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Using Patient-Reported Outcomes in Real-Time Shared Decision-Making

How to Activate Data in Value-Based Healthcare

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Abstract

This paper examines how data can be activated in the care cycle to support the strategic transition toward value-based healthcare. We used the value-based healthcare framework and applied the cross-industry standard process for data mining methodology to create a data infrastructure showing how real-time, shared decision-making, and clinical support systems can be built and applied in real-time to patients referred to a hip or knee replacement. The results demonstrated that using outcomes in real-time combined with archive data like risk factors enhances the implementation of outcome measurement and, thus, a shift toward VBHC.

Keywords

Value-based healthcare, Prediction models, Shared Decision-Making, CRISP-DM

1 INTRODUCTION

Most western countries, including Denmark, face significant challenges with rising healthcare cost due to a large elderly population, new and expensive treatments, and higher expectations for healthcare delivery from both patients and politicians [1]. As a result, in 2006, Porter and Teisberg [2] introduced the value-based healthcare (VBHC) framework based on the assumption that the above-mentioned challenges can be solved by shifting focus from volume to value. VBHC is often described as a concept or agenda consisting of several components: 1) integrating practice units; 2) measuring outcomes and costs for the entire care cycle; 3) bundling payments; 4) integrating care delivery across separate facilities; 5) expanding excellent services across geography; and 6) building and enabling the information technology platform [3]. One of the most central points of the concept is its explicit focus on value creation during the entire care cycle, measuring outcomes and costs for each patient as well as the integration of relevant information between IT systems and sectors [3]. Several hospitals have accepted the VBHC framework and implemented some of the components, however most of them have focused on collecting and using patient-reported outcomes (PRO) [4-7], new reimbursement systems based on pay for performance or bundled payments [8-11], and the implementation of integrated practice units [12]. All of the above-mentioned studies have described the current data infrastructure as a challenge, specifically the availability of already collected data, flexibility, and the ability to share the collected data across facilities and sectors [3,13-16].

Denmark, like most Scandinavian countries, has a long history of collecting and digitalising healthcare data, which has generated a significant amount of data, driven by the demand for record-keeping, compliance, regulatory requirements, and patient care [17]. Healthcare data can consist of historical data like previous diagnoses and resource consumption, as well as real-time or close-to-real-

time data like patient-reported outcomes collected prior to examination [18-19]. Most of the historical data is stored in the business intelligence (BI) unit, with some of the data being subjected to a comprehensive quality control process using error lists in order to establish its accuracy; however, this can cause an inevitable delay in the availability and flexibility of data usage [17]. In contrast to historical data, real-time data is available and can be used by the clinic to, for example, inform patients of their health status, or clinical support systems like Ambuflex, which relies on PRO-data for visitation purposes [20]. When using real-time data, especially real-time patient-generated data, quality control systems cannot be applied to the same extent as with historical data stored in the BI unit, which ultimately can be a risk factor when creating decision systems based on data [21]. Moreover, some patient-generated data is transferred to local BI units and stored as historical data, but, primarily, the data is either non-retractable or stored in business systems outside the hospital/region. In Denmark, this is true for most PRO-data. The fact that data is stored in different systems that cause different delays and collected for various purposes, like patient treatment, research, or statistics, creates significant barriers regarding the availability and flexibility of data [13] in supporting VBHC. This article describes the ways in which a hospital in Denmark has tested how data can be activated in the care cycle, using both historical data from the patient administrative system (PAS) and the laboratory system (LABKA) as well as real-time generated PRO-data to support the transition toward VBHC through the creation of both clinical support systems and shared-decision making systems [4, 22-23].

2 METHOD

The present case builds upon Aalborg University Hospital's experiences applying the VBHC framework to patients receiving hip or knee replacements (THA and TKA). This case is a part of the national VBHC project, examining the

development of outcomes by using recommended tools from VBHC, like the process map. Furthermore, the cross-industry standard process for data mining (CRISP-DM) methodology [24] was employed to investigate the ways in which data can be activated during the care cycle to create more value.

