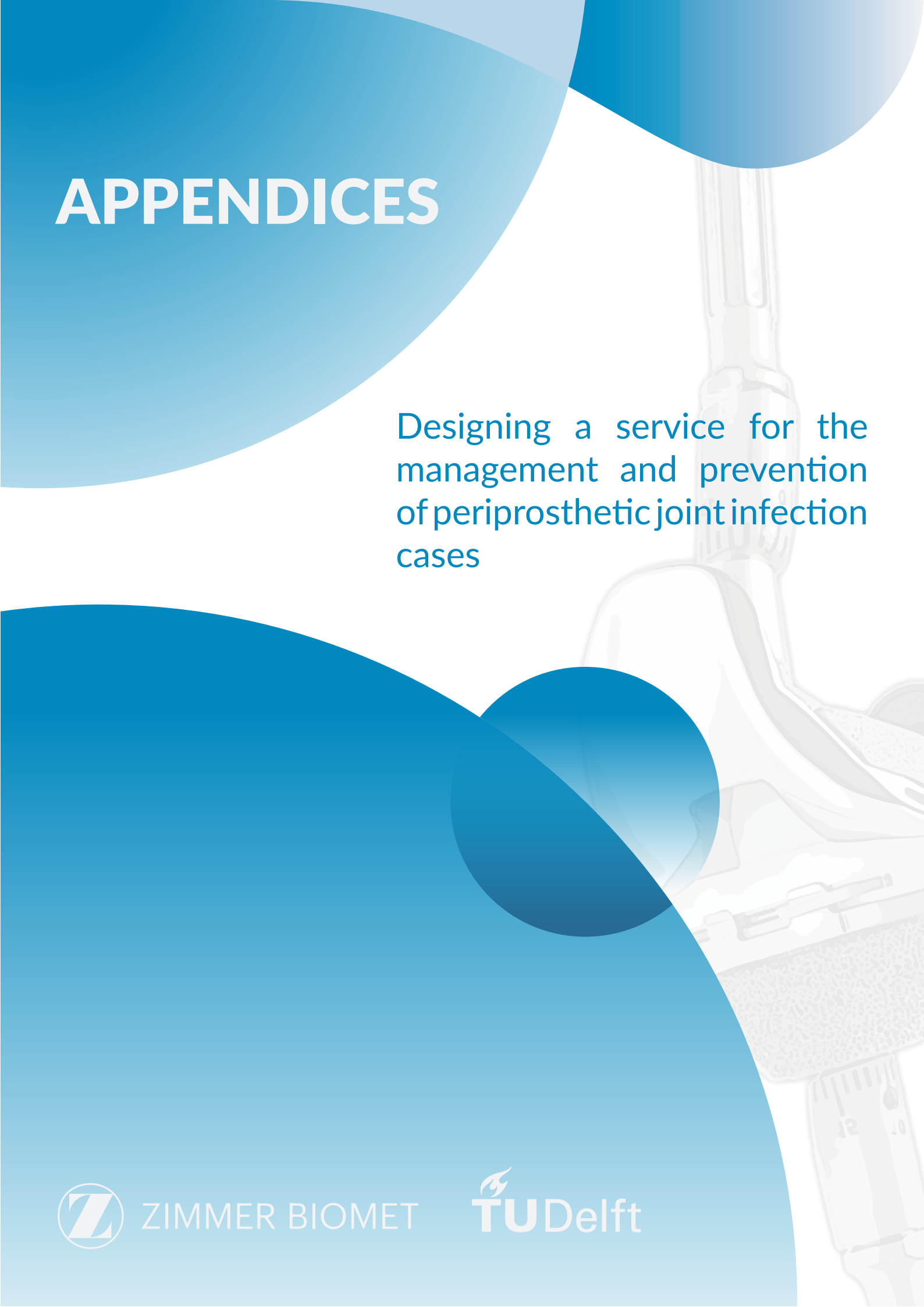
APPENDICES

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



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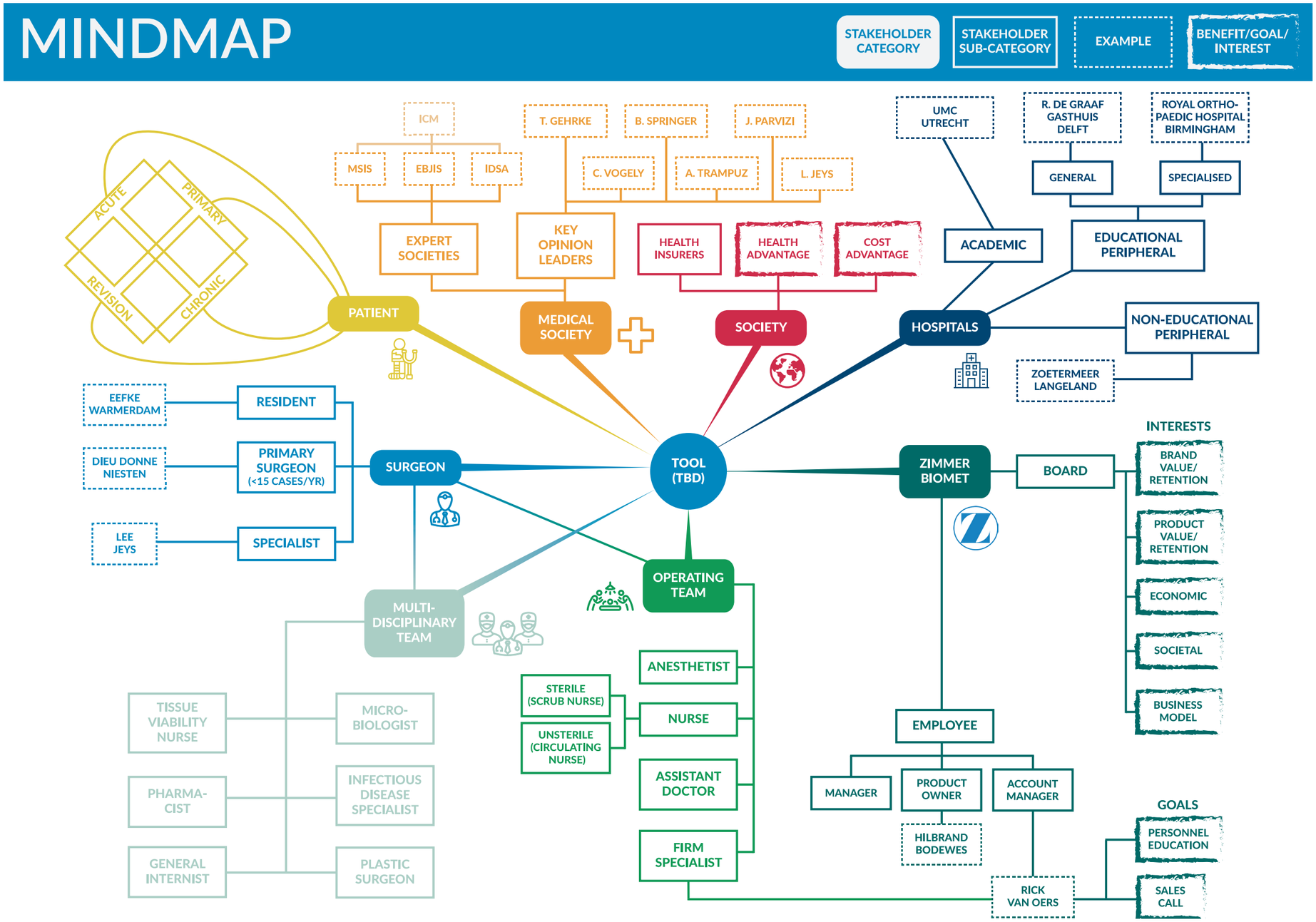
REFERENCES & APPENDICES

Appendix A - Mindmap



Appendix B - No clear standard

Clinical practice guidelines have been released by the Swiss Orthopaedics and Swiss Society of Infectious Diseases (SOSSID) & European Bone and Joint Infection Society (EBJIS) - who's standpoints are similar -, the Musculoskeletal Infection Society (MSIS) & International Consensus Meeting group (ICM) - the ICM guideline is an adaptation of the MSIS guideline (Parvizi, Gehrke, 2014) - and the Infectious Diseases Society of America (IDSA). Clinics and surgeons from different areas in the world adopt different guidelines, resulting in no clear consensus. . A visual representation of how divided these views are and how unclear it even is in other areas, is shown in Figure 51.

In August 2013, the International Consensus Meeting on PJI was held in Philadelphia. More than 400 experts from 52 countries and representatives from over 130 societies convened. It should be noted that most of these experts hailed from the United States. This meeting has resulted in consensus guidelines, though far from all surgeons adopt these guidelines. In July 2018 there has been a new ICM, with many more participants from all over the world: 800 delegates from over 100 countries who are actively involved in the Delphi process that has generated the document to be voted on by even (many) more visitors. Definitions of risk factors, criteria, guidelines etc. still differ per society. For this reason, the following appendix will use definitions and consensus from the ICM to give an introduction to the subject. Other consensuses may sometimes be referred to.

Figure 51. Visual representation of which expert society guideline is used where in the world. Much is still unclear, which is a harsh but just resemblence to the knowledge and available help on managing a PJI case.

REFERENCES & APPENDICES

Appendix C - Literature review

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. The occurrence of prosthetic joint infections is increasing and is predicted to increase even more.

> *"The key to success is based on well-defined and detailed hospital infrastructure, including a meticulous preoperative aspiration regime, planning, aggressive intraoperative surgical approach, and postoperative individualized patient care." (Springer, Parvizi; 2013)*

Incidence

There are nearly one million THAs or TKAs being performed in the US annually (Berbari et al). This number is predicted to grow to four million in 2030. (Kurtz et al, 2007) A study from 2012 shows the historical number of infections following THA or TKA, as well as the projected number of infections, within the USA between 2001 and 2020. These numbers are visualised in Figure 52.

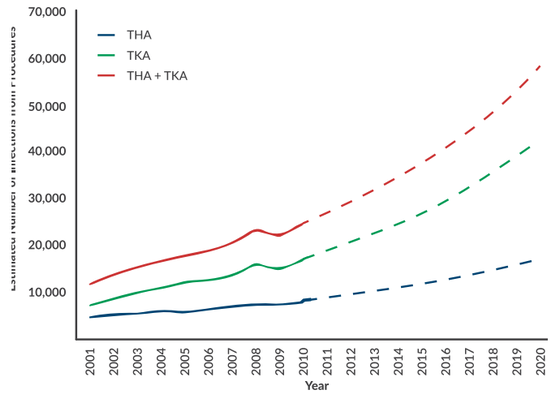


Figure 52. Historical and projected number of infections with THA, TKA and combined THA and TKA procedures within the USA between 2001 and 2020. (adapted from Kurtz et al, 2012)

Economic impact

The impact that PJI has on the healthcare system is enormous. The cost that is linked to revision cases caused by infection is increasing rapidly, as shown in Figure 53.

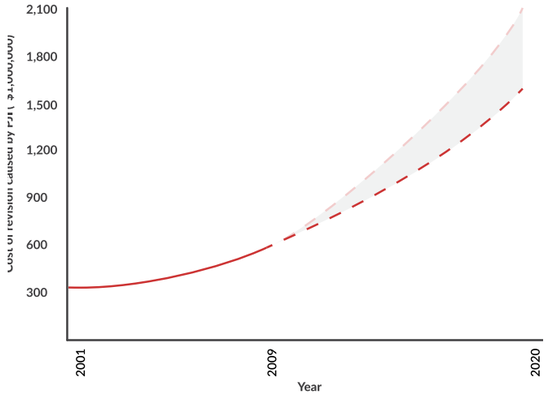


Figure 53. Cost of revision cases caused by PJI, in the United States. (based on Kurtz et al, 2012)

In the United States, these costs were $320 million in 2001. In 2009, they had increased to $566 million and by 2020, they are projected to exceed $1.62 billion. (Kurtz et al, 2012) However, as stated by Tande, Patel, 2014, it is likely that this is still a highly underestimated number since only the estimated hospital cost is included in the survey, a lot of additional indirect and direct costs are neglected. A treatment of an infection following TJA for a single patient has in the past been said to cost between roughly $60,000 to $100,000 and it causes longer hospital stays. (Kurtz et al, 2007)

Risk factors

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

Timing (definition)

Zimmerli and Trampuz classify PJI based upon the timing of symptom onset after implantation with < 3 months, between 3 and 24 months, and > 24 months from index surgery representing early, delayed, and late infections, respectively. (Gehrke, Parvizi, 2014) Another way to classify PJI based on the timing is by differentiating between acute and chronic PJI, which

represents, respectively, within 90 days of implantation or after. (Parvizi, Gehrke, 2014) Acute PJI itself can occur either postoperatively, meaning that the bacteria causing the infection is present due to the surgery, or via hematogenous spreading: the bacteria has spread through the bloodstream. (Kuiper et al, 2014) Early and delayed PJI are the most common biomaterial-related infections and are often the result of perioperative contamination. (Gbejuade, Lovering, Webb, 2015)

Preoperative

There are many patient conditions that can increase the risk of developing an infection. These conditions include, but are not limited to:

- Malnutrition
- Uncontrolled diabetes
- Morbid obesity (BMI > 40)
- Chronic renal disease (kidney failure)
- Rheumatoid arthritis
- Pulmonary disease (COPD)
- Valvular heart disease
- Preoperative anemia
- Peripheral vascular disease
- Metastatic tumor
- Psychosis
- Exorbitant alcohol (ab)use (> 40 units/week)
- Excessive smoking (> one pack/day)
- Sever immunodeficiency
- Male gender
- Recent hospitalisation
- Depression

(Del Gaizo et al, 2014; Shahi, Parvizi, 2015)

Two studies performed by Bozic et al, show the hazard ratios for PJI in several risk factors for medicare patients with TKA or THA. These ratios are shown in Figure 59.

Intraoperative

A lot of intraoperative elements can decrease the risk of PJI. Minimising the number of bacteria in the surgical wound and minimising the number of bacteria in the operating room environment are the two key elements. These elements can be achieved by minimising OR traffic, using sterile equipment and executing enough glove changes at the right moment. Properly preparing and washing the skin of the patient as well as OR staff washing their hands is also crucial, since surgical site infections (SSI) are very commonly caused by native microorganisms of the skin, like Staphylococcus aureus. (Lee et al, 2006; Prokuski, 2008; Shahi, Parvizi, 2015)

> *"Traffic in the OR is a major concern during TJA. Revision cases demonstrated a particularly high rate of traffic. Implementation of strategies, such as storage of instruments and components in the operating room and education of OR personnel, is required to reduce door openings in the OR." (Panahi et al, 2012)*

Other ways to achieve a smaller chance of infection is to minimise the handling of lights, wear surgical masks and wear clean OR attire. To this point, no conclusive evidence exists that assigns wearing body suits to a decreased occurrence of PJI. (Gehrke, Parvizi, 2014)

Total knee arthroplasty		Total hip arthroplasty	
Risk factor	Adjusted hazard ratio	Risk factor	Adjusted hazard ratio
Congestive heart failure	1.28	Rheumatologic disease	1.71
Chronic pulmonary disease	1.22	Obesity	1.73
Preoperative anemia	1.26	Coagulopathy	1.58
Diabetes	1.19	Preoperative anemia	1.36
Depression	1.28	Diabetes	1.31
Renal disease	1.38	Cardiac arrhythmia	1.30
Pulmonary circulation disorders	1.42	Peripheral vascular disease	1.29
Obesity	1.22	Depression	1.38
Rheumatologic disease	1.18	Psychosis	1.48
Psychosis	1.26	Congestive heart failure	1.22
Metastatic tumor	1.59	Alcohol abuse	1.72
Peripheral vascular disease	1.13	Hypertension	1.14
Valvular disease	1.15	Malignancy	1.13

Figure 59. Risk factors in elderly medicare patients with TKA and THA (adapted from Bozic et al, 2012; Bozic et al, 2012)

The positive influence of applying laminar air flow is a matter that remains unclear and on which disagreement exists. Other factors during surgery that are important to define the risk for infection include kind of operation (primary/revision), kind of joint (e.g. hip/knee), operative time, previous procedure in the operating room and anaesthetic management.

Postoperative

Postoperatively, infections can arise because of, for instance, hematogenous spreading, or exposure to risky environments.

Increasing hospital length of stay increases the risk for establishment of PJI. Other factors include dental work, subsequent surgery and long-term stay in a healthcare facility. (Springer, Parvizi, 2013)

Patient/surgeon journey

Presentation

Prior to the patient's first - concerning this condition - visit, also called 'presentation', the patient is very likely to have had complaints for a while concerning pain, irritation, etc. Patients tend to not come to the orthopaedic surgeon immediately due to own reluctance, lack of knowledge of their general practitioner or other reasons.

> *"Clinically, patients often present an acutely inflamed, painful, swollen knee joint with or without associated adjoining erythema or a discharging sinus. The patient may also complain of stiffness of the joint and difficulty weight bearing on the affected limb." (Infected Joint Journey, 2017)*

Acute and chronic infections can be suspected through differing factors. These factors are listed in the table in Figure 54.

Acute	Chronic
Fever	Sinus formation
Wound drainage	Stiffness of the joint
Erythema	Difficulty weight bearing
	Instability
Swelling pain	

Figure 54. Suspicions of infection (adapted from Infected Joint Journey, 2017)

Diagnosis/assessment

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. How these definitions differ, is visualised in Figure 60 (on the next page) for three expert societies. Furthermore, a lot of tests exist, these are still being optimised and new tests arise.

> *"No universally accepted definition is available"*

As stated by an expert on PJI diagnostics: "Diagnosis of infection is like pieces of a mosaic." The team performing the diagnosis needs to detect those pieces, followed by interpreting those pieces and finally they need to use all the pieces of the mosaic to come to a conclusion (M. Heier, personal communication, April 4, 2018)

It is important that the risk factors for PJI are taken into consideration when commencing diagnosis. Patients that are at higher risk for PJI need a more extensive diagnostic evaluation than those at lower risk. Risk factors to be taken into consideration include those shown in Figure 60 (on the next page), as well as history of a superficial surgical site infection, history of prior joint infection and operative times longer than 2.5 hours. (Springer, Parvizi, 2013)

Several intraoperative tests also exist, to help diagnose PJI. These include gram staining, frozen section, synovial cell count, leukocyte esterase, sonication, polymerase chain reaction, gene expression and biomarkers. (Springer, Parvizi, 2013)

Criterion	Definition of prosthetic joint infection					
	MSIS		ICM		IDSA	
	Definitive evidence	Supportive evidence	Definitive evidence	Supportive evidence	Definitive evidence	Supportive evidence
Sinus tract communicating with the prosthesis	x		x		x	
Identical microorganism isolated from two or more cultures	x		x		x	
Purulence surrounding the prosthesis		x			x	
Acute inflammation upon histological examination of periprosthetic tissue		x		x		x
Single culture with any microorganism		x		x		
Single culture with a virulent microorganism						x
Elevated synovial fluid leukocyte count		x		x		
Elevated synovial fluid neutrophil percentage		x		x		
Elevated serum ESR and CRP values		x		x		

Figure 60. Proposed definitions* for criteria for prosthetic joint infection. (adapted from Tande, Patel, 2014)
*The MSIS definition requires 4 supportive criteria; the International Consensus meeting definition requires 3 supportive criteria.

Decision

During the choice of treatment, several variables need to be taken into consideration. These include:

- Depth of infection
- Timing of infection
- Status of soft tissues
- Fixation of prosthesis
- Involved pathogenic organism
- Ability of host - patient - to fight infection
- Resources of physician
- Patient's expectations

Prosthetic retention is a preferred choice; it is a low-morbidity option for the patient (though the results are of limited success). If this is not possible, total joint arthroplasty will be performed.

The multidisciplinary team in charge of diagnosing the case and deciding on the treatment, also needs to choose the approach of the operation. Simply, this can be split up into six options (in order of severity):

- Holding off surgery and using antibiotic suppression
- DAIR (debridement, antibiotics and implant retention)
- One-stage revision
- Two-stage revision
- Arthrodesis
- Amputation

Decision tools

There are currently a few tools that provide guidelines to surgeons and healthcare professionals. The 'Pocket Guide to Diagnosis & Treatment of PJI' is a small booklet that helps with performing the diagnosis and with making decisions for a case of PJI. It is made by the PRO-IMPLANT Foundation, led by Dr. Andrej Trampuz and Dr. Nora Renz. This booklet is also available as a mobile application. A highlight from the booklet is shown in Figure 55 to see the full booklet, you are referred to Appendix S. (Renz & Trampuz, 2017)

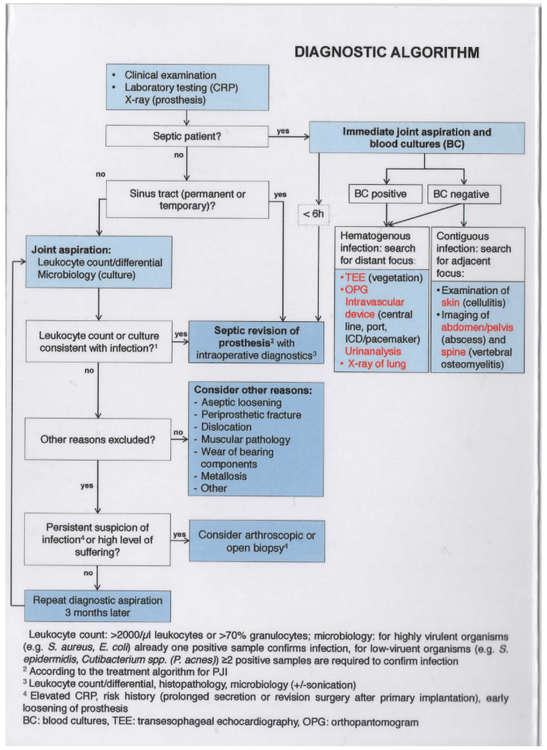


Figure 55. Highlight from the 'Pocket Guide to Diagnosis & Treatment of PJI'. (Renz & Trampuz, 2017)

Another mobile application, named 'PJIDx', incorporates the algorithm for diagnosis of PJI produced during the International Consensus Meeting of 2013. This application takes you through each step of the diagnosis - be it succinct - to offer you a treatment recommendation. (*PJIDx*, 2016) Some highlights of the application are shown in Figure 56, Figure 57 and Figure 58.

Figure 56. Highlight from the 'PJIDx' mobile application. (*PJIDx*, 2016)

Figure 57. Highlight from the 'PJIDx' mobile application. (*PJIDx*, 2016)

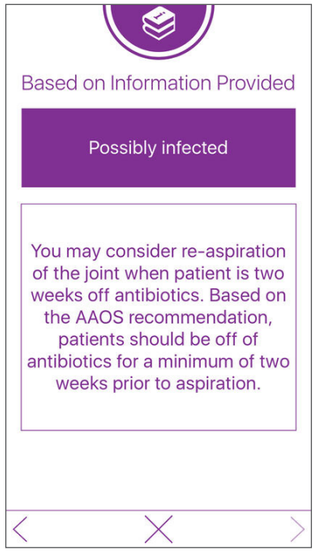


Figure 58. Highlight from the 'PJIDx' mobile application. (*PJIDx*, 2016)

Treatment

The antibiotic regime should be tailored to patient-specific factors. It is important that the operating room (OR) setup is adequate to the case of an infection. The use of protective body exhaust suits and laminar flows is preferred, though data on the benefits is conflicting. (Hooper et al, 2011; Miner et al, 2007) Debridement and irrigation is performed to clean the infected joint and area and to ridden it of all infected tissue. After this phase, the OR team should use a separate set of sterile instruments. This is to prevent reintroduction of infection from previously used instruments. Changing into new gown and gloves is also suggested.

Aftercare

The patient goes home and there is relatively little he/she can do from this point on. See the points under postoperative prevention in the following section as to what the patient should communicate prior to coming surgical procedures.

Prevention

There are several elements that can reduce the risk of PJI for the patient. These can be present preoperatively, intraoperatively and postoperatively.

