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Abstract

Whereas the promises of (predictive) analytics in healthcare are clear and extensively reported, the executive practicalities are not. Mapping the factors that have a hand in the implementation and continuation (i.e. deployment) of such projects improves the execution of prediction models and hence improves diagnostic and prognostic healthcare for patients. This research takes a design science approach to create an artifact aimed at successful deployment of clinical prediction models (CPMs). Through a literature review, various factors that play a role in the deployment of CPMs are categorized. Interviews with an extensive expert panel lead to the development of the CRISP-DM Deployment Extension for CPMs. Next to opinions on the importance of each factor, new insights are collected on related topics. A case study at a Dutch hospital allows for the testing of the artifact. A gap analysis is conducted, leading to a practical advice in terms of successful deployment. The research concludes with a proposed deployment strategy and a list of eight recommendations that can be considered the determinants for successful deployment of clinical prediction models.

Key words	clinical prediction models · big data · predictive analytics · healthcare industry · deployment strategy · critical success factors · project management · CRISP-DM · design science · CRISP-DM Deployment Extension for CPMs
Notes	This study is conducted as part of a graduation internship at BDO Nederland.

DETERMINANTS FOR SUCCESSFUL DEPLOYMENT OF CLINICAL PREDICTION MODELS

A design science research in the Dutch healthcare sector

Master Thesis
International Master in Management of IT

Author:
Stefanie Creemers

June 2019
Utrecht, Netherlands

"Study the past if you would define the future."

— Confucius 仲尼

PREFACE

'The time has come,' the Walrus said,

To talk of many things:

'Of shoes — and ships — and sealing-wax —

Of cabbages — and kings —

And why the sea is boiling hot —

And whether pigs have wings.'

– Lewis Carroll,
The Walrus and the Carpenter
from his book Through the Looking-Glass (1871)

The time has come (again). For the second time I am able to let this poem exemplify the completion of a master's degree. The past two years have been marked by an unforgettable experience in France, Finland and the Netherlands. With this thesis I complete the triple master program International Master in Management of IT (IMMIT) at IAE Aix-Marseille Université, Turku University, and Tilburg University.

I would like to thank all colleagues at BDO Audit & Assurance Nederland for the pleasant working environment and for giving me the opportunity to discover the field of IT risk assurance while writing my thesis. Furthermore, I would like to express my sincerest gratitude to everyone who has been so generous to dedicate his or her time to my thesis project. It would not have been possible to conduct this research without the insights of the many professionals that I was able to interview.

Furthermore, I would like to thank all fellow students and professors that were involved in our cohort. Semesters in three different countries have given me an unprecedented experience, providing me with new knowledge and skills that I will carry with me in my upcoming career. Both on a professional and personal level I have experienced tremendous growth in the past period.

Grateful acknowledgement is made to all my close family and friends who have supported me since the beginning.

Stefanie Creemers
Utrecht, June 2019

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LIST OF ABBREVIATIONS

AI	Artificial intelligence
ASUM-DM	Analytics Solutions Unified Method for Data Mining
BI&A	Business Intelligence and Analytics
BU	Business understanding (first phase of CRISP-DM)
CCPM	Critical Chain Project Management
CDSS	Clinical decision support system
CPM	Clinical prediction model
CRISP-DM	Cross-Industry Standard Process for Data Mining
CRISP-MED-DM	Cross-Industry Standard Process for Data Mining - medical extension
CSF	Critical success factor
EHR	Electronic health records
GDPR	General Data Protection Regulation
IMMIT	International Master in Management of IT
IoT	Internet of Things
IPM	Integrated Project Management
IT	Information technology
KDD	Knowledge Discovery in Databases
PA	Predictive analytics
PM	Project management
PMBOK	Project Management Body of Knowledge
PMI	Project Management Institute
PMLC	Project Management Life Cycle
PRINCE2	Projects IN Controlled Environments
PRiSM	Projects integration Sustainable Methods
SEMMA	Sample, Explore, Modify, Model, and Assess
UMC	University Medical Center
UMCU	University Medical Center Utrecht

GLOSSARY

Clinical decision support systems	Applications that use data analysis to provide support to healthcare providers in decision-making in order to improve patient care.
Clinical prediction model	A predictive data mining algorithm that provides risk estimates for diagnosis or prognosis of a disease for an individual patient.
Clinical prediction tool	A clinical prediction model captured in a tool that can be used by health practitioners to support the diagnosis and prognosis of diseases.
Continuation	The stage after implementation, when all predetermined requirements have been met in accordance with the initial design and the software can be used. The focus is on daily activities, operations, and management surrounding the software that must ensure its success over the long-term.
Data mining	The process of discovering meaningful patterns in large datasets through computer algorithms.
Data science	The field of study that aims to extract meaningful insights from data by combining domain expertise, programming skills, and knowledge of statistics.
Deployment	The overarching term for the period starting from the actual implementation until the daily continuation of the new software.
Descriptive analytics	Type of business analytics that looks that provides reporting analytics with visualizations, ad hoc reporting, and trend analysis of past events.
Design science	An information technology research methodology that concentrates on development and performance of artifacts
Diagnostic analytics	Type of business analytics that valuates why something happened by detecting root causes of a problem in the data.
Diagnosis	The discovery and identification of a disease.
Etiology	The causes and origins of a disease.
Implementation	The stage where a project is materialized or realized, initiated when a project has been assessed as feasible. In terms of the project life cycle, implementation is part of the execution phase.
Machine learning	The use of algorithms and statistical models by computers to automatically learn information and patterns from data, without explicit instructions.
P4 medicine	Predictive, preventive, personalized, and participatory medicine.
Personalized medicine	Individualized patient care; a move away from the ‘one size fits all’ approach to healthcare.

Predictive analytics	Type of business analytics that generates prediction power from data in order to forecast future activity, behavior, or trends.
Prescriptive analytics	Type of business analytics that determines ways in which business processes should evolve or be modified.
Prognosis	The expected development of a disease over time.
Project management	An approach to achieve specific project objectives in a finite timespan by applying certain processes, methods, skills, and experience.
Project success	A project is considered a success when objectives are achieved in accordance with the acceptance criteria formulated at the start of a project.
Time series forecasting	A method to transform past values into future estimates based on machine learning techniques based on certain time series assumptions.

1 INTRODUCTION

We are at the forefront of the big data revolution in healthcare. The application of big data and predictive analytics has the promise to play a momentous role in our healthcare, as pointed out in academic literature (Belle et al., 2015; Groves et al., 2013; Chawla & Davis, 2013; Sun & Reddy, 2013). Slowly, hospitals are implementing and experimenting with predictive models. However, the practical side remains undiscovered and hospitals lack experience in the implementation and continuation of clinical prediction models. It seems as if the promised revolution is stuck in first gear.

1.1 General research area

As a subset of data science, predictive analytics revolves around creating empirical predictions and prediction power from extremely large datasets (Shmueli & Koppius, 2011). Techniques such as data mining, machine learning and statistical modeling are utilized for the development of advanced algorithms that can detect patterns in data. These patterns are able to predict future outcomes and trends, ensuring an acceptable level of reliability. Analysts use what-if scenarios and risk assessments to create forecasts for the unknown future.

Predictive analytics hold advantageous effects on all kinds of business areas, such as supply chain management (Waller & Fawcett, 2013), manufacturing (Shin et al., 2014), and human resources (Fitz-enz & Mattox, 2014). However, the application in healthcare is most beneficial to us all, as humans. It allows us to detect diseases in earlier stages and improve the quality and accuracy of clinical decisions (Wang et al., 2018). Clinical prediction models (CPMs) for specific medical domains are being further developed and improved every day. At the same time, hospitals are carefully considering the potential benefits for their specific departments, specializations, and services. The barriers for deployment of predictive models consist partly of generic elements that apply to most types of organizations. On the other hand, some barriers are not generalizable; they are inherent to the identity of the healthcare sector.

1.2 Problem indication

The demand for good healthcare keeps rising. We live in an era in which population ageing is a serious matter. The percentage of people over 65 years old amplifies; a development that directly touches our healthcare system. Moreover, increased economic prosperity causes higher expectations from healthcare and its capabilities. Technological developments enable healthcare innovation, but that does not mean we need less healthcare. Diseases that used to be fatal have turned into chronic diseases, with lifelong need of treatment and medicine. The same economic prosperity also causes an expanding number of diseases related to our lifestyle, such as diabetes or cardiovascular diseases. All these elements contribute to a staggering increase of healthcare costs in the coming years. The Dutch Rijksinstituut voor Volksgezondheid en Milieu estimates that healthcare expenditure in the Netherlands will rise to 174 billion euros by 2040 (RIVM, 2018). That is a doubling of healthcare costs compared to 2015. However, the real problem that accompanies this future outlook resides in the huge lack of health professionals. Currently, the Uitvoeringsinstituut Werknemersverzekeringen (UWV, 2018) already expects an employee deficit in the Dutch healthcare system of hundreds of thousands the coming years. In other words, the demand for healthcare keeps growing, but the number of professionals to deliver the supply cannot keep up. Therefore, it is time to take advantage of other resources. That is where data science and predictive modeling comes in. By utilizing the power of data science, it is possible to optimize the activities of health professionals and to transform available health data into value that can support clinical decision making.

At this point in time, research is required in order to learn which challenges arise when predictive models are utilized in healthcare organizations. Whereas publications on CPMs are multiplying and news articles about pilot programs are spreading, there is a lack of academic research on the practicalities around actual application of the models. Hospitals are eager to explore the hyped theme of big data analytics in healthcare, but struggle to find actionable knowledge. Incomplete understanding on how the generated medical predictions should be integrated in practice, has increased the risk of technological backlash. According to Manlhiot (2018), the risk of backlash is a consequence of the new wave of overhyped expectations of predictive analytics in the medical field. Indeed, healthcare in particular shows astronomical expectations with regards to the capabilities of predictive models. Together with the general insufficiency of required technological infrastructure in most medical settings, a serious need for a pragmatic deployment strategy resides. This thesis aims to bridge the gap between theoretical research and the actualities of CPMs.

1.3 Motivation

A more hands-on approach towards predictive models in healthcare is required for successful deployment. The goal of this thesis is to gather actionable knowledge for hospitals and to provide a supportive framework in the follow up of technological opportunities that arise. Bridging the gap between theory and practice is essential in avoiding a potential tech backlash. The direct customers of this research are (academic) hospitals that proactively engage in clinical prediction model solutions and encounter stagnation in its deployment.

Firstly, this research is provoked by my personal motivations. As a data scientist, the immense opportunities that reside in complex healthcare data spark my fascination and galvanize me into action. Prediction models that can benefit clinical accuracy specifically take my interest.

Secondly, the scientific relevance of this topic makes a contribution to the information management field by presenting a different type of investigation into predictive analytics in healthcare. Rather than the development of a CPM or the assessment of its potential, this thesis goes a step further in the process and investigates the deployment challenges of an actual tool in hospitals. Figure 1 shows the position of this research topic in literature (step 4). It is time that we move from discovery, development and analysis of CPMs towards practical assessments (Dorajoo & Chan, 2017; Khalilia et al., 2015). First cross-sectional, but in the future also longitudinal. A thoughtful set of best practices for deployment is needed to guide the rise of healthcare predictive analytics (Amarasingham, 2014).

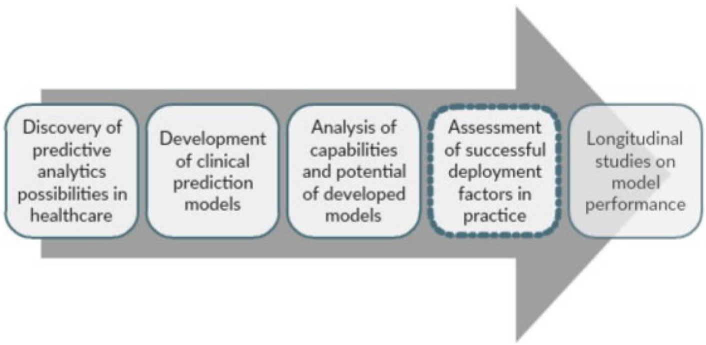


Figure 1 Position in literature based on factor time

Thirdly, this research provides practical contribution to society in various ways. Healthcare organizations in different regions of the Netherlands are currently figuring out how to create value from predictive models. By conducting qualitative research in various health organizations, the experiences, opinions, and knowledge of these diffused groups are connected. This thesis serves as a binding force to unify the efforts of multiple innovative health organizations nationwide. Furthermore, the outcomes of this study can improve CPM usability and hence users' daily activities. Identification of successful factors for deployment implies that pain points can be overcome, and that usage of CPMs can be simplified and streamlined. On the side of the patient, whose personal data is inserted into the predictive model, the outcomes of this study aid in improving the quality of their care and hence their well-being. Figure 2 shows that successful deployment of CPMs is a mediating variable between activities of healthcare professionals and the well-being of patients. On the side of the organization, the outcomes of this research can bestow better preparations for deployment of these new models and tools. Identification of critical success factors (CSFs) allows hospitals to anticipate deployment efficiently and effectively.

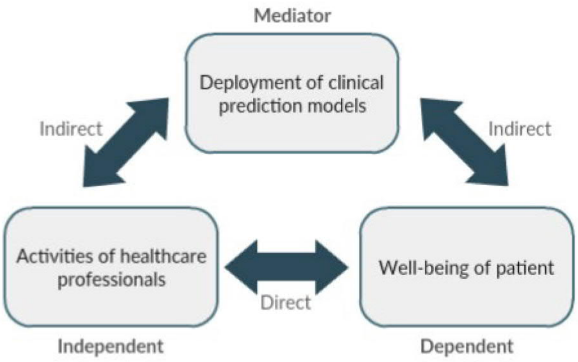


Figure 2 Practical contribution of research as mediating variable

Fourthly, as this thesis is effectuated in parallel with a graduate internship at BDO, the relevance for the IT audit healthcare team is shortly discussed. The technological playground of hospitals is changing and new innovations are being introduced. Undoubtedly, more and more hospitals will make use of predictive analytics over the course of time. The use of data-driven solutions implies increased caution with regards to patient privacy and data security, and the need to keep an eye on changes in the IT processes as the controlling requirements might shift in the future. In general, it is useful for BDO to closely follow these technological developments and to dispose of in-depth knowledge. The advisory line of service within BDO already focuses on the power of data analytics and counsels many organizations in their data analytics strategy. The outcomes of this study can be a worthwhile addition to the advisory portfolio in the healthcare sector.

1.4 Problem statement and research questions

Whereas the promises of business analytics in healthcare are clear; the executive practicalities are not. Mapping the factors that have a hand in implementation and continuation (i.e. deployment) improves execution of these models and hence improves diagnostic and prognostic healthcare for patients. The problem statement at the heart of this research is:

"How to design a successful deployment strategy for clinical prediction models in hospitals?"

In order to answer this problem statement, various research questions are formulated. The research questions (RQ) are each connected to different parts of the study and thus investigated using different methods. RQ1 is answered based on a thorough literature review. RQ2 and RQ3 are answered by a requirements collection and multiple expert interviews. RQ4 and RQ5 are answered by combining the results from the literature review, requirements collection, and expert interviews. RQ6 aims to test the designed artifact by applying it to a case study through a gap analysis. The research questions are stated in Table 1.

Table 1 Research questions

RQ1	What are the factors for successful deployment of BI&A according to existing literature?	Chapter 4
RQ2	What deployment factors of CPMs in hospitals are identified by health professionals?	Chapter 5.1
RQ3	What artifact can be designed to successfully deploy CPMs in hospitals?	Chapter 5.1.4
RQ4	What are the CSFs in a deployment plan for CPMs in hospitals as identified by health professionals?	Chapter 5.2
RQ5	What other factors have a hand in the successful deployment of CPMs in hospitals according to health professionals?	Chapter 5.3
RQ6	How to test the designed deployment strategy in a case study?	Chapter 6

The ultimate product of this research is the design of a deployment artifact with an accompanied strategy for deployment success.

1.5 Research design

The nature of this study is exploratory and qualitative, as the focus is on collecting new insights in a flexible manner whilst considering all potential aspects of the problem statement. The method of the research is design science. This method aims to design new artifacts in order to complement social capabilities with human competency (Hevner et al., 2010). In this thesis, the problem context of CPM deployment in hospitals is unraveled by the design and validation of an artifact.

The problem statement is partitioned into multiple research questions. Firstly, a literature review is conducted to collect secondary data on the implementation and continuation factors for BI&A projects, and more specifically for prediction models (chapter 4). The outcomes of the literature review function as the base to the conceptual model. Secondly, in order to validate the literature review, requirements collection interviews are conducted (section 5.1). The artifact is constructed, serving as the backbone for this thesis (subsection 5.1.4). After that, multiple expert interviews are conducted in order to validate the developed artifact (section 5.2) and to acquire additional insights (section 5.3). Lastly, a case study at a hospital in the Netherlands is conducted to test the developed artifact in a real situation through a gap analysis (chapter 6). Finally, the recommendations emanated from the artifact lead to the design of a successful deployment strategy for clinical prediction models. Figure 3 shows a graphical representation of the research design steps.

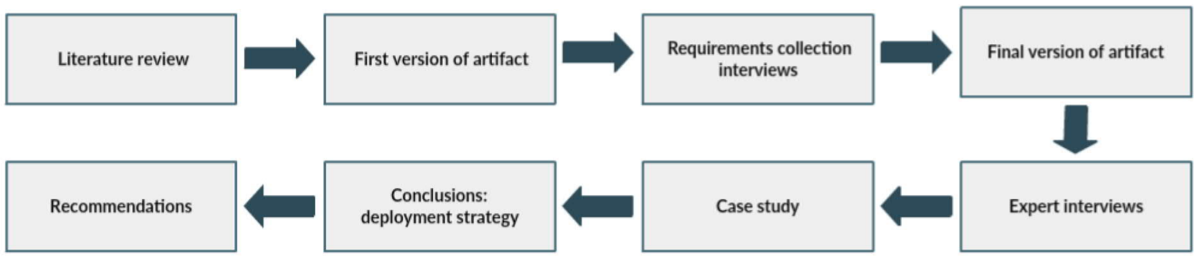


Figure 3 Research design

1.6 Research scope

This research is explicitly limited in scope by various borders. Firstly, in the field of business analytics, this research focuses on big data analytics with sufficient volume, variety, velocity, and veracity. Moreover, the research concentrates on predictive modelling based on machine learning and statistical techniques. Within healthcare these predictive models are aimed to support medical diagnosis and prognosis, and are thus called clinical prediction models (CPMs). Secondly, of the broad healthcare sector only general and academic hospitals are included. Thirdly, the interview target group are experts in the following four areas: clinical specialists, data scientists, IT experts, and health software companies. This creates a mix between CPM users, developers, functional managers, and commercial vendors. Figure 4 provides a graphical representation of the research scope.

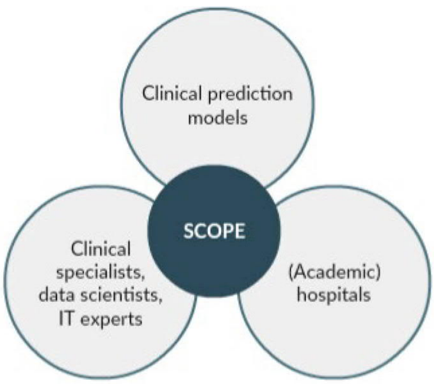


Figure 4 Scope of the research

1.7 Outline

This thesis is structured as follows. Chapter 2 provides an extensive literature background, discussing the topics of predictive analytics, project management and their applications in the healthcare sector. Chapter 3 explains the methodology behind the research. Chapter 4 is a literature review, in which the various factors for successful deployment of business analytics models are summarized. Chapter 5 consists of the results from the requirements collection interviews and the expert interviews. The artifact is constructed and insights are collected on the deployment factors and related topics. Chapter 6 is dedicated to a case study in a Dutch hospital were the artifact is operationally tested through a gap analysis. Chapter 7 presents the conclusions, recommendations, limitations and future directions of this research.

2 LITERATURE BACKGROUND

In this chapter, a literature background is presented, in order to place the thesis topic and problem statement in context. The chapter makes use of the funnel technique, starting with generalities and gradually narrowing down to the focus of the thesis (Figure 5). In section 2.1, the field of Business Intelligence and Analytics (BI&A) is explained including various related concepts, industry methodology standards, and the topic of predictive analytics. In section 2.2, the field of predictive analytics is specified for clinical purposes. The uniqueness of BI&A in healthcare is discussed, as well as various applications of data analytics for healthcare. In section 2.3, existing project management (PM) strategies are demonstrated. First general information technology (IT) implementation plans are highlighted, later the section zooms in on standards specifically for data mining projects. Section 2.4 takes the topics of clinical prediction models (CPMs) and the deployment phase in project management together.

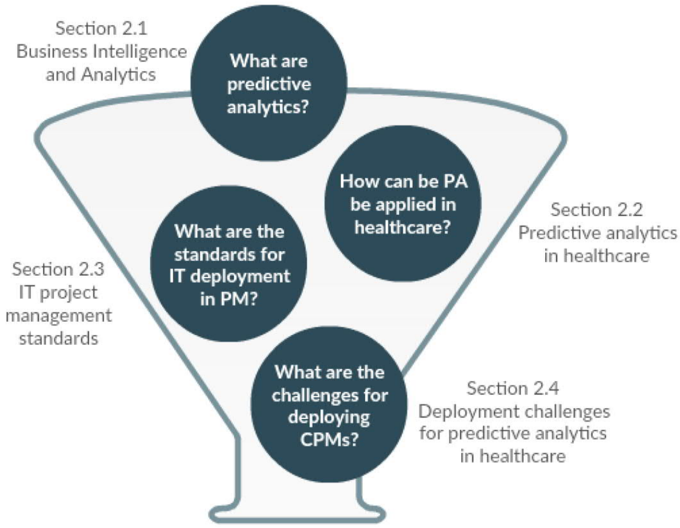


Figure 5 Structure of chapter 2

2.1 Business Intelligence & Analytics

From insurance companies to sport analysts to streaming platforms to hospitals: the use of big data analytics for future predictions is the subject of attention. By dint of big data, faster computing, cheaper storage and advanced algorithms, we are now able to forecast the future.

2.1.1 Concepts of BI&A

A definition of BI&A is "the techniques, technologies, systems, practices, methodologies, and applications that analyze critical business data to help an enterprise better understand its business and market and make timely business decisions" (Chen et al., 2012, p.1166). As such, BI&A is the overarching umbrella of various types of data-driven technologies.

All BI&A efforts are based on the availability of big data. Without the presence of large volumes of data, BI&A would not exist. There is a difference between business intelligence (BI) and business analytics (BA). BI helps organizations to make intelligent decision for current operations. Data is monitored, collected and reported for interpretation and quickly communicated in dashboards to implement the findings. BA aims to understand the trends behind the data, using statistical algorithms to allow for future outlooks. Rather than figuring out *what* happened *when* to *who*, BA attempts to figure out *what will happen*. The methods are not reports or dashboards, but different types of analytics (descriptive, diagnostic, predictive, and prescriptive), data mining, statistical analysis, or simulations. The academic branch of data science is mainly concentrating on BA. Predictive analytics (PA) is one subset of business analytics that uses data to forecast the future. Clinical predictive modeling is the application of predictive analytics in the healthcare sector. Various characteristics related to the disease, patient, or treatment are combined to predict a diagnostic or prognostic outcome. In order to do that, certain techniques are used, such as data mining and machine learning.

Data mining is carried out by an individual who uses computer programs with machine learning capabilities to find patterns in data. Data mining techniques are for example cluster analysis, classification, regression trees, and neural networks. These techniques can be either unsupervised or supervised. With unsupervised data mining the focus is on discovery since the answers are unknown, whereas supervised data mining does have the correct answers. Using machine learning, the computer is able to study algorithms to extract information automatically. It is called 'machine learning' because the machine, i.e. the computer, is able to learn from experience and simultaneously improve its performance. These procedures are often derived or inspired by classical statistics.

The term artificial intelligence (AI) is also often used in the BI&A context. AI aims to program a computer in such a way that it can behave as an intelligent agent. In other words, it allows the performance of certain tasks by systems that normally require some type of human intelligence. AI is based on machine learning, and even more advanced, on deep learning. Deep learning is a subfield of machine learning that makes use of algorithms based on artificial neural networks which imitate the functionality of the human brain. Figure 6 provides a graphical overview of the explained concepts of BI&A.

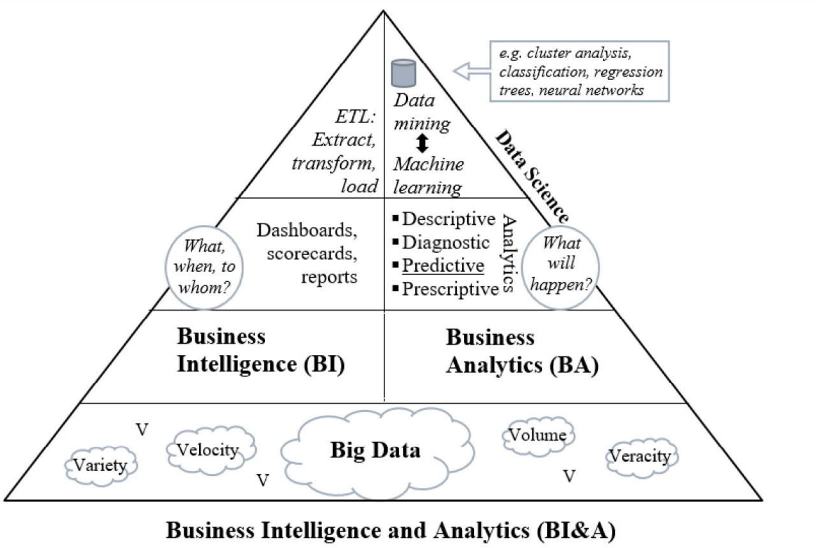


Figure 6 Concepts of BI&A visualized

2.1.2 Big data

Nearly every step you take is recorded by some device that collects data. Bundling all this isolated data into one big pile results in what is called ‘big data’. Big data makes it possible for managers to measure, and thus know, fundamentally more about what is going on in their business (McAfee et al., 2012). This results in increased performance due to the ability to improve decision-making. As McAfee et al. (2012, p.4) state: “you can’t manage what you don’t measure”.

According to Davenport (2012), three points differentiate organizations that utilize traditional data analysis from organizations that capitalize on big data. Firstly, organizations using big data follow continuous flows and processes, rather than events that occurred in the past. Secondly, they employ data scientists, not data analysts. This implies the mastering of a variety of skills, ranging from programming to business. Solely analytical capabilities do not suffice. Thirdly, the analytics function receives prominent attention and is placed into the core business operations.

As depicted in Figure 7, three characteristics describe what big data entails: *volume*, *variety*, and *velocity* (Zikopoulos et al., 2012). First, the massive volumes of data can be overwhelming to organizations. In 2012, we no longer speak about terabytes but about petabytes. In 2018, research group IDC predicts that by 2025 we will be creating 163 zettabytes (or 163 trillion gigabytes) of data worldwide (Reinsel et al., 2018). Second, the variety of data adds a factor of complexity to big data. Rather than the traditional relational data, big data also contains raw, semi-structured and unstructured entries. This implies a fundamental shift in the requirements of data analysis. Third, the velocity of big data considers how quickly data is generated, stored and retrieved. Big data analytics needs to take into account the volume and variety of data that is still in motion.

Over the past years, the V-model has been extended with many extra characteristics starting with the letter 'v'. *Veracity* refers to the amount of data reliability and trust given its source, and *variety* corresponds to the monetary merits that stem from big data analytics (Assunção et al., 2015). Uddin & Gupta (2014) even propose 7 V's that capture big data, adding *'visible'* and *'visual'*. More V's are wandering around with potential to be added to the V-model (volatility? vulnerability? validity? variability? viability? vitality?), but arguably the most important one overall is *value*. Without deriving value from big data, the other V's are unimportant. Value is the holy grail of big data and what all organizations are ultimately looking for.

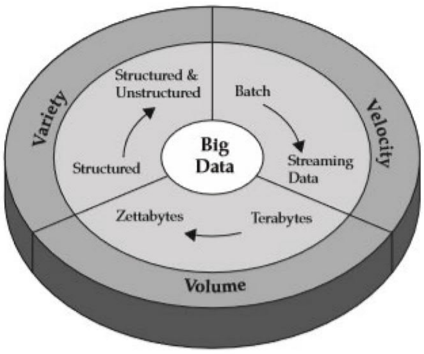


Figure 7 Big data: volume, variety, velocity (Zikopoulos et al., 2012)

2.1.3 Business analytics

The overarching term of 'business analytics' entails all technologies, applications, and skills connected to the continuous and iterative investigation of big data for business insights (Beller & Barnett, 2009). According to Gartner (2016), business analytics can be descriptive, diagnostic, predictive, or prescriptive in nature:

- Descriptive analytics, or reporting analytics, wants to find out 'what happened' through visualization, ad hoc reporting, and trend analysis of past events.
- Diagnostic analytics evaluates 'why it happened'. Root causes of a problem are detected in the data.
- Predictive analytics uses statistical and data mining techniques to predict potential future outcomes. It asks the question of 'what is likely to happen'.
- Prescriptive analytics goes beyond the description, explanation and prediction of data, and wants to know 'what should be done about it'. Courses of action are suggested that lead to optimization of future business processes.

