

Improving cardiovascular disease management by implementing value-based healthcare principles

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IMPROVING CARDIOVASCULAR DISEASE MANAGEMENT BY IMPLEMENTING VALUE-BASED HEALTHCARE PRINCIPLES

DENNIS VAN VEGHEL

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Improving cardiovascular disease management by implementing value-based healthcare principles

PROEFSCHRIFT

Ter verkrijging van de graad van doctor aan de Technische Universiteit Eindhoven, op gezag van de rector magnificus prof.dr.ir. F.P.T. Baaijens, voor een commissie aangewezen door het College voor Promoties, in het openbaar te verdedigen op donderdag 29 augustus 2019 om 13.30 uur

door

Hendrikus Petrus Andreas van Veghel

Geboren te 's Hertogenbosch

Dit proefschrift is goedgekeurd door de promotoren en de samenstelling van de promotiecommissie is als volgt:

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Het onderzoek of ontwerp dat in dit proefschrift wordt beschreven is uitgevoerd in overeenstemming met de TU/e Gedragscode Wetenschapsbeoefening.



La création commence par la vision

Henri Matisse

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aan hartklep daalt fors

Introduction and research perspectives

CHAPTER 1

INTRODUCTION

As in many countries, healthcare costs in the Netherlands have increased over the last few decades. [1,2] Several studies have indicated a considerable increase of costs in the next few decades due to many factors. These factors include the introduction of new treatment options, the increasing prevalence of chronic diseases and higher life expectancy. At the same time, differences in quality in healthcare are observed, leading to differences in clinical outcomes. [3-10] Increased healthcare costs may result in the repression of other government expenditures, the exceeding of public debt and an increase in taxes and premiums. [11,12] Consequently, the community is in need for high quality, reduction in healthcare costs and transparency regarding healthcare quality. It is expected that following the strategy of continuing the current leading principles in healthcare, e.g. cost control, budgeting and volume incentives, will not be sufficient to shift the curve of costs in healthcare and decrease the variety in quality in healthcare by improving outcomes.

Value-based Healthcare (VBHC) was introduced by Porter and Teisberg in 2006 as a strategy to improve healthcare systems by improving outcomes and reducing costs. [13] Patient value is defined as the achieved health outcomes divided by costs of care delivery. [14] Worldwide, VBHC is seen as a promising strategy to solve the crisis in healthcare. Improving the performance and accountability in healthcare depends on having a shared goal that unites the interests and activities of all stakeholders. [15] In VBHC, achieving high value for patients becomes the overarching goal in healthcare delivery, as this goal is what matters most to patients and unites the interests of all actors in the healthcare system. [15]

THEORETICAL VALUE-BASED HEALTHCARE FRAMEWORK

While healthcare organizations have never been against improving outcomes, their central focus has been on growing volumes and maintaining margins. [15] Embracing the goal of value at the senior management and board levels is essential, because the value agenda requires a fundamental departure from the past. [16] When planning to shift towards a value-driven system, senior management of healthcare organizations should define the mission, vision and strategy of the organization. [17]

In specific perspective of VBHC, it is advised that senior management ask themselves six specific and elementary questions, when defining the strategic course of the organization: [17]

- 1. What is our fundamental goal?
- 2. What business are we in?
- 3. What scope of businesses should we compete in?
- 4. How will we be different in each business?
- 5. What synergies can we create across business units and sites?
- 6. What should be our geographic density and scope? [17]

Answering these questions will help organizations to define a strategy, amongst others by making choices that are necessary to distinguish an organization in meeting customers' needs. [17] In VBHC, customers are defined as a patient group with the same medical condition. After defining this patient group and answering the six questions, the VBHC implementation strategy should be designed with help of six important strategic domains (Figure 1), that are mutually reinforcing [16]:

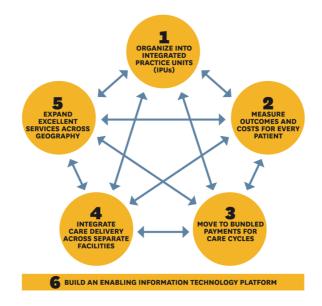


FIGURE 1. The six domains needed to design value-based healthcare implementation strategy [16]

- Organize into Integrated Practice Units (IPUs)
 In an IPU, the organization is structured around the need of the customer, patient groups with the same medical condition. A shift is made from today's siloed organizations towards departments including all specialisms that are needed to organize healthcare delivery for the patients' medical condition.
- Measure Outcomes and Costs for Every Patient Outcomes, the numerator of the value equation, are specific per medical condition and multidimensional, as no single outcome captures the results of healthcare. [15] As outcomes are the results of the full cycle of care, it is important to have clear insight in the full care delivery value chain (Figure 2). [18]

WLEDGE						\ \
FORMING	Education and reminders about regular exams Lifestyle and diet counseling	 Counseling patient and family on the diagnostic process and the diagnosis 	 Explaining and supporting patient choices of treatment 	patient and family on treatment and prognosis	Counseling patient and family on rehabilitation options and process	Counseling patient and family on long term risk management
EASURING	Self exams Mammograms	Mammograms Ultrasound MRI Biopsy BRACA 1, 2,		Procedure- specific measurements	Range of movement Side effects measurement	Recurring mammograms (every 6 months for the first 3 years)
CCESSING	Office visits Mammography lab visits	Office visits Lab visits High-risk clinic visits	Office visits Hospital visits	Hospital stay Visits to outpatient or radiation chemotherapy units	Office visits Rehabilitation facility visits	Office visits Ammographic labs and imaging center visits
ACCESSING	MONITORING/ PREVENTING • Medical history • Monitoring for lumps • Cantrol of risk factors (obesity, righ fat diet) • Cinical exams • Genetic screening	HAGNOSING Hedic al history Determining the specific nature of the disease Genetic evaluation Choosing a treatment plan	PREPARING ·Medical counseling ·Surgery prop (anesthetic risk assessment, EKG) ·Patise or anco- plastic surgery exclusion	INTERVENING *Surgery (breast preservation or mastectomy, oncoptastic atternative) *Adjuvant therapies (hormonal medication, andior chemotherapy)	RECOVERING/ REHABING • In-hospital and outpatient wound heating • Psychological counseling • Treatment of side effects (skin damage, neurotoxic, cardiac, nausea,)ymphodema and chronic latique) • Phy sical Herapy	MONITORING/ MANAGING Periodic mammography -Olber maging -Followup clinical examp for exit 2 years - Treatment for any concerned side effects

The Care Delivery Value Chain Breast Cancer Care

FIGURE 2. Integrating access the cycle of care [18]

Process and structure measures can be helpful in measuring preconditions for outcomes (Figure 3). [19]

In the end, the outcomes that matter most to patients are the main goal. The outcome measure hierarchy helps to understand the relation between the different outcomes by weighing their relative importance to patients.

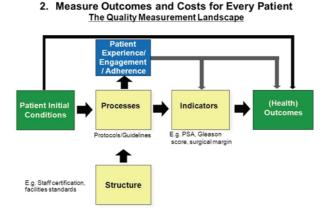


FIGURE 3. Measuring outcomes and costs for every patient [19]

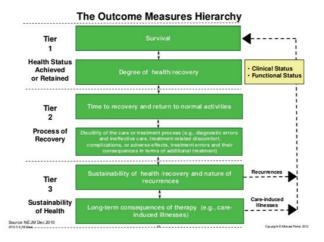


FIGURE 4. Hierarchy of outcome measures [15]

This is achieved with help of three tiers: Health Status Achieved or Retained, Process of Recovery, and Sustainability of Health (Figure 4). Ultimately, this hierarchy can be used to prioritize the outcomes. [15]

Outcome measures that matter most to patients should be selected carefully, with involvement of patients. For quality monitoring and improvement, it is advised to use a limited set of outcome measures covering all tiers of the outcome measure hierarchy.

Costs, the denominator, should reflect the total costs of the full cycle of care for the patients' medical condition, including all involved healthcare providers. In VBHC, it is believed that measuring these costs over the entire cycle of care and weighing them against the outcomes will enable truly structural outcome improvement and cost reduction. This is achieved by re-allocation among services, elimination of non-value-adding services, better use of capacity and shortening the cycle time. [15] Costs should be measured on a detailed level with use of Time Driven Activity Based Costing. [18]

3. Move to Bundled Payments for Care Cycles

The bundled payment approach, which is best aligned with value when covering the full cycle of care, is believed to directly encourage teamwork and highvalue care. [16] The bundle includes all healthcare activities that are relevant in the care delivery value chain. Also incentives for outcomes can be added to the payment system. Providers can benefit from improving efficiency while maintaining or improving outcomes.

4. Integrate Care Delivery Systems

Healthcare for many medical conditions is delivered by multiple directly involved healthcare providers. Patient outcomes depend on and might be improved by optimal coordination and system integration in this network of healthcare providers. To achieve true system integration, healthcare providers should face four challenges: defining the scope of services, concentrating high volume services in fewer locations, select the right location for each service and integrate care for patients across locations. [16]

5. Expand Geographic Reach

When delivering high patient value, superior providers for particular medical conditions should expand their geographic reach, remaining focused on value not on volume. In general, two principle forms are available. The hub-and-spoke

model is based on satellite facilities that are established and, at least partially, staffed by the parent organization. In the clinical affiliation model, IPU's partner with other providers using their facilities rather than adding capacity. [16]

6. Build an Enabling IT Platform

Information Technology (IT) systems often complicate multidisciplinary and network care. An IT platform that can enable value-driven health delivery should be centered on patients, use common data definitions and encompass all type of patient data (e.g. notes, lab tests, images). Also it should be accessible for all healthcare providers involved and include templates and expert systems for medical conditions. Finally, it should easily enable information extraction. [16]

Measuring outcomes

Given these key elements in the VBHC strategy, it is recommended to start with measuring outcomes for the following five reasons: [20] 1. Outcomes define the goal of the organization and set direction for its differentiation; 2. Outcomes inform the composition of integrated care teams, as outcomes can bridge the disciplinary divide in healthcare by creating a shared goal for multidisciplinary teams; 3. Outcomes motivate physicians to compare their performance and learn from each other; 4. Outcomes highlight value-enhancing cost reduction, because insights in outcomes also enable physicians to evaluate the added value of prescribed medicine, applied therapies and other investments in daily healthcare delivery; 5. Outcomes enable payments to shift from volume to results. [20]

Physician-driven program

Although it is essential that senior management of healthcare providers defines and designs the VBHC strategy for its organization, VBHC should be implemented as a physician-driven change program. Physicians are the key in organizing and optimizing patient pathways and collaborate with other providers in daily healthcare delivery. In addition, they have the knowledge to define outcome measures, interpret outcomes measured and define hypotheses how to improve outcomes by improving the process of healthcare delivery. [21-23]

EXAMPLES OF THE IMPLEMENTATION OF VBHC

The VBHC strategy is partly based on key elements of best practice organizations. For instance: Porter described Virginia Mason's Spine Clinic as an IPU example [16], Martini Clinic is a leading example for outcome measurement and improvement routine [24], University of California Los Angeles' (UCLA) kidney transplant program is a bundled payment example and the Children's Hospital of Philadelphia is renowned for the integration of their network. [16] So, all over the world, VBHC initiatives are initiated by healthcare providers to shift towards a value-driven system. Most providers focus on measuring and improving outcomes or introducing bundled payment models. [3-9] The International Consortium for Health Outcomes Measurement (ICHOM) initiative stimulates this shift by defining standard sets of outcomes for the most common diseases and creating an international benchmarking and learning community. [25] Although VBHC has been created mainly by the healthcare organization in the United States [16], many of the defined problems that need to be solved in order to improve patient value still exist in the Netherlands.

In the beginning of this decade, quality management in Dutch healthcare was focused on process and structure measures, rather than outcomes. [26] Integrated Practice Units (IPU's) were not well-developed for most of the diseases (medical conditions). Hospital payment systems are based on diagnosis – treatment combinations (DOT's). Although DOT's are defined as a short bundle, volume is still being rewarded. The connection to quality as well as its in-hospital payment needs to be defined. Network integration could benefit from the improvement as most organizations primarily focus on the element of the patients' total value chain they provide. Therefore, the implementation of VBHC principles can be valuable and useful for the Dutch healthcare system.

Over the last 5 years, a shift towards a more value-driven healthcare system has been initiated in the Netherlands. Several organizations and initiatives, such as ParkinsonNet, Diabeter and Santeon, have contributed to this development. Nowadays, the Ministry of Healthcare has embraced VBHC as a leading principle in their policy for the next years. [27]

CARDIOVASCULAR DISEASES IN THE NETHERLANDS

Cardiovascular disease is the most common cause of death in the whole world. [28] In the Netherlands, cardiovascular disease is the second most frequent cause of death (27%). [29] Management of cardiovascular diseases in the Netherlands requires the most financial investments in Dutch healthcare. Coronary heart disease is one of the most prevalent chronic diseases [30], often correlated with poorer quality of life. [31] Other chronic high prevalent cardiovascular diseases like heart failure, atrial fibrillation and aortic valve disease are renowned for their impact on survival and quality of life as well as on healthcare costs. Therefore, the domain of cardiovascular diseases is an interesting field to implement VBHC principles and evaluate the impact of this promising theory.

1

IMPLEMENTATION OF VBHC PRINCIPLES IN DUTCH CARDIAC CARE

In the beginning of this decade, the first physician-driven efforts in Dutch healthcare to move towards a more value-driven cardiovascular healthcare system were started in cardiac care. These initiatives have focused on measuring outcomes that matter most to patients and quality improvement.

The "Meetbaar Beter" initiative

In 2011, the heart centers of the Catharina Hospital in Eindhoven and the St. Antonius Hospital in Nieuwegein, two leading Dutch heart centers, initiated a national, transparent outcome benchmarking initiative, called 'Meetbaar Beter'. Outcome measures that matter most to patients were selected using a solid methodology based on the VBHC theory. This involved all high-volume cardiac medical conditions, e.g. coronary artery disease, aortic valve disease, atrial fibrillation and mitral valve disease. [7] In addition, the most important patient initial conditions were selected to be able to study subgroups of patients and apply risk correction in the analysis. The selection was validated by independent international experts per medical condition. The Dutch patient organization was involved to ensure patients perspective. Health insurance companies, the Dutch healthcare inspection, the Dutch ministry of healthcare and other regulators were informed and asked for advice on the process level. Outcomes of the participating hospitals, including mortality, complications, reinterventions and quality of life, were published transparently, as public reporting is known to contribute to better outcomes. [32, 33] This initiative expanded as many hospitals started to join the effort to improve transparency and quality in Dutch cardiac care. In 2017, 14 out of 16 Dutch cardiac centers and 7 centers performing Percutaneous Coronary Interventions (PCI) without local back up were joining the program. The participating hospitals yearly published their outcomes. Consequently, several improvement initiatives within hospitals were observed. In 2014, the first roll out project of possible best practice, namely the Isala Safety Check was initiated; this was selected because of significant lower mortality in Isala.

In 2017, Meetbaar Beter was merged with the Netherlands Cardiovascular Data Registry and the "Begeleidingscommissie Hartinterventies Nederland" into the Netherlands Heart Registration (NHR). The NHR is an integrated cardiology and cardiac surgery registration, which enables the monitoring of outcomes on the level of a medical condition in addition to the level of a specific treatment. This is relatively unique in an international perspective. The nationwide registration organization with

all participating Dutch hospitals, is supported by the Dutch society of cardiologists (NVVC) and the Dutch society of cardiothoracic surgeons (NVT). The cardiac anesthesiologists participate in the registry via their own cardiac center. The NHR is expected to be able to contribute to quality assurance and improvement in Dutch cardiac care through creating insights in outcomes that matter most to patients and facilitating the sharing of good or best practices. Also, the central database is expected to be able to reduce workload of registration. Within the NHR, a specific VBHC program is organized to continue the innovative and physician-driven philosophy of "Meetbaar Beter".

The Catharina Heart Center

In parallel, the heart centers of the founding fathers of Meetbaar Beter, the St. Antonius Hospital and Catharina Hospital, started to implement the VBHC strategy in a broader perspective. The St. Antonius Hospital started to adopt the VBHC strategy organization wide and implemented VBHC principles in several projects in the years following. Amongst others, the St. Antonius Hospital embedded patient-relevant outcomes in the yearly quality meetings between the executive board and the physician teams, implemented outcome-based incentives in the payment structure for physicians and started a VBHC research program containing 10 researchers in 2019. In 2018, the St. Antonius Hospital started to publish outcomes on its website to inform patients starting with cerebrovascular accidents (CVA), cancer bladder and obesity. Both the Catharina Hospital and the St Antonius Hospital are members of the Santeon group, which became a partner of ICHOM and contributed to the implementation of VBHC on a national and international level for several medical conditions in oncology. At the core of the Santeon program are the multidisciplinary, multicenter teams that are building a shared quality improvement cycle based on outcomes, costs and process measures. [34]

The Catharina Heart Center (CHC) started the implementation of the VBHC strategy in 2012 by creating an integrated practice unit (IPU). The outcomes selected in "Meetbaar Beter" were used for quality monitoring and improvement. In addition to the yearly transparent benchmark, CHC implemented dashboards to monitor its own outcomes over time. A quality committee was introduced to monitor outcomes in a multidisciplinary setting. Several improvement initiatives were organized, contributing to improved survival rates, fewer complications and less re-intervention for different patient populations in cardiac surgery, interventional cardiology and electrophysiology. Subsequently, more domains of the VBHC strategy were covered by the implementation of new collaboration models; for instance with referral cardiologists in St. Jan Gasthuis (SJG) Weert. Also in the Netherlands Heart Network, a joint network initiative of general practitioner organizations "De Ondernemende Huisarts (DOH)", "Stichting Gezondheidscentra Eindhoven (SGE)" and "Praktijk Ondersteuning Zuid Oost Brabant (POZOB)" and cardiologists from Elkerliek Hospital, Maxima Medical Center (MMC) and St Anna Hospital healthcare providers in the region were connected aiming to improve patient value. The introduction of the Netherlands first bundled payment model was organized in collaboration with CZ health Insurance company. The CHC, together with nine other hospitals, also joined the bundled payment project organized by the Netherlands Heart Registration and Menzis health insurance company. Finally, a model to measure both outcomes and costs including risk correction was developed and implemented.

AIM OF THE DISSERTATION

The aims of this dissertation are to describe the development of a transparent national outcome-based learning community, to illustrate the introduction of different VBHC-strategies in a hospital setting and to present the results of improvement actions implemented in a Dutch heart center.

Research questions

Given societal urgency and the increase of data availability in healthcare:

- 1. How can VBHC be implemented in a physician-driven way in cardiovascular care:
 - a. In a network with a focus on outcomes and quality improvement?
 - b. In a heart center and its network?
- 2. How can the VBHC strategy be embedded in health management models enabling the implementation of VBHC beyond measuring and improving outcomes?

OUTLINE OF THIS DISSERTATION

In part I of this dissertation, the results and lessons learned of the "Meetbaar Beter" initiative are presented. An overview of the "Meetbaar Beter" project is presented in chapter 2. Outcomes that matter most to patients were selected with the use of a solid methodology, based on the key elements of the VBHC theory. This methodology is presented in chapter 3. Furthermore, chapter 3 contains the first results of the national

benchmarking initiative. The results of the 19 centers joining the program in 2016, for the treatment of coronary artery disease (CAD) are presented in chapter 4, including the progress that has been achieved in the data quality management system. Chapter 5 presents an example, in patients with aortic valve disease, of how data collection and analysis on a national level can create insights in the evolution of outcomes that matter most to patients over time. Creating insights in outcomes has led to an increased level of transparency and to several outcome improvement projects within and amongst hospitals. Also, the first years of experience in the implementation of VBHC in a national community have led to insights in the key elements that need to be developed for VBHC to reach its maximum potential. The lessons learned from the national initiative are presented in chapter 6. Finally, in chapter 7, the current state of the organization of outcome-based improvement cycles in several Dutch heart centers is analyzed and discussed.

In Part II, we explore the possible VBHC models and prerequisites for implementation in the Catharina Heart Center and its network. The first outcome-based purchasing contract in the Netherlands was introduced and is presented in chapter 8. Examples of integrating care delivery across separate facilities between hospitals and in a network including hospitals and general practitioners are presented in chapters 9 and 10. In chapter 11, we present a model to measure both outcomes and costs in a risk-adjusted and physician-relevant manner. This model leads to a quantification of patient value and could enable risk-adjusted benchmarking on patient value, outcomes and costs.

In Part III, chapter 12 provides an overview of the results, also in terms of improved outcomes, and lessons learned in the physician-driven VBHC implementation journey in the Catharina Heart Center. A perspective on changes that are needed in health management and financial models in healthcare in order to reach the maximum impact of VBHC is also addressed. An example of an improvement project related to re-explorations after open heart surgery, as a result of national benchmarking and learning from best practices, is presented in chapter 13.

Finally, in chapter 14, the main findings of the current dissertation are summarized and discussed. Future perspectives are outlined and conclusions are given.

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Building a transparent national outcome-based learning community



CHAPTER 2

Meetbaar Beter: value-based healthcare for heart patients

aan hartklep daalt for:

D. van Veghel, P. van der Nat, E. Daeter

Health Management 2017; 17: 49-52

INTRODUCTION

Meetbaar Beter (En: Measurably Better) is a doctor-driven and patient-focused initiative with strong scientific roots that aims to improve the transparency and quality of cardiovascular care in the Netherlands.

Meetbaar Beter has become an international best practice in the implementation of value-based healthcare (VBHC). The project started as an initiative of two hospitals, and by now 19 heart centres participate, covering over 85 percent of complex heart care in the Netherlands. In 2016, outcomes that matter most to patients have been published for over 150,000 patients, including the treatment of high prevalence medical conditions like coronary artery disease, aortic valve disease, atrial fibrillation and mitral valve disease. Limited sets of outcome measures per medical condition, selected by doctors (cardiologists and cardiothoracic surgeons) and validated by international experts, form the basis for the open learning and development culture of Meetbaar Beter. Doctors gain insight in outcomes and use this information to cooperate and continuously improve the quality of care for heart patients. [1] In this article we share the approach that has led to the success of Meetbaar Beter.

THE GOAL OF MEETBAAR BETER

Meetbaar Beter's aim is to facilitate quality improvement for patients with heart diseases in the Netherlands. Its focus is on health outcomes that matter most to patients. The hypothesis, based on Porter's VBHC[2], is that improvement of outcomes will lead to a reduction of costs. Measuring costs will be included in Meetbaar Beter, in a later phase. Transparency of outcomes is an intermediate but important goal as it helps build high levels of trust between heart centers and stakeholders such as patient organizations, health insurance companies and government organizations. Transparency is considered a sine qua non in being able to identify best practices. Study results support the importance of transparency and its strong relation with quality. [3]

LEADING PRINCIPLES

Meetbaar Beter has a few leading principles. Firstly, it is doctor-driven. Doctors and their teams regularly create changes in healthcare. In Meetbaar Beter, the board of directors, advisory board and outcome team typically consist of doctors making lead decisions. Strong connections have also been built with the Dutch societies

of cardiologists and cardiothoracic surgeons. Secondly, Meetbaar Beter is patientcentered. The organization and improvement work is structured around medical conditions. Outcomes are measured for medical conditions both independent and dependent of the chosen treatment. The selection of outcome measures is validated by large patient groups and outcomes are published in a comprehensible manner for patients. For instance, infographics have been developed (Figure 1). Thirdly, transparency is a leading principle. In Meetbaar Beter, strict data quality and data completeness criteria are used. When the data quality of a hospital fulfils the minimum quality criteria, data is published independent of the results. This has proven to be a strong stimulation for heart centers in improving the guality of data. Already in the very early stage of Meetbaar Beter, the publication of data led to hypotheses for quality improvement. Lessons have been learned quickly by heart centers in organizing outcomes-based quality improvements. Finally, Meetbaar Beter focuses on outcome measures. Outcome measures are considered leading with respect to process and structure measures. Outcomes are influenced by the initial conditions of patients and the quality of care delivery. For an insight in quality of care, in several analyses, outcomes are corrected for the initial conditions of patients. A limited number of process and structure measures can be included to facilitate learning. For example, to evaluate the success rate of techniques.

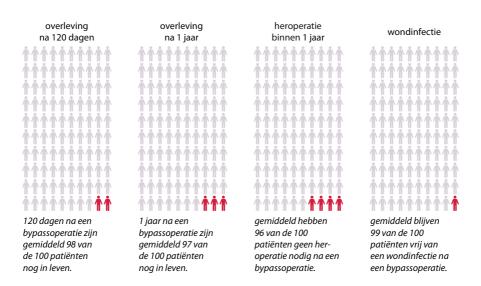


FIGURE 1. Infographic example of a comprehensible outcome publication for patients. The figure includes a 120-day and 1-year survival rate, reoperations and deep sternal wound infections in patients with coronary artery disease (CAD) treated with a Coronary Artery Bypass Graft (CABG).

SOLID METHODOLOGY

The VBHC theory has been implemented within the Meetbaar Beter practice. This is one of Meetbaar Beter's cornerstones of success and it is seen as guidance for other initiatives.

Key factors Include:

- Outcomes Teams. Outcomes teams are formed to select, define, and perform maintenance on the most relevant outcome measures and initial conditions. Outcomes teams are multidisciplinary and are organized around one medical condition. They include both cardiologists and cardiothoracic surgeons from participating heart centers.
- Care Delivery Value Chain. The Care Delivery Value Chain (CDVC) is one of the main elements of Porter's VBHC theory. [4] The CDVC is described by the outcome team and is used to define the medical condition, inclusion/exclusion criteria and any potentially relevant outcome measures.
- Selection Criteria and Outcomes Hierarchy. After defining the medical condition and CDVC, a list is created of all the available outcome measures using scientific and grey literature, the best practices, guidelines and so on. Subsequently, a small, feasible subset of the most relevant outcome measures is made by categorizing them according to the Tiers of Porter's Outcomes Hierarchy. [2] Outcomes within each Tier are then selected and ranked based on the following criteria:
 - 1. Patient Relevance. What is the impact of this outcome on the patient's quality of life? Large patient groups are involved to assess this criterion.
 - **2. Medical Relevance.** To what extent is it possible for healthcare professionals to positively influence the outcomes?
 - **3.** Patient Volume. How many patients is the outcome relevant to? How often does a negative outcome occur?
- Validation. Validation is organized at several levels. Validation is a continuous process that ensures the independence and quality of Meetbaar Beter.
 Internal Validation: Medical and statistical experts engage in total quality management and medical decision-making.

External Validation: An international academic advisory council (IAAC) is organized which consists of independent internationally renowned experts. The IAAC consists of three dimensions:

- Methodology council five experts in VBHC, change management and quality improvement.
- Medical council over 25 renowned medical experts.
- Data management & statistics council two internationally renowned experts.

External Validation: A sounding board is organized to ensure the involvement of health insurance companies, patient organizations and government organizations. Discussions in this sounding board have shown to be helpful in creating an alignment in strategic goals and ensuring a correct interpretation of published data.

- Data Quality System. All participating heart centers are responsible for the completeness and quality of their own data. The Meetbaar Beter organization is responsible for data quality control and for reporting feedback to heart centers. Meetbaar Beter has developed a data quality control system that includes quality control formats, audits performed by medical experts and compliance statements that must be signed by medical leadership at the heart centers.
- Maintenance Cycle. After the annual publication of outcomes, the selected outcome measures and initial conditions are evaluated at several levels. Subject to evaluation are the standard sets of outcome measures, the definitions, data analysis methods and so on. Meetings are organized, questionnaires are sent to medical experts and data managers from participating heart centers and all comments are discussed by the outcome teams. Any adjustments made in the maintenance cycle are regularly checked against all elements of the Meetbaar Beter methodology, such as the selection criteria described above.

Publication of Outcomes

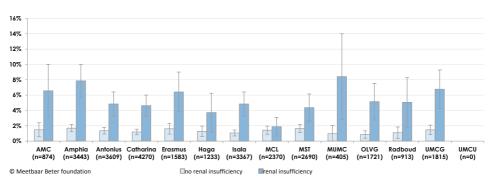
Meetbaar Beter publishes the outcomes per individual hospital and all heart centers combined in the annual Meetbaar Beter Books. [5] The primary goal is to provide insight into the outcomes and to facilitate generation of valid hypotheses on potential improvement. To define such hypotheses, data on outcomes must always be combined with medical expertise. Outcomes are published at three levels. The first level of publication is uncorrected results (Figure 2). The percentage of events

is presented without taking differences in population characteristics into account. Although the comparison of heart centers based on these uncorrected results is not possible, it still gives insight into the true outcomes and offers possibilities for improvement. The second level of publication is segmented outcomes. Outcomes are presented in subgroups of initial conditions without risk correction (Figure 3). This gives doctors a deeper insight into the outcomes for relevant subgroups. Finally, if statistical data are adequate, regression analysis is made. Outcomes are corrected for the impact of the case mix across heart centers. Comparison between heart centers then becomes possible using these analyses (Figure 4).

	AMC	Amphia	Antonius	Catharina	Erasmus	Haga	Isala	MCL	MST	мимс	OLVG	Radboud	UMCG	пмсл	Completeness
Year	'11-'14	'13-'14	'11-'14	'11-'14	'11-'14	'12-'14	'11-'14	'11-'14	'11-'14	2013	'11-'14	'13-'14	'12-'14	'12-'14	
Number of patients	5664	2775	5766	9365	5820	3483	6838	4647	5657	1262	6793	1597	4063	2269	
Outcome measures 30-day mortality	3.0	2.6	2.0	3.3	3.4	3.0	2.1	2.7	2.0	3.2	2.3	3.9	3.1	3.2	99.3
1-year mortality	6.4	5.8	4.4	6.4	6.7	5.5	4.7	5.2	4.4	5.4	4.5	7.6	6.2	7.4	99.1
Quality of life															
Angiography not successful	3.3	3.9	4.1	4.3	5.1		5.4	4.8	2.8	8.0	4.7		3.3	6.8	99.3
Urgent CABG	0.2	0.3	0.3	0.5	0.2	0.6	0.4	0.2	0.2	0.4	0.2	0.1	0.5	0.1	100.0
Occurence of MI	1.1		1.3	1.4	1.3		0.9		1.0					1.9	96.9
Occurrence of TVR	7.8			7.9			7.4		2.9		6.8			12.5	94.1

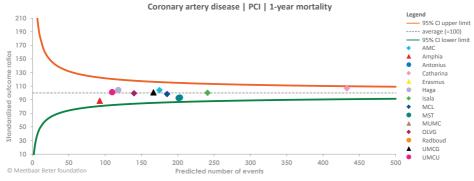
Uncorrected results and distribution of patient initial conditions – Coronary artery disease | PCI

FIGURE 2. The uncorrected results (2015 included 14 centers) for the treatment of patients with CAD by a percutaneous coronary intervention (PCI). (TVR = Target Vessel Revascularization, MI = Myocardial Infarction). Source: Meetbaar Beter Foundation



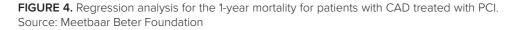
Coronary artery disease | CABG | 120-day mortality | renal insufficiency

FIGURE 3. The dependence of the 120-day mortality on the risk factor 'renal insufficiency' for patients with CAD treated by CAB G. Source: Meetbaar Beter Foundation



C-statistic = 0.83 (goed)

Corrected for Chronic total occlusion, diabetes mellitus, previous MI, previous CABG, gender, age, multi-vessel disease, renal insufficiecy, resuscitation, shock and urgency of the procedure. The regression analysis indicates natural variation between the centers.



Quality Improvement

Meetbaar Beter organizes events that encourage doctors and heart centers to use insights in outcomes as a way to initiate quality improvement projects. Examples are round table sessions where doctors can select best practices; internal events that encourage the organization of quality improvement projects and cycles and finally. brainstorm sessions with doctors to advance data analyses and create more insights. Several heart centers have been successful in organizing improvement projects, and as a result have seen a progress in outcomes. Examples are the reduction of mortality after PCI for patients with renal insufficiency (in OLVG from 9.2% to 5.0%) and complications after PVI (reduction of tamponades in Catharina Hospital from 3.6% to 0.7%) and CABG (reduction of deep sternal wound infections in St. Antonius Hospital from 1.5% to 0.8%). More examples have been published in the Meetbaar Beter Books. [5] A successful practice in Meetbaar Beter was rolled out in 2013. The 2013 regression analyses showed a significant lower mortality rate in Isala. The hypothesis proposed that a check in the operating room called the Isala Safety Check (ISC) contributed strongly to this relatively low mortality rate. The ISC was implemented in six other heart centers that voluntarily joined the project. The implementation will be subject to scientific evaluation.

In 2016, three potential best practices have been selected. These projects include the Haga Braincare Strategy, a protocol to reduce CVAs after heart surgery, a protocol for PCI patients with renal insufficiency used in OLVG; and the Cleveland Checklist used by the Catharina Hospital to reduce reoperations after heart surgery. These projects will be presented to other heart centers for a roll out in 2017.

CONCLUSION

VBHC is a concept that supports and encourages the improvement of quality and efficiency in healthcare. Meetbaar Beter has implemented VBHC in practice, creating an internationally unique and transparent learning environment. The solid methodology of Meetbaar Beter has created traction in Dutch healthcare, built enthusiasm amongst doctors and heart centres and has made a great leap forward in the transparency of healthcare quality. The first results of quality improvement projects within and amongst heart centers are more than promising. The ultimate success of Meetbaar Beter and VBHC will be concluded within a few years. With regards to Meetbaar Beter, success is defined by improved outcomes over the full range of medical conditions in heart care.

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CHAPTER 3

First results of a national initiative to enable quality improvement of cardiovascular care by transparently reporting on patient-relevant outcomes

D. van Veghel, M. Marteijn, B. de Mol on behalf of the Measurably Better Study Group (The Netherlands) Advisory Board.

European Journal of Cardio-Thoracic Surgery 2016; 49:1660-9

ABSTRACT

Objectives: First, to assess patient-relevant outcomes of delivered cardiovascular care by focusing on disease management as determined by a multidisciplinary Heart Team. Second, to establish and share best practices by comparing outcomes. Third, to embed value-based decision-making to improve quality and efficiency in Dutch heart centers.

Methods: In 2014, twelve Dutch heart centers pooled patient-relevant outcome data, which resulted in transparent publication of the outcomes, including long-term followup up to five years, of approximately 86 000 heart patients. This study presents the results of both disease- and treatment patient-relevant outcome measures for coronary artery disease (CAD) and aortic valve disease (AVD). The patients included were presented to a Heart Team and underwent invasive or operative treatment. In-hospital and out-of-hospital patient-relevant outcome measures were collected as well as initial conditions. Quality of life was assessed using the Short Form (SF)-36 or SF-12 health survey.

Results & Discussion: In the Netherlands, patient-relevant and risk-adjusted outcomes of cardiovascular care in participating heart centers are published annually. Data were sufficiently reliable to enable comparisons and to subtract best practices. The statistically lower risk-adjusted mortality rate after coronary artery bypass grafting (CABG) resulted in a voluntary roll-out of a peroperative safety check. The in-depth analysis of outcomes after percutaneous coronary intervention (PCI) resulted in process improvements in several heart centers, such as pre-hydration for patients with renal insufficiency and the need of target vessel revascularizations within a year.

Conclusion: Annual data collection on follow-up of patient-relevant outcomes of cardiovascular care initiated and organized by physicians, appears feasible. Transparent publication of outcomes drives improvement of quality within heart centers. The system of using a limited set of patient-relevant outcome measures enables reliable comparisons and exposes the quality of decision-making and operational process. Transparent communication on outcomes is feasible, safe and cost-effective and stimulates professional decision making and disease management.

Key words: outcomes, patient-relevant, cardiovascular, quality improvement, transparency, value-based healthcare

INTRODUCTION

Determining the costs of cardiovascular care and measuring patient-relevant health outcomes are essential in order to assess the relationship between the benefits to the patient and the costs incurred per patient and per institution. [1, 2] In the Netherlands, the cardiothoracic surgical community is fortunate to have a registry which contains elements of the European system for cardiac operative risk evaluation (EuroSCORE), the in-hospital mortality and morbidity of all Dutch cardiothoracic centers.[3] This registry has been publishing the EuroSCORE-adjusted in-hospital mortality rates from Dutch cardiothoracic centers since 2013.

For two decades it has been general practice in Dutch heart centers that a multidisciplinary Heart Team decides on the timing and modality of treatment for patients presented for an intervention. Although the cardiothoracic surgical registry enables partial assessment of the decision performance of the Heart Team and the heart center in general, the aggregation of these outcomes with the outcomes of patients with the same cardiac disease who do not receive surgical treatment does complete the assessment of the disease management decisions and treatments. This methodology is in line with the Value Based Healthcare (VBHC) theory, which describes that the patient-relevant outcomes should be evaluated based on the full cycle of care for the patient's medical condition, rather than comparing isolated interventions. Therefore, outcome analyses should be based on patient groups with the same medical condition. From this point of view all patients with coronary artery disease (CAD) or aortic valve disease (AVD) should be included in the study enabling the evaluation of the performance of heart centers. For instance, the medical condition CAD includes patients with proven ischemia, treated with coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI) or optimal medical treatment (OMT). Similarly, the medical condition AVD includes symptomatic patients with proven severe aortic valve stenosis and/or aortic valve insufficiency treated with aortic valve replacement (AVR), transcatheter aortic valve implantation (TAVI) or optimal medical treatment (OMT).

Today in healthcare, it is not only survival but also complications, re-interventions and a gain in or restoration of quality of life (QoL) in relation to costs that are considered to be the standard elements to measure quality of performance and cost-effectiveness. [4, 5] The urgent need for good financial management and efficiency is not only a priority for a cost-saving strategy but also for making resources available for innovation projects.

The initiative and organization

A large and growing group of members of the Dutch community of cardiac interventionists (both cardiologists and cardiac surgeons) is convinced that further improvement of quality and patient safety can be achieved only by measuring patient-relevant outcomes and sharing and adopting each other's best practices. The physician's motivation is not only driven by the desire for figures and analyses, but also by a drive to adopt improvement strategies based on outcomes research other than the usual reports on mortality and complications. A previous study has already shown the improvement of outcomes as a result of the implementation of a registry that focuses on quality improvement. [6] The emphasis will be on measuring the sustainability of the improved health situation and QoL. In time, the outcomes will be compared to the wide variety of costs made. [1, 2]

This has resulted in a national bottom-up initiative by cardiac surgeons and cardiologists to further improve the quality and transparency of care for patients with a heart disease by systematically and voluntarily collecting outcome data with, amongst other outcomes, a long term follow-up of at least a year, and often longer. Outcome data comprises all patients with the same medical condition and all interventions carried out. This initiative is known as the Netherlands Joint Outcomes & Transparency Initiative and came about at the instigation of physicians, not institutions or health care insurers. It carries the working title *Meetbaar Beter*, which means Measurably Better. For the purpose of this communication we will use the term Measurably Better (MB).

The selected outcome measures are maximally patient-oriented and clinically relevant and form the basis of the transparent reporting of the results of care for patients, physicians, health care insurers, government and other decision makers. Furthermore, these outcomes include mortality and complication rates during hospital stay and long-term follow-up thereby enabling to provide a clear overview of the overall performance of a heart center. In previous studies, it was observed that it made a significant difference to let the assessment of performance be determined by in-hospital mortality and overall 30-day mortality or longer-term survival. [7, 8]

The participation of heart centers in MB is voluntary and signing on means commitment by contract to deliver authentic, complete, and transparent data and to agree on publication of the results. Reporting on patient-relevant outcomes may serve as the starting point for a cycle of improvement within each of the participating heart centers. These improvement cycles are based on the plan-do-study-act (PDSA) method. [9, 10] This method is widely accepted to drive improvement in healthcare.

Furthermore, reporting on outcomes may help in sharing relevant insights, stimulating learning effects and adopting each other's best practices. Also, bench-marking or comparisons on supra-institutional level are helpful to expose shortcomings and best practices. A previous study showed significant differences in 30-day mortality rates after acute myocardial infarction between the United Kingdom and Sweden, which indicates the relevance of a simple set of parameters and a need for sharing best practices at international level. [11]

Every year, MB organizes public and internal events where best practice, projects for improvement and analysis are being shared. In this way MB facilitates an environment for learning, sharing and improving. MB contributes to making well-documented and preferably evidence-based decisions on care for heart patients in the Netherlands.

METHODS

General principles

The MB initiative is driven by the VBHC methodology developed at Harvard Business School by Porter. [1] The core idea of VBHC is the assumption that care can be improved by concentrating on maximizing the 'value' for patients, defined as the outcomes of care and QoL in relation to the costs of care. The implementation of VHBC has turned out to be feasible in all aspects of the MB initiative.

Supported by an International Academic Advisory Council of medical and methodological experts, which ensures the validity of the parameters collected as well as their relevance and impact, the first task of MB was to select those standardized outcome measures which are most relevant for the patient and scientifically validated. For each medical condition an integrated outcome team, consisting of cardiologists and thoracic surgeons of the participating heart centers, has been created. These teams carry out the selection of outcome measures and initial conditions. Furthermore, the teams are also involved in the annual maintenance cycle. During this cycle the selection and definitions of the outcome measures and initial conditions are further improved when necessary.

The outcome hierarchy of Prof. Porter was used to select the outcome measures in all relevant matters from a patient's point of view. [1] The first criterion in the selection of outcome measures is the impact on the QoL of patients. The other criteria are the prevalence of the outcome and the possibility for physicians to influence the outcome. Furthermore, the feasibility of data collection and the quality of the definition were

considered to decide whether or not the outcome measure is included. The initial conditions that are considered to influence the outcomes, were selected based on the impact on the outcome measures, feasibility of data collection and volume.

In case MB selects an outcome measure or an initial condition that is part of an existing registry, and this registry already has proper definitions for outcome measures or initial condition, MB copies these definitions in order to keep the workload of registration as low as possible.

To date, MB has defined and collected data for sets of outcome measures and initial conditions for common and relevant heart diseases such as CAD (CABG, PCI and OMT), AVD (AVR, TAVI and OMT) and atrial fibrillation (catheter pulmonary vein isolation and surgical pulmonary vein isolation). Data on outcomes and QoL for these medical treatments are collected from the integrated care systems at the participating centers, including both short-term follow-up and a follow-up of 12 months or longer. Data from emergency procedures are also included in CABG and PCI, as are data from patients who have not been discussed by the Heart Team. MB has defined sets of outcome measures, and initial conditions for other heart diseases such as mitral valve disease, tachycardia and for conditions such as being at risk for sudden cardiac death. Data on these heart conditions has not yet been collected due to the data collection workload at participating heart centers. Mortality, QoL, morbidity and re-interventions are examples of outcomes being measured and presented publicly. The sets of outcome measures and initial conditions are available on the MB website (http://www.meetbaarbeter.com).

Once the professional groups at a heart center decide to participate in MB, they are charged equally for the expenses incurred in running the MB organization, which is a non-profit foundation. The Board of Directors and the Advisory Board of MB is made up exclusively of physicians. Each participating heart center has a representative on the Advisory Board. The Board discusses important strategic and tactical issues as well as the yearly budget of MB.

MB works closely with the International Consortium for Health Outcomes Measurement (ICHOM). Although the CAD outcome measures set is a bit more focused it is strongly aligned with the outcomes defined by ICHOM. [12] The sets will merge over time as MB physicians join the medical expert groups of ICHOM. The development of an indicator set for heart failure will be a joint effort, with MB physicians joining the expert group and MB sharing the implementation experience.

