



A METHODOLOGICAL APPROACH TO INTEGRATED PRODUCT DEVELOPMENT IN TOTAL HIP ARTHROPLASTY

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Abstract

Hip joint arthroplasty is considered to be a safe, successful and cost-effective procedure to restore hip joint functionality. However, a successful hip joint arthroplasty affects different stakeholders e.g. patient and surgeon and depends on various influencing factors within the product life cycle as well as the applied technological opportunities. Due to the complex dependencies between influencing factors, technological opportunities and stakeholders, this contribution introduces an IPD-based approach to improve the quality of total hip arthroplasties.

Keywords: design methods, integrated product development, knowledge management

1. Introduction

Hip joint arthroplasty is considered to be a safe, successful and cost-effective procedure for restoring hip joint functionality in patients with serious joint diseases. For painless mobility, several hundred thousand patients undergo hip arthroplasty every year (Kärrholm et al., 2018). Due to an ageing population and the limited lifespan of prosthesis, the number of primary hip joint arthroplasty and revisions is expected to increase further.

A successful hip joint arthroplasty depends on various influencing factors within the product life cycle. These factors include, for example, implant design, surgical technique, surgical experience, and forces that occur as a function of the patient's physical activity during the use phase. Further development in the field of hip joint arthroplasty has led to an extensive portfolio of various hip endoprostheses in recent decades. For example, the use of short-stem endoprostheses facilitates bone preservation and the combination of different metal alloys reduces wear. At the same time, new manufacturing techniques such as additive manufacturing in combination with diagnostic imaging techniques such as 3D-CT enable the fabrication of customized endoprostheses that are fixed by osseointegration or bone cement. The majority of these developments only takes into account certain phases within the product life cycle. However, with the approach of integrated product development (IPD), it is possible to consistently incorporate the entire product life cycle, taking into account the interactions between product and process. The aim of this integral approach is to positively influence all aspects of the development process in order to achieve optimum product quality at the lowest possible cost and in the shortest possible time. According to Ehrlenspiel and Meerkamm (2017), a

methodology for IPD should be concretizable and adaptable for specific products and operations as well as suitable for the entire product life cycle. Simultaneously, the method must support integrated thinking and operating processes by corresponding to natural thinking. In addition, it should be easy to learn and didactically favorable (i.e. should be supportive in the area of teaching and learning), so that it can be used equally by beginners and advanced users in all areas of the company. Further attributes of the method are the range-specific expandability, flexibility regarding time and work as well as the algorithmizability in partial ranges for computational engineering.

This contribution introduces an approach to IPD in medical engineering using the example of total hip arthroplasty (THA), which has been developed as part of an international summer school for integrated product development. The objective is to connect selected stakeholders (manufacturer, health insurance, surgeon and patient), taking into account various influencing factors, in order to extend the life cycle of endoprostheses and thus reduce the revision rate.

2. Challenges in IPD for total hip arthroplasty

2.1. Procedure to develop a service to improve THA quality

To reach this aim, a literature review was performed with regard to the current state of THA treatment and usage of up-to-date technologies in this field. This was followed by a gap analysis, to identify whether there is potential to improve THA quality by applying an IPD based method. The gap analysis results in two key findings: (1) there is no holistic concept to quantify and improve THA quality and (2) very little new opportunities from technology improvements are exploited. Based on the IPD approach, the next step was to create an overall understanding of the issue (Vajna, 2014). Therefore, a stakeholder analysis was conducted to identify all relevant stakeholders involved or affected by THA across the whole life cycle of THA treatment. These stakeholders were narrowed down to a limited number of key stakeholders. Then the stakeholder needs of each key stakeholder were analysed, compared and merged to a set of stakeholder needs (section 2.2). This set represents all stakeholder needs from the relevant stakeholders and allocates them to certain life cycle phases of THA treatment. The degree of need satisfaction is from now on referred to as quality of THA and the core of the quality framework. Considering all stakeholders' point of view has led to an overall understanding of the issue and enabled the development of a solution. This was done in two parallel actions. On the one hand, a quality framework was developed to enable a holistic quality assessment and show leverage points to improve the quality (Figure 1).