Preoperative

A whole-body skin cleansing regimen with chlorhexidine gluconate (CHG) is suggested to begin at least one night prior to surgery by the International Consensus Meeting (ICM) group When CHG is unavailable or the host is sensitive to it, an alternative use of antiseptic soap is allowed. (Froimson et al, 2014)

It is highly recommended to administer prophylactic antibiotics to the host. This measure has shown to be highly effective in preventing infections and is believed to be highly important in the prevention of PJI (Fogelberg et al, 1970; Mauerhan et al, 1994; Meehan et al, 2009; Pavel et al, 1974)

It is suggested to not shave the body that is up for surgery, closely prior to it. There is a high chance that the operation can not move forward if the patient has done so. (S. Wiersma, personal communication, March 23, 2018) Shaving is also mentioned to have higher rates of infection. (Tanner et al, 2011) If the OR personnel does want to remove hair, though there is no evidence that it reduces the chance of infection, ICM suggests to do it as close to surgery as possible and with the use of clippers. (Shahi, Parvizi, 2015)

Intraoperative

Surgical site infections (SSI) are highly commonly caused by the native microorganisms of the skin. (Lee et al, 2006; Prokuski, 2008) The use of a skin preparation agent is therefore highly recommended. It is also recommended that the OR staff wash their hands at least two minutes before surgery. This is ought to be done with an antiseptic agent. (Shahi, Parvizi, 2015)

"The use of a preparation agent for the patient's skin and an antiseptic agent for the OR staff's hands are higly recommended."

It is recommended to wear sterile surgical gloves. The ICM group translates this into a suggestion to use double gloving. They also recognise that triple gloving has theoretical advantages. (Shahi, Parvizi, 2015)

The chances of PJI are believed to be reduced when using cement that is impregnated with antibiotics. Its application should therefore be considered. (Shahi, Parvizi, 2015)
Allogeneic blood transfusion (someone else's blood) is believed to increase the risk for PJI. Neuraxial anesthesia - anesthesia affecting the nervous system, like spinal anesthesia - is therefore endorsed, since it minimises blood loss and therefore conserves the patient's own blood. (Shahi, Parvizi, 2015) This eliminates the need for blood transfusion.

When considering the environment of the OR, it is recommended to minimise the duration of the operation and to minimise the OR traffic. The ICM group takes no position on the use of OR's equipped with a system that creates laminar air flow. Suction tips are recommended to be changed every hour, gloves are recommended to be changed every 90 minutes, after cementation, or when a breach of the sterile environment occurs (e.g. the glove has a cut). (Shahi, Parvizi, 2015)

Postoperative

The administration of prophylactic antibiotics is recommended in several surgical procedures occurring any time after the total joint arthroplasty. Especially when the patient is of high risk to develop PJI postoperatively, it is recommended to administer prophylactic antibiotics before a dental procedure or other minor surgical procedures (e.g. colonoscopy and endoscopy). (Shahi, Parvizi, 2015)

Appendix D

Interview guide medical expert

What is your profession/role?

** Explain project and goal**

PREVENTION OF PJI

What problems do you encounter when trying to cope with/minimise the occurrence of infections?

When you try to minimise the occurrence of infections, what barriers do you stumble upon?

PJI PRESENT

Explain journey

Where could such a tool help most?
- During what phase could such a tool help most?
- Let's fill in this timeline together:

```
----------|----------|----------|----------|----------|----------|---
     Presentation  Diagnosis  Decision  Treatment  Surgery  Recovery
```

Who could such a tool help most?

What touchpoints are most important/relevant within the current journey?

Do you see any gaps in the current journey?
- Could you supplement it?

Do you feel this tool could have an informative role?

Do you feel this tool could have an advisory role?

Do you feel this tool could have a connecting role; bringing together surgeons' views on treating PJI?

What do you feel are the main needs of surgeons and their staff, at each phase (prevention, diagnosis, treatment, aftercare)?

Do you feel there is a lot to be gained by informing and helping the patient?

Do you feel we can help the surgeon in managing a case of infection?

Do you feel we can fulfill an educational role?

Do you feel we can speed up the process, diagnosis?

REFERENCES & APPENDICES

Do you see an advantage in combining the different 'schools of thought' (of MSIS, IDSA, EBJIS, ICM)?
- What about offering the different views as advice?

How do you feel about a service that combines all aforementioned roles: informative, advisory, connecting, educational. What if through different interfaces multiple stakeholders could use, learn and profit from such a platform?

Appendix E

Interview guide surgeon

What is your profession/role?

How many cases of PJI do you treat per year?

** Explain project and goal**

PREVENTION OF PJI
What problems do you encounter when trying to cope with/minimise the occurrence of infections?

When you try to minimise the occurrence of infections, what barriers do you stumble upon?

PJI PRESENT

Explain journey

Can you explain what you do at each phase, as described in this timeline?
- Let's fill in this timeline together:

```
----------|----------|----------|----------|----------|----------|---
     Presentation  Diagnosis  Decision  Treatment  Surgery  Recovery
```

Who could such a tool help most?

Can you describe what problems and barriers you experience at each phase?

Where could you use some help?
- During what phase could you use some help?

What are your main needs, at each phase?

Who could use some help, the most?

How do you feel about a service with an informative role?

How do you feel about a service with an advisory role?

How do you feel about a service with a connecting role; bringing together surgeons' views on treating PJI?

How can we help the patient?

How can you be helped in managing a case of infection?

How do you feel about a service with an educational role?

How do you feel about a service that speeds up
- The process
- The diagnosis

Do you see an advantage in combining the different 'schools of thought' (of MSIS, IDSA, EBJIS, ICM)?
- What about offering the different views as advice?

How do you take your decisions?
- During diagnosis
- During surgery

How do you think you can optimise those decisions?

How do you feel about a service that combines all aforementioned roles: informative, advisory, connecting, educational. What if through different interfaces multiple stakeholders could use, learn and profit from such a platform?

Appendix F

Interview guide Zimmer Biomet employee

What is your profession/role?

How many cases of PJI have you seen?

** Explain project and goal**

** Explain journey (if necessary) **

- Let's have a look at this timeline together:

----------|----------|----------|----------|----------|----------|---
Presentation Diagnosis Decision Treatment Surgery Recovery

Can you describe what problems and barriers you see occurring at each phase?

Where could we offer help?
- During what phase could we offer help?

For whom do you think ZB can provide most help

How do you feel about a service with an informative role?

How do you feel about a service with an advisory role?

How do you feel about a service with a connecting role; bringing together surgeons' views on treating PJI?

How can we help the patient?

How can surgeons be helped in managing a case of infection?

How do you feel about a service with an educational role for surgeons?

How do you feel about a service with an educational role for ZB employees?

How do you feel about a service that speeds up
- The process
- The diagnosis

Do you see an advantage in combining the different 'schools of thought' (of MSIS, IDSA, EBJIS, ICM)?
- What about offering the different views as advice?

How do you feel about a service that combines all aforementioned roles: informative, advisory, connecting, educational. What if through different interfaces multiple stakeholders could use, learn and profit from such a platform?

Appendix G

Interview guide member OR team

What is your profession/role?

How many cases of PJI do you experience per year?

** Explain project and goal**

PREVENTION OF PJI
What problems do you encounter when trying to cope with/minimise the occurrence of infections?

When you try to minimise the occurrence of infections, what barriers do you stumble upon?

PJI PRESENT

Explain journey

Can you explain what you do at each phase, as described in this timeline?
- Let's fill in this timeline together:

```
----------|----------|----------|----------|----------|----------|---
Presentation  Diagnosis  Decision  Treatment  Surgery  Recovery
```

Can you describe what problems and barriers you experience at each phase?

Where could you use some help?
- During what phase could you use some help?
- Could you use help with the products?
- Could you use help with the preparation?
- Do you experience a lack of knowledge?

What are your main needs, at each phase?

Who could use some help, the most?

How do you feel about a service with an informative role?

How do you feel about a service with an advisory role?

How can we help the patient?

How can you be helped in managing a case of infection?

How do you feel about a service with an educational role?

How do you feel about a service that speeds up
- The process
- The diagnosis

How do you feel about a service that helps you with your personal tasks?
- What tasks could you be helped with?

How do you feel about a service that combines all aforementioned roles: informative, advisory, connecting, educational. What if through different interfaces multiple stakeholders could use, learn and profit from such a platform?

Appendix H

Interview guide member MD team

What is your profession/role?

How many cases of PJI do you examine per year?

** Explain project and goal**

PREVENTION OF PJI
What problems do you encounter when trying to cope with/minimise the occurrence of infections?

When you try to minimise the occurrence of infections, what barriers do you stumble upon?

PJI PRESENT

Explain journey

Can you explain what you do at each phase, as described in this timeline?
- Let's fill in this timeline together:

```
----------|----------|----------|----------|---------
     Presentation  Diagnosis  Decision  Treatment
```

Can you describe what problems and barriers you experience at each phase?

Where could you use some help?
- During what phase could you use some help?
- Do you experience a lack of knowledge?
- Could you use advice?
- Could you use help to direct your decision?

What are your main needs, at each phase?

Who could use some help, the most?

How do you feel about a service with an informative role?

How do you feel about a service with an advisory role?

How do you feel about a service with a connecting role; bringing together surgeons' views on treating PJI?

How can we help the patient?

How can you be helped in managing a case of infection?

How do you feel about a service with an educational role?

How do you feel about a service that speeds up
- The process
- The diagnosis

How do you feel about a decision tree?

Do you see an advantage in combining the different 'schools of thought' (of MSIS, IDSA, EBJIS, ICM)?
- What about offering the different views as advice?

How do you take your decisions?
- During diagnosis

How do you think you can optimise those decisions?

How do you feel about a service that combines all aforementioned roles: informative, advisory, connecting, educational. What if through different interfaces multiple stakeholders could use, learn and profit from such a platform?

Appendix I

Interview guide patient

You have (had) an infection at your joint prosthesis, is that correct?

Was this your first prosthesis, or have you had it replaced before?

How long after the placement of the prosthesis did the infection arise?

Do you know what caused the infection?

Did you take any measurements surrounding your personal hygiene after the placement of the prosthesis?

Did you receive any information on how to properly care for yourself after the surgery?

Would/Do you like to receive information on how to properly care for yourself after the surgery?

Can you explain what you do at each phase, as described in this timeline?
- Let's fill in this timeline together:

```
----------|----------|----------|----------|----------|----------|---
          Presentation  Diagnosis  Decision  Treatment  Surgery  Recovery
```

Can you describe what problems and barriers you experience at each phase?

Where could you use some help?
- During what phase could you use some help?

What are your main needs, at each phase?

How do you feel about being informed?
- On the subject
- On your progress

Optional:
How do you feel about receiving advice?
- *On the subject (of PJI)*
- *On actions you should take*

What do you think about the contact you have with the surgeon
- During each phase

What kind of surgery did you undergo? (One-stage/Two-stage/DAIR)

Two-stage:
How did you feel during the waiting period?

Is there anything you missed during the period between both surgeries?

How did you experience the frequency of surgeon visits?

Appendix J - Interviews

As explained, interviews with several stakeholders were held, in this appendix a more elaborate documentation and recollection of each interview is given.

#1 - PJI expert

On 1st March the first interview of this project with a stakeholder was held. The interviewee is an orthopaedic surgeon at UMC Utrecht. He is also the general secretary of a renowned society. He is viewed as an expert on the topic of PJI.

The surgeon saw great room for improvement in the area of different approaches. These different approaches arise from cultural differences and also from different guidelines set out by expert societies, like Musculoskeletal Infection Society (MSIS), Infectious Diseases Society of America (IDSA), EBJIS and the consensus guidelines resulting from the International Consensus Meeting (ICM in 2013. In July 2018 there will be a new ICM, with many more participants from all across the world: 800 delegates from over 100 countries who are actively involved in the Delphi process that will generate the document to be voted on by many more visitors.

Furthermore, he named the multidisciplinary team, executing the diagnosis, as an interesting group to offer help to. He sees much room for improvement in the duration of the diagnosis and subsequently coming to a plan of treatment. Providing answers to the questions: “How can we improve the diagnosis?” and “How can we improve the treatment?” can help this team greatly. He offers an idea to give an advice that combines the different schools of thought and lets the multidisciplinary team decide between them. A lot of diagnostic methods are still in development, this makes it more difficult to keep track of all possibilities.

Finally, the expert mentions that surgeons require much more knowledge of the matter at hand, being (diagnosing and treating) PJI. A worldwide database that offers this exchange of knowledge seems profitable in his eyes.

#2 - Orthopaedic surgeon

The interviewee is an orthopaedic surgeon at the Reinier de Graaf hospital. A conversation was held about setting up a collaboration between this graduation project and the Reinier de Graaf hospital. This would allow the designer to utilize the expertise of surgeons and supporting staff, involve them in co-creative sessions, test prototypes when the time arrives and attend surgeries.

Firstly a surgery in the OR was attended, where this surgeon was present. This will be elaborated on in the next section. At a later point, and after a second meeting, it became clear that the collaboration between this project and the hospital wouldn’t stretch beyond answering question via email. There simply was not enough time available on their end. At the second meeting a mention was made about a direction of opportunity for the service. Connecting the service to the goal of (hospital-) internal education seemed like a valuable path, to both this surgeon and another, who was also present at that meeting.

#3 - ZB Account manager/Firm specialist

This interviewee is an account manager at Zimmer Biomet, performing in a sales role. He is often present at the OR to help surgeons and the OR staff with the tools provided by Zimmer Biomet. He is also familiar with the goings of a surgery since he was a surgery assistant prior to his current job.

The interviewee spoke of hygienic precautions differing greatly per area/country/culture. Having attended surgery in other countries, he was sometimes astounded by the etiquette of the staff in the OR. Think about:

- Door openings
- Washing hands
- Wearing jewellery
- Amount of people
- Wearing mouth caps
- Changing gloves

He also was the first to mention that hierarchical behaviour occurs quite often in the OR. Surgeons may not wear a helmet, or glasses even, when they are performing surgery. From this interview forward, more has been mentioned on the peculiarities related to the hierarchical behaviour of surgeons.

#4 - ZB Marketing Director

This interviewee is a Marketing Director at Zimmer Biomet. He gave a short educative lecture in which he elaborated on PJI. He said to not speak of infected and uninfected tissue. It can’t be approached in such a black and white fashion. Think of it as affected and unaffected tissue.

> *The line between infected and uninfected tissue is vague and undefinable. It is better to speak of affected and unaffected tissue.*

He also gave some great analogies as to better understand the subject. These analogies can be found throughout this chapter, prior to this section. Furthermore, an infection consists of both the invasion of non-human cells and the reaction to this invasion of the host’s cells. Not all bacteria cells are bad; among all of the bacteria cells there can be some that are ‘terrorists’, wearing a bomb vest; the bad bacteria among the good.

#5 - ZB Strategy Manager

This interviewee is a Senior Manager at Zimmer Biomet, the designer and he are often in contact, so he will have inspired more elements of this project than just the things mentioned here. Still, in the beginning of the project he clarified a lot of elements that sped up the progress of this project. One thing that will be emphasised here is that he shed some light on the workings of the world of healthcare/orthopaedics/surgeons. “It is very complex, you will keep discovering. You’ve been diving in for a month and a half now, but trust me: there’s still so much to find out. There are so much nuances to the behaviour and the traits of how it (and the people) all works.” *(Paraphrased slightly)*

More

During OR visits, questions were asked throughout the surgery to all people present. This gave a broader insight on what the views and needs of other stakeholders as, anesthetists, assistant doctors and scrub and circulating nurses are. These insights are shared in the next appendix.

REFERENCES & APPENDICES

Appendix K - OR visits

The OR visits have been eye-opening experiences, during which a formerly completely unknown world (to the designer) opened itself up.

Visit #1

Revision Operation (No infection) | One-stage

During the surgery, where a firm specialist was also present, zero door openings occurred. The sterile and unsterile parts of the OR remained greatly separated due to precision of the staff. In the beginning, before the patient arrived, people did speak without a mouth cap. The two doors present in the OR can never be opened simultaneously. After the patient arrived, a time-out occurred: the surgeon checked if this was the correct patient, if they were going to perform surgery on the correct leg, and so on. During the preparation of the patient, the sterile part of the operating team leaves the room to wash up and become fully sterile, also wearing sterile suits, gloves and helmets. The sterile suit and helmet (Steri-shield) isn't used everywhere: in the Netherlands it's used in about 10% of the hospitals. (Zimmer Biomet account manager, personal communication, March 23, 2018)

Figure 61. The OR staff checks if everything is in order, the surgeon asks the patient a few control questions.

In a room next to the OR, all materials, tools and the staff are being sterile prepared. After the area to operate has been separated (using drapes) from the rest of the patient - securing the sterile area - gloves are changed.

A lot of decisions that need to be made can not be made prior to the surgery: the decisions need to be made with the knowledge gained during surgery. Also, unexpected occurrences are far from rare: there is just a lot you can not plan ahead for. One of these things is how to properly prepare the prosthesis, so it will fit in the patient's body, onto its bones. This can only be measured out during the surgery, using the necessary specialised tools.

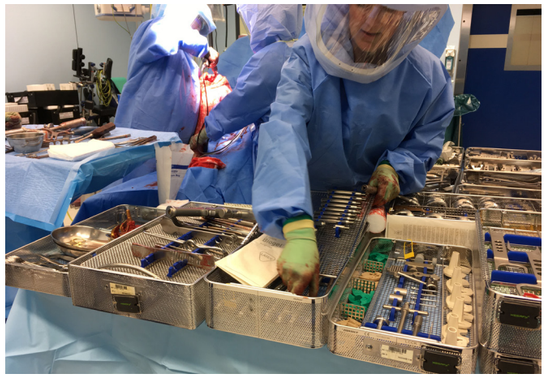


Figure 62. The amount of tools present in the OR is immense. This is the reason the firm specialist is present, bringing specialised knowledge.

After the surgery there is a 'sign-out': an OR-report is filled out, all necessary values and particularities are noted and the patient file is supplemented. The patient is being placed in a bed and moved to 'recovery', where he will remain for an hour or so, after which he will spend 1-2 days in the orthopaedics ward. Between each surgery, a cleaning crew cleans the OR. At the end of every day, a cleaning crew thoroughly cleans the OR.

It is clear that protocol takes place, which on the one hand is a good thing: the OR team knows what to do when, and does not forget to do it. On the other hand, these protocols can stand in the way of improvement.

Visit #2

Revision Operation (Infection) | Two-stage

Prior to the operation, a firm specialist, the surgeon, the company mentor and the designer had a short talk. The morning of the surgery, a different patient shaved his legs, the surgery could therefore not be executed and had to be moved back two weeks. Another thing that was noted, is that a one-stage approach is almost only used when there is clarity about what kind of infection is being faced. In a two-stage approach, there is a waiting period for the patient. As the surgeon stated: "An infection creates a lengthy process the patient and surgeon have to pass. The patient and I will see each other every two weeks, until the infection is gone and the revision implant can be placed."

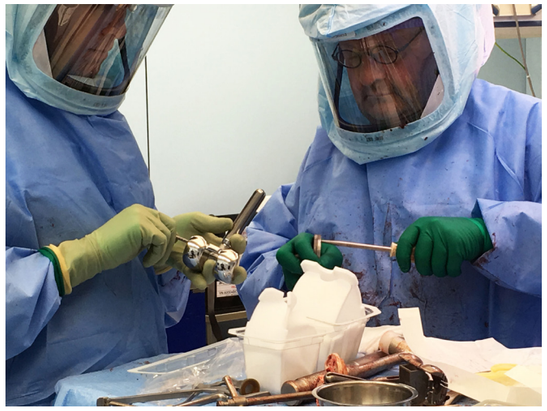


Figure 63. The surgeon and the firm specialist are preparing the prosthesis for implantation.

The operation, operating room, materials, tools etc. look a lot less professional than at the attended hospital during the first visit. As the company mentor noted later on, though: looks can be deceiving. The fact that the materials looked less modern and eye catching, does not necessarily mean that they are worse. Throughout the surgery, the OR team takes cultures several times. These cultures are being taken from a lot of different places and are taken to be analysed. Something that stood out is that the OR team can be 'rough' with/about the patient, both physical and verbal. The physical roughness is necessary to remove and measure out the implants. The verbal roughness will probably not be perceived as rough by the team itself, but calling the affected tissue "snot" or "mucus" or something similar is quite common.

At a certain point during the surgery, the spacers needed to be made. These are made with antibiotically treated cement. The kind of antibiotics has been decided on prior to the surgery. After the femur spaces had been measured out and placed, the tibia spacer had to be made. This was done in a provisional ('clumsy') way, due to a lack of tools. A nurse hands the surgeon a syringe, after which it's being cut to size and placed into the setting cement, to complement the mold. The syringe functions as a cylinder to align the spacer correctly onto the tibia.

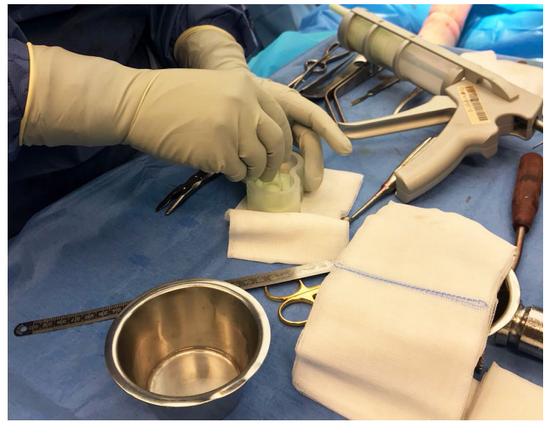


Figure 64. The surgeon places a cut-off syringe in the tibia spacer mold.

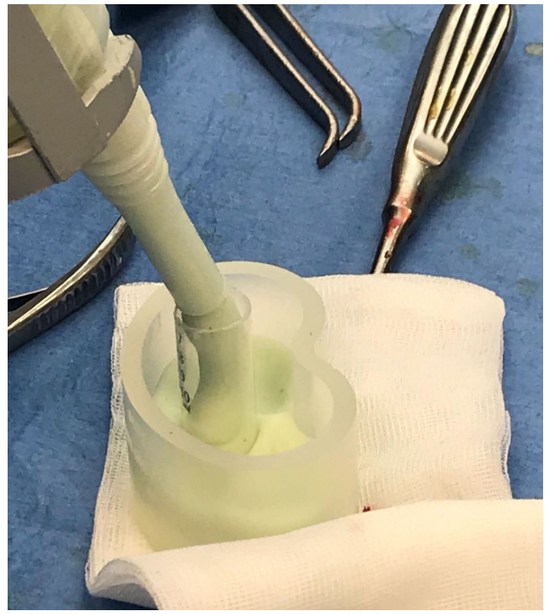


Figure 65. The surgeon fills up the (newly added) syringe part of the mold with cement.

After the visit to this second surgery, it became quite clear that nuances in the process can differ a lot. Where it may have been clear earlier on that there are great differences between cultures and countries, it is now apparent that these differences - be it on a smaller level - are also present between hospitals.

Visit #3

DAIR procedure (Acute infection) | Second surgery

Four weeks ago, this patient underwent total knee arthroplasty. Shortly thereafter, his knee became swollen and he was experiencing pain. Quickly, it became clear that this was due to an acute infection. This infection was due to the bacteria Staphylococcus aureus, which is a bacteria that a lot of people carry on their skin and is therefore also the most common cause of acute infections. Two weeks ago, the patient underwent a first part of the DAIR procedure, during which they took out the liner, cleaned both the liner and the patient, and then put the same liner back in. During this surgery - the second part of the DAIR operation - the liner is taken out and replaced with a new one.

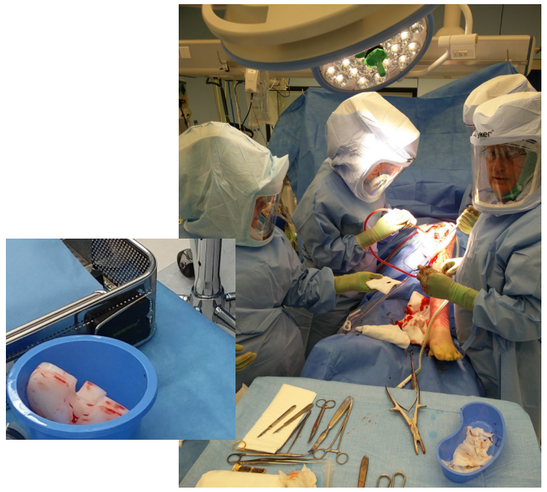


Figure 66. The OR staff taking out the liner & the removed liner

In the beginning of the surgery, a lot of cultures were taken from the patient. These cultures are taken from different parts in the knee. They will tell the surgeon what the current state of the infection is and if there are any other bacteria than they knew before. Another thing that will tell the surgeon and the OR team what the current state of the infection is, is plainly what they see in the knee during the surgery. During the entire first half of the surgery (being: up to the point the lavage started) four cultures were taken.