As depicted in Figure 8, the four analytics capabilities are divided on the continuum between human-centered and machine-centered. Moreover, the further in the continuum, the closer analytics come to actual decision making and action. PA is fairly close to machine-centered decision making, but is restricted to just prediction of future events. PA helps organizations to understand the future, but does not give advice on possible outcomes.

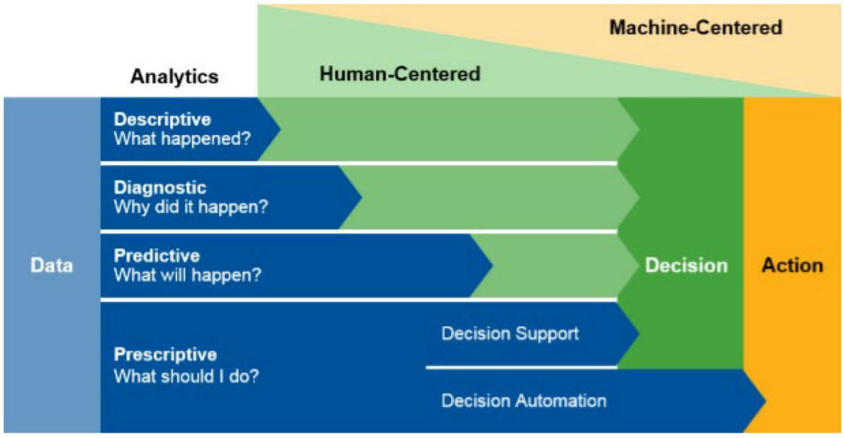


Figure 8 The four business analytics capabilities (Gartner, 2016)

2.1.4 Data mining

Data mining can be explained as the process of detecting meaningful patterns in large datasets (Larose, 2015). Machine learning algorithms are applied to go through the collected data and find these patterns. With data mining, multiple types of tasks can be performed: description, estimation, classification, clustering, association, and; prediction. Predictive analytics (PA) is a technology that allows us to predict the future behavior of individuals by learning from the past (Siegel, 2013). It distinguishes itself from other types of analytics by the way it approaches data: predictive models are induced by data-driven algorithms rather than by assumptions of the analyst. Moreover, data mining can only become predictive when in combination with domain knowledge. Powerful induction of algorithms automates the process of finding meaningful patterns.

2.1.5 Benefits of predictive analytics

When implemented successfully, PA can generate considerable improvements in decision-making, efficiency and return on investment (Abbott, 2014). Especially when PA projects are incorporated into the business strategy, significant benefits can be realized

(Siegel, 2013). Examples of such benefits are: optimized productivity, cost efficiency, error detection, waste elimination, lower process cycle time, resource optimization, improved sales forecasts, dynamic pricing, and much more (Attaran & Attaran, 2019). In a way, PA has the power to improve an array of different operational and organizational activities in all kinds of sectors.

Wang et al. (2018) use a multidimensional benefit framework to categorize the advantages of 26 big data cases in healthcare. The five dimensions are: IT infrastructure, operational, managerial, strategic, and organizational. The various dimensions and accompanied benefits are depicted in Table 2.

Table 2 Multidimensional benefit framework of PA (Wang et al., 2018)

Dimension	**Description**	**Examples**
IT infrastructure benefits	Sharable and reusable IT resources that provide a foundation for present and future business applications	▪ Building business flexibility for current and future changes ▪ IT cost reduction ▪ Increased IT infrastructure capability
Operational benefits	The benefits obtained from the improvement of operational activities	▪ Cost reduction ▪ Cycle time reduction ▪ Productivity improvement ▪ Quality improvement ▪ Customer service improvement
Managerial benefits	Business management activities which involve allocation and control of the firms' resources, monitoring of operations and support of business strategic decisions	▪ Better resource management ▪ Improved decision making and planning ▪ Performance improvement
Strategic benefits	The benefits obtained from strategic activities which involve long-range planning regarding high-level decisions	▪ Support for business growth ▪ Support for business alliance ▪ Building for business innovations ▪ Building cost leadership ▪ Product differentiation
Organizational benefits	When the use of an enterprise system benefits an organization in terms of focus, cohesion, learning, and execution of strategies.	▪ Changing work patterns ▪ Facilitating organizational learning ▪ Empowerment ▪ Building common vision

2.2 Predictive analytics in healthcare

The healthcare industry and big data analytics go hand in hand. Available healthcare information is stored in all types of sources, such as electronic health records (EHR), patient portals, clinical decision support systems, research and development, Internet of Things (IoT) devices, social media, and genetic databases (Raghupathi & Raghupathi, 2014). The application of advanced analytics to patient profiles for predictive modeling is a terrific opportunity.

2.2.1 BI&A in healthcare

The umbrella term BI&A includes many different data-driven techniques (subsection 2.1.1). In healthcare, BI is related to the conduct of business of a healthcare organization. For example, optimization of the number of available beds or the logistics behind available devices for surgery. It is about the processes surrounding the actual care; the business improvements that increase efficiency, effectiveness and quality of care. BA goes to the core of clinical healthcare. Rather than using historical data to improve current operations, it uses data mining to create algorithms for machine learning. EHRs are one of the major sources of clinical data science, including laboratory values (tabular data), doctor's notes (semi-structured or free text), medical imaging (audiovisual data), and computerized order entry systems (Kubben et al., 2019). For example, BA in healthcare can use MRI scans to predict the progression of dementia (Korolev et al., 2016) or predict the chance of developing genetic colorectal cancer based on health record (Drost et al., 2018).

2.2.2 Uniqueness of data mining in healthcare

Data mining in healthcare needs to tackle some issues inherent to the industry. The safety critical context of medicine demands the inclusion of ethics and the cost of prediction (Bellazzi & Zupan, 2008). Compared to other industries, the healthcare industry has a few unique features when it comes to data mining. Cios & Moore (2002) identify four principal points that are unique to medical data, and that influence (predictive) data mining opportunities. These points are:

- Heterogeneity of medical data;
- Ethical, legal, and social issues;
- Statistical philosophy;
- Special status of medicine.

The healthcare industry produces monstrous amounts of data every day. Medical imaging, patient interviews, laboratory data, and practitioner's notes are all potential inputs for data mining algorithms. Since medical data is coming from a variety of sources, their structure and quality are not always comparable. Moreover, a canonical form of elements in biomedicine is often not present. For one type of diagnosis, numerous distinct expressions exist that are medically equivalent. Unlike other disciplines, this poses a challenge to the coding of medical data.

The discussion of data ownership of medical data is ongoing (Telenti et al., 2018). Do individuals own their own medical data? Or are the clinicians that collect the data the owners? Can hospitals actually use this data? The ethical and legal considerations behind this are complicated–more complicated than data that is not medical. Hospitals' fear for lawsuits is a logic consequence of this confusion.

Healthcare is primarily about patient care and curing people. Only secondarily it serves as a resource to research. The majority of the data collection is possible only because it benefits the patient. Statistical philosophy requires repeatable experiments with predetermined parameters. Experiments cannot be interrupted, but in reality this is complicated to align with the well-being of patients.

A unique feature of medicine is its special status in science and society. Healthcare is a necessity rather than an optional convenience, and it touches every single one of us in the weighty matter of life and death. Medicine is a safety critical context that requires supportive explanations in every decision (Fox & Das, 2000). Expectations of healthcare are high; we expect that sick people can get better. At the same time, society is highly critical about what goes on in healthcare. When medical care regrettably fails, responses are vengeful. This makes the development and deployment of data mining techniques a unique endeavor. Compared to other industries, data mining in healthcare could be the most rewarding, but only if all its particular challenges are taken into consideration.

2.2.3 Etiology, diagnosis, prognosis and treatment

In medicine, there is a significant difference between terminologies for disease acknowledgement of which the average person is not aware. For correct communication between data scientists and healthcare professionals on the objectives, context, and consequences of clinical prediction models, it is critical to have an identical understanding of the terminology. Especially data scientists must invest in this knowledge, as it is not part of their standard academic or professional curriculum. Medicine recognizes four types of disease evaluation:

- Etiology: the causes and origins of a disease;
- Diagnosis: the discovery and identification of a disease;

- Prognosis: the expected development of a disease over time;
- Treatment: the medical attention given to combat a disease.

Data analysis is mostly applied to the diagnosis and prognosis types of healthcare (Van Kuijk et al., 2018). A predictive model aiming at diagnosis uses data to identify the disease at the moment of prediction and to give it the right name. A predictive model aiming at prognosis uses data to predict the expected outcome of a disease.

2.2.4 Time series forecasting

Time series forecasting is a method to transform past values into future estimates based on mathematical or statistical models that include certain assumptions in terms of time patterns (Bui et al., 2018). In a clinical setting, the distinct features of time series forecasting can be applied with great impact. Short-term time series forecasting is potentially valuable for emergency care, whereas long-term forecasting can assess the health conditions years after discharge based on treatment effects and risks. In healthcare, it is important that the collected data points are measured at “uniformly spaced time intervals” (Soyiri & Reidpath, 2013). Time series forecasting provides the statistical settings that are required to describe health data that seems to be random and fluctuating and to project the data series into the future (Chatfield, 2004; Shumway & Stoffer, 2006). Various conditions need to be taken into consideration when tackling time series data (Soyiri & Reidpath, 2013):

- Trend: the long-term variation in a time series without any irregular, systematic fluctuations;
- Cyclicality: the extent to which data points are influenced by general patterns;
- Seasonality: the extent to which data points are influenced by general patterns related to annual events with a yearly trend line;
- Randomness: unexpected anomalies of existing or expected trends;
- Lag: the lapse of time prior to the manifestation of an effect;
- Stationarity: the level of variation in statistical properties (e.g. mean, variance, autocorrelation) over time. Most forecasting methods assume stationarity of the data, therefore non-stationary data is often mathematically transformed.

2.2.5 Personalized medicine and its challenges

Personal clinical, genetic, genomic, and environmental information is the base of personalized medicine (Ginsburg & Huntington, 2009). It is an integrated, coordinated, and evidence-based approach that aims to individualize healthcare. La Thangue & Kerr (2011) describe the application of personalized medicine in the oncology field. As a result of progress in biomarker technology, the molecular and genetic composition of tumors are reflected and aligned with the most appropriate treatment. As such, the population-based 'one drug fits all' treatment model has shifted towards a more personalized approach in which predictive biomarkers provide diagnostic and prognostic assistance.

A myriad of obstacles must be overcome before personalized medicine can be employed in real life (Hamburg & Collins, 2010; Soroushmehr & Najarian, 2016). Patients need to be confident in the reliability of the clinical tests. Understanding patients' needs and readiness for adoption are similarly important as the actual development of the technologies (Issa et al., 2009). Another critical step for achieving personalized medicine is the integration of data into validated information that can be used directly for diagnosis, prognosis, or treatment (Castaneda et al., 2015). Generally, big data analytics poses some inherent challenges, such as missing data, imprecise data, and heterogenous data. The employment of data analytics in healthcare adds certain issues to this list, such as patient privacy, data ownership, confidentiality, and repeatability of biological data. Additionally, inadequate knowledge about the human system is a challenge to personalized medicine. Limited access to the brain leads to incomplete understanding of the biological networks and thus treatment outcomes. More investment is required towards the understanding of the human body through computational models.

2.2.6 'P4' medicine

Sagner et al. (2017) propose a 'P4 Health Continuum' as a framework to harness technology and evidence-based interventions. This new way to address medicine is predictive, preventive, personalized and participatory; together labeled as 'P4'. Pioneered fifteen years ago by Hood (2004), the 'P4' approach was back then expected to naturally lead to personalized medicine that would revolutionize healthcare. Over the past decade, the major elements of the 'P4' vision have indeed been largely adopted (Flores et al., 2013). The 'P4 Health Continuum' framework focuses on chronic disease management and aims to reduce the burden and societal impact of chronic illnesses. Other recent research highlights the application of 'P4' medicine in myopenia (Morley & Anker, 2017), obstructive sleep apnea (Pack, 2016), cystic fibrosis (Corvol et al., 2016), asthma (Canonica et al., 2018), and many more diseases.

2.2.7 *Clinical decision support systems*

Clinical decision support systems (CDSS) use machine learning to learn from past events by recognizing patterns in clinical data (Berner, 2007). Through electronic systems, CDSS can communicate the predictions coming from the mathematical algorithm through user-friendly interfaces at the front-end (Castaneda et al., 2015). Moja et al. (2015) state that the use of CDSS in healthcare will increase in the near future due to several factors: the quality of medical care receives growing concerns, there is a continuous call for meaningful use of health IT, and clinicians are increasingly familiar with the use of advanced technologies.

Various studies aim to provide recommendations on how to make predictive modelling and CDSS more effective (Ash et al., 2012; Lobach et al., 2012; McGinn et al, 2012; Moxey et al., 2010; Osheroff et al., 2012). For example by means of governance, training, logistics, or design features. A study by Roshanov et al. (2011) found that CDSS have the power to modify practitioner test-ordering behavior. For optimization of the use of clinical prediction models in practice, it was found that system design, user interface, local context, and implementation strategy are potentially important factors. In terms of design, a CDSS tool can be considered directive when therapeutic recommendations are given, and assistive when simply the model predictions are presented. The lack of direct comparison between a directive and an assistive prediction format in a single population, may lead to bias or generalizability issues (Kappen, 2015).

Kawamoto et al. (2005) argue that healthcare organizations should implement CDSS with automatic decision support as part of the user's workflow, providing actionable recommendations that are delivered in time. Less crucial but still desirable features of the CDSS are periodic performance feedback, request documentation of why a recommendation was not followed, and sharing decision support results with patients. Although the foundation of this quindecinnial research continues to be relevant, requirements of successful CDSS nowadays are more extensive. The Healthcare Information and Management Systems Society (HIMSS) is an American non-profit organization that aims to improve the quality, safety, and cost effectiveness of healthcare through IT. In their books on clinical decision support systems, they provide authoritative guidance on the implementation of CDSS (Osheroff et al., 2012). HIMMS presents the book as a guidebook for successful deployment of CDSS, with tips and tricks on how to overcome various challenges. The most common reasons that CDSS are not yet deployed are the challenge to convert data into a clinically relevant model, the complexity to integrate the model into the clinical workflow, and the ethical and legal repercussions of computerized recommendations (Belard et al., 2017).

2.2.8 Existing clinical prediction models

Scientists have published the development of various CPMs. Each model specifically targets one disease type and is the result of specialized expertise of a clinical area. In this subsection, a few existing CPMs are mentioned.

Dawes et al. (2017) use supervised machine learning to predict patient survival and mechanisms of right ventricular failure due to high blood pressure in the arteries to the lungs. They conclude that their algorithms indeed allow for more accurate predictions of patient outcome and that machine learning based on cardiac magnetic resonance imaging (MRI) could guide diagnostics. Desautels et al. (2016) investigated a prediction method for sepsis, a serious infection caused by the immune system, which they call *InSight.* Based on a minimal set of variables from EHR data, *InSight* is found to be an effective tool for sepsis onset prediction. A study using routine clinical data focused on the risk prediction of cardiovascular diseases, such as stroke and heart failure (Weng et al., 2017). They conclude that the established algorithm was able to identify patients eligible for preventive treatment, while avoiding unnecessary remedies for other patients. Another risk prediction model designed by Thottakkara et al. (2016) concentrates on postoperative complications. Meretoja et al. (2017), propose a validated prediction model and online risk calculator that identifies patients at high risk for developing enduring pain after breast cancer surgery. In the mental health domain, Walsh et al. (2017) applied machine learning to EHRs in order to predict future suicide attempts and found it to be a more accurate method than traditional statistical methods. No clear consensus on the best methodology for building clinical prediction models exists, therefore Lee et al. (2016) and Steyerberg & Vergouwe (2014) summarized several steps for development and validation.

Besides the academic development of CPMs, the commercial developments by large corporations are also noteworthy. IBM consider themselves as one of the pioneers with regards to AI software for medicine (IBM, 2019). For instance, the IBM Watson for Oncology technology uses medical records to identify potential treatment options ranked by degree of confidence. This tool supports the oncologist in the decision-making of appropriate treatments for a specific diagnosis and prognosis. Other big players, such as Google, Apple and Amazon also gain ground in clinical prediction research. Google has made most progress in the diagnosis of diabetic eye disease and breast cancer detection (Google, 2019). Figure 9 shows an example of tumor detection by Google. An algorithm is able to autonomously evaluate biopsy imaging of lymph nodes and predict whether tissue patch is benign or a tumor.

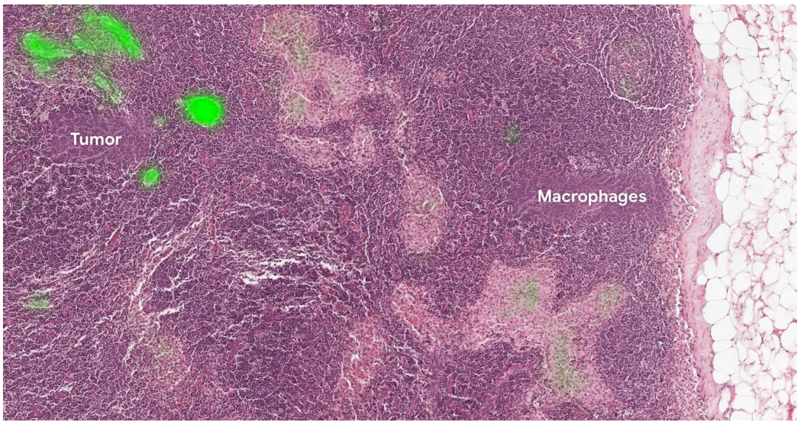


Figure 9 Close-up picture of a lymph node biopsy. Google's algorithm can accurately identify the tumor region, without confusion by the macrophages.[1]

2.2.9 Deceleration of the predictive analytics revolution

With a myriad of research on predictive analytics in medicine and the development of specialized prediction models, it is only intuitive to wonder why they are not yet widely implemented. What causes the deceleration of the promised PA revolution in healthcare?

Poor data quality and incompatible datasets has been a limitation ever since the beginning of machine learning (Cortes et al., 1995; Dhindsa et al., 2018; Obermeyer & Emanuel, 2016). EHR databases require prudent curation and processing before they are usable. The digitalization and integration of EHRs and platforms comes with some constraints: confidentiality of genomic data, technological security breaches, and the logistics between and amongst healthcare providers and researchers (Castaneda et al., 2015). The solution according to Dhindsa et al. (2018) resides in the adoption of data standards that guarantee data quality and compatibility between institutions. For the advancement of patient care with PA, it is essential that new data policies are established by joint effort of clinicians, data scientists, patients, and society. Moreover, data fragmentation is a major issue in clinical data science. Traverso et al. (2018) point out four restraining barriers to big data exchange:

- Administrative barriers: the additional efforts required from the hospital facility, leading to increased personnel costs;
- Ethical barriers: various data privacy concerns and national legislations regarding privacy and confidentiality;
- Political barriers: data sharing resistance, no joint effort by the community;
- Technical barriers: scarce interoperability across healthcare organizations.

[1] Source: https://ai.google/healthcare/

The technical barriers directly call attention to another problem: the lack of highly skilled data experts. This talent shortage will only grow; the Quant Crunch report (Markow et al., 2017) indicates an expected rise in demand for data scientists of 28% by 2020.

Furthermore, the concerns with regards to privacy are a restriction for the (predictive) analytics revolution (Patil & Seshadri, 2014; Raghupathi & Raghupathi, 2014). Grover et al. (2013) proposes that in order to sustain the momentum, the collective mindset about sharing patient data must shift from “protect” towards “share, with protections”.

According to Iniesta et al. (2016) the main challenge of applying CPMs in practice is the external validation of the models. Generalization to other populations can be a problem. The cross-trial study by Chekroud et al. (2016) externally validated their findings and conclude that for depression a machine learning model is able to forecast the treatment efficacy of antidepressants. Most studies (Dawes et al., 2017; Desautels et al., 2016; Thottakkara et al., 2016; Weng et al., 2017) rely solely on internal cross-validation and are thus less likely to be generalizable to other populations and health systems.

Another reason for the revolution slowdown is the hype around it. Since 2017, machine learning is exiting the ‘peak of inflated expectations’ in the hype cycle for emerging technologies (Figure 10). It is thus expected that now we will enter a ‘trough of disillusionment’ in which interest fades and implementations fail to deliver. Stronger appreciation of the capabilities and limitations of PA might soften the crash into this next stage (Chen & Asch, 2017). Hopefully it is then possible to move on as soon as possible towards the ‘slope of enlightenment’ stage, in which data will improve our collective health by virtue of the predictive analytics revolution.

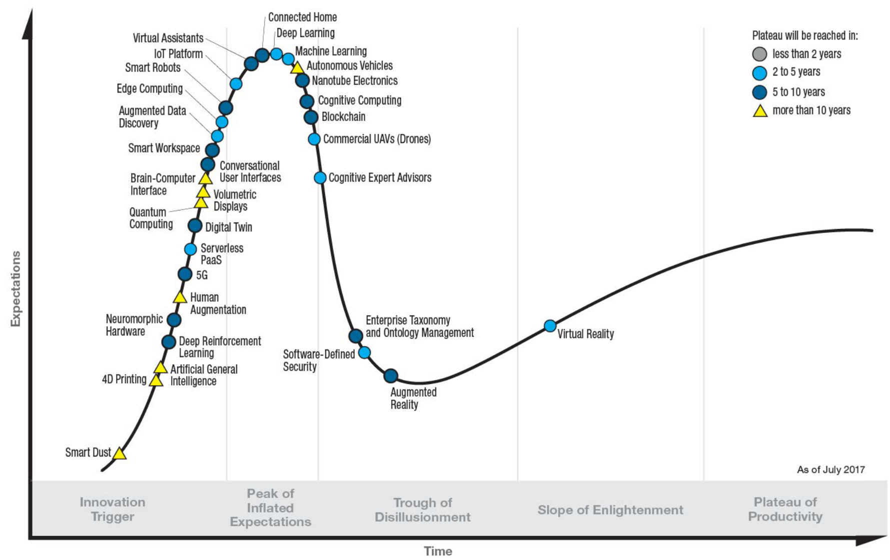


Figure 10 Hype cycle for emerging technologies in 2017. Machine learning is exiting the ‘peak of inflated expectations’ phase. (Gartner, 2017)

Lastly, inconsiderate use of prediction results are a serious danger. An example is the model calculating risk of death of patients that arrived at the emergency room with a pneumonia (Caruana et al., 2015). This model predicts that patients with both a pneumonia and asthma have a relatively favorable prognosis compared to patients with pneumonia and no asthma. Thus, the model indicated that the former group could be sent home safely. This unintended consequence was due to the fact that the model did not take into account the aggressive treatment and hospital admission of patients with both pneumonia and asthma, which made it seem they had a relatively positive prognosis (Cabitza et al., 2017). Hence, the scope of one 'wrong' model implemented in practice is considerably bigger than the scope of one 'wrong' assessment of a clinician. The possibility of predictive models to disseminate misinformation and cause harm suggests the need for more oversight, especially in profit-driven markets (Shah et al., 2018)

2.3 IT project management standards

Numerous standards for IT project management help to make projects a success. A project follows a series of stages, in which different activities play the main role. Next to general approaches to IT project management, specific models exist for data mining projects in particular. In this section it becomes clear that the phase of deployment is an important step in the data mining project management standards.

2.3.1 Project management methodologies

Project management (PM) is an approach to achieve specific project objectives by applying certain processes, methods, skills, and experience (Larson & Gray, 2017). A project is considered a success when the objectives are achieved in accordance with the acceptance criteria, including constraints in scope, time, quality, and budget. This implies that project management follows a final deliverable in a finite timespan, rather than an ongoing management process.

Over the years, various PM methodologies have been developed, tested, and utilized in practice. Some are specifically directed to software development. The waterfall methodology was one of the first approaches developed by Royce in 1970. This sequential methodology is divided into discrete stages that must be entirely completed before moving onto another. The agile methodology was developed as a response to the shortcomings of the waterfall technique in complex projects. This approach is iterative with small, incremental steps that are responsive to external changes. This makes it more flexible and adaptable, and hence better suited for projects which do not have a clear end point. It is possible to choose a hybrid approach, combining waterfall and agile. Scrum is an approach that can be used in agile projects. It is fast-paced following short sprints and has a focus on self-organized and self-managing teams. Similar is Kanban, where collaborative teams work on continuous delivery through workflow visualizations.

Other PM methodologies are not specific to software development. Lean methodology promotes the flow of value while minimizing waste. The Six Sigma methodology focuses on quality improvements by reducing errors. The Critical Path Method categorizes all activities into a breakdown structure and maps durations and dependencies. The Critical Chain Project Management (CCPM) reuses this approach through the lens of resource management. The Integrated Project Management (IPM) methodology emphasizes sharing and process standardization through the organization. Projects integration Sustainable Methods (PRiSM) focuses on minimization of harmful environmental impacts of a project, extending beyond the end of a project to maximize sustainability. Projects IN Controlled Environments (PRINCE2) is the official methodology of the United Kingdom government. Clearly defined stages and a lifecycle, measurable products and predefined responsibilities are part of it. The Project Management Life Cycle (PMLC) methodology divides a project into stages and builds an approach around that. The Project Management Institute (PMI) created the Project Management Body of Knowledge (PMBOK), which is more a set of standard terminology and guidelines rather than a methodology. It can be used to weigh in on the best practices for a project.

2.3.2 Project process model for information systems

The numerous PM methodologies, with each their specified practices, techniques, and procedures, generally share the notion of phases. Processes run across various phases which break down a project into more digestible parts and allows the tracking of deliverables. An example of PM phases are: initiation, planning, execution, control, and closing. Cadle & Yeates (2004) propose a process model as a generic framework for information systems projects (Figure 11).

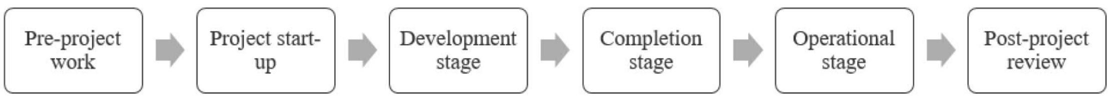


Figure 11 Project process model (Cadle & Yeates, 2004)

The model can be tailored according to the requirements of a specific project. The sequential nature of the activities implies a waterfall approach. However, various types of life cycles are allowed within the stages of the model, such as a phased delivery approach or a spiral model. As in most methodologies, the process model shows a project divided into a number of stages from start to finish with clear deliverables. For the successful deployment of a data mining solution it is rudiment to acknowledge and follow a project process model such as the one illustrated in Figure 11.

2.3.3 Implementation strategies for IT

The implementation (or execution) phase revolves around putting the project plan into motion, and is hence the start of project deployment as defined in this thesis. Already 30 years ago, the importance of implementation management for the maximization of benefits from IT investments was stressed (Cooper & Zmud, 1990). The adoption of a comprehensive framework and examination of related constructs in a systematic manner can prescribe what issues should dominate in each of the IT implementation stages. Gottschalk (1999) created an IT strategy implementation matrix with a clear priority on elements in the implementation plan. Important factors are the description of responsibility of time, budget, intended benefits, and user involvement. When looking at the user perspective on change, a study by Joshi (1991) uses equity theory to describe resistance to change by information systems users. Users evaluate their net gain of a change, in this case a new IT-related implementation. The model provides a useful framework for managing resistance to change during implementation from a behavioral perspective. The definition of a clear and comprehensive IT implementation strategy is key in any type of IT implementation, in any type of organization.

2.3.4 CRISP-DM

Next to general PM methodologies, standards exist for the managing of data mining projects. For an industry-neutral, tool-neutral, and application-neutral approach towards data mining, the Cross-Industry Standard Process for Data Mining (CRISP-DM) was developed in the 1990s (Chapman et al., 2000). This freely available standard provides a common, structured method for the planning and executing of data mining techniques for strategic problems (Larose, 2015). Praised for its powerful practicality, flexibility and usefulness, it is widely used in PM and academic research.

The CRISP-DM declares six lifecycle phases of a data mining project (Figure 12). Critical to note is that the CRISP-DM is both adaptive and iterative in nature. That is, phases often depend on outcomes associated with previous phases, and lessons learned from the past serve as input for new projects.