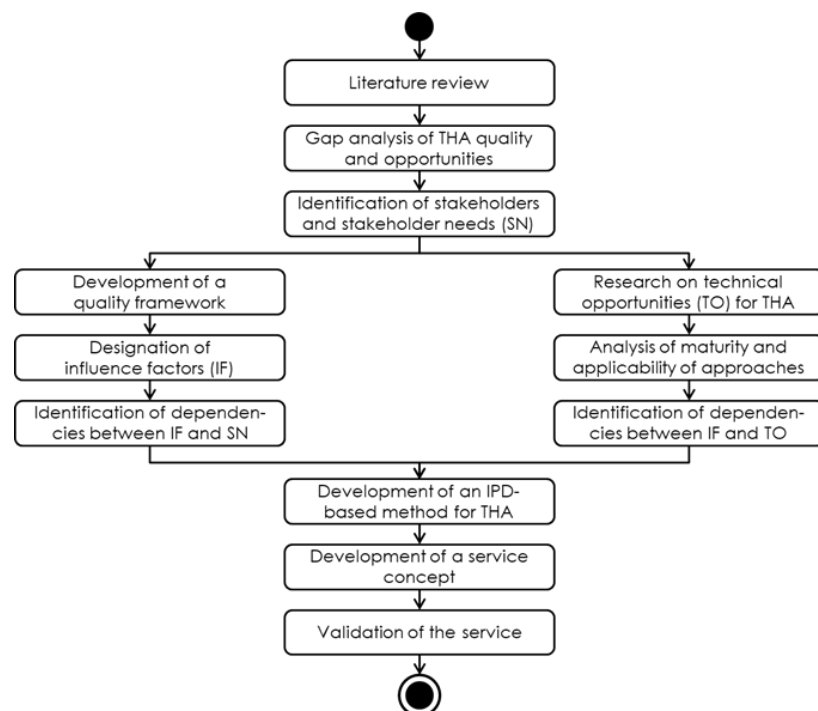


Figure 1. Procedure to develop a service to improve THA quality

On the other hand, technological opportunities which potentially improve the THA quality were gathered. The quality framework consists of the stakeholder needs and leverage points to increase the satisfaction of those needs. Those leverage points were called influencing factors and came from an in-depth analysis of the THA treatment and endoprosthesis itself. After the designation of influencing factors, they were assessed, based on their potential to improve a specific stakeholder need (section 2.3). In parallel, new technological opportunities were rated based on their maturity and applicability for THA treatment. The most relevant ones have been in the center of further investigations regarding their ability to affect at least one of the influencing factors (section 2.4). Those two parallel actions were then merged to an overall method to improve THA quality. The method enables to identify hidden technological opportunities and use them to improve THA quality (section 3). In order to ensure practical applicability and transferability of this method, it was integrated into superordinate service concept. This concept is also based on the IPD approach and therefore not just addresses the solution itself, but also an implementation concept and a sustainable business model for practical application (section 4). Finally, the proposed service was validated (section 5).

2.2. Identification of stakeholder needs

The identification of stakeholder needs started with the definition of product life cycle phases to be considered. Then a stakeholder analysis was performed, to identify stakeholders across the whole life cycle and assess their relevance. As a final step the stakeholder needs are elicited and assigned to life cycle phases.

The product life cycle of a THA endoprosthesis and treatment is divided into six phases according to (Walden et al., 2015): Concept, Development, Manufacturing, Transition, Use and Disposal. For each phase relevant stakeholders were identified. Then the key stakeholders were selected, based on the degree of influence on and from THA quality. For example, the patient is a key stakeholder, because he/she is strongly affected by the treatment quality in terms of pain, functionality, life span of the endoprosthesis and so on. The patient's family or employer are also stakeholders, since they are affected by the patient mobility and performance level as well. To reduce complexity and number of needs and stakeholders, those stakeholders with indirect relations to THA quality were excluded. The underlying reasoning is that their needs are adequately represented by the needs of key stakeholders, who have a direct link to THA quality. Based on this, the stakeholder analysis led to four key stakeholders with a strong and direct influence on and from THA quality:

- Manufacturer (provides, develops and/or manufactures the endoprosthesis)
- Health insurance (instance that purchases the THA treatment and provides it to the patient)
- Patient (person who is treated)
- Surgeon (representative for people who execute the THA treatment)