Figure 67. Culture being placed in cup

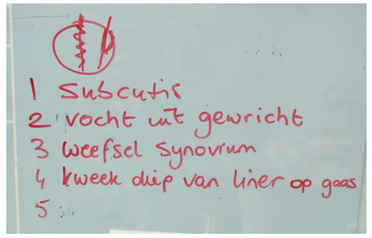


Figure 68. Cultures and their origin (in Dutch)

The lavage itself used 6 litres of saline. This way the OR staff tries to clean the affected tissue of the patient, and hopefully ensure a disappearance of the infection altogether.

A DAIR procedure is tough on the patient, though without removing the entire prosthesis, this procedure - which consists almost always of more than one surgery - has a ~90% succes rate. (Orthopaedic surgeon, personal communication, May 2, 2018) The procedure went well and it took relatively short, compared to the other surgeries discussed in this report. The procedure itself took no longer than an hour.

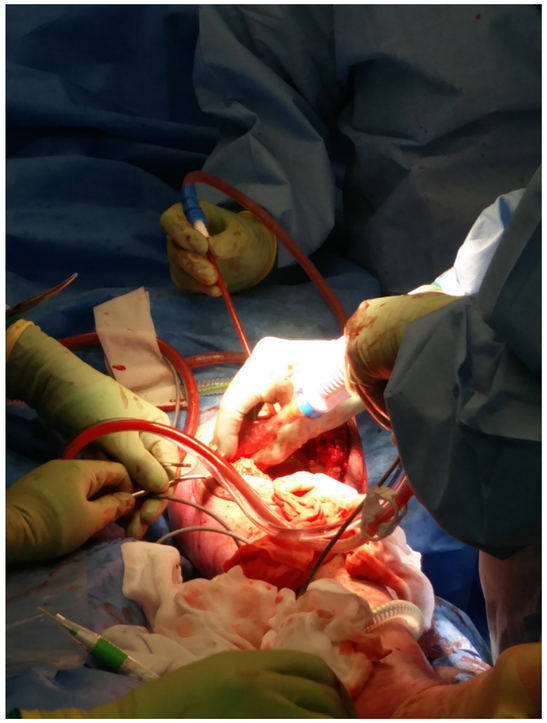


Figure 69. Lavage being executed using the Pulsavac Lavage from Zimmer Biomet

After the surgery, the designer spoke briefly with the surgeon and an orthopaedic surgery resident about the procedure, PJI at this hospital and PJI in general. There was a clear consensus on the fact that a prosthetic joint infection is underestimated in how badly it devastates the lives of the patients. They lie around in bed for months on end and it's absolutely awful for them. They become unhappy and depressed and it ruins lives. It's also the worst thing that can happen to an orthopaedic surgeon, since it's the absolute last thing you want to happen after performing surgey. (Orthopaedic resident surgeon, personal communication, May 2, 2018)

Sometimes the OR team can be viewed as carpenters: hammering away at the patient to loosen and remove the implants. Other times one could compare the OR team to mechanics: working on the patient like it's routine, the operation is performed in a very clinical manner - luckily so. The OR team makes a lot of chit-chat and treats the patient like it's just another case, which is probably a good thing.

> *"The OR can also be compared to an airplane: the surgeon is the captain who runs the operation, he needs to cooperate with colleagues that don't always fall under his command. The nurses are the flight attendants who help the captain in taking care of the patient (the travelers)."*

Appendix L - Creative sessions

Empathise sessions

The first creative sessions of this graduation project - to be facilitated by the graduating designer - which are planned to last 2½ to 3 hours, will lead participants through a creative process in order to utilise their expertise and insights to empathise with the subject.

Theory and elements

Journey Mapping

The session is kicked off with an empty customer journey map, adapted from the Infected Joint Journey, which is shown in Figure 70. This map is used as a tool to define elements in the process that can be improved ('Pains'), elements that are possible opportunities to exploit, since they are beneficial to the process ('Gains') and needs of different stakeholders during each step. The tasks describe each step that is taken during the defined phases. Because of time restrictions the tasks are thought out and written down on Post-Its beforehand by the designer, based on the Infected Joint Journey.

The session starts with the facilitator going through all the tasks, trying to pinpoint any missing, redundant or inadequately formulated tasks. Afterwards, Zimmer Biomet's products will be linked to the specific phases. When the participants are familiar with the journey and the steps involved, they are asked to name 'Pains' and

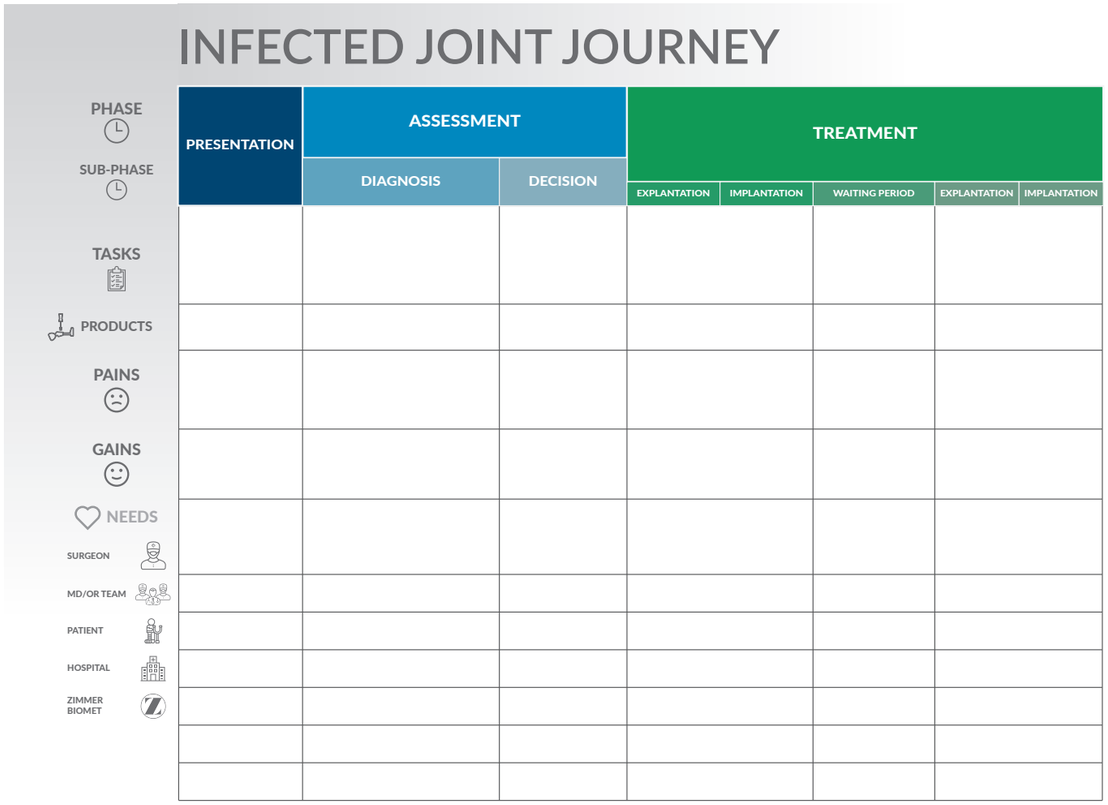


Figure 70. Journey Map used during the creative sessions. (For higher quality, you are referred to Appendix M)

'Gains'. This is done per phase and sometimes - when deemed very important - per task. Subsequently,the participants think about the needs that different stakeholders have during these steps. The facilitator asks questions to the participants to kickstart and maintain the creative atmosphere. All participants receive Post-Its and a fineliner. An insight is written down on these Post-Its by either the facilitator or a participant, after which it is placed in the corresponding phase on the journey map.

Key Insights

Following customer journey mapping, 'Key insights' will be formulated. These A5-sized 'cards', shown in Figure 72, facilitate the process of formulating insights, derived from the journey map.

The cards are split up into 4 parts that help the participant to focus on a *stakeholder*, what that stakeholder *wants to do*, for *what reason* and *what is restraining him/her*. When several insights have been formulated and there is spare time, 'laddering' will be performed to create an insight that describes an underlying need. Laddering is a technique often used during explorative interviews to discover latent needs. (Reynolds, Gutman, 1988) The most simple way to do this is by asking 'Why?'. In this case, however, laddering will be done by taking the content of the 'need' box and moving it one box up, to the 'action' box. This forces the participant to think of deeper needs of the stakeholder.

Figure 72. Key insight (adapted from Stickdorn, 2018)

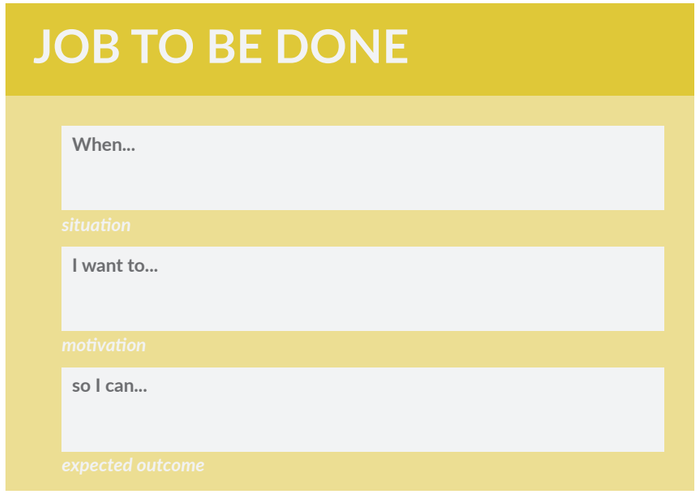


Figure 71. Job to be done insight (adapted from Stickdorn, 2018)

Job To Be Done Insights

Next, 'Job to be done insights' will be formulated. These A5-sized 'cards', as shown in Figure 71 also facilitate the process of formulating insights, only this time focussed on something somebody *wants* to do, during a certain *situation*, with a *desired/expected outcome*.

H2?

How to...

?

...answer to a desired action
...answer to a need
...aid in a motivation
...help fulfill an expected outcome

Figure 73. How To?

How To?'s

When a good amount of insights have been formulated, the session will continue with formulating 'How To?'s, with the help of cards, as shown in Figure 73.

'How To?'s are questions that help during the next step, the ideation process. The questions trigger the participants to think of solutions that *answer to a desired action*, *answer to a need*, *aid in a motivation*, *help fulfill an expected outcome*, etcetera. (IDEO, 2015)

Brainstorming

The next and final exercise of the session is 'Brainstorming'. Brainstorming is done in a group and keeps participants productive by using a few rules. These rules also ensure an environment with no judgement and high divergence.

The rules are as follows:

- **More is better:** go for quantity
- **Withhold criticism:** defer from judgement
- **Think crazy:** no idea is dumb or too wild
- **Combine and improve:** build on each other's ideas.

(adapted from Applied Imagination, 1953)

Participants name ideas which are written down (on a Post-It) on a board by the facilitator. This generates a big amount of ideas in a small amount of time. (Stickdorn, Hormess, Lawrence & Schneider, 2018)

Result of session #1 - Empathise

Planned to be present at the first creative session are a Marketing Director at Zimmer Biomet, an Account Manager at Zimmer Biomet, an IPD student at DUT and intern working for, who was also present, the company mentor and the graduating designer. Sadly, the account manager could not make it, so the group of participants was decreased to 4, including the facilitator.

Prior to the creative session, an educative session led by the marketing director was held. This session took a bit longer than expected, which led to a shorter amount of time being available for the creative session. During the creative session, an amount of the participants' focus was also still on the educational aspect of the day. The facilitator could have done a better job at holding the participants' focus on the creative part and sticking to the directive of the creative session, being formulating new insights on pains, gains and needs. The tasks were discussed in too much detail, which occupied too much time. Eventually, an hour was available for the creative session and the result can be seen below, in Figure 74.

The session began with the designer explaining the goal of his project as well as the goal of the session. Subsequently, the tasks were being discussed and placed on the journey. Missing tasks were added, redundant

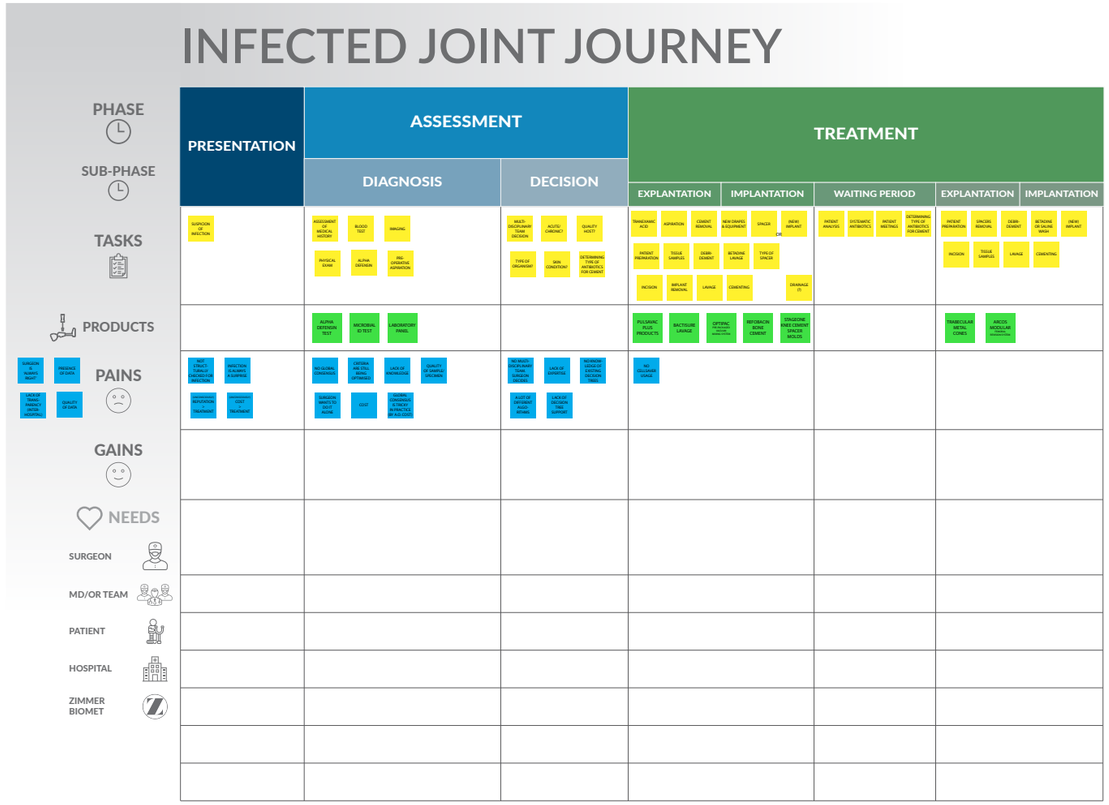


Figure 74. Journey Map with the results from the session on the 4th of April. (For higher quality, see Appendix N)

tasks were removed and inadequately formulated tasks were reformulated. Next, the products were placed on the map, at which point it was mentioned that not all products were relevant. Therefore, a lot of products, prepared by the designer to be placed on the map, did not end up being used. Thereafter, the pains and gains were discussed and formulated.

Some of the things that caused the session to not go as planned, were out of the hands of the facilitator. However, there were also several things that the facilitator can influence. The lessons learned during this session, which are described before, will be applied in the next session.

Result of session #2 - Empathise

The next session took place shortly after the first. The company mentor and the designer went on a trip to visit a renowned surgeon, professor and key opinion leader in the field op PJI. About an hour and 45 minutes was used for the creative session prepared by the designer. Present were the surgeon, the company mentor and the designer. The session began where the previous session ended. The journey resulting from the previous session, acted as a starting point for this session. After briefly going through the tasks, products and pains already formulated, the participants continued by discussing more pains and gains. This was done both on a phase-specific level as well as on more of a macro-level. The surgeon needed less creative facilitation than prepared. The result of the session was the journey map shown in Figure 75. On this map, the participants managed to fill in several elements that can be improved as well as answer

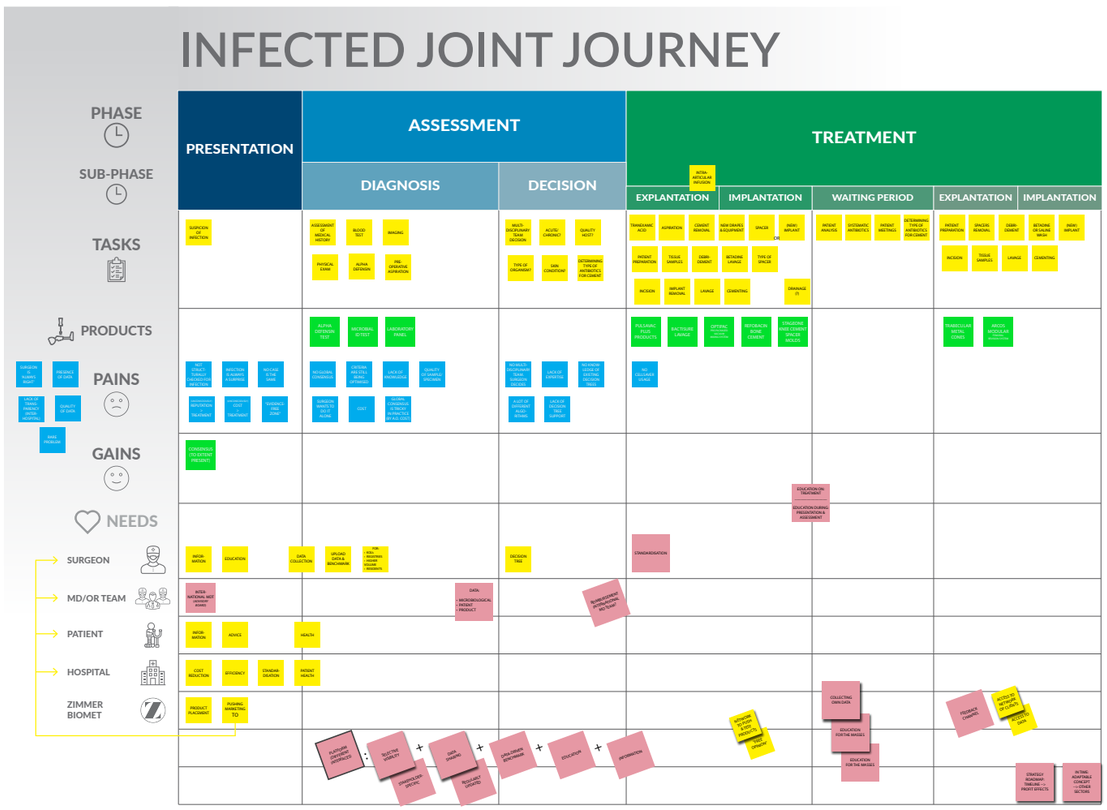


Figure 75. Journey Map with the results from the session on the 6th of April. (For higher quality, see Appendix O)

to needs of specific stakeholders. The participants were also able to share insights and thereafter share and constructively form ideas.

A concise summary of the general idea the surgeon envisioned as a solution for several problems is an overarching service/platform that responds to multiple needs of multiple stakeholders. More concretely formulated: during this phase of the project, the designer has repeatedly asked himself :"What approach, for the service to be designed, is best: informative, advisory, educational, connecting (via consensus and/or sharing data), reflective (with own data), ...?" During the session, a vision became apparent of a platform that makes all of these elements accessible and allows different stakeholders to use different elements (and/or have access to different parts, with their own interfaces). The platform also allows space for product placement, providing an advantageous position to Zimmer Biomet. Finally, it will provide new customers, higher customer retention and an improved brand image.

Altogether, the session was very productive and helpful. The insights shared by the surgeon helped the project progress. The ideas constructively formed will be taken into consideration. It is, however, very important for the designer to not indiscriminately adapt the opinion of one man, be it a man with a lot of expertise in the field, both on micro- and macro-level. More interviews are planned to be held after this session, with different people. The insights and ideas that derived from this session are planned to be validated in interviews and sessions, but always at the very end, in order to not *lead (*)* the conversation and answers.

**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?".*

Ideation sessions

The following creative sessions of this graduation project - to be facilitated by the graduating designer - which are planned to last 1½ to 2½ hours, will lead participants through a creative process in order to utilise their expertise and insights to come up with ideas that answer to the chosen solution direction.

Theory and elements

The session starts off with an introduction of the project, the steps executed up to this point, and the conclusions drawn and decisions made. The problem, solution direction and design goal are communicated to the participants.

How To?'s

After communicating the design goal, it is translated into manageable pieces. This is done by forming several 'How to?' questions. These questions have been formed by the facilitator prior to the session. Two examples of these questions are shown in Figure 76 and Figure 77 . All of the 'How To?' questions can be found in Appendix P.

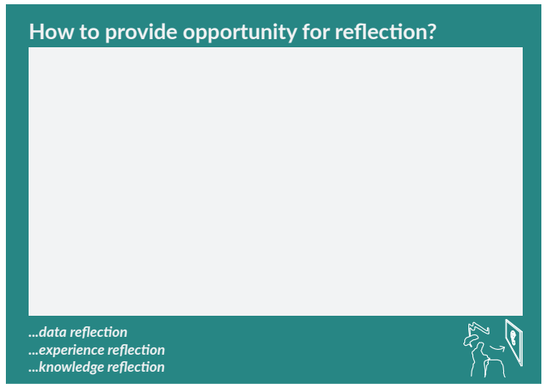


Figure 76. 'How To' question used during ideation session

Every participant is given a different A3 sheet, that has a 'How To?' question on it. They are all given 2 minutes to answer the question on their sheet, by writing ideas on (their colour of) Post-It notes and pasting them on the sheet. After these 2 minutes, the sheets rotate and every participant receives a new question. They will now answer the question that they find on their new sheet, while being allowed to build on ideas that prior participants have written down.

This part of the session ends with a discussion on everyone's ideas and how they built on each other's ideas.

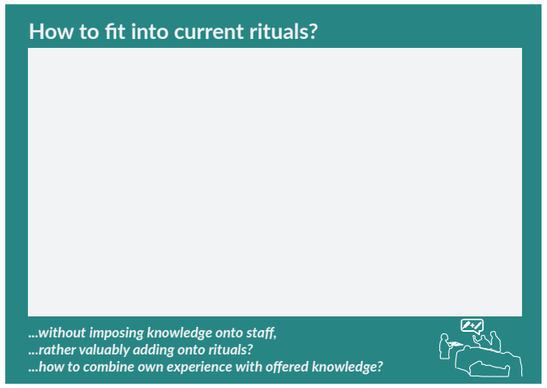


Figure 77. 'How To' question used during ideation session

10 plus 10

The following element of the session firstly consists of picking, as a group, the best ideas from the previous element. These will serve as a starting point to continue to come up with ideas. These new ideas can be variations, elaborations, inspirations, etc. Each participant is given 3 minutes per chosen idea, during which they can write/ draw their ideas on 'idea sheets'. This sheet can be seen in Appendix Q. Again, this element ends with a discussion on everyone's ideas. (Stickdorn, 2018)

Brainstorming

If the session calls for more ideas, more group inspiration or a different approach, a brainstorm can be held. During this brainstorm, the facilitator is the only person that is writing ideas on Post-It notes. The participant are allowed, encouraged even, to yell out as much ideas as possible and build on each other's ideas.

Clustering

The ideas will be clustered on a large wall (or a flip-over). Categories will be defined, this provides some final discussion as to how all of the ideas interact.

Dot-voting

The session ends with dot-voting. Every participant receives five small stickers (dots). Each participant is allowed to place their dots on ideas they find most promising. This helps the facilitator (and the participants) in clarifying what the most valuable (directions for) ideas are. (Stickdorn, 2018)

Result of session #3 - Ideation

The first ideation session took place abroad. The company mentor and the designer went on a trip to visit a man who is both a renowned surgeon and a professor. Also present and actively participating were another surgeon and a marketing lead from Zimmer Biomet.