The CRISP-DM methodology consists of six generic phases; business understanding, data understanding, data preparation, modelling, evaluation, and deployment [24]. The translation of each generic phase to the healthcare sector was made with the sole purpose of using known terminology when interacting with healthcare professionals. Phase one, business understanding, was translated into the understanding of the entire care cycle, which can be obtained using a process map [25]. Phase two, data understanding, involved measuring outcomes and defining risk factors for subgroup analysis, which can be obtained using a Delphi Process [26]. Phase three, data preparation, consisted of extracting relevant patient data containing information on both outcome and risk factors, establishing the data quality, and conducting statistical analysis with the purpose of developing algorithms to identify the prediction and visitation thresholds for shared decision-making. Phase four, modelling, was translated into the development of a data infrastructure within the local BI environment, containing extraction of patient data on relevant risk factors, the developed algorithms and the results of the algorithms visualized as scales and color-coding figures launched into the electronic health record (EHR) used by physicians. Phase five, evaluation, consisted of evaluation of the data infrastructure in terms of correct data extraction, correct prediction, and availability of the result in the EHR. Phase six, deployment, was translated into the implementation of the prediction model as well as the visitation threshold for follow-up visits.

2.1 Understanding the care cycle

Understanding of the care cycle was conducted using a process map developed at a national level and facilitated by Quorum consulting. The purpose was to outline all activities, from general practice referral to rehabilitation, occurring in the municipality. A national expert group, consisting of physicians, an employee from the national patient association for arthrosis, and health economists, participated in the process. The expert group further defined challenges in healthcare delivery during this process.

2.2. Outcomes and risk factors

The national expert group conducted the definition of outcomes and risk factors. The expert group defined the relevant outcomes of the care cycle based on the process map and in accordance with the VBHC framework [25]. Furthermore, they defined all the relevant risk factors that could affect the outcomes of a THA and TKA treatment. To define these relevant risk factors, the project group used the Delphi Process, a commonly used process to obtain knowledge from a group of experts [26]. The project group provided the expert group with a list of relevant risk factors obtained through a literature search, and the national expert group then added new risk factors to the list based on their

medical expertise. Following this, the project group initiated the Delphi-process, which consisted of two rounds. During the first round, the national expert group scored each risk factor on a numeric scale from one to ten, for which one equalled not relevant and ten equalled highly relevant. Based on the scores, each risk factor was placed in one of three groups: 1) relevant; 2) potentially relevant; and 3) not relevant. If more than 70% of the expert group ranked a risk factor as a seven or above, the risk factor was defined as "relevant", and similarly, if more than 70% of the expert group ranked a risk factor with a three or below, the risk factor was defined as "not relevant". Otherwise, the risk factor was defined as "potentially relevant". During the second round of the Delphi Process, the expert group received a new list with only the risk factors marked as relevant or potentially relevant. They were once asked to judge all the risk factors in the "potentially relevant". If the expert group believed the potential risk factor was relevant, they were asked to note a "yes" and, if not, a "no". If more than 50% of the expert group marked a risk factor with a yes, the risk factor was included into the project for further analysis.

2.3 Data Preparation

Data definitions were based on the literature and definitions from regional quality databases when possible (RKKP). If none data definitions existed, medical expertise were used. Furthermore, the project group identified legal barriers like e.g. was the data collected allowed to be reused in patient treatment, and availability barriers by analysing registration validity and updating the frequency for each identified data source. Based on the legal and availability barriers, the project group adjusted some of the data definitions to include only data from registries approved for patient treatment. When adjusting a risk factor and thereby deviating from a best practice definition, the project group consulted a medical expert within the area. After completion of the data definitions, the project group extracted data on all patients who had delivered both a baseline patient-reported questionnaire and a one-year post-operative follow-up questionnaire between November 2015 and December 2017. The project group excluded one of the observations if the patient had received the same type of operation in both left and right knees and the hip. Furthermore, the project group excluded observations containing missing information in baseline data regarding type of operation, operation site, and patient-reported outcomes on function and quality of life. The identification of risk factors was achieved for each observation, and every risk factor was subjected to statistical analysis estimating its impact on functional outcome and the risks associated with an operation. A group of physicians at hospital was presented with the relevant material, and, based on the unadjusted results, they chose the relevant risk factors for the prediction model and threshold values. Algorithms for prediction were based on linear and logistic regressions, while threshold values for one-year post-operative follow-ups were based on information from previous literature and the medical knowledge of the expert group.

