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Development of a Decision Support System for the Implementation of a 3D Printing Centre at Point of Care

Master's Thesis

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Graz, May 2021

Affidavit

I declare that I have authored this thesis independently, that I have not used other than the declared sources/resources, and that I have explicitly indicated all material which has been quoted either literally or by content from the sources used. The text document uploaded to TUGRAZonline is identical to the present master‘s thesis.

Graz, May 21, 2021

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Abstract

The interest of use cases for 3D (3 Dimensional) printing is increasing tremendously in all industries. Especially the highly customizable area of healthcare provides enormous potential for this kind of technology. Hence, healthcare providers are keen to implement 3D printed medical devices into their treatment portfolio.

This thesis is meant to develop a decision support system (DSS) for the implementation of a 3D printing centre (3DPC) at point of care (POC). The DSS aims to iteratively support early strategic decision making and consists of two parts. On the one hand, the qualitative business ecosystem analysis evaluates value exchanges and social interactions at the 3DPC. On the other hand, the quantitative simulation tool (ST), consisting of a demand model, an operational simulation model, and a cost-benefit calculation, assesses the manufacturing process and economic aspects along the implementation.

With this DSS, changes in relevant societal relationships, impact of different resource setups and demands, cross influences of cost drivers as well as pros, and cons of certain decisions can be evaluated. Therefore, this approach serves as an early strategic decision support at the CAMed project for the implementation of a 3DPC at the LKH University Clinic Graz.

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Contents

Abbreviations

- 3D - 3 Dimensional
- 3DPC - 3D Printing Centre
- 3DPP - 3D Printed Part
- ABCmod - Activity-Based Conceptual modelling
- ABS - Agent Based Simulation
- AM - Additive Manufacturing
- BE - Business Ecosystem
- BEA - Busiess Ecosystem Analysis
- CAD - Computer-aided Design
- CBA - Cost Benefit Analysis
- CT - Computed Tomography
- DSS - Decision Support System
- ERM - Enterprise Resource Management
- ESG - Environmental, Social , Governmental
- FIFO - First in first out
- HCDESLib - Hierarchical Control Descrete Event Simulation Library
- HCCM - Hierarchical Control Conceptual modelling
- KPI - Key Performance Indicator
- MACBETH - Measuring Attractiveness by a Category-Based Evaluation Technique
- MCDA - Multi-Criteria Decision Analysis
- Med Uni - Medical University
- MRI - Magnetic Resonance Imaging
- NPV - Net Present Value

- OEE - Overall Equipment Efficiency
- OP - Operation
- PEEK - Polyetheretherketone
- POC - Point of Care
- QM - Quality Management
- R&D - Research & Development
- ROI - Return of Investment
- SD - System Dynamics
- ST - Simulation Tool
- TBOA - Time between Order Arrivals
- TCO - Total Cost of Ownership
- TEI - Total Economic Impact

1 Introduction

Additive Manufacturing (AM), also known as 3D printing changes the approach how we produce things. It is not only a promising field for rapid prototyping, but also a possibility to shift current production techniques and habits along the whole supply chain. In many different branches of technical production, 3D printing is becoming more cost efficient, reliable, and easier to use. As the use of 3D printers in production increases, their infrastructure become more affordable and the costs to produce parts tend to decrease steadily more and more. Due to that, even further applications and higher production volumes tend to pay off. Hence, 3D printing is now available to more businesses. (Van der Straeten, 2017)

Despite many positive implications of 3D printing, such as decentralised manufacturing close to the customer, the technology has not scaled-up quickly. Reasons for that include the slow manufacturing time, a lack of process stability and high unit costs. Moreover, data about the benefits of 3D printing is not sufficiently available. The limited experience about 3D printing materials and manufacturing structure make particularly quality certification and process stability important issues to address when scaling-up 3D printing. (Fan, Sotelo, and Sundareswaran, 2020)

Especially in the field of medical healthcare, 3D printed parts can yield an enormous advantage, due to their individual customization for each patient. Based on data from the patient's computed tomography (CT) or magnetic resonance (MR) images, a computer-aided design (CAD) software program can create personalized anatomical 3D models. This digital model enables further processing with 3D printers and therefore personalized solutions for the patient. Current applications for 3D printed parts in healthcare are craniofacial implants, anatomical models to help the surgeon prepare for a surgical intervention, and customized tools to improve the patient treatment (Medizinische Universität Graz, 2021). More medical applications include tumour bio models, pathological fracture, customized surgical tools, and prosthetic aids. Additionally, especially in university hospitals, 3D printed anatomical models can enhance education quality. (Li et al., 2015)

So far surgical guides which have contact with the patient's blood are mainly outsourced. Such medical devices need a lot of expertise, therefore are often printed externally by certified companies. However, production shifted to POC due to the fact that desktop 3D printers prices getting lower and that biocompatible materials are more affordable. Besides, the insight of hospitals that a huge amount of interaction is needed to produce high quality personalized medical devices, POC manufacturing has gained noticeable attention. (Honigmann et al., 2021)

All this advantages and possibilities led to the CAMed project (see Section 1.2). The plan is to integrate a 3DPC into the LKH University Clinic Graz. Many new challenges such as manufacturing within the hospital, interdisciplinary communication between medical and technical staff, process design, procurement, and setup of the right resources come up with such a project. As a result, this thesis aims to develop a DSS based on a combination of qualitative and quantitative analysis to foster the assessment of the novel business case of 3D printing at POC as a whole. The proposed DSS tool integrates qualitative data gained from a business ecosystem analysis and quantitative data out of a simulation model and a cost-benefit calculation. With this approach, uncertainties and risks are estimated and can be mitigated. Additionally, the general ramp up of production, resource capacities and process design can be evaluated.

The presented master's thesis is organised in four main sections. First, theoretical inputs to DSSs (Section 2), business ecosystem analysis (Section 3) and modelling and simulation (Section 4) are given. This enables an application of these methods to the given business case of 3D printing at POC in Section 5. There the introduced theory is applied to the specific domain of 3D printing at POC. This case study is executed within the CAMed project, see Section 1.2. For this project a DSS for the implementation of a 3DPC at POC, consisting of a qualitative and a quantitative analysis, is developed. Moreover, first results of the use of the designed DSS are presented at the end of Section 5. Finally, a discussion of the results, limitations of this thesis and an outlook about further research is given in Section 6.

1.1 3D Printing at Point of Care

"Our aim is to bring the technology to the theatre. While patients are having their cancer removed in the operating theatre, in the next room, we are custom printing an implant to precisely fill the space left after removal of the diseased bone.", said RMIT Professor Milan Brandt (Saunders, 2017), the lead researcher of the project "Just in time implants[1]".

This quote shows one great advantage of a 3DPC directly at POC. The goal is to deliver medical devices just in time to reduce the time of patient's recovery and time spent in the hospital. Due to the fact that the implants could be produced right around the corner and parallel to the surgery, one additional operation to fit the implant could be saved. Moreover, thanks to 3D printing directly from a digital model, expensive material is not wasted, an increased precision can be achieved, and there is less room for error. (Hendricks, 2016)

3D printed medical devices have turned out to be very helpful in patient-specific orthopaedics too. Use cases include anatomical models for surgical planning, education, and patient-specific tools. The possibility to produce such devices at POC with direct

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[1] https://www.imcrc.org/2017/10/29/just-time-implants-set-radically-advance-tumour-surgery/

involvement of the requesting surgeon leads to a lot of advantages and better patient's treatment. (Wong, 2016)

To implement such procedures, the main challenge for the hospital is to become an additive manufacturer itself. To launch a 3DPC at POC needs not only space. The main goal is to set up a reliable process which includes the printing process itself, as well as regulation requirements, effective working communication, quality management, and the documentation procedures of the process. Medical device regulations are exorbitantly high, which leads to high standards of the production process. All these are additional challenges for hospitals. Futhermore, hardware, software, post processing, slicing, and the selection of material need to be considered. Operating such a 3DPC would give many new possibilities, even though some initial costs are necessary, such as for example training of 3D printing manufacturing for the staff. The overall goal is that 3D printing specialists, engineers, material scientists, radiologists, and physicians work side by side to enable a sound process to deliver customized parts. For all these factors, the clinic has to enable a communicative space for this interdisciplinary team consisting of medical, technical, and workflow specialists. This might be challenging at the start. More critical questions to deal with are: what infrastructure could be used for POC 3D printing, what kind of equipment is additionally needed and how much involvement of the clinical team in the manufacturing process is necessary. (Chen and Gariel, 2016)

As mentioned above, advantages for the hospital could include a reduction of time for the treatment of patients, better surgeon performances, and less time and costs for the aforesaid medical cases (Zhao et al., 2018). Further, a 3DPC at POC could leverage a better preparation for the operation, a reduction of intraoperative radiation exposure up to 50%, a higher willingness for the patient to get an implant, and the possibility for internal research within the hospital (Cherkasskiy et al., 2017). The main advantage of 3D printing over traditional manufacturing processes is the possibility to print complex geometries without additional effort, making mass customization easy (Chen and Gariel, 2016). Especially the shorter supply chain gives crucial benefits (Rogers-Vizena, Flath Sporn, Daniels, Padwa, and Weinstock, 2017). Less dependencies, less transportation and delivery costs, and a better medical output, due to the direct inquiry and involvement of the physicians, are just a few to mention (Rogers-Vizena et al., 2017). Disadvantages of POC manufacturing are the need of special facilities for the production within the hospital and the additional required staff, which has to be qualified and integrated into the operational system in a hospital (Chen and Gariel, 2016). Moreover, the regulatory and legal issues of producing medical devices have to be considered (Chen and Gariel, 2016). All this leads to the question how this manufacturing process can be established in a hospital, to make use of all the benefits and avoid disadvantages. Especially the high expenses to arrange such a manufacturing process in the hospital is an obstacle in the course of such a project.

1.2 CAMed Project

The whole master's thesis is initiated and supported with data and domain expert knowledge from the COMET K-project CAMed[2]. The project's goal is to embody 3D printing into the sensible area of medicine. Personalized 3D printed medical devices are able to perform better patient's treatment and would increase patients satisfaction. Medical devices like implants, anatomical models, and tools can be used in different medical areas to shorten treatment duration and improve patient's well-being. For this 5 research institutions and 13 companies are working together to establish a reliable process for 3D printing in the clinic. (Medizinische Universität Graz, 2021)

Figure 1: CAMed Project's Logo (Medizinische Universität Graz, 2021)

The long term goal of the project is to establish a medical 3DPC at the LKH University Clinic Graz. So far a research 3D printing facility, to test the manufacturing process and future applications is already in place. Within this pilot 3DPC the project aims to develop the efficient manufacturing process of medical devices and in the long run the successful implementation within the clinic. The current research in this phase indicates a promising future.

1.3 Goals of the Master's Thesis

The following master's thesis attempts to develop a DSS to evaluate societal characteristics, operational structures, and business related aspects of the implementation of a 3DPC at POC. The whole DSS is then applied to the CAMed project's use case at the LKH University Clinic Graz, see Section 1.2. Due to it's emergence only in the last few years, the whole area of research for medical 3D printing is still a data poor environment. Within the transition to a regular operation and becoming a medical device manufacturer at POC, many crucial decisions have to be made. Relationships of different actors, many uncertainties and monetary issues have to be cleared up and assessed to enhance management decisions. Therefore, the whole implementation to normal operation (optimal

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[2] https://www.medunigraz.at/camed/ueber-camed/

capacity utilization) after ramp-up of the 3DPC at POC is observed.
First, the business ecosystem is analysed. Therefore the acting entities and the environment of the 3DPC are defined and evaluated. This should give a general overview about the interactions, relationships of the stakeholders and their value exchanges. The domain specific context of manufacturing in a hospital leads to new challenges for the physicians and producers. Communication and expectations of both parties have to be considered, making the business ecosystem analysis crucial for understanding the underlying motivation and influences of the participating entities.
Second, efficient operation-processes within the 3DPC are evaluated. They are critical for a successful implementation. Therefore, a simulation model is set up to analyse impacts of varying demand, resource setup, and activity duration for the performance of the 3DPC. This model should be able to detect crucial resources, bottlenecks, and operational characteristics of the system. Additionally, various key performance indicators have to be included to estimate the capacity and capability of the 3DPC. With this gathered data, the basis for resource setup about staff levels, amount of printers, tools, and other resources for a certain demand scenario should be possible.

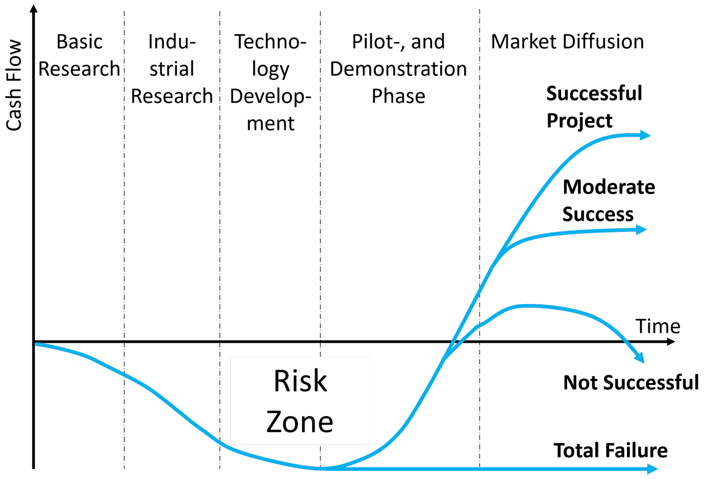

Figure 2: Cash Flow at Innovation Processes (Bachhiesl, 2020)

Third, economic aspects, a crucial part of each business case, are assessed. As seen in Figure 2, especially in the pilot and demonstration phase of an innovation project decisions within the project are crucial for a it's success. Different decisions about the final implementation and target use case of the innovation, the production scale up, and the acceptance of key customers are just a few difficulties one faces when launching an innovation. Hence one target of this thesis is to develop a tool that allows the economic evaluation of a 3DPC at POC. Based on different scenarios from the operational simulation, the goal is to calculate overall costs, order specific expenditures, and benefits from manufacturing at POC. For this different revenue channels, cost factors, capital considerations, and investment paths are considered to support the decision making within the implementation process.

All this should enable a decision maker to perform a holistic business case analysis for different scenarios. Hence, the approach have to consider costs, benefits, flexibilities and risks of the realization of a 3DPC at POC.

The overall goal of this thesis is to support the implementation phase of a 3DPC with the development of a DSS. The DSS shall be applied within the CAMed project, for the assessment of the 3DPC at the LKH University Clinic Graz. Therefore an ecosystem analysis of the 3D printing at POC domain, a flexible model of the demand for 3D printed medical devices, the identification of operational issues like bottlenecks and main time drivers of the manufacturing process, an assessment of the 3DPC under different future scenarios, an overview of all cost factors and their impact, and an identification, assessment and calculation of costs and benefits shall be conducted within this master's thesis.

Summing up, this thesis is meant to analyse quantitatively and qualitatively possible benefits, costs, opportunities, and risks of a 3DPC at POC. This mitigates the uncertainties of an investment and gives a hospital a sound basis for decision making.

2 Decision Support Systems

This section describes the theoretical background of decision support systems, as an assessment technique for difficult decision making problems. This should provide a sound knowledge base for the establishment of such a system for the specific case study, see Section 5.

Decision making in a techno-economical network is difficult. In such a network, social actors and physical technical entities are strongly intertwined. Together with economic pressure, this leads to many uncertainties. Therefore managers who make decisions are inevitably exposed to risk. Current acceleration of change, globalisation and more complex relationships make successful decisions more and more difficult. Therefore, modelling of such socio-technical systems is of great advantage in order to show system components, levels, and dynamics. (van Dam, Nikolic, and Lukszo, 2013)

A risk situation exists when a decision maker knows the probability of certain possible implications in the future. If the allocation of probabilities to environmental factors or events is not possible, they speak about uncertainty. Both focus mainly on the reasons not on the effects of future events. To assess these risks and uncertainties, methods to support decision making are needed. Moreover, it gets increasingly critical to assess impacts and influences of decisions made beforehand. (Gleißner and Romeike, 2005)

This section provides an introduction to DSSs for the assessment of complex business cases. The general differences of cost-based and multi-criteria decisions support systems are outlined. Moreover, the pros and cons of different existing DSS are evaluated with a literature review and show possible use cases. Finally, possible implementations of DSSs in the domain of novel manufacturing technologies are shown.

2.1 Definition

Generally the term ”Decision Support System” is a multifaceted word which can describe different methods and techniques. DSSs can be a simulation of the future, a summary of data or just a collection of information to support operational, tactical, or strategic decisions within a business context. Moreover, managers can use them to match their own expectations with a set of data. (French and Turoff, 2007)

R. H. Sprague and Watson (1996) define DSSs as an interactive computer based system that assists decision makers to understand complex, unstructured or semi-structured problems. DSSs often merge legislative, technical, and economical issues to solve complex, multidisciplinary problems (Bani et al., 2009).

Figure 3 shows the pattern of a DSS, by representing the flow of information and the system boundaries of such systems. It should assist a user by generating outputs of pre-

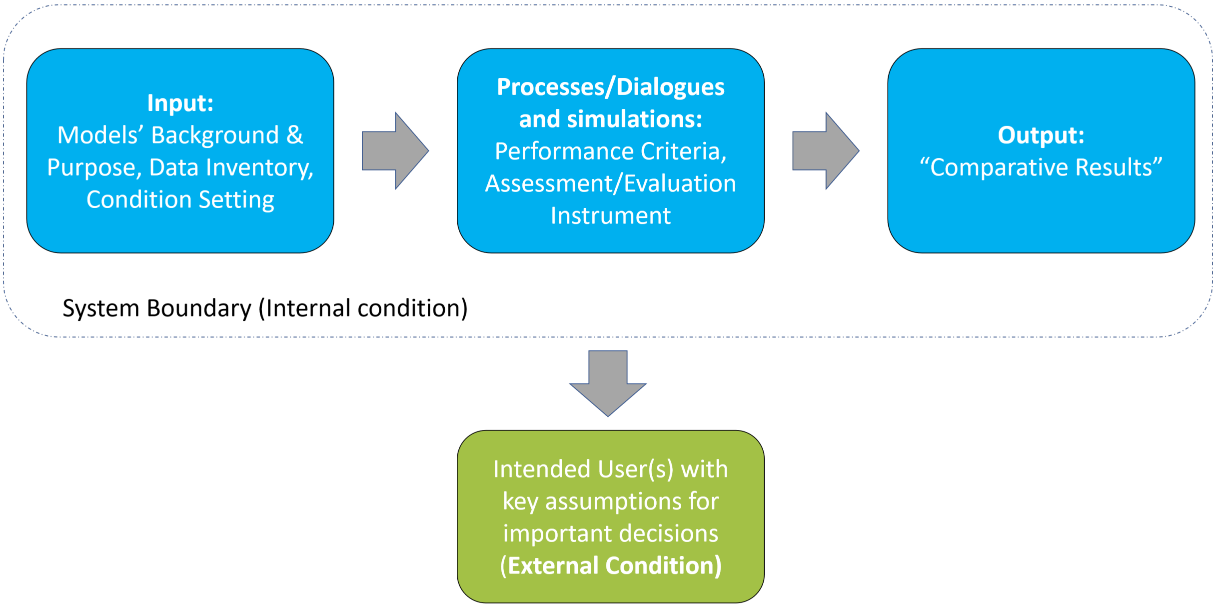

Figure 3: Generalized Decision Support Model (R. H. Sprague and Watson, 1996)

defined criteria. Therefore, data, conditional settings, and assumptions are fed into the model, which assesses the given information with respect to a certain target. A DSS has to be tailored for it's use case and the organisation. It should assist choosing the right strategy. DSSs are for long-term, strategic decisions and need to determine and balance goals. Especially in the domain of waste management DSSs are widely in use. (French and Turoff, 2007)

Adenso Diaz, Tuya, and Goitia (2005) p:2 define them as *"an information system which tries to discover what would happen if a series of decisions are taken, or going even further, by automatically providing the decisions or suggestions that assist the manager."*

The basic DSS consists of the following three components (R. Sprague and Watson, 1986):

- Information input from user
- Evaluation model
- Initial data about problem structure

Database management refers to the organisation of domain specific data, model base management to the assessment of this data via a simulation model and the user inferface to the input and output window for the interaction with the user of the DSS. Particularly, the database management is crucial because with the collection and transmission of data causes a lot of possibilities of potential errors. A specific task of a DSS is to show conflicting data and bring it to the attention of the user. The database could origin from the (Enterprise Resource Management) ERM system of the decision maker, from specific research, or from explicit inputs of relevant stakeholders. The developed DSS tool processes the data with respect to the decision's background, purpose and assumptions to generate an output. This output can be used as an assistant for planners, investors, or policy makers. (French and Turoff, 2007)

2.2 Types of Decision Support Systems

This sections compares different DSSs according to their approaches of assessing various requirements of decision makers. Bani et al. (2009), which conducted an overview of DSSs, classified them into three different categories:

- Environmental impact models
- Cost-based models
- Multi-criteria models

The target of the environmental impact models is to show the decisions to make to have the lowest environmental impact and the best support of sustainable development. This method works with a life cycle impact approach of the considered decision. With a system perspective all relevant impacts caused by the decision are considered. This model adds up all environmental harm over the life cycle of the system or process of the decision. With this rating a decision maker can choose according to the most preferably output from his or her point of view. (Hauschild, Rosenbaum, and Olsen, 2018)

The cost-based models employ methods like cost-benefit analysis and have a minimum cost or maximum profit objective. Costs and benefits are assessed for each scenario. The maximization of economic efficiency is the predominant factor of the assessment of the model. Many time this lacks an inclusion of social or environmental criteria. (Chang, Pires, and Martinho, 2011)

Multi-criteria models take various specific and often contradictory criteria, such as environmental, social, governmental, and economical indicators, into account. The optimization is multidimensional, which makes the model more complex, but also more robust. The different target-criteria can be set by the developer of the model, therefore can include environmental as well as the cost impact of certain decisions. (Pires, Martinho, and Chang, 2011)

In the following subsections cost-based and multi-criteria models for decision support are investigated in more detail, because they are most relevant for the given problem.

2.3 Cost-based Models for Decision Support

As mentioned in the previous section, cost-based DSSs mainly consider monetary issues for development. For this thesis, the following three cost-based decision models are analysed in more detail:

- Total cost of ownership calculation (TCO)
- Cost-benefit analysis (CBA)
- Total economic impact evaluation (TEI)

TCO and TEI are most commonly used in the domain of information technology. Whereas CBA is a general framework used for decision making in various fields.

2.3.1 Total Cost of Ownership Calculation

One way to approach cost-based DSSs for an assessment is the Total Cost of Ownership calculation. It gives an overview about the cost structure of different implementation paths related to a project. Most frequently TCO is used for the decision about an IT system, inside a company. The main goal is to build a concept where all cost factors, within the whole lifetime of a system, are taken into account. This should give a broader perspective of the business case to enable a more sophisticated decision making before an investment. (Wild and Herges, 2000)

Generally costs of investment and operational costs of a system diverge tremendously. Particularly in the field of IT and high tech manufacturing applications the cost of running a system exceed those of the installation significantly. Therefore, the Gartner Group invented in 1987 a framework where all cost factors of an investment are considered. Especially in the field of predicting the expenditures of IT-infrastructure the TCO model is highly successful. Due to the pragmatical character and the most of all non-educational use of the framework academic literature is vaguely available. Overall goal of a TCO concept is to provide a systematic approach for the calculation of the lifetime cost of a system. This enables to show cost structures and benchmark similar systems with each other. (Wild and Herges, 2000)

First of all, the costs are divided into two elementary cost categories: direct and indirect costs. Direct costs are all expenditures which are directly linked to the working system or department in which the new investment was established. That includes depreciation for hardware, software, leasing fees, and loans for employees of that department. These costs are relatively easy to measure. (Wild and Herges, 2000)

Indirect costs of an infrastructure are expenses that inhibit efficiency of running a system. Including for example downtime , self-, or peer-to-peer support costs. This costs are

indirect because they are caused by an imperfect performance of a system. If a system runs perfect, indirect costs tend to go to nearly zero, the system runs perfect throughout its lifetime. Usually indirect costs are more difficult to quantify and are therefore often neglected. Studies have shown that a reduction of just 1$ in direct costs can cause productivity losses up to 4$. This makes an evaluation of the indirect costs highly needed and leads accordingly to a drop in overall costs. (Wild and Herges, 2000)
Following, elementary cost cateogries of each group are enumerated (Wild and Herges, 2000):

Direct costs:

- Hardware
- Software
- Operations
- Administration

Indirect costs:

- Self- and Peer-to-Peer-Support
- Non-formal learning
- Software development by end users
- Downtime

The TCO approach considers all costs of a system. This supports business goals like cost-reduction and profit maximisation, but lacks all the benefit that an investment could deliver. General positive aspects of a TCO calculation are the sophisticated representation of the costs of the implementation of a system and to make stakeholders more sensitive towards hidden costs when setting up an important infrastructure. On the one hand, this enables the managers to already make relatively good decisions when considering an investment. On the other hand, the TCO model is lacking the integration of possible benefits into the model. Any possible value added due to an investment are not taken into account. This leads to a less efficiency orientated approach, possible performance goals of a system are not fully included. (Wild and Herges, 2000)
Gartner[3] therefore invented the Total-Value-of-Ownership model where costs are compared to services offered when investing in an infrastructure. This or other approaches like the cost-benefit analysis (see Section 2.3.2), or the return of investment (ROI) method consider the business impact in terms of user efficiency and the effectiveness too. (Wild and Herges, 2000) At the same time the Giga Information Group[4] invented the Total Economic Impact model, which is a further development towards the true costs of an investment. This approach is discussed in Section 2.3.3.

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[3] https://www.gartner.com/en
[4] https://www.gigagroup.us/

2.3.2 Cost Benefit Analysis

Cost benefit analysis (CBA) was developed in business sciences and attempts to find the decision which will achieve the greatest overall economical welfare. It takes socio-economic impacts like costs (negative impact) and benefits (positive impact) of each decision alternative into account. CBA aims to analyse these impacts over the whole lifetime of the system. Usually a CBA does not include potential positive side effects. (Marleau Donais, Abi-Zeid, Waygood, and Lavoie, 2019)

The CBA uses the net present value (NPV) as a key metric for estimating the value of an alternative. The NPV is an aggregated economic number discounting all the costs and benefits to the present. Discount rates depend on the entity conducting the CBA, its creditworthiness and the decisions reference period. (Sjöstrand, Lindhe, Söderqvist, & Rosén, 2018)

Sjöstrand et al. (2018) define the NPV as following:

$$NPV_a = \sum_{t=0}^{T} \frac{1}{(1+r_t)^t} * [B_{a,t}] - \sum_{t=0}^{T} \frac{1}{(1+r_t)^t} * [C_{a,t}]$$

In this case, a represents the alternative decision, t the time when benefit or costs occur, T is the overall time span, and r_t the discount rate at time t. $C_{a,t}$ are the costs and $B_{a,t}$ the benefits of a decision at a certain point t in time.

The reference period is usually the lifespan of the investment decision or the time the decision has implications for the project. Due to the discount rate benefits or costs that turn up earlier after the projects implementation have more relevant impacts on the decision. The higher the discount rates, the lower the monetary worth of future costs and benefits in the NPV. A positive net present value is a sign that the decision is economically efficient. The method of CBA is often used in practice and has been adapted to different circumstances over the years, also taking societal or environmental values into account. To do this first of all these impacts have to be transformed into monetary values occurring at a specific point in time. This conversion into hard effects is often difficult to perform and the implications are problematical to quantify. (Marleau Donais et al., 2019)

Advantages of the CBA method, according to Hickman and Dean (2018) are:

- Comparability between decisions and projects
- Highlighted economic efficiency
- Formalised process
- Widely used method

Marleau Donais et al. (2019) state that weaknesses of CBA are:

- Focus on only monetary issues
- No general consensus how intangible values are monetised
- No consideration of the distribution of the welfare among socio-economic groups
- Difficult measurement of environmental, social, and governmental (ESG) performance

The main problem at this point is the measurement of such ESG effects. Moreover, Beukers, Bertolini, and Te Brömmelstroet (2012) showed that the strict focus on the NPV hinder decision makers from holistically comprehend the different consequences of their decisions. The stakeholders using CBA but who were not involved in the development process of the cost and benefit models perceive the plain number, not thinking about further impacts (Beukers et al., 2012).

2.3.3 Total Economic Impact Simulation

Gliedman (2003) p:1 quotes that *"The Total Economic Impact Methodology is the foundation of sound technology investment."* Due to increasing economic pressure, evaluating where an organization should spend money is a highly important decision for it's business. Not only the spendings over lifetime of a system are important, especially the return in benefits of the money invested is crucial. To assess this a holistic approach, with potential business benefits, future options, and relative risks in comparison with the arising costs of operating a technological system, is needed. Therefore, Giga Research developed a return on investment-based methodology for evaluating investment decisions. A TEI model is a predictive tool and allows the measurement of the effectiveness of a technological project. It can be used in different stages of a project to justify a decision and refine and structure information. As shown in Figure 4 the TEI methodology approaches cost analysis, business benefits and flexibility, and tempers all categories with potential risks. (Gliedman, 2003)

Using the TEI methodology enables organizations to make effective project and investment decisions based on their individual goals. This leads to better aligned strategic decisions, harmonized with their special business needs. Moreover, an prior assessment of different factors of an investment leads to better understood risks which can be mitigated more easily. Traditional measurements focus on either technical perfection or cost minimization. A sound evaluated business case facilitate funding and project approval and force decision makers to execute a general analysis which contributes to better investment choices. Difficulties lie in the proper assessment, quantification, and monetarisation of

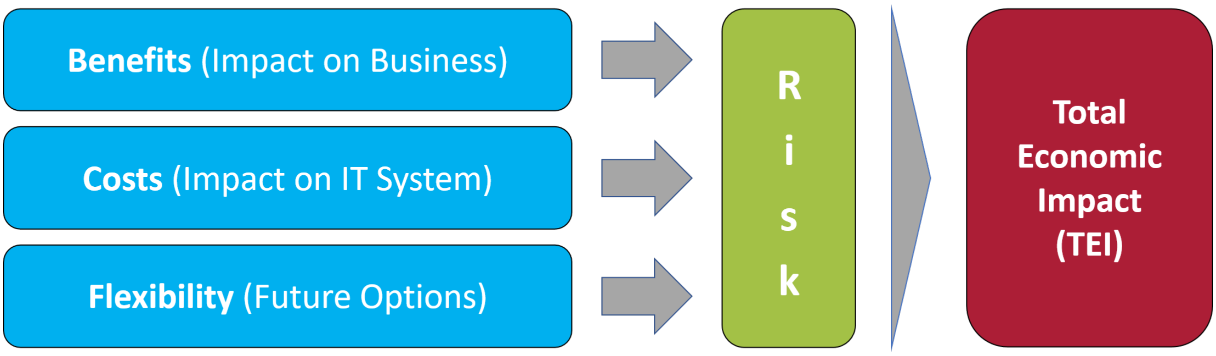


Figure 4: Total Economic Impact Components (Gliedman, 2003)

business benefits. Furthermore, flexibility and the risks are often difficult to evaluate. Moreover, all possible stakeholders have to be taken into account when mapping out such a business case. Each group usually has it's own point of view and can enrich the case with valuable insights in different directions. Once everyone sees that there is a sound business case they are more likely to support an investment and the project will be easier to implement. All this boosts the project's performance and ensures that project and business goals are met. (Gliedman, 2003)

Generally the TEI model consists of the impact on project costs, the impact on the business benefits, the future options, or flexibility created and the risk and uncertainty caused by the project. (Gliedman, 2003)

In the following, the four main elements (see figure 4) of the TEI methodology are explained.

Costs

The cost estimation has to include the following cost factors (Gliedman, 2003 p:4):

- *"**Capital costs** of the hardware and software, including the initial purchase price of the hardware and software and their upgrades."*
- *"Ongoing **maintenance** and **operations** of the technology, including the IT staff and services it took to deploy, maintain and support the users of the technology during the evaluation period."*
- *"**Administrative costs** for the acquisition and tracking of the technology assets by the IT department."*

TEI methodology is especially concerned with the changes of spendings that an investment will cause. These costs are initially usually higher, but decrease over time. This can be evaluated with a break even point analysis to calculate that point in time where the initial payment will pay off. Furthermore, expenditures in other support departments for the execution of a project have to be taken into account. All costs should be visible for the entire environment to improve the credibility of an investment. (Gliedman, 2003)

Benefits

Benefits of an investment should be aligned with the business goals. This leads to increased efficiency and better purchase decisions. Quantifying business benefits must be executed from the perspective of an individual organization. The project alignment to the goals and it's assistance to strategic contribution can be measured as follows (Gliedman, 2003 p:5):

- *"**User productivity**, as measured by gained capacity to take or fulfill orders"*
- *"**Program effectiveness** towards market growth"*
- *"**Organizational efficiency** in terms of inventory turns or days of inventory in stock"*
- *"**Customer satisfaction**, in terms of additional sales to current customers or decreases in account turnover"*

TEI quantifies data which are related to the whole organization. Therefore, harvesting the benefits requires changes in the supply chain and personal behaviour of the effected users and departments. Hence, the organization have to adopt to the ongoing changes to foster the benefits as a whole. This means that an initial upturn in costs is very likely. All that should be compensated by an improved long-term productivity gain. Benefits are often challenging to measure, especially if an organization does not have experience with evaluating indirect profits. In the TEI methodology benefits have to be classified and labelled with a key figure, which is backed up with a quantified cash index. (Gliedman, 2003)

A possible approach is to look at two parallel versions of the organization at a certain point in the future - one with the investment and system change and one without. Comparing these two future situations with the system and organizational strategic goals can easily uncover benefits of the system. Moreover, it is important that the ownership of the benefits for the business case can be lead back to the initiating department, which is responsible for the investment. The definition of this accountability beforehand is important to really track back the positive benefits to the implemented project. (Gliedman, 2003)

Flexibility

Flexibility is to measure the possibilities and opportunities an investment can kick off in the future. The advantages show up especially when companies are innovation leaders in their branch. More options occur with the investment and possibly the system can only be bought to the same price in the future, if you invest today. All this adds additional value to the investment and has to taken into account when evaluating a business case. Generally speaking, future options enable you to do a second project with a supplementary investment at any point in the future. Only after that second project new benefits will arise. Especially opportunities and new use cases for the system when accomplishing an investment have to be considered to have a holistic approach. (Gliedman, 2003)

Risk

Every change and investment causes risk. To bear this in mind uncertainties of the expected outcome, of each aforementioned component of the TEI, have to be evaluated. Risk expands any cost, benefit or flexibility analysis into a range of potential end-results. If you do the same investment within different organizations, it is more than likely that there are a lot of different outcomes. Just due to external and internal factors which cannot be switched off. This range of outcomes and the possible scenario have to be considered beforehand. That gives the organization the chance to act and mitigate sources of irritation in advance. Still there will be a range of outcomes for the investment. (Gliedman, 2003)

Key risk factors that can have a huge impact on the costs are as follows (Gliedman, 2003):

- **Project size**, the larger the project the less accurate the prediction of the model.
- **Technology risk**, means that the invested technology will not deliver the expected functions and features.
- **Vendor risk**, is the risk that the supplier of the technology needs to be replaced at some point in the project.
- **Resource availability**, change in staff and knowledge needed for the project, resulting in further costs.
- **Legal or legislative risk**, external rules from government might change, causing a modification of the technological outcome.