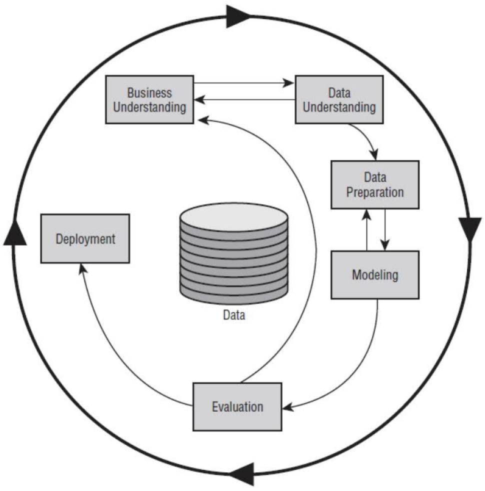


Figure 12 Phases of CRISP-DM process (Chapman et al., 2000)

The process starts with an understanding of the business and the problem definition in the *Business Understanding* phase. The importance of this phase is further highlighted in part 2.4.4. After data collection, the data quality is evaluated in the *Data Understanding* phase. Following are the labor-intensive *Data Preparation* phase and the *Modeling* phase. After the model settings are calibrated for an optimal result, the *Evaluation* phase comes to a decision regarding the use of the data mining results. Those results are carried out in the last step; the *Deployment* phase. Here, the discoveries of the data mining model are used in practice to improve parts of the business. The integration of these discoveries into use is exactly where the topic of this thesis is located. Although this phase is recognized in the CRISP-DM, there is no further instruction on the tactics for deployment. Detailed steps of the CRISP-DM process are provided in Table 3.

Table 3 Detailed steps of the CRISP-DM process phases

Phase 1: Business understanding	1.1: Determine business objectives
	1.2: Assess situation
	1.3: Determine data mining goals
	1.4: Produce project plan
Phase 2: Data understanding	2.1: Collect initial data
	2.2: Describe data
	2.3: Explore data
	2.4: Verify data quality
Phase 3: Data preparation	3.1: Select data
	3.2: Clean data
	3.3: Construct data
	3.4: Integrate data
	3.5: Format data
Phase 4: Modelling	4.1: Select modelling technique
	4.2: Generate test design
	4.3: Build model
	4.4: Assess model
Phase 5: Evaluation	5.1: Evaluate results
	5.2: Review process
	5.3: Determine next steps
Phase 6: Deployment	6.1: Plan deployment
	6.2: Play monitoring and maintenance
	6.3: Produce final report
	6.4: Review project

2.3.5 CRISP-MED-DM

Niaksu (2015) created an extension to the CRISP-DM specifically for the medical domain. The CRISP-MED-DM addresses the typical data mining issues portrayed in the healthcare sector in each of the steps of the framework. Those issues include the mining of non-static datasets, clinical information system interoperability, semantic data interoperability, ethical and social constraints, patient data privacy, and the active involvement of clinicians in the knowledge discovery process (Niaksu, 2015). The general tasks, activities and associated deliverables of the extension all apply to phases 1-4. For the evaluation phases and the deployment phase, Niasku (2015) states that no significant changes are required. Part of the deployment phase is the 'identification of possible problems'. Although this might not require a significant variation from the original CRISP-DM, it does need a more extensive and complete explanation of how exactly health organizations can do this. This thesis perfectly fills that gap.

2.3.6 ASUM-DM

The Analytics Solutions Unified Method for Data Mining (ASUM-DM) is a refined version of the CRISP-DM process methodology created by IBM in 2015 (Haffar, 2015). New activities, templates, and guidelines were added in an attempt to compensate for the weaknesses of the old model (Angée, 2018). The ASUM-DM is described as a hybrid agile and traditional implementation approach that is enterprise-ready, scalable and user-friendly (IBM Analytics, 2016).

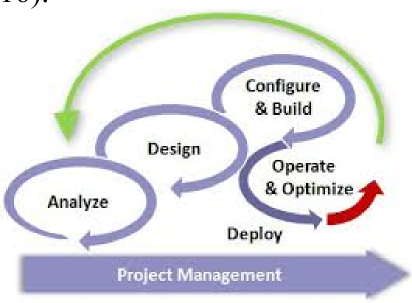


Figure 13 Phases of ASUM-DM process (IBM Analytics, 2016)

Rather than six phases, the ASUM-DM has five phases in which each phase is overseen by a project management stream (Figure 13). The PM stream is a crucial component as it ensures coordination in communication and collaboration. The five phases are *Analyze, Design, Configure & Build, Deploy, and Operate & Optimize*. The main difference compared to CRISP-DM is that deployment and operation are separated and that new facets, such as collaboration, compliance, security, and version control are added in those phases.

CRISP-DM and by extension ASUM-DM are considered the most popular methodologies for data mining projects and thus for PA projects. Employing those frameworks avoids reinvention of the wheel and duplicate efforts by companies and researchers (Larose, 2015).

2.3.7 Other data mining standards

Next to the data mining standards described in the previous subsections, some other data mining methodologies are shortly presented.

SEMMA stands for Sample, Explore, Modify, Model, and Assess. It is developed by SAS Institute as an alternative to CRISP-DM (Matignon & SAS Institute, 2007). SEMMA is different from CRISP-DM because it was developed specifically for the software package *Enterprise Miner*. SAS describes it as a “logical organization of the functional toolset of SAS Enterprise Miner for carrying out the core tasks of data mining” (Dean, 2014). Due to its focus on *Enterprise Miner* and on model development specifically, SEMMA follows a lighter approach towards the initial planning stages (business understanding and data understanding in the CRISP-DM). The deployment phase is entirely removed.

KDD stands for Knowledge Discovery in Databases and involves seven steps: data cleaning, data integration, data selection, data transformation, data mining, pattern evaluation, and knowledge representation (Fayyad et al., 1996). The overall goal is to extract knowledge from large databases. In order to do so, patterns are evaluated and interpreted and transformed into new knowledge. The process of KDD is iterative, hence new data can be added, algorithms can be updated, and evaluation measures enhanced. Compared to CRISP-DM, KDD focuses more on the steps to execute data mining, rather than a description of a project management approach.

2.4 Deployment challenges for predictive analytics in healthcare

This section starts off with clarifying the concept of deployment. The deployment of IT in healthcare and the deployment of PA comes with some challenges. However, literature on deployment challenges for predictive models specific to the healthcare industry are scarce. In order to fill this literature gap, the role of business understanding in deployment and the concept of project ‘success’ is highlighted.

2.4.1 Deployment, implementation, and continuation

The terms deployment, implementation, and continuation are used interchangeably in various external sources, but actually have a different meaning. It is important to elucidate the meaning of each term throughout this thesis.

The 'implementation' stage entails the stage where a project is materialized or realized. Implementation is initiated when a project has been assessed as feasible (Bonnal et al., 2002). In terms of the project life cycle, implementation is part of the execution phase. Since the project at hand is a CPM, it is a software implementation.

The 'continuation' stage follows after the implementation stage. When the software is up and running and all predetermined requirements have been met in accordance with the initial design, the implementation phase is over. Now, it is about the daily activities, operations, and management surrounding the software that must ensure its success over the long-term.

The term of 'deployment' is used to describe "the action of bringing resources into effective action" ("deployment", n.d.). Deployment of a project includes both implementation and continuation. Thus, it is the overarching term for the period starting from the actual implementation until the daily continuation of the new software. Figure 14 visualizes the relationship between the three concepts in the context of this thesis.

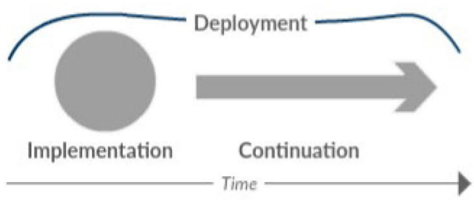


Figure 14 Deployment, implementation, and continuation of a project

2.4.2 IT deployment challenges in healthcare

Successful deployment of new technologies in healthcare is complex, due to a range of interrelated organizational, technical and social factors (Cresswell & Sheikh, 2013). Introduction of new technologies in healthcare is a process that is dynamic and iterative in nature, rather than linear (Cresswell et al., 2010). For successful implementation it is necessary to achieve a degree of alignment between the three factors (i.e. organizational, technical, social). In contrast, Cresswell & Sheikh (2013) conclude that such normative approach to success is not possible due to the complexity in the relationships between the dimensions. They do however recognize several crucial factors for IT implementation and continuation in healthcare: user involvement, effective leadership, early demonstrable benefits, training and support, and close fit with organizational processes,

For a successful implementation of patient care information systems, several challenges might hamper the process (Berg, 2003). First, the transformational character affects both the implementing organization and the implemented technology, as they transform each other. Second, such a strategic process can only work if supported by management and future users. This requires a top-down framework in which users are directed into a coherent steering force. Third, a careful balance is needed between proactively initiating organizational change through IT implementation, and drawing upon the technology as a change agent. In other words, healthcare organizations must find the balancing line between setting direction for change and simply drifting with the created current. Experimenting and mutual learning is more important than planning and control. However, this does not imply to lie in wait.

A study by Greenhalgh et al. (2017) aims to create an evidence-based, pragmatic framework for the prediction and evaluation of success of technology-supported healthcare solutions. Those solutions are often promising, but fail because they are not adopted by individuals. Moreover, it is possible that those tech innovations fail to scale up locally, do not spread globally or have difficulties in endurance in the long-term. Their non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework helps to identify technological innovations and their potential of large-scale, sustained adoption.

Edmondson et al. (2001) investigated new technology deployment in hospitals. Specifically, they examined the relation between team learning and the way new routines are developed when existing routines are fortified by technology. Four process steps of successful implementers were found: enrollment, preparation, trails, and reflection. This way, team motivation, psychological safety, and shared meaning were created. Technology adoption and corresponding routines are thus influenced by the collective learning process of those directly responsible for the new implementation.

Sharifi et al. (2013) focus on the e-health deployment challenges in medical organizations in Iran. A qualitative study compared general challenges gathered from existing literature to experts' claims about Iranian medical organizations (Table 4). Although Iran engages in organizational e-health projects, it is a developing country in the Middle East, and hence not equivalent to Western countries. The authors recognize this in the challenge of privacy and security. Iran uses offline systems for e-health applications, which completely changes the privacy and security conditions. For all the other challenges, the authors argue that Iranian cases are similar to that of other countries.

Table 4 General implementation challenges with examples and solutions in Iran (Sharifi et al., 2013)

Deployment challenge	**Example**	**Solution**
Lack of standardization of e-health applications	Multiple data formats	Nationwide data standards
Cost of systems	Huge demand for hardware, software, and maintenance	Centralized policies to mitigate overlap and duplicate costs
Training costs	Workshops	Extension of e-health courses at medical universities
Legal challenges	Rejection of e-evidence in judicial courts	Legal agreement between judiciary and government
Privacy and security	Required to take systems offline	Appropriate firewalls and antivirus programs
Implementation and acceptance time	Management concerns	Develop instructions and rewards
Technical difficulties	Server downtime	Adopt business continuity instructions
Educational issues	Different shifts of nurses	Different learning sessions
Resistance to change	Medical staff does not want to follow new rules	Education and awareness of potential benefits

2.4.3 Barriers for deployment of predictive analytics

PA tools often run into some obstacles during implementation, regardless of the industry. According to Abbott (2014), the four categories of most common reasons for failure are: obstacles in management, obstacles with data, obstacles with modeling, and obstacles in deployment. For clarification purposes: Abbott (2014) identifies one category as 'obstacles in deployment'. The term 'deployment' is used in this context to refer to the period after implementation. This thesis uses another meaning of the term deployment. If the fourth category of Abbott (2014) would be named in a way consistent with this thesis, it would be referred to as 'obstacles in continuation'. Table 5 gives an overview of the four categories and more detailed explanation. On a critical note: the overview by Abbott (2014) does not include obstacles that are related to the alignment of the initial problem and the abilities of the prediction model.

Table 5 Four categories of most common reasons for unsuccessful predictive models (Abbott, 2014)

Obstacles in management	• No top management support • Lack of resources • Lack of political will
Obstacles with data	• Data in wrong format • Leakage of (unknown) future data
Obstacles with modeling	• Overfitting • Overambition of the analyst
Obstacles in deployment	• Model not consistent with operational system • Data not in deployment format

A research paper on behalf of IBM has also identified challenges encountered by organization in their PA implementation. Attaran & Attaran (2019) list these challenges, divided into technical and organizational type of challenges (Figure 15). Although the authors talk about 'implementation', most factors are also important for the continuation of PA projects. Furthermore, the authors warn for five strategic pitfalls of PA implementation (Attaran & Attaran, 2019). They argue that organizations should not approach PA in the same fashion as other BA projects due to the following five pitfalls:

- Lack of planning. For a successful PA implementation, companies must think strategically upfront. A comprehensive planning and assessment of needs versus resources is required.
- Data inaccessible for analysis. For the integration, unification, and standardization of data coming from various sources, effective data management must be incorporated by PA tools.
- Inexperience of users. Successful implementation requires thorough knowledge of the techniques behind the PA tool. If the skills and experience are not present in-house, a hired team of data experts can be the solution.
- No clear responsibilities. Different roles within the organization should receive specific responsibilities. For example, data scientists should not be given the business responsibilities that actually belong to business managers.
- Lack of focus. One business initiative should be the focal point at each point in time. It is easy to become distracted when too many indicators are tracked and traced at the same time.

Technical	• Volume of required data; too expensive to measure • Difficulty of source data access • Difficulty of using results • Difficulty of integrating PA into IT systems
Organizational	• Lack of resources (skills) • Lack of budget • Lack of awareness on how to apply PA to business problems • Lack of in-house experts to implement the results • Low accuracy of results

Figure 15 Implementation challenges of PA (Attaran & Attaran, 2019)

2.4.4 The importance of business understanding

The numerous approaches to PM differ to a certain extent in the description and sequence of the stages. However, for data mining projects such as clinical prediction models, the recommended starting point is mostly the understanding of the business domain. As proposed by Niaksu (2015) in the CRISP-MED-DM, a terminology more fit to the healthcare sector would be 'problem understanding', to avoid the business case approach in the clinical application domain. This stage generally encompasses the development of project objectives both from a clinical and healthcare management perspective, the associated success criteria, and an evaluation of the required resources. Sharma & Osei-Bryson (2009) find in their research that this phase is often implemented ad hoc. They argue that the reason for this unstructured approach is the general lack of attention to the importance of this phase. This leads to inefficiencies in time and resource planning, or could even steer the project towards a direction other than intended.

In the business understanding (BU) phase of CRISP-DM, the success factors of the project are supposed to be determined. That means that the BU phase pervades all other project phases. Menger et al. (2016) propose a CRISP-IDM method and find that domain understanding (BU phase) cannot be underestimated, as it forms the basis for data selection thereby directly influencing the successfulness of the project. It also is the first step in interacting with the local workforce. Involvement of healthcare professionals turned out very helpful in the deployment phase, especially in terms of practical support. Sharma & Osei-Bryson (2009) utilize the CRISP-DM model to create a framework that depicts the dependencies between phases (Figure 16). This is based on the observation that output from certain tasks may serve as the inputs to other tasks. In conclusion, the authors argue that the BU phase is pivotal to the success of a data mining project, since its choices and outcomes affect all other phases, including the deployment. The output of the BU phase produces a project plan for the deployment of the project.

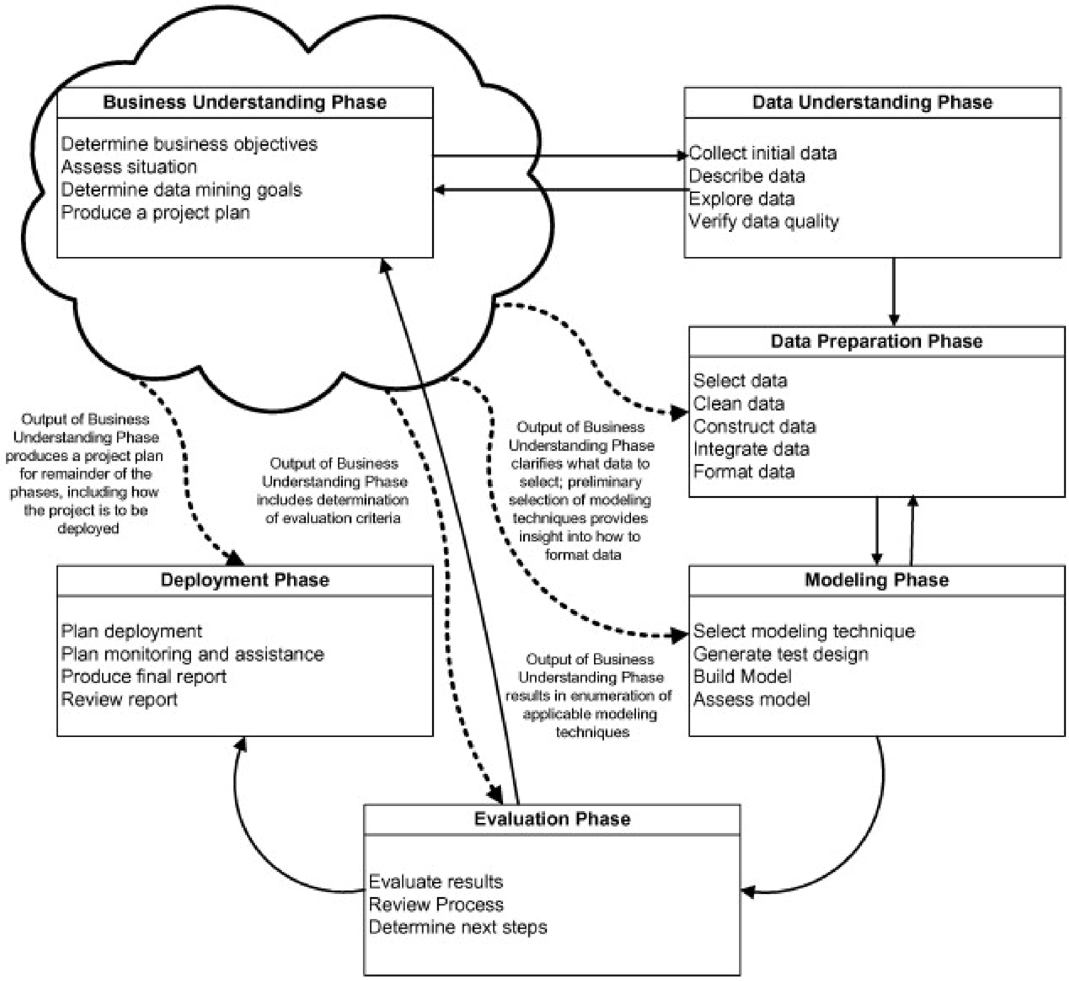


Figure 16 The business understanding phase pervades and impacts all other phases of a data mining project (Sharma & Osei-Bryson, 2009)

2.4.5 When is project deployment considered a success?

The success or failure of a project is difficult to assess, since different people have different definitions of success. Myers (1994) argues that the perception of stakeholders on project success determines when success is achieved. However, perceptions can be influenced by unrealistic expectations (Szajna & Scamell, 1993). It is a human tendency to underestimate challenges and overestimate personal capabilities under conditions of uncertainty (Kahneman et al., 1982). On the other hand, those responsible for a project may be positively biased, since success implies prolongation of the project (Wilson & Howcroft, 2002). It is impossible to assess success in a simplistic one-dimensional measure, since all projects are different and are measured on various dimensions (Wateridge, 1998). Therefore, success is a multidimensional construct that varies per project.

Thomas & Fernández (2008) found that three effective practices aid in reaching success of IT projects: an agreed definition of success, consistent management, and the use of results. Success in project management used to be based on constraints in time, cost, and performance as embodied in the Project Triangle. This model, whose origins are unclear, states that changes in one constraint directly demand changes in another constraint or else project quality will suffer. Kerzner (2009) states that nowadays project success is dependent on more than just these three constraints:

- Within the allocated time period;
- Within the budgeted cost;
- At the proper performance or specification level;
- With acceptance by the customer/user;
- With minimum or mutually agreed upon scope changes;
- Without disturbing the main work flow of the organization;
- Without changing the corporate culture.

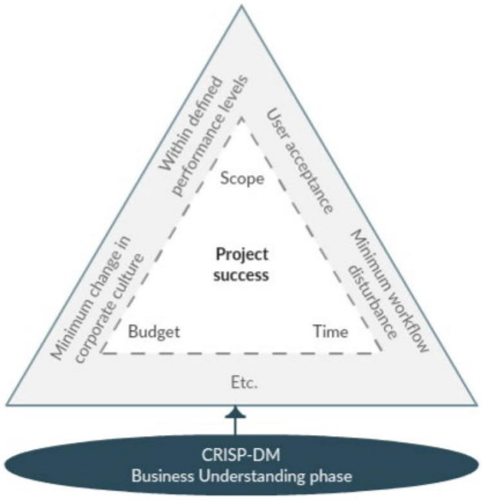


Figure 17 The traditional project triangle extended and linked to CRISP-DM business understanding phase

The definition of success is directly linked to the BU phase, as discussed in the previous subsection. In this first phase, the objectives and goals are determined, which must be achieved in order to call the ultimate deployment a success. In conclusion, the very act of defining and measuring project success in the BU phase contributes to success itself. The deployment of a data mining project is considered a success when the predetermined, concrete objectives are met with a certain level of assurance. Whether this means technical performance, employee satisfaction, budget, time, or something else, is thus established in the first phase of project management. Figure 17 shows the extended project triangle and the CRISP-DM BU phase at the base for the recognition of project success.

3 METHODOLOGY

This chapter describes the methodology that is used for this research in detail. An overview of the research design is provided, as well as an explanation of design science. Moreover, the various data collection methods are highlighted.

3.1 Research design

The nature of this study is exploratory and qualitative, as the focus is on collecting new insights in a flexible manner whilst considering all potential aspects of the problem statement. A problem is investigated that has not yet been clearly defined. Ultimately, the outcomes of this thesis intend to clarify the existing problem, but will not provide conclusive results. Again, the problem statement:

"How to design a successful deployment strategy for clinical prediction models in hospitals?"

Firstly, a literature review is conducted to collect secondary data on the implementation and continuation factors for BI&A tools and more specifically for CPMs. In order to validate the literature review, requirements collection interviews are conducted. Based on the outcomes, a deployment artifact is constructed, serving as the backbone for this thesis. After that, multiple expert interviews are conducted in order to validate the developed artifact. According to the outcomes of the requirements collection and expert interviews, the artifact is modified into the most accurate and complete representation of the context. Followed by these interviews and artifact modification is a case study at a hospital in the Netherlands. Here, the goal is to test the developed artifact in practice. Two sets of questionnaires are used to compare the baseline objectives in terms of deployment factors with the current status of the deployment factors. Finally, the recommendations emanated from the artifact lead to the design of a successful deployment strategy for clinical prediction models. Figure 18 visualizes the research design of this thesis project.

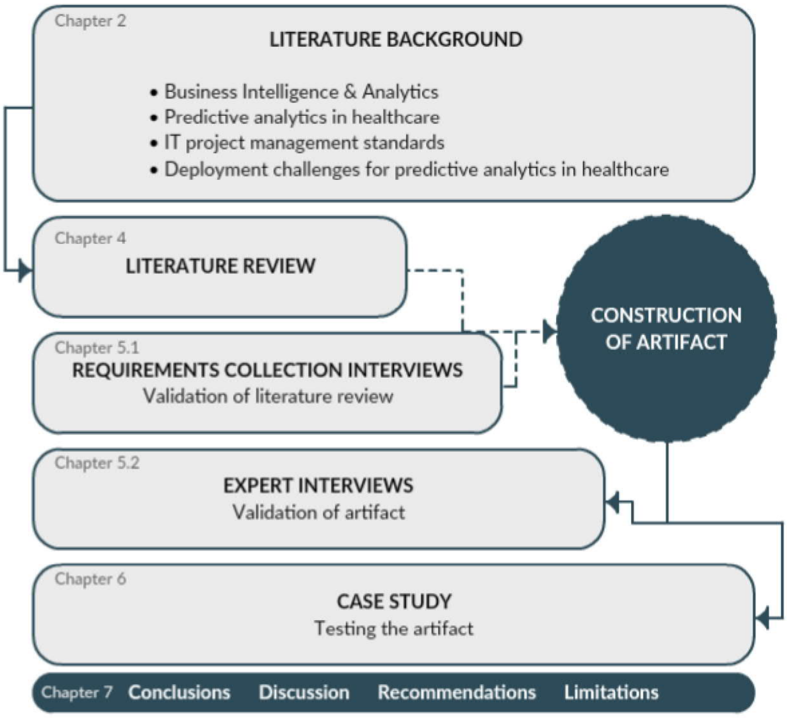


Figure 18 Research design

3.2 Design science methodology

Design science is "the design and investigation of artifacts in context" (Wieringa, 2014, p.3). Design science "creates and evaluates IT artifacts intended to solve identified organizational problems" (Hevner et al., 2004, p.77). By designing an artifact a problem context is identified and improved (Wieringa, 2014). Hence, the goal is the develop an artifact and improve its functional performance. In this thesis, the problem context of CPM deployment in hospitals is unraveled by the design and validation of a deployment artifact. In short: a model for successful deployment is created.

The design science process revolves around six steps: problem identification and motivation, definition of the objectives for a solution, design and development, demonstration, evaluation, and communication (Peffers et al., 2007). Figure 19 provides an overview of the six steps.

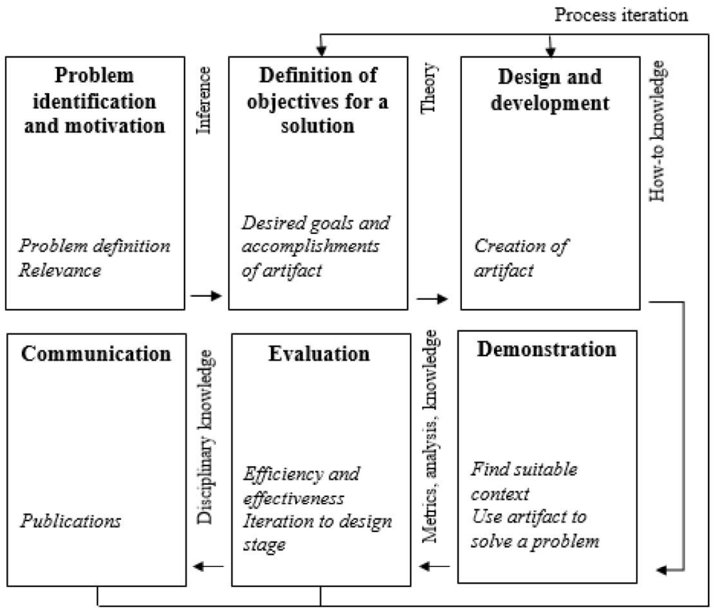


Figure 19 The design science process (Peffers et al., 2007)

3.3 Data collection

In order to create and validate a new conceptual model based on design science, this thesis uses a multi-method approach. By means of methodological triangulation it is possible to study a phenomenon using more than one method (Casey & Murphy, 2009; Risjord et al., 2001). This thesis is a 'within-method study', meaning that more than one data collection procedure is utilized, but never in a mix of qualitative and quantitative (Bekhet & Zausz-niewski, 2012). All data collection is primarily qualitative, with a combination of existing literature review, interviews and a final case study.

3.3.1 Literature review

The first part of the research consists of a theory development on the implementation and continuation of BI&A tools. Through an extensive literature review, a conceptual model is created. The appropriate literature is gathered through online libraries and databases, as well as hard copies from the university collection. In the quest for relevant papers, different search strategies have been used. Key words and concepts derived from the problem statement are combined, as well as relevant synonyms. For some searches, the periodic range has been limited to ensure only recent work is found. The reference list of appropriate papers is consulted to discover related papers that confirm, apply, improve, extend or correct findings. The literature review is utilized for the creation of the artifact.

3.3.2 Requirements collection

In this step, the literature review overview (Appendix A) is presented to experts with the goal to validate the findings. The outcomes of the requirements collection are utilized for the conceptual model and the construction of the artifact. The factors as identified in the literature are considered, and possibly removed, altered, or new ones are added. Moreover, the categorization is reviewed and possibly altered as well.

The requirements collection phase consists of four interviews. Respondents with different professional backgrounds were questioned in order to incorporate various point of views (Table 6). One expert provided input from a risk management perspective. This relatively distant perspective allows for a more broad, oversight outlook. Due to time constraints and limited access to relevant interviewees, a total of four people is considered as sufficient. The limitations with regards to this choice are discussed in chapter 7.3.

Interviewees received a short explanation of the study. The first phase of the interview consists of an open discussion. In the second phase, interviewees are asked to give their opinion on each factor of the literature review. Semi-structured questions were prepared as back-up, but the interviews were mostly conducted in an unstructured fashion. The interview format can be found in Appendix B.

Interviewees for the requirements collection were approached through online channels. Searches for news articles, organization websites, and LinkedIn descriptions were used to track down relevant experts. After a positive response to an introduction message, a physical meeting was planned. The ability to interact face-to-face contributes to the quality of the gathered information as the relationship with the interviewee is strengthened (Lavrakas, 2008). All interviews were conducted in Dutch. For interpretation by the international audience of this thesis, all interviews are transcribed into English. The transcriptions are part of additional documentation that can be shared upon request.

