IMPACT

Intelligence based iMprovement of Personalized medicine And Clinical workflow supporT

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Clinical Business Information Systems

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Deliverable review procedure:

- **2 weeks before due date**: deliverable owner sends deliverable –approved by WP leader– to Project Manager
- **Upfront** PM assigns a co-reviewer from the PMT group to cross check the deliverable
- **1 week before due date**: co-reviewer provides input to deliverable owner
- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer

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1 Executive summary

A clinical business information system (CBIS) combines both medical and business information to address broader topics such as efficiency or quality of care which are influenced by many underlying and often interrelated factors. The healthcare industry is an extremely complicated environment. With recent advances in analytics technology such as cloud computing and machine learning becoming more widely available, and growing cost and quality challenges in the healthcare industry, CBIS are on the rise. The Healthcare analytics market is projected to grow to 70+ Billion dollars until 2027.

Several opportunities and challenges face the CBIS market. In terms of opportunities there are a number of technological advancements that have become within reach of hospitals in recent years including cloud storage, data warehouses and data lakes, intuitive business intelligence (BI) tools, advances in interoperability between systems, artificial intelligence tools such as ML and the increase of Internet of Things data. None the less the industry is still plagued by a number of hard-to-solve challenges including low data quality, a high number of legacy systems which still pose interoperability challenges, a lack of semantic and technological standardization, budget limitations in the midst of an overheated employment market and privacy and data security challenges. As a consequence there is no one size fits all solution for CBIS and there is expected to continue to be a market for different types of clinical BI solutions including large consulting firms (e.g. E&Y; KPMG), medical device vendors (e.g. Philips, Medtronic), information technology companies (Google, Microsoft) but also smaller BI consultancy companies and companies offering specialized tools for specific workflows or departments.

Within the IMPACT project, two partners have created solutions that contributed to the spectrum of available solutions available on the CBIS market. Inovia, together with other partners has created a Medical Data Lake system solution which is a microservice-based solution that aims to store magnetic resonance imaging (MRI) images and provides the intelligence to segment MRI images and ML to retrain the module used for image segmentation. This addresses the need to make data lake technology available to medical imaging research. NewCompliance, together with Philips and other partners has created a data warehouse and analytics tool for the Catherization lab department, responding to a need for improved Cath lab efficiency which is currently not met by generic CBIS tools.

2 Glossary

AI	Artificial intelligence
API	Application programing interface
BI	Business intelligence
CBI	Clinical business intelligence
CBIS	Clinical business information system
CIS	Clinical information system
CPOE	Computerized physician order entry
EHR	Electronic health record
ERP	Enterprise resource system
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
HL7	Health Level 7
HR	Human resource
IoT	Internet of Things
IT	Information technology
ML	Machine learning
MDL	Medical data lake
MRI	Magnetic resonance imaging
OR	Operating room
PHI	Personal health information
PII	Personal identifiable information
VBHC	Value-Based Healthcare
WHO	World Health Organization

3 Introduction – What are clinical business information systems?

Business intelligence (BI) consists of activities, technologies and strategies that focus on the analysis of business information (Negash & Gray, 2008). Within the medical field BI is applied as clinical business intelligence (CBI), which includes software that allows for aggregation, analysis and utilization of data to support decision-making specifically aimed at issues within the healthcare environment (Ashrafi et al., 2014). The information used is retrieved from different sources within the hospital's clinical information systems (CIS) e.g., the electronic health record (EHR), the radiology system and computerized physician order entry (CPOE) combined with data from other operational systems such as the enterprise resource system (ERP), personnel planning systems, building management systems etc. In short, a clinical business information system (CBIS) combines both medical and business information to address broader topics such as efficiency or quality of care which are influenced by many underlying and often interrelated factors (Khedr et al., 2017; Mettler & Vimarlund, 2009).

The healthcare industry is an extremely complicated environment. With recent advances in analytics technology such as cloud computing and machine learning (ML) becoming more widely available, and growing cost and quality challenges in the healthcare industry, CBIS are on the rise (Mehta & Pandit, 2018). Improvement programs such as Value-Based Healthcare (VBHC) rely heavily on data analytics to identify opportunities for improvement and measure outcomes (Foshay & Kuziemsky, 2014). Within CBIS different environments with corresponding levels of attention can be distinguished (figure 1) which will be discussed in greater detail in chapter 4.1:

- **International healthcare:** data related to international health affairs e.g., relevant to the World Health Organization (WHO).
- **National and regional healthcare systems:** data related to national or regional health affairs, relevant to governmental bodies and health insurers.
- **Healthcare organizations:** data related to the functioning of a hospital, clinic or group of such organizations, used to for example track hospital-wide costs and quality.
- **Hospital departments:** data related to the functioning of specific departments within the hospital or clinic, used to for example monitor efficiency of resource planning. Since the CBIS developed as part of this project is aimed at specific hospital departments, this level will be a main focus of this document.
- **Individuals:** data related to the functioning of individual clinicians to, for example, analyze individual compliance towards patient safety protocols.

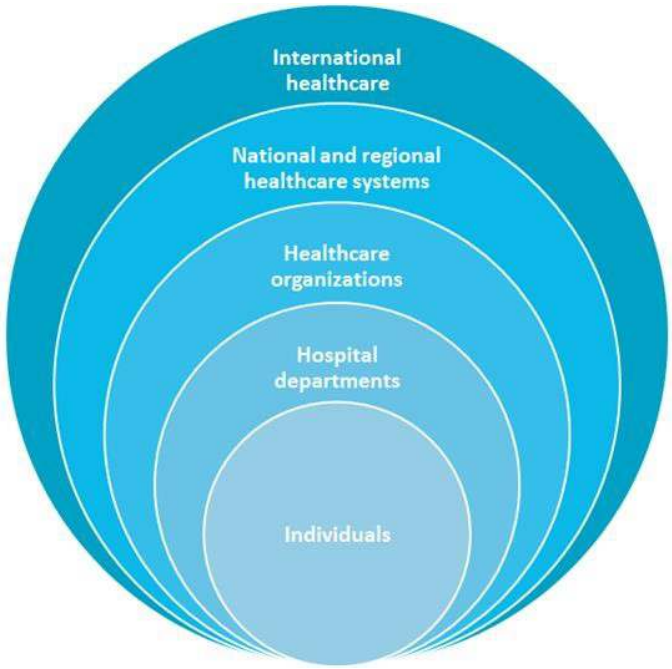

Figure 1: focus levels of CBIS.

Together, these different layers form a complex adaptive system including numerous underlying factors with dynamic relations within and in between (Khan et al., 2018; Kuziemsky, 2016). Setting benchmarks, or in other words comparison-based standards, can help to identify metrics of attention and formulate corresponding objectives. In this way, learning is possible at each of the mentioned levels by comparing insights, identifying opportunities for improvement, and evaluating outcomes (Ettorchi-Tardy et al., 2012). If performed correctly, organizational entities can be driven towards continuous improvement (Hovlid et al., 2012). To accomplish this, there are four main types of analytics to support any learning trajectory (figure 2):

- **Descriptive analytics:** explanations of what has occurred.
- **Diagnostic analytics:** explanations of why something has occurred.
- **Predictive analytics:** predictions of what can occur in the future.
- **Prescriptive analytics:** recommendations based on what can occur in the future.