These four key stakeholders have very diverse needs in context of THA quality. The manufacturer competes on the market and has economically interests. Therefore, profit has to be sustainable for this stakeholder (high functionality at low cost). The health insurance is interested in fixing immobility, and minimizing life cycle cost. The life cycle costs contain the initial THA treatment as well as all follow up treatments (e.g. revision surgery). Needs of the patient are mainly focused on getting the best possible treatment to lower the immobility caused by THA with minimal side effects/risks (e.g. low pain or mortality rate). Having all preconditions (e.g. information, tools and high endoprosthesis fit) to execute the treatment as good as possible and within the given time and cost constraints, can be considered the main needs of the surgeon. The variety of stakeholder needs can be narrowed down to a set of eleven needs: Bio-compatibility, bone conservation, sales price, surgery price, fixation, surgery mortality, pain, fit, mobility, revision, and mortality during usage.

2.3. Designation of influencing factors

In order for a hip endoprosthesis to be able to perform its purpose various influencing factors, which for instance influence the patient's recovery or the quality of the endoprosthesis, have to be taken into account. These factors are strongly dependent on the needs of the stakeholders to be considered. The geometry and design of the endoprosthesis, for example, are among these influencing factors that

strongly influence the patient as a stakeholder. In order to reduce the risk of aseptic loosening and the associated revision, a precise geometric alignment of the endoprosthesis is required. Simultaneously, the design should support the desired bone preservation in an ideal way. Short-stem endoprostheses are particularly suitable for this purpose, as they are designed to allow the highest possible bone preservation and also facilitate more physiological loading of the proximal part of the femur. Compared to cementless prostheses, the use of short-stem endoprostheses can reduce stress shielding around the stem, which can be associated with thigh pain, bone loss and an increased risk of aseptic loosening (Engelhardt et al., 2018).

Another essential aspect in the decision making process for a suitable endoprosthesis are wear processes that occur depending on the function and duration of the implant in the organism. Wear particles from prosthesis components enter the surrounding tissue and lead to an interaction between implant and organism. There is evidence that all materials used (metal alloys, plastics and ceramics) are subject to wear, but hip endoprostheses applying plastic components for shock absorption and low-friction mobility, exhibit significantly less wear than their metal or ceramic counterparts. However, plastic wear particles lead to somewhat stronger tissue reactions in the surrounding tissue (Hanna et al., 2015).

Other influencing factors are the mechanical properties of the endoprosthesis, which have a significant influence on the life span of the endoprosthesis. Furthermore, the life span is influenced by the biocompatibility of the material and a solid osseointegration. To achieve solid osseointegration, graded structures can be used between the prosthesis and bone, in which the porosity and pore size of the graded structures have a significant influence on the degree of osseointegration (St-Pierre et al., 2005). However, increased functionality of endoprostheses through osseointegration can also be achieved by incorporating and controlling sufficient strength, since the individual activity is associated with the variation of the friction parameters (Damm et al., 2015).

Finally, the surgeon's experience should be addressed as another important influencing factor for a successful THA. In many cases, the choice of a suitable hip endoprosthesis is made on the basis of the surgeon's experience, since in many cases the patient's knowledge of the individual features of different prostheses and possible treatments is limited. According to the surgeon's practice in line with local guidelines and procedures including general medical doctors, anaesthesiologists, and other orthopaedic surgeons the surgeon determines the best surgical approach (e.g. direct anterior approach, direct lateral approach, posterior approach) and treatment (e.g. pre-, peri- and post-operative antibiotic regimens, analgesia) to use for each patient (Strange et al., 2016). Each surgical approach has its advantages and disadvantages. For example, the posterior approach is more susceptible to dislocation (Dudda et al., 2010), while the anterior approach offers less muscle trauma, less pain, earlier and easier recovery, and a lower probability of hip dislocation (Moretti and Post, 2017). For this reason, the surgical approach is chosen on a patient-specific basis and with various precautions taken to reduce the risk of injury during surgery.