Table 6 Expert panel for requirements collection

ID	Point of view	Functional description
RC-01	Medical	Head of clinical department
RC-02	Medical/Data	Applied data analytics in medicine
RC-03	Data	Clinical data scientist
RC-04	Risk management	Sr. manager IT risk assurance

3.3.3 Expert interviews

By means of expert interviews, the created conceptual model is validated. In terms of design science, this model is referred to as the artifact. The completeness, correctness, and applicability of the artifact is tested. Semi-structured interview questions are used in order to gather detailed and directed qualitative data (Sekaran, 2003). Moreover, the various factors are ranked by the experts based on their importance to success. A 6-point Likert-scale from “highest importance” to “absolutely no importance” is used to let the interviewee pick a level of criticality. However, since the approach is qualitative, the interviewee is asked to explain their choice with extensive arguments. Hence, the Likert-scale serves as a guiding tool to provide a qualitative opinion. This way, correct interpretation of the expert opinions by the interviewer is guaranteed. The results of the Likert-scale in combination with the explanations are used to determine the average level of importance to success for each of the factors. The goal is to ultimately identify CSFs.

The expert interviews consist of a series of eight interviews. In these interviews experts from different function groups express their opinion. Table 7 provides an overview of the expert panel. The clinical medicine side is represented, as well as the data medicine side. Interviewees come from mix of hospitals and UMCs, and from health IT software companies. The mix of these backgrounds creates an interesting blend of opinions. Since “the typical criteria regarding sample size are irrelevant” (Yin, 1994, p.50), there is no hard rule on the required number of participants. Rather, the sample size should be sufficiently large to ensure saturation, that is, to ensure no new significant findings are uncovered. Again, limitations in time and access are at play in the decision of the sample size.

Interviewees for the expert interviews were approached through online channels. Searches for news articles, organization websites, and LinkedIn descriptions were used to track down relevant experts. After a positive response to an introduction email or message, a physical meeting was planned to interview the expert face-to-face. The ability to interact face-to-face contributes to the quality of the gathered information as the relationship with the interviewee is strengthened (Lavrakas, 2008). All interviews were conducted in Dutch. For interpretation by the international audience of this thesis, all interviews are transcribed into English. The interview format and transcriptions are part of additional documentation that can be shared upon request.

Table 7 Expert panel for expert interviews

ID	Functional description	Organization type
EI-01	Intensivist	UMC
EI-02	Data scientist	Health IT software services
EI-03	Sales consultant	Health IT software services
EI-04	Data analyst	Hospital
EI-05	Data scientist	Hospital
EI-06	Head of Business Intelligence	Hospital
EI-07	Anesthesiologist	UMC
EI-08	Head of Health Solutions	Healthcare innovation

3.3.4 Case study

After the validation of the theory development and artifact, a case study is conducted to apply the artifact in practice. How can this artifact actually be used in a real life situation? The method of case study is chosen to understand a real-world case and its contextual conditions that are pertinent to the artifact (Yin & Davis, 2007). By testing the artifact in practice, the aim is to assess its usability and utility. In other words, can the artifact be used in practice, for a useful purpose (Wieringa, 2014).

The organization, or 'the case', is chosen because of the sufficient data access and the relevant activities related to applied predictive modeling. The case at hand is the Department of Psychiatry at the UMC Utrecht, where a prediction model for violence risk is developed. More details of the case company are provided in chapter 6.

The goal of the case study is to perform a gap analysis of the deployment factors. The initial goals at the start of the project are compared with the current situation. To what extent are the different deployment factors currently in place? A comparison between the two situations allows for a clear overview on the differences between the initial plans and the current situation. This directly links to the CRISP-DM model: the initial plans are developed in the BU phase. The current situation should preferably be tested at the deployment phase. However, since the CPM at hand is not yet widely implemented, the current situation is at the evaluation phase of the CRISP-DM.

Data is collected through questionnaires with a standardized set of questions about each deployment factor. The reason for this data collection instrument is the gathering of practical, fast results that can be easily compared. The baseline questionnaire is designed to ascertain the mission statement and strategic objectives of the project at the very start. Due to time limitations, it is not possible to hand out this questionnaire at the actual start of the project. Therefore, the respondent is asked to provide retrospective answers. The respondent plays a large role in the project team from the earliest days of the project. The second questionnaire is designed to ascertain to what extent the various factors are currently in place. Four respondents with various backgrounds have filled in this questionnaire. This results in a mix of perspectives including medicine, project management, and data. Table 8 provides an overview of the panel. The two interview formats are part of the additional documentation that can be shared upon request.

The questionnaires contain a 5-point Likert scale ranging from 'very little extent'-'very large extent'. At the end of the questionnaire, the option is given to provide textual explanation to the answers. The results of a Likert scale fall within the ordinal level of measurements, for which mean and standard deviation are inappropriate statistical calculations (Jamieson, 2004). Therefore, all outputs of the second questionnaires are treated as separate answers. Due to the restricted number of respondents, outputs are visualized in radar charts. Traditional visualizations such as histograms, heatmaps, or Likert charts are not used, as their power increases with larger volumes of output.

The end product of the gap analysis is an operational control between phase 1 (BU) and phase 6 (deployment) of the CRISP-DM model. In this case study, phase 6 is exchanged for phase 5 (evaluation), thereby creating an interim control of the original end product.

Table 8 Expert panel for case study (second questionnaire)

ID	Functional description
CS-01	Psychiatrist
CS-02	Project team lead
CS-03	Medical policy officer
CS-04	Data manager

3.3.5 Confidentiality

The data collection involving interviews deals with confidentiality issues. Since various organizations are participating within the same industry, identities are not revealed in order to avoid publishing private company information. Interviewees are all anonymized with an individual code, as can be found in Table 6, 7 and 8. The interviewees were informed about this confidentiality clause prior to the interview. The interviews will be audio-recorded for analysis purposes, but will not be made available to the public. Moreover, it was made clear that no internal documentation or patient data was needed for this research.

4 CONCEPTUAL MODEL: LITERATURE REVIEW

In this chapter the two fields of PA in medicine and IT PM merge together in an effort to answer RQ1. Analysis of the literature on BI&A deployment resulted in the identification of five broad categories with multiple factors that are critical to success:

- Management (section 4.1.);
- People (section 4.2.);
- Technology (section 4.3.);
- Processes (section 4.4.);
- Data (section 4.5.).

The five categories are deducted from existing literature (Akter et al., 2016; Olszak & Ziemba, 2012; Yeoh & Koronios, 2010) and tailored to this research topic. The factors that make up these categories are often intertwined and interdependent. An overview of all factors with corresponding variable name, description, and literature is provided in Appendix A. For each factor, a decision is made on whether it is generic and thus applicable to various sectors, or specific to the healthcare sector. The result is a comprehensive table that provides an overview of all deployment factors of CPMs.

RQ1	What are the factors for successful deployment of BI&A according to existing literature?	Chapter 4

4.1 Management

The category ‘Management’ looks at success of deployment from the organizational dimension. Sponsorship and *support of top management* is widely acknowledged as crucial for success of any analytics tool (Akhavan & Salehi, 2013; Gao et al. 2015; Hawking & Sellitto, 2010; Popovič et al., 2018; Saltz & Shamshurin, 2016; Wamba et al., 2015). It is therefore a generic factor. Consistent support of top management allows for sufficient funding, skilled staff, and overall motivation of the team (Yeoh & Koronios, 2010).

Proper *planning and scoping* is necessary to understand the key objectives and how the deployment can have optimal impact on those objectives (Attaran & Attaran, 2019). This also includes the definition of clear goals, project size, budget, and deadlines. This generic success factor ensures flexibility and adaptability and the opportunity to focus on crucial milestones (Cresswell et al., 2013; Farzaneh et al., 2018; Gao et al., 2015; Hawking & Sellitto, 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Yeoh & Koronios, 2010). Akhavan & Salehi (2013) add that also a strong evaluation plan must be in place which measures the outcomes of the major milestones based on scope creep, budget, and time.

From the very early stages, effective involvement of stakeholders and clear communication of the implementation process by the managerial level are crucial (Juciute, 2009; Saltz & Shamshurin, 2016; Wamba et al., 2015; Yeoh & Koronios, 2010). *Stakeholder engagement* involves all the activities that are undertaken to involve the stakeholders in a positive manner (Greenwood, 2007). The stakeholders in this situation following the onion model (Alexander, 2005) are: the users i.e. clinicians (normal operators), the patients and their families, the board of the hospital (financial and political stakeholders), the responsible project management team (functional beneficiary), the developers and/or the vendors of the tool (maintenance and operational support), the billing and audit functions, legal regulators, the government, and the related academic community. Hospitals should involve all stakeholder in the strategic decision-making process, as this impacts the operational level (Malfait et al, 2017). Especially end users must be engaged in order to meet their demands and expectations. Moreover, end users know better what is needed for successful deployment as they have direct experience with the tool in practice (Yeoh & Koronios, 2010).

Leadership style of the project owner affects the way employees perceive the deployment process (Øvretveit et al., 2007). *Strong clinical leadership* contributes to IT adoption because of the creation of a long-term commitment vision, motivation, and the capability to maintain confidence and stability (Bezemer et al., 2019; Buntin et al., 2011; Ingebrigtsen et al., 2014). Clinical leadership encapsulates healthcare staff who set, inspire, and promote values and vision, using their clinical experience and knowledge to ensure patient well being is at the center of organizational goals (Jonas et al., 2010). Clinical leaders are thus able to enhance quality and transform clinical services towards excellency. Although generally a strong project management leadership is recognized as critical (Farzaneh et al., 2018; Goa et al, 2015), clinical leadership is something specific to the healthcare industry.

Strategic alignment includes functional integration between business strategy, BI&A strategy, infrastructure, and processes (Williams & Williams, 2010). An *aligned vision and strategy* is a generic factor important to all types of analytics project deployment in a company (Akhavan & Salehi, 2013; Gao et al., 2015; Saltz & Shamshurin, 2016). Hence, also in hospitals the fit between the strategy in the visioning phase and the proposed BI&A tool must be ensured (Altuwaijri, 2012). A project should only be selected for deployment if it matches the long-term vision of the hospital. Big data initiatives are driven by the management, therefore a strategic vision must direct the implementation and continuation. If the business vision is not well understood, the adoption and outcome of the deployment will be affected (Yeoh & Koronios, 2010). Table 9 gives an overview of the complete Management perspective.

Table 9 Literature review: the Management perspective

The 'Management' perspective	Generic (G) or specific (S)?
Top management support	G
Planning and scoping	G
Stakeholder engagement	G
Strong clinical leadership	S
Aligned vision and strategy	G

4.2 People

The human element is critical to IT deployment in healthcare in numerous ways. Both on the strategic and operational level, *roles and responsibilities* have to be clearly defined, since a well-defined organizational structure is key for big data projects (Saltz & Shamshurin, 2016). Responsibilities must be appointed to people for dealing with changes in scope and complexity of the algorithms (Marinos, 2004). Changes in external conditions can demand for adjustments of the algorithm. Also, the intricate integration of a predictive model into existing clinical workflows must be supervised. The cost of ownership that comes with responsibilities of oversight can be a significant barrier for the correct and secure employment of predictive tools (Amarasingham et al., 2014). Ownership is a type of responsibility regarding the outcome and quality of the project. This also includes aftercare: the monitoring and maintenance of algorithms to guarantee long-term quality.

Multidisciplinary self-steering teams are required for the success of big data projects (Saltz & Shamshurin, 2016). Multidisciplinary teams consist of members with analytical and technical skills, as well as clinical experts and a business champion who follows a primarily business-centric perspective (Gao et al., 2015). Self-steering teams operate autonomously and have shorter operationalization times due to their self-steering character. Yeoh & Koronios (2010) found that BA teams should aim for the so-called "best of both worlds": to be cross-functional and composed of both technical and business employees. In the case of hospitals, there is a third group required representing the side of clinical medicine. Data scientists and healthcare professionals need to team up in an interprofessional manner, preferably together with patients (Bezemer et al., 2019).

When employees are committed to the mission and goals of their organization, and deem their daily activities truly interesting, their productivity and satisfaction raises. In order to see the benefits from health IT such as CPMs, it is crucial to have *employee 'buy-in'* (Bezemer et al., 2019; Buntin et al., 2011). Buy-in promotes the engagement and willingness to make a new BI&A solutions successful. A higher level of employee involvement in hospitals that go through a technological change, leads to increased performance and the potential to enhance the effectiveness of health IT (Litwin, 2011). Employee commitment in BI&A deployment is multiple times highlighted in literature (Akhavan & Salehi, 2013; Farzaneh et al., 2018). Since employee buy-in as a CSF also applies to other industries, employee buy-in is a generic factor.

Another factor that is important in all types of IT deployment plans, is the schooling of staff (Saltz & Shamshurin, 2016). Investment in training and *education* of staff that uses the predictive tool is a necessity (Cresswell et al., 2013). Most clinical professionals do not have a background in data science, and thus must receive at least a basic course in the world of informatics (Krumholz, 2014). Simultaneously, clinicians must be trained into a new data mindset that is comfortable with new approaches to medicine. If a user is not familiar with the tool, does not understand how it is build, or does not see its benefits, the tool will most likely not be utilized the way it was intended. Clinical staff must be equipped with the relevant competencies to use predictive tools, for example the ability to interpret results appropriately (Wang et al., 2015). Next to that, *knowledge sharing* between users and other clinical staff is important to better understand the CPM and the organizational goals. Knowledge can be shared through documentation, learning by watching, or teaching one another. Reciprocity, behavioral control, and trust are factors that positively affect the knowledge sharing intention of hospital employees (Lee & Hong, 2014).

Top management, project teams, and users need a degree of *awareness of recent developments* in the BI&A area (Gao et al., 2015), as well as the related uncertainties and risks (Akhavan & Salehi, 2013). For hospitals, new CPMs that are developed in various clinical areas are interesting to follow. Often, clinicians are highly specialized in their own branch of medicine and follow related developments closely. However, following technological developments in other medical areas helps to fully grasp the opportunities and limitations of CPMs and to remain critical. Due to the uniqueness of medical data that influence (predictive) data mining opportunities (see subsection 2.2.2) this factor is quite specific to healthcare.

Documentation skills are important for successful operationalization of a BI&A tool. Employees need a certain degree of awareness for proper documentation. Creating and maintaining documentation is vital for the long-term success of a new innovative system (Gao et al., 2015). Access to documentation is closely related to *knowledge sharing* as it allows staff to use the expertise of others about the same tool (Farzaneh et al., 2018).

Continuing on the human element, the issue of *patient consent* is highlighted. Although the deployment of a scientifically stable tool to support clinicians sounds ideal, it is the patient who decides whether or not their EHR can be used, and whether or not they want to cooperate with a new technology. The Dynamic Consent model is proposed, in which patients can tailor their preferences on the extent to which they want to share their data at any time (Kaye et al., 2015; Spencer et al. 2016; Williams et al., 2015). In the qualitative research by Spencer et al. (2016), 98% of the participants believe that the altruistic benefits of data sharing outweigh the risks. Traditional consent policies often imply that individual control of data outweighs societal benefits of sharing data (Roski et al., 2014). Davis (2012) states that in order to harness to potential of big data analytics, a different approach towards consent is needed. Rather than strict regulations for each individual case, consent should evolve to a balance between personal control and informed sharing for the greater good of public healthcare. Patient consent is a challenge that is unique to the healthcare industry.

Furthermore, the impact of the use of the tool on *doctor-patient relationship* can be a more long-term challenge. It must be ensured that at no point in time the shared doctor-patient decision-making is replaced by a tool (Amarasingham et al., 2014). Clinical diagnosis and prognosis depends highly on complex personal factors that cannot be captured by a tool, and thus the doctor-patient relationship should always have a leading role (Schoenhagen & Mehta, 2016). Trust between doctor and patient is highly important for a good-natured treatment.

Successful teams have *collaborative communication.* Team members communicate frequently, both indirectly and directly, within the multidisciplinary team and with other stakeholders (Farzaneh et al., 2018; Saltz & Shamshurin, 2016). Collaborative communication enables the transfer of expertise and the integration of various individual and functional resources of knowledge. It is therefore a direct antecedent of *knowledge sharing*. Collaborative communication can also be linked to other CSFs. Cresswell et al. (2013) state that open channels of communication between users and project management avoids scope creep. In a way, all factors are, to some extent, influenced by the communication between stakeholders. This is a factor important in any project, in any industry. Table 10 gives an overview of the People perspective.

Table 10 Literature review: the People perspective

The 'People' perspective	**Generic (G) or specific (S)?**
Roles and responsibilities	G
Multidisciplinary self-steering teams	G
Employee buy-in	G
Education and knowledge sharing	G
Technology development awareness	S
Documentation skills	G
Patient consent	S
Doctor-patient relationship	S
Collaborative communication	G

4.3 Technology

In the ‘Technology’ section, the factors surrounding technological components are discussed. System *interoperability* between various health platforms can be a challenge to many, slightly outdated, IT infrastructures. Patient information often resides in different EHR platforms, hence it can be a problem to collect the full data profile of a patient and feed it to the predictive model. Issues in system interoperability can slow down the scalability of the tool (Amarasingham et al., 2014). As long as the storage and dissemination of patient data is not a shared effort between multiple platforms, it remains impossible to get optimum results from the analysis of that data (Marcheschi, 2017). Data fragmentation is one of the major issues in handling clinical data (Lustberg et al., 2017). The issue becomes even more enhanced in multicenter studies with data from multiple institutions, for example in the case of model validation. *Integration* of datasets involves the combination of multiple tables or records in order to create a new dataset. Part of the quality of the system of a tool is the ability to integrate data (Gao et al., 2015; Yeoh & Koronios, 2010). Just access to relevant data sources is not enough, integration of data is needed for optimal delivery (Popovič et al., 2018).

The creation and dissemination of documentation should be a fixed part of a BI&A project (Gao et al., 2015; Saltz & Shamshurin, 2016). *Document collection and access* is important to ensure the model can use data from traditional systems, structured IoT data, and unstructured data. Data availability and access is at the core of big data developments (Demchenko et al., 2013). Also in the deployment phase, the collection and access of data is crucial. Since it is only possible to find answers in data when using the right documents, document collection and access to sources is a significant problem (Gao et al., 2015).

Flexibility and scalability of the infrastructure are important to respond to dynamic business needs (Cresswell et al., 2013; Yeoh & Koronios, 2010). The IT infrastructure should be able to answer quickly to external changes and growth. With a flexible technical infrastructure, system expansion is possible according to evolving information needs (Olszak & Ziemba, 2007). Moreover, it becomes easier to adjust to problem situations or unexpected changes (Gao et al., 2015). Both user and data capacity should be quickly scalable to hospital demand. Table 11 gives an overview of the Technology perspective.

Table 11 Literature review: the Technology perspective

The ‘Technology’ perspective	Generic (G) or specific (S)?
Interoperability and integration	G
Document collection and access	G
Flexibility and scalability of infrastructure	G

4.4 Processes

From the ‘Processes’ point of view, multiple potential obstacles can be found in the literature. The existence of clear processes for specific goals is an important part of successful deployment.

Data governance is about the responsibilities for a collection of data management methods for the acquisition, storage, and aggregation of data (Khatri & Brown, 2010). The big data analytics architecture at the organization in question must include some sort of *data governance* layer for data quality management (Saltz & Shamshurin, 2016). This layer controls how the data flows through the organization. According to Wang et al. (2018), the first component of data governance is the master data management. This entails the proper standardization and cleaning of data in order to create a complete, reliable and accurate master data file. This master data file is used for supporting data analysis and decision-making. The data lifecycle management is the second component of data governance. Here, data is archived, maintained, tested, delivered, and deleted according to its position in the life cycle. It is important to manage data effectively over its lifetime to be able to respond to internal and external needs and goals. The third component focuses on data security and privacy management. Patient privacy is particularly critical in healthcare environment as the information is highly sensitive and subject to medical confidentiality. A data governance mechanism is imperative to ensure regulatory and legal compliance. In her framework, Philips-Wren (2015) addresses this challenge by looking at the strategic, tactical, and operational levels. For the strategic level, the entire big data spectrum should be covered by the governance layer. This includes use of the right data sources, use of the right technologies, and ensuring the appropriate skills to handle it in an informed and timely manner.

An *iterative, standardized methodology* is advised throughout the deployment of a new BI&A tool (Gao et al., 2015; Yeoh et al., 2010). An iterative approach entails the adoption of incremental delivery, with small changes following each other. Short, measurable steps are taken over every iteration, which reduces risk. The development methodology of BI&A is often a challenging issue, as organizations must make sure that both successes and shortcomings are measured (Farzaneh et al., 2018). When an organization tackles a BI&A deployment non-iteratively, the risks and impact are harder to manage. At the same time, a degree of standardization based on the consensus of different parties helps to maximize interoperability and quality. Business process standardization establishes best practices for carrying out processes related to the deployment of analytical models.

A proper, user-oriented *change management* strategy should guide the process of change (Cresswell et al., 2013; Saltz & Shamshurin, 2016; Yeoh & Koronios, 2010). The layout of multidisciplinary teams must support the ability to respond on the changes (Gao et al., 2015). Problems along the way require immediate action and cannot be ignored.

Resistance to change accompanied with deploying PA can arise in different shapes. For example, Finlay (2014) describes the human vs. machine judgment. Evidence shows that field experts do not easily trust predictive models over their own judgement.

Project evaluation is a generic step in project management and aims to determine the level of achievement in terms of objectives, effectiveness, efficiency, impact, and sustainability. For the operational *evaluation* of a BI&A project, a specific process should be in place that is able to measure project outcomes and its algorithms (Akhavan & Salehi, 2013; Gao et al., 2015). Evaluation metrics of big data projects are often generic, but there is no universal metric available (Saeed & Ahmed, 2018). The ability to evaluate a BI&A project goes hand in hand with a certain level of clarity of project deliverables (Saltz & Shamshurin, 2016). Moreover, evaluation is not a static process. Rather, algorithmic performance should be continuously monitored. If needed, the system should be tuned regularly to meet operational goals (Gao et al., 2015). Closely related to evaluation is value measurement. Whereas evaluation is about continuous monitoring of the algorithmic performance, value measurements focuses on measuring the impact of the project. Value measurement registers the realized impact of an analytical tool and is a business responsibility. Another important aspect of evaluation is alignment with the initial goal. In terms of CRISP-DM, this implies that phase 1 (business understanding) has a two-way relationship with phase 6 (deployment). A deeper explanation of this is provided in subsections 2.4.4 and 2.4.5. In the evaluation process it should be assessed whether the model actually does what is required from it. In other words, does the way the model is utilized align with how it was initially planned to be utilized.

In the long term, it is a challenge to ensure the *sustainability* of a BI&A solution. The sustainability is largely dependent on other deployment challenges; if these are overcome, it is more likely that the tool will live a long life. It is therefore important that during implementation and continuation, the long-term goals are kept in mind by means of a future roadmap. Moreover, the development of an information sharing, data-driven culture in the organization is part of the requirements for lasting success (Wang et al., 2018). All stakeholders, including the users, payers, vendors and patients, should support and advocate the use of CPMs. An overview of all Processes factors is provided in Table 12.

Table 12 Literature review: the Processes perspective

The 'Processes' perspective	**Generic (G) or specific (S)?**
Data governance protocol	G
Iterative, standardized methodology	G
Change management	G
Evaluation	G
Sustainability of the tool	G

4.5 Data

Lastly, the 'Data' perspective takes on issues that are inherent to the data. *Patient data privacy* is an ever growing concern in big data analytics in healthcare. The developer or vendor must be able to verify privacy laws and agreements are respected and that sensitive information is kept private regardless of internal and external forces (Abouelmehdi et al., 2018). Cohen et al. (2014) recommend that if the developers have complied with the regulations on privacy, the patient data can then be freely used for further development without explicit consent. Healthcare data security solutions must be working alongside the model to protect sensitive data assets while satisfying healthcare compliance mandates. The understandable worries of patients about their data's secondary use are a challenge for adoption and utilization of the CPM if security cannot be guaranteed.

Transparency of the model could encourage and facilitate cooperation among stakeholders, thereby increasing trust and diffusion of the CPM (Amarasingham et al., 2014). A clinician should be able to take a look into the model in order to compare the logic and weighing factors with his or her own assessment. However, objections to full transparency touch again upon the issue of patient privacy. Therefore, transparency should be allowed only to oversight bodies, not to the general public (De Laat, 2018).

High quality of big data is key to add BI&A value in the organization (Akhavan & Salehi, 2013; Farzaneh et al., 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Wamba et al., 2015). The actions resulting from a BI&A project often have significant consequences for the organization, which makes it crucial to ensure data quality (Gao et al., 2015). Especially in hospitals, where results of a CPM directly affect human wellbeing, data quality cannot be underemphasized. The following five data dimensions all relate to data quality: availability, usability, reliability, relevance, and presentation quality (Cai & Zhu, 2015). *Data availability* encompasses the easy accessibility of data in a timely manner. Data should be regularly updated with new instances and processed into the algorithm. *Data usability* refers to the challenge of credibility. The source of the data must be reliable and coming from specialized organizations. Moreover, the data should be checked regularly to assure correctness of the content. *Data reliability* consists of four factors: accuracy, consistency integrity, and completeness. This indicates that data must reflect the true state of the information source without any ambiguity. Over a certain time period, the data must remain consistent and verifiable. Furthermore, the data format requires a degree of standardization and should be consistent with structural integrity and content integrity. *Data relevance* relates to the fitness of data. The retrieval theme of the BI&A goal must match with the information theme. In other words, the collected data must clarify the initial problem understanding and goal setting. The *presentation quality* includes readability of the data. Hence, data content and format should be clear and understandable. Also, data description, classification, and coding content are easily comprehensible. In Table 13, all factors of the Data perspective are listed.

Table 13 Literature review: the Data perspective

The 'Data' perspective	Generic (G) or specific (S)?
Patient data privacy	S
Data transparency	G
Data availability	G
Data usability	G
Data reliability	G
Data relevance	G
Data presentation quality	G

The practical application of BI&A tools in healthcare make it a unique playground (Niaksu, 2015). In Appendix A an overview is provided on each of the deployment factors per category, including variable name, description and corresponding literature. Figure 20 provides an overview of the results from this chapter, with the various factors divided over the five categories. This overview serves as the first version of the developed artifact.

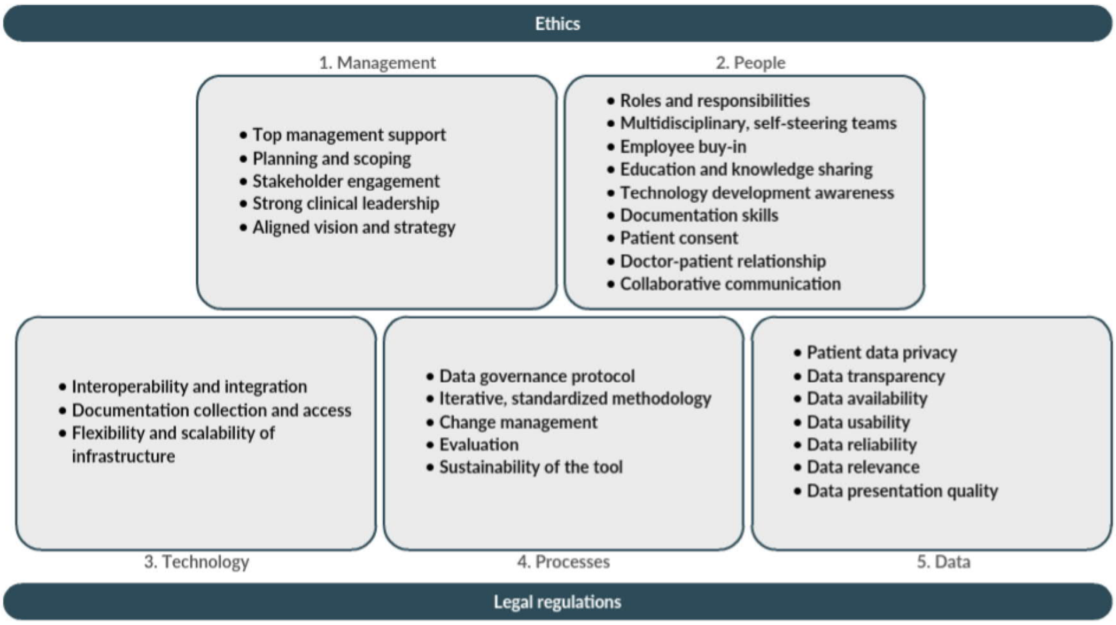


Figure 20 Overview of literature review results: first version of artifact

5 CONCEPTUAL MODEL: INTERVIEWS

This chapter answers RQ2, RQ3, RQ4, and RQ5. The literature review of the previous chapter is first validated by means of requirements collection interviews (RQ2). Based on these interviews, various factors are added, removed, or changed. This results in the development of the artifact (RQ3). In the second part of this chapter, the artifact is validated by means of expert interviews (RQ4). All factors are discussed with their relative importance to successful deployment according to the interviewees. The chapter concludes with new insights on various topics are deducted from the interviews (RQ5).

