same protocols to manage a case of PJI. A certain base set of variables and protocols will always be present within the dashboard, whether the hospital uses it or not. The dashboard is, after all, also intended to advise the users on optimally managing cases of PJI, based on guidelines set by the largest collection of experts on the subject. However, some variables and protocols that are used by some hospitals and not used by others can fit a modular approach. For most variables no extra development steps need to be taken: if there are hospitals that do not enter certain variables, these will simply not aid to the diagnosis. For some protocols, however, it can be chosen whether or not the hospitals want to use them and/or which protocol they choose to use (since, for some decisions, multiple protocols exist that differ in execution). During development, this modular setup can be considered. A possible option is to create an interface in which hospital staff chooses the protocols. Another option is to discuss it with the hospital application specialist, that will manage the system, and the implementing party, after which the system will be adjusted accordingly.

So, how do hospitals go about acquiring and implementing such a system? Validation with several experts has yielded an overview of this process, as shown in Figure 44. It shows the acquisition process of an IT system in a hospital. On the top left you can see that a division in the hospital, in this case the orthopaedic division, expresses a desire towards the IT board (this name differs per hospital). This entails that someone/people within the division see a need for a system or a tool, miss a functionality or see opportunities for added value to be brought to the care process. Together, they will assess the importance and added value of the request. Subsequently, (members of) the division and the board combinedly define a Program of Requirements, that includes among others technical and functional requirements. When all requirements and desires are defined, they try to find what solutions are available to answer their needs. When a solution is found, the team researches how it can be implemented into the hospital's IT infrastructure. The preferred way of implementation is within the hospital's HIS. Other solutions are not uncommon. Finally, the team reaches a proposal for a budget, which includes development, implementation, maintenance, management and exploitation (for a defined number of years). The funding for the new IT solution originates either from the IT board, or from other foundations, (patient) associations and sponsors. Divisions often maintain close ties to sponsors who aid the hospital in improving the care process. After implementation of the system, the IT board is the department that manages the system. Application specialists are responsible for this (P3; P5)

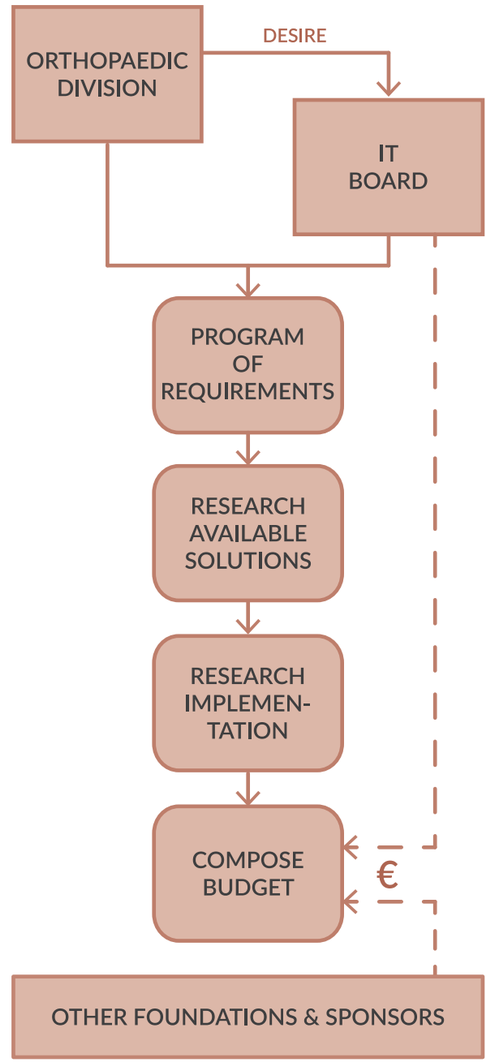


Figure 44. Acquisition process of an IT system in a hospital. (P3; P5)

It also occurs that when a division has their eyes on an interesting IT solution, they find the funds on their own. After closing the deal, they hand the system over to the IT board for it to be managed. The IT board prefers that they are consulted in this process. The purchase of a new IT solution often succeeds, the management of the system afterwards should, however, not be forgotten. (P3).

When the technical implementation of the system is succesful, an application specialist needs to be appointed who will cover the management of the system. Next to this the staff needs to be instructed. Depending on how intrusive the new tool is, this can happen individually, in group instruction sessions or in individual sessions. The 'instructor' can be the 'key user'/'ambassador' (more on this in the next section) and/or the application specialist (that covers management of the system) and/or firm specialists (if necessary). (P5)

This explanation on acquisition and implementation of an IT system is an example of how it can and does look in several hospitals. However, each hospital has a different organisational setup, so there are hospitals where this model may not apply, or applies in a slightly different fashion.

Client acquisition & cost

Now that it is clear how hospitals acquire and implement new IT solutions like the MDT dashboard, it is important to consider how Zimmer Biomet can ensure that that will happen.

Further validation of the client acquisition strategy posed in the chapter 'Strategy' has yielded that the suggested top-down fashion of selling the system may not be the best approach. As can be seen in Figure 44, it is members of the orthopaedic division that firstly address the need or desire for such a system. They are also the ones to instigate these decisions to be made. (P3; P5) Thus, it is the surgeons and other intended users of the system to which the system's value needs to be conveyed. Zimmer Biomet has several kinds of employees who can make this happen.