During the meeting, the company mentor introduced the project and communicated developments. The views of the present surgeons were discussed and some discussions about present problems and opportunities were held. Next, the designer began with the ideation session. Firstly, the graduation project was introduced and the analysis, insights and goal were presented. Consequently, the participant received their first sheets. The link between the goal and the question was clarified, and the discussion started flowing concerning one of the sheets. All participants were actively discussing the question and Post-Its were being pasted. During the discussion the facilitator abstracted some ideas out of the conversation and also pasted them on the sheet, to keep the creative juices flowing. The result of this first discussion can be seen in Figure 78, and in more detail in Appendix R, along with the other results of the session.

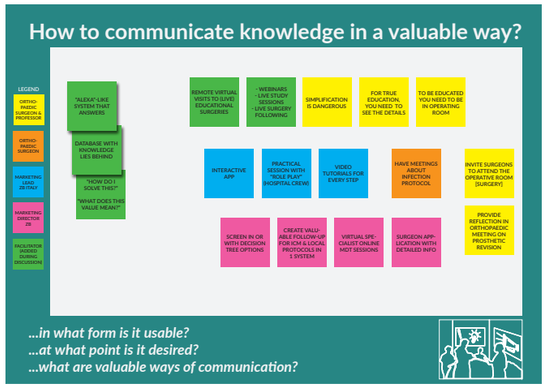


Figure 78. Result of the first question, which was discussed as a group.

After this first discussion, the session continues with one less participant. The remaning three participants all take a sheet in front of them and switch sheets every 2 minutes, coming up with their own ideas and building on each others'. This method seemed to work quite well, since the participants really progressed on each others' ideas. An example of this is shown in Figure 79 and in more detail in Appendix R.

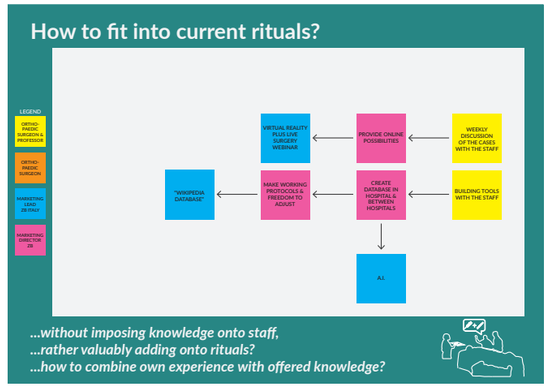


Figure 79. Result of one of the questions, in which the participants built on each others' ideas.

When every sheet had been in front of each participant, the results were discussed as a group. This offered some more insights, such as the fact that true learning of new knowledge works best if the student is present during an actual surgery and the idea that virtual reality may aid to this logistic issue. The facilitator furthermore abstracted that an 'aid' or 'assistant' in the OR should not impose any limits on the staff, rather making it easier. This may be achieved with a system that 'listens', 'understands' and 'speaks'. It may be compared with a system like Amazon Echo or Google Home.

INFECTED JOINT JOURNEY

APPENDIX M

PHASE	PRESENTATION	ASSESSMENT		TREATMENT				
SUB-PHASE		DIAGNOSIS	DECISION	EXPLANTATION	IMPLANTATION	WAITING PERIOD	EXPLANTATION	IMPLANTATION
TASKS								
PRODUCTS								
PAINS								
GAINS								
NEEDS								
SURGEON								
MD/OR TEAM								
PATIENT								
HOSPITAL								
ZIMMER BIOMET								

INFECTED JOINT JOURNEY

APPENDIX N

PHASE

SUB-PHASE

TASKS

PRODUCTS

PAINS

GAINS

NEEDS

SURGEON

MD/OR TEAM

PATIENT

HOSPITAL

ZIMMER BIOMET

PRESENTATION	ASSESSMENT		TREATMENT				
	DIAGNOSIS	DECISION	EXPLANTATION	IMPLANTATION	WAITING PERIOD	EXPLANTATION	IMPLANTATION
SUSPICION OF INFECTION	ASSESSMENT OF MEDICAL HISTORY; BLOOD TEST; IMAGING; PHYSICAL EXAM; ALPHA DEFENSIN; PRE-OPERATIVE ASPIRATION	MULTI-DISCIPLINARY TEAM DECISION; ACUTE/ CHRONIC?; QUALITY HOST?; TYPE OF ORGANISM?; SKIN CONDITION?; DETERMINING TYPE OF ANTIBIOTICS FOR CEMENT	TRANEXAMIC ACID; ASPIRATION; CEMENT REMOVAL; NEW DRAPES & EQUIPMENT; SPACER; (NEW) IMPLANT; OR; PATIENT PREPARATION; TISSUE SAMPLES; DEBRI-DEMENT; BETADINE LAVAGE; TYPE OF SPACER; INCISION; IMPLANT REMOVAL; LAVAGE; CEMENTING; DRAINAGE (?)		PATIENT ANALYSIS; SYSTEMATIC ANTIBIOTICS; PATIENT MEETINGS; DETERMINING TYPE OF ANTIBIOTICS FOR CEMENT	PATIENT PREPARATION; SPACERS REMOVAL; DEBRI-DEMENT; BETADINE OR SALINE WASH; (NEW) IMPLANT; INCISION; TISSUE SAMPLES; LAVAGE; CEMENTING	
	ALPHA DEFENSIN TEST; MICROBIAL ID TEST; LABORATORY PANEL		PULSAVAC PLUS PRODUCTS; BACTISURE LAVAGE; OPTIPAC PRE-PACKAGED VACUUM MIXING SYSTEM; REFOBACIN BONE CEMENT; STAGEONE KNEE CEMENT SPACER MOLDS			TRABECULAR METAL CONES; ARCOS MODULAR FEMORAL REVISION SYSTEM	
NOT STRUCTURALLY CHECKED FOR INFECTION; INFECTION IS ALWAYS A SURPRISE; (UNCONSCIOUSLY) REPUTATION > TREATMENT; (UNCONSCIOUSLY) COST > TREATMENT	NO GLOBAL CONSENSUS; CRITERIA ARE STILL BEING OPTIMISED; LACK OF KNOWLEDGE; QUALITY OF SAMPLE/ SPECIMEN; SURGEON WANTS TO DO IT ALONE; COST; GLOBAL CONSENSUS IS TRICKY IN PRACTICE (BY A.O. COST)	NO MULTI-DISCIPLINARY TEAM. SURGEON DECIDES; LACK OF EXPERTISE; NO KNOWLEDGE OF EXISTING DECISION TREES; A LOT OF DIFFERENT ALGORITHMS; LACK OF DECISION TREE SUPPORT	NO CELLSAVER USAGE				
SURGEON IS 'ALWAYS RIGHT'; PRESENCE OF DATA; LACK OF TRANSPARENCY (INTER-HOSPITAL); QUALITY OF DATA							

INFECTED JOINT JOURNEY

APPENDIX O

PHASE

SUB-PHASE

TASKS

PRODUCTS

PAINS

GAINS

NEEDS

SURGEON

MD/OR TEAM

PATIENT

HOSPITAL

ZIMMER BIOMET

PRESENTATION

ASSESSMENT

DIAGNOSIS

DECISION

TREATMENT

INTRA-ARTICULAR INFUSION

EXPLANTATION

IMPLANTATION

WAITING PERIOD

EXPLANTATION

IMPLANTATION

TASKS

- SUSPICION OF INFECTION
- ASSESSMENT OF MEDICAL HISTORY
- BLOOD TEST
- IMAGING
- PHYSICAL EXAM
- ALPHA DEFENSIN
- PRE-OPERATIVE ASPIRATION
- MULTI-DISCIPLINARY TEAM DECISION
- ACUTE/ CHRONIC?
- QUALITY HOST?
- TYPE OF ORGANISM?
- SKIN CONDITION?
- DETERMINING TYPE OF ANTIBIOTICS FOR CEMENT
- TRANEXAMIC ACID
- ASPIRATION
- CEMENT REMOVAL
- NEW DRAPES & EQUIPMENT
- SPACER
- (NEW) IMPLANT
- PATIENT PREPARATION
- TISSUE SAMPLES
- DEBRI-DEMENT
- BETADINE LAVAGE
- TYPE OF SPACER
- INCISION
- IMPLANT REMOVAL
- LAVAGE
- CEMENTING
- DRAINAGE (?)
- PATIENT ANALYSIS
- SYSTEMATIC ANTIBIOTICS
- PATIENT MEETINGS
- DETERMINING TYPE OF ANTIBIOTICS FOR CEMENT
- PATIENT PREPARATION
- SPACERS REMOVAL
- DEBRI-DEMENT
- BETADINE OR SALINE WASH
- (NEW) IMPLANT
- INCISION
- TISSUE SAMPLES
- LAVAGE
- CEMENTING

PRODUCTS

- ALPHA DEFENSIN TEST
- MICROBIAL ID TEST
- LABORATORY PANEL
- PULSAVAC PLUS PRODUCTS
- BACTISURE LAVAGE
- OPTIPAC PRE-PACKAGED VACUUM MIXING SYSTEM
- REFOBACIN BONE CEMENT
- STAGEONE KNEE CEMENT SPACER MOLDS
- TRABECULAR METAL CONES
- ARCOS MODULAR FEMORAL REVISION SYSTEM

PAINS

- SURGEON IS 'ALWAYS RIGHT'
- PRESENCE OF DATA
- LACK OF TRANS-PARENCY (INTER-HOSPITAL)
- QUALITY OF DATA
- RARE PROBLEM
- NOT STRUCT-TURALLY CHECKED FOR INFECTION
- INFECTION IS ALWAYS A SURPRISE
- NO CASE IS THE SAME
- (UNCONSCIOUSLY) REPUTATION > TREATMENT
- (UNCONSCIOUSLY) COST > TREATMENT
- "EVIDENCE-FREE ZONE"
- NO GLOBAL CONSENSUS
- CRITERIA ARE STILL BEING OPTIMISED
- LACK OF KNOWLEDGE
- QUALITY OF SAMPLE/ SPECIMEN
- SURGEON WANTS TO DO IT ALONE
- COST
- GLOBAL CONSENSUS IS TRICKY IN PRACTICE (BY A.O. COST)
- NO MULTI-DISCIPLINARY TEAM. SURGEON DECIDES
- LACK OF EXPERTISE
- NO KNOW-LEDGE OF EXISTING DECISION TREES
- A LOT OF DIFFERENT ALGO-RITHMS
- LACK OF DECISION TREE SUPPORT
- NO CELLSAVER USAGE

GAINS

- CONSENSUS (TO EXTENT PRESENT)

NEEDS

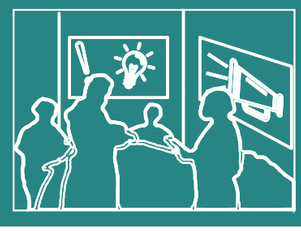
- INFOR-MATION
- EDUCATION
- DATA COLLECTION
- UPLOAD DATA & BENCHMARK
- FOR:
  - KOL's
  - REGISTRIES
  - HIGHER VOLUME
  - RESIDENTS
- DECISION TREE
- STANDARDISATION
- EDUCATION ON: TREATMENT
- EDUCATION DURING: PRESENTATION & ASSESSMENT
- INTER-NATIONAL MDT (ADVISORY BOARD)
- DATA:
  - MICROBIOLOGICAL
  - PATIENT
  - PRODUCT
- REIMBURSEMENT INTERNATIONAL MD TEAM?
- INFOR-MATION
- ADVICE
- HEALTH
- COST REDUCTION
- EFFICIENCY
- STANDAR-DISATION
- PATIENT HEALTH
- PRODUCT PLACEMENT
- PUSHING MARKETING TO
- PLATFORM (DIFFERENT INTERFACES) : SELECTIVE VISIBILITY (STAKEHOLDER-SPECIFIC) + DATA SHARING (REGULARLY UPDATED) + DATA-DRIVEN BENCHMARK + EDUCATION + INFORMATION
- NETWORK TO PUSH & TEST PRODUCTS
- "FREE OPINION"
- COLLECTING OWN DATA
- EDUCATION FOR THE MASSES
- EDUCATION FOR THE MASSES
- FEEDBACK CHANNEL
- ACCESS TO NETWORK OF CLIENTS
- ACCESS TO DATA
- STRATEGY ROADMAP: TIMELINE --> PROFIT EFFECTS
- IN TIME: ADAPTABLE CONCEPT --> OTHER SECTORS

REFERENCES & APPENDICES

Appendix P - ‘How To’ questions

How to communicate knowledge in a valuable way?

...in what form is it usable?
...at what point is it desired?
...what are valuable ways of communication?



REFERENCES & APPENDICES

How to ensure implementation of such a system?

...how to ensure participation & adaptation?
...what elements does it need?
...what organisational changes are necessary?

REFERENCES & APPENDICES

How to provide opportunity for reflection?

...data reflection
...experience reflection
...knowledge reflection

REFERENCES & APPENDICES

How to fit into current rituals?

...without imposing knowledge onto staff,
...rather valuably adding onto rituals?
...how to combine own experience with offered knowledge?

REFERENCES & APPENDICES

How to build trust among surgeons & medical staff?

REFERENCES & APPENDICES

How to move from data to information?

...during a multi-disciplinary meeting?
...for reflection?

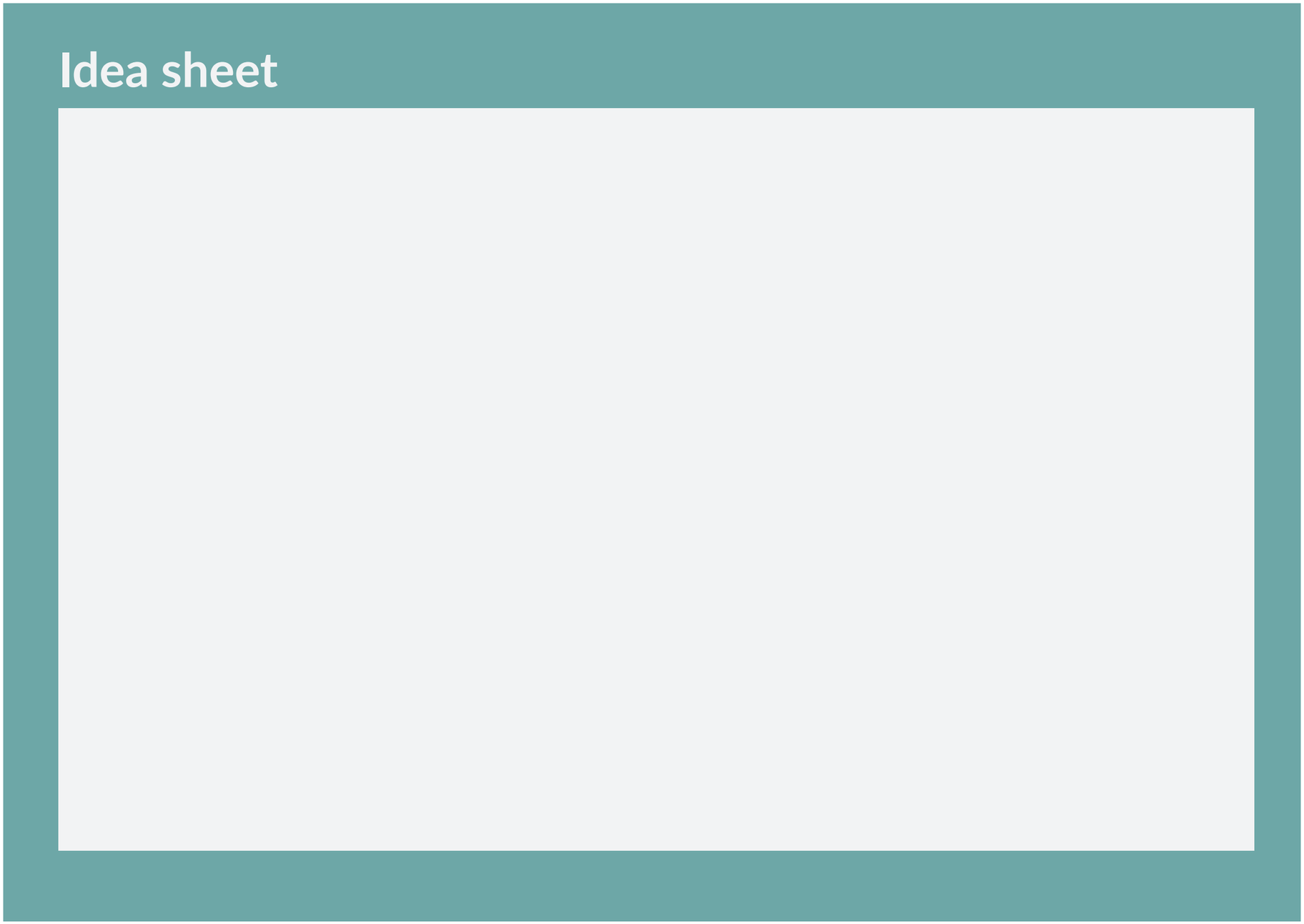
REFERENCES & APPENDICES

How to communicate/implement preventive measures?

...in what form should it be communicated?
...at what time should it be communicated?
...how to ensure implementation?

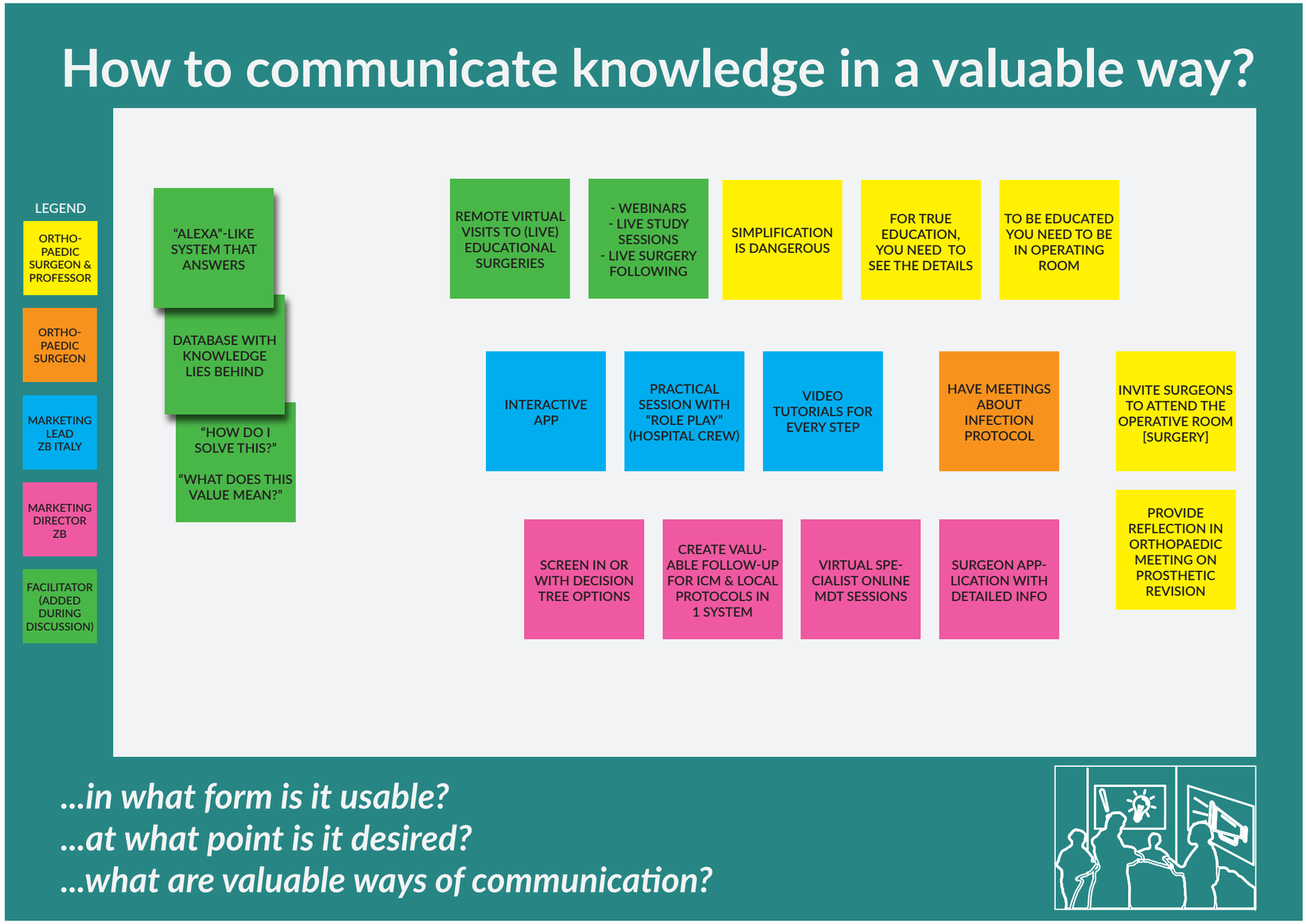
REFERENCES & APPENDICES

Appendix Q - Idea sheet



REFERENCES & APPENDICES

Appendix R - ‘How To’ results



REFERENCES & APPENDICES

How to ensure implementation of such a system?

LEGEND

- ORTHO-PAEDIC SURGEON & PROFESSOR
- ORTHO-PAEDIC SURGEON
- MARKETING LEAD ZB ITALY
- MARKETING DIRECTOR ZB

TOP DOWN IMPLEMENTATION

USER FRIENDLY METHOD (WEBSITE/APP/..)

THIS SYSTEM DESERVES ATTENTION OF OTHERS THAN ORTHOPAEDIC SURGEONS

HOSPITAL MANAGEMENT NEEDS TO SUPPORT

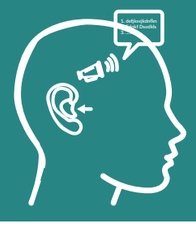
CREATE "CHAMPION" FOR IMPLEMENTATION

DTC CAMPAIGN FOR PATIENT AND FOR OTHER STAKEHOLDERS

SET UP A MULTI-DISCIPLINARY MEETING WITH MICROBIOLOGIST

SET UP A DATA HOME ON INFECTED CASES, AND REFER ON IT EVERY 6 MONTHS

...how to ensure participation & adaptation?
...what elements does it need?
...what organisational changes are necessary?



REFERENCES & APPENDICES

How to provide opportunity for reflection?