Data collection & management

Data manuals are provided to ensure consistency in data collection in all participating centers. The detailed definitions of the outcome measures and initial conditions are included in these manuals, which are available at the MB website (http://www. meetbaarbeter.com). These manuals are updated on a yearly basis as a result of the annual maintenance cycle. MB conducts annual audits at each of the participating heart centers, both on a medical and a process level. In order to guarantee the quality of the results quality requirements are imposed on the completeness of the data. To ensure that data of all patients, who are eligible for inclusion, indeed are submitted to MB, the medical specialist of the participating hospital is made formally responsible for the quality of the data delivery and transfer; he needs to sign for the accuracy and completeness of the data. The number of submitted patients are compared with the number of treated patients published in the annual reports of the hospitals. Also, auditing teams do conduct checks on completeness and the integrity of the data. Data collection and analysis process steps are objectively and completely documented to ensure that medical and methodological choices and potential changes can always be traced and evaluated. For instance, the outcomes of morbidity and mortality are collected each year. Subsequently, the risk-adjusted outcomes are published and used for learning by transparent comparisons of performance.

In this article we discuss the patient-relevant outcomes of CAD and AVD. The focus is on the surgical procedures CABG, PCI, AVR and TAVI, which also showed near complete datasets and follow-up. The study includes patients who were treated in the 12 participating heart centers between January 1, 2009 and December 31, 2013 for CABG, AVR and TAVI and between January 1, 2011 and December 31, 2013 for PCI. The data were used to benchmark patient-relevant outcomes, including long-term follow-up outcomes.

Follow-up

The follow-up data including out-of-hospital data were collected by well-trained students visiting the regional hospitals and/or by written surveys sent to the patients. Heart centers are mandatory to demonstrate that the follow-up has been carried out for the complete patient cohort. A maximum of 10% random missing values is allowed.

QoL of elective patients was assessed using the SF-36 or SF-12 health survey before the intervention (maximum 2 months before intervention) and 10-14 months after the intervention using a written survey. Participation in the survey was voluntary and the patients filled out the survey by themselves at home or in the hospital. Only patients who survived the follow-up period of one year and who completed the pre- and postintervention survey were included in the analysis. The pre- and post-intervention QoL scores were divided into the eight healthy domains that have been validated in a series of cross-cultural studies. [13, 14] At least 50% of the questions of each domain had to be filled out for inclusion. Furthermore, the QoL score of each domain was compared with the mean score for healthy volunteers. [25]

Statistics

To ensure good quality data, heart centers with more than 10% missing data for an outcome measure were excluded from the analyses for the outcome measure concerned. In addition, patients for whom a specific outcome measure was unknown were excluded from the analyses. The mortality data were collected using the electronic database of regional municipal administration registration (Gemeentelijke Basis Administratie (GBA)) resulting in almost 100% completeness of the mortality data. The completeness of the data related to complications was between 95% and 100%. For the analyses related to one-year follow-up outcome measures, patients treated in 2013 were excluded since not all patients have a complete follow-up of one year when executing the analyses in May, 2014.

The patient-relevant outcomes have been published on three levels:

- 1. The uncorrected percentages of the prevalence for each selected outcome measure were calculated
- 2. The segmented uncorrected percentages of the prevalence for each selected outcome measure were calculated, which indicates the dependence of the outcome measure relative to the most important selected initial conditions.
- 3. If a power calculation indicated that the power was sufficient to show reliable differences between heart centers, a logistic regression analysis was performed enabling the presentation of the outcome measure in a funnel plot. In the funnel plot the percentage of the standardized number of cases was plotted against the number of expected cases. The percentage of the standardized number of cases was calculated by dividing the number of observed cases by the number of expected cases multiplied by 100. The number of expected cases was calculated after adjustment for the selected initial conditions. If a heart center had more than 10% missing values for an initial condition, the condition was excluded from the logistic regression analysis for that heart center. Heart centers with more than one missing initial condition, were also excluded from the logistic regression analysis. In general, initial conditions were excluded from the

logistic regression analysis if 25% or more of the heart centers were not able to provide data for this particular initial condition. The funnel plot also displays 95% confidence limits.

Long-term survival graphs were created for the long-term follow-up outcome measures with a maximum follow-up of five years. The survival curves are created by using a multivariate Cox proportional hazard analysis, which is risk-adjusted for the selected initial conditions.

Both low volume and high volume outcome measures are published. For low volume outcomes the risk-adjustment is often statistically impossible, however clinically relevant insights can still be gained by reporting on low volume outcome measures, as clinical relevance and statistical significance are two different things.

Calculations were performed using SPSS 17.0 (SPSS Inc., USA). The level of statistical significance was set at α =0.05.

RESULTS

Patient-relevant outcomes from daily practice in Dutch heart centers have been collected for approximately 86 000 patients. A complete overview of all reported outcomes is available at the MB website (http://www.meetbaarbeter.com). The results are clustered in accordance with the levels of the outcome hierarchy defined by Porter, i.e. 1) survival, 2) degree of health/recovery, 3) time to recovery and return to normal activity, 4) disutility of the care of treatment process, 5) sustainability of health/ recovery and nature of recurrences, and 6) long-term consequences of the therapy).

Disease specific outcomes

Survival

Figure 1 shows the risk-adjusted 120-days mortality for all so-called consolidated AVD, based on inclusion of both AVR and TAVI treated patients. The 120-days mortality rate was risk-adjusted for age, gender, renal insufficiency, urgency of the procedure, left ventricular ejection fraction, and history of cardiac surgery. The model shows a C-statistic of 0.64, which indicates a relatively moderate predictive accuracy. These preliminary results provide a first step towards the publication of disease specific outcomes. The next step is to complete these results by inclusion of OMT treated patients.

Chapter 3

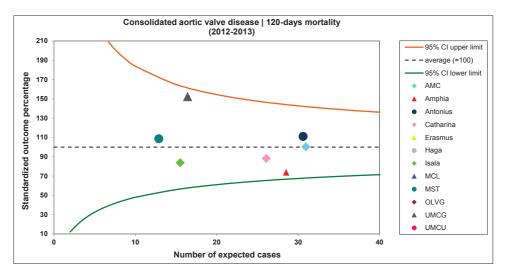


FIGURE 1: Funnel plot of risk-adjusted 120-day mortality rates after consolidated AVD (AVR + TAVI) for 2012-2013. 120-day mortality rates are adjusted for age, gender, renal insufficiency, urgency of the procedure, left ventricular ejection fraction, and history of cardiac surgery.

Sustainability of health/recovery and nature of recurrences

Figure 2 shows the risk-adjusted readmission due to myocardial infarction within 30 days rates for consolidated CAD for 3 heart centers, based on inclusion of CABG, PCI and OMT treated patients. The readmission due to myocardial infarction was risk-adjusted for age, gender, diabetes mellitus, and renal insufficiency. The model shows a C-statistic of 0.69, which indicates a relatively moderate predictive accuracy.

Treatment specific outcomes

Survival

The risk-adjusted 120-day mortality after CABG reported in 2013 is shown in Figure 3. This follow-up period for the mortality after CABG was selected based on advice of independent medical experts and a study in which the most adequate follow-up period for the evaluation of mortality rates after cardiac surgery was analyzed. [8] The 120-day mortality was risk-adjusted for age, sex, diabetes mellitus, renal insufficiency, urgency of the procedure and left ventricular ejection fraction. The model shows a C-statistic of 0.82, which indicates a relatively high predictive accuracy. One heart center shows a statistically lower 120-day mortality rate after CABG (p<0.05). The observed variance between the other heart centers should be interpreted as natural variance. It was hypothesized that the use of a stringent perioperative safety check was the most striking difference in surgical practice amongst the centers.

First results of a national initiative to enable quality improvement of cardiovascular care by transparently reporting on patient-relevant outcomes

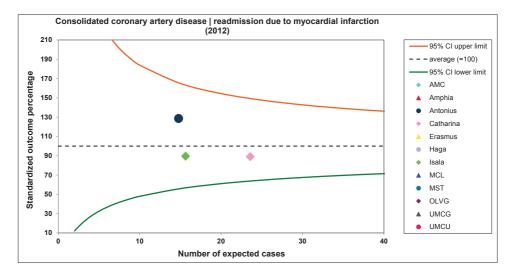


FIGURE 2: Funnel plot of risk-adjusted number of readmissions due to myocardial infarction within 30 days of consolidated coronary artery disease (CABG, PCI and OMT) for 2012. Readmission due to myocardial infarction rates are adjusted for age, gender, diabetes mellitus, and renal insufficiency.

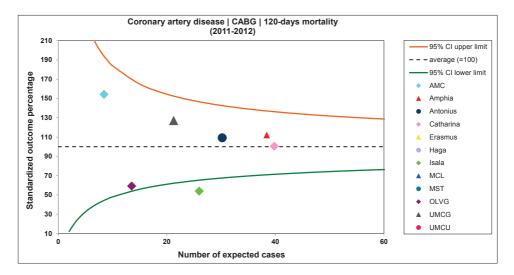


FIGURE 3: Funnel plot of risk-adjusted 120-day mortality rates after CABG for 2011-2012. 120day mortality rates are adjusted for age, gender, diabetes mellitus, renal insufficiency, urgency of the procedure and left ventricular ejection fraction. The risk-adjusted 1-year mortality after PCI reported in 2014 is shown in Figure 4. The 1-year mortality was risk-adjusted for age, gender, diabetes mellitus, urgency of the procedure, renal insufficiency, history of myocardial infarction, multi-vessel disease, history of CABG, chronic total occlusion, shock and resuscitation. The model shows a C-statistic of 0.83, which indicates a relatively high predictive accuracy. No significant differences between heart centers were observed. Mortality rates at the Dutch heart centers are similar or likely to be comparable with or lower than the mortality rates of some other Western countries. [16-18]

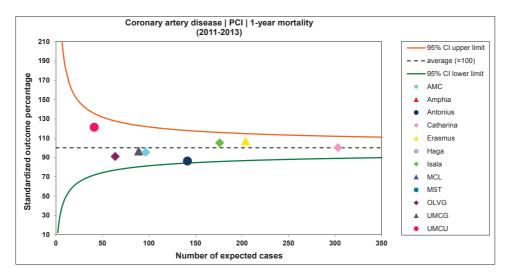


FIGURE 4: Funnel plot of risk-adjusted 1-year mortality after PCI for 2011-2013. 1-year mortality rates are adjusted for age, gender, diabetes mellitus, urgency of the procedure, renal insufficiency, history of myocardial infarction, multi-vessel disease, history of CABG, chronic total occlusion, shock and resuscitation.

The 2014 results in Figure 5 show the long-term survival rates after AVR for each heart center. The long-term survival was risk-adjusted for gender, diabetes mellitus, urgency of the procedure, left ventricular ejection fraction, endocarditis, history of cardiac surgery and history of stroke. The results demonstrate that the heart center with the highest survival rate had a significantly higher survival rate than three other heart centers (p<0.05). These differences will be subjected to further analyses to investigate if heart centers can learn from each other.

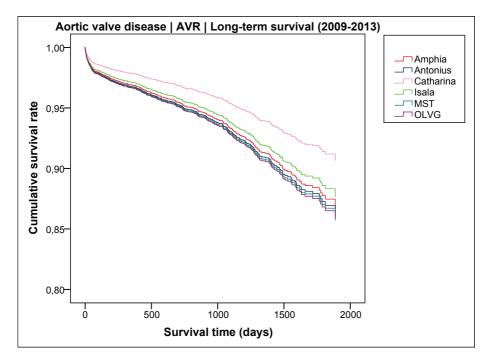


FIGURE 5: Risk-adjusted long-term survival after AVR for 2009-2013. The long-term survival is adjusted for gender, diabetes mellitus, urgency of the procedure, left ventricular ejection fraction, endocarditis, history of cardiac surgery and history of stroke.

Degree of health/recovery

Figure 6 depicts the QoL results from one of the heart centers collecting QoL, which was assessed using the SF-36 pre-operative and one year after CABG. Results for all eight health domains included in the SF36 are presented separately. Although the data lacked more than 10% values, it was still decided to publish the results of QoL. The main reason for this decision is that QoL is of central importance in the evaluation of the quality of medical treatment, and publishing results stimulates heart centers to improve the data collection processes.

Disutility of the care of treatment process

The results from 2014 presented in Figure 7 show significant differences between heart centers in the number of risk-adjusted implantations of a new permanent pacemaker within 30 days after TAVI. The selection of this outcome measure was based on a previous study and was risk-adjusted for gender, renal insufficiency, history of cardiac surgery and history of mitral valve disease. [19] The model shows a

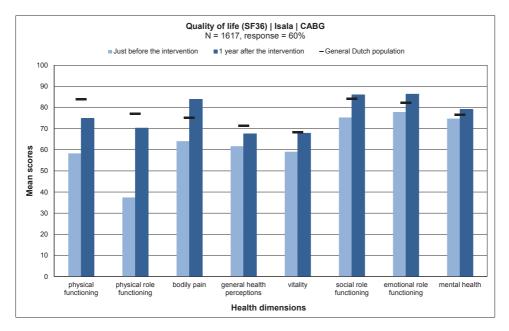


FIGURE 6: SF-36 scores of 1617 patients at baseline and 12 months after CABG for one heart center (Isala). The grey bar represents the mean score for healthy volunteers.

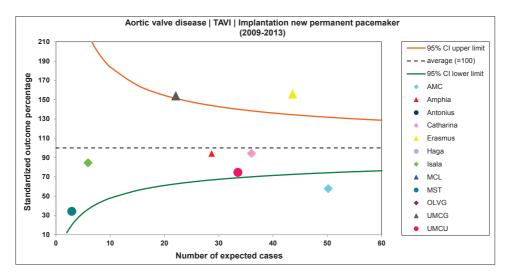


FIGURE 7: Funnel plot of risk-adjusted number of implantations of new permanent pacemaker after TAVI for 2009-2013. The number of implantations a new permanent pacemaker have been adjusted for gender, renal insufficiency, urgency of the procedure, history of cardiac surgery and history of mitral valve disease.

C-statistic of 0.62, which indicates a relatively moderate predictive accuracy. In order to examine where these differences originate from, these findings are to be subject to further analyses.

Sustainability of health/recovery and nature of recurrences

Figure 8 depicts the 2014 risk-adjusted target vessel revascularization (TVR) rate within 1 year of PCI for five heart centers. This outcome measure was selected based on the results of previous studies. [25-26] The TVR rate was risk-adjusted for age, gender, diabetes mellitus, urgency of the procedure, renal insufficiency, history of myocardial infarction, multi-vessel disease, history of CABG, chronic total occlusion, shock and resuscitation. The model shows a C-statistic of 0.65, which indicates a relatively moderate predictive accuracy. Although no statistically significant differences were reported, one of the heart centers initiated an internal improvement project to decrease the TVR rate.

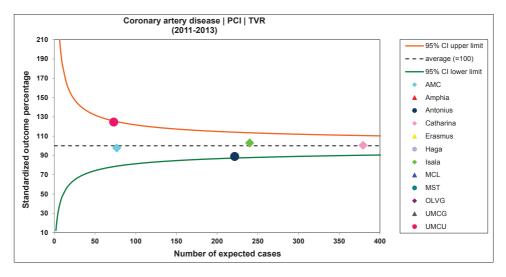


FIGURE 8: Funnel plot of risk-adjusted number of target vessel revascularizations (TVR) within 1 year of PCI for 2011-2013. TVR are adjusted for age, gender, diabetes mellitus, urgency of the procedure, renal insufficiency, history of myocardial infarction, multi-vessel disease, history of CABG, chronic total occlusion, shock and resuscitation.

DISCUSSION

Measurably Better – Meetbaar Beter - has shown that insights into patient-relevant outcomes contribute to the improvement of delivered cardiovascular care in at least two ways. First of all, the discrepancy in outcomes acts as a trigger for individual heart centers to review their current care process. The participating heart centers are motivated to understand where this discrepancy originates from and how they can improve their outcomes. This has resulted to several improvement projects initiated by a number of heart centers. Secondly, insight into outcomes provides incentives for hospitals for mutual learning. It enables the flow of best practices between individual heart centers. MB facilitates the sharing and implementation of these best practices. The participating heart centers remain autonomous in deciding whether they want to implement the identified best practice. Today, the first steps towards identifying and sharing best practices have been taken with the implementation of a Safety Check, the methodology to identify and select best practices within the MB initiative can be further improved.

The MB initiative entails not only a shift from specialist and intervention-oriented care to patient and disease management-oriented care, but also from "in-hospital" orientation to a "full cycle of care" approach as several outcome measures are based on long-term follow-up. [13] MB aims not only to focus on the results of an individual treatment or specialization, but also on the results of the integrated care for patient groups, both inside and outside the hospital, where the census intervention took place. As it is not only the intervention itself that influences the outcomes, but also the follow-up in the outpatient clinic of a referral center, specialists are stimulated to collectively organize integrated care even better. The methodology of MB enables to define the performance of the full cycle of care that starts with a Heart Team discussion. MB assumes that all non-elective patients undergoing an intervention or cardiac surgery are discussed by a Heart Team. For the inclusion in the OMT cohort of CAD, ischemia needs to be proven and the patient has to been discussed by the Heart Team. Figure 2 shows the first results of a CAD specific outcomes measure "readmission due to myocardial infarction", for which CABG, PCI and OMT treated patients are included. The clear benefit of taking the medical condition as starting point for benchmarking patient-relevant outcomes is the prevention of risk-avoidance for the sickest patients. MB also collects information regarding whether a Heart Team discussion took place. The next step is to use this information to perform analyses verifying the added value of a Heart Team discussion. Furthermore, in the near future also the OMT treated patients will be included in the AVD analyses providing an improved overview of the AVD outcome measures. The results of disease specific outcomes are increasingly important for AVD patients, as TAVI has been introduced for AVD-patients who were judged inoperable, but as the technique improves and experience in the TAVI-centers grows, indication criteria for AVR, TAVI and OMT are changing.

In this article the results of one disease specific outcome measure for both CAD and AVD are presented. These results show the first step towards the evaluation of the Heart Team decision performance. The availability of the so called consolidated data is in development, thereby showed in limited extent. The other results represent multiple treatment specific outcome measures for CABG, PCI, AVR and TAVI.

By publishing patient value or loss of value due to complications, health care insurers are given a more explicit insight into guality of care. For the first time the opportunity to reward quality of care is created and new purchasing models based on patient value can be developed. Based on the results of the MB report of 2013, it appeared that the risk-adjusted 120-day mortality rate for surgical interventions to treat coronary artery disease was statistically lower when compared with other heart centers. The internal findings of one of the participating centers indicated that the peri-operative safety check they developed and implemented may have contributed to the lower mortality rate in patients treated with CABG. This conclusion was not supported by conventional scientific evidence. However, it was decided in an expert meeting that a voluntary roll-out of the specific safety check may be a valuable initiative of which the efficacy in other centers is worthwhile to be investigated. Since the strong hypothesis that the safety check could explain the lower mortality rate, seven other participating Dutch heart centers are now implementing the safety check. This rollout project will be subject to scientific research in order to gather scientific evidence to support the added benefit of the Safety Check and to investigate whether the increase in attention to process and quality may have contributed to improved patients outcomes (the Hawthorne effect). [21]

Besides results showing possible significant differences in performance between heart centers, publication of results that show no significant differences may initiate improvement projects. For example,–insights based on the TVR rates after PCI, resulted in an initiative at one of the heart centers aimed at lowering the TVR rate. Other examples are improvement projects to reduce mortality after AVR, tamponade after PVI and deep sternal wound infections after CABG. This indicates that statistically significant results are not necessarily a prerequisite for initiating improvement cycles in a clinical setting. Chapter 3

Therefore,, not only 'hard' end points are important to assess the quality of delivered care, but also 'soft' end points like QoL are crucial since improved QoL is a major goal for carrying out an intervention. [22, 23] The participating heart centers have demonstrated that it appears feasible to collect pre- and post-intervention QoL of multiple cardiovascular treatments. Given the importance of publishing QoL data, MB stimulates the participating heart centers to improve the response rates, despite the time consuming aspect of these surveys. However, it needs to be mentioned that the post-intervention QoL might be overestimated since only survived patients are included in the analyses. [3] In addition, patients with a low preoperative QoL, high operative risk and older age are at higher risk for drop-out, which may result in a biased conclusion regarding changes in QoL. [24]

The MB initiative fills in a space between scientific research and evidence and facilitating quality of healthcare in daily practice. Its first successful quality improvement projects have been observed. However, it will sometimes remain difficult to prove success in terms of statistical evidence, as numbers remain small and power for analysis is poor. The MB initiative has shown that physicians can start learning, improving and sharing to improve quality in healthcare without, or even despite, statistical significance. As clinical relevance will always be the key factor in decision-making by physicians in healthcare, there is no reason to postpone learning and improvement.

Consensus has been created on a small set of outcome measures and initial conditions. Most definitions have shown to be very solid and feasible. Some outcome measures appeared to remain subject of debate, which make expert groups indispensable to generate consensus. In general, we conclude that the use of a small set of outcome measures enables reliable comparisons between Dutch heart centers. Also, that risk-adjustment other than by Euroscore is feasible despite a limited set. Good and undisputed data quality is the key prerequisite to analyze and to start the learning and improvement cycles in the participating heart centers. However, reality demands that MB allows a limited amount of missing data, thereby enabling to publish data of more participating heart centers which accelerates learning cycles. Within three years, the maximum of missing data has to be increased to 5%. Furthermore, to generate credibility and acceptance it is essential that results are reported transparently and in accordance with suggestions from relevant patient advocacy groups. In combination with physician-given information, patient-preferred decision-making is stimulated by openly communicating best practices either gleaned from one's own hospital or adopted from colleagues. The influence of patients will increase over time. First, by involving them in the yearly maintenance cycle of the set of outcome measures. This is a process which guarantees the continuous improvement of the set of outcome measures and definitions used. Second, by publishing the outcomes in a specific patient-orientated way.

This practical approach, using a very restricted set of outcome measures and initial conditions, has made the MB initiative one of the international leaders in the implementation of Prof. Porter's Value Based Healthcare theory. Although the costs of healthcare delivered are not within the scope of the MB initiative, transparent reporting on patient-relevant outcomes has become standard in the Netherlands.

The future

In the coming years, the focus of MB will gradually shift towards using valuable insight into outcomes to actually facilitate improvement in the quality of care. The base will be accordance with and support by the use of the international best practice guidelines. MB has connected to centers of best practice worldwide such as Cleveland Clinic, UCLA in U.S.A, and Schön Klinik and Martini Klinik in Germany thereby building an international network on the implementation of VBHC. Insights into the methodology that is used to create effective improvement programs based on patient-relevant outcomes are being gathered and will be shared with participating heart centers.

Creating practices and guidelines is a gigantesque task exceeding a national level or profession. MB provides the warehouse, this internationally created information as well as the data storage management for the participating heart centers. Only this way the implementation of an effective quality improvement cycle can be developed and maintained. To increase the push on performance in the participating heart centers, several levels of membership and rewards will be designed. These could be based on completeness of data, quality of data and quality of the organization of the improvement cycle at the heart centers. Models for regional cooperation, changes in culture and innovations in purchasing for healthcare will be designed by either the participating hospitals or MB. The decision making for quality in healthcare, enabling best patient value, will continue to develop in care for Dutch heart patients. Using patient-centered decision-making, tools will be developed to support the decisionmaking of patients by providing them with insights into the outcomes of delivered healthcare.

In The Netherlands, only licensed hospitals are allowed to perform PCI treatments. There are two different types of Dutch hospitals performing cardiac interventions: 1) heart centers, 2) intervention hospitals without cardiothoracic surgery on-site. Today, the latter can participate in MB as well. The intervention hospitals without cardiothoracic surgery on-site do have joint Heart Teams sessions with a 'full heart center" prior to carrying out elective and urgent PCI. The participation of these hospitals in MB enables to obtain a complete overview of the nationwide Heart Team decision performance and the quality of the collaboration between the heart center and the PCI-hospital. Furthermore, we fore see that over time the national patient cohort for CAD will consist of all Dutch patients with proven ischemia. The first results for the intervention hospitals without cardiothoracic surgery on-site will be published in the Meetbaar Beter Book 2015.

Advisory board:

Academisch Medisch Centrum , Amsterdam: dr. Wim Jan P. van Boven; Amphia Ziekenhuis, Breda: dr. Peter den Heijer; St. Antonius Ziekenhuis, Nieuwegein: dr. Benno.J.W.M Rensing; Catharina Ziekenhuis, Eindhoven: dr. Bart van Straten; Isala Kliniek, Zwolle: dr. Jan-Henk Dambrink; Onze Lieve Vrouwe Gasthuis, Amsterdam: dr. Giovanni Amoroso; UMC Groningen, Groningen: drs. Tjalling W. Waterbolk; UMC Utrecht, Utrecht: dr. Pieter R. Stella; Medisch Spectrum Twente, Enschede: dr. Jurren M. van Opstal; Medisch Centrum Leeuwarden, Leeuwarden: drs. Jo S.E. Haenen; Haga Ziekenhuis, Den Haag: drs. Matthijs Bax; Erasmus MC, rotterdam: dr. Tjebbe W. Galema; Maastricht UMC, Maastricht: dr. Kevin Vernooy; Radboud UMC, Nijmegen: dr. Luc Noyez; Medisch Centrum Alkmaar, Alkmaar: dr. Victor A.W.M. Umans; Elisabeth-TweeSteden Ziekenhuis, Tilburg: drs. Michael Magro; Tergooi Ziekenhuizen, Blaricum: drs. Stijn L. Brinckman

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CHAPTER 4

Defining and measuring a standard set of patientrelevant outcomes in coronary artery disease

E. Daeter, M.Timmermans, A. Hirsch , E. Lipsic, S. Houterman, Meetbaar Beter advisory board, D. van Veghel, P. van der Nat

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ABSTRACT

Systematic outcome measurement enables to continuously improve treatment results and stimulates dissemination of best practices. For patients suffering from coronary artery disease (CAD), no examples yet exist of standard sets of patientrelevant outcome measures that have already been fully implemented at a large scale in clinical care. The aim of this paper is twofold: 1) To share the standard set of outcome measures as developed by Meetbaar Beter; and 2) To show how the standard set is presented and published in order to support improvement of cardiac care. A step-wise approach was followed by an expert panel to construct a standard set of outcome measures. This approach resulted in a comprehensive set of relevant outcome measures, comprising 4 generic and 11 treatment-specific outcomes. Both short-term outcome measures as well as long-term outcomes up to 5 years of follow-up were included. Relevant initial conditions were selected to enable casemix adjustment. The standard set has been implemented in 21 hospitals across the Netherlands. The results and experiences have been used to fine-tune the set in 4 reporting cycles in 2012-2016, using an annual maintenance cycle. Currently about 83,000 percutaneous coronary interventions (PCIs) and 30,000 coronary artery bypass graftings (CABGs) are included in the dataset, covering the majority of all PCIs and CABGs in the Netherlands. In conclusion, Meetbaar Beter has defined and implemented a comprehensive set of patient-relevant outcome measures for CAD, and the variation of the results among the centers indicates that there are sufficient opportunities to further improve cardiac care in the Netherlands.

Key words: Coronary artery disease, Quality improvement, Value-based healthcare, Patient-relevant outcomes, Transparency.

INTRODUCTION

Cardiovascular diseases are the most important cause of death in almost all countries of the European Union, of which coronary artery disease (CAD) affects most people. [1-3] In the face of increasing treatment costs and uncertain outcome gains, valuebased decisions about how and where to treat patients with CAD are needed. [4] Value-Based Healthcare has been proposed to improve quality of care. In this framework, value is defined as a patient's outcome divided by the costs to achieve the outcome.[5] Key to measuring value is defining condition-specific outcomes that matter to patients. Systematic outcome measurement enables to continuously improve treatment results and share best practices. To be able to compare outcomes over time and between hospitals, standard sets of well-defined outcomes that provide a complete overview of quality of care for a specific medical condition are needed. In 2012, Dutch physicians started Meetbaar Beter (English: Measurably Better) in order to select, define and evaluate treatment outcomes in heart care.[6] Meetbaar Beter is a physician-driven and patient-focused initiative that aims to improve quality of cardiovascular care in the Netherlands by creating transparency on patient-relevant outcomes. Meetbaar Beter has defined standard sets of outcome measures and initial conditions for several heart conditions, which currently are being used in 21 hospitals to improve cardiac care. The aim of this paper is to share the standard set of outcome measures for CAD and to show how it is yearly presented and published in order to support quality improvement.

METHODS

A fixed step-wise approach was followed to construct a standard set of patientrelevant outcome measures for CAD. The aim was to select a limited number of up to 10 outcome measures per treatment option, including both disease-generic measures and treatment-specific measures, leading to a practical standard set that can be fully implemented in any hospital and not impacting the administrative burden too much. The treatment options are: 1) coronary artery bypass grafting (CABG): Patients where the intention is to perform an isolated CABG (patient is included from the moment that a skin incision is made); 2) percutaneous coronary intervention (PCI): Patients where the intention is to perform an isolated PCI by the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy) and 3) conservative treatment (CT): Patients with CAD for which the local Heart Team (team of different cardiovascular specialists, including interventional cardiologists and cardiac surgeons) decided to opt for a conservative treatment due to the high risk of mortality or complications when performing an intervention.

To select outcome measures, an outcomes team of 4 physicians was composed, comprising both cardiologists and thorax surgeons with expertise in the field of CAD. Next, a modified Delphi procedure was conducted, in which the ideas and tools of Value-Based Healthcare were integrated. [5-7] First, a long-list of potentially relevant outcome measures related to the treatment of CAD was constructed. This was done by describing in detail each of the steps of Michael Porters' Care Delivery Value Chain (i.e. monitoring/preventing, diagnosing, preparing, intervening, recovering/ rehabbing and monitoring/managing) and identifying outcomes of each of those steps. [8] In addition, potential outcomes were extracted from relevant documents such as national guidelines, scientific publications, clinical trials and international best practices. This led to the identification of in total 94 outcome measures for CABG, 105 for PCI and 83 for CT. Second, these outcomes were ranked by all team members on the following criteria: 1) Patient relevance, defined as the impact on patient quality of life; 2) Medical relevance, defined as the level of impact health professionals can have on the outcome and 3) Patient volume, defined as the number of patients affected by the (negative) outcome. In supplemental Figure S1, as an example, the scores of the top 30 outcome measures for PCI are presented. Third, the top 30 outcome measures were ranked on the feasibility of data collection and the quality of the outcome definition. The rankings were performed by each team member separately. Differences in prioritization between team members were discussed in detail until consensus was reached. The results were clustered in accordance with the 3 tiers of the Outcome Hierarchy: 1) Health status achieved or retained; 2) Process of recovery and 3) Sustainability of health.[5] To provide a complete overview of quality of care, it was a requirement that each tier was represented in the final set of outcome measures.

Baseline data are essential to make meaningful comparisons between patients. A selection was made of 10-15 risk factors or *initial conditions* related to the patient at the moment of diagnosis with highest impact on the patient outcomes. This was done by constructing a long-list of initial conditions from literature and outcomes team discussions. The first selection resulted in 115 initial conditions. The final selection of initial conditions, resulted from a prioritization based on impact on outcomes, feasibility and patient volume.

The systematic approach used for the set development and the final standard set of medical outcomes and initial conditions was validated by an international academic advisory council (Supplemental Table S1). This council consists of 3 separate parts: 1) A methodology council, with 5 experts in Value-Based Healthcare, change management and quality improvement; 2) A medical council, with 19 medical experts, of which 6 provided feedback on the standard set of CAD; and 3) A data management & statistics council, with 3 internationally renowned experts. Also a sounding board validated the final set, representing national health-insurance companies, patient organizations and government organizations.

A standard set of outcome measures needs to be validated in practice. Insights from data collection and use for quality improvement leads to refinements in the selection and definition of the outcome measures and initial conditions. Also, for example improvement in outcomes over years and developments in treatment protocols and operation techniques can impact the standard set. Therefore, annual maintenance cycles are organized with the medical experts of the outcomes team. During these cycles, both the selected outcome measures and the initial conditions are systematically evaluated. Based on results and feedback from all participating centers and new scientific evidence, specific outcome measures and/or initial conditions could be added to the standard set. Measures can also be removed, for example in case an initial condition turned out to have no predictive value for the outcome measures. In addition, definitions of the included measures are further improved when necessary. The maintenance cycles led in the first year to 34 refinements in definitions and minor changes in the composition of the outcome measure set and the initial conditions. In the cycle of 2016 only 1 change was implemented, showing that the standard set has become stable and ready for publication.

The standard set for CAD was implemented in 2013. To date, 21 hospitals across the Netherlands are participating. Each participating hospital annually collects data on the outcome measures and initial conditions from patient records and submits data of the 5 most recent years. Data regarding events which occurred in other hospitals than the hospital where the patient was initially included in the cohort, were collected by means of active follow-up. Patient-reported outcome measures were collected by 2 questionnaires which were sent maximum 2 months before the intervention and 10-14 months afterwards. All initial outcomes were collected prior to treatment initiation.

To ensure validity and consistency of the data, Meetbaar Beter provides a detailed data manual. [9] Clear criteria were defined in order to guarantee data quality: 1)

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data was collected according to the definitions as described in the data manual; 2) the percentage of random missing values was maximum 10% per measure; 3) the electronic database of the regional municipal administration registration (Gemeentelijke Basis Administratie) was used for obtaining mortality data and 4) a clear demonstration that the data collection regarding the outcomes considering outof-hospital data was carried out for the complete patient cohort. Subsequently, the validity of data was centrally controlled within Meetbaar Beter by means of checks on incorrect values, logical checks of specific entries with respect to other data of the same patient, and the presence of extreme outliers. In addition, medical and nursing experts of Meetbaar Beter conduct annual audits at each of the participating centers to check the integrity and completeness of the data. During the audit, a selection of the data which was submitted to Meetbaar Beter is compared with the information in the medical records.

Before submission to Meetbaar Beter, the medical specialist who is responsible for the quality of the data needs to sign for the accuracy and completeness of the data. When the data checks by Meetbaar Beter are completed successfully, data is assumed to be appropriate for statistical analyses. Center-specific results will be published independent of the outcomes, without possibilities for withdrawal. Hospital names are specified in all published results, allowing hospitals to contact each other based on published results.

Descriptive statistics with means (with SDs) or counts (with proportions) were used to present uncorrected center-specific and national performances. In case of a sufficient number of events, segmented uncorrected percentages of the prevalence for each selected outcome measure were calculated. This indicates the dependence of the outcome measure relative to the most important selected initial conditions.

To be able to compare center-specific performances, multivariable logistic regression analyses were performed with risk-adjustment for the selected initial conditions. First, power calculations were conducted in order to calculate whether the power was sufficient to show reliable differences between centers. In case of sufficient power, the number of expected cases for dichotomous outcome measures was calculated per center by means of multivariable logistic regression analyses, using the outcome measure as dependent variable and the selected initial conditions as independent variables. For each center, the calculated number of expected cases was plotted against the percentage of the standardized number of cases in a funnel plot. The percentage of the standardized number of cases multiplied by dividing the number of observed cases by the number of expected cases multiplied by 100. In addition, a mean ratio for all centers together was calculated with corresponding 95% confidence intervals, to be able to assess which centers deviate significantly from the national mean. A *c*-statistic was calculated to indicate the discriminatory power of the predictive model. The *c*-statistic takes on values between 0.5 (classification no better than a coin flip) to 1.0 (perfect classification). [10]

For outcomes regarding time that passes before the event occurs, multivariable Cox proportional hazard analysis was performed, with risk-adjustment for the selected initial conditions. The results are presented in risk-adjusted Kaplan Meier curves.

Several exclusion criteria were specified for analyses to ensure the validity of the outcomes. If a center had more than 10% missing values for an initial condition, the condition was excluded from the regression analyses for that center. In case a center had more than 1 missing initial condition, the whole center was excluded from the analysis. An initial condition was totally excluded from the regression analyses if 25% or more of the centers were not able to provide data for this particular condition. Patients with 2 or more missing initial conditions were excluded, as well as patients who died prior to complete follow-up and for which the event did not occur (competing risk). All analyses were performed per treatment option as well as for the total group of patients with CAD , regardless of the specific treatment (i.e. consolidated CAD). For both the funnel plots and the Kaplan-Meier curves, missing data were imputed via multiple imputation. [11] Analyses were performed using SPSS 23.0 (SPSS, Inc., USA). The level of statistical significance was set at $\alpha = 0.05$.

RESULTS

The stepwise procedure of outcome measure development resulted in a set of 4 generic outcome measures covering all patients with CAD. In addition, 6 outcome measures which were specific for CABG, 3 measures which were specific for PCI and 2 measures which were specific for CT were included in the standard set. Table 1 shows the final set of outcome measures and initial conditions. The outcome measures are clustered in accordance with the levels of the Outcome Hierarchy. The definitions of the outcome measures are presented in supplemental Table S2. Table 1 also indicates how many hospitals collected data for each treatment. Two (high volume) hospitals collected data for all medical treatments, resulting in 25,259 patients in the consolidated CAD group. Per treatment option, the means and proportions (%) for all outcome measures and initial conditions are presented in Table 1 when appropriate, indicating that data collection is feasible.

				Consolidated CAD 2 hospitals 25259 patients	CABG 13 hospitals 30240 patients	PCI 19 hospitals 91697 patients	CT 3 hospitals 112 patients
		ОМ	Group	National mean (SD)	National mean (SD) or proportion (years 2011 till 2015)	2011 till 2015)	
Tier 1 Sur	Survival	Long-term survival (≤ 5 years)	AII	*	*	*	*
		1-year mortality	AII	971/20453 (5%)	765/24142 (3%)	3814/69260 (6%)	4/95 (4%)
		120-day mortality	CABG	n/a	606/30093 (2%)	n/a	n/a
		30-day mortality	PCI	n/a	n/a	2463/91318 (3%)	n/a
Dec	Degree of health/ recovery	Quality of life 'mean (SD) Physical health	AII	÷		÷	+
		baseline 1 year			54 (21) 68 (20)		
		baseline 1.coar			60 (20) 67 (18)		
		Chest nain (< 1 vear)	Ľ	e/u		e/u	++
Tier 2 Tim anc nor	Time to recovery and return to normal activities		5		1	5	
Dis	Disutility of the	Surgical reexploration (≤ 30 days)	CABG	n/a	1172/26763 (4%)	n/a	n/a
car pro	care or treatment process	Cerebrovascular accident (CVA) (≤ 72 hours)	CABG	n/a	199/29129 (1%)	n/a	n/a
		Deep sternal wound infection (≤ 30 days)	CABG	n/a	245/28312 (1%)	n/a	n/a
			C	-1	0/0		-1-

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				Consolidated CAD 2 hospitals 25259 patients	CABG 13 hospitals 30240 patients	PCI 19 hospitals 91697 patients	CT 3 hospitals 112 patients
Tier 3	Sustainability of	Myocardial infarction (≤ 30 days)	AII	180/21632 (1%)	303/19877 (2%)	444/52458 (1%)	6/111 (5%)
	health/recovery and nature of recurrences	Occurrence of target vessel revascularization (TVR) (≤1 year)	PCI	n/a	n/a	2586/37427 (7%)	n/a
		Free of myocardial infarction	CABG	*	*	*	*
		Free of coronary artery reintervention	CABG	*	*	*	*
		Free of Major Adverse Cardiac Event (MACE)	CT	*	*	*	*
	Long-term consequences of therapy						
		Initial condition	Group	National mean (SD)	National mean (SD) or proportion (years 2011 till 2015)	011 till 2015)	
	Demographic	Age mean (SD)	All	65 (11)	66 (10)	65 (12)	69 (10)
	characteristics	Gender male female	AII	18842/25259 (75%) 6417/25259 (25%)	24061/30240 (80%) 6179/30240 (20%)	65821/91694 (72%) 25873/91694 (28%)	77/112 (69%) 35/112 (31%)
	Medical condition	Left ventricular ejection fraction EF>50% EF 30-50% EF <30%	All	6831/7755 (88%) 550/7755 (7%) 374/7755 (5%)	20534/27615 (74%) 5852/27615 (21%) 1229/27615 (5)	**	70/109 (64%) 30/109 (28%) 9/109 (8%)
		Diabetes mellitus	All	5145/24944 (21%)	7643/30224 (25%)	18331/89584 (21%)	40/110 (36%)
		Multivessel disease	All	15335/25197 (61%)	22914/24311 (94%)	44647/91080 (49%)	62/99 (63%)
		Renal insufficiency	AII	4828/24004 (20%)	6059/30217 (20%)	14083/67273 (21%)	36/112 (32%)
		Logistic EuroSCORE I mean (SD)	CABG	n/a	4.9 (7.0)	n/a	n/a
		Logistic EurosSCORE II mean (SD)	CABG	n/a	2.3 (3.9)	n/a	n/a
		Chronic lung disease	CABG	n/a	S	n/a	n/a

Defining and measuring a standard set of patient-relevant outcomes in coronary artery disease

TABLE 1. Continued

4

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TABLE 1. Continued						
			Consolidated CAD 2 hospitals 25259 patients	CABG 13 hospitals 30240 patients	PCI 19 hospitals 91697 patients	CT 3 hospitals 112 patients
	Cardiogenic shock	PCI	n/a	n/a	2505/ 89371 (3%)	n/a
	Chronic total occlusion	PCI	n/a	n/a	5104/91092 (6%)	n/a
	Resuscitation	PCI	n/a	n/a	3774/90571 (4%)	n/a
	Urgency of the procedure** Urgent Elective	AII	6958/25256 (28%) 18298/25256 (73%)	1711/30161 (6%) 28450/30161 (94%)	24436/74920 (33%) 50484/74920 (67%)	0/112 (0%) 112/112 (100%)
	Indication PCI Elective NSTEMI &Instable angina STEMI	PCI	n/a	n/a	28886/80835 (36%) 25761/80835 (32%) 26188/80835 (32%)	
Medical history	Previous heart surgery	CABG	n/a	651/30190 (2%)	n/a	n/a
	Previous CABG	PCI	n/a	n/a	9386/90889 (10%)	n/a
	Previous myocardial infarction	PCI, CT	n/a	n/a	19111/87194 (22%)	52/111 (47%)
	Previous CABG or PCI	CT	n/a	n/a	n/a	76/112 (68%)
Note: The standard set presente S3 reflects the most recent versi, Abbreviations: CABG = coronary inter PCI=percutaneous coronary inter *Because these outcome measu ⁺ Measured at baseline and bety conservative treatment [‡] Because too much centers had	Note: The standard set presented in this table can differ slightly from the set presented in supplemental Table S3, as the results in this table cover the period 2011-2015, while Table S3 reflects the most recent version of the standard set (year 2017). Abbreviations: CABG = coronary artery bypass grafting: CAD = coronary artery disease: CT = conservative treatment; n/a = not applicable for the concerning treatment option: PCI=percutaneous coronary intervention. OM = outcome measure Tecarate these outcome measures represent survival rates over time (up to 5 years of follow-up), no event rate can be presented "Measured at baseline and between 10 till 14 months after treatment by the SF-36 or SF-12. This outcome measure has not yet been implemented for treatment with PCI and for conservative treatment the servative treatment	presented tery diseas 5 years of 5 SF-36 or percentage	in supplemental Table ie; CT = conservative follow-up), no event rat SF-12. This outcome m es cannot be presented	S3, as the results in thi treatment; n/a = not al e can be presented easure has not yet be	s table cover the period oplicable for the conce en implemented for tre	d 2011-2015, while Table rning treatment option; atment with PCI and for

§ As chronic lung disease is recently added to the standard set, no measures can be presented yet ** For analysis of the consolidated CAD, all patients with a conservative treatment are assumed to be elective. Level of urgency for the patients treated with a PCI is based on the

initial condition 'indication of PCI'

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Survival is measured at several time points. For all treatment options, survival is assessed at 1 year after inclusion. In addition, long-term survival is measured up to 5 years of follow-up. Thirty-day mortality is selected as outcome measure for patients treated with a PCI, while mortality of patients treated with CABG is measured at 120 days. For the CABG group, mortality is measured at 120 days, because previous research of Siregar et al. showed that 60-120 days after surgery, the survival curves of patients who underwent CABG stabilized after an initial steep decline. At 120 days post-surgery, all cardiac surgery-related mortality was covered. [12] For PCI, mortality is measured at 30-days, as risk of death seems to move from cardiac to non-cardiac after a period of 30 days post PCI. [13] For all selected time periods, the outcomes team decided to assess all-cause mortality using central death registers. Disease-specific mortality was not selected as it was considered to be less meaningful to patients than all-cause mortality. Besides, the validity of the data may be limited if cause of death is not clinically assigned.

