

Healthcare faces a dual challenge: improving patient outcomes while making sustainable use of limited resources.

This dissertation presents a data-driven roadmap for operationalizing Value-Based Healthcare in daily hospital practice. Across eight studies in cardiovascular and other clinical settings, it demonstrates how data, process improvement and continuous feedback can support clinical decision-making and redesign care pathways. The studies further show how low-value care can be reduced, capacity and resources used more effectively, and patient-relevant outcomes improved relative to the costs of achieving them.

By bridging theory and practice, this work shows that sustainable value improvement depends on continuously improving the processes through which care is delivered, making value an everyday reality for patients, healthcare professionals and society.

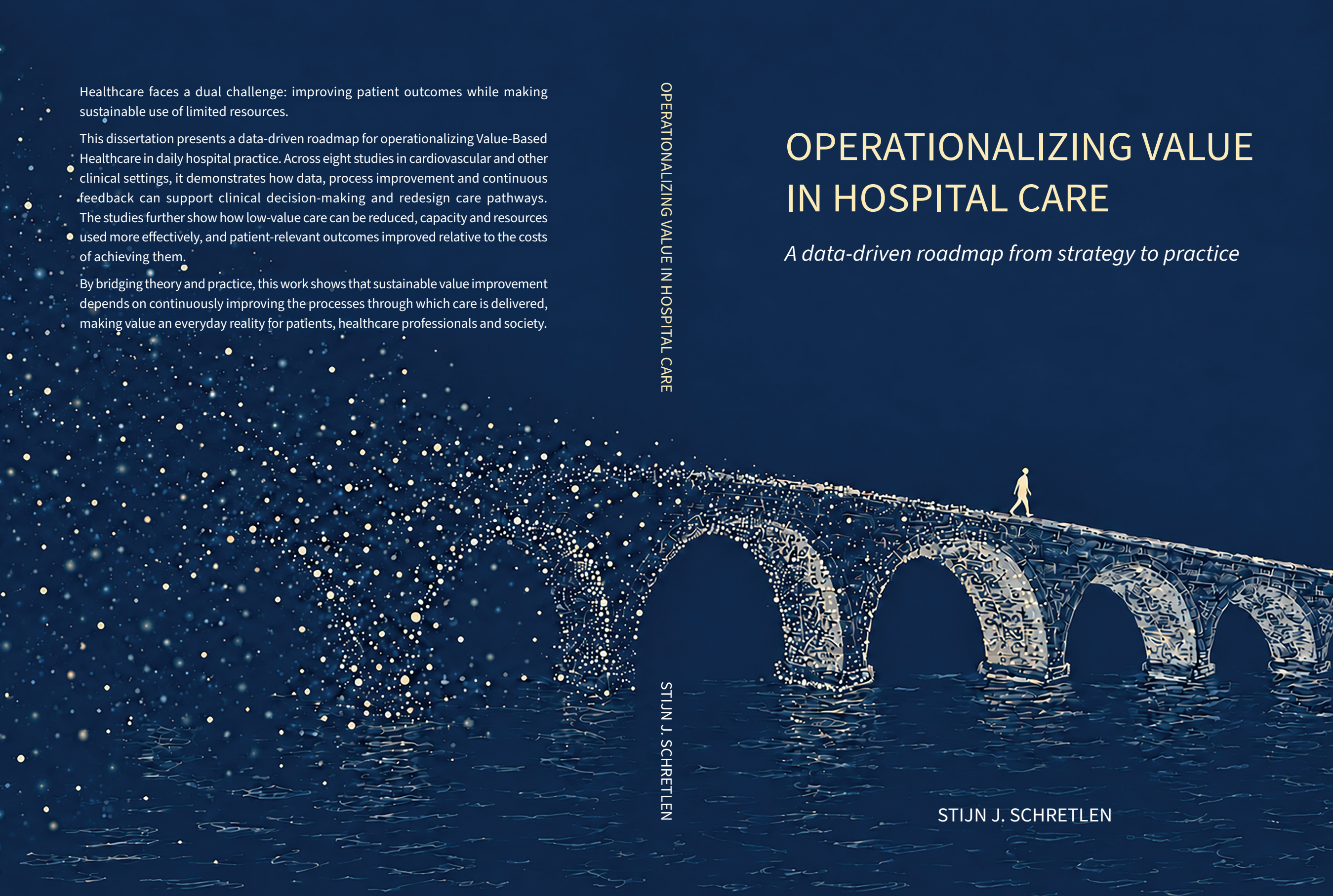
OPERATIONALIZING VALUE IN HOSPITAL CARE

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A data-driven roadmap from strategy to practice

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Operationalizing Value in Hospital Care:

A data-driven roadmap from strategy to practice

PhD thesis, Maastricht, The Netherlands

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DISSERTATION

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Candidate Contribution Statement

This dissertation includes empirical chapters based on multi-author publications. In these studies, the doctoral candidate worked in close collaboration with clinical co-authors and supervisory team members. The doctoral candidate's specific contribution varied by chapter, but included conceptualisation, methodological design, implementation support, data collection, formal analysis, manuscript preparation, and integrative synthesis.

The individual contribution of the doctoral candidate is specified in detail in the Author Contributions per Chapter section at the end of this dissertation. The introduction, methods chapter, general discussion, impact paragraph, summary, and Dutch summary were written by the doctoral candidate. The integrative synthesis and the Value Improvement Roadmap represent the doctoral candidate's primary intellectual contribution, developed under supervision and grounded in the empirical studies included in this dissertation.



1

GENERAL INTRODUCTION



1.1 Systemic pressure and resource constraints in health care

The long-term sustainability of health systems worldwide is increasingly compromised by a widening gap between escalating care demand and constrained resources. Healthcare expenditure has risen steadily over recent decades, driven by population ageing, increasing chronic disease complexity, and the diffusion of costly medical technologies. In most high-income countries, health spending now exceeds 10% of gross domestic product, with the United States reaching 17.8%, the highest share among advanced economies (OECD, 2023). As healthcare costs continue to grow, they increasingly compete with other public investments such as education, infrastructure, and defense, intensifying societal and political debates on affordability and value.

Alongside rising expenditures, healthcare systems face growing capacity constraints. Workforce shortages, particularly in nursing and specialized clinical roles, have become a defining challenge across many high-income countries. In the Netherlands, the healthcare sector already employs approximately one in six workers, a proportion projected to rise substantially in the coming decades if current trends persist (Wetenschappelijke Raad voor het Regeringsbeleid [WRR], 2021). These shortages translate into limited treatment capacity, increasing waiting times, and growing pressure on healthcare professionals, thereby constraining system performance and resilience (van Merode et al., 2024; van Beers, van Dun, & Wilderom, 2022). In this dissertation, capacity is understood as a multidimensional concept. It encompasses the availability of healthcare professionals, physical infrastructure such as beds and operating rooms, temporal capacity within care pathways, and the organizational capability to align these resources effectively. While these pressures affect healthcare systems broadly, this dissertation focuses specifically on hospital care, where such capacity constraints are operationalized through care pathways, multidisciplinary coordination, and routine service delivery.

Importantly, these challenges are not purely financial. Capacity has emerged as a critical dimension of value in healthcare delivery, alongside patient outcomes and costs. Even when effective clinical interventions are available, limited availability of staff, beds, and procedural slots can delay care and undermine population

health. This tension between medical capability and organizational capacity has become increasingly visible in routine hospital care delivery.

Despite sustained investment and repeated reform efforts, inefficiencies remain pervasive within healthcare systems. A substantial proportion of healthcare spending is estimated to constitute waste, largely due to poorly designed processes, redundant diagnostics, and fragmented coordination, rather than inadequate clinical knowledge (Verkerk et al., 2022). Such inefficiencies not only drive unnecessary costs but also consume scarce capacity and professional time, exacerbating existing workforce and access challenges.

Together, these developments suggest that the central challenge facing contemporary healthcare systems is not the absence of effective medical treatments, but the limited ability to organize, adapt, and continuously improve care delivery under conditions of resource scarcity. Addressing this challenge points to the need for operational approaches that enable healthcare organizations to create more value with existing resources by systematically improving processes, strengthening learning mechanisms, and aligning daily clinical practice with broader value-oriented objectives.

1.2 Value-based healthcare as strategic intent and its implementation gap

In response to the growing pressure on healthcare systems to deliver better outcomes with limited resources, Value-Based Healthcare (VBHC) has emerged as one of the most influential strategic frameworks for healthcare reform. Introduced by Porter and Teisberg, VBHC reframes the goal of healthcare delivery around maximizing patient-relevant outcomes relative to the costs required to achieve them, thereby offering a coherent alternative to volume-driven models of care (Porter & Teisberg, 2006; Porter, 2010).

To operationalize this vision, VBHC proposes a set of mutually reinforcing principles. These include organizing care around medical conditions rather than specialties, systematically measuring outcomes and costs for every patient, and

fostering multidisciplinary collaboration across the full cycle of care. Over the past two decades, these principles have been widely adopted in policy discourse and hospital strategy, both in the Netherlands and internationally. As such, VBHC provides a compelling strategic orientation for aligning clinical quality, efficiency, and patient-centeredness.

However, despite its conceptual appeal and broad endorsement, the practical implementation of VBHC has proven challenging in real-world healthcare settings. A growing body of literature indicates that most healthcare organizations adopt VBHC only partially (Vijverberg et al., 2022; van Staalduinen et al., 2022). In practice, implementation efforts often focus on isolated elements such as outcome measurement or the establishment of multidisciplinary teams. However, as argued by Van der Nat (2022), the original strategic agenda for value transformation needs to be expanded to include a systematic approach for value-based quality improvement. Without such an explicit improvement strategy to translate measurement into action, broader transformation of care delivery remains limited. Systematic reviews consistently report barriers such as fragmented information systems, limited data maturity, professional silos, and resistance to change (De Mattia et al., 2024; Khalil et al., 2025). Together, these factors impede the translation of strategic intent into daily clinical practice.

In this dissertation, the hospital organization itself is the primary level of action, in particular its clinical leadership and operational management at the meso-level. The meso-level refers to hospital departments and care pathways where multidisciplinary teams coordinate, govern, and improve care delivery, translating strategic value ambitions into routine clinical practice. While national policy and reimbursement frameworks define the broader conditions, the empirical findings show that sustainable value creation is mainly driven by organizational actors who align strategic intent, process redesign, and data-driven learning within hospitals.

Importantly, these challenges do not suggest a fundamental flaw in the underlying principles of VBHC. Rather, they point to a persistent implementation gap between the strategic articulation of value and the operational realities of healthcare organizations. While VBHC defines what constitutes value and why care delivery should change, it provides limited guidance on how healthcare teams can redesign care processes. It also offers little direction on how variation can be managed and

how continuous learning cycles can be established under conditions of resource scarcity.

This dissertation builds on the premise that closing this implementation gap requires complementing the strategic intent of VBHC with robust operational and data-driven improvement mechanisms in hospital organizations, where value-based ambitions must be translated into day-to-day clinical practice. By explicitly focusing on the meso-level of care delivery, this research seeks to contribute to a more pragmatic understanding of how value-based objectives can be translated into sustainable improvement in everyday clinical practice.

1.3 Lean Six Sigma as an operational approach to value improvement

Against the background of increasing cost pressures, capacity constraints, and persistent inefficiencies in healthcare systems, the translation of strategic objectives into daily clinical practice remains a major challenge. As discussed in the preceding section, Value-Based Healthcare provides a coherent framework for defining value in terms of patient-relevant outcomes relative to costs, but offers limited guidance on how such objectives can be operationalized within complex care delivery processes.

In practice, operational improvement initiatives in healthcare have often evolved independently from strategic value-based frameworks. Many hospitals have adopted Lean Six Sigma (LSS) as a structured approach to improve efficiency, throughput, and reliability of care processes, frequently driven by operational bottlenecks, cost containment pressures, or local improvement needs rather than explicit alignment with value-based objectives or clinical outcome measures (DelliFraine et al., 2010; Antony et al., 2018; van Staalduinen et al., 2022).

Originating from industrial production systems, LSS combines principles from Lean thinking and Six Sigma methodologies. Lean focuses on waste reduction and flow optimization, while Six Sigma aims to reduce variation and defects in processes. Within healthcare settings, LSS has been applied across a wide range

of clinical and operational domains, including surgical pathways, outpatient logistics, and administrative processes. Empirical studies demonstrate that such interventions can lead to measurable improvements in efficiency, throughput, and selected clinical outcomes when applied to clearly defined processes (DelliFraine et al., 2010; Improta et al., 2018).

At the same time, the application of LSS in healthcare has often been restricted to an independent and tool-oriented approach. Lean is fundamentally a strategic management system designed for strategy deployment. One such mechanism is Hoshin Kanri, which translates strategic objectives into operational goals and priorities through structured alignment. However, its execution in clinical settings frequently reveals important limitations (Antony et al., 2018). Many initiatives focus primarily on process efficiency and short-term performance gains in silos, while paying limited attention to broader organizational alignment or sustained professional ownership.

This dissertation conceptualizes Lean Six Sigma not merely as a set of tools, but as an operational improvement approach that requires a unifying strategic direction to overcome local suboptimization and reach its full potential in complex healthcare environments. Increasingly, the literature suggests that the impact of LSS in healthcare depends not only on the technical application of improvement tools, but on its use as a broader operational approach.

A related perspective is offered by the Shingo Model, which distinguishes between improvement tools, management systems, and guiding principles (Spear & Bowen, 1999). From this perspective, initiatives that remain confined to the tools level may generate local improvements, but are unlikely to create sustained organisational learning unless they are embedded in systems that shape behaviour and are guided by a clear value-oriented purpose. Such an operational approach emphasizes alignment with organizational goals, involvement of clinical professionals, leadership engagement, and the systematic use of data to support learning and decision-making over time.

When embedded in this way, LSS can provide a structured foundation for continuous improvement, while remaining sensitive to the complexity and variability inherent in healthcare delivery. In this dissertation, Lean Six Sigma is

therefore conceptualized as an operational improvement approach that helps teams redesign and stabilize care processes. Its contribution to value creation depends on alignment with strategic goals and routine feedback on outcomes and resource use. The findings presented in the subsequent chapters demonstrate that its contribution to sustainable value creation depends critically on how process improvement efforts are connected to broader strategic objectives and outcome-oriented frameworks.

1.4 Data-driven organizational learning and feedback mechanisms in healthcare improvement

The recurring limitations of isolated improvement initiatives highlight a fundamental challenge in healthcare improvement: without systematic feedback and learning, process changes cannot be reliably evaluated, sustained, or scaled. While operational improvement approaches such as Lean Six Sigma emphasize structured problem solving, their long-term effectiveness depends critically on the availability of data. Such data enables organizations to assess how changes are associated with patterns in outcomes. Improvement efforts that are not supported by learning mechanisms risk remaining episodic, person-dependent, and weakly connected to clinical impact.

The importance of measurement as a prerequisite for improvement has long been recognized in healthcare quality research. Batalden and Davidoff conceptualize quality improvement as an iterative learning process, in which data are essential to determine whether changes in care delivery result in improved outcomes, system performance, and professional development (Batalden & Davidoff, 2007). From this perspective, improvement and learning are inseparable: without feedback, organizations cannot distinguish effective change from unintended consequences.

Empirical studies of large-scale quality improvement programs further demonstrate that the absence of robust learning and feedback mechanisms represents a major barrier to sustainable improvement. Dixon-Woods and colleagues show that many healthcare improvement initiatives struggle to achieve

lasting impact because organizations lack the capability to generate, interpret, and use performance data to guide adaptation over time (Dixon-Woods et al., 2012). As a result, improvement efforts may succeed locally but fail to translate into organizational learning or system-level value creation.

Within a value-based context, data-driven learning requires insight into how care processes unfold in practice, how resources are utilized, and how variations in care delivery relate to patient-relevant outcomes. However, traditional performance measurement systems in healthcare often rely on aggregated indicators and static reporting structures. As a result, they offer limited visibility into the dynamic and sequential nature of care pathways. This limits the ability of healthcare organizations to understand why outcomes vary and where improvement efforts should be targeted.

Advances in healthcare data availability create new opportunities to strengthen learning at the meso-level of care delivery. Process-level data, combined with information on costs and outcomes, enable a more granular assessment of how care is delivered over time. When embedded within structured improvement approaches, such data can support iterative feedback cycles that connect process redesign to outcome-oriented evaluation.

In this dissertation, data-driven learning and feedback mechanisms are therefore positioned as enabling conditions for sustainable improvement rather than as independent solutions. They provide the analytical foundation required to assess the effects of process improvements and to support organizational learning over time. In doing so, they help bridge the gap between operational interventions and value-based evaluation.

1.5 The clinical domains as empirical settings

While the challenges addressed in this dissertation apply broadly across healthcare, the empirical studies are conducted in two distinct clinical domains that together support the generalizability of the findings. The cardiovascular domain serves as the primary empirical setting, within the context of Dutch

secondary and tertiary hospital care, where capacity constraints and data availability increasingly shape daily clinical decision-making. The cardiovascular domain is characterized by high resource utilization, complex multidisciplinary care pathways, rapid technological innovation, and a relatively high level of data maturity, reflected in the routine availability of detailed clinical and outcome data. As such, it provides a particularly demanding and informative context for studying the integration of value-based objectives and operational improvement approaches.

In contrast, low back pain represents a high-volume care domain with substantial practice variation and strong interfaces between primary and secondary care. In this setting, challenges are less driven by technological complexity and more by coordination, referral behavior, and appropriate resource use. Studying improvement mechanisms in this context allows examination of how similar principles of process optimization and governance operate under different organizational and informational conditions.

Together, these domains function as complementary empirical settings. Cardiovascular care represents a high-complexity, data-rich environment, while low back pain reflects a more generic care pathway. Demonstrating improvement across both settings supports the relevance of the proposed approach beyond a single clinical domain.

1.6 Theoretical framework: linking structure, process, outcomes, and learning

To provide a coherent analytical foundation for examining the integration of strategic intent and operational execution, this dissertation adopts Donabedian's Structure–Process–Outcome (SPO) model as its overarching theoretical framework (Donabedian, 1966). Within this framework, outcomes are not viewed in isolation, but as the consequence of how care processes are organized and performed, within the constraints of existing organizational structures. The SPO model offers a widely accepted logic for studying quality and value in healthcare and remains foundational in health services research. In this dissertation, the

framework is used as an analytical lens to structure empirical observations across heterogeneous improvement initiatives, rather than as a normative model.

In the context of this dissertation, Value-Based Healthcare primarily articulates the desired outcomes of care delivery, emphasizing patient-relevant outcomes in relation to costs (Porter & Teisberg, 2006; Porter, 2010). Lean Six Sigma, in turn, provides a structured operational approach for improving care processes through the reduction of waste, variability, and inefficiencies (Antony et al., 2018). The structural dimension of the SPO model encompasses the organizational conditions required to enable this relationship. These include multidisciplinary collaboration, governance arrangements, and data infrastructures at the meso-level of hospital care.

However, improving outcomes through process optimization requires more than static alignment between structure and process alone. Sustainable improvement depends on the ability of healthcare organizations to learn from performance data and to adapt care delivery over time. Therefore, this dissertation complements the SPO model with insights from organizational learning theory. Argyris and Schön distinguish between single-loop learning, in which errors are corrected within existing norms, and double-loop learning, in which underlying assumptions and routines are questioned and revised (Argyris & Schön, 1978). In healthcare, such learning cycles are essential for translating outcome measurement into meaningful process redesign rather than isolated performance monitoring.

By combining Donabedian's structural logic with a learning-oriented perspective, this framework enables examination of how value-based objectives and operational improvement approaches interact in routine hospital practice. It also allows analysis of how data-driven feedback supports this interaction over time. It provides the conceptual basis for analyzing not only whether improvements occur, but how and under which organizational conditions integration between strategic value ambitions and operational execution can be sustained.

1.7 Problem definition and research objectives

Despite the growing prominence of Value-Based Healthcare (VBHC) as a guiding principle for healthcare reform, a persistent implementation gap remains between strategic ambitions and daily clinical practice. While value-based frameworks emphasize maximizing patient-relevant outcomes relative to the costs required to achieve them, healthcare organizations often struggle to translate these objectives into concrete operational changes at the level of care delivery.

1

In parallel, many hospitals have adopted structured operational improvement approaches, including Lean Six Sigma (LSS), to address inefficiencies, variability, and capacity constraints within care processes. These initiatives are frequently initiated in response to local operational pressures and tend to focus on process efficiency and reliability. When applied in isolation, however, such efforts risk suboptimization, limited clinical engagement, and weak alignment with broader strategic objectives and patient-relevant outcomes.

As a result, strategic value-based initiatives and operational improvement efforts have often evolved in relative separation within healthcare organizations. This separation limits the ability of hospitals to consistently evaluate whether process changes contribute to value creation. It also constrains the establishment of feedback loops for learning and the ability to sustain improvement over time. Bridging this gap requires approaches that connect strategic intent, operational execution, and outcome-oriented evaluation at the meso-level of hospital care, where care pathways, multidisciplinary collaboration, and data use interact.

This dissertation addresses this challenge from the observation that, in hospital practice, value-based ambitions are widely articulated, while operational improvement efforts often remain fragmented and weakly connected to outcomes. Rather than treating VBHC and Lean Six Sigma as competing paradigms, the dissertation examines their complementary roles and the mechanisms through which their integration can support sustainable improvement at the meso-level of hospital care.

Research question:

How can the strategic principles of Value-Based Healthcare and structured operational improvement approaches be coherently integrated at the meso-level of hospital care to support sustainable improvements in outcomes, efficiency, and organizational learning?

To address this overarching question, the dissertation pursues the following sub-questions:

- 1. How does the integration of Value-Based Healthcare principles influence the focus, scope, and evaluation of Lean Six Sigma-driven process improvement initiatives within complex care pathways?**
- 2. How do data-driven feedback mechanisms enable multidisciplinary learning and evaluation of value-oriented process improvements over time?**
- 3. Under which organizational and contextual conditions can the integration of Value-Based Healthcare and Lean Six Sigma be sustained in routine hospital practice?**

1.8 Scope and contributions of the dissertation

This dissertation explicitly focuses on the meso-level of healthcare delivery. This level comprises hospital departments and care pathways where operational processes, multidisciplinary collaboration, and data use directly interact. The scope of the research is deliberately limited to the design, implementation, and evaluation of process improvement interventions within existing organizational and reimbursement structures. It does not aim to assess system-wide Value-Based Healthcare reforms, such as bundled payments or full care-chain integration, but instead examines how value-oriented objectives can be translated into daily clinical practice.

Empirically, the dissertation draws on a series of case studies conducted in secondary and tertiary care settings across different clinical domains. These

studies investigate how structured process improvement approaches can be applied to redesign care pathways, improve coordination, and address capacity constraints under conditions of resource scarcity. Despite differences in clinical context, the cases share a common focus on operational processes, data use, and outcome-oriented evaluation.

Methodologically, this dissertation contributes by demonstrating how Lean Six Sigma can function as a structured operational improvement approach in healthcare, and how data-driven methods can support learning and evaluation over time. Rather than introducing new improvement methodologies, the research shows how established approaches can be applied and embedded across different clinical contexts.

Conceptually, the dissertation advances literature by explicitly articulating and empirically examining the complementary roles of Value-Based Healthcare and Lean Six Sigma. It reframes the implementation challenge not as a lack of strategic intent, but as a misalignment between strategic value ambitions and the operational logic through which care is delivered. By demonstrating how strategic value objectives and operational process improvement can be structurally aligned in routine hospital practice, the dissertation clarifies the conditions under which these approaches can operate in a mutually reinforcing manner. Taken together, the dissertation provides empirically grounded insights and conceptual clarification on how operational process improvement and value-based evaluation can be aligned to support sustainable improvement in hospital care.

1.9 Methodological approach

This dissertation adopts a retroductive, realist-informed synthesis of improvement programmes, a theory-driven methodological approach aimed at identifying recurring mechanisms and contextual conditions that plausibly explain value-oriented improvement in routine hospital practice (Pawson & Tilley, 1997; Rycroft-Malone et al., 2012). The empirical studies presented in the subsequent chapters were conducted between 2018 and 2025 in Dutch secondary and tertiary care

settings. They originated as distinct improvement initiatives rather than as components of a single, prospectively designed research programme. While each study addressed a specific operational or evaluative challenge within its local context, they share a common analytical focus on data-driven process improvement at the meso-level of hospital care. Although not all empirical chapters explicitly label their interventions as Value-Based Healthcare or Lean Six Sigma, they are analytically examined through these lenses in the cross-case synthesis, focusing on their contribution to value-oriented process redesign and learning.

By synthesizing insights across these studies, the dissertation abducts recurring patterns in how value-based objectives, operational improvement approaches, and data-driven feedback mechanisms interact in practice. This retrospective synthesis enables an integrative analysis of processes, outcomes, and learning across heterogeneous clinical contexts, without implying causal attribution to a single intervention model. The methodological emphasis of this dissertation is therefore not on hypothesis testing or prospective evaluation of a predefined framework, but on retroductive theory building grounded in empirical observations. The final chapter builds on this synthesis to develop the Value Improvement Roadmap as a middle-range theory that captures conditions, mechanisms, and design principles for aligning strategic value ambitions with operational execution in routine hospital practice.

1.10 Thesis outline and structure

Following this introduction, **Chapter 2** establishes the methodological foundation of the dissertation. It details the retroductive, realist-informed methodological approach, the data sources used, and the analytical framework that guides the interpretation of findings. The remainder of the dissertation is organized into two main parts. These parts reflect the progression from operational improvement in clinical practice to data-driven evaluation and learning. Together, these parts examine how value-based objectives can be translated into sustainable improvements in care delivery at the meso-level of healthcare organizations.

Part I focuses on the design and implementation of operational improvement interventions. **Chapter 3** examines the application of Lean Six Sigma to reduce surgical cancellations within a coronary artery bypass grafting pathway. **Chapter 4** extends this perspective to the redesign of a cardiac resynchronization therapy care pathway, emphasizing multidisciplinary coordination. **Chapter 5** addresses quality improvement in Heart Team decision-making. **Chapter 6** evaluates the implementation of a 1.5-line care model for low back pain. It illustrates the applicability of similar improvement principles in a high-volume, transmural care setting. **Chapter 7** presents a systematic review of Lean Six Sigma applications in surgical care, synthesizing existing evidence on mechanisms and patterns of change, while highlighting recurring methodological limitations and challenges related to sustainability and alignment with clinical outcomes.

Part II focuses on data-driven evaluation and organizational learning. **Chapter 8** introduces process mining as a method to visualize and analyze real-world care pathways in support of learning and performance monitoring. **Chapter 9** evaluates the impact of a redesigned cardiac resynchronization therapy pathway on clinical outcomes, costs, and capacity. **Chapter 10** provides a comparative system-level evaluation of transcatheter versus surgical aortic valve replacement, examining implications for outcomes, resource use, and healthcare capacity.

The final chapter integrates the findings across both parts of the dissertation and presents the results as a Value Improvement Roadmap, outlining conditions for aligning operational improvement, data-driven learning, and value-based evaluation.

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2

METHODS AND DESIGN



2.1 Study design and overall methodological approach

This dissertation employs a retroductive, or abductive, realist-informed research logic to develop a middle-range theory of value creation as a dynamic capability: from observed improvements across organizationally embedded improvement initiatives, the analysis abducts the organizational mechanisms through which hospitals sense, seize, and transform value under resource constraints. This approach prioritizes contextual theory building over universal causal claims.

More specifically, the dissertation adopts a realist-informed synthesis of improvement programmes, examining how strategic value-based objectives and operational improvement approaches interact in routine hospital practice (Pawson & Tilley, 1997; Rycroft-Malone et al., 2012). The empirical chapters draw on distinct improvement initiatives conducted between 2018 and 2025 in Dutch secondary and tertiary care settings. These initiatives emerged from local operational challenges rather than as components of a prospectively designed research programme.

The retrospective and embedded character of this design reflects the realities of improvement-oriented research in healthcare organizations, where structured interventions typically arise in response to immediate clinical or operational needs. Each empirical study addresses a specific problem within its local context, yet all share an analytical focus on data-driven process improvement at the meso-level of hospital care. This enables a post hoc synthesis of insights across heterogeneous clinical settings without implying causal attribution to single interventions.

The research design is explicitly structured to address the central research objective formulated in Chapter 1, aiming to bridge the gap between strategic intent and operational execution. Consistent with this aim, the dissertation does not seek to test predefined hypotheses or to evaluate the effectiveness of a single intervention model. Instead, the analytical emphasis is on identifying mechanisms and contextual conditions that plausibly explain observed improvements across comparable settings.

The analytical approach is grounded in two complementary frameworks. Donabedian's Structure–Process–Outcome model provides a logic for relating organizational structures and care processes to outcomes (Donabedian, 1966). This is complemented by an organizational learning perspective (Argyris & Schön, 1978), which informs how data-driven feedback supports learning over time, from incremental process adjustments to more fundamental adaptations of care pathways. Together, these frameworks operationalize the dynamic capability perspective: SPO maps the structural and process dimensions, while organizational learning theory explains the mechanisms through which hospitals transform measured performance into improved practice.

Mechanisms and contextual conditions were identified through cross-case comparison and analytical interpretation rather than through formal Context–Mechanism–Outcome (CMO) coding. While informed by realist evaluation, the design does not involve prospectively specified programme theory or formal CMO-configuration coding. Rather, it constitutes a retrospective cross-case synthesis with a realist orientation, reflecting the applied nature of the empirical material.

The culmination of this synthesis is the Value Improvement Roadmap, an empirically derived model that integrates insights across studies to articulate conditions, mechanisms, and design principles for aligning strategic value ambitions with operational execution. This roadmap is not a pre-existing framework to be validated, but a middle-range theory of how hospitals build dynamic capabilities for value creation under resource constraints.

2.2 Empirical components and context

This dissertation is based on a set of empirical studies conducted between 2018 and 2025 in Dutch secondary and tertiary care settings. These studies originated as distinct improvement and evaluation initiatives, each addressing a concrete operational or organizational challenge within its local clinical context. Although not designed as components of a single prospective research program, all studies share a common analytical focus on data-driven process improvement at the meso-level of hospital care.