Further risk factors that can change estimated benefits are (Gliedman, 2003):

- **Management risk**, change in strategic management decisions alter the assumptions underlying in the benefit calculations.
- **Market risk**, means that the market can always change, new competitors can arise.
- **Training** for the new system is not working out as expected.
- **Business process risk**, internal processes have to be modified to enable the maximum benefit.

- **Culture** of the internal organization must change to enable the best outcome.
- **Legal or legislative risk**, external rules from government might change, reducing the size or duration of the expected profit.

In the Total Economic Impact methodology risk is quantified and possible future outcomes are evaluated. The quantification helps to decide which kind of risk mitigation processes or strategies have to be executed to have the best possible outcome for the business case. To sum up, the TEI methodology gives a sound business case analysis and quantifies all benefits, costs, and potentials of a project. Hereby high effort have to be put into the credibility of the numbers used. All metrics should be evaluated with all stakeholders to consider every point of view related to an investment. This also mitigates the chances of having just a single-minded approach from the person developing the business case. (Gliedman, 2003)
Table 1 shows a comparison of different cost-based methodologies for analysing a technological investment.

		TCO	Cost-Benefit Analysis	TEI
Cost Impact	Costs of Implementation	✓	✓	✓
	Cost Savings	✓	✓	✓
Business Impact	User Efficiency		✓	✓
	Business Effectiveness		✓	✓
Risk / Uncertainty	Risk Mitigation			✓
	Risk versus Reward			✓
Strategic Impact	Scalability			✓
	Flexibility			✓

Table 1: Comparison of Cost-based Decision Support Systems (Gliedman, 2003)

The consideration of risk, uncertainty, and the strategic impact makes the TEI methodology the most sophisticated one. (Gliedman, 2003)

2.4 Multi-criteria Models for Decision Support

The multi-criteria model or multi-criteria decision analysis (MCDA) was developed in the area of operational research. This method takes common value structures of stakeholders and multidimensional aspects into account. Usually it requires only qualitative evaluation about the desirability of different outputs. The scheme solely quantifies the relative value of an option in comparison to each other. Over recent years MCDA is becoming more popular, due to it aims to support interactive learning within a group of decision makers. Moreover, stakeholders are involved in the process. (Bana E Costa, De Corte,

and Vansnick, 2012)
The method consists basically of four steps (Schafer and Gallemore, 2015):

- Bring together relevant stakeholders around an issue
- Design criteria upon which the alternatives can be evaluated
- Evaluate the different substitutes
- Aggregate the rankings into a recommendation

The first two phases are called problem structuring phase and the latter two alternative assessment phase, see Figure 5. The first phase tries to identify the values, concerns and the focuses of the stakeholders and to formulate objective criteria for the assessment. This judging rules are rooted in the stakeholders preferences and targets. The second phase serves to gather data about the alternatives to evaluate their performance with respect to the previously developed criteria.

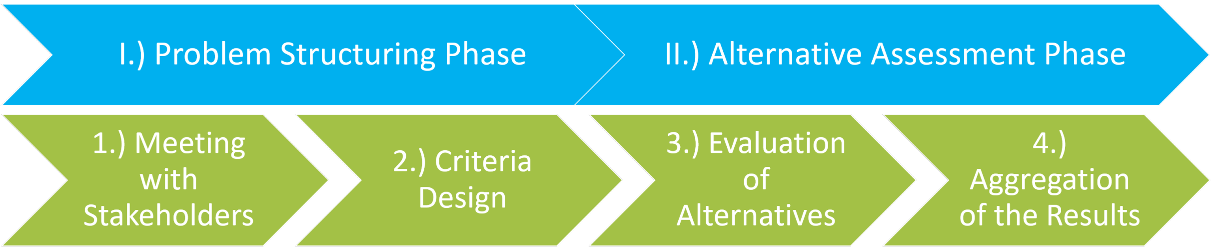


Figure 5: Process of MCDA (Marleau Donais, Abi-Zeid, Waygood, and Lavoie, 2019, Schafer and Gallemore, 2015)

According to Marleau Donais et al. (2019) p:7 a *”MCDA can help solve three types of problems: choice problematic (selection of one or of a small set of alternatives among several), sorting problematic (classification of alternatives according to predefined categories) and ranking problematic (partial or complete ordering of alternatives)”* Due to the process driven decision making, a consensus of all related parties can be found. Moreover, stakeholders can discuss during the structuring phase about their personal targets and explain them to another. Rathnayaka, Malano, and Arora (2016) suggests the subdivision of the criteria into economic, environmental, social, risk-based, and functional criteria. Economic criteria consider the cost of capital, maintenance, and operational costs. Energy and material use, greenhouse gas emissions or waste produced are possible environmental effects to be considered. Common social criteria options are human health or public awareness. Resilience is often introduced to evaluate the risks of a decision. Moreover, risk of failure, its magnitude, and reliability can be considered. The last, functional criteria

use technical feasibility, capacity, and flexibility as assessment criteria. All these different criteria have to be developed especially for the use case of the decision making process with the involvement of all stakeholders. The produced assessment system is highly influenced by the values and experience of the stakeholder, making it a mainly subjective DSS. (Rathnayaka et al., 2016)
According to Marleau Donais et al. (2019) the strengths of the MCDA procedures are:

- Stakeholders are included
- Implementation of ESG criteria
- Integration of qualitative and subjective criteria
- Driven by objectives of the stakeholders
- Transparency of the process

Weaknesses can be seen in (Marleau Donais et al., 2019):

- Only Qualitative and subjective assessment
- Resource consuming
- Weighting issues, consensus driven
- No focus on economic efficiency

2.4.1 Category-Based Evaluation Technique

One specific scheme of a MCDA is the Measuring Attractiveness by a Category-Based Evaluation Technique (MACBETH). This approach focuses mainly on step 2.) criteria design (see Figure 5). It combines the integration of information technology with user friendly operation. Main goal is to allow an intuitive, interactive value modelling. Usual MCDA has the problem of using ordinal ranking of attractiveness of an option. (Carlos Bana e Costa, De Corte, & Vansnick, 2003)
This approach uses a non-numerical pairwise comparison questioning mode to quantify the attractiveness of an alternative. It only needs qualitative evaluation about differences of value to assess options on each criterion, weight criteria, and distinguish options in terms of attractiveness for the decision maker. The qualitative judgements, instead of quantitative is more user friendly. It avoids difficulties and uneasiness of quantifying a preference which was observed by evaluators. In the MACBETH terminology the decision maker is asked for a qualitative choice about the magnitude of difference in value between two choices x and y. The judgement about size of value gap is categorized in six classes:

very weak, weak, moderate, strong, very strong, or extreme difference. Through the assignment about the magnitude of difference between two options it is not necessary to perform all paired comparisons. (Bana E Costa et al., 2012, Bana e Costa, 1994)
If n is the number of elements to be compared, only $n - 1$ judgements are required. Still von Winterfeldt, Von Winterfeldt, and Edwards (1986) suggest to perform consistency checks, to verify the coherence of the decisions made. The rating of the elements leads to a scale about their importance for the decision. Bana E Costa et al. (2012) p:9 states that *"In the end the MACBETH scale should represent the proportion between the respective difference in attractiveness"* (Figure 6).
To sum up, MACBETH is a helpful tool, especially in step 2.) criteria design, see Figure 5. It offers the advantage of verification of the reliability of the information elicited. The output is a multi-criteria evaluation model which numerically gives the relative attractiveness of different choices for the evaluator. The use of words as qualitative input and a numerical scale as a quantitative output reflects a excellent combination of usability and profound cardinal rating of alternatives. It especially makes the valuation of alternatives more objective and robust. Therefore, the decisions made are of better quality. (Bana E Costa et al., 2012)

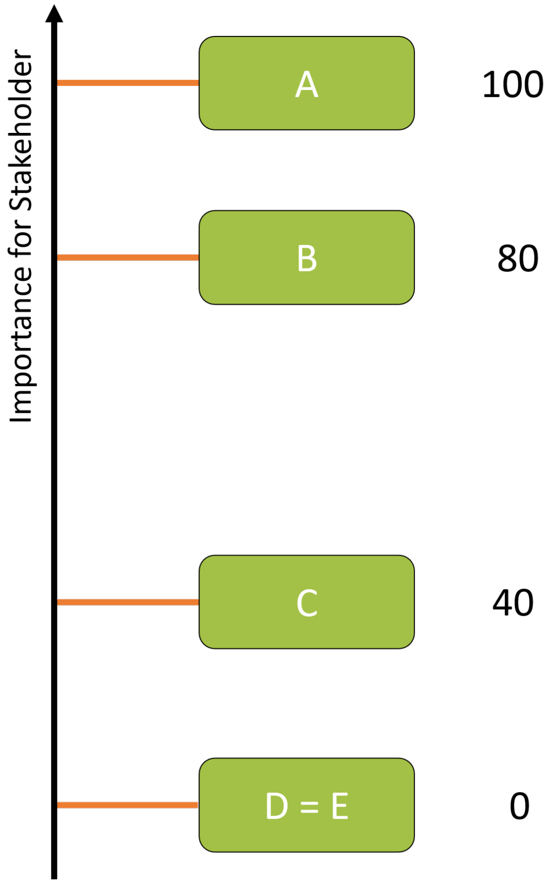


Figure 6: MACBETH Scale of Importance of Choices (Bana E Costa et al., 2012)

2.5 Domain-specific Decision Support Systems

For successful introduction of new technologies in companies, a sound approach to evaluate the risks and benefits of the new system is needed (Liebrecht, Jacob, Kuhnle, and Lanza, 2017). This section aims to systematically analyse methods and DSSs, which evaluate the choices taken during the implementation of novel technologies.

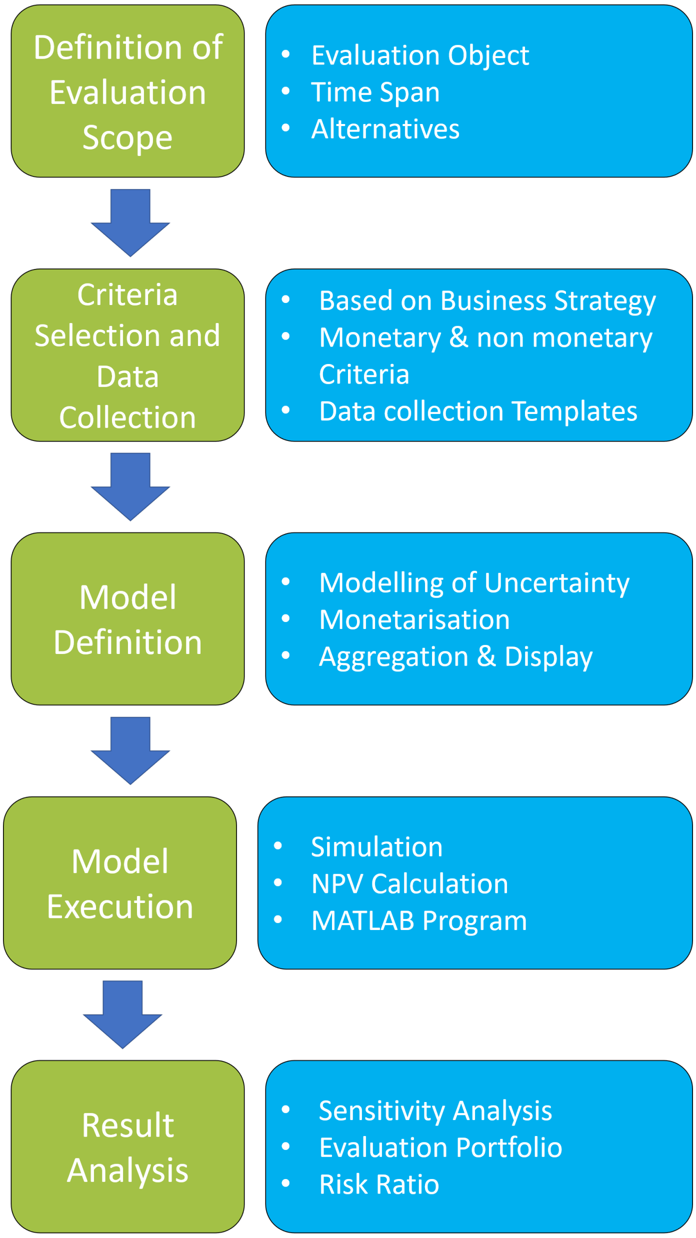


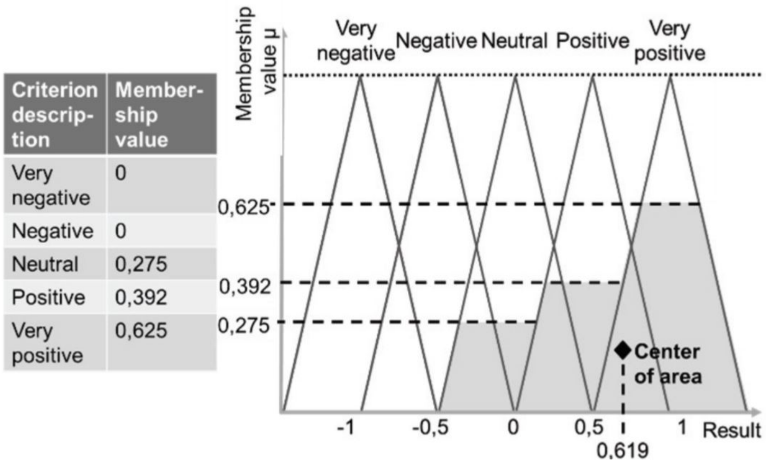
Figure 7: Evaluation Process
(Liebrecht et al., 2017)

The introduction of novel manufacturing 4.0 systems into a production process results in many uncertainties. There is often no experience in the implementation, utilization, and benefits of a technology. Therefore, there is a need for an evaluation method which specially focuses on these uncertainties. Due to Liebrecht et al. (2017) evaluations of manufacturing systems can be split into two categories. Evaluations in the first category focus mainly on transparency and coherence, but miss an integration of uncertainty and a holistic financial assessment. The second category, on the one side, integrates unpredictability and gives a complete financial evaluation. On the other side, the approaches in this category lack flexibility and comprehensibility, due to complex modelling techniques, like Monte-Carlo Simulation. (Liebrecht et al., 2017)

Novel technology assessment generally implements figures like key performance indicators over lifetime (von Briel, 2002), utility analysis and net present value calculation (Gleißner and Romeike, 2005). Other approaches like Winkler, Seebacher, and Oberegger (2016) calculate the overall equipment effectiveness (OEE) of different systems to assess the overall efficiency of a manufacturing system. A novel approach especially for the evaluation of Manufacturing Systems 4.0 is introduced by Liebrecht et al. (2017).

This assessment method involves five steps and is shown in Figure 7. The process begins with the definition of the alternatives, time span, and the scope of the evaluation object.

This step defines how many possible investment, or technology alternatives are included in the evaluation. The subsequent definition of criteria based on the decision makers business strategy and a general data collection, sets the basis for the assessment model. In general profitability is an important target, but also non-monetary and qualitative criteria can be included. The evaluation and prioritisation of this kind of benchmarks can be done via MCDA, see Section 2.4, or the MACBETH framework (Section 2.4.1).
Data can be collected via observations, time measurement of existing production processes or expert interviews. Following this, the model definition with the simulation of uncertainty, the conversion of non-monetary criteria into monetary and other steps are performed. For the inclusion of the qualitative factors the fuzzy set theory can be used. According to Guiffrida and Nagi (1998) p:2 the fuzzy set theory has the *"ability to quantitatively and qualitatively model problems which involve vagueness and imprecisions."* This concept is used to model the linguistic uncertainty.



Criterion description	Membership value
Very negative	0
Negative	0
Neutral	0,275
Positive	0,392
Very positive	0,625

Figure 8: Application of Fuzzy Set Theory
(Liebrecht, Jacob, Kuhnle, and Lanza, 2017)

The example in Figure 8 shows an evaluation of a linguistic term, and how to cope with that uncertainty. With fuzzy set theory one can evaluate how negative or positive a word is. The membership - value describes how much a word belongs to each of the associated criterion description. In the example in Figure 8 corresponding predefined triangular membership functions to each criterion is shown. For this example the fuzzy set evaluation can be shown as $A = \frac{0}{very-negative} + \frac{0}{negative} + \frac{0,275}{neutral} + \frac{0,392}{positive} + \frac{0,625}{very-positive} = 0,619$ which is the centre of the area which the value of the membership functions and the corresponding functions fill up. With this technique a former qualitative criteria can be converted into a quantitative value. This number can then be then converted into money, depending on the impact it has on the decision. This process is called monetarisation, where the weight of the impact is specified in monetary terms. The weight or influence of the qualitative criterion can be directly calculated, estimated or simulated. Nevertheless, each assessment of a criterion requires the definition of it's corresponding financial impact. This can be time consuming and should be only applied for major impact factors. (Liebrecht et al., 2017)

Coming back to the main process described in Figure 7 with fuzzy set theory the monetarisation, aggregation and visualisation of information can be performed. Hence the model is fully defined and the actual simulation model development can take place. The model is set up in a suitable coding language. With this the NPV calculation and the visualisation of the results of different scenarios can take place. The present value of the project or decision therefore considers all monetary criteria and all the above determined financial impacts, which take the non-monetary criteria into account. The formula and discount rate for the calculation of the NPV is already described in Section 2.3.2. If uncertainties are considered with probability distributions, the calculation of the results have to be conducted several times. This is called Monte-Carlo Simulation, which gives again a probability distribution of the final present value of the project. Finally, the decision or project with the highest NPV, or the highest average value of the probability distribution should be chosen. Last but not least the results of the chosen alternative are analysed and for example a sensitivity analysis for identifying risks is conducted. Especially crucial modelling assumptions have to be analysed in detail (Liebrecht et al., 2017).

Developing a domain specific DSS for novel manufacturing technologies takes a lot of effort. After defining the scope and technologies to be compared, data has to be collected. Quantitative factors are analysed, valued and monetised. Moreover, the quantitative and qualitative data have to be gathered resulting in monetary flows in and out at a specific point in time. For this process a simulation model has to be set up in a programming language. Finally, the NPV can be simulated with a Monte-Carlo Simulation, which takes uncertainties into account. Resulting in a probability distribution of the NPV with which decisions about novel manufacturing systems can be assessed holistically.

3 Business Ecosystem Analysis

Business ecosystem (BE) is a concept, inspired by nature, to model the environment a business is surrounded. In the "Harvard Business Review" J. F. Moore (1993) p:2 concluded that *"a company be viewed not as a member of a single industry but as part of a business ecosystem."* This ecosystem includes all enterprises work cooperatively and competitively to generate new innovations. A business ecosystem is never static, but like its biological counterpart, evolving out of an idea, moving from a chaotic infrastructure, like in start ups, to a more structured community. (J. F. Moore, 1993)
For Nuseibah and Wolff (2015) the main advantage of the business ecosystem concept is its comprehensiveness and the inclusion of the surrounding entities of a business.
This section presents concepts for analysing such business ecosystems. First, a definition (Section 3.1) and an explanation of the development process (Section 3.2) of a business ecosystem analysis (BEA) is given. In Section 3.3 two types of BEAs are introduced.

3.1 Definition

BEA is the holistic examination of a business ecosystem. It is used for identifying the main actors and their contribution to a business. It shows how the maturity, interconnectedness, and continuity of such actors can be cultivated leading to sustainable business environments. Moreover, a BEA can be used to analyse strengths and weaknesses of such a business environment. The main idea of creating a business ecosystem is to organise all elements into an interconnected network. (Nuseibah and Wolff, 2015)
There are three layers in a business ecosystem (J. Moore, 1996):

- **Core business** - centre of a BE, consisting of first- tier suppliers, distribution channels and direct contributors
- **Extended enterprise** - customers, standards bodies, and second tier suppliers
- **Business ecosystem** - all other relevant stakeholders like regulatory bodies, investors, governments, competitors, labour, and trade unions

Every BE should be able to create value itself and sharing it within the ecosystem. The capability to create value and to grow is inherent to a BE. Analysing a BE requires a lot of knowledge and experience about the entities, characteristics, and value exchanges within such a network. Metrics to evaluate a BE can be it's **health**, which refers to productivity, effectiveness of value creation, robustness, ability to innovate. Furthermore, the **complexity** and **interconnectedness** can be shown, this means to understand the interactions and connections between the entities. Another metric a BE could be identified, is it's **diversity**. Diversity stands for the existence of various kinds of different entities, data, and types of cooperation in the ecosystem. The diversity of a BE should be in an equilibrium, too much diversity results in lack of orientation, too little in reduced stability because of the dependence on specific players. Furthermore, political factors, local factors, structure, performance, activities, and the BE life stage have to be considered when analysing a BE. The evaluation to understand a BE is crucial to improve it's performance and it's success. (Nuseibah and Wolff, 2015)

3.2 Process of Business Ecosystem Analysis

There are five steps to be iteratively performed for analysing a business ecosystem. The general process is shown in Figure 9. The first step "1.) Understanding BE concept" refers to the roles and requirements entities have. Moreover, it analyses the relationships between entities and the specific background and setup of the BE. In "2.) Defining BE value proposal & components" the analyst should understand the mission, vision, value, and audience of the BE. With "3.) Analysing stakeholders & distributing value" one tries to understand the members and their roles, what are effects for each stakeholder, how does the information flow, the supply chain and the cooperation between the entities. Additionally, the environment of the BE should be understood properly. The fourth step "4.) Supporting business logic" seeks information about financial aspects and the underlying business case. One tries to answer the question of the monitoring and measurement of the performance of a BE. The last step "5.) sustaining BE value" calculates the values defined

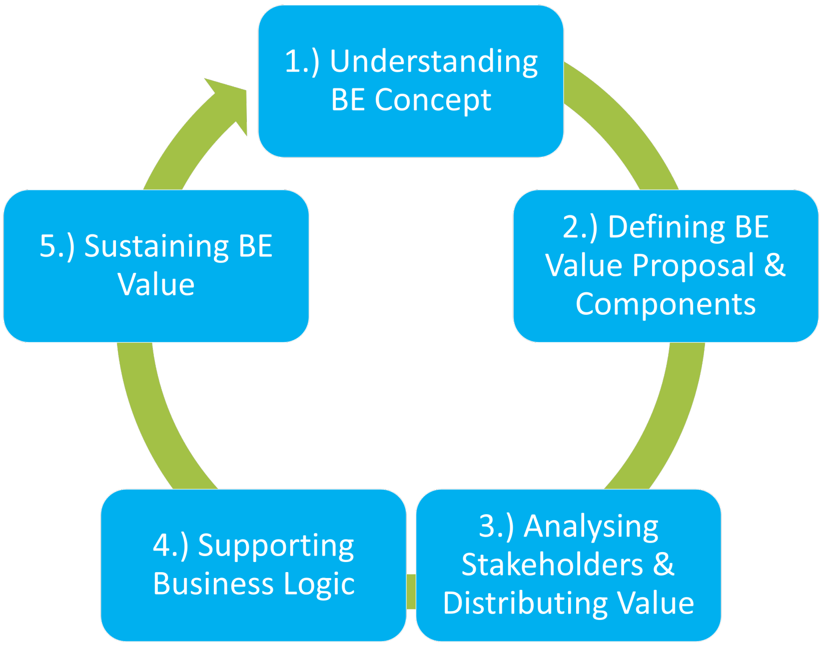


Figure 9: Process of Business Ecosystem Analysis (Nuseibah and Wolff, 2015)

in step four and tries to build up a plan to maintain the performance or even increase it. The target is to detect challenges or changes in advance and to develop sustainable long-term strategies. (Nuseibah and Wolff, 2015)
One example for such business ecosystem analysis in the health care sector was conducted from Dupont et al. (2017). They developed and analysed the ecosystem emerging from the implementation of a trustworthy hospital electronic health records data platform. First, they defined an ecosystem with the multi-stakeholder value chain and defined their needs, incentives, and potential barriers coming up with the use of such a platform. Further a business model and strategies were defined and accordingly a simulation model was developed to model the profitability of the emerging ecosystem. This and many more examples show the wide range of applications and possibilities when conducting a business ecosystem analysis. (Dupont et al., 2017)

3.3 Types of Business Ecosystem Analysis

In the following sections, two specific, well-known ways of analysing a business ecosystem are introduced. Section 3.3.1 shows the stakeholder analysis, which originally comes from project management. The value network, presented in Section 3.3.2 is a way to visualize interdependencies in between stakeholders, using different layers.

3.3.1 Stakeholder Analysis

Reed et al. (2009) p:1 outline that stakeholder analysis is *"a process that: i) defines aspects of a social and natural phenomenon affected by a decision or action; ii) identifies individuals, groups and organisations who are affected by or can affect those parts of the phenomenon (this may include nonhuman and non-living entities and future generations); and iii) prioritises these individuals and groups for involvement in the decision-making process."* A lot of different definitions what exactly stakeholders are can be found in the literature. An early definition from Freeman (1984) states that a stakeholder is someone who influences or is incluenced by a decision or behaviour. A more holistic definition comes from Starik (1995) p:10, for him a stakeholder is *"any naturally occurring entity which affects or is affected by organisational performance."* To sum up, a stakeholder is a person, group or organisation which is influenced, affected or has interest in any aspect of a decision or project. A stakeholder can be seen as an external entity which is interested in actions and has to be informed (Stakeholder management) or as an active player included in the actions and decisions (Stakeholder engagement). The given fact that stakeholders affect the success of an enterprise led to the need to analyse stakeholders. It is performed to analyse relevant actors and their impact, behaviour, and influence on the decision-making process. Moreover, understanding the power dynamics and establishing transparency and equity is important for high quality decision making. (Reed et al., 2009) A major drawback of stakeholder analysis is it's relatively static approach. It does not consider that the stakeholders issues, interests, and interactions can alter over time. Furthermore, the bias of the analysers, which have a particular perspective, can negatively influence the analysis. Yet understanding the stakes of entities involved in a decision making process is crucial for it's positive outcome. (Rowley and Moldoveanu, 2003)

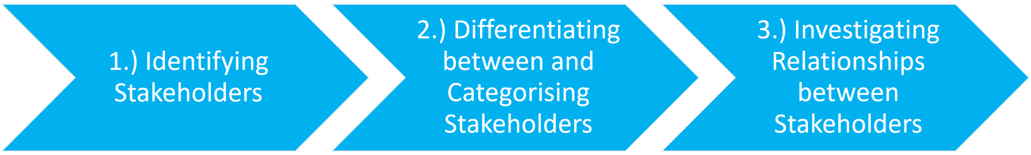


Figure 10: Process of Stakeholder Analysis (Reed et al., 2009)

Figure 10 shows the general process of a stakeholder analysis. To perform such an analysis the stakeholders can be involved or it can be conducted without their participation. Methods for determining stakeholders can be a small group brainstorming of stakeholders identifying other relevant entities. The result is a cluster of stakeholders categorised into different groups, called stakeholder map (Figure 11). A first assessment about attitude towards the project can be described with adding a "+", "∼", or "-" to each stakeholder. Moreover, the distance from the centre can be a value for the influence of the entity. The closer to the project / decision the stakeholder is, the higher its impact. (PMI, 2013)

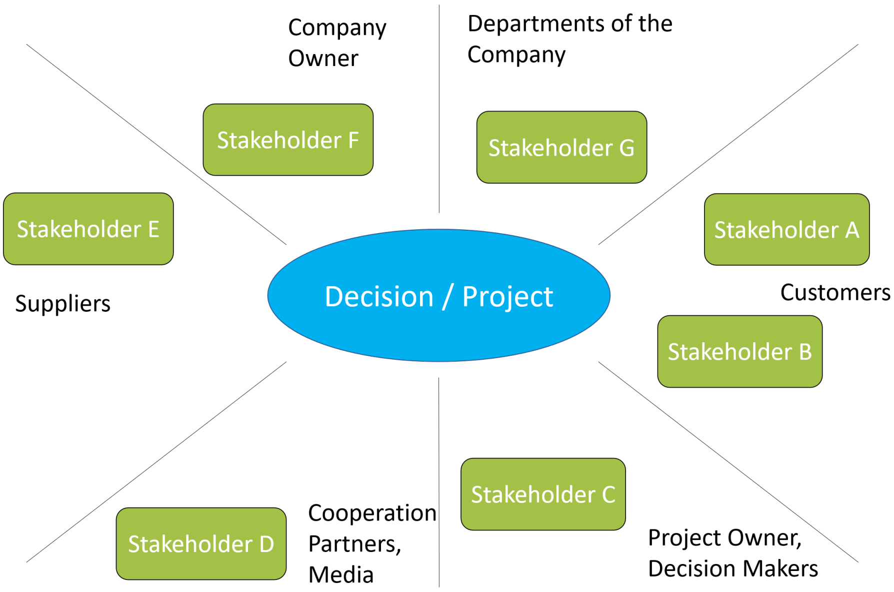


Figure 11: Structure of a Stakeholder Map (PMI, 2013)

The second step - 2.) Differentiating between and categorising stakeholders - includes the assessment of values, power, and interests of the stakeholders. This leads to the power / interest matrix which is shown in Figure 12. Whereby the power is the ability to influence the organisation. This can origin from their position, resource power, or from their credibility as an expert. The interest dimension is measured by the extent they will participate in the project. Depending on their power and interest the stakeholders are classified into four different groups. The categorisation into ”monitor”, ”keep satisfied”, ”keep informed”, and ”manage closely” shows the advised way of how to deal with stakeholders having a certain power and interest within the project or decision making environment. (PMI, 2013)

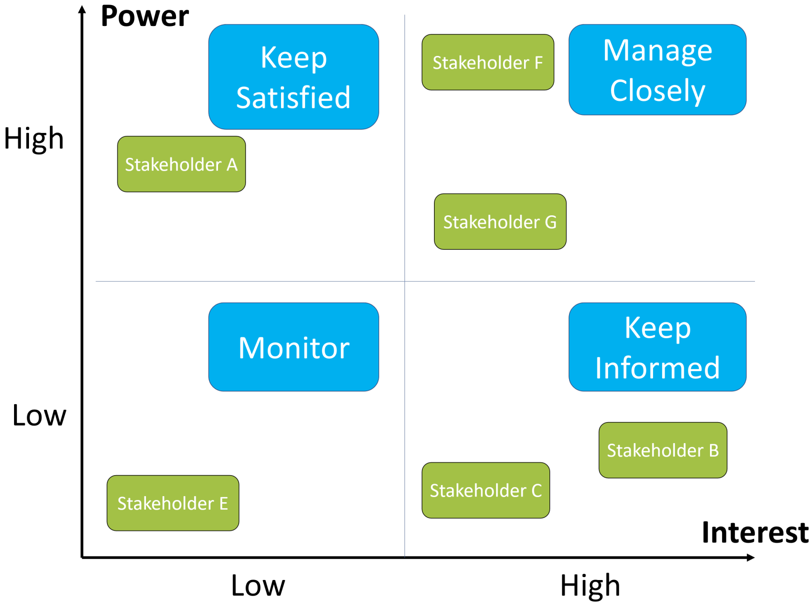


Figure 12: Power Interest Matrix (PMI, 2013)

The investigation of relationships between stakeholders is the last step of the stakeholder analysis. It can be performed in a social network analysis, which identifies ties between stakeholders through the use of structured interviews. Another method is knowledge mapping which extracts data with semi-structured interviews to identify interactions. This visualization of information serves as a continuously evolving storage of information within an organisation. Moreover, it collects data about the relationship with it’s external environment. Such a map shows dominant flows of knowledge, linkages, knowledge bottlenecks and assist individuals to understand the types of knowledge of different entities within the system (Reed et al., 2009). It is an effective memory to list important knowledge and herby enhances organisational learning. (Wexler, 2001)

Generally there is a wide range of methods which can be used for stakeholder analysis. Herby the most important matter is to follow the process introduced in Figure 10. Moreover, it is important to identify the focus of the stakeholder analysis and it's inherent boundaries. After collecting and interpreting information necessary, future actions can be derived and have to be executed to improve the output of the decision making or the project. (Reed et al., 2009)

3.3.2 Value Network Analysis

Enterprises in the 21th century are increasingly connected. To offer a service or product more and more suppliers and resources are intertwined along the value chain. Moreover, these actors have a lot of different needs, values and are all integrated in a more and more complex socio-technical system. To successfully manage a company, develop a business, or make a decision, a profound analysis of the resulting complex network of actors along the value chain is necessary. (Vorraber and Müller, 2019)

With the V2 Value Network of Vorraber and Vössner (2011), which enhances the notation of Biem and Caswell (2008), different kinds of relationships in between companies and partners within a business ecosystem can be analysed. The concept of a value networks goes back to Allee and Kong (2003) and has been further developed by Biem and Caswell (2008). They describe a set of elements which typifies an economic entity and is connected in a network. All entities can exchange values within the network and are exposed to various factors influencing their decisions. Vorraber and Vössner (2011) captures this external or internal influences with the V2 value network notation, that is described in this section in more detail.

A value network consists of economic entities, who are the stakeholders or agents, participating in an business ecosystem. Such an economic entity, also called agent consists of three clustered components, see Figure 13 (Biem and Caswell, 2008):

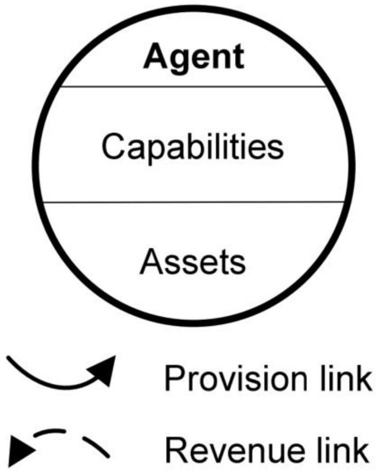


Figure 13: Economic Entity participating in a Value Network (Biem and Caswell, 2008)

- **Agent** - entity participating in the business network
- **Capabilities** - dynamic aspects, like processes and activities which can be performed by the economic entity
- **Asset** - tangible and intangible objects that are related steady or temporary to the entity

Each entity has to be connected with links representing the exchange of value between the entities. Two types of lines can be differentiated: If the value supply goes in the direction of the end customer, it is a provision link (solid line). If the entity has to pay for the value transfer this is visualised with a dotted line, called revenue link. In between entities different kinds of values, or objects can be exchanged. This is visualized with different kinds of triangles on the link. (Vorraber and Vössner, 2011)
The V2 notation extends the information and service types from Biem and Caswell (2008) with adding monetary and intangible value as transfer objects between actors (Figure 14).