On the level of *degree of health/recovery*, quality of life (QoL) is assessed by the Short-Form 36 (SF-36) questionnaire. The SF-36 is a widely used generic measure in QoL, developed and validated in the Medical Outcomes Study to assess important QoL domains relevant to patients suffering from a wide range of medical conditions. [14] The SF-36 consists of 8 QOL domains that comprise 2 summary measures: the physical component and the mental component. The SF-36 hasalready proven to be valid for measuring quality of life among coronary patients. [15,16] To address the considerable burden placed on respondents to fill out the questionnaire, some hospitals choose to use the SF-12, which is a shorter form of the SF-36. Both measures have been found to be highly correlated. [17] The SF questionnaire is assessed at baseline and between 10-14 months after treatment.

Three high-impact outcome measures in the tier 'process of recovery' concern only the CABG patients: cerebrovascular accident within 72 hours, surgical exploration within 30 days, and deep sternal wound infection within 30 days after surgery. For patients who undergo a PCI, urgent CABG within 24 hours was included. Some outcomes such as 'in hospital cardiac arrest', 'cardiac tamponade' and 'intubationrelated damage' do have high impact on patients but were not included because of their relatively low incidence.

'Myocardial infarction' (MI) was included as generic outcome measure for patients with CAD. For all treatment options, MI is assessed at 30 days after start of the treatment. Both for the CABG group and the conservative treatment group, MI is measured up to 5 years of follow-up as well. Free of coronary artery reintervention

was selected specific for CABG, while occurrence of target vessel revascularisation (TVR) within 1 year was selected for PCI. Free of Major Adverse Cardiac Event, in which MI, reintervention (CABG or PCI) and mortality are included, is measured for the conservative treatment group.

The outcomes teams identified the baseline case-mix variables considered to be essential for risk adjustment to enable meaningful comparisons between hospitals. Initial conditions common to all CAD patients were defined as well as treatment dependent initial conditions. In addition to the total score on The European System for Cardiac Operation Risk Evaluation (EuroSCORE) I and II, several specific risk factors were selected which have a main impact on one or several outcomes. [18,19] All selected initial conditions are presented in Table 1. The corresponding definitions are described in supplemental Table S2.

Figures 1 to 6 show a selection of results to indicate how the standard set is presented and published. The types of graphs are selected in order to optimally facilitate benchmarking and outcomes-based quality improvement within the centers. The selection is made such that every tier in Porters hierarchy is represented. All other tables and figures are available online. [6] The names of the centers are explicitly included for transparency and to stimulate and allow for sharing and learning between individual centers.

Outcomes are published both unadjusted and risk-adjusted (in case of sufficient power), as both types of presentations have proven to be a useful starting point for quality improvement in practice. Three different levels can be distinguished.

 The uncorrected percentages of the incidence for each selected outcome measure. An example for urgent CABG after PCI is presented in Table 2. As incidence rates are relatively low, no additional analyses were performed for this measure.

	Included years	Number of patients	Urgent CABG (%)
AMC	2012-2015	5190	0.2%
Amphia	2012-2015	5386	0.3%
Antonius	2011-2015	7207	0.3%
Catharina	2011-2015	11225	0.4%
Erasmus	2011-2015	7343	0.2%
Haga	2012-2015	4833	0.3%
Isala	2011-2015	8430	0.4%
MCL	2011-2015	5868	0.3%
MST	2011-2015	6936	0.2%
MUMC	2013	1257	0.4%
OLVG	2011-2015	8579	0.1%
Radboud	2013-2015	2390	0.1%
UMCG	2012-2015	5369	0.5%
UMCU	2012-2015	3071	0.1%
ETZ	2013-2014	1387	0.0%
JBZ	2015	957	0.0%
Maasstad	2015	1374	*
Noordwest	2013-2015	3427	0.0%
Tergooi	2014-2015	1468	0.1%

TABLE 2. Uncorrected incidence of urgent coronary artery bypass grafting after percutaneous

 coronary intervention per hospital

Abbreviations: CABG = coronary artery bypass grafting, AMC = Academic Medical Centre Amsterdam, Amphia = Amphia Hospital, Antonius = St. Antonius Hospital, Catharina = Catharina Hospital, Erasmus = Erasmus MC, Haga = Haga Hospital, MCL = Medical Centre Leeuwarden, MST = Medical Spectrum Twente, MUMC = Maastricht University Medical Centre +, Radboud = Radboud University Medical Centre, UMCG = University Medical Centre Groningen, UMCU = University Medical Centre Utrecht, ETZ = Elisabeth-TweeSteden Hospital, JBZ = Jeroen Bosch Hospital, Maasstad = Maasstad Hospital, Noordwest = Noordwest Hospital group

* As this hospital had more than 10% missing data for the outcome measure urgent CABG, the incidence rate is not reported

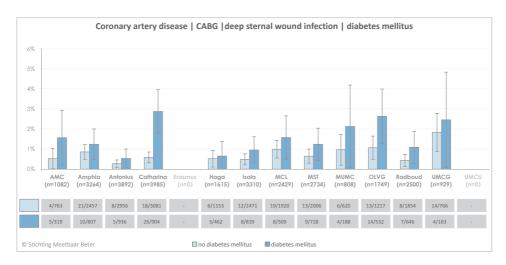


FIGURE 1. The incidence of deep sternal wound infection after coronary artery bypass grafting (CABG), segmented to diabetes.

Abbreviations: CABG=coronary artery bypass grafting

Note: the incidence rates for 2 hospitals are not presented in the figure because of incomplete data

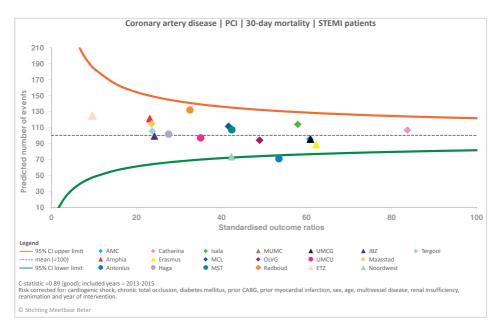


FIGURE 2. Funnel plot for 30-day mortality after percutaneous coronary intervention (PCI) in STEMI patients

Abbreviations: PCI=percutaneous coronary intervention

- Uncorrected percentages of the incidence for each selected outcome, segmented for preselected initial conditions. An example is presented in Figure
 This graph shows the impact of the initial condition diabetes on the outcome measure deep sternal wound infection within 30 days after CABG. Further analysis has to point out whether such variation is caused by differences in case-mix, or by differences in the care process.
- 3) In case of sufficient power, risk-adjusted results are presented. Most outcomes are presented in funnel plots, in which per center the observed event rate is plotted against the predicted event rate. Examples are presented in Figure 2 and 3, which represent the outcomes for respectively 30-day mortality after PCI for STEMI patients, and myocardial infarction within 30 days after PCI.

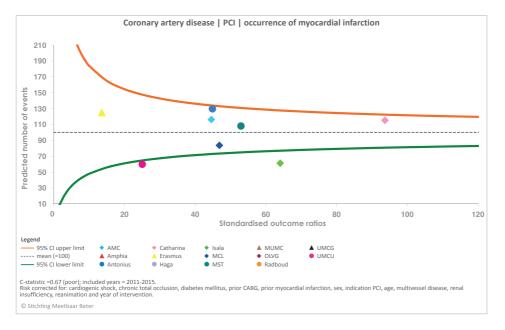
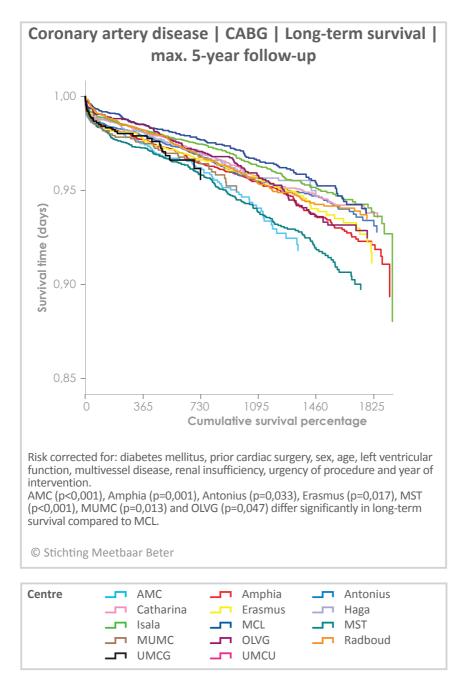
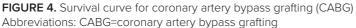
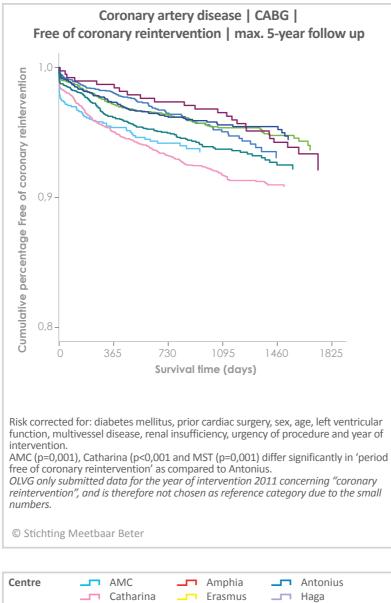


FIGURE 3. Funnel plot for myocardial infarction after percutaneous coronary intervention (PCI) Abbreviations: PCI=percutaneous coronary intervention Note: 6 hospitals are not presented in the funnelplot because of incomplete data

Survival rates over time are presented in risk adjusted Kaplan Meier curves. For example, Figure 4 and 5 present risk-adjusted curves for mortality after CABG and coronary reintervention after CABG.

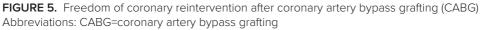






Isala MCL MST MUMC OLVG Radboud

г



UMCU

Note: 7 hospitals are not presented in the figure because of incomplete data

UMCG

Center-specific risk-adjusted survival rates are compared with the center with the highest survival rate, showing the potential for further improvement of the quality of care. In addition, critical time points during the follow-up period of 5 years can be noticed. Figure 6 presents the quality of life for CABG across 3 hospitals. Both the physical component and the mental component has improved 1 year after the intervention. Next to the average QoL at baseline and 1 year (10-14 months) after the intervention, we also show the proportions of patients who had an increased QoL after the intervention and who had an equal QoL after the intervention and who had a decrease of QoL.

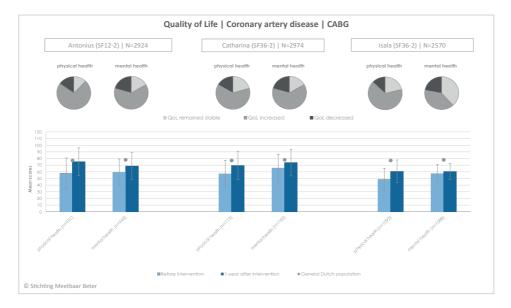


FIGURE 6. Quality of life of patients after coronary artery bypass grafting (CABG) Abbreviations: CABG=coronary artery bypass grafting

DISCUSSION

Meetbaar Beter has defined a standard set of patient-relevant outcome measures for CAD. The set has been fine-tuned using a yearly maintenance cycle for 3 consecutive years. Now the set has become stable and is considered to be suitable for scientific publication. It is the first set of patient-relevant outcome measures for CAD that has been published, fully implemented at a large scale, and is being used as a basis for quality improvements in routine clinical care. In 2016, about 83,000 PCIs and 30,000 CABGs were included in the dataset, covering the majority of all PCIs and CABGs in the Netherlands. The variation of the results among the centers indicates that there is potential to further improve cardiac care in the Netherlands. Several hospitals have already been successful in conducting improvement projects for patients with CAD, based on the presented figures. [6,20] However, presented data has to be interpreted cautiously. The c-statistics, describing the discriminatory power of the predictive models which underlie the funnel plots, varied from 0.59 (poor discriminatory power) to 0.89 (good discriminatory power).[21] Possible reasons for the relatively low predictive accuracy of some of the regression models are: 1) relevant initial conditions are missing in the standard set, 2) The reliability of the data is uncertain, as more soft endpoints like myocardial infarction and TVR are difficult to assess objectively than hard endpoints like mortality; or 3) differences in care delivery processes influence the outcome. The annual maintenance cycle in combination with the data quality checks are used to continuously improve the dataset and thus reduce the chances that a relatively low predictive value is caused by scenario's 1 or 2. In case of the third scenario, differences between centers are caused by quality differences in the underlying care processes, which can indicate potential for improvement. This can include patients' adherence to therapy and lifestyle. Although the c-statistics is clearly important, we believe that also funnel plots with a relatively low discriminatory power are valuable to present. In general, more variation has been found for short-term endpoints than for the long-term endpoints. A reason might be that short-term results are more dependent on the initial care provided around the cardiac intervention, while long-term results might reflect other processes as well. [22]

A strength of the standard set is that it has been validated in clinical practice. The results and feedback from the participating centers led to fine-tuning of definitions and changes in the composition of the standard set. Last year, no new outcome measures were added. However, it is important to recognize that the set is a work in progress, and should not limit the inclusion of additional variables to optimize the prediction models. Another strength is that the standard set includes both treatment-

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specific outcome measures as well as generic outcome measures covering all patients with CAD. We selected treatment-specific measures, because the outcomes of care and the care delivery process differ among the treatment options. In addition, generic outcome measures are used to create insight in the quality of treatment decisions. The interpretation of the generic outcome measures will require further research. At last, a strength of this standard set is that Meetbaar Beter provided detailed definitions of the outcome measures and initial conditions. This is important to assure valid data collection in order to allow comparison between time points and hospitals.

The standard set has been developed in 2012 and has been published about 5 years later. In the meantime, the International Consortium for Health Outcomes measurement (ICHOM) has proposed a standard set of outcome measure as well. [23,24] Although the sets do largely overlap, some differences can be highlighted. The main difference is that the set of ICHOM includes a larger number of outcome measures. For instance, acute renal failure, prolonged ventilation and patient reported outcomes such as angina, dyspnea and depression are not included in our standard set. Although these measures are clearly important, we aimed to restrict our set to limit administrative burden on patients and involved professionals from the participating centers and to increase the feasibility to use the standard set in practice. Another difference is that the Meetbaar Beter standard set has been validated by its implementation and use in clinical practice. Currently the first steps are taken to cooperate with ICHOM in order to create internationally comparable data on patient-centered outcomes. The current presented outcomes can be seen as first proof of principle of the ICHOM set in practice.

Avoidance of high-risk patients is an important topic when using outcome measures to assess center-specific performance. [25] To minimize this type of risk avoidance, Meetbaar Beter analyses disease generic outcomes next to the treatment-specific outcome measures for CAD. In the disease generic analyses, all patients with CAD are included, including high-risk patients who received a conservative treatment. Also not submitting high-risk patients for registries is an example of risk-avoidance. Therefore, participation to Meetbaar Beter is voluntary, but completeness of the submitted data is mandatory. This type of risk avoidance was not detected during the audits organized by Meetbaar Beter. Finally, Meetbaar Beter invests in an open culture with high levels of trust between physicians, in which potential limitations and misinterpretations of the data are openly discussed. A challenge is the improvement of the implementation of the standard set for CT. Patients are included in the CT group in case the multidisciplinary heart team decides to give the patient a conservative treatment due to the high risk of mortality or complications when an intervention would be performed. A limitation is that, even though according to the guidelines all patients that are eligible for an intervention for CAD should be discussed in a heart team, in practice this is most likely not happening for all patients. [26] The local policies can have major impact on the number of included patients in the CT group and thus on the completeness of the data. Currently, a project is started to evaluate the proposed methods for data collection for the CT group. Another challenge is the implementation of the QoL questionnaires. The number of patients who returned both questionnaires was low, as response rates varied from 26% to 42%. In addition, no systematic approach has yet been developed to interpret variations in QoL in terms of quality of the care delivery process.

In conclusion, Meetbaar Beter defined a comprehensive set of patient-relevant outcome measures for CAD. The implementation of the set has proven to be feasible. The variation of the results among the centers indicates that there are sufficient opportunities to further improve cardiac care in the Netherlands. Further research is mandatory to investigate whether this initiative indeed leads to an increased quality of care for patients with CAD. The standard set in combination with the detailed definitions and measurements of the indicators can function as benchmark data for heart centers from other countries.

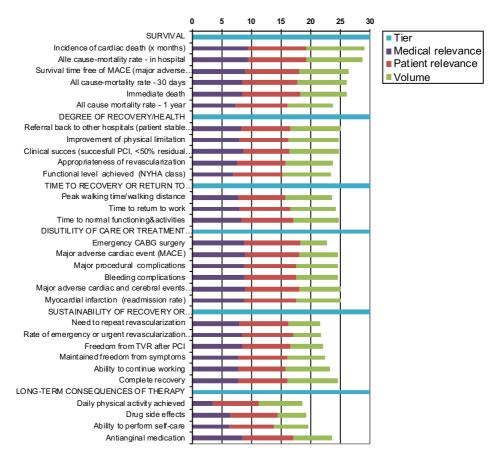
Collaborators group: Meetbaar Beter advisory board

- G Amoroso, Department of Cardiology, Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands
- S Aydin, Department of Cardiology, VieCuri Medical Center, Venlo, the Netherlands
- M Bax, Department of Cardiology, Haga Hospital, Den Haag, the Netherlands
- WJ van Boven, Department of Cardiothoracic Surgery, Academic Medical Center, Amsterdam, the Netherlands
- SL Brinckman, Department of Cardiology, Tergooi Hospital, Hilversum, the Netherlands
- JHE Dambrink, Department of Cardiology, Isala Hospital, Zwolle, the Netherlands
- S de la Fuente, Department of Cardiology, Jeroen Bosch Hospital, 's-Hertogenbosch, the Netherlands
- M van der Ent, Department of Cardiology, Maasstad Hospital, Rotterdam, the Netherlands
- TW Galema, Department of Cardiology, Erasmus Medical Center, Rotterdam, the Netherlands
- J Haenen, Department of Cardiothoracic Anesthesioly, Medical Center Leeuwarden, the Netherlands
- AO Kraaijeveld, Department of Cardiology, University Medical Center Utrecht, the Netherlands
- M Magro, Department of Cardiology, Elisabeth-TweeSteden Hospital, Tilburg, the Netherlands
- L Noyez, Department of Cardiothoracic Surgery, Radboud University Medical Center Nijmegen , the Netherlands
- JM van Opstal, Department of Cardiology, Medisch Spectrum Twente, Enschede, the Netherlands
- BJWM Rensing, Department of Cardiology, St. Antonius Hospital, Nieuwegein, the Netherlands
- AHM van Straten, Department of Cardiothoracic Surgery, Catharina Hospital Eindhoven, Eindhoven, the Netherlands
- VAWM Umans, Department of Cardiology, Noordwest Hospital, Alkmaar, the Netherlands
- K Vernooy, Department of Cardiology, Maastricht University Medical Center, Maastricht, the Netherlands
- J Vos, Department of Cardiology, Amphia Hospital, Breda, the Netherlands
- TW Waterbolk, Department of Cardiothoracic Surgery, University Medical Center Groningen, Groningen, the Netherlands
- P. Rademaker, Department of Cardiology, ZorgSaam Hospital, Terneuzen, the Netherlands

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SUPPLEMENTAL FIGURE S1. Prioritised outcome measures for Coronary Artery Disease treated with Percutaneous Coronary Intervention

Note: The figure presents the ranking of the top 30 outcomes on the long-list for Percutaneous Coronary Intervention, based on impact on patients (Patient relevance), number of patients affected (Volume) and impact of health professionals on the outcome (Medical relevance).

SUPPLEMENTAL TABLE S1. International academic advisory council

Methodology council

- Prof. F. Lega, Bocconi University, Milan, Italy
- Prof. F. van Eenennaam, The Decision Group, Amsterdam, The Netherlands
- Prof. L. Svensson, Cleveland Clinic, Cleveland, United States
- Prof. L.H. Friedman-George, Washington University, Washington, United States
- Prof. M. Adil, NHS, Edinburgh, Scotland

Medical council

- Prof. B. Bridgewater, University of Manchester, Manchester, England: combined aortic valve disease and coronary artery disease
- Prof. J. Cacchione, Cleveland Clinic, Cleveland, United States: coronary artery disease
- Prof. H. Calkins, Johns Hopkins Hospital, Baltimore, United States: atrial fibrillation
- Prof. L.H. Cohn, Harvard Medical School, Boston: aortic valve disease
- Prof. R. DiBartolomeo, University of Bologna, Bologna, France: Combined aortic valve disease and coronary artery disease
- Dr. J.R. Edgerton, The Heart Hospital Baylor Plano, Plano, United States: atrial fibrillation
- Prof. H. Heidbuchel, University Hospital Leuven, Leuven, Belgium: atrioventricular nodal reentrant tachycardia
- Prof. P. Herijgers, University Hospital Leuven, Leuven, Belgium: aortic valve disease
- Prof. P. Kirchhof, University of Birmingham, Birmingham, England: sudden cardiac death
- Prof. H. Klein, university of Rochester Medical Center, Rochester, United States: atrial fibrillation
- Prof. P. Lancellotti, University of Liège, Liège, Belgium: aortic valve disease
- · Prof. H. Schäfers, Saarland University Medical Center, Homburg, Germany: mitral valve disease
- Prof. P.Sergeant, University Hospital Leuven, Leuven, Belgium: coronary artery disease
- Prof. G. Stone, Columbia University Medical Center, New York, United States: coronary artery disease
- Prof. H. Treede, Universitty Heart Center Hambyrg, Hamburg, Germany: aortic valve disease
- Prof. T. Walther, Kerckhoff-Klinik, Bad Nauheim, Germany: aortic valve disease
- Prof. T. Weimar, Sana Heart Surgery Clinic Stuttgart, Stuttgart, Germany: atrial fibrillation
- Prof. W. Wijns, Onze Lieve Vrouwe Hospital Aalst, Aalst, The Netherlands: coronary artery disease
- Prof. P. Zamorano, University Hospital Ramon y Cajal, Madrid, Spain: aortic valve disease

Statistical council

- Prof. S. Paddock, Pardee RAND Graduate School, Santa Monica, United States
- Prof. S. Normand, Harvard Medical School, Boston, United States
- Prof. E. Steyerberg, Leiden University Medical Center, Rotterdam, The Netherlands

Outcome measure	Definition
30-days mortality	All-cause mortality within 30 days (≤ 30 days) after the intervention. 1) yes; 2) no; 3) unknown
120-days mortality	All-cause mortality within 120 days (≤ 120 days) after the intervention. 1) yes; 2) no; 3) unknown
1-year mortality	All-cause mortality within 1 year (≤ 365 days) after the intervention or start of the conservative treatment. 1) yes; 2) no; 3) unknown
Chest pain	Grading of chest pain using the Canadian Cardiovascular Society (CCS) scale between 10-14 months after the start of conservative treatment. 1) no chest pain; 2) grade I; 3) grade II; 4) grade III; 5) grade IV; 6) unknown
CVA	Cerebral Vascular Accident within 72 hours (≤72 hours) after the intervention, diagnosed by a neurologist, excluding Transient Ischemic Attacks. 1) no CVA; 2) CVA; 3) unknown
Deep sternal wound infection	Deep sternal wound infection* within 30 days after the intervention. * = infections of the muscle, sternum, or mediastinum (surgical drainage, positive wound cultures, and/or antibiotic treatment due to the sternal wound) 1) no deep sternal wound infection; 2) deep sternal wound infection; 3) unknown
Freedom of coronary artery reintervention	Freedom of coronary reintervention (CABG, PCI or CABG/PCI combined with another intervention) of the treated artery or any other artery, as function of days after the intervention. Number of days free of coronary artery reintervention
Freedom of MACE	Freedom of myocardial infarction, intervention (CABG of PCI) and death as function of days after start treatment. Number of days free of MACE
Freedom of myocardial infarction	Freedom of myocardial infarction* as function of days after the intervention, including peri-procedural myocardial infarctions * = definition according to Third universal definition of myocardial infarction (2012, Thygesen et al.) Number of days free of myocardial infarction
Long-term survival (up to 5 years)	Long-term survival after start of the intervention or start of the conservative treatment, with a maximum follow-up of 5 years. Number of days of survival
Occurrence of myocardial infarction	 STEMI or non-STEMI within 30 days (≤ 30 days) after the intervention or start of the conservative treatment , excluding peri-procedural myocardial infarctions*. * = definition according to Third universal definition of myocardial infarction (2012, Thygesen et al.) 1) no myocardial infarction; 2) myocardial infarction; 3) unknown

SUPPLEMENTAL TABLE S2. Definitions of outcome measures and initial conditions

Outcome measure	Definition
Occurrence of TVR	Revascularization (defined by both a PCI or CABG intervention) of the treated artery (or arteries) within 1 year (≤ 365 days) after the intervention , excluding urgent CABG's ≤ 24 hours. 1) no TVR; 2) TVR; 3) unknown
Surgical reexploration	Every rethoracotomy within 30 days (≤ 30 days) after initial closing of the thorax (e.g. due to bleeding, cardiac tamponade or cardiac problems). 1) no surgical reexploration; 2) surgical reexploration; 3) unknown
Quality of life	Quality of life of the patient measured before (max. 2 months) and after the intervention/start treatment (between 10-14 months). Preferably measured by using the SF-36-2, the SF-12-2 is also accepted). Score per dimension
Urgent CABG	Urgent CABG within 24 hours (≤ 24 hours) after the intervention as a result of acute complications (e.g. tamponade) or ongoing ischemia, independent of the treated lesions. 1) no urgent CABG; 2) urgent CABG; 3) unknown
Initial condition	Definition
Age	Age in years at the moment of the start of the intervention/start treatment. Number of years
Cardiogenic shock	Shock at the moment of start intervention. 1) no cardiogenic shock; 2) cardiogenic shock; 3) unknown
Chronic total occlusion	A chronic total occlusion in at least one of the treated arteries, for which the intervention is scheduled. 1) no chronic total occlusion; 2) chronic total occlusion; 3) unknown
Chronic pulmonary disease	Diagnosed chronic pulmonary disease prior to the intervention, for which prolonged bronchusdilators or steroids are used. 1) no pulmonary disease; 2) pulmonary disease; 3) unknown
Diabetes mellitus	Diabetes mellitus type 1 or type 2. 1) no diabetes mellitus; 2) diabetes mellitus; 3) unknown
Gender	Gender of the patient. 1) male; 2) female; 3) unknown
Indication PCI	The state of the patient at the start of the intervention: 1) elective; 2) non-ST-elevation myocardial infarction (NSTEMI) and instable angina pectoris; 3) ST-elevation myocardial infarction (STEMI)
Left ventricular function	Left ventricular function expressed as ejection fraction 1) EF >50%, 2) EF 30-50%; 3) EF < 30%; 4) unknown
Logistic EuroSCORE I	Last measured logistic EuroSCORE I prior to the intervention. Logistic EuroSCORE I
Logistic EuroSCORE II	Last measured logistic EuroSCORE II prior to the intervention. Logistic EuroSCORE II
Multivessel disease	Multivessel disease at the moment of start intervention. 1) no multivessel disease; 2) multivessel disease; 3) unknown

SUPPLEMENTAL TABLE S2. Continued

Initial condition	Definition
Previous CABG	Previous CABG (or CABG combined with another intervention) at the moment of start intervention throughout entire life. 1) no previous CABG; 2) previous CABG; 3) unknown
Previous CABG or PCI	Previous CABG or PCI (or CABG/PCI combined with other intervention) at the moment of start of the conservative treatment throughout entire life. 1) no previous CABG or PCI; 2) previous CABG or PCI; 3) unknown
Previous cardiac surgery	Previous cardiac surgery throughout entire life, for which opening of the pericardium was needed. 1) No previous cardiac surgery; 2) previous cardiac surgery; 3) unknown
Previous myocardial infarction	Previous myocardial infarction* at the moment of start of the intervention or start of the conservative treatment throughout entire life (myocardial infarctions which are the indication for executing the intervention are excluded). * = definition according to Third universal definition of myocardial infarction (2012, Thygesen et al.) 1) No previous myocardial infarction; 2) previous myocardial infarction; 3) unknown
Resuscitation	Resuscitation took place in the period between the start of the constraints and prior to the start of the intervention, regardless of the location where the resuscitation took place. 0) No resuscitation; 1) resuscitation; 2) unknown
Renal insufficiency	Renal insufficiency determined by a decrease in Glomerular Filtration Rate (GFR) < 60 ml/min/1.73 m ² . The GFR is calculated by using the MDRD formula. 1) \geq 60 ml/min/1.73 m ² ; 2) 30-59 ml/min/1.73 m ² 3) 15-29 ml/min/1.73 m ² ; 4) <15 ml/min/1.73 m ² ; 5) unknown
Urgency of the procedure	Urgency of the procedure. 1) Elective; 2) Urgent; 3) Extremely acute; 4) unknown

SUPPLEMENTAL TABLE S2. Continued

Note: The categories mentioned in this table can differ slightly from the presented categories in Table 1, as the results in table 1 cover the period 2011-2015, while in this table, the most recent version of the standard set (year 2017) is presented. Abbreviations: CABG=coronary artery bypass grafting; PCI=percutaneous coronary intervention ; TVR=target vessel revascularization



CHAPTER 5

Recent trends in aortic valve interventions in the Netherlands, Aantal storing data of the Netherlands Heart Registration 2018

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> E. Daeter MD*, **D. van Veghel** *, S.Houterman, J. Olsthoorn, M.Soliman-Hamad; on behalf of the registration committees cardiac surgery and Transcatheter Heartvalve Interventions (THI) of the Netherlands Heart Registration (NHR). * both contributed equally to this work

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ABSTRACT

Objectives: Transcatheter aortic valve implantation (TAVI) has evolved from a bail out for inoperable patients to an alternative to surgical aortic valve replacement (SAVR) in higher risk groups. The study's objective is to describe these clinical trends in TAVI and SAVR in patients with aorta valve disease.

Method: We analyzed data of the Netherlands Heart Registration 2018 (NHR) to explore the trends in TAVI and SAVR among 14 centers in the Netherlands.

Results: Between 2013 and 2017, a total of 7432 isolated SAVR and 5929 TAVI procedures have been performed. A 43.9% increase in the total number of procedures was observed, mainly due to the considerable increase in the number of TAVI procedures. In 2017, there was a decline in SAVR procedures. In TAVI group, procedural mortality, 30-day and 120-day mortality decreased significantly from 2.7%, 7.2% and 10.6% in 2013 to 1.4%, 3.4% and 5.7% in 2017, respectively. In the SAVR group, the 30-day and 120-day mortality decrease from 1.7% and 2.9% in 2013 to 1.2% and 1.7% in 2017 respectively. Outcomes showed a significant decrease in vascular complications in TAVI. The risk profile of TAVI patients has changed over time.

Conclusion: The developments in TAVI have contributed to the increasing numbers of aortic valve interventions in the Netherlands. Mortality rates after SAVR and TAVI declined as did the rate of complications after TAVI. Furthermore, a trend towards decrease of preoperative risk was observed.

Keywords: Aortic Valve Disease, Surgical Aorta Valve Replacement (SAVR), Transcatheter Aorta Valve Implantation (TAVI), Value-based healthcare.

INTRODUCTION

Aortic valve disease (AVD) is the leading valvular pathology in the Western World and is strongly linked to the phenomenon of an ageing population. [1, 2] The incidence of AVD in patients >65 years varies between 2 and 9%. [3-5] Untreated AVD might lead to cardiovascular mortality, acute myocardial infarction and congestive heart failure. [6-8] Current treatment options and patient outcomes depend on the exact valvular pathology. The most frequent native valve disease in Europe is currently aortic stenosis (AS), other pathologies include aortic valve insufficiency or combined pathology. [9, 10]

The implantation of a new aortic valve is the only definitive therapy for patients with severe AS. Current guidelines recommend aortic valve surgery in all symptomatic patients with severe AS or aortic valve insufficiency. Furthermore, asymptomatic patients with decreased left ventricular ejection fraction (LVEF) should be referred for surgery. [11] Any intervention designed to relieve AS carries the potential of benefit and risk. Surgical aortic valve replacement (SAVR can be performed in a highly-standardized manner with low perioperative morbidity and mortality and is therefore the current treatment option of choice. [12, 13] Surgical substitution of the native valve is associated with better prognosis and improved quality of life. SAVR is recommended in all patients at low surgical risk (logistic EuroSCORE I < 10%) with no other risk factors. [14] In patients who are at increased surgical risk, an increasing influence is appointed to the heart team, to decide between SAVR and TAVI based on patient's characteristics.

Recent evolution of treatment modalities has shown a transition from SAVR towards TAVI. Several trials showed TAVI to be a safe and viable alternative for patients with advanced age, low LVEF and other comorbidity, deemed ineligible for conventional cardiac surgery. [15-17] Initially, TAVI was considered an escape strategy for these patients. However, with gaining experience and better devices in the transcatheter approach, TAVI is now also considered in lower/intermediate risk patients. [18-20] Despite being less invasive than SAVR through sternotomy, TAVI remains associated with potential serious complications. In comparison with SAVR, the transcatheter approach is associated with a higher stroke rate and a higher incidence of heart block with the need for permanent pacemaker implantation. [21, 22]

The Netherlands Heart Registration (NHR) is a nationwide multicenter registry of cardiac surgeons and cardiologists to improve the quality and transparency of care

for patients with heart disease, designed to fulfill the principles of Value-Based Healthcare. [23]. Within the NHR, trends, outcomes and patient selection in isolated TAVI and SAVR between 2013 and 2017 can be analysed.

METHODS

Study design

The main aim of the NHR is to monitor the current incidence and outcome of a plethora of different cardiovascular interventions in daily practice and to evaluate safety, effectiveness and quality of life. The registry is driven by quality improvement ambitions of the participating hospitals. In total, 14 out of 16 existing Dutch heart centers in the Netherlands participated in this registry. The institutional review board of the Catharina Hospital and internal board of the NHR waived the need for informed consent due to the observational and anonym character.

Outcome selection and data acquistion

Prior to data collection, relevant outcomes were selected using a fixed step-wise methodology by an integrated team, consisting of cardiologists and cardiothoracic surgeons of the participating heart centers [see supplementary table]. The selected outcome measures are maximally patient-oriented and clinically relevant and form the basis of transparent reporting. The stepwise methodology resulted in a selection of 9 outcome measures for both SAVR and TAVI. A more detailed description about the selection and definitions of baseline characteristics and outcome measures has been published earlier [24]

Aortic valve disease is defined as a medical condition fulfilling one or more of the following criteria:

Aortic stenosis:

- Aortic valve area (AVA) of < 1.0 cm²
- AVA index of < 0.6 cm²
- Mean systolic gradient of > 40 mmHg
- Maximum jet velocity of > 4.0 m/s
- Speed ratio of < 0.25

Aortic insufficiency:

- Effective regurgitation area of > 30 m²
- Regurgitation volume of > 60 ml/beat

All data is collected by the center performing the initial treatment in compliance with data definitions documented by the NHR. Preoperative data is collected from the electronic health records of the hospital. Data regarding outcomes occurring after patient discharge or in the center of referral is collected by the primary center. Quality of life was assessed using the Short Form Health Survey-36 (SF-36; version 2) or the Short Form Health Survey-12 (SF-12; version 2) and was conducted 2 months prior to intervention and 10-14 months postoperative. Mortality data was obtained by checking the regional municipal administration registration. Data verification is accomplished by performing outlier analyses. Additionally, an auditing team performed randomly on site checks on completeness and the integrity of the data. In 2017, the focus of the auditing team was primarily on the TAVI cohorts.

For the TAVI group, mortality data included procedural mortality, 30-day mortality, 120-day mortality and 1-year mortality For the SAVR group, mortality data included 30-day mortality, 120-day mortality and 1-year mortality. One-year mortality data was not available for the cohorts of 2017.

Definitions

SAVR is defined as any aortic valve replacement through an open procedure. TAVI is defined as any aortic valve intervention by use of a catheter through vascular or transapical approach. All patients with TAVI or isolated SAVR between 1 January 2013 and 1 January 2018 were included.

Baseline demographic data included age, sex, logistic European System for Cardiac Operative Risk Evaluation (log EuroSCORE I). Data was also collected on previous cardiac surgery, prior cardiovascular accident (CVA), endocarditis and comorbidities such as diabetes mellitus (oral therapy or insulin dependent diabetes), chronic obstructive pulmonary disease (COPD) (prolonged use of steroids or other lung medication), renal disease (a reduced renal function prior to surgery with an estimated Glomerular Filtration Rate (eGFR) <60 ml/min/1.73 m²), and left ventricular ejection fraction (LVEF): good >50%, moderate 30–50% or poor <30%).

Based on logistic EuroSCORE I, patients were allocated into 3 groups, low risk (logistic EuroSCORE I < 10), intermediate risk (logistic EuroSCORE I 10-20) and high risk (logistic EuroSCORE I > 20).

Outcome measures include mortality, postoperative complications including surgical re-exploration within 30 days after intervention, deep sternal wound infection within 30 days, CVA within 72 hours, vascular complications within 30 days, pacemaker implantation within 30 days and valve re-intervention during follow-up.

Statistical analysis

Characteristics of patients are presented as absolute numbers and percentages. Outcomes were analyzed using multivariable logistic regression analyses with risk adjustment for the selected patient characteristics, using 2013 as the reference year. All data were analyzed using SPSS version 23.0 (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY).

RESULTS

Table 1 shows the baseline characteristics of both groups. The study included 7432 patients undergoing SAVR and 5929 TAVI patients. Overall, a 43.9% increase in the total number of aortic valve procedures was observed from 2174 procedures in 2013 to 3128 procedures in 2017 (Figure 1). This increase is mainly associated with the growth (161%) of the total number of the TAVI procedures. In 2017, there was a slight decline in SAVR (from 1505 in 2013 to 1380 in 2017).

Risk profile

At baseline, patients in the TAVI group had higher mean logistic EuroSCORE I, compared to the SAVR group (Figure 2). In both groups, a trend towards a decrease of risk profile of patients was observed. In the SAVR group, the median EuroSCORE decreased from 5.4 (3.1-9.0) in 2013 to 4.6 (2.9-7.3) in 2017. In the TAVI group, the median EuroSCORE decreased from 16.5 (11.0-25.5) in 2013 to 12.3 (8.4-19.4) in 2017. Most patients referred for TAVI ("82%) were older than 74 years (Table1). However, a slight decrease in the number of patients older than 85 years (from 26.6%to 24.7%) as well as a decrease of patients with a low left ventricular ejection fraction <30% from 9.2% to 6.6% was seen. Patient selection for TAVI showed a decrease in very high risk patients (logistic EuroSCORE I > 20), from 38.3% in 2013 to 24.4% in 2017. Additionally, an increase in TAVI patients with a lower risk (logistic EuroSCORE I < 10), from 18.2% in 2013 to 32.5% in 2017 was found. In SAVR group, a decrease in the

	2013		2014		2015		2016		2017	
Variable	SAVR n= 1505	TAVI n= 669	SAVR n= 1481	TAVI n= 929	SAVR n= 1512	TAVI n= 1222	SAVR n= 1554	TAVI n= 1361	SAVR n= 1380	TAVI n= 1748
Male	866 (57.5%)	309 (46.2%)	872 (58.9%)	420 (45.2%)	881 (58.3%)	561 (45.9%)	941 (60.6%)	695 (51.1%)	839 (60.8%)	880 (50.3%)
Age, years	71 (63-77)	81 (77-85)	70 (62-76)	81 (77-85)	70 (62-76)	81 (77-85)	70 (63-76)	81 (77-85)	69 (62-74)	81 (77-84)
< 75	695 (46.2%)	118 (17.6%)	727 (49.1%)	170 (18.3%)	750 (49.6%)	214 (17.5%)	765 (49.2%)	244 (17.9%)	726 (52.6%)	330 (18.9%)
75-84	595 (39.5%%)	373 (55.8%)	577 (39.0%)	481 (51.8%)	592 (39.2%)	671 (54.9%)	633 (40.7%)	769 (56.5%)	557 (40.4%)	986 (56.4%)
≥ 85	215 (14.3%)	178 (26.6%)	177 (12.0%)	278 (29.9%)	170 (11.2%)	337 (27.6%)	156 (10.0%)	348 (25.6%)	97 (7.0%)	432 (24.7%)
EuroSCORE	5.4 (3.1-9.0)	16.5 (11.0-25.5)	5.2 (2.9-8.3)	14.9 (10.0-23.0)	5.0 (2.9-8.1)	13.9 (9.2-21.0)	4.7 (3.0-7.7)	13.9 (9.2-21.0)	4.6 (2.9-7.3)	12.3 (8.4-19.4)
< 10%	1165 (77.8%)	121 (18.2%)	1169 (80.2%)	197 (22.5%)	1236 (81.9%)	297 (25.3%)	1284 (83.1%)	345 (25.9%)	1173 (85.1%)	491 (32.5%)
10-20%	250 (16.7%)	290 (43.5%)	225 (15.4%)	383 (43.7%)	207 (13.7%)	542 (46.2%)	196 (12.7%)	601 (45.2%)	142 (10.3%)	651 (43.1%)
> 20%	83 (5.5%)	255 (38.3%)	64 (4.4%)	297 (33.9%)	66 (4.4%)	334 (28.5%)	66 (4.3%)	385 (28.9%)	64 (4.6%)	368 (24.4%)
LVEF										
> 50%	1149 (82.5%)	384 (58.8%)	1216 (82.3%)	533 (57.7%)	1231 (81.4%)	755 (62.5%)	1268 (81.6%)	842 (63.5%)	1109 (80.5%)	1046 (63.2%)
30-50%	199 (14.3%)	209 (32.0%)	226 15.3%)	296 (32.1%)	245 (16.2%)	367 (30.4%)	253 (16.3%)	393 (29.7%)	235 (17.1%)	501 (30.3%)
< 30%	45 (3.2%)	60 (9.2%)	36 (2.4%)	94 (10.2%)	36 (2.4%)	86 (7.1%)	32 (2.1%)	90 (6.8%)	34 (2.5%)	109 (6.6%)
eGFR ≥ 60 mmol/L	1118 (74.9%)	312 (46.8%)	1099 (74.5%)	426 (45.9%)	1168 (77.4%)	566 (46.6%)	1203 (77.5%)	616 (45.5%)	1054 (76.4%)	838 (49.0%)
eGFR 30-59	346 (23.2%)	301 (45.1%)	352 (23.8%)	415 (44.7%)	313 (20.7%)	554 (45.6%)	329 (21.2%)	652 (48.2%)	307 (22.3%)	767 (44.9%)
eGFR 15-29 mmol/L	20 (1.3%)	44 (6.6%)	16 (1.1%)	71 (7.7%)	21 (1.4%)	71 (5.8%)	14 (0.9%)	65 (4.8%)	15 (1.1%)	90 (5.3%)
eGFR < 15 mmol/L	6 (0.6%)	10 (1.5%)	9 (0.6%)	16 (1.7%)	8 (0.5%)	23 (1.9%)	6 (0.4%)	20 (1.5%)	3 (0.2%)	15 (0.9%)
COPD	181 (12.0%)	138 (21.2%)	180 (12.2%)	232 (25.0%)	200 (13.2%)	271 (22.2%)	214 (13.9%)	289 (21.3%)	152 (11.0%)	356 (20.8%)
Prior CVA	76 (5.4%)	77 (11.5%)	61 (4.4%)	146 (15.7%)	55 (4.1%)	135 (11.1%)	89 (6.6%)	158 (11.7%)	61 (5.0%)	206 (12.0%)
Prior cardiac Surgery	147 (9.8%)	174 (26.3%)	134 9.0%)	195 (21.1%)	117 (7.7%)	238 (21.9%)	128 (8.2%)	317 (23.4%)	119 (8.6%)	370 (21.6%)
Diabetes	287 (20.5%)	N/A	325 (22.0%)	N/A	270 (17.9%)	N/A	305 (19.7%)	N/A	243 (17.9%)	N/A
Active endocarditis ¹	70 (4.7%)	N/A	75 (5.1%)	N/A	71 (4.7%)	N/A	69 (4.5%)	N/A	92 (6.7%)	N/A

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Recent trends in aortic valve interventions in the Netherlands, data of the Netherlands Heart Registration 2018

number of patients with a logistic EuroSCORE I >10- <20 and a significant reduction in the percentage of patients over 80 years old (from 14,3% to 7%) was observed. No other significant changes in parameters contributing to the EuroSCORE were observed (Table 1).