The empirical work spans two complementary clinical domains. Cardiovascular care serves as the primary empirical test bed. Its high resource intensity, complex multidisciplinary coordination, rapid technological innovation, and relatively mature data infrastructures make it a demanding and informative context for examining the interaction between value-based objectives, operational process redesign, and outcome-oriented evaluation. In addition, one study focuses on low back pain as a contrasting, high-volume condition characterized by substantial practice variation and strong interfaces between primary and secondary care. This domain enables assessment of whether similar improvement principles apply in settings with lower technological complexity and different coordination challenges.

The empirical components are analytically organized into two parts. Part I focuses on the design and implementation of operational process improvements, primarily using Lean Six Sigma methodologies. Part II emphasizes data-driven evaluation, learning, and system-level impact assessment, including the use of process mining and comparative outcome analyses. Together, these studies provide the empirical basis for examining how value-based objectives, operational improvement approaches, and feedback mechanisms interact in routine hospital practice.

Rather than treating each study as an isolated case, this dissertation synthesizes insights across the empirical components to identify recurring mechanisms, contextual conditions, and design principles. This synthesis supports retroductive theory building and underpins the development of the Value Improvement Roadmap presented in the final chapter.

Table 2.1. Overview of empirical chapters and their methodological focus

Chapter	Clinical domain	Primary focus	Methodological approach	Contribution to synthesis
3	Cardiovascular (CABG)	Reduction of surgical cancellations	Lean Six Sigma case study	Demonstrates process redesign under capacity constraints
4	Cardiovascular (CRT)	Redesign of care pathway	Lean Six Sigma–based pathway optimization	Illustrates multidisciplinary coordination and flow improvement
5	Cardiovascular (Heart Team)	Improvement of decision-making quality	Process analysis and improvement intervention	Highlights organizational structure and governance effects
6	Low back pain	Reduction of unnecessary hospital visits	Implementation study of 1.5-line care model	Provides contrasting high-volume, low-complexity context
7	Surgical care (multiple domains)	Evidence synthesis of LSS applications	Systematic literature review	Contextualizes empirical findings within broader literature
8	Cardiovascular (multiple pathways)	Visualization of real-world care pathways	Process mining analysis	Supports data-driven learning and feedback mechanisms
9	Cardiovascular (CRT)	Evaluation of outcomes, costs, and capacity	Pre–post evaluation study	Links process redesign to value-based outcomes
10	Cardiovascular (TAVI vs. SAVR)	System-level comparative evaluation	Observational comparative analysis	Extends value assessment to system-level implications

2.3 Research questions and analytical logic

This dissertation is guided by a set of interrelated research questions that structure the analysis of how strategic value-based objectives and operational process improvement approaches interact in routine hospital care. Consistent with the retrospective design, the questions support retroductive, explanatory and interpretive analysis rather than hypothesis testing. Their purpose is to identify mechanisms, learning dynamics, and contextual conditions under which integration between Value-Based Healthcare and Lean Six Sigma can be realized and sustained at the meso-level of hospital care.

The central research question, introduced in Chapter 1, is:

How can the strategic principles of Value-Based Healthcare and structured operational improvement approaches be coherently integrated at the meso-level of hospital care to support sustainable improvements in outcomes, efficiency, and organizational learning?

To address this overarching question, three sub-questions are examined across the empirical chapters:

1. How does the integration of Value-Based Healthcare principles influence the focus, scope, and evaluation of Lean Six Sigma–driven process improvement initiatives within complex care pathways?
2. How do data-driven feedback mechanisms enable multidisciplinary learning and evaluation of value-oriented process improvements over time?
3. Under which organizational and contextual conditions can the integration of Value-Based Healthcare and Lean Six Sigma be sustained in routine hospital practice?

Together, these questions distinguish between process-level mechanisms, learning dynamics, and organizational context. This structure allows variation across clinical settings, intervention types, and data availability while maintaining a coherent analytical logic.

Sub-question 1 focuses on the interaction between strategic intent and operational execution by examining how value-based objectives shape the design, prioritization, and evaluation of improvement initiatives. Sub-question 2 addresses the role of data in enabling learning, with emphasis on the use of process, outcome, and capacity data in iterative improvement cycles. Sub-question 3 examines the organizational and contextual factors that influence whether such integration can be embedded and sustained beyond individual projects.

The research questions are informed by the Structure–Process–Outcome framework and an organizational learning perspective. Care processes are analyzed in relation to outcomes and capacity, with explicit attention to feedback loops that enable learning at the meso-level of hospital care. Rather than being answered within a single chapter, the questions are addressed cumulatively across multiple empirical studies. Each chapter contributes partial insights, which are synthesized in the final chapter to develop an integrated understanding of mechanisms, conditions, and design principles for value-oriented operational improvement.

2.4 Data sources and measurement

This dissertation draws on routinely collected clinical, operational, and administrative data extracted retrospectively from hospital information systems. The data reflect real-world care delivery rather than data collected for research purposes. This aligns with the applied nature of the improvement initiatives and supports interpretive assessment under routine operational conditions.

Across the empirical studies, three categories of data are distinguished: process data, outcome data, and resource utilization data. Process data describe the sequencing, timing, and coordination of care activities within defined care pathways. These data originate primarily from electronic health records, scheduling systems, and hospital administrative databases. Typical variables include timestamps of diagnostics, interventions, transfers, and multidisciplinary

decision moments. Where relevant, these data are used to reconstruct patient-level care trajectories over time.

Outcome data capture patient-relevant clinical outcomes and, where available, patient-reported measures. The specific outcomes differ by clinical domain and study objective. In cardiovascular care, outcomes include procedure-specific endpoints, complications, and mortality. In the low back pain domain, outcomes primarily concern care utilization patterns and referral appropriateness. The inclusion of patient-reported outcome measures is constrained by routine data availability and completeness.

Resource utilization data provide insight into the use of scarce healthcare capacity. These data include operating room time, length of stay, bed occupancy, staffing deployment, and procedure volumes. Cost information is derived indirectly through resource use and reimbursement categories rather than through full patient-level cost accounting. This reflects the limited granularity of cost data in routine hospital systems and is consistent with the evaluative focus of the studies.

Measurement strategies are tailored to the objectives of each empirical chapter but follow a shared analytical logic rooted in the Structure–Process–Outcome framework introduced in Chapter 1. Process measures assess how care is organized and delivered, outcome measures capture the effects of process redesign, and resource measures reflect implications for capacity and efficiency. This triangulation enables a multidimensional assessment of value without implying causal attribution.

Data quality and completeness vary across studies due to differences in information system maturity and documentation practices. These variations are treated as characteristics of real-world healthcare improvement rather than as purely methodological limitations. Where data constraints influence analysis or interpretation, they are explicitly addressed in the relevant empirical chapters.

By relying on routinely collected data, this dissertation emphasizes ecological validity and practical relevance. Heterogeneity in data sources limits direct comparability across studies and reinforces the role of synthesis at the programmatic level.

2.5 Analytical approach and data analysis

The analytical approach of this dissertation is retroductive, exploratory and explanatory rather than confirmatory. Analyses aim to understand how care processes are organized, how they change following improvement interventions, and how these changes relate to outcomes, resource use, and learning over time. This approach aligns with the retrospective and programmatic nature of the research and avoids claims of causal inference beyond what the data support.

Across the empirical chapters, analysis follows a consistent process-oriented logic. First, existing care pathways are described and visualized to establish a baseline understanding of routine care delivery. This includes identifying variation, bottlenecks, rework, and coordination challenges across multidisciplinary teams. Second, improvement interventions are designed and implemented using Lean Six Sigma principles adapted to the local clinical context. Third, post-intervention analyses examine patterns of change in processes, outcomes, and resource utilization relative to baseline.

Quantitative analyses are primarily descriptive and comparative. Pre-post comparisons are used to explore patterns of change over time within the same organizational setting. Where appropriate, basic statistical techniques are applied to compare distributions or central tendencies. The analytical emphasis remains on pattern identification and plausibility rather than hypothesis testing. Statistical significance is therefore not treated as a prerequisite for relevance, given the operational and context-dependent nature of the interventions.

In selected chapters, process mining is used to reconstruct and analyze real-world care pathways based on event-level data. Process mining supports visualization of patient flows, identification of process variants, and comparison of pathways before and after interventions. Within this dissertation, it functions as a diagnostic and learning tool rather than as a predictive or optimization method. Its primary purpose is to support multidisciplinary reflection and to link process redesign to observed outcomes.

Quantitative analyses are complemented by qualitative insights derived from multidisciplinary meetings, improvement workshops, and stakeholder reflections.

These insights support interpretation of observed changes and help explain mechanisms underlying improvement or resistance. Formal qualitative interviews aimed at theory testing were not conducted.

At the programmatic level, findings from individual chapters are synthesized through cross-case comparison. Rather than aggregating results statistically, the synthesis identifies recurring mechanisms in how strategic value objectives, operational improvement approaches, and data-driven feedback interact across clinical contexts. This synthesis supports retroductive theory building and underpins the development of the Value Improvement Roadmap presented in the final chapter.

Throughout the analyses, organizational context, data availability, and implementation conditions are treated as analytically meaningful. Differences in information system maturity, governance, and professional engagement are treated as explanatory conditions rather than as sources of bias. This perspective reflects the dissertation's focus on understanding how value-based improvement can be operationalized under real-world constraints.

2.6 Collaborative research model and candidate contribution

The empirical studies included in this dissertation were conducted in collaboration with clinical teams across multiple hospital settings. This collaborative model reflects the nature of quality improvement and implementation research in healthcare, where methodological expertise, operational improvement capability, clinical domain knowledge, and access to routine care data need to be combined. The doctoral candidate's contribution varied across chapters but consistently included one or more of the following roles: conceptualisation, methodological design, implementation support, data collection, formal analysis, interpretation, manuscript preparation, and synthesis across studies. A detailed account of the doctoral candidate's contribution per chapter is provided in the Author Contributions section of this dissertation.

2.7 Ethical considerations and data governance

This dissertation is based on retrospective analyses of routinely collected clinical and administrative data, combined with process improvement activities embedded in routine hospital practice. No experimental interventions were introduced for research purposes, and patient care was not altered beyond standard improvement initiatives initiated by the participating healthcare organizations.

All empirical studies were conducted in accordance with applicable ethical standards and Dutch regulations governing the use of healthcare data. For each study, approval or formal waiver was obtained from the relevant institutional review boards or medical ethics committees, in line with the Medical Research Involving Human Subjects Act (WMO). Where applicable, studies were classified as non-interventional and therefore exempt from full ethical review.

Data handling complied with the General Data Protection Regulation (GDPR). Patient-level data were pseudonymized prior to analysis, and access to identifiable information was restricted to authorized personnel within the participating organizations. Researchers worked exclusively with de-identified datasets stored on secure hospital or institutional servers. No data were transferred to external commercial platforms without explicit institutional approval.

Data governance arrangements varied across study sites, reflecting differences in local information infrastructures and organizational policies. These contextual differences are treated as an empirical characteristic of routine healthcare improvement rather than as methodological limitations. Where data access, quality, or documentation practices influenced analytical choices or interpretation, this is explicitly reported in the relevant empirical chapters.

Multidisciplinary improvement teams participated in process redesign activities as part of their professional responsibilities. Insights from meetings, workshops, and reflective sessions were used to support interpretation of findings but were not collected through formal qualitative interviews aimed at theory testing. As such, no additional informed consent procedures were required beyond standard organizational participation in quality improvement activities.

The realist synthesis presented in this dissertation does not aim to establish causal relationships or to generalize findings statistically beyond the studied contexts. Ethical responsibility is addressed through transparency in reporting, careful interpretation of findings, and explicit acknowledgment of contextual dependencies. This approach aligns with the dissertation's objective to contribute to practice-informed understanding of value-based improvement under real-world conditions.

2.8 Methodological limitations and considerations

Several methodological limitations inherent to the research design should be acknowledged to frame the empirical findings presented in this dissertation.

First, the retroductive research design limits causal inference. The empirical studies were not conducted under controlled experimental conditions. Consequently, observed patterns of change in processes, outcomes, or capacity cannot be attributed unequivocally to specific interventions, but rather reflect patterns and associations observed in real-world improvement initiatives.

Second, the empirical material is based on opportunistic sampling. The included studies originate from healthcare organizations that actively engaged in improvement initiatives and possessed sufficient data availability to support analysis. This introduces potential selection bias, as organizations with lower data maturity or limited improvement capacity may be underrepresented.

Third, variation in data quality and availability across study sites constrained analytical depth and comparability. Differences in electronic health record structures, coding practices, and documentation completeness influenced which process steps, outcomes, and cost proxies could be quantitatively analyzed. Constraints specific to individual studies are addressed in the corresponding empirical chapters.

Finally, the researcher's dual role as analyst and participant in some improvement initiatives introduces potential interpretive bias. This risk was mitigated through

systematic documentation of the improvement process and triangulation across multiple data sources.

Taken together, these limitations underscore that the contributions of this dissertation are primarily analytical and conceptual. The findings aim to advance understanding of how value-based objectives, operational improvement approaches, and data-driven learning can be aligned in practice. Rather than providing definitive causal evidence of effectiveness, the dissertation develops plausible explanations of how such alignment emerges under real-world conditions.

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PART I

OPERATIONAL IMPROVEMENT IN CLINICAL PRACTICE





3

REDUCING SURGICAL CANCELLATIONS: A SUCCESSFUL APPLICATION OF LEAN SIX SIGMA IN HEALTHCARE

Schretlen, S.*, Hoefsmit, P.*, Kats, S., van Merode, G., Maessen, J., & Zandbergen, R. (2021). Reducing surgical cancellations: A successful application of Lean Six Sigma in healthcare. *BMJ Open Quality*, 10, e001342. <https://doi.org/10.1136/bmjopen-2021-001342>

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Abstract

Objective

The COVID-19 pandemic emphasises the need to use healthcare resources efficiently and effectively to guarantee access to high-quality healthcare in an affordable manner. Surgical cancellations have a negative impact on these. We used the Lean Six Sigma (LSS) methodology to reduce cardiac surgical cancellations in a University Medical Center in the Netherlands, where approximately 20% of cardiac surgeries were being cancelled.

Method

A multifunctional project team used the data-driven LSS process improvement methodology and followed the 'DMAIC' improvement cycle (Define, Measure, Analyse, Improve, Control). Through all DMAIC phases, real-world data from the hospital information system supported the team during biweekly problem-solving sessions. This quality improvement study used an 'interrupted time series' study design. Data were collected between January 2014 and December 2016, covering 20 months prior and 16 months after implementation. Outcomes were number of last-minute coronary artery bypass graft cancellations, number of repeated diagnostics, referral to treatment time and patient satisfaction. Statistical process control charts visualised the change and impact over time. Student's two-sample t-test was used to test statistical significance. A $p < 0.05$ was considered as statistically significant.

Results

Last-minute cancellations were reduced by 50% ($p=0.010$), repeated preoperative diagnostics (X-ray) declined by 67% ($p=0.021$), referral to treatment time reduced by 35% ($p=0.000$) and patient Net Promoter Score increased by 14% ($p=0.005$).

Conclusion

This study shows that LSS is an effective quality improvement approach to help healthcare organisations to deliver more safe, timely, effective, efficient, equitable and patient-centred care. Crucial success factors were the use of a structured data-driven problem-solving approach, focus on patient value and process flow, leadership support and engagement of involved healthcare professionals through the entire care pathway. Ongoing monitoring of key performance indicators is helpful in engaging the organisation to maintain continuous process improvement and sustaining long-term impact.

3.1 Introduction

Healthcare systems are confronted with increasing healthcare expenditure and ageing populations.¹ This requires improvement of organisation efficiency and increased focus on value adding healthcare for patients. The recent COVID-19 outbreak reinforces the fundamental need for more efficient use of scarce hospital resources to keep healthcare systems sustainable.^{2,3}

Coronary artery disease is the leading cause of mortality worldwide.^{4,5} Treatment is organised in different care pathways depending on disease progression, with coronary artery bypass graft (CABG) being one of the final treatment options.⁶ CABG is the most frequently performed procedure within cardiac surgery, representing annual volumes of approximately 200,000 isolated cases in the USA and an average incidence rate of 62 per 100,000 inhabitants in western European countries.⁷⁻⁹ Cardiac surgery has a high impact on patients and hospital resources. To make efficient use of hospital resources such as the operating room (OR) and intensive care unit (ICU), an aligned planning process across the full care pathway is essential. However, last-minute surgical cancellations occur frequently and have a significant impact on hospital resources, costs and quality of care.^{10,11} Prolonged waiting times and delays in treatment for CABG increase the risk of adverse events.^{12,13} The aim of reducing surgical cancellations is consistent with the influential framework created by the Institute of Medicine for addressing

quality improvement in healthcare, covering six domains: safe, timely, effective, efficient, equitable and patient-centred care (STEEEP).¹⁴

Maastricht University Medical Center (MUMC+), a Dutch academic hospital with 5500 employees, 715 beds and 26 ORs, was confronted with approximately 20% last-minute cancellations of planned CABG- procedures in 2014. Besides the significant negative impact on hospital revenue, with a reimbursement of approximately €12,000 per case, the cancellations resulted in lower OR utilisation, prolonged referral to treatment time (RTT), administrative burden of rescheduling operations, repeating of diagnostics, extended length of stay (LOS) and suboptimal patient and staff satisfaction. Furthermore, a decline in production would potentially set the hospital's license to perform certain cardiac surgery at risk.

Under the umbrella of a hospital-wide operational excellence deployment, the department of cardiothoracic surgery initiated a quality improvement project to reduce the number of CABG cancellations.¹⁵ Lean Six Sigma (LSS) is a structured quality improvement methodology that helps organisations to reduce waste and improve flow. It has been effectively applied to healthcare to sustain accessibility, affordability and quality.^{16–21} The aim of this project was to apply LSS to increase the amount of CABG procedures by reducing the number of last-minute cancellations by 50%.

3.2 Methods

This is an 'interrupted time series' quality improvement study according to the Standards for Quality Improvement Reporting Excellence Guidelines 2.0.²² All scheduled CABG surgeries in the MUMC+ between January 2014 and December 2016 were included in this study, covering 20 months prior to full implementation of the changes and 16 months after.

3.2.1 Outcomes

Primary endpoint was the percentage of cancellations 24 hours prior to CABG surgery per month. Secondary endpoints were RTT (in days), number of patients with repeated preoperative diagnostics per month (X-ray) and patient satisfaction.

3.2.2 Data collection and analysis

The surgical planning team registered the number of surgeries and reasons for cancellations in the hospital information system. Data regarding RTT and number of patients with repeated diagnostics were automatically generated in the hospital information system. It was extracted from the hospital system and collected in a separate database. Analysis was performed by using Minitab Statistical Software V.18.1, typically used for LSS projects.

Patient satisfaction was measured by a phone interview with the patient 30 days after discharge from the hospital and presented in the Net Promoter Score (NPS). NPS was based on scores of 0–10, calculated by subtracting the percentage of detractors from the percentage of promoters. Patients were considered promoters (score 9 and 10), passives (7 and 8) and detractors (0 till 6). Statistical difference was tested with Student's t-test for two samples. Descriptive statistics are shown as 95% CIs. A $p < 0.05$ is considered significant.

3.2.3 Lean Six Sigma

The project applied the LSS quality improvement methodology.^{23 24} The project started with shaping a multifunctional team, consisting of the department head of cardiothoracic surgery, an outpatient-clinic staff member, an OR scheduler, the head nurse, a team leader of the ICU, a business intelligence representative and a staff cardiothoracic surgeon. The team participated in a training to understand the five principles of Lean (define value, map the value stream, create flow, establish pull and pursuit perfection) and Lean tools.²⁵ Supported by an LSS master black belt, the project followed the Define, Measure, Analyse, Improve, Control (DMAIC) improvement cycle: 'Define' to identify and scope the challenge,

‘Measure’ to understand and map the baseline capability, ‘Analyse’ to identify the root cause of problems (Value Stream Mapping (VSM), Pareto Analysis and ‘5× Why’), ‘Improve’ to design the new normal and change the way of working based on prioritised countermeasures and ‘Control’ to sustain the gain and measure final capability. Through all phases, real-world data from the hospital information system supported biweekly problem-solving sessions. Work floor visits (Gemba Walks) helped the project team to better understand how value was created and learn about perceived bottlenecks.²⁵

Value stream mapping

VSM is an important tool of LSS to understand the process of value creation from referral to discharge.²⁶ The CABG care pathway consists of the following steps: (1) referral, (2) multidisciplinary heart team meeting to identify the right patient for the right treatment, (3) preoperative visit to perform necessary diagnostics, inform the patient and establish final decision for surgery, (4) admission to the ward to prepare the patient preoperatively, (5) surgery, and subsequently (6) ICU, (7) MCU, (8) ward to recover and (9) discharge.

The project team identified 60 bottlenecks, which hindered patient flow and potentially lead to last-minute cancellations. Most important bottlenecks were used for a more in-depth root cause analysis (5× Why).

Pareto analysis

Pareto analysis of the CABG cancellations presents a hierarchy of the most frequent causes of cancellations (figure 1). Forty-eight per cent of cancellations (n=74) were caused by overrun of previous surgery, in 27% of the cases (n=40) patients were incompletely prepared for surgery, 11% (n=18) was caused by unavailability of ICU beds, 9% (n=14) by medical complications, cardiac surgeons not available (4%, n=5) and last-minute change of treatment plan (1%, n=2).

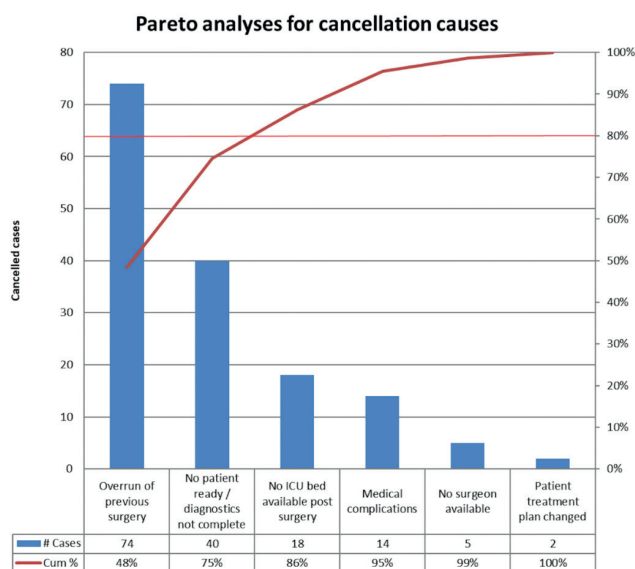


Figure 1. Pareto analyses for cancellations causes

Root cause analysis

The most important VSM bottlenecks and Pareto analysis were input for ‘5× Why root causes analysis’ (figure 2). This methodology is used to understand causes of cancellations more thoroughly. Analysis showed that causes of cancellations were present during all phases of the CABG care pathway:

Preoperative: incomplete preparation of the patient prior to surgery, due to suboptimal documentation, absence of crucial information by referrer, overfull heart team meeting agenda and expired diagnostic tests.

Perioperative: unavailability of an OR because of an overrun of previous surgery. This was caused by inaccurate planning (not tailored to patient characteristics, complexity of procedure and/or staff experience) or late starts (patient, staff or materials arrived late).

Postoperative: bottlenecks in postoperative flow from ICU to MCU and/or ward, caused by inability to discharge patients to the referring centre, rehabilitation clinic, nursing home or directly back home.

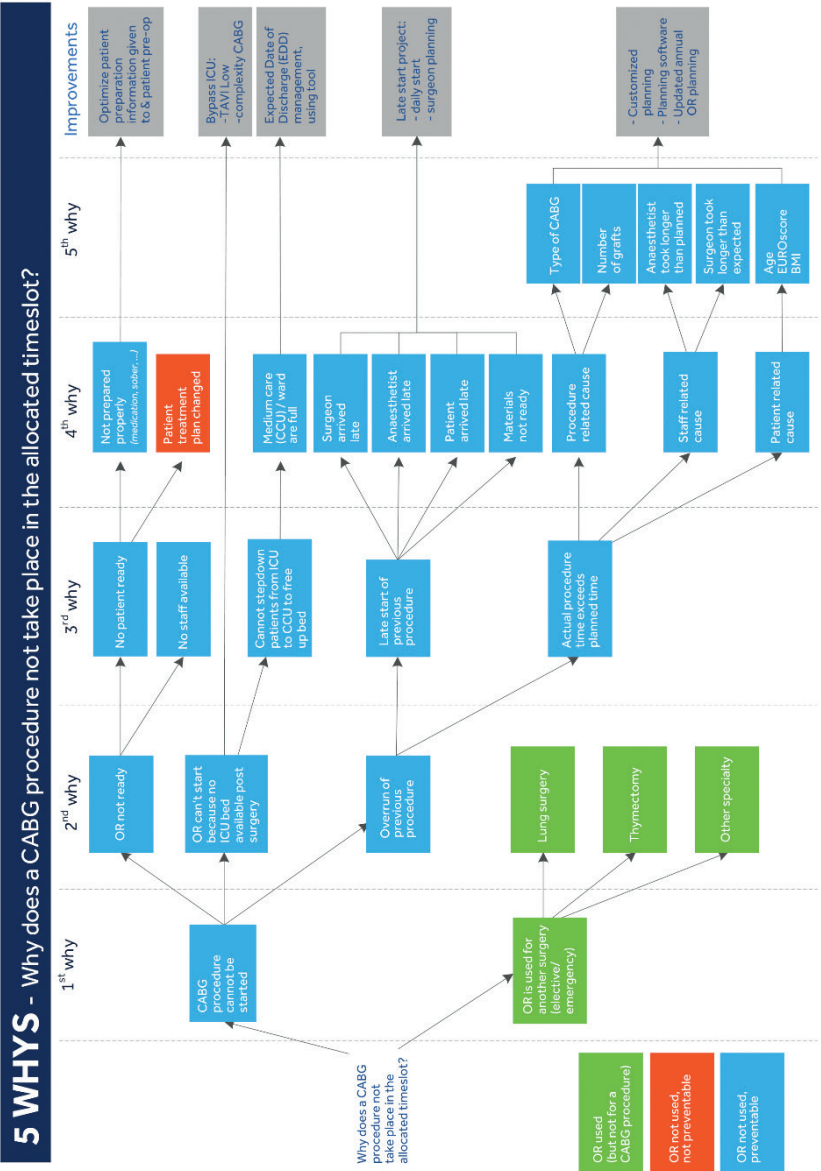


Figure 2. Root cause analysis. BMI, body mass index; CABG, coronary artery bypass graft; ICU, intensive care unit; OR, operating room; CCU, cardiac care unit; TAVI, Transcatheter Aortic Valve Implantation.

3.3 Improvements

Guided by the third and fourth principle of Lean, ‘create flow’ and ‘establish pull’, the project team identified, prioritised and implemented countermeasures for the root causes of the problems. A summary of improvements to optimise patient flow per process phase is presented in figure 3.

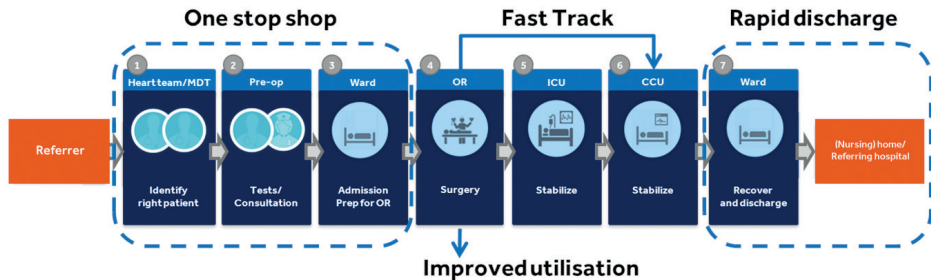


Figure 3. Process map with high-level improvements. MDT, Multidisciplinary Team Meeting; OR, Operating Room; ICU, Intensive Care Unit; CCU, Cardiac Care Unit.

3.3.1 Preoperative phase

Optimising preparation heart team meeting

During heart team meetings, cardiac surgeons and cardiologists discuss all referred patients that are eligible for surgery and decide on treatment plan and priority. Incomplete patient information frequently led to delays in decision making. To tackle this, a checklist for administrative requirements from referring centres was introduced. Patients were only accepted for the heart team meeting if all required information was complete. Second, another cause for delayed decision making was an overfull list of patients being offered for treatment. Therefore, a secretary was appointed to enhance preparation of the heart team meeting with a detailed agenda and an overview of complete patient information. These countermeasures eliminated time of searching for patient information during the meeting and supported timely preparation of patients for surgery. Furthermore, time was saved by standardisation of documentation after decision making and direct, electronic communication to referring centres and practitioners.

One-stop-shop preoperative clinic

To minimise the number of preoperative visits and reduce time to treatment, a one-stop shop care carousel was created. During a single hospital visit, patients were consulted by a nurse practitioner (NP) or physician assistant (PA), anaesthesiologist and cardiac surgeon for all required diagnostics (ECG, bloodwork, X-thorax). Doctor assistants coordinated patient flow. They ensured the exchange of all required information and documentation for successful admission and surgery as well. The one-stop-shop visit was not planned before the date of surgery was known, which prevented repeating of preoperative diagnostics (eg, X-ray), if they were older than 6 weeks. This is an example of the application of the Lean ‘pull’ principle, which assumes that one should only produce if there is demand. In this case, a patient should only be prepared for surgery once a date of the surgery is planned, so that preoperative diagnostics are still up to date at the time of the surgery.

3.3.2 Perioperative phase

Smart OR scheduling

The Pareto chart shows that overrun of a previous surgery is the most common reason to cancel a surgery. ‘5× Why’ analysis showed that ‘unrealistic planning’ is an underlying root cause, for example, scheduling two subsequent high complex cases in one OR. We, therefore, introduced a new flexible OR schedule, consisting of basic weekly schedules with time slots. Patients were assigned to time slots depending on the predicted duration of the surgery. More accurate time predictions together with risk stratification were implemented. Characteristics used to predict time durations for CABG were complexity of the procedure and patient characteristics, for example, number of bypasses, type of CABG and Euroscore II.²⁷ Time slots were reserved for urgent surgery to avoid cancellations of elective cases. There was an additional list created of elective cases to fill the time slot if there was no patient for emergency surgery.

Surgery check-in

Another cause for overrun of procedures were 'late starts'. A specific problem-solving session (Kaizen) on this topic resulted in the introduction of a surgery check-in with all involved healthcare professionals present before the procedure started.^{23 28} This forced the team to arrive on time, check completeness of materials and discuss potential bottlenecks and challenges, avoiding delays during surgery.