RQ2	What deployment factors of CPMs in hospitals are identified by health professionals?	Chapter 5.1
RQ3	What artifact can be designed to successfully deploy CPMs in hospitals?	Chapter 5.1.4
RQ4	What are the CSFs in a deployment plan for CPMs in hospitals as identified by health professionals?	Chapter 5.2
RQ5	What other factors have a hand in the successful deployment of CPMs in hospitals according to health professionals?	Chapter 5.3

5.1 Results requirements collection

During the requirements collection period, four experts were questioned about the findings of the literature review. The literature is validated from a medical, data, and risk management angle. The artifact is adjusted accordingly.

5.1.1 New factors

Based on the data collected from the requirements collection interviews, new factors are added to the model that were not yet identified as such in the literature review.

In the category ‘Management’ a new factor was added named “*clear strategy*” (1.1.). Two interviewees emphasized the importance of this factor on successful deployment. A clear strategy at the management level entails having a clear sense of direction and commitment towards the action plans that were designed for the achievement of the strategic goals. If there is no clear strategy with regards to BI&A efforts in the hospital, this affects all other factors in the ‘Management’ category directly.

In the category ‘Technology’ a new factor was added named “*user-friendly tool*” (3.5.). The piece of software on which the prediction model runs must be designed in such way that the user intuitively knows how it works. This includes the easy retrieval of accurate and reliable solutions, as well as simple and intuitive displays, and easy navigation. Prediction tools can be directive or assistive. Directive tools provide risk-corresponding decision recommendations to the user, whereas assistive tools do not. The format of the prediction tool should be designed in a way that minimizes any unintended effects (Kappen, 2015).

Next to new factors inside the categories, three general, overarching components are added. During the requirements collection, it became clear that three topics are of importance in all categories. *"Legal regulations"*, "*information security",* and "*ethics*" influence each category and its factors in various ways. Legal regulations affect people, processes, and organizations. Data privacy is one of the biggest issues related to data analytics, together with information security. Next to that, there are laws about using software as medical supportive device, laws about intellectual property, laws about patient involvement, laws about quality of healthcare, etcetera. The legalities surrounding hospitals are extensive and complex. With the arrival of BI&A, these legal regulations need to be updated in accordance with the current possibilities and threats. Medical data and surrounding processes need to be secured airtight. This is an ongoing operation:

> *"Regulations do not know how to deal with self-learning algorithms. It is not possible to validate a self-learning algorithm according to law."*
>
> *"Technology is faster than the legal regulations."*

Information security refers to the technical and operational measures that ensure data is safe and secure. All processes and working aspects inside the organization should adhere to appropriate information security levels. Therefore, this needs to be tackled on the organizational level. For example, by hiring professional privacy officers, creating awareness under employees, and ensuring appropriate access rights. These efforts should prevent external and internal cyberattacks, such as malware, viruses, and hacking, as well as physical, non-electronic security breaches.

The ethics behind data-driven analytics is another topic that touches all categories in a unique way. Who owns medical data? What is the price of data? Should we know when our data is used? Next to a legal issue, privacy and consent are also ethical issues. Our healthcare system in the Netherlands is based on the solidarity principle. That means that citizens pay for other citizens' healthcare. Does that mean we should also be solidary with our data and make it available to improve care for everybody? What is the role of the hospital in the big data era in terms of corporate responsibility and compliance? There are countless standpoints that play a part in the possible discussions about healthcare ethics in the big data era. All of them are potentially challenges to successful deployment of CPMs.

5.1.2 Removed factors

In the 'People' category, the factor "*documentation skills*" has been removed due to incorrect interpretation. Documentation skills were described as the "creation and maintenance of proper documentation regarding deployment of the tool". In other words, users (i.e. health professionals) need to document important activities and errors regarding the usage of the tool. However, the way this is formulated implies a substantial increase in the administrative workload of the user. This is not underlying meaning of the factor. Therefore, this factor is removed. The fact that the users must be aware of the importance of proper documentation and data collection, is included in the "education and knowledge sharing" factor. For data quality reasons, users must see the value of good documentation. Accuracy of predictive models increases when high quality data is used. Thus, when users develop a 'data mindset', proper documentation skills will follow and become part of the workflow. Another way to interpret this factor, is that proper documentation skills leads to better monitoring of the performance of the tool. Documentation of the outcomes of the tool ensures high performance in the future. This perspective is included in the changed factor "durability" (4.4.).

5.1.3 Changed factors

Based on the data collected from the requirements collection interviews, multiple factors have changed either linguistically or in terms of content. These changes reflect the practical truth in (academic) hospitals and thus improve the literature review findings.

In the category 'Management', the factor "aligned vision and strategy" has been replaced by "*organizational alignment*" (1.6.). The reason is that the old factor focused solely on vision and strategy, and the link to business objectives. However, this description steers too much towards a business case approach, whereas that is not the desired approach to be taken in healthcare innovation projects.

> *"Indeed, you need to think about your vision and strategy, and what you want to do with predictive models. But there is a difference between doing that in order to make clinical care more efficient and optimizing processes, or because you want to improve healthcare. (...) Alignment between vision and strategy is more important than making it measurable objectively."*

The current description includes a more complete organizational alignment, focusing on alignment between strategy and all types of organizational aspects (e.g. capabilities, resources, systems, culture, etc.). This removes the focus on hard numbers of strategic alignment with business objectives.

In the category ‘People’, the factor “roles and responsibilities” is exchanged for “*predefined roles and responsibilities*” (2.1.). Roles and responsibilities should not be shaped along the way. This creates a risk that team members take on roles that are not supposed to be part of their activities.

> *“Clear roles should already be defined by the project leader. This avoids that a data scientist does the work of the data engineer, or the doctor starts to do things that are not part of his or her job. Such as planning meetings.”*

Moreover, when roles and responsibilities are predetermined, the learning capabilities of employees can enlarge. When everybody exactly knows what is expected from them, a clear, open, and collaborative atmosphere can be created. On the one hand, it allows people to address their co-workers in a positive way, for example by asking how that person is doing with a certain task or by offering help. On the other hand, a feeling of responsibility generates more initiations towards collaboration. Everyone is eager to make their part a success, and thus is more likely to want to work together.

In the same category, the ‘self-steering’ part is removed, establishing the factor “*multidisciplinary teams*” (2.2.). Whereas multidisciplinarity of teams was considered as an absolute requirement, interviewees indicated that teams should not be self-steering.

> *“I do not believe at all in self-steering teams. You have a corporate policy with guidelines, and within these borders teams can organize themselves, but not steer.”*

When teams are self-steering, there is a risk that, out of enthusiasm, they will steer the project towards a wrong direction. A direction that does not follow organizational alignment. Thus, instead, teams should be self-organizing, managing responsibilities and timelines in accordance with the corporate policy. Another interviewee noted that often steering within the team goes automatically, as long as roles and responsibilities are predefined and there is a clear project strategy and vision.

The factor of “patient consent” is changed into “*patient involvement*” (2.6.). The previous description of patient consent, included two different things: legal consent and voluntarily engagement. The legal aspect of patient consent is part of many different legal regulations that play a role in the deployment of CPMs. Therefore, it is removed as a specific factor, but represented in an overarching component of “*legal regulations*”. The voluntary part of patient consent remains, and is renamed into “patient involvement”. This entails the positive attitude and active involvement of a patient regarding the deployment of CPMs in their situation.

In the category ‘Processes’, the factor “iterative, standardized methodology” is changed into “*agile and standardized methods”*. The iterative approach to project management resides inside the agile working methodologies. Therefore, the more broad term of 'agile' is used to capture all instruments that are part of the agile process, such as scrum, lean, kanban, stand-up meetings, user stories, and retrospectives.

Another important change has been made to the "sustainability of the tool". The name is changed into "*durability*". This term captures much better the underlying meaning of the factor. Sustainability can be confused with the need to have a triple bottom line. However, the intention was to include the long-term view of the prediction model. A durable model is a model that is made for success over a long period of time with continuous high performance. To achieve this, various processes need to be in place to ensure software durability, hardware durability, durable stakeholder support and efforts, and a general data-driven culture in the hospital. Moreover, the 'of the tool' part is removed.

> *"You need to trust the process around to algorithm, not that specific algorithm. You need to be sustainable in the way of working. That also makes it easier to maintain stakeholder support."*

It is less important to have a sustainable tool, compared to having a sustainable way of working. Thus, a specific algorithm that is translated into a tool does not necessarily have to be durable. Rather, the mission to work with PA for better healthcare must be durable.

5.1.4 The CRISP-DM Deployment Extension for CPMs

The artifact, called the CRISP-DM Deployment Extension for CPMs, that is constructed after the literature background, literature review and requirements collection interviews is depicted in Figure 21. On the top, on the left hand side, the CRISP-DM is positioned. In order to define "success", the deployment factors must be linked to the business understanding phase at the start of the CRISP-DM development model. A two-way relationship between phase 1 (business understanding) and phase 6 (deployment) is added to the existing model. This represents the importance of business understanding for the measurement of project success, as explained in subsections 2.4.4 and 2.4.5. The arrow pointing from the deployment phase towards the levels 0, 1 and 2 visualizes where this thesis research is positioned in the CRISP-DM model.

The lower part of the artifact is composed of three levels. Level 0 corresponds to the goal of this thesis: a successful deployment strategy of CPMs for hospitals. Levels 1 and 2 correspond to the 5 categories and the 30 deployment factors that are, each to a different extent, important to success. To what extent each factor contributes to success according to experts, is discussed in section 5.2. Three overarching factors are depicted at the bottom. An overview in table format including descriptions of each factor can be found in Appendix C.

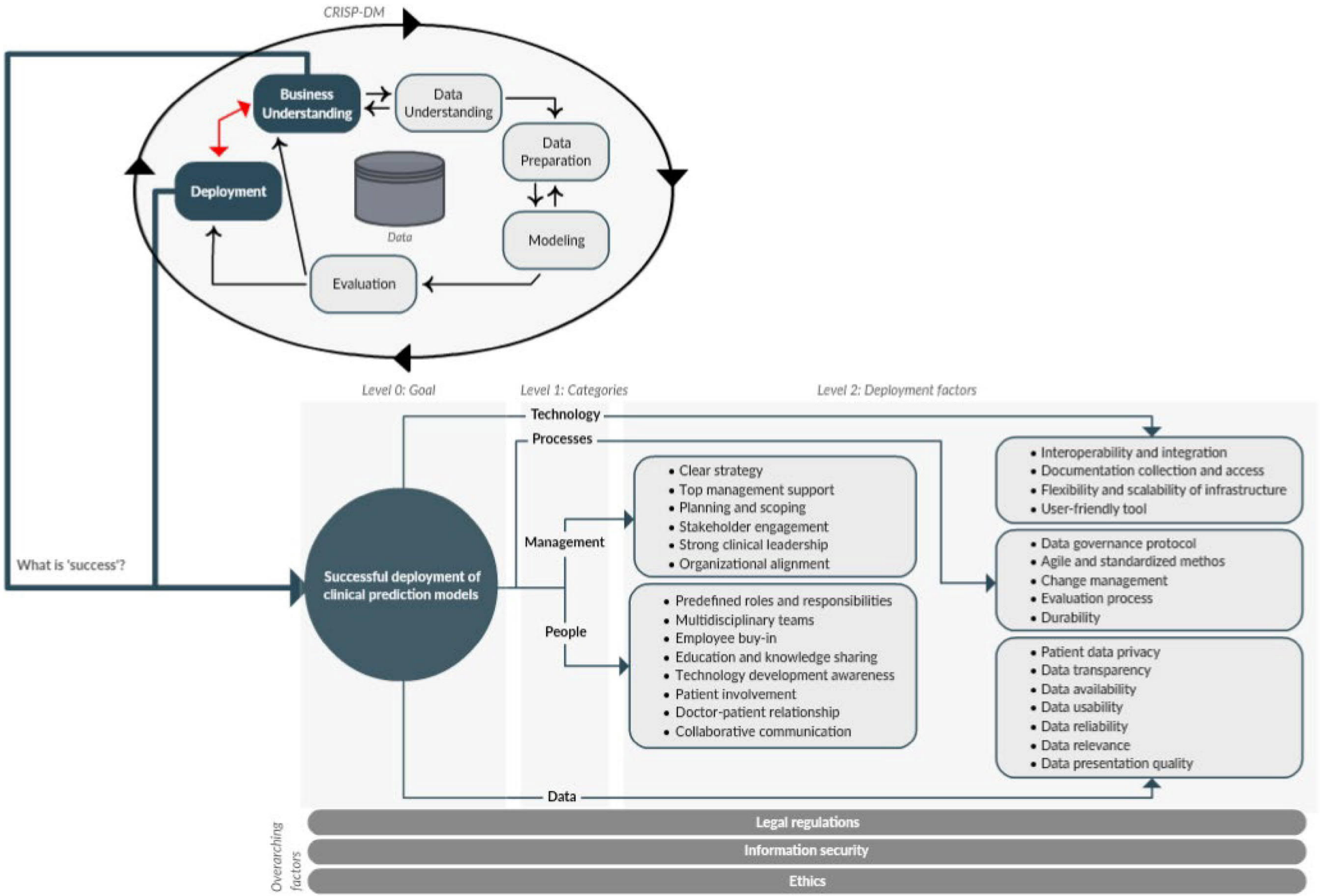


Figure 21 The CRISP-DM Deployment Extension for CPMs

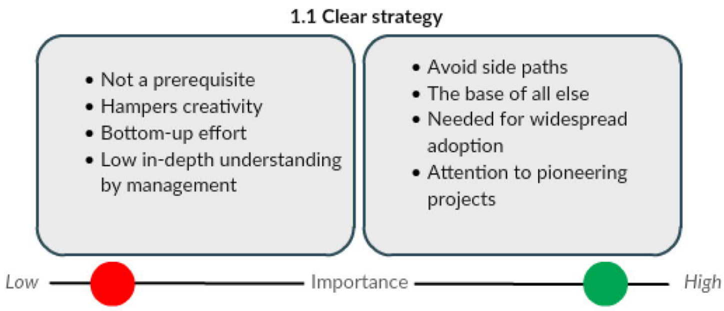
5.2 Results expert interviews: deployment factors

During the expert interview period, eight experts were questioned about the artifact in terms of importance to success. This results in an average level of importance to success for each factor, illustrated in 30 small tables. A green-colored circle indicates that the majority agrees to high or very high importance. An orange-colored circle indicates intermediate importance, and a red-colored circle indicates low or very low importance. When there are two circles with different colors, the opinions are substantially dissimilar.

5.2.1 Management category

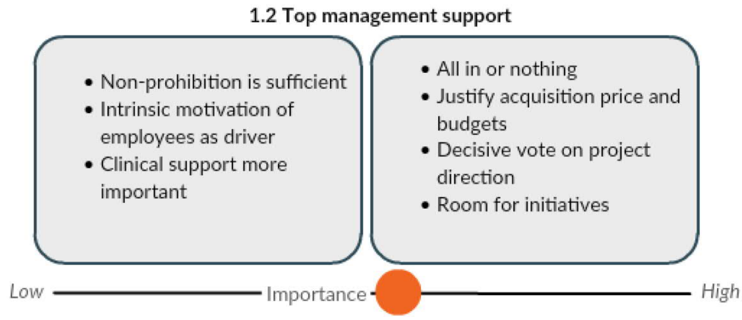
- Clear strategy

A lot of division exists about the need for a clear strategy hospital-wide. On the one hand, it is considered as crucial to widespread success of CPMs, and at the base of all other factors. Formulating a clear strategy prior to deployment avoids wandering off to side paths that surpass the real goal. On the other hand, a clear strategy is considered as something that is not necessarily needed, since most initiatives come from bottom-up, and top management level is not always involved in these developments. The type of investment also makes a difference: if it is a truly pioneering project, it should be part of the strategy. That way, it is possible to show stakeholders the advancements in the strategy.



- Top management support

In general, top management support is considered as important to success. Especially from the budget-side, it is required that top management gives room for these type of initiatives. However, some argue that even without concrete top management support, the intrinsic motivation of employees can make deployment successful from a bottom-up approach. As long as they do not forbid it and provide some resources, a CPM could be a success according to them. Other interviewees go against this by saying that top management support should be an 'all in or nothing' strategy. Doing it half-way will not lead to any positive result.

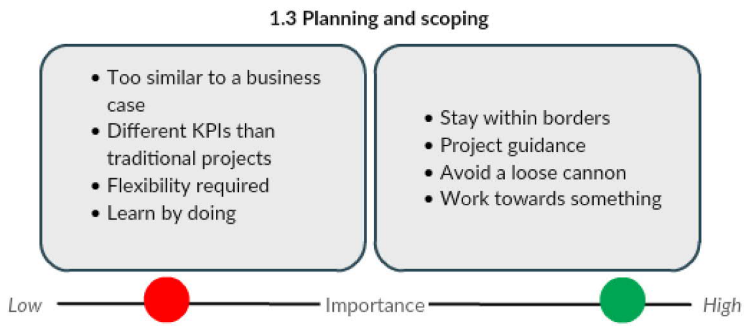


- Planning and scoping

Planning and scoping is another factor in which there is a division between the opinions of interviewees. On the one hand, predetermined phases ensure a project stays within its borders. If planning and scoping is not in place, the project will become a loose cannon that cannot be controlled. An interviewee notes:

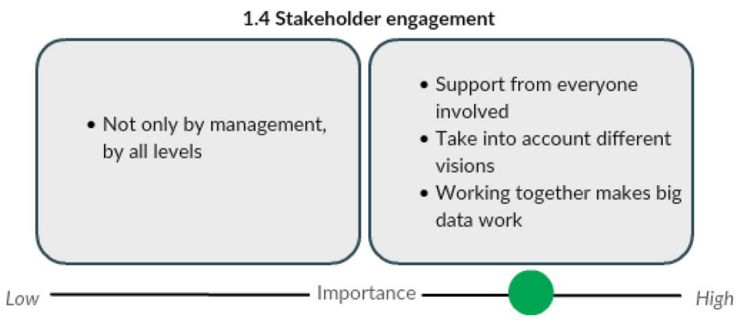
> *"The less you agree on before implementation, the lower the chance it will succeed. People shape their activities and efforts in accordance with the set timeline or budget. It is good to have this clear for everyone."*

On the other hand, especially professionals working at hospitals fear for an approach that is too much like a business case. The value is not necessarily in euros, key performance indicators (KPIs) such as a steep learning curve is more important for innovative projects than hitting the target budget-wise or time-wise. Moreover, a certain degree of flexibility is needed to be able to deal with adjustments along the road. There needs to be some room for modification of the planning and scoping according to the deployment journey. Moreover, the description of the factor consists of elements with each a different level of importance to success. Predefined goals, deadlines, scope, and budget are not all evenly important according to the interviewees.



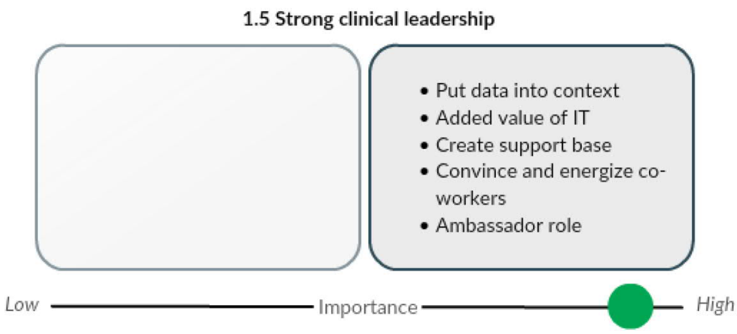
- Stakeholder engagement

The majority of the interviewees indicated that stakeholder engagement is of moderate to high importance. Many different people need to support the deployment of clinical prediction models, from doctors to developers to patients to the government, and more. Good stakeholder engagement ensures all visions are taken into account and everyone supports the project. The only way to make big data work, is by working together. Within hospitals, but also between healthcare organizations. The only note is that stakeholder engagement is not necessarily only a task of the higher management, but from all levels.



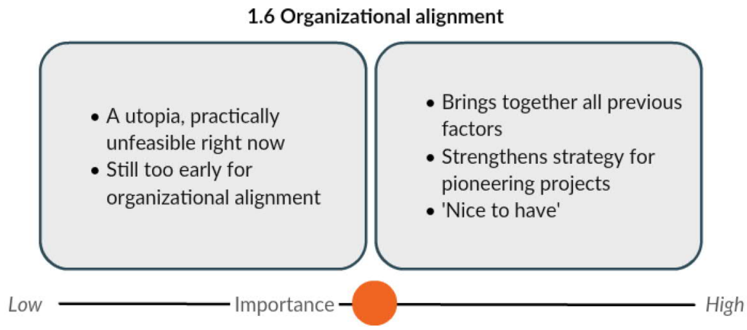
- Strong clinical leadership

Strong clinical leadership is unanimously supported as a CSF. Firstly, it is critical to have a clinician as part of the central team who can determine the added value of an IT investment for healthcare. The chief medical information officer (CMIO) is the clinical authority involved in IT decisions, but also on lower levels a doctor can show clinical leadership. Their medical knowledge is needed to put the data into context and assist with interpretation of the model, problem indication, and patient profiles. Secondly, the clinical leader plays a pivotal role in creating a support base. When known critics or leaders support a product or tool, they can convince and energize colleagues of the benefits. It is difficult to enforce an analytical supportive tool from the management board only. Strong clinical leadership and ambassadorship makes the medical staff automatically more supportive.



- Organizational alignment

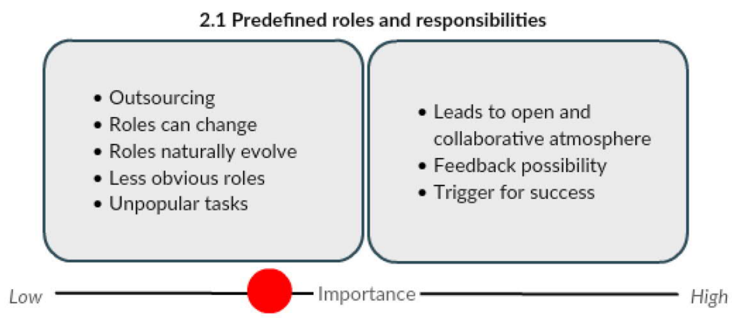
The opinions about the importance of organizational alignment for clinical prediction projects differed. On the one hand, organizational alignment brings all previous factors together, and is seen as a prerequisite for any successful analytics project in hospitals. If the deployment is a true pioneering project that makes you a front runner hospital, it is important to align the organization in order to strengthen the related strategy and communication. On the other hand, it is considered as a utopia, something that is practically impossible to reach. Hospitals that deploy these models are already a big step ahead of the average hospital. To also align the entire organization with the deployment efforts, is considered as unrealistic and unfeasible in these early stages. Surely, there needs to be an atmosphere that allows for innovation in which CPMs can foster and blossom. However, it is not a CSF; without complete organizational alignment, such projects are still expected to become successful.



5.2.2 People category

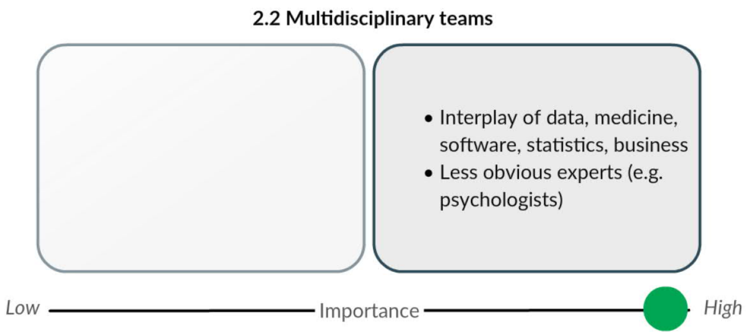
- Predefined roles and responsibilities

The discussion about roles and responsibilities is whether they should be predefined or not. Some interviewees think predefinition is crucial to put the right persons with the right tasks. In order to enlarge the learning capabilities of employees, predefined roles and responsibilities are important for a clear, open and collaborative atmosphere. This allows for positive feedback moments and more teamwork. Next to that, it creates a feeling of responsibility that triggers employees to cooperate more in order to reach success. Some other interviewees think predefinition is not desirable. Hospitals often do not have the appropriate expertise in-house for such projects, which means they might need help from external parties. Moreover, roles can change during projects. It is more about the capabilities of the team, than about predefining their roles. When the team is innovation-driven and wants to collaborate, roles and responsibilities will get an appropriate division by themselves. In reality, people are often capable of taking over a role that might initially not be very obvious. There needs to be room for this. Lastly, a remark is made about predefined roles that can turn out to be unpleasant. Getting the responsibilities of a less popular task is demotivating. Rather, such tasks should be evenly divided, a process that often goes naturally in well-performing teams, according to an interviewee.



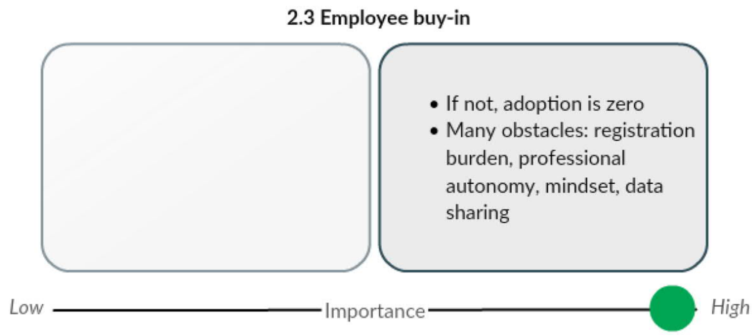
- Multidisciplinary teams

Multidisciplinary teams is one of the factors that received the highest score for importance. It is an ultimate CSF that teams are an interplay of people that understand (clinical) medicine, people that understand data, software and statistics, and people that understand the healthcare business. Next to that, the input of the patients is mentioned a few times. This will be further discussed in the factor patient involvement and doctor-patient relationship. One interviewee mentioned the presence of a psychologist in the multidisciplinary team. A psychological perspective ensures the human aspect is represented, and that the ultimate tool is reachable for user and patient. It can thus be worthwhile to include people with less obvious backgrounds in the team. Some team members are multidisciplinary by themselves: they are highly knowledgeable in more than one specific domain. In conclusion, all interviewees agree that people with different expertise join forces and collaborate in a team in order to successfully deploy CPMs.



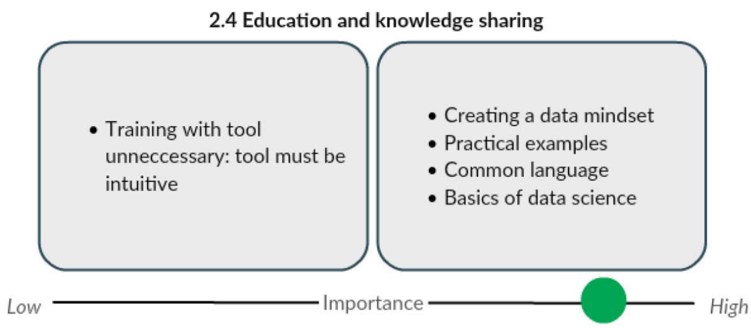
- Employee buy-in

Another factor that received the highest score for importance is employee buy-in. Doctors and nurses must have a positive attitude towards the tool, otherwise adoption is zero. There are many challenges to overtake in this area, since many employees are skeptical. A major concern is that more electronic services increase the registration workload. Levels of documentation are already high in healthcare, some simply refuse to let this grow higher. Because employees do not always see the value of proper documentation, they are sloppy in their documentation which decreases data quality for CPMs. Another concern is that PA touches the professional autonomy and take over or outperform current jobs. Employees are rarely enthusiastic about something that automates their job. New tools are often perceived as difficult, inferior, and extra workload. It is therefore crucial that hospitals work on a change in mindset. In that sense, employee buy-in is highly interdependent with the factor of change management. Good examples from practice increase the number of enthusiastic employees and their willingness to work with CPM. Another challenge is to overcome the hesitation in data sharing. Healthcare professionals are often reluctant to share ‘their’ valuable database with others, because it is perceived as property personally collected. Although it requires serious effort to increase employee buy-in, it is definitely a CSF according to the interviewees. A supportive CPM cannot be forced by the upper management, as might be the case with analytical tools in other industries. It is the doctors and the nurses who decide if the tool is actually used at the hospital bed in accordance with its potential.



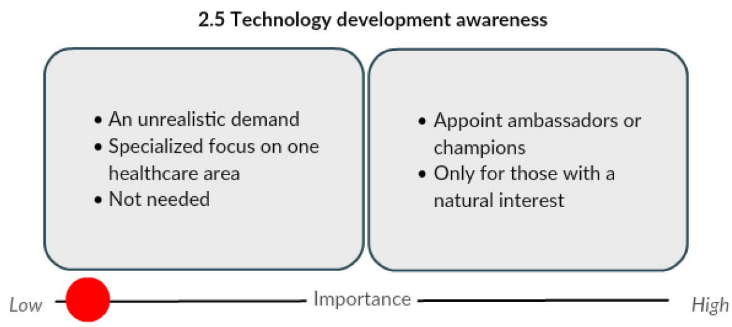
- Education and knowledge sharing

Similarly to the issue discussed in the prior factor, the real challenge behind proper education and knowledge sharing is the lack of a data mindset. The majority of the interviewees agrees that it is critical to transform the vision of healthcare professionals with regards to data. Employees must understand that what they insert, directly influences the models that can make their work easier. This requires the development of the right knowledge, which in turn can change their mindset. Practical examples, creating a common language, awareness, and some basic lessons on the core of data modelling is thus essential for adoption and deployment of clinical prediction models. Training with the tool is considered as not important, since the tool should be entirely intuitive to any user.