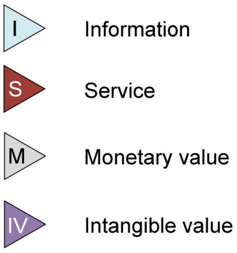


Figure 14: Transfer Objects in a Value Network (Biem and Caswell, 2008)

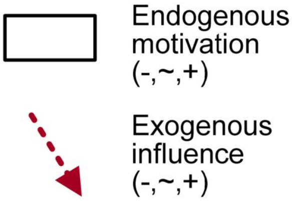


Figure 15: Endogenous motivation and exogenous influences (Vorraber and Vössner, 2011)

The information object refers to the transfer of knowledge in different aspects. A service object converts the condition of something at the receiving entity. Monetary value flows with the direction of the arc from one entity to another - visualized with a monetary value transfer object. Lastly the transfer object, intangible value, expresses exchanges of worthy services which are immaterial. (Biem and Caswell, 2008)
In order to explain dynamic, intrinsic forces, and external influences on the entities two enhancements are added to the above described structure. This adds another layer describing the relationships of actors in a value network. Therefore, as seen in Figure 15, endogenous motivation and exogenous influences are introduced. The first describes the internal motivation within an entity to participate in the value generation. The drivers can be personal or organisational values. Entities herby decide depending on their endogenous ambitions how much energy they will invest in the accomplishment of their tasks in the value network. (Vorraber and Vössner, 2011)
The endogenous motivation block can be rated with either +, ∼, or - referring to the entity's level of motivation. Active (+) rating links to a high priority of the value generation for the entity. Neutral (∼) refers to a unbiased motivation of the entity. A defensive (-) estimation shows less attention to the fulfilment of the task for the entity. (Vorraber and Vössner, 2011)
Exogenous influences or forces, shown with a dotted arrow to the entity, visualises the external influence from management or the boss to the actor. An external force can ei-

ther facilitate or restrain participation of the actor in the value network to fulfil his value generation activity. There are three classification rankings of exogenous influence: Active (+), the external force actively promotes and assists the value generation of the entity. Neutral (∼), the external force is uninvolved, unbiased about the value generation of the actor. Defensive (-), outer drivers discourages the entity at value generation. (Vorraber and Vössner, 2011)

The evaluation of the blocks can be done in a workshop, with a questionnaire or via personal interviews of representatives of each entity. Entities can be departments, stakeholder groups, or a category of people which share an interest. Moreover, the project, or decision-making unit, and it's responsible persons should be an entity too. (Vorraber and Vössner, 2011)

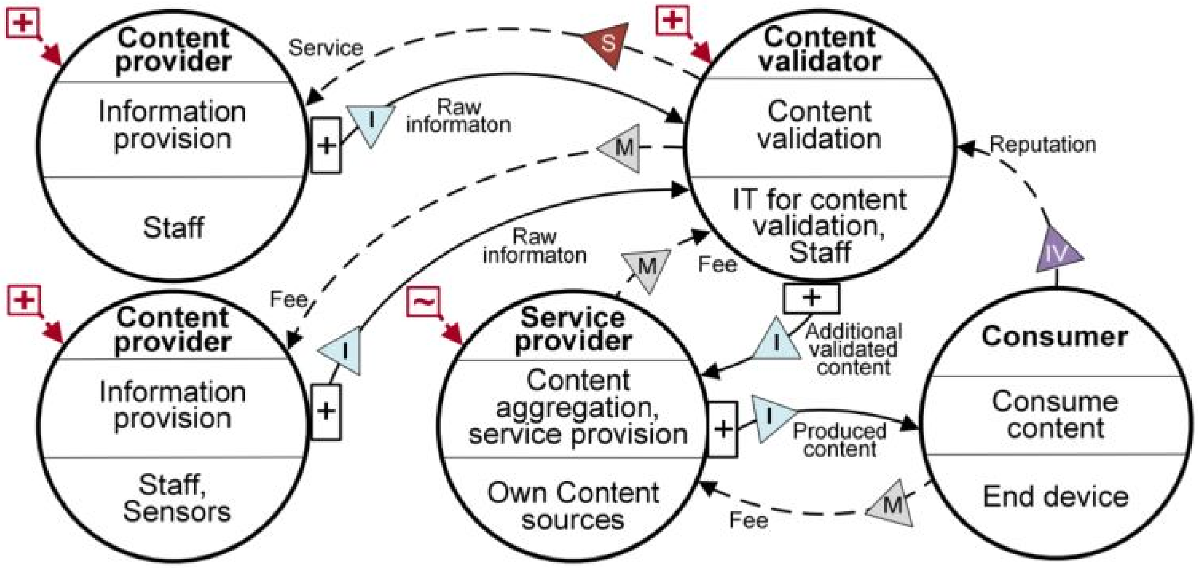


Figure 16: Example for a Value Network (Vorraber and Vössner, 2011)

Every combination of endogenous motivation and exogenous have different influences on the social dynamics of a business ecosystem. If both blocks of an entity are estimated to be defensive, it is a strong indicator that the dynamics within this value network can be influenced negatively originated from this entity. Depending on the importance of the entity even the whole project can be in trouble. Therefore, interventions should be considered, to figure out reasons and prevent damages for the proceeding of the project. Another combination could be defensive endogenous motivation and active exogenous influence. In this scenario the employees often do not understand the why behind the project and the management is forcing them to participate in value generation. Managers, decision makers, or project leads facing this combination should try to convince members of the specific department about the bigger reason of the whole project. The best combination, consisting of active endogenous motivation and active exogenous influence can lead to a real positive drive in the project. The entity as a high performer can lead to overall project success engaging others to also participate with more energy. (Vorraber and Vössner, 2011)

The evaluation of especially the motivational layer of a value network can yield captivating insights about dynamics within a business ecosystem. The V2 notation provides an easy to understand notation for modelling influences on entities within a network. An evaluation in the early stage of a project can give valuable information about system dynamics. Experiences have shown that especially social and motivational influences can drive success of projects and decisions. Therefore, an evaluation of social, inter-personal opportunities, and threats is vital for a project's favourable outcome. (Vorraber and Vössner, 2011)

Figure 16 shows an example for a value network based on the V2 notation introduced by Vorraber and Vössner (2011).

4 Modelling and Simulation

Modelling and simulation techniques are more and more important for research and deeper understanding of operational and organisational systems. They are widely applied in various fields like business organisations, computer networks, manufacturing processes, ecology environment systems, and many other complex processes. The main goal is to design a model of a real world organisation or process, verify and validate that model to conduct experiments with the model to better understand a system. Investigations of different performances under distinct operating conditions can improve comprehension of an organisation or process and hence improve decision making. With the process of designing a model of a conceptual system and carrying out experiments, different management strategies and decisions can be evaluated. (Shannon, 1983)

Modelling and simulation provide methods to assess the behaviour of a real world system. Moreover, the construction of the model often leads to a deeper understanding of a system or process. (Maidstone, 2012)

The three most commonly used simulation techniques according to Maidstone (2012) are:

- Discrete Event Simulation (DES)
- System Dynamics (SD)
- Agent Based Simulation (ABS)

In this section the general modelling and simulation process is shown in Section 4.1. The purpose of modelling (Section 4.2) and conceptual modelling as a highly important step in the simulation and modelling process (Section 4.3) are presented. Furthermore, the simulation and modelling approaches SD (4.4.2) and ABS (4.4.1) are described briefly. DES, the later applied simulation technique, is described in more detail in Section 4.4.3. Finally, advantages, disadvantages, a comparison and typical use cases of the introduced modelling techniques are discussed in section 4.4.4.

4.1 Process of Modelling and Simulation

To successfully build up a simulation model one has to follow a structured path to include comprehensively different aspects of the problem. Therefore, an organised process is important when approaching a modelling and simulation task. This section explains one process to follow when facing such problem. (Birta and Arbez, 2019b)

A general guide through the process of modelling and simulation is shown in Figure 17. Step 1.) includes the definition of the research matter and the desired outcomes of the simulation. Following, Step 2.), the specific purpose of the simulation experiments with

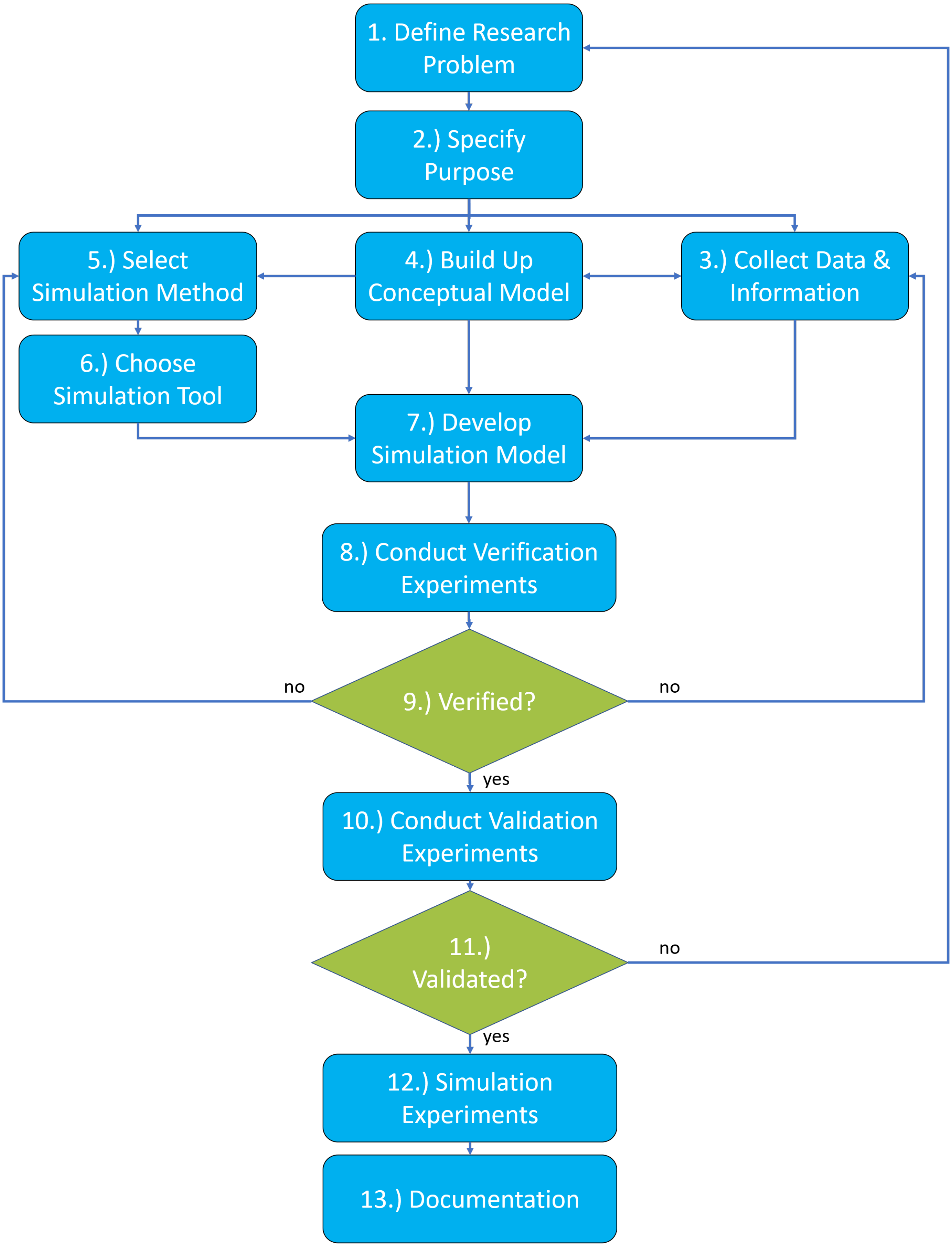


Figure 17: Modelling and Simulation Process (Yin and McKay, 2018)

their targets is determined. Then, in Step 3.), data and information needed for the conception of the model is collected. Generally data is typically aggregated iteratively through the whole process with the stakeholders. This information is used later as the input for the simulation experiment. Step 4.) contains an elaboration of a conceptual model with respect to the particular research question. This is described in more detail in Section 4.3. Relevant relationships for the research problem have to be represented in this model. Accordingly a suitable simulation method, Step 5.), (Section 4.4) is selected. Based on this a coding language in which the simulation will be implemented is chosen in Step 6.). Both steps should particularly emphasize feasibility to make Step 7.), the development of the simulation model, simple. Subsequently in Step 8.), the verification experiments have to be conducted. This checks, if the simulation model produces expected, solid outputs for predetermined inputs. If this step is successful, Decision 9.), a validation, Step 10.), can take place. The conducted experiments should ensure whether the model got adequate accuracy to assess the research problem. Results from this experiments are discussed with experts and validated with specific methods. If the verification or validation steps are not performed successfully, earlier steps have to be conducted again. If Decision 11.) can be answered with yes, simulation experiments to simulate real-world scenarios, Step 12.), can be carried out. The outcomes are discussed and examined with the research group and stakeholders and a plausibility check is performed. Step 13.) includes the documentation of the results and experiments conducted. This is especially important for further use and improvement of the simulation model. (Yin and McKay, 2018)

This basic structure of approaching a simulation and modelling problem provides a general guide for different real world problems and can be applied to every domain.

4.2 Purposes of Modelling and Simulation

Simulation has become a conventional tool for scientific research. Some even state that it is a new third way of doing science, next to induction and deduction. Still it is often not clear for what purpose simulation can be used. (Axelrod, 1997)

This section aims to give an overview about different use cases and purposes of simulation and modelling, based on a literature research.

An unambiguous purpose of simulation is **prediction**. A simulation model can process diverse inputs in a build up algorithm and generate output based on the given data and system characteristics. An example would be the prediction of failure rates of machines. **Performance**, as another reason for simulation, means that the model performs certain tasks instead of humans. Possible use cases can be medical diagnosis and process optimization based on a computer model. Another very important purpose is **training**, since long ago simulation systems were used to train people to deal with new environments. A well known example for this application is the flight simulator for the education of pilots, providing a dynamic real world simulation for the take off and landing of an air plane.

Entertainment and **education** are other ways to use simulation models, on a less scientific level. State of the art computer games or testing environments for the assessment of certain capabilities of humans are good examples. A very important purpose of modelling and simulation from a researchers position is **proof**. A simulation model can be a first proof of a set of rules developed in theoretical studies. Moreover, **discovery** of certain behaviour of systems is a very important and successful use case of simulation in the research domain. A simulation model can give very profound knowledge about relationships and interdependencies of a system, even from simple models. Therefore, models can be used to discover the effects of changes in the inputs, or the reaction of entities to a specific stress scenario. (Axelrod, 1997)

A more specific differentiation about the role and reasons for modelling and simulation is shown by Birta and Arbez (2019a) p:5, they alphabetically classify purposes in:

- *"Comparison of control policy options"*
- *"Engineering design"*
- *"Evaluation of decision or action alternatives"*
- *"Evaluation of strategies for transformation or change"*
- *"Forecasting"*
- *"Performance evaluation"*
- *"Prototyping and concept evaluation"*
- *"Sensitivity analysis"*
- *"Support for acquisition/procurement decisions"*
- *"Uncertainty reduction in decision making"*

In the best case the simulation model can replace a real world experimental study, which safes a lot of time and money. Furthermore, real world experiments can be too dangerous and could have irreversible impact on the system under investigation. (Birta and Arbez, 2019a)

Especially in the domain of innovation and product development modelling and innovation offer a broad range of applications. With this, diffusions of innovations, organisational strategies and knowledge and information flows can be represented in a virtual computer model. A very interesting use case is to assess the effects of the network externalities, the word-to-mouth or viral marketing influence, and the social networks in an innovation diffusion process. Moreover, organisations can evaluate impacts of different strategies or changes in their portfolio management. The exploration of information and knowledge flows in a supply chain network are another important application of simulation models. (Garcia, 2005)

There can be various different purposes and reasons for a simulation model development. In a researchers domain it is most used in the prediction, proof of concept, and in the discovery of behaviour of systems under different circumstances. Generally simulation models have to be developed especially for their purpose to meet the predefined requirements and answer the questions asked in advance. Especially when there is high risk and a lot of money to be invested, simulation is the most favourable approach. (Birta and Arbez, 2019a)

4.3 Conceptual Modelling

According to Robinson (2011) p:1 *"Conceptual modelling is the abstraction of a simulation model from the real world system that is being modelled; in other words, choosing what to model, and what not to model."* Many people agree that this step is the most crucial and important part of the modelling process, shown in Figure 17. There are a lot of different opinions about the benefits, purpose, and nature of conceptual modelling in the simulation process. Still there is little scientific research on that difficult task. (Birta and Arbez, 2016)

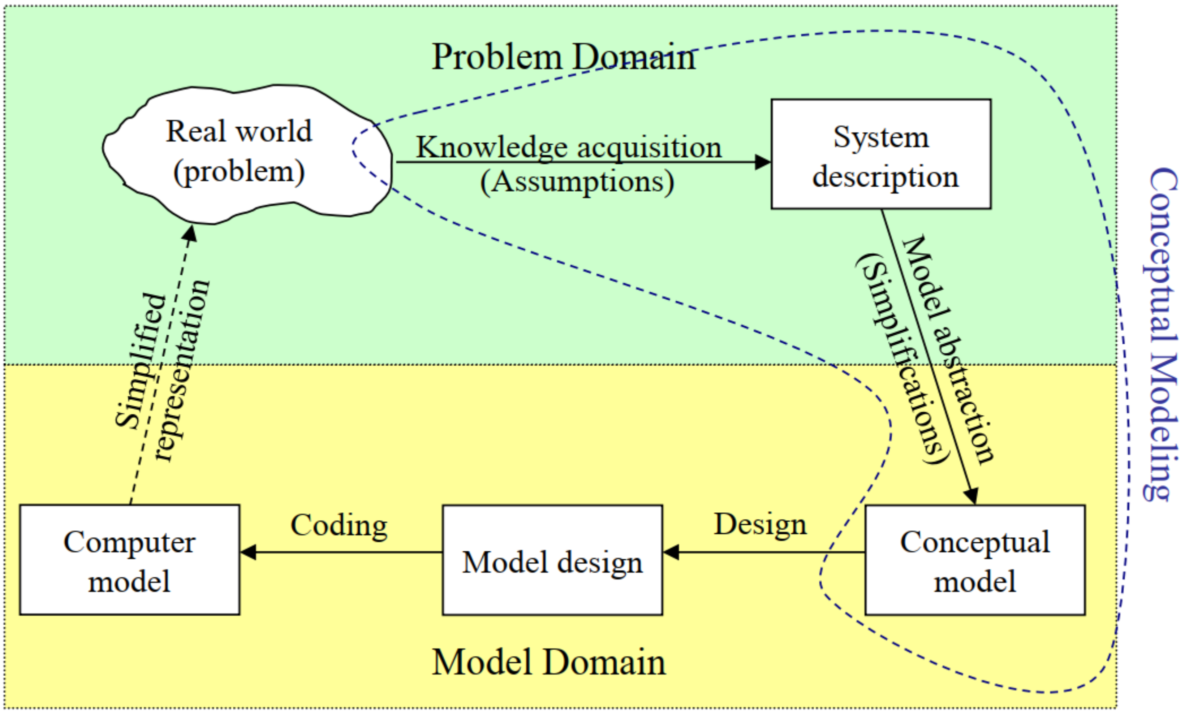


Figure 18: Conceptual Modelling (Robinson, 2011)

A conceptual model tries to determine the subject matter of a simulation model. The main task is to understand the underlying real world system, to extract important information in a conceptual model and turn it to a suitable simulation model. Figure 18 shows that conceptual modelling sits directly at the transition from the real world to the abstraction. Hence the process abstracts the reality in the problem domain and represents it in as a concept in the model domain. Such a representation of the reality, should picture every important aspect of the system to fulfil the purpose defined in the previous step. The modeller always has to balance needed accuracy with simplicity and resource availability. Moreover, often there is limited knowledge about the system available. This can be due to time reasons, but also because the real system often rarely exists and the modelling and simulation process is performed to assess the uncertainties of the system in advance. All this makes it impossible to represent the reality in every small detail. Moreover, every modeller interprets data differently. Therefore, every model of each person may look differently. One aim of conceptual modelling is to set the right level of abstraction according to the purpose and desired output of the simulation model. (Robinson, 2011)
Birta and Arbez (2016) states that conceptual modelling should serve as a specification for the computer program to discuss the systems behaviour with stakeholders. It is not represented as code, usualy represented in a formal language, and solution-independent. Still, it describes the computer simulation model with its objectives, inputs, outputs, assumptions, and simplifications. Such a model tries to collect all relevant information of the real world problem to clarify the research questions with stakeholders. The benefits lay in the documentation and uniform understanding of the problem. A conceptual model sets the scope and purpose of the simulation project and therefore is the basis for the actual model development in code. (Birta and Arbez, 2016)
The facts presented in this section call for a framework to tackle the mentioned problems with a predefined approach. Such approaches to represent a system in a formal way are introduced and discussed in the following sections.

4.3.1 Activity-Based Conceptual Modelling Framework

The Activity-Based Conceptual modelling framework (ABCmod) introduced by Birta and Arbez (2019a) p:123 provides a process and an environment for model specification. It builds up on two main categories: entity structures and behaviour constructs. The first one specifies instances of entities in a model more precisely. Entities can be classified into consumers, resources, groups, and queues. In the second, behaviour constructs are sorted into activities and actions. Activities are interactions among entities which need time and resources. They always have a start and end event where state changes of the model occur. Actions on the other hand are singular events in the system, like the arrival of an order. The ABCmod framework summarises all components of a system and divides them into two levels. The high level provides a structural overview of the entity structure and a list of date modules and behavioural constructs. On the detail level structural, data, input, output, and behavioural components are aggregated. Representing all attributes, conditions, and state change routines. (Birta and Arbez, 2007)

4.3.2 Hierarchical Control Conceptual Modelling framework

Another conceptual model framework is the Hierarchical Control Conceptual Modelling (HCCM) framework. It offers more flexibility than the ABCmod framework by using the concept of control structures. Hence DES models are not only represented by queuing systems. (Furian, O'Sullivan, Walker, Vössner, and Neubacher, 2015)

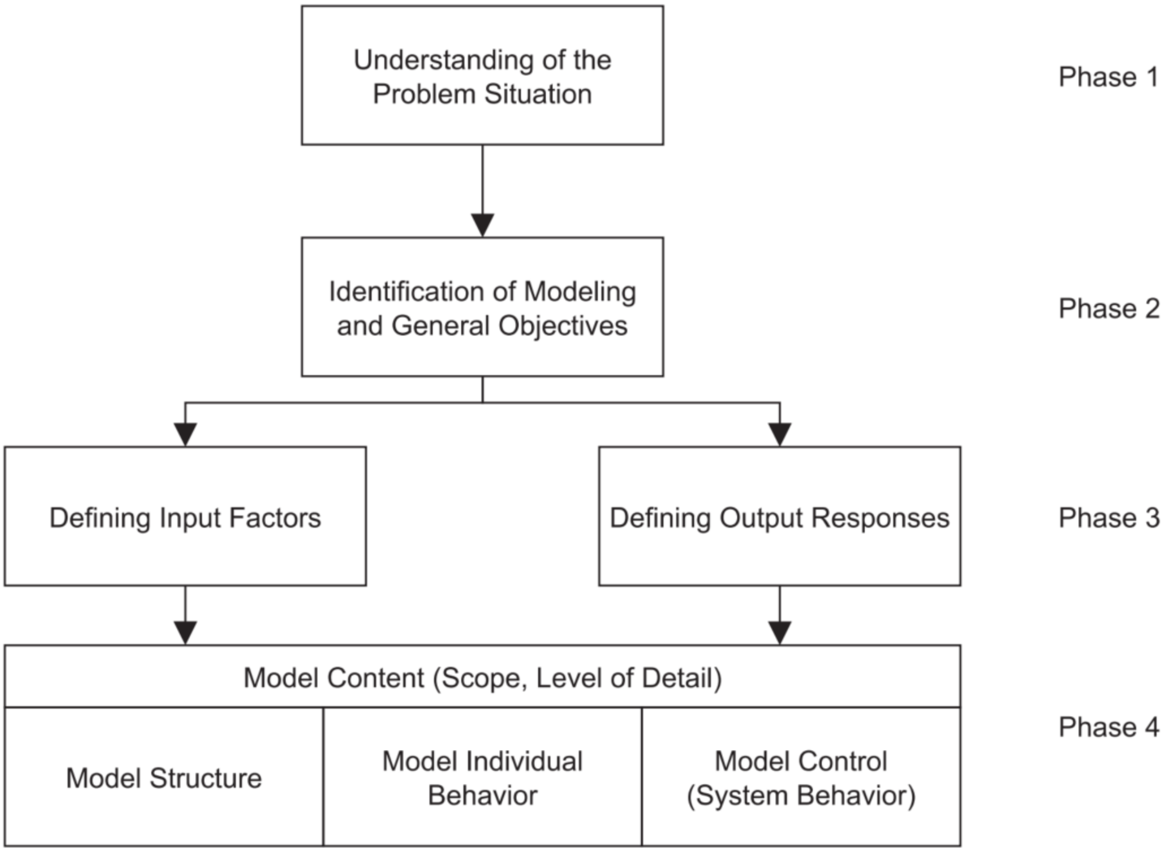


Figure 19: Structure of the HCCM Framework (Furian, O'Sullivan, Walker, Vössner, and Neubacher, 2015)

The framework offers a new conceptual modelling process which includes four phases, which can be iteratively repeated (see Figure 19). In the first phase the underlying problem situation have to be understood. Every stakeholder should have the same understanding about the behaviour of the system, resulting in an informal, written description of the situation to be modelled. Second, the objectives of the model have to be defined.

According to Robinson (2008a) it can be differentiated between general and modelling objectives. ”General” refers to the essential properties of the simulation, like flexibility to changes, visualization, run-times. Modelling objectives are derived from the purpose of the simulation, see Section 4.2. They include particular output requests and domain specific KPIs (Key Performance Indicator) that have to be simulated. In the third phase, the input and output factors based on the modelling objectives are defined. Input factors are often derived from experts experience or general pre-assumptions. They usually change when performing different experiments with the finished model. Yet they have to be specified, how they are used in the model and in what magnitude they can vary from the base input. These factors do not have to be necessarily numbers, but also strategic rules or company policies. Outputs can be a numerical value, often of statistical nature or time series data. In production sciences typically throughput time and workloads of resources are defined as outputs. In phase four, first the model structure with entities and their core elements are outlined. The HCCM framework does not distinguish between queues and groups like the ABCmod. It only includes active and passive entity structure, whereas active entities can change their role. Passive entities are not taking part in the process flow and are rather static. Like mentioned in Robinson (2008b), the amount of entities to include defines the scope of the model. Moreover, the level of detail and entities included have to be decided and described in the conceptual model. The overall goal is to have a graphical visualisation of the model structure that every stakeholder can understand. In the following, one should explain the individual behaviour of the entities. At this point, every simplification of the behaviour of entities have to be discussed. The output can be a visual flow chart representing the entities flow through the system. Moreover, a table with all activities including their type, attributes, state changes is recorded. This documentation should also include needed resources for performing the activity and under which circumstances they can be interrupted or terminated. Finally, the system behaviour can be defined. In this case, the HCCM framework is different compared to others like the ABCmod. Where in other frameworks events are put in queues, HCCM uses a hierarchical tree structure of control units which rule the execution of events and activities. This structure contain rules which decide the conditional behaviour of the model and adds different levels of decision making. The aforementioned control unit can trigger events based on the models definition or include optimization strategies for several output parameters. With this concept entity waiting structures like queues and groups are substituted. This enables more sophisticated dispatching and entity regulation. The control unit structure offers a centralized definition of the systems behaviour. Therefore, queue handling and request dispatch modes are combined in a single location in the model. In the conceptual modelling process this structure has to be previously defined. Hence

dispatching rules, model decisions, and hierarchical structures of decision-making must be determined. (Furian et al., 2015)
Overall the HCCM framework provides a solid process for the development of conceptual models. With the centralized logic structure it offers a better oversight of the decision policies. Therefore, it facilitates the modelling of complex systems with enabling more flexible trigger decisions of events. (Furian et al., 2015)

4.4 Simulation Techniques

In this section the simulation techniques ABS, SD, and DES are described and compared. This refers to step 5.) in Figure 17, ”Select simulation method”.

4.4.1 Agent Based Simulation

The ABS approach of modelling and simulation is based on individual, autonomous, interacting agents. Agent-based modelling and simulation's main advantage is the ease of representation of individual behaviours and their effect on other agents. Each entity, in this case called agent, included in the system's conceptual model (see Figure 17 step 4.), has an independent way of doing things and reacting to certain circumstances. Therefore, ABS can represent a number of autonomous and heterogeneous agents which comprehensively interact with each other. (C. Macal and North, 2015)
This makes ABS ideal to model individual decision-making, social, and organisational behaviour. An agent could be nearly everything, starting from humans in an organisation, birds in a natural habitat, cells in a body to trees in a forest. This versatility makes it very flexible and able to represent a huge range of situations. (Bonabeau, 2002)
Mainly a ABS simulation model, according to Maidstone (2012) and C. Macal and North (2015), consists of:

- **Autonomous Agents** - self-directed, independent objects, interacting with each other and the environment
- **Predefined Rules** - that agents stick to, to achieve their goals
- **Model Environment** - surrounding where the agents work towards their targets and interact with each other

The interaction of the different elements can be seen in Figure 20. C. Macal and North (2015) state that ABS is used in a wide range of domains. Beginning with the infectious disease transmission to understand the patterns of contact of individuals, product entries in new markets, firms supply chains where each agent is a link of the chain, to the effective

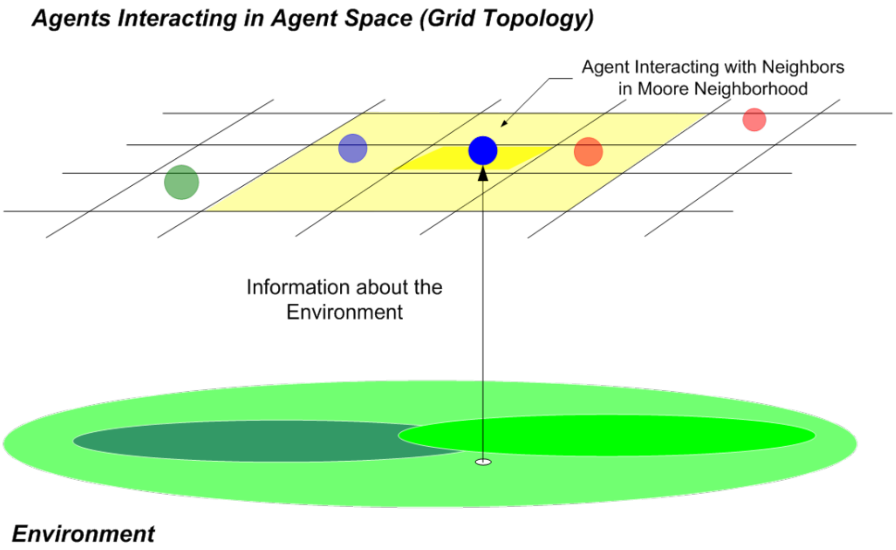


Figure 20: Elements of an Agent-Based Simulation (C. Macal and North, 2015)

navigation of robot's search for a resource in a territory. Usually this is modelled to run a simulation over time, similar to DES, see Section 4.4.3. (C. Macal and North, 2015)

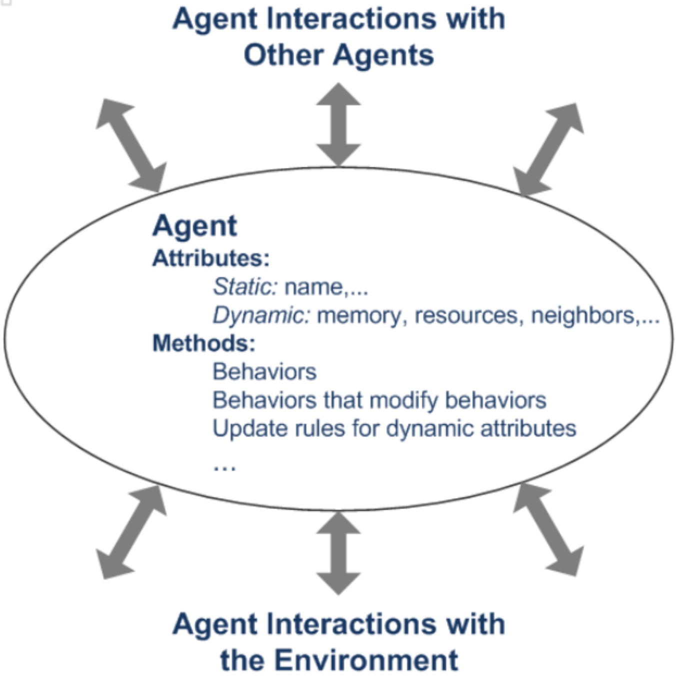


Figure 21: Agent Interaction in ABS (C. Macal and North, 2015)

The central entity of a ABS is the agent which is identifiable and therefore an individual with a set of characteristics, behaviours and it's own decision rules. The agent has boundaries, is acting in his model environment where he is steadily communicating with other agents and his surrounding. They are autonomous and flexible. Moreover, an agent can

adapt behaviour based on past experiences changing his predefined rules over a simulation run. (C. M. Macal and North, 2005)
To sum up, ABS can be the most fitting modelling and simulation approach when the problem can be represented as a set of agents with different decisions and behaviours. Particularly, when these rules reflect how individuals actually behave, or when entities of the simulation are dynamic and can adapt and change their behaviours. Furthermore, when these agents are embedded in an interacting environment, if the structural changes and behaviour of the agents is not known in advance and should be an output of the simulation. (C. Macal and North, 2015)
ABS can therefore model best the complexity resulting from individual behaviour and interactions that happen in the real world (Siebers, MacAl, Garnett, Buxton, and Pidd, 2010).

4.4.2 System Dynamics

System dynamics combines qualitative and quantitative aspects. It aims to understand an identified problem, structure it and comprehend relationships between variables in a more sophisticated way. It is widely used in many different fields such as defence analysis, project management, and health care. (S. Brailsford and Hilton, 2001)
SD models are generally deterministic and consist of stocks and flows. In this system of stocks and flows constant state changes happen over time. Initially, elements which are fundamental to the system and have influence on the modelled problem are identified. These elements are sketched in a stock and flow diagram, see Figure 22. The state of these elements changes continuously over a small amount of time (Δt). These elements, variables of a system cannot be tracked down while the simulation is running. (Tako and Robinson, 2009)

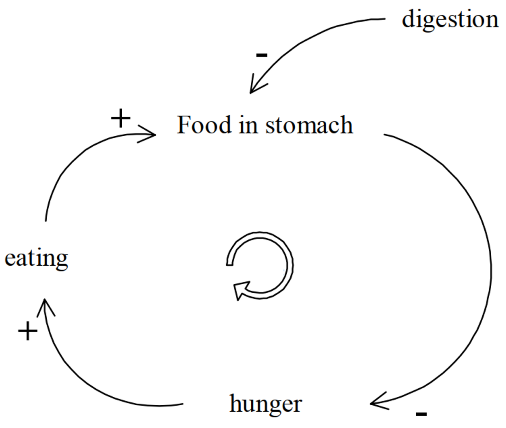


Figure 22: Notation (influence diagram) of a simple SD Model (S. Brailsford and Hilton, 2001)

As seen in Figure 22 the elements are linked by arrows, whereas the ”+” and ”-” shows the nature of the influence. In this example eating increases food in the stomach, which is shown by a ”+”. At the time the body digests, food in the stomach decreases, indicated by the ”-” next to the arrow. Since food in the stomach reduces hunger and hunger respectively leads to eating. With this connection the SD influence diagram is closed, resulting in a closed loop. The different stages of this process are modelled deterministically with

equations and the time spent at each stage is represented with delays. In this way influence loops of systems can be drawn and complex problems can be visualised clearly. With this representation general influences of variables on each others can be shown and investigated. The influence diagram in Figure 22 shows a balanced loop, which is regulating itself. The other type would be reinforcing loops, where the system's variable mutually increase each other, leading to exponential growth. (S. Brailsford and Hilton, 2001)
To sum up, system dynamics focuses on flows in a network, the main elements are **stocks** - where a variable, object is stored, **flows** - the fluctuation of objects between the stocks in a network and **delays** - representing the process of change at a stock, where values of variables are change (Maidstone, 2012). According to Tako and Robinson (2009) SD are used for modelling the strategic nature of problems, to gather a holistic view and wider general focus on a complex and abstract system. SD uses quantitative and qualitative data and most often deterministic relationships to provide an universal picture of a systems performance (Tako and Robinson, 2009).