Culture of engagement

The project team members admitted that working in independently organised 'silos' in the CABG care pathway resulted in suboptimal working practices and the inability to see the impact of actions in other parts of the process. The VSM sessions, the analysis of patient surveys and shared experiences by the project team, provided insights in the impact of delays and cancellations. It is strongly believed that the Kaizen procedure would result in increased responsibility and commitment by the full team towards the patient, the treatment plan and the schedule of the day.

Support from the board

To encourage finishing the entire elective OR programme, even when the last procedure was expected to end later than scheduled, the hospital board approved extended surgical hours and additional payment for overtime.

3.3.3 Postoperative phase

To secure availability of beds in the ICU, MCU and ward after surgery, the following countermeasures were implemented in the postoperative phase:

Dedicated ICU beds

To guarantee availability of ICU beds after surgery, a service-level agreement was signed to allocate four beds for cardiac surgery on a daily basis.

Fast-track ICU

Postoperative patient flow was optimised by the implementation of 'fast-track'-procedures where patients, if possible, were directly admitted to the MCU after surgery, bypassing the ICU.

Rapid discharge

To support in-time discharge and consequently reducing preventable hospital stay that impacted patient flow, an Information Technology (IT) discharge planning tool was implemented to monitor and visualise LOS per patient. Service-level agreements were made with referring centres and nursing homes to secure availability of beds when patients were ready for discharge.

3.3.4 Continuous improvement

Key performance indicator dashboard

After implementation of countermeasures, dashboards with key performance indicators (KPI) were developed and monthly reviewed by the team to anticipate when cancellations or underlying causes tend to increase again.

3.4 Results

The outcomes are presented in figure 4 and table 1. Per month 84 CABG procedures were scheduled. The implemented countermeasures reduced the number of cancellations per month from 16 to 8 ($p=0.010$). Annually, this led to an increase of 95 procedures. Within the Six Sigma methodology, the error rate is defined as number of defects (cancellations) per million opportunities (DPMO). DPMO is calculated as sigma level (6 sigma equals 3.4 defects per million opportunities). This project improved the sigma level from 2.4 to 2.8.

Number of repeated diagnostic X-thorax decreased by 67%, from preintervention 3 to postintervention 1 per month ($p=0.021$). RTT decreased by 35% from 71 to 46 days ($p=0.000$).

From the 399 patients interviewed preintervention, 20% were promoter, 74% passive and 6% detractor, resulting in an NPS of 14%. NPS postintervention (n=546) is 28%, consisting out of 30% promoters, 68% passives and 2% detractors. NPS improved with 14% ($p=0.005$).

3.4.1 Unintended consequences

Without being outcomes of this project, employee satisfaction and LOS were also positively impacted. Participation in the project increased awareness and engagement, which improved team morale. The OR-scheduling team mentioned they experienced a higher work satisfaction. Due to implemented countermeasures that enabled later admission and earlier discharge LOS was reduced from 10.5 to 9.8 days per patient on average, equalling approximately 600 hospital bed-days annually. The opportunity of extending surgical hours and paid overtime did result in more finished programmes, but not in remarkable prolonged surgical time.

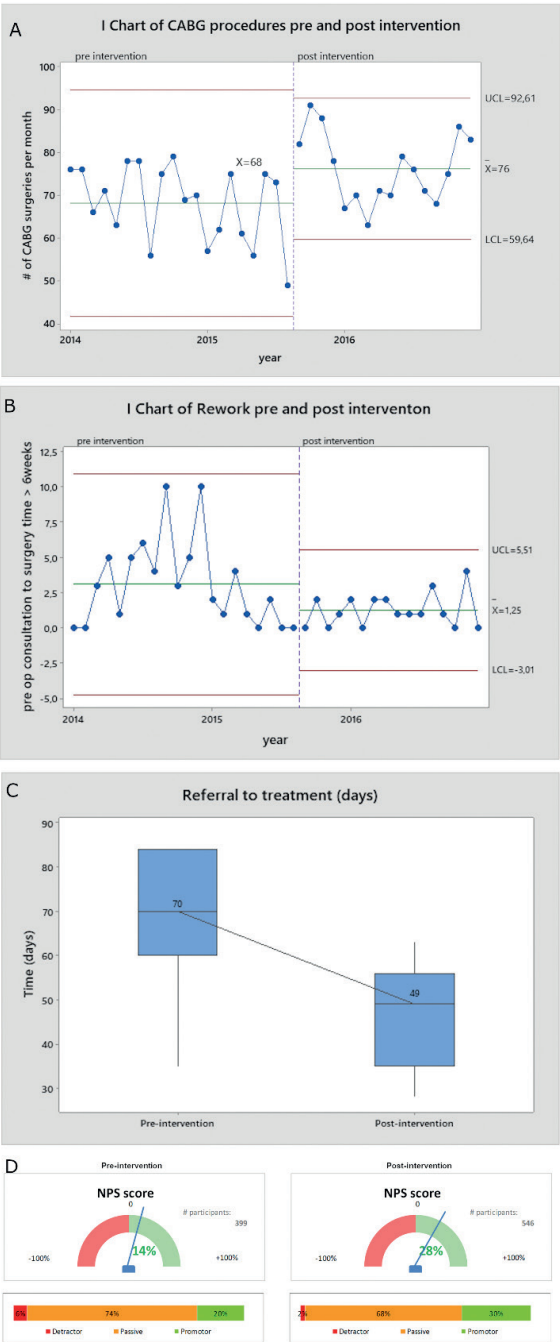


Figure 4. Impact of intervention(s) on (a) number of procedures per month, (b) % of rework, (c) referral to treatment time and (d) patient satisfaction. cabg, coronary artery bypass graft; nps, net promoter score; lcl, lower control limit; ucl; upper control limit.

Table 1. Outcomes

KPIs	Preintervention	Postintervention	Difference	P value
Cancellations per month	16 (19%)	8 (10%)		
DPMO	190476	95238	7.88 (95% CI 2.06 to 13.69)	0.010
Sigma level	2.4	2.8		
Patients with repeated preoperative diagnostics (X-thorax, per month)	3	1	-1.85 (95% CI -3.39 to -0.31)	0.021
Referral to treatment times (days)	71	46	-24.36 (95% CI -33.48 to -15.24)	0.000
Patient satisfaction (NPS)	14% (n=399)	28% (n=546)	13.65 (95% CI 4.57 – 22.72)	0.005

DPMO, Defects Per Million Opportunities; KPIs, Key Performance Indicators; NPS, Net Promotor Score.

3.5 Discussion

This quality improvement project reports a successful application of LSS to significantly reduce the number of surgical cancellations in a University Medical Center in the Netherlands. By applying tools such as VSM, data-driven root cause analysis, patient experience surveys (voice of the customer) and Gemba Walks, improvement opportunities along the full CABG care pathway were identified. This led to the implementation of prioritised countermeasures preoperative: (1) integrating preoperative activities in a one-stop-shop care carousel, (2) better preparation of multidisciplinary heart team meetings, (3) increased focus on ‘first time right’ diagnostics by ‘pull’ planning. Perioperative improvements included (4) flexibility of OR planning and (5) increased focus on timely start of the surgical programme. Postoperative patient flow improved by (6) introduction of ICU-fast track, (7) service-level agreements to dedicate ICU beds for cardiac

surgery and (8) proactive discharge planning. These countermeasures resulted in improvements covered by the STEEP principles.¹⁴ More efficient use of OR and hospital bed capacity enabled eight additional CABG procedures per month ($p=0.010$) and freed up approximately 600 hospital bed days annually, more effective scheduling of preoperative diagnostics (eg, X-rays) cut 67% of duplicated tests ($p=0.021$), with positive impact on patient safety (less radiation), reduction of waiting times by 35% ($p=0.000$) guaranteed timely access for all patients in need for care (equitable), and the more patient-centred care process increased patient satisfaction (NPS) by 14% ($p=0.005$).

Key strength of this study is the in-depth root cause analysis performed by the project team, represented by healthcare professionals throughout the entire CABG care pathway. Patient focus was considered as crucial. In total, 945 patients were interviewed 2 weeks after surgery. Their feedback provided the project team insights to improve the process and consequently the patient experience. Three full years of CABG surgery data were obtained, enabling enough power to prove significant improvement on all defined KPI's. Data were automatically generated in the hospital information system, allowing replicability and scalability. No major changes other than the process optimisation took place during the included period. Additionally, training the project team about the LSS methodology combined with support from an external LSS master black belt contributed to comprehensive and structured problem solving. We observed that involving team members across the value stream changed their perspective from independently functioning players to team players with a more holistic view on patient value across the complete care pathway. A possible contribution to the success of this project is the commitment by the board of directors to allow overtime payment, supporting to finish the surgical programme. This indicates that leadership engagement and organisational alignment are important to successfully implement the necessary change.²⁹

Lean aims to reduce waste and optimise flow, where Six Sigma is a structured data-driven way to reduce defects and process variation. The combination of Lean with Six Sigma has been reported to have a synergetic effect.³⁰ Nicolay *et al* performed a systematic review regarding quality improvement efforts, among which LSS, for surgical patients.¹⁷ Even though they included more studies that used Lean ($n=4$) or Six Sigma ($n=5$) separately, they found one study by Niemeijer

et al implementing LSS (DMAIC) to reduce LOS with 3 days with a 10-month follow-up for patients with trauma.³¹ In their study, a VSM was performed from admission to discharge to discover factors that impacted LOS. Nevertheless, they do not report a quantitative Pareto analysis and an in-depth root cause analysis. Also, patient satisfaction was not monitored. Several publications about successful applications of LSS to various aspects in healthcare exist. LSS has been effectively applied to introduce care pathways,^{20 32} improve OR efficiency,^{16 18 19 33} shorten RTT,¹⁶ streamline discharge procedure,³¹ improve patient outcomes³⁴ and improve financial performance.^{16 17} For reducing OR cancellations, we found only one study using Six Sigma.³⁵ Our study combined LSS to reduce OR cancellations and focused on optimising flow in the entire care pathway and patient value, rather than a single step in the process or financial impact. Cook *et al* implemented LSS tools such as VSM to create a ‘focused factory model’ for cardiac surgery in Mayo Clinic (Rochester, Minnesota).³⁶ They reduced resource use, LOS and costs by decreasing the variation within care delivery for specific patient groups, using information technology tools and empowering non-physicians at the bedside for patient care.³⁶ The authors also reported that cultural change, persistence and leadership is essential, besides the implementation of change management itself.³⁶

Our study supports the evidence that the right application of LSS leads to a more efficient organisation of healthcare, with improved use of resources and higher patient satisfaction. We believe that the improvements in this study can be successfully applied to other hospitals and medical conditions, yet we stress the importance of hospital teams going through the DMAIC problem solving methodology themselves. Surgical cancellations are common and not unique for cardiac surgery.^{37–40} Our improvements may be suitable for other hospitals, for example, organising preoperative activities in a one-stop-shop setting or a fast-track ICU. However, situations and contexts differ. Adopting change may be complicated because of hidden or unexpected powers that backfire on solutions that work perfectly elsewhere. Also, the concept of ‘not-invented-here-syndrome’ may complicate adopting change as well.

The Define, Measure and Analyse phases enhance understanding of the context and complexity, and thus preventing jumping to solutions if the root causes of problems are not identified before implementing countermeasures. Furthermore,

this method encourages shaping a project team with representatives of different stakeholders from the entire care pathway, and therefore, contributing to team engagement and adopting change.⁴¹ Although we do not recommend to blindly copy improvement actions from one place to the other without understanding the context, we do recommend sharing of best practices by publishing and by exchange visits between hospitals. The latter may also strengthen team morale, inspire out-of-the-box ideas and prevent tunnel vision.

This project illustrated the consequence of fragmentation in care processes and healthcare systems in general. The system is generally organised around independent care providers (silos) rather than in care pathways around the patient, which is where the majority of inefficiencies can be found.⁴² Inefficiencies in care delivery systems lead to imbalance and suboptimal flow, resulting in waste such as cancellations, repeating of diagnostics, prolonged RTT, waiting lists and consequently lower staff satisfaction. This is a vicious downward spiral between process waste (Muda), unevenness or variation (Mura) and overburden of the system (Muri).⁴³ The challenge of improving healthcare finds itself in understanding the complex whole of interrelated and interconnected parts, rather than separate entities.⁴⁴ This also means that technical solutions by themselves do not adequately counter problems that are influenced by a complex health system.²⁹ Our approach ensured a pathway-centred way of identifying and resolving inefficiencies by comprehensive analyses of the context of surgery cancellations from multiple perspectives (patients, healthcare professionals with different functions, management) through the entire value stream. The visualisation of process performance and impact on the patient helped to create sense of urgency and improve team commitment, which significantly contributed to sustainable and accepted change.

The primary focus of this project was to improve quality instead of optimising hospital revenue. However, by improving the process, the hospital increases production with 96 extra surgeries annually. This gets accompanied with €1.15M additional revenue. Since hospital costs on staff and ORs are generally made regardless of cancellations, the amount of value (quality) created per euro spent on society level is increased. The in-hospital burden of rescheduling procedures, duplicated diagnostics, frustrations and negative morale have significantly

improved, and these resources can now be spent to contribute positively to a sustainable system.²⁹

The COVID-19 pandemic emphasises that healthcare capacity is scarce, and that efficient and effective use of it is required to guarantee access to high quality and affordability of healthcare. Surgical cancellations have a negative impact on all these challenges, which encouraged us to share and publish our LSS project a few years after the project was finalised.

The study has several limitations. It is a single-centre study focusing on one specific procedure. As the pre time frame and post time frame do not exactly cover the same number of months, the difference in average number of CABG procedures performed per month may be partly explained by seasonality. The large number of countermeasures implemented in the same time period, as well as the intrinsic motivation of involved project team members, makes it difficult to evaluate what the most meaningful interventions were. For example, this study has not analysed the influence of a smarter scheduling on surgical cancellations exclusively from other implemented improvements. Even though the reduction in number of repeated diagnostics is significant, it is based on a limited number. The improved NPS could also have been affected by other factors, such as a positive outcome of the surgery. The interpretation of causal relationships between interventions and results may also be compromised due to the used 'interrupted time series' study design. A randomised controlled trial could control for this. However, it may be a challenging study design for an LSS quality improvement project. We encourage further research to the sustainability of the improvements, for example, reported in the study of van der Voort *et al.*⁴⁵ We believe that hospital information systems support more structured data capturing and thus facilitating real-time evaluation of KPIs, such as cancellation rates and its root causes. We recommend further research to the impact of real-world data on engagement of healthcare professionals and continuous improvement.

3.6 Conclusions

LSS is a proven structured approach that helps organisations to reduce waste and improve flow through the entire care pathway. This study shows how the application of LSS in healthcare, and particularly for reducing surgical cancellations, leads to significant improvement of resource utilisation, patient satisfaction and engagement of healthcare professionals.

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4

DEVELOPMENT AND IMPLEMENTATION OF A CARDIAC RESYNCHRONISATION THERAPY CARE PATHWAY: IMPROVED PROCESS AND REDUCED RESOURCE USE

Van Stipdonk, A. M. W.*, **Schretlen, S.***, Dohmen, W., Brunner-La Rocca, H. P., Knackstedt, C., & Vernooij, K. (2021). Development and implementation of a cardiac resynchronisation therapy care pathway: Improved process and reduced resource use. *BMJ Open Quality*, 10, e001072. <https://doi.org/10.1136/bmjoq-2020-001072>

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Abstract

Objective

Cardiac resynchronization therapy (CRT) requires intensive, complex and multi-disciplinary care to maximize the clinical benefit. In current practice this is typically a task for highly specialized physicians. We report on a novel multidisciplinary, standardized CRT care pathway (CRT-CPW) with structured aids to transfer heterogeneous physician- to standardized nurse-led care with a reduction in resource use.

Design and setting

Electrophysiologists and HF cardiologists developed a structured CRT-CPW with simple and broadly applicable aids based on clinical evidence and identified shortcomings in current CRT care. The resulting CPW was implemented at the Maastricht University Medical Center.

Participants and measures: Benchmarked usual care (2012-2014, 122 patients) was compared to the CRT-CPW (2015-2017, 115 patients). The primary outcomes were process-related: number of physician consultations, nurse consultations, length of stay (LOS) at implantation and total hospitalization days during 1 year follow-up, number of in person visits to the outpatient clinic, and referral to treatment time.

Results

Patients in the CRT-CPW consulted nurses and technicians significantly more often than patients in the usual care group (2.4 ± 1.5 vs 1.7 ± 2.0 , $p < 0.0001$ and 4.3 ± 2.5 vs 3.7 ± 1.5 , $p = 0.026$, respectively). CRT-CPW patients consulted physicians significantly less often (1.7 ± 1.4 vs 2.6 ± 2.1 , $p < 0.001$). Referral to treatment time was significantly reduced in the CRT-CPW group (23.6 ± 18.4 vs 37.0 ± 26.3 days, $p = 0.002$). LOS at implantation and total hospitalization days were significantly

reduced in the CRT-CPW group (1.1 ± 1.2 vs 1.5 ± 0.7 days, $p < 0.0001$ and 2.4 ± 4.8 vs 4.8 ± 9.3 , $p < 0.0001$, respectively).

Conclusion

The introduction of a novel CRT-CPW resulted in a successful transition of physician- to nurse-led care, with a significantly reduced resource utilisation. Future evaluations are needed to identify impact on outcomes versus costs, to evaluate cost-effectiveness of the CRT-CPW.

4.1 Introduction

4

Cardiac resynchronization therapy (CRT) is one of the most successful heart failure (HF) therapies that have emerged over the last few decades. Several randomized clinical trials have shown that CRT reduces symptoms of HF, improves exercise capacity and quality of life, and reduces hospitalizations and mortality.¹⁻⁴ Clinical guidelines of the European Society of Cardiology and the American College of Cardiology Foundation/American Heart Association endorse these results and recommend utilisation of CRT in selected HF patients.^{3,5-7}

Despite guidelines and experts' consensus, variability in patient selection, implantation techniques, in-hospital management and follow-up is observed in clinical practice.⁸⁻¹⁰ A recent multicentre registry revealed significant heterogeneity in both definition of response and non-response to CRT, and consequential optimization of therapy¹³. Overall the rate of suboptimal benefit from CRT remained as high as 30%.¹¹ In order to overcome suboptimal benefit from CRT, care for these patients requires thorough selection for treatment, skilled implanting physicians and a comprehensive follow up treatment and comorbidity management. Few studies have introduced CRT care programs, including resource intensive, specialised follow-up, personalized therapy delivery and frequent visits of patients after CRT implantation. These studies generally show a positive effect on outcomes.¹²⁻¹⁴ The extensive and comprehensive nature of these optimization programs however limits the widespread implementation in clinical practice.

In general HF care, the transition from physician led to nurse led care has been well accepted, as studies show that nurse-led multidisciplinary HF programmes result in a reduced risk of HF hospitalization. These programmes have been broadly adopted in clinical practice.¹⁵⁻¹⁹ Moreover, studies have shown that structured aids in HF care programs can lead to improved adherence to guidelines.^{20 14 21} These developments in general HF care, however, have not been introduced into CRT care programs yet.

The present study describes the development and implementation of a CRT care pathway (CRT-CPW), a blueprint for CRT care transition from physician led to a standardized, nurse led care program, which aims to reduce healthcare and patient burden at equal or better quality of care, with help of structured aids and advanced planning.

4.2 Methods

4.2.1 CRT care pathway design

In 2013 three expert centres (Maastricht University Medical Center (MUMC+), the Netherlands; Liverpool Heart & Chest Hospital, England; and Rigshospitalet Copenhagen, Denmark) took the initiative to collectively design a CRT-CPW. Consensus meetings were conducted to evaluate and discuss currently available evidence for patient evaluation and selection, device implantation, follow-up care, and process-related factors. CRT-CPW design was deepened into an operational CRT-CPW for the MUMC+, detailing actions and resources needed, as shown in Figure 1. Checklists were created to be applied during specific contact moments with the patient. Detailed descriptions of the operational care pathway, including process maps and checklists, are provided in the supplementary material of the original publication. The final consensus CPW consisted of 4 important elements aiming to maintain or improve quality with effective resource use: (1) structured involvement of both heart failure and electrophysiological expertise in the process steps, (2) transition of tasks from physicians to specialized nurses and technicians, (3) ensuring to check and control variables contributing to optimal CRT care by

means of checklists at each process step, and (4) structured planning of patient visits (incl. hospitalisation for implantation) for each process step, with one-stop-shop visits, to reduce unnecessary resource use and patient burden (Figure 1-3).

4.2.2 Operational CRT-care pathway (figure 1-3).

For patients referred for CRT implantation a weekly multidisciplinary meeting with HF cardiologists and electrophysiologists was set up to assess eligibility. Baseline parameters possibly affecting patient outcomes are checked following the 'referral review' checklist. In case additional work-up is needed for a patient, the referring physician is contacted, and the patient is re-evaluated after completion of diagnostic evaluations and/or optimization of general HF therapy. After approval for CRT, the implantation is scheduled; a one-stop-shop outpatient was planned for pre-operative assessment, including education and informed consent of the patient. This consultation is conducted by the implanting physician and a dedicated nurse, guided by a 'pre-assessment' checklist. The operational elements of the referral review and pre-assessment are displayed in Figure 1.

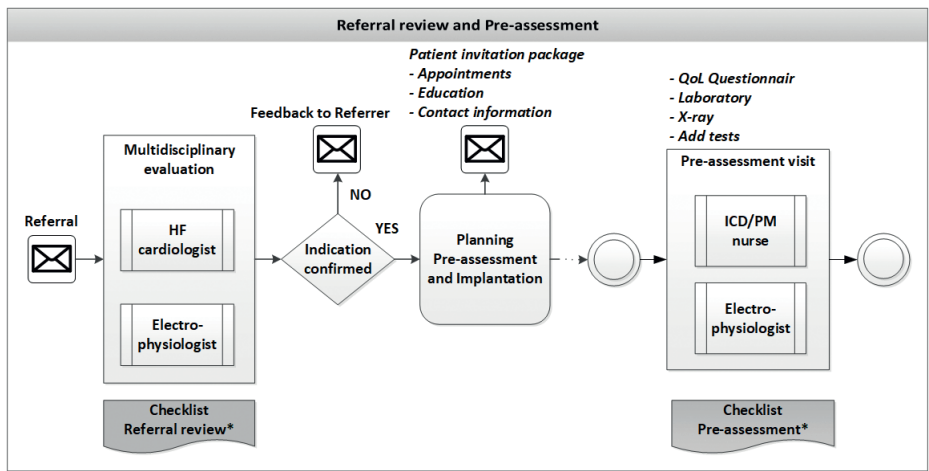


Figure 1. Operational CRT care pathway; referral review and pre-assessment. An overview of the referral review and pre-assessment parts of the implemented operational CRT care pathway with steps a patient goes through in the care pathway are indicated with content of the assessments and structured aids available for the assessment.

CRT-CPW changes related to implantation procedure focused on the structural collection of patient- and implantation related information, to be able to facilitate same-day discharge and availability of implantation related information needed during follow-up. Hospital discharge was supported by a ‘pre-discharge’ checklist which is introduced to verify the absence of implantation related complications, medication verification, patient education and follow-up management planning. The operational CRT-CPW implantation phase is summarized in Figure 2.

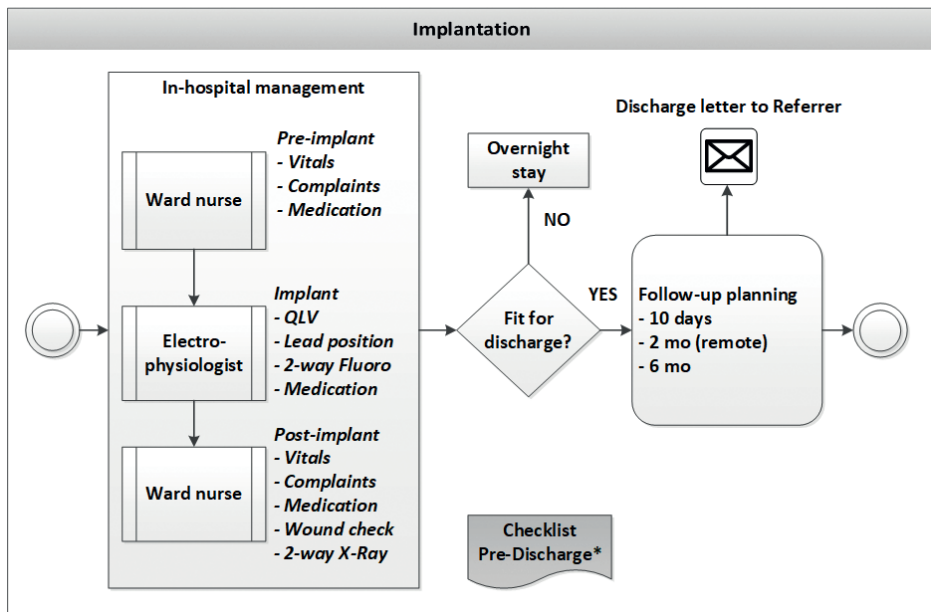


Figure 2. Operational CRT care pathway; Implantation. An overview of the implemented operational CRT care pathway with steps a patient goes through in the care pathway are indicated with content of the assessments and structured aids available for the assessment.

The CRT-CPW follow-up management consists of pre-planned visits from hospital discharge onwards, up to follow-up consultation at 6 months after implantation including echocardiographic evaluation. One-stop-shop consultations with PM/ICD nurse and device technician at 1 to 2 weeks, and thereafter HF nurse and technician at 2 months and 6 months take place. The device technician checks and if applicable change device programming and report on device HF diagnostics. The dedicated HF nurses act upon device information, optimize HF medical regimen considering comorbidity affecting treatment, and support the patient with medication compliance and lifestyle changes. All post implant consultations are guided by an 'optimization' checklist. Whenever optimal conditions are not met, consequent actions are taken. In case specialist intervention is considered (e.g. Atrial fibrillation or His-ablation), this is discussed in the multidisciplinary meeting. At 6 months the one-stop-shop consultation includes echocardiographic evaluation, and benefit from CRT is assessed accordingly. Whenever a patient is thought to have improved too little from CRT, the patient is evaluated in the multidisciplinary meeting. The CRT-CPW allows for planning extra consultations if

needed from a device or HF perspective with respective specialists and/or nurses. The operational CRT-CPW follow-up phase is displayed in Figure 3.

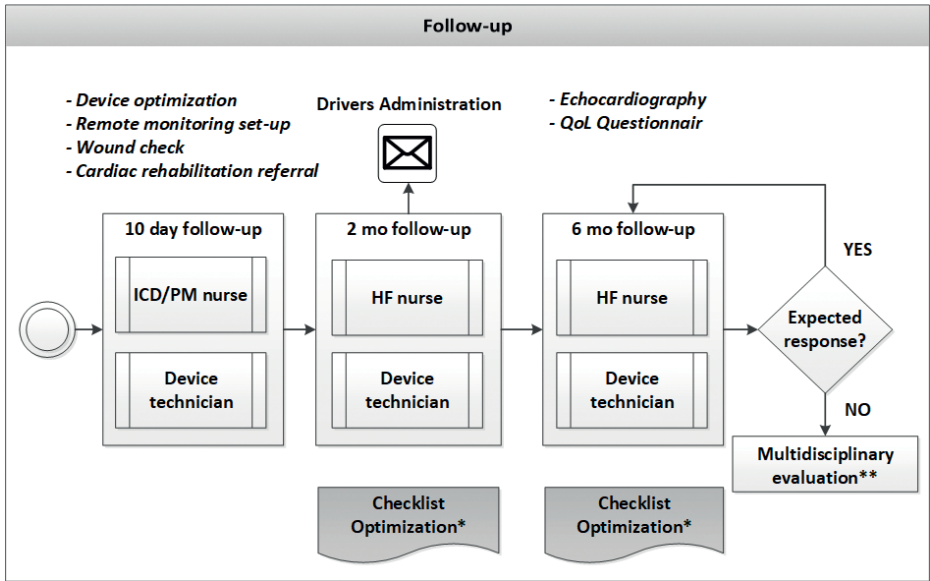


Figure 3. Operational CRT care pathway; follow-up. An overview of the follow-up part of the implemented operational crt care pathway with steps a patient goes through in the care pathway are indicated with content of the assessments and structured aids available for the assessment.

4.2.3 CRT care pathway implementation

The CRT-CPW has been implemented at the MUMC+. A phased implementation strategy was used to introduce the CRT-CPW in functional parts of the care process; being the patient referral and pre-assessment, the implantation procedure, and finally the follow-up management, as different stakeholders are involved in these steps. Between January and September 2014 all stakeholders were trained on the CRT-CPW, using the checklists provided and introducing logistical and IT support changes to improve planning of consultations for the patients.

4.2.4 Data collection and analysis

The study was performed according to the Declaration of Helsinki and was approved by the Medical Ethics Committee. Baseline characteristics and process metrics from all patients, from 6 months before the device intervention until one year after device implant were collected by extracting data from the MUMC+ (electronic) Hospital Information System. All patients that received care in the MUMC+ before and after the intervention, and had a non-urgent “de novo” CRT device implantation or upgrade to CRT were eligible for the study. Patients treated before the implementation of the CRT-CPW (January 2012 up to December 2014; usual care) were compared with patients treated after the implementation of the CRT-CPW (January 2015 up to December 2017). This research was done without patient involvement.

4

4.2.5 Study outcomes

Process Key Performance Indicators (KPI's) were used as primary outcome measures. Process metrics were calculated for the period of 6 months prior to implantation of the CRT device, up to 12 months after the implantation of the CRT device.

Successful transition of care was measured by the number of physician and nurse and/or technician consultations, with specification of the specialism of the physician consulted. Resource utilisation was evaluated by number of consultations and number of outpatient visits (defined as consultations that are not on the same day). Moreover, time from referral to CRT device implantation, the length of stay in days (LOS) after implantation, and the total hospitalization days during follow-up were evaluated.

4.2.6 Statistical analysis

Results are reported with means and standard deviations for numeric variables and counts and percentages for categorical variables. Variables are compared using Student's t-test or Wilcoxon ranksum test for continuous variables, Fisher's

exact test for proportions, and the Cochran-Mantel-Haenszel test for trend in ordinal variables.