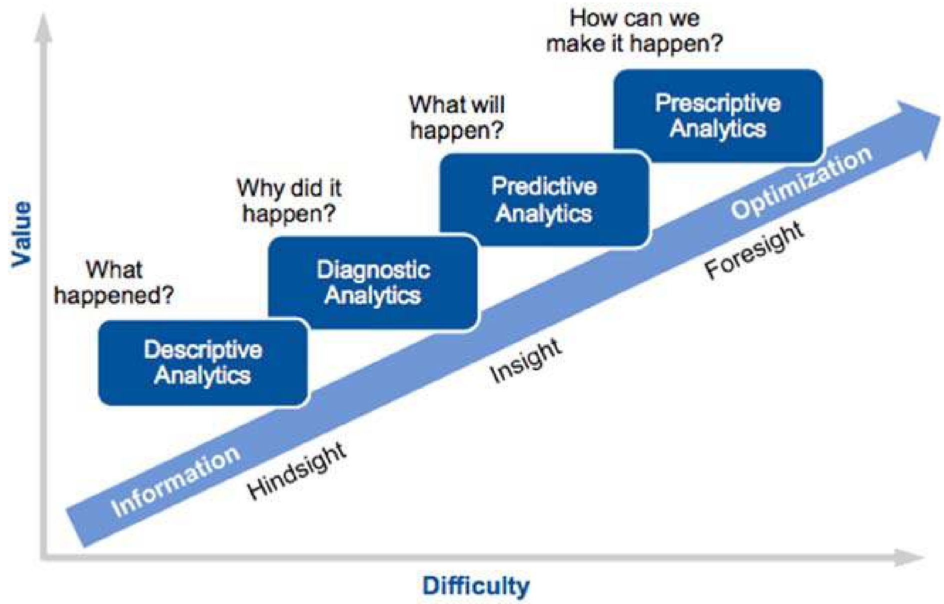

Figure 2: the four main types of analytics differentiated by value and difficulty.

Existing CBIS mainly provide descriptive and diagnostic analytics but there is a shift towards “smarter” solutions relying on more advanced techniques such as ML (Bhardwaj et al., 2017; Waring et al., 2020; Wiens & Shenoy, 2018). Chapter 5 will review examples of the applicability of each type in greater detail.
CBIS do not rely exclusively on Clinical data - 4 data types can be distinguished:

- **Medical data:** data related to patient health and care such as heart rate and antibiotics provision.
- **Logistics and financial data:** data related to operations and resources e.g., hourly costs per OR and procurement numbers by instrument.
- **Internet of Things (IoT) data:** data produced by and communicated between devices such as sensors, for example room temperature.
- **Human resource (HR) data:** data related to hospital staff, such as working hours per month or employee turnover.

The capabilities and quality of CBIS are heavily influenced by the quality of the data and the available technologies for collecting, storing and retrieving this data (Brooks et al., 2015; Foshay & Kuziemsky, 2014; Popovič et al., 2009). In chapter 5 the state of the art of these technologies will be discussed as well and advantages and challenges of various options.

Collecting and analyzing data alone, does not drive change. For this to happen, an organization needs to embed the solution in the day to day business through a workflow which includes review of data, decision-making around the data, change management, effect measurement etc. There are many methodologies out there for continuous improvement such as Kanban or Agile (figure 3) (Patri & Suresh, 2017; Stelson et al., 2017).

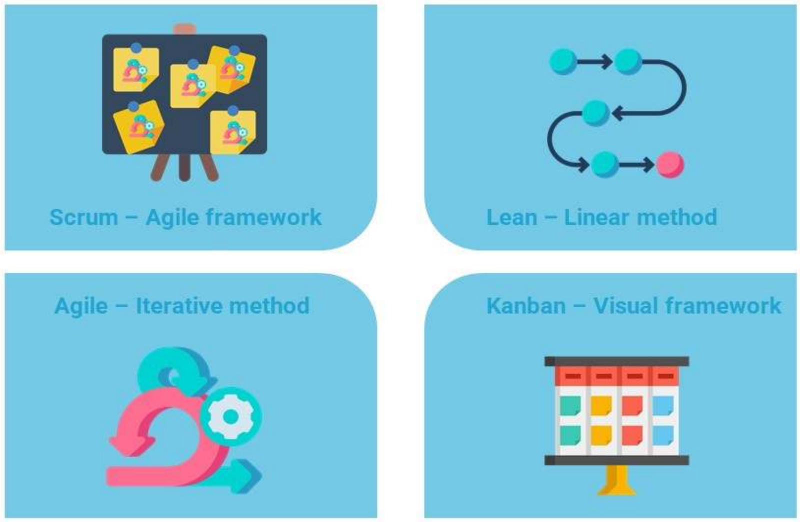

Figure 3: different methodologies to realize continuous improvement of a process, product or project.

Healthcare organizations struggle to get the most value out of their data at every level of the organization, especially since data processing and analysis is not part of their core business and workflow changes can have far reaching implications, making employees, at times, change-averse (Olaronke & Oluwaseun, 2016). The market has responded to this with different solutions. Since the CBIS developed as part of this project is aimed at the hospital or hospital department, chapter 4.2 describes different problem-solving approaches to CBIS for hospitals and clinics available in the market today together with some of their advantages and disadvantages.

For CBIS, by necessity, large amounts of privacy sensitive Personal Health Information (PHI) are collected and processed (Abouelmehdi et al., 2018; Patil & Seshadri, 2014). An overview of the challenges and available solutions of processing privacy sensitive data is provided in chapter 5.4. Moreover, chapter 6 summarizes the state of the market concerning CBIS and analyzes how the developments made in the IMPACT project fit within this picture.

4 Types of clinical business information systems

Because of the organizational complexity inherent in the Healthcare industry, the different information infrastructures and the myriad of metrics to measure, aggregate and analyze, no CBISs are completely identical to one another. However, it is possible to identify some generic levels of CBI focus, solutions, and data types. Within this chapter, these are outlined, and associated advantages, disadvantages, challenges, and opportunities are described.

4.1 Clinical business intelligence focus levels

For CBI to be of added value it is important that the CBIS aligns with the objectives of the end users. Clinical or business data on a medical topic from a regional study or source may not be representative for national or hospital-specific purposes. Therefore, it is convenient to be aware of the distinction between different layers of attention within the hierarchy of CBISs. To illustrate, a CBIS from a governmental body may contain HR-data from several organizations and institutions, whereas a hospital relies on its own HR-system, and an individual specialist only receives partial access to personal HR information. Within the following sections, systems are distinguished at five levels: 1) international; 2) national or regional; 3) hospital-wide; 4) hospital department; and 5) individual.

4.1.1 International CBI

The first and highest level of CBI may not be considered as being part of a CBIS similar to what is identified at lower levels, where information flows from fixed sources towards a structured data warehouse, but rather as a system of organizations, initiatives and institutions that collect targeted data from lower-level CBISs to support decision-making on international health affairs such as obesity, mental health and substance abuse. The strength of international clinical data is that it allows for comparison between and within countries to gain insights into international standards, differences and issues to act upon (Vest, 2012). Within this field, the inter-governmental WHO can be identified as a leader when it comes to international health. Their mission is to identify, analyze and act upon human health-related issues across borders. On an annual basis, the WHO collects data from its member states and presents the “World Health Statistics”, which is a collection of open-source data and statistics. In turn, this information can be used within CBISs at lower levels.