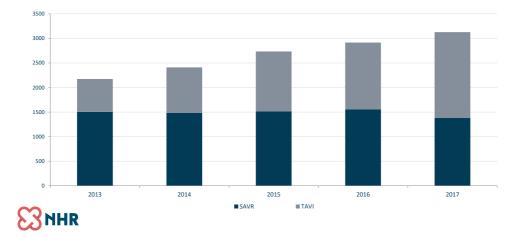


FIGURE 1. Total number of patients undergoing SAVR and TAVI per year of the registry period.

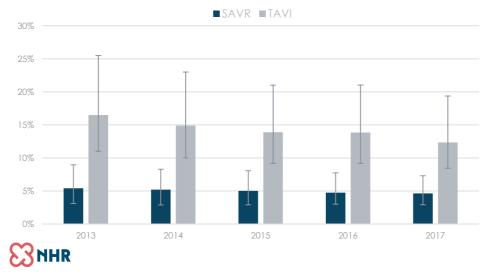
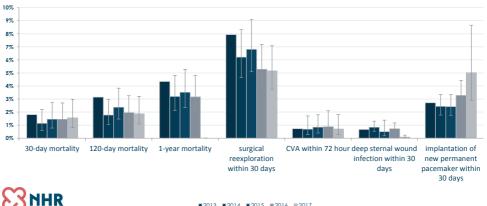


FIGURE 2. Logistic EuroSCORE for both groups per year of the registry

Mortality

in SAVR patients, the 120-day and one-year mortality showed an overall decrease from 2.9% and 4.3% in 2013 to 1.7% in 2017 and 3.0% in 2016 respectively . The procedural mortality of TAVI patients decreased from 2.7% in 2013 to 1.4% in 2017 (Table 2). Additionally, both 30-day and 120-day mortality in TAVI patients decreased, from 7.2% and 10.6% in 2013 to 3.4% and 5.7% in 2017 respectively. This significant decline was also seen in the risk-adjusted outcomes (Figure 3,4).



■2013 ■2014 ■2015 ■2016 ■2017

FIGURE 3*. Postoperative outcome measures in the SAVR group per year of the registry period * 1-year mortality data are not yet available for the cohort of 2017. CVA, cerebro-vascular accident

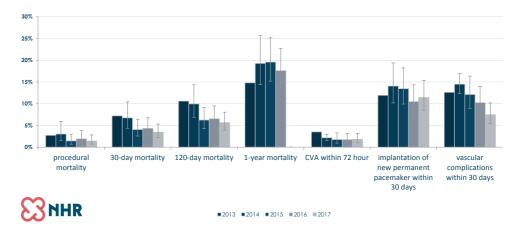


FIGURE 4*. Postoperative outcome measures in the TAVI group per year of the registry period CVA, cerebrovascular accident. *1-year mortality data are not yet available for the cohort of 2017

TABLE 2. Outcome measures of the two study cohorts per year of the registry period	easures of th	ne two study	∕ cohorts pe	er year of the	registry pe	eriod				
	2013		2014		2015		2016		2017	
Variable⁺	SAVR n= 1505	TAVI n= 669	SAVR n= 1481	TAVI n= 929	SAVR n= 1512	TAVI n= 1222	SAVR n= 1554	TAVI n=1361	SAVR n=1380	TAVI n=1748
Procedural mortality	N/A	15 (2.7%)	N/A	23 (3.0%)	N/A	15 (1.5%)	N/A	21 (1.8%)	N/A	21 (1.4%)
30-day mortality	25 (1.7)	40 (7.2%)	17 (1.2%)	52 (6.8%)	18 (1.2%)	42 (4.1%)	19 (1.2%)	48 (4.2%)	17 (1.2%)	52 (3.4%)
120-year mortality	44 (2.9%)	59 (10.6%)	27 (1.8%)	78 (10.2%)	32 (2.1%)	67 (6.5%)	27 (1.7%)	75 (6.5%)	24 (1.7%)	86 (5.7%)
1-year mortality	64 (4.3%)	86 (15.4%)	46 (3.1%)	119 (15.6%)	49 (3.3%)	144 (13.9%)	46 (3.0%)	130 (11.3%)		
CVA	11 (0.7%)	22 (3.4%)	10 (0.7%)	18 (2.3%)	12 (0.8%)	20 (1.9%)	11 (0.7%)	22 (1.8%)	8 (0.6%)	29 (1.9%)
Implantation of new permanent pacemaker	21 (2.7%)	74 (11.9%)	20 (2.5%)	113 (13.3%)	19 (2.4%)	152 (12.9%)	26 (3.3%)	131 (10.1%)	36 (5.2%)	191 (11.4%)
Vascular complications	N/A	79 (12.6%)	N/A	109 (14.0%)	N/A	126 (12.0%)	N/A	116 (9.9%)	N/A	111 (7.3%)
Surgical re-exploration	110 (7.9%)	N/A	91 (6.6%)	N/A	95 (6.7%)	N/A	75 (5.2%)	- A/N	68 (5.3%)	N/A
Deep sternal wound infection	9 (0.7%)	N/A	12 (0.9%)	N/A	7 (0.5%)	N/A	10 (0.7%)	N/A	1 (0.1%)	N/A
Data are presented as n(%) ⁺ Not all outcome measures are delivered by a ⁺ One-year mortality data are not yet available	are delivered by not yet availab	delivered by all hospitals ot yet available								

CVA, cerebro-vascular accident N/A, not applicable

Chapter 5

Complications

In SAVR patients, the overall need for surgical re-exploration within 30-days decreased from 7.9% in 2013 to 5.3% in 2017 (Table 2). The rate of both CVA, deep sternal wound infections and pacemaker implantation remained stable. Patients referred for TAVI showed a decreased rate of CVA, from 3.4% in 2013 to 1.9% in 2017 (Table 2). Furthermore, an overall decrease in vascular complications after TAVI is observed, with an incidence of 12.6% in 2013 to 7.3% in 2017. The risk-adjusted outcomes showed a significant decrease in surgical re-exploration for SAVR patients and a significant decrease in CVA and vascular complications in TAVI patients (Table 2, Figure 3,4).

Quality of life

Patients in the TAVI group showed a significantly lower physical health before the intervention (mean 46.7) compared to one year after the intervention (mean 55.5) (Figure 5). As regards to mental health, there was a non-significant increase in quality of life. In SAVR patients, both the physical health and the mental health showed an increase in quality of life one year after the intervention compared to baseline (mean 54.4 to 64.8 and mean 64.9 to 70.8 respectively).

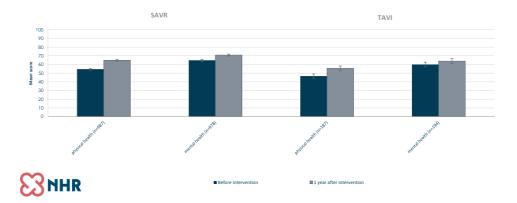


FIGURE 5. Pre- and postoperative quality of life scores in the two groups of the study.

DISCUSSION

This study describes the most recent trends in TAVI and SAVR in 14 cardiac centers in the Netherlands. Between 2013 and 2017, an increase in the total number of aortic valve procedures was observed, apparently due to an increase in the number of TAVI procedures performed. Similar to earlier studies [25,26] this study shows an increase in the total number of patients treated for aortic valve disease, caused by an increase of the number of TAVI's and a stable number of SAVR until 2016. In 2017, the increase in the number of TAVI's continues and a decrease in the number of SAVR is observed.

The early mortality rates of TAVI patients decreased significantly. This trend was also observed in SAVR patients. Furthermore, perioperative complications in TAVI patients significantly decreased with an increasing number of TAVI procedures performed. In both groups, a trend towards decrease of risk was observed with less patients with logistic EuroSCORE I > 20. Both treatments showed an increased physical and mental health 1 year after the intervention.

A substantial group of patients used to be denied for surgery because the operative risk was deemed prohibitively high, owing to comorbidities. [27] As TAVI was primarily introduced for these inoperable patients, an increase in the total number of patients treated was expected. Furthermore, SAVR has shown to be effective in reducing all-cause mortality in patients with AS, compared with the best medical therapy. Increased awareness from general practitioners and referring cardiologists might be an explanation for the increase in the total number of patients being treated as it was undertreated until 2009 [28]

During the observed period complication rates of TAVI patients have rapidly declined, but are still higher than in the SAVR group such as the need for a pacemaker and CVA. The reasons for improved outcomes are probably multifactorial and include more strategic patient selection, better preoperative planning, increased operator experience, improved delivery systems, better facilitated postoperative care, the use of rapid deployment valves [29], mini-extracorporeal perfusion systems, and the increasing use of biological prosthesis in the SAVR group Reducing postoperative complications in TAVI patients will be a pre-condition for adaptation of TAVI in lower risk patients, as SAVR nowadays can be performed with low perioperative morbidity and mortality [30]. It is conceivable that the decrease of the percentage of patients with an EuroSCORE 10-20 in the SAVR group is mainly caused by the observed transfer of higher aged patients from SAVR to TAVI treatment since higher age is an important factor in the EuroSCORE1 contributor to the log EuroSCORE1. In the TAVI group, the trend towards a decrease of the average EuroSCORE 1 is due to the decrease in percentage of patients older than 85 years old and the percentage of patients with a low left ventricular ejection fraction (EuroSCORE 1 <30%) and the increase in lower risk (EuroSCORE 1 <10%) patients. A similar pattern has been observed in the evolution of average risk profiles of patients described in the PARTNER [31,32] and SURTAVI [33] trials.

Although the mean EuroSCORE 1 in the TAVI group declined from 16.5% to 12.3%, the average EuroSCORE 1 in the TAVI-group remains statistically significant higher than the average EuroSCORE 1 in the SAVR group, indicating an important difference in risk profiles between both groups. To illustrate this risk: the average patient treated with TAVI in 2017 in this study has an EuroSCORE 1 of 12.3%, this is a patient of 79 years old with a moderate left ventricular function and previous cardiac surgery. This is still a high risk patient for surgery.

This registry represents real-life, unbiased data, from 14 cardiac centers in the Netherlands. The registry allows to observe the implementation of new techniques in daily practice, which might be different from patterns shown in randomized trails or observational studies. A national benchmarking initiative can support quality assurance and improvement on a hospital level, by analyzing risk-corrected outcomes between hospital [24]. Additionally, the registry allowed to observe trends, that will not always be visible at a hospital level. These trends may be of importance to physicians and policy makers in healthcare. Most of all, transparent reporting of outcomes is known to contribute to quality improvement. [34]

Limitations

The current study does have some limitations. It was not designed to differentiate between different vascular approaches and different valve types used for TAVI. Furthermore, the study was not adjusted for any difference in experience with TAVI between the different centers. Our objective was to present the unbiased trends and outcomes of TAVI in comparison with SAVR in the Netherlands. Some variables and outcome measures were not delivered by a few centers.

Currently, there is increasingly interest in SAVR through a mini-sternotomy. This study did not differentiate between the approaches used in SAVR. Therefore, the

results could be influenced by early experience in minimally-invasive SAVR. Also, the incidence of patients suffering from AVD and coronary artery disease might be higher in the TAVI-group, as patients treated with PCI in the same period of time were not excluded in both groups.

Despite the data-quality management system implemented by the NHR, data quality may vary between different hospitals. Data collected from daily practice is inevitably subjected to missing values and differences in interpretations. However, the specific audits on patient data contributes to a high data quality and accuracy in this study.

In the observations of the quality of life outcomes, the limited number of TAVI patients that are included needs to be taken into account.

Conclusion

In percentage of, the use of TAVI considerably increased, and has overtaken SAVR for the treatment of AVD in the Netherlands. Importantly, the early mortality rates have decreased in both SAVR and TAVI. Also, morbidity rates after TAVI are rapidly declining. Mortality- and complication-rates are higher in TAVI, as is the risk profile of patients. Furthermore, a trend towards decrease of risk profile of patients was observed in both groups mostly by the shift of high age patients from SAVR to TAVI.

So one may conclude that the choice for each treatment option has matured in time and consequently the outcome of the whole group of patients treated for aortic valve disease improved over the years. This results in more patients being referred for a tailored choice for treatment by SAVR or TAVI.

Acknowledgement

This work has been supervised and approved by the registration committees cardiac surgery and Transcatheter Heart Interventions (THI) of the Netherlands Heart Registration (NHR). We would like to thank all the fourteen Dutch cardiac centers who participated in this registry and made it possible to perform this study. We have added a supplementary table with the name of cardiac surgeons and cardiologists representing every center.

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None

Conflict of interest statement

None

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Chapter 5

34. Carlhed R, Bojestig M, Peterson A, Aberg C, Garmo H, Lindahl B *et al. Improved clinical outcome* after acute myocardial infarction in hospitals participating in a Swedish quality improvement initiative. Circ Cardiovasc Qual Outcomes 2009;2:458-64. **SUPPLEMENTARY TABLE.** List of the cardiac centers participating in the registry with the names of the representing cardiac surgeons and cardiologists.

Hospital	Cardiac surgery committee	THI committee
Academic Medical Center	W.J. van Boven	M.M. Vis
Maastricht University Medical Center	P. Segers	S. Kats
Amphia Hospital	S. Bramer	J. Vos
Catharina Hospital	B.M.J.A. Koene	W.A.L. Tonino
Erasmus Medical Center	J.A. Bekkers	J.A. Bekkers
Haga Hospital	G. Hoohenkerk	C.E. Schotborgh
Isala Clinic	A.L.P. Markou	V. Roolvink
Leiden University Medical Center	T.J. van Brakel	F. van der Kley
Medical center Leeuwarden	F. Porta	F. Porta
Medical Spectrum Twente	R. Speekenbrink	M.G. Stoel
OLVG Amsterdam	W. Stooker	G. Amoroso
Sint Antonius Hospital	E. Daeter	J. ten Berg
Radboud University Medical Center	M. Verkroost	H.R. Gehlmann
University Medical Center Utrecht	N.P. van der Kaaij	P.R. Stella
University Medical Center Groningen	G. Mecozzi	H.W. van der Werf
VU Medical Center	E.K. Jansen	J. Lemkes

THI, Transcatheter Heartvalve Interventions



CHAPTER 6

Organization of outcomes-based quality improvement in Dutch heart centers

Aantal sterfgevallen bij operatie aan hartklep daalt fors

D. van Veghel, E. Daeter, G. Amoroso, M. Bax, Y. Blaauw, C. Camaro,
 P. Cummins, F. Halfwerk, I. den Hamer, J. de Jong,
 W. Stooker, P. van der Wees, P. van der Nat.

European Heart Journal - Quality of Care and Clinical Outcomes 2019, qcz021

mensan) tijdens of kort na de operatie. In 2016 was dit gedaald operatie.

Opvallend

Dimen de NHR worden de resultaten van alle M elkaar vergeleken, "Als blijkt dat één zie-heeft, kunnen andere ziekenhuizen directeur Dennis van Veghei * tussen ziekenhuizen ** bijdrage aan de deVolkskrant

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ABSTRACT

Aims: Fourteen Dutch heart centers collected patient-relevant outcomes to support quality improvements in a value-based health care initiative that began in 2012. This study aimed to evaluate the current state of outcome-based quality improvement within six of these Dutch heart centers.

Methods and results: Interviews and questionnaires among physicians and health care professionals in the heart centers were combined in a mixed-methods approach. The analysis indicates that the predominant focus of the heart centers is on the actual monitoring of outcomes, and that a systematic approach for the identification of improvement potential and the selection and implementation of improvement initiatives is lacking. The organizational context for outcome-based quality improvement is similar in the six heart centers.

Conclusion: Although these heart centers in the Netherlands measure health outcomes for the majority of cardiac diseases, the actual use of these outcomes to improve quality of care remains limited. The main barriers are limitations regarding 1) data infrastructure, 2) a systematic approach for the identification of improvement potential and the selection and implementation of improvement initiatives, 3) governance in which roles and responsibilities of physicians regarding outcome improvement are formalized, and 4) implementation of outcomes within hospital strategy, policy documents and the planning & control cycle.

INTRODUCTION

Internationally, healthcare providers are transforming into more value-driven care organizations with the implementation of value-based health care (VBHC). [1] The first step in implementing VBHC is to measure and improve outcomes. [1] To support outcome measurement, several standard sets of outcome measures have been developed in recent years. [2-5] However, little is known on how to use these insights into outcomes to drive improvement of patient value. [6]

In 2012 a VBHC project was initiated for cardiac diseases in the Netherlands leading to publications of patient-relevant outcomes, including short and long-term survival, complications, re-operations and quality of life. [7, 8] By 2016, 19 hospitals had voluntarily joined this initiative. In 2017 the Netherlands Heart Registration (NHR) was founded, merging this initiative with the national registries of cardiology and cardiothoracic surgery. The annual public report in 2018 included outcomes of different treatment options for coronary artery disease, aortic valve disease, atrial fibrillation and mitral valve disease, containing data for approximately 80,000 new patients annually. [9, 10]

Public benchmarking of outcomes has led to several improvement initiatives. [11-13] However, the structural embedment of outcomes within the organization and in quality management programs is a prerequisite for long-term successful quality improvement. [14-16]

In order to evaluate the current state of outcome-based quality improvement, a study was initiated in six of these Dutch heart centers. The focus was twofold: firstly, we looked at how insights into outcomes drive quality-improvement initiatives and, secondly, how outcome-based quality improvement is embedded in the organization.

METHODS

Framework

Two models were used to study outcome-based quality improvement in the six heart centers. The *outcome-based improvement cycle* (left part of Fig. 1) was used to investigate how insight into health outcomes drives quality improvement initiatives. This model is related to the PDSA model, which is explained in Table S1. [17] The 7S

model of McKinsey was used to study the organizational context in which outcome measures were used. [18] This model was adapted to focus specifically on health outcomes (right part of Fig. 1).

1. Monitoring outcomes	Element	Short description
T. Monitoring outcomes	1. Strategy	How is outcome-based quality improvement embedded in strategy, policy documents, and planning & control?
	2. Governance (structure)	How is outcome-based quality improvement embedded in governance
2. Identification improvement potential	3. Culture (shared values)	To what extent is outcome-based quality improvement part of the organizational culture?
	4. Leadership (style)	To what extent does formal or informal leadership embrace and stimulate outcome-based quality improvement?
3. Selection improvement initiatives	5. Infrastructure (systems)	To what extent does IT infrastructure support outcome-based quality improvement ?
	6. Staff	To what extent is dedicated staff available (physician, support staff) to support outcome-based quality improvement?
4. Implementation improvement initiatives	7. Skills	What skills are available in the organization to support outcome-based quality improvement?

FIGURE 1: The outcomes-based improvement cycle (left) and an adapted version of the 7S model of McKinsey (right) to study the organizational context in which outcome measures are used.

All centers involved in the 2016 VBHC initiative were invited to participate in the project. Of these, six heart centers accepted the invitation to participate. Apart from their motivation to join, these six heart centers had an average level of participation in the outcome registration (data completeness and years of participation).

Design

A mixed-methods approach was applied. Data were collected through questionnaires and semi-structured interviews conducted in parallel. Results were validated in group meetings at each participating heart center. Methodological triangulation was used to study the status of outcome-based quality improvements in each of these centers and to reach validity, combining questionnaires with interviews.

The full study took 12 months, from September 2016 until September 2017. At each heart center, three local group meetings were organized: a kick-off meeting, a meeting to discuss the first insights, and a final meeting to discuss and validate the results. Participants were selected to ensure a good representation of each heart center, resulting in the inclusion of at least one cardiologist, one cardiothoracic surgeon,

managers of the heart center (medical and non-medical), and a data analyst. The questionnaire was based on the models and steps shown in Fig. 1 [see Table S2]. [18] In total, 42 detailed questions were posed in the steps of the combined model.

The questionnaire was sent to each center using an online survey tool. The group members of each heart center filled out the questionnaire together. For each heart center, 6-8 separate interviews were conducted. In addition to the selected participants, a member of the hospital board of directors was also interviewed. In total 41 semi-structured interviews were conducted of approximately 45-60 minutes each. An interview guide was used, based on the model in Exhibit 1. For each of the themes in the model, open questions were developed and probing questions were asked to obtain more detailed information. [18]

The interviews were conducted face to face by two researchers. Both researchers participated in each interview. For each of the interviews, detailed minutes were taken by the two researchers independently. The minutes were coded and analyzed in Atlas.ti 8.2 using a thematic analysis with a deductive approach. [19] The study results are presented as a list of themes in which the findings from the interviews and the questionnaires are combined. Triangulation of the two data sources across the identified themes was conducted to demonstrate alignment or consistency between the sources.

RESULTS

The main results of this study are presented in Table 1, categorized within the 4 steps of the outcomes-based improvement cycle and the 7 elements of the organizational context.

Outcome-based improvement cycle

The predominant focus of the heart centers is on the monitoring of outcomes (Step 1). A systematic approach for the identification of improvement potential, and the selection and implementation of improvement initiatives is lacking (Steps 2-4). Physicians explicitly mentioned that they struggle with this. For example, one center had a significantly higher rate of wound infections compared to the national average. The urgency to improve was felt, but the cause of the poor performance was not identified and a systematic approach toward improvement was lacking.

Outcomes-based improvement	
cycle	Themes
1. Monitoring outcomes	 a. Monitoring of outcomes is more developed within cardiothoracic surgery , compared to cardiology (more data, more frequent discussions, use of more advanced data analysis). b. Focus is on hard clinical outcomes. Insight in and use of PROMs including Quality of Life is limited. c. Interpretation of outcome data is mainly an activity initiated by individual physicians. d. Outcomes are typically monitored and discussed in between quarterly and annually for the majority of heart diseases. e. The national benchmarking systems are the main tools for monitoring outcomes. f. Continuous real-time insight in and monitoring of outcomes has not been realized.
2. Identification improvement potential	 a. No targets are set on available outcome measures. b. Performance on outcomes only leads to improvement initiatives if the hospital significantly underperforms with respect to the average in a national benchmark (after risk correction) or if a negative trend in time is observed. c. Differences in outcomes between individual surgeons are monitored and discussed. Within some centers this performance is part of a formal assessment of individual surgeons. d. Several outcome measures have been selected where the heart centers aim to improve. e. The outcome reports in 2015 and 2016 have led to 1-4 improvement initiatives per hospital. f. Improvement projects are more often driven by incidents, calamities, and complication meetings (i.e. related to individual patients) and not by outcome reports (i.e. related to performance for all patients with a specific medical condition).
3. Selection of improvement initiatives	 a. A systematic approach (method) to select improvement initiatives is lacking. b. No standard organizational structure exists for improvement projects. c. Improvement initiatives are mostly ad-hoc. d. Improvement initiatives are mostly based on internal analyses. Outcome performance or benchmarking hardly ever leads to hospitals contacting each other to learn from one another. e. Outcome reports lead to additional in depth data analyses.
4. Implementation improvement initiatives	a. A systematic approach to implement and evaluate improvement initiatives is lacking.

TABLE 1. Status of implementation of outcome-based improvement within six Dutch heart centers.

Organizational context	Themes
1. Strategy	 a. Quality is often part of key elements in the defined strategy. b. Quality is often not well defined and is limited to high level definitions in the strategy. c. Outcome performance hardly plays a role in the strategy and yearly policy documents. d. Steering on required quality indicators (e.g. by the Health Care Inspectorate) and steering on outcomes at medical condition level are often separate worlds (discussed, analyzed and reported in different meetings at different levels in the organization). e. In some hospitals physician income has been coupled for a small percentage to steering on outcomes (e.g. participation in VBHC projects).
2. Governance	 a. The initiative for measuring and improving outcomes comes from physicians. Hospital management supports this trend, but does not initiate this. b. The heart centers have a multidisciplinary organizational structure. However quality improvement and steering on outcomes is dominantly organized within the individual specialties. c. Multidisciplinary meetings are organized to discuss outcomes. d. Clinical outcomes are only discussed within the hospital and not with GPs or referring hospitals. Nurses and patients are not involved in discussing clinical outcomes. e. Roles and responsibilities regarding outcome performance have not been formalized. f. Reporting and discussion of outcomes at the level of the board of directors is limited and focuses on general outcomes (HSMR, complications) that are required by external parties (Such as the Health Care Inspectorate). Outcomes at the medical condition level remain most of the time at lower levels in the organization.
3. Culture	 a. A culture exists to openly discuss outcomes within each specialty. Much less openness exists to discuss outcomes between specialties. b. A culture exists to continuously improve health care. c. It is unclear whether strong support for outcomes-based quality improvement exists. Opinions on this highly differ within and between individual hospitals. d. A large group of healthcare professionals are not actively informed on the outcomes and are not involved in discussions of the outcome data (physicians and nurses).
4. Leadership	 Strong medical leadership to develop the outcomes-based quality improvement cycle exists within the centers.

TABLE 1. Continued.

TABL	E 1.	Continued	

Organizational context	Themes
5. Infrastructure	 a. Data infrastructure, data management and acquiring high quality data is seen as one of the largest barriers to realize outcome based improvements. b. Structural out-of hospital follow up data collection processes are under construction. c. Extraction and visualization of outcomes require significant man hours (Bl, data-analysts), this is not automated and data comes from several different sources. d. Hospitals are working on the development of quality dashboards. Dashboards exist in some hospitals, but in all hospitals this is work in progress.
	e. Most hospitals recently transitioned to a new Electronic Hospital Record (EPIC or HiX) or were planning to do so. Most hospitals are experiencing difficulty in this transition phase in extraction data needed to calculate and report on outcomes.
6. Staff	a. Physicians have no or limited dedicated time to discuss and analyze outcome data (evening hours).
7. Skills	a. The basic expertise to measure and analyze outcome data is available.b. In some hospitals physicians have received training in VBHC and/or steering on outcomes.

Benchmarking of outcomes with other hospitals in the yearly NHR reports is the dominant manner in which outcomes are used to identify improvement potential. Typically, only being a statistically significant outlier with respect to the national average leads to improvement initiatives. In general, improvement initiatives arise more often from incidents, calamities and complication meetings than from monitoring of outcomes.

Organizational context (1): Strategy

Quality performance and improvement was mentioned by all participants as part of the hospital strategy. However, none of the centers has defined measurable goals, and outcome performance does not play a significant role in the planning and control cycle. Steering on mandatory quality indicators, as required by the Health Care Inspectorate or health insurance companies, takes precedence over steering on outcomes at the medical condition level. The centers differ in their approach to using outcome measures in their strategy. One center states endeavors to monitor outcomes for all cardiac care and to achieve steady annual improvements in outcome measures. Another center defined focus areas (i.e., aortic valve disease) in which the center aims to outperform with respect to the top five in a national benchmark on a number of specific outcome measures. A third center aspires to monitor outcomes without setting targets on the outcomes themselves but instead on the implementation of outcome-based improvement initiatives as a process measure.

Organizational context (2): Governance

Independent of whether the physicians are employees or organized in physicians units, the roles and responsibilities regarding outcome performance have yet to be formalized. Outcome performance and improvement is partially discussed within specialties (the doctor's unit'cardiothoracic surgery'), partially appropriated by initiatives from individual physicians and partially in project teams (e.g., anesthesiologists, cardiologists, and cardiothoracic surgeons within a multidisciplinary team on quality improvement). Physicians taking initiative either individually or within project teams generally do not enjoy a formal mandate within the organization. However, in most centers in-hospital multidisciplinary meetings are organized to discuss outcomes. Referring cardiologists, nurses or general practitioners are not involved, leaving part of the cycle of care uncovered.

Organizational context (3): Culture

A culture exists to openly discuss outcomes within each specialty, but less openness exists to discuss outcomes in a multidisciplinary setting. Although the culture within the six hospitals seems to support continuous quality improvement, it is unclear whether strong support for *outcome-based* quality improvement exists. Opinions on this differ greatly within and between the six hospitals. A large group of healthcare professionals (including both physicians and nurses) is not actively informed on the outcomes and is not involved in discussions of the outcome data.

Organizational context (4): Leadership

Strong medical leadership is reported to exist within the heart centers. Each of the heart centers has one or more cardiologists or cardiothoracic surgeons who are active in outcome measurement, data analysis and outcome improvement initiatives. However, these physicians are not always in formal leadership positions.

Organizational context (5): Infrastructure

Insufficient data infrastructure, data management and data quality are seen as the largest barriers to realizing outcome-based improvements. In this phase, resources are invested in solving this problem. All heart centers expressed the ambition to realize automatic extraction of data, automatic visualization of outcome measures

- including PROMs - and real-time insight into outcomes. None of the heart centers have realized this yet, partly due to the introduction of the new Electronic Health Records.

Organizational context (6): Staffing

Most heart centers mentioned time of physicians as an important resource to realize outcome-based quality improvement. However, most centers do not have dedicated time available for physicians to work on outcome analysis and outcome-based improvement initiatives.

Organizational context (7): Skills

All hospitals have access to data analysts and epidemiologists to extract and analyze outcome data. Some hospitals had specifically trained members of their staff with regard to VBHC and/or steering on outcomes.

DISCUSSION

The results show that, with regard to outcome-based quality improvement and VBHC, the focus of the heart centers is on collecting data and monitoring the outcomes. The actual use of outcomes to improve quality of care is limited. However, the interviewees - both physicians and non-medical management - expressed the ambition to realize an outcome-based quality improvement cycle. There are several barriers to realizing this.

First, insufficient data infrastructure is mentioned as the main barrier to successful outcome-based quality improvement. This barrier is widely recognized in the VBHC community; developments in this area are ongoing and improvements can be expected in the coming years. [20]

A second significant barrier seems to be that the lack of a systematic approach to identifying and implementing improvement initiatives. According to Porter, measuring outcomes is an essential step in implementing VBHC. [1] However, VBHC does not give any guidance on how to use outcome measurement as a starting point for quality improvement. Benchmarking of outcomes is suggested, but how this supports improvement projects in practice remains unclear. [12] Sound methodology is needed in the hospitals with regard to the interpretation of differences in outcomes (i.e., when is a difference relevant and should a project to improve be initiated) and the research and selection of changes in processes in healthcare to improve the outcomes.

The third barrier concerns governance. The roles and responsibilities regarding outcome improvement are not yet formalized. Clear roles and responsibilities are often mentioned as preconditions for successful quality improvement and implementation of PDSA cycles. [21, 22] This may require only minor efforts, as outcome monitoring for quality improvement is relatively new and the physicians taking on this challenge are not always in formal leadership positions. However, a more fundamental issue seems to be that outcome measures are defined for medical conditions (e.g., coronary artery disease) and several specialties are involved in and responsible for these outcomes. This is where the implementation of outcome-based guality improvement directly relates to Porter's work on VBHC and his proposal to organize care in Integrated Practice Units. [1] The heart centers currently seem to be characterized by cooperation between disciplines, but not full integration and multidisciplinary steering on outcomes covering the full cycle of care. Specialties within the heart centers are moving towards more integration, openness and standardization of quality management. However, it is not yet clear whether IPUs are needed to realize successful outcome-based quality improvement, and to what extent involvement of other healthcare providers (e.g. general practitioners) is essential.

A fourth barrier is the lack of the implementation of outcomes within the hospital strategy, policy documents, and planning & control cycle. This is not yet realized as the focus is mainly on mandatory process or structure indicators from the Health Care Inspectorate or health insurance companies. Apart from the task of implementing outcome measures in dashboards, performance reports, annual plans etc., the implementation of outcomes in the hospital's strategy will require a shift in thinking for most hospitals. The study shows that typically hospitals initiate quality improvement efforts when they do not reach a certain norm. This norm is determined by external stakeholders, such as the inspectorate. However, with the growing focus on outcome measures, hospitals seem to be moving from using quality measures in a reactive manner to a situation where outcome measures are used to set internally defined quality targets.

Little research has been conducted on how to use outcome measures as part of effective quality improvement in hospitals. Earlier research indicates that providing feedback on health outcomes at the level of the team involved in care delivery for a medical condition is important. [14, 23] The first publications on VBHC implementation indicate that comparing outcomes between institutes helps centers identify improvement potential. Defining concrete goals on outcomes as a part of the hospital strategy might support this. However, the most difficult step seems to be identifying

what should be changed in the care delivery process to improve outcomes. One approach is to use the available data to directly identify and prove the cause for worse (or better) performance in outcomes. This is perhaps the ideal approach, and it is used for instance at the Martini Klinik. [15] However, so far few such examples are available and in many cases this is not possible due to limited statistical power (smaller patient groups) or a simple lack of data. Moreover, evaluation of outcomes at the level of individual patient files is an often used methodology. Observations in Dutch cardiac care suggest that this strategy rarely leads to initiation of improvement projects, as negative outcomes can often be explained or are acceptable due to conditions of the patient. Experience in Dutch cardiac care seems to indicate that a more viable approach is data-driven selection and testing of good practices. [12, 13] Here, outcome data and process analyses are used to define hypotheses regarding their interrelation. In parallel, discussions between healthcare professionals of these centers in combination with literature review etc. are used to formulate and evaluate improvement projects.

Limitations

This study has a number of limitations. First, the aim of this study was to attain insight into the current state of outcome-based quality improvement in cardiac patient care in the Netherlands. However, the six centers that participated in the study volunteered to do so and might therefore not be representative due to potential positive bias towards the subject matter. Second, the work culture in participating centers was only assessed by interviews and questionnaires, none of which were anonymous. More specific and anonymous questionnaires regarding the culture in these centers may be warranted in the future.

CONCLUSIONS

Even though heart centers in the Netherlands are measuring health outcomes for the majority of cardiac diseases, the actual use of these outcomes to improve quality of care remains limited. Defining goals and outcomes and adopting a methodology for selecting improvement projects seem to be important next steps.

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 $\ensuremath{\mathsf{TABLE}}\xspace$ S1 - Relation between the PDSA-cycle and the outcomes-based quality improvement cycle

Steps PDSA Deming (1993)	Description	Steps outcomes- based quality improvement cycle	Description
Plan	Plan a change or test aimed at improvement	Monitor outcomes	Continuously monitor a standard set of patient relevant health outcomes (Plan - 1)
		Identification improvement potential	Identify for which outcomes improvements are possible and desired (Plan – 2)
		Selection improvement initiatives	Determine which changes in the process or structure of care delivery have highest impact on the outcomes identified in step 2. (Plan -3)
Do	Carry out the change or test	Implementation	Implement the improvement
Study	The results –what did we learn? What went wrong?	improvement initiatives	initiative (Do). Including evaluation (Study) and adopting the change or
Act	Adopt the change or abandon it, or run through the cycle again.		abandoning it (Act)

No	Questions	Answer options	Results
. м	onitoring outcomes		
	How frequent are health outcomes measured and discussed within the heart center? (for one or more medical conditions)	Not	0.0%
		Less than once a year	0.0%
	medical conditions	Once a year	16.7%
		Between once a year and quarterly	33.3%
		Quarterly	33.3%
		Between quarterly and monthly	0.0%
		Monthly	16.7%
		More often than monthly	0.0%
	Which specialties are involved in the periodic	Cardiology	100.0%
	measurement and discussions of health outcomes (in joint or separate meetings). More than one answer	Thoracic surgery	100.0%
	possible	Electrophysiology	83.3%
		Anesthesiology	50.0%
		These meetings do not take place	0.0%
	How many physicians take active knowledge of the	0	0.0%
	health outcomes of your hospital (for instance through meetings in which the annually reported outcomes are	1	0.0%
	discussed)?	2-5	50.0%
		10-20	16.7%
		More than 20	33.3%
	At what level within the organization and/or care chain are health outcomes discussed? (more than one answer possible)	Not	0.0%
		Among physicians (doctor's units, departments)	100.0%
		Nursing ward	16.7%
		Hospital management	83.3%
		Medical board	33.3%
		Board of directors	83.3%
		General practitioner	0.0%
		Referring hospitals	66.7%
	Are quality dashboards (or other tools) used to monitor	Yes	50.0%
	outcomes of heart care?	No	50.0%
lo	lentification improvement potential		
	When do outcome reports (such as national benchmarks) lead to improvement initiatives within your hospital? (more than one answer possible)	Never	0.0%
		Only when the hospital is performing significantly worse than the average of other hospitals	50.0%
		When the report leads to clinically relevant insights that can be starting point for improvements (for instance a negative trend in the data or performance of subgroups within the patient population)	50.0%
		When one or more (other) hospitals are performing significantly better than average	16.7%
		Other (please specify)	0.0%

TABLE S2: Questionnaire used to assess the state of outcomes-based quality improvement in heart center

No	Questions	Answer options	Results
7	Does the heart center look at trends in the data on health outcomes periodically (based on all available tables, figures, etc.)?	No	16.7%
		No, only the comparison between centers is looked at (using funnel plots)	16.7%
		Partially, the comparison between center and dependencies of outcomes on risk factors is looked at	50.0%
		Yes, all figures and tables available are looked at	16.7%
8	Have targets been set for all outcome measures	No	83.3%
	provided in outcome reports (e.g., 30-day mortality < 0.5%)?	Yes, for one or some outcome measures for all heart care provided by the heart center.	16.7%
		Yes, for one or some outcome measures for each of the medical conditions for which outcomes are available (e.g., coronary artery disease, atrial fibrillation)	0.0%
		Yes, for all outcome measures	0.0%
9	Have outcome measures been selected for which	No	16.7%
	improvement are to be realized (with or without actual measurement of these outcomes; more than one answer possible)	Yes, for 1-5 outcome measures for all heart care provided by the heart center.	16.7%
	answer possible)	Yes, for one or some outcome measures for each of the medical conditions for which outcome reports are available (e.g., coronary artery disease, atrial fibrillation)	66.7%
		Yes, for more than 5 outcome measures for all heart care provided by the heart center.	0.0%
		Yes, for all outcome measures for which outcome reports are available.	0.0%
3. S	election improvement initiatives		
10	How many improvement initiatives has monitoring of	None	16.7%
	outcomes resulted in, in 2015 and 2016?	1	33.3%
		2-4	50.0%
		5 or more	0.0%
11	How many improvement initiatives have been started in	None	16.7%
	2015 and 2016 for which it is expected that this will lead to better health outcomes (independent of the fact if this was triggered by outcome reports)?	1	33.3%
		2-3	33.3%
		4 or more	16.7%
2	Is a standard methodology used to select improvement	Yes	16.7%
	initiatives (with impact on outcomes)?	No	83.3%
3	When reported outcomes are such that further action	There is no approach for this	0.0%
	is required, who is in charge to act in order to execute further analyses and suggest improvement initiatives? (more than one answer possible)	This is determined ad-hoc	33.3%
		A team meeting	33.3%
		Small improvement teams	66.7%
		Depending on the topic one of the physicians takes the lead	66.7%
		A specific physician is always in charge	0.0%
		Other (please specify)	16.7%

No	Questions	Answer options	Results
4	Have additional data analyses been performed in 2015 or 2016 based on the outcome reports? (aiming to better understand results and possibly to suggest	No	16.7%
		Yes, 1	33.3%
	improvement initiatives)	Yes,2-4	50.0%
		Yes, 5 or more	0.0%
5	Have analyses been performed in 2015 to detect	No	50.0%
	differences in performance between physicians?	Yes, 1	33.3%
		Yes, 2-4	16.7%
		Yes, 5 or more	0.0%
5	Did the outcome reports or meetings in which outcomes	No	66.7%
	were discussed lead to contacting other hospitals (to learn from potential good practices)?	Yes, for 1 topic	33.3%
	real from potential good practices):	Yes, for 2 or more topics	0.0%
,	How many improvement initiatives that focus on	None	50.0%
	outcomes of care of other hospitals have you implemented in your heart center?	1	50.0%
	inspendence in your rear center:	2-4	0.0%
		5 or more	0.0%
Ir	nplementation improvement initiatives		
8	Is it standard practice to monitor the implementation of improvement initiatives? (e.g., do you check if improvements are implemented correctly and for all eligible patients?)	No, never	33.3%
		No, most of the time not	33.3%
		Yes, most of the time	33.3%
		Yes, always	0.0%
	Is the effect of improvement initiatives monitored? (impact on outcomes or intermediate outcomes)	No	33.3%
		Yes, annually using the outcome reports	33.3%
		Yes, more often than annually, during regular team meetings.	33.3%
C	Do you have evaluation moments at which point you	No, never	16.7%
	decide to continue the initiative or not?	No, most of the time not	50.0%
		Yes, most of the time	33.3%
		Yes, always	0.0%
	Did any improvement initiatives triggered by outcome	No	83.3%
	reports result in scientific publications?	Yes, 1x	0.0%
		Yes, 2-4x	16.7%
		Yes, 5x or more often	0.0%
S	rategy		
2	To what extent is measuring and improving outcomes using outcome measures part of the strategy and annual plans of the heart center?	The heart center is now mainly focusing on registration of outcome measures	83.3%
		The heart center has set clear targets in the annual plan (or annual plans of the individual departments) aiming to improve outcomes of specific patient groups.	16.7%
		Performance on outcomes is a central part of the long-term strategy of the heart center. This results in specific annual targets that are monitored using outcome measures.	0.0%

No	Questions	Answer options	Results
23	Is the performance on outcome measures being used	No	66.7%
	strategically in the contact with external stakeholders? (more than one answer possible)	Yes, for marketing and communication purposes	33.3%
		Yes, to inform/educate patients	0.0%
		Yes, for the negotiations with health insurers	33.3%
		Yes, other (please specify)	16.7%
2. G	overnance (Structure)		
4	Is there a multidisciplinary meeting of the involved	No	16.7%
	specialties in which outcomes of care are discussed (e.g., involving cardiology, thoracic surgery, and anesthesiology for coronary artery disease)?	Yes	83.3%
25	How are involved in the regular meetings in which the outcomes of care and improvement initiatives are	This does not take place	0.0%
	discussed? (more than one answer possible)	Only physicians	83.3%
		Nurses	0.0%
		Team leaders	50.0%
		Specialist nurses	16.7%
		Physicians from referring hospitals	0.0%
		General practitioners	0.0%
		Data manager/data-analyst	83.3%
		Department management	33.3%
		Hospital management	16.7%
		Patients or patient representatives	0.0%
		Support staff from the quality department	66.7%
		Other (please specify)	33.3%
6	Is the organization structure multidisciplinary (e.g., do	No	0.0%
	you have an integrated heart center)?	Yes	100.0%
7	Are outcomes discussed with and are joint improvement	No	50.0%
	initiatives started with partners in the care chain? (e.g., referring hospitals, general practitioners)	Yes	50.0%
8, C	ulture (Shared values)		
28	What is the involvement of physicians in the	No involvement	0.0%
	measurement and improvement of outcome measures?	Small. One physician has responsibility for data delivery to external stakeholders. Apart from that no physicians are involved.	16.7%
		Reasonable. Some physicians are involved.	50.0%
		Large. There is a wide involvement.	33.3%
		Very large. All physicians are involved.	0.0%
9	What level of trust exists within specialties to discuss	Poor	0.0%
	outcomes openly (e.g., variance between physicians)?	Moderate	0.0%
		Fair	16.7%
		Good	83.3%
		Very good	0.0%

No	Questions	Answer options	Results
30	What level of trust exists between specialties to discuss outcomes openly (e.g., between thoracic surgery, cardiology, and anesthesiology)?	Poor	0.0%
		Moderate	0.0%
		Fair	33.3%
		Good	66.7%
		Very good	0.0%
I. L	eadership (Style)		
31	How many physicians are ambassadors of measuring and using outcome measures? (i.e., physicians with a leadership role to stimulate development of the hospital	None	0.0%
		1	0.0%
	in this area and who are able to get colleagues along)	2	16.7%
		3	33.3%
		More than 3	50.0%
2	At which level(s) in the organization is initiative taken to realize an outcomes-based improvement cycle within	Physicians	83.3%
	the heart center? (more than one answer possible)	Management of the department or heart center	100.0%
		Hospital management	0.0%
		Nurses	0.0%
		Hospital quality department	50.0%
		Board of directors	0.0%
		Medical board	16.7%
		Other (please specify)	16.7%
5. Ir	nfrastructure (Systems)		
3	How is outcome data for external reports collected (excluding follow-up data)? Please select what best matches the current situation.	Not	0.0%
		Retrospectively by combing several sources. Involving still a lot of manual work	66.7%
		Prospectively build in and connected to the HER	16.7%
		Prospectively build in and connected to the HER. Insight in outcomes is available continuously and real-time.	0.0%
		Other (please specify)	16.7%
4	In what form is data extracted from the IT-system?	Raw patient data	66.7%
		Automatically calculated outcome measures	0.0%
		Automatically graphic display of outcome measures using graphs, bar charts, etc.	0.0%
		Graphic user interface with in addition to graphic display of graphs and bar charts also possibility to perform basic analyses, such as showing trends in time, selecting subgroups, or individual patients.	0.0%
		Other (please specify)	33.3%
5. S	taff		
35	How many data managers are available for the heart center (in FTE)?		1.8 (average)
36		0	33.3%
	discuss outcomes and follow-up analyses (for some hours a month)?	1	16.7%
	nouis a monuny:	2-3	16.7%
		4-5	16.7%
		More than 5	16.7%

TABLE S2:	Continued
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No	Questions	Answer options	Results
37	Is support available to perform basic data analyses (trend analyses, plotting results for subgroups, etc.)?	No	16.7%
		Yes	83.3%
38	Is support available for executing advanced data analyses (making VLAD curves, performing regression analyses, prediction models, etc.)?	No	50.0%
		Yes	50.0%
39	Who gets time to work on realization of an outcomes- based improvement cycle? (more than one answer possible)	Physicians (FTE)	0.15 (average)
		Quality managers (FTE)	0.22 (average)
		Internal advisors (FTE)	0.52 (average)
		Medical management (FTE)	0.16 (average)
		Department management (FTE)	0.17 (average)
		Others (FTE)	0.25 (average)
7. S	kills		
40	Are there employees within the hospital with the explicit task as part of their job to work on the realization of an outcomes-based quality improvement cycle (e.g., manager value-based healthcare, advisor)	No	50.0%
		Yes	50.0% (1.5 FTE on average)
41	How many physicians in the heart center have expertise and affinity with data management and data analysis?	0	0.0%
		1	33.3%
		2-3	33.3%
		4-5	33.3%
		More than 5	0.0%
42	Are physicians trained/educated in value-based healthcare and/or the use of outcomes within an	No	50.0%
	improvement cycle?	Yes, once	33.3%
		Yes, periodically	16.7%

*1 FTE in Dutch healthcare equals 36hrs/wk.