LEGEND

- ORTHO-PAEDIC SURGEON & PROFESSOR
- ORTHO-PAEDIC SURGEON
- MARKETING LEAD ZB ITALY
- MARKETING DIRECTOR ZB

PEOPLE HAVE TO "FEEL" THE PROBLEM, SO THEY SHOULD "PLAY THE ROLE"

SEE THE PROBLEM AND DO NOT IGNORE IT → HONOR "THE BEST SOLUTION" OF TEAM MEMBERS

ORGANISE MEETING IN THE HOSPITAL ON THIS TOPIC

AND PUT IN "BEST PRACTICE"

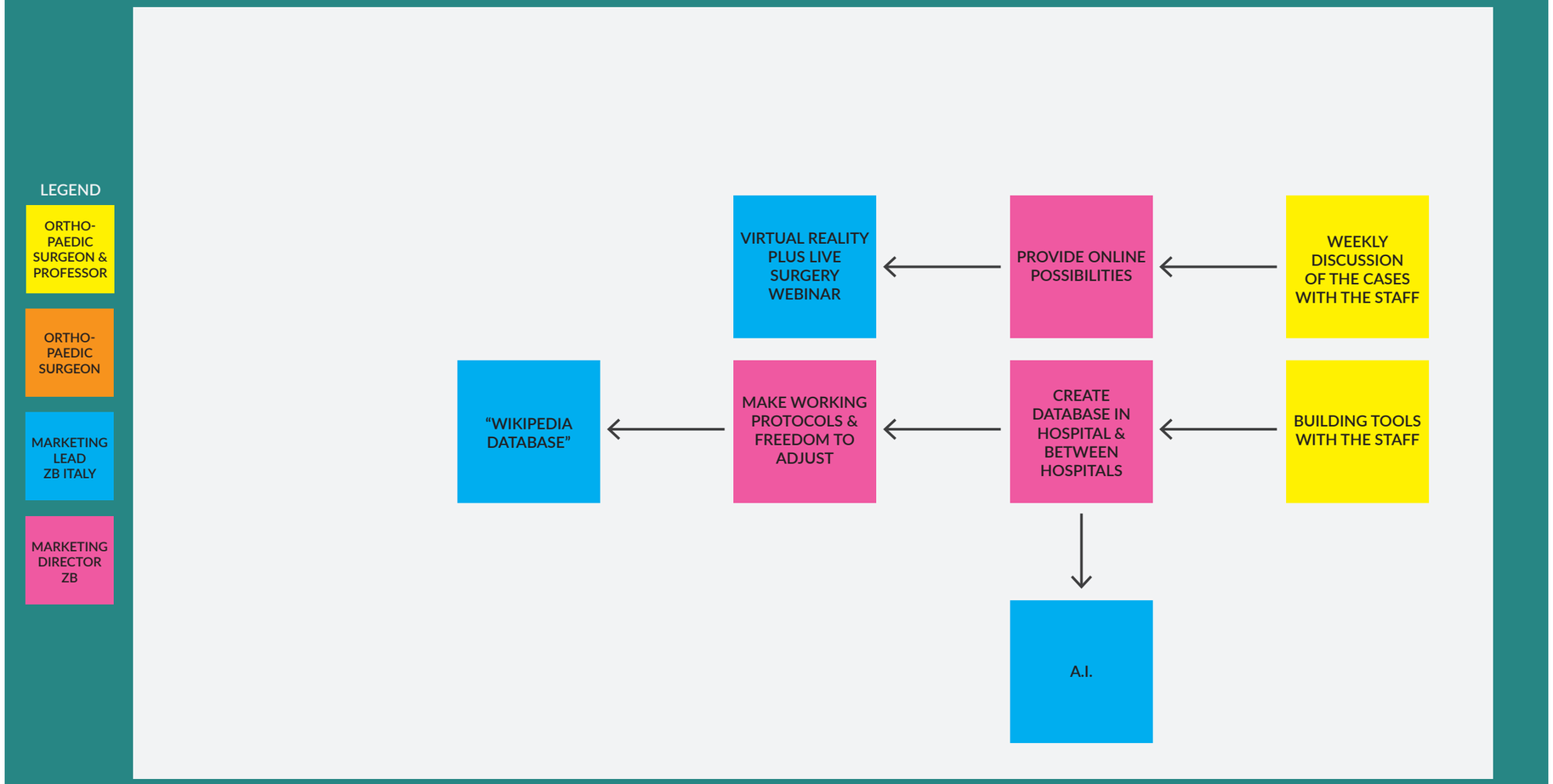
MEETING ON [...] BASED COMPLICATION

CREATE TRANSPARANT USER INTERFACE FOR MDT

...data reflection
...experience reflection
...knowledge reflection

REFERENCES & APPENDICES

How to fit into current rituals?



...without imposing knowledge onto staff,
...rather valuably adding onto rituals?
...how to combine own experience with offered knowledge?

Appendix S - Pocket Guide to Diagnostics & Treatment of PJI

Pocket Guide to Diagnosis & Treatment of Periprosthetic Joint Infection (PJI)

PRO-IMPLANT FOUNDATION

Version 6:
1 July 2017

For individual recommendations contact our Consultation Service portal at: cs.pro-implant-foundation.org
For more information register for our Workshop on PJI at: www.pro-implant-foundation.org/events/workshops

DEFINITION

Periprosthetic joint infection is diagnosed, if ≥1 criterion is fulfilled:

Test	Criteria	Sensitivity	Specificity
Clinical features	Sinus tract (fistula) or purulence around prosthesis[a]	20-30%	100%
Periprosthetic tissue histology[b]	Inflammation (≥2 granulocytes high-power field)	≈90%	≈95%
Leukocyte count in synovial fluid[c]	> 2000/µl leukocytes or > 70% granulocytes (PMN)	≈90%	≈95%
Microbiology	Microbial growth in:		
	• Synovial fluid or	60-80%	97%
	• ≥2 tissue samples[d] or	70-85%	92%
	• Sonication fluid (>50 cfu/ml)[e]	85-95%	95%

[a] Metal-on-metal bearing components can simulate pus («pseudopus»), leukocyte count is normal or elevated (often metal debris is visible)
[b] Classification after Krenn and Morawietz: PJI corresponds to type 2 or type 3
[c] Leukocyte count can be high without infection in the first 6 weeks after surgery, in rheumatic joint disease (including crystalopathy), periprosthetic fracture or luxation. Leukocyte count should be determined within 24 h after aspiration by microscopy or automated counter· clotted specimens are treated with 10 µl hyaluronidase
[d] For highly virulent organisms (e.g. *S. aureus*, streptococci, *E. coli*) or patients under antibiotics, already one positive sample confirms infection
[e] Under antibiotics, for *S. aureus* and anaerobes, <50 cfu/ml can be significant

REFERENCES & APPENDICES

RECOMMENDED ANTIMICROBIAL TREATMENT

Empiric antibiotic therapy:
Ampicillin/sulbactam[c] 3 x 3 g i.v. (+/- vancomycin[e] 2 x 1 g i.v. in septic patients, known MRSA-carriers, multiple previous surgeries, suspected low-grade infection)

Suppressive therapy

Microorganism	Antibiotic (according to susceptibility, dose see table below)
Staphylococcus spp.	Cotrimoxazole, doxycyclin, clindamycin
Streptococcus spp.	Amoxicillin, clindamycin, levofloxacin
Enterococcus spp.	Amoxicillin, (linezolid)
Anaerobes (gram-positive)	Clindamycin, amoxicillin
Anaerobes (gram-negative)	Metronidazole, clindamycin
Gram-negative organisms	Ciprofloxacin, cotrimoxazole
Fungi (*Candida spp.*)	Fluconazole

Targeted eradication therapy (deescalate as soon as the pathogen is known):

Microorganism (red: difficult-to-treat)	Antibiotic[a] (check pathogen susceptibility before)	Dose[b] (blue: renal adjustment needed)	Route
***Staphylococcus* spp.**			
- Oxacillin-/methicillin-susceptible	Flucloxacillin[c]	4 x 2 g	i.v.
	(+/- Fosfomycin)	(3 x 5 g)	i.v.
	for 2 weeks, followed by (according to susceptibility)		
	Rifampin[d] +	2 x 450 mg	p.o.
	Levofloxacin or	2 x 500 mg	p.o.
	Cotrimoxazole or	3 x 960 mg	p.o.
	Doxycyclin or	2 x 100 mg	p.o.
	Fusidic acid	3 x 500 mg	p.o.
Oxacillin-/methicillin-resistant	Daptomycin or	1 x 8 mg/kg	i.v.
	Vancomycin[e]	2 x 1 g	i.v.
	(+/- Fosfomycin)	(3 x 5 g)	i.v.
	for 2 weeks, followed by an oral **rifampin** combination as above		
Rifampin-resistant	Intravenous treatment according susceptibility for 2 weeks (as above), followed by long-term suppression for ≥1 year		
***Streptococcus* spp.**	Penicillin G[c] or	4 x 5 million U	i.v.
	Ceftriaxon	1 x 2 g	i.v.
	for 2-3 weeks, followed by:		
	Amoxicillin or	3 x 1000 mg	p.o.
	Levofloxacin	2 x 500 mg	p.o.
	(consider suppression for 1 year)		
***Enterococcus* spp.**			
Penicillin-susceptible	Ampicillin +	4 x 2 g	i.v.
	Gentamicin[f]	1 x 120 mg	i.v.
	for 2-3 weeks, followed by:		
	Amoxicillin	3 x 1000 mg	p.o.
Penicillin-resistant	Vancomycin[e] or	2 x 1 g	i.v.
	Daptomycin	1 x 10 mg/kg	i.v.
	+		
	Gentamicin[f]	1 x 120 mg	i.v.
	(+/- Fosfomycin)	3 x 5 g	i.v.
	for 2-4 weeks, followed by		
	Linezolid (max. 4 weeks)	2 x 600 mg	p.o.
Vancomycin-resistant (VRE)	Individual; removal of the implant or life-long suppression necessary		

Microorganism (red: difficult-to-treat)	Antibiotic[a] (check susceptibility before)	Dose[b] (blue: renal adjustment needed)	Route
Gram-negative			
Enterobacteriaceae (*E. coli, Klebsiella, Enterobacter* etc.)	Ciprofloxacin[g]	2 x 750 mg	p.o.
Nonfermenters (*Pseudomonas aeruginosa, Acinetobacter* spp.)	Piperacillin/tazobactam or	3 x 4.5 g	i.v.
	Meropenem or	3 x 1 g	i.v.
	Ceftazidim	3 x 2 g	i.v.
	+ Tobramycin	1 x 300 mg	i.v.
	(or gentamicin)	1 x 240 mg	i.v.
	for 2-3 weeks, followed by:		
	Ciprofloxacin	2 x 750 mg	p.o.
Ciprofloxacin-resistant	Depending on susceptibility: meropenem 3 x 1 g, colistin 3 x 3 million U and/or fosfomycin 3 x 5 g i.v., followed by oral suppression.		
Anaerobes			
Gram-positive (*Cutibacterium, Peptostreptococcus, Finegoldia magna*)	Penicillin G[c] or	4 x 5 million U	i.v.
	Ceftriaxon	1 x 2 g	i.v.
	for 2 weeks, followed by:		
	Rifampin[d] +	2 x 450 mg	p.o.
	Levofloxacin or	2 x 500 mg	p.o.
	Amoxicillin	3 x 1000 mg	p.o.
Gram-negative (*Bacteroides*)	Ampicillin/sulbactam[c]	3 x 3 g	i.v.
	for 2 weeks, followed by		
	Metronidazol	3 x 400 mg or 500 mg	p.o.
Candida spp.	Caspofungin[h]	1 x 70 mg	i.v.
Fluconazole-susceptible	Anidulafungin	1 x 100 mg (1st day: 200 mg)	i.v.
	for 1-2 weeks, followed by:		
	Fluconazole	1 x 400 mg	p.o.
	(suppression for ≥1 year)		
Fluconazole-resistant	Individual (e.g. with voriconazole 2 x 200 mg p.o.); removal of the implant or long-term suppression		
Culture-negative	Ampicillin/sulbactam[c]	3 x 3 g	i.v.
	for 2 weeks, followed by:		
	Rifampin[d] +	2 x 450 mg	p.o.
	Levofloxacin	2 x 500 mg	p.o.

[a] **Total duration** of therapy: **12 weeks**, usually 2 weeks intravenously, followed by oral route

[b] Laboratory testing 2x weekly: leukocytes, CRP creatinine/eGFR, liver enzymes (AST/SGOT and ALT/SGPT). Dose-adjustment according to renal function and body weight (<40/>100kg)

[c] **Penicillin allergy** of NON-type 1 (e.g. skin rash): cefazolin (3 x 2 g i.v.). In case of anaphylaxis (= type 1-allergy such as Quincke´s edema, bronchospasm, anaphylactic shock) or cephalosporin allergy: vancomycin (2 x 1 g i.v.) or daptomycin (1 x 8 mg/kg i.v.) Ampicillin/sulbactam is equivalent to amoxicillin/clavulanic acid (3 x 2.2 g i.v.)

[d] **Rifampin** is administered only after the new prosthesis is implanted. Add it already to intravenous treatment as soon as wounds are dry and drains removed; in patients aged >75 years, rifampin is reduced to 2 x 300 mg p.o.

[e] Check **Vancomycin** through concentration (take blood before next dose) at least 1x/week; therapeutic range: 15-20 µg/ml

[f] Give only, if **gentamicin high-level (HL)** is tested susceptible (consult the microbiologist). In gentamicin HL-resistant *E. faecalis*: gentamicin is exchanged with ceftriaxone (1 x 2 g i.v.)

[g] **Add i.v. treatment** (piperacillin/tazobactam 3 x 4.5 g or ceftriaxon 1 x 2 g or meropenem 3 x 1 g i.v.) in the first postoperative days (until wound is dry)

[h] After a loading dose of 70 mg on day 1 reduce dose to 50 mg in patients weighing < 80 kg from day 2

LOCAL ANTIMICROBIALS IN BONE CEMENT

(Supportive to surgical and systemic antimicrobial treatment)

Microorganism (S = susceptible, R = resistant[a])	Antimicrobial[b]	Dose[c] (g per 40 g cement)	Mechanical stability[d]	Synergistic elution[e]	Commercial product available[f]
***Staphylococcus* spp.**	Gentamicin +	1 g			
Oxacillin-/methicillin-S	Clindamycin	1 g	++	+	Yes
Oxacillin-/methicillin-R	Gentamicin +	0.5 g			
	- Daptomycin or	2 g	+	+	No
	- Vancomycin	2 g	++	+	Yes
***Streptococcus* spp.**	Gentamicin +	0.5-1 g			
	Clindamycin	1 g	++	+	Yes
***Enterococcus* spp.**					
Vancomycin-S/ aminoglycoside-S or R	Gentamicin + Vancomycin	0.5 g 2 g	++	+	Yes
Vancomycin-R/ aminoglycoside-S or R	Gentamicin +	0.5 g			
	- Linezolid or	1 g	+	+	No
	- Daptomycin or	2 g	+	+	No
	- Fosfomycin	1-2 g	+	0	No
Enterobacteriaceae					
Aminoglycoside-S	Gentamicin (+/- Clindamycin[g])	1 g 1 g	++	+	Yes
ESBL-producer or aminoglycoside-R	Gentamicin[g] + Meropenem	0.5 g 2 g	0	0	No
Carbapenem-R or aminoglycoside-R	Gentamicin[g] + Colistin	0.5 g 1-2 g	+	+	Only: Colistin + Erythromycin
Nonfermenters					
Aminoglycoside-S and Fluoroquinolone-S	Gentamicin + Ciprofloxacin	0.5 g 2 g	+	+	No
Multi-R	Gentamicin +	0.5 g			
	- Colistin or	1-2 g	+	+	Only: Colistin + Erythromycin
	- Fosfomycin	1-2 g	+	+	No
Anaerobes (gram-positive)	Gentamicin + Clindamycin	1 g 1 g	++	+	Yes
***Candida* spp.**	Gentamicin[g] +	0.5 g			
	- Amphotericin B[h] liposomal (Ambisome) or	0.2-0.3 g	+	0	No
	- Amphotericin B non-liposomal (Fungizone) or	0.2-0.8 g	+	0	No
	- Voriconazole	0.3-0.6 g	0	0	No

[a] Resistances in antibiogram are based on systemic application and might differ for the local application due to higher local concentrations and possible synergisms

[b] Side effects and interactions of local antibiotics are rare, but serum concentrations of **vancomycin** and aminoglycosides (gentamicin) should be measured in patients with kidney insufficiency (creatinine clearance (<60 ml/min) and concomitant intravenous administration of same antibiotic. Only use sterile antibiotics in powder form. Liquid antibiotics are not recommended. Antibiotics that interfere with polymerization process (e.g. **imipenem, rifampicin or metronidazol**) or which are not thermostable (e.g. some beta lactams) should not be used

[c] The minimal effective dose is shown in table. Especially for the fixation of implants maximal recommended total dose of antibiotics **should not exceed 10%** of the weight of bone cement powder. Recommendations are based on studies with PALACOS®/COPAL® bone cements and literature data

[d] According to ISO 5833 2002; Legend: (++) = registered product ; (+) = ISO requirements fulfilled (published or laboratory data); (0) = no data available

[e] Legend: (+) = improved drug release in combination (synergy); (0) = no data available
Manual addition of antibiotics to bone cement leads to reduced mechanical stability and often lower release of antibiotics compared to commercial products

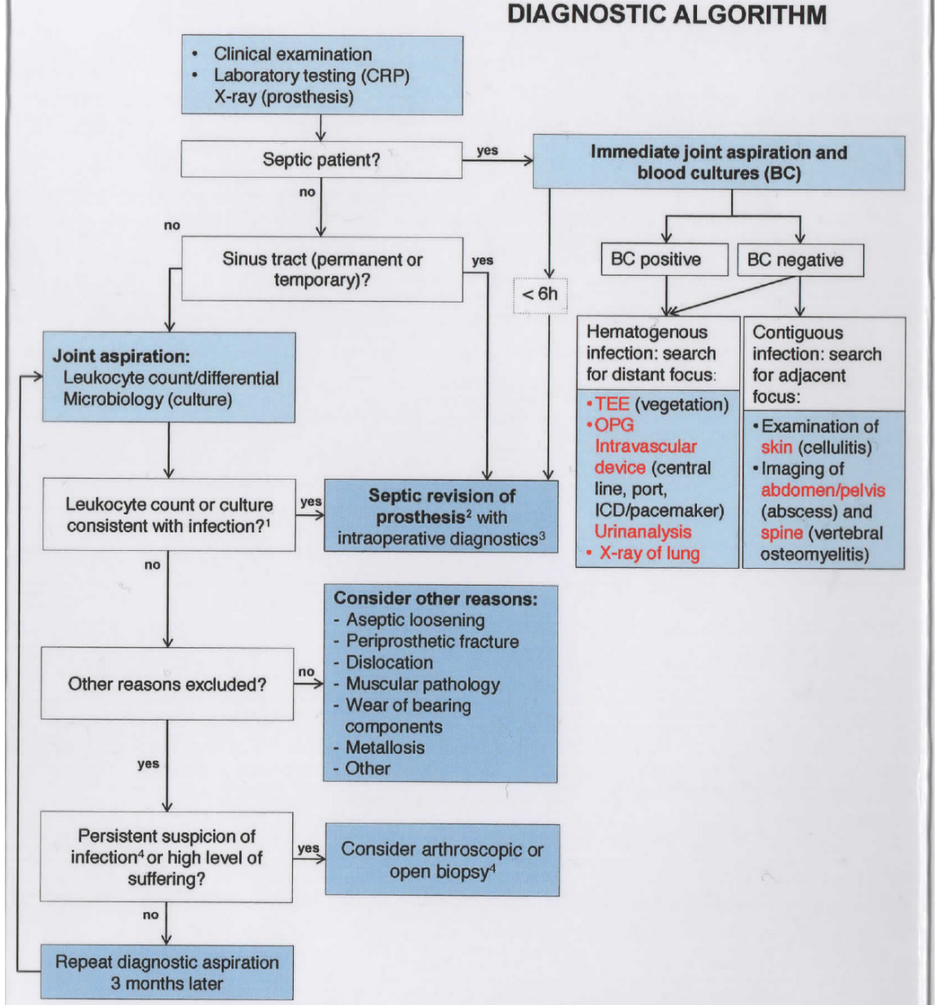
[g] Combinations with **gentamicin / clindamycin** lead to higher release of antibiotics (synergy)

[h] Since non-liposomal amphotericin B has been shown to interact with bone cement during the chemical reaction, **liposomal amphotericin B** is preferred

CLASSIFICATION

	Acute PJI (immature biofilm)	Chronic PJI (mature biofilm)
Pathogenesis		
▪ Perioperative	<4 weeks after surgery (early)	≥4 weeks after surgery (delayed/low-grade)
▪ Hematogenous or per continuitatem	<3 weeks of symptom duration	≥3 weeks of symptom duration
Clinical features	Acute pain, fever, red/swollen joint, prolonged postoperative discharge (>7-10 days)	Chronic pain, loosening of the prosthesis, sinus tract (fistula)
Causative microorganism	High-virulent: *Staphylococcus aureus*, gram-negative bacteria (e.g. *Escherichia coli*, *Klebsiella*, *Pseudomonas aeruginosa*)	Low-virulent: Coagulase-negative staphylococci (e.g. *Staphylococcus epidermidis*), Cutibacterium (formerly *Propionibacterium)* spp.
Surgical treatment	Débridement & retention of prosthesis (change of mobile parts)	Complete removal of prosthesis (exchange in one or two stages)

DIAGNOSTIC ALGORITHM



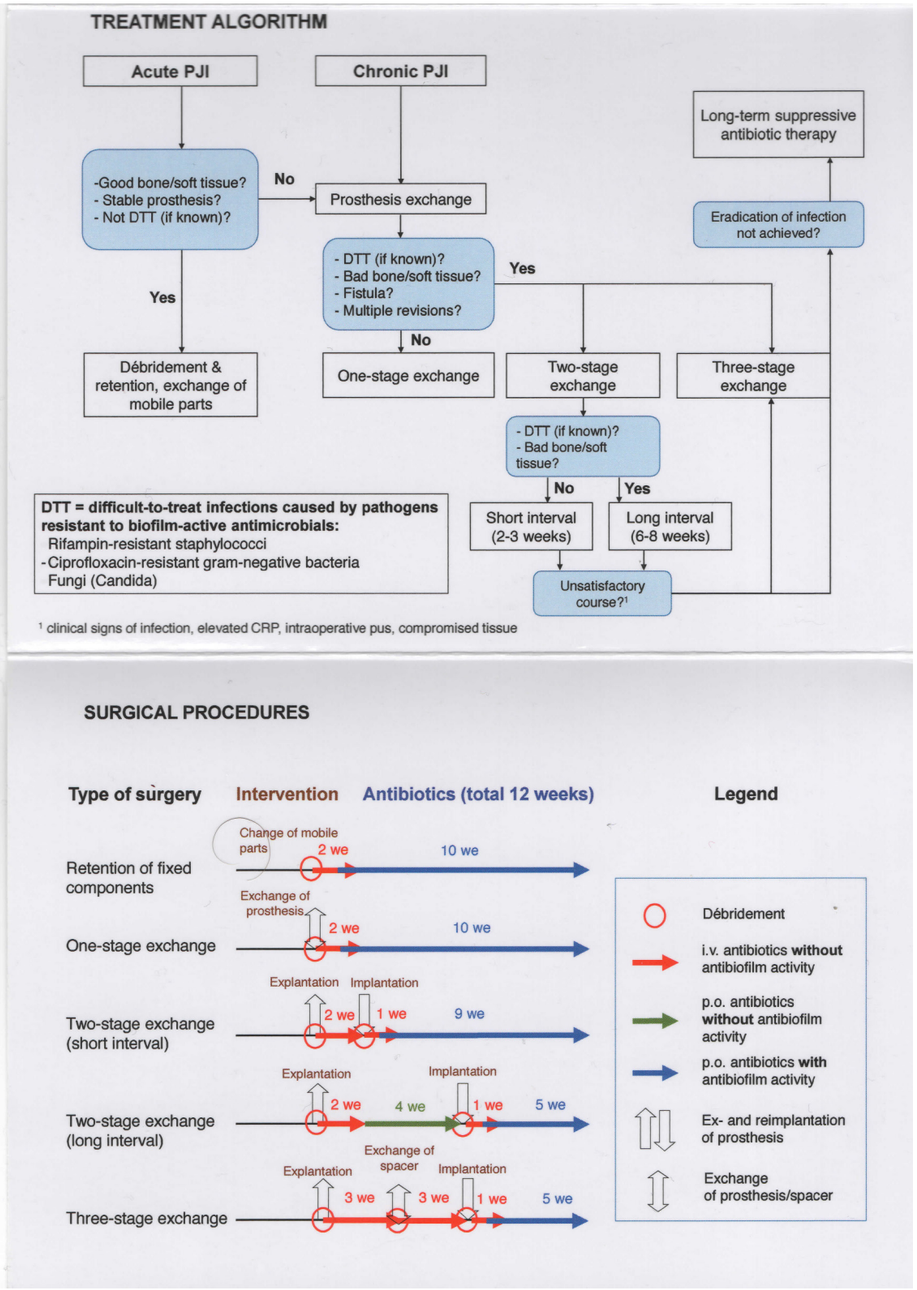
Leukocyte count: >2000/µl leukocytes or >70% granulocytes; microbiology: for highly virulent organisms (e.g. *S. aureus, E. coli*) already one positive sample confirms infection, for low-viruent organisms (e.g. *S. epidermidis, Cutibacterium spp. (P. acnes)*) ≥2 positive samples are required to confirm infection

[2] According to the treatment algorithm for PJI

[3] Leukocyte count/differential, histopathology, microbiology (+/-sonication)

[4] Elevated CRP, risk history (prolonged secretion or revision surgery after primary implantation), early loosening of prosthesis

BC: blood cultures, TEE: transesophageal echocardiography, OPG: orthopantomogram



REFERENCES & APPENDICES

Appendix T - Analysis on the wall

To take a step back, and see gathered insights in perspective, an analysis on the wall (a.k.a. research on the wall/research wall) has been executed. This helps to find links between insights, as welll as links between insights, opportunities and solutions. It provides an overview of the situation and problem and allows for abstractions and implicit insights to be reached.