Figure 45 shows that Zimmer Biomet has a multitude of account managers. These are employees that are often in close contact with surgeons and other staff of hospitals which are their accounts. The tile that reads 'orthopaedic division', is the same tile as the one in the top left in Figure 44. Zimmer Biomet's account managers also often function as the firm specialist, in the OR. This is described earlier in the report and can be seen in the mindmap in Appendix A. Account managers currently speak to the surgeons and other staff a lot about Zimmer Biomet's physical products, to try to maintain and extend their position as supplier of orthopaedic medical devices. They are thus in the perfect position to promote (and sell) this new service.

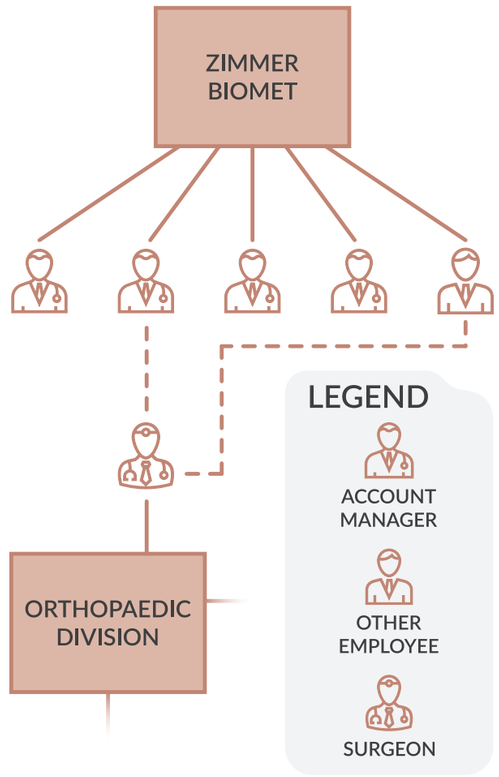


Figure 45. Possible routes to acquire clients for the dashboard

Furthermore, meetings take place between other employees of Zimmer Biomet and surgeons and other decision makers in the orthopaedic division. These decision makers are for instance members of boards within the orthopaedic division, presidents of associations: people who occupy secondary tasks next to their primary role as a physician. During these meetings, future strategies concerning optimal treatment and prevention are discussed. (Zimmer Biomet sales manager, personal communication, June 2018; Zimmer Biomet senior manager, personal communication, 2018) 'Other employees' can be sales managers, directors, senior managers: employees that occupy more strategic positions in the company. These meetings are also perfectly suitable to convince hospital staff of the dashboard's added value.

Ambassadors

Both of the aforementioned groups of ZB employees are in touch with the hospital employees that are the perfect candidates to become 'ambassadors'/'key users'/'product owners' of the dashboard within the hospital. Namely, they are in touch with decision makers in the orthopaedic division, with orthopaedic surgeons and with the intended users of the dashboard.

To ensure the adaptation and implementation of the dashboard, it is crucial to create these ambassadors. (P3; P5) These ambassadors will communicate the value of the system to others in the division and will sell them on its merit.

In conclusion, Zimmer Biomet can achieve creating these ambassadors by utilising their current channels within hospitals. These employees should emphasise the added value of the dashboard, which can for instance be found in the subsections 'Communication', 'Knowledge' and 'Reduction of infection (and cost)' under the section 'Concept development', previously in this report. Ofcourse, the totality of this report is the best persuader. Furthermore, the digital prototype can be used to present the dashboard. It is recommended to allow a UX designer to make a visually more attractive prototpe that is developped and tested in close cooperation with intended users (MDT members (to be)), to fine-tune functionalities and content.

FINAL RECOMMENDATIONS

Introduction

The title of this thesis is ‘designing a service for the management and prevention of PJI cases’ and as far as that design process has come, there is still room for further development and research. This chapter includes recommendations based on insights gathered during the entirety of the project. These recommendations concern various aspects, from unresearched opportunities to interface development recommendations.

Recommendations

Unresearched opportunities

In the chapter ‘Empathise’ it is discussed that not all stakeholder groups have been interviewed. It is recommended to interview patients, general practitioners (GPs) and MDT members to research their needs during the management of a case of PJI. These interviews may yield new insights, which can cause new areas of opportunity to be found. It is furthermore recommended to execute creative sessions with OR staff and MDT members. These stakeholders have important insights and needs to share. These creative sessions uncover more and/or different insights and latent needs of these stakeholders, which is valuable to incorporate in the analysis. (Stickdorn, 2018) How these creative sessions are recommended to be executed is described in Appendix L.

After the initial analysis, insights were synthesised and areas of opportunity were defined. To come to a design brief, decisions were made as to what areas of opportunity to focus on. Other areas were not/barely researched further. It is recommended to further research interesting areas of opportunity (optionally with the newly found insights from interviewing previously uninterviewed stakeholder groups). Possible areas are providing the GP with a support tool, providing a system dedicated to the mental care of patients, providing a system that informs patients on the process and risks (during after-care), and providing a system that facilitates reflection for hospitals and/or hospital staff.