CHAPTER 7

Insights on value-based healthcare: implementation from Dutch heart care

Aantal sterfgevallen bij operatie aan hartklep daalt fors

P. van der Nat, **D. van Veghel**, E. Daeter, H. Crijns, J. Koolen, S. Houterman, M. Soliman-Hamad, B. A. de Mol & Meetbaar Beter Study Group (2017)

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ABSTRACT

Value-based healthcare has been introduced in 2006. Ten years later, this concept is adopted by a growing number of healthcare organization. However, little is known about the practical implementation of value-based healthcare within hospitals. While working on the implementation of VBHC in Dutch heart care, physicians are confronted with three main challenges that still need to be addressed to make value-based healthcare successful. First, it will require a shift in our thinking to actually use outcomes as drivers for quality improvement instead of as end points in scientific studies. Secondly, it will require tools for linking outcomes to quality of care processes enabling quicker and continuous improvement cycles. Finally, platforms are needed where benchmarking on outcomes is connected to an open learning and sharing environment where physicians can discuss good care delivery practices.

Keywords: Value-based Healthcare; quality management; benchmarking; cardiovascular diseases; measurement of quality.

In 2006, *value-based healthcare* (VBHC) was introduced by Porter and Teisberg VBHC puts 'patient value' (health outcomes over costs) central in organization and delivery of care. [1, 2] Ten years later, this concept gets more and more traction internationally. A steady movement of quality registrations moving towards defining and measuring outcomes can be observed. The International Consortium for Health Outcomes Measurements (ICHOM) supports this development by defining standard sets of outcomes.

However, value-based healthcare is still in its infancy. The actual *use* of outcomes to improve patient value will be a litmus test of value-based healthcare. Best practices in the implementation of VBHC concern isolated organizations, like the Martini Klinik and Schön Klinik in Germany, UCLA in the USA and Karolinska Hospital in Sweden. But the claim of value-based healthcare is much broader. It should enable providers 'to compare performance, spark competition, and foster learning', according to Porter. [3]

Within the Dutch Meetbaar Beter initiative, cardiologists and cardiothoracic surgeons have worked towards the next level of implementation of VBHC by creating a physician-driven, patient-centered and transparent learning and improving environment. [4] In three years' time Meetbaar Beter has become a network including nineteen hospitals covering more than 85% of Dutch complex heart care. Standard sets have been defined and are reported on annually for the main heart conditions. [5] The reports include all treatment options, including conservative treatment, in order to avoid risk selection of patients. In 2016, outcomes of more than 150,000 patients were reported in the annual outcome reports, highlighting hospitals and subgroups of patients that show excellent results or improvement potential. Within Meetbaar Beter outcomes, good or best practices, and innovative ideas are shared. A striking openness and willingness to share and learn is observed, even between competing heart centers.

Patient-relevant outcomes for treatment of heart diseases in the Netherlands have improved over the period of 2011-2015. The largest improvements are seen in mortality, especially for patients with aortic valve disease (from 6.5% in 2011 to 2.6% in 2015, combining all treatment options) and coronary artery disease treated with bypass surgery (from 3.8% in 2011 to 2.6% in 2014). [5] Even though the contribution of Meetbaar Beter to realize these improved outcomes cannot be measured, the outcome reports have inspired more than forty quality improvement initiatives in the participating hospitals (see Figure 1 for examples).

Chapter 7

Medical Condition	Outcome Measure	Hospital	Improvement Initiative
Coronary Artery Disease treated with CABG	120-day mortality 3.0% 2.0% 0.0% 2009-2013 (all hospitals) (Isala)	Isala, Amphia, Catharina, Haga,TCT, OLVG, St. Antonius	Isala has shown a significantly lower 120-day mortality over the period 2009-2013. Discussions on the care process at Isala led to the hypothesis that a unique peri-operative safety check contributes to the good outcomes. Six other hospitals have adopted the safety check in 2015 and a scientific evaluation is currently in progress.
Aortic Valve Disease treated with Transcatheter Aortic Valve Implantation (TAVI)	Vascular complications 20% 15% 0% 2010-2014 (all hospitals) 2010-2014 (Amphia)	Amphia	Amphia shows a significantly lower rate of vascular complications in the period 2010-2014. Additional analyses show large variations in approach (transfemoral, transapical, etc.). Amphia uses the transfemoral approach in > 90% of TAVIs using a surgical cutdown, which could explain the lower complication rate. This has led to additional analyses and increased awareness regarding the used approach in several other hospitals.
Atrial Fibrillation treated with point- by-point AF ablation, PVAC RF ablation, or Cryo ablation	Proven AF recurrence (2015) 20% 10% 0% point-by- point PVAC RF Cryo	All hospitals	One of the treatment options for Atrial Fibrillation is catheter pulmonary vein isolation (PVI). Cathether PVI can be performed using conventional point-by-point ablations, Pulmonary Vein Ablation Cathether (PVAC) Re balation, and Cryo ablation. Even though differences in the outcome 'Proven AF recurrence' might be explained by different patient selection, these results led to several hospitals reconsidering their treatment approach.
Coronary Artery Disease treated with PCI	30-day mortality (patients with kidney failure) 10% 5% 0% 2014 2015	OLVG	Analysis of the outcomes after PCI for patients with coronary artery disease indicate a higher 30-day mortality for patients with kidney disease than without. Even though this is expected, cardiologists at OLVG aimed for improvements for these higher risk patients. Changes include a more rigorous registration system in which elective patients without GFR/creatinine measurement in the last 2 months are not scheduled for PCI, and the heart team calculating the maximum allowed contrast agent dose in advance.
Coronary Artery Disease treated with CABG	Re-explorations	Catharina	An increase in the number of surgical re-explorations (re- thoracotomies) was observed at Catharina hospital during regular outcome discussions. Searching for improvement options, the surgeons were inspired to implement a checklist developed in Cleveland. This check aims to support surgeons to double check the backside of the sternum and the mediastinum before closing their patients. The check was implemented in 2015.
Combined Aortic Valve Disease and Coronary Artery Disease	120-day mortality 10% 5% 0% 2014 2015	St. Antonius	In comparison to other medical conditions, the mortality rates after AVR-CABG are relatively high for all heart centers. Although the mortality rate in St. Antonius did not differ significantly from other centers, it was decided to set up specific actions to reduce the mortality rate within this high-risk patient group. An example is that since the start of 2015 this patient group is only treated by experienced staff members (cardio surgery and anaesthesia).

FIGURE 1: Examples of improvement initiatives based on evaluation of patient-relevant outcome measures. In green, examples are shown of insights in data that have triggered improvements. In blue, examples are shown of improvements that were achieved. Details, including corrections for the complexity of the patient population per hospital, are presented in the Meetbaar Beter Books.

While working on the implementation of VBHC in Dutch heart care, Meetbaar Beter is being confronted with three main challenges that we consider general success criteria for the implementation of VBHC in any disease area in any country.

#1 A paradigm shift is needed to use outcomes for quality improvement.

Scientifically, one would typically consider using an outcome measure - for instance within a randomized controlled trial - if it can be measured with sufficient statistical power to observe the effect of an intervention. For quality improvement this is the ideal situation. However, a large fraction of healthcare exists of diseases or treatments with small numbers of events per hospital. Although statistical power is often insufficient to compare outcomes between hospitals, measuring outcomes can still create important insights. Meetbaar Beter chooses to publish the uncorrected outcomes and dependencies on risk factors even when differences between hospitals cannot be made visible with reliable statistical significance. Although one should be cautious for 'over-interpretation', the data do create awareness regarding outcomes and enable physicians to generate hypotheses for improvement. Several improvement initiatives have been initiated based on clinical relevance, with or without observing statistically significant differences between heart centers.

#2 Value-based healthcare needs to be extended with tools and methods to facilitate systematic outcome-based quality improvement

One of the main challenges to realize outcome-based improvements is linking outcomes to the quality of underlying care practices. Hospitals may formulate targets on outcomes, such as mortality, re-operations, and quality of life, but how can these targets be implemented in an internal quality improvement cycle? The list of factors in care delivery influencing them is long.

Cleveland Clinic, Martini Klinik and Schön Klinik are known to have quality systems in place using outcome measures. However, their methods differ and publications are too scarce to identify a valid approach. Meetbaar Beter uses benchmarking. Differences in outcomes and care delivery processes are discussed between hospitals and underlying good practices are shared.

Even though the development of different methods is a positive sign, a systematic VBHC 'way of working' is still lacking in which outcomes are used to select, implement, monitor, and evaluate improvement initiatives within a standardized PDSA cycle.

#3 To make value-based healthcare successful, new transparent networks of physicians with high levels of trust are required.

For value-based healthcare to reach its full potential will require new networks in which physicians meet in an open environment to learn and inspire each other. The learning potential as well as adoption rate of best practices becomes much larger when health outcomes are used to 'foster learning' between providers at a national or international level. A lot can be gained when physicians discuss outcomes and underlying local protocols, and techniques with peers from other hospitals. Such networks currently do not exist. In order to create them, transparency, physician leadership and trust are essential.

Transparency stimulates quality improvement and enables healthcare professionals to contact each other based on performance on outcomes. **Physician leadership** is needed as it is the physicians that –after experiencing positive effects of working with outcomes - can mobilize their peers. Finally, the least tangible, but probably most important ingredient in creating a learning community is **trust**. Benchmarking outcomes requires physicians and stakeholders to trust each other and each other's data. Trust helps to focus on positive use of data for quality improvement, in contrast to a focus on punishment for performance.

In heart care, Meetbaar Beter used these ingredients to build an open national learning environment of thoracic surgeons and cardiologists. The Meetbaar Beter foundation is fully run by physicians at all organizational levels. Trust amongst the centers has been created by focusing on quality improvement instead of creating hospital rankings. The transparency is achieved by reporting outcomes and by physicians of different hospitals contacting each other. This has allowed for several of the improvement initiatives, such as the reduction of 30-day mortality for PCI-patients with renal insufficiency (see Figure 1). In contract to Porter who focuses on the importance of competition between healthcare providers, within Meetbaar Beter the tendency of physicians of different hospitals to cooperate is much stronger than it is to compete.

We believe value-based healthcare can contribute to much quicker and better quality improvement in healthcare. This will require a shift in our thinking to optimally use outcomes for quality improvement. It will also require tools for linking outcomes to quality of care processes enabling quicker and continuous improvement cycles. Finally, platforms are needed where organizations working on the implementation of value-based healthcare across disciplines can connect to share best practices. This includes cooperation to organize quality improvement, data collection, analysis methods and open networks for physicians to share and learn based on insight in outcomes.

Acknowledgments

This publication has been made possible by the cooperation with the cardiologists, thoracic surgeons, data managers and project leaders of the participating heart centers and in particular by the study group members.

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How to adopt value-based healthcare models in medical practice?



CHAPTER 8

Health insurance outcome-based purchasing: the case of hospital contracting for cardiac interventions in the Netherlands

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ABSTRACT

Innovative forms of value-based purchasing contracts, based on outcome instead of volume, are imperative to face the imminent cost crisis in health care. The objective of this study was to design and implement a model for an outcome-based purchasing contract between a hospital and a health insurance company. The model was implemented in 2015. A study cohort (n=14,944) from patients with coronary artery disease or atrial fibrillation treated in 2014 was compared to a historical reference cohort from patients treated between 2010-2013. The outcome measures and the model are based on Porter's value-based healthcare principles. Improvements in outcomes were observed, leading to a financial incentive to be spent on further quality improvement. Implementation of this model is a first step towards enabling inclusion of patient-relevant outcomes in purchasing for healthcare. It aligns the focus of health insurance companies and hospitals on patient value.

BACKGROUND

As in many countries, healthcare costs in the Netherlands have increased over the last few decades. [1-3] Increased healthcare costs may result in the repression of other government expenditures, the exceeding of public debt, cost-sharing and an increase in taxes and premiums. [3-5] Value-based healthcare, aiming at maximizing patient value by focusing on outcomes and costs, is considered a strategy for solving these problems. [6] One of the key elements of the value-based healthcare strategy urges us to define a new reimbursement approach in which quality of care is leading instead of the number of procedures or consumables. [7]

Measuring patient-relevant outcomes is increasingly performed in many countries. [8] In the Netherlands, outcomes of cardiac interventions are collected in a nation-wide initiative (Meetbaar Beter). [9-12] The insights in risk-adjusted outcomes contribute to continuous quality improvement and hence, gains in patient value. [13] In our hospital, routinely implementing improvement projects, based on measuring patient-relevant outcomes and applying value-based healthcare principles, was initiated during 2013 onwards.

In Dutch healthcare, health insurance companies purchase healthcare by contracting hospitals. [14] So far, in these contracts, the main focus has been on finance and volume. [15] In some dimensions these contracts contradict the concept of quality improvement as lower re-intervention rates can be counteracted by lower reimbursement levels due to lower volumes. Implementing value-based contracts is an essential step in this respect. [16] As stated in one of the eight principles of value-based competition by Porter and Teisberg, 'innovations that increase value must be strongly rewarded'. [17] With growing interest in value-based healthcare worldwide, there is a growing awareness that pay-for-service approaches should be replaced by pay-for-performance approaches or outcome-based payment. [18-27] Hence, payment approaches that reward value are suggested as a suitable direction for change. [21]

In this study, we aimed at developing a model that includes value-based healthcare principles, makes it possible to assess changes in quality and in which improvement in quality is financially rewarded and loss of quality leads to reduction of financial compensation. The main goal of this paper is to describe the development of a model for an outcome-based purchasing contract between a hospital and health insurance company. In addition, the suitability of the model to assess changes of quality over time is evaluated.

METHODS

Study population and inclusion criteria

The study population consists of coronary artery disease patients treated by either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG), as well as atrial fibrillation patients treated with catheter pulmonary vein isolation (PVI). These high-risk, high-impact treatments were selected because they are frequently performed. Patients who have undergone these treatments between January 1, 2010 and December 31, 2013 were included in the reference cohort; patients treated between January 1 and December 31, 2014 constitute the study cohort – regardless of their health insurance company. A detailed description of the inclusion criteria has been published elsewhere. [11]

Purchasing model

A project group was formed to develop a model rooted in value-based healthcare principles. This project group consisted of representatives of the hospital (i.e. physicians, value-based healthcare experts, quality officer and sales officer) and representatives of the health insurance company (i.e. purchaser and medical advisor). Development of the model, supported by an epidemiologist and a statistician, was based on the fundamental work by Porter[5], as well as on other leading examples [28].

Crucial principles of value-based healthcare are integrated in this model: the whole medical condition can be included; quality is measured by patient-relevant outcome measures concerning the entire care delivery value chain; outcomes are risk-adjusted; the outcome measures hierarchy is applied; and quality improvement is rewarded. [6] These core value-based healthcare principles underlying the model are described in more detail in Table 1.

The project group decided on the following arbitrary elements that were required for comparing cohorts, deciding on relevant changes in outcomes and consequences in the payment model:

Reference and study cohorts. It was decided that evaluation of changes in quality of care was done by comparing risk-adjusted outcomes over time within the same hospital. As quality improvement projects were implemented since the embedding of value-based healthcare principles in the heart centre's strategy, a study cohort from patients treated in 2014 was compared to a historical reference cohort from

patients treated between 2010-2013. In this exploratory phase, both organizations the hospital and the health insurance company—agreed to first choose patient target groups with relatively large numbers of patients and the availability of high quality data. Therefore within the medical conditions 'coronary artery disease' and 'atrial fibrillation' treatment options PCI / CABG and catheter PVI have been selected, respectively.

TABLE 1. Value-based healthcare (VBHC) principles underlying in the outcome-based purchasing model

VBHC element	Application and explanation
Including the aggregate medical condition	It is important to include the whole medical condition in order to avoid selection bias.[29] This means that not only the results of a specific treatment should be evaluated, but the model should also be able to evaluate the results of treatments of all patients with a specific medical condition. Consolidated outcome measures, which refer to all treatments that can be performed when a patient has a certain medical condition, may be used.[9]
Using patient- relevant outcome measures	When using quality as the key factor, relevant measures are a prerequisite. A limited number of outcome measures that are relevant for the patient needs to be selected and defined, based on the full cycle of care.[30] This is because care for a medical condition typically comprises various specialties and interventions, and many actors are involved in the treatment process of a patient.[6] Both short- and long-term effects should be investigated.
Risk-adjusted outcomes	To be able to analyse and interpret results properly, outcomes should be risk- adjusted to all risk factors.[6, 18] When performing the statistical analyses (logistic regression analyses) to determine the rate of quality change over the years, the model corrects for relevant patient initial conditions.
Applying the outcome measures hierarchy	According to Porter, the outcomes for any medical condition can be ordered in a hierarchy framework consisting of three tiers, in which each tier can be subdivided into two levels.[6] Results on the lower tiers partly depend on the results of the higher tiers. A range of outcome measures covering all tiers of the outcome measures hierarchy is essential to include all significant outcomes that are important to the patient and to reveal the links between processes of care or pathways and the outcomes achieved.
Rewarding quality improvement	A possible step in solving the healthcare problem by applying value-based healthcare is to create both financial and nonfinancial incentives for increasing the value.[31,32] For each treatment, an incentive of a predetermined amount can be earned by the hospital. The hospital receives a bonus for quality improvement and a malus for quality impairment. In case of no change, no incentives are given. All incentives are summed up to calculate the total amount the hospital or the health insurance company receives for the year.

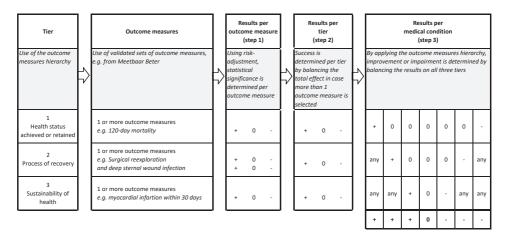
1. Health status achieved or retained 120-day mortality ¹ 2. Process of recovery 1-year mortality ¹ 2. Process of recovery Surgical re-exploration ²⁷ 3. Sustainability of health Myocardial infarction ²⁸ 3. Sustainability of health Myocardial infarction ²⁸ Initial conditions Age Gender Diabetes ² UvEF ³ Lvernoof the anthic version ²⁸	30-day mortality ¹ 1-year mortality ¹ Urgent CABG ^{2,9} ion ²⁷ Myocardial infarction ²⁷	30-day mortality ¹
Æ		
£		
		Cardiac tamponade ^{2.7}
	Myocardial infarction ^{2,7}	
	Target vessel revascularization ^{2,8}	Re-PVI ^{2,8}
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LVEF ³ Renal insufficiency ²	Diabetes ²	Duration of atrial fibrillation
Renal insufficiency ²	LVEF 3	LVEF 3
	Renal insufficiency ²	Previous mitral valve disease ²
	⁴ Previous myocardial infarction ²	Previous ablation ²
	Multivessel disease ²	Type of atrial fibrillation $^{ m 6}$
	Chronic total occlusion ²	
	Resuscitation ²	
	Shock ²	

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Chapter 8

Initial conditions and outcome measures. A subset of the patient initial conditions and outcome measures as selected within Meetbaar Beter was used in this study. [9, 33] These measures are almost completely aligned with the selection made by the International Consortium for Health Outcomes Measurement (ICHOM). [34] The set of outcome measures for each procedure, the time periods that were used as end points and patient initial conditions are presented in Table 2.

Determining final result. The steps to determine the rate of quality improvement, based on the hierarchy principles by Porter[6], are presented in Figure 1. For each outcome measure, we analysed whether results from the 2014 cohort were better (+), indifferent (0) or worse (-) compared to the results of the four-year period before (Column 3). Second, success was determined per tier (Column 4). When two or more outcome measures were selected within one tier, the rate of success was determined by balancing the total effect for both/all outcome measures. Third, success on the medical condition or treatment level was determined by applying the outcome measures hierarchy (Column 5). Results of Tier 1 were dominant over Tiers 2 and 3. Likewise, in case of non-significant results in Tier 1, results from Tier 2 were dominant over Tier 3. In case both Tier 1 and 2 were not different compared to their reference, results from Tier 3 determine the overall outcome.



Note: + = improvement; 0 = no change; - = impairment

FIGURE 1. Steps in determining the rate of quality improvement in healthcare over time

An alpha of 0.25 was considered indicative for a relevant difference because of the low event rates in the relatively low number of patients in the study cohort. The rationale for this choice was that also small changes in outcomes should be remunerated by the model either as an incentive or a reduction in financial compensation. The project group decided that incentives ought to be granted on further quality improvement projects.

Statistical analyses

First, general descriptive statistics were used to describe patient characteristics, by focusing on demographic characteristics and initial conditions. Second, descriptive statistics were used to describe the outcomes in the period 2010-2013 and the outcomes of the year 2014. Third, logistic regression analyses were conducted to measure the level of quality improvement over time. Different outcomes measures (e.g. 120-day mortality; 0=event did not occur, 1=event occurred) were the dependent variables. Patient initial conditions were included in the model as predictors. All analyses were done with the programme SPSS 23.0.

RESULTS

Patient characteristics

Patients included in this study had a mean age of 65.0 years and 73.8% was male. Baseline characteristics of the three patient groups can be found in the appendix.

Short and long-term evaluation of outcomes

In Table 3, the results are presented. Significant improvements in quality were found in all three medical treatments. Regarding CABG, significant improvements were found in Tier 1: a reduced 120-day mortality rate in 2014. In general, there was no change in outcomes in both Tier 2 and Tier 3. In Tier 2, the increase of surgical re-explorations is balanced by the reduction of deep sternal wound infections. Regarding PCI, significant improvements were found in Tier 1 and 2: a reduced 1-year mortality rate in 2014 and less urgent post-PCI CABG's in 2014, respectively. Since Tier 1 and 2 are dominant over Tier 3, the increase of myocardial infarction did not influence the overall outcome. In catheter PVI's, significant improvements were found in Tier 3 (less re-PVI's in 2014).

TABLE 3. Results of quality improvement over time among heart patients treated with CABG, PCI or catheter PVI, by using logistic regression analyses with different outcome measures (0 = event did not occur; 1 = event occurred) as dependent variable

		Uncorrected outcomes		Corrected outcomes ^{1,2,3}	Results per			
Tier	Outcome measures	2010-2013	2014	OR 75% CI	outcome measure	Results per tier	Conclusion	
CAB	G ¹							
1	120-day mortality	2.24% (79/3,600)	1.16% (8/695)	0.60 0.387 – 0.934	+	+	+	
	1-year mortality	3.08% (111/3,600)	2.73% (19/695)	1.02 .755 – 1.374	0			
2	Surgical re- exploration ⁴	5.38% (184/3,604)	7.48% (49/704)	1.44 1.190 – 1.751	-	0		
	Deep sternal wound infection ⁴	1.32% (47/3,604)	0.72% (5/704)	0.54 0.314 – 0.942	+			
3	Myocardial infarction ⁵	2.05% (69/3,356)	1.51% (10/664)	0.73 0.493 – 1.089	0	0		
	Re-intervention ⁵	4.95% (167/3,375)	5.99% (40/668)	1.22 0.986 – 1.500	0			
PCI	2							
1	30-day mortality	3.46% (242/7,243)	3.06% (62/2.086)	0.89 0.725 – 1.079	0	+	+	
	1-year mortality	6.38% (462/7,237)	5.71% (117/2.048)	0.82 0.715 – 0.945	+			
2	Urgent CABG ⁶	0.61% (44/7,271)	0.29% (6/2,094)	0.52	+	+		
3	Myocardial infarction ⁴	1.23% (87/7,136)	2.11% (41/1,983)	1.53 1.220 – 1.928	-	-		
	Target vessel revascularization ⁵	6.70% (454/6,773)	6.36% (113/1,778)	1.05 0.920 – 1.199	0			
Cath	eter PVI 3							
1	30-day mortality	0.20% (2/997)	0% (0/272)	0.00	0	+	+	
2	Cardiac tamponade ⁴	1.94% (19/996)	1.12% (3/272)	0.56 0.255 – 1.208	0	0		
3	Re-PVI ⁵	27.55% (281/1,020)	22.65% (65/287)	0.25 0.615 – 0.914	+	+		

¹Corrected for: age | gender | diabetes | left ventricular ejection fraction | renal insufficiency | urgency of the procedure; ²Corrected for: age | chronic total occlusion | gender | diabetes | left ventricular ejection fraction | renal insufficiency | previous myocardial infarction | multivessel disease | resuscitation | shock; ³Corrected for: BMI | CHADSVASc | duration of AF (except for re-PVI) | previous ablation | left ventricular ejection fraction | previous mitral valve disease | type of AF; ⁴ within 30 days; ⁵ within 1 year; ⁶ within 24 hours

Financial incentives

In accordance with the purchasing model, the hospital is financially rewarded for the significant improvements of outcomes after CABG, PCI and catheter PVI. For every patient group, an incentive was given for the purpose of further quality improvement projects in the heart centre.

DISCUSSION

Outcome-based model

This paper describes an innovative value-based healthcare-aligned outcome-based payment model. The model signifies that parties have been able to create shared targets and the needed level of mutual trust to implement new models creating shared focus on value for patients. The observed quality improvements may be ascribed to different improvement projects that have been implemented in the hospital since the embedding of value-based healthcare in the heart centre's strategy since 2013. A focus on outcomes led to several organizational changes and process optimizations. For example, the preferred treatment strategy of atrial fibrillation patients was changed as well as the supervision of the specialized atrial fibrillation outpatient clinic, resulting in less re-PVI's. In addition, more time was reserved for multidisciplinary heart team discussion, an intensive care specialist was added for the discussion of high-risk patients and a multidisciplinary patient review was arranged in the preoperative day, resulting in reduced mortality after CABG. Since pertinent improvements have been concluded, a financial bonus, as per contract destined for new quality projects, was provided.

Impact for patients

The alignment in the focus on outcomes between hospitals and health insurance companies is a leap forward in the development of a value-based healthcare system. The model introduces patient-relevant outcomes, and therefore the most relevant quality measures, into the purchasing for healthcare process in the Netherlands. The model applies to all selected outcome measures, including long-term outcome measures. Since these long-term effects are also largely determined by the quality of care in the referring centres, this means that the hospital takes on accountability for the results of the entire care delivery chain. Pressure on quality management in the entire cycle of care (i.e. also outside the treatment centre) is thus created. For patient safety, it is important that treatment is not refused for patients showing high-risk characteristics because of the possible poor outcomes. Adding the multidisciplinary

heart team discussion is an important factor that optimizes the decision making in high-risk patients. The model is risk-adjusted and additionally offers the possibility to include the entire medical condition. This means that both patients treated with interventions and patients not treated or treated with medication form part of the model. This way, all patients with a certain medical condition can be included in the analysis.

Implications for international practice

Apart from the national healthcare system or purchasing models, our model makes it possible to motivate hospitals in case of quality improvement determined by outcome measures that are most important for patients. An advantage of the outcome-based purchasing model is that it can be implemented on top of other financing systems which means that it is not necessary to modify the current financing system. Hence, the model has the potential and offers the possibility to be applied in all countries – as long as the financer is not the healthcare provider. This model creates a shared goal for specialists, health insurance companies and financial managers. Additionally, the model is attractive to be implemented in other countries and health systems since it offers the possibility of step-by-step implementation (e.g. for one specific treatment, disease or specialism first).

In our model, long-term outcome measures are included based on value-based healthcare compared to other systems that are mainly focused on intermediate outcomes. [35] By using long-term health outcomes, the hospital takes its responsibility for the ultimate result of the intervention even if further steps take place elsewhere in the care chain. Thus, integrated care across separate care delivery systems, as one of the principles of value-based healthcare, is also applied.

The model can be adopted for other medical conditions as well. However, an outcome registry is then necessary to be linked to reimbursement. [36] Patient-relevant outcomes must be selected and measured, and risk-adjustment for patient initial conditions is necessary when applying the model. We recommend to make use of national registries and/or internationally developed standard sets. For example, the outcome measure sets as developed by ICHOM can be used for this purpose. [34, 37-39]

Hurdles and aids of implementing the model

For a successful implementation of the outcome-based payment model, it is relevant to dare being transparent. It is impossible to design the perfect model at

once, therefore it is partially learning by doing. We advise to work pragmatically, and continuously evaluate whether the new model is better than the old one. On the other hand, the model requires a scientific basis as much as possible, thus expert opinions are needed in an early stage, for instance from the perspective of epidemiology. Furthermore, trust between both parties (i.e. hospital and health insurance company) is a precondition. In order to extend trust, it may help to involve a third party, especially for controlling data quality and reliability. In our case, we participate in 'Meetbaar Beter' that regularly performs data quality checks. We advise to use validated standard indicator sets which are already developed and used by others, preferably internationally, instead of reinventing the wheel (e.g. standard sets of ICHOM). [34,37-39]

In the first phase of implementation, the model introduces uncertainties. The model needs testing in practice. Therefore, we recommend using incentives with a limited financial impact in order to create a safe learning environment. However, small amounts of incentives may be not enough to change the way hospitals are doing business. [40] Therefore, we advise to increase incentives in the course of time.

It is important to choose large patient groups for which inclusion criteria should be clearly defined and patient identification should be clear. Outcome measures with sufficient positive events are preferred, and only outcomes that can be influenced by the healthcare providers should be included. Last but not least, it is most interesting and relevant when high-cost treatments are studied and finally improved.

Strengths and limitations

The model, which is theory-based and which satisfies the various criteria of valuebased healthcare, places patient-relevant outcomes at the centre of purchasing for healthcare. [6, 32] The hospital acts transparently and is continuously striving for the maximum achievable quality of care. The use of a limited set of both short- and long-term patient-relevant outcome measures makes the model concise and broadly applicable in the field of cardiology, cardiothoracic surgery and other medical specialties. The model stimulates improvements on all different tiers of the outcome measures hierarchy. [6] In case that outcomes, such as mortality, are not likely to change, outcome measures belonging to lower tiers of the outcome measures hierarchy become determinative. This means that the focus will be shifted to other patient-relevant outcome measures, such as complications and re-interventions, in order to create successful changes. Additionally, it is possible to add or replace outcome measures. Quality improvement is continuously stimulated through the agreement, as the incentives the hospital may receive are to be used for further quality improvement in the heart centre. Finally, the model stimulates reduction of costs as well, as several outcomes are directly (e.g. myocardial infarction or target vessel revascularization) or indirectly (e.g. re-thoracotomy) related to costs in the Dutch payment system.

Some elements in the model may give rise to discussion. First, we chose a confidence interval of 75% instead of the commonly used statistical 95% reliability since clinical relevance is the prime concern. Improvements in or loss of quality at the 75% level are considered as relevant and are enumerated with an incentive of reduction in financial compensation. The chance on a type I error increases, but parties agreed on this balance between spontaneous variations and the low frequency of certain outcomes in relatively small patient cohorts. This arbitrary choice will be subject to further evaluation. Second, the first implementation was performed with retrospective data and, therefore, the observed improvement in outcomes cannot be attributed to the implementation of the model. Third, in the early phase of implementing the outcome-based contract, the hospital and the health insurance company were not able to evaluate results at the level of the entire medical condition, but only at the level of treatments. Due to limited availability of retrospective data on the conservative treatment of coronary artery disease and the minimally invasive surgical PVI-group from the 2010-2013 cohort these treatments are not included in this first study, excluding analyses at the level of the overall medical conditions. Optimal comparison and assessment of quality improvement with this model using prospective, consolidated data covering the entire medical condition will be possible in the near future. Positive overall conclusions should not lead to overlooking elements requiring improvement. For example, we found an increase in surgical re-explorations after CABG and an increase in myocardial infarctions after PCI, obviously necessitating attention and further improvement.

Future challenges

This study describes the first step in setting up an outcome-based purchasing contract and further optimization of the model will take place. In the long-term partnership between the hospital and the health insurance company, the model will be evaluated and improved every year. For example, confidence intervals and reference groups should be re-considered. The impact of the model on quality and costs in healthcare delivered will also be subject to evaluation. In the future, we will be able to analyse whether incentives that are used for further improvement actions will lead to additional cost savings. More patient-reported outcome measures, such as quality of life data, as well as outcomes for the full medical conditions should

be integrated into the model. In time, QALY's might be used in the model, as the willingness to pay of patients was found to be related to QALY's. [41] Stimulating health education programmes for patients could help to change patient behaviour and consequently outcomes. Because the developed model uses standardized outcome measures and initial conditions, it can be applied by other hospitals and health insurance companies as well. In time, patient value in terms of outcomes over costs can and should be introduced into the model, probably in a shared savings model.

CONCLUSION

A health insurance company and a hospital have succeeded in creating a reimbursement model in which value-based healthcare principles are integrated and changes in quality can be measured and rewarded. The presented model is a first step that offers great promise in aligning hospitals and health insurance companies in using patient-relevant outcomes in healthcare purchasing. To further increase patient value, on-going optimization of the model and evaluation of its impact on quality of care is necessary requiring new long-term collaboration models based on trust.

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APPENDIX 1.	Patient	characteristics	(N=14,944)
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	CABG (n=4,308)		PCI (n=9,329)			Catheter PVI (n=1,307)		
	2010- 2013	2014		2010- 2013	2014		2010- 2013	2014	
	n (%) / ı	mean (SD)	p	n (%) / r	nean (SD)	p	n (%) / m	iean (SD)	р
Age	65.7 (9.72)	65.4 (9.75)		65.2 (11.54)	65.8 (11.33)		61.1 (9.51)	59.6 (9.72)	*
Gender									
men	2827 (78.4)	546 (77.6)		5205 (71.9)	1532 (73.4)		708 (69.4)	215 (74.9)	
Diabetes			*						
yes	794 (22.0)	179 (25.4)		1381 (19.1)	364 (17.4)		-	-	
unknown	0	0		112 (1.5)	70 (3.4)		-	-	
LVEF						*			
30-50%	424 (11.8)	90 (12.8)		172 (2.4)	138 (6.6)		-	-	
<30%	101 (2.8)	12 (1.7)		177 (2.4)	66 (3.2)		-	-	
unknown	311 (8.6)	44 (6.3)		3509 (48.4)	1049 (50.3)		-	-	
Renal insufficiency						*			
yes	760 (21.1)	149 (21.2)		1399 (19.3)	438 (21.0)		-	-	
unknown	23 (0.6)	2 (0.3)		496 (6.8)	244 (11.7)		-	-	
Urgency of the procedure				-	-				
urgent	106 (2.9)	13 (1.8)		1814 (25.0)	500 (24.0)		-	-	
emergency + rescue	288 (8.0)	44 (6.3)		2904 (40.1)	799 (38.3)		-	-	
unknown	0	0		3 (0)	0		-	-	
Chronic total occlusion									
yes	-	-		525 (7.2)	147 (7.0)		-	-	
unknown	-	-		10 (0.1)	0		-	-	

	CABG (n=4,308)	PCI (n=	PCI (n=9,329)			Catheter PVI (n=1,307)		
	2010- 2013	2014	2010- 2013	2014		2010- 2013	2014		
	n (%) / ı	mean (SD) p	n (%) / I	mean (SD)	р	n (%) / m	ean (SD)	р	
Previous MI					*				
yes	-	-	1783 (24.6)	585 (28.0)		-	-		
unknown	-	-	95 (1.3)	53 (2.5)		-	-		
Previous CABG					*				
yes	-	-	992 (13.7)	232 (11.1)		-	-		
unknown	-	-	57 (0.8)	38 (1.8)		-	-		
Multivessel disease					*				
yes	-	-	3528 (48.7)	1102 (52.8)		-	-		
unknown	-	-	1 (O)	0		-	-		
Resuscitation									
yes	-	-	299 (4.1)	71 (3.4)		-	-		
unknown	-	-	247 (3.4)	7 (0.3)		-	-		
Shock					*				
yes	-	-	321 (4.4)	74 (3.5)		-	-		
unknown	-	-	310 (4.3)	5 (0.2)		-	-		
BMI								*	
25-30	-	-	-	-		491 (48.1)	153 (53.3)		
>=30	-	-	-	-		246 (24.1)	46 (16.0)		
ChadsVasc score									
medium (2-4)	-	-	-	-		430 (42.2)	87 (30.3)		
high (>=5)	-	-	-	-		22 (2.2)	3 (1.0)		

APPENDIX 1. Continued

APPENDIX 1. Continued

	CABG (n=4,308)	PCI (n=	PCI (n=9,329)		Catheter PVI (n=1,307)		
	2010- 2013	2014	2010- 2013	2014	2010- 2013	2014		
	n (%) / r	nean (SD) p	n (%) /	mean (SD) p	n (%) / m	nean (SD)	p	
unknown	-	-	-	-	30 (2.9)	65 (22.6)		
Previous ablation							*	
yes	-	-	-	-	273 (26.8)	41 (14.3)		
unknown	-	-	-	-	1 (O.1)	0		
Previous mitral valve disease							*	
yes	-	-	-	-	94 (9.2)	37 (12.9)		
unknown	-	-	-	-	67 (6.6)	55 (19.2)		

*Note:*p<.05*; Significant differences: CABG diabetes p=.049; PCI LVEF p<.001; PCI renal insufficiency p=.005; PCI previous myocardial infarction p<.001; PCI previous CABG p=.004; PCI multivessel disease p=.001; PCI shock p=.010; Catheter PVI age p=.014; Catheter PVI BMI p=.015; Catheter PVI previous ablation p<.001; Catheter PVI previous mitral valve disease p=.008



CHAPTER 9

Enhancing regional integration between cardiac centres and referring hospitals: Aantal ster Impact on patient satisfaction and clinical outcome

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ABSTRACT

Background: Regional integration is one of the main principles to improve patientrelevant outcomes in value-based health care. Optimal collaboration between cardiac centres and referring hospitals necessitates structural changes in both sides. This article addresses the results of enhanced collaboration between Catharina Heart Center and its referring hospital "St. Jans Gasthuis". Our aim was to evaluate clinical outcomes, patient satisfaction, and process and structure measures as a result of setting up a regional integrated care delivery system.

Methods: Since 2013, both hospitals have implemented interventions to improve clinical outcomes, the degree of patient satisfaction and the compliance to important process and structure measures. A baseline and a re-evaluation were performed to identify the effect of applying such interventions. Clinical data extracted from the electronic health records and cardiac databases of Dutch hospitals well as survey-based data were used.

Results: Re-evaluation showed improvement of event-free survival of patients treated for coronary artery disease between 2014 and 2016 compared to patients treated between 2011 and 2013 (97.4% vs. 96.7% respectively), leading to significant better outcomes for patients referred from the St. Jans Gasthuis compared to patients referred from other hospitals. The level of patient satisfaction was improved and reached a statistical significance regarding patient information and education (p=.013), quality of care (p=.007), hospital admission and stay (p=.032), personal contact with the physician (p=.024), and total impression (p=.007). Evaluation of process and structure measures showed an increase of the number of process and structure measures that were scored as "completely available" (in 2013, 62 out of 116 indicators (53.4%) were scored completely available, which increased to 94 (81.0%) in 2015).

Conclusions: An intensified collaboration in the care chain, organized in a structured manner between a cardiac centre and a referring hospital and aiming at high quality, resulted in improvement in clinical outcomes, degree of patient satisfaction and more compliance to process and structural measures. We encourage others to organize the whole care chain to continuously improve patient-relevant outcomes.

BACKGROUND

Traditional components of health care quality have been broadly delineated as structure, process, and outcome measures. [1] In value-based health care, it is recommended to integrate care delivery systems at a regional level because outcomes are influenced by various specialties and interventions in the treatment process of a patient. [2] Patient-relevant outcome measures should be used to measure patient value. In the Netherlands, the 'Meetbaar Beter' foundation started to play a role in implementing value-based health care in cardiac care in 2011, using standard sets of outcome measures that are aligned with the sets developed by the International Consortium for Health Outcomes Measurement (ICHOM). [3, 4] Process measures, on the other hand, can be a helpful tool to investigate aspects of improvement and can be used to detect the underlying reasons or mechanisms for specific results. [2,5] Additionally, patient satisfaction is often related to outcomes as well as processes and can be described as an indirect or proxy indicator of the quality of doctor or hospital performance. [6]

In an earlier Dutch report, Roeg et al. concluded that intensive community-based care requires a highly complex organization, which is reflected by the diversity of the clusters. [7] The emphasis on cooperation with other institutes is significant, and this should ideally be characterized as a chain of care. [8] This means that single services provided by separate institutes need to be strongly linked and that interorganisational and interdisciplinary service is essential for an intensive community-based care.

In the Catharina hospital's cardiac centre (situated in Eindhoven, The Netherlands), approximately 7,000-8,000 cardiac interventions are performed yearly. These interventions include open heart surgery, interventional cardiology and electrophysiology. Almost 70% of these patients is referred from regional hospitals and transferred back within a few days after the intervention. The "St. Jans Gasthuis" (SJG) in Weert is one of the referring hospitals.

Since 2013, the Catharina Heart Center and the SJG Weert intensified their collaboration. Optimization of care within an institution is often the main goal of current quality systems of healthcare providers. The aim of the present report is to analyze the effects of setting up a regional integrated care delivery system on patient-relevant outcomes, patient satisfaction and process and structure measures.