4.1.2 National or regional CBI

Similar to international CBI, national or regional CBI allows users to address issues related to a broader target group. Aggregate data at this level is suitable to e.g., compare national or regional quality standards of care, reduce procedural costs, or optimize treatment pathways (Hersh et al., 2015; Menachemi et al., 2018). By collaborating and exchanging data, hospitals can learn from each other to minimize variation and strive to continuously improve the healthcare system within a given region (Adler-Milstein et al., 2011; Walker, 2018). For example, waiting lists can be compared between hospitals with regards to surgical procedures and based on this a better distribution of specialistic care can be made.

Within such a collaboration of hospitals, the willingness to exchange information and therefore transparency is key to draw data-driven conclusions (Miller & Tucker, 2014). Transparency is a rather general concept but in the case of national or regional CBI it entails the willingness to share not only data, but also contextual information about processes. Data on a specific subject such as surgical waiting lists in hospitals is one piece of the puzzle but the power of an analysis into this topic will be enhanced by contextual information such as demographics of patients and details about the surgical department of each hospital. By openly engaging in conversations about challenges and successful practices, the delivery of healthcare in the region can improve (Yaraghi et al., 2015).

4.1.3 Hospital CBI

Several use cases can be identified when it comes to CBI at the hospital-level. Three of the main areas of focus relate to organizational and financial management and the tracking of quality for audit purposes. In the current era, hospitals are faced with a rising demand for care combined with an increase in treatment advances which raise the cost of individual treatments resulting in increasing pressure on financial and human resources (Tortorella et al., 2020; Tuli et al., 2019). Hospital management can utilize CBI to get a better understanding of the business processes and corresponding overall performance of the hospital as an organization. Especially for the hospital leadership, it is of great importance to be able to form the most holistic picture possible of the hospital situation at any given time, based on combined medical, financial and HR data in order to formulate realistic strategies, take informed decisions and monitor the resulting outcomes (Shen et al., 2017).

To be allowed to provide a certain type of care, hospitals must meet national standards which are determined in collaboration between healthcare providers, patient organizations, insurers and the national inspecting body. During inspections, hospitals are tested on policy and procedural practices focused on quality, expertise, patient numbers, risks, and calamities. The board of directors is expected to act proactively to ensure that care provision meets the national requirements. Therefore, hospital management define and use indicators on for instance post-operative wound infections, number of patients per nurse, and mortality rates to monitor for deviations from the required standards and support continuous improvement efforts.

4.1.4 Hospital department CBI

Vast differences between hospital departments concerning workflow, patient volume, patient demographics and severity of illness mean comparison between departments or at the hospital level may not be granular enough to inform decision-making. For instance, one of the biggest challenges of an operating room (OR) department is efficient and appropriate scheduling (Samudra et al., 2016). In order for a surgery to be successful not only the patient but also the personnel, room, equipment and materials need to be in the right place at the right time. These “resources” are all very expensive and each have their own rules such as breaks for team members or cleaning and charging protocols for equipment. On top of that some surgeries are planned far in advance while others are unscheduled while duration of each surgery varies (Zhu et al., 2019). In such a situation, scheduling becomes increasingly complex (Levine & Dunn, 2015). As a consequence, an OR manager will be very interested in efficiency and utilization metrics such as schedule deviations, average procedure duration and trends in the utilization of rooms and equipment. An Intensive Care unit on the other hand has very different concerns and metrics. Utilization is measured in days not minutes and treatment protocols are extremely complex, tailored to very sick patients, each with a unique set of symptoms.

4.1.5 Individual CBI

At the clinician level, CBI can allow available data about performance & choices to be translated into individual achievements, learning goals or topics of discussion. The idea of measuring, analyzing and visualizing this information, possibly in relation to the data of peers, is to create awareness on workflows, habits and other performance-related indicators. Change can only occur through the individual actions of team-members, starting with awareness of certain behavior. By using CBI-tools, cause-and-effect relationships underlying both simple and complex problems can be more easily uncovered using real-world data. Involving hospital staff in analyses on their own operations can initiate a dialogue for improvement or an environment of healthy competition. In this way, clinicians will feel personally responsible to work together to make improvements to their daily procedures.

4.2 CBI solutions for hospitals

Bringing specialist human expertise and computer-driven data solutions together does not automatically imply that issues identified will be solved (Sittig & Singh, 2015). Healthcare organizations struggle to get the most value out of their data at every level of the organization, especially since data processing and analysis is not part of their core business and workflow changes can have far reaching implications, making employees in this industry, at times, change-averse (Shahbaz et al., 2019). The market has responded to this with different solutions. Since the CBIS developed as part of this project is aimed at the hospital or hospital department, the following chapter will review some commonly encountered CBI solutions available to these organizations.

4.2.1 Hospital-wide BI departments

In recent years most hospitals have instituted a central BI team, usually supported by a central data repository where data from different source systems is stored for analysis. Advantages of this approach include centralizing know-how and human resources concerning data analysis. This is especially relevant since data analysis is not a core business activity for hospitals and many hospitals struggle to build-up know-how and attract and retain talent in this field. Through centralization, requests can be prioritized according to the greatest value to the organization as a whole. To support such a team, data from different sources is stored centrally, usually in a data warehouse, providing a complete picture and allowing for re-use for various purposes (Johnson, 2011).

Some challenges have been reported with this approach. Usually, complaints from end users such as clinicians, administrators and department heads fall into 3 categories:

- Data quality: data is collected automatically from many different source systems. Little quality control is performed before it is being fed into the data warehouse. As a consequence the data can contain many gaps or errors leading to incomplete or incorrect reports and analyses (Boyer et al., 2010; Johnson, 2011).
- Report quality: BI analysts are centrally managed, far away from the daily operations of departments and clinicians. As a consequence they may not understand the daily business sufficiently, resulting in reports that miss the mark or require many iterations before adding value.

- Time between request result: processes are put in place to request reports or analyses. These processes require explaining the need and the value through, for instance, a business case. Such an explanation is then reviewed and prioritized, resources are assigned according to the priority etc. Although being important, this process can be lengthy while BI departments are chronically understaffed. As a result it can take months before a department-head receives a requested report, at which point the request may no longer be relevant (Boyer et al., 2010).

There are hospital-wide analytics tools available that support hospital-wide BI departments to overcome the challenges mentioned. Companies such as LOGEX healthcare analytics and Performation deliver pre-built reports and dashboards as well as data warehouses that provide a clearer infrastructure and user-interface, making it easy to find data in order to apply it to specific challenges through analysis and reports.

4.2.2 Department or workflow specific CBI solutions

Many software systems in the hospital such a EHRs or CPOEs include their own reports and analysis tools. There is also a growing market for analysis and reporting tools that combine data from multiple systems but focus on a specific workflow or department. Such systems can augment a hospital-wide BI department by reducing the pressure and putting some of the analysis capabilities in the hands of department team members who are closer to the processes they are trying to analyze. Data quality also tends to be higher since these tools are specialized and may contain built-in checks and alerts for missed or incorrect data (Parenteau et al., 2016).

Of course such systems require additional investment. A patch-work of department specific systems cannot replace hospital-wide BI solutions. They may create reports that are not compatible with the reports of other departments and they require additional data collection. Ideally department specific systems augment hospital-wide BI solutions by improving the quality and level of detail for specific high-cost, complex environments and processes such as the logistics and planning around treatment rooms, ORs and imaging departments (Eckerson, 2010; Johnson, 2011). As part of the IMPACT project, NewCompliance has developed a department-specific CBI tool for the Catherization department which can generate reports on a number of efficiency indicators which research has shown can drive significant improvement (Reed et al., 2018a; Reed et al., 2018b).