4.4.3 Discrete Event Simulation

DES is probably the most well known simulation method in use. It models queueing networks where individual objects, called entities, proceed through a series of activities. Each activity consists of a start and end event, where the state of the entity and model changes at a discrete point of time (Tako and Robinson, 2009). The system is modelled in a process. Rules set the order in which activities occur and the conditions that has to be fulfilled that an activity can be performed. The duration of such activities are sampled using statistical distributions. Entities can be tracked down on their flow through the modelled process. The flexibility of the flow of entities in that process is without limitation and can be adapted to the expectations of the modeller. (S. Brailsford and Hilton, 2001)
DES are developed using three types of concepts (Maidstone, 2012):

- **Events** - which changes the value of some of the model's variables, the state of the model and entities
- **Entities** - objects which move through the system
- **Resources** - objects needed to trigger events

In a DES the entities and models state are changed at discrete events, which occur at a specific point in time. This process can be shown in an activity diagram, to visualize the logic flow of entities through queues and activities. This leads to a process flowchart consisting of different activities. An activity is composed of two events, the start and the end event. At the start event the entity which flows through the system has to be ready. Moreover, the resources needed for this specific activity have to be available. Then the activity can start, the corresponding start event is executed. This event occupies the resources and changes the state of the entity. Additionally, the end event, depending on the duration of the activity is set. Again the end event changes the stage of the entity and the model, for example a variable that represents the completion of a certain task is set to true. In this process from event to event the underlying, previously modelled process is executed. The simulation itself searches for the next event in the timeline to execute and the corresponding tasks are performed. This jump from one event to another makes DES a discrete simulation method. The state of the model changes only discontinuously, in case of an event, at discrete points in time. (S. Brailsford and Hilton, 2001)

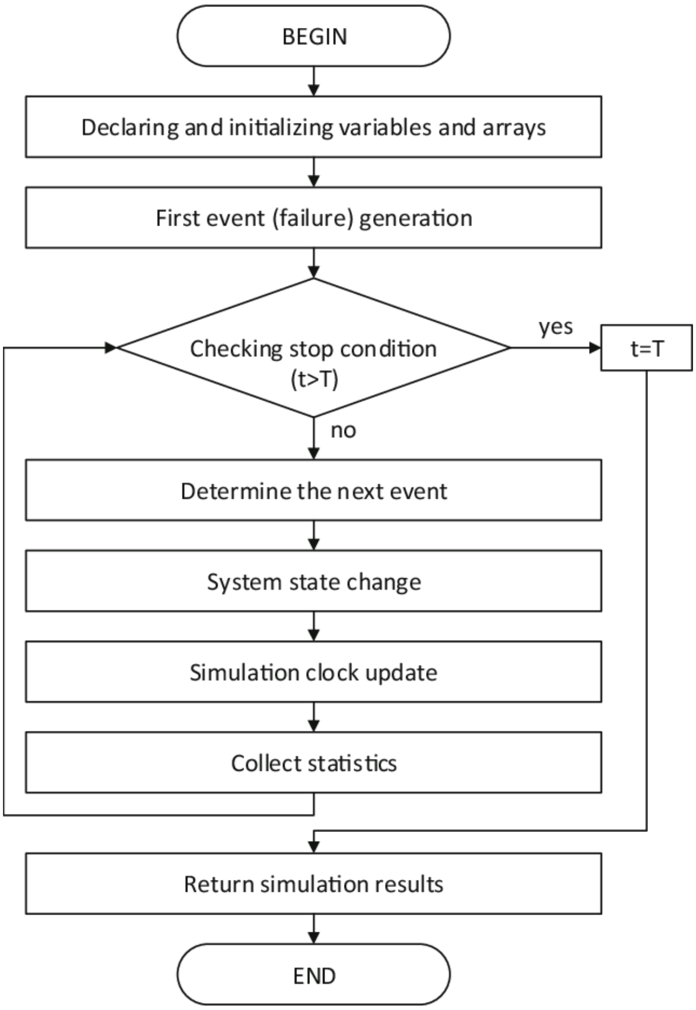


Figure 23: Logic Flowchart of a DES Model (Rykov and Kozyrev, 2018)

As seen in the previous paragraph, the central concept of a DES is the event. For Birta and Arbez (2019a) p:155 there are *"two main types of events: conditional events and scheduled events."* In the simulation model the execution of these events have to be defined. Therefore, the required changes of the model's status are determined in the event specifications. Conditional events are triggered, if a specific combination of states is fulfilled. Scheduled events occur at a specific point in time when they are set. Furian, O Sullivan, Walker, and Voessner (2014) state that another type of events are sequential events. They are triggered immediately after the termination of a preceding behavioural artefact. (Birta and Arbez, 2019a)

In Figure 23 the general flow of a DES simulation model is shown. Beginning with the generation of a first event, the simulation jumps from event to event, updates the time and changes the state of the model. The determination of the next event can be carried out by the above mentioned ways: conditional, scheduled, sequential. This procedure is repeated till there are no events on the list left or the stop condition is satisfied. (Rykov and Kozyrev, 2018)

DES is mostly used for tactical or operational problems. The method provides an analytic view and is able to model great complexity and detail, due to the flexible sequencing of activities. Usually a concrete process with quantitative data is the input and randomness is represented by the use of statistical distributions. For example defining the duration of an activity or the probability of an additional iteration loop within the process. Hence to the modelled probability distributions, the model results of one simulation run are just one realisation of the output of the system. This realisation may not be representative. Therefore, many iterations are required, reducing the variance of the results and giving a range of outputs of a certain scenario. (Birta and Arbez, 2019a)

4.4.4 Comparison

All simulation techniques have advantages and disadvantages and are applicable in different contexts and situations. The main driver of choosing the right framework for simulation according to S. Brailsford and Hilton (2001) p:12 is the purpose of the models: *"What sort of questions do we want our model to answer?"* Table 2 provides a comparison and overview of the three simulation techniques ABS, SD, and DES. In the table, the scope indicates the preferable application of the associated modelling and simulation technique. Elements refer to the main building blocks of each simulation, as described in the previous sections. The different purposes, as mentioned in Section 4.2, on which the different approaches can be applied is shown in the fourth row. Specific characteristics of systems which can be addressed with specific simulation approaches are described in the following rows. Main focus here is the difference in the simulation approach itself and the way of representing the modelled system.

	DES	SD	ABS
Scope	Micro, operational, tactical	Macro, strategic	Flexible
Central concept	Events	Flows	Agents
Elements	Events, entities, resources	Stock, flows, delays	Agents, rules, model environment
Purpose	Optimisation, prediction, comparison of system setups	Gain understanding about the system	Simulation of many various individuals having a different attitudes and interplays with each other
Simulation approach	Process orientated, network of queues, top-down	Flow oriented, top-down	Behaviour, interaction orientated, bottom up
System representation	Analytic, focus on complexity and detail	Holistic, focus on generally understanding the system	Anatomic, focus on the active agents behaviour
Number of entities	Small	Large	Large
Relative timescale	Short	Long	All
Statistic nature	Stochastic	Deterministic	Stochastic
Advantages	Variability, ability to model great complexity, and detail, well known in research community, fast ”quick and dirty” solutions possible,	Combination of quantitative and qualitative aspects provides a full picture of systems performance	Model complexity of individual actions in real world, system, agents can learn, wide range of applications
Disadvantages	Relative static framework	High amount of time needed to develop the model	Long development time, not fully established in scientific community yet

Table 2: Comparison of Simulation Techniques, based on Tako and Robinson (2009), Maidstone (2012), Siebers, MacAl, Garnett, Buxton, and Pidd (2010), S. Brailsford and Hilton (2001), and S. C. Brailsford, Desai, and Viana (2010)

Examples for choosing SD over DES are when looking at the broad context and the interaction with other systems. Moreover, SD is superior when also qualitative output is a target. On the other hand DES is better for a specific context, when there is little relationship with the outer world or to compare different setup scenarios, for example different staffing levels. (S. Brailsford and Hilton, 2001)

Comparing DES with ABS first leads to the difference in the behaviour of entities. In ABS agents have their own goals and are active. Whereas in DES entities are rather passive, their behaviour (flow in the process) is determined by the system. Another distinguishing attribute is the bottom up approach of ABS, compared to the top down in DES. When one would implement active entities in DES and make them as the centre of focus and not the process itself, it would be difficult to differ those two propositions of modelling (Siebers et al., 2010). When one compares ABS with SD they look very different at a first glance, but C. M. Macal (2010) p:4 proved in his "Agency Theorem for System Dynamics" that *"every well formulated SD model has an equivalent formulation as an ABS model."* However, it is often not preferable due to the fact that ABS models are much more difficult to set up than SD models. (Maidstone, 2012)

Finally, there is to mention that modellers tend to use the approach which they have most experience with. The better way would be to choose the technique according to the research question, purpose, and desired output of the model. A lot of knowledge about the described modelling techniques, the system under investigation, and objectives of the simulation have to be known to choose the right method accordingly. (Maidstone, 2012)

5 Case Study - Development of a Decision Support System

This section describes the practical implementation of the concepts described in the sections before. All methods are applied in the case study of the CAMed project (see Section 1.2) to support the design of a 3DPC at POC. Within the case study, a DSS is developed to support decision making towards the integration of such a 3DPC, as well as long term strategic decisions of the whole business case. The general situation of the case study is at a very early stage of the implementation. Hence, the case study, at this stage, offers a relatively poor data environment. The introduced DSS is split in a business ecosystem analysis (Value Networks) and a simulation tool (demand model, operational simulation and a cost benefit calculation). This DSS unites qualitative criteria in the value network with quantitative factors in the simulation tool and should enable a holistic assessment and support for decision making. The novelty of manufacturing directly in the hospital and the widely unknown consequences of the implementation of such a facility makes a sound evaluation of implications and contributing factors crucial for the project's success. The 3DPC is currently in a research state already set up with two printers and low demand for testing the facility and the workflow. The goal is to contribute to the successful implementation of the targeted full operational state. Most of the data used in this DSS is gathered with experts around that facility. Moreover, expert interviews and the validation of the simulation model are performed with support by the CAMed project. In this section, the application of the methods to this specific case is shown in more detail. The aim is to provide a sound DSS for the decision makers such as project owners or healthcare provider managers, to support the successful integration of the 3DPC. Due to the initial data poor situation still many assumptions are required, nevertheless the DSS shall act as base for further development. Hence, the DSS is generally designed flexible to allow many changes in input parameters and to avoid later additional programming efforts as soon as more accurate data is available.

Figure 24 presents an overview of the assessment structure of the developed DSS. Beginning with the business ecosystem analysis, two value networks are developed and the motivations, social interactions, and influences are assessed with stakeholder interviews. For that, two points of view, the operational and strategical point of view are distinguished. Furthermore, the quantitative evaluation including the operational simulation and the monetary assessment of the business case is mapped out. For this key performance indicators, representing the capabilities and economic profitability, have to be selected. In the last part of this section an aggregation of the results and an interpretation of the given business case are performed. The presented DSS, with the collected information and eval-

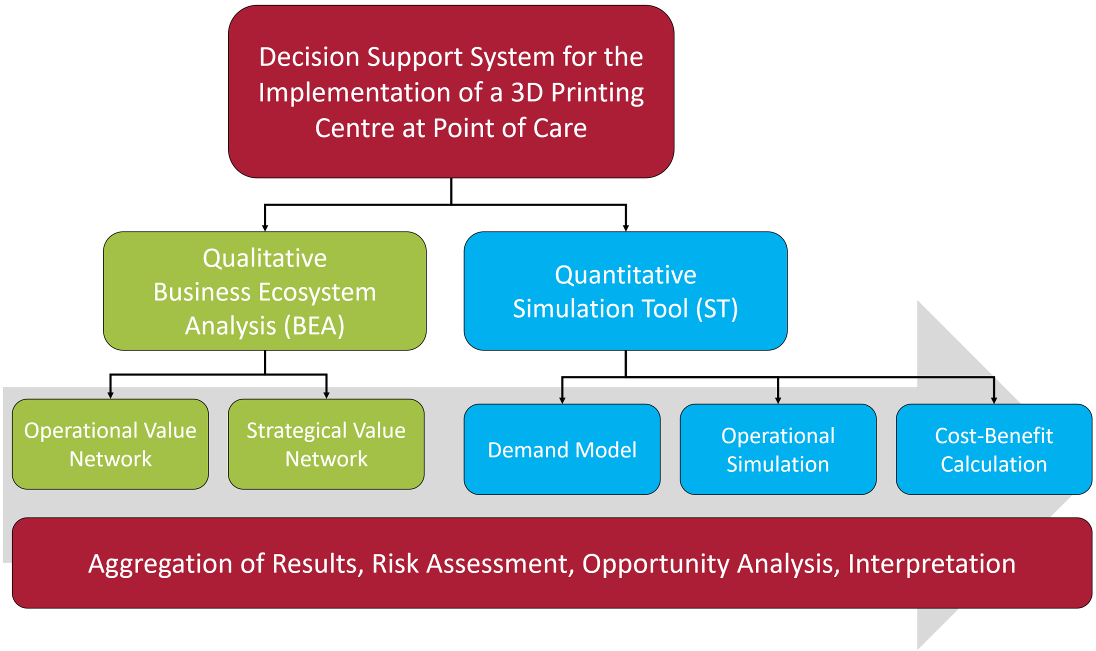


Figure 24: Overview - Development of a DSS for the Implementation of a 3DPC at POC

uation of first results should allow stakeholders to make better informed decisions about further development of a 3DPC at POC at the LKH University Clinic Graz. Finally, the author states that the introduced DSS shall also be applicable to similar cases for other hospitals. It is a general decision support framework and shall be applicable to assist the implementation of a 3DPC at POC in other hospitals too. For this, small modifications in simulation and demand input have to be conducted and stakeholder interactions have to be analysed. Basically the fundamental, underlying holistic approach of evaluation stays the same in other cases.

5.1 Qualitative Business Ecosystem Analysis

For a holistic understanding of dynamics and interactions of stakeholders within a system, an analysis of the business ecosystem, where the project is embedded, is crucial for a successful implementation of a novel system. Especially the actors, relationships, and interactions in this use case are widely new and not evaluated yet. Within this section, first two Value Networks (see Section 3.3.2) with different point of views are introduced. The operational layer looks at interactions when manufacturing and delivering a 3D printed part. The strategical layer shows the integration of the 3DPC from a more general, long-term perspective. This results in a specific business ecosystem analysis, as explained in Section 3. Moreover, this layer includes an internal motivational and external influence assessment of the stakeholders. This is evaluated with stakeholder interviews. The interviews were conducted to get a holistic view of the endogenous motivations and exogenous influences driving the value generation of the stakeholders. Finally, all results are interpreted and summed up.

5.1.1 Operational Value Network

The operational layer of the value network of the 3DPC shows the interaction and relationships of the participating entities in the actual manufacturing process. The triangles on the arrows show items and values that are interchanged in the network. In Figure 25 all actors, their interactions, and their affiliation to a stakeholder group are illustrated. Table 3 shows these actors and their capabilities and assets. Capabilities show their direct impact on the participation and value generation within the 3DPC. Assets are static options of tangible and intangible nature connected to the actor, see also Section 3.3.2. The value network shows a possible future scenario when the 3DPC runs smoothly. Therefore, future aspects as additional actors such as QM, which are not available today, are included.

The green coloured actors are internal members of the 3DPC. It is assumed, that they will work full time at the 3DPC and have a lot of interactions with different other stakeholders. The highlighted actors in blue are stakeholders within the hospital. They work closely together with the employees of the 3DPC and are customers and users of medical devices, as you can see in the rose triangle in the value network, Figure 25. The actors in white are participating in the value generation from outside of the hospital. This includes the different suppliers, the hospital operator managing the healthcare services, the patients, and the medical university as a research and education facility. End users of the manufactured medical devices can be patients or the research and development department in the medical university. In education, 3D printed parts are mainly used as education material and mock ups for research.

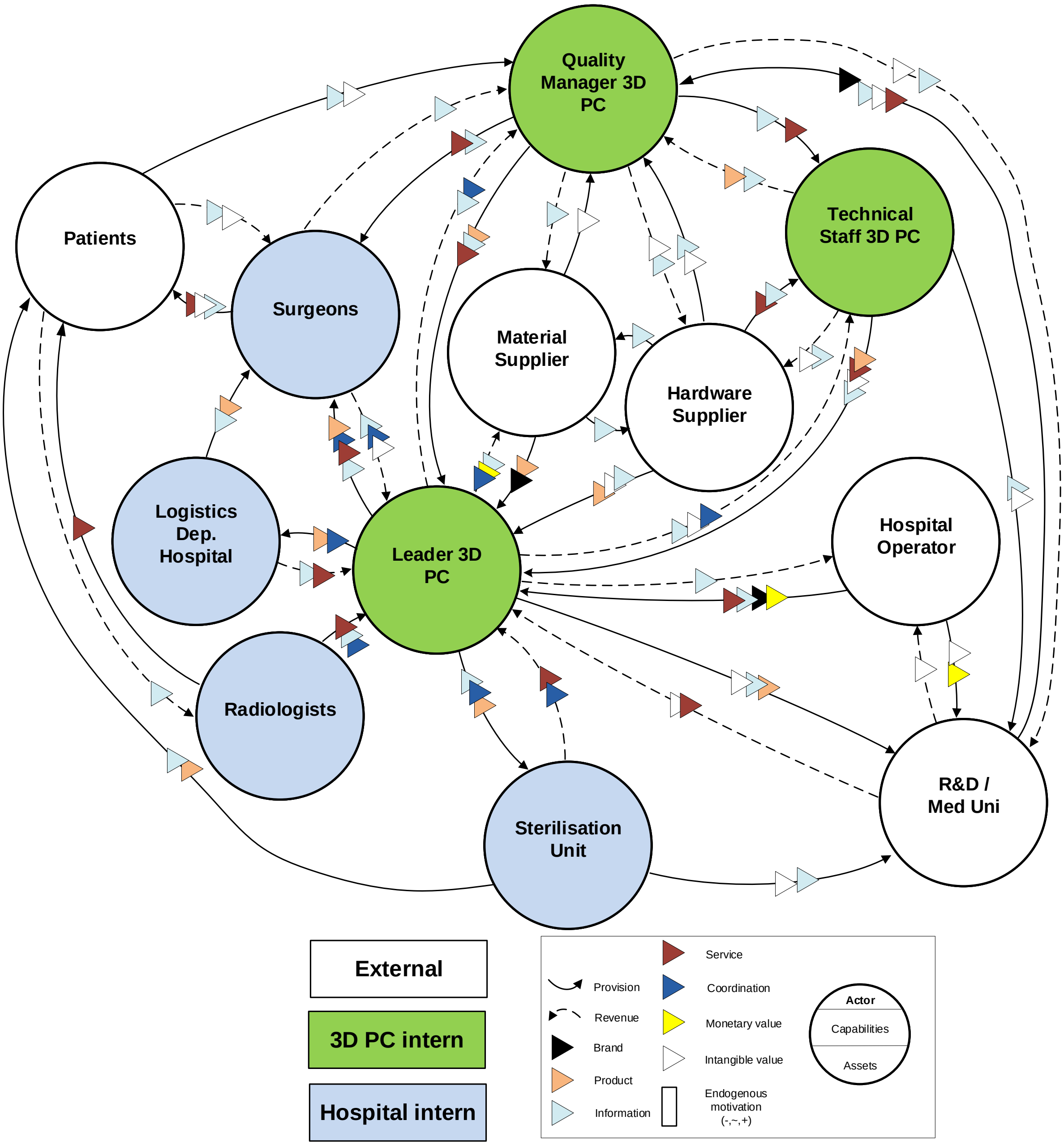


Figure 25: Value Network 3DPC - Operational Layer

Description of the actors

In the following, Table 3 the actors, their capabilities and assets are summed up in a tabular form.

Actors	Capabilities	Assets
Leader 3DPC	Manages technology and orders, develops process chain, accounting	Network and Process knowledge
Quality managers 3DPC	Verificate, validate medical dev., establish maintain QM system	QM Know How: regulations, QM, processes
Technical staff 3DPC	Manufacture medical dev.; maintain, repair, set up printers	Technical / process knowledge, AM expertise
Surgeons	Customise, set requirements, uses medical dev. for surgery	Med. Knowledge, Patient specific data, experience
Logistics Department Hospital	Distributes, stores medical devices	Internal service of hospital, supply chain management
Radiology Technicians	Segment, extract 3D model out of CT, MR picture	Knowledge segmentation, modelling
Sterilization unit	Sterilises medical devices	Internal process hospital, validated sterilisation process
Material suppliers	Deliver material and certificates, consult with process quality	Extrusion process knowledge, material experience
Hardware suppliers	Deliver printers, maintain printers, consult with process quality	Process-, production-, failure- knowledge
Hospital operator	Funds 3DPC performs accounting, provides IT system	ERM- IT system money authority, organisational structure
R&D / Medical University	Benefit from medical dev. test, perform research, provide quality feedback	R&D experience, public reputation
Patients	Benefit from medical dev., provide feedback, deliver MR, CT picture	End-User, feedback authority

Table 3: Actors of the Operational Value Network

5.1.2 Strategical Value Network

In the strategic layer of the Value Network, the embedding of the 3DPC into it's business environment is shown. Furthermore, it's connection to suppliers and other departments on a macro level is demonstrated (see Figure 26). Again, the representation shows a possible future state of the 3DPC. It is shown that all provision links are directing towards the patient or the Medical University and research and development, which are currently planned to be the end users of the medical devices produced in the 3DPC. Moreover, there is a lot of interaction in between the suppliers and scientific partners. A more detailed explanation of the actors can be found in Table 4.

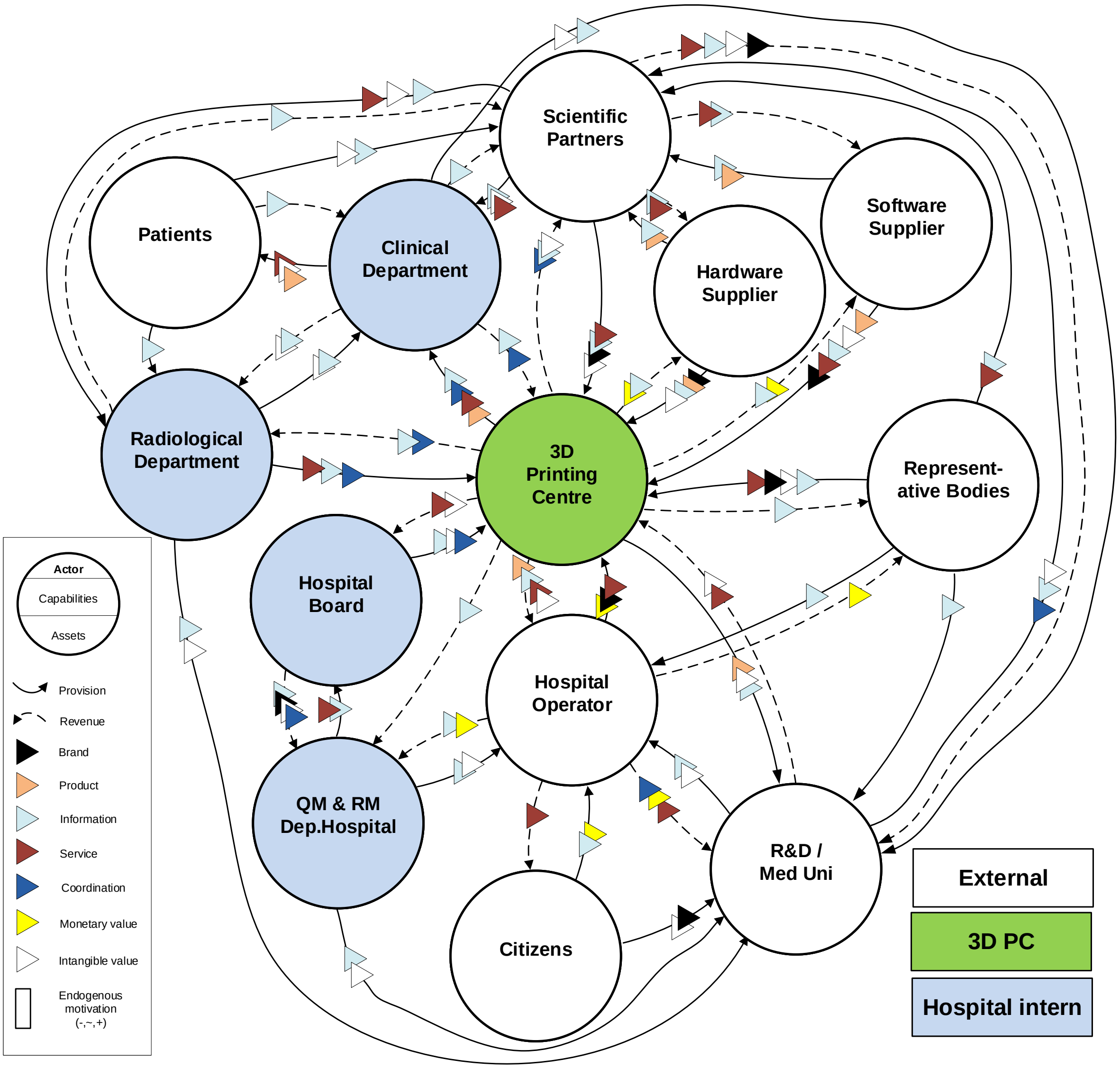


Figure 26: Value Network 3DPC - Strategical Layer

Description of the actors

Table 4 shows the actors, their capabilities, and assets. Their contribution to the value generation can be seen in the capabilities column.

Actors	Capabilities	Assets
3D printing centre	Produces 3D printed medical devices, manages quality, processes orders	Process expertise, production network, quality management know how
Clinical department	Uses medical dev., sets requirements, provides feedback orders 3DPP	Anatomical knowledge, authority for acceptance of 3DPP within hospital
Radiological department	Develops 3D model, segments, executes MRI- CT scans	3D modelling, segmenting MRI,CT scan expertise
Hospital board	Develops strategy of hospital, provides rooms and inclusion in hospital	Staff provision, decision making authority
QM & RM department hospital	Certifies, validates, legislates medical dev. for internal use	Requirements expertise, validated certification process, QM expertise
Patients	Request product, provide feedback, deliver MRI-, CT- picture	Reputation authority, End-user
Scientific partners	R&D, enhance process, develop new product	Different point of view, specific knowledge, reputation public funding
Software suppliers	Develop slicing, segmentation software, model 3D models, manage different software, train the staff	Certificate for medical domain, software expertise
Hardware suppliers	Deliver special 3D printers and material, validate quality, maintain printers, train staff	3D printing expertise, certificate for medical domain
Representative bodies	Assign licence, control process chain, set regulations, execute audit	Allocation of certification, legal authority
Hospital Operator	Funds 3D PC, executes accounting, provides IT system	ERM- IT system, money authority, organisational structure
Citizens	Set acceptance of medical 3DPP in society, determine reputation	Authority of public reputation
R&D / Med. University	Benefits from medical dev., tests, develops process, provides quality feedback	R&D experience, good public reputation

Table 4: Actors of the Strategical Value Network

5.1.2.1 Analysis of Strategical Value Network

At this point of view, the center of the Value Network is the 3DPC. There is a large amount of interaction to the 3DPC to sustain such a facility in the long run. Figure 26 shows that in a substantial magnitude, information (light blue), services (brown), and coordination issues (dark blue) are exchanged within the actors in the value network. Moreover, only little monetary value, but a great amount of intangible value is traded. This makes the 3DPC a good example for a socio-technical system, which cannot be assessed only on monetary issues. The most crucial part in the authors opinion will be the information flow, which is nearly in between all actors. In many cases, the communicating actors are not from the same domain. For example, usually 3D printing equipment and software suppliers are used to an interaction with industry, but here this industry-facility is embedded in a hospital. Two domains meet each other in a unusual way and may use different ways of interaction and communication. The health care provider domain has a close affiliation to general infrastructure as societies basic medical supply and are regulated by state. Whereas the suppliers operating in the open, non-regulated economy. A circle of important information exchange is the one of the clinical, radiological department, the patients, the 3DPC, and the scientific partners. These actors have to keep up the high quality and the customer centred manufacturing process. All these actors have to work collaboratively on a high quality level and the exchange of patients, health information like CT and MRI pictures have to be as easy as possible. Furthermore, a steady quality check of processes within the 3DPC is crucial for the long-term success of the whole project. Hence, a continuous improvement of the quality of the medical devices can be reached. This could not only affect the 3DPC itself, but also other stakeholders in the business ecosystem such as suppliers and scientific partners.

At the bottom part of Figure 26, the interaction of actors within the hospital and the hospital operator as a general manager of the health care provision is shown. A crucial part here is to put emphasis on the value added in the better treatment of patients. Citizens have to be informed properly about current research and the overall societal benefit from better treatment, less OP costs, state of the art research in the hospital, due to the implementation of the 3DPC. Furthermore, the successful integration of the 3DPC in the IT and ERM infrastructure of the hospital and health care management infrastructure is a key step and essential for the smooth operation of such a facility.

The strategical layer shows the whole business ecosystem of the 3DPC and it's interaction with different stakeholders on a qualitative level. Generally, the interdisciplinary communication, focus on non-monetary value, integration in the hospital infrastructure, establishment of fruitful relationships with suppliers and the focus on customer satisfaction can be concluded as crucial areas of the success of a 3DPC at POC. Adding to that, patients, as one of the most important end customers, have to be aware of the value added by 3D printed medical devices to compose a positive picture in society.

5.1.3 Assessment of Endogenous Motivations and Exogenous Influences

To get a more holistic picture about the actual interactions, attitudes, and relationships among the stakeholders, an assessment of the societal dynamics and motivations is performed. With the V2 notation, introduced in Section 3.3.2 and developed by Vorraber and Vössner (2011), the author aims to identify the endogenous motivation of and the exogenous influences on the stakeholders. These two terms are explained in Section 3.3.2. To get such an integrated picture of the motivations and internal dynamics, appearing at the establishment of a 3DPC, stakeholder interviews were performed. This section explains the process of the qualitative assessment of societal dynamics and motivational influences in the 3DPC at the given use case of the LKH University Clinic Graz.

For the gathering of qualitative data, stakeholder interviews within the CAMed project were performed with different participating members of the previously introduced stakeholder groups. In the online conducted interviews, the concept of Value Networks was introduced first. As a second step, the actors and the general concept of evaluation were explained. Finally, the interviewees were asked about their particular estimation about the endogenous motivation and exogenous influence of each actor in the value network. As explained in Section 3.3.2, the interviewed individual could choose in between ”active”, ”neutral” and ”defensive”. Due to the fact that not everybody has touchpoints with every actor interviewees could also choose ”not specified”. The estimation of each stakeholder about each actor, including the one he is an individual of, lead to a multi-perspective rating of the internal motivations. Moreover, the different estimations of external influences, like the rating of the influence of managers on the different actors, give a holistic picture about the whole business ecosystem and it’s social dynamics. Overall seven stakeholder interviews were performed. An extract of the analysis of those interviews is shown in the next section.

5.1.4 Assessment and Interpretation of Results

Figure 27 shows an example of the evaluation of the stakeholder interviews explained in the previous section. The whole evaluation process is based on the approach explained in Section 3.3.2. Hence, the relationships were evaluated with value engines and value brakes.

The presented evaluation is based on the interview outcomes. The different estimations were merged into one rating for each actor about their internal and external influences on the participation in the network. If the assessment was undecided among the interviewees,

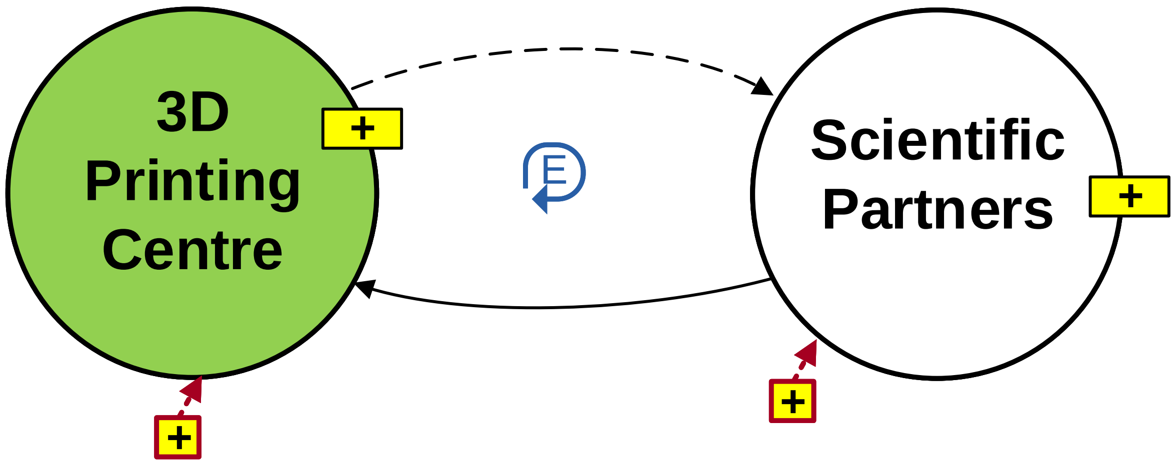


Figure 27: Evaluation Example Endogenous Motivation and Exogenous Influence

for example the same amount of ratings were at ”+” and ”∼”, it was evaluated with both. The example shows a very positive reinforcing loop in the operational relationships between the 3D printing centre and the scientific partners. Both, exogenous influences and endogenous motivations are rated as positive. Therefore their relationship can lead to a reinforcing loop, which indicates a strong drive towards active participation in the value generation within the 3DPC processes. Due to the fact, that they are intrinsically motivated to produce a high quality medical device, they can reinforce other actors within the 3DPC to do it the same way. Such a relationship is a vital sign for a positive outcome of a value network. As the example shows, this evaluation can yield more valuable outcome in understanding the underlying connections, drivers and relationships within a business ecosystem.

To sum up, the qualitative analysis of the business ecosystem shows a wide range of interactions in the project network. Particularly, the focus on non-monetary value exchange and the positive relationship on the operational manufacturing actors can be shown due to this analysis. Moreover, the intensive flow of information and services in between the actors can be seen in the Value Network. Through the interaction of actors of different domains, a clear and unproblematic communication channel has to be developed.

5.2 Quantitative Simulation Tool

In this section, the main part of this master's thesis, the development of the quantitative part of the DSS, a domain specific simulation tool, is demonstrated. It can be used for the support of the implementation of a 3DPC at POC. The whole elaboration of the ST is based on methods introduced in Sections 2 and 4. The ST consists of a demand generator, an operational simulation, and a cost-benefit calculation, which are all developed in a C# coded computer model. The development is incorporated in the CAMed project and should enhance decision making towards the integration of a 3DPC at POC. Due to the early stage of the project, the presented ST is based on limited data available. Therefore, the suggested ST is designed in a modular and hence flexible way, and enables simple input changes.