Figure 80. Analysis on the wall in progress

After setting up a framework of phases and relevant stakeholders/themes, the process starts by defining insights. When insights are gathered and defined, the next step is to come to opportunity directions. After opportunity directions are defined, the following step is to think of solutions. As this is an iterative process, there is no rule against going back to an earlier step. The process itself will bring forth new implict insights and abstractions as well. This can furthermore result in the addition of new relevant themes. A framework of this process is shown in Figure 47.

By following this framework the designer firstly took the time to think about relevant problems and place previous gathered insights onto the wall. Subsequently,

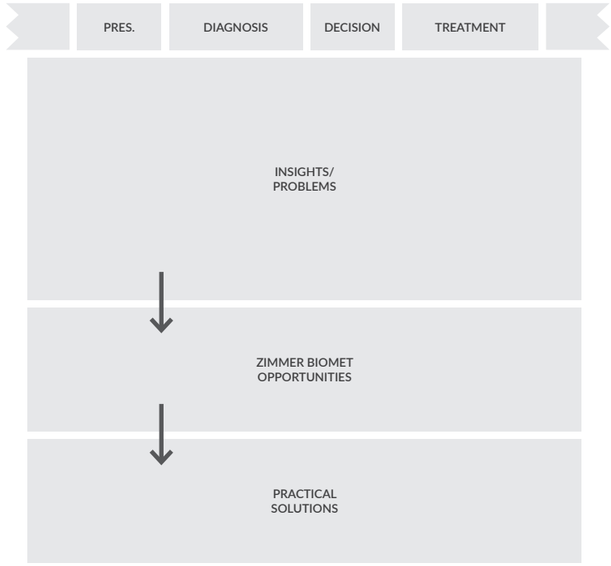


Figure 81. Framework of the process for 'analysis on the wall'.

the designer defined opportunities for Zimmer Biomet related to the insights and problems gathered. After coming back to this step a few times, the following step has been to come up with practical solutions that answer to these problems and fill these opportunities. During the process an 'information' layer has been added since a lot of insights revolved around this theme. The result of this process is visualised in Figure 81. For the sake of clarity, the visualisation mainly shows results that are relevant to the defined design brief.

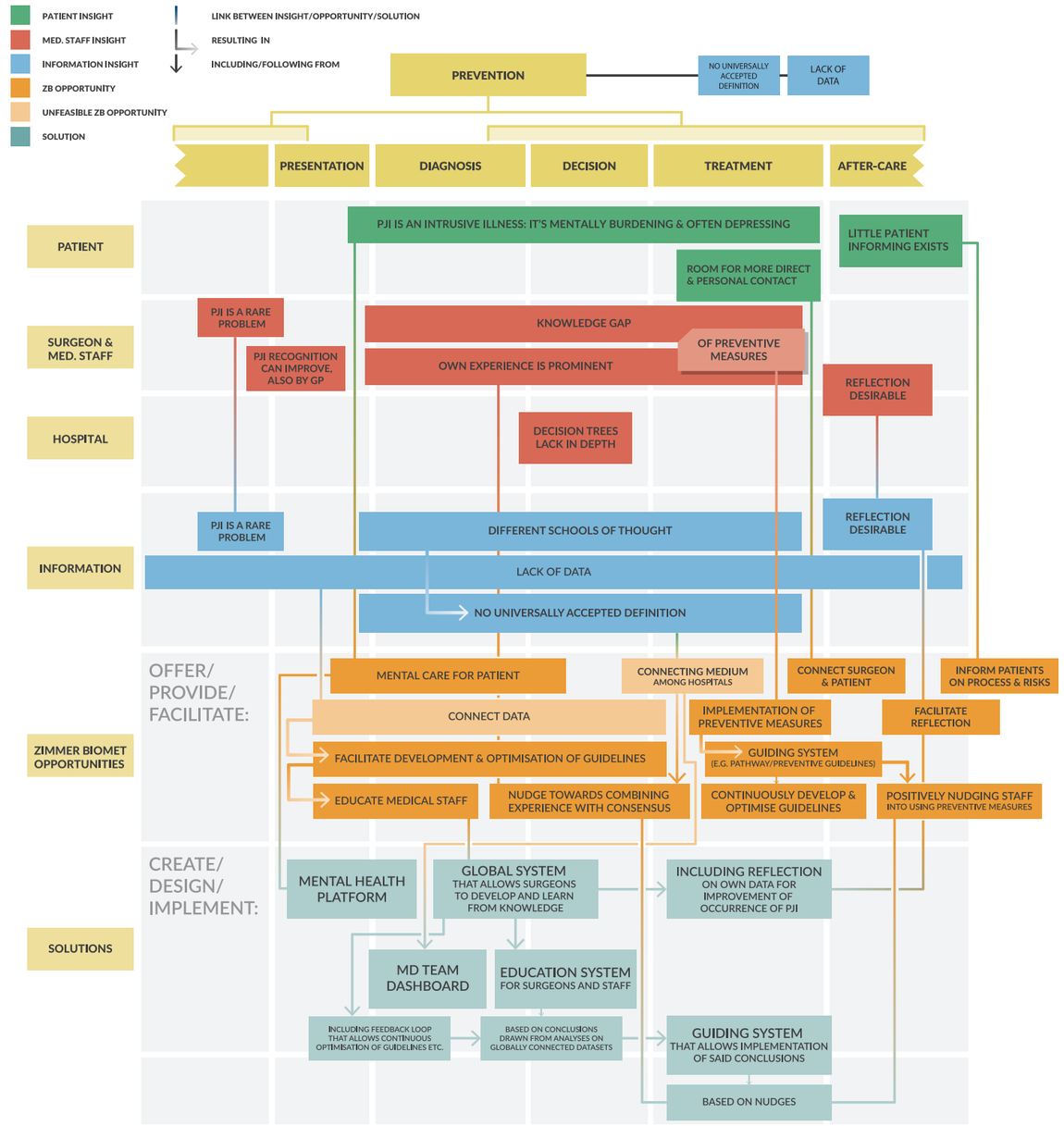


Figure 82. Results of analysis on the wall

Appendix U - Ideation methods

WWWWWH

The name of this method stands for “Who, What, Where, When, Why and How”. This method is valuable to use when you want to analyse the problem at hand thoroughly, from different angles or just another time. It allows you to see the problem more clearly, understand elements of it better and discover aspects you had not yet before thought of.

The method helps you to deconstruct the problem you are facing. The questions that this methods makes you ask yourself, allow you to do this in a systematic way. The context of the problem will become clearer and underlying problems can come to light. (Curedale, 2012; Van Boeijen et al, 2014)

Primary results of this method can be seen in Figure 83.

How To

Next to the use of ‘How To?’ questions in a group setting, it can also be used to stimulate ideation on an individual level. The method works rather simple, but is very effective: you take a problem, opportunity, solution direction or goal and form it into a question. (Stickdorn, 2018) For instance, if an opportunity is “mental care for patient”, then the question would read: “How to provide mental care for patient?” This way you try to tackle all problems you’ve encountered and try to exhaust all options for answering to opportunities, solution directions and goals.

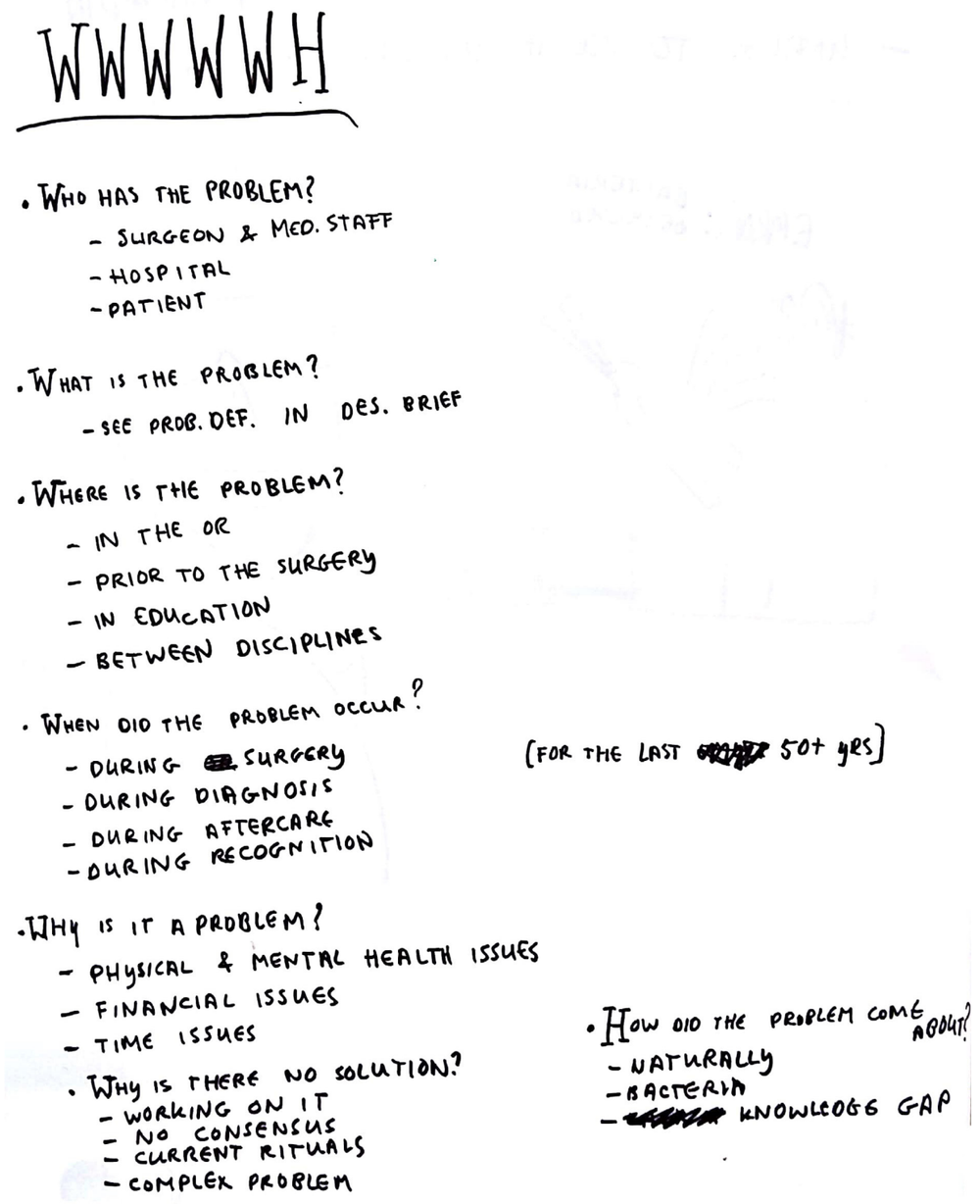
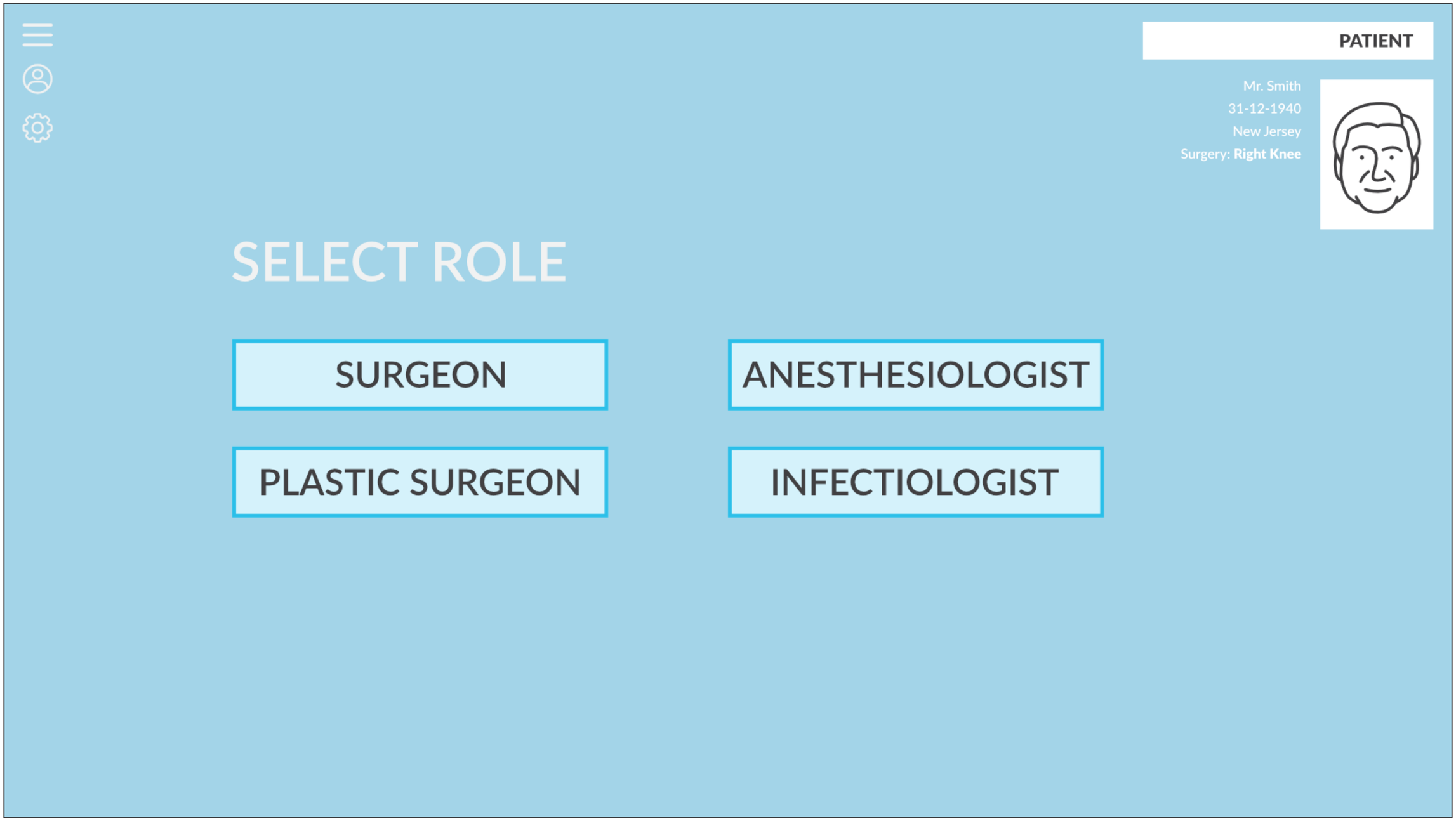


Figure 83. Primary results of the WWWWWH method

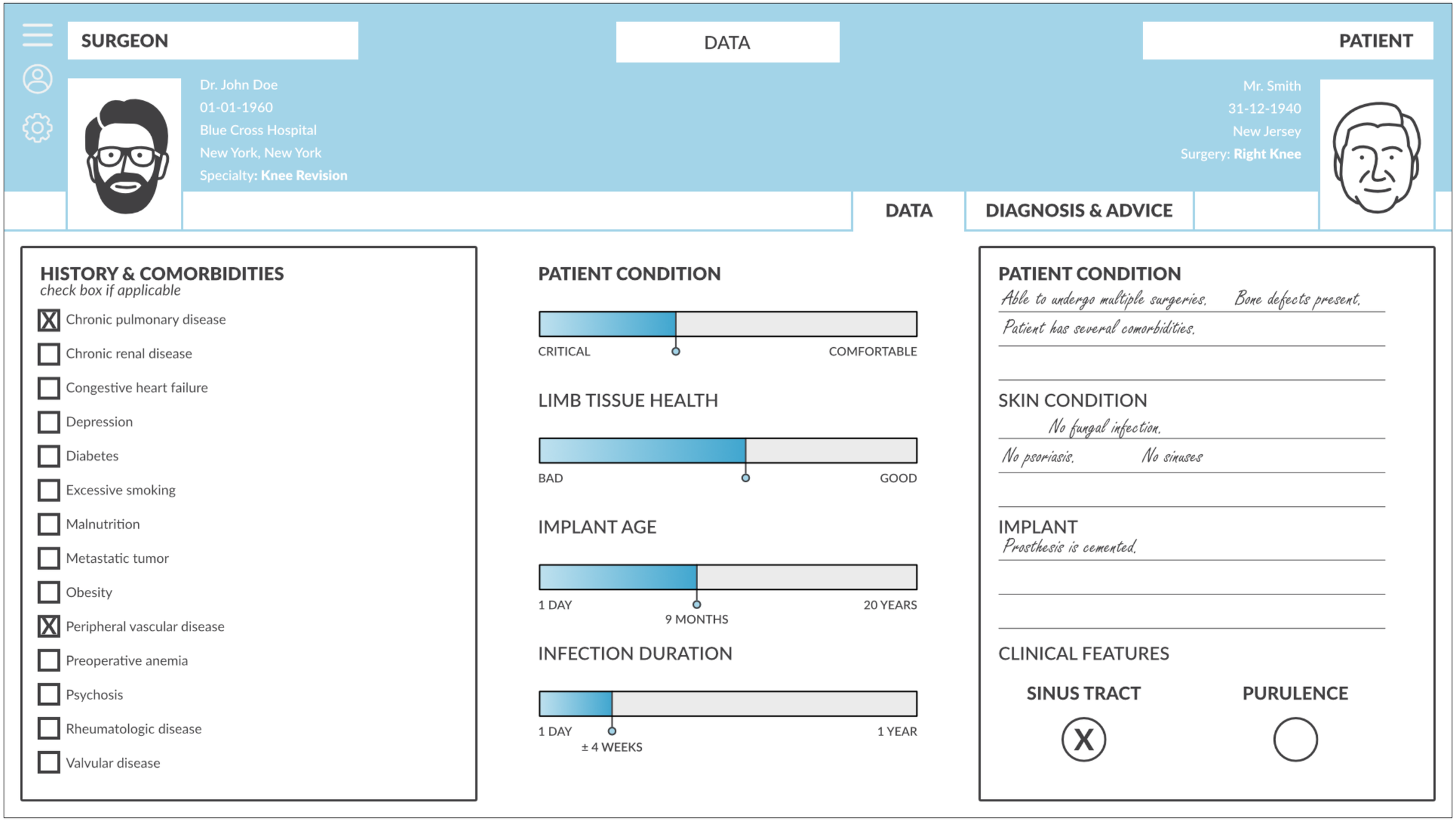
REFERENCES & APPENDICES

Appendix V - MDT Dashboard interfaces

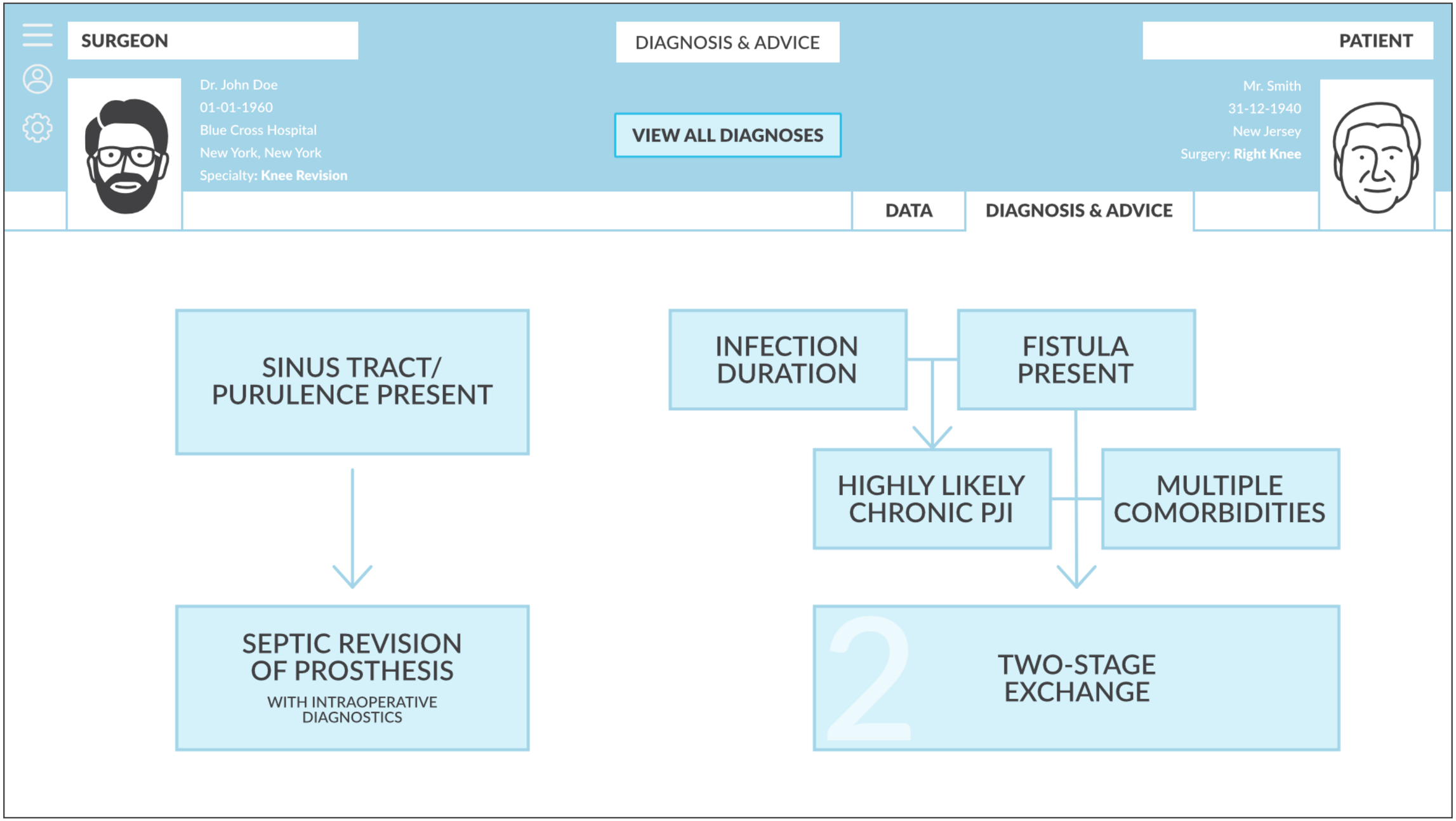
REFERENCES & APPENDICES



REFERENCES & APPENDICES



REFERENCES & APPENDICES



REFERENCES & APPENDICES

PLASTIC SURGEON

Dr. Pete Sakes
05-05-1955
Blue Cross Hospital
New York, New York
Specialty: **Joints**