4.2.3 Consulting services

While CBI systems allow for monitoring and tracking various metrics of interest, this might not always provide sufficient actionable advice on how to improve on these metrics. This is where consultancy services could come in. With the help of CBIs, consulting services can serve a multitude of purposes.

- Operational and clinical transformation: As healthcare organizations strive to provide quality care with limited resources, they must continuously increase clinical effectiveness and efficiency while transforming care delivery. With data obtained via CBIs as a foundation, combined with clinical expertise and technology know-how, consultants can provide actionable insights to support improved outcomes, increased efficiency, and an enhanced patient experience.

- Environment and experience design: data collected and analyzed by CBIs can also facilitate experience improvement. To create an optimal experience for patients and staff when planning to build a new hospital, renovate a department, or improve the patient environment, consulting services use CBI data analytics to understand the situation and utilize their specialties such as space and functional planning and design thinking in order to help create better healthcare experience for both patients and staff.
- Technology transformation and analytics: to drive healthcare innovation, organizations must continuously adapt to new technology and industry trends, such as integrated data governance which effectively manages medical data as well as other relevant data types such as logistics, financial, IoT and HR data, as described in Section 4.3. Consultants guide strategic planning and technology integration to bring various data types into CBIs. With the consolidated data analytics, consultants provide data-driven insights and performance dashboards to support performance improvement.

CBI consulting is a fast-growing market with players from different backgrounds including large consulting firms (e.g. E&Y; KPMG), medical device vendors (e.g. Philips, Medtronic) but also smaller BI consultancy companies and companies specialized in consulting and supporting hospital IT departments.

4.3 Data types

Nowadays, vast amounts of data are generated by various sources within a hospital. These data sources not only generate clinical data, but also other data types. Within the CBIS of a hospital, four main types of data can be distinguished:

- Medical data: data related to patient health and care such as heart rate and antibiotics provision.
- Logistic and financial data: data related to operations and resources e.g., procurement numbers by instrument.
- IoT data: data produced by and communicated between devices such as sensors, for example room temperature.
- HR data: data related to hospital staff, such as working hours per month or employee turnover.

Each of these data types are discussed in more detail in the following sections.

4.3.1 Medical data

Medical data is het most obvious type of data being generated in hospitals. It comprises all health-related information that is associated with patient care; such as patient background information, all sorts of measurement results, imaging results, reports, etcetera. These data were traditionally entered and compiled in paper medical records, however today they are increasingly being entered digitally in the EHR of the hospital. Approximately 80 mB of data are generated per patient per year, which continues to grow as new technologies become available and reliance on technology increases (Hutchings et al., 2020). A vast amount of data is generated each year in healthcare systems (figure 4).

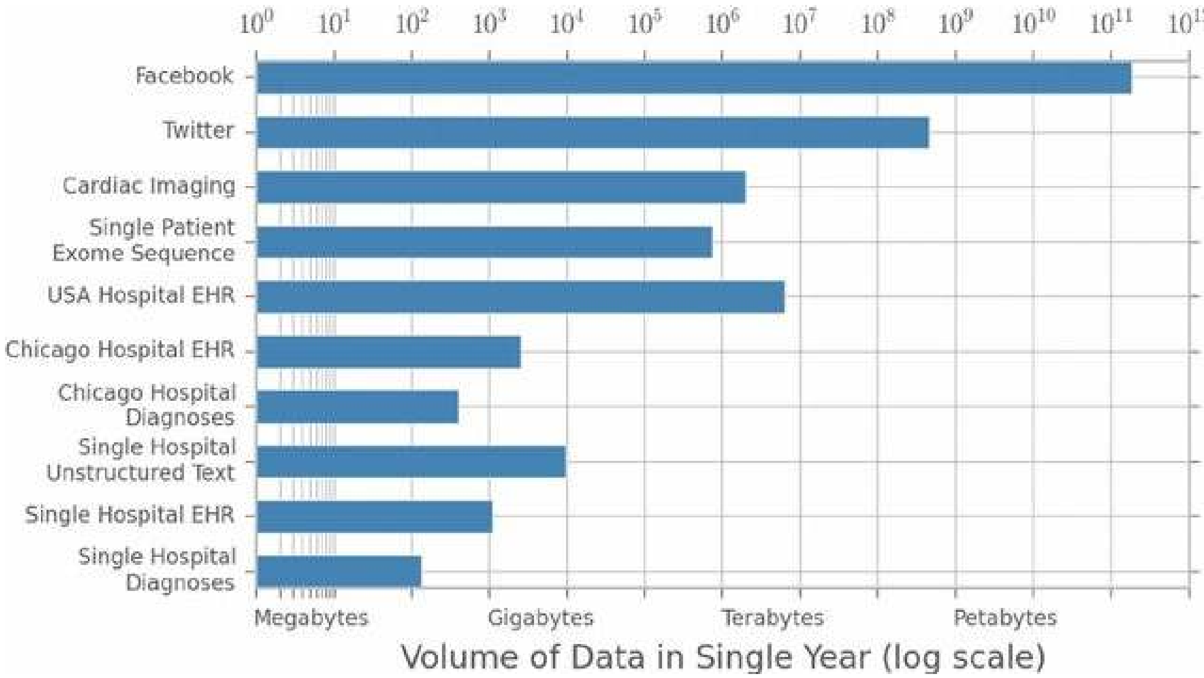

Figure 4: volume of data generated in a single year for various sources. **The size of " Single Hospital Diagnoses " is calculated only for data related to patients and diagnoses (ICD-9 codes) at an individual hospital, while " Single Hospital EHR " represents diagnoses, labs, medications, procedures, and vitals data from an individual hospital. The " Single Hospital Unstructured Text " is the size of unstructured free text (i.e., written notes from a physician) at an individual hospital (Pah et al., 2015).*

One of the main advantages of the EHR is that medical information is more readily available if needed, which may improve coordination, efficiency, quality and safety. Medical data is obviously the primary data source for CBIs. However, there is still a lot of room for improvement in the use of medical data: it has been estimated that 80% of medical data still remains unstructured or untapped after it is created, which makes it hard for the CBIS to access (Kong, 2019). Causes for this challenge include poor quality of data due to incomplete reporting or reporting in unstructured form, differences in data format between different systems and unnoticed errors in automatically generated data such as monitor data.

4.3.2 Logistic and financial data

30 to 40% of total hospital expenses are spend on logistics and supply chain. Research suggests that almost half of the costs related to supply chain processes could be eliminated by using best practices. In many industries it is endorsed that a well-functioning logistics system improves the operations of an organization and leads to improved quality, efficiency and customer satisfaction. It is argued that this also applies to hospitals, although its importance is still largely underestimated within the sector (van der Ham et al., 2019).

Logistics and financial data are readily available in hospitals and often analyzed on request by BI units. For example, in an OR setting, surgical material stock and use is registered in the ERP. These data are a vital element to enable improvement of logistics and financial processes. Introduction of theories and methods from other industries in healthcare, such as supply chain management and lean six sigma, may facilitate these improvements. These methods promote alignment of activities along the patient or material flow and integration, with a focus on activities that adds value and reduction of waste. For example, it was found that efficient departments in a hospital do not necessarily make a hospital efficient, while increased cooperation between hospital departments, which may make a department on itself less efficient, was found to both improve efficiency and patient satisfaction (van der Ham et al., 2019).