2.4. Technological opportunities

Within the last decades many new or improved technologies were introduced, especially in the field of manufacturing. This results in new technological opportunities in many areas, including THA. Taking into account the identified stakeholders and the individual phases within the product life cycle, a literature review on the latest technological opportunities in the field of THA was conducted. A categorized overview of various technological opportunities is given in Table 1. The categorized technological opportunities were then linked to the influencing factors and evaluated in terms of their relevance.

As one example of a technological opportunity, imaging techniques, which are getting more and more attractive in terms of reduced costs and increased image quality, will be used here. To predict hip fractures, computer tomography (CT) can be used in combination with finite element analysis (FEA) (Dragomir-Daescu et al., 2011). Conversely, CT scans in combination with additive manufacturing can be used to develop customized hip endoprostheses (Rahmati et al., 2012). These examples also demonstrate that different technological opportunities can be combined to improve the quality of THA. In line with industry 4.0, smaller sensors are available that have increasingly better wireless data transfer as well as a better power supply. Because of this, it is possible to integrate such sensors into hip endoprostheses to receive more information about forces or temperatures. Furthermore, the opportunity of additive manufacturing enables the fabrication of hip stems with drug delivery functionality (Bezuidenhout et al., 2015).

Table 1. Categorized overview of various technological opportunities

Category	Technologies
Additive manufacturing processes	Selective Laser Melting (SLM) for metal
	Electron beam melting (EBM) for metal
	Stereolithography (SL) for ceramics or polymers
Imaging techniques and navigation	Magnetic resonance imaging (MRI)
	Computer tomography (CT)
	Radiography
	Infrared (IR)
Integration of sensors	Acceleration
	Temperature
	Force
	Strain gauge

The following example explains the link between technological opportunities and influencing factors. Reducing the probability of a revision (stakeholder need) during surgery requires a precise alignment of the hip endoprosthesis. However, the exact alignment of the endoprosthesis strongly depends on the surgeon’s experience (influencing factor). Using infrared technology, a navigation tool (for example the software Intellijoint HIP®) supports the surgeon during operation. This smart tool is able to measure leg length, offset and cup position in real-time, so that the surgeon can insert the implant precisely. The benefits of such a technical solution have been scientifically validated through testing and lead to the product becoming commercially available (Grosso et al., 2016). Technological opportunities that are less mature in terms of testing, validation and marketability were rated as less strong.

3. Development of an IPD-based method for THA

Having present the data on all previously described research results, a unified and simple representation in the form of a matrix of the obtained knowledge is made. This matrix is used to visualize the dependencies of the different information from the research. Technology decisions have an impact on influencing factors, which in turn determine the degree to which the stakeholder’s needs are met. These in turn determine the overall satisfaction of the stakeholders. “Matrix 1”, which relates individual needs to generic (technology-independent) influencing factors, is a direct subset of the first stage of QFD (Chan and Wu, 2002), which is commonly referred to as the “House of Quality” (Hauser and Clausing, 1988). This term relates to a triangular matrix giving a quantitative estimation of trade-off effects between influencing factors (which are frequently referred to as product characteristics in the context of QFD) visualized on top of the matrix, thereby resembling a roof on top of a typical house. From this, the meaningfulness of this “roof” in the context of the present investigation was examined. As discussed in (Ramaswamy and Ulrich, 1993), the usage of the QFD matrix poses several challenges in practice. Relevant limitations in the present context are: The choice of a set of influencing factors so that no technology could ever change the trade-off coefficients will be challenging. Furthermore it is inherently impossible to guarantee this condition for any new technology added in the future. Consequently, there is the necessity to re-evaluate the “roof” for every technology. The number of required data in this process increases with the square of the number of influencing factors considered and may thereby be relatively costly. Finally, diverse technologies may trivially yield the same entries in the “roof”, thereby making this representation unsuitable for a direct meaningful comparison of technologies. Hence, the inclusion of this data structure was rejected for the application targeted by this work. Figure 2 shows the discussed matrix with its neighbouring matrices resulting from the previously described investigations. All matrix entries are to be understood as an indication for the strength of influence or correlation between the respective dimensions. The values are chosen to be positive (and arbitrarily limited by a value of 1), as dimensions – in particular the influencing factors – will not be suitable for a meaningful mapping onto a single real axis.