2.4 Data infrastructure

The creation of the data infrastructure, consisted of developing a platform in the local BI unit, in which the risk factors of newly referred patients could be extracted, calculation based on the developed algorithms could be performed, and the results could be visualized upon preliminary examination. Patients referred to the hospital under relevant diagnoses was included in the database table. From this, the system searched for relevant risk factor information based on specific risk factor data definitions and personal identification IDs. This specifically embodies all previously completed PRO questionnaires, diagnose-related group (DRG) database information, PAS data containing information on comorbidity, procedures, and referrals for both outpatient and inpatient contacts, LABKA containing laboratory information, and the pharmaceutical reimbursement database. The data platform transformed and filtered the raw data by date to represent the correct data definition of a risk factor and then saves the information as background data. Before the first consultation, the patient filled in the first PRO questionnaire on-site. After submission of this form, the PRO data is stored in a database table. The platform then automatically extracted the information and merged it with the background data in a data table on the platform where calculations was made based on pre-trained algorithms. Numeric estimates from the algorithms as well as explanatory factors was saved in a persistent database. Batch jobs and web services performed all communication between databases and algorithms. The estimates was presented in a web interface linked to the hospital's sign-in. This so-called front-end was developed and tailored specifically to this field with the possibility of visualizing specific estimates or performing a standardized walk-through of all available information. A business intelligence module of overall patient flow and individual patient look-up is available for the chief physician. One year after surgery, the patient answered a new PRO-questionnaire, and the data was stored in the same database table as the first PRO data, which enabled the possibility of calculating the value creation for each patient to determine the need for one-year post-operative follow-up.

2.5 Evaluation

Evaluation consisted of evaluating the data infrastructure. The project group produced a test document, physicians tested the time from entering ID to the graphic appearance

of the expected result. Both the Physicians and the project performed the test of correct data extraction and calculation. In beginning of 2018 the project group extracted data on a random patient group (20 THA patient and 20 TKA) referred to treatment after 01.01.2017 and thereby not included in the original data for analysis. The patients had answered both a baseline PRO questionnaire and a one-year follow-up questionnaire. For every observation, the physicians examined the EHR, and noted relevant risk factors. Subsequently, a staff member in the economy department crosschecked the notes made by the physicians with the data extracted on the patient from the data infrastructure. Lastly, the predicted result for every ID was crosschecked with the actual score one year after surgery.

2.6 Implementation

The data infrastructure was implemented with the prediction model for THA and TKA on the 1st of April 2018. The project group initiated the implementation process through a futuristic workshop with all the physicians. A futuristic workshop is a concept for investigating new areas in which no previous experience is available like e.g. how to implement PRO data in the clinic. The theme of the futuristic workshop was "PRO in the cycle of care for hip and knee surgery." At the beginning of the workshop, the chief surgeon presented the prediction model, the visitation threshold and the results from evaluation. The physicians then discussed the possibilities and challenges of using data, PRO, and prediction models. Furthermore, the physicians discussed the visitation threshold for one-year follow-up.

3 RESULTS

The national process map resulted in an in-depth description of the major activities in the care cycle, from referral to the hospital to rehabilitation, as illustrated in Figure 1. The challenges identified in the care cycle included patient satisfaction resulting in patient complaints due to different reasons:

1. Poor alignment between patient expectations and clinical expectations regarding the result of an operation.
2. Some patients would benefit from physiotherapy before or instead of an operation.