Logistic and financial data is not only found in ERP or planning systems. Many data elements in the EHR, such as point of care use of materials or on-time starts of procedures can provide information about the efficiency of a hospitals logistic processes. The strength of CBIS lies in combining EHR, ERP and other system data to provide a complete picture and identify opportunities for efficiency improvements and cost-saving opportunities while maintaining or improving quality of care. For this reason, improvement programs such as VBHC rely heavily on data analysis of the complete process, including logistic, financial and clinical data.

4.3.3 Internet of things

In recent years, IoT has been introduced into many aspects of everyday life, such as homes, cities, industry, agriculture and healthcare organizations. IoT is defined as: ‘a system of wireless, interrelated and connected digital devices that can collect, send, store and receive data over a network without requiring human-to-human or human-to-computer interaction’ (Kelly et al., 2020). In a healthcare setting, one may think of sensors that measure temperature and door movements in ORs, wearables that are able to measure vital parameters such as blood pressure or pulse, tracking of surgical instruments with tags and sensors, and more. IoT essentially consists of three layers: a perception layer that collects data (e.g. infrared sensors, cameras, RFID, medical sensors, etc.), a network layer for data communication (e.g. Bluetooth, low-power Wi-Fi or 4/5G networks) and storage (e.g. locally or a cloud server), and an application layer that interprets, applies and delivers data to the user (Kelly et al., 2020).

The great variety of IoT applications provide opportunities to improve infrastructure in healthcare to increase quality and keep costs in check. Also, it provides an opportunity to make healthcare more patient-centered, for example by enabling remote monitoring and self-management of chronically ill patients. Surgical instrument tracking provides real-time information on the location, availability and maintenance status of instruments which in turn can ensure the right instrument at the right time in the right place. This has both cost and quality of care implications because an incorrect or defect instrument results in additional work, a longer procedure and a risk for the patient. As is clear from this example, IoT data may improve efficiency and quality of care but not on its own. the vast amount of data collected by IoT should be integrated with data from other CISs such as the EHR to enable predictive and prescriptive analytics (see chapter 5.3).

4.3.4 Personnel and planning data

In healthcare, effective HR management is particularly important since employees are the most expensive resource of a hospital. Healthcare workers are also a scarce resource, which requires years to train. Effective scheduling, appropriate training, pay and rewards, communication, teamwork, equal opportunities and flexible job design all influence quality of care, patient satisfaction and efficiency (Ramadevi et al., 2016).

Data related to this topic, such as, accreditation, training and shift-planning data for personnel is usually spread over multiple software tools including HR, planning and EHR solutions. Combining this data with the other data sources allows for a more complete picture and a stronger CBI tool. Use cases include identifying inefficiencies, flagging non-compliance or suggesting the right team-members for a patient or procedure. In addition, effective HR management increases staff retention and attraction for recruitment. It is estimated that by 2035, there will be a shortage of 12.9 million professional worldwide, due to an increase in chronic disease and decreasing availability of healthcare personnel (WHO, 2014).

5 Underlying technology

Many of the recent advances in CBI are due to advances in available technology. From humble beginnings as an after-thought, CBIS have become free standing, intuitive tools relying on the latest technological advances to provide actionable insights. The following chapters will describe the technological advances and challenges underlying CBIS.

5.1 Interfacing

The first requirement for a successful BI tool is data. CBISs rely on data from other systems in the hospital. As a consequence, almost any CBIS tool requires data collection from other software systems. This activity is commonly referred to as interfacing, which was originally somewhat of an after-thought for many CISs and other software systems in hospitals.

Many different techniques were used for exchanging or extracting data from direct database queries to batch updates or manually triggered data exchanges. Eventually a standard was developed, at least for clinical data. This standard is commonly referred to as Health Level 7 (HL7). HL7 has been in development since the 80s but only became widely used in the late 90s. It consists of a data format, as well as a control protocol for such things as query-response handling, acknowledgements and error handling.

As the number of systems in hospitals increased, so did the number of integrations leading to the rise of "integration engines" – systems intended to manage and monitor the exchange of data. A modern HL7 interface V2.x or V3.x routed through an integration engine provides a robust solution for data exchange. Although much has improved since the early days of interfacing, connecting to multiple sources within a hospital through HL7 V2 or V3 with integration engine can still come with many challenges:

- Most hospitals run systems from different vendors and different ages resulting in different interfacing capabilities and therefore the need to develop multiple integrations.
- Each interface development can be a lengthy and costly process that almost always requires the involvement of both vendors. The vendor of the system that the data is extracted from may be hesitant to cooperate in order to protect its competitive advantage or because the company has a long backlog or other priorities.
- Although HL7 provides a standard, this standard can still be interpreted differently by different vendors. The challenge can be in the message structure but more commonly challenges arise due to different "vocabulary". The smoking status of a patient may be stored in one system as a simple yes/no Boolean field whereas another system may have multiple options such as "not currently but has smoked in the past" or "smokes x number of cigarettes a day" – translating one to the other poses a real challenge.

Recent developments in terms of standards and technology try to address these issues:

- Standards have been developed and continue to be developed to agree on the vocabulary and nomenclature. The most widely adopted of these is SNOMED.
- Application programming interfaces (APIs) are becoming more widely used. APIs are provided by vendors as a generic solution for retrieving data from their systems. The current "gold standard" for interfacing in healthcare is an API that follows the Fast Healthcare Interoperability Resources (FHIR) standard. FHIR is the latest standard released by HL7 and is intended for use with APIs.

Using these solutions, many of the challenges described above can be overcome. More and more vendors are providing FHIR APIs and structure their data according to standards like SNOMED but hospital traditionally run a lot of legacy systems and vendors may still control what data is made available through their APIs to protect a (perceived) competitive advantage. As a consequence, the reality "on the ground" is that interfacing will still have a significant effect on the cost and success of almost any CBIs development and implementation project.

5.2 Data storage

As described in chapter 4.3, a very large amount of data is generated in healthcare on a daily basis. Following the collection process, the next step and challenge is storage. Data storage has become much cheaper in recent years, which has brought advanced analytics within reach for healthcare organizations. But there is more to data storage than the cost involved. CBIS requires large amounts of secure and easily retrievable data.

Originally, the different systems in use in a hospital each used their own database or set of databases. A database is a collection of related data which represents some elements of the real world. It is designed to be built and populated with data for a specific task. The specific task within a hospital software system is usually the storage and retrieval of specific data elements grouped within a record, for instance a medical record of a specific patient or the purchase & maintenance record of an instrument. As such these databases are not generally designed for retrieval and analysis of large datasets. Attempting to complete such a query on for instance an EHR database can result in slow response times and even downtime for the application because the database is not accessible.

As a first step, systems may offer parallel databases through techniques such as mirroring to prevent negative implications on the production database but this does not solve the problem that the query may take a very long time. These solutions also don't allow for the combination of data from different systems. As a solution to these challenges, data warehouses and data lakes have emerged as a new technology.

5.2.1 Data warehouses

A data warehouse is a central repository of data from multiple systems. Before being stored the data is cleaned, transformed and catalogued and stored in a way that supports data retrieval for analytics. For instance it may be of interest to analyze the duration between two steps in a treatment process for patients of a specific department to identify inefficiencies. In the EHR only the individual time stamps of each step are stored. These timestamps are extracted for the data warehouse. As a next step, the data will then be cleaned for instance by checking for incorrect documentation resulting in missing timestamps or timestamps in the wrong order.