4.3 Results

4.3.1 Patient characteristics

In total 837 patients received a CRT device between January 2012 and December 2017 at MUMC+. Of these patients, 531 were referred by external physicians, with incomplete follow-up available for analysis. 61 patients had urgent (clinical) implants, and hence not able to complete the entire CRT-CPW, and 8 patients were excluded because of missing data on the primary outcomes. The study cohort comprised a total of 237 patients available for analysis.

Data collected from 122 patients referred for elective implantation of a CRT device according to usual care and data from 115 patients after introduction of the CRT-CPW were analysed. The baseline characteristics of the two groups were largely comparable (table 1). CRT-CPW patients more frequently underwent an upgrade procedure (23.5 vs 12.3%, $p=0.027$) and more frequently had a history of myocardial infarction (47.8 vs 33.6%, $p=0.034$).

Table 1. Overview of baseline patient characteristics

Baseline characteristics	Usual care (N = 122)	CRT-CPW (N = 115)	P-value*
Male	90 (73.8%)	81 (70.4%)	0.66
Age (years)			0.16
18-64	35 (28.7%)	24 (20.9%)	
65-74	43 (35.2%)	45 (39.1%)	
75-99	44 (36.1%)	46 (40.0%)	
NYHA class			0.071

Table 1. Overview of baseline patient characteristics *Continued.*

Baseline characteristics	Usual care (N = 122)	CRT-CPW (N = 115)	P-value*
Class I	5 (4.1%)	6 (5.2%)	
Class II	70 (57.4%)	46 (40.0%)	
Class III	25 (20.5%)	29 (25.2%)	
Class IV	1 (0.8%)	5 (4.3%)	
missing	21 (17.2%)	29 (25.2%)	
LBBB	61 (50.0%)	59 (51.3%)	0.90
QRS duration (ms)	161.5 ± 29.1	159.7 ± 29.2	0.62
LVEF (%)	29.4 ± 8.4	30.2 ± 8.8	0.50
Ischemic Cardiomyopathy	52 (42.6%)	59 (51.3%)	0.19
Hypertension	48 (39.3%)	41 (35.7%)	0.59
Myocardial Infarction	41 (33.6%)	55 (47.8%)	0.034
Atrial Fibrillation	49 (40.2%)	57 (49.6%)	0.15
Chronic Lung Disease	18 (14.8%)	14 (12.2%)	0.58
Diabetes	21 (17.2%)	32 (27.8%)	0.061
Glomerular Filtration Rate (MDRD formula)	62.2 ± 27.5	59.4 ± 21.1	0.38
Beta blocker	103 (84.4%)	98 (85.2%)	1.00
ACEi / ARB	106 (86.9%)	99 (86.1%)	1.00
MRA	56 (45.9%)	68 (59.1%)	0.051
Upgrade	15 (12.3%)	27 (23.5%)	0.027
ICD	90 (73.8%)	79 (68.7%)	0.39

4.3.2 Process metrics

Table 2 summarizes the process metrics for the usual care and CRT-CPW. Patients referred for a CRT device after CRT-CPW implementation had a comparable number of hospital visits as usual care patients (10.1 ± 4.3 vs 10.8 ± 4.1 , $p=0.21$). However, there were significantly more pre-implantation visits in the CRT-CPW group, than in the usual care group (1.6 ± 1.4 vs 1.2 ± 1.5 , $p=0.010$). CRT-CPW visits included significantly more individual consultations than in the usual care group (9.9 ± 4.2 vs 8.1 ± 3.4 , $p<0.0001$). The number of consultations were significantly higher in the pre-implantation phase (2.1 ± 1.8 vs 1.2 ± 1.5 , <0.0001) and showed a trend toward significant increase in the post-implantation phase (7.8 ± 3.7 vs 6.9 ± 2.8 , $p=0.059$). (Table 2)

Patients in the CRT-CPW consulted HF nurses, Pacemaker/ICD nurses and pacemaker/ICD technicians significantly more often than patients in the usual care group (2.4 ± 1.5 vs 1.7 ± 2.0 , $p<0.0001$, 0.8 ± 0.7 vs 0.0 ± 0.3 , $p<0.0001$, and 4.3 ± 2.5 vs 3.7 ± 1.5 , $p=0.026$, respectively). At the same time CRT-CPW patients consulted physicians significantly less often (1.7 ± 1.4 vs 2.6 ± 2.1 , <0.001) (Table 2). Although consultations to all subspecialties of physicians that were involved with CRT care showed a reduction, only HF cardiologist consultations decreased significantly (0.4 ± 0.7 vs 1.0 ± 1.7 , $p=0.008$).

Time from referral to implantation of the CRT device was significantly reduced in the CRT-CPW group (23.6 ± 18.4 vs 37.0 ± 26.3 days, $p=0.002$). Total hospitalization days during the observation period was significantly reduced in the CPW patient group (2.4 ± 4.8 vs 4.8 ± 9.3 , $p<0.0001$). This reduction includes a significant reduction in LOS at implantation (1.1 ± 1.2 vs 1.5 ± 0.7 days, $p<0.0001$), with a significant increase in patients with a same day discharge and only one night stay at implantation (7 vs 28% and 43 vs 78%, respectively). (Table 2)

Table 2. Process metrics for the usual care and CRT-care pathway

Process metrics	Usual care (N = 122)		CRT care pathway (N = 115)		P-value*
	mean $\pm$ SD	median (IQR)	mean $\pm$ SD	median (IQR)	
Time to treatment	37.0 $\pm$ 26.3	29.2 (16 - 53)	23.6 $\pm$ 18.4	21.0 (10 - 31)	0.002
Outpatient clinic visits (n)	10.8 $\pm$ 4.1	10.0 (8 - 13)	10.1 $\pm$ 4.3	10.0 (7 - 12)	0.21
Pre procedure	1.2 $\pm$ 1.5	1.0 (0 - 2)	1.6 $\pm$ 1.4	1.0 (0 - 2)	0.010
Post procedure	6.8 $\pm$ 2.7	7.0 (5 - 8)	7.5 $\pm$ 3.5	7.0 (5 - 10)	0.099
Outpatient clinic consultations (n)	8.1 $\pm$ 3.3	8.0 (6 - 10)	9.9 $\pm$ 4.2	10.0 (7 - 12)	< 0.001
Pre procedure	1.2 $\pm$ 1.5	1.0 (0 - 2)	2.1 $\pm$ 1.8	2.0 (0 - 3)	< 0.0001
Post procedure	6.9 $\pm$ 2.8	7.0 (5 - 8)	7.8 $\pm$ 3.7	7.0 (5 - 10)	0.059
Physician	2.6 $\pm$ 2.1	2.0 (1 - 4)	1.7 $\pm$ 1.4	2.0 (1 - 2)	< 0.001
HF nurse	1.7 $\pm$ 2.0	1.0 (0 - 3)	2.4 $\pm$ 1.5	2.0 (1 - 3)	< 0.0001
Pacemaker/ICD nurse	0.0 $\pm$ 0.3	0.0 (0 - 0)	0.8 $\pm$ 0.7	1.0 (0 - 1)	< 0.0001
Pacemaker/ICD technician	3.7 $\pm$ 1.5	3.0 (3 - 4)	4.3 $\pm$ 2.5	4.0 (3 - 5)	0.026
Length of hospital stay (days)	4.8 $\pm$ 9.3	2.0 (1 - 2)	2.4 $\pm$ 4.8	1.0 (1 - 2)	< 0.0001
Post procedure (implant to discharge)	1.5 $\pm$ 0.7	2.0 (1 - 2)	1.1 $\pm$ 1.2	1.0 (0 - 1)	< 0.0001
Same day discharge (%)	7%		28%		< 0.0001
$\leq$ 1 night stay (%)	43%		78%		< 0.0001
Follow-up (discharge to 1 year)	3.2 $\pm$ 9.2	0.0 (0 - 0)	1.3 $\pm$ 4.6	0.0 (0 - 0)	0.27

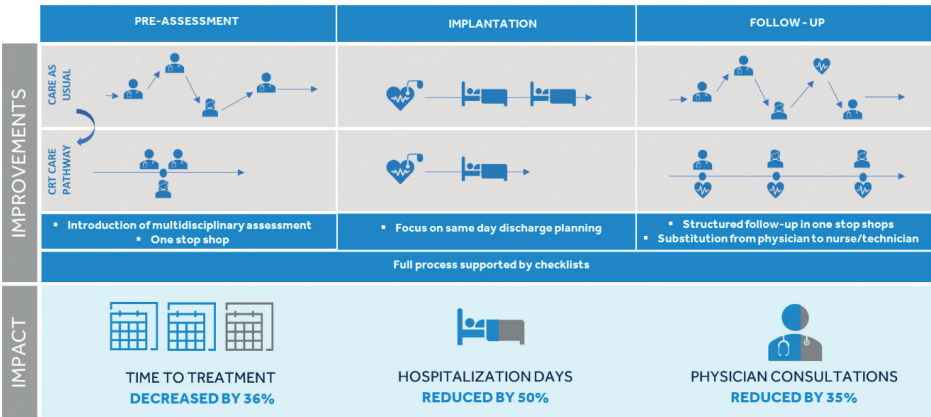


Figure 4. Schematic overview of process changes and measured improvements

4.4 Discussion

Implementing a CRT-CPW using multidisciplinary care, in a structured, checklist driven patient management protocol resulted in a successful transition of physician-led usual care to nurse-led CRT patient management. Moreover, it led to a significant reduction in resource utilization, with a reduction in hospitalization days and physician consultations.

Mullens et al. were the first to show that the use of a standardized algorithm in patients that did not derive benefit from CRT could identify factors associated with suboptimal treatment, and if corrected this was associated with improved clinical outcome.¹⁴ Importantly, these favourable effects appeared to be driven not only by appropriate device and arrhythmia management but also by improved HF care.²² These results were recently strengthened by another study comparing multidisciplinary, comprehensive CRT care to conventional CRT care.¹² A common factor in the programs evaluated in these studies however, is that they require intensive, specialised, physician guided follow-up, with extensive resource use, which hampers widespread adoption in clinical practice.

The CRT-CPW as applied at the MUMC+ shared the aim to improve quality of care for CRT patients by applying multidisciplinary expertise, in a structured way in

order to identify any opportunity for optimization of treatment at any moment in the care process. But at the same time, the current CPW aimed to establish a transition of care from highly specialized (physicians-led) care to protocolized, nurse-led care, with structured planning of patient visits to establish a reduction in resource use.

The current study showed that a transition was made from physician-based care to the nurse-led program. Non-dedicated physician-led care, incorporating different kind of specialized cardiologists, was transferred to the CRT-CPW nurse-led care. The evaluation showed that there still were physician contributions to HF care in the CRT-CPW patient group. This may be explained by destabilized HF which demanded physician consultation, specialised consultation to target factors contributing to suboptimal treatment, or simply incomplete implementation of the CRT-CPW. In addition, implementation of the new CRT-CPW may have been incomplete as simultaneous and complete training of all contributors to CRT care before the start of the practical use of the CRT-CPW was not possible. As implementation of new CPWs expands over time, especially when contributors see the added value of it, we expect the number of physician consultations to decrease further over time. However, as specialized interventions (e.g. Atrial fibrillation or His ablation procedures) may be required in structured optimization, physician consultations will remain at a minimal level needed to reassure optimal CRT care.

Even though we successfully transferred care for these patients to dedicated CRT and HF nurses and technicians, the number of visits was not significantly lower in the CRT-CPW group. Due to the uncoordinated care in the usual care group, we expected this to be lower in the CRT-CPW group. Our data shows that the introduction of the one-stop-shop visits in the CRT-CPW resulted in a reduced need for repetitive visits, as the overall number of consultations significantly increased in the CRT-CPW, but patient visits to the outpatient clinic were not different. This is possible as the pathway allowed for deviations when either optimization or stabilization of HF required this. One explanation may therefore be that in the checklist driven CRT-CPW more possibilities for optimization were identified, requiring extra consultations, e.g. optimization of HF medication, treatment of congestion, or device reprogramming. Another explanation may be an increase in destabilized HF, however if the excess consultation would have been the result of this, we would expect to have seen a coinciding increase in overall

hospitalization days during follow-up. Other studies introducing structured checklist into general HF care have shown that restructuring HF care, aided by checklists helped to improve guideline adherence for the outpatient and admitted HF population respectively ^{20,21}, therefore we believe that future evaluations will reflect this in improved patient outcomes.

Another result of the enhanced coordination and planning by the multidisciplinary team is the reduced time between referral and device implantation, with more than 35% reduction. Time to any intervention generally contributes greatly to patient satisfaction with their medical treatment ²³. Moreover, in HF patients, timely intervention may prevent hospitalization due to destabilized HF. With the use of a 'referral' review and 'pre-assessment' checklists incomplete diagnostic work-up or lack of general HF optimization can be identified at referral and managed in a coordinated way. Moreover, the reduction in device-implantation related LOS was possible due to 1) discussion of and consent to a discharge plan with the patient at the pre-implantation one-stop-shop meeting, and 2) the introduction of a discharge checklist, available to the ward-nurse to reassure absence of any complications, enabling an early discharge.

Finally, the current evaluation showed a significant reduction with respect to hospitalization LOS. Even though this was not the aim of the current evaluation, the reduced overall LOS may also point to an improved clinical outcome, as reduction of HF hospitalization is one of the main targets in HF patient management. Moreover, hospitalizations remain the largest expense in HF care²⁴, and a reduction may lead to a significant reduction in healthcare costs.

Obviously, the current evaluation of the introduced CRT-CPW lacks evidence on superiority (or non-inferiority) of care based on clinical outcomes. Efforts are currently being made to evaluate relevant medical outcomes and costs, in order to report on cost-effectivity of the CRT-CPW.

4.4.1 Strengths, limitations

This CRT-CPW allows for adjustments to local practices and hospital care teams, while still providing quality care for CRT patients by making use of standardized

forms and algorithms. Further improvement of data collection by automatic data entry into the hospital information system combined with integration of the CRT-CPW into standard medical practice will provide a unique opportunity to standardize and continuously evaluate patient care. This potential may lead to continuous improvement of quality of care, resource use and innovation in CRT care.

This study uses historical control to evaluate the CRT-CPW effect on process metrics, this introduces a possible bias. Other influences on process outcomes may have been introduced over time, affecting the results. Furthermore, even though the pathway aims to be simple and adoptable to any clinical practice, it is uncertain whether the results presented will be similar in other centres. Other hospitals have started to implement the CRT-CPW, which provides opportunities for future evaluations. A limited number of patients were included in both cohorts, patients referred from other hospitals and hospitalized patients were excluded because of incomplete follow-up. Next to patient clinical outcomes, patient satisfaction with the care pathway has not been investigated; however, it may be expected that patients appreciate the reduced time to treatment, improved communication between stakeholders and the efficient care team interaction.

4.5 Conclusion

The introduction of a CRT-CPW using a protocolised, multidisciplinary approach with structured aids, led to a successful transition of physician led care to nurse led care, with a significant reduction in hospital resource use.

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Author contributions

AVS, WD, HP B-LR, CK, KV: contributed significantly to the concept, design and implementation of the work; the acquisition, analysis, interpretation of data for the work and writing of the manuscript, SS contributed to the implementation, data acquisition, analysis, interpretation of data and writing of the manuscript. All authors read and approved the final manuscript

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Data availability statement

The data were made available from the Hospital Administration System for this study and is not publicly available. Supplementary materials associated with this chapter are not reproduced in this thesis and can be found in the original publication.

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5

QUALITY AND PROCESS IMPROVEMENT OF THE MULTIDISCIPLINARY HEART TEAM MEETING USING LEAN SIX SIGMA

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* Shared first authorship. Although the published article lists the clinical co-author first, both authors contributed equally as first authors. The doctoral candidate's individual contribution to this chapter is specified in the Author Contributions section of this dissertation.



Abstract

Introduction

The Heart Team is a multidisciplinary meeting for shared decision-making in cardiology and cardiothoracic surgery. A quality improvement project to optimise the Heart Team was initiated after the merger of the cardiac centres of Amsterdam University Medical Centre.

Interventions

Seven areas of improvement were introduced. Key elements were the improvement of the patient referral process, introduction of a structured agenda, task division and balanced planning of patients, better exchange of information, improved availability of diagnostics and supportive tools and information technology. Work agreements were introduced to support a positive work culture and mutual respect.

Results

Lean Six Sigma designed an optimised Heart Team to improve efficiency by better resource utilisation, first time right decision-making, patient selection, complete and better access to information and elimination of waste. It leads to higher quality decision-making by involving physicians in more structured preparation, attendance of an imaging cardiologist, meeting duration within limits, installation of standard operating procedures, increased involvement of the referring cardiologists and a better engaged team.

Conclusions

Heart Teams are essential to make evidence-based, patient-centered treatment plans for optimal patient outcomes. However, clinical practice and experience showed that it is challenging to have an efficient and effective discussion with complete patient information and to bring together healthcare professionals. The application of Lean Six Sigma resulted in an optimised Heart Team and created a best practice design for patient-centered, evidence-based decision-making. After implementation and process stability, a postintervention analysis could clarify long-term success and sustainability.

Background

5

What is already known on this topic

Heart Teams are multidisciplinary team meetings for complex cardiac patients in cardiology and cardiothoracic surgery. It is essential to make evidence-based, patient-centered treatment plans for optimal patient outcomes. However, clinical practice and experience showed that it is challenging to have an efficient and effective discussion with complete patient information and to bring together healthcare professionals.

What this study adds

The merger of two academic centres in Amsterdam, The Netherlands, is a unique situation. It consequently led to the centralisation of the cardiac centre. Lean Six Sigma was applied to integrate and create a best practice Heart Team design for patient-centered, evidence-based decision-making. To the best of our knowledge, this is the first article sharing knowledge on quality and process improvement through the application of Lean Six Sigma to optimise multidisciplinary team meetings.

How this study might affect research, practice or policy

Heart Teams are the backbone of cardiovascular interventions in which the essence of medical practice can be found. It is the start of a patient's journey. If decision-making is suboptimal in the Heart Team, it affects the entire care process. The importance of Heart Teams is perhaps underexposed, since there is an increased attention on limited resources and capacity in the operating room and intensive care unit that has been aggravated after the COVID-19 pandemic. The application of quality improvement methodologies, such as Lean Six Sigma, provided a structured approach to design an optimal Heart Team by creating the fundament for optimal, best evidence, shared decision-making. This establishes the best conditions so that an optimal treatment strategy can be advised that results in the highest quality of care. The project can inspire other hospitals to introduce quality and process improvement themselves.

5.1 Introduction

The Heart Team (HT) is a multidisciplinary meeting for shared decision-making in cardiology and cardiothoracic surgery. Since 2010, HTs have been integrated into the European Society of Cardiology revascularisation guidelines.¹ During the HT meeting, treatment plans for complex cardiac patients are discussed with the purpose of providing an optimal, best evidence, patient-centered treatment strategy in a shared decision-making environment.^{2,3} For example, the decision for either medical therapy, percutaneous coronary intervention or coronary artery bypass graft (CABG) for patients with coronary artery disease (CAD) is made with consideration of patient characteristics and preferences, local expertise and procedural or operational risk as displayed with the SYNTAX and the European System for Cardiac Operative Risk Evaluation II.^{4,5} The implementation of an HT proved to provide a designated approach to evaluating complex cardiac patients.⁶ HTs are expanded to other cardiac conditions, such as heart failure, endocarditis and congenital cardiac diseases.

It is essential that the HT functions optimally to strive for the best treatment plan for each individual patient. However, a process and quality-related potential for

improvement exists. To start with, not all centres have implemented a HT with required elements for an optimal performance. Therefore, the first potential for improvement would be to implement HTs in all centres. Yates *et al* reported that only 8% of patients with severe CAD were discussed at a multidisciplinary meeting after the introduction of the 2010 guidelines on myocardial revascularisation at a large-volume cardiac centre in the UK in 2014.⁷ Besides the implementation of HTs in daily clinical practice, there is a significant potential for improvement of the process of the HT itself.⁸⁻¹⁰ Consistency of HT decisions was evaluated by Pavlidis *et al* by prospectively analysing 51 HTs and 399 patients.⁹ They found that in 20% of identical cases, a different treatment strategy was advised by the HT. This suggests that HT decisions are not entirely reproducible, and patients with similar conditions may have different treatment strategies and consequently outcomes. Thus, another potential for improvement of the HT could be a reduction of variation of decision-making. A more standardised HT process could result in more reproducible decisions and herewith quality of care.

Incomplete information and inadequate documentation are elements that can cause inefficiencies of the HT process. These inefficiencies could result in deviations from HT decisions, suboptimal organised waiting list and rediscussions. This again could affect the entire care pathway, since suboptimal preparation of patients can lead to last-minute cancellations.¹¹ Due to the COVID-19 pandemic, the time to treatment is increased since resources and capacity are progressively limited.¹²⁻¹⁵ Prolonged time to treatment for patients with severe CAD and valve pathology can plausibly lead to more adverse events (both prior the invasive procedure and perioperatively).^{12 14 16 17} Comprehensive documentation and delivery of complete patient information contributes to better insight of patients and their conditions, priority and risk of adverse events.^{14 18} It is therefore necessary to organise waitlists adequately, which can be achieved at the start of the care pathway concomitant with the HT.

In the concept of value-based healthcare, optimising the HT by striving for efficiency contributes to better accessibility, affordability and quality of care.¹⁹ Lean Six Sigma (LSS) is a quality improvement (QI) methodology originated from the manufacturing industry that has the potential to create and implement improvements throughout the organisation by its data-driven, in-depth multidisciplinary approach to improve both process efficiency and quality of

care.^{11,20,21} The cardiac centre (cardiology and cardiothoracic surgery department) of the Amsterdam University Medical Centre (Amsterdam UMC), the Netherlands, initiated a QI project to optimise the HT with the aim of improving efficiency and quality of care. In 2019, the merger of two academic hospitals to Amsterdam UMC led to the lateralisation of the cardiac centre (cardiothoracic surgery and cardiology department) to one location with expected completion in 2024. For over 10 years, both centres integrated the concept of a HT as a multidisciplinary approach to provide the best treatment strategy for cardiac patients. Optimal shared decision-making directly impacts quality of care, creates educational value, optimises efficiency and positions the hospital for referring centres.²² The project is in concordance with the six aims for improvement prioritised by the STEEP principles: safe, timely, effective, efficient, equitable and patient-centered care.²³ The purpose was to apply LSS to support the merger of the HTs and to create opportunities for a synergic integration of best practices and aimed to study the following: (1) identification of the current HT process and its performance, quality and efficiency, measured by Critical to Quality (CTQ) characteristics, (2) identification of the root causes of problems and (3) introduction of the countermeasures improving the HT's CTQ characteristics.

5.2 Methods

This is a QI report according to the Standards for Quality Improvement Reporting Excellence Guidelines 2.0.²⁴ The project was performed at the cardiac centre of Amsterdam UMC, the Netherlands, and started on 1 September 2021 until 1 January 2022 in collaboration with experts from Integrated Health Solutions, Medtronic. All team members were familiar with the basics of LSS, and the project leaders were certified (Master) Black Belts.²⁵

5.2.1 Lean Six Sigma

The project applied LSS and used the Define, Measure, Analyse, Improve and Control (DMAIC) cycle.²⁵⁻²⁷ In the Define phase, the goal, scope, process and business case were defined. The multidisciplinary team consisted of two

cardiothoracic surgeons, two cardiologists, two members of the surgical and cardiology planning team and business intelligence representatives. Both premerger locations were represented equally. Five DMAIC problem-solving sessions took place. In the Measure phase, data were collected based on the chosen performance metrics named CTQ characteristics. Process mapping and gemba walks (shop floor observations) were performed to better understand the processes. A SIPOC (suppliers, inputs, process, outputs, customers) diagram was visualised for documenting the process. Interviews with healthcare professionals and surveys measure staff and referring centre satisfaction, understand their requirements and identify bottlenecks in the process. The Analyse phase was used to determine the causes of inefficiencies in the process and to define countermeasures to improve value and flow. The Five Whys technique identified root causes of the problems. The lean tools line balancing, poka-yoke, failure demand, first time right and standardisation supported the team to identify countermeasures to eliminate waste in the current process. The project team was inspired by best practices from other hospitals and literature. During the Improve phase, the project team developed and implemented improvements. The Control phase will be used to measure final capability of the process when stability is reached and to sustain the gains and set up for continuous improvement.

5.2.2 Data collection and analysis

Quantitative and qualitative data collection supported the LSS project to obtain understanding of the baseline performance of the HT in line with the CTQ characteristics. Data were extracted from the hospital information system and collected in a separate database. Missing data were added through patient file inspection. All patients discussed during the HT meeting of both centres between April 2019 and April 2020 were included. Metrics included number of patients referred to the HT per year and per day, total time spent per patient on average in minutes (calculated by the sum of time spent by all HT resources as reported by planners and physicians, divided by the number of unique patients per year), time from referral to HT decision in days and percentage of patients who were rediscussed with the reason for rediscussion (during rediscussions patients were discussed more than once within the same referral). Qualitative data collection was performed through interviews with healthcare professionals (n=17) and

surveys to measure satisfaction of staff (n=14) and referring centres (n=21). The staff and referring centre satisfaction was measured with a score from 1 to 10. There were seven HT observations performed that categorised: value-added time (discussion), required time (administration, searching for patient information) and non-value-added time (late start, waiting, disturbances and unnecessary discussion of patients). Analysis was performed using Minitab Statistical Software V.18.1.

5.3 Results

Seven CTQ characteristics were identified by the multi-disciplinary project team, which were valued as crucial to drive and measure quality and efficiency of the HT. The CTQ flow down presents the relation of strategic goals of the project to measurable CTQ characteristics (figure 1).²⁵ Process mapping and SIPOC were performed to identify the process. The Five Whys root cause analysis is presented in figure 2. The HT process was divided into six phases: referral, triage, preparation, HT, follow-up and treatment.

1. Number of patients referred to HT per year and per day.
2. Total time spent per patient on average in minutes.
3. Lead time: time from referral to HT decision in days.
4. Rediscussions: percentage of patients discussed more than once within the same referral.
5. HT efficiency: proportion of value-added time of the HT.
6. Referrer satisfaction.
7. Staff satisfaction.

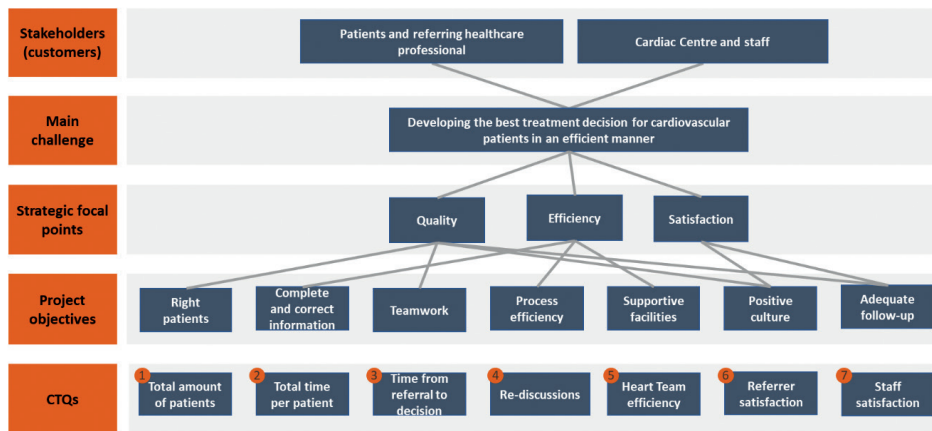


Figure 1. Critical to quality (CTQ) flowdown

5.3.1 Measure

5

From April 2019 to April 2020, 3500 consecutive patients were discussed during 250 HTs at both locations (location A 64%, n=2250 and location B 36%, n=1250). An average of 14 patients were discussed per day (location A n=9, location B n=5), with a range of 5–25 patients per day. The sum of time spent by healthcare professionals related to HTs per year divided by the number of unique HT patients resulted in an average time of 64 min per patient per HT discussion. The median time from referral to decision was 2 days, which was considered acceptable by the project team. Patients discussed in the HT once (first time rights) occurred in 77%. Rediscussions occurred in 23% of the patients. The main reasons for rediscussions were incomplete information/diagnostics, not enough time to finish discussion list and expertise not present. Time measurements of the HT performance showed that only 46% of the time was spent on value-added activity, which was considered the actual patient discussion contribution to a decision on a treatment strategy. There were interviews with referring specialists (n=17), surveys with staff (n=14) and referring centres (n=21). Overall staff satisfaction scored an average of 5.8 out of 10 (SD 1.2). Specifically concerning the quality of the decision, staff scored an average of 7.0 out of 10 (SD 1.1), efficiency of the process 5.5 (SD 1.7), communication 5.5 (SD 1.8) and support 5.3 (SD 1.6). Overall satisfaction by referring centres was scored 6.6 out of 10 (SD 1.0). The admission process scored 7.4 (SD 0.7), communication with planning team 7.3 (SD 1.4), communication with

doctors 6.5 (SD 1.6), information resources 6.5 (SD 1.2), involvement within decision of HT 6.4 (SD 1.1) and information technology tools and infrastructure 5.7 (SD 1.9). Survey respondents defined characteristics of a successful HT as follows: an evidence-based, patient-centered, optimal treatment advice through a structured discussion including necessary information, transparency and clarification on the decision and responsibilities, fast and transparent communication to referrer and service that is trustworthy and provides perspective into referred patients. The observations of HT efficiency resulted in the following results (figure 3). Categorised as value added was discussion (46%) and non-value-added time were administration (18%), rediscussions (18%), late start (16%) searching for patient information (10%) and disturbances (4%).

5.3.2 Bottlenecks and five whys root cause analysis

Five meetings with the multidisciplinary project team took place. Quantitative and qualitative root cause analyses resulted in a long list of 94 bottlenecks. We first categorised these into seven main improvement areas. In a matrix, these seven groups were related to the CTQ characteristics to make sure all were covered. In a failure mode and effects analysis workshop with the project group, countermeasures for most impactful and frequent bottleneck were designed based on expert opinions, literature and best practices in other centres.