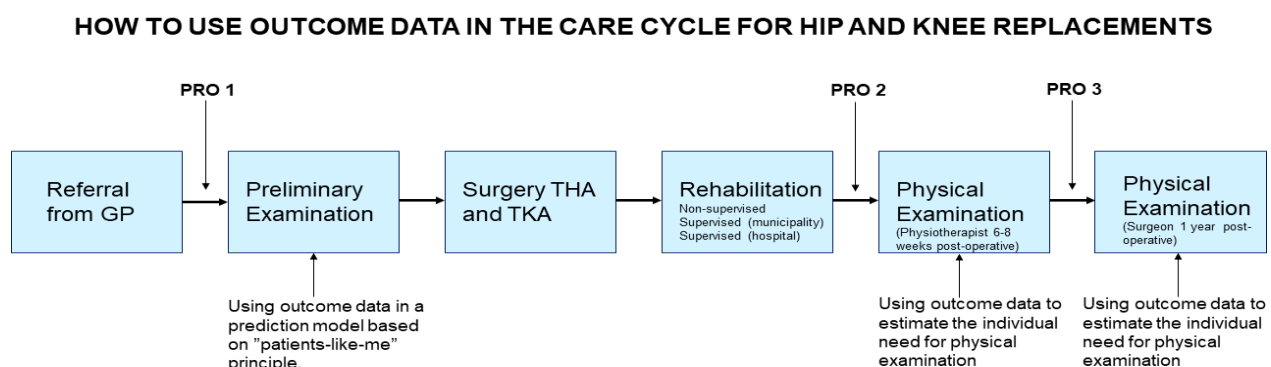


Figure 1 The major activities of hip and knee replacement (THA / TKA) identified in the national process map and the possibilities of patient-reported outcome (PRO) measurement data in the care cycle for value creation.

Furthermore, the group identified difficulties in differentiating the need for post-operative follow-up one year after surgery prior to actual physical examination, with one of the major reasons being missing information on effect (defined as difference between pre-operative and post-operative scores).

Based on the care cycle, six relevant outcomes were defined: function, quality of life, satisfaction with the result of the operation, complications within 30 days, re-operation, and the ability to return to work. Four of the identified outcomes were available in the regional databases as well as a local PRO database at the hospital. Furthermore, the expert group identified 48 relevant risk factors, of which 20 were available in the aforementioned databases, mainly risk factors concerning patient characteristics and chronic diseases.

The data analysis was based on a dataset consisting of a total of 243 THA and 208 TKA, which fulfilled the inclusion criteria. Based on the unadjusted estimates on the outcome of each risk factor, the physicians at the hospital chose four relevant risk factors for the local prediction model: age, BMI, pre-function, and number of chronic conditions. To create a prediction model available in real-time upon preliminary examination, the physicians explicitly demanded there be no extra registration tasks for the healthcare professionals. Furthermore, the data infrastructure had to be capable of searching for relevant risk factors in the different systems and merge them with the information available from the PROM-questionnaire answered minutes prior to the examination, thus making it possible to visualize the expected results for the patients upon preliminary examination.

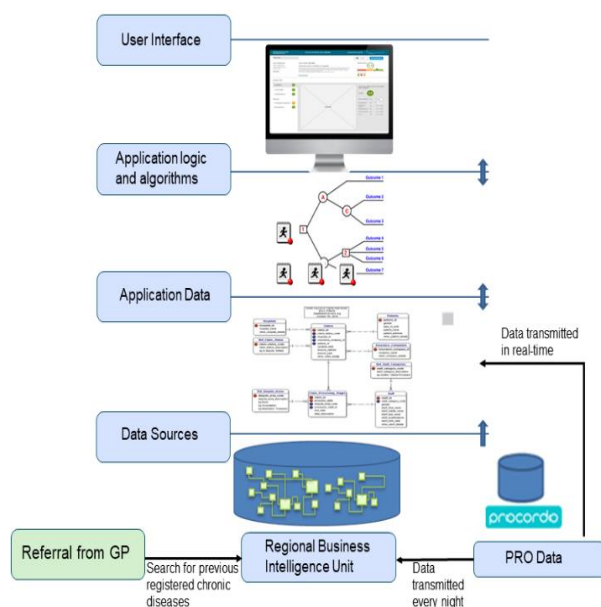


Figure 2 Data pathway from business intelligence units to algorithms used to predict the expected effect of surgery. PRO = patient reported outcome.