Since the importance of the duration between the timestamps may already be known, as a last step, the data warehouse may not only store the timestamps but also the calculated duration between them. If a user now wants to pull up a report showing the trend in duration, the response of the CBI tool will be near instantaneous and the data will be of high quality.

As part of the IMPACT project, NewCompliance developed a data warehouse for department specific efficiency analysis (figure 5). This Data warehouse combines data from multiple sources such as planning software, EHR and devices/IoT. It is especially relevant for time-sensitive treatment departments such as the OR and the Catherization lab where accurate planning, timing and resource usage can have a large financial and quality of care impact.

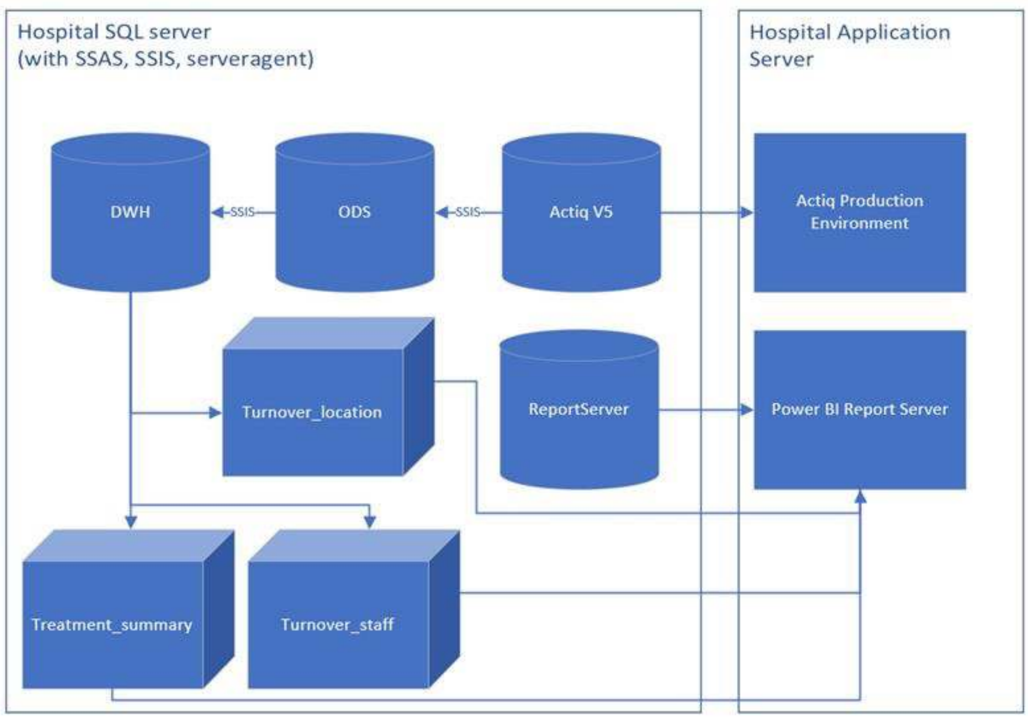

Figure 5: structured overview of the data warehouse as developed by NewCompliance for the IMPACT project to run department specific efficiency analyses.

5.2.2 Data lakes

Data warehouses have many advantages but some of the challenges include the time it takes to develop, since each step of cleaning, transforming and cataloguing requires decision-making and development. Another challenge is that data warehouses are not well suited for non-structured data such as (medical) imaging. Data lakes solve some of these challenges for specific uses such as training artificial intelligence (AI) on imaging or combining not only different sources but also different data types. A medical data lake (MDL) was developed as part of the IMPACT project by consortium partner Inovia.

The MDL is a secure and scalable distributed storage for medical images, structured data, and unstructured data. Additionally, it serves as an execution platform for analytics and is optimized for easy training and deployment of AI. In the course of this, it is possible to use open source ML algorithms/models and the ability to develop proprietary algorithms/models. Moreover, the MDL includes data anonymization for General Data Protection Regulation (GDPR) compliance to allow broader analyses.

Inovia's MDL system solution is a microservice-based solution that aims to store magnetic resonance imaging (MRI) images and even provides the intelligence to segment MRI images and ML to retrain the module used for image segmentation. Figure 6 shows the data flow for the project.

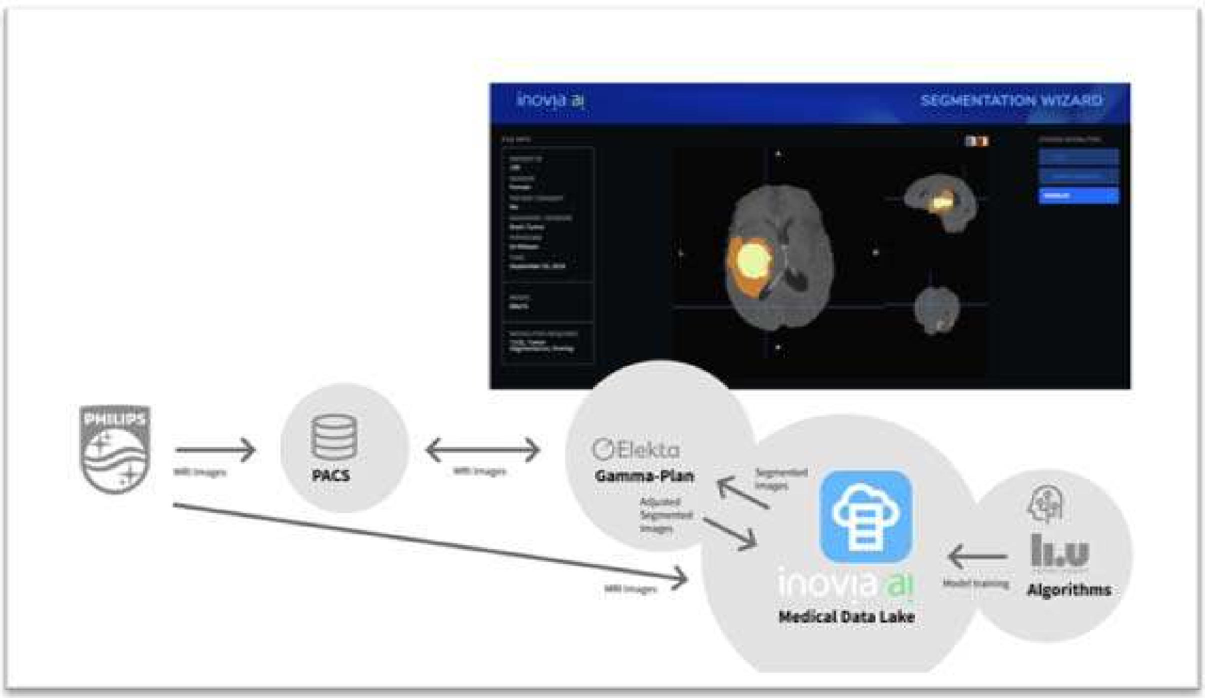

Figure 6: structured overview of the data flow between partners for the IMPACT project.

5.3 Types of analysis

With the increasing availability and accessibility of health data through integrated and interoperable health information systems, healthcare analytics are becoming more sophisticated. Consequently, the types of analytics being performed and with it the level of use is changing. As described earlier, four main types of health analytics are commonly distinguished that describe its function (figure 7):

- **Descriptive analytics:** explanations of what has occurred.
- **Diagnostic analytics:** explanations of why something has occurred.
- **Predictive analytics:** predictions of what can occur in the future.
- **Prescriptive analytics:** recommendations based on what can occur in the future.