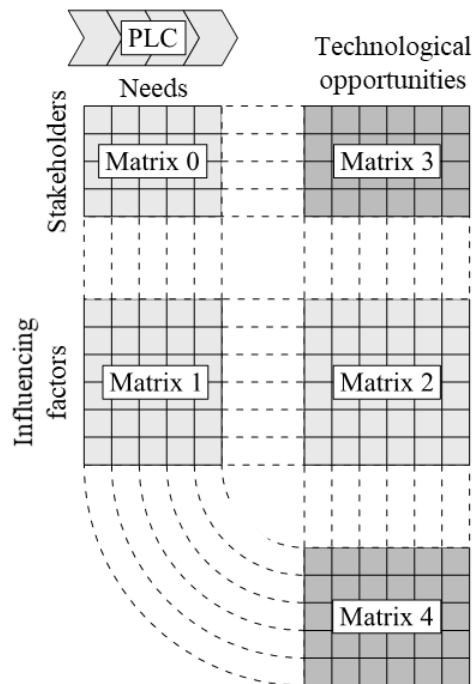


Figure 2. Matrix-based derivation of the method for THA

“Matrix 0” matches the Stakeholders’ needs to the actual stakeholders – multiple stakeholders may have the same (or very similar) needs, but still differ in their subjective choice of importance. The needs may be aligned along the product life cycle for clarity. The resulting order will not be strictly defined, as needs may persist over several phases of the life cycle, but still give some visual indication of when certain effects are predominantly present in later analysis.

As discussed above, “Matrix 1” relates the stakeholders’ needs to the chosen influencing factors, and may therefore share the columns with the previously described “Matrix 0”. “Matrix 2”, on the other hand, is the result of the analysis of technological opportunities and matches those under investigation against the chosen influencing factors. This matrix to some extent resembles the competition benchmark section frequently incorporated in the bottom part of the “House of Quality”. Both intention and meaning of this matrix are still significantly different in this comparison: rather than quantifying different (existing) solutions with respect to the chosen dimensions, it gives an unsigned indication of influence of (potential) solutions. Having a well-researched database in form of those three matrices present, obviously gives the possibility to derive further data. As a total of four dimensions was used, a maximum of three additional influence/correlation matrices are possible.

“Matrix 3” is the missing fourth in the predefined two-by-two scheme and directly relates stakeholders to technological opportunities. With the help of “Matrix 3” a manufacturer can choose a technological opportunity, which has the highest influence on other stakeholders. As a starting point, values of this matrix may be calculated by a tensor-like multiplication of the initial matrices. For consistency, some normalization has to be performed, the type of which depends on the intended application. For starting off with a technology and calculating the most relevant stakeholders, a column-wise scaling may be appropriate while for the reversed direction of reasoning a line-wise treatment may be better suited. As this calculation only gives an indication for the maximum degree of dependence consistent with the initial matrices, further investigations may be performed to determine more realistic (actual) dependencies. For very low-ranked fields, research could be foregone assuming consistence of the pre-existing data. Considering that stakeholders’ needs can more easily defined in a “directional” sense, a signed version of this matrix may be the result of such investigation. Analogously, “Matrix 4” can be derived for relating needs to technological opportunities. Again, the meaningful normalization of the calculated values will depend of the path of reasoning. Also, a signed individually researched variant is possible. A last possible influence/correlation matrix, “Matrix 5”, could connect stakeholders to influencing factors. In context of the following service concept, a beneficial use of this “matrix 5” was

challenging to perceive, which is why it was rejected for lack of applicability. Finally, in the present context the matrices were filled (Figure 3).