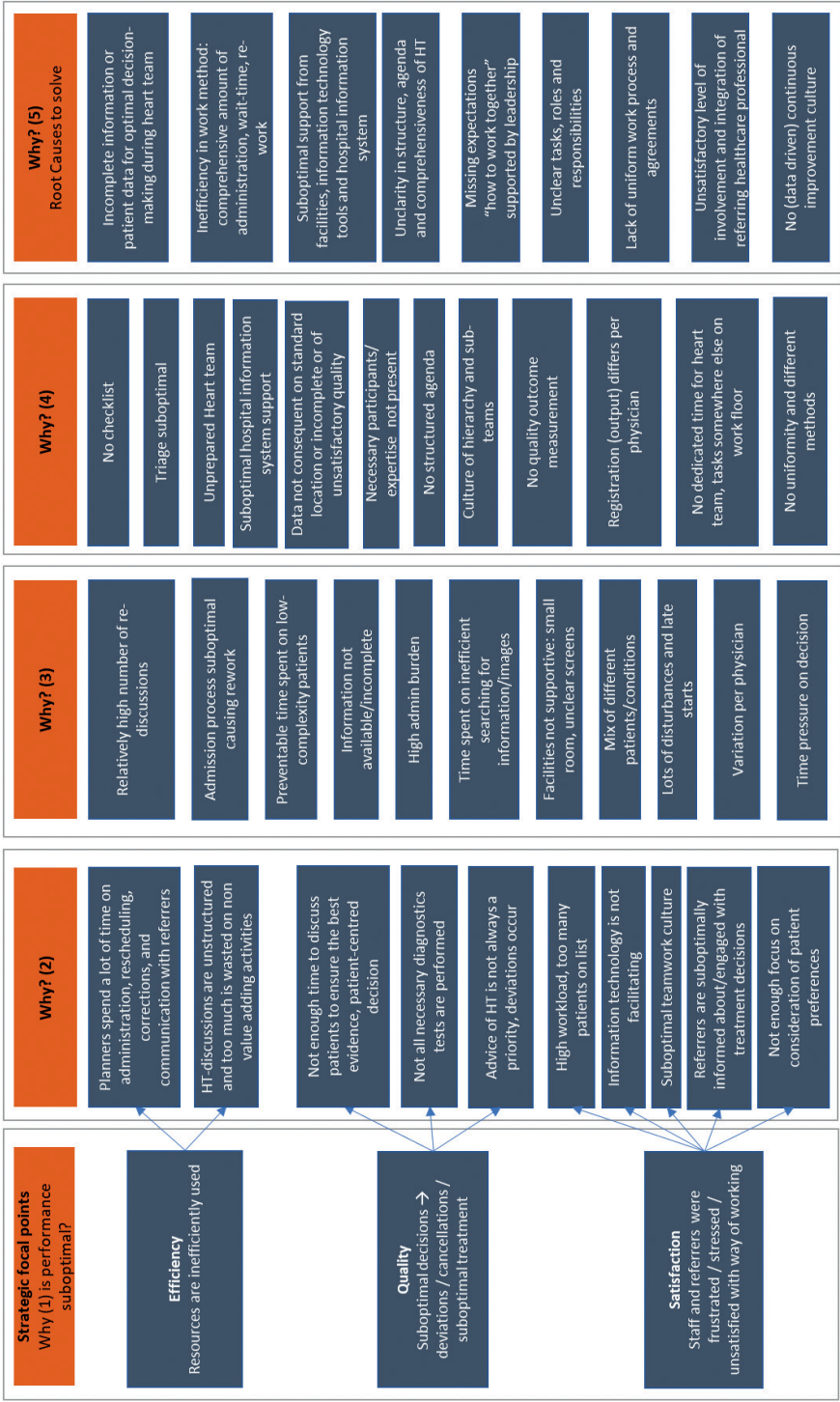


Figure 2. Five whys root cause analysis

With a Five Whys root cause analysis, the following root causes were defined (figure 2):

- Incomplete information or patient data for optimal decision-making during HT meetings.
- Inefficiency in work method: comprehensive amount of administration, waiting time and rework.
- Suboptimal support from facilities, information technology tools and hospital information system.
- Unclear structure, agenda and comprehensiveness of HT.
- Missing expectations on teamwork supported by leadership.
- Unclear tasks, roles and responsibilities.
- Lack of uniform work process and agreements.
- Unsatisfactory level of involvement and integration of referring healthcare professional.
- No data-driven continuous improvement culture.

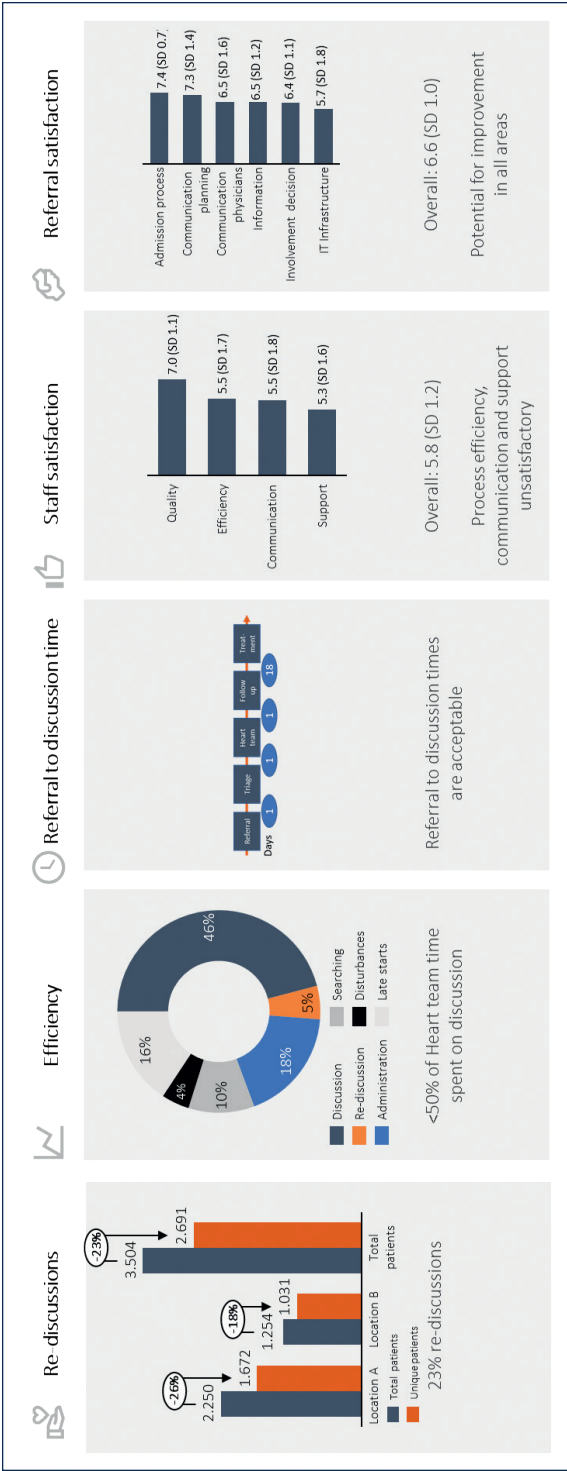


Figure 3. Results of baseline measurement

5.3.3 Six Sigma score

The Greek symbol σ (sigma) is used in statistics as a measure of variation and has become a basis for the definition of a measure for conformance quality: the sigma metric or sigma level.²⁵ The sigma level indicates the performance of a process, that is, which percentage of products or service conforms to the specifications (or equivalently non-conforms to the specifications). For example, a 3-sigma level process means 6.7% non-conforming and a 6 sigma level process means a defect rate of 3.4 per million opportunities. Assuming that optimal preparation of the HT with the ideal facilitation of patient information and expertise would lead to almost 100% first time right (~6 sigma), the current sigma score with 77% first time right would be 23% non-conforming or 2.2 sigma level.

5.3.4 The heart team design

The application of LSS resulted in a newly designed and optimised process of the HT. The improvements were organised in seven areas. After implementation, the improvements are expected to have beneficial consequences for the CTQ characteristics, as reported in table 1. Information was gathered from both premerger locations and other centres for benchmarking that was used to identify HT’s best practices.

Table 1. CTQ characteristics

CTQ characteristics	Baseline	New Heart team design
1 Number of patients referred	3500 patients per year in both centres An average of 14 patients were discussed per day (location A n=9, location B n=5), with a range of 5 to 25 patients per day	Provides the opportunity to grow by better satisfaction Maximum of 15 patients per day with low standard deviation
2 Total time spent per HT patient on average in minutes	64 minutes (without imaging cardiologist) 75 minutes (with imaging cardiologist)	Although imaging cardiologist will take seat in every HT, reduced rediscussions and more efficient discussions reduce the expected total time spent per patient to 53 minutes (reduction of 30%)

Table 1. CTQ characteristics *Continued*.

CTQ characteristics	Baseline	New Heart team design
3 Lead time: time from referral to HT decision	Majority 1-2 days, rediscussions add lead time	Prevents rediscussions, thus reduction is expected
4 Rediscussions	23% The main reasons: information/diagnostics incomplete, not enough time to finish discussion list and expertise not present	All prerequisites in place to make decisions first time right, expected to result in less rediscussions and less last-minute cancellations
5 HT efficiency: value added time	Value added time: 46% is spent on patient discussions Nonvalue added time: external disturbances (4%), late starts (16%), re-discussions (18%), administration (18%) and searching for patient information (10%)	A better prepared HT, as well as a more structured, orchestrated and timely HT is expected to reduce nonvalue-added activities (waste) and increases the proportion of value-added time
6 Referrer satisfaction	Overall: 6.6 (SD 1.0) Admission process: 7.4 (SD 0.7) Communication planning: 7.3 (SD 1.4) Communication physicians: 6.5 (SD 1.6) Information: 6.5 (SD 1.2) Involvement: 6.4 (SD 1.1) IT-infrastructure: 5.7 (SD 1.9)	At least a score of 7 out of 10 is expected because of: • Proactive expectation management • Better communication • Informing/communicating on reasons for decision • Involvement
7 Staff satisfaction	Overall: 5.8 (SD: 1.2) Efficiency: 5.5 (SD: 1.7) Support: 5.3 (SD: 1.6) Quality: 7.0 (SD: 1.1) Communication: 5.5 (SD: 1.8)	At least a score of 7 out of 10 is expected because of: • Improved work circumstances, facilities and culture • Clearer tasks, expectations and responsibilities • Reduced administration burden

5.3.5 Coherent and structured HT

Integrating two Heart Team meetings into one

In the premerger stage, two cardiac centres scheduled two separate HTs daily during work days. Both HTs were different in process, structure, agenda and subspecialty of the attending healthcare professionals. The most influential differences between centres were the admission method and location for referring patients, differences in required documents, independent organisation by a department for preparation of a patient, course of events during the HT meeting, attendance and role of involved healthcare professionals, dedicated time of medical specialists, cultural factors, facilities and use of information technology tools and the communication of decision and follow-up to referring centres. The LSS principle of standardised work inspired the project team to focus on reduction of variation between and within the HT. A standardised process was expected to increase focus on content and reduces ad hoc activities to act on deviations. By centralisation to one location, and thus having one HT instead of two, the process efficiency (CTQ 5) and staff satisfaction (CTQ 7) are expected to be of more optimal use of resources and healthcare professionals' time. From both centres, best practices were shared during the QI sessions, which contributed to a synergic development of new working agreements.

Redesigning the HT-structure and differentiation of HT per subspecialty

There were 11 different subspecialised HTs in both centres: general (CAD and valve disease), transcatheter heart valve implantations, congenital cardiology, endocarditis, high risk, high-risk rhythm conditions, devices, electrical cardioversion and chronic total occlusion CAD on different locations. Because of the redesign, the content and structure of the HT was transformed (figure 4) to gain more focus on the selection, triage and discussion of the right patients at the right place, with the right expertise. This is expected to reduce waste (CTQ 2), improve process efficiency (CTQ 5) and first-time right discussions (CTQ 4).

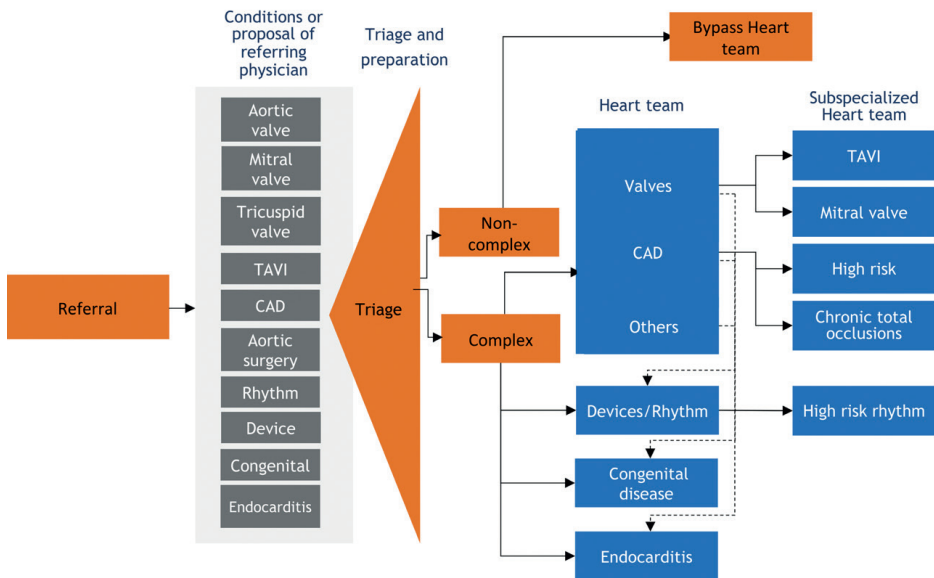


Figure 4. Triage and structure. cad, coronary artery disease; tavi, transcatheter aortic valve implantation

Triage of patients

Triage of patients by doctors together with the support of secretaries and medical planners resulted in two improvements: (1) only patients needed to be discussed were added to the HT agenda which prevents unnecessary patient discussions (within lean known as overprocessing), and (2) if patients needed to be discussed in subspecialised HTs, they were directly referred instead of via the general HT meetings. Decided by the doctors, low-complex patients for which a discussion would not have additional value were left out of the discussion list. Furthermore, an automatic system for triage based on external referrals was designed. Better preparation of the HT was required, so that time could be more efficiently spent during the HT meeting. Integrated in the hospital information system, a care pathway was developed to clarify and outline the process steps required and if necessary, space to add extra activities.

Complete patient information

The survey with referring centres scored 7.4 out of 10 (SD 0.7) on the admission process. Rediscussions occurred in 23% of the cases on average (26% in location A and 18% in location B). Incompleteness of data was the major cause for rediscussions, which was considered as preventable. Interviews with stakeholders identified the incompleteness of information as bottleneck. The involved medical planners stated that incomplete data led to rework and non-value-adding activities and wasteful time. The root cause of this problem was identified as the lack of uniformity in admission criteria and process. Before the project, there were multiple methods, requirements and locations for admission to the HT. There was no standardised requirement for patient information. Improvements were identified that led to the organisation of a central admission point per department. One location for referrals for cardiology and cardiothoracic surgery was organised with all a standardised method and similar requirements for documentation. A standardised and clarified overview was developed to inform referring centres of the admission process, including information provided for specific medical conditions (CAD, valve disease, rhythm conditions, aortic disease, congenital heart disease and others). This improvement ensured completeness of patient information. By improving the process of admission, countermeasures were introduced that contributed to improving the first-time rights (CTQ 4). Following the lean principle of poka-yoke (mistake proofing), a mandatory checklist was integrated into the hospital information system to prevent passing patient cases with incomplete information to the HT. Also, the quality of the images was assessed. If not of a substantial quality to form a treatment plan, the referring centre was asked for better images prior to HT to prevent rework. This contributed to improved process efficiency (CTQ 5) and staff satisfaction (CTQ 7).

Structured agenda and balanced planning

A total of 14 patients were discussed per day (location A n=9, location B n=5) on average, with a variability of 5–25 patients per day. This variability led to suboptimal time division, peaks in demand and stress levels, and consequently dissatisfaction of healthcare professionals involved. For example, it frequently occurred that on certain days 20 patients needed to be discussed, and the day after there were only 5. The agenda of the HT was transformed into two parts: valve disease and CAD. Per HT, prespecified time slots were addressed for patients with

valvular disease (30 min) and patients with CAD (60 min). Clinical and emergency patients were discussed first. Inspired by the lean principle of line balancing and takt time data analyses showed that scheduling a maximum of 15 patients per day would reduce variation in workload and consequently overburdening of staff. According to the new standard, when more than 15 patients are referred, elective patients should be scheduled and discussed during the next day's HT meeting with a maximum delay of two working days per patient. This led to more balanced number of patients to be discussed per day instead of variability in the number of discussed patients. This contributed to a better focus and satisfaction (CTQ 7) of involved healthcare professionals, which is compromised when discussing too many patients during a single meeting.

Clear responsibilities and work method for healthcare professionals involved

The survey and interviews identified potential for improvement concerning the attendance and task division of involved healthcare professionals to better use their expertise and reduce waste of talent. Work agreements were made to improve efficiency and communication. Physicians required to be present at an HT meeting were an interventional cardiologist, a cardiothoracic surgeon and an imaging cardiologist. All physicians were appointed to a specific task to improve communication, efficiency and quality. Dedicated medical specialist time during the HT meeting prevented disturbances. Thus, the utilisation of HT time is optimised. An HT coordinator was appointed for the administration. Because of this, cardiologists and cardiothoracic surgeons had more time for discussion. A summary of required patient data was introduced by the HT coordinator, which created a clear overview of required information for an optimal and efficient discussion. Flow diagrams were introduced in concordance with database registrations. Information technology improvements were developed with screens presenting the hospital information system overview and images. These measures improve process efficiency, quality and satisfaction and cover all CTQ characteristics.

Patient information available, accessible and supportive information technology infrastructure

Before the project, there were different methods to share images. The differences in accessibility of images led to waste by searching for images during the HT meeting. Improvements in the process were introduced to make uniform the availability of images directly from the hospital information system instead of from different platforms. Additional screens in the discussion room for presenting the images provided a better overview and visibility of all relevant patient information. Upfront preparation of patient characteristics and clinical information ensured availability of all required information during the actual HT. This improved efficiency by reducing time spent searching for information and improved satisfaction of HT participants. The survey with healthcare professionals involved with the HT scored the information technology support a 5.3 out of 10 (SD 1.6). Screens and an allocated room were already available before the QI project. To improve supportive facilitation and information technology, the registration method was reorganised by a standardised HT decision dashboard, based on lean principle of visual management. Diagnostics were collected and available in one centralised information technology system. Parallel with the HT, the registration of data in the hospital system is standardised and structured data input instead of free text entry is encouraged to save administration times and ease standardised data extraction for registries.

Patient-centered care and referring centre involvement

Although both premerger locations received 70% of the HT patients from referring centres, there were differences in referrer experiences (failure demand). Both quantitative and qualitative analyses provided more information on opportunities for improvement. From the analysis, there can be concluded that a more personal-focused, transparent and better facilitated efficient process is desired. Involvement of the referring centre in the HT process is expected to improve referral satisfaction. In this way, consideration of patient's preferences will be better represented, which could impact treatment decisions. A patient-centered and more tailored HT decision could be advised that it is expected to lead to better quality of care.

Clear correspondence and communication

Survey and interviews with referring cardiologists showed an unmet need to better inform referrers about the treatment decision, especially when the HT decisions deviate from the referrer's proposed decision. Inadequate communication frequently resulted in additional work and process disturbances (failure demand). It led to rework when the referrer tried to collect missing information or argumentation and referred the patient repeatedly to the HT. Referrers could often not properly reproduce to patients the reason certain treatment proposals were advised. The new way of working incorporates proactive follow-up via a standard format, with more information adjusted to the referrer's requirements. Referrers were contacted by phone when deviated from the proposed treatment. This was expected to positively impact referral satisfaction (CTQ 6) and process efficiency (CTQ 5). Referring cardiologist involvement is expected to contribute to better consideration of patient's preferences. Less time would be spent on follow-up and unclarity of HT decisions. Patient management tools ensured an overview of patients on hold, requiring additional diagnostics or other information. A template for standardised correspondence was introduced for communication of HT decisions to referring centres. The HT coordinator was made responsible for this. The referrer is responsible for communicating HT decisions to patients.

5.3.6 Beneficial consequences

Adequate waiting list organisation

Due to the COVID-19 pandemic, the cardiac centre was challenged by limited capacity and resources. For cardiothoracic surgery, this resulted in prolonged waiting lists and referral to treatment times. It consisted of approximately 250 patients awaiting cardiac surgery at the start of the project, which was a greater amount compared with before the COVID-19 pandemic. Longer waiting lists and referral to treatment times made it increasingly necessary to have complete, structured waiting list organisation to provide insight of the patient's condition and risk of adverse events while awaiting cardiac surgery. In the premerger HTs, it occurred that HT decisions were made without complete information, for example, if a patient had CAD but the transthoracic ultrasound to evaluate valve disease was not yet performed, the HT had already advised on a treatment strategy and the patient was added to the waiting list. This in some cases led to

new insights that changed treatment strategies during preoperative screening and eventually caused last-minute cancellations. By the new HT design and especially improving the quality of HT decisions by completeness of patient information, there was a better insight of a patient's status, condition and priority. This aimed to improve waiting list organisation, and consequently operating room planning and preoperative assessment.

Data-driven continuous improvement

A structural data-driven performance dashboard is developed for continuous improvement purposes. The combination of improvements aimed to improve the completeness of data for research purposes. Data collection was standardised, which simplified selection of patients for studies, clinical audit and feedback systems.

5.3.7 Monetary consequences

The entire HT process from preparation, patient discussion and follow-up requires time from physicians. Data analysis of the baseline situation at two locations showed that 2250 medical specialist hours per year were needed to process all referred patients. According to the study of the Dutch Healthcare Authority, one medical specialist's full-time equivalent has 1691 productive hours/year and costs the organisation about €212 000.²⁸ This results in €282 000 for capacity needed in total. If an imaging cardiologist would structurally take seat in all HT meetings, this number will increase to 2875 hours/year or €360 000. If both quality and efficiency measures are implemented, only 1750 hours of physicians will be needed which is equal to €219 000 of physician costs. This will result in an annual savings of €141 000. Indirect monetary consequences are the costs of poor quality. With the right information and expertise during the HT meeting, a reduction of disturbances and rush most probably leads to better treatment decisions and prioritisation of patients. This prevents cancellations due to suboptimal preparation or last-minute change of treatments.¹¹ In a hospital with 1000 CABG procedures annually and 15% last-minute cancellations, the amount equals about 150 CABGs per year.¹¹ Out of those, an estimated 20% (30 cases per year) could be prevented by a better HT and follow-up. An estimation of the average revenue per procedure of €12,000

would result in missed revenues of €360,000 annually. Another indirect monetary consequence to be expected is related to staff satisfaction. Well-trained quality staff is scarce. Creating a healthy, satisfiable working environment is a prerequisite for retaining staff. Recruiting and training new staff is costly, just to fill gaps in illnesses due to overburdening of staff. This is a common challenge in healthcare systems. In the long term, improvements in referring centre satisfaction may also lead to more referrals and higher revenues.

5.3.8 Practical implications

Several challenges were faced when implementing the change. By the merger of the two centres with two medical specialties, we were faced with four different work cultures, which challenged the design and implementation greatly. Positively seen, the merger provided an ideal situation to initiate change management and share best practices. We experienced that a data-driven scientific approach, education, engagement of all involved healthcare professionals through the LSS approach, leadership and support from the cardiac centre board supported implementing change. The most important recommendations for improving a HT are:

- Find a common goal that engages everyone, which is the quality of care for patients in this project
- Connect the proposed countermeasures to the main goal to create buy-in from all stakeholders
- Use data to support 'sense of urgency' and to convince stakeholders for the process change
- Divide implementation activities into separate themes or categories and set up a governance structure with clear roles and responsibilities
- Set up a clear communication plan to inform and engage stakeholders via multiple channels
- Assign department leads as 'champions' to accelerate change, move barriers and facilitate implementation
- Standardise work method to improve teamwork and create focus on content during the discussion, so that every participant knows their role/task and can follow the discussion

- Standardise reporting of arguments and HT decisions for clear communication within hospital and for referral communication
- Implement checklist to prevent missing information before and during the HT meeting
- Triage patients so that they are discussed at the right place, the right time with the right expertise
- Triage and prepare patients adequately so that there is a filter that prevents unnecessary discussions
- Implement a structured HT agenda with consideration of the priority and condition
- Reduce variation in workload by scheduling a maximum number of patients per day
- Dedicate time for healthcare professionals during the HT meeting to prevent disturbances
- Standardise accessibility of information and images in one hospital information system
- Register and report in a manner that simplifies data extraction for registries and research

5.4 Discussion

5.4.1 Summary, key findings and particular strengths of the project

This QI project applied LSS to optimise the process of the HT after the merger of two academic medical centres in the Netherlands. The application of QI methodology led to the identification and implementation of countermeasures based on the root cause of problems, supported by data based on seven CTQ characteristics. As a result, an improved HT is designed. Efficiency is improved by decreased rediscussions through first time rights. Triage of low-complexity patients by the cardiologist or cardiothoracic surgeon prevented unnecessary discussions. Less time is spent per patient through preparation, the availability of complete patient information, improved accessibility of diagnostics and the support of an HT coordinator. Work agreements resulted in less disturbances. Quality of care is improved because of the admission of an imaging cardiologist

to the team, more involvement of referring cardiologist in decision-making and communication, and the creation of an optimal organisation for evidence-based, patient-centered and shared decision-making. Furthermore, an improved administration of the HT resulted in better organisation of the waiting lists, and thus provided better insights of the patient's conditions, priority and risk of adverse events. This is especially necessary in times when the risk of adverse events is increased by longer referral to treatment times, caused by lower productivity due to the resource scarcity that developed during the COVID-19 pandemic.¹²⁻¹⁵ The project is in concordance with the STEEP principles focused on quality through the involvement of the patient and referral's preferences, process efficiency, better insight and organisation of the waiting list, timeliness and effectiveness.

The merger of two academic centres in the Netherlands created a unique opportunity to integrate both best practices. Strengths of this project are the data-driven multidisciplinary approach. The project team identified CTQ characteristics and translated efficiency and quality into measurable elements. Nevertheless, it would be informative, for instance, what the effect of the optimised HT is on other process metrics such as last-minute cancellations. The application of LSS ensured a methodological approach to identify the correct improvements based on the bottlenecks experienced and the root cause of problems. Also, the strength of the application of a QI methodology finds itself in the implementation of the improvements in the process. Because of this, together with a multidisciplinary approach and the involvement of healthcare professionals throughout the organisation, the optimised HT is better supported.

The importance of shared decision-making for CAD by an HT has been reported as essential for the quality of care.^{1,16} Therefore, the first importance is to use and implement an HT. The SYNTAX trial and other publications showed the benefits of a multidisciplinary approach in cardiovascular medicine.^{6,10,29,30} A shift to surgical revascularisation was seen since the implementation of the multidisciplinary team and the time interval from referral to revascularisation was shortened.¹⁰ Consequently, guidelines for myocardial revascularisation and percutaneous coronary intervention included the multidisciplinary approach as a class 1C recommendation.¹ Moreover, if the HT is implemented in an organisation, it should function optimally and needs to contain the preconditions required

for optimal evidence-based multidisciplinary decision-making. This can be divided into process elements and cultural factors. Certain preconditions for an optimal performance of an HT are advised, including the presence of an imaging cardiologist, an interventional cardiologist and a cardiac surgeon, shared decision-making with consideration of the patient's preferences, a dedicated room with supporting tools, leadership, complete and available patient information, support of HT coordinator and a safe culture with positive dynamic with mutual respect where all contributions are acknowledged.³¹ Other process elements contributing to improved efficiency are the structured agenda, work agreements, leadership and task division. A set number of patients to discuss guarded focus and ensured enough time to discuss all the patients. Furthermore, cultural factors were improved through work agreements. For example, the HT decision is leading which consequently demonstrated the importance of shared decision-making and prevented unnecessary deviations from HT decision. Better communication to referring centres improved satisfaction. Raine et al performed a prospective observational study to the effectiveness of multidisciplinary meetings. They identified recommendations for improving the effectiveness of multidisciplinary team meetings, mainly focused on the following elements: purpose, processes, content of discussion (availability of patient information) and the role of the patient. The observations of the HTs showed that abundant time is spent sub-optimally, and only 46% of time for content-related discussion. Therefore, the project led to the implementation of counter-measures to use the HT time more efficiently.³² Improved organisation creates better support for optimal shared decision-making and therefore contributes to quality of care. Lamb et al performed a systematic review on the quality of clinical decision-making through multidisciplinary cancer teams and included 37 studies.³³ They have reported that there is potential for improvement related to taking the patient's preferences into account. Furthermore, issues pointed out in their conclusion are that time pressure, excessive case load, low attendance, poor teamwork and lack of leadership lead to incomplete information and deterioration of decision-making. In the current project, the issues are similar for which the application of LSS provided countermeasures based on the root cause of problems. LSS has proven to be effective in healthcare through minimising costs, reducing waiting lists and referral to treatment times and maximising patient safety.^{20 21 34} Alongside with standardising and optimisation of processes, LSS has considerable impact on a cultural change in teamwork and a sense of

common goal. To the best of our knowledge, studies related to the application of LSS to improve multidisciplinary meetings are limited. This project showed that LSS is a successful methodology and has the potential to improve the quality, efficiency and culture of multidisciplinary meetings. It provided a structured and effective approach to eliminate inefficiency and to improve the process, so that preconditions for an optimal HT are met and a fundament is created to ensure optimal shared decision-making. It focused on five principles: define value, map the value stream, create flow, establish pull and pursue perfection.

After the design phase, the new HT design was presented to the cardiac centre board. They approved the full implementation. All healthcare professionals were educated and informed about the new HT design and work method. Prerequisites took place that made it possible to change. For a couple of weeks, the cardiac centre board and members from the project team were present during the HT meeting to assist during the change. After full implementation and stability of the new HT design, a postintervention study on the outcomes would be informative to clarify long-term success.