In addition to this classification, health analytics can be classified into three levels of performance and engagement:

- **Operational level analytics:** focus on visualization and reporting of basic performance indicators in routine settings within daily operations.
- **Tactical level analytics:** focus on longer term objectives and results to assist management.
- **Strategic level:** focus on assisting long term decision-making that affect the strategic direction of an organization.

In general, health analytics are currently shifting from mainly simple descriptive towards more complicated diagnostic, predictive and prescriptive analytics (Khalifa, 2018). As a result, the use of analytics is increasingly moving from the operational level into the strategic level of healthcare organizations. This move is supported by the increasing availability and accessibility of different types of detailed data from integrated and interoperable CISs. The different types of analytics will be discussed in more detail in the following sections.

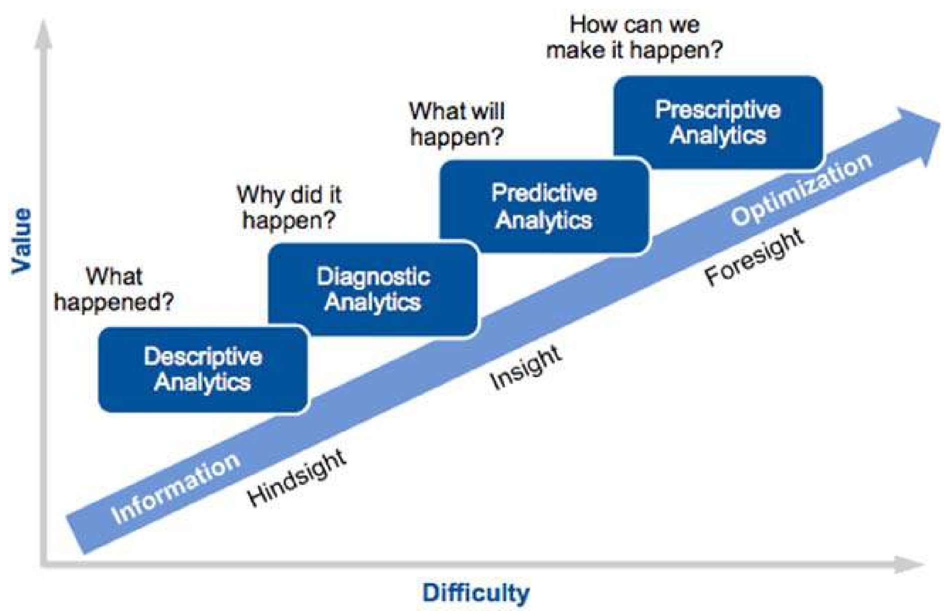

Figure 7: the four main types of analytics differentiated by value and difficulty.

5.3.1 Descriptive analytics

Descriptive analytics are the simplest and easiest to use type of analytics. From a typically large dataset, the main features are aggregated, categorized and quantitatively described without further extensive analysis, exploration or correlation between the variables in the dataset. The main aim is to reduce the amount of data to easily consumable information. Therefore, descriptive analytics are usually visualized in an at a glance format such as trend charts, pie charts or one key number. These data insights are used to present performance results to healthcare professionals in the workplace, to make everyone within the organization aware and create a feeling of ownership.

Descriptive analytics are mainly used at the operational level to near real-time manage performance goals in daily operations. An example of descriptive analytics from a hospital setting would be hanging a printed poster at the coffee machine of the OR lunchroom stating the % of checklists that were filled in during surgical procedures last week (figure 8).

Figure 8: example of descriptive performance analytics in the hallway of a hospital.

5.3.2 Diagnostic analytics

Diagnostic analytics focus on answering why something has occurred by more extensive and targeted analysis of data, in order to go to the root cause or causes of a problem. The result is that (input) factors and processes are identified which are correlated with the problem. In a healthcare setting, this helps realize the nature and impact of problems, which is an important first step towards solving them. Diagnostic analytics are commonly carried out using data drill down and statistical techniques. An example of diagnostic analytics would be to track down the cause or causes of decreasing compliance to surgical checklists on specialism, specialist or type of procedure and emergency level. The Analytics developed by NewCompliance for the Catherization lab fall into the Diagnostic analytics category, allowing users to drill down to examine the possible causes for efficiency issues.

5.3.3 Predictive analytics

Predictive analytics focus on predicting something that will occur in the future by analyzing data from past and current situations. The predictions are based on patterns and correlations within these data, while assuming that the current trends and actions are continued (Sappelli et al., 2017). Predictive data models may range from relatively simple (e.g. a linear regression model) to very complex forms. An example of predictive analytics in a healthcare setting could be to predict development of a surgical site infection after surgery before it has actually occurred, by automatically analyzing the extensive quantity of available patient and measurement data. Another, less complicated example of predictive analytics is to forecast the supplies needed in the hospital pharmacy.

5.3.4 Prescriptive analytics

Prescriptive analytics go one step further than predictive analytics by not only analyzing extensive amounts of data to predict what will happen, but also by providing a recommended way forward in order to reach the best possible outcome. Prescriptive analytics are more complex than predictive analytics, since the effects of a single event or a sequence of events is predicted with interactions between events and hypothetical effects of which no historical data is available. Therefore, the amount of data that needs to be taken into account is much larger than in predictive analytics (Sappelli et al., 2017). Successful prescriptive analytics rely on the availability of both structured and semi-structured data, integration of predictions and prescriptions, consideration of all possible side effects, easily adaptable algorithms to each situation and robust feedback mechanisms (Khalifa, 2018).

An example of prescriptive analytics is providing support to clinicians with making treatment decisions by automatically analyzing all sorts of data available in different CISs (e.g. MRI scans, patient family history, blood pressure measurements) and comparing these to most recent scientific research, in order to recommend the most suitable personalized treatment for that specific patient. In this way, prescriptive analytics may increasingly enable patient-centric care within a VBHC approach (Kaur et al., 2017).

5.3.5 Benchmarking

To enhance the learning potential from data analytics, benchmarking can be applied. Benchmarking is defined as “the continual and collaborative discipline of measuring and comparing the results of key work processes with those of the best performers in evaluating organizational performance.” (Lovaglio, 2012). Through comparison of data, practices are evaluated and opportunities for improvement can be identified. These comparisons can be made either internally, within the hospital, or externally, between hospitals. Internal benchmarking involves the evaluation of internal data and thereby allowing for comparisons over time to identify the hospital’s best practices. Several levels of the internal organization can be benchmarked, such as different departments but also different specialisms. In practice, identifying a best practice and setting this as a standard could look like the following. Data shows that during a particular observational period, the orthopedic specialty scores the best with regards to their compliance to normothermic protocols during surgeries. To learn from this ‘best practice’, this specialty will be asked to share how they achieve such results to the other specialties. When and where suitable, other specialties can adopt their practices and strive to comply to normothermic protocols as set by the standard of the orthopedic specialty.

External benchmarking encompasses the evaluation of comparative data between hospitals to evaluate their performances, assess practices, and thereby identifying improvements. Moreover, external benchmark analyses allow for sharing of ideas, processes, and interventions between the hospitals. This means that to enable hospitals to learn, not only data should be shared, but also underlying information on organizational structures, settings and procedures.