As illustrated in Figure 2, the data pathway begins with the referral from the general practitioner, which initiates the search for risk factors in the regional databases. When the task is completed, the data is stored in a separate location in the business intelligence environment. Before the

preliminary examination, the patient answers the first PRO questionnaire. Then, when the patient enters the preliminary examination, the physician enters the unique patient ID into the EHR and from there accesses the prediction model. The prediction model aligns all risk factors in the database table, and, when a PRO-questionnaire is answered, the PRO data is merged with the risk factors in real time, and the algorithms are applied. The results of the algorithms, which were presented to the physician and patient at the preliminary examination, are illustrated in Figure 3.

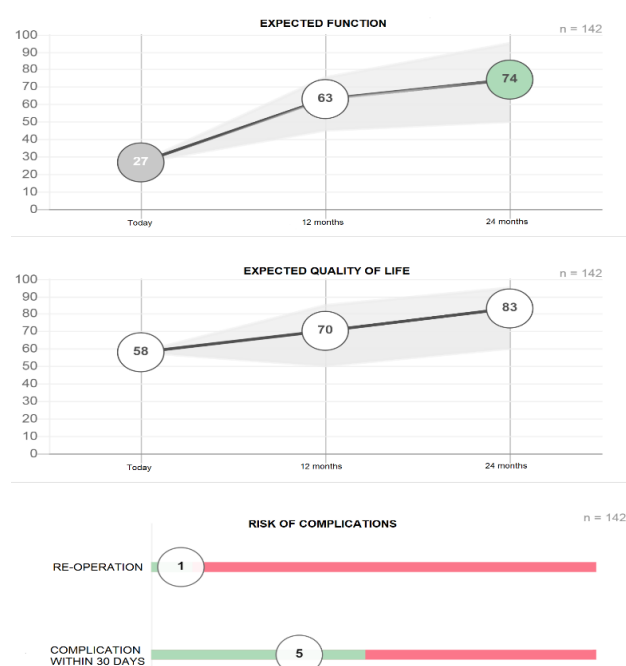


Figure 3 The transformation of the algorithms into graphs. The graphs were made available to the physician and patient as a shared decision-making system in the EHR.

All data was stored in the model; when the patient answered a new PRO-questionnaire one year after surgery, the PRO-data was merged with the stored data. Based on the information, the department then could evaluate the need for physical follow-up based on an actual increase in function. If a patient did not exhibit an increase of more than 14 percentage points in function score, he was contacted by telephone by a nurse. Approximately 10% of the patients were contacted by telephone in this study.

The stored data in the data infrastructure was saved, making it possible for the chief physician to oversee all patient records and create status report for each physician. Thereby, the saved data in the data platform also serves as registry available for the chief physician and used for quality, research and benchmarking purposes.

Evaluation studies of the data infrastructure indicate that the data was extracted correctly, while challenges with data information on mental disorders like depression and anxiety were present, as many patients were treated by their general practitioner without ever being diagnosed at the hospital. The time span from entering the patient ID into the EHR to making the prediction was determined to be between two and three minutes. Early studies indicate that the predicted results of the model vary between $\pm 20\%$.

However, the evaluation also illustrated that a prediction indicating an improvement did, in fact, result in an improvement. Furthermore, early studies indicate that the visitation threshold seems to be at a proper level in order to differentiate between the patient's need for physical follow-up one year after surgery. Based on the result, the clinic accepted both models in the futuristic workshop by demanding new modelling in the future to ensure the most accurate prediction. The physicians also demanded an investigation of potential challenges relate to higher resource consumption among secretaries and nurses when creating new workflows using PRO.