5.2.1 General Description of the Development Procedure

Figure 28 shows the process of the development of the quantitative part of the DSS for a 3DPC at POC. First, the scope and the general structure of the system have to be defined. Therefore, the manufacturing process to be analysed is defined and system boundaries are set. Moreover, scenarios for the verification and the evaluation of the manufacturing process are designed. In the second step, KPIs for the evaluation of the performance are chosen. This key figures are selected to get a holistic picture of the system. Hence, monetary and non monetary criteria are used to assess the system. The data acquisition is conducted with experts from the CAMed project and other involved stakeholders such as manufacturers and accounting departments. Furthermore, relevant data is gathered with internet research and from relevant academic literature. In the third step (Model definition) the modelled system is explained in more detail. Specific properties and assumptions of the model are explained, the involved uncertainties are assessed, and their impact on the ST is shown. After that, the execution of the model based on the HCDES Library from Furian et al. (2014) is presented. The actual coding structure and the realisation of the evaluation models are demonstrated. Moreover, the calculation of the selected KPIs and the user interfaces are explained. Finally, the result analysis with the verification and validation of the ST with the proposed scenarios is conducted.

In the subsequent sections these steps are described in more detail to give an overall picture about the development of this ST for the decision support of the implementation of a 3DPC at POC.

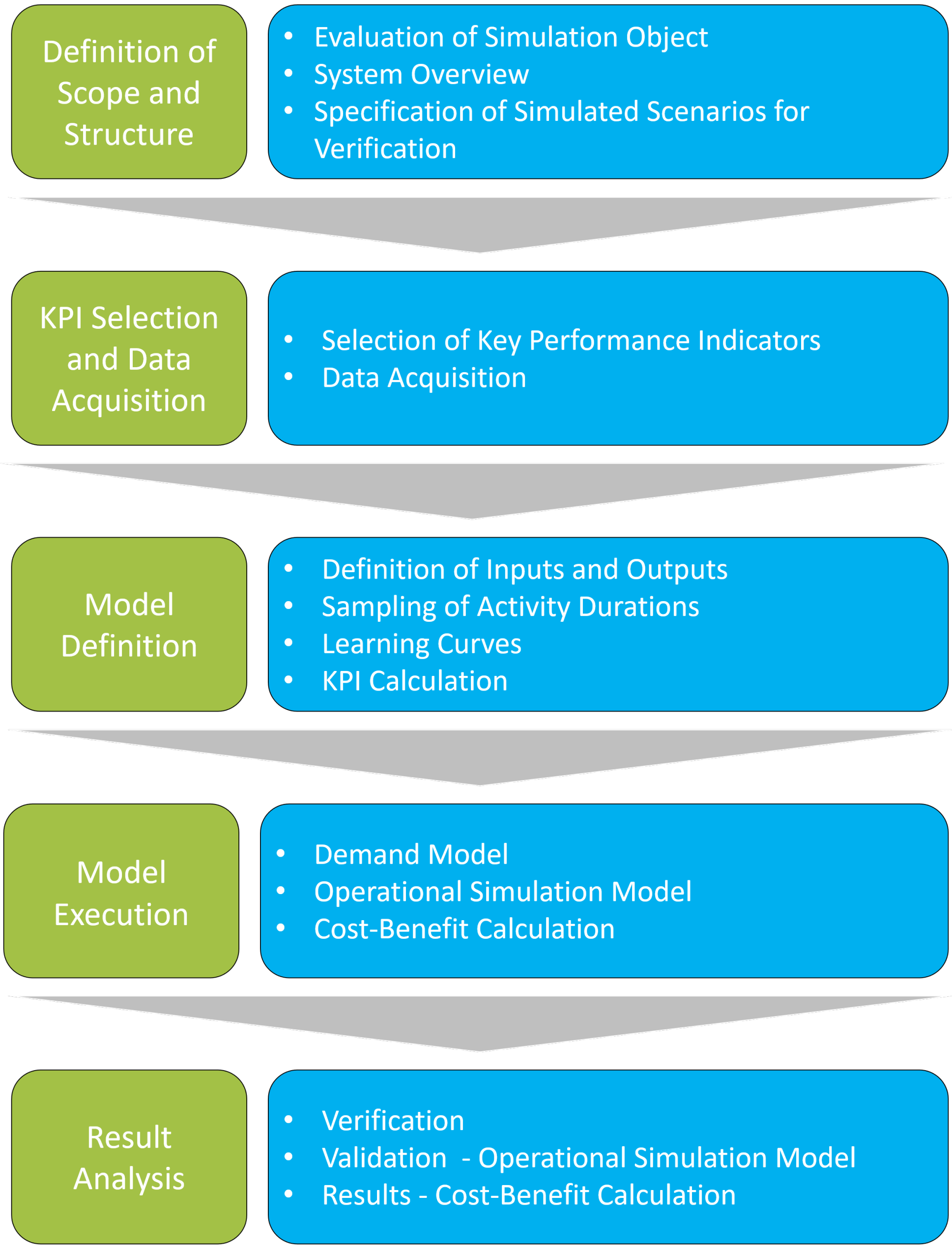


Figure 28: Structure of ST Development for 3DPC at POC, based on Liebrecht, Jacob, Kuhnle, and Lanza (2017)

5.2.2 Definition of Scope and Structure

Initially, the scope and general structure of the ST are defined. For this purpose, the general assessment object, respectively the manufacturing process, is described in more detail. Moreover, future scenarios, which are executed for the verification of the ST and the evaluation of the performance of the 3DPC are presented.

5.2.2.1 Evaluation of Simulation Object

This ST should support decision making during the implementation of the 3DPC at POC at the LKH University Clinic Graz. The object to evaluate is the 3DPC with focus on manufacturing and support processes. This facility within a hospital is by now set up at a research state. The goal of the ST is to support the transition to a normally operating facility in the hospital. Most importantly, the manufacturing process itself has to be evaluated. With this the, yet not known, performance and interaction of resources in the 3DPC under normal manufacturing conditions can be estimated. The normal manufacturing conditions in future, depending on the demand of the hospital, are not known so far. Therefore, the ST should be adjustable given certain circumstances. Hence, flexible in- and output parameters are essential for further use. With the ST, the best resource setup regarding the number of printers and process resources should be identified under different demand scenarios.

5.2.2.2 System Overview

The defined evaluation object is the manufacturing process of 3D printed medical devices. This production process consists of four basic steps, see Figure 29. First, in ”1.) Request part”, a new part is requested by customers. For this process, the technical staff checks the feasibility of the order with his computer. Customers can be surgeons, doctors, and later in the future, research facilities or the Medical University for education purposes. Then the completeness of the order is checked and - if complete - the request is confirmed. In the second step, ”2.) Manufacture part”, the requested medical device, i.e. an implant, and anatomical model, or a tool, is manufactured. Thus, the patient’s-specific CT and MR images attached to the order are segmented. Medical image segmentation is the identification of human organs and parts of the body from CT or MR images (Hesamian, Jia, He, and Kennedy, 2019). This enables a customization of the medical device and is carried out by a radiologist or radiology technician using special software. In the following, the edited pictures are processed into a three dimensional computer model. This customized 3D model has to be approved by a doctor and can then be used as an input for the 3D printer. Afterwards, a corresponding print job of the generated model has to be created. Again, specific software for slicing (cutting the 3D model into layers and generating an executable geometrical code with coordinates and build up rate for the 3D printer) is needed. Then the printer can be prepared and can manufacture the customized medical device. Depending on the medical use case and required printing material an appropriate printer is chosen. E.g. an implant requires polyetheretherketone (PEEK) material and a high temperature printer. After the part is printed, the post-processing can start. The part is taken out and the printer is checked for failures. Moreover, a

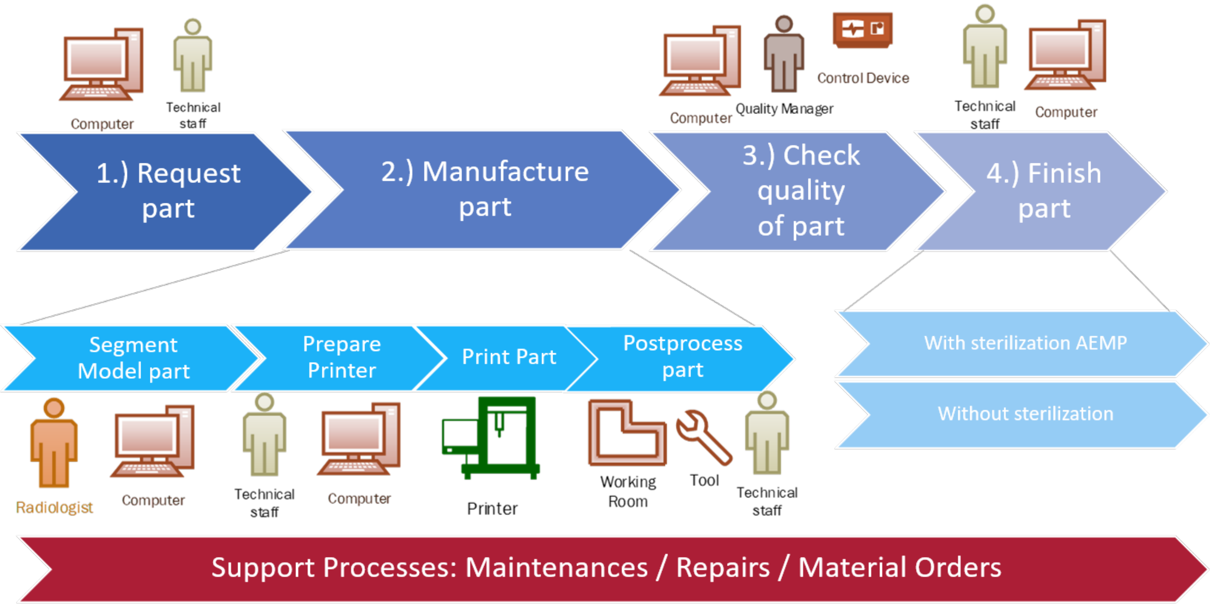


Figure 29: System Overview of Operational Simulation

post treatment process is performed if needed and the whole manufacturing procedure is documented in a protocol.

Figure 30: Resources included in the Operational Simulation

Subsequently, in step "3.) Check quality of part", the produced part's quality is checked. In this step of the process, the part is visually checked, compared with the order, and it's general requirements are checked with a specific device. This step is still under research and hence not fully defined yet. If one of these steps fails, the part has to be manufactured again. If the quality inspection is ok, the protocol can be completed and the part can be finished.

The fourth step, "4.) Finish part", is executed depending on the requirements of the medical device. If sterilisation is needed, the part is prepared and then sent for sterilisation. This is planned to be executed in an already existing hospital department. If no sterilization is needed, the part can be packed and prepared for pick-up by the customer. With this step, the overall manufacturing and order processing in the 3DPC is finished. In such a process one medical device is manufactured in the 3DPC.

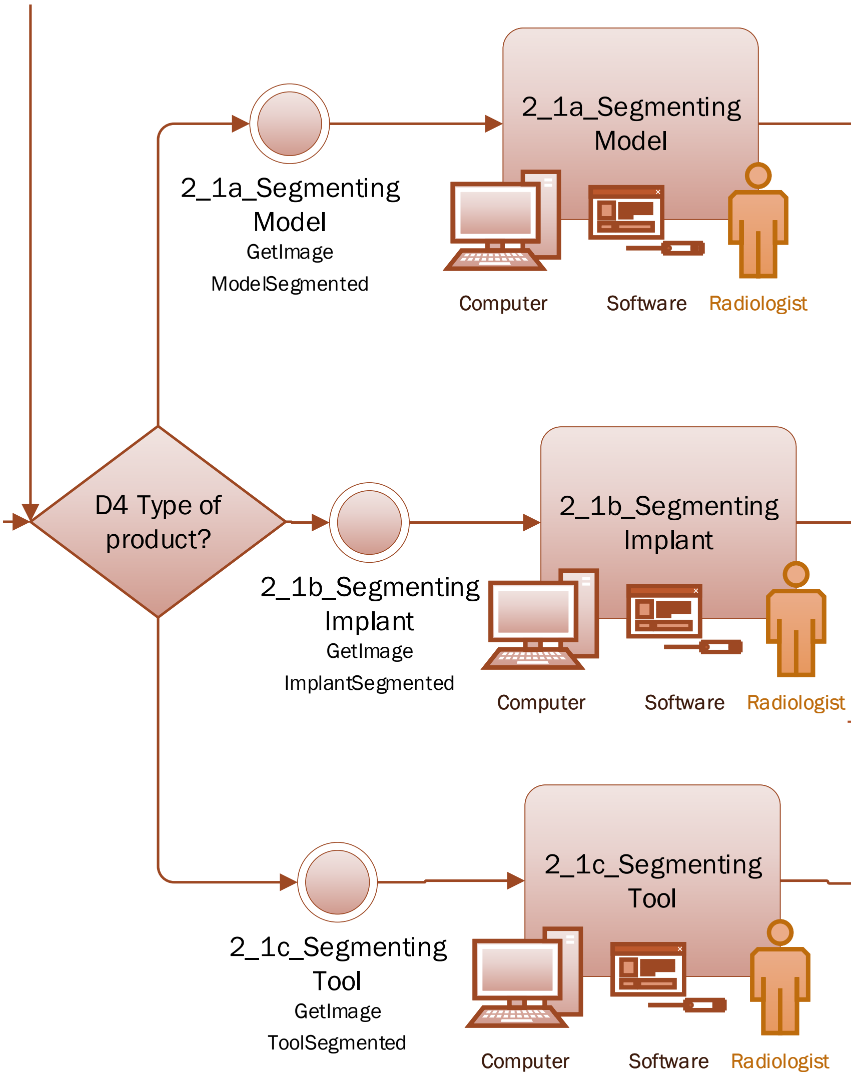
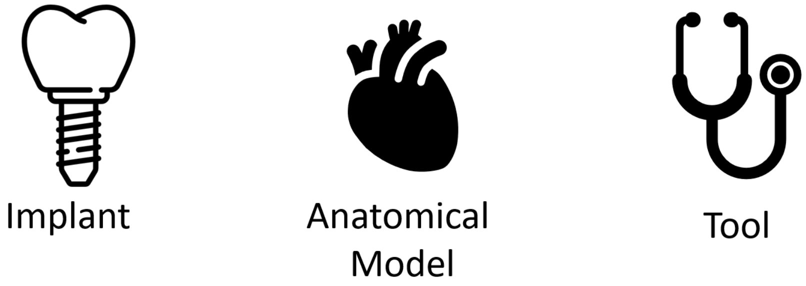


Figure 31: Example Process Flowchart - Decision: Segmenting of different Order Types

Figure 31 shows an example of a decision in the manufacturing process. After confirming the order in the "1.) Request part" process the segmenting is performed. Depending on the type of the order, the execution of the segmenting activity is different. This is modelled with different durations of the activities. Moreover, before starting the activity a request to start is sent to the control unit. This checks if resources (see icons under the activity) are sufficiently available for fulfilment and finally starts the activity.

In parallel, support processes such as maintenance actions of the printers, repairs after failures, and material orders are executed. All process activities explained in this section have a certain duration, which can vary within different scenarios.

Included resources in the modelled process are explained in Figure 30. Different resources are needed for the execution of various activities, see Figure 29. Hence, resources are not always available. The allocation and use of these resources are crucial parts to assess within this simulation model.



Source: Windows icons

Figure 32: Types of different Orders included in the Operational Simulation

Types of different medical devices included in the assessment of the manufacturing process are implants, anatomical models, and tools, see Figure 32. Differences in the production process lie in the segmentation, modelling, printing (printer and related build up rate), material, and the need for sterilization.

Support processes

The support processes have to performed during normal order processing actions. In the following, these activities and their triggering behaviour are explained in more detail.

There are four maintenance processes implemented, see Figure 33. The triggers are adjusted to the current experiences at the current 3DPC dedicated to research and can be seen in Figure 33. The nozzles are changed with a certain probability, which can be set in the inputs. The other maintenance actions depend on the printers working hours. Respectively, the checks of the manufacturer have to be fulfilled once a year. At this activity no resources except the corresponding printer are needed. The repair action in red is triggered with a probability. At the start of each printing process a new evaluation is performed and hence the printers have to be repaired or not. This probability is defined with a learning curve, see more in Section 5.2.4.2.

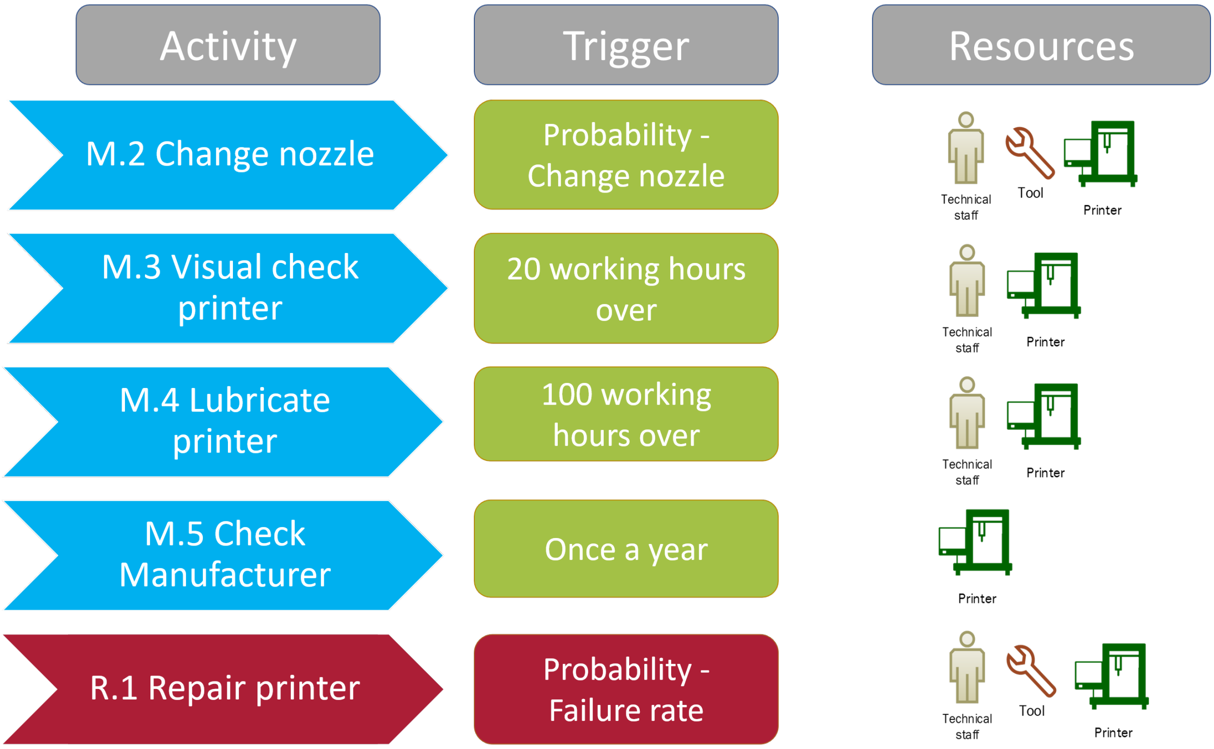


Figure 33: Support Processes along the Manufacturing Process

5.2.2.3 Specification of Simulated Scenarios for Verification

For the verification and a first evaluation of the 3DPC at POC, possible future scenarios of demand and therefore workloads for the process resources in the hospital are defined. These different courses of events should represent various demands and assess the impact on performance of various resources. With the simulation of these scenarios, an initial assessment of bottleneck behaviour and resource utilization under different circumstances is conducted. Due to the focus on anatomical models and implants, in all scenarios no demand of tools is included. The application of tools as medical devices is not yet deeply investigated. Still, due to flexibility reasons of the ST, they are inlcuded in the simulation model.

Following, the simulated scenarios for the verification and a first evaluation of the performance of the manufacturing of 3D printed medical devices in the 3DPC are specified in more detail.

Scenarios for verification

Verification 1 - One year scenario

For the verification of the simulation model, a low demand scenario is assumed. In this case the overall demand is 90 orders per year. To check the proper performance of the simulation model variations of different resources and the expected impacts, a verification of the simulation model are conducted. Hereby the demand, activity times and probabilities always stay the same, only the resource setup is changed. Therefore, the changes from these certain resources are encapsulated, and can be assessed due to their expected outcome.

Verification 2 - Five years scenario
With the second verification scenario, the proper reaction to demand growth of the model is examined. The initial demand is the same like in the first verification scenario but grows with 12% over time. This enables the assessment of the correct long term performance of the simulation. Additionally, a stress test for the simulation code due to the longer simulation durations is conducted. In the results, an increase in the workloads of the resources due to the higher demand of medical devices should be seen.

5.2.3 Key Performance Indicator Selection and Data Acquisition

For the evaluation of the above described system (see Figure 29) with different demand and different resource setup, meaningful and informative indicators to measure the performance of the 3DPC have to be chosen. This section focuses on the selection of KPIs to measure the operational, ecological, social, and economical performance of such a facility at POC. The selected KPIs have to be significant, informative and aligned with project's goals. Moreover, the process of data acquisition is briefly described.

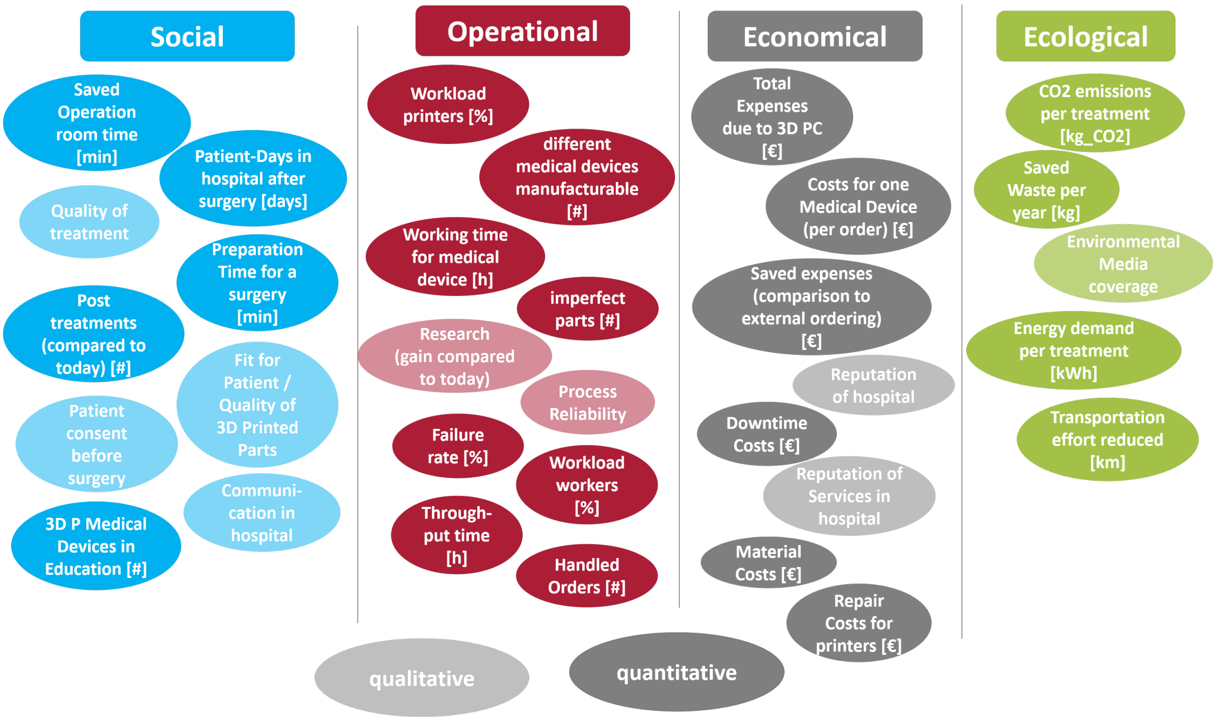


Figure 34: Drafted, classified KPIs for Performance Evaluation

5.2.3.1 Selection of Key Performance Indicators

The selection of KPIs for the ST of the 3DPC is based on the importance for the project's success and the ease of evaluability with the simulation or calculation. First, possible KPIs to evaluate the performance of the 3DPC are drafted and classified into four categories: social, operational, economical, and ecological. The formulated and categorized KPIs are shown in Figure 34. If it is a quantitative KPI, the units are displayed in square brackets. Afterwards, the mapped out KPIs are assessed in a matrix, see Figure 35. Together with the project owners, the set up key figures are rated due to their importance for the project's success. Furthermore, their evaluability with the ST is assessed. This resulted in the mentioned matrix with four sectors: "omit" / "include" / "estimate, simulate" / "calculate, simulate". Through limited operational project data and time resources

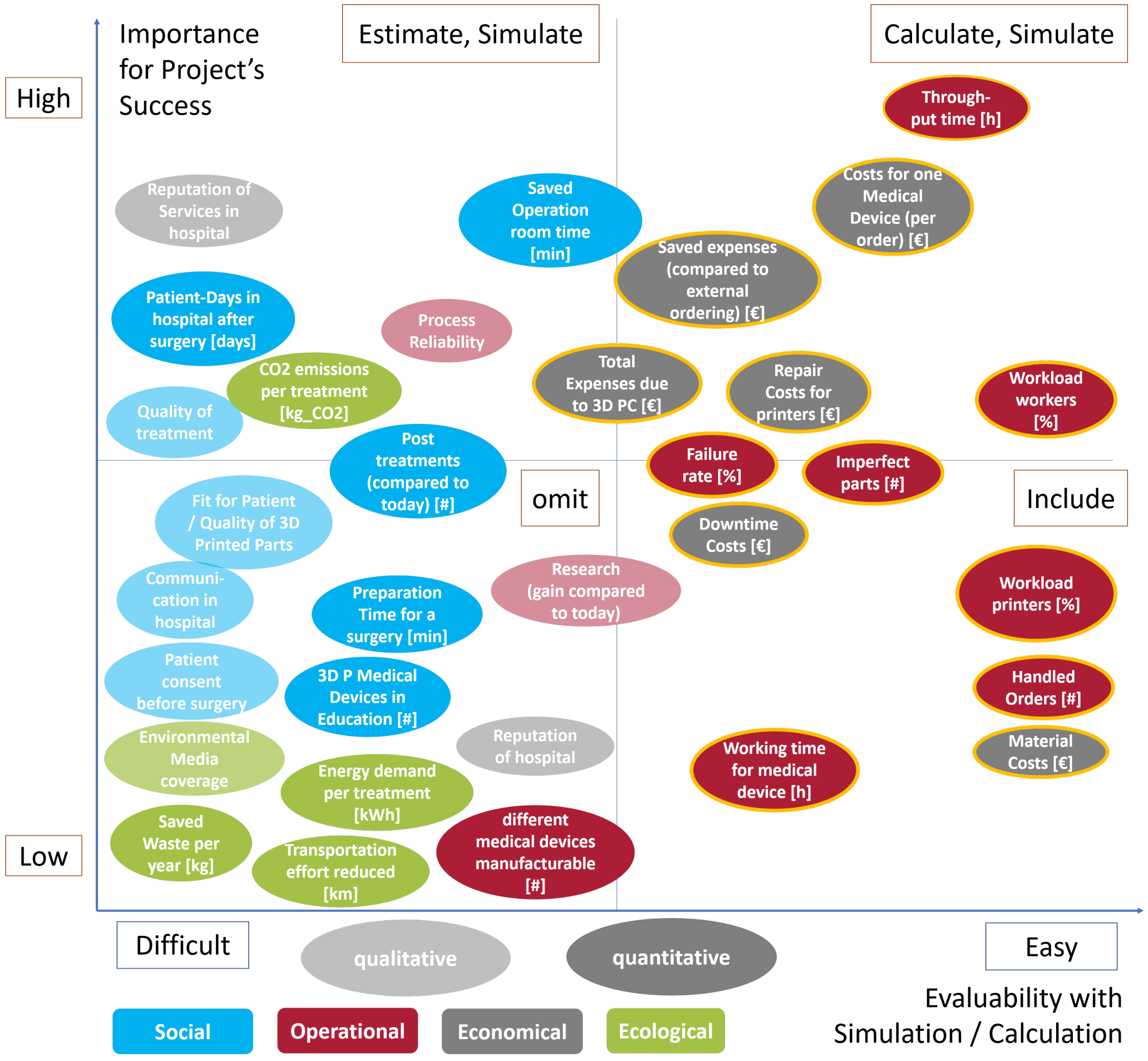


Figure 35: Selection of KPIs for Performance Evaluation

available, only KPIs that are important and easy to evaluate are chosen. They are in the upper and lower right sector - calculate, simulate and include and are highlighted with orange borders. Hence, the throughput time, which is highly important for project owners, is a key indicator. Moreover, the costs for the medical devices, the comparison to current ordering costs, different resource workloads, and the failure rates are included in the ST. Additionally, the working time, other costs, and the total amount of handled orders are evaluated.

5.2.3.2 Data Acquisition

The acquisition of data was mostly performed with interviews of domain experts participating in the CAMed project. Moreover, internet research and special academic literature were used to gather data for the ST. Due to the early research stage of the project, especially meaningful demand data was hardly available. Additionally, hospital executives were asked to estimate the need for anatomical models in the future, when surgeons use them to prepare for operations. The durations of the activities of the manufacturing process, described in Section 5.2.2.2, are obtained with time measurement of the manufacturing of completed orders in the existing research facility. Due to the fact that the sample was quite small this can be only seen as a first estimation. Hence duration times are not fixed values and can be changed easily. In addition, maintenance frequencies, printing build-up rates, and resource specification data were gathered in the research 3DPC. Furthermore, manufacturers of 3D printers were asked to estimate prices, build up rates, maintenance efforts and failure rates of different printers.

5.2.4 Model Definition

In this section the actual simulation model for the ST is introduced. Due to the processual structure of the manufacturing process (see Section 5.2.2.2) a Discrete Event Simulation, which is introduced in Section 4.4.3, is set up. To satisfy the need of high flexibility, all inputs can be changed in a graphical user interface. Moreover, the whole model was split into three parts, see Figure 36. The splitting has several advantages such as better failure handling within the simulation. Furthermore, one can use the exactly same input to test different resource setups. This makes comparability and input fitting to actual scenarios easier. Another reason for the split is the better data, output handling and a clear focus on operational KPIs in the operational simulation model.

The demand model takes inputs about the frequency and types of orders and generates a demand input file. This is a list of incoming orders where several scenarios, as shown in Section 5.2.2.3, can be represented. This input is processed in the operational simulation model, which is the simulation of the defined manufacturing process. In this part, the

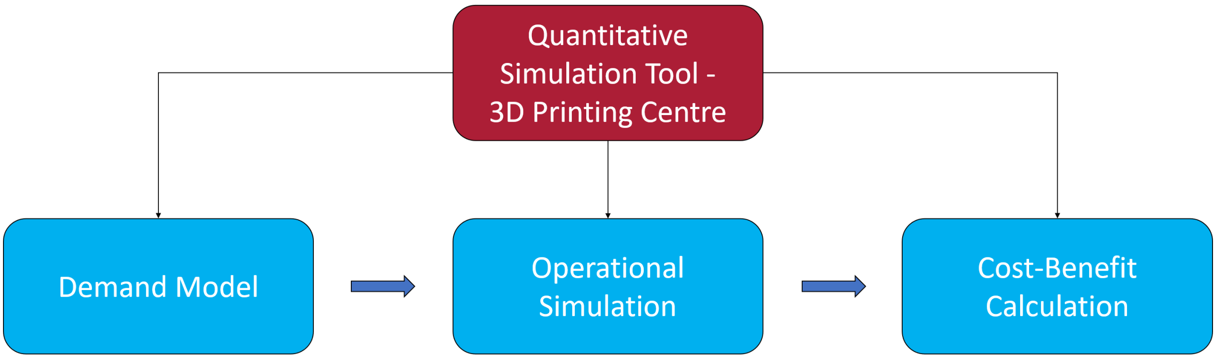


Figure 36: Overview of Simulation Tool

operational KPIs are evaluated. In the last step, the cost-benefit calculation, process data from the previous step are taken and the caused costs from manufacturing the medical devices are calculated. Furthermore, the generated benefits in form of saved expenses are computed. The modularisation into three parts leads to more transparency about the input parameters, traceability of errors, a better understanding of impacts of input variation and an overall enhancement of model flexibility.

In the subsequent sections, the demand model, the operational simulation model and the cost-benefit calculation are presented in more detail.

5.2.4.1 Demand Model

With the demand model, the user of the ST can generate different scenarios for demand of 3D printed medical devices within the hospital.

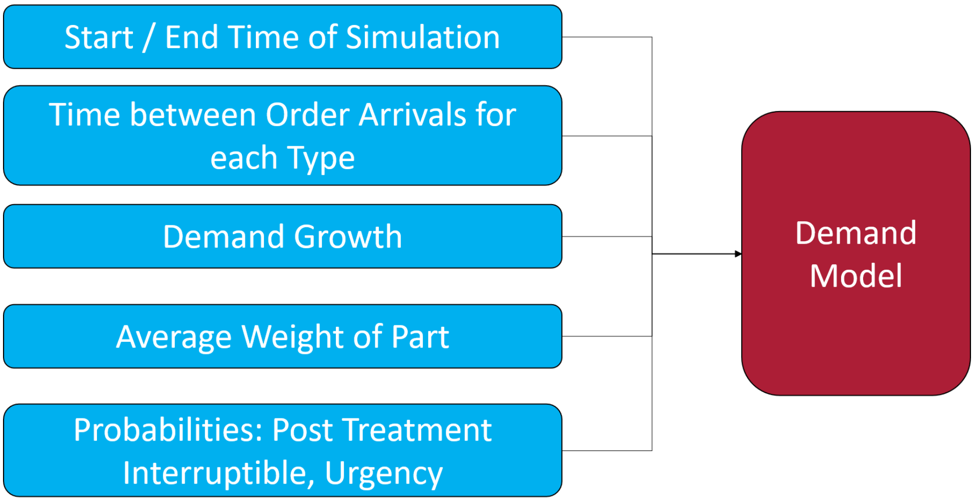


Figure 37: Input Parameters of the Demand Model

Inputs

The overall time for the generation of order requests has to be determined in the model. Before that, a pre-simulation time is included, due to the fact that when the simulation starts, orders should be already waiting for manufacturing, when the simulation starts. Moreover, the frequency of orders with the time between order arrivals (TBOA) has to be put for each type of medical device. This frequency can alter over time with a demand growth or decline, which can be set in percent per year, based on the inputs of TBOA given. All order types can be set to zero arrivals too. Additionally, the average weight of the different medical devices and probabilities about urgency, post treatment, and the interruptibility during the printing process have to be defined (see Figure 37).

Demand generation, model behaviour, sampling

The demand generation is based on the TBOA of different types. When generating an order, the arrival of the next of that type is calculated with the input of the TBOA and an exponential distribution. Therefore, the arrival of the next order can vary significantly to that one before. When assuming demand growth, the input average variable of the distribution sampler is decreasing - more orders arrive in average. This does not guarantee the immediate orders arrival in between shorter time spans, only the average input value of the exponential distribution declines. Additionally, the weight of the parts of the orders is sampled with a Gaussian distribution. According to the given average value input, the weight of the medical device in grams is calculated. The standard deviation of the distribution is 20%.