External benchmarking requires the exchange of PHI, but hospitals remain apprehensive about this. Explanations include the negative connotation that has been given to benchmarks in the past, which have focused on pointing fingers at low performing hospitals or hospital employees. As a result, hospitals keep their cards close to their chest. Hospitals and employees are more likely to share their practices if the emphasis of benchmarking is placed on the learning potential of benchmarking and if this is communicated to all employees. Furthermore, the wide variety of definitions and protocols disables one-to-one comparisons since data is registered, monitored and analyzed differently within the different hospitals. In a sense, hospitals are afraid of comparing apples and oranges. Although this is a fair concern, this problem can be overcome if hospital actively collaborate on setting the same standards. Only in this way, the collected benchmarked information can apprise learning, sharing, and adopting of best practices to drive organizational improvement.

5.4 Data security and privacy

CBI requires collection, structuring, transmission, and analysis of data. These activities represent data processing. As this concerns PHI, the processing of data must adhere to legislative standards. The GDPR sets data processing standards that aim to ensure privacy-respecting practices (Cortez, 2020). Any company, organization, or institution that works with privacy sensitive data needs to respect the GDPR (2016). Due to the sensitivity surrounding medical data, the GDPR prescribes additional rules. Personal data consists of any data that can be related back to an individual person. This is referred to as personal identifiable information (PII). Examples of PII are name, date of birth, and gender. Under the GDPR (2016), the medical data of patients fall under the scope of sensitive (personal) data because any data concerning an individual's health touches at the very core of human beings. Unauthorized disclosure or access of such data, is considered a grave violation of one's privacy.

The GDPR officially prohibits the processing of health-related data, but it recognizes the need for exceptions in the interest of public health and scientific research. Article 9 (2) stipulates a list of exceptions on the condition that only the minimum amount of data is processed, and reduces the risk of identifying it back to an individual. In order to process data, a valid legal basis is necessary. Following Article 6 (1), a legal basis may be obtaining informed consent of an individual, fulfilling a legal obligation, acting in the public interest, vital interest, or legitimate interest. In the healthcare sector, obtaining informed consent is the most common legal basis to use. The crucial considerations here are that consent a) is received before the data processing activity and b) can be withdrawn at any time. Additionally, patients enjoy the right to access data which is processed and the right to data erasure (GDPR, 2016). Those responsible for data processing are obliged to implement proper technical and organizational measures. The measures are necessary to prevent data breaches, incidents, or violations. If not implemented correctly, authorities can impose fines on the company, organization, or institution in question.

As described earlier, large amounts of data are needed for CBI. But with the stringent GDPR standards, processing large amounts of medical data is difficult. There are several solutions to this challenge. Traditionally, organizations have used data anonymization and data aggregation techniques. But valuable information may be lost in these processes. Two new techniques have emerged recently that hold promise for the future. One of these is synthetic data: as the name suggests, this is data that is artificially created rather than being generated by actual events. It is often created with the help of algorithms and is used for a wide range of activities, including as test data for new products and tools, for model validation, and in AI model training. With the latest tools, synthetic data can be created to mimic the original data set in terms of statistical distributions and other properties (Dilmegani, 2018; El Emam et al., 2020). Federated learning is a technique that trains an AI algorithm across decentralized devices or servers (i.e., nodes) holding data samples without exchanging those samples, enabling multiple parties to build a common ML model without sharing data liberally. That's in contrast to classical decentralized approaches, which assume local data samples are widely distributed (Wiggers, 2019).

6 State of the market

Healthcare is becoming increasing expensive and complex thanks to a combination of an aging population and advances in research. Access needs to be improved in the developing world while cost and quality need to be managed in the developed world. At the same time, advances in technology have put advanced data analytics tools within reach of the healthcare industry. These two trends create a perfect storm for the healthcare analytics market. This is reflected in market analyses which project a growth to 70+ Billion dollars until 2027 (Business Wire, 2021).

CBI is only one type of Healthcare analytics but as described in this document it has great potential to address the challenges facing healthcare today. By combining clinical data with business data, better decisions can be made that improve both the quality and the cost of care. It will come as no surprise that one of the most popular improvement programs in healthcare today, VBHC, has clinical BI at its heart.

Many companies are seeing the potential and jumping into the healthcare analytics market including large consulting firms (e.g. E&Y; KPMG), medical device vendors (e.g. Philips, Medtronic), IT companies (Google, Microsoft) but also smaller BI consultancy companies and companies offering specialized reporting tools. There are some trends in the market:

- Hospitals are taking more control over the analytics happening under their roof. Centralized BI departments with a single tool of choice are becoming the norm. Companies operating the healthcare analytics space either by building tools, offering consulting services or some combination thereof should take note and adjust their strategy accordingly. They may for instance have to considering offering their tools and training their workforce to work with multiple commonly used BI tools.
- Solutions on offer are becoming more mature, products that offer purely descriptive analytics are becoming obsolete. Diagnostic analytics are now the norm and hospitals and companies are experimenting in public private partnerships with predictive and prescriptive analytics.
- Modern technologies such as cloud storage, synthetic data generation, data lakes and ML are reaching a price-point that makes it accessible for hospitals although hospitals may still lack the expertise to benefit from these. Companies in the CBIS market could benefit from this development by partnering with technology partners offering such solutions and/or employing experts in these fields in order to support hospitals in taking advantage of these opportunities for advancement.

Despite these trends, there are still significant challenges in CBIS including challenges in bringing data together from disparate systems, challenges with data quality and challenges prioritizing CBIS activities within the limited budget available to a hospital. As such, there will continue to be a market for each of the different CBI solution types available on the market from large, generic BI tools to department and workflow specific reporting solutions and tailored consulting services. The solutions developed as part of the IMPACT project provide important advances in CBIS.

Data lakes are a cutting edge technological solution that is not yet widely deployed in healthcare. The MDL is a secure and scalable distributed storage for medical images, structured data, and unstructured data. Additionally, it serves as an execution platform for analytics and is optimized for easy training and deployment of

AI. In the course of this, it is possible to use open source ML algorithms/models and the ability to develop proprietary algorithms/models. Moreover, the MDL includes data anonymization (for GDPR compliance) to allow broader analyses. Inovia's MDL system solution is a microservice-based solution that aims to store MRI images and even provides the intelligence to segment MRI images and ML to retrain the module used for image segmentation.

Catherization labs are growing because of aging populations, and advantages in research which allow more treatments to move from the OR to the catherization lab. Where a hospital may have had 1 or 2 Cath labs in the past, most (larger) hospitals nowadays have a full-fledged catherization lab department with at least 4-6 catherization labs. With the growth in size comes a growing complexity. Research suggests that a lot can be won in terms of efficiency and therefore cost by improving on certain efficiency metrics in a modern catherization lab department (reference). This will also improve quality since certain catherization lab treatments such as ST-elevation myocardial infarction treatments, are extremely time-sensitive.

Effective CBI will require combining data from the planning, the EHR and the image-guided therapy system. There are no tailored CBIS on the market yet for the Catherization lab. The Catherization lab analytics tool created by NewCompliance as part of the IMPACT project is a tool providing reports and advanced diagnostic analytics tool for the most important Cath lab metrics allowing users to identify inefficiencies and drill down to determine causes. The tool consists of a data warehouse which can be accessed by all major BI tools on the market and reports and visualization created on the most commonly used BI tool. As such it can be easily integrated in any hospital BI environment.

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