It is furthermore recommended to further research and develop the two other concepts: ‘VR education platform’ and ‘Guiding system’.

Development recommendations

It is crucial that, as suggested before, a group of MDT members (surgeons, infectiologists, plastic surgeons, anesthesiologists, microbiologists), PJI (diagnosis) experts and IT (algorithm) developers work together. Firstly, they ought to research what guidelines are necessary for PJI diagnosis (next to the ICM 2018 guidelines). Then, all guidelines need to be researched to pinpoint what variables are required. Subsequently, the origin of that data point (variable) should be pinpointed as well as what type of data it is, to outline steps for translation to another data type (if necessary). In parrallel, the required guidelines will be adapted to a diagnosis algorithm: examples of this process are given in Figure 85 on page 228 and Figure 43 on page 90.

Following this research, it is recommended to develop the dashboard based on the HL7 CDA and HL7 FHIR communication standards. It is furthermore recommended to take the results of the research into variables and origins of data points, and allow the dashboard to be able to read files of all found data types.

It is furthermore recommended to keep a close eye on the development of HCIMs and the BgZ and execute further research on implementing these standards. Consequently, it may be interesting to research if implementation options based on HCIMs or other options are more feasible, desirable and viable than options proposed in this report.

Interface

It is recommended to involve UX designers in the process of further interface development, to optimally answer to the needs of the end-users. UX designers tend to throw away any assumptions of what they think the user of a digital service will need and instead test all functionalities. (Unger, Chandler, 2012) Testing all functionalities with intended users results in a desirable application that MDT members will be happy to use. It is therefore also recommended to validate the functionalities of the prototype with MDT members.

It is recommended to do this by organising meetings with individual MDT members. Prior to the validation it is important to explain the goal of the validation to the participant by showing Figure 39 on page 81, to receive relevant feedback. The validation begins by describing a scenario to the participant that states that they are about to execute their part of the diagnosis for a patient. The basic functions and value of the concept are explained and the participant tests the functions of the digital prototype relating to the diagnosis. Afterwards, a second scenario states that an MDT meeting is taking place and the participant will at that point use the functionalities of the concept that are intended for use during a live MDT meeting. In a final scenario, the meeting does not take place in a physical space, but remotely, via the dashboard. The user will test the functionalities of the concept that allow the meeting to take place digitally and that aid the members in presenting their data, diagnoses and advice, as well as discussing the optimal form of treatment.

It is recommended that an algorithm is written for the calculation of infection risk. Inspiration for this risk calculator can be gathered from the PJI risk calculator resulting from the ICM 2018 (Nicholson & Penna, 2018) and its substantiating journal article. (Tan et al, 2018). Also, it is recommended to evaluate the added value of linking the outcome of the risk calculation in the ‘advice’ tab to the hospital’s KPIs. The hospital/team has decided what they aim to achieve. If you can link the risk calculation to their KPIs, it can be calculated how ‘risky’ a surgery is in their eyes. This is because one hospital might define the same surgery as less risky than another. (P1)

It is furthermore recommended to research whether or not it is desirable to implement a remote/video conferencing functionality within the system, or if this functionality can be established by providing compatibility with currently used remote/video conferencing tools - if present.

Cost

Research on costs of developping and implementing clinical decision support systems barely exists. (Mazanec, 2016) Thus, it is recommended to supplement the research done in this report and to perform a more extensive analysis on cost and profit.

Implementation recommendations

It is recommended to further develop and execute the plan to research the guidelines and develop the algorithms, as first discussed on page 77.

It is recommended to validate the concept with more MDT members in general, as well as with a wide variation of the disciplines included in such teams. This may bring forth important insights that have not yet been found or thought of. Validation with these staff members - who are the intended users of the dashboard - allows one to find out their specific needs and their exact requirements for the dashboard.

To strive for adoption of the dashboard, it is recommended to persuade relevant hospital staff of its value: efforts should be aimed at creating ambassadors for the dashboard in hospitals, as described on page 93, which is the right path to get such systems sold.

“Creating ambassadors for the dashboard in hospitals is the path to get this system sold”.

The proposed ways of implementation in Figure 41 on page 87 and Figure 84 on page 227 both have their advantages. It is recommended to further research whether HIS software can perform the necessary calculations to allow the dashboard to perform its operations. It is furthermore recommended to consider both (and perhaps other) options on technical feasibility, cost, potential profit and desirability from (future) clients. The designer recommends to implement the dashboard according to Figure 41 on page 87.

It is recommended to research if the dashboard can be implemented as a service (SaaS: system as a service). This way the client (hospital) needs to install no hardware nor software, since the system is offered as an online service. The HISs are able to visually integrate the system via the web-based integration. ‘Infera’ is offered in such a way (“Inferscience”, 2018), but is only compatible with four EHRs. This system is becoming compatible with more EHRs, including common ones as Cerner and Epic (Nihalani, 2017). It may thus be interesting to further research this option for the dashboard.