Assumptions, restrictions

Assumptions of the demand models are that orders arrive with the same probability on weekends and holidays. Moreover, no seasonal fluctuations and less order arrivals during night are considered. The urgencies are fixed over time and the same for each type of medical device. The same applies with respect to the probabilities of post treatment and interruptible. Even if it is to expect that implants have to be manufactured with higher importance, no differentiation in between the types is implemented.

Outputs

The demand model's output is a list of orders, which will arrive. Once a txt file for an overview is generated. The second output is a xml file, which is used in the operational simulation model consisting of the same orders. These output files are based on the given inputs explained before. As seen in Figure 38, an order is specified with the corresponding arrival time, type, weight, urgency, material, probabilities of post treatment, and interruptibility. Furthermore, each order has a related customer and ascending order number.

Materials are defined due to the type of the medical device. Anatomical models and tools are produced out of a standard non biocompatible polymer filament. For implants a biocompatible plastic is needed. In this case, the thermoplastic PEEK is used. It possesses excellent chemical resistance characteristics up to high temperatures.

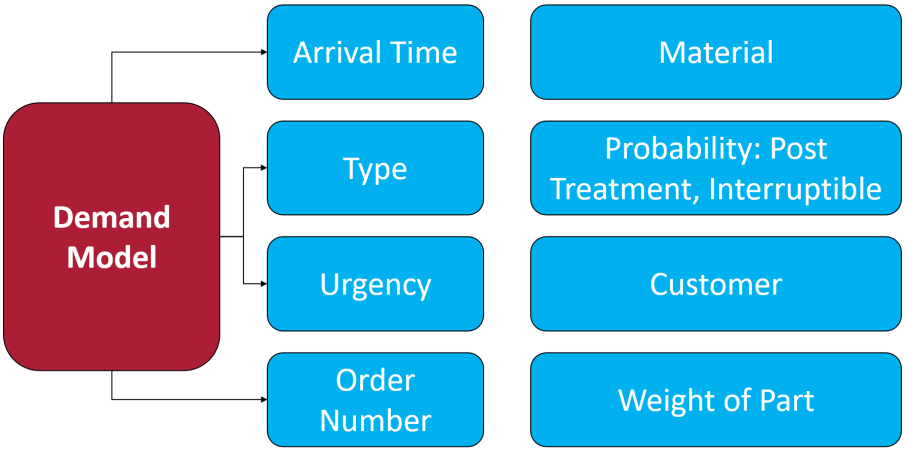


Figure 38: Output of the Demand Model

5.2.4.2 Operational Simulation Model

Taking the output of the demand model, the operational simulation model simulates and assesses the manufacturing process of a medical device. Introduced in Section 5.2.2.2, all activities are performed with their corresponding durations to evaluate the production of such parts. This model is developed based on an existing simulation model from Paal (2020). The whole simulation is based on the HCDESLib from Furian et al. (2014). It was initially developed based on the HCCM framework from Furian et al. (2015). Due to the processual manufacturing procedure, a DES was used. In this thesis, based on this existing basic simulation model many enhancements were implemented. The whole underlying manufacturing process was changed, learning behaviour, new inputs, maintenance, and repair actions were added. Furthermore, the input of the demand model and the output for the cost model were implemented. In this section, this enhanced operational simulation model is defined. This model can be used to assess the operational performance of the 3DPC and hence answer many questions for decision makers.

Inputs

As mentioned, one key input is the generated file from the demand model introduced in Section 5.2.4.1. Additional inputs for the operational simulation model are the activity durations for each activity, the number of staff members of each type and the amount of resources. Furthermore, the materials and their order behaviour have to be defined. Also the failure and decision probabilities in the ongoing manufacturing process need to be parametrized. Some of those values have a learning behaviour, which is described in Section 5.2.2.2 and Figure 41.

All the above mentioned inputs (see Figure 39) can be set by the user of the simulation model via the graphical user interface. Separate xml input files are used for the definition of the printers including printing build up rates, the amount of printers, and printable materials. Moreover, the computers with their installed licences and the materials have to determined in an separate file (see Figure 40).

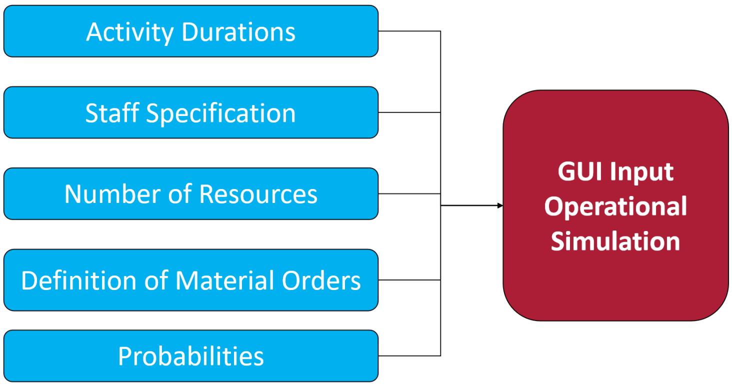


Figure 39: Input Parameters via Graphical User Interface of Simulation Model

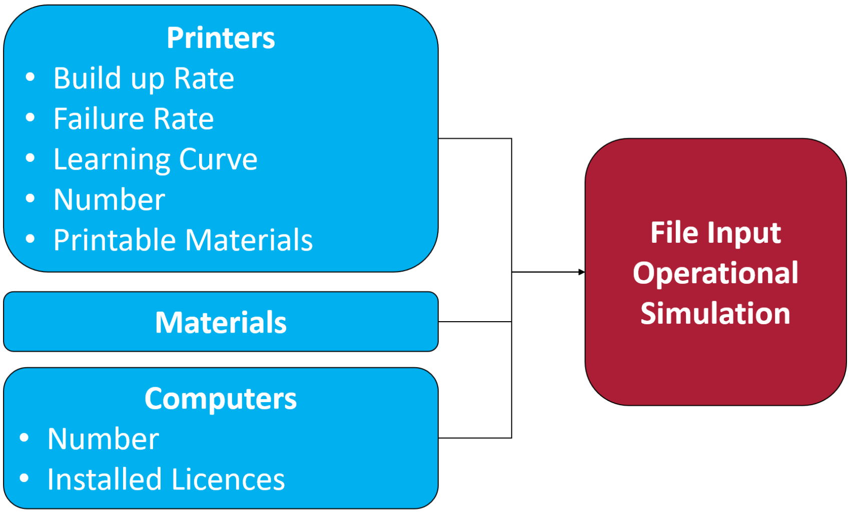


Figure 40: Input Parameters via Files of Simulation Model

Learning Curve

To represent reality accurately, learning processes over time are included in the simulation model. Especially in the three processes in Figure 41, performance enhancement can be expected. Therefore, this is modelled with learning curves in the related decisions of those processes. For this, two input variables for each learning probability are defined, the target value P_{Target} and the starting value P_{Start}. To model the progress of learning over time, the following formula is used:

$$P_t = P_{Target} - (P_{Target} - P_{Start}) * e^{\frac{-t}{100}}$$

The decay constant is set to 100 to have a proper curve. This indicates that the target value is reached within one year. The time t has to be set in days. After one year, the

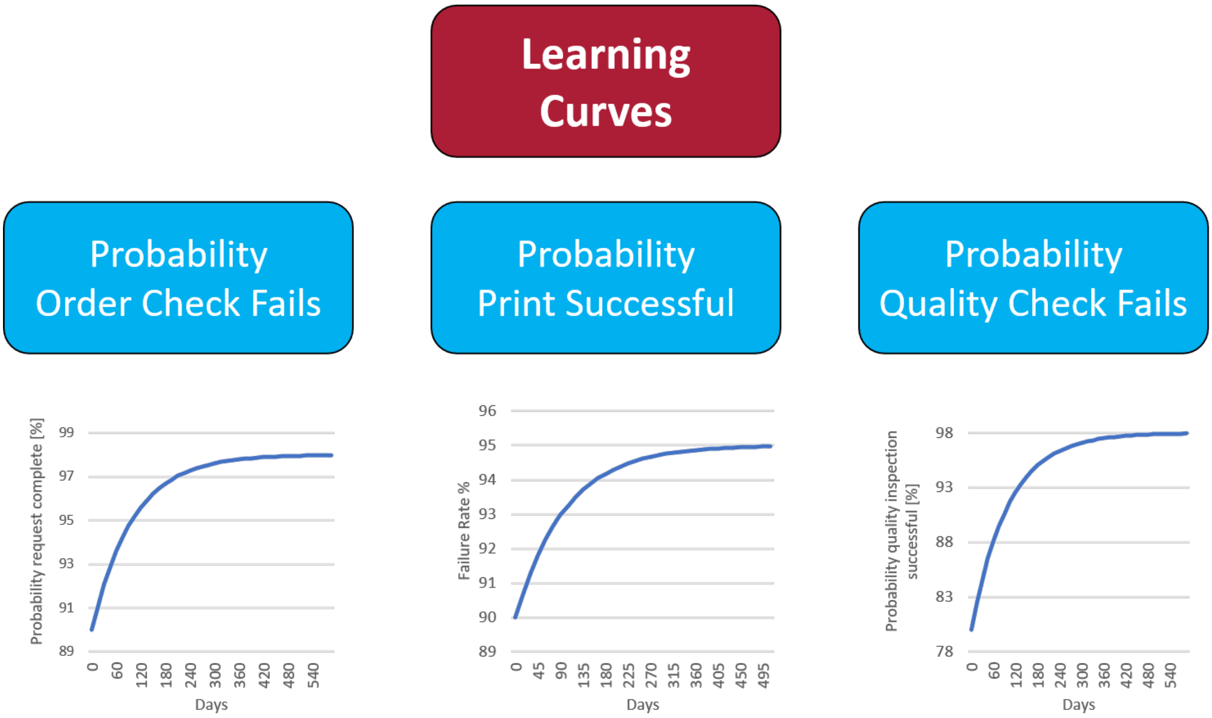


Figure 41: Learning Curves of Operational Simulation

target value is reached with a small deviation of 0,14 % due to the curve fitting. In a first estimation, the probability that the order request from customers is complete will increase from 90 to 95% over a year. The same is applied for probability of a successful printing process of a medical device. For the quality inspection, a steeper learning curve is estimated. The start value is 80%, which means that 20% of the parts are of bad quality and manufacturing has to be repeated. In one year this value is increased to 95% of proper quality. In all other processes, the set input value is constant over time, see Figure 41.

Sampling

With sampling, the duration of different activities is distributed in a certain way. In this simulation model for the segmenting activity a triangle distribution is used. This distribution is represented with three values the min, peak, and max value. This is chosen due to given process data from the research 3DPC. There is a wide range of possible and no clustering behaviour of duration spans of the segmenting activity, therefore this distribution fits best. Because of the poor data situation, a wide range of possible segmenting duration is chosen.

Another sampled activity duration is set for the modelling of the different medical devices. At this point, data shows the behaviour that some of the modelling activities take really long time and most of them can be executed in a certain shorter time. This is fitted with an exponential distribution, as shown in Figure 42. The average input value for the distribution is different for the segmenting and modelling activity of each medical device.

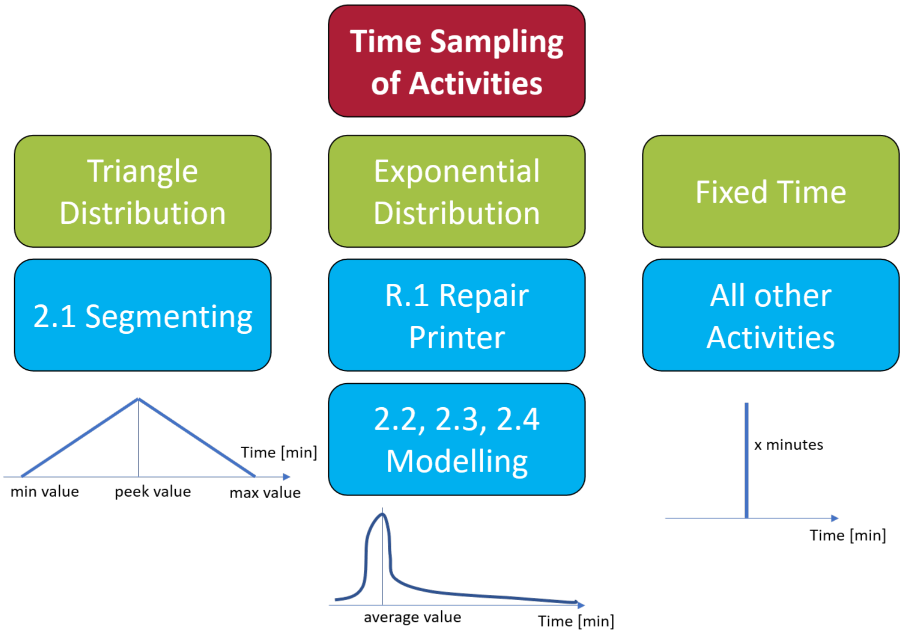


Figure 42: Sampling Distributions of Operational Simulation

This represents the distinct complexities of anatomical models, implants, and tools. All other activities are not sampled and modelled with a fixed time duration of the activity. The uncertainties of the execution of those activities are considered with probabilities of iterations throughout the whole manufacturing process. Moreover, the current lack of sound production times data under expected operational conditions makes a more exact determination unrewarding.

Assumptions, Restrictions

Assumptions of the operational simulation model, which are not considered in this approach, are discussed in this paragraph. An important assumption is that no vacations, sick leaves, breaks, or days off are included. Staff members can work overtime until they finish their activity. Furthermore, the build up rate is only based on the weight of the part and not separated by different complexities. One printer is only able to print several types of materials which are defined in the input sheet, there is no improvement of the printer's abilities to print materials. Moreover, printers are repaired by the technical staff, hence, there is never a waiting time for external support. This case is approximated with an exponential distribution of the printer repair activity. Further assumptions are that most activity durations are fixed, just the probability and not failures in printing or types of orders decide post treatment. Additionally, radiology technicians are always available within 30 min without sampling.

Major restrictions of the model besides the presented assumptions are the poor data situation of the activity durations. Especially segmenting and modelling processes are widely unknown in terms of complexity and hence their duration. Research shows that within years it could be possible to fully automate the extraction of a 3D model out of CT, MR images. This would significantly decrease the duration of those processes. Furthermore, maintenance actions are only evaluated in the research 3DPC and not in an operational real production environment. Printer failure behaviour is assessed with a small sample, the learning curve with information provided by 3D printer manufacturers. This makes this input factor to some extent vague. Due to the early stage of the project, all first assumptions are made rather conservative and cautious. Therefore, there could be potential for progress in performance of the 3DPC.

Outputs and Simulated Key Performance Indicators of the Operational Simulation

This paragraph describes the implemented calculation of different KPIs in the operational simulation model. As already explained in Section 5.2.3, KPIs are chosen to assess the performance of the manufacturing process accurately. In Table 5 all general and order related, simulated KPIs are shown with their units.

KPI	unit	KPI	unit
Total working time	h	Total simulation time	h
Total arrived orders per type	#	Total finished orders per type	#
Overall needed material GreenTecPro	g, units	Average weight per type	g
Overall needed material PEEK	g, units	Total not feasible orders	#
Needed material per month and type	g/month	Number material orders	#
Number of orders in process	#	Process data of not feasible orders	-
Number of printer repairs	#	Printer repair time	h
Number of printer maintenances	#	Maintenance time	h
Average working time per order	h	Average throughput time per order	h
Average throughput time per priority (urgent, normal, low)	h	Average throughput time per type (anatomical model, implant, tool)	h
Median throughput time per type (anatomical model, implant, tool)	h	Minimum throughput time per type (anatomical model, implant, tool)	h
Maximum throughput time per type (anatomical model, implant, tool)	h	Average throughput time per type, per year of simulation	h
Average working time per order, per type	h	Average waiting time per order, per type	h
Rejected orders within process requests, models, parts	#	Working time of each process (total, average, median, min, max)	min
Waiting times of each process (total, average, median, min, max)	min		

Table 5: Simulated KPIs (order performance) in Operational Simulation Model

Table 6 shows the simulated key performance indicators. It shows different indicators including their name, and unit. The specific output for each order is presented in Table 7. All KPI outputs are calculated automatically within the simulation and presented in a txt file after a simulation run. Moreover, it is possible to conduct an average calculation of the KPIs of a certain amount of simulation runs with the same input parameters. This reduces the statistical deviation of the KPIs due to the sampling of some input activity durations, see previous section. For this, a flexible data structure is needed and set up in the simulation model.

Resource	KPI	unit
Printer	Working hours	h
	Workload	%
	Busy hours (pre & post processes, repairs, maintenances included)	h
	Maintenance time	h
	Repair time	h
	Workload busy (pre & post processes, repairs, maintenances included)	%
	Downtime	%
	Workload per month	%/month
All other resources	Total working hours	h
	Workload	%
	Workload per month	%/month

Table 6: Simulated KPIs (resource performance) in Operational Simulation Model

KPI	unit/value	KPI	unit/value
Type	implant, anatomical model, tool	Weight	g
Urgency	low, normal, urgent	Customer	Surgeon xy
Material	PEEK, GreenTecPro	No. of computer model	no.....
No. of print job	no.....	No. of part	no.....
Printing time	h	Sterilisation	done, needed
Working time: radiology technician	h	Working time: technician	h
Working time: quality inspection	h	Sterilisation time	h
Total working time	h	Throughput time	h

Table 7: Simulated KPIs - Order Specific Output

5.2.4.3 Cost-Benefit Calculation

Following, the cost and benefit calculation is explained in more detail. It takes inputs from the previous described operational simulation model as well as additional input from the user and assesses the costs accordingly. With this approach, future scenarios with certain demand and resource setup can be evaluated with different cost and benefit developments. The major part of the calculation is the cost assessment. Due to the lack of specific information about the benefits gained from one medical device, a fixed benefit value for each type of order is assumed. This section presents the cost structure, inputs, the cost-benefit calculation approach, and the generated outputs.

Cost Structure

The general cost calculation approach of the 3DPC can be found in Figure 43. The identification of the cost elements is based on the TCO model (see Section 2.3.1).

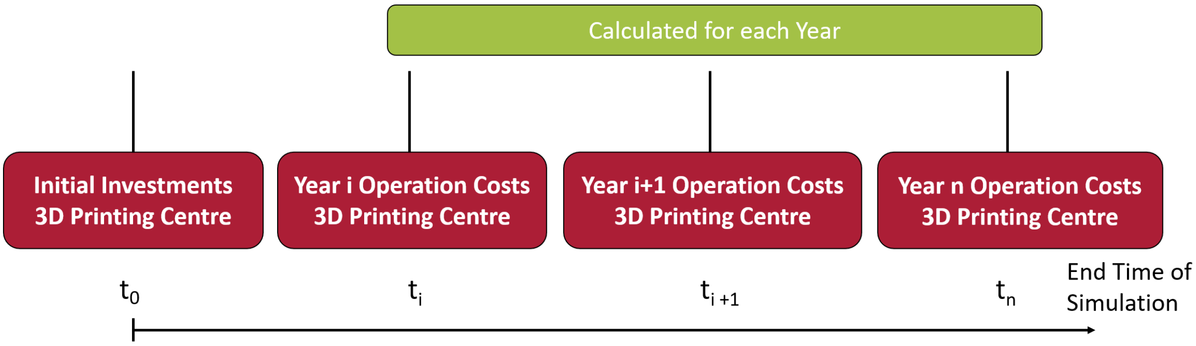


Figure 43: Approach for Cost Calculation

The calculation first takes all initial investments at t_0 and adds them up to the a certain amount of money which have to be invested to set up the 3DPC. All considered initial investments are shown in Figure 44. The calculation is based on the setup used in the operational simulation model. The quantity of resources is multiplied with their associated price. Moreover, room infrastructure, the establishment of the quality management of 3D printed medical devices and other quality inspection equipment are taken into account.

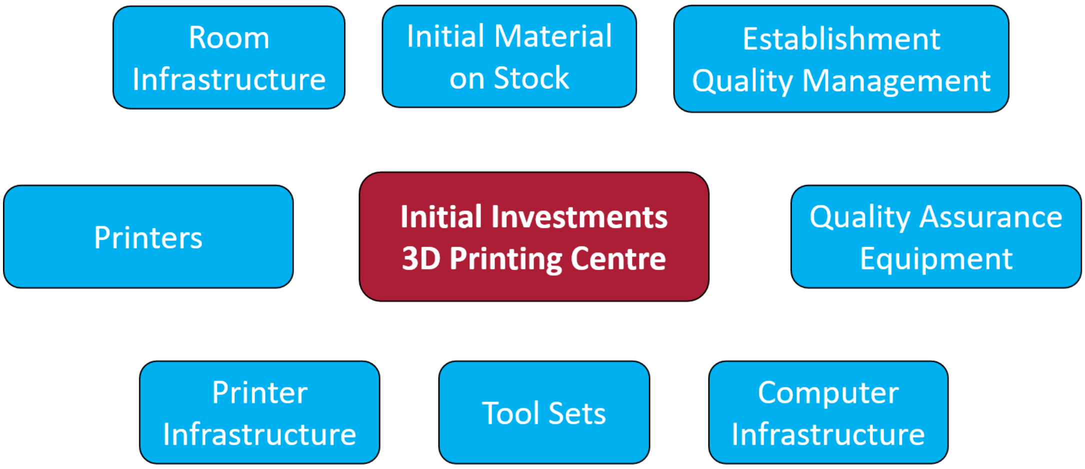


Figure 44: Initial Investments of 3DPC

Figure 45 shows an overview of the operational costs which occur over time and are summed up for each year, see Figure 43. A more detailed description of the calculation is shown in the *description of the calculation* paragraph.

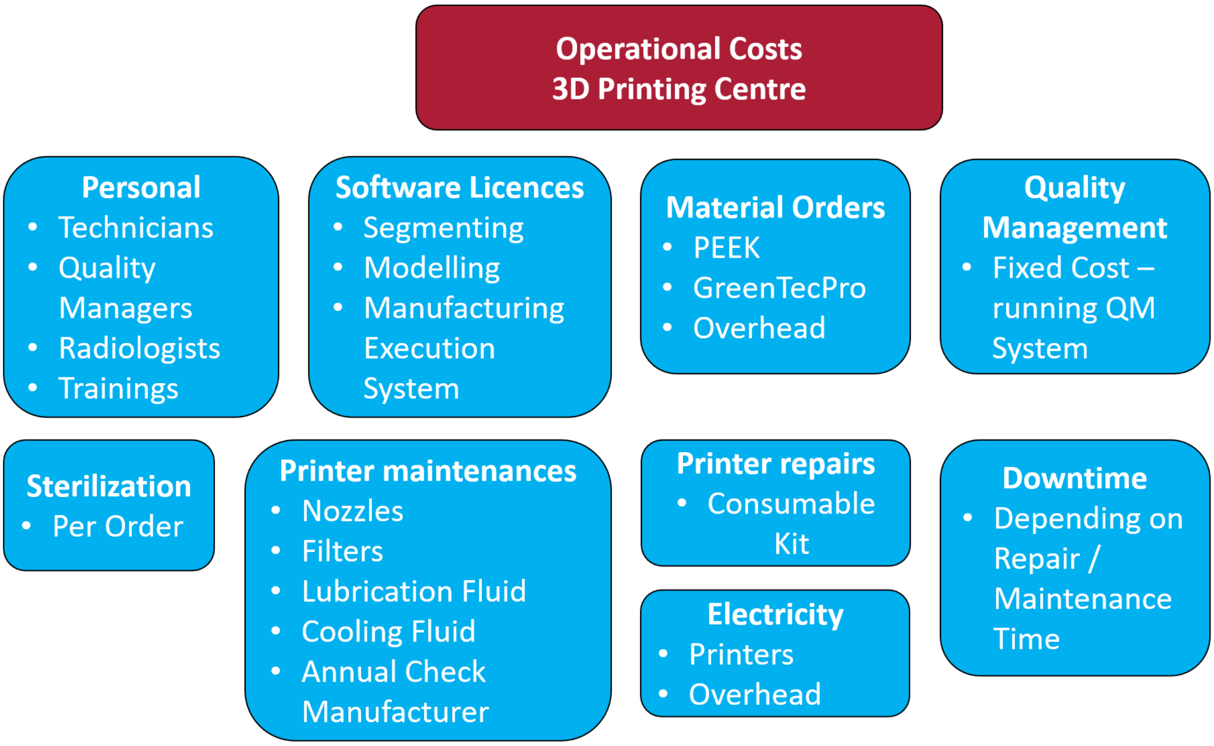


Figure 45: Operational Expenses of 3DPC

Benefit Structure

The benefits are calculated per finished order. It is assumed, that each order type has specific costs arising when a medical device is ordered externally. In the case of operating the 3DPC at POC by the hospital itself, these are the saved expenses, the benefit that is created with the establishment of an POC manufacturing facility. Therefore, the difference of caused costs per order of the 3DPC and the saved expenses due to not ordering externally is the profit of each order. The overall profit for one simulation run is equivalent to the the sum of all profits gained in this specific run. This is further on, one specific business case scenario with one demand, one resource and simulation setup, and a certain cost input. It is also important to mention, that benefits occur indirectly. For example, reduced operation times, less preparation for difficult operations, and fewer surgeries in general come up with the use of anatomical models. Due to the early stage of the project and lack of data available to assess such implications, these benefits are not taken into account. This leaves a lot of potential for additional benefits gained by the implementation and operation of a 3DPC.

Cost-Benefit Calculation - Input Variables

The calculation of the costs takes inputs from the user of the cost calculation application window and the cost report output file of the operational simulation model. In the following Figure 46, the inputs from the user interface are shown. Needed inputs are expenditures for staff and material, prices of the initial equipment, maintenance, and repair costs. Moreover, the associated benefits per type of the orders have to be defined.

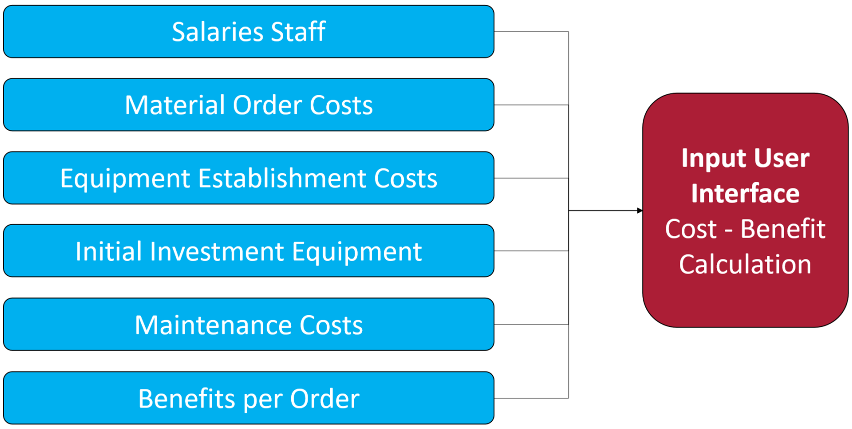


Figure 46: Inputs from the User Interface for Cost-Benefit Calculation

Other inputs are taken from one run of the operational simulation model. For one simulation run, an input file for the cost calculation of that specific case is generated. In that file, operational data which is needed for cost calculation, like finished orders in simulation time or the number of different resources are gathered. An overview about the inputs from the simulation model for the cost benefit calculation is shown in Figure 47.

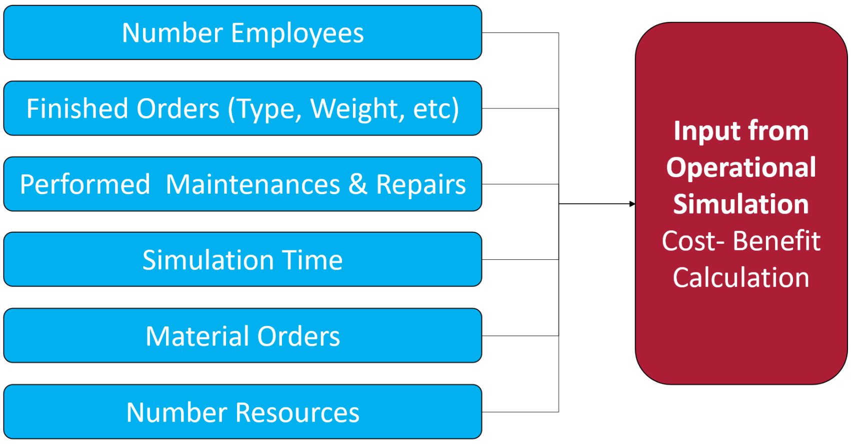


Figure 47: Inputs from the Operational Simulation for Cost-Benefit Calculation

Description of the Calculation

The calculation of costs and benefits of the 3DPC takes the previously described inputs from one run of the operational simulation model and user input to assess the manufacturing of medical devices on a monetary level. In the following, a general overview about the calculation is given, more detailed formulas and a description of the formula symbols can be found in Appendix A.

Cost calculation is divided into two parts. First, the initial expenses are calculated with summing up all needed equipment, the material on stock, and the establishment of a quality management infrastructure:

$$INI = INI_{Pr} + INI_{EstablPrEq} + INI_{ToolSets} + INI_{Computers} + \\ INI_{QAInfrastruc} + INI_{QM} + INI_{Room} + INI_{Mat}$$

Second, the operational costs occurring each year are calculated from staff, software licence, material, electricity, sterilisation, maintenance, repair, and downtime costs. In this case, the staff costs consist of the fixed costs for the quality manager technical staff. As both are working full time at the 3DPC, full salary has to be paid. The costs for the radiology technician are calculated variable, per hour of actual working time at the 3DPC.

$$C_{Total} = C_{Staff} + C_{Software} + C_{Mat} + C_{Elec} + C_{Ster} + C_{QM} + C_{Maint} + C_{Repair} + C_{Downtime}$$

These costs are assessed for a certain resource setup and demand of medical devices. Depending on the simulation time span, staff and software costs are summed up. These costs are considered as fixed, not being influenced by demand. Employees and software have to be available whenever needed. Therefore, the impact of these costs on the order profits is highly dependent on the overall processed orders. The hourly rate of a technician for example is calculated by the overall costs over the simulation time divided by the productive working hours:

$$hc_{Tec} = \frac{n_{Tec} * S_{Tec} * \frac{t_{Sim}}{365}}{wh_{tot_{Tec}}}$$

At this point, n_{Tec} is the number of technicians working in the 3DPC, S_{Tec} their yearly salary, t_{Sim} the simulation time in days and $wh_{tot_{Tec}}$ the overall productive working hours of all technicians manufacturing and processing medical devices.
Repeating this procedure to all resources and breaking down initially, software and other costs per order, production costs for each finished order can be calculated. For this purpose, the associated working hours are multiplied with the hourly rate and other costs for material, sterilisation, software, and the weighted initial costs are summed up accordingly.

$$C_{tot_{Order}} = wh_{Rad} * s_{Rad} + wh_{Tec} * hc_{Tec} + wh_{QM} * hc_{QM} + wh_{Pr} * (hc_{Pr} + c_{electr} * Power_{Pr} * \\ (1 + OH_{otherElectConsumpt})) + w_{Part} * c_{Mat} + c_{Steril} + c_{Software_{Order}} + c_{other_{Order}} + c_{weightedINI_{Order}}$$

Above, the $C_{tot_{Order}}$ refers to the total costs of the examined order. wh_{Rad}, wh_{QM}, and wh_{Tec} are the interrelated working hours of the radiology technician, quality manager and technician. s_{Rad}, hc_{QM}, and hc_{Tec} are their hourly rate or hourly salary. wh_{Pr} are the working hours of the printer corresponding to this order. hc_{Pr} is the hourly rate of the printer of the corresponding simulation run, depending on workload, repairs, maintenances and initial investment costs. c_{electr} are the costs of electricity per kilowatt-hour and $Power_{Pr}$ the power of the printer. The symbol $OH_{otherElectConsumpt}$ refers to the electricity overhead, which takes the consumption of electricity of other devices into account. w_{Part} is the weight of this part and c_{Mat} are the specific costs of the corresponding material. Other costs are: c_{Steril} specific costs for sterilisation, $c_{Software_{Order}}$ weighted software costs, $c_{weightedINI_{Order}}$ weighted initial investment costs, and $c_{other_{Order}}$ other costs. More detailed infos about the formation of the costs can be found in the Appendix A.

The benefits are calculated by adding up all related savings in respect to external ordering:

$$B_{tot} = \sum_{i=0}^{I} c_{ext_i} + \sum_{m=0}^{M} c_{ext_m} \sum_{t=0}^{T} c_{ext_t}$$

The indices refer to their type (i-implant, m-anatomical model, t-tool) of medical device produced in the 3DPC and c their related specific costs when ordered externally.

With both the total benefits and the total costs a net present value (NPV) of the implementation of the 3DPC at POC can be calculated. This is performed by summing up all, initial investments (negative), operational costs (negative), and benefits (positive) per year and discounting them to day zero:

$$NPV = -INI - \sum_{t=0}^{N} \frac{C_t}{(1 + i_{Calc})^t} + \sum_{t=0}^{N} \frac{B_t}{(1 + i_{Calc})^t}$$

With the NPV, different resource setups, demands, finished orders, and their benefits can be compared with a single monetary number. Therefore, the ideal resource setup with respect to other restrictions like required throughput time or limited staff availability can be calculated.

Outputs

Outputs of the cost-benefit calculation are summarized in Table 8.

Moreover, a cost-benefit and profit breakdown per order is executed within the calculation tool. In this case, each order's caused costs are broken down to different categories, which can be seen in Table 9. In this table, different cost categories and their dependencies on different cost factors and inputs are summed up. Finally, for each order the **total caused cost** in € and their **benefit** are shown. With these two accumulated figures, the overall **profit** of the **order** is calculated and presented for each finished order.

Output	Unit	Output	Unit
Initial Investment per Type	€	Total Initial Investment	€
Total yearly Operational Expenses per Category	€/year	Net Present Value	€
Total caused Costs	€	Total Benefits	€
Printer hourly Rates	€/h	Staff hourly Rates	€/h
Weighted keep QM running Costs	€/Order	Weighted Initial Investment Costs	€/Order
Weighted Software Licence Costs	€/Order	Average Order Costs per Staff Type	€/Order
Average Printer Costs	€/Order	Average Material Costs PEEK	€/Order
Average Material Costs GreenTecPro	€/Order	Total Order Costs (average, median, min, max)	€
Total yearly Benefits	€/year		

Table 8: General Outputs - Cost-Benefit Calculation

Cost Category	Dependent upon	Unit
Printer	Printer hourly Rate, Working hours, Workload	€
Radiology Technician	Radiology Technician - hourly Rate, Working Hours	€
Technician	Technician hourly Rate, Working hours, Workload	€
Material	Weight Part, Printer Failures, Material Type-Costs	€
Sterilisation	If needed, Price Sterilisation	€
Software	Resource Setup, Workload	€
Weighted Initial Investment	Resource Setup, Utilization, Workload, Simulation Time	€
Keep running QM	Workloads, Resource Utilization	€

Table 9: General Outputs - Cost-Benefit Calculation

5.2.5 Model Execution

This section describes the actual model execution in more detail. The structure of the simulation, including the different input windows for user interaction in the ST, is presented. For better failure handling and several other reasons, the whole simulation is divided into three parts, like explained in Section 5.2.4. Furthermore, used libraries and execution specific points are shown.