METHODS

Aim and design of the study

The aim of this study was to assess the impact of the quality improvement projects between SJG Weert en Catharina Heart Center, the following three aspects by performing baseline and effect evaluations: (1) clinical outcomes; (2) degree of patient satisfaction; and (3) process and structure measures. Data were derived from various Dutch hospitals. The different study cohorts that are used for the evaluations will be described in detail below.

Patients and inclusion criteria

In this study, we included different study cohorts: For the evaluation of clinical outcomes, we included data of all patients diagnosed with coronary artery disease (CAD) referred from other hospitals to Catharina Heart Center and back for coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) between 2011 and 2016. We subdivided the cohort into patients referred from SJG Weert and patients referred from all other to the Catharina Heart Center referring hospitals.

For assessing patient satisfaction, patients referred from SJG Weert to Catharina Heart Center in the year 2013 and in the period January until September 2015 received questionnaires delivered by post.

For assessing effects on process and structure measures, a quality inspection was executed by two professionals in 2013 (baseline) and 2015 (follow-up). Quantitative data were collected by using standardized questionnaires.

Clinical outcomes

To analyze outcomes for patients with CAD who underwent CABG or PCI, all outcome measures as selected in and used by Meetbaar Beter [9], with a clinically relevant follow-up duration up to a maximum of 120 days are included, i.e. 30-day mortality, 120-day mortality, cerebrovascular accident (CVA) within 72 hours, deep sternal wound infection (DSWI) within 30 days, surgical re-exploration within 30 days, urgent CABG within 24 hours, and myocardial infarction (MI) within 30 days. For patients treated with a PCI, 30-day mortality is used whereas for patients treated with CABG, 120-day mortality is used. This choice is based on previous research that has shown that all cardiac surgery-related mortalities were covered at 120 days post-surgery [10] whereas for PCI, risk of death seems to move from cardiac to noncardiac after a period of 30 days post-PCI. [11] For all outcome measures, definitions and

time periods as defined by Meetbaar Beter are adopted in the present study. [9] All outcomes are combined in "event-free survival" (i.e. no mortality within 120-days (CABG) and 30-days (PCI) respectively), no complications (i.e., none of the before mentioned outcomes) and no MI within 30 days after the intervention). Outcomes are retrieved from the electronic health record, cardiac databases used in the Catharina Heart Center and results recorded in SJG Weert.

Patient satisfaction

To measure patient satisfaction, self-administered questionnaires were used (see additional file 1). A total of 28 items were included to assess the following topics: communication with the hospital (2 items); communication between the hospitals and the patient's general practitioner (2 items); education and education material (4 items); consistency/compatibility between the two hospitals (2 items); access time (2 items); quality of care (4 items); unexpected events and complications (3 items); hospital stay (4 items); and personal contact with physician in both hospitals (2 items). On a scale from 1 to 10, patients were asked "To what extent are you satisfied with ...", followed by the specific item. All questions were assessed separately regarding both hospitals. Patients were asked to give an overall grade of the delivered care in both hospitals on a scale from very bad (=1) to excellent (=10).

Process and structure measures

Objective evaluations of process and structure measures took place regarding the organization, cooperation, outpatient clinic, echo and ergometry, coronary care unit and the cardiac catheterization lab. This quality inspection was based on the existing formats of the Dutch Association of Cardiologists (NVVC), including the KISZ survey of the Dutch Association of Internists and standard operating procedures. [12] To analyze the data, peer debriefing was applied: All results were evaluated by two independent professionals, namely a cardiologist and a quality management expert. Every item was scored independently by the professionals on a scale from 1 to 3 to indicate whether the indicator *completely exists, partly exists* or *does not exist.* After the assessment the professionals integrated their scores. Where different, arguments were discussed and in consensus the overall score was decided.

Interventions to improve the care chain

The following interventions have been implemented since 2013:

• Information and communication: improvement of the communication within and between both hospitals regarding patients referred to and discussed in the

heart team meetings; a new protocol for patients' discharge in Catharina Heart Center and SJG Weert, modifying patient brochures in both hospitals to better adhere to each other.

- Knowledge transfer on daily basis by introducing a daily discussion session regarding hospitalized patients for the entire consultant team. Also frequent multidisciplinary meetings to discuss complex patients were introduced.
- Consultant resources: the consultant capacity was increased from 4 full-time equivalents (FTE) to 4,5 FTE. Time investment was made into in-patient care by separating supervision tasks for the emergency department and coronary care unit respectively the cardiology nursing ward. Also at the outpatient clinic, there was a modification of planning, leading to more time reserved for new patients. Supervision of the imaging department was improved by reserving time of an imaging-consultant, and on a routine basis an educational plan for employees of the imaging department was started.
- Care for complex patients: introduction of outpatient clinics prior to complicated procedures and for specific patient groups run by consultants from Catharina Heart Center and a special attention to discussing high-risk patients.
- Improving guideline adherence: introduction of "time-outs" in the catheterization lab and change of discharge policy.

Statistical analyses

Data were analyzed using SPSS software, version 23 (IBM Corp, Armonk, NY, USA). Descriptive statistics were used to describe the baseline characteristics and (uncorrected) outcomes for the following two study groups: patients referred from SJG Weert between 2011 and 2013 (patient cohort 1) and patients referred from SJG Weert between 2014 and 2016 (patient cohort 2). To be able to study the effects of this project and exclude effects of generic quality improvement projects in the Catharina Hospital, outcomes of patients of SJG Weert were also compared with outcomes of patients of other referring hospitals treated for CAD in the Catharina Hospital during the same period regarding "event-free survival". Differences in outcomes between patients from SJG Weert compared to patients from all other referring hospitals at pre- and post-measurement were explored by means of logistic regression analyses using the top-down procedure. The dependent variable was event-free survival. Risk-adjustment was performed for the following patient characteristics: age, gender, diabetes, renal insufficiency, multi-vessel disease, LVEF and urgency of the procedure.

To examine whether significant differences exist between patient satisfaction at baseline and two years later, the mean scores of the two groups on the different aspects were explored by means of independent samples t-tests.

To analyze the process and structure measures, descriptive statistics were used by summing up the indicators that were available in 2013 and 2015 respectively.

Tests were performed at alpha=.05.

RESULTS

Clinical outcomes

In total, 1,475 patients referred from SJG Weert to the Catharina Heart Center for a treatment for CAD were included in the analyses. The baseline characteristics are shown in Table 1. The baseline cohort included patients treated during the period from 2011 through 2013 (n=820). The evaluation cohort included patients treated between 2014 and 2016 (n=655).

Variable	2011-2013	2014-2016	р			
Male gender	628 (76.6%)	509 (77.7%)	.610			
Age, year, mean	65.6 ± 10.7	66.3 ± 10.8	.243			
Diabetes	126 (15.4%)	97 (15.3%)	.947			
Renal insufficiency	151 (18.5%)	117 (19.1%)	.772			
Multivessel disease	455 (55.6%)	363 (55.7%)	.984			
LVEF (<50%)	88 (12.0%)	92 (16.4%)	.042			
Non-elective procedure	405 (49.4%)	329 (50.2%)	.749			

TABLE 1. Patient characteristics (coronary artery disease: PCI and CABG)

Data are presented as mean ± SD or number (%); CABG, coronary artery bypass grafting; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention

Table 2 presents the uncorrected clinical outcomes for the two cohorts. When combining both groups (i.e., PCI and CABG), we observed an improvement in all outcomes (Table 2).

	2011-20	2011-2013		16
	n	%	n	%
CABG	184		128	
120-day mortality	1	0.5	0	0.0
CVA	1	0,5	0	0.0
DSWI	3	1.6	1	0.8
Surgical re-exploration	10	5.4	6	4.7
PCI	636		527	
30-day mortality	9	1.4	5	0.9
Urgent CABG	2	0.3	0	0.0
MI	3	0.5	5	1.0
Coronary artery disease*	810		643	
Mortality	10	1.2	5	0.8
Complications	17	2.1	11	1.8
Event-free survival (short-term)	780	96.7	603	97.4

TABLE 2. Clinical outcome comparisons between patient cohort 1 (2011-2013) and patient cohort 2 (2014-2016)

* Treated with either CABG or PCI

For the second part of the outcome analysis, all to the Catharina Heart Center referred patients treated by CABG or PCI between 2011 and 2016 were included (n=12,013). As demonstrated in Table 3, the results of the logistic regression analysis show that event-free survival was statistically significantly higher in SJG Weert compared to the that of patients of all other referring hospitals in 2014-2016. The difference in event-free survival between the hospitals was not statistically significant in 2011-2013.

TABLE 3. Results of the logistic regression analysis with event-free survival (0 = no event; 1 = event) as dependent variable among patients with coronary artery disease¹

	SJG Weert	Patients from all other referring hospitals	OR	р
2011-2013	96.7%	95.4%	1.05	.653
2014-2016	97.4%	95.1%	1.39	.046

¹ Exclusion of patients who underwent a second procedure (PCI or CABG) within 120 days after the initial procedure

Patient satisfaction

Half of the patients (n=108) completed the questionnaire in 2013 and the other 108 patients filled out the questionnaire in 2015. The mean scores on both survey points are shown in Figure 1.

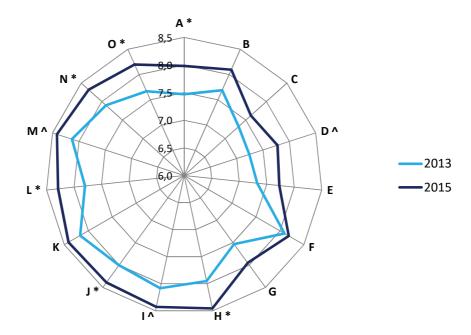


FIGURE 1. Results of patient satisfaction questionnaires

The score referring to education and education material, which was related to both hospitals, was significantly higher in 2015 compared to 2013. In the SJG Weert, the mean scores regarding the overall grade is significantly improved, and the scores on the specific items regarding quality of delivered care, hospital admission and the personal contact with the medical specialist were rated significantly higher in 2015 than in 2013. In the Catharina Heart Center, the personal contact between patient and medical specialist seemed to be improved. As presented in Table 4, borderline significant differences (p<10) were found regarding other aspects, too.

Patient satisfaction variable	2013 n=108	2015 n=108	р
A. Patient information and education	7.47	7.98	.013
B. Expectation management	7.69	8.09	.127
C. Alignment between both hospitals	7.33	7.62	.214
D. Communication with the GP (SJG Weert)	7.24	7.77	.086
E. Communication with the GP (Catharina)	7.33	7.73	.189
F. Duration to approach and pathway (SJG)	8.09	8.18	.729
G. Duration to approach and pathway (Cath)	7.53	7.95	.134
H. Quality of care (SJG Weert)	7.95	8.46	.007
I. Quality of care (Catharina)	8.08	8.43	.057
J. Admission and stay (SJG Weert)	8.00	8.39	.032
K. Admission and stay (Catharina)	8.17	8.41	.155
L. General mark (SJG Weert)	7.80	8.29	.007
M. General mark (Catharina)	8.13	8.42	.070
N. Personal contact between patient and physician (SJG Weert)	7.90	8.32	.024
O. Personal contact between patient and physician (Catharina)	7.67	8.20	.031

TABLE 4. Differences regarding patient satisfaction between patients treated in 2013 and patients treated in 2015

Process and structure measures

Evaluation of process and structure measures were analyzed in a radar chart, as shown in Figure 2. Only the measures that scored 1 (completely available) are presented. The results show an increase of the number of measures that have been scored as "*completely available*". In general, in 2013, 62 out of 116 indicators (53.4%) have been rated as "*completely available*", which increased to 94 (81.0%) in 2015. There was a decrease in both the measures that have been rated as "*partly available*" (from 19 to 13) or "*not available*" (from 35 to 9). All dimensions included in the analysis showed a higher score in 2015 than in 2013 (Figure 2).

Enhancing regional integration between cardiac centres and referring hospitals: Impact on patient satisfaction and clinical outcome

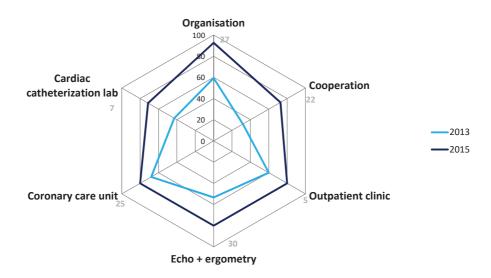


FIGURE 2. Results of process and structure measures evaluation with numbers of items belonging to each category

DISCUSSION

This report presents the results of intensifying the collaboration between Catharina Heart Center and the referring hospital SJG Weert. We described the measures taken to achieve this cooperation and as a result, improvement of both the clinical results and patient satisfaction have been achieved. In addition, quality standards improved as measured by the Dutch cardiology quality organizations.

Regional integration of health care delivery systems is one of the key elements of value-based health care. It was advised to organize patient pathways for patient groups with the same medical condition. [2] This requires new forms of collaboration between health care professionals and providers. In the Dutch health care system, mergers of hospitals have been observed over the last decade. However, these mergers are rarely successful in perspective of quality improvement. [13]

Our study revealed better outcomes for SJG Weert patients than for patients referred from other hospitals. The finding of this study encourages us to implement similar projects with other referring hospitals. As multiple interventions have been implemented in this collaboration project, it is difficult to identify strong correlations between individual interventions and both improved clinical outcomes and higher patient satisfaction. In general, redefining of the scheduling of physicians and the decision to increase physician staffing might have had positive effects on several endpoints. [14] In a recent report concerning the rate of readmissions [15], quality improvement efforts to improve inpatient care and the coordination of transitional care can prevent many unnecessary hospital readmissions. On the other hand, in a 2007 systematic review [16], only half of studies concluded that better hospital-level processes were associated with lower mortality; 18% found results in the opposite direction.

In addition to the collaboration project, there have been quality improvement projects in both SJG Weert and the Catharina Heart Center that might have influenced the results of this study. For instance, in Catharina Heart Center, improvement projects have been implemented within the cardiothoracic surgery department with positive effects on outcomes. [17]

The primary means of assessing how patients feel about the care they receive in a health care setting is measurement of patient satisfaction. Patients have different views from health professionals when judging the quality of care and services. [18] Besides, associations have been found between patient satisfaction and outcomes, such as readmissions. [15,19] We have used the results of a patient satisfaction survey to further improve care management and promote the quality of outcomes of referred patients.

Donabedian has noted that patient satisfaction is not only an important component of quality of care, but also a heavy contributor to the definition of quality from the perspective of clients' values and expectations. [20] Different studies have shown that satisfied patients are more likely to better comply with providers' medical regimens and orders, to continue using medical care services and to cooperate or maintain relationship with specific providers when compared to unsatisfied patients. [20-23]

The present report shows improvement of all elements used to measure patient satisfaction as a result of applying structural measures. Some of these elements reached statistical significance. In both hospitals, the degree of patient satisfaction about the personal contact between patient and physician was significantly improved. This is a reflection of better and efficient planning, less work pressure, and consequently more attention for the individual patient.

Strengths and limitations

One of the major strengths of this study was the focus on a wide range of indicators: clinical outcomes, patient satisfaction, and process and structure measures. A limited, but well-defined and widely accepted set of patient-relevant outcome measures has been included. As a result of an intensified collaboration in the care chain, improvement on all three kinds of indicators have been observed. The positive results of the NVVC-audit in 2016 are strongly aligned with the findings presented in this study and indicate a relatively high level of objectivity.

The present study also has its limitations. First, multiple interventions have been implemented. Further research is required to identify correlations between individual interventions and improved clinical outcomes, higher patient satisfaction and higher compliance to process and structure measures. Second, we have used a combined end-point to assess effects on clinical outcomes to increase power. Moreover, further follow-up is needed to confirm our results. Finally, we did not include the role of the general practitioner in the improvement measures of the care chain, which is equally important and must be considered.

CONCLUSIONS

This study shows the promising effect of improving healthcare in the full cycle of care. Different improvement actions have been implemented to improve quality in healthcare as part of enhancing the collaboration between hospitals. In our study, a cardiac centre and a referring hospital succeeded in improving clinical outcomes, patient satisfaction and compliance to process and structure measures.

List of abbreviations

CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CVA	CerebroVascular Accident
DSWI	Deep Sternal Wound Infection
FTE	Full-Time Equivalents
ICHOM	International Consortium for Health Outcomes Measurement
KISZ	Quality Investigation and signaling care processes (Kwaliteits
	Inventarisatie en Signalering Zorgprocessen)
LVEF	Left Ventricular Ejection Fraction
MI	Myocardial Infarction
NVVC	Dutch Association of Cardiologists (Nederlandse Vereniging voor
	Cardiologie)
OR	Odds Ratio
PCI	Percutaneous Coronary Intervention
SJG	St. Jans Gasthuis

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ADDITIONAL FILES

Additional file 1: Questionnaire patient satisfaction

Questionnaire patient satisfaction

General questions

In this questionnaire, we ask for your opinion, with 1 being the lowest and 10 being the highest grade. You can also select "not applicable" (n/a).

Was your referral from St. Jans Gasthuis to Catharina Hospital a planned or an emergency transfer?

O Planned O Emergency

	1	2	3	4			7	8		10	n/a
To what extent are you satisfied with the information you received / the communication between you and your hospital during your entire care process?	0	0	0	0	0	0	0	0	0	0	О
To what extent did the treatment correspond with what you had been told in advance?	0	0	0	0	0	0	0	0	0	0	0

Education and education material

	1	2	3	4			7	8		10	n/a
To what extent are you satisfied with the verbal education prior to your treatment?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the education material you received prior to your treatment? * * N.B. You can skip this question if you have been referred urgently.	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the verbal education after your treatment?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the education material you received after your treatment?	0	0	0	0	0	0	0	0	0	0	0

	1	2	3	4	5	6	7	8	9	10	n/a
To what extent was it clear to you to whom you could go with your questions at what time?	0	0	0	0	0	0	0	0	0	0	0
To what extent did the two hospitals possess the same information?	0	0	0	0	0	0	0	0	0	0	0

Communication between St. Jans Gasthuis and Catharina Hospital

Communication with the patient's general practitioner (GP)

	1	2	3	4	5	6	7	8	9	10	n/a
To what extent are you satisfied with the communication between the medical specialists at St. Jans Gasthuis and your GP?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the communication between the medical specialists at Catharina Hospital and your GP?	0	0	0	0	0	0	0	0	0	0	0

Access time

	1	2	3	4	5	6	7	8	9	10	n/a
To what extent are you satisfied with the time you had to wait until you could go to St. Jans Gasthuis with your complaints?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the time between your referral by the physician at St. Jans Gasthuis and the moment you could go to the Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0

Quality of care

	1	2	3	4	5	6	7	8	9	10	n/a
To what extent are you satisfied with the quality of care provided at the outpatient clinic at St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the quality of care provided at the outpatient clinic at Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the quality of care provided at the nursing ward in St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the quality of care provided at the nursing ward in Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0

Unforeseen events or complications

Did any unforeseen events or complications occur?

O yes

O no (continue with question block "Hospital stay" on the next page)

	1	2	3	4	5	6	7	8	9	10	n/a
To what extent are you satisfied with the treatment of these unforeseen events / complications in St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
To what extent are you satisfied with the treatment of these unforeseen events / complications in Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0

Hospital stay

	1	2	3	4	5	6	7	8	9	10	n/a
To what extent do you appreciate the way in which you were welcomed at the outpatient clinic at St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
To what extent do you appreciate the way in which you were welcomed at the outpatient clinic at Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0
To what extent do you appreciate your stay at the nursing ward in St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
To what extent do you appreciate your stay at the nursing ward in Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0

Overall grade

	1	2	3	4	5	6	7	8	9	10	n/a
Which grade do you award the overall care provided by St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
Which grade do you award the overall care provided by Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0

Personal contact

	1	2	3	4	5	6	7	8	9	10	n/a
How do you rate the personal contact between you and your doctor at St. Jans Gasthuis?	0	0	0	0	0	0	0	0	0	0	0
How do you rate the personal contact between you and your doctor at Catharina Hospital?	0	0	0	0	0	0	0	0	0	0	0

Suggestions

Do you have any suggestions on how St. Jans Gasthuis and Catharina Hospital can improve the care provided to you?

Thank you very much for answering the questionnaire.

CHAPTER 10

Introducing a method for implementing valuebased healthcare principles in the full cycle of care: Aantal sterfgevallerusing atrial fibrillation as a proof of concept

D. van Veghel, L. Dekker, L. Theunissen, J. Janssen, M. Burg, E. Huijbers, P. Voermans, P. van der Wees, H. Cremers.

Submitted

ABSTRACT

Background: Value Based Health Care (VBHC) is a well-known strategy to improve patient relevant outcomes and reduce healthcare costs, in which it is advised to start with measuring and improving outcomes. However, until now no methodology is present to implement VBHC principles in the full cycle of care. Therefore, this study describes a stepwise approach to implement and continuously improve patient relevant outcomes in the total care delivery value chain.

Methods: Key principles of VBHC are used to develop the stepwise methodology in a suburban area in the Netherlands, in which healthcare providers of primary, secondary, and tertiary care collaborate in a physician driven initiative, called the Netherlands Heart Network. The stepwise methodology incorporates the Plan-Do-Study-Act cycle to continuously improve patient relevant outcomes. To outline the presented methodology a prevalent cardiac condition (i.e. atrial fibrillation) is used as a proof of concept.

Results: By using the presented methodology the key principles of VBHC are implemented, resulting in an adequate registration of patient relevant outcomes and a structured evaluation of adherence to prevailing guidelines (i.e. process-and structure indicators). Based on the followed methodology detailed improvements are defined in order to optimize patient relevant outcomes.

Conclusions: The presented methodology is successful in implementing VBHC principles in the full cycle of care, and therewith includes the preconditions for improving patient relevant outcomes in the total care delivery value chain. However, since this methodology is a first introduction, future research is challenged to use and asses the stepwise methodology in other fields and for different medical conditions.

INTRODUCTION

Value Based Health Care (VBHC) is a well-known strategy in healthcare in order to improve patient value, defined as outcomes that matter most to patients divided by costs created by healthcare delivery. [1-5] Key principles of VBHC as defined by Porter (i.e. organizing healthcare around a specific medical condition, indicate patient relevant outcomes and costs, weigh and prioritize outcomes using the outcome measure hierarchy, define process-and structure indicators, apply statistical techniques for risk correction, and organize healthcare in the full cycle of care) are used to structurally measure and improve patient value for specific medical conditions. [2, 4-7] It is advised to start the shift towards a more value driven system by measuring and improving outcomes. [4-6] Although various best practices are mentioned in literature regarding some elements of the VBHC strategy, so far focus is mostly only on measuring and improving outcomes within institutions. [3, 8-11]. This leaves important parts of the total care delivery value chain uncovered. Moreover other elements of the value based healthcare strategy are still to be implemented. Currently, this limits the impact of VBHC because all dimensions of the VBHC strategy are expected to be mutually reinforcing, and should thus be covered. [6]

One of the elements introduced by Porter is 'integrate care delivery across separate facilities' [6], which intends to strengthen the collaboration between healthcare professionals in primary, secondary, and tertiary care, as all involved healthcare providers contribute to the outcomes achieved and costs caused in the treatment of all patients with the same medical condition. [5, 6] In such a multi-institutional network other crucial aspects in VBHC become increasingly challenging. Valid and reliable registration of outcomes in accordance with the quality measures that matter most to patients [12], as well as using process-and structure indicators that are interrelated to these outcomes [1], and are in accordance with (inter)national guidelines, is essential for making VBHC work in a care network. Numerous studies have indicated that adherence to guidelines within institutions has a positive impact on improving patient relevant outcomes [13-17]; such data are lacking for care networks. In addition, until now, information is absent which steps should be taken in order to improve outcomes of the full cycle of care in an active multidisciplinary quality network of healthcare providers.

Atrial fibrillation is the most frequently diagnosed arrhythmia in Europe and often treated by multiple healthcare providers. [18] Prior research by Porter suggested that extensive collaboration between healthcare providers in primary, secondary, and tertiary care may enable improvements in patient relevant outcomes and reduced

healthcare costs. [6] However, until now such multi-institutional quality network for atrial fibrillation care for measuring and continuously improving patient relevant outcomes and health care costs has not been initiated yet.

Continuous improvement of patient relevant outcomes using quality indicators and interrelated process-and structure indicators is crucial in VBHC. [1, 4-6, 19] The cycle of Deming (i.e. Plan-Do-Study-Act cycle) has shown to be a successful and validated framework to continuously update indicators in quality research. [20,21] Therefore it may also be an useful instrument in accordance with the VBHC-strategy, for continuously improving patient relevant outcomes in the full cycle of care.

The aim of the present study is to introduce a stepwise methodology to implement and continuously improve patient relevant outcomes in the total care delivery value chain. In addition, completeness of data collection on outcomes and adherence to process-and structure indicators will be shown for atrial fibrillation to outline the presented methodology.

METHODS

Design and setting

In the present study a stepwise methodology is introduced using key principles of the VBHC strategy to define, implement, evaluate, and continuously improve patient relevant outcomes and costs in the full cycle of care. This stepwise methodology is developed within a clinician driven network initiative, involving both hospitals and general practitioner (GP) organizations in a suburban region in the Netherlands (i.e. South East Brabant region), called the Netherlands Heart Network (NHN). [22] The NHN is an example of an organization that facilitates the integration of care delivery facilities and aims to contribute to continuous improvement of value for patients with a heart disease. In order to develop a VBHC network, NHN develops transmural standards of care for highly prevalent medical conditions, associated with high costs and strong need for multi-provider collaboration. The NHN provides a platform for healthcare providers to collaborate and to improve patient value by defining transmural quality standards using VBHC principles as well as a shared Plan-Do-Study-Act cycle (PDSA cycle), in the total care delivery value chain. The participating multidisciplinary healthcare providers, including providers in primary, secondary, and tertiary care (i.e. cardiologists, nurses, GPs, pharmacists, ambulance service, home care organizations, etc.), remain responsible for the implementation of the quality standards and improvement projects within their own professional field.

In order to outline the results of this stepwise methodology an elaboration of one highly prevalent medical condition in the field of cardiology will be illustrated in this paper, namely atrial fibrillation (i.e. arrhythmic disorder). [23]

Stepwise methodology

To be able to improve patient relevant outcomes in the full cycle of care through a stepwise approach, a transmural standard of care is developed by healthcare providers in primary, secondary, and tertiary care. Support for the development and implementation of the transmural standard of care is enlarged by giving multidisciplinary healthcare providers the lead in this procedure, following a predefined roadmap concerning the following elements (Figure 1):

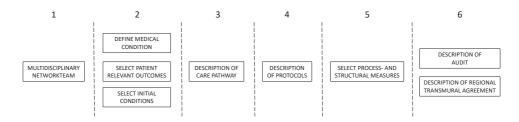


FIGURE 1: Stepwise methodology

- STEP 1: A *multidisciplinary networkteam* is formed with a delegation of multidisciplinary healthcare providers from primary (i.e. GPs and primary care nurses), secondary (i.e. cardiologists and nurses), and tertiary care (i.e. electrophysiologists and cardiac surgeons).
- STEP 2: The medical condition is defined in which an uniform definition is described for the primary, secondary, and tertiary care process (i.e. based on prevailing medical standards and guidelines). Subsequently, a selection is made of the most relevant outcomes and initial conditions for the medical condition. For this procedure the validated indicator sets of the Netherlands Heart Registration are used. [24] These sets cover all three tiers of the outcome measure hierarchy (Health status achieved or retained, Process of recovery, and Sustainability of health). [1]
- STEP 3: A description is made of the *care delivery value chain* (CDVC) of the medical condition in which the pathway of the patient is described in the full cycle of care. Within this care pathway also a description is

made when the patient is with which healthcare provider and what kind of activities and procedures are performed by the specific healthcare providers.

- STEP 4: A description is made of the required *protocols* of essential elements in the CDVC, contributing most to outcomes and costs. For instance, the referral and back-referral criteria are indicated, including the information needed by the 'receiving' healthcare provider. Through this procedure, quality of information is assured.
- STEP 5: A selection of *process-and structure indicators* regarding elements that contribute most to managing outcomes (1) and costs is made in order to indicate which activities in the care pathway and the organizational structure should be performed and assessed via quality indicators.
- STEP 6: In order to assess whether the implementation is performed as intended an *audit* is conducted based on the quality indicators (i.e. patient relevant outcomes, process-and structure measures). In establishing the audit criteria, healthcare providers determine the norm of implementation of the various indicators. Finally, a *Regional Transmural Agreement* (RTA) is developed as a summary of the relevant steps in the transmural standard of care. This RTA is, furthermore, communicated to all relevant health care providers involved as a leading document for the medical condition.

Plan – Do – Study – Act cycle

An important aspect in the stepwise methodology is the continuous improvement of the patient relevant outcomes, since outcomes are the leading element in the VBHC strategy. The stepwise methodology incorporates the PDSA cycle in order to facilitate continuous (e.g. yearly) improvement using a structured and proven effective procedure. [20,21] After the finalization of the transmural standard of care this continuous improvement cycle is started and includes the following elements (Figure 2):

- 1. A first step after the development is the *implementation* of the transmural standard of care in the full care cycle. The participating healthcare providers have the responsibility to implement the agreements regarding the healthcare process in their own organizations.
- 2a. Within 6 months after the implementation an *audit* is performed by an audit team of healthcare providers. In every organization, at least 2 auditors assess whether the implementation is performed as intended. During the audit, the

completeness of patient relevant outcomes is assessed. Based on Porters' outcome measurement landscape, process-and structure indicators are supportive towards the outcomes. [1] This stresses the importance of substantive testing of adherence to process- and structure indicators, as a measure of guideline adherence. Afterwards, an audit report is composed with the findings and advices for the specific organization.

The audit not only provides insights in quality of care and compliance to the RTA for the healthcare provider. Also, the NHN gains information about the feasibility of the RTA. These insights are a source of information for the continuous improvement cycle of the RTA.

- 2b. At the moment of implementation in the healthcare organizations the *patient relevant outcome measures* are registered in the Electronic Medical Records (EMR) of the healthcare organizations. Every year the outcomes are extracted by data analysts in order to analyze the outcomes to include most relevant findings in the revised standard of care.
- 2c. To include the opinion of patients, *focus group interviews* are annually organized for every medical condition. Suggestions of patients are also used to update the current standard of care.
- 2d. Subsequently in the process of continuous improvement the *guidelines and national standards* are reviewed and renewals are taken into account to update the current standard of care.
- 2e. Since the full cycle of care is organized by using the stepwise methodology, the possibility arises to initiate transmural innovation projects. Therefore, in the process of continuous improvement, leading organizations are invited to pitch *potential innovations* for the medical condition. Suitable innovations have the potential to increase patient relevant outcomes and reduce healthcare costs.
- 3. Based on the results of the audit, guidelines and national standards, focus group interviews, patient relevant outcomes, and potential innovations in the multidisciplinary networkteam, a decision is made which improvements to the transmural standard of care are needed to enable improving the relevant outcomes and reducing the healthcare costs. Criteria used for decision making in this perspective are:
 - a. The improvement must concern a large group of patients;
 - b. The improvement needs to have an impact on the (reduction of) healthcare costs;
 - c. A maximum of 3 improvements are suggested per cycle (for every medical condition). By restricting the amount of improvements the effects can be evaluated and the implementation is more feasible;

- d. At least 1 improvement needs to be implemented regarding the patients' perspective;
- e. The improvement has to have an impact on patients' satisfaction;
- f. The improvements have an impact on the healthcare providers in primary, secondary, and tertiary care.
- 4. Thereafter, adaptations to the standard of care are made and the standard of care is re-implemented in practice, for which the healthcare providers are responsible.

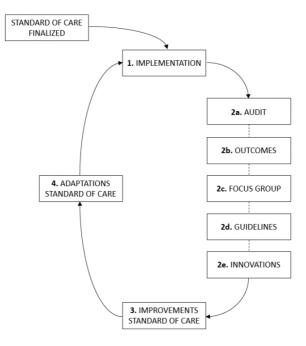


FIGURE 2: PDSA cycle within the NHN

Relationship between the stepwise methodology and VBHC principles

As already mentioned, the stepwise methodology is based on the VBHC principles to develop, implement, assess, and continuously improve the most relevant outcomes for patients with a cardiac condition. Furthermore, the stepwise methodology follows a structured procedure for continuous improvement of the outcomes using the PDSA cycle. In Table 1 the relationship between the stepwise methodology and the embedded VBHC principles is outlined.

PDSA CYCLE	OPERATIONALIZATION NHN	EMBEDDED VBHC PRINCIPLES
PLAN	 Organizing multidisciplinary networkteam Defining medical condition Indicating most relevant outcomes and initial conditions Defining protocols Indicating process-and structure indicators Defining RTA (see Figure 1) Implementation of standard of care (see Figure 2) 	 All tiers of the outcome measure hierarchy The care delivery value chain in the full cycle of care Measure and improve relevant process-and structure indicators contributing to the outcomes that matter most to patients
STUDY	 Performing audit Analyzing patient relevant outcomes Organizing focus group interviews Reviewing national guidelines and standards Evaluating potential innovations (see Figure 2) 	 Measure and improve costs related to healthcare delivery Integrate care delivery systems Use a patient centered approach, involve patients in deciding what matters most Let physicians lead the change
ACT	 Defining improvements to the standard of care Adaptations towards the standard of care (see Figure 2) 	

RESULTS

Based on the PDSA cycle (Figure 2), an outline is provided below of the application of the stepwise methodology in the NHN for atrial fibrillation. Subsequently, the results of the registration density of the patient relevant outcomes and the adherence to guidelines and protocols (i.e. based on the process-and structure indicators) is presented.

Stepwise methodology for atrial fibrillation

PLAN

For atrial fibrillation a multidisciplinary networkteam is formed of 4 cardiologist (of 4 different hospitals), 2 GPs (with special knowledge and interest of heart conditions), 4 nurses of the outpatient atrial fibrillation clinic, and a delegation of the diagnostic

center. Together this networkteam develops the transmural standard of care for atrial fibrillation. In Table 2 the main elements of the transmural standard of care are outlined.

The final element of the transmural standard of care is the development of the RTA. The RTA is a summary of the standard of care and is distributed to all healthcare providers in primary, secondary, and tertiary care. By using this approach all healthcare providers are informed about the agreements regarding the diagnostic and treatment trajectories for patients with atrial fibrillation.

DO

For the implementation of the transmural standard of care, the healthcare providers are responsible themselves. The healthcare providers need to adjust their procedures (i.e. in accordance with the process-and structure measures) and register the needed indicators (i.e. patient relevant outcomes and initial conditions) in their own organizations.

STUDY

As indicated in Figure 2 in the STUDY phase of the PDSA cycle several activities are performed to analyze the implementation of the transmural standard of care and information is gathered to improve the standard. The results indicated in the tables below originate from 4 hospitals in the Netherlands in which the transmural standard of care is implemented and evaluated.

Based on (inter)national guidelines, protocols, and consensus of healthcare professionals involved in the multidisciplinary networkteam a norm score is presented for the completeness of registrations of the patient relevant outcomes. During the audit it is assessed whether the healthcare providers assess the outcomes as agreed on. As indicated in Table 3 the EHRA score, CVA or TIA, major bleedings, atrial fibrillation related admissions, and the adverse effects of medication score all above the norm (97,5%). The Quality of life score, assessed with a self-administered questionnaire (AFEQT), illustrates to score below (77,9%) the norm score of 90%.

TABLE 2: Main elements of the transmura	I standard of care for atrial fibrillation
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	ATRIAL FIBRILLATION
1. Definition (23)	 Concerns an arrhythmic disorder characterized by (1) irregular RR interval (without the presence of a repetitive pattern), (2.) absence of P-waves on the surface ECG, and (3.) variable atrial cycle length (if visible). In addition, also an arrhythmic disorder is present when atrial fibrillation for at least 30 seconds is observed by cavitation or rhythm recording. AF is categorized into: <u>First diagnosed AF</u> (i.e. AF that has not been diagnosed before, irrespective of the duration of the arrhythmia or the presence and severity of AF-related symptoms) <u>Paroxysmal AF</u> (i.e. self-terminating, in most cases within 48 hours. Some AF paroxysms may continue for up to 7 days) <u>Persistent AF</u> (i.e. AF that lasts longer than 7 days, including episodes that are terminated by cardioversion, either with drugs or by direct current cardioversion, after 7 days or more) <u>Long-standing persistent AF</u> (i.e. continuous AF lasting for ≥1 year when it is decided to adopt a rhythm control strategy)
2. Outcome measures (25)	 <u>EHRA score</u> (i.e. measured by EHRA I= No symptoms; EHRA II= Mild symptoms, norma daily activities not affected; EHRA III= Severe symptoms, normal daily activity affected; EHRA IV= Disabling symptoms, normal daily activity discontinued) <u>CVA or TIA</u> (i.e. amount of CVAs or TIAs) <u>Major bleedings</u> (i.e. measured with the BARC-index) <u>Admissions (AF related)</u> <u>Quality of life</u> (i.e. measured with the validated AFEQT questionnaire (26)) <u>Adverse effects of medication</u> (i.e. percentage of patients that report serious adverse events due to rate or rhythm control medication)
3. Initial conditions (25)	 <u>Age</u> <u>Gender</u> <u>Type of AF</u> (i.e. first diagnosed AF, paroxysmal AF, persistent AF, long-standing persistent AF, permanent AF) <u>Comorbidities</u> (i.e. hypertension, coronary artery disease, heart failure, peripheral artery disease, CVA, diabetes mellitus, Chronic Obstructive Pulmonary Disease, thyroid disease, obesity, valvular heart disease, OSAS) <u>CHA2DS2-VASc score</u> <u>HAS-BLED</u>
4. Process indicators (23)	 Type of AF is documented AF is established using ECG registration/rhythm recording Choice for rate/rhythm control is documented Echocardiogram is performed within 6 months after diagnosis Results of laboratory research are documented The CHA₂DS₂-VASc-score is documented Stable AF-patients are referred to GP For instable AF-patients the reason for outpatient follow-up is documented AF-patients with persistent complaints are referred to a tertiary center For all AF-patients who are registered for an ablation regarding AF, the referring hospital is informed within 7 days about the decision of the heart team Time between setting the indication and the ablation is not more than 12 weeks

TABLE 2: Continued

	ATRIAL FIBRILLATION
5. Structure indicators	 In the hospital an outpatient AF clinic is operational for newly diagnosed AF-patients The outpatient AF clinic is operated by an AF-nurse and supervised by a cardiologist In the outpatient clinic the needed facilities are arranged to inform and physically examine AF-patients A referral system is designed to refer new AF-patients by the GP Registrations in the outpatient AF clinic are performed in an EMR In the tertiary center the EP-team meets at least once a week to discuss AF-patients The ECG with AF has been received from the GP

AF= atrial fibrillation; RR= Riva-Rocci (blood pressure); ECG= electrocardiogram; EHRA= European Heart Rhythm Association; CVA= cerebrovascular accident; TIA= transient ischemic attack; BARC= Bleeding Academic Research Consortium; AFEQT= Atrial Fibrillation Effect on QualiTy of life; OSAS= obstructive sleep apnea syndrome; CHA₂DS₂-VASc= score for atrial fibrillation stroke risk; HAS-BLED= score for major bleeding risk; GP= general practitioner; EMR= Electronic Medical Record; EP= Electro Physiologists.

PATIENT RELEVANT OUTCOMES	NORM SCORE	AUDIT SCORE
EHRA score	90%	97,5%
CVA or TIA	90%	97,5%
Major bleedings	90%	97,5%
Admissions (AF related)	90%	97,5%
Quality of life	90%	77,9%
Adverse effects of medication	90%	97,5%

TABLE 3: Completeness of registrations of patient relevant outcomes

AF= atrial fibrillation; EHRA= European Heart Rhythm Association; CVA= cerebrovascular accident; TIA= transient ischemic attack.

To assess the adherence to guidelines, the process-and structure indicators are measured. In Table 4 the norm- and audit scores for adherence to both indicators is shown. The table illustrates that only the 'ECG registrations with AF are received from the GP' score below the set norm (90%).

In VBHC, patients are central in the healthcare process. [7,8] Therefore, focus group interviews are performed using the stepwise methodology to receive information by patients on specific topics (i.e. experiences of the outpatient atrial fibrillation clinic, received information, communication between healthcare providers, alignment between healthcare providers, and questions regarding the aftercare process). In Table 5 the main improvements mentioned by 6 patients (i.e. at least one AF-patient from each of the 4 hospitals involved in the NHN) with atrial fibrillation participating in the focus group are presented.

•			
	NORM SCORE	AUDIT SCORE	
PROCESS INDICATORS			
Type of AF is documented	95%	98.8%	
AF is established using ECG registration/rhythm recording	90%	97.5%	
Choice for rate/rhythm control is documented	90%	95%	
Echocardiogram is performed within 6 months after diagnosis	95%	98.8%	
Results of laboratory research are documented	95%	98.8%	
The CHA ₂ DS ₂ -VASc-score is documented	90%	97.5%	
Stable AF-patients are referred to GP	90%	90%	
For instable AF-patients reason for outpatient follow-up is documented	90%	95%	
AF-patients with persistent complaints are referred to a tertiary center	90%	90%	
For all AF-patients who are registered for an ablation regarding AF, the referring hospital is informed within 7 days about the decision of the heart team	90%	96.7%	
Time between setting the indication and the ablation is not more than 12 weeks	90%	96.7%	
STRUCTURE INDICATORS			
An outpatient AF clinic is operational for newly diagnosed AF-patients	90%	95%	
The outpatient AF clinic is operated by an AF-nurse and supervised by a cardiologist	90%	97.5%	
In the outpatient clinic, facilities are present to inform and physically examine AF-patients	100%	100%	
A referral system is designed to refer new AF-patients by the GP	100%	100%	
Registrations in the outpatient AF clinic are made in an EMR	100%	100%	
In the tertiary center the EP-team meets at least once a week to discuss AF- patients	100%	100%	
The ECG with AF has been received from the GP	100%	90%	

TABLE 4: Results of adherence to process-and structural measures

AF= atrial fibrillation; RR= Riva-Rocci (blood pressure); ECG= electrocardiogram; EHRA= European Heart Rhythm Association; CVA= cerebrovascular accident; TIA= transient ischemic attack; BARC= Bleeding Academic Research Consortium; AFEQT= Atrial Fibrillation Effect on QualiTy of life; OSAS= obstructive sleep apnea syndrome; CHA₂DS₂-VASc= score for atrial fibrillation stroke risk; HAS-BLED= score for major bleeding risk; GP= general practitioner; EMR= Electronic Medical Record; EP= Electro Physiologists.

In the yearly cycle for the transmural standard for atrial fibrillation no new guidelines or standards were introduced. However, the literature states that approximately 20% of ischemic strokes can be attributed to (undiagnosed) atrial fibrillation. [27, 28] For that reason, the healthcare providers in the multidisciplinary networkteam assessed potential innovations to detect undiagnosed atrial fibrillation patients in primary care.

TABLE 5: Main improvements regarding the focus group interview

FOCUS GROUP INTERVIEW

- More information prior to the consultation with the outpatient atrial fibrillation clinic
- Information regarding referral to GP (i.e. reason of referral and follow-up by GP)
- More alignment between cardiologist and GP regarding the process of care
- Mention who can be contacted in case of questions or medical complaints regarding patients' atrial fibrillation
- Prior to the consultations information how the process of care is organized

ACT

In the ACT phase of the PDSA cycle for atrial fibrillation the results regarding the audit, focus group interviews, review of guidelines, pilot for potential innovations, and results of the patient relevant outcomes improvement projects are defined to enhance the relevant outcomes of patients diagnosed for this specific medical condition. Based on the results and the criteria for selecting improvement projects the following developments were defined:

- Update of the patient information folder for atrial fibrillation patients;
- Adaptations to the referral system in order to receive all ECGs of patients that were diagnosed with atrial fibrillation and referred to the hospital;
- In the diagnostic centers the possibility is created to view the needed information by other relevant healthcare providers;
- Atrial fibrillation nurses were instructed to call and remind patients to complete and send the quality of life questionnaire back to the outpatient clinic;
- Strategy to screen for undiagnosed atrial fibrillation by GPs with an innovative instrument.