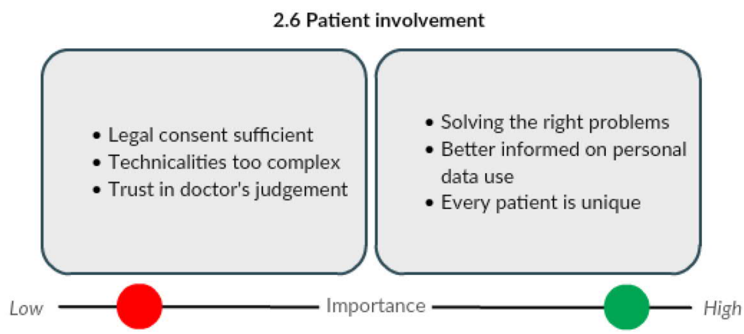
- Technology development awareness

The factor that is considered as least critical to success is technology development awareness. Interviewees think it is not needed and simply impossible to demand this awareness from all stakeholders. Doctors and nurses are often specialized and very focused on their own tiny piece of healthcare. If they do not have a natural interest in technology-related topics, that should not be a problem. However, some argue their should be at least a few members of each team that do have higher than average knowledge about technological developments. An idea is to appoint ambassadors or champions that are responsible for following such developments. When working in a multidisciplinary team, the information can be easily spread between people with varying functions.



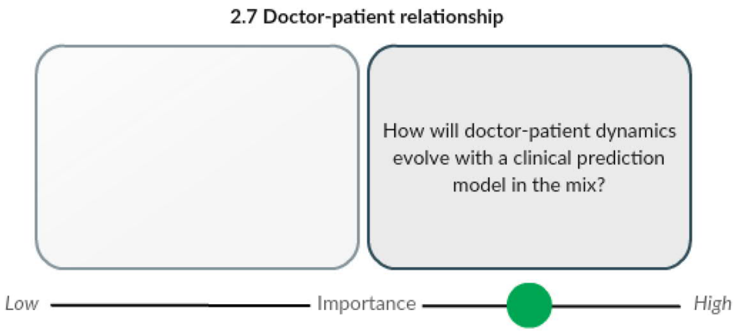
- Patient involvement

Patient involvement is a factor that generated different opinions with regards to the extent of the involvement. On the one hand, interviewees argue that patients need to be involved to a large extent. First, because this avoids solving problems that are not actually problems or the desired solution according to the patient. Second, because patients need to be informed better about the use of their personal data and how it can improve healthcare. Third, because every patient is different and requires a different approach. There is no such thing as 'the' patient, and thus everyone's personal opinion should be weighed when taking the decision to use predictive modeling. On the other hand, some interviewees argue that legal consent already implies that the patient has a positive attitude towards the tool. Moreover, it is simply not possible to involve the patients in such complex matters as predictive modeling. There is a difference in involving the patient in the technical side of the tool and involving the patient in the general journey of PA in healthcare. Lastly, some interviewees believe in the judgement of the doctor. There is a reason that a doctor is treating a patient: they are simply more knowledgeable and experienced in that field. With or without the support of predictive models, it is the doctor who reaches a diagnosis or prognosis. The patient needs to trust the doctor in this.



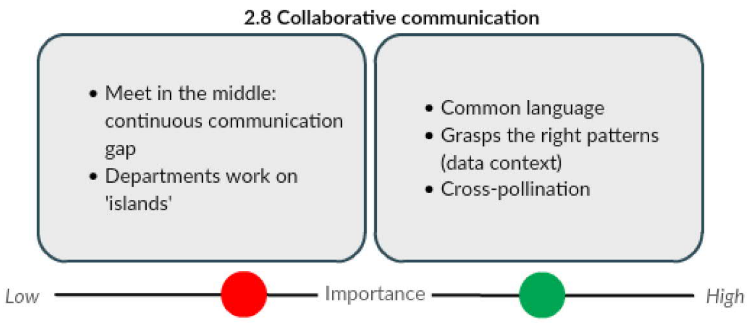
- Doctor-patient relationship

The majority of the interviewees agrees that the doctor-patient relationship is a factor that should be considered carefully in order to be successful. However, it remains unclear how the doctor-patient relationship will change when there is a CPM involved. One notion is that the relationship will become triangular, with an extra player added to the traditional doctor-patient dynamics. Another notion is that there already is an invisible third player: the protocol. That is what doctors have to follow, and a predictive model will become part of it. This implies it is more about trust of both the doctor and the patient in new technologies, rather than a doctor-patient-computer relationship. Another interviewee argues that a patient does not directly interact with the prediction model, hence there is no relationship there. At least not for now, perhaps in the future that will change. Another notion is that it is the doctor that uses the tool and who involves the patient with it. The tool gives an advice, and the doctor explains this together with own experience and knowledge. That would imply a linear relationship, rather than a triangular. Although it is unclear how the doctor-patient dynamics will evolve when deploying clinical prediction models, one concept that keeps coming back is trust. There needs to be trust in many different things: trust in the computer, trust in the doctor, trust in the algorithm, trust in the developer, trust in the system, etcetera. In conclusion, doctor-patient relationship is a CSF that needs to be further explored.



- Collaborative communication

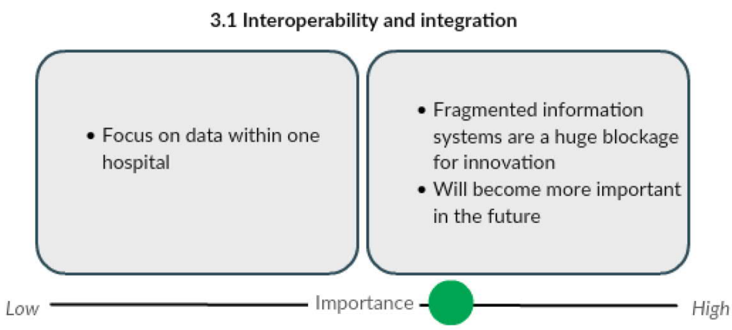
The opinions about the importance of collaborative communication varied. On the one hand, collaborative communication was identified as crucial in order to grasp the right patterns in data. Clinicians and data scientists need to frequently talk with one another in order to get the data in the right context. A common language is one of the most important elements of collaborative communication. One interviewee indicates that physical meetings are required in order to create unity of language. Next to communication within teams, communication across teams is also important. This leads to cross-pollination: problems, ideas, and solutions are shared between teams which causes change. One team follows the useful practices of another team. On the other hand, collaborative communication is less important due to the continuing gap between healthcare and data professionals. Although both parties are putting in effort to meet each other in the middle communication-wise, this gap will always exist. As long as they understand each other's core messages, it is possible to successfully collaborate. Moreover, within hospitals different departments often work on their own 'islands'. The developments on that island are carefully communicated, but what happens in other departments is not necessarily of interest to the employees. For the deployment of one specific prediction model, this might indeed not be necessary. However, when implementing models in multiple departments, hospitals must be wary not to reinvent the wheel over and over again.



5.2.3 Technology category

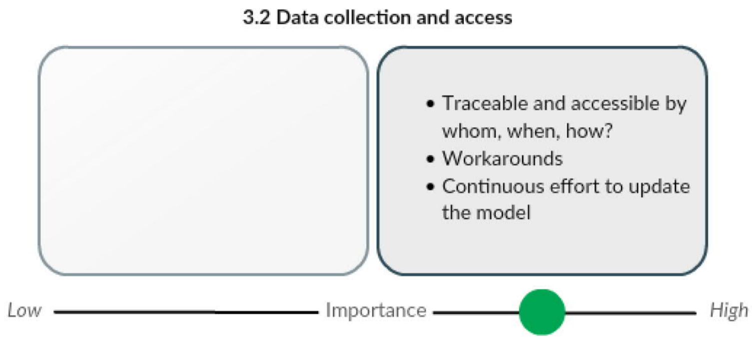
- Interoperability and integration

The majority of the interviewees think that interoperability and integration of systems and platforms is important to success and poses a true challenge. The healthcare industry is currently dominated by two large software companies that provide EHR systems: Epic and ChipSoft. Some strongly emphasized the blockage that fragmented information systems in Dutch healthcare cause. For example, tests need to be redone when a patient changes hospital, because the patient data cannot be easily transferred. Others indicated that it is important albeit not crucial to success, since CPMs often focus on data within one hospital. This will change in the future, when such models roll out more broadly. However, not only technological constraints hamper interoperability and integration. Cultural differences and privacy are also issues that arise.



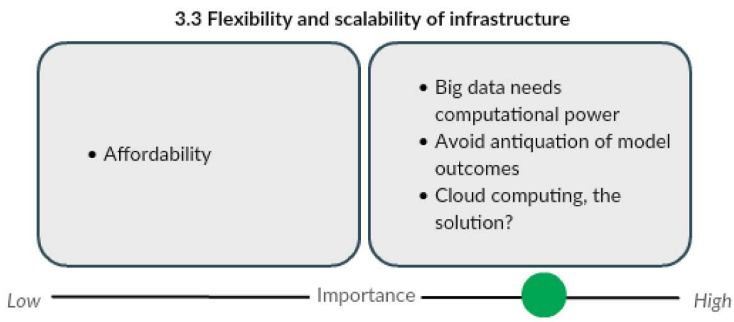
- Data collection and access

The majority of the interviewees think that data collection and access is important to success and poses a challenge to deployment. Data needs to be traceable and accessible. Decisions need to be made about how data is accessible, by whom and in what time period. The hardware needs to support this, to save and store data and run the algorithm. Data harmonization, combining and extracting data is perceived as a frustration. Complex workarounds are invented to solve these problems, which makes the process less efficient. The importance of proper collection and access of data is emphasized because of the need to recalibrate the prediction model. It is a continuous effort to keep the model up to date, which means data needs to be collected and accessed continuously as well.



- Flexibility and scalability of infrastructure

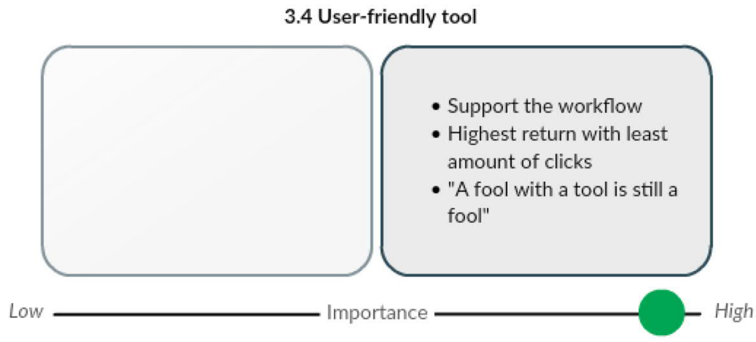
The majority of the interviewees recognizes flexible and scalable infrastructure as important to success. The very nature of big data analytics demands high computational power. For big user groups, it is therefore a requirement to have the appropriate infrastructure or to work with a cloud solution. An interviewee points out that especially in healthcare the available computer systems are outdated and lack capacity for big data solutions. Moreover, when making predictions on human lives it is especially important to respond to certain analytical questions quickly, otherwise data is already antiquated. The discrepancy is between flexibility and affordability. Outsourcing computational power through cloud solutions can provide external tooling to execute advanced analytics.



- User-friendly tool

The user-friendliness of the front-end tooling is considered as extremely important to successful deployment. The user should not experience the prediction model as extra workload; it should support their workflow, not hamper it. That means that the tool needs to be intuitive and interpretable by anyone. The goal when designing the tool is to get the highest possible return with the least amount of clicks. A tool that is not easy to use, will not be used. As one of the interviewees stated:

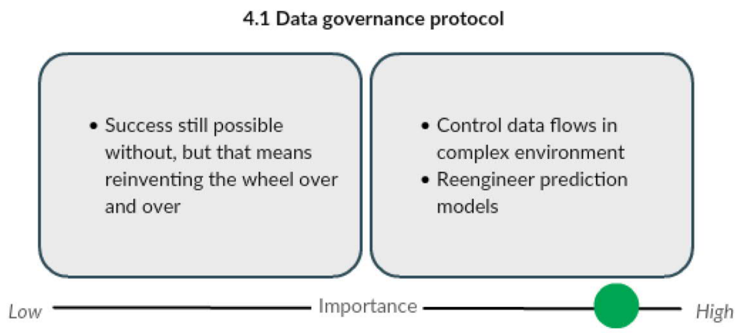
"A fool with a tool is still a fool"



5.2.4 *Processes category*

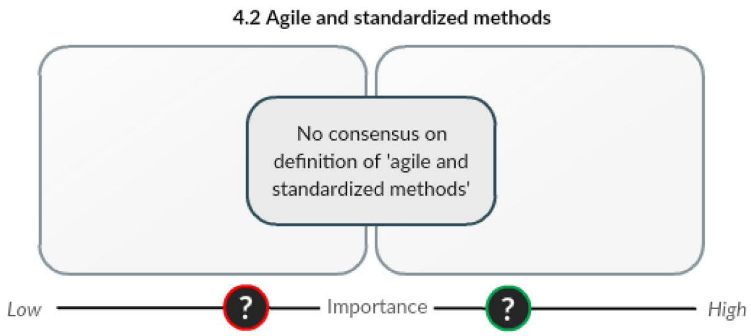
- Data governance protocol

The majority of the interviewees considered a data governance protocol as important to success. The many rules, regulations, and administration create a complex environment where a data governance protocol is needed. Especially for scalability of models a protocol is important. Although it is possible to still be successful without a data governance protocol, it would mean you need to reinvent the wheel every time another clinical prediction project is started. Next to that, one interviewee pointed out the importance of such a protocol to be able to reengineer the prediction model. A timestamp of the exact data that was inserted in the algorithm is needed to be able to go back to the data that created a certain prediction. Healthcare data, such as oxygen levels or blood pressure, changes every second, which increases the importance of a data governance protocol that controls the data flows.



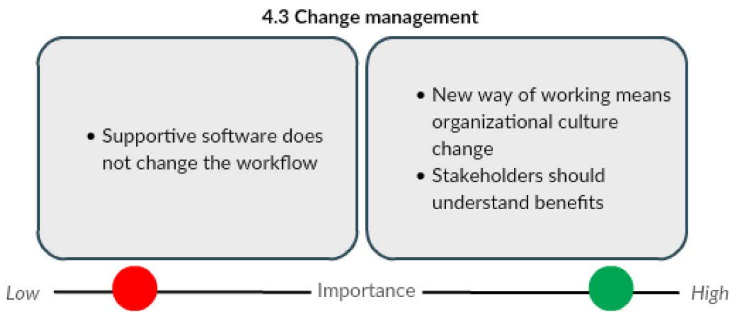
- Agile and standardized methods

Interviewees' definition of 'agile' is not aligned. For some, agile means predefined goals and deadlines, while for others 'predefined' does not match agile thinking. It is also noted that in healthcare, methods are often called 'agile', but in essence they are not actually agile. Agile methods are more familiar to the IT world and the business perspective. Not everyone working in hospitals understands what agile working means and it is certainly not always part of the way of working. Certainly, opinions about the importance of agile methods therefore differ. On the one hand, iterative and small steps adaptable to external change is considered as something only important in the development phase, not in deployment. On the other hand, short cycles with deliverables are also found important during implementation and continuation. Some think IT deployment processes are generally very standardized, whereas others think it is wrong to treat innovative projects as traditional projects with standard methods. Moreover, the combination of agile and standardized also caused confusion, since these seem to be contradictory.



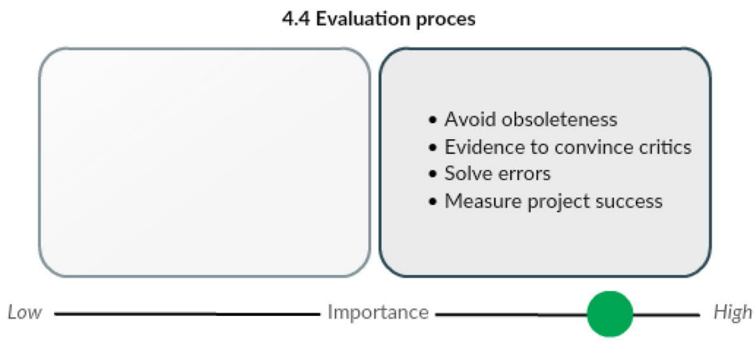
- Change management

The opinions about the importance of change management strongly differ. On the one side, it is considered as an extremely important element of successful deployment. The entire system needs to be transformed: from patient, to healthcare professional, to management. This requires a change in the organizational culture, which is often a challenge. First, the identification of change is difficult. Second, being open to change, and third, adopting change. New data analytics are sometimes perceived as a ‘threat’ against professional autonomy. The job is not finished when an algorithm is implemented; from the start, all stakeholders need to be identified and benefits need to be clearly explained. Interviewees clearly link change management to employee buy-in. These two factors are highly interdependent. On the other side, change management is considered as not important because it is not relevant. A CPM is simply supportive software used in the background of the consultation. Following that argument, end users should not experience the deployment as a big change in their workflow. The healthcare process is not really changing, rather existing processes are supported in novel ways.



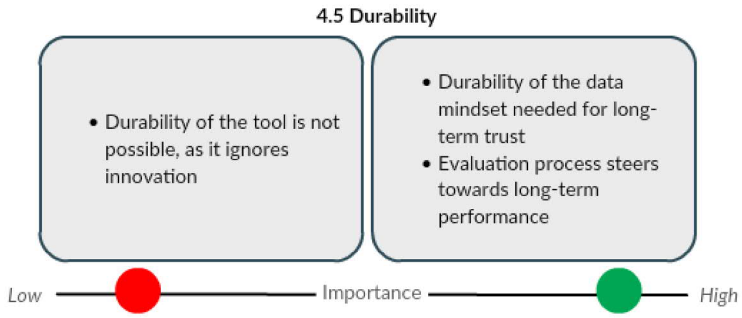
- Evaluation process

The majority of the interviewees identifies the evaluation processes as critical to success. Firstly, because algorithms’ performance needs to be monitored continuously to avoid that it becomes obsolete or useless over time. Secondly, the evaluation process provides the evidence that can convince critical professionals of the benefits to healthcare. Thirdly, it is a means to deal with errors and breakdowns and improve the model accordingly. Fourthly, because it allows you to measure all the time, money, and effort that goes into the project and benchmark it against the initial goals. In other words, it allows you to measure whether a project is a success and to do honest evaluation of the added value. Although documentation for evaluation purposes increases workload, it is broadly considered as the duty of the developers and users to put in the effort for accurate and complete registration. The evaluation process was often linked to agile methods, because of its incorporated feedback loops. A minority considered evaluation processes as less crucial, for the reason that when there is an error, complaints will follow automatically. However, that is only one of the objectives of the evaluation process.



- Durability

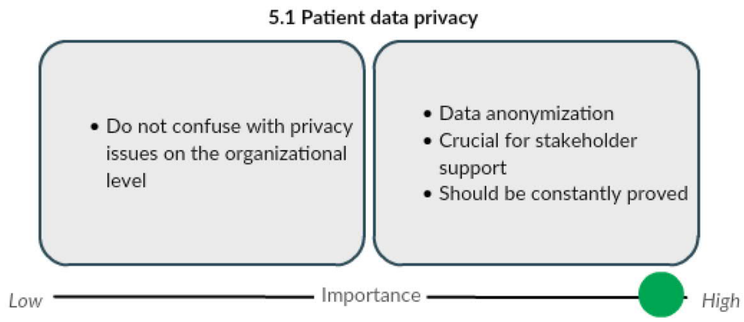
The factor 'durability' requires a partitioning into two areas. The durability of the model or tool itself is considered as not important. It is inherent to these models that they are connected to new technologies. If a model is designed with the promise of a long-term solution, it ignores the constant stream of technological innovations. Thus, the actual solution should by definition be changing in accordance with innovation. The durability of the data mindset, the structure behind the solution, is highly important. The mindset needs to be one of continuous learning and continuous improvement in order to enlarge the trust in the technology. In other words, it is not about trust in one algorithm, but about trust in the system that produces algorithms and in the way algorithms work. That creates long-term trust. Moreover, the right maintenance and service is required to ensure performance in the future. Durability is hence often linked with the evaluation process, as this process allows for the measuring and steering towards long-term performance.



5.2.5 *Data category*

- Patient data privacy

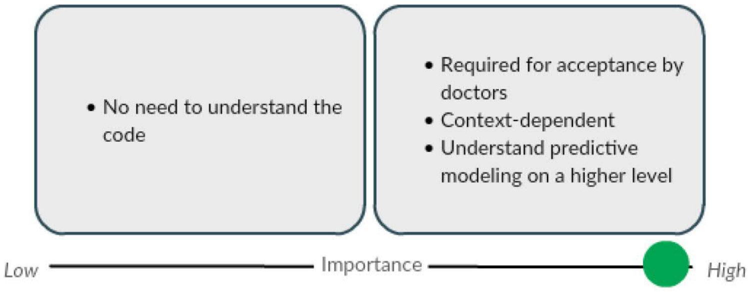
All interviewees scored patient data privacy as extremely important to success. If data privacy is not taken into account as CSF for deployment, a project is not likely to succeed. All stakeholders, internally and externally, will lose their support. In the development phase, data privacy solutions must be initiated, and afterwards it needs to be constantly showed and proved that privacy is on the agenda. The data and surrounding processes need to be secured airtight, with the help of lawyers and privacy officers. Some critical interviewees noted that patient data privacy should not be located at the data level, but rather at the organizational level. Indeed, the overarching factor of ‘legal regulations’ and ‘information security’ captures the privacy issues on a higher level. In this privacy factor on the data level, the anonymization of data plays an important role.



- Data transparency

All interviewees consider data transparency as a CSF for deployment, mainly because it is the only way to generate acceptance by end users. Doctors want to know how the results from a CPM are constructed, and simply do not accept it if it cannot be explained. However, this is context-dependent, since in some situations the doctor can simply check if the model is right. For example, the detection of a tumor can simply be confirmed. But for the prediction of chemotherapy outcome, the doctor certainly wants to know why a certain prediction is computed. Next to that, it is important to make a differentiation between the transparency of the data and the transparency of the algorithm. On a higher level it must be clear how a predictive algorithm works and on what data it is based. However, it is not feasible to expect transparency and understanding of the actual code.

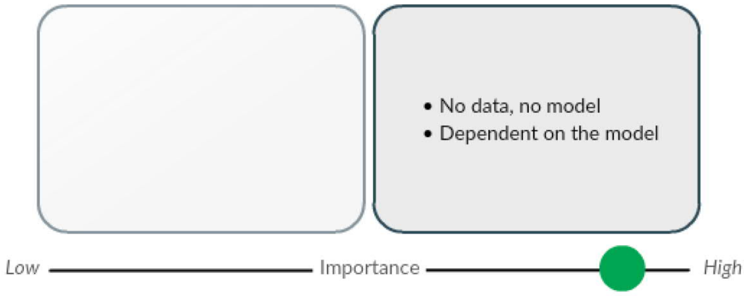
5.2 Data transparency



- Data availability

Data availability is generally considered as important, but with the side note that it is dependent on the specific model. For example, self-learning models need near real-time data, others do not. Also, in some cases it is crucial that the results of the model are delivered immediately, in other cases results can come hours later and still be of substantial support. However, in general holds: no data, no model.

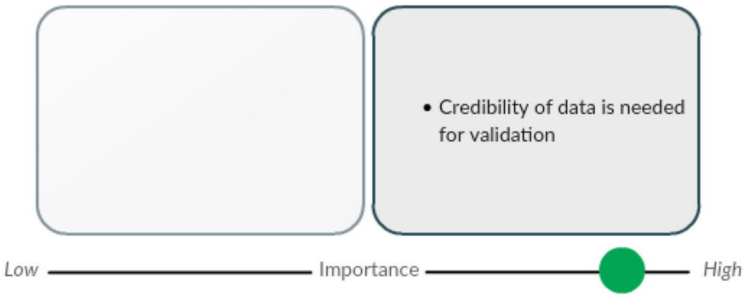
5.3 Data availability



- Data usability

In general, the credibility of the data is considered important. Algorithms must be trained on expert data, otherwise they cannot be validated. Especially when 'big data' is not that 'big', it needs to come from reliable sources.

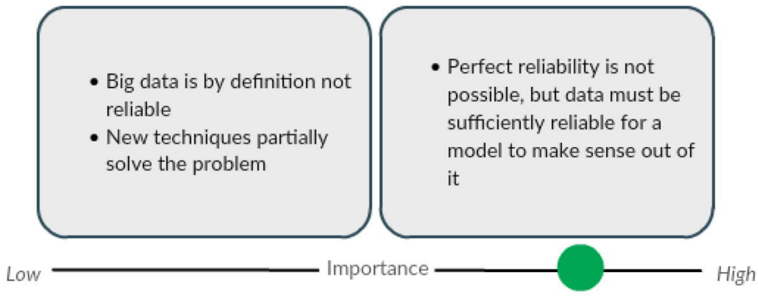
5.4 Data usability



- Data reliability

Data reliability is also considered important, albeit with some side notes. Big data is inherently not reliable. By definition, data is not complete, consistent, or accurate. If a model works only on complete, crystallized data, it will not work in real life. A model should be able to deal with a pile of very diverse data in terms of reliability, and make sense out of that. That is very difficult, but necessary for practical application. Also, data reliability is getting less important, because of new techniques such as transfer learning. Thus, although perfect data reliability cannot be expected, it is important to have data that is reliable enough for a model to make sense out of it.

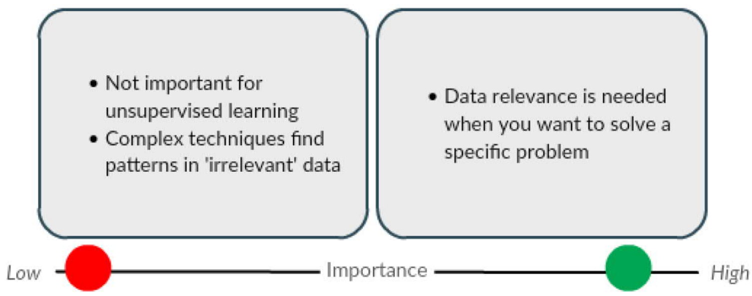
5.5 Data reliability



- Data relevance

Data relevance is another factor that is considered important, but with a big side note. The way you approach the data makes a big difference: do you want to solve a specific problem and then start looking for data, or do you have data and then see what you can do with it? With unsupervised learning the output values are initially unknown. Complex data mining techniques can find patterns in data that we might consider irrelevant. On the other hand, using too much (irrelevant) data increases issues with privacy, security, scalability, and flexibility. Moreover, if the goal is to predict a certain situation, it is very important that somewhere in the data the answer resides.

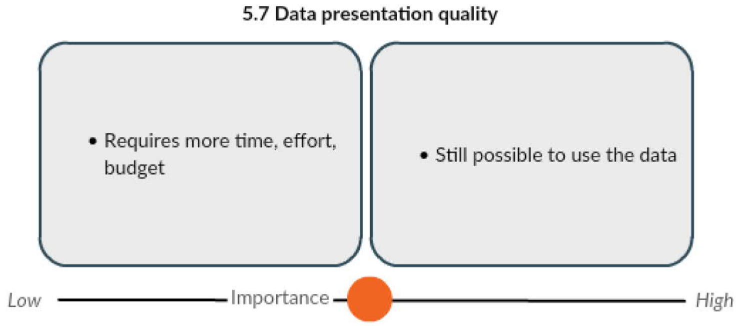
5.6 Data relevance



- Data presentation quality

The level of data presentation quality is considered less important compared to the other data quality factors. Data that does not have proper presentation quality can still be used, albeit the data cleaning will require more effort, time, and budget. An interviewee states:

> *"If you are a good data scientist, this shouldn't really matter. It is part of your job."*



5.3 Results expert interviews: new insights

Next to the opinions on the deployment factors, the interviews also provoked comments on related topics. This section highlights the most interesting and most quoted topics, and aims to provide new insights alongside the developed artifact. Figure 22 shows a word cloud generated from all transcripts which gives a look into the words most frequently used by interviewees. Next to ‘data’, ‘people’, and ‘tool’ (front-end CPMs) it appears that the verbs ‘will’, ‘can’, ‘think’, ‘want’ mostly convey an aspect of future possibilities.

Figure 22 Word cloud of conducted interviews

5.3.1 Overview of (to be) implemented clinical prediction models

Each interviewee was asked to tell something about the (to be) implemented projects on clinical predictions. In order to provide a general overview of types of prediction models in hospitals, Figure 23 lists some of the answers given by interviewees. The figure gives a good indication of what is currently topical in practice, and in which medical fields prediction projects prevail. It is important to emphasize that all these examples are in a different stage, from non-validated algorithms to tools currently used by doctors.