The execution of the simulation model as shown in the previous section is performed in C#. Therefore, an already existing code from Paal (2020), based on the HCDESLib from Furian et al. (2014), was enhanced on many different levels. Following, the execution of the three parts of the ST, as explained in the previous section, are presented.

5.2.5.1 Demand Model

The demand model generates the demand of 3D printed medical devices for a certain time span. The user interface (see Figure 49) allows a simple configuration of the demand properties. All different types of orders can be excluded and all input parameters, as explained in Section 5.2.4.1, are variable.

The demand model uses a discrete event like order generation. Depending on the config-

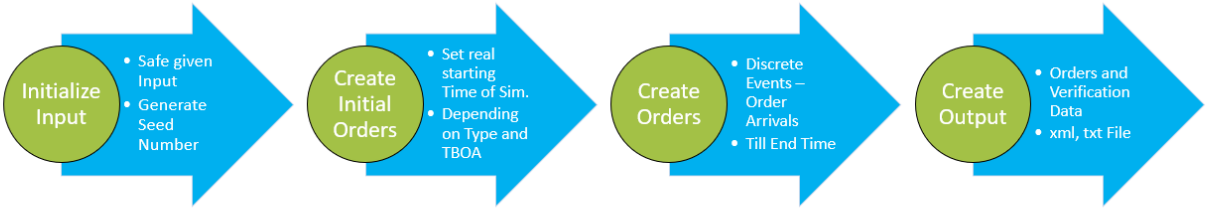
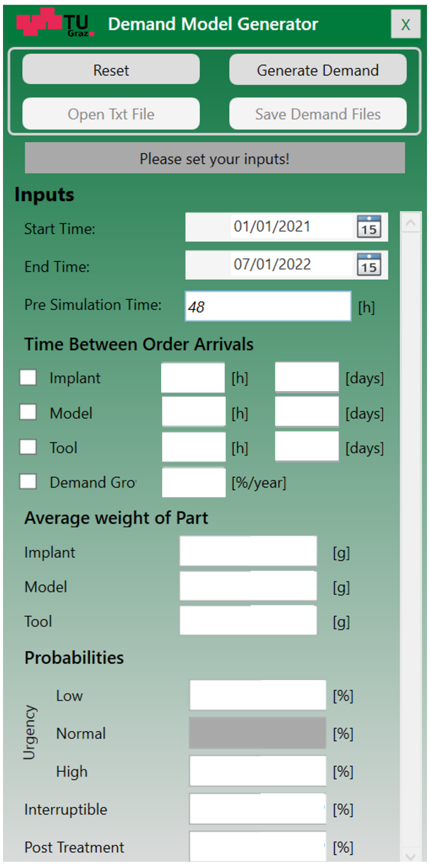


Figure 48: Execution Sequence of Demand Model

ured order parameters, initially orders of the selected types are generated. Then the time moves on and as the time of the initially generated order is reached, this order arrives in the model. Moreover, the next order depending on the time between order arrivals of that specific type is generated at the exact same time. All orders are collected within a list. For a better overview about the concrete output and model verification, different output parameters are calculated. This includes a summary of the created orders per type, a monthly timeline of orders created to check the demand growth. Moreover, the used seed number for sampling is exported. This number is calculated with the hash code of several input data and the second of the actual demand generation. Figure 48 shows the progression of commands and methods when generating a new demand.



Please set your inputs!

Start Time: 01/01/2021

End Time: 07/01/2022

Pre Simulation Time: 48 [h]

Figure 49: Graphical User Interface of the Demand Model

5.2.5.2 Operational Simulation Model

The operational simulation model is the heart of the ST. The manufacturing process is represented in a discrete event simulation based on a library from Furian et al. (2014). At this point, the whole model intelligence is collected in the control unit, see also Section 4.3.2. In this class, the rules for the accomplishment of the manufacturing process are set. Based on the implemented execution rules and free resources available, activities are started. Following, the command structure of the triggering order is explained. The hierarchy is inherent to the simulation model and a key part of the real world representation. First, maintenance, repairs, and material orders are conducted, if necessary. With this functionality of printers and availability of material are ensured. Second, activities needing the printer are triggered. These are pre- and post-printing activities like creating the print job, checking, and cleaning the printer. This is done for all order urgencies. Third, activities which start the actual printing process are triggered. The control unit checks, if orders are waiting for the printing activity, and if a suitable printer is available and hence triggers this activity. If an urgent order is waiting, a running printing activity can be interrupted and the urgent part is printed first. Then activities to finish waiting urgent orders are triggered. At this point, the hierarchy within the process is to finish orders first. Moreover, the dispatch principle first orders in first orders out (FIFO) is executed. Fifth, normal urgency and sixth low urgency orders are handled according to the same principle. This activity dispatching hierarchy can be seen in Figure 50. Both, the dispatching structure and information are determined in the simulation model code and cannot be changed by the user.

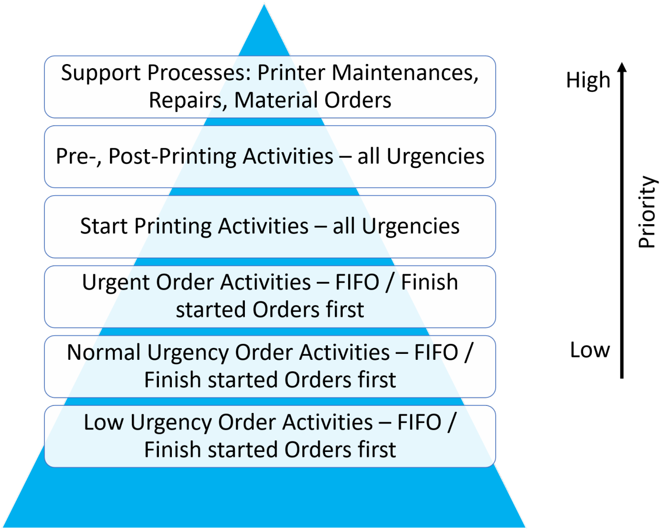
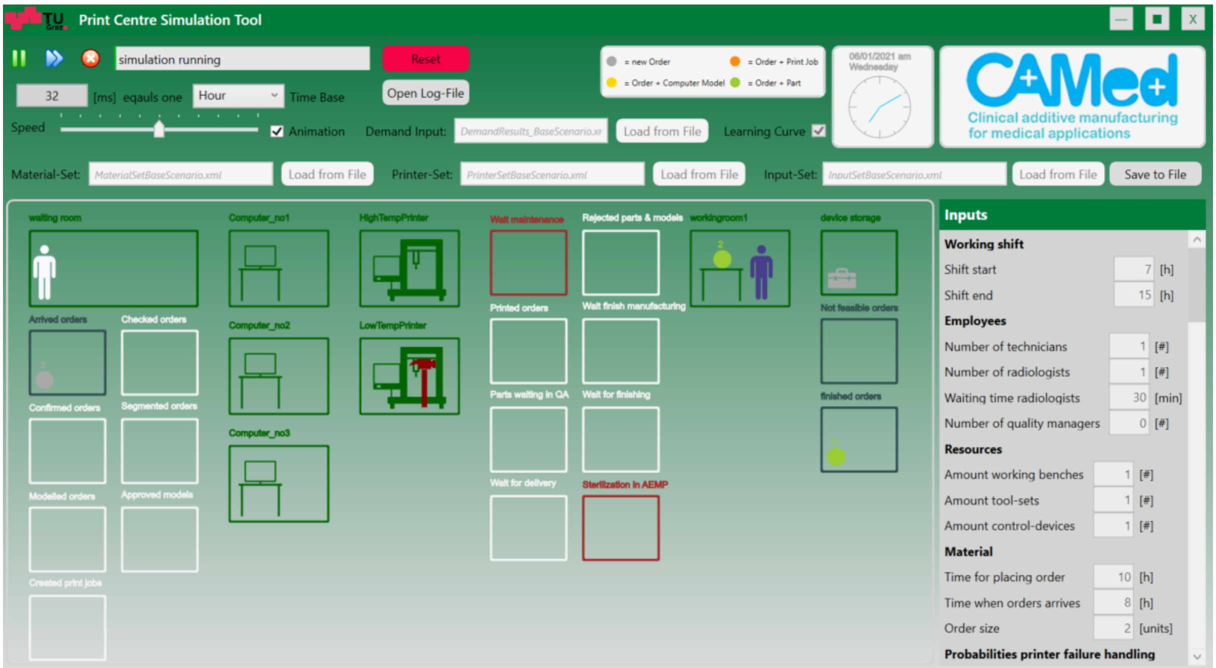


Figure 50: Hierarchy of Order Processing in Operational Simulation Model

The inputs for the operational simulation can be set within the graphical user interface, see Figure 51. Activity durations, working shifts, amount of resources and the probability of decisions can be specified on the right hand side of the user interface. These inputs can be set by users, saved and reused at other simulation runs. Other inputs, like the demand file from the previously described demand model, the specification of printers and computers can be set with extra files.



simulation running

32 [ms] eqauls one Hour Time Base

☑ Animation

Demand Input: DemandResults_BaseScenario.xr

Learning Curve ☑

06/01/2021 am
Wednesday

Material-Set: MaterialSetBaseScenario.xml

Printer-Set: PrinterSetBaseScenario.xml

Input-Set: InputSetBaseScenario.xml

Inputs

Working shift

Shift start	7	[h]
Shift end	15	[h]
Employees		
Number of technicians	1	[#]
Number of radiologists	1	[#]
Waiting time radiologists	30	[min]
Number of quality managers	0	[#]
Resources		
Amount working benches	1	[#]
Amount tool-sets	1	[#]
Amount control-devices	1	[#]
Material		
Time for placing order	10	[h]
Time when orders arrives	8	[h]
Order size	2	[units]

Probabilities printer failure handling

Figure 51: Graphical User Interface of the Operational Simulation Model

Generally speaking, activity and request classes inherit from the mentioned HCDESlib and are numbered according to the introduced process described in Section 5.2.2.2. Three output files are generated: the operational result file, the cost-benefit calculation input file and a logger, which is a summary of all the handled events during the simulation. Furthermore, an experiment manager, where a set of simulation runs with the same inputs can be executed, is implemented. This gives the opportunity to average results of different simulation runs and eliminate statistical deviations in the output. Therefore, all executed simulation runs are saved and an additional output file, with the averages of the presented KPIs (Section 5.2.3), is generated. For statistical reasons, more than 100 simulation runs get to be averaged to have a viable result.

Within the interaction screen, see Figure 51, at the left lower part of the window, the manufacturing process, resource utilization, and other activities can be followed. This visualization enables a vivid demonstration of waiting times, bottleneck behaviour and a general explanation of the modelled manufacturing process for project stakeholders.

5.2.5.3 Cost-Benefit Calculator

The cost-benefit calculator computes the presented outputs of Section 5.2.5.2. Therefore, it uses one input file from the operational simulation model and given data from the user interface, see Figure 53. Due to this, various price structures of the same operation input can be analysed and interpreted. The succession of the calculation process can be seen in Figure 52. To calculate the costs and benefits of one demand scenario and resource setup of the 3DPC first the program initializes the inputs from the operational simulation and the cost-benefit inputs from the GUI. Second, the initial investments depending on the given inputs are calculated. Then the running operational costs are summed up and the order and resource allocated costs are computed. Fourth, the benefits are calculated corresponding to the order type and time when the order is finished. Finally, all data is gathered to provide a comprehensive output file in txt format for further analysis. To compare different scenarios, costs and benefits per year are broken down per year and the net present value of this calculation instance is presented.

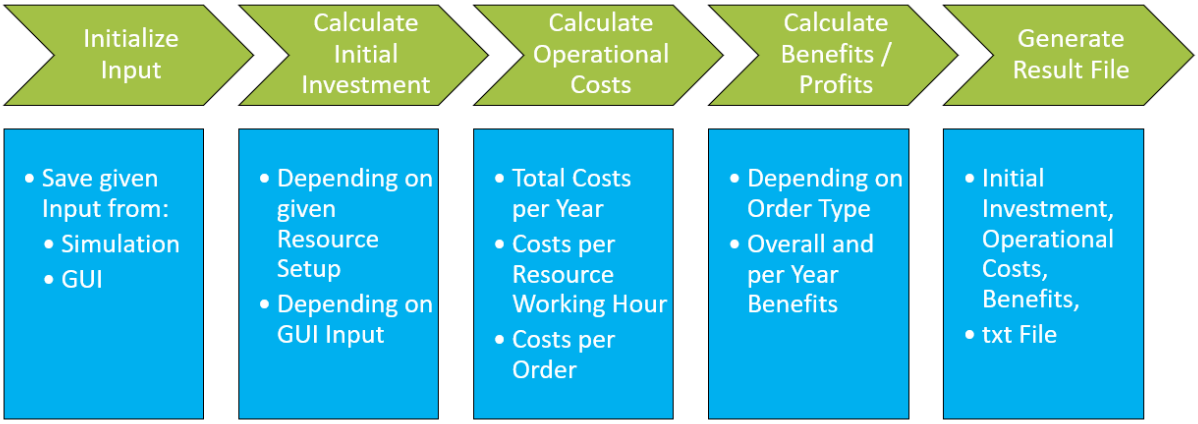


Figure 52: Processual Sequence of Cost-Benefit Calculation

The graphical user interface of the cost-benefit calculator is shown in Figure 53. All relevant cost factors can be set by the user of the ST to assess different setups. Current standard inputs are discussed with stakeholders to have a base cost and benefit input for analysing costs of different future demand scenarios.

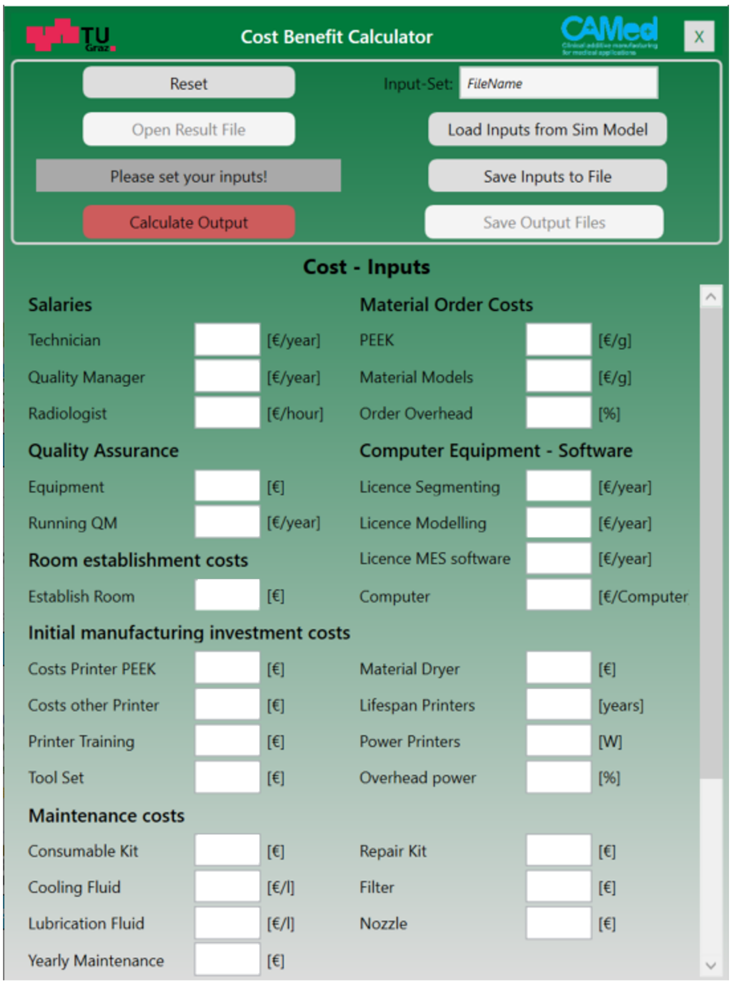


Figure 53: Graphical User Interface of the Cost-Benefit Calculation

5.2.6 Result Analysis

In this section, results of the verification scenarios (see Section 5.2.2.3) and the validation of this ST are shown. Moreover, first results of the cost-benefit calculation are outlined. Due to the fact that the cost and benefit inputs are not validated yet, only a first estimation about the impacts and magnitude of several cost factors can be presented. More results of the presented ST are planned to be published in a paper. Further validation and evaluation of other scenarios will be conducted as well within the CAMed project in an ongoing work.

5.2.6.1 Verification

In this section the verification of the whole simulation model is conducted. The demand model is verified by checking if different inputs lead to varying amount of orders generated. This was checked within the model execution process and not further outlined here. Furthermore, the verification of the cost-benefit calculation was executed in the same way, during the development process. Both verification steps showed a proper reaction of the developed model to changes in the inputs. Hence, the verification of these two modules of the simulation tool can be seen as successful. Subsequently the verification of the operational simulation model is outlined in more detail, due to the more sophisticated approach.

In order to verify the operational simulation model, scenarios with different demand inputs are generated and tested with specified resource setups, see Section 5.2.2.3. All scenarios are repeated 200 times and averaged to avoid statistical deviations. Each verification test-run has a certain demand file. Therefore, the demand for all verification 1 and all verification 2 scenarios is constant, only resources are changed within the different variations. An overview of the first verification scenarios is shown in Table 10. The initial assessment is that no tools in the first place and two times more anatomical models than tools are required. With this demand, resource variations are performed and evaluated to verify the operational simulation. Moreover, a 5 year scenario to test the model under increasing demand was performed, see Table 15. With this the proper reaction to increasing demand, changing resources of the simulation model was tested and thus verified. Following, the verification procedure is explained more precisely. Due to space problems in the tables the term ”models” always stands for anatomical models in this section.

Scenario Verification 1 - One year

Table 10 shows the different resource scenarios to test the operational simulation model. In each scenario, the same demand was assumed, only the resource setup is changed. Different increases in working time (two, three shifts), additional printers, or staff were examined for the verification. Finally, the model behaviour with no radiology technician as a setup was tested. With this setup, no finished orders due to the need of the radiology technician for certain activities are expected.

Demand Input Scenario	Name	Repli-cations	Resource Scenario	Arrived Orders Type Model	Arrived Orders Type Implant
base	1.1	200	base resources, no learning curve	67	35
base	1.2	200	base resources, with learning curve	67	35
base	1.3	200	Two Shifts, with learning curve	67	35
base	1.4	200	double staff, with learning curve	67	35
base	1.5	200	double printers, with learning curve	67	35
base	1.6	200	double resources, with learning curve	67	35
base	1.7	200	double equipment, single staff, three shifts, with learning curve	67	35
base	1.8	200	base resources, no radiology technician	67	35

Table 10: Verification 1 - Definition of Scenarios

Table 11 shows order related results of the different simulation runs. With the current resource setup all orders can be finished even with base resources. As expected, results show a decrease in throughput time due to the learning curve. Average working time is constant and not changing with different resource setups. Only waiting and throughput time decreases especially with longer working time (two, three shifts) of the staff. Additionally, in the last 1.8 scenario, with no radiology technician, no orders can be finished, which leads to a throughput time of infinity. In Figure 54, the reduction of throughput time with added resources can be seen in a box plot.

Scenario Name	avg finished orders model [#]	avg finished orders implant [#]	avg throughput time model [h]	avg throughput time implant [h]	avg working time model [h]	avg working time implant [h]	avg waiting time model [h]	avg waiting time implant [h]
1.1	64,81	34,48	99,5	129,84	35,59	61,81	63,91	68,03
1.2	64,88	34,38	86,61	114,48	31,38	57,26	55,23	57,23
1.3	64,94	34,51	58,34	88,25	31,41	57,11	26,93	31,13
1.4	64,84	34,52	80,41	100,8	31,49	57,38	48,92	43,42
1.5	64,9	34,4	83,36	110,92	31,3	57,36	52,07	53,56
1.6	64,88	34,5	75,99	95,64	31,29	56,94	44,7	38,7
1.7	64,83	34,44	47,31	75,02	31,36	57,5	15,94	17,52
1.8	0	0	∞	∞	∞	∞	∞	∞

Table 11: Verification 1 - Order Output Information

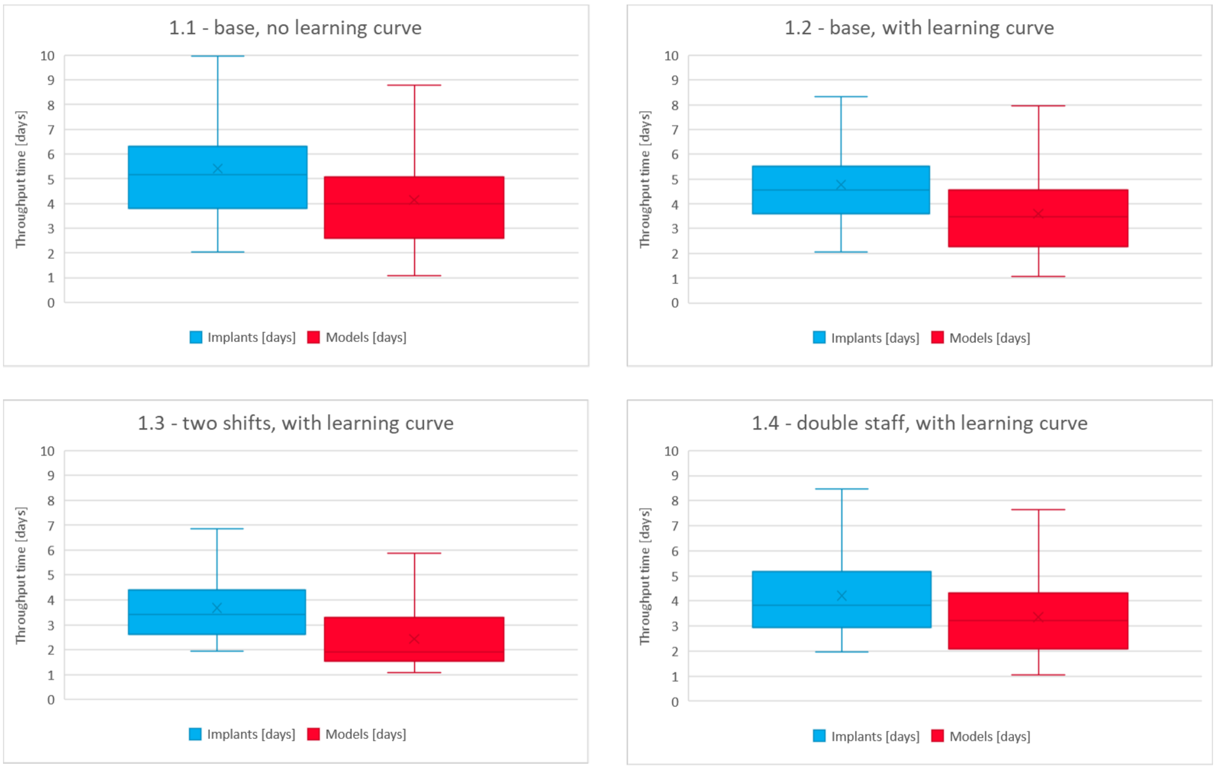


Figure 54: Verification 1 - Throughput Times of different Resource Setups

Table 12 shows the workloads of the different resource types of the 3DPC. One can see that the learning curve reduces the workload of all entities. This is caused by the more efficient manufacturing process with less repairs and iterations after the organisational learning in one year, as stated in Section 5.2.4.2. Furthermore, adding one resource and adding shifts leads to lower workloads, which is also a predicted output of the simulation model. The general changes in workloads with different setups can be seen in Figure 55. When more than one resources per type is present, only the resource with the highest workload is shown. Due to the succeeding assignment of the computers and the use with staff members, more than two computers are only used in scenarios where more staff is added. Apart from that, the no radiology technician scenario (1.8) shows the correct performance of the simulation model. Through the upstream needed processes of segmenting and modelling which cannot be carried out without radiology technician, the orders stuck in that processes. Hence, orders never reach the printers and their workloads are zero.

Scenario Name	printer high temp	printer low temp	technician	radiology technician	computer 1	computer 2	computer 3	tool	working room	Control Device
1.1	9,96	17,14	27,47	32,24	47,7	5,03	0	4,97	10,56	5,86
1.2	8,57	14,67	24,04	30,81	44,78	4,2	0	4,04	9,09	5,03
1.3	8,53	14,73	12,1	15,39	23,27	1,27	0	2,04	4,56	2,52
1.4	8,63	14,71	18,89 / 5,27	26,03 / 4,92	37,68	10,11	1,45	4,05	9,12	5,05
1.5	8,01/0,61	13,44/1,2	24,08	30,7	44,71	4,21	0	4,07	9,1	5,03
1.6	7,53/0,95	12,69/1,94	18,28/5,66	25,94/4,81	37,55	10	1,25/0,11	3,57/0,43	8,1/0,98	4,47/0,56
1.7	7,87/0,79	13,34/1,31	8,04	10,28	15,71	0,65	0	1,35/0	3,03/0	1,68/0
1.8	0	0	5,11	-	5,11	0	0	0	0	0

Table 12: Verification 1 - Workload of Resources [%]

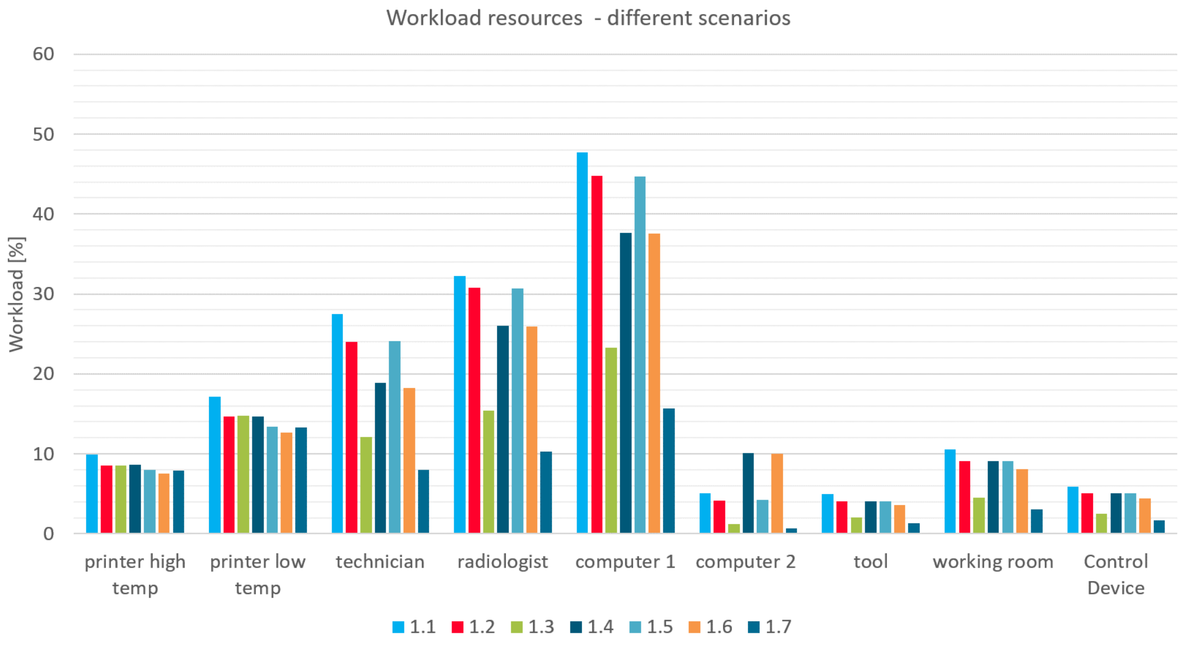


Figure 55: Verification 1 - Workloads [%] of different Resource Setups

The below Tables 13 and 14 show the defined KPIs and differences in throughput time with different resources. Results demonstrate that the lowest throughput time can be reached with three shifts. Due to the fact that staff members can perform activities 24 hours on working days, orders can be finished faster. Additionally, the proper activity triggering, see Section 5.2.5.2, is shown. Urgent orders are processed faster than others. This can be seen in Figure 56, where the difference in throughput times of implants and models with different urgencies is shown.

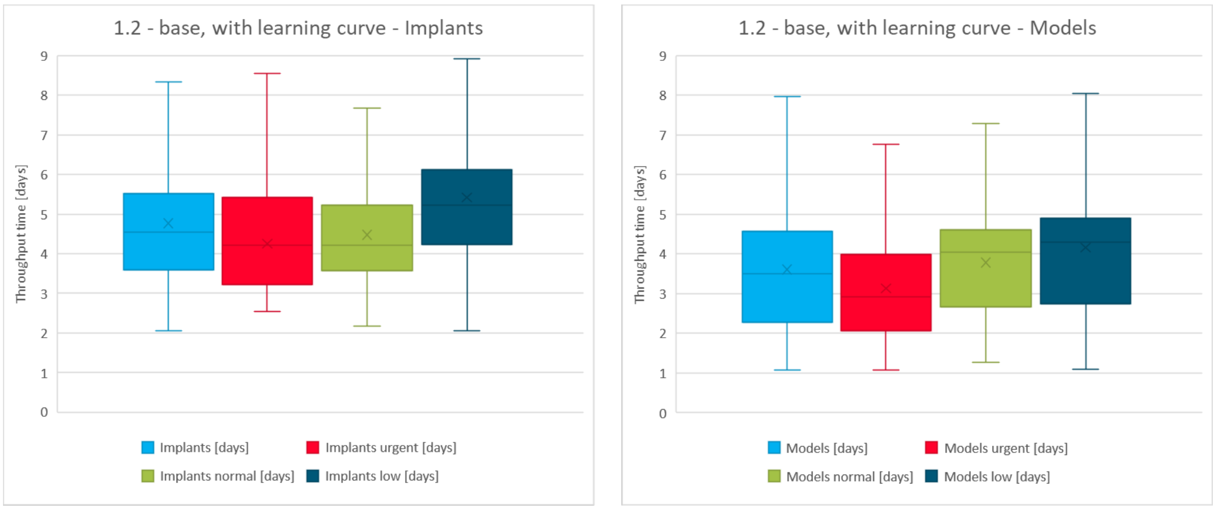


Figure 56: Verification 1 - Throughput Times with different Urgencies

	Throughput time - all orders				Throughput time - per urgency		
Scenario Name	average	median	min	max	median-urgent	median-normal	median-low
1.1	4,15	3,99	1,09	21,62	3,21	4,29	4,51
1.2	3,61	3,49	1,07	24,5	2,92	4,04	4,3
1.3	3,68	3,41	1,94	20,19	3,22	3,08	4,14
1.4	3,35	3,22	1,05	13,66	2,72	3,59	3,73
1.5	3,47	3,41	1,09	12,56	2,87	3,9	4,08
1.6	3,17	2,91	1,07	14,47	2,57	3,3	3,45
1.7	1,97	1,47	1,05	7,52	1,49	1,35	1,54
1.8	-	-	-	-	-	-	-

Table 13: Verification 1 - Model Throughput Times

Scenario: Verification 2 - Five years

In the second demand scenario for the verification of the operational simulation model, the behaviour of the model under increased number of orders is tested. Table 15 shows the general inputs. At this point, only changes in the working shifts are simulated for verification. With adding shifts the average waiting time can be decreased (see Table 16). Moreover, the workloads go down due to longer working hours of the resources. This shows faultless calculation of these KPIs.

The following Table 17 shows the workloads of the resources as an average of the 5 years simulation period. Due to increasing demand, a rise in the workload of the resources can

	Throughput time - all orders				Throughput time - per urgency		
Scenario Name	average	median	min	max	median-urgent	median-normal	median-low
1.1	5,41	5,18	2,06	27,21	4,31	4,62	5,55
1.2	4,77	4,55	2,06	27,23	4,22	4,22	5,23
1.3	2,43	1,92	1,08	12,5	1,88	1,88	2,64
1.4	4,2	3,83	1,97	24,34	3,78	3,55	4,46
1.5	4,62	4,41	2,06	27,28	3,84	3,87	5,22
1.6	3,98	3,74	1,96	20,18	3,77	3,32	4,22
1.7	3,13	2,7	1,93	24,11	2,78	2,36	3,38
1.8	-	-	-	-	-	-	-

Table 14: Verification 1 - Implant Throughput Times

Demand Input Scenario	Scenario Name	Replications	Resource Scenario	Arrived Orders Type Model	Arrived Orders Type Implant
5 year	2.1	200	base resources, with learning curve	389	213
5 year	2.2	200	two shifts, with learning curve	389	213
5 year	2.3	200	three shifts with learning curve	389	213

Table 15: Verification 2 - Definition of Scenarios

Scenario Name	avg finished orders model [#]	avg finished orders implant [#]	avg throughput time model [h]	avg throughput time implant [h]	avg working time model [h]	avg working time implant [h]	avg waiting time model [h]	avg waiting time implant [h]
2.1	381,05	209,78	152,82	109,46	42,47	53,34	110,34	56,11
2.2	381,98	209,76	96,59	84,16	42,48	53,45	54,12	30,71
2.3	381,86	209,42	80,16	72,19	42,49	53,41	37,67	18,77

Table 16: Verification 2 - Order Overview

be expected. This is shown in Figure 57. The solid lines represent the trend-line of the workload, which has a positive slope for every resource. Hence, the previously mentioned assumption can be verified, the simulation model is working as expected.
Tables 18 and 19 show again the differences in throughput times of different order types. Once more the decrease with higher urgency and more shifts can be demonstrated.

Scenario Name	Printer high temp	Printer low temp	Technician	Radiologist	Computer 1	Computer 2	Tool	Working room	Control device
2.1	8,79	27,3	28,7	36,57	51,49	6,52	4,43	10,37	5,81
2.2	8,8	27,32	14,37	18,34	26,97	2,1	2,22	5,2	2,91
2.3	8,79	27,31	9,59	12,2	18,31	1,05	1,48	3,46	1,94

Table 17: Verification 2 - Workloads Resources [%]

With the tables and figures presented in this section the proper working of the simulation model is demonstrated. The scenarios show that the developed simulation reacts as expected to certain changes in resources setup and demand. Therefore, the verification of the simulation model can be considered as successful.

Figure 57: Verification 2 - Workloads of Resources over Time [%]

	Throughput time - all orders				Throughput time - per urgency		
Scenario Name	average	median	min	max	median-urgent	median-normal	median-low
2.1	6,37	5,41	2,06	41,6	4,68	5,51	6,88
2.2	4,02	3,6	1,58	27,72	3,25	3,67	4,03
2.3	3,34	3,01	1,54	26,38	2,54	3,14	3,31

Table 18: Verification 2 - Model Throughput Times

	Throughput time - all orders				Throughput time - per urgency		
Scenario Name	average	median	min	max	median-urgent	median-normal	median-low
2.1	4,56	4,55	1,93	15,4	4,29	4,64	4,75
2.2	3,51	3,3	1,73	13	2,96	3,61	3,26
2.3	3,01	2,66	1,59	10,04	2,51	2,96	2,61

Table 19: Verification 2 - Implant Throughput Times

5.2.6.2 Validation - Operational Simulation Model

As a first validation step, feedback from CAMed project members and domain experts of the presented simulation model were obtained. The results explained in Section 5.2.6.1

were presented and responses about the throughput times and workloads with the different setups were collected. With these new findings several adoptions on activity durations and resource availability, for example of the radiology technician, were implemented. Due to the early stage of the project, no real operational data from the 3DPC is available. Nevertheless throughput times of the existing research lab meet the simulated figures from the base scenario without learning (see verification scenario 1.1). Also the corresponding workloads of the printers seem valid and can be confirmed by the research lab operators. In consequence of the fact that the data for the build up rate calculation originates in the same centre, this was expected. Regardless no real validation with an existing 3DPC, working under real demand conditions is performed. Hence, the validation is still to be improved and results can only be considered as accurate for the existing research 3D printing facility or similar setups.