Inspiration

Inspiration for further development of the dashboard may be gathered from the ‘Applied Data Analytics in

Medicine' (ADAM) program at the University Medical Center Utrecht (UMCU). ("Data analytics", 2018) ADAM is a program that researches the possibilities of data analytics. Their applications include clinical decision support tools. ("Data analytics projecten", 2018) Cooperation with this program may also be interesting, especially since Zimmer Biomet already has links with this hospital.

Inspiration and/or cooperation may furthermore be looked for at the developers of 'Infera', which is a clinical decision support tool similar to the dashboard. ("Best Clinical Decision Support Systems", 2018)

Scope

Because of the complexity of the context - protocols differ per hospital and even more per country, as does the application of multidisciplinary team meetings - it is best to firstly focus on implementing the dashboard in the Netherlands, since that is where nearly all research has taken place. Afterwards, it is recommended to expand to Germany and the UK, where MDT meetings occur and where the dashboard can aid in making its occurrence more common. Besides, Zimmer Biomet is highly active in these countries and local experts that are more familiar with healthcare practices in these countries have been actively involved in this project.

It is recommended to apply the option presented in Figure 41 on page 87 to implementing the dashboard in the Netherlands. Furthermore, the organisational implementation should be executed as described in Figure 44 on page 91 and Figure 45 on page 92. The necessary guidelines are to be researched as described in Figure 38 on page 77.

Pilot

Pilot testing for implementation or actual implementation may be executed at the UMCU. As stated before, Zimmer Biomet has links with this hospital. Furthermore, this hospital has developed the 'Enterprise Data Warehouse', which might significantly simplify the implementation of the dashboard. (P9; "Data engineer", 2018) This simplification of implementation can provide the possibility to pilot test the dashboard as quickly as possible, with as little effort as possible.

Another opportunity for implementation is at the Reinier de Graaf Gasthuis in Delft, with which Zimmer Biomet also has close ties. The way of implementation as described in Figure 41 on page 87 is primarily based on information from and validation with experts at this hospital and the UMCU, next to the HIS manufacturers.

Conclusion

In conclusion, it is recommended to continue the development of the dashboard, as it is deemed lucrative by the designer. It is feasible, desirable and viable and it will aid in the management and prevention of PJI cases. Next to aiding surgeons and MDT members, it will improve patient outcome and will serve an economic and societal goal.

FINAL RECOMMENDATIONS

PROCESS GUIDELINES

Introduction

This chapter summarises all process guidelines mentioned throughout the report and supplements that list to make it as complete as possible. The guidelines are intended to aid in the execution of an innovation process in the medical world. Amongst others, they tell you how to approach such a process, what factors of succes and of consideration are and how to acquire information from stakeholders during the process. They can be applied by anyone who is executing such a process. The guidelines are primarily created for students, but can also be applied by, for instance, an academic researcher or a business.

Contact

When trying to establish contact with stakeholders, for instance to acquire information on a subject, to pick their brain to acquire insights or to hear their views on some of your thoughts, it's important to consider a few things. Medical staff, and surgeons in particular, are extremely busy. Their days are filled with surgeries from 8 am till 6 pm, after which they often still have meetings to attend or other work to finish. It is therefore crucial to keep your request as concise as possible, and be very flexible in your suggestions on meeting. Another aspect that is important in this regard, is that your request is convincing enough for the other party to accept, and give you part of their time. To achieve this, it is important to create goodwill: you either have to have something to offer that provides them with an advantage, you have to be able to help them progress, or your proposal has to be on a subject that is particularly interesting to the other party. It either has their interest greatly, or they are convinced by the added value of your suggestion. This means that your message needs to be specific enough to enthuse the stakeholder, yet concise enough to retain their focus. To convey your message in a convincing way, it is recommended to use visuals that explain the situation and trigger the recipient.

"Your message needs to be specific enough to enthuse the stakeholder, yet concise enough to retain their focus"

If, for some reason, you lose contact, you should not take it too personally. It is possible that political and hierarchical relations have caused this, and it is futile to try to fix this. Available time can be another factor to cause it. Subtle reminders can be sent, but more than once or twice will not aid your image and your attention is better aimed elsewhere.

Hierarchy

The medical world is a hierarchical one, which allows experience to play a crucial role in caring for patients. The experience of medical staff is vital to providing the optimal care that patients require. It is also very important in diagnosing, treating and making decisions. A lot of the decisions made are based on years and years of experience. The aforementioned hierarchy is important to take into account in all matters of your innovation process. Surgeons are looked up to and they (will) have the last word in a lot of scenarios. This is crucial to consider when making contact, maintaining contact, having conversations and meetings, visiting the OR, facilitating sessions and designing products and services.

Creative facilitation

When following an innovation process, you are very likely to organise sessions that include the stakeholders of your assignment. During the preparation and execution of these sessions it is important to consider a couple of matters. You should know who will be attending and what their roles are: the hierarchical relations are important during such a session. Keep in mind that the participants are likely to have a more practical approach than you're used to: count on less 'out of the box' thinking, more existing solutions and substantiations. Try to find a way to cut through this. You can, for example, let people attend of whom you know they are creative thinkers, to trigger the other participants. Also, the participants may need more guidance: give examples, push them into directions, help them, 'pull' the ideas out of them. You might need to speak more than you are accustomed to. Furthermore, the course of the sessions can be approximately split up into two scenarios. These scenarios and their corresponding guidelines are outlined below.