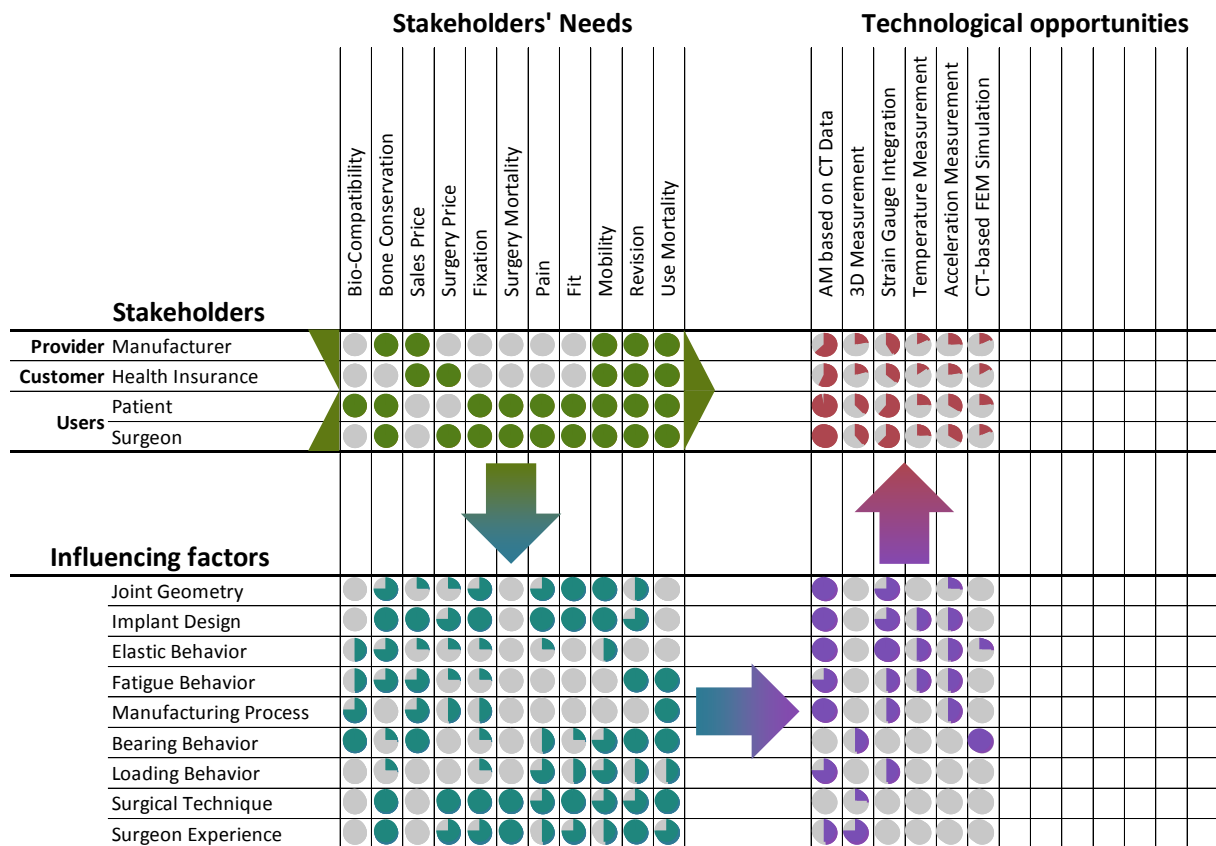


Figure 3. Comprehensively filled matrices considering stakeholders and their needs, influencing factors and technological opportunities

There are two different ways on how this matrix can be applied. In both cases the first step is to analyse the stakeholder's initial situation. Then either the selection of new technological opportunities to be utilized or the selection of stakeholder needs to be addressed can be continued. If the selection of new technological opportunities is decided upon, the next step is the derivation of relevant influencing factors. Next, an assessment is made of the stakeholder needs that have to be satisfied. Subsequently, a stakeholder need is selected which shall be improved. These steps lead to the establishment of a connection to supporting partners and the implementation of changes and eventually to an improvement of the quality of THA. If the analysis of the initial situation of the stakeholder is followed by the selection of stakeholder needs to be addressed, the next step is also to derive relevant influencing factors. Following an assessment of the strength of technological opportunities that can be used to meet stakeholder needs, the opportunities to be utilized are finally selected. The outcome here is also an improvement in the quality of THA.

4. Service concept and business model to improve THA quality

The service concept to improve quality of THA is based on three core elements: a method to identify leverage points for quality improvement, an implementation concept and a business model (Figure 4). To ensure that the service is sustainable and can be put into practice, a business model canvas (Osterwalder and Pigneur, 2010) was developed. It clarifies amongst others the intended customers, key activities and revenue streams. As a key result, the need for a methodical approach to identify the improvement potentials is shown. The method serves as the core of the service and enables to systematically identify improvement potentials from a stakeholder perspective. The implementation of

this method is done by means of a software and facilitates the application of the method as well as updating the underlying data. All three elements will be explained in more detail in the following.