In the future, HT decision-making can be supported by predictive analytics and the use of patient characteristics, process measures and retrospective data in line with the Control phase of the LSS DMAIC cycle. Complete registration of patient information in a data set is the first step for this development. An HT data set can demonstrate effectiveness of decided treatment plans, follow-up on patients discussed, evaluate patient outcomes after HT decision and monitor and improve HT efficiency. Clarke et al showed that the implementation of a dashboard with information tools and clinical decision support with computer algorithms have the potential to improve HT efficiency.^{35 36}

5.4.2 Limitations

The QI project to integrate and optimise the HT was initiated after a merger of two academic centres, which is a unique situation itself. The new design could be generalisable by sharing the application of a quality and process optimisation methodology for a HT and by sharing best practices. We argue that hospitals apply a QI methodology themselves to improve their HT, since every HT has its own

specific areas for improvement. Difficulties faced with the implementation of this study were the engagement of all healthcare professionals, which was especially challenging in a merging environment. Structured interviews and involvement during QI sessions contributed to identifying best practices from each centre. Leadership and support of the cardiac centre board contributed to better support of the changes. A preintervention and postintervention study could inform if the improvements led to statistically significant improvements, analysed by CTQs. The project led to the introduction of an HT database of patient characteristics, decisions and patient outcomes after procedures.

5.5 Conclusions

Multidisciplinary HT meetings are essential to make evidence-based, patient-centred treatment plans for optimal patient outcomes. However, clinical practice and experience showed that it is challenging to have an efficient and effective discussion with complete and available patient information and to bring together healthcare professionals. Through the application of LSS, the project team designed an optimised HT in a merged academic cardiac centre and created a best practice design for patient-centred, evidence-based decision-making. Data-driven structured problem-solving techniques were key to identifying root causes for problems. Countermeasures were implemented to improve quality, efficiency and satisfaction. The project can inspire other hospitals to introduce quality and process improvement themselves. After achieving process stability, a postintervention measurement could clarify long-term project success. Effectivity of HT decisions on patient outcomes and process measures will be further investigated, starting with a structured HT data set and the introduction of continuous improvement cycles.

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6

REDUCING UNNECESSARY HOSPITAL CARE FOR PATIENTS WITH LOW BACK PAIN; IMPLEMENTATION OF A 1.5-LINE OUTPATIENT CLINIC

Branje, D.*, **Schretlen, S.***, Brouwer, B., de Meij, N., van Zundert, J., Muris, J., & Willems, P. (2022). Het reduceren van onnodige ziekenhuiszorg voor patiënten met lage rugpijn; implementatie van een 1.5-lijnpoli [Reducing unnecessary hospital care for patients with low back pain; implementation of a 1.5-line outpatient clinic]. *Nederlands Tijdschrift voor Pijn en Pijnbestrijding*, 41, 5–9

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Abstract

Ineffectively organized care for low back pain (LBP) and its consequences for the sustainability of the healthcare system are well-documented. Multiple studies recommend improving LBP care by promoting the implementation of multidisciplinary guidelines, yet limited evidence is available on their practical uptake and effects.

At the initiative of Maastricht University Medical Center (MUMC+), a regional multidisciplinary intermediate-care LBP pathway was developed to provide patients with the right care at the right place more rapidly and to reduce costly hospital visits. To develop and evaluate the “intermediate-care LBP” setting, the DMAIC methodology (Define, Measure, Analyze, Improve, Control) was applied. Healthcare utilization and patient flows before and after implementation of the new pathway were evaluated. National registry data were used as a control group. Data on healthcare use, appropriateness of care, referrals, and triage performance were collected between January 2014 and December 2018. Descriptive statistics were used for the analysis.

The volume of inappropriate care in the MUMC+ hospital setting decreased by 55%, representing a tenfold greater reduction compared with the national-level reduction observed in the control group. The proportion of appropriate care, defined as care that could be delivered in a multidisciplinary primary care setting, increased from 69% to 86%. Triage performance of the new pathway was excellent, with a correct referral rate exceeding 96%. A multidisciplinary intermediate-care setting (1.5-line outpatient clinic) with standardized triage can be an effective approach to improving healthcare efficiency. Further research is needed to strengthen these findings, assess cost-effectiveness, and test generalizability to other settings.

6.1 Inleiding

Lage rugpijn (LRP) is een groeiend gezondheidsprobleem dat het leven van veel mensen beïnvloedt en een aanzienlijke economische last vormt voor de westerse wereld.¹ Tachtig tot negentig procent van de bevolking zal één of meer episodes van LRP in hun leven ondergaan, met een 1-jaarsprevalentie van 38% wereldwijd. LRP is de belangrijkste oorzaak van invaliditeit bij volwassenen en de meest voorkomende musculoskeletale aandoening waarvoor patiënten hun huisarts raadplegen.²⁻³

Tot op heden is de organisatie van de zorg voor LRP-patiënten complex ingericht. Historisch gezien is er een grote verscheidenheid aan (para)medische disciplines betrokken bij patiënten met de diagnose en behandeling van LRP. Omdat succesvolle behandeling echter uitblijft, bestaat al decennialang een situatie waarin te vaak dure medische (ziekenhuis)zorg (bijv. multiële specialistische consulten, beeldvorming, percutane interventies en chirurgie) wordt verleend in de eerste-, tweede- en derde-lijnszorg.⁷⁻⁹

Deze ontwikkeling heeft verstrekkende gevolgen voor alle betrokken partijen. Vanuit het perspectief van de patiënt leidt dit tot meer tijd tot diagnose, onduidelijkheid over diagnose en behandeling, risico op overmatige, dure en mogelijk schadelijke medische behandeling en algehele ontevredenheid over de ontvangen zorg.¹⁰ Vanuit het perspectief van de zorgverlener leidt dit tot frustratie en verspilling van talent, terwijl vanuit het maatschappelijk perspectief deze benadering leidt tot hoge zorguitgaven, verloren productieve levensjaren en maatschappelijke kosten.^{5,11}

Meerdere internationale klinische richtlijnen en diverse beleidsmaatregelen van de overheid zijn ontwikkeld om dit fenomeen van overmedicalisering van LRP tegen te gaan of te voorkomen.¹²⁻¹⁹ Uniformiteit in diagnostische triage van LRP moet leidend zijn voor de juiste toewijzing van patiënten aan behandelingen en onnodige zorg verminderen. De meeste richtlijnen zijn monodisciplinair van aard en richten zich ofwel alleen op LRP of op het lumbosacraal-radiculair syndroom, in tegenstelling tot de schaarse multidisciplinaire klinische richtlijnen, zoals de NICE-richtlijnen en de richtlijnen ontwikkeld door het Belgisch Kenniscentrum (KCE).¹⁸⁻²⁰

Bovendien laten recente onderzoeken sterk bewijs zien dat de naleving van richtlijnen minimaal is en dat LRP nog steeds niet adequaat behandeld wordt in zowel landen met hoge als met lage inkomens over de hele wereld.^{4, 8, 21-22} Een publicatie uit Nederland laat zien dat het aantal diagnostische testen middels beeldvorming en het aantal verwijzingen naar de tweede lijn de afgelopen 5 jaar fors is gestegen.²³ Daarnaast varieert het aantal unieke diagnosebehandelingscombinaties (DBC's) voor LRP tussen de 1 en 22 per patiënt, met een gemiddelde van 2,15 DBC's in Nederland.²⁴ Het grootste deel van de kosten hiervan wordt toegerekend aan de disciplines anesthesiologie en neurologie.

Deze bevindingen laten een discrepantie zien tussen theorie en praktijk met betrekking tot de zorg van LRP, eerder beschreven als de “know-do-gap”.^{22, 25} Gebrek aan middelen, tijd en inhoudelijke kennis van huisartsen wordt als mogelijke oorzaak van deze lacune genoemd. Bovendien kunnen de persoonlijke overtuigingen en ervaring van een arts ook van invloed zijn op diens gedrag met betrekking tot de behandeling van LRP-patiënten. Om tot een systeem te komen waarin duurzame en richtlijnconforme zorg wordt verleend, zijn verschillende organisatorische ingrepen nodig. Een combinatie van overheidsbeleid en financiële steun, samen met het aanmoedigen van clinici en patiënten om weloverwogen keuzes te maken, is essentieel om de juiste zorg te bieden aan degenen die dit het meest nodig hebben.^{8,22,26,27}

Met dit in gedachten ontwikkelde een groep zorgprofessionals van het Maastricht Universitair Medisch Centrum (MUMC+) een nieuw LRP-zorgtraject. Het traject is gebouwd rond een zogeheten ‘anderhalvelijnszorg’ setting buiten het ziekenhuis, onderdeel van een initiatief van de Provincie Zuid-Limburg om duurzame zorg volgens het triple aim-principe te bevorderen.²⁸ In deze anderhalvelijnszorg setting gericht op LRP, voeren specialisten en gespecialiseerde verpleegkundigen uniforme triage uit om LRP-patiënten toe te wijzen aan de juiste zorgverlener op de juiste plek en om onnodige verwijzingen naar de tweede lijn te voorkomen. In deze studie beschrijven we de ontwikkeling van dit anderhalvelijnszorg traject en vergelijken we de LRP-gerelateerde zorgconsumptie in de tweede lijn voor en na de implementatie. We veronderstellen dat de implementatie van deze nieuwe route geassocieerd is met een vermindering van LRP-zorg in de ziekenhuisomgeving.

6.2 Methode

De resultaten van dit voor- en na onderzoek, met behulp van een controlegroep, worden gerapporteerd volgens de Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0).²⁹

Het MUMC+ is een groot, stedelijk universitair medisch centrum, waar jaarlijks meer dan 1.650 nieuwe patiënten met rugpijn worden behandeld, waarvan de overgrote meerderheid van de patiënten wordt doorverwezen naar neurologen, orthopedisch chirurgen en anesthesiologen.

Om het idee van een anderhalvelijnszorg setting voor patiënten met LRP naar de praktijk te vertalen, werd een gestructureerde stapsgewijze aanpak (definieer en meetfase, analysefase, verbeterfase, controlefase) volgens de Lean Six Sigma DMAIC-probleemoplossende methode gehanteerd.³⁰

Definieer en meetfase

Na het definiëren van de projectdoelen en het vormgeven van het projectteam, is eerst de patiënt journey in kaart gebracht om inzichtelijk te maken hoe patiënten met LRP werden doorverwezen, gediagnosticeerd en behandeld in het MUMC+. Daarbij is de techniek van ‘process mining’ gebruikt om de variatie in dit proces beter te begrijpen.

Analysefase

Tijdens de ‘Analysefase’ zijn de problemen in het ‘huidige LRP-zorgtraject’ in kaart gebracht en weergegeven in Figuur 1. (conventioneel zorgproces). In Nederland is de huisarts de poortwachter die patiënten met LRP alleen naar het ziekenhuis mag verwijzen voor consultatie door een specialist volgens bepaalde criteria in de richtlijnen. De specialist besluit vervolgens om de patiënt te behandelen of hem/haar door te verwijzen naar een andere specialist of terug naar de eerste lijn. Er zijn verschillende verbeterpunten geïdentificeerd binnen het conventionele

proces, zoals 1) lange tijd tot diagnose sinds eerste bezoek, 2) meerdere consulten door meerdere specialisten,

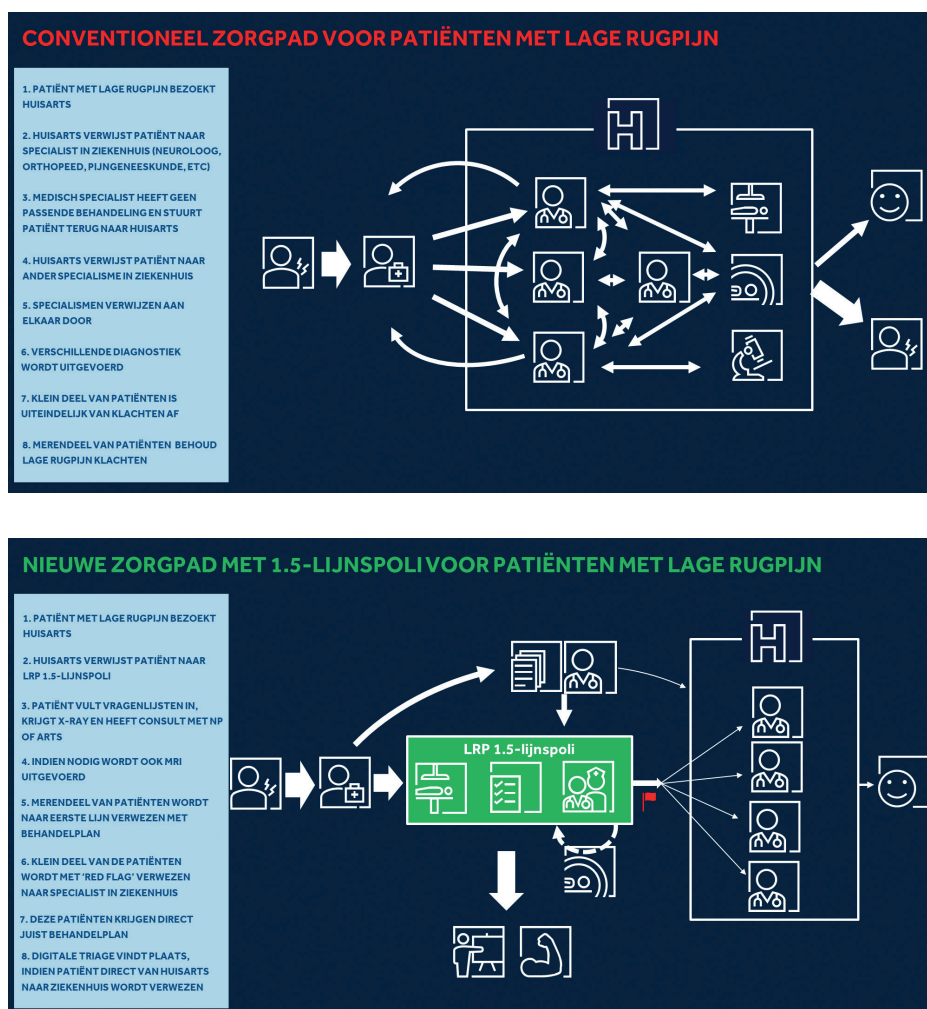
3) een groot aantal onnodige verwijzingen naar de 2^e lijn. Voor het kwantificeren van de problemen en als achtergrond- en controlecijfers zijn registergegevens uit het ziekenhuisinformatiesysteem gebruikt.

Verbeterfase

Tijdens de ‘Verbeterfase’ werd aan de hand van een reeks, door het projectteam, geselecteerde verbeteringsmogelijkheden, het toekomstige zorgtraject ontwikkeld (Figuur 1).

Het idee was om een ‘anderhalvelijnspoli voor lage rugpijn’ (1.5-lijnspoli) op te zetten tussen de eerste- en tweede-lijnszorg waar patiënten in een uniforme multidisciplinaire setting worden gezien vanuit biopsychosociale benadering ondersteund door digitale vragenlijsten (Kwaliteit van Leven, Visueel Analoge Schaal pijnschaal, Pijn Catastroferen Schaal (PCS), Hospital Anxiety and Depression Scale (HADS)), met een verpleegkundige of physician-assistent (PA) die scant op rode vlaggen en overlegt met een specialist. Patiënten zonder rode vlaggen of vermoeden van specifieke lage rugpijn (SLRP) of lumbosacraal-radiculair syndroom worden terugverwezen naar de huisarts met een persoonlijk behandelplan op basis van resultaten uit de biopsychosociale analyse. Patiënten met een vermoeden van SLRP of LSRS krijgen aanvullende beeldvorming of bloedonderzoek en krijgen een vervolgspraak op de 1.5-lijnspoli, of worden direct doorverwezen naar de tweede lijn voor verdere behandeling. Om uniformiteit van diagnostische triage en behandeling te garanderen, worden alle patiënten van de dag besproken binnen een team (verpleegkundige, PA, orthopeed en neuroloog/pijnspecialist of anesthesioloog/pijnspecialist).

Samenvattend omvat de ‘1.5-lijnspoli’ een patiëntgerichte, uitgebreide uniforme methode aangepast aan behoeften en verwachtingen van patiënt, zoals (1) holistische zorg via de biopsychosociale benadering, (2) gedeelde besluitvorming, (3) educatie en een gepersonaliseerd behandelplan, (4) kortere tijd tot diagnose en (5) verbeterde toegankelijkheid tot zorg.^{10,32} (Figuur 1).



Figuur 1. Beschrijving van het conventionele en nieuwe zorgpad voor patiënten met lage rugpijn

Controlefase

Tijdens de controlefase zijn protocollen en checklists ingevoerd en zijn zorgprofessionals getraind om protocolair te werken. Om alle betrokken partijen te informeren, is een communicatiecampagne gestart met informatie op maat voor de specifiek betrokkenen hulpverleners, zoals huisartsen en medisch specialisten.

6.2.1 Onderzoeksdesign

Vervolgens is aan de hand van voor- en nameting de implementatie van de 1.5-lijnspoli LRP in de regio Maastricht op basis van geregistreerde gegevens van LRP-zorgconsumptie en patiëntenstroom, geëvalueerd (Figuur 2). Daarnaast zijn de gegevens vergeleken met nationale DBC-registraties (DisData) om te zoeken naar tijdtrends als controle voor maturatie-effecten.³¹ Gegevens uit de nationale DBC-registraties komen exact overeen met onze gegevens, aangezien beiden de incidentie van dezelfde specifieke DBC-diagnoses onderzoeken.



Figuur 2. Tijdslijn pre-, tijdens en post-implementatie 1.5-lijnspoli lage rugpijn

6.2.2 Uitkomstmaten

De volgende uitkomsten voor de evaluatie van de implementatie van de 1.5-lijnspoli zijn gebruikt:

Primaire uitkomstmaat: het verschil in het aandeel onjuist zorggebruik in het ziekenhuis voor en na implementatie. Secundaire uitkomstmaat: het percentage patiënten dat correct is verwezen (volgens richtlijnen) na consultatie op de 1.5-lijnspoli.

6.2.3 Gegevensverzameling

In de dagelijkse praktijk coderen zorgprofessionals alle ziekenhuisactiviteiten die plaatsvinden met of voor patiënten rondom een bepaalde diagnose direct in het ziekenhuisinformatiesysteem. Alle werkzaamheden binnen een bepaald tijdsbestek voor een bepaalde diagnose worden automatisch gegroepeerd in een DBC. De afdeling financiële controle van het MUMC+ heeft alle LRP-patiënt

activiteiten en gerelateerde DBC-codes gedurende 2013-2019 uit het systeem gehaald en in een onderzoeksdatabase gezet voor analyses.

‘Correcte zorg’ en ‘Incorrecte zorg’

Alle DBC's zijn gestratificeerd in 'Correcte Zorg (CC)' of 'Incorrecte Zorg (IC)' op basis van een indeling gemaakt door een multidisciplinaire groep van drie ervaren (>10 jaar) specialisten (orthopedisch chirurg, neuroloog-pijnspecialist en een anesthesioloog-pijnspecialist). Een DBC werd geclassificeerd als CC wanneer de bijbehorende diagnose behandeling of diagnose in de tweede lijn rechtvaardigde, zoals specifieke spinale pathologie (diagnose bijv. tumor, infectie) en radiculair syndroom. Alle andere DBC's waren gemarkeerd als IC, wat aangaf dat op basis van de DBC-diagnose geen verdere analyse of behandeling in de tweede lijn werd aanbevolen en daarom werd bestempeld als 'onnodige zorg' (Figuur 3). Gegevens uit de landelijke DBC-database zijn op dezelfde manier gestratificeerd als de ziekenhuisgegevens (MUMC+).

Specialisme	Incorrect Care (IC)		Correct Care (CC)	
	Code	Diagnoses	Code	Diagnoses
ANESTHESIE	89/071	Mech/discogen lg rugkl (psrad)	89/076	Chron neurogene lage rugklacht
			89/075	(Sub)ac neurogen lg rugkl/rad
NEUROLOGIE	30/1204	Pseudorad syndr lumbo-sacr	30/1203	Rad syndr / HNP lumb-thorac
	30/1231	Lumbago	30/1211	Spinale stenose lumbaal
			30/1221	Postlaminectomiesyndroom
ORTHOPEDIE	05/1398	Pijn eci thoracale/lumbale wk	05/1350	Kanaal stenose
	05/1340	Chron aspecifieke lage rugkl	05/1360	HNP thoracale/lumbale wk
			05/1365	Failed back surgery syndroom
			05/1370	Spondylolysis/lithesis
			05/1395	Osteoporotische inzakking
			05/1301	Arthr/spondylos thora/lumb wk

Figuur 3. Indeling 'correcte' en 'incorrecte' lage rugpijn zorg

6.2.4 Gegevensanalyse

Correcte vs Incorrecte DBC's: Het Nederlandse vergoedingssysteem kent 24 diagnosecodes voor LRP, verdeeld over 4 disciplines. Vijf van deze codes werden door een multidisciplinair team bestempeld als 'Incorrect Care'(IC). De overige 19 werden als 'Correct Care' (CC) beschouwd. Alle codes zonder unanieme consensus werden als CC beschouwd (Figuur 3).

Correcte vs. incorrecte patiënten: Patiënten kunnen in de loop van de tijd meerdere DBC's ontvangen bij een bezoek aan een of meer medische disciplines. Patiënten met minimaal één CC-DBC in hun traject (binnen 12 maanden na hun eerste ziekenhuisactiviteit) worden beschouwd als terecht verwezen naar het ziekenhuis en gedefinieerd als CC-patiënt. Patiënten zonder CC-DBC in hun traject worden gedefinieerd als IC-patiënten.

Jaren: Het jaar van het eerste (ziekenhuis/1.5-lijns poli) contact van de patiënt definieerde het patiëntjaar. De jaren 2014 tot en met 2018 zijn geanalyseerd. Gegevens uit 2013 zijn gebruikt om patiënten uit 2014 uit te sluiten die in 2013 al in het ziekenhuis waren gezien. Gegevens uit 2019 zijn gebruikt om 12 maanden follow-up mogelijk te maken voor nieuwe patiënten in 2018.

Om de effectiviteit van de triage te evalueren, werden beschrijvende statistieken gebruikt om de totale aantallen en proporties van CC- en IC-patiënten en DBC's in zowel ziekenhuis als de 1.5-lijns poli te beschrijven.

6.3 Resultaten

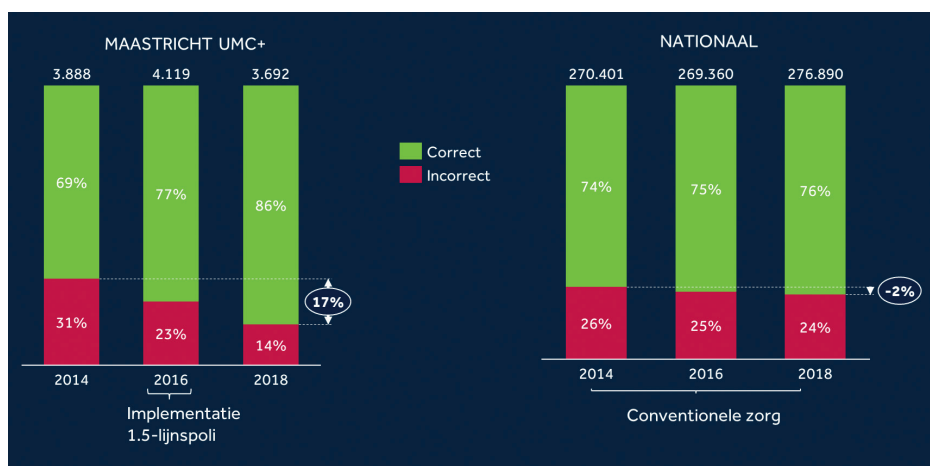
6.3.1 Onnodige zorgconsumptie

Figuur 4 illustreert het gebruik van LRP-zorg in de tweede lijn (MUMC+ en landelijk) tussen 2014 en 2018 uitgedrukt in DBC's, opgesplitst in IC en CC.

In de jaren 2014 tot 2018 is het aantal IC-DBC's in het MUMC+ met 55% gedaald (1202 vs. 535) en CC-DBC's met 18% gestegen (2686 vs. 3157). Daarmee is het aandeel CC-patiënten gestegen van 69% in 2014 naar 86% in 2018. In dezelfde periode is het aandeel correcte zorg op landelijk niveau slechts met 2% gestegen (van 74% naar 76%).

6.3.2 Uitkomsten triage 1.5-lijns poli

In 2017 en 2018 werden in totaal respectievelijk 431 en 467 unieke patiënten doorverwezen naar de 1.5-lijns poli. De grote meerderheid (84%) van de patiënten werd terugverwezen naar de eerste lijn zonder doorverwijzing naar de tweede lijn. Van de 16% die naar de tweede lijn werd verwezen, werd 75% correct doorverwezen naar de juiste specialist (CC), terwijl bij 1 op de 4 patiënten een onjuiste doorverwijzing werd vastgesteld (IC). Ook constateerden we dat de triageprestaties van de 1.5-lijns poli goed waren, aangezien de overgrote meerderheid van de patiënten (96%) correct werd doorverwezen naar de eerstelijnszorg of tweedelijnszorg.



Figuur 4. Aandeel 'correcte zorg' in MaastrichtUMC+ t.o.v. nationaal

6.4 Discussie

Het doel van deze studie was het beschrijven en evalueren van een innovatief LRP-zorgtraject in een anderhalvelijnszorg setting in vergelijking met conventionele zorg in een ziekenhuisomgeving. Een sterke afname van onnodige ziekenhuisbezoeken voor LRP-patiënten na implementatie van de 1.5-lijns poli werd aangetoond, terwijl het percentage geïndiceerde ziekenhuisbezoeken toenam.

Verscheidene factoren (organisatorische en inhoudelijke) hebben een essentiële rol gespeeld bij het welslagen van dit nieuwe LRP-traject dat ten goede komt aan patiënten, zorgverleners en de samenleving als geheel. Er was sprake van een intrinsieke motivatie en een gemeenschappelijk doel bij alle betrokken zorgverleners en belanghebbenden die ernaar streefden om laagdrempelig zorg van hoge kwaliteit te bieden via een snel en uniform zorgproces. De provincie Limburg bood financiële ondersteuning en flexibiliteit om praktische belemmeringen op te heffen en transmurale zorgtrajecten mogelijk te maken. Samenwerking in het onderzoeksteam tussen zorgprofessionals en experts in 'operational excellence' heeft geleid tot een efficiënt en duurzaam zorgtraject met verbeterde communicatie tussen zorgprofessionals en naar patiënten toe. Bovendien verschilt de zorg op de 1.5-lijns poli aanzienlijk van de zorg in een conventionele setting en is deze in overeenstemming met internationale multidisciplinaire richtlijnen.¹⁸⁻¹⁹

Er zijn positieve resultaten op het verminderen van dure ziekenhuisbezoeken en de triagecapaciteit van de 1.5-lijns poli behaald. Daarbij is gebruik gemaakt van nationale DBC-registraties om te corrigeren voor rijpingseffecten. Aangezien de resultaten tienmaal hoger liggen dan de nationale cijfers, kan worden aangenomen worden dat de resultaten geen algemene trends zijn, maar verband houden met de implementatie van de 1.5-lijns poli. Vanwege ontbrekende gegevens kan er geen objectieve informatie verstrekt worden over het effect van de 1.5-lijns poli op onderdeel 'tijd tot diagnose' in vergelijking met de conventionele route. Desalniettemin verwachten we dat de totale 'tijd tot diagnose' drastisch is afgenomen. In het conventionele proces werden patiënten vaak gezien door meerdere specialisten, met doorverwijzingen binnen en tussen disciplines en kregen ze vaak verschillende diagnoses in de loop van weken, maanden of zelfs

jaren. In het nieuwe proces kreeg de overgrote meerderheid van de ‘incorrecte’ patiënten één afspraak op de 1.5-lijns poli, waar ze dezelfde dag een diagnose en behandelplan kregen. Wat betreft de ‘correcte’ patiënten is aangetoond dat deze patiënten vaak direct werden doorverwezen naar de juiste zorgverlener in de tweede lijn.

Dit onderzoek beschrijft de praktische evaluatie en procesbeschrijving van een zorginnovatie. Het gebruikte onderzoeksdesign (voor- en nameting) is er een waarvan bekend is dat het gevoelig is voor vertekening.³⁴ De huidige studie heeft dan ook enkele beperkingen die van invloed kunnen zijn op de behaalde resultaten. Desondanks beschouwen onderzoekers deze beperkingen niet als een substantiële bedreiging voor de resultaten van de primaire uitkomstmaten. Alle patiënten die het MUMC+ en 1.5-lijns poli bezochten voor LRP-consultatie werden geïnccludeerd voor analyse, wat selectiebias hoogst onwaarschijnlijk maakt. Toewijzing van een specifieke DBC aan de IC- of CC-groep werd uitgevoerd door een groep experts, onafhankelijk van elkaar, wat het risico op instrumentatiebias verkleinde. De toewijzing was gebaseerd op algemeen aanvaarde multidisciplinaire klinische richtlijnen. Bovendien is de triage van LRP in het algemeen een uitdaging vanwege de sterk wisselende klinische presentaties in deze populatie.³⁴⁻³⁵ Het is daarom onvermijdelijk dat sommige patiënten toch een specialist in de tweede lijn zullen raadplegen, terwijl dit achteraf incorrecte (duurdere) zorg is. Vanwege het pragmatische karakter van de opzet konden patiënten die terugverwezen werden naar de eerste lijn niet op langere termijn gemonitord worden. Er is daarom geen inzicht in het aantal patiënten dat ten onrechte is terugverwezen naar de eerste lijn en/of vervolgens een ander ziekenhuis buiten de regio heeft bezocht. Een sterk punt is dat het effect 10 keer zo groot was als dat van een tijdtrend in een nationaal register in dezelfde periode.

In de nabije toekomst is de verwachting dat de 1.5-lijns-poli voortgezet en versterkt wordt door een grotere betrokkenheid van diverse eerstelijnszorgprofessionals en paramedici. Onderzocht wordt hoe patiëntenvoorlichting en medezeggenschap in de vorm van Samen Beslissen de zorg ten goede kunnen komen en ook of substitutie van zorg mogelijk is. Gedacht wordt aan bijvoorbeeld een traject waarbij opgeleide arts-assistenten, physician-assistants, fysiotherapeuten of huisartsen met interesse in het bewegingsapparaat de triage-activiteiten overnemen. Daarnaast zijn fysiotherapeuten opgenomen in ons netwerk

om behandeltrajecten in de eerste lijn te implementeren. Verder wordt geïnvesteerd in het verzamelen van patiëntrelevante uitkomstgegevens over het hele zorgcontinuüm om continue verbetering van zorgmodellen mogelijk te maken en zo de waarde voor patiënten in de regio te vergroten. In overleg met zorgverzekeraars kan mogelijk ook gekeken worden naar nieuwe betalingsmodellen, passend bij 'Value Based Healthcare'. Op basis van interesse van enkele andere ziekenhuizen worden de mogelijkheden onderzocht om de 1.5-lijns poli uit te breiden naar andere regio's.