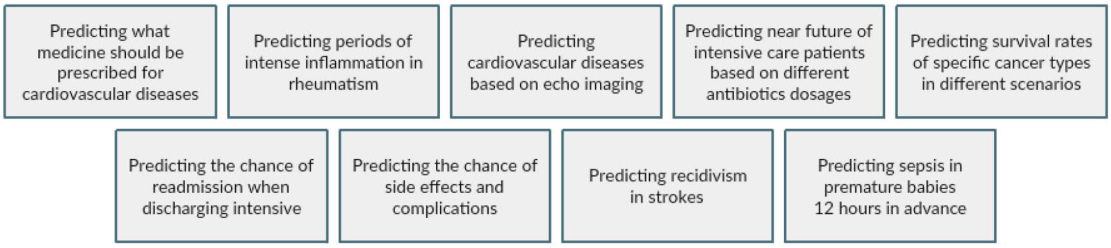


Figure 23 Overview of (to be) implemented CPMs as reported by interviewees

5.3.2 Healthcare industry specificities

Based on existing literature, subsection 2.2.2 explains what makes data mining unique in healthcare compared to other sectors. The specificities of the healthcare industry were also emphasized by multiple interviewees. Although many parallels exist when it comes to deployment challenges of BI&A solutions in different sectors, there surely are some characteristics that differentiate the healthcare industry from others.

The providence of healthcare involves rationality, however, on the patient side healthcare is anything but rational. Whereas efficiency is a crucial measure for the profitability of many businesses, it is not most important in healthcare. The role of sentiment is critical in how people perceive healthcare. The result is always maximized from a patient perspective, which often involves emotions rather than logic or rationality. The most efficient solution is not always preferred for providing the highest quality of life. Two interviewees illustrate this:

> *"What makes sense practically or analytically, does not always make sense to the patient. (...) You can't say to a patient: "It is statistically not feasible to treat your life-threatening disease"."*
>
> *"Healthcare is a sector that is different from, for example, the financial sector, where many predictive models are used. In healthcare, we deal with humans and human behavior, which cannot be generalized like financial data."*

As touched upon in subsection 2.2.2, the ethical considerations behind data mining efforts are specific in healthcare, since the ultimate goal is not business related but extremely social, personal, and directly affecting someone's life. Therefore, it could be argued that the development of predictive models comes with a degree of responsibility. When utilizing someone's data for analytical purposes, the responsibility to make the outcomes available could be considered an ethical obligation. An interviewee mentions about data coming from the intensive care unit:

> *"I think there is a moral obligation to do something with the data you gather from extremely sick patients, when you have created a predictive model that works. (...) We must fight to make the model available to patients. If you don't do that, you are just calculating things because you like it. However, you are using patient data for it. Data of really sick patients, of which a lot of them die."*

The organizational structure inside hospitals is complex. A board of directors is responsible for the quality, safety and continuity of care by formulating and acting upon higher strategies. The supervisory board proactively supervises the board of directors and provides critical advice. Next to that, there is often a medical board that organizes itself in a medical staff association, and monitors the quality of healthcare from a medical perspective. This creates distinct dynamics in the management of healthcare organizations. Groups with business and medical perspectives need to cooperate on the strategy, vision, and mission of the hospital. This can cause a conflict of interest, since business goals and medical goals do not always align. Rather than a CIO who takes the big IT decisions, it is a joint effort of the board of directors, supervisory board, the CMIO, and the medical staff association.

Furthermore, next to the organizational specificities in healthcare organizations, there are other factors that affect the adoption of IT innovation. The many different stakeholders with each their own agenda, financial challenges, governmental legislations and public policy, and the demand of accountability of health innovations all hamper the speed of adoption in a way that is different from other industries (Herzlinger, 2006). An interviewee illustrates the problem with varying agendas of stakeholders:

> *"Things move slowly in the medical world. We are on top of a huge treasure chest filled with data. However, the realization of stakeholders is not always present."*

Another interviewee highlights why big IT decisions in healthcare involve a different dynamics than in the corporate world:

> *"In healthcare, professionals are often organized in groups. For example, a group of specialists in oncology. Inside these groups there is a culture of deliberation with one another, whereas in corporate companies, implementation comes from top-down initiatives. That is why in healthcare there is more discussion; it is more important to look for a consensus."*

5.3.3 Data standards for clinical data

The adoption of standards for clinical data is low, leading to less usable data for predictive modeling. For proper statistical analyses, data needs to be in a structured form and with an appropriate balance between scope and granularity. In healthcare, communication between health professionals is key. However, each specialty has its own vocabulary and character set, with different meanings in different contexts. That implies that free text is semantically not interoperable. The problem of local data dictionaries and missing contextual descriptions can be partly solved by following the FAIR principles. Data should be findable, accessible, interoperable, and reusable (Wilkinson et al., 2016). One of the interviewees provided a real-life example that stresses the importance of data standards. Doctors and nurses used over 50 different notations to write down a specific antibiotics called Augmentin in the EHR of neonatal care babies (Figure 24). Clinical data standards would directly increase data quality and hence the possibilities for clinical prediction modelling.

Augmentin

A	Au	Aug	Augmentin	Augmentint	Augemntin
Augemtenin	Augemtin	Augentin	Augm	Augmantin	Augmenstin
Augmenti	Augmentien	Augmetiin	Augmentim	Augmentin\	Augmentine
Augmenting	Augmentinm	Augmentinn	Augmentint	Augmentn	Augmentu
Augmetin	Augmetnin	Augmintin	Augmmentin	Augmnentin	Augmnetin
Augnemtin	Augnmentin	Auhmentin	Aum	Aumentin	(even more)

Figure 24 Varying notations of the antibiotics Augmentin in data streams of a neonatal care unit.[2]

5.3.4 Data context

Closely linked to the need for clinical data standards, is the importance of a data context. Data in itself does not provide much information. It is essential to understand which data holds information about the cause of a disease, and which data holds information about the consequences. The measured values gain meaning when interpreting them in a certain context.

[2] Source: https://www.mobilehealthcare.nl/syllabus/

An example of what can go wrong when data context is not guaranteed, was provided by an interviewee. A group of data scientists had created a prediction model for sepsis. When explaining it to the medical staff, the reasoning behind the model was not understood by the medics. It turned out that a wrong table with almost identical data was used as input to the model. Due to the wrong interpretation of the data context, the wrong patterns were captured. This highlights the importance of collaborative communication in multidisciplinary teams. Another example is that of blood sugar levels; they are highly dependent on the meals you have recently consumed. A number is not just a number in healthcare, it always requires a context.

5.3.5 Data stewardship

A fundamental part of clinical research is data stewardship; the long-term sustainable care for research data (Jansen et al., 2018). In data stewardship, the FAIR principles are applied in the long-term, including data management, data archiving, and data reuse. This way, all stakeholders are able to benefit from the outcomes of high quality data sharing. New knowledge and treatments can be developed from FAIR (findable, accessible, interoperable, and reusable) research data.

Data stewardship is related to data collection and access. The system in which the data resides needs to be easily traceable and accessible in a timely manner. If data is not stored accurately, cannot be collected or accessed appropriately, data stewardship is in danger. Data stewardship is also related to durability. A durable data-driven mindset can only be achieved when there is good data stewardship.

5.3.6 Automated data governance

The growth of data initiatives and need for data stewardship calls for better data governance. The use of CPMs are empowered by making data access easy and intuitive. A data governance protocol is one of the factors for deployment. Indeed, thinking about the data, building a plan for it, allocating responsibilities, measuring the quality of data, knowing what the data means when it is created, are all part of the data governance process. There is a need to understand the life story of the data. Automated data governance entails software that helps users across an organization agree on how data is used, shared, and protected. This way, organizations ensure automatically that all departments are using the data in a consistent manner. All data sources are located and catalogued, which aids in the identification of inappropriate or faulty data sources. An automated data governance process can provide controls for data management, but is not the ultimate answer.

Employee buy-in and stakeholder engagement are required to make to make data governance automation software work.

5.3.7 *Privacy and the GDPR*

The legal regulations surrounding privacy were strongly emphasized by multiple interviewees. The General Data Protection Regulation (GDPR) that came into effect in May 2018 for the entire European Union, changed the regulatory goals for researchers and health organizations (European Union, 2016). Awareness of the GDPR rules and compliance goals is important for the success of a clinical prediction project. Especially in a large scale clinical setting, the consideration of data protection issues must be on the agenda already at the early stage.

The GDPR protects the individual rights of all citizens, and allows for free and safe data sharing. However, the regulations are considered to many as complex, which leads to a conservative reality in which actual sharing is rarely accomplished. Next to that, parts of the GDPR regulations are not conclusive, leading to grey areas. Scared to break the law in such grey areas, organizations tend to stay out of them, leading to more conservatism. The trade-off between protecting privacy and sharing information is out of balance, with privacy protection getting the upper hand. This jeopardizes the realization of the high promises coming from the exploitation of data. An interviewee notes:

> *"We are experiencing some issues with our software provider, whose prediction model requires us to comply to the American data protection regulation. This plays a big role in the further development of the tool here in the Netherlands. That is very unfortunate. I think it is more about the feeling of privacy than actual privacy."*

The role of privacy and related legislation is substantial. But for some interviewees, a critical attitude prevails. All the turmoil surrounding this topic in the past years has given privacy a significance that may be overrated. The feeling of privacy and actual privacy are not always the same. Another interviewee puts forward the presence of our human solidarity as the solution to privacy issues. If the right, concrete questions are asked accompanied with a proper explanation of what the data is going to be used for, this might make privacy a non-issue. Our solidarity for one another surpasses the need to detain our (anonymized) data. Next to that, combining and extracting data is a big frustration. The difficulty often resides in consent or privacy. However, is it truly privacy that refrains people from data sharing, or do they simply not want to share what is often considered as a personal property? An interviewee notes:

> *"I think sometimes privacy reasons are used as excuses. Access to data can go wrong on multiple dimensions. However, I think the real underlying reason is the*

ego of people. People think they own their own data and don't want to share it. That undermines the common goal."

5.3.8 Missing data

The presence of missing values is arguably part of data science. A model should not only work on complete, crystallized data as this does not represent a real life situation. The challenge of a predictive model is to make sense out of a pile of data that is diverse in terms of reliability. Nevertheless, it is valuable to look behind the reasons of missing values and possibly extract information from that. Two interviewees explain why there can be value in missing data:

> *"I believe that from the missing data valuable information can be retrieved. Calculations that show the difference between an ideal dataset and the actual dataset provides metadata which can lead to interesting insights."*
>
> *"When a doctor does not write something down, it can mean multiple things. Maybe he doesn't know, maybe it is not observed with the patient, or it was simply not written down. Only doctors can explain the meaning of missing data."*

On the other hand, missing data leads to lower statistical precision and can introduce bias. A solution to missing data is to impute it: replace empty cells with actual values. The goal of imputation is to allow all observations to be used for the analysis, not to add new information to the dataset (Van Kuijk et al., 2018). It must be ensured that no bias is introduced due to this technique, which depends on the randomness of the missing data.

5.3.9 Transfer learning

New techniques make it easier to solve data reliability issues. Reliability is explained in terms of accuracy, consistency integrity, and completeness of data. As stated by an interviewee, transfer learning is a technique that enables data scientists to do more with less data reliability.

Transfer learning utilizes the knowledge of a machine learning model that has already been trained and applied to a different problem. The knowledge that was learned is exploited in another dataset with few reliable instances. The known patterns that stem from the first model serve as the starting point for the second model. This allows a less reliable dataset to build a solid model with comparatively little training data. Moreover, using this technique makes running models a lot more time-efficient. Although a certain level of data reliability remains a requirement, transfer learning allows us to do more and more with less data. This is an example of a technique, mentioned during the interviews, that has a direct effect on the importance of one of the factors on deployment success. The rapid developments in the data science field must be carefully followed in order to guarantee the CSFs are recent.

5.3.10 Gartner's bimodal IT

The nature of CPM deployment is considered as disruptive and innovative by the majority of the interviewees. The implementation and continuation of such models should therefore not be treated as a traditional IT project. The effectiveness of a model is usually not yet perfectly clear and requires a lot of finetuning. Every use case can serve as a learning project to perform better on the next one. In order to better explain this innovative information stream, the bimodal IT of Gartner is introduced.

Bimodal is the "practice of managing two separate but coherent styles of work: one focused on predictability and the other on exploration" (Pettey, 2016). These two streams are acknowledged as *Mode 1* and *Mode 2.* Mode 1 focuses on exploitation of well-understood, predictable areas, while improving legacy systems in a way that fits modern, digital demands. Mode 2 is optimized for areas of uncertainty, which allows it to explore and experiment with new problems. The combination of the two modes is essential to create bimodal capabilities of an organization. That way, organizations are able to solve today's business problems through continuous re-innovation, whilst also creating tomorrow's possibilities through experimentation with emerging technologies. It is important that IT projects with an uncertain character are identified as such, and that the appropriate approach is used.

At the same time, it must be noted that from an academic perspective there are some critical voices. A consensus on bimodal IT's content and its implementation approaches has not been reached (Horlach et al., 2016). Moreover, it is argued that the bimodal IT design is an interim stage in a larger transition, rather than the destination (Haffke et al., 2017). Keeping in mind these pitfalls, hospitals should carefully look at their IT projects and make a clear distinction in terms of uncertainty in order to choose the right approach for PA projects.

5.3.11 The action perspective

The successful deployment of data science projects can generally be described from a model that combines four components. First, data must be accessed and prepared in the data engineering component. Second, the algorithmic models are coded in the data mining component. Third, the information that stems from the model is presented with corresponding decision options in the data visualization component. Fourth, the action perspective of the created model is highlighted in the data entrepreneurship component. Overarching these four components are data strategy, ethics, and legislations. Figure 25 illustrates this data science approach.

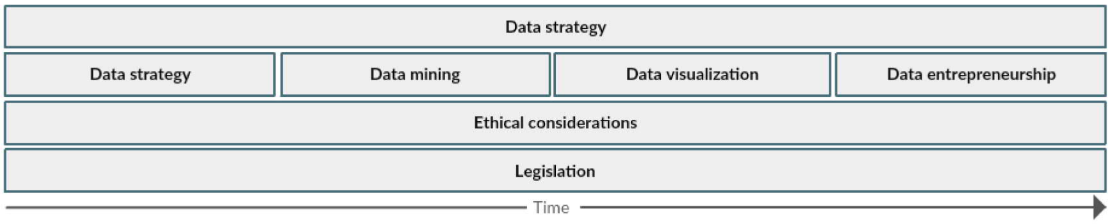


Figure 25 Data science approach with data entrepreneurship (action perspective)

In the implementation and continuation of a data science project such as a CPM, the last component of data entrepreneurship should be as clearly defined as the first three components. Whereas these first components are active mostly in the stages before implementation, the data entrepreneurship comes into play later. The term entrepreneurship should not be confused with the traditional concept of starting a new business. Rather, it is about having an action perspective. This implies that what is predicted has the potential or possibility to be actually put into action. Can behaviors or processes actually be changed with the outcome of the predictive models? The goal should not to predict something simply because it is possible to predict something.

5.3.12 Different perspectives

Part of the goal of the interviews was to generate a holistic outlook on the conceptual model, including viewpoints from medical experts, data experts, and IT experts. Although there was a consensus on many points, there were also clear differences in the way these functions perceive challenges and CSFs of clinical prediction models.

The risk management perspective balances the impact versus the likelihood of all risks associated with deployment. A project management angle is taken, including benefit realization, investments outcomes, and thinking in terms of a business case. The medical perspective is generally resistant towards such an attitude. Thinking in terms of business case concepts is not part of their demeanor. The patient is at the core of everything, and that should prevail in all activities that are part of their job. The data perspective is also intrinsically motivated to ‘do good with data’. However, surely they emphasize the value of data in everything they do. For example, data quality is something that data scientists build on, whereas health professionals might see it as an extra administrative burden. A data scientist notes:

> *"It seems as if, in the healthcare industry, data is considered a burden, rather than an opportunity. There is so much data that is not being used. It is considered a registration burden. However, if you start to see that it can actually improve quality of healthcare, it becomes an opportunity."*

The different perspectives from various stakeholders clearly come forward in this research. Especially the disunity between data scientists and medical experts is a challenge specific to the healthcare sector that must be addressed when deploying CPMs.

6 CASE STUDY AT A DUTCH HOSPITAL

This chapter is dedicated to a case study at a Dutch UMC. The goal is to test the developed artifact in practice through a gap analysis. Two sets of questionnaires are used to compare the baseline objectives in terms of deployment factors with the current status of the deployment factors. The results are depicted in radar charts, and present the practical contribution of this research to future projects.

RQ6	How to test the designed deployment strategy in a case study?	Chapter 6

6.1 Case description

The Department of Psychiatry of the University Medical Center Utrecht (UMCU) in the Netherlands is currently researching a CPM that is able to predict aggressive behavior of hospitalized patients. A violence risk assessment detects patients at greatest risk of violent incidents, such as verbal and physical aggression against medical staff or other patients. The relevant activities related to applied predictive modeling make this department a suitable case study subject.

The prediction model published by Menger et al. (2018) applies both deep learning and classical machine learning techniques on textual data from EHRs. Data entered by psychiatrists and nurses in the first 24 hours of admission is used to estimate a patient's risk of aggression in the following 30 days. The model is based on a binary classification decision that classifies the violence risk as low or high. Performance of the model in terms of Area Under Curve (AUC) of the Receiver Operator Curve (ROC) is 0.788. Estimates of the AUC provide and indication of the utility of the model and allows for comparison between two or more models. The higher the AUC (between 0 and 1), the better a model can distinguish between classes. A score of 0.788 implies a very promising CPM based on text classification, but a degree of caution remains due to unavoidable overfitting.

The violence risk model is currently being validated in further research. Simultaneously, the UMCU Psychiatry department has established a project team focusing on big data innovation. The deployment of the CPM is under investigation, including discussions with clinicians, nurses, data scientists, and also patients.

The team members that are part of the case study have a different expertise and background. The results are based solely on their opinions, which should be taken into account when weighing the conclusions.

6.2 Results

Data is collected through questionnaires with a standardized set of questions about each deployment factor. This data collection instrument is able to gather practical, fast outputs that can be easily compared. The baseline questionnaire is filled in by a main member of the project team, who took a retrospective look on the initial objectives of the project on each of the factors. Four members of the project team have filled in a questionnaire about the current status of the various factors; to what extent is each factor currently in place in the organization. One respondent (CS-03) was not able to fully grasp the current situation of the project surrounding technology, processes or data. Due to the limited number of answers, this questionnaire was disregarded for the radar charts. The remaining three questionnaires contained a few unanswered questions, which led to gaps in some radar charts.

The five main categories are represented in a radar chart. The radar chart starts at the core and ascends to its periphery in accordance with the Likert scale from ‘very little extent’ to ‘very large extent’. The baseline line (in bold grey) shows the desired situation as formulated in the first phase (BU phase of CRISP-DM) of the project. The other lines (in orange, yellow, blue) represent the answers of three respondents about the current situation of the arrangement of the factors. By comparing the baseline to the current situation, practical insights are gathered on the progress of the factors. Do the critical success factors as determined at the start of the project match the current deployment status? In other words: can the project be considered a success?

6.2.1 Management category

The radar chart of the Management category shows a relatively high match between baseline and current situation (Figure 26). Respondents have aligned opinions on the current status of most factors, visualized by the larger, multi-colored dots. *Organizational alignment* and *planning and scoping* need to receive somewhat more attention. Interestingly, *strong clinical leadership* was not highlighted as a major CSF, but does receive a high score in the current situation. *Top management support* is exactly where it is intended to be. The factor c*lear strategy* is outperforming compared to the initial goals. All in all, the team shows a good performance in the managerial category.

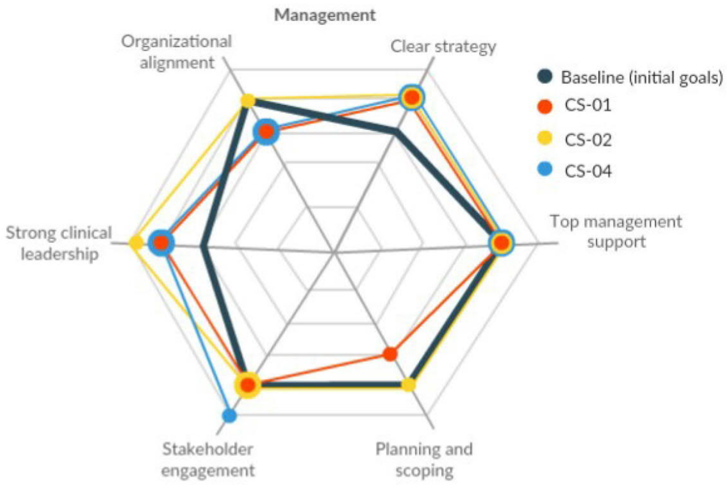


Figure 26 Case study results: Management category

6.2.2 People category

The initial CSFs for the People category varied: whereas some factors are considered as major CSFs, others are less important to success (Figure 27). The major CSFs, *multidisciplinary teams, employee buy-in, patient involvement,* and *doctor-patient relationship*, all score relatively low in the current situation. This indicates that the project team should dedicate extra attention to these factors. Since the project is still in pilot phase, there is still ample time to further develop these factors. For example, patients were already involved via focus groups in the modelling phase of the project, albeit in the later stages. In the deployment phase this can be further expanded. *Technology development awareness* is less critical to success, but already well developed. About *education and knowledge sharing* a respondent notes that the UMCU has been focusing on predictive analytics for a long period of time, which has led to a decent amount of shared knowledge amongst the team. *Collaborative communication,* although not a major CSF, still needs some attention. A respondent explains that this will be further developed in the future, when more teams are dedicated to the deployment of CPMs. Unfortunately, no baseline was given for *predefined roles and responsibilities*, therefore it cannot be compared.

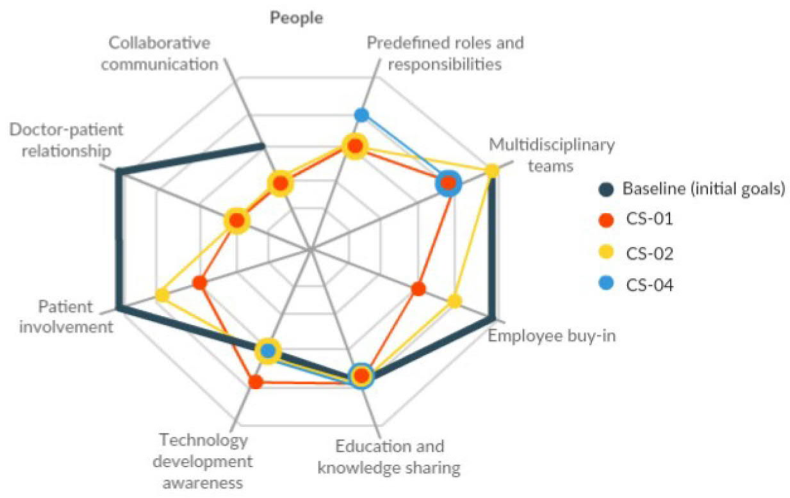


Figure 27 Case study results: People category

6.2.3 Technology category

In the Technology category there is still much to be gained, as depicted in the radar chart (Figure 28). The major CSFs, *interoperability and integration* and *user-friendly tool*, are not yet sufficiently in place. Both should receive serious attention in the advancement of the project. A respondent notes that the technicalities behind integration with the EHRs are difficult to realize. The opinions about the user-friendliness of the tool vary. This can be explained by the subjectivity of the concept. What one person considers as usable, does not necessarily apply to the other. The other two factors, *data collection and access* and *flexibility and scalability of infrastructure*, are approximately at the status that was envisioned at the start of the project.

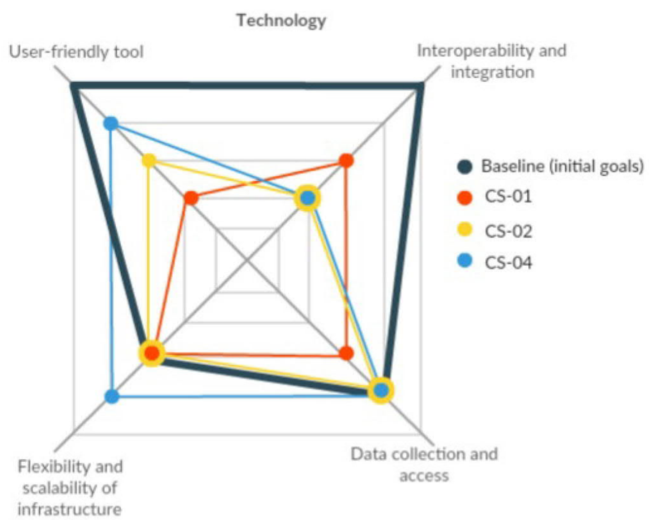


Figure 28 Case study results: Technology category

6.2.4 Processes category

The Processes category shows an interesting mismatch in the radar chart (Figure 29). Whereas the factors considered as moderate to low importance have outperformed, the factors considered as highly important to success have underperformed. *Agile and standardized methods* and *change management* are not the key pillars, but are currently in place to a high extent. It is worthwhile for the team to reflect on the made efforts, and whether factors have developed automatically or if they have deprived resources that could have been allocated differently. A *data governance protocol* is almost considered as sufficiently in place. However, for *durability* the team should put forth extra time and effort. This observation is not surprising, since the project is still in pilot phase and the development of a durable data driven-solution with long-term success is rather future-oriented.

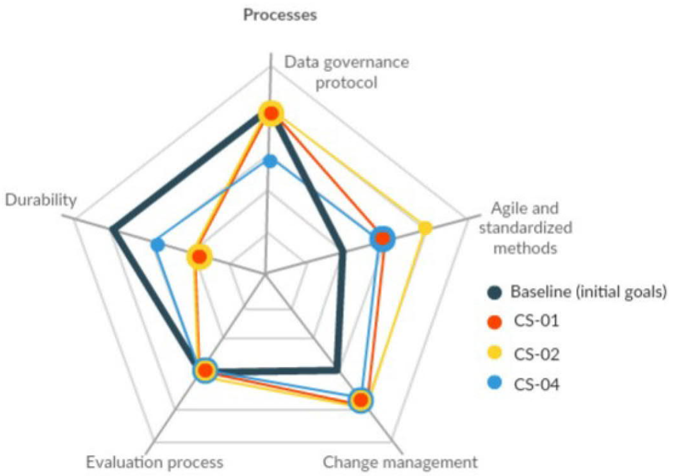


Figure 29 Case study results: Processes category

6.2.5 Data category

Virtually all factors in the Data category are considered as CSFs (Figure 30). Most factors need to be further developed in order to reach the initial goal. Respondents' opinions are aligned about the current status of the factors. All data factors except *data presentation quality* score lower in their current deployment compared to the baseline. However, the differences are not alarmingly high and can be overcome. This means that most factors are already in place to a 'large extent', but not to a 'very large extent'. *Data transparency* is the only factor that shows a larger gap. A respondent explains the complexity of transparency and the current efforts to develop an adequate interpretability of the CPM.

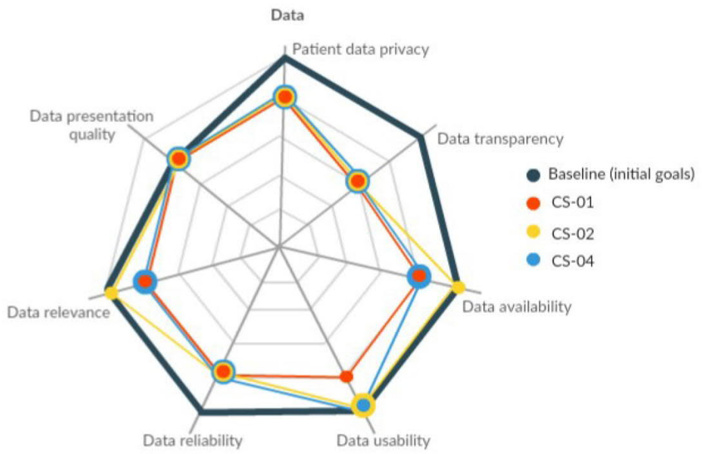


Figure 30 Case study results: Data category

6.2.6 *Practical advice*

On a practical note, an advice is now given to the case study team on the successful deployment of their violence risk model.

On the one hand, it is recommended that the team examines the factors that are underperforming compared to the initial goals. These are the factors: *planning and scoping, organizational alignment, multidisciplinary teams, employee buy-in, patient involvement, doctor-patient relationship, collaborative communication, interoperability and integration, user-friendly tool, durability, patient data privacy, data transparency*, and the *data quality* factors. Possibly, more resources need to be allocated to the further development of these factors. Activities can be directed towards the enhancement of these factors to ensure they will be successful in the future.