The chief physician, the physician responsible for research and the project group, developed a learning programme, emphasizing that the prediction model should be used together with a normal physical examination and compared to patient expectations to create shared decision-making. To secure the correct use of the prediction model, the chief physician had overseen preliminary examinations for each physician to support questions from both the patients and physician on how to interpret the results. The project group then implemented a control system, with the purpose of providing an overview of the physicians using the system. A newly extracted statement illustrated seven out of ten doctors are currently using the system.

4 DISCUSSION AND CONCLUDING REMARKS

Previous literature has mainly described how measuring outcomes can improve value by, for example, benchmarking through clinical registries and the GLOBE program [5,7,14], or using outcomes in new reimbursement models [8-11]. Although the value created through using outcomes for quality improvements has been documented, several studies have emphasized that the future of outcome measurement and VBHC involves using outcomes and other collected data in shared decision-making in real-time in the clinic [4-5, 22-23]. However, many previous studies have also reported challenges with the existing data infrastructure, which supports the transition from using data and measured outcomes as historical data to using data in real-time. This paper demonstrated the feasibility of combining the VBHC framework with the CRISP-DM model, which can be used to activate data in the care cycle in real-time by developing a shared decision-making system usable in preliminary examination as well as a clinical support system for identifying the patient needs for physical follow-up one year after surgery. The CRISP-DM methodology fit well in the VBHC framework, as the method has an explicit focus on creating business-value, business understanding (defined in healthcare as the care cycle), data understanding, and data preparation. All of these concepts are important in determining how data activation can improve value creation in healthcare, as defined in component six of the VBHC framework.

The CRISP-DM methodology has previously been criticized for its lack of definition and details [27]; however, its explicit focus on the care cycle, outcomes, and risk factors in the VBHC framework provides a guiding principle for the methodology. Resultantly, the critique of CRISP-DM methodology can, in this case, be viewed as a strength as the methodology, enabling DM projects within

different patient groups to be tailored to disease-specific areas (e.g., in terms of how and when to measure outcomes and the possibilities of transforming data into clinical, actionable knowledge).

This study identified a general method and guideline through which to integrate both historical and real-time data from different systems into clinical support systems and shared decision-making systems. The present case also illustrated that an important component of data activation involves understanding the care cycle and identifying the data usable for value creation as well as building a data infrastructure that enables the merging of both historical and real-time data. The data infrastructure establishes the access necessary for transforming the data into usable information in real-time without burdening healthcare professionals with extra registration tasks. The ability to transform historical and real-time data into real-time shared decision-making creates new possibilities to not only use patient-reported outcomes for evaluation and quality improvement but also for acting upon these collected outcomes, improving the results for each specific patient. Establishing a usable data infrastructure has enforced the clinical implementation of outcome measures and patient involvement in terms of shared decision-making, which is fully aligned with the VBHC framework [22].

This case illustrated how data can be activated, but the project did not fully investigate the entire value creation of both the prediction model and visitation threshold for one-year post-operative follow-up. Furthermore, the value creation based on the data models should be evaluated in accordance with the entire VBHC framework [28]. This includes not only the evaluation of the feasibility of the models but also whether the organizational set-up, reimbursement models, and health care delivery facilities support new decisions and quality improvement based on the models (e.g., decreased number of operations or referrals to supervised rehabilitation).

Future models based on the data infrastructure could expand to include, among others, the prediction of treatment for both operative and non-operative patients, prediction of subgroups benefitting from supervised rehabilitation compared to non-supervised rehabilitation, and clinical decision-making systems for individual patients needing postoperative physical follow-up based on baseline data compared to post-operative data. When scaling this case to other medical specialties, the data infrastructure can be reused but the other phases of CRISP-DM model combined with the VBHC framework should be repeated. Further, the infrastructure is capable of extracting data for risk stratification; however, the risk profile is based on the data available in the regions and at the hospitals and may not have sufficient data to provide a proper data definition. In this case, this was illustrated by some of the mental disorder definitions, like depression, which were difficult to identify since most of the patients were diagnosed and treated by their general practitioner. Furthermore, the data infrastructure can only be used when extracting data from registries owned by the region or hospital and where data are where the legal purposes for the collected data is patient treatment or quality development.

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