6.5 Conclusie

Na het implementeren van een anderhalvelijnszorg traject voor patiënten met LRP, werd een grote vermindering van onnodige LRP-zorgconsumptie in het ziekenhuis geconstateerd, die 10x de nationale gegevens overtrof. Deze reductie is volgens het onderzoeksteam te danken aan een goede triage en uniformiteit in de '1.5-lijns poli'. Aanvullend onderzoek is nodig om de (kosten)effectiviteit van de klinische paden voor LRP-patiënten in de eerste lijn longitudinaal te monitoren.

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7

CAN QUALITY IMPROVEMENT METHODOLOGIES DERIVED FROM MANUFACTURING INDUSTRY IMPROVE CARE IN CARDIAC SURGERY? A SYSTEMATIC REVIEW

Hoefsmit, P. C., **Schretlen, S.**, Burchell, G., Van den Heuvel, J., Bonjer, J., Dahele, M., & Zandbergen, R. (2022). Can quality improvement methodologies derived from manufacturing industry improve care in cardiac surgery? A systematic review. *Journal of Clinical Medicine*, 11, 5350. <https://doi.org/10.3390/jcm11185350>



Abstract

Objectives

Healthcare is required to be effectively organised to ensure that growing, aging and medically more complex populations have timely access to high-quality, affordable care. Cardiac surgery is no exception to this, especially due to the competition for and demand on hospital resources, such as operating rooms and intensive care capacity. This is challenged more since the COVID-19 pandemic led to postponed care and prolonged waiting lists. In other sectors, Quality Improvement Methodologies (QIM) derived from the manufacturing industry have proven effective in enabling more efficient utilisation of existing capacity and resources and in improving the quality of care. We performed a systematic review to evaluate the ability of such QIM to improve care in cardiac surgery.

Methods

A literature search was performed in PubMed, Embase, Clarivate Analytics/Web of Science Core Collection and Wiley/the Cochrane Library according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis methodology.

Results

Ten articles were identified. The following QIM were used: Lean, Toyota Production System, Six Sigma, Lean Six Sigma, Root Cause Analysis, Kaizen and Plan-Do-Study-Act. All reported one or more relevant improvements in patient-related (e.g., infection rates, ventilation time, mortality, adverse events, glycaemic control) and process-related outcomes (e.g., shorter waiting times, shorter transfer time and productivity). Elements to enhance the success included: multidisciplinary team engagement, a patient-oriented, data-driven approach, a sense of urgency and a focus on sustainability.

Conclusions

In all ten papers describing the application of QIM initiatives to cardiac surgery, positive results, of varying magnitude, were reported. While the consistency of the available data is encouraging, the limited quantity and heterogeneous quality of the evidence base highlights that more rigorous evaluation, including how best to employ manufacturing industry- derived QIM in cardiac surgery is warranted.

7.1 Introduction

Quality Improvement Methodologies (QIM) from the industry have been applied to healthcare to improve value, enhance access, control increasing expenditure and improve quality.¹⁻⁵ This has led to a number of publications concerning the application of such QIM to surgical care.⁶⁻¹² Lean methodology and Six Sigma are examples of QIM that have successfully improved performance in healthcare.^{13,14} The fundamental approach to these QIM involves identifying the care pathway to be improved, defining the correct outcome metrics, and performing a baseline measurement, followed by process analysis, identifying inefficiencies and subsequently implementing improvements in the care pathway. Finally, measurements are performed to quantify whether the desired gains and improvements have been realised. In this paper, we focus on cardiac surgery, which is associated with an intensive and complex perioperative process, a large amount of supporting equipment, involvement of multiple well-trained multidisciplinary healthcare professionals and considerable expense.¹⁵ Examples are the use of cardiopulmonary bypass, post-operative stay in the Intensive Care Unit (ICU) and intensive monitoring in the cardiac care unit or surgical ward (telemetry, vital signs, bloodwork, X-rays, electrocardiography) to prevent and manage post-operative complications, including cerebrovascular ischemic events, myocardial infarction, renal dysfunction, atrial fibrillation, cardiac tamponade and deep sternal wound infections.¹⁶ Such complications can increase the length of in-hospital stay after cardiac surgery. Since cardiac surgery considerably impacts limited hospital resources¹⁷⁻²¹, it is vital to maximise its quality and value by optimising care pathway efficiency and patient flow. Any additional stress on the healthcare system, such as that experienced during the COVID-19

pandemic, which reduces ICU and operating room capacity, only increases the necessity for efficiency and value.²²⁻²⁴ Furthermore, inefficiencies are expensive and cause delays and cancellations, which may be followed by compromised patient outcomes and dissatisfaction.^{25,26} As an example of the potential for cost savings, Hawkes et al. calculated that a better flow of patients through the care pathway in cardiothoracic surgery could save 45 million (M) pounds (52 M euros) annually in England.²⁷ This demonstrates that there is a considerable opportunity and potential for quality and value improvement in cardiac surgery.²⁸ We performed a systematic review to evaluate the effectiveness of QIM on the pre-, intra-, and postoperative care process in cardiac surgery. The focus of this review is specifically on manufacturing industry-derived QIM, one feature of which is a simultaneous focus on both quality improvement and process efficiency. It is not a review of other improvement measures that have had a major impact on quality and have previously been extensively reviewed in the literature, including, for example: large national or regional databases; use of risk-adjusted mortality rates; site visits; and advocating a minimum volume of procedures per unit, or per surgeon.

7.2 Materials and Methods

A literature search was performed based on the methodology described in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.²⁹

7.2.1 Search strategy

To identify relevant publications, we conducted systematic searches focused on the pre-, intra- and post-operative process in cardiac surgery and QIM in the bibliographic databases PubMed, Embase, Clarivate Analytics/Web of Science Core Collection and Wiley/the Cochrane Library from inception up to February 15th, 2021. The search included keywords and free text terms for (synonyms of) ‘cardiac surgery’ combined with (synonyms of) ‘quality improvement methodologies’. The particular QIM included in this paper are consistent with prior publications and

literature.^{2,11} A full overview of the search terms per database can be found in the Supplementary Information (see Supplementary Tables S1 and S2). No systematic review protocol was registered. No limitations on date or language were applied in the search. Duplicate articles were removed. The references of the identified articles were searched for relevant publications.

7.2.2 Selection process

Studies were included in the final review if they were published in a peer-reviewed journal, described the application of one of the QIM included in the search, were directed at improving the pre, intra- or post-operative process of adult cardiac surgery, written in English, available as a full article and published after 2000 (therefore in the last two decades). Only including English articles is in accordance with the strategy used by Moher et al.³⁰ Studies were excluded if the article was a conference abstract or editorial. The cardiac surgery care pathway comprised the pre-, intra- and post-operative processes and was defined as the period between referral until discharge after cardiac surgery. Two reviewers (P.C.H. and R.Z.) independently screened potentially relevant articles and abstracts for eligibility. If necessary, the full-text article was assessed. Overall, there was good concordance between the reviewers, with minor differences resolved through consensus.

7.2.3 Data assessment

The full text of relevant articles was obtained. Two reviewers (P.C.H. and R.Z.) independently evaluated the full-text papers, and extracted relevant information, including author, year, country, duration, objective, number of analysed procedures, QIM, interventions applied and results.

7.2.4 Data analysis

In this instance, consistent with the number of identified articles, we performed a review and summarised the details and outcomes of the included studies.

7.2.5 Assessment of risk of bias in included studies

Quality assessments of each included study were conducted using the Newcastle-Ottawa Scale for observational studies.³¹ Three elements were scored: selection, comparability and outcome. The quality of the included studies was rated good, fair or poor.

7.2.6 Quality improvement methodologies

The Toyota Production System is a complete quality improvement system that aims at the complete elimination of waste and the continuous pursuit of the most efficient processes.¹⁴ Lean is a philosophy, of which the Toyota Production System is an example, that consists of five principles (value, value stream, flow, pull and perfection) and methods that create optimal value for patients and organisations by reducing waste, optimising resource utility, and improving efficiency on a continuous basis.^{13,14} Tools used in Lean include Kaizen, process mapping, value stream mapping, and poka-yoke. Six Sigma is a more data-driven team-elaborated QIM focused on removing errors. Lean and Six Sigma are often combined to strive for operational excellence.¹³ The approach of Define, Measure, Analyse, Improve and Control (DMAIC) is often used in Lean Six Sigma. Plan-Do-Study-Act (PDSA)/ Plan-Do-Check-Act (PDCA) cycles are comparable methods and frequently applied to smaller-scale process improvement. Both are considered independent methods and a part of Lean. Statistical Process Control, also integrated into Six Sigma, monitors and controls a process by using tools such as run and control charts.³² Total Quality Management engages all employees in continuous, customer-focused improvement to achieve excellence and success. It can be traced back to the early days of modern quality improvement and inspired Lean and Six Sigma. Clinical Audit is a method that checks if defined quality standards are met.²

7.3 Results

The results of the search are summarised in Figure 1 and Table 1. After removing duplicates, the literature search generated a total of 1214 references: 251 in PubMed, 649 in Embase, 314 in Clarivate Analytics/Web of Science Core Collection and 3 in Wiley/the Cochrane Library. Reviewing the abstracts led to exclusion of 1179 articles. The main reasons for exclusion were unrelated to the pre-, intra- and post-operative cardiac surgery process, a non-manufacturing industry-derived QIM, or the reference was not available in English. After examination of the full text of the remaining 35 articles, a total of 10 articles met the inclusion criteria.

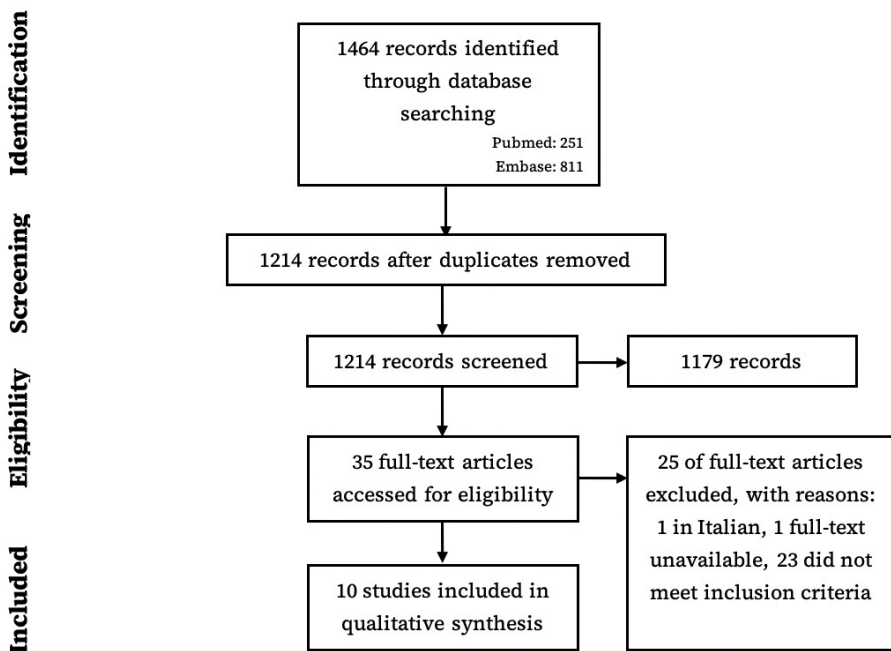


Figure 1. Flowchart of the search and selection procedure of studies

Table 1. Results

Author, Year, Country	Duration	Patients/Procedures	Objective	Quality Improvement Methodology	Main Interventions	Outcomes
Geoffrion et al. (2020) USA ³³	24 months (January 2015 - March 2018)	Hand-offs pre-intervention (n=64) and post-intervention (n=62)	Reduce handoff (transfer of care) time	Twelve steps implementation process in four phases (planning, engaging, executing and evaluating)	Redesign and implementation of the handoff process, implementation of handoff bundle and team training	Reduced total handoff time (in room to completion) from 12.6 ± 3.6 to 10.7 ± 2.2 minutes (p < 0.014) ,
		Number of fidelity measurements (overall conformance score) (n=57) Number of provider satisfaction measurements in redesign phase (n=82), after 6 months (n=98) and after 2.5 years (n=81)		QIM activities: process mapping, PDSA cycles and multiple rapid-cycle process improvements		Improved fidelity from 18.5 ± 4.0 to 32.8 ± 9.5 (p < 0.001) Improved provider satisfaction after 6 months (84 versus 80 of 100, p<0.02) and 2.5 years (84 versus 87 of 100, p=0.133)
Culig et al. (2011) USA ³⁴	28 months (March 2008 – June 2010)	Improve patient outcomes, reduce costs and improve patient satisfaction	Improve patient outcomes, reduce costs and improve patient satisfaction	Toyota Production System	Daily stand-up meetings Collaborative bedside rounds	Lower risk-adjusted mortality/incidence of adverse events of 61%/57% than regional rate in Society of Thoracic Surgery database
		CABG (n=253)		QIM activities: team training, value stream mapping, pull methodology, root cause analysis, visual management, Kanban, standardization, one-by-one processing, 5S: sort, set in order, shine, standardize and sustain, stand-up meetings	Pre-operative briefing Intra-operative implementation of checklist, ultrasonographic aortic imaging and cerebral oximetry, handoff standardization Post-operative protocol for medication administration, extubation and glycaemic control	Costs savings of \$884,000 for CABG (\$3497 per CABG)

Table 1. Results *Continued*.

Author, Year, Country	Duration	Patients/Procedures	Objective	Quality Improvement Methodology	Main Interventions	Outcomes
Kles et al. (2015) USA³⁵	32 months (May 2012 – December 2014)	CABG (n=262)	Reduce surgical site infection	Six Sigma (DMAIC) and Contextual model QIM activities: chart review, process mapping, direct observations of the process in real-time, flow-chart, standardization, root cause analysis, contextual model	Infection prevention strategies: hair removal outside OR, routine use of mupirocin, glycaemic control, prophylactic antibiotic administration, antibiotic-impregnated sutures, soft silicone silver-impregnated dressing, dressing midsternal incision for 7 days	Reduction in incidence rate of surgical site infections from 3.74 to 0.7 per 100 procedures, and ultimately to 0 during 30 months and 590 procedures
Gutsche et al. (2014) USA³⁶	12 months (July 2011 – July 2012)	Cardiac surgeries total (n=404), pre-intervention (n=195) and post-intervention (n=171)	Improve rates of early extubation	Lean methodology QIM activities: spaghetti diagram, fishbone diagram, value stream mapping, root cause analysis, PDSA	Development of extubation guideline Countermeasures: usage of air warming blankets to prevent hypothermia, use of pain scale to titrate pain medication, treatment of hypertension with antihypertensive drugs (instead of opioids), improved weaning process and availability of equipment for extubation to prevent delays	Intervention predicted extubation in < 6 hours improved from 27% to 50% (p=0.0001) Lower median length of intubation from 9.7 to 6.1 hours (p=0.0019)

Table 1. Results *Continued.*

Author, Year, Country	Duration	Patients/Procedures	Objective	Quality Improvement Methodology	Main Interventions	Outcomes
Lytsey et al. (2015) Sweden ³⁷	9 months (September 2009 – July 2010)	CABG patients requiring surgical revision due to deep sternal wound infections pre-intervention (n=80) and post-intervention (n=13)	Illustrate that root cause analysis following by quality improvement can reduce DSWI after CABG	QIM activities: root cause analysis	Hygienic interventions in the pre-, intra and post-operative care, e.g., hand gloves, disinfection, ultra clean air, antibiotic prophylaxis, blood glucose control, wound dressing in place for three days	Deep sternal wound infection incidence per CABG operation decreased from 5.1% pre-intervention to 0.9% post-intervention
Watling et al. (2020) Canada ³⁸	24 months (September 2016 –2018)	Cardiac surgery (including TAVI) pre-intervention (n=788) and post-intervention (n=873)	Reduce waiting times	Lean methodology QIM activities: 5-day Kaizen (rapid improvement) workshop, impact-effort analysis, weekly dashboards	Fast-tracking from ICU to ward or bypassing the ICU Improved scheduling and listing Day of surgery admission Discharge protocol	Reduced wait time with 35% from median 52 to 35 days Increased annual number of surgical interventions from 788 to 873 (10.8%) An increase in cancellations of 7.5% due to limited ICU resources
Van Tiel et al. (2006) The Netherlands ³⁹	Not reported (Start –Autumn 2003)	CABG OR baseline (n=116), follow-up (n=248) and monitoring phase (n=117) Ward baseline (n=16), follow-up (n=22) and monitoring phase (n=18)	Improve compliance with infection control measures for the care of patients during and after cardiothoracic surgery	PDSA cycles	Instruction and training of correct hygienic procedures based on infection control in the OR and on the ward Feedback on the results of baseline measurement Use of posters in the OR Presence of QI team in the OR	Overall compliance score improved in the OR and surgical ward from baseline versus follow-up phase versus monitoring phase

Table 1. Results Continued.

Author, Year, Country	Duration	Patients/Procedures	Objective	Quality Improvement Methodology	Main Interventions	Outcomes
Berry et al. (2009) USA⁴⁰	17 months (August 2005 – February 2007)	CABG pre-intervention (n=137) and post-intervention (n=117)	To test whether process redesign by an integrated delivery system could implement evidence based medical practices	ProvenCare programme QIM activities: multidisciplinary team meetings to review and validate best practice evidence, interview with patients, PDSA cycles	Implementation of 40 process elements (e.g., patient education materials, glycaemic control protocol, standard pre-operative anticoagulation protocol, diagnostics and medication, intra-operative time-out, documentation, antibiotic prophylaxis, and post-operative standardization documentation, medical management, order sets)	Receiving all 40 elements in first month (59%) versus post-intervention 100% (p=0.001) Patient outcomes improved in 8 out of 9 measures (only discharge location to home significant)
Hefner et al. (2016) USA⁴¹	12 months (January to June 2010 – January to June 2011)	CABG surgeries pre-intervention (n=68) and post-intervention (n=58)	Reduce prolonged mechanical ventilation after CABG surgery	Lean methodology QIM activities: gap analysis, retrospective chart review, interviews with stakeholders and focus groups, root cause analysis, standardisation	Standardized extubating protocol Dry erase boards in patients' room to facilitate team communication Edits of post-operative ICU order set to facilitate correct medication administration	Mechanical ventilation duration reduced from 11.4 hours to 6.9 hours (p<0.001) Number of patients reintubated reduced from 11.8% to 3.5% (p=0.08) Rate of prolonged ventilation decreased from 29.4% to 8.6% (p=0.004)

Table 1. Results *Continued*.

Author, Year, Country	Duration	Patients/Procedures	Objective	Quality Improvement Methodology	Main Interventions	Outcomes
Martinez et al. (2011) USA⁴²	4 years (January 2003 – March 2007)	Cardiac surgery patients admitted to CSICU total (n=1892), baseline (n=390) and final phase (n=310)	Generate a substantial and sustainable improvement in perioperative glucose control	Lean Six Sigma (DMAIC) QIM activities: baseline chart audit, baseline capability, process mapping, fishbone diagram, focus groups, standardization	Perioperative insulin protocol Educational events	Admission glucose < 200mg/dL at baseline 76% versus final 94% (p<0.001)
		Glucose checks total (n=81333), baseline (n= 3778) and final phase (n= 19043)				Glucose control >6 hours at baseline 0 versus final phase 11% (p<0.001)
						Glucose measurements increased from baseline 3 to final phase 12 per patient per day (p<0.001)
						Hypoglycaemic events decreased from 1.7% at baseline to 0.9% at final phase (p<0.001)

7.3.1 Descriptive synthesis of the results

Seven of the ten articles originated from the United States of America (USA) and the remaining three from Canada, Sweden and the Netherlands. Most studies were published as quality improvement reports with a pre- versus post-intervention study design. The various QIM could be divided into (1) larger-scale quality improvement systems: Lean (n = 3), Toyota Production System (n = 1), Six Sigma (n = 1) and the combination of Lean and Six Sigma (n = 1), or (2) individual quality improvement related-activities, including: PDSA (n = 4), root cause analysis (n = 5), process mapping (n = 3), value stream mapping (n = 2), pull methodology (n = 1) and Kaizen (n = 1). Berry et al. applied their self-developed 'ProvenCare' improvement programme, which included PDSA and resulted in the implementation of 40 process elements based on recommendations of the American College of Cardiology American Heart Association (ACC/AHA) guideline for CABG surgery.⁴⁰ Three articles redesigned the complete pre-, intra- and post-operative phases. The main, discrete improvements that were introduced and implemented because of applying the QIM can be summarised as: process elements and better teamwork, education and communication. Important process elements included the redesign of the transfer process, fast-tracking, the standardisation of perioperative drug administration, hygienic measures, glucose management, and implementation of checklists and extubation guidelines. Team training, education, stand-up meetings, pre-operative briefings, collaborative bedside rounds, work agreements and methods to improve communication were also impactful. More detailed information is included in Table 1. All articles showed improvements in both patient (infection rates, ventilation time, mortality, adverse events and glycaemic control) and process-related outcomes (shorter wait times, shorter transfer time and increased productivity), however, not all were statistically analysed or significant. Furthermore, improvements in patient and staff satisfaction and financial performance were reported.

Patient related outcomes

The application of Six Sigma in a 350-bed regional medical centre resulted in reduced rates of surgical site infections from 3.74 to 0.7 per 100 procedures, and ultimately to 0 for 30 months, representing 590 procedures.³⁵ In-depth root cause analysis resulted in a decrease in the incidence rate of deep sternal wound

infection from 5.1% to 0.9% during a 9-month period.³⁷ Compliance with infection control measures during the care of cardiac surgery patients was improved through the application of PDSA cycles.³⁹ Lower rates of mortality and major adverse events after CABG surgery following the application of Toyota Production System based improvements were reported compared to the regional Society of Thoracic Surgeon database.³⁴ The ProvenCare programme decreased the number of complications from $n = 53$ (39%) to $n = 41$ (35%, $p = 0.55$) in a total of 254 CABG procedures over a period of 17 months.⁴⁰ Multiple outcomes were analysed, but only discharge location to home showed a significant improvement from 81% ($n = 111$) versus 90.6% ($n = 106$, $p = 0.03$).⁴⁰ A summary of the main interventions of the ProvenCare programme is provided in Table 1. The application of Lean methodology increased the proportion of patients extubated within 6 hours from 27% to 50% ($p = 0.0001$) and decreased the median length of intubation from 9.7 to 6.1 hours ($p = 0.0019$).³⁶ Significant reductions in ventilation time were also reported by Hefner et al.⁴¹ Lean management led to shorter duration of ventilation from 11.4 hours to 6.9 hours ($p < 0.001$), fewer patients reintubated (11.8% to 3.5%, $p = 0.08$) and a lower rate of prolonged ventilation (29.4% to 8.6%, $p = 0.004$). Lean Six Sigma improved glycaemic control assessed using multiple parameters in the cardiac surgery ICU and there were significantly fewer hypoglycaemic events.⁴²

Process related outcomes

Geoffrion et al. redesigned the handoff process, resulting in a significantly shorter time to transfer from the operating room to the ICU (12.6 to 10.7 minutes).³³ The ProvenCare programme focused on increasing the rate of performance of 40 discrete elements in patient care. The performance rate of all 40 elements, which can be found in Table 1, rose from 59% to 100% after the programme ($p = 0.001$).⁴⁰

Watling et al. in Canada applied Lean as QIM during a period of 24 months, which resulted in 17 days shorter waiting time for cardiac surgery and increased annual production from 788 to 873 cardiac surgeries (10.8%), despite a 7.5% increase in cancellations, mainly due to limited ICU resources.³⁸

Patient and staff reported outcomes

Geoffrion et al. reported improved staff satisfaction at 6 months ($p < 0.02$) and 2.5 years ($p = 0.133$) after applying a twelve-step implementation process, PDSA cycles and multiple rapid-cycle process improvements for redesigning the handoff process.³³ Culig et al. reported a constant patient satisfaction rate at the ICU of 99% and improved staff satisfaction after applying the Toyota Production System to the care pathway.³⁴

Financial performance

costs savings of us \$3497 per cabg and us \$884,000 in total were reported after the application of the toyota production system.³⁴ kles et al. found that a reduction in surgical site infection rate led to estimated cost savings of us\$606,498 in 590 cabg procedures over 30 months.³⁵

Risk of bias assessment

the quality of the included papers was assessed with the Newcastle Ottawa scale and was rated as following: good $n = 433,36,37,40$ fair $n = 134$ and poor $n = 535,38,39,41,42$ (table 2).

Table 2. Risk of bias assessment

Study	Selection	Comparability	Outcome	Quality
Geoffrion et al. (2020) ³³	3	1	3	Good
Culig et al. (2011) ³⁴	2	1	3	Fair
Kles et al. (2015) ³⁵	4	0	3	Poor
Gutsche et al. (2014) ³⁶	4	2	3	Good
Lytsy et al. (2015) ³⁷	4	1	3	Good
Watling et al. (2020) ³⁸	4	0	3	Poor
Van Tiel et al. (2006) ³⁹	2	0	2	Poor
Berry et al. (2009) ⁴⁰	4	2	2	Good
Hefner et al. (2016) ⁴¹	4	0	3	Poor
Martinez et al. (2011) ⁴²	4	0	3	Poor

7.3.2 Relevant disclosures and conflict of interests

Relevant disclosures and conflicts of interest were reported for two studies (Table 3).^{34,38} The project of Culig et al. was supported by a grant. Waitling et al. had a partnership with Integrated Health Solutions, Medtronic.

Table 3. Relevant disclosures and conflicts of interests

Study	Relevant disclosures and conflict of interest
Geoffrion et al. (2020) ³³	Not mentioned
Culig et al. (2011) ³⁴	Supported by grant from the Highmark Foundation of Western Pennsylvania
Kles et al. (2015) ³⁵	None
Gutsche et al. (2014) ³⁶	Not mentioned
Lytsy et al. (2015) ³⁷	None
Watling et al. (2020) ³⁸	Partnership with Integrated Health Solutions, Medtronic.

Table 3. Relevant disclosures and conflicts of interests *Continued.*

Study	Relevant disclosures and conflict of interest
Van Tiel et al. (2006) ³⁹	Not mentioned
Berry et al. (2009) ⁴⁰	None
Hefner et al. (2016) ⁴¹	No financial disclosures
Martinez et al. (2011) ⁴²	None

7.4 Discussion

We identified ten articles that used manufacturing industry-derived QIM to improve the pre, intra- or post-operative cardiac surgery process. Seven out of the ten projects were performed in the USA. Although seemingly limited, the number of studies meeting the inclusion criteria is reasonable when compared to a similar analysis reviewing the application of comparable QIM or Lean and Six Sigma in all fields of surgery ($n = 35$ studies and $n = 23$).^{10,11} All papers analysed a substantial number of procedures and showed improvements in one or more process- and/or patient-related outcomes. However, the bias assessment highlighted that five of the quality improvement initiatives were rated as poor which limits the level of evidence. Nonetheless, the suitability of some of these benchmarks for quality improvement studies such as these is debatable. For example, the independent blind assessment may not be applicable for quality improvement projects, since implementing changes in clinical practice is visible to all involved.

Even though a significant number of procedures were analysed, most studies were of a single-centre study design with a pre- versus post-intervention analysis. This may limit how representative/generalisable the outcomes are; and the consequences of applying any given QIM may vary between organisations, depending for example on the underlying problems and root causes. Nonetheless, the findings of this review indicate that multiple QIM have been effective in improving various aspects of cardiac surgical care.

Therefore, it can be argued that the application of a QIM (its methodological approach) seems likely to be generalisable, even though the outcome and subsequent impact of any improvement measure(s) may vary. Indeed, one of the merits of the QIM that we have studied is their systematic approach to discovering the root cause of inefficiencies and shortcomings in a specific process, the subsequent identification and implementation of improvements based on the root cause analysis, and the long-term focus on sustaining, and even bettering the improvements.

Key areas where improvements in patient-related outcomes were seen included: ventilation time, wound infection, glycaemic control, mortality, major adverse events and discharge to home. Culig et al. reported a 61%/57% lower risk-adjusted mortality/incidence of major adverse events compared to regional rates by implementing the Toyota Production System throughout the entire care pathway.³⁴ Berry et al. reported improved patient outcomes.⁴⁰ Nevertheless, these results were not significant with the exception of the outcome 'discharge location home', which may be explained by small numbers when comparing the number of any complication (n = 60) to discharge location (n = 217). Heffner et al. reported 4.5 hours shorter ventilation and Gutsche et al. reported a 3.6-hour shorter median length of intubation, but without including information on, for example, actual ICU or hospital length of stay.^{36,41} Meaning that while shorter ventilation times are clinically relevant, there might also be additional benefits for outcomes that were not measured. Better compliance with infection control measures, as reported by Van Tiel et al. would be more meaningful to patient care if incidence/rates of infections were also included, as in the paper of Lytsy et al. and Candis Lee Kles et al.^{35,37,39}

Key process-related improvements included: increased productivity, shorter wait times, more efficient transfer of care from the operating room to the ICU and better compliance with hygiene measures. However, it is important to determine whether the reported improvements are clinically relevant to the process being studied and to patient care. For instance, shortening hand-off times by 1.9 minutes seems limited, but added up over the course of many procedures, it may become relevant.³³

The identified articles showed that the application of QIM can result in improved patient and process outcomes, and therefore improvements in the quality of care; increased productivity and shorter referral to treatment time help to improve access; and financial performance can be improved through higher efficiency and cost savings. A focus on improving value and quality of care for patients not infrequently leads to improved financial performance. Nonetheless, we acknowledge the narrow scope of some of these studies, the challenges in developing a high-quality evidence base for this (manufacturing-derived) subset of QIM, and the importance of organisational context in their impact and generalisability. Innovative study designs and discussion about what constitutes high-level evidence for quality improvement, merit discussion. This is analogous to the wider discussion currently taking place about the conventional randomised controlled trial (RCT) design in medicine.⁴³ In addition, the investment required to implement and embed these QIM in the “organisational DNA” should not be underestimated.