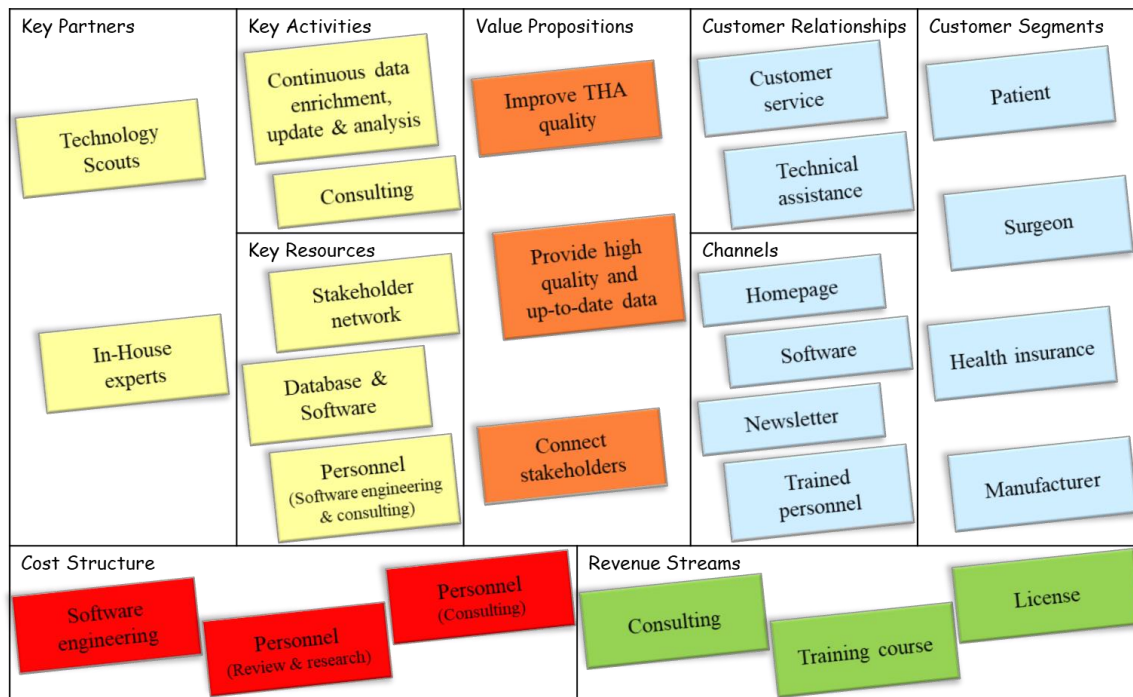


Figure 4. Business model canvas to improve THA quality

The core of the business model is the value proposition. The service aims to improve THA quality as its primary value proposition by applying the method. Quality in this case represents the satisfaction of stakeholder needs introduced in section 2. To enable this, high quality and up-to-date data on technological opportunities is provided. Furthermore, stakeholders with a common interest in knowledge exchange or cooperation are connected with each other. For example, a health insurance which is interested in sensor enriched endoprostheses to lower the revision rate will be connected to a manufacturer that offers such endoprostheses. Customers can be all stakeholders, but health insurance companies and manufacturer probably will take the highest share, since both are on one end of the revenue stream. As a key resource to provide the value and interact (e.g. consulting) with the customers, a software will be developed. A software in this case is the most beneficial implementation strategy, because it can be updated with little effort to the latest knowledge and scaled and enriched by further products very easily. This software is based on the database on technological opportunities and their benefits, and enables the systematic application of the method. Therefore, it highlights the best leverage points to improve THA quality in the present situation. The software will be used internally but also provided for customer use by a license model.

The license model as well as trainings to teach the usage of the software are part of the revenue stream from the service. The license model is proprietary, but the cost calculation differs depending on the customer. For manufacturer the software cost will be based on the revenue stream they receive from an improved product. The percentage can vary depending on the quantity and selling price. For the health insurance, surgeon or patient the cost will be based on a pay per use concept. Beside those, a substantial part of the revenue stream will come from the consulting service. The consulting will also be based on the data-base and the software, but provide a more extensive approach to improve the THA quality. Therefore, further knowledge is added, which comes from the stakeholder network, previous projects and expertise from in-house experts and technology scouts. The cost structure includes onetime development cost of the software and ongoing cost, which mostly result from personnel to update the database and executes the consulting service and training courses.