The PDSA cycle is yearly repeated, meaning that during the following audit procedure is evaluated whether the improvement project result in better patient relevant outcomes and reduced healthcare costs.

DISCUSSION

In this study a first introduction of a stepwise methodology to implement and continuously improve patient value in the full cycle of care using key principles of VBHC is presented and outlined for atrial fibrillation as a proof of concept. Results showed that the stepwise approach is feasible in implementing VBHC principles in the total care delivery value chain by using a multi-institutional network. Furthermore,

the PDSA cycle was successfully applied in order to continuously improve patient relevant outcomes and to define improvement projects to increase value for cardiac patients.

Results of using this stepwise methodology for atrial fibrillation proved that it is feasible to implement VBHC principles in a network organization. Using the methodology, healthcare providers in primary, secondary, and tertiary care involved in the NHN succeeded in defining patient value in terms of outcomes and costs as a shared goal. Subsequently they agreed on standards of care, directly eliminating cases of inefficiency and improving several parts of the care pathway, e.g. by improving communication between healthcare providers. The results show a high registration density of patient relevant outcomes and a structured evaluation of adherence to prevailing guidelines (i.e. process-and structure indicators). As reported in prior research in the field of VBHC [1], process-and structure indicators can be interrelated and supportive towards patient relevant outcomes. [19] In atrial fibrillation care, this relationship is in accordance with the results presented in a study by Hendriks et al. in which adherence to guidelines, by introducing a protocol-driven outpatient atrial fibrillation clinic, resulted in improved patient relevant outcomes and reduced healthcare costs. [29] In addition, conditions that potentially result in improved healthcare quality in the total care delivery value chain (i.e. transmural agreements, registration of main patient relevant outcomes, adherence to guidelines, following a PDSA cycle) are included in the presented stepwise methodology which increases the potential of improved patient relevant outcomes. Although results for this stepwise methodology are not presented in this article, the first positive trends have already been demonstrated. [30]

A crucial aspect in VBHC is that (multidisciplinary) healthcare providers are the main drivers of initiatives. [6] The presented stepwise methodology to implement VBHC principles in the full cycle of care focusses on the medical conditions in which healthcare providers in primary (i.e. GPs, ambulance service, thrombosis service, pharmacists, and diagnostic centers), secondary care (i.e. cardiologists and nurses), and tertiary care (i.e. electrophysiologists and thorax surgeons) are in the lead. By using this approach the responsibility and support for both the development and implementation of the transmural standard of care stays among the healthcare providers, and is free of institutional interests. It is to be expected that administrative interference in healthcare organizations enables discussions in which institutional interests (i.e. budgets or substitution of care) may be more central than the perspectives of patients.

Limitations

A major concern of this study is the lack of results of the patient relevant outcomes and costs. By focusing first on improving the care pathway and the registration of process- and structure indicators, all selected because of their proven relation with the selected outcomes that matter most to patients, it is expected that providers will be able to improve patient relevant outcomes. As a consequence of improved outcomes, healthcare providers are also expected to be able to reduce costs, as improving quality of care may be related to a reduction of costs. [31, 32]

A second limitation of the presented methodology may be that currently only patient relevant outcomes are included. In the patient value equation both outcomes and costs are the main aspects of VBHC. Since improving outcomes is most relevant for patients and most interesting for healthcare providers, it is advised in leading VBHC literature first to focus on outcomes. [5,6] Nevertheless, after the effectiveness of the stepwise methodology is shown regarding outcomes, healthcare costs will be assessed and become a part of the PDSA cycle in the nearby future.

The presented methodology seems to be an effective approach, however, it may be that the lack of support of participating organizations decreases the strength of the implementation of the transmural standards of care. Prior initiatives, such as the Children's Hospital of Philadelphia, have already shown to be effective by a central management. [6, 33] Therefore, the stepwise methodology may have even more impact in an integrated healthcare system in which other aspects of the VBHC strategy, e.g. build Integrated Practice Units or introduce bundled payment models, can be centrally implemented.

CONCLUSIONS

A first stepwise methodology is presented in order to implement VBHC principles in the full cycle of care in a network organization. Based on the preliminary findings it can be concluded that the methodology was used successfully for defining a multiprovider care standard based on VBHC principles, implementing a shared PDSA cycle and results in a high registration density of patient relevant outcomes and the adherence of prevailing guidelines. These are all preconditions for improvement of patient relevant outcomes. Also first elimination of double diagnostics was observed as an example of reduction of costs. For that reason we invite researcher to use and assess the effectiveness of VBHC in healthcare using the presented methodology.

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CHAPTER 11

Introduction of a model to measure patient value: assessing outcomes and costs in patients Aantal sterformant undergoing coronary artery bypass surgery

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ABSTRACT

The primary aim of this study was to develop and apply a risk-adjusted model that measures patient value (PV) by assessing outcomes and costs, as an important addition to the currently available forms to report on patient value. In this model, performed in the field of cardiac surgery, patient-relevant outcomes outweigh costs. Outcomes (120-day mortality) and in-hospital costs of patients who underwent coronary artery bypass grafting between 2012 and 2013 (n = 350) were compared with those of patients treated between 2014 and 2015 (n = 293). Additionally, costs are subdivided and analysed for diverse types of activities. Multivariate logistic (expected outcome) and linear (expected costs) regression analyses were performed. The dependent variables were: age, gender, diabetes mellitus, renal insufficiency, severe left ventricular dysfunction and urgency of the procedure. Changes in PV were observed, although not statistically significant. The calculated PV for patients treated in 2014–2015 was higher (PV= 1.034; prediction interval: 0.948 (2.5%) – 1.060 (97.5%)) than that in the benchmark period (2012-2013: PV = 1.0042). The model was successfully applied to a compare PV in CABG patients over time and might add relevant insights to the current forms of reporting on patient value. Further implementation of the model is desirable in order to achieve benchmarking, offer more insights into both outcomes and costs and enable improvements in quality and efficiency.

INTRODUCTION

The essence of value-based healthcare (VBHC) is the concept of patient-relevant outcomes in relation to costs. Outcomes that matter most to patients have been selected by several organizations [1-5] and are presented in the outcome hierarchy. [6] Studies have shown variation in risk-corrected outcomes between hospitals, between primary caregivers and over time within a hospital. [7-14] When measuring costs in healthcare, it is important to adjust them for case-mix variation, as costs are related to co-morbidities. [15] Also, as in cost-effectiveness research, it is important to decide what costs should be included. [16] Several methods have been used to report on both outcomes and costs. [17-18] Although these models include all parameters that represent patient value, a solid methodology to measure patient value (PV) as a concept and enabling benchmarking or monitoring patient value over time is still lacking. [19-20]

The Heart Centre of the Catharina Hospital Eindhoven (the Netherlands) (CHC) has implemented VBHC since 2013 by measuring and monitoring outcomes and executing improvement projects. Outcomes are measured and improved for several medical conditions using the sets of outcomes measures defined and published by the Netherlands Heart Registration (NHR). The NHR is a physician-driven and patientcentred initiative in which outcome data of almost all heart centres in the Netherlands are registered and published transparently. [23] The NHR sets are aligned with the ICHOM standard sets when available [1] and cover all tiers of the outcome measure hierarchy. [24] In the CHC the organizational structure is adjusted, and several process optimizations have taken place that often have a simple, practical execution. For example, a checklist is implemented in the operating room, leading to a decrease in surgical re-explorations among patients who undergo coronary artery bypass grafting (CABG). [21] Improvement projects and adjustments have led to improvements in clinical outcomes, determined in the quality evaluation as a part of a unique outcome-based payment model. [22] However, whether PV has improved is unknown, as the influence on the costs of care has not yet been studied.

In this article we present a model for measuring PV in addition to the state of the art forms to report on outcomes and costs in healthcare. We suggest to add the PV model to the publication of all selected outcome measures and the costs of healthcare delivery. The model was applied to patients suffering from coronary artery disease treated with CABG in our institution, up to a 120 day follow up. This model is designed to be risk-corrected and practical. It focusses on survival and includes complications by including the costs associated, as many studies have

shown the impact of complications of costs in healthcare. [15] With the aim to facilitate improvement of decision making by physicians, the model only holds elements of costs in healthcare that can be influenced directly by physicians in healthcare delivery. In modern healthcare, quality is the main goal, and outcomes and associated costs cannot be compared in a 1:1 manner. Therefore, in our model, we presume that outcomes should outweigh costs when analysing PV.

METHODS

Patient data

A cohort of 643 consecutive CABG patients was included in our study. The following inclusion criteria were applied: (1) patients who had undergone CABG between January 2012 and December 2015 in the Catharina Hospital Eindhoven and (2) patients whose follow-up was planned in the outpatient clinic of the Catharina Hospital Eindhoven. Clinical data including initial conditions (baseline characteristics) of the patients were collected from the database of the Department of Cardiothoracic Surgery.

To evaluate possible changes in PV due to quality improvement projects over time, the total population was divided into two cohorts operated on during two periods:

- Cohort A, operated on in the period 2012-2013; n = 350
- Cohort B, operated on in the period 2014–2015; n = 293

Comparison between the two cohorts was performed regarding initial conditions, outcome, costs and ultimately PV.

The Institutional Review Board has accepted the study and waived the need for informed consent.

Initial conditions

The initial conditions included in the analysis were age, gender, diabetes mellitus (type I or type II), renal insufficiency (defined as a decrease in glomerular filtration rate (GFR) <60 ml/min/1.73 m², using the MDRD formula to calculate GFR), left ventricular function (defined as ejection fraction in the following categories: poor (<30%), moderate (30%–50%) and good (> 50%)) and urgency of the procedure. Both the selection and definition of the initial conditions were based on the set defined by the NHR. [23]

Outcome measures

The primary outcome measure for measuring quality of care in this study was 120day mortality [25], defined as all-cause mortality within 120 days after the operation. Follow-up data concerning patient mortality were checked by the Municipal Population Register. The follow-up was performed on April 30, 2016.

Costs

The aim of the model is to enable physicians to improve healthcare processes. Therefore, in the evaluation, costs that can be directly influenced by physicians are analysed. Only 'in-hospital' costs that could be directly related to the CABG procedure were considered in this study. Costs were considered from the day the heart team made the decision to operate [11] up to 120 days after the operation. Resource utilization at the patient level (e.g. laboratory orders, operation room time and ward stay) was extracted from the Hospital Information System (HIS) for specialties and diagnoses that might be connected to the cycle of care for patients who underwent CABG (including non-cardiac complications).

All complications occurring during hospitalization were considered in calculating the costs. After discharge, a selection of the costs of CABG-related complications within 120 days was jointly made by two experienced cardiac surgeons (M.S-H and A.vS). Examples of these CABG-related complications are

- 1. neurological hospitalization after cerebrovascular accident or transient ischemic attack,
- 2. abdominal operations for intestinal ischemia,
- 3. hospitalization due to fever of unknown aetiology and
- 4. management of pleural effusion or pulmonary problems.

In some cases (n = 12), the patients' charts were checked to evaluate the relevance of the complication.

Standardized cost prices, based on the average costs of more than 40 Dutch hospitals, were used in this study. For each hospital, costs per activity have been calculated using the "time-driven activity-based costing" (TDABC) methodology, an advanced method for understanding hospital costs. [24] The unique identification number of each patient was used to match patients from the HIS to the financial information in the financial database of X-IS, a consultancy firm that calculated the average cost prices; this matching was successful in >95% of the cases.

The most recent cost price model was used for the whole study period (2012–2015) to avoid differences caused by inflation or variations in time. Different activities are divided into activity categories. All activities consisted of direct and indirect costs. For example, direct costs for an inpatient day admission (category 'ward') consisted of (a) personnel, such as the salaries of ward nurses and administrative personnel, (b) material costs, such as bed linen and bandages and (c) depreciation of equipment, such as ward inventory. Examples of indirect costs are those related to information technology, building depreciation, cleaning and catering.

Patient value

Patient value was analysed using the observed and expected outcomes and the observed and expected costs. The cohort of the period 2012–2013 (cohort A) was used as a benchmark to determine a model for expected costs and outcomes for the period 2014–2015 (cohort B). The observed outcome was defined as the 120-day mortality in the cohort. The expected outcome for cohort B (adjusted 120-day mortality) was estimated using a logistic regression analysis. The ratio of the observed and expected outcomes was defined as R outcome:

Patient value was expected to improve when the outcome improves. As mortality is a negative outcome, outcome was defined as 1/R outcome.

The observed costs were defined as the total costs of the whole cohort. The expected costs were estimated using a linear regression analysis. The ratio of the observed and expected costs is defined as R costs:

$$R \ costs = \frac{Observed \ costs}{Expected \ costs}$$

To calculate PV, Porter's formula (outcomes/costs) was used. [24] In order to create a higher weight for outcome than for costs, 1/R outcome was squared. This seems reasonable because a twice as bad outcome against a 50% reduction in costs should not be seen as having equal PV. The following formula, using the sum of costs and outcome, was used to estimate PV:

$$PV = \frac{(1/\Sigma R \text{ outcome})^2}{\Sigma R \text{ costs}}$$

Statistical analyses

Two periods were used: 2012–2013 and 2014–2015. The patient characteristics in the 2012–2013 (cohort A) and 2014–2015 (cohort B) cohorts were compared using a chi-square test or Fisher's exact test in the case of categorical variables and a t-test or Mann-Whitney U test for continuous variables, depending on normality. Multiple imputation according to predictive mean matching and assuming that values were missed completely at random was used to impute missing patient data.

Multivariate logistic regression was used to calculate the expected outcome, and multivariate linear regression was used to calculate the expected costs. In both models, cohort A was used as the benchmark, and correction was carried out for initial conditions (i.e. age, gender, diabetes mellitus, renal insufficiency, severe left ventricular dysfunction and urgency of the procedure). In the cost analyses, log transformation was applied due to a non-normal distribution of the data. From the benchmark, the predictive distribution of PV was simulated. Prediction intervals were estimated with the assumption that if the performance is according to the benchmark model, with 95% probability, PV will be between the 2.5% and 97.5% percentiles of the predictive distribution. A P-value of .05 was considered statistically significant. Statistical analyses were performed using R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient characteristics

Table 1 presents the baseline characteristics of the total population (N=643) as well as for the two study cohorts separately. No statistically significant baseline differences were found between the two cohorts.

	Total	2012-2013	2014-2015	_ .
	(n = 643)	(cohort A; n = 350)	(cohort B; n = 293)	P value
Age (years), mean ± SD	64.1 ± 10.0	64.5 ± 10.1	63.6 ± 10.0	.24
Sex, n (%) Men	528 (82.1)	280 (80.0)	248 (84.6)	.15
Diabetes mellitus, n (%) Type I or type II	134 (20.8)	74 (21.1)	60 (20.5)	.91
Left ventr. ejection fraction, n (%)ª 30%–50% <30%	85 (13.4) 17 (2.7)	47 (13.7) 7 (2.0)	38 (13.1) 10 (3.4)	.55
Renal insufficiency, n (%) GFR <60 ml/min/1.73 m²	116 (18.0)	62 (17.7)	54 (18.4)	.89
Urgency, n (%) Emergency	70 (10.9)	37 (10.6)	33 (11.3)	.88

TABLE 1 Patient characteristics of CABG patients according to period

^a left ventricular ejection fraction was not known for 10 patients

Outcomes

Table 2 presents the 120-day mortality of the study cohort. The incidence of 120day mortality was higher in cohort A than in cohort B. Table 3 shows the observed and expected 120-day mortality for both cohorts. In cohort B, the observed 120-day mortality was lower than expected.

TABLE 2 120-day mortality of CABG patients according to the period

	Total (n = 643)	2012-2013 (cohort A; n = 350)	2014-2015 (cohort B; n = 293)	P value
120-day mortality, n (%)				
Yes	8 (1.2)	7 (2.0)	1 (0.3)	.08

TABLE 3 Observed and expected 120-day mortality of CABG patients according to period

	2012–2013 (cohort A)			2014–2015	2014–2015 (cohort B)		
	Observed	Expected	Ratio	Observed	Expected	Ratio	
120-day mortality (N)	7	7	100	1	5.98	16.7	

Note: Ratio = (observed/expected)*100

Costs

Table 4 presents the costs incurred for the total sample and for the two study cohorts separately. Due to a non-normal distribution of the data, the median costs (and IQ proportion) are shown. No statistically significant difference was found between the two cohorts regarding the total incurred costs. However, when the costs were separated into distinct categories, statistically significant differences were found regarding the following categories: consulting, intensive care, laboratory and costs categorized as "other" (e.g. materials, dialysis, medical procedures, such as preoperative screening, anaesthesia and first aid).

	Total (n = 643)	2012-2013 (cohort A; n = 350)	2014-2015 (cohort B; n = 293)	P value
Imaging	226 (90-2,478)	226 (90-2,478)	226 (90-2,153)	.09
Consulting	2,227 (271-6,444)	1,968 (271-5,422)	2,369 (1,338-6,444)	<.001
Intensive care	3,766 (0-86,626)	3,766 (0-86,626)	3,921 (0-35,288)	<.001
Ward	2,971 (0-38,206)	2,972 (0-16,221)	2,972 (0-38,206)	.51
Laboratory	491 (140-12,382)	505 (140-12,382)	478 (146-5,323)	.03
Operation	5,554 (2,050-20,046)	5,573 (2,630-18,219)	5,542 (2,050-20,046)	.16
Other	1,411 (28-38,015)	1,571 (97-38,015)	1,203 (28-27,370)	<.001
Total costs	16,697 (7,254-160,620)	16,807 (7,254-160,620)	16,440 (8,592-68,204)	.85

TABLE 4 Median costs (min-max) per CABG patient in Euros per category in both study cohorts

In Table 5, both the observed and expected costs (total costs and costs divided into categories) are presented for the whole patient population. In both patient cohorts, the observed total costs were higher than the expected total costs. The higher costs in cohort A are mainly ascribed to costs for intensive care, laboratory, imaging and costs belonging to the category "other". In cohort B, the costs regarding consulting, intensive care and ward were higher than expected; all other observed costs were lower than expected.

	2012–2013 (cohort A)			2014–2015	2014–2015 (cohort B)		
	Observed	Expected	Ratio	Observed	Expected	Ratio	
Imaging	111,949	109,256	103	87,324	90,864	96	
Consulting	739,300	754,680	98	735,780	629,732	117	
Intensive care ^a	1,781,818	1,670,544	107	1,363,175	1,337,884	102	
Ward⁵	1,242,658	1,239,499	100	1,090,930	1,018,193	107	
Laboratory	267,667	251,698	106	181,875	210,320	87	
Operation	2,108,621	2,100,396	100	1,711,587	1,752,409	98	
Other	881,288	864,009	102	678,045	705,420	96	
Total costs	7,133,303	7,016,095	102	5,848,715	5,842,427	100	

 TABLE 5
 Total observed and expected costs (Euros) per category of all CABG patients according to period

Note: Ratio = (observed/expected)*100; ^a 4 patients in 2012–2013 and 9 patients in 2014–2015 with zero costs were not included in the prediction model; ^b 2 patients in 2012–2013 and 1 patient in 2014–2015 with zero costs were not included in the prediction model

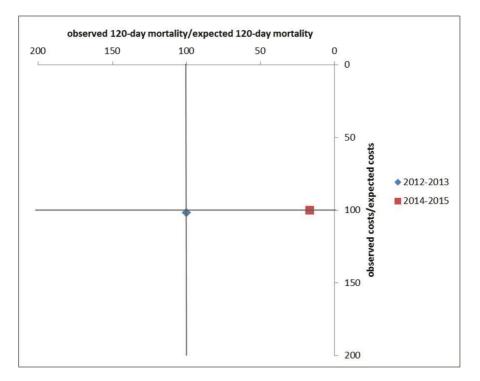


FIGURE 1 Ratio of costs (y-axis) and ratio of 120-day mortality (x-axis) of CABG patients according to period

Patient value

The ratio of the observed and expected costs (R costs) and observed and expected outcome (R outcome) were plotted in a chart (see Figure 1). In cohort B, PV was higher, mainly because of the lower mortality ratio. This difference was not statistically significant (2012-2013: PV = 1.0042; 2014-2015 PV = 1.034; prediction interval: 0.948 (2.5%) – 1.060 (97.5%)).

DISCUSSION

In VBHC, there is a need to measure and quantify PV, enabling healthcare providers to continuously improve based on insights into differences in outcomes and costs. [27] The primary aim of this study was to develop and apply a risk-adjusted model that measures PV by calculating a number to be used for comparisons, e.g. over time or between hospitals. We succeeded in further developing the formula of Porter [24] into a formula that can be used in practice.

State of the art models to report on outcomes and costs propose to include outcome measures that matter most to patients and costs of healthcare delivery. [28] However, until now, these models dot not analyse the ratio of outcomes and costs. A solid methodology to measure outcomes in relation to costs can be of great importance as many observations on variation on outcomes and costs can be hard to interpret without quantifying their interdependency. Of course, worse outcomes realized against higher costs will raise questions and motivate all involved parties to improve healthcare. But an addition to the current model is needed to interpret situations with better outcomes against higher costs, or worse outcomes against lower costs.

To the best of our knowledge, this is the first study to develop and implement a PV model that combines both outcome and costs and in which the outcome weighs more heavily than the costs. In an earlier study by De Beurs et al. [17], cost per outcome was used as a performance indicator. In their study, case mix correction was applied, but potentially relevant predictors were missing, and outcomes and costs were weighted equally. In our study, we chose to square the outcome ration (R outcome). As (R outcome) is a relative number, it seems logical to use an exponent.

According to Porter and Lee [28], it is essential to measure certain outcomes that matter to patients, but it should be considered that the selected outcomes can be influenced by the physician. [11] In various VBHC initiatives, different outcome measures are assessed for patients with coronary artery disease. [1,11,29] In our

study, we selected one of these widely accepted outcome measures, which are placed as highest in the outcome measures hierarchy; i.e. 120-day mortality. [1,11] Outcome measures other than 120-day mortality, such as post-CABG complications (e.g. cerebrovascular accident and deep sternal wound infection) and surgical re-explorations and re-interventions are indirectly reflected in the calculation of the costs, as these outcomes lead to additional activities in the hospital, which will be reflected in higher costs. [30] Since PV is expected to improve when outcome improves, we chose to use 1/R outcome, instead of using the positive outcome 'survival'. As the relative difference between small percentages (100 - x; survival), the model is much more sensitive to any change in quality. To make quality outweigh costs, we have made the arbitrary choice to square the outcome ratio.

Concerning the issue of costs, it is essential to exactly define the scope and the information that is relevant to the target group. [16] By using the X-IS data, based on their methodology, we applied the TDABC-model, where both time and costs are considered. [26,31] We used mean/standardized cost prizes for every healthcare activity. Only activities that are directly related to the original procedure (CABG) were considered. The choice of these CABG-related activities or procedures was made by two experienced cardiac surgeons. In this way, all physician-dependent cost parameters in the cycle of care were covered. To increase the relevance of the analysis to physicians and to support them in optimizing decisions in healthcare delivery, we excluded overhead and capital charges. In our model, the various kinds of costs were categorized so that the most important cost drivers could be identified.

Correction for care needs (i.e. initial conditions) was necessary because of the correlation between comorbidity and outcomes and costs. [32-35] Finally, we developed a method to determine the level of statistical significance of the differences between periods or hospitals, so that differences became more sensitive.

VBHC and improvement projects

In our study, a comparison of PV over time was done between two cohorts. The PVs for patients who underwent a CABG in recent years (2014–2015; cohort B) and in earlier years (2012–2013; cohort A) were calculated and compared. We observed an improvement in PV over time, although the difference was not statistically significant. Applying this model to compare larger cohorts of patients might lead to a statistically significant difference. In the present population, improvement over time is a consequence of the decrease in mortality rates after CABG in our hospital over time. This decrease in mortality may be ascribed to different improvement projects

that have been implemented in the hospital since the embedding of VBHC in the heart centre's strategy. These improvements were achieved by adopting several organizational changes and process optimizations. These improvement projects and adjustments might have contributed to the improvement in outcomes. [21] Furthermore, the burden of care of the patients treated in 2014–2015 seemed to be decreased: both the expected outcomes and expected costs were lower in 2014–2015 than in 2012–2013. It has been shown that quality improvement often leads to a reduction of hospital costs. [19,36-39]

Strengths and limitations

By adding the new model to the current forms to publish outcomes and costs, PV can be guided and monitored in addition to solitary outcome measures and costs. Our model makes it possible to interpret the balance between outcomes and costs and to establish whether potential differences in PV relate to variances in outcomes or in costs (or both outcomes and costs). In combination with data on each selected outcome measure and costs of healthcare delivery, one can weigh the importance of variation in e.g. costs. In the presented model, regarding costs, one can further identify in which cost category of activities differences exist. In this way, focused opportunities for improvement may be sought, and one can investigate where hospitals can learn from each other. Moreover, relations between the financial values of certain activities are presented. Costs are based on mean cost prizes from 40 Dutch hospitals, and a fixed amount for every activity is used. The model is applicable for benchmarking hospitals and enables physicians to see whether there are differences, the model offers the possibility to learn from findings that may be clinically relevant.

Our study had some limitations. The first limitation concerns the fact that the calculation of costs, as determined by TDABC, differs for some of the healthcare activities. For example, costs regarding the operating room are calculated per minute, whereas the costs of using the intensive care unit are calculated per day (independent of the exact duration of use or length of stay). The costs of an echocardiogram are fixed, which is a limited sub-optimization as echocardiograms are often conducted in fixed time slots. More research is needed to improve the model by assessing all activities based on time investment. In particular, when comparing the results of hospitals, the actual time investment of all activities might be investigated instead of averages. In the case of our study, in which we compared two patient groups treated in the same hospital, this issue is less relevant because we assume that the duration of different activities did not change significantly. Second, our study suffers from statistical limitations due

to the relatively small cohort and the small number of events (mortality). However, we used the available clinical data just as a demonstration to apply this model. In a larger patient cohort, statistical power could be revealed.

Future challenges and recommendations

This study proposes a model to measure patient value in addition to the state of the art models to report separately on outcomes and costs. The study suggests opportunities for optimizing the model by validating it and by learning from the findings. For future studies, we recommend applying the model to more than one hospital with the aim of comparing PV between hospitals. We hypothesize that larger differences in PV will exist between hospitals than between two patient cohorts of the same hospital, because of the differences in logistics between healthcare institutions. The model enables benchmarking and can offer several insights into both costs and outcomes. Whether applying the model in hospital benchmarking projects will lead to learning and an improvement of PV by improving outcomes and reducing costs remains to be shown. A second hypothesis is that comparing PV will lead to both quality improvement and cost reduction in healthcare. The added value of the combination of outcomes and costs in one parameter needs to be proven in the future.

In future studies, other outcomes that also matter to patients [24], such as quality of life, could be addressed in the model. In this way, it would be possible to compare hospitals that do not differ in terms of gains in quality of life, but that differ in costs. In time, quality of life can be added by weighing the survival and introducing quality-adjusted life years as the outcome that is used in the model.

It poses a challenge for future research to include the whole care delivery value chain (i.e. intramural and extramural care). This is important for both outcomes and costs and might involve, among others, referring hospitals, general practitioners and pharmacies.

CONCLUSIONS

We succeeded in further developing Porter's PV-formula [24] into a risk-adjusted model that can be used in practice in addition to the current models to report on outcomes and costs. The developed risk-adjusted model to measure PV was successfully implemented in the field of cardiac surgery. The model quantifies value by bringing outcomes and costs together in one estimate for PV. Further implementation is desirable in order to achieve benchmarking and to offer further insights in both outcomes and costs.

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Implementation and first results of value-based healthcare in the Catharina Heart Center



CHAPTER 12

The need for new financial models in the implementation of value-based healthcare

D. van Veghel, D.N. Schulz, M.A. Soliman-Hamad, L.R.C. Dekker.

Under review

INTRODUCTION

All over the world, healthcare systems are shifting from volume-based to valuebased models. Such a move in healthcare delivery is aiming at delivering better care while enhancing patient-perceived value, defined as outcomes that matter most to patients divided by costs of healthcare delivery. [1] For this purpose, it is necessary that all parties involved in healthcare are focusing on this primary goal: improving patient value. [1]

The VBHC strategy is based on six components that are interdependent and mutually reinforcing. [2] As professionals should be able to use outcome measures to improve patient value, culture and leadership seem to be essential factors in implementing a value-based model in care delivery. [3] Although all stakeholders should follow this strategy, physicians should be directing the implementation of VBHC by optimizing healthcare processes, leading to better outcomes and lower costs. [4] The influence of physicians, however, is often limited to the care delivery process. This raises the question which changes in health management are needed to: (1) enable and support successful physician-driven VBHC implementation and (2) to align perspectives of all stakeholders to maximize the impact for patients in the shift towards a value-based health care model. In this article, we take a closer look at how healthcare delivery models are changing from volume-based models to value-based models, and how new financial models could support the change towards a more value-driven healthcare system.

Physician-driven VBHC implementation in a Dutch heart center

In 2011, physicians of Catharina Heart Center (CHC), a large heart center in the Netherlands performing more than 6,000 transcatheter interventions and open heart operations of which over 70% are referred by cardiologists from other hospitals, started to implement VBHC by measuring outcomes. In 2019, the heart center's physician-driven VBHC implementation covers examples of four out of six strategic areas defined by Porter, including "measuring outcomes and costs for each patient", "build an Integrated Practice Unit", "move to bundled payments for care cycles" and "integrate care delivery across separate facilities". Two areas are still to be covered: "geographic expansion of excellent services" and "building an enabling IT platform". [2] First, CHC started to measure outcomes, not only within the heart center, but also by initiating a national outcomes benchmarking initiative "Meetbaar Beter", which was recently merged with the national cardiac and cardiothoracic registries into the Netherlands Heart Registration. [5] Investments were made in data collection and

validation, as data quality is a precondition for outcome monitoring, public reporting and successful implementation of VBHC. Second, by merging the cardiology and cardiothoracic surgery departments into an integrated practice unit (IPU), a new governance structure was created. The core of this structure is the multidisciplinary Quality Committee, which monitors outcomes with the help of standard sets of outcome measures and a national risk-adjusted benchmark of the Netherlands Heart Registration. [6,7] Outcomes are monitored over time, per first operator as well as per referring hospital for the main cardiac conditions, including coronary artery disease, aortic valve disease, mitral valve disease and atrial fibrillation. Outcome measurement covers more than 95% of all invasively treated patients. The committee also takes organizational responsibility for the initiation and facilitation of quality-improvement projects in the full cycle of care when necessary. Similar structures have been recommended by others. [8,9]

Several quality-improvement projects were implemented and there was a statistically significant improvement in patient-relevant outcomes in several medical conditions. These improvement projects included the following: expanding the multidisciplinary team approach, new surgical techniques and protocols; improving educational programs for fellows; introducing additional checklists; and deciding on portfolio changes for operators. [6] Table 1 shows examples of outcomes, before and after implementation of these projects. The first projects to measure and improve patient value, in terms of outcomes and costs of healthcare delivery, in the full cycle of care have been initiated. The data of these projects have not been published yet.

Third, considering that patient-relevant outcomes pertain to a period of time beyond the hospital stay, the CHC started to implement value-driven pathways with referring cardiologists for referred patients (70% of complex treatments), thus covering the third element of the VBHC strategy. For example, improvement projects in cooperation with one referring hospital – including efforts to improve guideline adherence, adjusting patient information and the introduction of discussion of complex patients – led to significant improvement of patient satisfaction (mean grade improved from 7.99 (SD=1.17) to 8.36 (SD=.97); t(198)=-2.44; P=.015) and significantly better event-free survival compared to patients referred from other hospitals (97.3% vs. 95.1%, Cl 1.01-1.93; P=0.046). In addition, the CHC initiated the Netherlands Heart Network (NHN), a regional collaboration in which four hospitals and four general practitioners organizations participate. In NHN healthcare providers measure and improve patient-relevant outcomes, amongst others by defining, implementing and

improving regional patient pathways. Regional collaboration can be evaluated with quality measures and contribute to improvement of outcomes. [10] In NHN, the first results for patients suffering from atrial fibrillation show improvement in outcomes. [11]

Fourth, a one of the Dutch health insurance companies and the CHC signed the Netherlands' first outcome-based payment contract in 2015, introducing a payment model in which quality is rewarded instead of volume. [7] This model is based on crucial VBHC principles, including Porter's outcome hierarchy [1], and short- and long-term outcomes that matter most to patients. In the model, selected outcome measures, such as survival, freedom from complications, re-interventions and quality of life, cover all tiers of the outcome measures hierarchy. [4] A bonus is provided if risk-adjusted outcomes improve compared to the baseline measurement in the CHC in the years before. On the other hand, if outcomes worsen, a refund is provided by the heart center. Due to quality improvements, the first implementation led to a financial bonus for the CHC, which was used for further quality-improvement projects.

Procedure	Outcome measure	Before quality- improvement project ¹	After quality improvement project ²	P ³⁻⁵	OR (Cl) ³⁻⁵
Coronary artery bypass grafting (CABG) ³	120-day mortality	2.3% (60/2585)	1.0% (22/2225)	.004	0.465 (0.276-0.784)
	1-year mortality	3.1% (80/2585)	2.0% (44/2225)	.058	0.685 (0.462-1.014)
Transcatheter Aortic Valve Implantation (TAVI) ⁴	30-day mortality	8.6% (32/371)	2.9% (5/171)	.020	0.313 (0.117-0.835)
Catheter pulmonary vein isolation ⁵	Cardiac tamponade	1.8% (18/1018)	0.4% (4/1019)	.004	0.190 (0.060594)
Catheter pulmonary vein isolation ⁵	Re-do procedures	28.7% (290/1010)	19.4% (196/1009)	<.001	0.53 (0.429-0.668)
CABG ³	Re-exploration for bleeding	5.0% (178/3544)	3.2% (41/1299)	.005	0.604 (0.426-0.857)

TABLE 1. Results of multivariate logistic regression analyses among different patient groups treated in the period 2011-2016, using the outcome measures as dependent variables (no event=0; event=1)

¹ Outcomes of patients treated in the period between 1 January 2011 and the implementation of improvement projects; ² Outcomes of patients treated in the period between the implementation of improvement projects and 31 December 2016; ³ Risk-adjusted for age, gender, chronic lung disease, diabetes mellitus, previous cardiac surgery, left ventricular ejection fraction, multi vessel disease, renal insufficiency, and urgency of the procedure; ⁴ Risk-adjusted for age, gender, chronic lung disease, previous cardiac surgery, left ventricular ejection fraction, mitral valve insufficiency, and renal insufficiency; ⁵ Risk-adjusted for age, gender, body mass index, CHA_DS₂-VASc score, previous ablation, left ventricular ejection fraction, mitral valve insufficiency, and type of atrial fibrillation

Future implications based on lessons learned

The physician-driven VBHC implementation in CHC has led to first successes and progress, but it is still incomplete. For example, two domains of the VBHC strategy, namely "geographic expansion of excellent services" and "building an enabling IT platform", still need to be covered. Moreover, the above-described cases sometimes do not involve all elements of the overall organization. For example, only one out of four large health insurance companies in the Netherlands is involved, and not all referring hospitals are participating in the intensified collaboration models that have contributed to improved outcomes. Yet, after seven years of bringing VBHC into practice, we have experienced and learned that, next to a strong physician-driven approach, a simultaneous policy change towards a VBHC system and involvement of all stakeholders is necessary for VBHC to reach its maximal impact.

Although ambitions are shared by some stakeholders, we have observed that hospital management and administrators, health insurance companies and medical companies are struggling in their shift towards a value-based system. Therefore, we propose three important next steps that should be implemented in financial management in healthcare, which will allow VBHC to reach its maximal impact. These proposed changes might align the focus of all stakeholders on patient value.

#1: Implement bundled payments covering the full cycle and of care and time to patient-relevant outcomes

First, as advised by Porter, bundled payments, including incentives on outcomes, need to be implemented on a large scale and with high financial impact. High quality outcomes data is a prerequisite. In our opinion, in order to create optimal incentives to maximize patient value in healthcare, bundled payments should include the full cycle of care and predicted outcomes, taking the complexity of patient groups into account. The time window of the bundle should be similar to the duration of the selected outcomes that matter most to patients, e.g. re-interventions within one year. Methods to avoid risk selection, by statistical correction for patient initial conditions and well-defined inclusion criteria, should be included. We believe that, for complex, costly and high-end invasive therapies, bundled payments should be contracted with the hospital performing the intervention, making IPUs responsible for the full cycle of care. The IPUs should enter into contractual agreements on healthcare activities and quality with other healthcare providers that are also a part of the cycle of care. These contracts should include terms on outcomes, costs, process measures and a shared continuous improvement cycle. This model will shift voluntary collaboration models between healthcare providers into structured, mandatory and manageable partnerships with a clearly responsible party and a focus on patient value. It will also enable re-allocation of health services when concentration of services is expected to lead to greater patient value. This redesign of payment systems and patient pathways will be a challenge for both health management and physicians. Due to the bundled payment models, the financial risk associated with quality in healthcare, for instance re-operations will shift from health insurance companies or public healthcare payment institutions to healthcare providers.

#2: Implement critical indicators on outcomes and costs in the hospital planning and control cycle

As a consequence, secondly, outcomes and related costs, that are leading in the bundled payment model, should be defined as the most important Key Performance Indicators (KPIs) for the IPUs and embedded in the planning & and control cycle of healthcare providers. Currently, volume of healthcare delivery and costs are leading in the boardroom of many healthcare providers [1], and outcomes are not embedded in the planning and control cycle of the hospital. [12] The change towards a focus on patient value in alignment with the bundled payment can steer management attention and increase the focus on, and willingness to invest in, quality improvement and improvement actions. As the bundle includes long-term outcomes, this will impact quality management both within the hospital and in the full cycle of care, including collaboration with other healthcare providers. As a consequence, in internal budgeting, the IPU's budget should depend on the parameters defined in the bundled payments. This will stimulate the shift towards a focus on patient value also on a more operational management level.

#3: Redefine purchasing contracts for medical devices into contracts including terms on outcomes, costs and process measures.

As hospitals become responsible for outcomes and costs instead of volume in the bundled payment model, purchasing contracts between medical companies and hospitals need to change into models in which the companies take a financial responsibility for the patient value that is created with the help of their products. Although purchasing terms differ per healthcare provider, price and volume are often most important. [13] Value-driven purchasing contracts should at least also include terms on outcomes and costs that are strongly related to the performance of the medical devices. For instance, the time to re-intervention for replacement of an Implantable Cardioverter Defibrillator (ICD) depends mainly on the longevity of the battery. From the perspective of the medical company, these contracts should also include process indicators that guarantee the compliance of the healthcare provider with guidelines and protocols that significantly influence the outcomes to ensure the optimal quality of the process in which medical devices are used. The introduction of these kinds of contracts will align business models for involved parties and thus create a shared interest in achieving the greatest possible value. Moreover, financial risks can partially be shifted from the healthcare provider to medical companies. This change urges the sharing of logistic and medical knowledge to optimize techniques and therapies in the full cycle of care and stimulate innovations like remote care and home monitoring.

Implications for healthcare management practice

In the VBHC literature it is advised to implement VBHC starting with physiciandriven measuring and improving of outcomes, as outcomes are the primary goal of healthcare delivered. Therefore, VBHC will not be able to become successful without improvement of outcomes. Currently, large variation in outcomes is reported on both a national and an international scale. Worldwide the VBHC strategy is being followed, leading to local improvement initiatives and international benchmarking projects. However, the value-based healthcare strategy describes more domains to be covered which are expected to be interacting, and this is a precondition for VBHC to reach its maximum impact. [2]

Based on the successful experience of the CHC regarding VBHC implementation, we advise healthcare management to keep up the pace with the physician-driven outcome measurement initiatives. Infrastructures for high-quality data capturing need to be implemented as a prerequisite. Financial models, and as a consequence management attention, need to be changed from a focus on volume and costs to a focus on patient value. The proceeding focus on outcome improvement might otherwise be limited or obstructed by lack of facilities or an organizational spilt, dividing physicians and healthcare management. Management knowledge and attention is needed to embed outcomes in healthcare providers' planning and control cycle, and facilitate and organize quality improvement in an effective and efficient manner. Current healthcare systems differ per country, but the optimal VBHC system is country independent. As the perfect value-driven financial models do not yet exist [14], new models need to be designed, implemented, evaluated and published, in the same way outcome measurement is being implemented, to enable active learning on an international level. [15]

First, experiments are needed to develop optimal healthcare provider payment models. These models should include the most important healthcare providers in the full cycle of care and at least include outcomes that matter most to patients and costs of healthcare delivery.

Second, subcontracting between healthcare providers, as a consequence of the bundled payment models, needs to be developed. Portfolio choices will and need to be stimulated, leading to further specialization and well-defined quality terms in the full cycle of care.

Third, healthcare management faces the challenge to accept the increased responsibility created by the developments above and share this responsibility with medical companies. As medical devices are a key cost driver in healthcare, producers of medical devices should take shared responsibility in outcomes and costs that are strongly related to the performance of their devices.

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The need for new financial models in the implementation of value-based healthcare

- 14 Hanadi Hamadi, Aaron Spaulding, D. Rob Haley, Mei Zhao, Aurora Tafili & Nazik Zakari (2019) Does value-based purchasing affect US hospital utilization pattern: A comparative study, International Journal of Healthcare Management, 12:2, 148-154, DOI: 10.1080/20479700.2017.1371388
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CHAPTER 13

Use of an intraoperative checklist to decrease the incidence of re-exploration for postoperative bleeding after cardiac surgery

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A. van Boxtel, **D. van Veghel**, M. Soliman-Hamad, D. Schulz, P. Stepaniak, A. van Straten.

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Interactive CardioVascular and Thoracic Surgery 2017;25(4):555-558.

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ABSTRACT

Objectives: We have implemented an intraoperative checklist aiming to reduce the incidence of re-exploration for bleeding after cardiac surgery. The present report addresses the results of adopting such a checklist regarding the incidence of postoperative bleeding.

Methods: The checklist was implemented by presenting it in several staff meetings of the Catharina Heart Center. Copies of the checklist were presented in every operating room. Data were collected by the Catharina Heart Center, aligned with the Meetbaar Beter data manual, and validated by Meetbaar Beter through their data quality system. The incidence of re-exploration for bleeding was analyzed in a variable life adjusted display (VLAD) curve. The patient population operated after the implementation of the checklist was compared with a recent historical population before its implementation.

Results: From January 2013 through April 2016, 4817 cardiac surgical procedures were performed in our institution. Before May 2015, 3210 procedures were performed (group 1), complicated by 112 re-exploration for bleeding (3.5%). The 'reoperation for bleeding checklist' was implemented at May 1st, 2015. After this date, the number of re-explorations for bleeding decreased to 29 (1.8%) out of 1607 cardiac surgical procedures (group 2) (p<0.05).

Conclusions: An intraoperative checklist is feasible to implement, low-cost, quick and simple measure with a significant reduction of the incidence of re-exploration for bleeding. This report shows an example of the positive effects of transparency in publishing outcomes' data in cardiac surgery.

INTRODUCTION

Postoperative bleeding is one of the major causes of re-exploration after cardiac surgery. It is correlated to increased morbidity and mortality. [1] Excessive blood loss increases the need for blood transfusion with subsequent increase in morbidity and mortality. [2] A recent investigation in coronary artery bypass grafting (CABG) revealed a 2.4% prevalence of reoperation for bleeding with an associated risk-adjusted mortality of 5.9%, compared with 2.0% for patients not having re-exploration. [3] In addition, re-exploration after cardiac surgery increases the risk of mediastinitis which has an adverse impact on outcome, hospital stay and costs. [4-5] For these reasons, re-exploration is considered an important outcome parameter for all projects aiming at quality improvement in cardiac surgery.