Introvert and/or passive participants

- Give little pushes in the right direction: 'tease' directions to ideate in
- Devise analogies
- Simplify used methods
- Give more elaborate explanations
- Take participants by the hand
- Ask a lot of questions
- Use methods to further expand on presented ideas and to think of variations
- First to last resort: nudge participants towards solution directions already thought of
- Last resort: nudge participants towards ideas already thought of

Active participants bring innovative ideas

- Speak less
- Let participants be more in control themselves
- Use creative methods
- Let creativity flow: accomodate their creativity
- Go along with presented ideas and ask questions
- Challenge the participants
- Use methods to generate large quantities of ideas
- Use methods to further expand on presented ideas and to think of variations

Implementation

When trying to ensure succesful implementation of guidelines, practice is as important as the medical and technical aspects of those guidelines. (Rogers, Shoemaker, 1971) This means that the guidelines that you are trying to implement, should be taught to the targeted users and should be executed repeatedly, in order for the users to become acquainted with and take ownership of those guidelines. Furthermore, when implementing new guidelines into a medical organisation, it is important to consider what the current workings of that organisation are and how the guidelines can be adapted to function properly. The strategic goals of a project and suggested guidelines need to fit with the organisational strategy of the institution they are being implemented in. (Sonnad, 1998) Research and efforts to align these two elements are thus highly recommended.

Further recommendations

It is important to find ways to reach the people that work in a field that heavily relies on protocols and conventions. How to get them to be able to cooperate in the innovation process is the next crucial step. Try to get an 'in': a contact that can help you reach and address the people whose help you could use greatly. Consider the fact that employing change may happen less fluently than expected. Know that experience (of surgeons) is of most importance and that it is heavily relied on, rightly so. Find ways to complement this experience, rather than replace it.

Expect a complex industry, which makes it crucial to cooperate with medical staff. (Kleijne-Thoonsen, 2017)

REFLECTION

Introduction

This chapter describes (personal) reflections on several aspects. Firstly, I reflect on the design methodology I used during this project. Subsequently, I reflect on my process during this thesis. I do this by dividing the process in to three distinguishable phases. In conclusion, I reflect on the process as a whole.

Design methodology

In the beginning of this project I defined the methodology I would use. This methodology, called service design, is something that I've come to love during an internship prior to this graduation project. This was an internship at a service & UX design consultancy. Already at the moment of defining the methodology for the project I had to rethink and reshape some of the elements that I had experienced at this company, but to a small degree. Not until further in the project, I adapted the process more intensively to create a better fit to the project and the problems at hand. Finally, I've come to a methodology that I could name my own, though it is based on multiple other methodologies and (personal) experiences.

The methodologies I've learned during my bachelor and master degree; the experience I've gained at my internship; their view on service design; others' views on service design; my knowledge on latent needs/ design abduction/Maslow's hierarchy of needs. They're all elements that have helped shape my perspective on design and have resulted in the methodology I've used during this project.

I am a strong believer of the presence of latent needs (a term popularised by Slater, Narver, 1998) among customers/users. In this theory, customers may sometimes desire or need something, but be unaware of it themselves. These needs can come to the surface when they are triggered. Explorative research is a method that is used to find latent needs among customers. (Stickdorn, 2018) When you want to design a product or service and know the intended end-users, you can find out their (latent) needs and answer to them.

Kees Dorst states in his article "The core of 'design thinking' and its application' that during the more complex form of design abduction - he calls this form of productive reasoning 'Abduction-2' - designers only know the end value we want to achieve. We don't yet know what to create, how to create it or how it should work. (Dorst, 2011) Within this project (and often within service design), the designer also does not know the end value he wants to achieve; in the beginning of the analysis, that is.

I believe that the method used - which has formed itself during this project - in this project, lies somewhere between these two methodologies. At the start of the project, I vaguely knew what I had to achieve, but that goal was far too broad and abstract to apply to a design problem. Extensive analysis has defined the design goal, and further sharpened this definition. At that point, I knew the end value I wanted to achieve. Further progress into the project made clear what had to be designed and for whom. Finally, the final stretch of this thesis has defined how all of this should be achieved, and how it can create that desired end value.

Analysis phase

As a rookie in this particular medical field, there was a lot to learn. Next to the sort of things that may be expected to learn, some interesting other elements also popped up. From assuming that an operating theatre appearing less professional to the eye of a rookie, also is of lower quality (which, to be clear, was not the case and was a wrong assumption) to finding out that a hierarchical setting among surgeons is of influence to the dealings of managing a case of PJI.

After the second creative session, it was my intention to interview more (and other) stakeholders and to hold more sessions. These sessions would have taken place with (an) open and unbiased mind(s), in order to not limit creativity. The insights and ideas that derived from the second session, the session before that and the executed interviews would have been validated in these sessions and in more interviews, be it only at the very end (as to not lead the conversation, as explained before). However, little more sessions that could aid the analysis phase were held and a few more interviews were held. Repeated efforts to get these meetings arranged sadly failed, amongst others due to strict rules on confidentiality and regulation. Channels that were found to arrange such meetings, sadly also didn't result in any meetings, amongst others due to tight schedules of the involved parties. Figure 46 visualises that some efforts for contact failed and others initially succeeded, but in time were not managed to result in creative sessions and more interviews.