DATA

PATIENT

Mr. Smith
31-12-1940
New Jersey
Surgery: **Right Knee**

DATA | **DIAGNOSIS & ADVICE**

SKIN CONDITION

No fungal infection.
No psoriasis. *No sinuses*

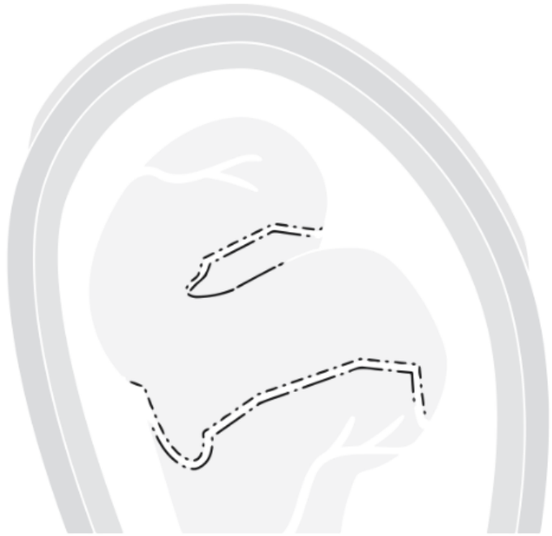
LIMB TISSUE HEALTH

- [x] ARTERIAL/VENOUS INSUFFICIENCY
- [ ] SENSORY & MOTOR NEUROPATHIES
- [x] SOFT TISSUE LOSS/DEFICIENCY

TISSUE QUALITY

BAD — GOOD

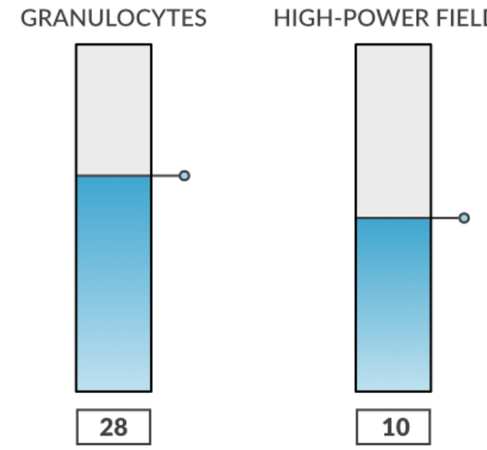
McPHERSON SCHEMA



PATIENT CONDITION

Inflammation expected.
Granulocyte test initiated

INFLAMMATION



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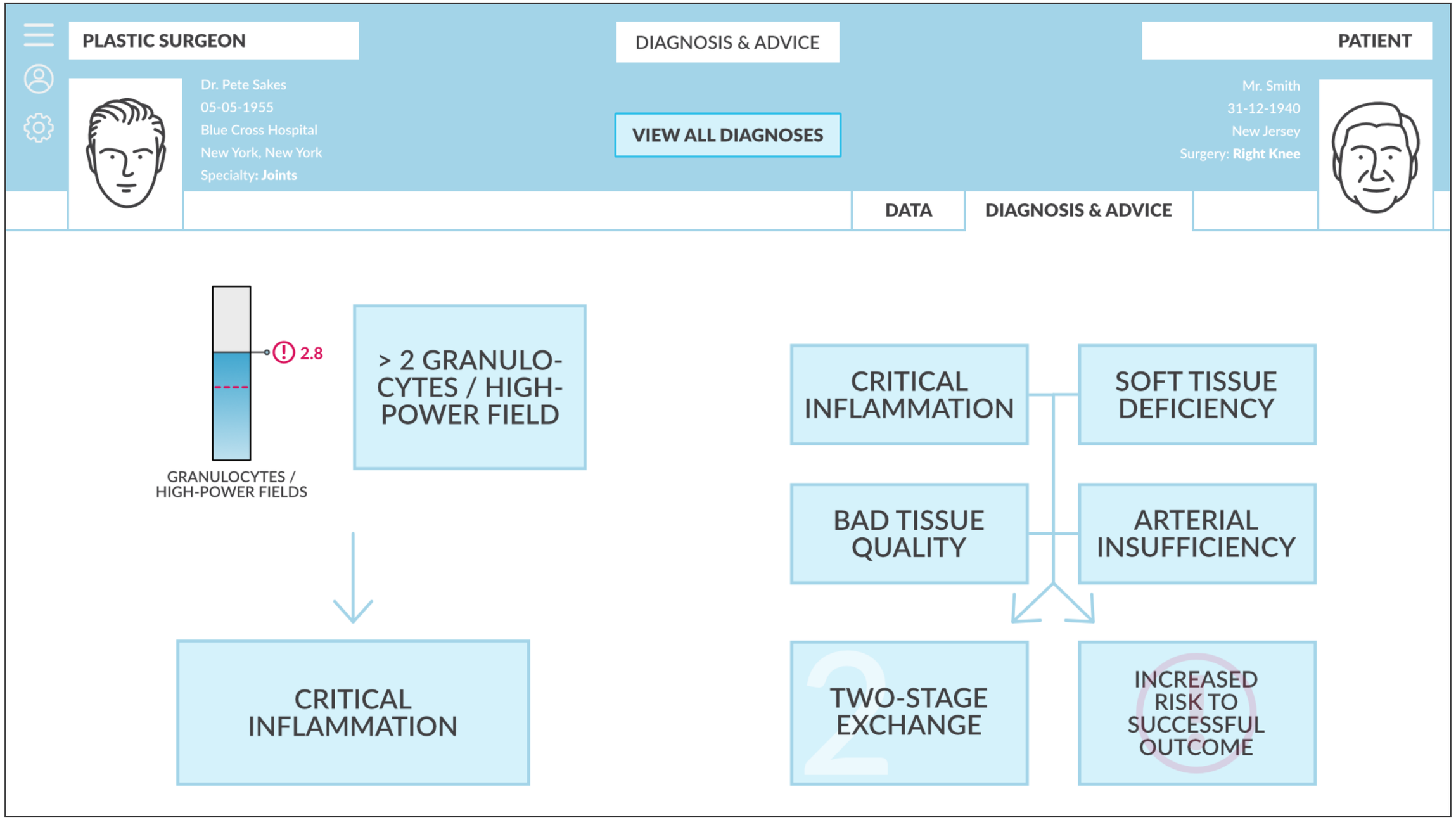


REFERENCES & APPENDICES

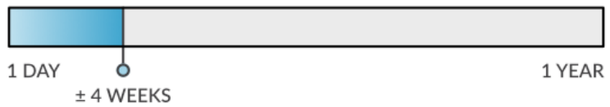
INFECTIOLOGIST | DATA | **PATIENT**

Dr. Margot Hide
03-03-1983
Blue Cross Hospital
New York, New York
Specialty: **Joint Infections**

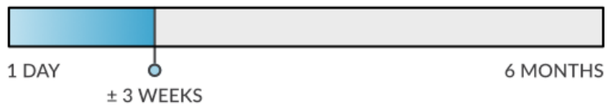
Mr. Smith
31-12-1940
New Jersey
Surgery: **Right Knee**

DATA | **DIAGNOSIS & ADVICE**

INFECTION DURATION



SYMPTOM DURATION



MICRO-ORGANISM

HIGH-VIRULENT

- Staphylococcus aureus
- Gram-negative bacteria

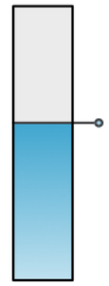
LOW-VIRULENT

- Coagulase-negative staphylococci
- Cutibacterium (formerly Propionibacterium) spp.

CLINICAL FEATURES

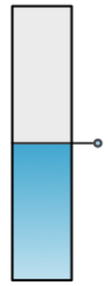
- ☐ Acute pain
- ☒ Chronic pain
- ☐ Fever
- ☐ Prosthesis loosening
- ☐ Red/swollen joint
- ☒ Sinus tract

DIFFERENTIAL LEUKOCYTE COUNT



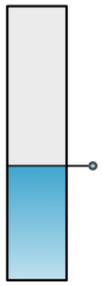
2640
LEUKOCYTES/µL

ERYTHROCYTE SEDIMENTATION RATE



39
mm/hr

C-REACTIVE PROTEIN LEVEL



81
mg/L

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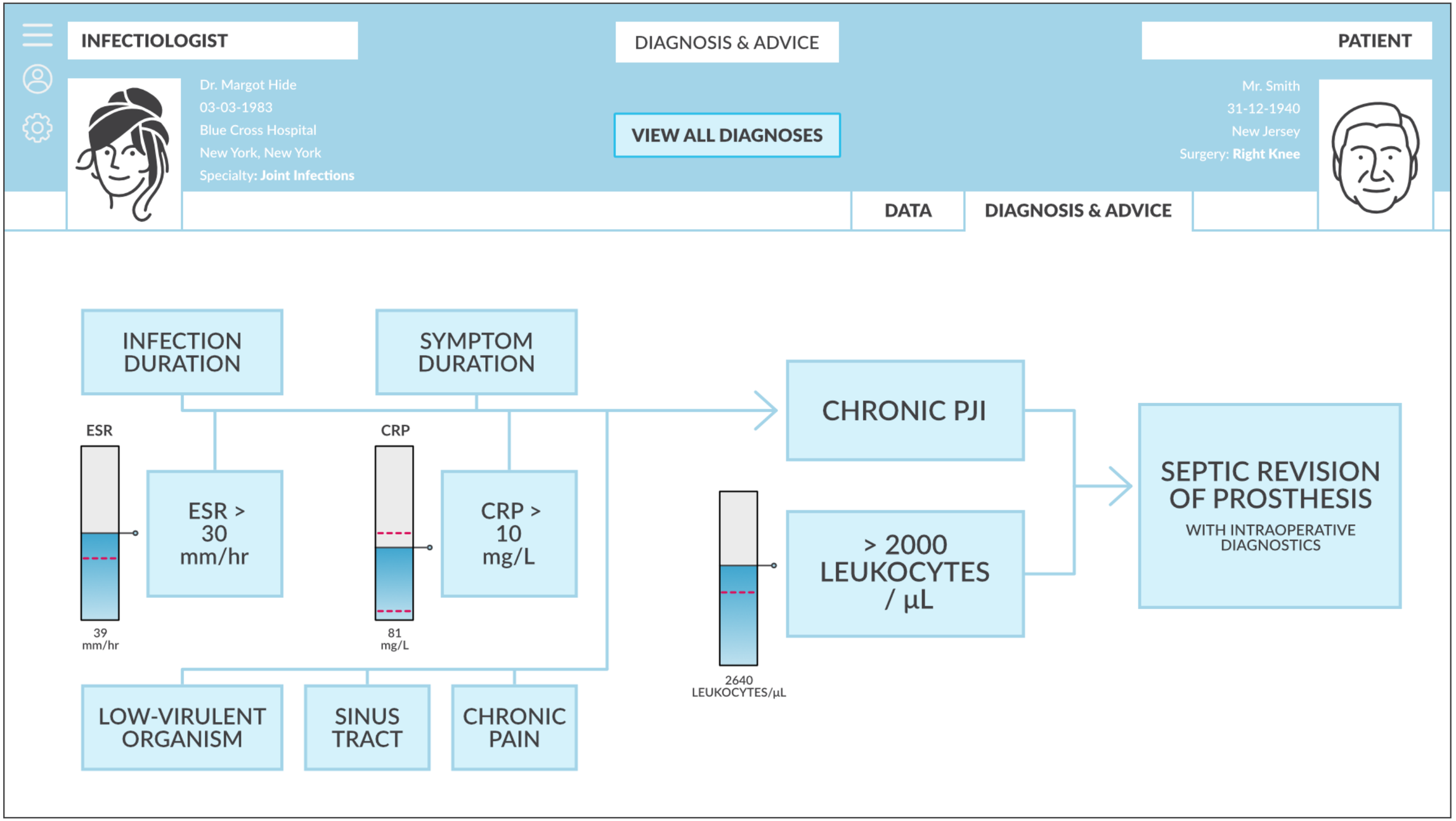

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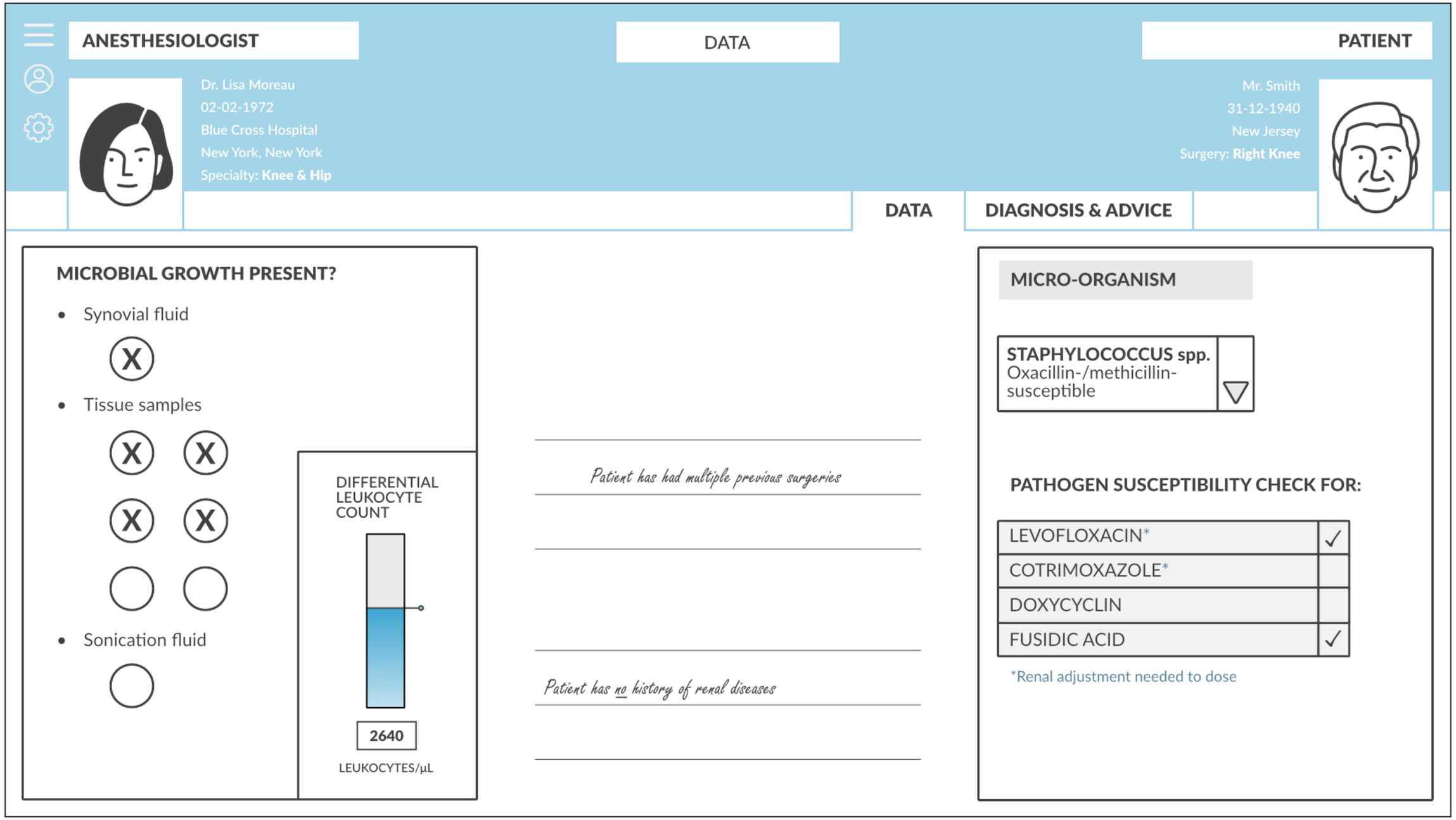

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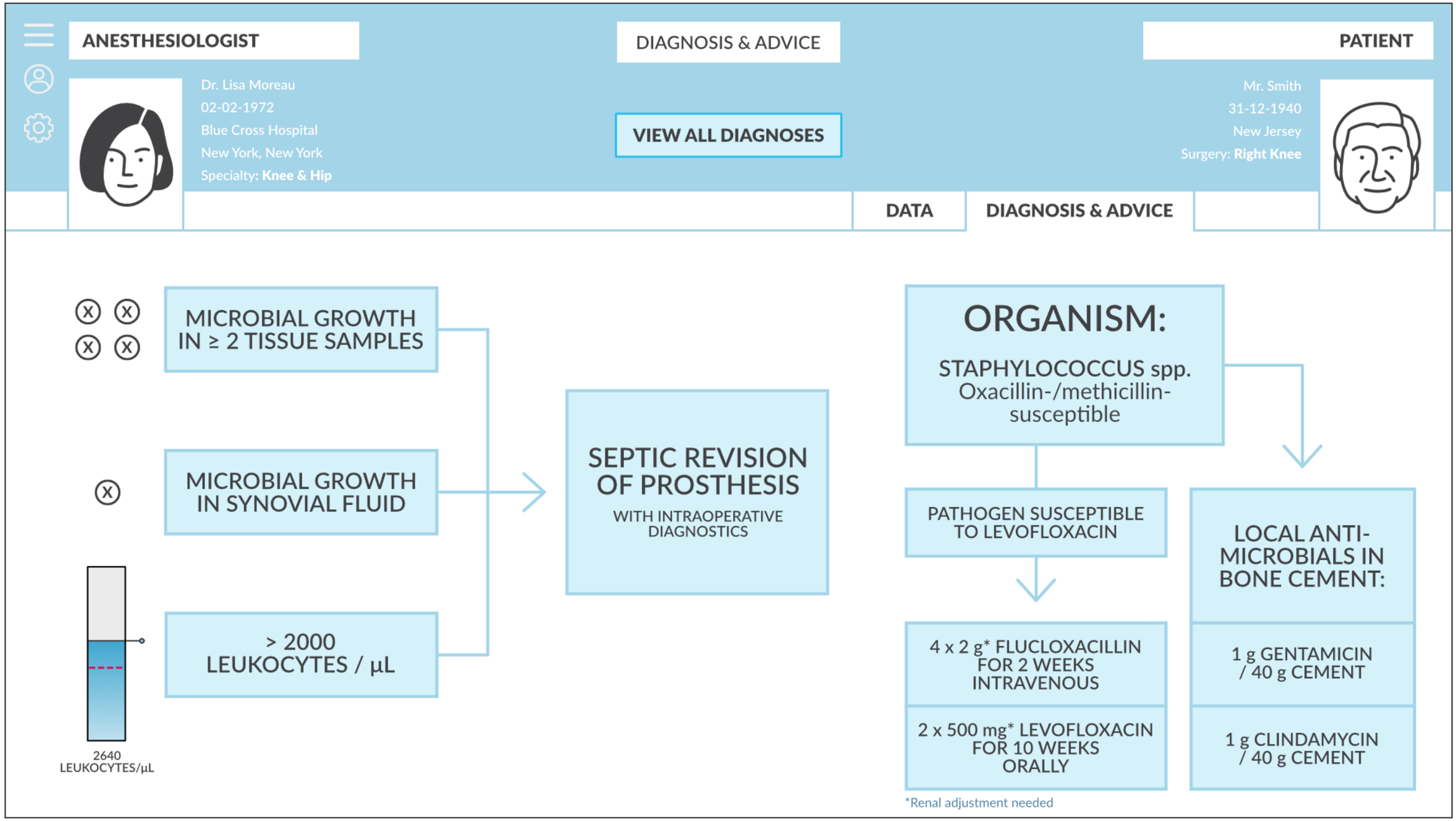

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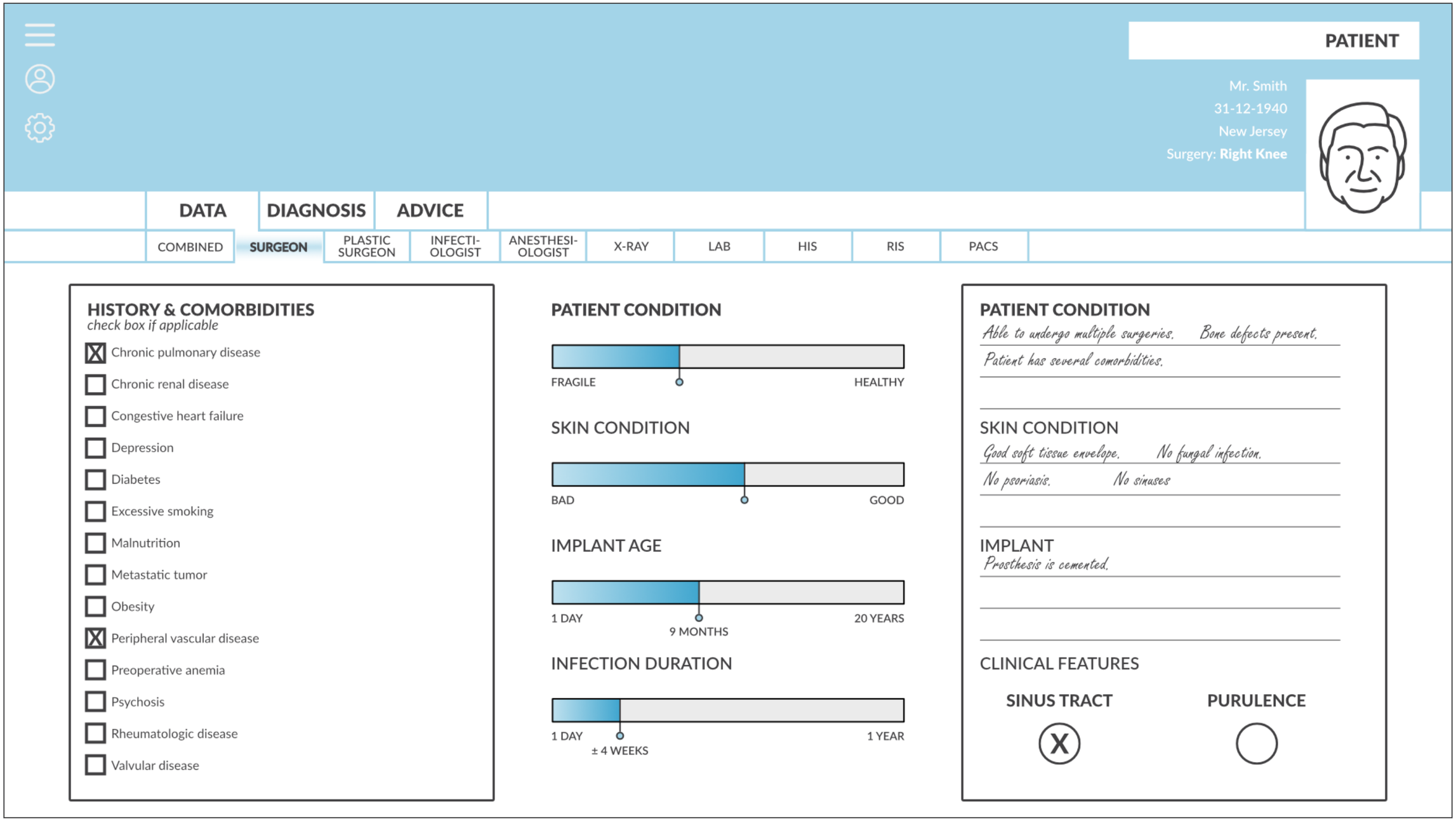

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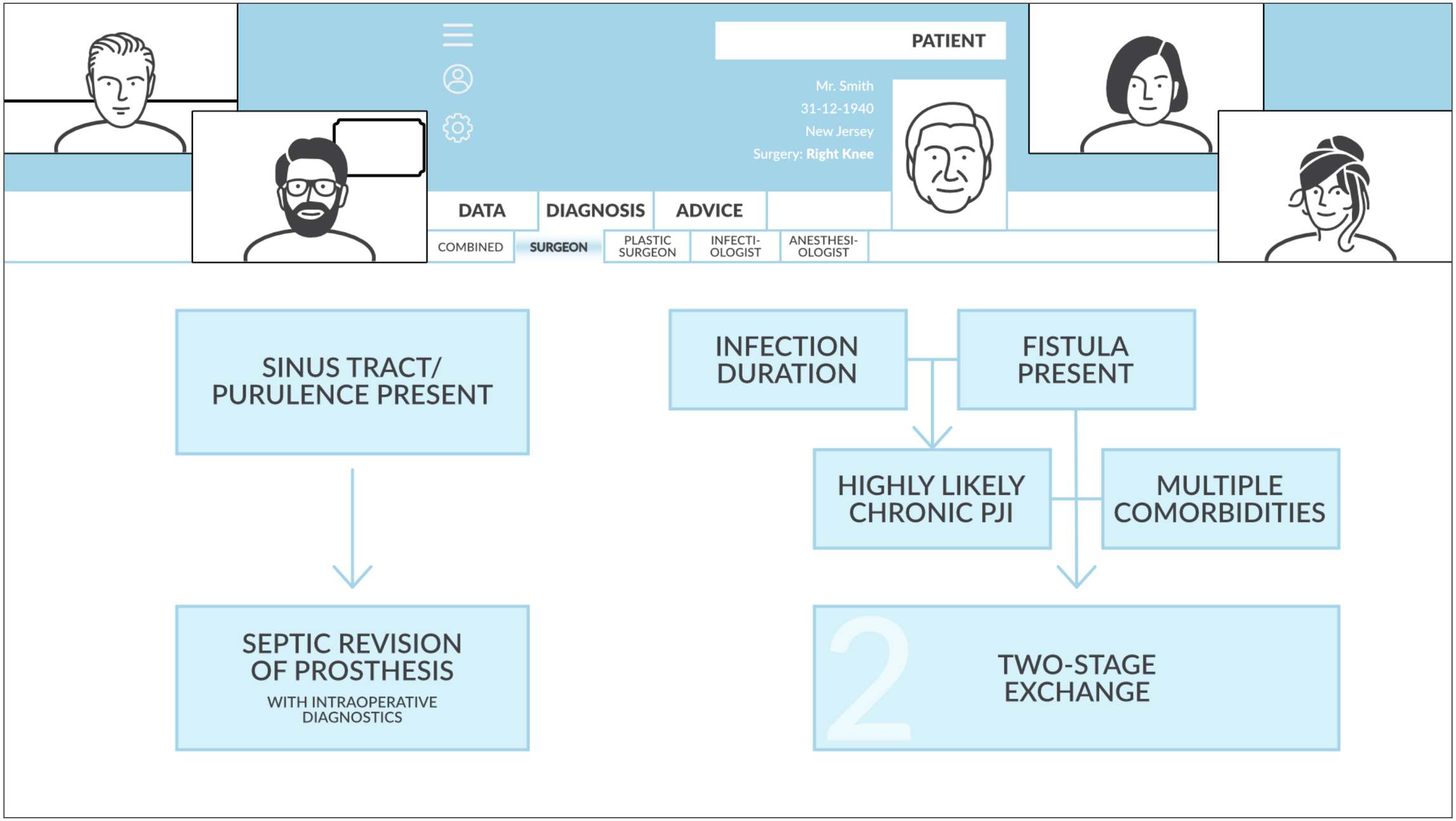