Meetbaar Beter (English: Measurably Better) is a Dutch foundation, initiated to facilitate quality improvement by publishing patient-relevant outcome measures of heart centers in the Netherlands.

Implementing the principles of the Value Based Healthcare (VBHC) theory of Porter [6], Meetbaar Beter promotes transparent reporting of results of care and sharing the processes leading to these results. Patient-relevant outcome measures are selected for different medical conditions, including coronary artery disease. The Outcome Measure Hierarchy is used as a framework for the selection of a range of both short and long-term outcome measures that are relevant to patients. [6] The sets of outcome measures are aligned with the indicator sets of the International Consortium for Health Outcomes Measurement. [7] Re-exploration after coronary artery bypass grafting (CABG) is selected by Meetbaar Beter as one of the most relevant outcome measures for patients undergoing CABG.

Earlier data of Meetbaar Beter, published in 2014 [8], showed a relatively high incidence of re-exploration in the Catharina Hospital (~ 9% for all cardiac procedures). Internal analyses did not lead to relevant hypothesis in order to improve the results as there were no obvious patterns found in the data. As shown in earlier studies, postoperative bleeding was the most common cause of re-exploration. [9] In 2013, Loor et al. described a policy to minimize the technical causes for re-exploration for bleeding. [10] This was achieved through the implementation of a checklist. This 'Cleveland Clinic reoperation for bleeding checklist' was also presented at the Meetbaar Beter symposium in 2014, Subsequently, we started to adopt this checklist

in all cardiac operations in our hospital starting from the 1st of May 2015. In the present report, the one-year results regarding the incidence of surgical re-explorations after implementation of this checklist are addressed.

MATERIALS AND METHODS

This report is based on the data collected by the Catharina Heart Center, aligned with the Meetbaar Beter data manual, and validated by Meetbaar Beter through their data quality system including data quality audits. These data included patients who were operated in the department of Cardiothoracic Surgery from January 2010 through May 2016. The checklist and its results were presented during several staff meetings in the Catharina Heart Center. [10] The quality committee of the Catharina Heart Center, responsible for the Plan-Do-Check-Act-cycle, decided to implement the checklist with the aim to reduce the percentage of re-explorations. The checklist was also discussed in the cardiothoracic chain meetings and during one of the complication meetings, where there was extra focus on re-explorations due to bleeding. After the decision to implement the checklist, copies of the checklist were presented in every operating room. The incidence of re-exploration was evaluated after three months and reported to the staff to stimulate the use of the checklist.

The implemented checklist is a list of four questions which have to be answered with 'yes' by the operator before closing the thorax: [11]

Prior to sternal wire closure:

- Surgical sites
 - Cannulation sites
 - Proximals/distals
 - Aortotomies/atriotomies/ventriculotomies
- Mediastinum
 - Thymus
 - Pericardium
- Chest wall
 - Mammary bed
- Sternum

Postoperative bleeding as a cause of the re-exploration was specially addressed, as this is the most frequent reason of re-exploration and it is the main element of the checklist. Re-exploration was defined as every re-operation within thirty days (\leq

30 days) after the initial closure of the thorax. The improvement plan was initiated by insights in the re-exploration rates after CABG. The checklist, however, was introduced for all procedures. In the analyses, patients were differentiated according to the operative procedure into: CABG and non-CABG cohorts. The trend of change in the incidence of re-exploration was traced in order to demonstrate the effect of applying the checklist. Moreover, the incidence of pericardial tamponade after the checklist implementation was compared with the historical incidence before the checklist.

Statistical analyses

Data were analyzed using SPSS v. 23 (SPSS, Inc., Chicago, IL, USA). The results of the implementation of the checklist in the Catharina Heart Center were analyzed in a Variable Life Adjusted Displays (VLAD) curve. In the VLAD curve, the outcome for is compared to a predicted outcome. If the outcome is better than predicted the curve increases with the predicted chance of a negative outcome. If the outcome is worse, the curve decreases with (1 – the chance of a negative outcome). So in case surgical re-exploration was done, the curve is decreasing; in case no surgical re-exploration was necessary, the curve is increasing. The historical rate of re-explorations in the Catharina Heart Center per subgroup was used as the predicted outcome. The historical rate is presented in the figures. On the x-axis, the results for every patient treated between January 1, 2013 and May 1, 2016 are presented. Statistical significance was determined using the χ^2 test. A p-value <0.05 was considered to be statistical significant.

RESULTS

From January 1, 2013 till May 1, 2016, 4817 cardiac surgical procedures were performed in our center. Before May 1, 2015, 3210 procedures were performed (group 1) complicated by 112 re-explorations for bleeding (3.5%). The checklist was implemented at May 1, 2015. After this date, the number of re-explorations for bleeding decreased to 29 (1.8%) out of 1607 cardiac surgical procedures (group 2).

Table 1 shows the preoperative data of both patient cohorts. In group 1 (before the checklist) there were less male patients and less patients with peripheral vascular disease (PVD) than in group 2 (after the checklist). There was no significant difference between the two groups concerning all other demographic data.

Variable	1-1-2013 / 1-5-2015 (n=3210) Group 1	1-5-2015 / 1-7-2016 (n=1607) Group 2	P value	
Age, years , mean	66.7±10.1	67.4±9.8	0.443	
Male gender, n (%)	2272 (70.8%)	1202 (74.8%)	0.003	
Diabetes, n (%)	666 (20.7%)	330 (20.5%)	0.88	
COPD, n (%)	266 (8.3%)	140 (8.7%)	0.62	
PVD, n (%)	309 (9.6%)	191 (11.9%)	0.02	
Serum creatinine, n (%)	91.4±37.9	95.8±55	0.034	
LVEF<35%, n (%)	109 (3.4%)	59 (3.7%)	0.62	
Logistic EuroSCORE	7.6±10.9	7.8±11.7	0.350	

TABLE 1. Demographic data of the two patients' groups

Data are presented as mean ± SD or number (%)

COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; PVD= peripheral vascular disease.

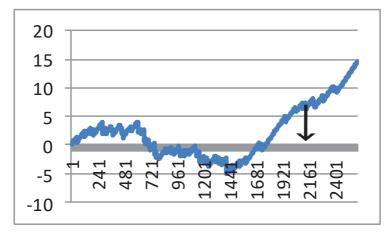
Table 2 shows the results of the χ^2 test which shows significant decrease in the incidence of re-explorations after implementation of the checklist. This table also shows a decrease in the number of re-explorations for cardiac tamponade.

TABLE 2: Number of re-explorations stratified by cause of re-exploration before and after implementation of the checklist

	CABG			All cardiac procedures		
	<01-05-2015 (n=1740)	>01-05-2015 (n=892)	p-value	<01-05-2015 (n=3210)	>01-01-2015 (n=1607)	p-value
All re-explorations	116 (6.7%)	22 (2.5%)	p<0.05	309 (9.6%)	78 (4.9%)	p<0.05
Bleeding	49 (3.3%)	10 (1.1%)	p<0.05	112 (3.5%)	29 (1.8%)	p<0.05
Tamponade	29 (1.7%)	7 (0.8%)	p<0.05	116 (3.6%)	38 (2.4%)	p<0.05

Figure 1 shows the VLAD curves of the incidence of re-explorations after CABG procedures. The x-axis represents the number of CABG procedures performed until a certain time point. The y-axis represents the incidence of observed re-exploration in correlation to the expected ratio. With every re-exploration, the curve goes down and with absence of re-exploration, the curve goes up. The curve in the figure show a strong positive improvement after the date of starting the checklist (arrow).

Figure 2 shows the VLAD curves of the incidence of re-explorations after all cardiac procedures. Interpretation of the curve in the figure is the same as in figure 1. The curve shows again considerable improvement after the date of starting the checklist (arrow).

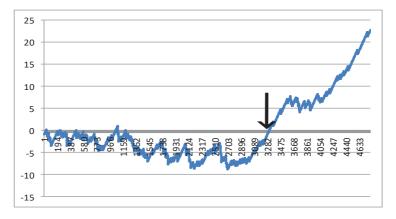


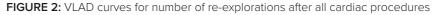


x-axis: number of surgical procedures performed until a certain time or date.

 \downarrow = date of implementation of the checklist

y-axis: Observed incidence of re-explorations in correlation with the expected incidence





x-axis: number of surgical procedures performed until a certain time or date.

 ${\downarrow}$ = date of implementation of the checklist

y-axis: Observed incidence of re-explorations in correlation with the expected incidence

DISCUSSION

This report demonstrates the effect of applying a standard checklist in the operation room on reducing the incidence of re-exploration for postoperative bleeding. This effect was observed in both CABG as well as non-CABG procedures. It was also associated with a significant reduction in the incidence of cardiac tamponade. These findings underline the statement that implementation of a simple checklist significantly improves outcomes in terms of re-explorations for bleeding after cardiac surgery. After the implementation of the checklist, the rate of re-explorations decreased, except for the non CABG procedures followed by re-exploration of all causes.

Transparent publication of outcomes indicated that the Catharina Heart Center had room for improvement regarding re-explorations. [4] Although internal analysis did not lead to a clear hypothesis for process improvement, the introduction of the checklist did improve the outcomes. According to Porter, one has to compare itself with the best. [11] The publication of Loor et al [10], showing success of the checklist in the same group of patients, encouraged us to implement and use the same checklist. Transparency on outcomes and the health care processes leading to the outcomes may be of added value in the implementation of VBHC, leading to sharing best practices and an improvement of patient-relevant outcomes. [12]

Improvement of patient outcome is guaranteed as a consequence of reducing the incidence of re-explorations. These re-interventions are proved to be an important risk for sternal wound infection which increases the morbidity and mortality as well as prolongation of the hospital stay. [1] The need for blood transfusion is higher in patients with bleeding and re-exploration. As a result of these consequences, the total costs of the whole treatment cycle is increased. In other words, implementing such a checklist would reduce the costs and improve the outcome. These two goals are the main elements of our definite aim to practice a VBHC. Improving the outcome the VBHC.

VBHC is a concept that evaluates health care based on six elements (i.e., safety, effectiveness, patient centeredness, timeliness, efficiency, and equity), with the goal to achieve optimal health outcomes with consideration of money spent for care. [6] Implementation of VBHC needs a strategy; making the choices necessary to distinguish an organization in meeting patients' needs. [13] The measurements performed before and after implementation took place within a year of each other. It is not expected that a change took place in patient demographics before and after implementation of the checklist. No other fundamental changes in policy or surgical care occurred in our hospital during that period, making it unlikely that the improvement was attributable to other factors. A technical limitation of the checklist is that it only reduces the technical causes for bleeding. Other causes like clotting disorders are not embedded.

Implementing standard routine checklists has always been used as a successful tool in complex circumstances. [14] The question remains why this checklist reduces the amount of bleedings needing a re-exploration. The anatomic sites where the checklist refers to are well-known by all surgeons to be at risk for bleeding. Although it is not investigated in this study, our hypothesis is that the checklist does not function as a reminder for theoretical background information but that it creates awareness. Awareness could be one of the main causes of the improvement shown. This has been also contributed to a Hawthorne effect—an improvement in performance because of the subjects' knowledge of being observed. [15] Operating teams may have improved their performance because of their awareness of being studied, however, the baseline period established the benchmark by which improvements were measured. One specific way the checklist may function is by introducing an internal Hawthorn effect whereby various members of the team serve to remind each other of important safety steps; however, this strengthens the effect of the checklist. Another contributing factor is its role in improving teamwork, communication, and attitudes toward quality and safety.

This study has some limitations. First, this is a retrospective analysis of a limited cohort of patients. Some confounding factors could have affected the results. In addition, this is an initial report addressing the results of the checklist for only one year. We have to follow the effect of such a checklist for a longer period to confirm its durability. However, the initial promising results show such a clear improvement that we can consider the checklist successful. Up to the date of this report, approximately one year after the introduction of the checklist, the percentage of re-exploration has become lower in our hospital.

CONCLUSIONS

The "reoperation for bleeding checklist" is easy to implement, low cost, quick and simple measure with a significant improvement in risk reduction for reoperation for bleeding. This report has shown the positive effects of transparency in reporting outcomes. It is an example of how measuring outcomes and being transparent about results can lead to improvement in quality and safety by inter-institutional learning.

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CHAPTER 14

Discussion, Future Perspectives and Conclusions

aan hartklep daalt fors

DISCUSSION

Many stakeholders in the Netherlands are striving to improve healthcare and bent the cost curve, in an effort to prevent a financial crisis and maintain accessibility of healthcare for all inhabitants. Value-based healthcare (VBHC) provides a strategy and method that challenges, amongst others, the existing structures and (quality) management methods in healthcare, by defining patient value as the overarching goal in healthcare. [1] Patient value is defined as outcomes that matter most to patients divided by costs of healthcare delivery. [1]

In this dissertation, we present the first results of physician-driven VBHC implementation efforts in Dutch cardiac care. In part I, the implementation and first results of a national benchmarking and quality improvement initiative are described. Part II presents the introduction of new models on a heart center level, covering several elements of the VBHC strategy as introduced by Porter. [1] In part III the improvement of patient-relevant outcomes in the Catharina Heart Center are presented.

This dissertation addresses three award-winning initiatives; Meetbaar Beter (VBHC prize 2014), Value-based purchasing contract between one of the health insurance companies in The Netherlands (CZ) and Catharina Hospital (VBHC prize 2016) and the Netherlands Heart Network (VBHC prize 2018). Also, national media has paid attention to many of the projects including reports on national TV, articles in several newspapers and online media. Projects described in this dissertation have initiated considerable changes in healthcare and were not always applauded by all involved parties. In case of criticism, it seemed to be based on fear for potential negative consequences of the transparent reporting or on a struggle in combining a more traditional medical scientific paradigm with guality improvement in daily practice. Some of the mentioned risks should be considered irrelevant because they are only the result of a worry about positions of the involved parties, not concerns about the patients. Some risks mentioned like the potential introduction of incentives to avoid treatment of high-risk patients [2], are relevant and should, therefore, be managed adequately. According to the results achieved, we can conclude that these projects have succeeded in managing these risks. At all times, the media attention has included a positive message. Physician leadership in creating transparency on outcomes was applauded by many parties, including the national politics. This positive attention proves the interest of the public in the evolution towards transparency and focus on patient value. This should encourage all involved parties in healthcare to continue and intensify the change towards a value-driven health system.

Leadership in the change towards a value-driven health system has also been rewarded by many stakeholders within healthcare. Transparency has resulted in an increase of trust between involved parties, for instance health insurance companies and healthcare providers. Mutual trust is a precondition for involved parties to succeed in optimizing value in healthcare. [3] Most involved parties have committed to the outcomes selected as the most relevant quality information. When a hospital is reported as a negative outlier of course questions are raised by other organizations like health insurance companies and the Inspection of Healthcare. So far, from the projects presented in this dissertation, the discussion between involved parties - to my knowledge - has always been about how to improve, not about penalties. Next to trust, leadership has also led to more tangible results, for instance in volume free contracts between healthcare providers and health insurance companies.

The implementation of VBHC is still in an early stage, as several elements of the strategy still need to be covered or implemented in a broader perspective. However, many positive and promising results in the journey towards a more value-driven healthcare system are presented in this dissertation.

VBHC has been introduced as a convincing philosophy and a strategic roadmap, based on identified best practices for parts of this strategy. [4] However, little has been published about het practical implementation of the mutually reinforcing elements of the strategic roadmap. Also, for several elements of the VBHC strategy, methods need to be developed to be able to implement VBHC in daily practice. For instance, methods for analyzing outcomes and the underlying processes as well as those for defining and monitoring improvement projects need to be developed. [5] Machine learning and artificial intelligence techniques are expected to play an important role in this development.

Depending on the culture, structure, financial and political situation in a country, VBHC as described by Porter might need to be adapted to the local situation to reach its maximum impact. Several projects in this dissertation show examples of how introducing transparency and collaboration between heart centers as an important principle, instead of competition as described by Porter, can contribute to the impact of VBHC and the improvement of outcomes that matter most to patients.

Strengths and limitations of this dissertation

In projects described in this dissertation, on a national, regional and institutional level, outcomes that matter most to patients have been selected, defined, measured and improved successfully with the use of solid methodologies. These methodologies include the main VBHC tools like e.g. the outcomes measure landscape, the outcome measure hierarchy and the care delivery value chain. [1] Although some projects mainly include patients treated with the similar treatment, in several projects, first steps are made to include all patients with the same medical condition, independent of the treatment performed.

In all projects, physicians have taken the lead in the change towards a more valuedriven healthcare system. This is essential as physicians have the knowledge to combine statistical information from real world data with clinical insights, which can lead to process optimization and improvement of outcomes. Outcomes have been reported both with and without correction for patient initial conditions. Variation in outcomes has been published transparently in several perspectives. Not only changes in outcomes over time on a national level and a hospital level have been reported, but also variation between healthcare providers has been published transparently. This transparency is essential as it contributes to the improvement of data-quality, enables foster learning and is known to push quality in healthcare. [6] In my experience, transparency has also contributed to redefining the relation between physicians, healthcare providers, health insurance companies and other stakeholders. Transparency has facilitated a growth of trust between parties involved and contributed to better circumstances for parties to embrace a shared goal as advised in VBHC. This is also because of the selected outcomes that matter most to patients, as this has made the numerator of the patient value equation more tangible for all involved parties.

For several elements of the VBHC strategy, including "measure outcomes and costs for each patient", "integrate care delivery systems" and "move to bundled payment models", in part II of this dissertation provides innovative models strictly using the VBHC principles. [4] Also, the results of the first implementation of these models are presented, proving the feasibility in daily healthcare practice. Several models are already being rolled out at larger scale, e.g. in projects in the NHR community. As these models can be changed and continuously improved over time, the main contribution of these first implementation projects might be that VBHC has been made applicable in daily practice in healthcare. This has created new insights and contributed to improvement in outcomes that matter most to patients.

Nevertheless, this dissertation has some limitations. First, although many elements of the VBHC strategy have been included in the projects, in most analyses, patients were included because of the treatment that was performed. Patients with the same medical condition who have not been treated, or were managed conservatively, are not included in the analysis. The decision whether or not to treat a patient invasively is, especially in high risk patients, a decision that should be included in the methodology, analysis and publication. [1] This can be achieved by measuring the outcomes of all patients with a specific medical condition, independent of the treatment. Although risk correction for initial conditions is performed in the analyses, only measuring outcomes of invasive therapies might stimulate risk avoidance in clinical decision making. [2] Although the methodology and models applied in many of the presented projects could include the conservatively treated patients, data of this patient group is often missing.

Second, this dissertation focusses mainly on outcomes that matter most to patients. In VBHC, patient value is defined as outcomes divided by costs. [1] However, until now, only outcomes and not costs are measured in the majority of projects. In chapter 11, a model is introduced for measuring patient value. It is not clear how better outcomes are related to costs of healthcare delivery. This, however, can be seen as a consequence of the early phase of the implementation of VBHC. Both from the VBHC-methodology and a change management perspective, measuring and improving outcomes should be the first step in the implementation of VBHC. [7] Additionally, outcomes are of most interest to physicians, who should be leading the way in improving healthcare delivery.

Third, the projects presented are typically reports of improvement and implementation projects from daily practice. Unlike randomized controlled trials, the study designs do not enable conclusions at the level of causality. Differences in outcomes can be observed, but they depend on several interventions or differences in processes in most projects. Improvement projects inevitably come with more awareness (e.g. about reducing procedural bleeding risks), which, by itself, might lead to better outcomes. [8] Observed differences in outcomes between hospitals cannot lead to a definite conclusion about quality in healthcare. They can drive motivation to improve healthcare by analyzing, research, defining hypothesis and implement process improvements.

Fourth, quality of data is an important issue. Predominantly in projects presented in part I, data-quality might differ per hospital as well as per outcome measure. As described, an advanced data quality management system within the NHR is appropriate, but there might be some doubt as hospitals sometimes use different methodologies for data collection. For mortality rates and analysis, there is little doubt about data-quality, as the definition and interpretation of possible events leave little chance for differences in interpretation. Also, all hospitals have used the same independent, reliable source, by checking each patient in the BPR (Dutch municipal personal records database). However, for instance, for long term follow up indicators like Target Vessel Revascularization (TVR), data collection is far more complex as follow up needs to be organized far beyond the moment the patient is discharged from the hospital performing the revascularization procedure (PCI or CABG). Hospitals have used different methodologies to organize this follow up. These differences will be eliminated, as the NHR will be able to facilitate the follow up of patients by selecting patients with a second procedure in the follow up. Also, definitions are sometimes complex and might lead to differences in interpretation per center.

Incompleteness of data is the fifth limitation. Although the selected outcome measures cover all tiers of the outcome measure hierarchy, data are not available for all outcome measures in several projects. When missing data on Quality of Life (QOL) and long term follow up for re-interventions, the presented outcomes do not completely reflect the added value for the patient. It is expected that the availability of data on QOL will increase as many involved parties realize the importance of this information. Long-term follow up will become far easier to achieve when all hospitals report all events to the NHR.

Finally, in perspective of data analytics, there might be room for improvement. Although the completeness of data was far higher in general, in most projects, except for mortality, a loss to follow up of at max 10% was allowed. For initial conditions, a maximum of 10% missing values was allowed too. For analyses, the missing data on initial conditions were imputed. Analyzing outcomes that matter most to patients in real-world data, for some outcome measures, leading to analysis with insufficient power or low c-statistics. As the statistics applied is only an effort to indicate whether differences in outcomes might be explained by differences in complexity of patient groups, this is not necessarily a drawback. Depending on the analyses, it might leave questions unanswered or create new questions. For instance, when the c-statistic remains low in analysis with sufficient power as presented in part I, questions might be raised to what extent differences in outcomes are caused by differences in processes.

FUTURE PERSPECTIVES

The implementation of VBHC as a strategy to improve quality and control costs in healthcare requires further development in several perspectives. The practical implementation of VBHC as presented in this dissertation should be extended by implementing the presented models for all patients suffering from the same medical condition. For instance, outcomes of patients receiving optimal medical treatment should be included in the analysis. Also, a solid methodology needs to be developed for quality improvement based on insights in outcomes and costs. So far, it is hard to distinguish which process-elements cause differences in outcomes, and structured information on these variables is often lacking. This information might be required to be able to improve outcomes even more effectively. Benchmarking on outcomes should be extended to benchmarking on both outcomes and costs. This will even create more learning opportunities for healthcare providers to improve patient value. In my opinion, guality improvement systems of healthcare providers, based on outcome improvement and costs control, need to be connected covering the full cycle of care. This will lead to integrated care delivery systems with a shared model to learn and improve. The design of outcome based bundled-payment models needs further development, leading not only to incentives on outcomes, but to an increase in the accountability for healthcare providers as well. This might be achieved by using longer-term bundled payment models, contracted with one healthcare provider, leading to subcontracts in networks of healthcare providers involved. The bundles should cover the full cycle of care, include outcomes, costs and process indicators, and be adjusted for risk profile of patients. The implementation and continuous development of these models requires close examination and frequent evaluation, also to prevent avoidance of high-risk patients.

In many perspectives, the data-quality and –availability are important limitations of projects presented in this dissertation. However, in the last few years, developments have taken place that will rapidly increase the data availability in healthcare. [9, 10] The introduction of Electronic Health Records (EHR) has, although not perfect yet, changed data-storage and availability in healthcare in many perspectives. [11] It is expected that the continuous improvement of the EHR will improve the ability to capture and export data in a structured way. [12] Intelligent IT-applications will also enable the interpretation of non-structured text data and therefore increase the availability of data even further. Also in many medical devices, varying from ultrasound, MRI and CT to pacemakers and ICD's, new possibilities to collect and share data are introduced. [13, 14] In non-medical devices, e.g. smartphones, fitbits, lwatch and other wearables, first possibilities to collect health-data are introduced. [15,16]

The increase in data-availability and the introduction of advanced data-analytics like machine learning and artificial intelligence are expected to enable insights in outcomes and costs and their relation to underlying processes. Prediction models will be improved, leading to better and more reliable identification of differences in outcomes and costs, and improvement potential in these perspectives, also by benchmarking hospitals. Real world data will provide insights based on other principles than insights from more traditional research like Randomized Controlled Trails (RCT). For example in an RCT, one would rather not accept a statistical model with insufficient power or a relatively low c-statistic. However, in measuring and improving outcomes in real world data in VBHC, for instance models with a low c-statistic might be a sign of high variety in processes. In my opinion, both sources of information represent their own strengths and weaknesses and should co-exist and mutually reinforce each other, leading to better information for decision making in healthcare.

As these developments take place not only on a national, but also on an international level, international communities should be built to benchmark and improve outcomes and costs. Standardization of outcome and other indicators will be a key to success when building these international benchmarking and learning platforms. The International Community of Health Outcomes Measurement (ICHOM) has initiated a promising platform. [17] Also, opportunities arise when national registries like Swedeheart and NHR start pooling data.

The increase in availability of outcome-, cost-, process- and patient-data, combined with advanced data analytics, are expected to facilitate retrospective analyses of results of healthcare delivered. First examples of supportive information from analysis of real world data to medical decision-making have already been published a few years ago. [18] Sharing prediction on outcomes and processes with patients is expected to become a cornerstone in shared decision making.

Combining these developments leads to a need for collaborations between different areas of expertise. Next to physicians, technical universities should be involved as well, as they hold expertise in the area of complex data-analytics and technological information. Medical companies should be also involved, as they are often the source of new techniques including new sources of information. The network in the Eindhoven area, including the Catharina Hospital, Maxima MC, other hospitals in the region, the well-organized general practitioners' organizations, TU/e and Philips, holds large potential to lead the way in the shift towards a more value driven healthcare system. New collaboration initiatives like e/MTIC are promising, hold large potential and might be an organizational form to unite different involved organizations.

The question remains who should be leading this multi-dimensional change towards a value-driven system? It seems logical for healthcare providers to play a leading role as they are the direct partners of patients, are responsible for quality and efficiency as a result of their processes, and will become more accountable when changing payment models toward bundled payments. Health insurance companies may stimulate leading healthcare providers and their collaboration with other healthcare providers. They should create facilities to manage uncertainty in the shift towards a value-based system. Examples of health insurance companies are CZ and Menzis; leading the change in health insurance companies, have been published in the last few years. [19] However, expertise of physicians will be the key, as only physicians can judge the impact of changes in health delivery processes on the outcome for patients. They are also leading in the design of healthcare processes and are able to combine insights from data-analytics and new technologies into process improvements. These perspectives will also change health management, facilitating physicians in their leading role. First, when shifting towards a value-based strategy, health management must assure that high-quality data are available. When introducing quality improvement cycles based on outcomes and costs, building networks with other providers and accepting accountability for patient value created in the full cycle of care in bundled payment models, health management decisions will shift from cost- and budget-based to value-based. This will require a change in health management, including organizing a management and control cycle based on patient value, designing collaboration contracts with health insurance companies, other healthcare providers and medical companies. Also, decision making on portfolio, innovation and other investments will have to be based on patient value, introducing outcomes that matter most to patients as a leading factor over costs, as data-driven improvement of patient value will become the core of the business model of all the involved parties.

Both in health management as in physician leadership, this will not only require education to increase knowledge, but a new type of leadership with a shift from focus on optimization of institutions, reimbursement and costs, to a focus on patient value, collaboration and innovation. Over the last few years, some examples of efforts to shift towards a more value-driven healthcare system are observed in Dutch healthcare, some of them are presented in this dissertation. However, these are mainly project-based and on top of the regular system. They might be seen as experiments in the right direction, as a starting point for a change that will require ambition, belief and a lot of efforts from all involved parties striving for a value driven, sustainable and manageable healthcare system.

CONCLUSIONS

In conclusion, building a physician-driven national benchmarking and learning environment is feasible and indispensable, as it contributes to insight and improvements of outcomes that matter most to patients. A patient-centered and physician-driven approach has proven to be successful. The outcome based learning and improving community that was created has enabled performance benchmarking and public reporting, quality improvement within hospitals and identifying and sharing of good or best practices amongst hospitals. Also, the monitoring of the impact of new technologies on patients, with a specific medical condition, in daily practice was enabled.

We also conclude that implementing VBHC in CHC and its network was feasible and contributed to the improvement of outcomes that matter most to patients. In addition, building networks with other healthcare providers to improve outcomes, measuring outcomes in relation to costs, and changing financial models towards a more value-driven system have successfully been introduced in the CHC network. The presented methodologies have shown to be feasible in daily practice, and have contributed to improvement of patient-relevant outcomes.

Regarding the organizational structures and collaboration models, there is room for improvement to increase the impact of VBHC on monitoring and improving of outcomes, including Patient Reported Outcome Measures (PROMS) and costs. In order to reach the maximal impact of VBHC, it is essential that all decisions made in healthcare are focused on patient value. This is essential to align the mindset of hospital board members, management, administrators, physicians, patients, government, health insurance companies and other parties involved. Transparency on outcomes and costs is expected to contribute strongly to this alignment. New ICT technology will rapidly increase the availability and reliability of data. As this will increase the potential of value-based management models, in our opinion, we should increase the pace of the implementation of VBHC.

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CHAPTER 15

Summary / Samenvatting

aan hartklep daalt fors

SUMMARY

The central theme in this dissertation is the implementation of value-based healthcare (VBHC) principles and concepts in the cardiovascular care in the Netherlands. As in many other countries, in Dutch healthcare there was a focus on volume and costs instead of on value for patients (outcomes divided by costs). Insight in outcomes that matter most to patients in daily practice was limited or completely absent.

In order to shift the focus of all the involved stakeholders towards patient value, several elements of the VBHC strategy were implemented. This was done at a national level by building a physician-driven transparent, outcome-based learning community with the help of a solid methodology. Outcomes were reported for several high-volume medical conditions. Examples of improvement projects in hospitals are addressed, and the organization of the quality improvement cycle was evaluated from a managerial perspective.

At a hospital level, these insights in outcomes were used to initiate improvement projects and improved outcomes. Also, the first implementation projects covering VBHC strategy elements "build an integrated practice unit", "integrate care delivery across separate facilities" and "move to bundled payments for care cycles" were performed in the Catharina Heart Center and its direct environment.

Although it is complex and is still in its infancy, we do believe that implementing VBHC principles will lead to improved patient value. In a pragmatic physician-drive approach, we cautiously delivered a proof of concept and feasibility for several elements of the VBHC strategy. In some cases, several elements of this strategy were implemented in one initiative. In our experience, this has led to an additional stimulus, also because of the involvement of other physicians, hospitals, general practitioners, health insurance companies or other stakeholders.

Chapter 1 first provides insights in the need for change in healthcare. This is followed by a general introduction in the theory of VBHC, the Meetbaar Beter initiative and the Catharina Heart Center (CHC).

In Part I, the building of a transparent, outcome-based learning community is described, including results and improvements for the main medical conditions, and new methodological and managerial insights. Chapter 2 provides a high-level oversight of the methodology and organization forming the basis for the learning community. Building on the heart team collaboration tradition of cardiologists and cardiothoracic

surgeons, in Chapter 3, early results of the first hospitals joining the transparent, public reporting VBHC initiative are reported. In Chapter 4, the methodology is described in more detail and the results of the application of the methodology for healthcare for patients suffering from coronary artery disease are presented. Outcome measures, that are important for patients, are published per hospital, both with and without taking complexity of patient populatins into account, leading to insights in variation in outcomes per hospital. The results and trends in the patient population and outcomes after treatment of aortic valve disease are presented in Chapter 5. Improvement of patient-relevant outcomes in a larger and more complex patient group being treated in the Netherlands can be observed. We have achieved important insights that can only be created by a multicenter pooling of data. In Chapter 6, we evaluated the organization of a quality improvement cycle in hospitals, given the availability of highquality real-world outcome data. Using the Deming cycle (PDSA) and the 7S-model of McKinsey, we conclude that in the participating hospitals focus is mostly on data collection and reporting. Some preconditions are available, but the organization of the PDSA cycle still needs to be designed and implemented. In chapter 7, we present the results and needed next steps in measuring and improving outcomes based on 5 years of multi-center VBHC-implementation experience in daily practice.

In part II, new models to implement VBHC principles in the daily practice of a Dutch heart center (i.e; CHC) and its environment are presented. In Chapter 8, the first outcome-based payment model that was implemented in the Netherlands is presented. In this model, variation of quality over time leads to financial incentives for the heart center, both positive (when outcomes improve) and negative (when outcomes worsen). Improvement of outcomes, patient satisfaction and compliance to process- and structure measures by intensified collaboration between a heart center and referral cardiologists are presented in Chapter 9. This is a preliminary example of integrating care across different facilities, using VBHC principles. In Chapter 10, a second example is presented. Based on a solid methodology, a network was build including a heart center, three referring hospitals, four large general practitioners corporations and several other healthcare providers. The presented methodology is compliant with the VBHC theory and has proven to be feasible in daily practice. Results for healthcare provided to patients suffering from atrial fibrillation are provided as a proof of concept. To enable a next step in the implementation of VBHC in Dutch cardiac care, measuring costs in relation to outcomes, a model to measure patient value is introduced in chapter 11. In this model, we suggest to measure patient value as a number, outweigh outcomes over costs and measure costs in a manner that is most relevant to physicians.

In part III, the impact of a few years of experience in implementing VBHC in Catharina Heart Center is presented. In Chapter 12, an overview of the journey towards a more value-driven system in a heart center is provided. VBHC-implementation projects are summarized and an overview of the impact on outcomes is presented, including significant decreases of mortality, complication rates and re-intervention rates. Based on this implementation experience, next steps in the implementing of new, value-driven financial models in healthcare are proposed to enable VBHC to reach its maximum impact. An example of a successful improvement project in cardiac surgery within the heart center is presented in Chapter 13. An intraoperative checklist, introduced and published by Cleveland Clinic, led to a significant decrease of the rate re-explorations after coronary artery bypass surgery.

Finally, Chapter 14 presents a general discussion on the findings in the three parts of this dissertation. Also, future directions for the organization of cardiovascular disease management and a broad sense within Dutch healthcare are introduced, as next steps towards a more value driven healthcare system in which patientvalue is the overarching goal.

SAMENVATTING

Het centrale thema in deze thesis is de implementatie van value-based healthcare (VBHC) principes en concepten in de cardiovasculaire zorg in Nederland. Zoals in veel landen was de primaire focus in de Nederlandse gezondheidszorg gericht op volume en kosten in plaats van patiëntwaarde (gedefinieerd als uitkomsten gedeeld door kosten). Inzichten in uitkomsten die belangrijk zijn voor patiënten, vanuit de dagelijkse praktijk, waren zeer beperkt of volledig afwezig.

Om de focus van alle betrokken partijen in de zorg te verschuiven naar patiëntwaarde zijn diverse elementen van de VBHC strategie geïmplementeerd. Op landelijk niveau is dit gedaan door, op basis van een gedegen methodiek, een arts-gedreven, transparante leeromgeving te ontwikkelen waarin uitkomsten van zorg centraal staan. Uitkomsten van zorg zijn gepubliceerd voor meerdere veel voorkomende medische condities. Voorbeelden van verbeterprojecten, gebaseerd op inzichten in uitkomsten van zorg, zijn gepubliceerd en de organisatie van de op uitkomsten van zorg gebaseerde verbetercyclus in de ziekenhuizen is geevalueerd vanuit een managementperspectief.

Op ziekenhuisniveau zijn de inzichten in uitkomsten gebruikt om verbeterprojecten te initiëren en uitkomsten van zorg te verbeteren. In het hartcentrum van het Catharina Ziekenhuis en haar zorgnetwerk zijn projecten vormgegeven waarin andere elementen ("build an integrated practice unit", "integrate care delivery across separate facilities" en "move to bundled payments for care cycles") van de VBHC strategie zijn geïmplementeerd.

Hoewel het een complexe strategie is, en de implementatie nog in de kinderschoenen staat, geloven wij dat het consequent implementeren van VBHC principes zal leiden tot verdere verbetering van patiëntwaarde. Gebruikmakend van een pragmatische en artsgedreven aanpak hebben we op zorgvuldige wijze bewezen dat diverse elementen van de VBHC strategy geïmplementeerd kunnen worden in de Nederlandse gezondheidszorg. In sommige projecten zijn zelfs meerdere elementen van de VBHC strategie in één keer geïmplementeerd. In onze ervaring heeft deze combinatie van elementen tot een extra stimulans geleid, mede omdat in deze projecten meerdere artsen, ziekenhuizen, huisartsen, zorgverzekeraars of andere stakeholders betrokken waren. In hoofdstuk 1 wordt geschetst waarom het noodzakelijk is dat er veranderingen worden doorgevoerd in de gezondheidszorg, gevolgd door een introductie in de VBHC theorie, Meetbaar Beter en het hartcentrum van het Catharina Ziekenhuis.

In deel1wordt de opbouw van een transparante, op voor patiënten relevante uitkomsten gebaseerde leeromgeving beschreven, inclusief resultaten, verbeterprojecten, de gehanteerde methodologie en verkregen inzichten vanuit managerial perspectief. Hoofdstuk 2 biedt op hoofdlijnen inzicht in de gehanteerde methodologie en organisatie die de basis vormen voor de artsgedreven leeromgeving. Voortbouwend op het multidisciplinaire hartteam van cardiologen en cardiochirurgen worden in hoofdstuk 3 de eerste resultaten van het transparante VBHC initiatief gepubliceerd. In hoofdstuk 4 wordt de gehanteerde methodologie in meer detail beschreven en worden de resultaten van de toepassing van de methodologie op het ziektebeeld coronarialijden gepresenteerd. Uitkomsten van zorg die belangrijk zijn voor patiënten worden gepubliceerd op ziekenhuisniveau, met en zonder correctie voor zorgzwaarte van de patiënten, waardoor inzicht verkregen wordt in verschillen in uitkomsten. Resultaten en trends in uitkomsten van patiënten die behandeld zijn vanwege aortaklepstenose worden gepresenteerd in hoofdstuk 5. Op landelijk niveau wordt in deze groep een verbetering van uitkomsten waargenomen, terwijl meer en ziekere patiënten behandeld worden. Deze belangrijke inzichten kunnen alleen verkregen worden doordat ziekenhuizen op uniforme wijze data verzamelen en deze samenvoegen. In hoofdstuk 6 wordt de organisatie van de op uitkomsten van zorg gebaseerde verbetercyclus geevalueerd. Gegeven de beschikbaarheid van inzichten in uitkomsten van zorg op basis van hoog kwalitatieve data, is met behulp van een model gebaseerd op de Deming cyclus (PDCA) en het 7S-model van McKinsey onderzocht hoe de inzichten in uitkomsten gebruikt worden voor verdere verbetering van zorg. Geconcludeerd wordt dat de deelnemende ziekenhuizen vooral gericht zijn op dataverzameling en het publiceren van resultaten. Sommige randvoorwaarden zijn goed aanwezig, maar de organisatie van de PDCA cyclus moet nog ontworpen en geimplementeerd worden. In hoofdstuk 7 worden de resultaten van 5 jaar VBHC implementatie door het meten, publiceren en verbeteren van uitkomsten in een netwerk van hartcentra gepubliceerd. Ook worden inzichten gedeeld in de noodzakelijke vervolgstappen om de maximale toegevoegde waarde van VBHC te bereiken.

In deel 2 worden nieuwe modellen gebruikt om in de dagelijkse praktijk van een Nederlands hartcentrum (hartcentrum van het Catharina Ziekenhuis) en haar netwerk VBHC principes te implementeren. In hoofdstuk 8 wordt het eerste op uitkomsten van zorg gebaseerde contract tussen een hartcentrum en een zorgverzekeraar gepresenteerd. In dit model ontvangt het ziekenhuis een additionale betaling bij verbetering van uitkomsten en betaalt het geld terug bij verslechtering. Een nieuwe samenwerkingsvorm tussen een hartcentrum en een verwijzend centrum welke heeft geleid tot verbetering van uitkomsten van zorg, hogere patiënttevredenheid en het beter voldoen aan proces- en structuurindicatoren wordt gepresenteerd in hoofdstuk 9. Dit is een voorbeeld van het verbeteren van zorg door het integreren van verschillende schakels in de keten. In hoofdstuk 10 wordt een tweede voorbeeld gepresenteerd. Met behulp van een solide methode is een patiëntgericht hartnetwerk gebouwd door een hartcentrum, drie verwijzende ziekenhuizen, vier grote huisartsenorganisaties en diverse andere zorgaanbieders. De methode is gebaseerd op VBHC principes. De eerste resultaten voor patiënten met boezemfibrilleren bewijzen dat de methode in praktijk geimplementeerd kan worden. Om een vervolgstap te kunnen maken in de implementatie van VBHC wordt in hoofdstuk 11 een model geïntroduceerd om patiëntwaarde te meten. In dit model wordt patiëntwaarde uitgedrukt in een getal, worden uitkomsten zwaarder gewogen dan kosten en worden kosten gemeten vanuit een perspectief dat voor artsten relevant is.

In deel 3 wordt de impact van een aantal jaren VBHC implementatie in het hartcentrum van het Catharina Ziekenhuis gepresenteerd. In hoofdstuk 12 wordt een overzicht gegeven van de afgelegde reis op weg naar een meer waardegedreven zorgsysteem in en rondom het hartcentrum. Projecten waarin VBHC principes zijn geïmplementeerd worden samengevat en de impact op uitkomsten worden gepresenteerd. Deze impact omvat onder andere significante afname van sterfte, complicaties en re-operaties. Op basis van de opgedane ervaring in praktijk worden, om de impact van VBHC verder te vergroten, voorstellen gedaan voor vervolgstappen op het terrein van financiële modellen in de zorg. Een voorbeeld van een succesvol verbeterproject in de cardiochirurgie wordt gepresenteerd in hoofdstuk 13. De implementatie van een intra-operatieve checklist, welke eerder was geïntroduceerd en gepubliceerd door de Cleveland Clinic, leidde tot een significante afname van re-exploraties na bypass operaties.

Hoofdstuk 14, tot slot, bevat de discussie gebaseerd op de drie delen van deze thesis. Ook worden suggesties geïntroduceerd voor de vervolgstappen voor de verdere optimalisatie van de organisatie van cardiovasculaire zorg en de Nederlandse gezondheidszorg in bredere zin, op weg naar een meer waardegedreven zorgsysteem waarin de toegevoegde waarde voor de patiënt centraal staat.

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CHAPTER 16

Appendix

Curriculum Vitae Dankwoord List of publications

onderlinge vergelijking

CURRICULUM VITAE

Dennis van Veghel was born on the 14th of July 1974 in 's Hertogenbosch, the Netherlands. He finished secondary school at the Titus Brandsma Lyceum in Oss, the Academy for Physical Education in Tilburg and the Academy for Physical Therapy in Breda. After finishing his professional soccer carreer, in which he played as a goalkeeper for Willem II, FC Eindhoven and MVV Maastricht, he studied Healthcare Management and Policy at the faculty of health sciences of the University of Maastricht.

In 2004, he started to work at health insurance company Univé as accountmanager hospital healthcare purchasing. After working as manager sales at Univé, he became deputy director diagnostics at Viataal in 2007. Since 2010, he is involved in the Catharina Hospital as the director of the cooperation of cardiologists and cardiothoracic surgeons.

In 2011, the project Meetbaar Beter was started. Being one of the initiators he initially was project leader and became board member in 2013, when the Meetbaar Beter foundation was initiated. In the same year he was elected most talented manager under 40 in Dutch healthcare. The Meetbaar Beter program was awarded with the value-based healthcare prize in 2014.

As project leader, he contributed to the merger of three foundations; BHN, Meetbaar Beter and NCDR. Since this merger in 2017, he is installed as boardmember of the Netherlands Heart Registration.

Being one of the initiators, he was closely involved with the value-based healtcare prize 2016 winning first outcome-based payment models between Catharina Hospital and CZ. As one of the initiators and program manager, he contributed to the initiation and development of the Netherlands Heart Network, the 2018 value-based healthcare prize winner.

He performed his research in the Catharina Hospital, the Meetbaar Beter foundation, the Netherlands Heart Network and the Netherlands Heart Registration.

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