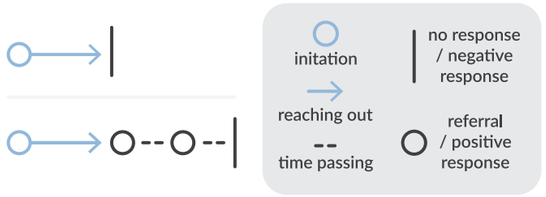


Figure 46. Efforts often failed or initial successes faded out to no result.

A valuable lesson has been learned from this: I wanted to interview every defined stakeholder, if not more than one per stakeholder group. It appeared to me that this could only be achieved via Zimmer Biomet. A reason for this was the manner of formulation, when I asked about this preference. This has taught me how to formulate differently as to think in opportunities that bypass (or breach) certain barriers instead of focussing on those barriers. At a later point during the project, I came to realise that assertiveness and some stubbornness could have aided in the realisation of these meetings. This will be discussed in a following paragraph.

The analysis phase of the research method used in this project requires a considerable amount of contact with stakeholders; via observation, one-on-one interviewing and creative sessions. At the start of this phase I had a clear vision of how this phase should transpire and what steps needed to be taken. After a short while, the stakeholders were mapped out and I was eager and hopeful to speak to them all. In hindsight, this attitude may have been a bit unrealistic and has caused some disappointment. A clear plan was set out in my mind, but there are much more factors at play in such an intense work environment. Planning ahead for more setbacks, would have been a good idea to cope with the progress of this project the first 2½ months. There are no people that dropped the ball during this phase. The effort that has been put in to meet my desires (to conclude a proper analysis), did not come short. Sadly, the harsh truth of the matter is, that the stakeholders I aimed to talk to are simply extremely busy and have tight schedules, it was tough to squeeze in a meeting.

For an optimal result of this analysis phase, more interviews would have been helpful. More creative sessions could also aid the completeness of the insights gathered. The result may have been that the conclusion would remain relatively similar (be it, with more nuance), though for all we know, it just may have been the case that other (currently unknown) insights would surface. How to tell if you've executed enough interviews, mostly comes down to experience.

Conclusions (from one ethnographic study) have been made that 97% of the insights were from the first 12 interviews and 94% from the first 6. (Guest et al, 2006) Another study, that surveyed 560 qualitative PhD research papers, found that they conducted 31 interviews on average. (Mason, 2010) So, again, experience will tell you if it still makes sense to do more interviews, or if you're not getting any new insights. I feel more insights could have been gained at the end of the initial analysis phase, this is visualised in Figure 47.

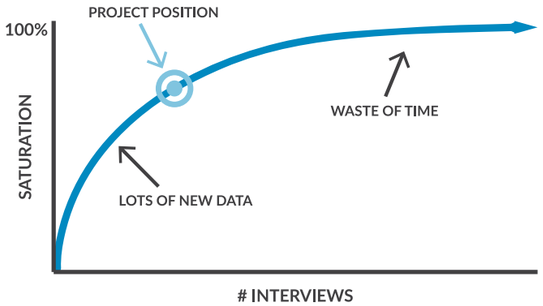


Figure 47. Data saturation in relation to amount of interviews done and this project's data saturation position. (adapted from Seaman, 2018)

Ideation & conceptualisation phase

The ideation phase started off fine, with some ideas I got in my head thanks to the entire analysis that had just passed, including the interviews, OR visits and creative sessions. Among these ideas were definitely some that were valuable, but for the sake of academic value, I wanted to come up with more ideas as to not jump to conclusions to quickly. This process did not expire completely smoothly. I tried different methods, to come up with more and different ideas. Some methods resulted in new ideas that had not crossed my mind yet, but never a lot. Because of the fact that it seemed I had a writer's block, I became more demotivated. This resulted in me spiralling (this word may make this passage more sinister than intended) in a bit of a rough patch. I therefore spent too much time ideating with too little result.

Finally, after having validating conversations, I found out that perhaps there wasn't much more to come up with in the first place. At that point I picked out ideas that I deemed most valuable (with which the conversation partners agreed). The chosen ideas actually resembled ideas that had sprung up in an early part of this ideation phase, hence the feeling of wasted time. They were however more elaborated and had a wider development of elements. I took these ideas to develop concepts. After presenting the concepts to my mentors, I got back on track and was energised again to continue and finish my project positively.

If I did present or choose concepts that appear obvious, I need to learn that it is okay to embrace that outcome, and focus on what is most important at that point of my graduation thesis, which is moving forward towards the validation and implementation.