5. Validation

In a first test phase, the method developed using the IPD approach was validated by a survey of two physicians, using semi-structured interviews. First, the matrices, their use and the assigned dependencies were explained to the stakeholder representatives. A questionnaire was then used to determine various criteria to evaluate the method. The probands were able to assess usability and completeness as well as the usefulness of the tool to improve THA and the presentation of dependencies within the matrices using a fixed scale (not at all, not too bad, good and excellent). In addition, the usefulness of the connection between stakeholders as a result of the method and the added value of consulting could be evaluated. Also, a comment field was provided to give stakeholders the opportunity to make comments and suggestions on how to improve the method.

Both physicians rated both the benefit and the usability of the method to be “excellent”. When asked whether aspects within the matrices were missing, one physician answered that there is a need of incorporating a family doctor as additional stakeholder in order to cover the postoperative process (follow-up) within the product life cycle even better. The other physician rated this question as “not at all”. The representations of the individual dependencies within the matrix using Harvey Balls (circular ideograms) were rated “excellent” by both physicians. The meaningfulness of connecting the stakeholders was rated “good” by one physician with regard to the aspect of pure communication exchange. The other physician rated the meaningfulness of the stakeholder connection as “excellent”. The concept of consulting to inform stakeholders about the current state of the art was rated “excellent” by both.

One physician stated in the comment area that the matrices are a valuable tool for a comprehensive and understandable processing of the increasing amount of data. This can be used to prepare reasonable decisions and achieve a better understanding of the needs of other stakeholders. However, a potentially resulting automatism in the choice of a particular technological option or stakeholder need (e.g. costs) is considered critical and should be prevented in an appropriate way.

6. Conclusion and outlook

In this contribution we introduced an approach in IPD for medical engineering using the example of total hip arthroplasty (THA) with the objective to increase the life span of hip endoprostheses and thus to reduce the revision rate, taking into account various influencing factors, stakeholders and technological opportunities. For this purpose, a literature review was conducted on the current status of THA treatment and the use of state-of-the-art technologies in this domain. Then a gap analysis was carried out to determine the potential to improve THA quality by applying an IPD-based method. The stakeholder analysis was then performed to identify and consider all relevant stakeholders and their needs, with the aim to consider the entire life cycle of THA. In order to achieve this, a quality framework was developed, which enables a holistic quality assessment and shows leverage points to improve quality. The resulting influencing factors on the quality of a THA were then linked to the needs of the stakeholders.

Simultaneously to the quality framework, technological opportunities to improve the quality of a THA were identified, collected and analysed with regard to their maturity and applicability. Similar to the quality framework, identified influencing factors and technological opportunities were then linked. The resulting dependencies between stakeholders, influencing factors and technological opportunities were then combined in an overall method to improve THA quality. In the penultimate step a service concept was presented, which is based on the method to identify leverage points for quality improvement in THA, an implementation concept and a business model to ensure the feasibility and applicability of the approach. To validate the service concept, semi-structured interviews were conducted with stakeholders in a first test phase. The usability and completeness of the method, the usefulness of connecting stakeholders and the added value of consulting were evaluated for example. As an outlook it can be concluded that wherever different stakeholders with various needs aim for a positive improvement of defined influencing factors by using new technological opportunities, the approach presented in this contribution as well as the service concept can be used. Besides the insurance sector, the field of energy technology represents an interesting and suitable area of application. Stakeholders such as energy companies, customers and citizens can use various technological opportunities for energy generation, such as nuclear energy, renewable energies or fossil energies, to positively influence CO₂ emissions,

costs or sustainability. If, for example, CO₂ emissions should be reduced and simultaneously the production costs for energy generation kept low, a regional energy supply using renewable energies can be targeted as a technological opportunity. As a result of the regionality, the transport costs of the energy can be reduced, which has a positive effect on the pricing of both the customers and the energy company. At the same time, CO₂ emissions are reduced, which benefits the energy company in terms of its image as well as the citizens and customers.

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