On the other hand, it is recommended that the team examines the factors that are overperforming compared to the initial goals. These factors are*: clear strategy, strong clinical leadership, agile and standardized methods*, and *change management*. It is possible these factors receive unnecessary attention that could be diverted to more critical success factors. It is also possible that these factors are developed automatically or unconsciously, without requiring additional resources. In that case, it is good to know that the project is outperforming on these factors, which perhaps opens new opportunities to capitalize on these factors. A last option is that the factors are actually adequately in place, but that the initial objectives do not match the current needs. In that case, it is valuable to recognize that the project goals have diverted from the initial targets.

Moreover, an extra weight can be given to the various factors by taking into account the importance levels. The most important CSFs that received unanimous agreement are: *multidisciplinary teams; employee buy-in, user-friendly tool, patient data privacy*, and *data transparency*. All these factors are underperforming, which makes it worthwhile to devote extra attention to these factors in the near future. For example, the team can try to trace back why these factors are not yet adequately in place, and what measures can be taken to change that. It is recommended that these factors are handled with priority.

Lastly, due to time constraints, the case study is performed with a retrospective analysis on the BU phase. For future projects, the importance of the BU phase should be emphasized. The objectives and project plan should directly link to the deployment objectives. This new link between the first and last phase of the CRISP-DM is key to successful deployment of CPMs.

7 DISCUSSION

The last chapter sums up the conclusions of this research. An answer to the problem statement is provided, as well as the practical and theoretical contribution. A list of recommendations sets out the determinants for successful deployment of CPMs. Lastly, the limitations and directions for future research are formulated.

7.1 Conclusions

The goal of this research is to give direction to (academic) hospitals on the factors they should bear in mind when planning the deployment of a clinical prediction model. The outcomes of this research are directed towards clinicians and hospitals in a practical sense, but also to the academic community as further research is required.

The literature review has identified deployment factors from relevant prior studies. The interviews have improved this initial model into the final artifact. The factors *multidisciplinary teams, employee buy-in, user-friendly tool, patient data privacy,* and *data transparency* received remarkably high levels of importance by the majority.

Consensus prevails on the importance to deployment success on the factors: *stakeholder engagement, strong clinical leadership, education and knowledge sharing, doctor-patient relationship, interoperability and integration, data collection and access, flexibility and scalability of infrastructure, data governance protocol, evaluation process, data availability, data usability,* and *data reliability*.

A consensus was reached on the intermediate importance of the factors: *top management support, organizational alignment,* and *data presentation quality.*

The majority agreed that the factor *technology development awareness* and *predefined roles and responsibilities* is of low importance to success. Sometimes the opinions differed substantially, hence no consensus was reached on the factors: *clear strategy, planning and scoping, patient involvement, collaborative communication, agile and standardized methods, change management, durability,* and *data relevance.* Table 14 provides an overview of the level of importance to success of all deployment factors according to the interviewees.

The factors that were identified as specific to the healthcare industry in the literature review (chapter 4) do not follow any particular pattern in terms of importance to successful deployment. The specific factors are spread out over different importance levels.

The practical functionality of the CRISP-DM Deployment Extension for CPMs is tested through a gap analysis in the case study. A practical advice is provided to UMCU. The effectiveness of the approach requires further research.

Table 14 Level of importance to success of deployment factor

Level of importance				
Extremely high	**High**	**Intermediate**	**Low**	**No consensus**
▸ Multidisciplinary teams ▸ Employee buy-in ▸ User-friendly tool ▸ Patient data privacy* ▸ Data transparency	▸ Stakeholder engagement ▸ Strong clinical leadership* ▸ Education and knowledge sharing ▸ Doctor-patient relationship* ▸ Interoperability and integration ▸ Data collection and access ▸ Flexibility and scalability of infrastructure ▸ Data governance protocol ▸ Evaluation process ▸ Data availability ▸ Data usability ▸ Data reliability	▸ Top management support ▸ Organizational alignment ▸ Data presentation quality	▸ Technology development awareness* ▸ Predefined roles and responsibilities	▸ Clear strategy ▸ Planning and scoping ▸ Patient involvement* ▸ Collaborative communication ▸ Agile and standardized methods ▸ Change management ▸ Durability ▸ Data relevance

Factors with an asterix (*) are identified as specific to the healthcare sector in the literature review

Moreover, new insights are gathered next to the deployment factors. An important characteristic that differentiates the healthcare industry from others is the interplay between rationality and sentiment. Moreover, the organizational structure inside hospitals is complex. Various stakeholders each have their own agenda, there are financial challenges, governmental legislations, and the demand of accountability of health innovations. This hampers the speed of adoption in a way that is different from other industries

The GDPR changed the regulatory goals for researchers and health organizations. Especially in a large scale clinical setting, the consideration of data protection issues must be on the agenda already at the early stage.

Data context is essential in the healthcare industry. In medicine, each specialty has its own vocabulary, with different meanings in different contexts. Even a missing value can have meaning in a certain context. Due to the low adoption of clinical data standards the amount of usable data decreases. Therefore, data stewardship should be an integral part of clinical research efforts. The growth of data initiatives also calls for better data governance. Automated data governance is a novel technique that helps organizations ensure all departments use data in a consistent manner. Other new techniques, such as transfer learning, make it easier to solve data reliability issues. Transfer learning utilizes the knowledge of a machine learning model that has already been trained and applied to a different problem.

Innovative projects such as CPMs are generally considered as disruptive, and thus require a non-traditional approach. The bimodal IT of Gartner is an example of how to tackle such projects. Organizations should pay specific attention to the last step of a data science project, to ensure data entrepreneurship. This action perspective helps to bring the prediction model into practice.

Lastly, the different perspectives from stakeholders clearly come forward in this research. Especially the disunity between data scientists and medical experts is a challenge that must be addressed when deploying CPMs.

7.1.1 Answer to the problem statement: deployment strategy

"How to design a successful deployment strategy for clinical prediction models in hospitals?"

This research has designed an artifact called the CRISP-DM Deployment Extension for CPMs. In combination with the table on importance levels for each deployment factor (Table 14), a deployment strategy can be formulated.

Hospitals that want to engage in CPMs can follow a strategy similar to the one demonstrated in the case study. At the start of the project, in the BU phase, the project objectives should be determined by following the various deployment factors. When the CPM is going into the deployment phase, the various deployment factors should be measured again through the opinions of various stakeholders. This way, a gap analysis is able to compare the desired status with the current status, and the project can be more efficiently and effectively steered towards success. Moreover, the importance level of the factors plays a role in weighing the significance and determining resource allocation.

In conclusion, a combination of the CRISP-DM Deployment Extension for CPMs and the importance levels of deployment factors provide a hospital the necessary determinants for a successful deployment strategy for clinical prediction models.

7.1.2 Practical contribution

This research provides a direct practical contribution through the answer of the problem statement. Hospitals are presented with a means to tackle CPM deployment through the CRISP-DM Deployment Extension for CPMs and the various importance levels of the factors. Following the deployment strategy, determinants for successful CPM deployment come forward. As illustrated in the case study, a gap analysis compares the baseline objectives with the current status. Additionally, new insights offer a look into the minds of an array of CPM experts. These insights can be taken into account alongside the deployment strategy.

By including visions and experiences from professionals in the medical field and data science field, this thesis connects two worlds that are simultaneously different in their approaches, but similar in their ambitions. Both groups look at the challenges and opportunities of clinical prediction models through a different lens. Nonetheless, the common end goal is to improve the quality of care, and that common aspiration is at the heart of successful deployment of clinical prediction models.

7.1.3 Theoretical contribution

In terms of theoretical contribution, this thesis has covered an academic area that is scarcely researched. Next to a review of the existing literature, this study contributes by providing a new conceptual model that can be further researched. In fact, each of the identified factors in itself can be the basis for a new topic in future research.

7.2 Recommendations

Based on the findings of this research, a set of recommendations for (academic) hospitals is established. These are the determinants (in no particular order) for successful deployment of clinical prediction models:

1. Realize that everything starts at the business understanding phase. The choices and outcomes of the first step in the CRISP-DM model affect all other phases. Since the output of the BU phase produces objectives and a project plan, it is inevitably linked to deployment. This new link within CRISP-DM is a crucial one when aiming for successful deployment of CPMs.
2. Determine what "success" means. When is a deployment successful? What is a CSF? These questions need to be answered at the very start of the project, in the business understanding phase. Traditional project triangles are nowadays extended beyond simple budget, time, and scope constraints.
3. Use the CRISP-DM Deployment Extension for CPMs. One way to tackle the formulation of success, is by following the various factors in this model. Make sure that the project team considers all deployment factors and overarching factors when working on a CPM project.
4. Consider the factors' different levels of importance to success. Whereas some factors are considered as highly important to success by an expert panel, others are considered as less important. Take this into account when developing the objectives, in order to allocate resources appropriately and effectively manage expectations of a project.
5. Follow a deployment strategy. Determine project objectives of the deployment factors at the BU phase, and compare them during the deployment phase through a gap analysis. Comparison of where a project currently is and where it should go allows for more efficient and effective steering towards success.
6. Take into account other challenges next to the deployment factors. For example, healthcare industry specificities, the need for data context and data standards, data stewardship, and automated data governance.
7. Do not underestimate the overarching effect that legal regulations (such as the GDPR), information security, and ethical considerations have on the successful deployment of CPMs.
8. Have an action perspective. It is easy to get distracted by all the barriers surrounding deployment of CPMs. Although it is necessary to solve these issues, they should not become the ultimate goal. In the end, the objective is to improve healthcare for patients through clinical prediction models that are deployed in our practical reality.

7.3 Limitations

In this section, the limitations of this thesis research are acknowledged. The problem statement and methodology were critically chosen and linked to relevant literature. However, whilst discovering new knowledge and conflating existing knowledge, various characteristics of the study design have impacted the interpretation of the findings.

Firstly, the recognized literature gap on deployment challenges for predictive models in the healthcare industry implies a lack of prior research on the exact topic. Prior studies focus on parts of the problem statement, which allowed for laying a foundation for understanding the research areas in their individual forms. However, there is little research available that combines prediction models with clinical settings and critical success factors for deployment. This made it impossible to compare the results to prior studies with similar or different methodologies and results.

Secondly, access to people and organizations was achieved through web searches and open invitations. Since not all organizations that work on the deployment of CPMs publish their efforts online, it was not possible to approach all relevant organizations. The pool of interviewees is therefore limited by those who were traceable online and who agreed to a meeting. This limited access created an imperfect group of respondents, but did not hamper the continuity of the study. However, it should be emphasized that the conclusions and recommendations of this study are based on the opinions of this imperfect group of interviewees, and can therefore not be considered as the absolute truth. The same holds for the group of employees that are part of the case study. More specific to the case study, a limitation is that the number of hospitals that are experimenting with CPMs is scarce. Therefore, it was not possible to find an organization that is already in the deployment phase. The gap analysis is therefore an interim control in this research. Moreover, due to the timespan of CPM projects, it was not possible to conduct the baseline interview at the start of the project. Although the respondent was able to think back to this period in time, there is some bias in retrospective answers. These limitations are important to acknowledge, as they have a direct impact on the quality of the case study.

Thirdly, the qualitative nature of the study generated some limitations. Respondent bias stems from interviewees that answer to questions based on personal notion of what is socially acceptable or desired, rather than their honest opinion. In this research that questions the level of importance, interviewees might tend to regard everything as important, as a socially acceptable answer. Moreover, self-reported data may contain sources of bias such as selective memory, telescoping (i.e. temporal displacement of events), attribution, and exaggeration. Researcher bias stems from the behavior of the interviewer. Although this bias was reduced by remaining as neutral as possible during the interviews, the personal characteristics of the researcher always play a role. The varied perspectives from interviewees are analyzed based on the limited understanding of the researcher, and different conclusions might be derived by a different researcher. Another limitation of the qualitative interviews is that it is not possible to acquire exact result verification, as the provided data is not quantifiable and cannot be checked. Similarly, it would be a challenge to repeat the research, since it is inseparably intertwined with the interviewer and the interviewees. This complicates confirmation or contradiction of the original research.

Fourthly, there are some constraints on the generalizability of the results. This study focuses solely on the Dutch healthcare industry, and can hence not be automatically applied to other countries. The same applies for the type of healthcare organization; this study focuses only on (academic) hospitals. Due to the labor intensive approach of qualitative data analysis, the scope of the study is limited to one case study. The validation of the artifact is therefore based on a single case study, which also hinders the generalizability to wider populations.

7.4 Future research

The limitations of this study are an opportunity for the suggestion of future research. The application of a more robust methodology with a set of respondents that is more representative of all experts in the research area of a specific country might address the problem statement more effectively in a future study. Moreover, the study can be expanded by following a multiple case study that allows cross-case analysis. The organizations should be questioned in the initial planning phases as well as in the deployment phase, in order to guarantee objective comparison between deployment factors. Future case studies can include a larger amount of answered questionnaires, to increase the possible Likert-scale calculations and statistical significance. Furthermore, future research can aim to determine a sequence of which factors should receive attention at which point in time. This way, the practical contribution for hospitals will become even more concrete. When more literature is available on the specific topic, the literature review should be revised to check if there are any factors that have not yet been included in the conceptual model. All in all, this thesis research has provided a better focus on the future directions of the unanswered questions of this research topic.

7.4.1 From predictive to prescriptive analytics

According to Gartner (2016), the step after predictive analytics is prescriptive analytics. Whereas predictive analytics answers the question of what will happen in the future, prescriptive analytics takes it even one step further. In this field of data mining, the underlying question is: ‘what should I do to make that happen?’ (Delen & Demirkan, 2013). This means that prescriptive analytics include the actions required to optimize an outcome, rather than just the outcome. It is not just about seeing the future, but also about shaping the future. With humans as the core of the objective that requires optimization, the application of prescriptive analytics in healthcare is complex (Sappelli et al., 2017). The range of options and possible actions are much more extensive and less predictable than a physical system. Moreover, the problems of heterogeneous data and patient privacy concerns are major slowdowns to prescriptive tools, even to a higher extent than predictive tools. It is expected that implementation and continuation barriers of such future models will be similar to the ones mentioned in this thesis. However, the level of importance and severities for success might shift due to the added complexity. When prescriptive tools make their entree in the medical world, further research into the deployment factors is required to find out to what extent there is an overlap with the outcomes of this thesis.

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APPENDICES

Appendix A: Literature review in table format

		Deployment factor	Variable name	Generic or specific	Description	Literature
1 Management	1.1	Top management support	*M_TMS*	G	Consistent support and sponsorship of top-level executives for the deployment	Akhavan & Salehi, 2013; Gao et al. 2015; Hawking & Sellitto, 2010; Popovič et al., 2018; Saltz & Shamshurin, 2016; Wamba et al., 2015; Yeoh & Koronios, 2010
	1.2	Planning and scoping	*M_PS*	G	Pre-defined goals, deadlines, scope, and budget	Akhavan & Salehi, 2013; Attaran & Attaran, 2019; Cresswell et al., 2013; Farzaneh et al., 2018; Gao et al., 2015; Hawking & Sellitto, 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Yeoh & Koronios, 2010
	1.3	Stakeholder engagement	*M_SE*	G	Effective involvement and clear communication by the management level with all stakeholders	Greenwood, 2007; Juciute, 2009; Saltz & Shamshurin, 2016; Wamba et al., 2015; Yeoh & Koronios, 2010; Malfait et al, 2017
	1.4	Strong clinical leadership	*M_SL*	S	A leader who ensures long-term commitment, vision, motivation, and stability by using their clinical experience and knowledge to ensure patient well-being is at the center	Bezemer et al., 2019; Buntin et al., 2011; Farzaneh et al., 2018; Goa et al, 2015; Ingebrigtsen et al., 2014; Jonas et al., 2010; Øvretveit et al., 2007
	1.5	Aligned vision and strategy	*M_AVS*	G	Clear link between business objectives, vision and strategies	Akhavan & Salehi, 2013; Altuwaijri, 2012; Gao et al., 2015; Saltz & Shamshurin, 2016; Williams & Williams, 2010; Yeoh & Koronios, 2010
2 People	2.1	Roles and responsibilities	*Pe_RR*	G	The specific tasks or duties that members are expected to complete as a function of their roles	Amarasingham et al., 2014; Marinos, 2004; Saltz & Shamshurin, 2016

	2.2	Multidisciplinary self-steering teams	*Pe_MST*	G	A mix of team members with analytical, statistical, and technical skills, clinical experts, and a business champion	Bezemer et al., 2019; Farzaneh et al., 2018; Gao et al., 2015; Hawking & Sellitto, 2010; Saltz & Shamshurin, 2016; Yeoh & Koronios, 2010
	2.3	Employee buy-in	*Pe_EB*	G	Engagement and willingness of employees; positive attitude of employees	Akhavan & Salehi, 2013; Bezemer et al., 2019; Buntin et al., 2011; Litwin, 2011; Farzaneh et al., 2018
	2.4	Education and knowledge sharing	*Pe_EKS*	G	Training with the tool; creating a data mindset; knowledge expansion	Cresswell et al., 2013; Krumholz, 2014; Lee & Hong, 2014; Saltz & Shamshurin, 2016; Wang et al., 2015
	2.5	Technology development awareness	*Pe_TDA*	S	Knowing what is happening in the field of (medical) BI&A	Akhavan & Salehi, 2013; Farzaneh et al., 2018; Gao et al., 2015
	2.6	Documentation skills	*Pe_DS*	G	Creation and maintenance of proper documentation regarding deployment of the tool	Gao et al., 2015
	2.7	Patient consent	*Pe_PC*	S	Approval of patient; positive attitude of patient	Davis, 2012; Kaye et al., 2015; Roski et al., (2014); Spencer et al. (2016); Williams et al., 2015
	2.8	Doctor-patient relationship	*Pe_DPR*	S	Shared doctor-patient decision-making; personal engagements; trust	Amarasingham et al., 2014; Schoenhagen & Mehta, 2016
	2.9	Collaborative communication	*Pe_CC*	G	Frequent, valuable communication between and across teams	Cresswell et al., 2013; Farzaneh et al., 2018; Saltz & Shamshurin, 2016
3 Technology	3.1	Interoperability and Integration	*T_II*	G	Data sharing between platforms; system compatibility	Amarasingham et al., 2014; Gao et al., 2015; Marcheschi, 2017; Popovič et al., 2018; Yeoh & Koronios, 2010
	3.2	Documentation collection and access	*T_DCA*	G	Enabling access to various data sources to collect the relevant documentation	Demchenko et al., 2013; Goa et al., 2015; Saltz & Shamshurin, 2016
	3.3	Flexibility and scalability of infrastructure	*T_FSI*	G	The capability of the system to respond quickly to external changes and growth	Cresswell et al., 2013; Gao et al., 2015; Olszak & Ziemba, 2007; Yeoh & Koronios, 2010

4 Pro-cesses	4.1	Data govern-ance protocol	*Pr_DGP*	G	Control data flows (master data management, data lifecy-cle management, data privacy and security); ensure regu-latory and legal compliance	Khatri & Brown, Saltz & Shamshurin, 2016; Philips-Wren, 2015; Wang et al., 2018
	4.2	Iterative, stand-ardized methodology	*Pr_ISM*	G	Incremental delivery of short, measurable steps in the de-ployment process	Farzaneh et al., 2018; Gao et al., 2015; Yeoh et al., 2010
	4.3	Change man-agement	*Pr_CM*	G	Processes to prepare, equip, and support individuals to successfully adopt change	Cresswell et al., 2013; Finlay, 2014; Gao et al., 2015; Saltz & Shamshurin, 2016; Yeoh & Koronios, 2010
	4.4	Evaluation	*Pr_E*	G	Measuring the level of achievement in terms operational benchmarks; value measurement; initial goal alignment	Akhavan & Salehi, 2013; Gao et al., 2015; Saeed & Ah-med, 2018; Saltz & Shamshurin, 2016
	4.5	Sustainability of the tool	*Pr_ST*	G	Long-term success; support by stakeholders; data-driven culture	Wang et al., 2018
5 Data	5.1	Patient data privacy	*D_PDP*	S	Compliance with privacy regulations; healthcare data se-curity solutions	Abouelmehdi et al., 2018; Cohen et al., 2014
	5.2	Data transparency	*D_DT*	G	Ability to take a look into the prediction model	Amarasingham et al., 2014; De Laat, 2018
	5.3	Data availability	*D_DA*	G	Easy accessibility of data in a timely manner (Part of data quality)	Akhavan & Salehi, 2013; Cai & Zhu, 2015; Farzaneh et al., 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Wamba et al., 2015
	5.4	Data usability	*D_DU*	G	Data credibility; data coming from reliable sources; data audits (Part of data quality)	Akhavan & Salehi, 2013; Cai & Zhu, 2015; Farzaneh et al., 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Wamba et al., 2015
	5.5	Data reliability	*D_DRy*	G	Accuracy, consistency integrity, and completeness of data (Part of data quality)	Akhavan & Salehi, 2013; Cai & Zhu, 2015; Farzaneh et al., 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Wamba et al., 2015

	5.6	Data relevance	*D_DRe*	G	Collected data clarifies the initial problem understanding and goal setting; fitness of data (Part of data quality)	Akhavan & Salehi, 2013; Cai & Zhu, 2015; Farzaneh et al., 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Wamba et al., 2015
	5.7	Data presentation quality	*D_DPQ*	G	Readability of data; content, format, description, classification is comprehensible (Part of data quality)	Akhavan & Salehi, 2013; Cai & Zhu, 2015; Farzaneh et al., 2018; Nemati & Barko, 2003; Saltz & Shamshurin, 2016; Wamba et al., 2015

Appendix B: Requirements collection interview questions

Project: “How to design a successful deployment strategy for clinical prediction models”

Date:...
Time:..
Location:...................................
Codified participant:................
Interviewer: Stefanie Creemers

Dear participant,

Thank you for taking the time for participating in this interview. This interview is part of the thesis research for the International Master in Management in IT (IMMIT), a joint program of IAE Aix-Marseille Université, University of Turku, and Tilburg University. The research is conducted in collaboration with BDO Nederland.

The aim of this interview is to discuss the implementation and continuation challenges of clinical prediction models in healthcare. Predictive analytics use extremely large datasets and computational algorithms to discover patterns. Based on data from the past, these patterns can predict with reasonable accuracy what will happen in the future. In the case of healthcare, the data coming from electronic health records provide a great source for predictive modeling. For example, algorithms can predict the chance of developing genetic colorectal cancer (Drost et al., 2018). Other health sources can also serve as an input to predictive models; for example for predicting the progression of dementia based on MRI scans (Korolev et al., 2016).
Academic literature agrees that these opportunities have a high promise and can improve patient care. However, it seems that we are stuck at the promise. Research on actual implementation is scarce. Therefore, this thesis aims to design a deployment strategy for successful predictive tools in healthcare. In order to design that strategy, various deployment challenges are deducted from existing literature and tested through these interviews. Based on opinions and experiences from experts in the areas of health analytics, predictive modeling and data-driven diagnosis and prognosis, the deployment challenges are rated based on importance for success and relative severities.
Ultimately, the outcomes of this research can provide a direction to healthcare organizations by clarifying which challenges deserve more attention and against which challenges they must hedge.

This interview is conducted for a requirements collection. The goal is to validate and adjust the identified deployment challenges based on a practical point of view. The interview will consist of two phases. First, an open discussion is started to hear the deployment challenges recognized in practice by the interviewee. Second, semi-structured interview questions will assess the findings of the theory development.

All information will be handled confidentially and will be processed anonymously in the thesis. The research is not connected to patient files, hence patient privacy is not an issue. If desired, outcomes of the study can be shared with you or your organization.

If you agree, the interview will be audio-recorded for transcription purposes.

Introduction
1. What is your official function? How would you describe your profession?
2. In what way are you professionally connected to big data analytics or predictive analytics?
3. For how long have you been professionally connected to big data analytics or predictive analytics?

PHASE 1: Open discussion

4. Tell me about your engagement in the development or implementation of predictive tools in your hospital.
5. Are these predictive tools also focused on medical diagnosis or prognosis?
6. Tell me about some of the challenges you have faced or expect to face with regards to the deployment of predictive tools.

PHASE 2: Semi-structured questions

7. I would like to present to you 29 deployment challenges for clinical prediction models. For each of these challenges I would like to know your opinion on their importance for successful implementation.
If you do not have actual experience with clinical prediction models, please think of the hypothetical situation in case it would be implemented in your hospital.
Please indicate for every factor whether they are part of the deployment challenges according to you and provide some explanation.

***** Appendix A: Literature review is handed out to interviewee *****

Guiding questions (in case not answered clearly yet)

8. Which challenges are, in your opinion, most important for hospitals to keep in mind? Why?
9. Which challenges are, in your opinion, least important for hospitals to keep in mind? Why?
10. Are there any factors that can be removed from this list? Why?
11. What are your thoughts on the five categories? Do some factors belong in other categories?
12. Are there any factors that are missing on this list? Why should they be added?
13. Are there any factors that require a different description? More extensive, less extensive?
14. What are your thoughts on the categorization of ‘generic vs specific’? Are there any changes required?

Wrap-up

15. Is there anything you would like to add? Are there any tips for my research?
16. Do you want the outcomes of the study to be shared when they are published? If yes, on which email address?

Thank you again for your participation in this interview. If desired, the interview report can be shared before it is used for further analysis. Once accepted, the anonymized report will be included in the multiple case study and cross-case analysis. The final thesis will be published by the three universities, presented for BDO Nederland, and can be shared with your organization.

Best regards,
Stefanie Creemers

Drost, M., Tiersma, Y., Thompson, B. A., Frederiksen, J. H., Keijzers, G., Glubb, D., ... & Boucher, K. M. (2018). A functional assay–based procedure to classify mismatch repair gene variants in Lynch syndrome. Genetics in Medicine, 1.

Korolev, I. O., Symonds, L. L., Bozoki, A. C., & Alzheimer's Disease Neuroimaging Initiative. (2016). Predicting progression from mild cognitive impairment to Alzheimer's dementia using clinical, MRI, and plasma biomarkers via probabilistic pattern classification. PloS one, 11(2), e0138866.

Appendix C: Artifact in table format after requirement collection interviews

Level 1	*Level 2*	*Level 3*
Category	**Factor**	**Description**
Manage-ment	1.1. Clear strategy	A clear sense of direction and commitment to the action plans that achieve the strategic goals
	1.2. Top management support	Consistent support and sponsorship of the board of directors for the deployment
	1.3. Planning and scoping	Predefined goals, deadlines, scope, and budget
	1.4. Stakeholder engagement	Effective involvement and clear communication by the management level with all stakeholders
	1.5. Strong clinical leadership	A leader who ensures long-term commitment, vision, motivation, and stability by using their clinical experience and knowledge to ensure patient well-being is at the center
	1.6. Organizational alignment	The alignment of all organizational aspects (capabilities, resources, systems, culture, etc.) with the realization of the strategy
People	2.1. Predefined roles and responsibilities	The predefined, specific tasks or duties that members are expected to complete as a function of their roles
	2.2. Multidisciplinary teams	A mix of team members with analytical, statistical, and technical skills, clinical experts, and a business champion
	2.3. Employee buy-in	Engagement and willingness of employees; positive attitude of employees
	2.4. Education and knowledge sharing	Training with the tool; creating a data mindset; creating a common language; knowledge expansion; digital skills of the users
	2.5. Technology development awareness	Employees knowing what is happening in the field of (medical) BI&A
	2.6. Patient involvement	Positive attitude of patient; active involvement of patient
	2.7. Doctor-patient relationship	Trust; shared doctor-patient decision-making; personal engagements
	2.8. Collaborative communication	Frequent, valuable communication between and across teams; creating a common language

Technology	3.1. Interoperability and integration	Data sharing between platforms; system compatibility; data fragmentation
	3.2. Data collection and access	Enabling access to various data sources to collect the relevant documentation
	3.3. Flexibility and scalability of infrastructure	The capability of the system to respond quickly to external changes and growth
	3.4. User-friendly tool	Easy retrieval of accurate, reliable solutions; simple and intuitive displays; easy navigation
Processes	4.1. Data governance protocol	Control data flows (master data management, data lifecycle management, data privacy and security); ensure regulatory and legal compliance
	4.2. Agile and standardized methods	Incremental delivery of short, measurable steps in the deployment process
	4.3. Change management	Processes to prepare, equip, and support individuals to successfully adopt change
	4.4. Evaluation process	Measuring the level of achievement in terms operational benchmarks; documentation by users; value measurement; initial goal alignment
	4.5. Durability	Long-term success; continuous high performance; support and effort by stakeholders; data-driven culture
Data	5.1. Patient data privacy	Compliance with privacy regulations; healthcare data security solutions
	5.2. Data transparency	Ability to take a look into the ‘black box’ prediction model
	5.3. Data availability	Easy accessibility of data in a timely manner. (Part of data quality)
	5.4. Data usability	Data credibility; data coming from reliable sources; data audits. (Part of data quality)
	5.5. Data reliability	Accuracy, consistency integrity, and completeness of data. (Part of data quality)
	5.6. Data relevance	Collected data clarifies the initial problem understanding and goal setting; fitness of data. (Part of data quality)
	5.7. Data presentation quality	Readability of data; content, format, description, classification is comprehensible. (Part of data quality)