Validation & strategic implementation phase

During this phase I had found renewed energy and ambition to finish this project as excellent as possible. I used my renewed energy to finish a prototype that could be used for validation, further develop one chosen concept, define an implementation strategy for Zimmer Biomet and finish this report from top to bottom. I reached out to find participants to validate my concept, and unfortunately it again appeared difficult. I initially came to a solution that involved the participation of medical staff that are not necessarily direct users of the concept. They do however have knowledge on the subject and the goings of the process. Optimally, I would have been able to validate the design with several MDT members, but sadly it only came to one. This compromise appeared to be the next best solution. However, after this initial solution, I decided to be a bit more assertive/cocky at reaching out to medical staff and threw some restraint aside. This appeared lucrative and resulted in multiple referrals. Via these referrals I eventually managed to receive helpful information from over half a dozen people active in the medical field. This information pertained to:

- development from guideline to diagnosis algorithm;
- hospital information systems;
- their acquisition, cost and implementation;
- the technical details of and links between the network of input and output systems present in a hospital;
- and the viability, desirability and technical and organisational feasibility of the MDT dashboard.

With this information I was able to make crucial additions to my project, which added to the viability and feasibiity of the presented solution. The process of acquiring this information is visualised in Figure 50 on page 104. The acquisition of this information, together with all other insights that have been gained since the initial analysis phase, furthermore resulted in a higher data saturation. This is visualised in Figure 48.

You might ask yourself (as did I), what caused the difference between what Figure 46 on page 101 shows and what Figure 50 on page 104 shows? I have learned that you might find yourself in a place where you can not simply contact any person you'd like to discuss your entire project with. The organisation that you're executing your research for has certain relationships with certain organisations, as well as a lack of relationships with other organisations. Relational and/or political considerations can play a role in making contact. Moreover, your project is likely to fall under a certain form of confidentiality. This can also be a large contributing aspect to not being able to discuss your project (entirely, with anyone). At this point it is important to not look at the glass being half empty - seeing only the barriers - but to look at it being half full, by trying to find solutions. Primarily, try to figure out what amount of your project you need to share at a minimum, in order to extract the information that you desire, without giving away too much of your own insights.

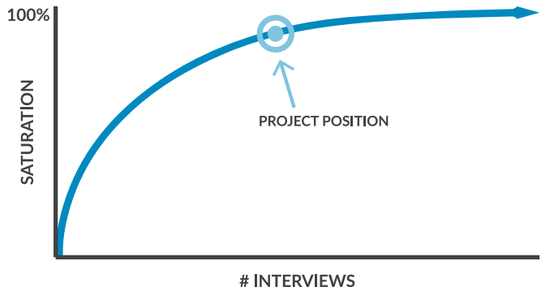


Figure 48. Data saturation in relation to amount of interviews done and this project's data saturation position. (adapted from Seaman, 2018)

Overall process

I will start this paragraph by reflecting on what my process looked like. The overall process is visualised in Figure 49. After the assignment was clear, both the literature review and the field research (consisting of interviews, OR visits and creative sessions) made me create an understanding