5.2.6.3 Results - Cost-Benefit Calculation

In this section, results of the cost-benefit calculation are summed up on a general level. All cost inputs are first estimations, therefore just allocations of the costs to different categories are shown.

Figure 58 shows the percentage distribution of the initial investment costs. The highest costs for the establishment of a 3DPC are those of the printers and the build up of a quality management system. This is due to the high requirements for medical devices. Domain experts from the medical industry predicted at least two years of manpower to build up a well-functioning QM system to 3D print at POC.

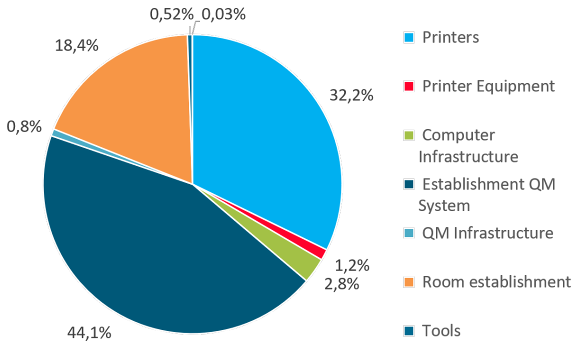


Figure 58: Allocation of Initial Investment Costs to different Categories

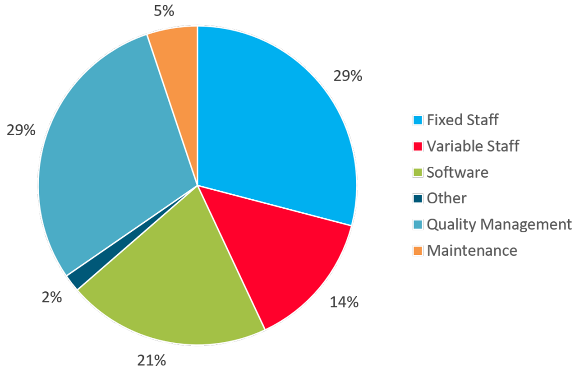


Figure 59: Allocation of operational expenses to different categories

Moreover, operational costs occur when running the 3DPC at POC. The allocation of operational costs can be seen in Figure 59. This picture shows that most of the costs for running the 3D printing facility are estimated due to personal costs. This includes the salaries for the technician and the quality manager. Besides, software licence costs are

estimated to be a critical part of the operational costs. The expenses for the variable staff (the radiology technician) have to be considered too as a remarkable cost factor.
In the following, the structure of the costs for the different order types are explained. At this point, two scenarios are differentiated. First, for the 1 year scenario from the Verification 1, with learning curve, the costs for manufacturing a medical device are calculated. All initial investment costs have to be attributed to the produced orders in one year. This leads to a high share of proportionate initial investment costs per order. Second, the 5 year scenario with the demand growth is the basis for the cost-benefit calculation, hence proportionate initial investment costs, due to the longer depreciation span, are lower. Figure 60 and 61 show the differences of the proportionate costs for producing one order type implant. In the Verification 1 - one year scenario 48% of the order costs are caused by the initial investment of the printers and other equipment. Compared to only 15% in the Verification 2 five years. Figure 61 gives a more realistic idea of the allocation of the costs, due to the expected longer lifespan of resources in the 3DPC. The 3D printers, for example, are expected to have a lifespan of 6 to 8 years. For implants there are several cost factors which have similar influence on the total costs. The strongest influence in this cost structure have the expenses for the quality management system, following by the technician and the weighted, proportioned costs for the establishment of the system. Moreover, material costs turning out to be approximately 15% have to be considered due to the high costs of the PEEK material.

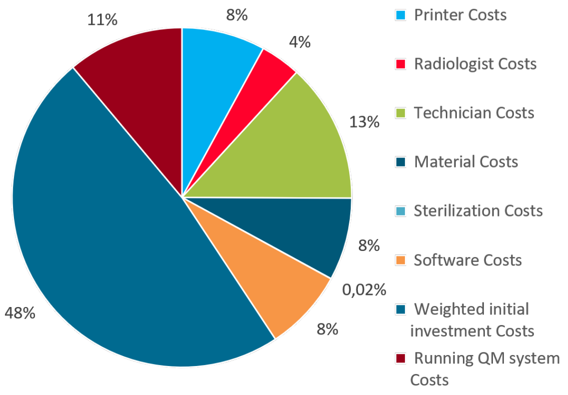


Figure 60: Allocation of Costs for an Order Type Implant - One year Scenario

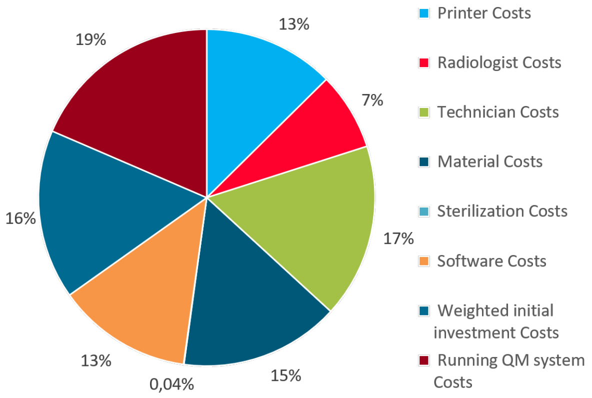


Figure 61: Allocation of costs for an order type implant - five years scenario

To compare the cost structure of different types of medical devices, the allocation of costs for the production of an anatomical model are presented in Figure 62 and 63. Again, the weighted initial investment costs of the one year scenario are tremendously higher. In the five year scenario, see Figure 63 the possible cost structure of an anatomical model in the planned operations of the 3DPC is shown. Compared to the implant, here technician costs are the highest, followed by the quality management and the proportionate initial investment costs. Giving the fact that anatomical models are heavier and hence need more time to print, this cannot be seen in the costs. This can be interpreted due to the low initial investment costs of those printers and therefore cheaper hourly rate of the printer for this material. Another interesting insight is the immense smaller share of material costs at this type of medical device. Only 1% of the costs comparing to 15% at implants are caused by material. The explanation for that, is once more the lower price of the material for printing anatomical models.

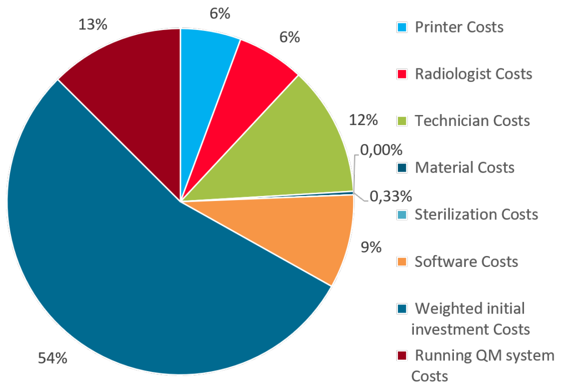


Figure 62: Allocation of Costs for an Order Type Anatomical Model - One year Scenario

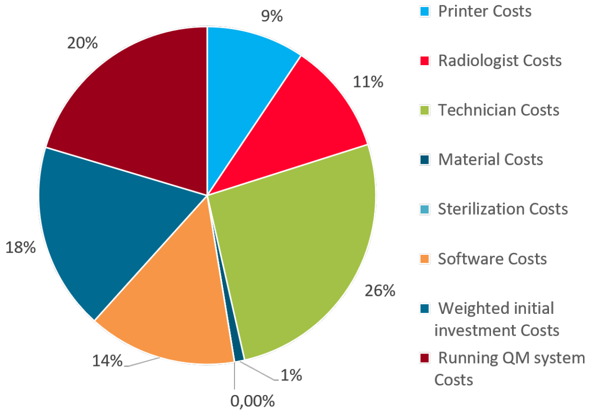


Figure 63: Allocation of Costs for an Order Type Anatomical Model - Five years Scenario

To sum up, one main cost driver in the cost structure of the 3DPC, is the quality management. This includes the establishment and running of the quality management system. Moreover, printer, staff, and licence costs are considered to have a high share of the overall costs of the operation of the 3DPC. The comparison of the one and five years scenario show that with the high initial investment a 3DPC only will be economical when operating many years. Additionally, the distinct proportions of material costs of implants and anatomical models are remarkable. First estimations show that implants tend to be more expensive, compared to anatomical models. This is due to higher material as well as printing costs, and longer segmenting and modelling durations.

Benefits are not included in the present result analysis. This is caused by the lack of sound data about the beneficial outputs of using implants and anatomical models in the hospital. Hence, only a first estimation about the saved expenses in comparison to ordering externally is so far taken into account in the benefit calculation.

5.3 Aggregation of Results

In this section, the results of the case study are summed up and discussed. This should give an overview of the possible quantitative and qualitative outcomes of the DSS. With those results, risks and opportunities, inherent to an implementation of a 3DPC at POC, are assessed. It is to mention, that the whole DSS is an evolving system and hence the presented results are only valid at the present point of time. Moreover the interpretations are the author's own opinion and hence not generally valid.

5.3.1 Summary

Both, the business ecosystem analysis (Section 5.1) and the ST (Section 5.2) focus on the interactions of the 3DPC with it environment. The BEA concentrates on the quality of the social interactions within the regarded case study. The ST concerns on the processual structure of the manufacturing procedure and money related issues. It is important to acknowledge that the characteristics of the social relationships influence the fulfilment of the manufacturing process. Hence, both parts of the DSS have an impact on each other. This cannot be assessed with a plain figure and has to be interpreted by analysing the results.

In the BEA, a future state of the operation of a 3DPC at POC is assumed. The differentiation into leader, quality manager, and technical staff as employees of the 3D PC is just viable at a mature state and high demand scenario of such a facility. In the execution of the operational simulation, only technical staff members and radiology technicians are differentiated (see Section 5.2.5.2). This represents the current plan for the road to the full implementation at the regarded case at the LKH University Clinic Graz. Furthermore, the capabilities of the actors mentioned in the BEA are used again in the operational simulation model to fulfil the activities for manufacturing. The ST supposes nearly perfect accomplishment of the tasks and interaction of entities. Only failures such as not-complete orders, printer break downs, or poor quality checks, are considered with decisions and probabilities after these activities. Initially, the accomplishment in the proposed process order may not be the case, because of the huge information flow in the Value Network presented. Due to the massive amount of information and services exchanged in between different departments, a functional communication is crucial for the fulfilment of the activities at the 3DPC. Still, the very positive interaction in between the radiological and clinical department, and the 3DPC leads to an optimistic valuation for the accomplishment. Still, due to the fact that the ST does not include the exchange of intangible value like information flows and organisational learning, the results have to be perceived from a cautious point of view. Especially in the implementation phase of the 3DPC a lot of ramp-up problems will occur and therefore some activities will take longer. This is modelled with learning curves in the decisions between some of the processes (see figure 41). Given the information that the durations time-spans of the simulation are already gathered in this research 3DPC makes this implication less severe. Yet, especially at the beginning, the involvement of communication and information issues has to be considered when predicting throughput times of medical devices.

Bringing together the results from Section 5.1 and 5.2, important aspects regarding the implementation of the 3DPC at the case are detected. First, the stakeholders have to be aware that the implementation to a functional operational state takes time and first outcomes will not reach the level of performance predicted. Therefore, involved entities have to be informed about the current state of the implementation and the evolving problems. With this, the entities in the business ecosystem know the state of quality of the produced medical devices and hence can bring in their expertise to tackle evolving difficulties efficiently. This would also be beneficial for the whole diffusion process and acceptance of the innovation within the hospital. With the location directly at POC, surgeons could customize anatomical models to their needs in close interaction with the 3DPC experts. Moreover, new types of medical devices could be developed together in the future. This would increase treatment quality and patients satisfaction, which is the underlying target of the whole implementation of the 3D printing facility.

The presented ST can improve the decisions about the time of additional staff employment, new printer acquisition, and the implementation of new technologies. Besides, production planning can be performed with the aid of the operational simulation. Fast estimations about the throughput and working times for different orders can be performed and hence the efficiency and predictability of manufacturing medical devices can be improved. The developed ST is flexible and able to process different scenarios of activity durations, printer build-up rates, and other process parameters. Hence, decision makers of the CAMed project can use it as a tool to compare their expectations, easily assess related investments, and implications of technology leaps or other organisational enhancements. Together with the qualitative data of the value network, it enables a holistic observation of different scenarios. Using the DSS, the output of the quantitative simulation can always be cross-checked with possible changes in relationships and value interactions. The introduced DSS allows an analysis of the business case 3D printing at POC on an organisational, operational, social, economical, and technical level.

To sum up, to know the expected demand of different medical devices is crucial for efficient resource setup. Besides, a flawless communication between the actors, which are performing the manufacturing, have to be ensured for a high quality production. This can be a challenge, due to the fact that different expertises from various domains are working together in the 3D printing facility. Further, outputs are that most of the manufacturing time is spent at printing, segmenting, modelling, and sterilisation. This should be considered first when aiming to reduce throughput and working time. Moreover, when continuing the implementation project's decision makers should especially emphasise communication issues, acceptance and monetarisation of the 3DPC. For this, the DSS introduced in this master's thesis can be used to successfully implement a 3DPC at POC. The flexible input structure makes it possible to easily use this DSS, with another validation step, in other cases too.

5.3.2 Assessment of Risks and Opportunities

Risks can occur from handling the massive information flow and the need of fruitful relationship between the participating actors. This social interactions are crucial for the successful implementation. Hence, the knowledge about capabilities of each participating entity and the communication channels have to be planned carefully before implementing the final setup. Moreover, uncertainties in the reliability of the printers, the upstream supply chain and the quality management procedure can have heavy consequences during the implementation phase. Another impactful influence to the project's success is the acceptance of POC manufactured 3D printed medical devices in the hospital. If the demand for parts is too low, an economic operation of a 3DPC at POC cannot be established. This is caused by the high initial investment and the fixed licence and staff costs when operating such a facility. Hence, the diffusion of the innovation in the hospital and ramp-up of the manufacturing have to be planned carefully. Quality problems and longer throughput times also have to be communicated, particularly at the initial implementation phase. This ensures that hospital-intern consumers understand technical problems in the production and can enable process enhancements through interdisciplinary interaction. The possibility for reimbursement of 3D printed medical devices from insurance companies will affect the economic profitability and their final use as well. Thereby, a clear and informative marketing strategy to convince these parties about the positive effects of POC manufactured 3D printed medical devices have to be conducted. This can also be seen in the strategic point of view of the Value Network.

Opportunities that are inherent with the implementation are shorter communication chains, direct interaction, and participation of the consumers at the manufacturing process and the ability to produce just in time. Particularly a professional communication among surgeons, radiology technicians and staff members of the 3DPC can enhance quality of the medical devices and hence the treatment of the patients. Furthermore, the implementation can yield more creativity in tackling medical problems through the interdisciplinary team at the 3DPC involved in the healthcare treatment. Cost savings can occur when demand is at a certain level. These economic profits can not only occur with fewer expenditures compared to external ordering. Literature like Ballard et al. (2020) also shows that with the use of 3D printed anatomical models operation time can be reduced significantly. Besides, the implementation would lead to a continuous enhancement of knowledge about medical 3D printing and could enable further research progress in this promising future trend. Especially in this topic the well-functioning interaction of the departments as shown in the strategical value network, see Section 5.1.2, is crucial for further development in that area. With successful research, other applications than assumed in this ST are possible, leading to higher demand and higher profitability and acceptance of the 3DPC at POC.

To conclude, there are a lot of opportunities coming with the implementation of a 3DPC at POC. Particularly, the faster production due to the shorter supply and communication chain leads to many opportunities. Nevertheless, a lot of risks and uncertainties are on the way to this technology diffusion within the hospital. The introduced DSS aims to map those risks and proposes tools and methods to clear out uncertainties. Hence, better informed decisions can be made to guide CAMed project owners through the complicated path of the implementation of a 3DPC at POC.

6 Conclusion

Throughout this thesis it has been shown that DSSs can be an important tool to enhance an organisation's performance and that they can give important insights when making a decision. Especially the fast changing sector of digitalised, high quality manufacturing makes the iterative assessment of possible future scenarios crucial for success. DSSs therefore present a flexible tool to evaluate personal expectations and decision implications resulting in a sound basis for successful implementation of novel technologies.

This section presents a critical summary of all outputs, challenges, and learnings of this master's thesis. Therefore, the overall concept of evaluation is discussed, limitations of the developed DSS are shown, and an outlook about the possible further evolution of the presented tool is outlined. A discussion and interpretation of the case study itself can be found in Section 5.3.

6.1 Discussion

The presented DSS, for the assessment of the implementation of a 3DPC, is an approach, that is based on the apprehension and interpretations of the author of this thesis. The used methods, which are the basis of the whole DSS, are shown in Sections 2 to 4. Supported by this theoretical background, the specific circumstances of the CAMed project about the implementation of a 3DPC at POC were assessed. This was done with expert interviews, literature research, and internet investigations. Thereby, a solid understanding of the case was gathered. This information lead to the decision of the development of a Value Network. A widely unknown business ecosystem has to be understood first. This method has been chosen because of it's comprehensive summary of interactions and the possibility to evaluate societal challenges and relationships in a qualitative way. Hence this approach leads to a better understanding of the underlying needed connections in-between the participating parties. Moreover, the endogenous motivation and exogenous influence assessment provide insights to the current state of the engagement level of the involved actors.

Based on the sound understanding of the business ecosystem, the framework for the ST has been assembled. Supported by this theoretical input and an existing operational simulation, a holistic approach focusing on different levels of performance of the 3DPC was chosen. Considering the inputs of project owners and the given data situation KPIs which define the behaviour and capabilities of the system were selected.

For a better structure and a division of operational and monetary KPIs, the presented ST is split up in the demand model, the operational simulation model and the cost-benefit calculation. The division into three parts leads to some advantages as explained in Section

5.2.4, but also have the drawback of many interfaces in between the different models. Considering the cost-benefit calculation, the lack of data led to uncertainties in the evaluation. Particularly the printer set-up with costs, the corresponding build-up rate, failure behaviour, and maintenances have to be discussed on a more detailed level. At this point, the current set up of the research 3D printing lab is used to examine the future state of manufacturing. As technology advances the performance of those printers will improve. New state of the art printers being able to work under sterile conditions, with higher build up rates can improve and change the whole manufacturing process. This could have a strong influence on the presented KPIs. Therefore, scenarios considering those facts can give supplementary information about the best resource set up and potential performance of the 3DPC. All this can be easily performed and adopted with the presented ST. Many possible future scenarios should be assessed to have further insights about performance changes, impacts of technology characteristics, and possible increases in failure behaviour. To sum up, the presented DSS enables an assessment of the interactions of the different resources. Moreover, the structure of the throughput time and costs can be assessed. This use of the DSS enables valuable insights about the levers for improvement, resource use, and correlations in the production chain. With the inclusion of the Value Network the highly important societal dimension of such an innovation project was added. The connection of the organisational structure on a human and a processual level puts light on the most important aspects. This includes the fact that even the best planned process relies on well-functioning interpersonal relationships. Hence the presented DSS can be used to holistically evaluate the threats, challenges, and opportunities that come along with the implementation of a 3DPC at POC. Therefore, it can enhance decision making of project owners and be an important part of the successful implementation of this innovative facility.

6.2 Limitations

Looking at the Value Network, only 8 expert interviews to grasp the relationships and value exchange are performed. Hence the endogenous and exogenous influences are only evaluated from a limited perspective. At this point, many more interviews can be performed to gather data from all introduced actors to validate the interaction structure and the attitudes of involved parties. Moreover, due to the present circumstances it was predominantly an individual elaboration of this business ecosystem. With more expert input and interaction with project stakeholders, extra value exchange, and further actors could be included in the future.

At the demand model, the simulation does not include sampling of order demand generation. Hence, in experiments with many simulation runs the same demand file is used, resulting in no sampling of the order arrivals for different iterations. Besides, the underlying manufacturing process for the operational simulation model was developed with no interaction and no personal exploration of the actual research facility. Together with project stakeholders and the supervisor of this thesis the production process was modelled. At this point more presence and involvement of the author in the 3DPC could have enhanced process accuracy and quality. Especially the differences in the production of different types of medical devices is in the authors opinion not considered sufficiently. Regardless the presented production represents the current state of development and could be adopted with more operational knowledge as the project advances.

Considering the cost-benefit calculation, there is a lack of inclusion of different benefits. Operation time savings and other possible cost savings, due to the use of anatomical models, tools, and implants are not considered. Moreover, the implication of advanced organisational learning and better patient treatment is not taken into account. Additionally, the POC manufacturing can increase medical device quality. Due to the widely unknown positive implications of the use of anatomical models, few data about the real benefits can be assessed. Besides, the DSS does not include the estimated positive experience and higher reputation of hospitals using 3D printing of patients. The overall increased welfare and patient's satisfaction with the gained trust in surgeons when explaining the operation with an anatomical model is difficult to measure and therefore not included in this evaluation.

Generally, there is a unsatisfactory validation of the simulation model. It was only performed within the project and not with the input of other domain experts. Hence the elaboration and validation of the model was executed by the same team. That is a severe shortcoming of the presented assessment framework. Remedy for this problem can be the validation with other already established 3DPCs at POC, like example in Basel or with the experts from Mayo Clinic in the United States.

Another weakness of the presented DSS is the shortage of actual interaction of the qualitative and quantitative part. Only a static point of view from the Value Network can be included in the operational simulation models. Dynamic changes in the communication and the inclusion of social quality are not linked to the ST. This would enable a lot of interesting insights into the influence of the relationships of the actors to their actual performance when manufacturing medical devices. Therefore, the impact of well-functioning communication in the 3DPC can only be interpreted and not assessed on a quantitative level.

To conclude, due to the limited data available, especially about benefits for POC 3D printed medical devices, many interesting indicators could not be evaluated sufficiently. Hence, indirect societal or monetary benefits of the implementation are not assessed. Furthermore, the lack of appropriate data and limited resources led to an exclusion of societal and ecological impacts in this thesis. Given the fact that sustainability is a rising trend and will reach as well the healthcare providers, KPIs like reduced CO2 emissions or waste and energy saved when implementing a 3DPC at POC could be interesting insights.

6.3 Outlook

According to the presented limitations, there is still high potential for further development of this DSS in the future. Particularly the inclusion of further benefits is crucial for a sound estimation of the business case. Moreover, input data quality should be improved with the inclusion of other domain experts, outside of the CAMed project. Special emphasis should be put on the important and high influential cost factors. Moreover, demands have to be assessed with more detail, using information from other clinics which 3D print at POC. The Value Network evaluation can be further enhanced with more expert interviews and an expert workshop bringing all relevant stakeholders together.

Moreover, with more time resources a better user interface summing up all three parts of the ST could be implemented making user interactions more intuitive.

Another important future step is the actual validation with external already established 3DPC to make the DSS more reliable. At this point, a future research collaboration with the 3D Print Lab in Basel[5] is already initiated.

Finally, the author outlines that the presented DSS is already in a state where it can provide useful information for decision making. Project owners can use the tool to assess different demand scenarios, resource setup decisions, changes in technology performance, and many more.

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[5] https://www.unispital-basel.ch/ueber-uns/departemente/theragnostik/kliniken/radiologie-und-nuklearmedizin/zuweiser/3d-print-lab/

List of Figures

List of Tables

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Appendices

A Formulas of the cost-benefit calculation

Initial Investments:

$$[€]\ INI_{Pr} = n_{HighTempPr} * P_{HighTempPr} + n_{LowTempPri} * P_{LowTempPr}$$

$$[€]\ INI_{EstablPrEq} = P_{PrTraining} + P_{MaterialDryer}$$

$$[€]\ INI_{ToolSets} = n_{ToolSet} * P_{ToolSet}$$

$$[€]\ INI_{Comp} = n_{Computer} * P_{Computer}$$

$$[€]\ INI_{QAInfra} = n_{ControlDevice} * P_{QAEquipment}$$

$$[€]\ INI_{QM} = 2 * S_{QM}$$

$$[€]\ INI_{Room} = P_{EstablishmentRoom}$$

$$[€]\ INI_{Material} = c_{Peek} * m_{IniPeek} + c_{GTP} * m_{IniGTP}$$

$$[€]\ INI = INI_{Pr} + INI_{EstablPrEq} + INI_{ToolSets} + INI_{Computers} +$$

$$INI_{QAInfrastruc} + INI_{QM} + INI_{Room} + INI_{Mat}$$

Legend I:
All inputs which are not marked with *input from sim model* are inputs from the application window of the cost-benefit calculation tool.

INI ... All initial investments [€]
INI_{Pr} ... Initial investment for printers [€]
$n_{HighTempPr}$ ... Number of high temperature printers (input from sim model) [#]
$P_{HighTempPr}$ ... Price of high temperature printer (initial investment) [€]
$n_{LowTempPr}$ ... Number of low temperature printers (input from sim model) [#]
$P_{LowTempPr}$ ... Price of low temperature printer (initial investment) [€]
$INI_{EstablPrEq}$ ... Initial investment for printer equipment [€]
$P_{PrTraining}$ ... Price of one initial training for know-how about printers [€]
$P_{MaterialDryer}$ ... Price of material dryer [€]
$INI_{ToolSets}$ ... Initial investment for tool sets [€]
$n_{ToolSet}$ ... Number of tool-sets (input from sim model) [#]
$P_{ToolSet}$ ... Price of tool-set [€]
INI_{Comp} ... Initial investment for computers [€]
$n_{Computer}$ ... Number of computers (input from sim model) [#]

$P_{Computer}$ ... Price of computer [€]
$INI_{QAInfra}$ ... Initial investment for QA infrastructure [€]
$n_{ControlDevice}$ ... Number of control devices (input from sim model) [#]
$P_{QAEquipment}$ ... Price of one QA equipment [€]
INI_{QM} ... Initial investment for establishing the QM infrastructure [€]
S_{QM} ... Yearly salary of a quality manager [€/year]
INI_{Room} ... Initial investment for establishing the facility and room infrastructure [€]
$P_{EstablishmentRoom}$ ... Price for establishing the facility and room infrastructure [€]
INI_{Mat} ... Initial investment for material on stock at the beginning of simulation [€]
$m_{IniPeek}$ ... Initial material PEEK on stock (input from sim model) [g]
m_{IniGTP} ... Initial material GreenTecPro on stock (input from sim model) [g]
c_{Peek} ... Specific costs for PEEK material [€/g]
c_{GTP} ... Specific costs for GreenTecPro material [€/g]

Calculation operational costs

Separate calculation in cost calculation in 2 cases. One if the simulation time is less than one year. The other if the simulation time is more than one year, so that the costs have to be calculated for each year separately

$$[€]\ C_{Staff} = n_{Tec} * S_{Tec} + n_{QM} * S_{QM} + n_{wh_{Rad}} * s_{Rad}$$

$$[€]\ C_{Software} = (n_{Rad} * p_{SegmLic} + n_{Rad} * p_{ModelLic} + n_{Tec} * p_{MESLic}) * \frac{t_{Sim}}{365}$$

$$[€]\ C_{Mat} = (n_{O_{Peek}} * m_{O_{Peek}} * c_{Peek} + n_{O_{GTP}} * m_{O_{GTP}} * c_{GTP}) * (1 + OH_{Mat})$$

$$[€]\ C_{Electr} = (\sum_{i=0}^{n} n_{wh_{Pr_i}} * c_{Electr} * Power_{Pr}) * (1 + OH_{otherElecConsumpt})$$

$$[€]\ C_{Sterilisation} = c_{Steril} * n_{OSteril}$$

$$[€]\ C_{QM} = C_{RunningQMSystem} * \frac{t_{Sim}}{365}$$

$$[€] C_{Maint} = n_{M.2}*c_{Nozzle}+n_{M.3}*c_{Filter}+n_{M.4}*c_{LubricFl}*0.6+n_{M.4}*c_{AnnCheck}+\frac{t_{Sim}}{14}*c_{CoolFl}$$

assuming 0.6 l lubrication fluid needed per maintenance action.

$$[€]\ C_{Repair} = n_{R.1} * C_{ConsumableKit}$$

$$[€/h]\ avg_{CostPrinter} = \frac{(P_{HighTempPrinter} + P_{LowTempPrinter}) * \frac{1}{2}}{T_{Printer} * 0.1 * 365 * 24 * 60}$$

assuming 10% workload per year of all printers

$$[€]\ C_{Downtime} = (\sum_{i=0}^{k} t_{iRepair} + \sum_{j=0}^{l} t_{jMaint}) * avg_{CostPrinter}$$

$$[€]\ C_{Total} = C_{Staff} + C_{Software} + C_{Mat} + C_{Elec} + C_{Ster} + C_{QM} + C_{Maint} + C_{Repair} + C_{Downtime}$$

Legend II:

t_{Sim} ... Simulation time (input from sim model) [days]

C_{Staff} ... Costs for staff [€]

n_{Tec} ... Number of technicians (input from sim model) [#]

n_{QM} ... Number of quality managers (input from sim model) [#]

S_{Tec} ... Salary technicians [€/year]

S_{QM} ... Salary quality managers [€/year]

$n_{wh_{Rad}}$ ... Total working hours radiology technician (input from sim model) [h]

n_{Rad} ... Number of radiology technicians (input from sim model) [#]

s_{Rad} ... Salary radiology technician [€/h]

$C_{Software}$ ... Costs for software [€]

$p_{SegmLic}$ ... Price per segmenting software licence [€/year]

$p_{ModelLic}$ ... Price per modelling software licence [€/year]

p_{MESLic} ... Price per manufacturing execution system software licence [€/year]

C_{Mat} ... Costs for material [€]

$n_{O_{Peek}}$ ... Number Orders PEEK (input from sim model) [#]

$n_{O_{GTP}}$ ... Number Orders GreenTecPro (input from sim model) [#]

$m_{O_{Peek}}$ ... Amount of material ordered per order PEEK [g]

$m_{O_{GTP}}$ ... Amount of material ordered per order GreenTecPro [g]

OH_{Mat} ... Organisational overhead of material orders [%]

C_{Electr} ... Costs for electricity [€]

c_{Electr} ... Costs per kWh electricity [€/kWh]

n ... Number of finished orders (input from simulation model) [#]

$Power_{Pr}$ ... Power of the printers [W]

$OH_{otherElectConsumpt}$ ... Overhead for power consumption out of printers [%]

C_{Repair} ... Costs for repairs [€]

$n_{R.1}$ ... Number of processes R.1 repair printer performed (input from sim model) [#]

$C_{ConsumableKit}$ ... Costs for one consumable kit [€]

$avg_{CostPrinter}$ ... Average hour rate of printers [€/h]

$n_{M.2}$ ... Number of processes M.2 change nozzle performed (input from sim model) [#]

$n_{M.3}$ ... Number of processes M.3 visual check printer performed (input from sim model)

[#]
$n_{M.4}$ ... Number of processes M.4 lubricate printer performed (input from sim model) [#]
$n_{M.5}$ ... Number of processes M.5 annual check manufacturer performed (input from sim model) [#]
c_{Nozzle} ... Costs per nozzle [€/#]
c_{Filter} ... Costs per filter [€/#]
$c_{LubricFl}$ ... Costs for lubrication fluid [€/ł]
c_{CoolFl} ... Costs for cooling fluid [€/ł]
$c_{AnnCheck}$ ... Costs for annual check of manufacturer [€/check]
$T_{Printer}$ ... Lifespan of printers [years]
C_{Ster} ... Costs for sterilisations [€]
c_{Steril} ... Specific internal costs for sterilisation [€/#]
$n_{OSteril}$ ... Number of orders sterilised (input from sim model) [#]
C_{QM} ... Costs for maintaining the quality management system [€]
C_{Maint} ... Costs for maintenance [€]
$C_{Downtime}$ ... Costs for downtime [€]
$t_{iRepair}$ ... Time of one repair [min] (input from sim model)
k ... Number of repairs (input from sim model) [#]
t_{jMaint} ... Time of one maintenance [min] (input from sim model)
l ... Number of maintenances (input from sim model) [#]
C_{Total} ... Total variable costs [€]

Calculation of Printer, resource - hourly rates

$$hc_{Pr} = \frac{\frac{P_{Printer}}{T_{Printer}} * \frac{t_{Sim}}{365}}{wh_{Printer}} + c_{mtg_{Printers}}$$

$$c_{mtg_{Printers}} = \frac{C_{Maintenance} + C_{Repairs} + C_{Downtime}}{wh_{tot_{Printers}}}$$

$$hc_{Tec} = \frac{n_{Tec} * S_{Tec} * \frac{t_{Sim}}{365}}{wh_{tot_{Tec}}}$$

$$hc_{QM} = \frac{n_{QM} * S_{QM} * \frac{t_{Sim}}{365}}{wh_{tot_{QM}}}$$

Costs per order

$$c_{Software_{Order}} = \frac{\sum_{i=0}^{k} C_{Software_i}}{n_{Orders_{finished}}}$$

$$c_{other_{Order}} = \frac{\sum_{i=0}^{k} C_{RunningQM_i}}{n_{Orders_{finished}}}$$

$$c_{weightedINI_{Order}} = \frac{INI_{EstablPrEq} + INI_{ToolSets} + INI_{Computers} + INI_{QAInfra} + INI_{QM} + INI_{Room}}{n_{Orders_{finished}}}$$

$$c_{Maintenance} = \frac{C_{Maint} + C_{Repair} + C_{Downtime}}{wh_{tot-printers}}$$

$$hr_{Printer} = \frac{\frac{P_{HighTempPr}}{T_{Printer}} \frac{t_{Sim}}{365}}{wh_{tot-printers}} + c_{Maintenance}$$

$C_{tot_{Order}} = wh_{Rad} * s_{Rad} + wh_{Tec} * hc_{Tec} + wh_{QM} * hc_{QM} + wh_{Pr} * (hc_{Pr} + c_{electr} * Power_{Pr} *$
$(1 + OH_{otherElectConsumpt})) + w_{Part} * c_{Mat} + c_{Steril} + c_{Software_{Order}} + c_{other_{Order}} + c_{weightedINI_{Order}}$

Benefits per order

Total benefits:

$$B_{tot} = \sum_{i=0}^{I} c_{ext_i} + \sum_{m=0}^{M} c_{ext_m} \sum_{to=0}^{To} c_{ext_{to}}$$

Legend III:
B_{tot} ... Total monetary benefits of produced orders [€]
c_{ext_i} ... External costs of implants [€/#]
I ... Total amount of implants manufactured [#]
c_{ext_m} ... External costs of anatomical models [€/#]
M ... Total amount of anatomical models manufactured [#]
$c_{ext_{to}}$ ... External costs of tools [€/#]
To ... Total amount of tools manufactured [#]

Other calculated outputs

Net present value:

$$NPV = -INI - \sum_{t=0}^{N} \frac{C_t}{(1 + i_{Calc})^t} + \sum_{t=0}^{N} \frac{B_t}{(1 + i_{Calc})^t} /$$

Legend VI:
NPV ... Net present value of business case [€]
i_{Calc} ... Interest rate - weighted average costs of capital (WACC) [€/year]
t ... Time [year] N ... Overall simulation time [years] C_t ... Summed up costs in year t [€] B_t ... Summed up benefits in year t [€]