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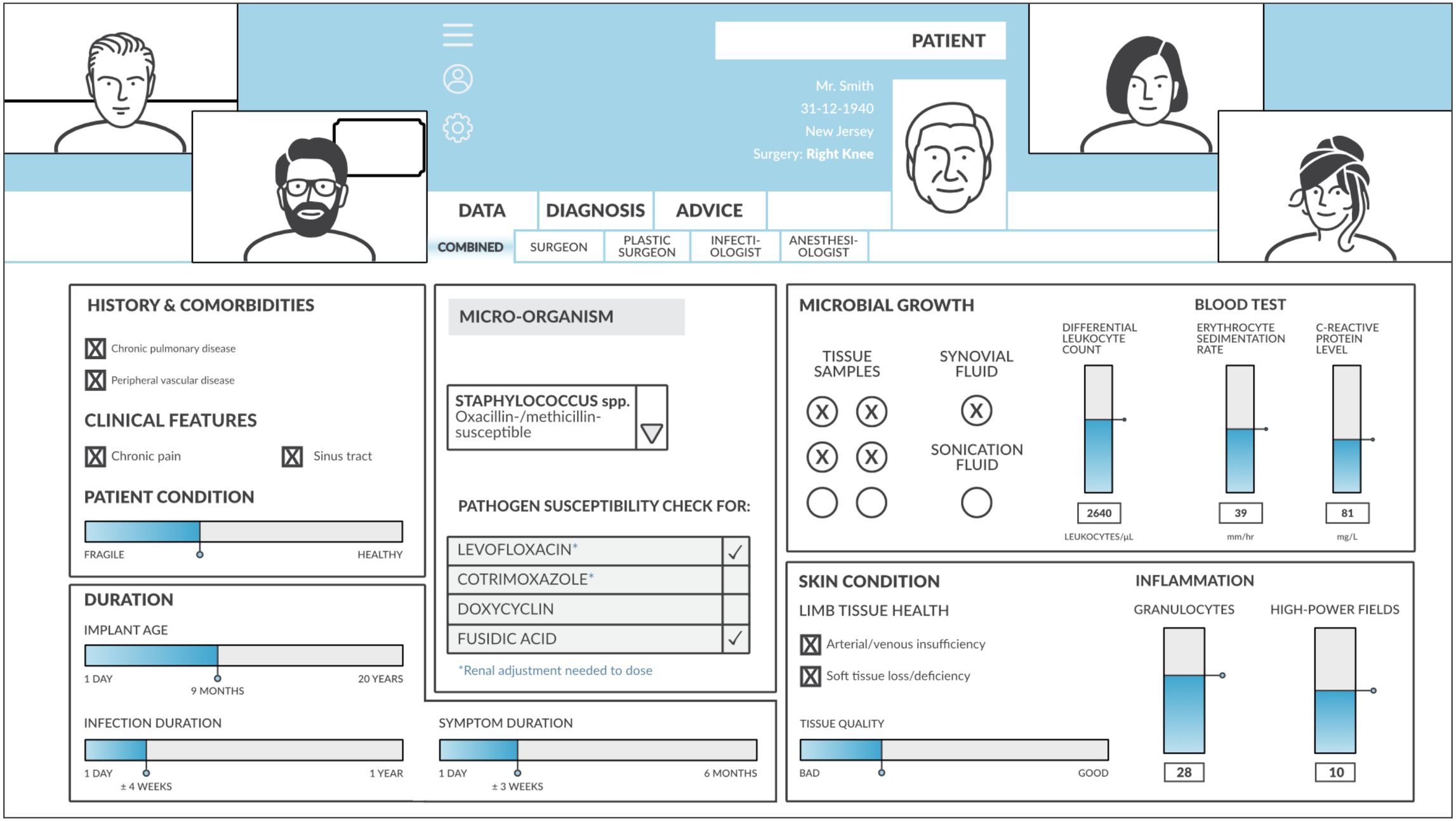

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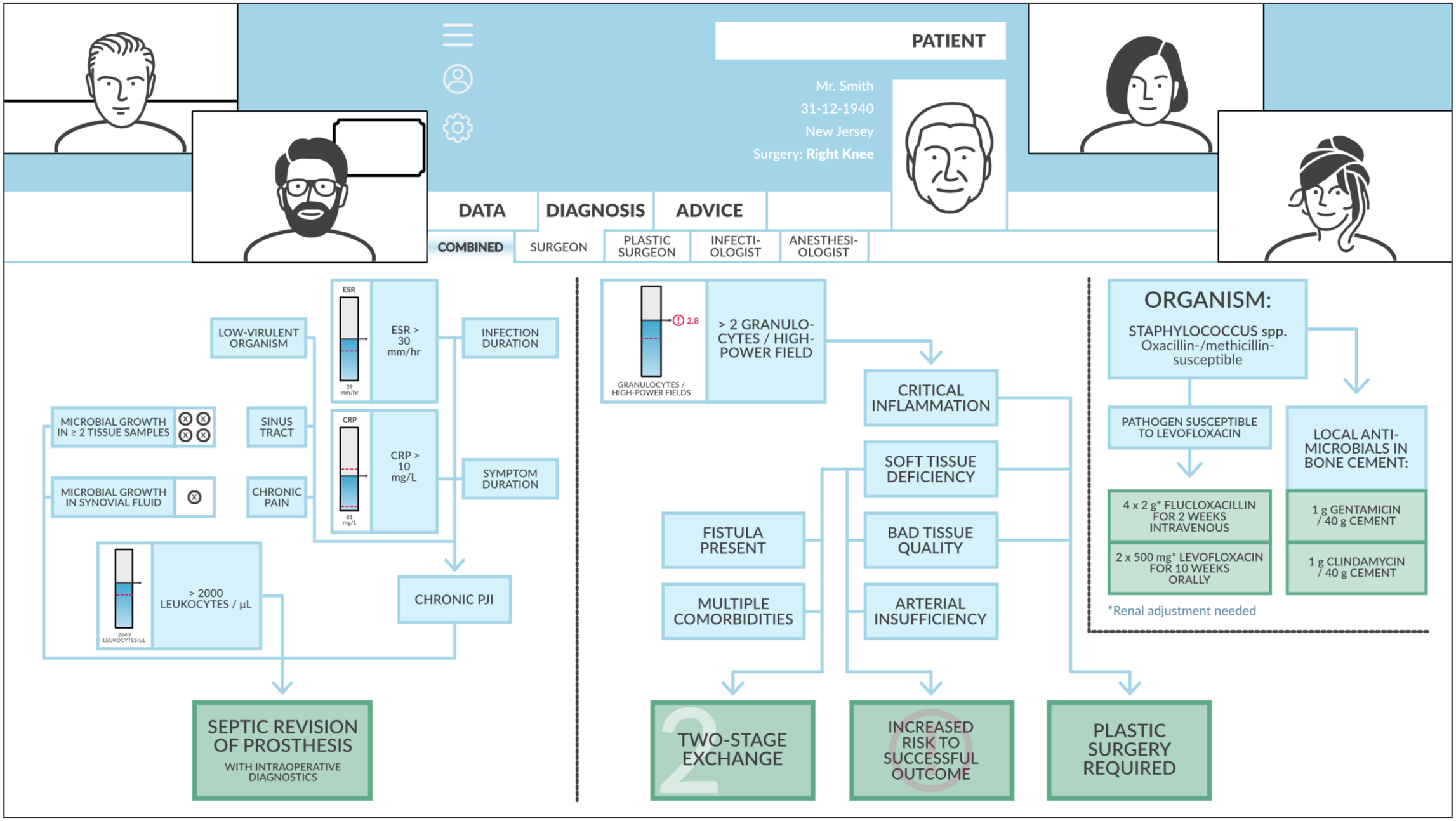

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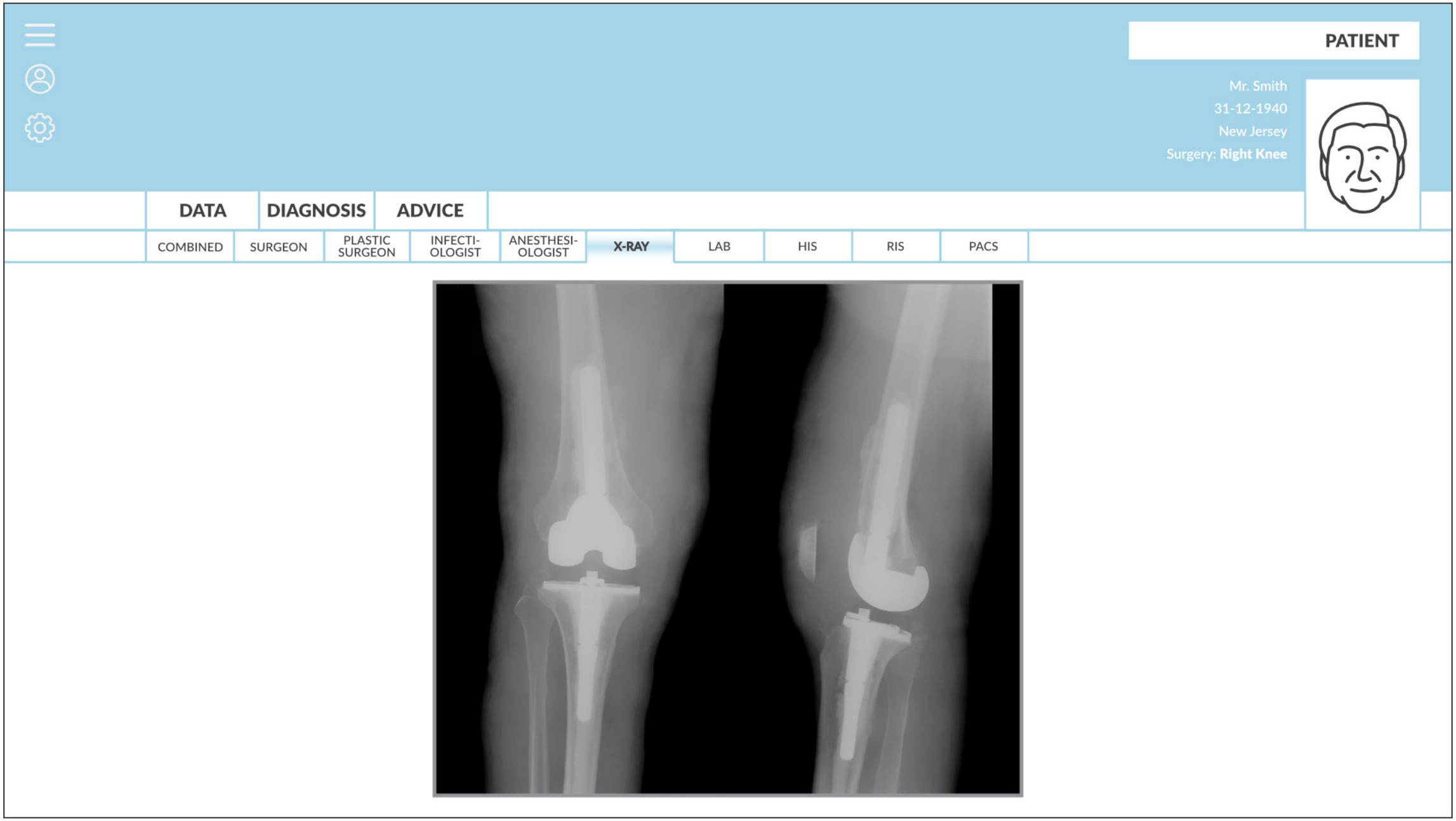


REFERENCES & APPENDICES

PATIENT

Mr. Smith
31-12-1940
New Jersey
Surgery: **Right Knee**

DATA | DIAGNOSIS | ADVICE

TREATMENT METHOD:

TWO-STAGE REVISION

- PREOPERATIVE TISSUE SAMPLING
- PLASTIC SURGERY REQUIRED

ANTIBIOTIC REGIMEN:

2 WEEKS INTRAVENOUS:
4 x 2 g* FLUCLOXACILLIN

10 WEEKS ORALLY:
2 x 500 mg* LEVOFLOXACIN

*Renal adjustment needed

IMPLANT:

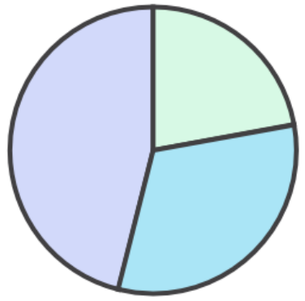
Vanguard 360 Revision Knee System

LOCAL ANTI-MICROBIALS IN BONE CEMENT:

1 g GENTAMICIN / 40 g CEMENT

1 g CLINDAMYCIN / 40 g CEMENT

INFECTION
RISK
11 %



CONTRIBUTORS TO RISK:

- HISTORY & COMORBIDITIES
- PATIENT CONDITION
- LIMB TISSUE HEALTH

Appendix W

Scenarios

Firstly, a scenario is described 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.

Question list validation session

What is your profession/role?

** Explain concept and value**

** Start prototype test **

- Do you see the advantage of a tool that helps members of the MD team to communicate data, diagnosis & advice during an MDT meeting?

- 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 being able to let experts, from around the world, on very specific subjects, join an MDT meeting to share their expertise on particularly rare & difficult cases?

- Do you see the advantage of visualising the data?
  - How can it be improved?

- Do you see the advantage of visualising the diagnosis?
  - How can it be improved?

- Do you see the advantage of proposing the treatment method?

- Do you see the advantage of visualising risk factors?
  - How can it be improved?

- Do you see the advantage of defining chance of risk and chance of succes?

- Do you see the added value of this dashboard prior to an MDT meeting?
  - How can it be improved?

- Do you see the added value of this dashboard during an MDT meeting?
  - Physical meeting
  - Remote meeting

  - Added value of communication
  - Added value of coming to decision
  - Added value of diagnosis & advice

  - How can they be improved?

- How do you feel about linking current information systems to this dashboard, to let only single entry be necessary and let the data flow into the dashboard?

- How do you feel about the dashboard being an overview system for all other information systems?

** Show proposed design **

- How do you feel about the future strategic vision of letting this dashboard turn into the sole information entry system?

Appendix X - Examples of implementation

Dashboard as a module

How the implementation of the dashboard as a module would operate is visualised in Figure 84. The burgundy-colored tile represents the hospital information system (HIS). 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) Chipsoft provides a list of healthcare institutions that data can be exchanged between, which is as follows:

- Hospital;
- General practitioner;
- Pharmacy;
- Home care;
- Postnatal care;
- Nursing home;
- Clinic;
- Hospice;
- Rehab centre;
- GGZ ("Zorgplatform", 2018)

Data enters the HIS via a multitude of information input systems. The teal-coloured tiles show some examples of different kinds of data that enter the HIS. Each example concerns data that is relevant to the use of the MDT dashboard. Some data such as patient clinical features like weight, height, cardiac function, comorbidites and more are either present in the HIS/EHR, or are (manually) entered into it, thus functioning as an input system. (P6; P8) Other data entering the HIS can originate from other information systems - functioning as input systems - such as laboratory information systems (LIS), radiology information systems (RIS), picture archiving and communication systems (PACS) and more. (Yang, Sun & Lai, 2011) GLIMS is, for instance, an example of a LIS (P6; "Laboratoriumbeheer", 2018), and Carestream is an example of a PACS. (P8; "PACS | Picture Archiving Communication System", 2018) This data is exchanged via a message broker, of which Cloverleaf is the one used by all experts the designer has spoken to. ("Cloverleaf - VANAD Enovation", 2018) 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 hospital information system, like HiX, has a multitude of modules. Together, all these modules ensure that all operations of a hospital can be managed, as discussed before. IncFigure 84, a few examples of these modules are shown in the light blue tiles, and as you can see the MDT dashboard is one of them. In theory, it is possible to develop the dashboard as a module of HiX, as other clinical decision support tools have been as well. (P6).

In the red tile the operations of the dashboard are described, which will take place within the HiX software. 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.

The proposed way of implementation in Figure 84 is preferred by all contacted hospital IT staff. (P3; P5; P7) This is because implementing the dashboard as a module of HiX, will give staff responsible for the management of these systems less extra tasks and cares. However, this way of implementation 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 tools similar to the dashboard (clinical decision support tools), HiX implements them as

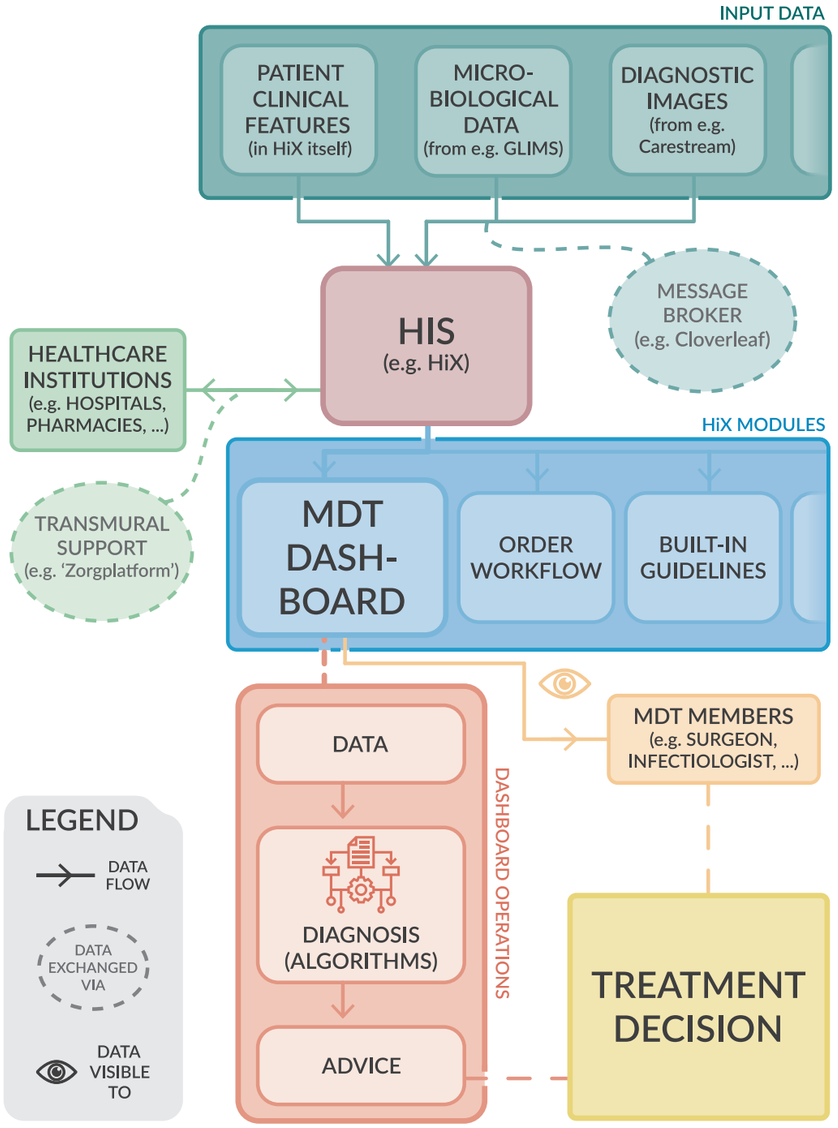


Figure 84. Optional way of implementation of MDT dashboard into hospital

separate modules or uses ‘Gaston’. Gaston is a tool that facilitates the creation of decision trees (de Clercq, 2004) - the algorithms that the dashboard uses are decision tree algorithms. Gaston is created for clinical decision support tools based on guidelines - which is what the dashboard is. However, the decision support of the dashboard (let alone the visual aids it brings) may be too complicated to develop within Gaston or as a separate module within HiX. (P5) It is recommended to research this further, following the further research into the exact data points/ variables that are necessary to execute the diagnosis. In conclusion: technical feasibility of the implementation of the dashboard is more likely in the way proposed in the chapter ‘Implementation.

Guideline implementation

The necessary steps for development of the algorithms have been shown in Figure 38 on page 77. In Figure 85 an example is given 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) Note: the ‘algorithms’ shown in Figure 85 are not created by an algorithm developer. They are merely intended to illustrate the entire process of developping the algorithms.

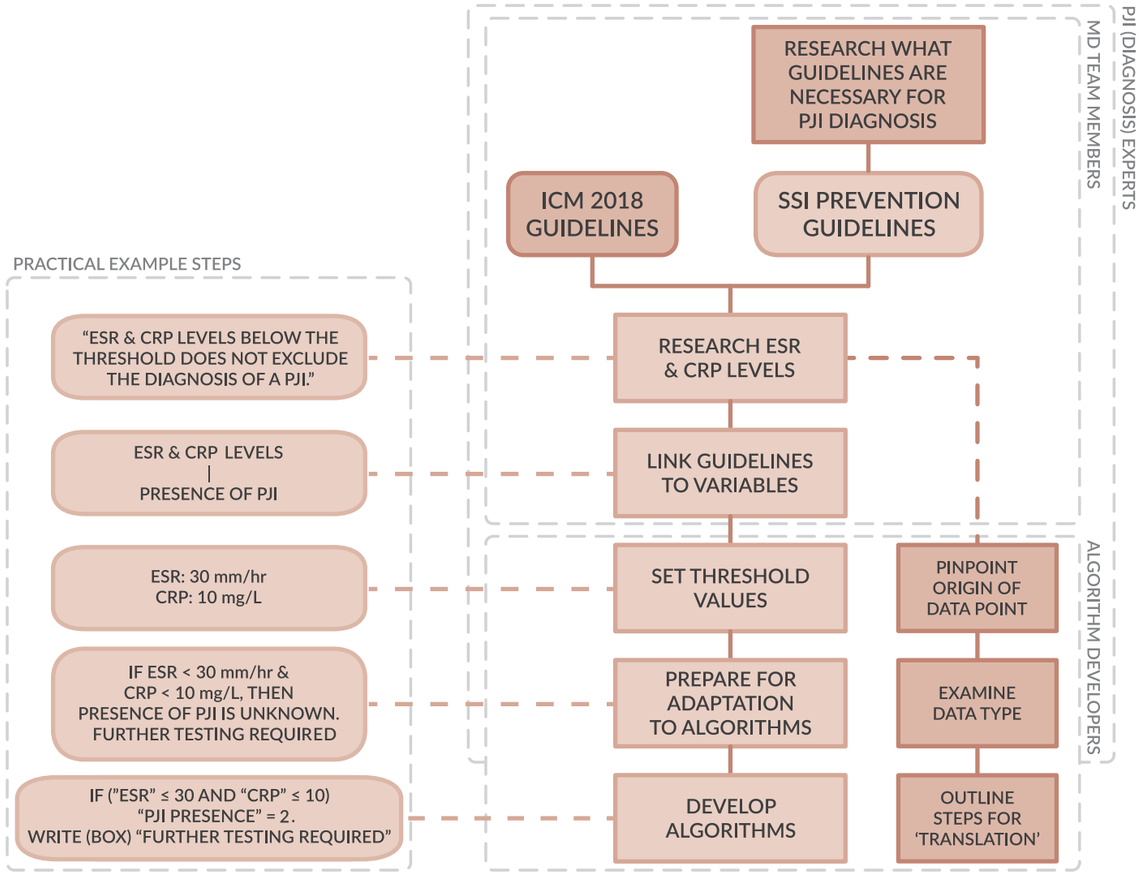


Figure 85. Practical example of steps necessary for development of algorithm (guideline content based on Parvizi, Gehrke, Mont & Callaghan, 2018)

REFERENCES & APPENDICES