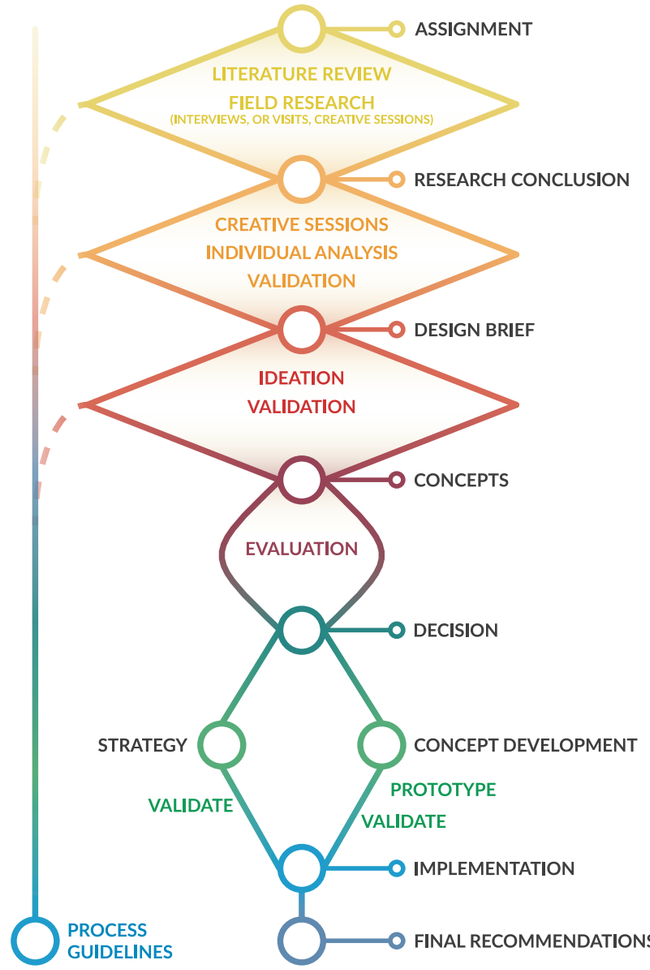


Figure 49. The overall process of this project

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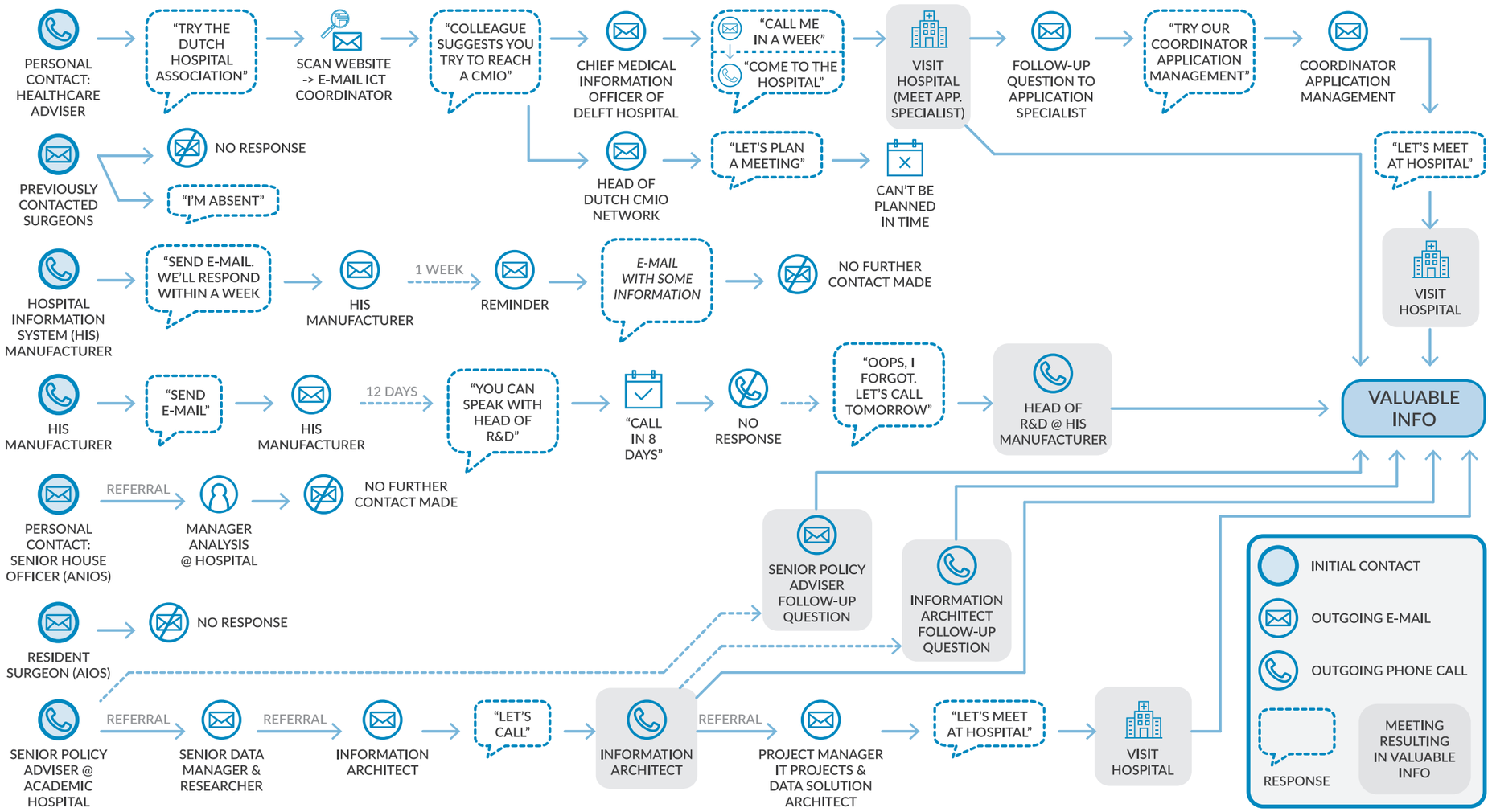

Figure 50. Process of making contact and acquiring information in the validation phase of this project

of the context. Thorough analysis of the findings of this phase, resulted in a conclusion. From that conclusion forward, further creative sessions and individual analysis resulted in a vision on the opportunities. Validation of these views resulted in a design brief. From that point, I continued with the ideation, to give substance to what the design brief requested. A phase of validation resulted in the presentation of three concepts. After evaluation of these concepts, one of them was developped further. At the same time, a strategy was developped for the beginning of the implementation of the PJI management system. After prototyping the developped concept, the strategy and various aspects of the developped concept were validated. This - and all other steps of the process - resulted in final recommendations. A parallel line has run through the project the entire time. My experiences during this project, and as a newcomer in the medical world, have resulted in process guidelines on how to approach an innovation process in the medical world and how to acquire information to kickstart this process.

Be it not without bumps in the road, I experienced the process as quite effective and pleasant. As mentioned before, I was in a bit of a creative rut - and therefore also lacked motivation in general - during the ideation phase. I've learned the most from events that I (during the project) experienced as setbacks. I've come to learn, however, that these events are normal elements of such a process. Events such as not being able to initiate as much contact as desired or not receiving as much responses as hoped for, have taught me important lessons concerning communication. Unforeseen circumstances that cause a decreased period of supervision have taught me lessons about how to deal with such events. I have to try to not throw in the towel, but rather take control of the situation.

Furthermore, I would like to add that I have found out that I am more productive when I am under (time) pressure. Finally, I've come to learn that I thrive on situations and projects where I can apply empathy to discover solutions. I am enthused by this and hope to be able to apply this as much as possible in my future endeavours.

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