To the best of our knowledge, there has not yet been a systematic review of manufacturing industry-derived QIM in cardiac surgery. However, publications concerning the application of such QIM to surgical care, in general, do exist. Nicolay et al. performed a systematic review of the application of comparable QIM in surgery.¹¹ Their findings are similar to our conclusion: QIM improves both patient and process-related outcomes in surgical care on different levels. In addition to the specific QIM we identified in cardiac surgery, they reported that Continuous Quality Management, Total Quality Management and Statistical Quality Control were also effective. Mason et al. conducted a systematic review regarding the application of Lean and Six Sigma in surgery. They reported that both could improve efficiency in patient flow, decrease operative complications and postoperative harms, and reduce mortality, unnecessary costs and length of stay.¹⁰ Lee et al. evaluated recent innovations in operating room efficiency.⁴⁴ The methodologies used in this publication were Root Cause Analysis, Six Sigma and Lean. They concluded that efficiency in the surgical process can be increased through redesigning operating workflow, standardising surgical trays and teams and deploying real-time locating systems. Application of these innovations resulted in improved process-related outcomes: decreased cancellations, improved on-time starts, increased operating room utilisation, reduced turnover time and a more streamlined intra-operative process.⁴⁴ Smith et al. implemented

Statistical Process Control, which is a part of Six Sigma, and reported improved OR throughput due to parallel processing.⁴⁵ Cerfolio et al. implemented Lean in a New York City Academic Hospital. They eliminated unnecessary, non-value-adding, steps through value stream mapping of the process and improved efficiency, which resulted in improved operating room turnover time.⁴⁶ These authors show that manufacturing industry-derived QIM can be successfully applied in different ways to different aspects of surgical healthcare. The success of the QIM may not be dependent on the specific QIM used, but on certain common elements within the available methods.

There are several factors for the successful implementation of QIM such as: the use of a structured problem-solving approach (e.g., PDSA), strong team engagement, a thorough understanding of the problem and goal, the use and analysis of data, and finally a culture of continuous improvement and leadership support. All projects introduced a multidisciplinary team approach to implement the QIM, which improved awareness and involvement of healthcare professionals from the complete care pathway. This has been reported as both essential and a challenge when initiating process redesign.^{5,47} Engagement of stakeholders such as healthcare professionals leads to improved satisfaction, and thus contributes to the effectivity of implementing and sustaining change.⁴⁷ Although not explicitly evaluated by the papers in this review, it is possible that the Hawthorne effect plays a role in this.⁴⁸

Reviewing the articles presented here, identified several challenges that need to be addressed when implementing change/QIM: (1) Seven of the ten articles that were identified, applied a QIM to improve a specific part of the care pathway, for example, ventilation time or perioperative glucose control. While various independent processes can be improved separately, it may be more effective if QIM projects are applied through the complete care pathway. As an illustration, increasing productivity in the operating room alone may not be sufficient when there is inadequate capacity in the ICU to monitor patients after surgery. So, the first challenge should be to create flow through the entire care pathway. Lean and Six Sigma reduce process variation and increase predictability by standardisation. It may be argued that standardisation of processes is difficult because every patient is different; (2) therefore, the second challenge is to demonstrate that different patients can still go through standardised parts of the care pathway,

creating opportunities to reduce variability. As an example, every patient in cardiac surgery requires a similar set of pre-operative diagnostics (e.g., blood samples, X-ray, transthoracic ultrasound and coronary angiography). Combining these activities in a standardised one-stop-shop process, documented in a standard operating procedure, will reduce process variation, errors, repeated work and other wastes. This results in more efficient use of resources and better patient flow. Another example of this could be the Enhanced Recovery After Surgery (ERAS) protocols, which represent an evidence-based improvement to surgical care.¹⁵ The application of QIM to ERAS and the investigation of whether the combination may lead to further gains in the ERAS pathway represent an interesting area for further study; (3) the third challenge is to focus on improving the right metrics. A part of QIM, especially Lean and Six Sigma, is to identify meaningful metrics, which are often called key performance indicators or critical to quality characteristics. Furthermore, the applications of QIM were mostly project-based. A focus on continuous quality and process improvement needs to be embedded in organisations and is important for the sustainability of improvements, even after the project is finished. This can be monitored by continuously assessing outcomes with, for example, dashboards.

Limitations

This systematic review has several limitations. The limited and heterogeneous data precluded a quantitative analysis and the quality (level) of evidence was limited. Most studies were uncontrolled and retrospective and only half included formal statistical analysis. No study was published according to the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines, which is recommended when publishing quality improvement projects.⁴⁹ Most of the papers were from the USA, where they have a healthcare system that is, in general, more competitive and financially driven when compared to, for example, Europe. Generalisability can be discussed for low-income countries with unstable healthcare systems. However, the goals of efficiency, value and quality are universal goals. The search strategy for this review was concerned specifically with articles focused on cardiac surgery and may not have identified more generic QIM publications that may nonetheless be relevant to cardiac surgery. There may be publication bias since

unsuccessful initiatives may not have been published. Full reporting of potential conflicts of interest is important in all quality improvement studies.

7.5 Conclusions

We identified ten articles relevant to the application of recognised manufacturing industry-derived QIM to cardiac surgery. Although the studies demonstrated some magnitude of improvement in the clinical process and/or quality outcomes and therefore contributed to raising the value of care for cardiac surgery patients, the amount and quality of the evidence were limited. This supports the need for wider awareness of these QIM and for a culture of continuous quality improvement to be embraced by cardiac surgery, while at the same time highlighting that more rigorous evaluation, including how best to employ such QIM, is warranted.

Supplementary materials

The following are available online at <https://www.mdpi.com/article/10.3390/jcm11185350/s1>, Table S1: Search Strategy, Table S2: PRISMA checklist.

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PART II

DATA-DRIVEN EVALUATION AND LEARNING IN HEALTHCARE





8

RECOMMENDATIONS FOR ENHANCING THE USABILITY AND UNDERSTANDABILITY OF PROCESS MINING IN HEALTHCARE

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Abstract

Healthcare organizations are confronted with challenges including the tension between tightening budgets and increased care needs. In the light of these challenges, they are becoming increasingly aware of the need to improve their processes to ensure quality of care for patients. To identify process improvement opportunities, a thorough process analysis is required, which can be based on real-life process execution data captured by health information systems. Process mining is a research field that focuses on the development of techniques to extract process-related insights from process execution data, providing valuable and previously unknown information to instigate evidence-based process improvement in healthcare. However, despite the potential of process mining, its uptake in healthcare organizations outside case studies in a research context is rather limited. This observation was the starting point for an international brainstorm seminar. Based on the seminar's outcomes and with the ambition to stimulate a more widespread use of process mining in healthcare, this paper formulates recommendations to enhance the usability and understandability of process mining in healthcare. These recommendations are mainly targeted at process mining researchers and the community to consider when developing a new research agenda for process mining in healthcare. Moreover, a limited number of recommendations are directed towards healthcare organizations and health information systems vendors, when shaping an environment to enable the continuous use of process mining.

8.1 Introduction

The healthcare sector is confronted with severe challenges, most importantly the contention between tightening budgets and increased care needs due to the aging population [1,2]. To face these challenges while achieving high quality of care standards, healthcare organizations such as hospitals are becoming increasingly aware of the need to improve their processes (i.e. interrelated sets of activities, decisions and events with a particular goal [3]). Processes play a central role in a healthcare organization's daily operations [1,4]. They can be subdivided in two categories: clinical processes (e.g. the emergency care process or the treatment process of a particular condition), and administrative/organizational processes (e.g. the inventory management process of materials or the billing process) [5,6]. Healthcare processes in general, and clinical processes in particular, possess some distinct characteristics compared to common business processes such as the order-to-cash process [6,7]. Healthcare processes can be characterized as loosely framed and knowledge-intensive [8,9]. A loosely framed process can be performed in a large, but finite and predefined, number of distinct ways [9]. This relates to the observation that healthcare processes typically exhibit high levels of variation [6]. The knowledge-intensive character implies that the execution of healthcare processes heavily depends on knowledge workers, such as physicians, and the knowledge-intensive decisions they make [8]. These complex decisions are made based on a wide range of criteria, including medical knowledge, patient-related characteristics and the experience of healthcare professionals [5,6,8,10,11]. Healthcare processes are typically also closely intertwined with each other and are multi-disciplinary, requiring cooperation between clinicians with different expertises, which adds to their complexity [5,6,8]. Besides their knowledge-intensive, loosely framed and multi-disciplinary character, healthcare processes are also highly dynamic as they typically continuously change over time due to advances in medical knowledge, technology or administrative procedures [5,6,10]. To identify opportunities for process improvement in such healthcare processes, a healthcare organization first needs to gain a profound understanding of the process under consideration. To gather insights in how the process is executed, staff members who are familiar with the process can be brought together for a discussion. This discussion can target the development of process models capturing process insights (such as the order of activities in a clinical process), which forms a basis for a process analysis. However, this is very time- and effort-

intensive, and the created process model tends to present an idealized view on the process which might have little connection to reality [12]. To uncover the real behavior of an executed process, a solution can originate from data already collected by health information systems such as a hospital information system. Using the data embedded in the databases of these health information systems, an event log can be generated which contains detailed process execution data for a healthcare process of interest. In this way, the event log contains real-life data about which activities were performed, when they were performed, who performed them and for whom (e.g. for which patient) [12,13]. Process mining is the research field concerned with the development of techniques to retrieve non-trivial information from such an event log [7,12]. Over the past decade, the process mining community has developed an extensive set of techniques which convey profound process insights based on real-life data [4,12]. These techniques relate to the discovery of process models from data, the detection of deviations between an existing model and reality, or the enhancement of an existing process model with, e.g., process performance information [12]. Process mining outcomes can be leveraged to instigate evidence-based process improvement initiatives in healthcare. The systematic use of process mining in healthcare would be consistent with the *Learning Healthcare System* concept [14] introduced by the Institute of Medicine. One of the basic pillars of a Learning Healthcare System is the implementation of data reuse mechanisms, which allow for learning from data generated during the execution of processes [15,16]. However, despite the potential of process mining, its uptake in healthcare organizations outside case studies in a research context is rather limited. This observation was the starting point for a two-day international brainstorm seminar.¹ The seminar brought together 18 experts from 11 different countries, both researchers and healthcare practitioners, to reflect upon how to enhance the usability and understandability of process mining in healthcare. This position paper synthesizes the conclusions of the brainstorm seminar. It specifies ten key recommendations that process mining researchers and the community are encouraged to carefully consider when developing a new research agenda for process mining in healthcare. While the focus of our work is predominantly on recommendations for researchers and the research community, three additional recommendations are formulated which explicitly target healthcare organizations and health information systems vendors. The remainder of this paper is structured as follows. Section 8.2 provides a primer to process mining in healthcare, encompassing both an introduction

to the topic and an overview of some applications in a healthcare context. Section 8.3 outlines the key recommendations for process mining researchers and the research community. Section 8.4 presents the key recommendations for healthcare organizations and health information systems vendors. Section 8.5 presents a brief conclusion.

8.2 A process mining in healthcare primer

To provide the required background to appreciate the formulated recommendation, this section provides a primer to process mining in healthcare. Section 8.2.1 introduces the basic concepts of process mining in healthcare. Building on these concepts, Section 8.2.2 outlines some applications of process mining in healthcare.

8.2.1 Introduction to process mining in healthcare

Process mining refers to the retrieval of process-related insights from an event log containing process execution information [12]. Fig. 1 positions this field in a broader context. As highlighted in the introduction, the clinical and administrative processes of a healthcare organization are increasingly supported/controlled by health information systems [17]. These systems, such as a hospital information system and a radiology information system, record data about the real-life execution of the process(es) they support in databases. Process execution data included in these databases can be used to create an event log. An event log consists of a set of events associated to a case such as a patient or a patient visit. Each event represents ‘something’ that happened within the real-life process which triggers a state transition in a health information system and is registered by the system [18]. An event often relates to the execution of a clinical or non-clinical activity (e.g. the start of a clinical examination for a particular patient or the completion of patient registration), but can also convey that something else took place for a particular case such as the arrival of a message (e.g. test results are available for a particular patient) or the occurrence of an alarm (e.g. a drop in blood pressure of a monitored patient) [3]. An event log minimally contains an

ordered set of events for each case, but can also include additional information such as a timestamp expressing when the event took place [12]. Table 1 exemplifies the structure of an event log in a fictitious emergency department setting. For each entry in the event log, i.e. for each event, the following characteristics are recorded [12]:

Case identifier (case id): the (potentially anonymized) identifier of the case (e.g. the patient or the patient visit) to which the event is associated

Timestamp: the time at which the event occurred

Activity type: the label of the activity in the system to which the event is associated

Transaction type: when applicable, the state of the activity type to which the event refers (e.g. its start or its completion)

Resource: the staff member or device associated to the event.

Table 1. Illustration of the event log structure.

Case id	Timestamp	Activity type	Transaction type	Resource	...
...	...	...	...	...	...
2478	27/06/2019 10:17:47	Register patient	start	Clerk Thomas	...
2478	27/06/2019 10:22:02	Register patient	complete	Clerk Thomas	...
2479	27/06/2019 10:22:18	Register patient	start	Clerk Thomas	...
2472	27/06/2019 10:22:58	Clinical examination	start	Physician Sue	...
2458	27/06/2019 10:23:44	Blood results available	complete	Lab	...
2479	27/06/2019 10:27:58	Register patient	complete	Clerk Thomas	...
2451	27/06/2019 10:29:44	Blood pressure alarm	complete	Device KN0412	...
2451	27/06/2019 10:30:18	Check-up patient	start	Nurse Peter	...
2472	27/06/2019 10:30:27	Clinical examination	complete	Physician Sue	...
2463	27/06/2019 10:31:27	MRI protocol available	complete	Radiologist Sarah	...
2454	27/06/2019 10:32:48	Execute RX- scan	start	Nurse Chris	...
2451	27/06/2019 10:33:04	Check-up patient	complete	Nurse Peter	...
2454	27/06/2019 10:33:45	Execute RX- scan	complete	Nurse Chris	...
...	...	...	...	...	...

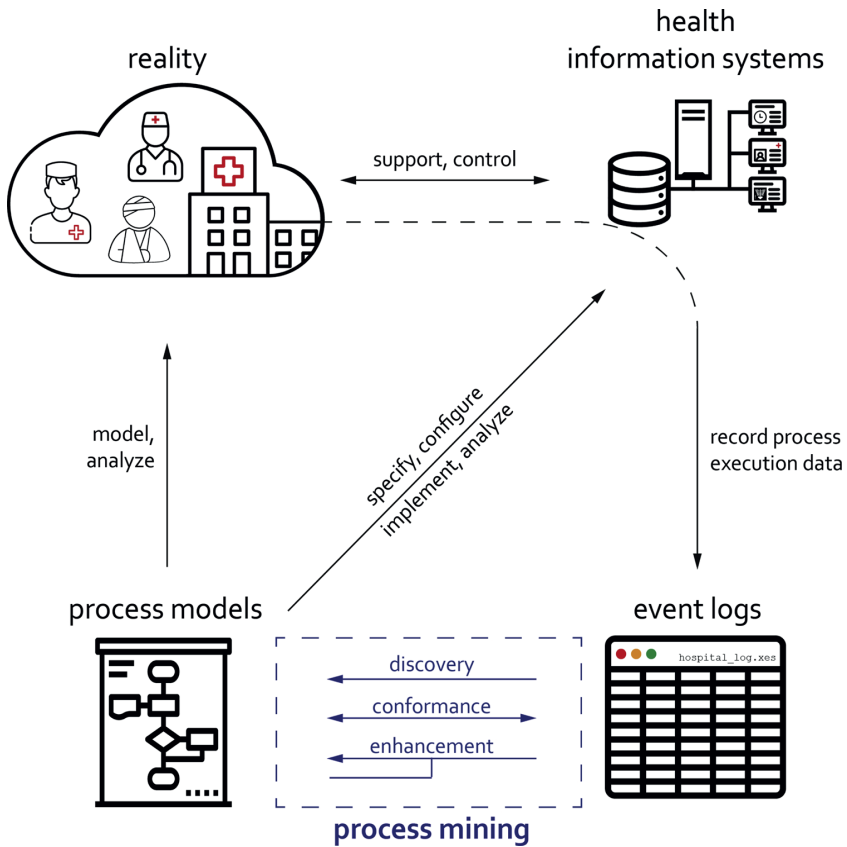


Figure 1. Positioning of process mining (based on [4,12]).

For instance: the first row in Table 1 shows that the registration of patient 2478 by administrative clerk Thomas started on June 27th at 10:17:47. He completed the registration at 10:22:02, as shown in the second row of Table 1. While the first two events are clearly related to the execution of ‘Register patient’, other events reflect, for instance, the availability of blood results for a patient or a blood pressure alarm for another patient. While Table 1, for illustrative purposes, only includes the most common components of an event log, it should be stressed that the event log typically also contains additional attributes about the case or the event. This could include patient attributes (e.g. the patient’s age, comorbidities), diagnostic attributes (e.g. blood results, notes from a physician), or care-related attributes (e.g. the medication that was used, whether the admission constitutes a readmission). The availability of such attributes in the event log

further enhances the potential usefulness of process mining for evidence-based process improvement. Taking an event log as an input, process mining techniques generate process-related insights, mainly in the form of process models. In general, three types of process mining are distinguished [12]:

Discovery: Discovery involves the creation of a process model from an event log. An important stream of discovery research relates to control-flow discovery, which retrieves and visualizes the order of activities based on an event log [12]. Within a clinical context, control-flow discovery unearths latent knowledge by making the actual order of clinical activities in the process explicit and visual [2, 19,20]. To obtain a control-flow model from an event log, a multitude of discovery algorithms have been developed, of which an overview is provided in De Weerd et al. [21] and Augusto et al. [22]. Specific control-flow discovery algorithms for clinical processes have also been proposed in literature [23,24]. Despite the predominant research focus on control-flow, some methods also allow for mining, for instance, resource-related models such as social networks [25, 26], resource profiles [27], resource roles [28,29] and work prioritization patterns [30]. Another example involves the integrated discovery of decision and control-flow models, a technique which has been developed in the context of the clinical process at the emergency department [31].

Conformance: While discovery automatically creates a new model from an event log, conformance checking compares an existing model (e.g. a prescriptive model) with an event log associated to the same process. This allows for both quality assessment of the process model, and the identification of deviations between the model and reality [12]. This latter enables, for instance, judging the compliance of the actual clinical process with clinical guidelines or pathways [32]. Such analyses have been conducted in the context of several pathologies such as unstable angina [7] and colon cancer [33], or in the simulation-based training of ultrasound-guided internal jugular central venous catheter placement [34]. Recent overviews of conformance checking literature are presented in Carmona et al. [35] and Dunzer et al. [36].

Enhancement: Enhancement refers to the extension or improvement of an existing process model based on insights from an event log [12]. This involves, for instance, the extension of a control-flow model with activity durations [37–39],

waiting time information [39], or the decision logic at decision points based on case characteristics [40,41]. This enables, for instance, the identification of bottlenecks in clinical processes prevailing in reality, which constitute valuable candidates for quality improvement projects [2]. Moreover, the enhanced process model provides a basis to support predictions within a clinical context, e.g. related to the length of stay [42] or the patient recovery time [20]. Within a clinical setting, the medical informatics discipline has traditionally approached process control from a top-down perspective. This implies that experts started from published clinical guidelines and iteratively formalized them to obtain computer-interpretable guidelines [43–45]. This top-down approach has to cope with limitations such as the complexity to share computer-interpretable guidelines and to adapt them to different local contexts [44]. In contrast, process mining proposes a bottom-up approach which allows the clinician to discover the real process. Moreover, it enables the clinician to discover which interventions would be necessary to reach a better compliance with, for instance, a published clinical guideline. In this way, a process mining approach has important advantages as it does not only inform measures to comply with a specific guideline, but also enables the clinician to investigate which process flows are followed by patients for which no clear guidelines are available. In the latter case, process mining analyses would enhance a healthcare organization's understanding of the patient flow, which can help to improve their treatment processes.

8.2.2 Applications of process mining in healthcare

For over a decade, process mining has been used to study healthcare processes in a data-driven way. This subsection outlines some applications of process mining in healthcare. Even though it should not be interpreted as an exhaustive list, the applications will illustrate the potential benefits of process mining for healthcare organizations. For a more extensive overview on process mining in healthcare, the reader is referred to literature reviews by Rojas et al. [4], Batista and Solanas [46], and Erdogan and Tarhan [47]. Moreover, dedicated literature reviews have been published on process mining for oncology [48], cardiology [49], primary care [50], and frail elderly care [51]. A key application of process mining involves gaining insights in the order of activities in a healthcare process prevailing in reality (i.e. control-flow discovery). For instance, Kempa-Liehr et al. [20] use process mining

to visualize the prevailing pathways for patients suffering from appendicitis to clinicians. Similarly, Kim et al. [52] retrieve the control-flow of the outpatient care process from an event log to gain insights into frequent process paths. These insights can be leveraged to support operational decisions such as the allocation of resources towards activities in such frequently occurring paths. As healthcare processes can exhibit a high degree of complexity and variability, Najjar et al. [11] use clustering techniques to discover treatment processes of elderly patients with heart failure from event logs, which can be used to identify treatment patterns with low mortality rates or patterns that require a closer follow-up. An alternative approach to handle the complexity of healthcare processes is proposed in Chiudinelli et al. [24]. They use topic modeling to synthesize the large number of detailed activities taking place during a particular hospital visit to generate a more high-level overview of the post-surgical treatment processes for breast cancer patients [24]. While the prior illustrations focus on clinical processes in which patients are directly involved, Forsberg et al. [53] study the use of a picture archiving and communication system by radiologists using process mining. This provides opportunities to learn from good practices, as well as becoming aware of potential points of improvement. Another common use case of process mining in healthcare is understanding how care processes in reality deviate from clinical guidelines or pathways (i.e. conformance checking). Within this context, Huang et al. [7] focus on patient's suffering from unstable angina and propose a method to detect local anomalies in their trajectory compared to the corresponding clinical pathway. Analyzing these patterns can show the need for an update in the clinical pathway or demonstrate that measures to enforce adherence to the pathway are required [7]. Geleijnse et al. [33] study deviations between the clinical pathway and the overall process performance for patients with colon cancer. Vroiling [54] relates such deviations from the clinical pathway to patient survival and highlight that deviations in particular treatment phases such as surgery has the largest (negative) impact on survival.

Besides these illustrations, healthcare organizations can use process mining to retrieve valuable insights in their processes in several other ways. They can, for instance, mine social networks to understand interaction patterns between healthcare professionals during the process [55], to identify parts/characteristics of the process contributing to an increased duration of the process [56] and to study the impact on the process of changes such as a move to new facilities [57]. All

of the aforementioned applications focused on a single healthcare organization. Process mining can also be used to compare processes between healthcare organizations. In this respect, Mans et al. [58] compare stroke treatment in two different processes. The same context, stroke treatment, is also considered by Montani et al. [59] to demonstrate a general comparison technique for clinical processes. Partington et al. [60] consider patients presenting themselves with acute coronary syndrome symptoms at the emergency department of four Australian hospitals. For this patient population, they compare the order of activities and relevant time intervals between the hospitals [60]. Using process mining for comparison purposes enables cross-hospital benchmarking and learning, creating opportunities to improve the efficiency and quality of care.

While the preceding examples highlight the potential of process mining in healthcare, some applications also cannot reach their full potential. Even though deficient aspects of an application are typically not explicitly articulated in published work, practical experience learns that the availability of reliable data is a key challenge in healthcare [61–63]. For instance, a process mining analysis at an emergency department focusing on a particular pathology was rescoped because it was impossible to distinguish patients with this condition in the event log. Changes in the project scope due to issues with data availability or quality are common in healthcare [64]. Similarly, the perception among healthcare professionals can also have an impact on a process mining project. For example, a process can typically not be studied from the resource perspective because physicians and nurses fear that the analysis results would be misused for individual performance measurement [63]. These challenges illustrate potential risks for successful process mining projects in healthcare. They will be taken into consideration in the remainder of the paper as the formulated recommendations aim to tackle challenges which are currently present. Taking these recommendations into account in the future will enable healthcare organizations to benefit from the full potential of process mining.

8.3 Recommendations for process mining researchers and the research community

Despite process mining's great potential to help healthcare organizations understand how their processes are actually executed, its use in healthcare outside a research context is limited. Starting from this observation, a two-day international brainstorm seminar took place to reflect upon how to enhance the usability and understandability of process mining in healthcare. This seminar brought together 18 experts from 11 different countries, both process mining researchers and healthcare practitioners. The aim of the seminar was to formulate recommendations for future efforts and originated from a shared ambition to stimulate a more widespread use of process mining given its potential to support evidence-based process improvement in healthcare. These recommendations are mainly directed to process mining researchers and the research community, but a limited number of recommendations are targeted to healthcare organizations and health information systems vendors.

This section will describe the recommendations for process mining researchers and the research community, which are summarized in Fig. 2. While some of these recommendations might also be relevant for other sectors, they also incorporate the specificities of process mining within the healthcare sector. In this way, researchers and the research community are encouraged to take these interconnected recommendations into account when developing a new research agenda for process mining in healthcare.

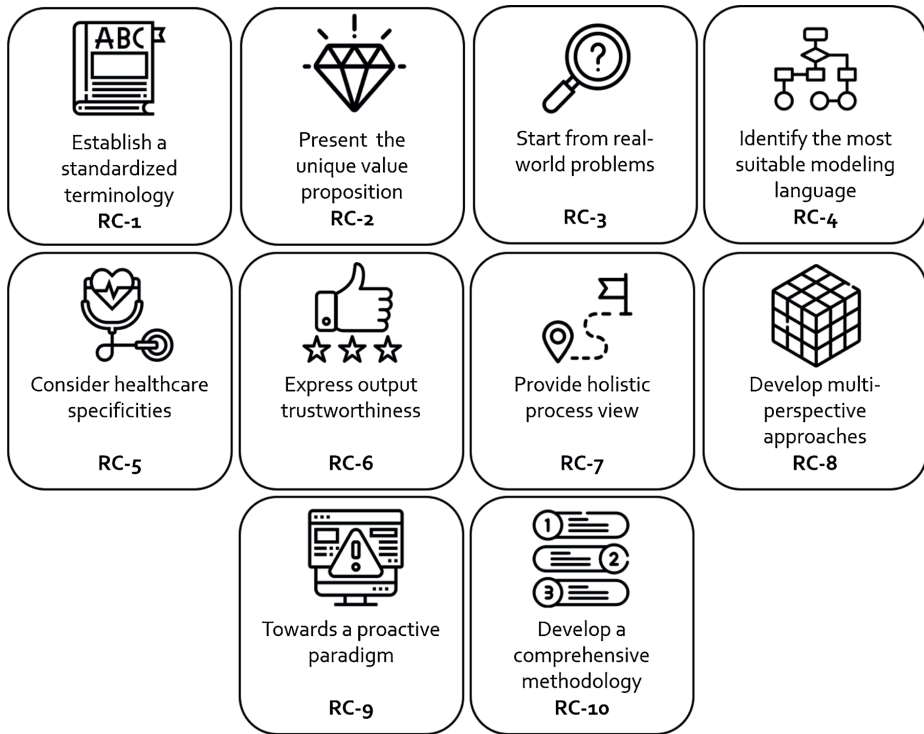


Figure 2. Overview of recommendations for process mining researchers and the research community.

8.3.1 Establish a standardized terminology to support process mining in healthcare (rc-1)

Within the healthcare domain, standardized terminologies are common to ensure a shared understanding on the meaning of particular concepts [65]. An example of a widely used terminology is the *International Classification of Diseases* (ICD), developed by the World Health Organization [66]. The most recent revision, ICD-11, defines about 55,000 codes to uniformly refer to injuries, diseases, and death causes worldwide [67]. Another example is the *Logical Observation Identifiers Names and Codes* (LOINC) for laboratory experiments [68]. Also within the context of healthcare processes, terminologies have been developed. Consider, for instance, the emergency department time measures and intervals based on the Performance Measures and Benchmarking Summit [69,70]. Some terminologies

are designed to act as reference terminologies with a wide coverage of healthcare concepts. That is the case for the *Systematized Nomenclature of Medicine Clinical Terminology* (SNOMED CT), which contains around 350,000 clinical terms [71]. SNOMED CT is based on description logic allowing for the definition of new concepts by combining existing ones [72]. Terminology standardization is also supported by efforts such as OpenEHR [73], which is an architecture aimed to support the interoperability of electronic health record systems. To this end, a wide range of clinical concepts have been standardized in clinical information models called archetypes [74,75]. OpenEHR archetypes are complementary to other terminology standardization as they can also include references to terminologies such as SNOMED CT [75].

In the process mining field, there is less of a standardization tradition. At the data structure level, a widely recognized process mining standard is the IEEE *Extensible Event Stream* (XES) standard [76]. XES is an XML-based standard providing a format which ensures interoperability in event logs and event streams [77]. This standard also provides a mechanism to add additional extensions [12], such as an extension to express the costs related a particular event [78]. Conversely, at the terminology level, the use of terms used by process miners can be ambiguous and their understanding can depend on the working definitions of individual academics or research groups. This ambiguity occurs in the varying use of terms such as event log, activity log, event, case, trace, activity, resource, classifier, process discovery, and process conformance. For instance: some process mining techniques claim that they use an event log as an input (i.e. each entry represents a single event with a single timestamp), while they in fact require an activity log to start from (i.e. each entry represents an activity instance, which can include multiple timestamps such as the start and completion time). When an event log is available in practice, a conversion to an activity log is required in order to apply the technique. This implies linking corresponding events to each other, an operation which is not always trivial, e.g. when an activity is executed multiple times for a particular patient [79]. The absence of a standardized semantic meaning for process mining terms is especially challenging in a multidisciplinary context, such as healthcare, because process mining terminology will be interspersed with healthcare terminology such as clinical pathway, clinical guideline, length of stay, and evidence-based medicine.

The previous discussion highlights the need to establish a standardized terminology to support process mining in healthcare. This does not imply, by definition, the specification of new terms, but should aim to achieve two key goals. Firstly, the terminology should provide clear descriptions of process mining concepts within the healthcare context. Secondly, it should make, whenever possible, the relationship to existing terminologies in the healthcare domain (such as the procedure branch of SNOMED CT) explicit. The establishment of a standardized terminology requires consensus building within the community to obtain a common understanding. A proposal by a dedicated working group can form a basis for a debate. Once a standardized terminology is established, it will not only facilitate communication among process mining researchers, but will also enable the use of a uniform terminology towards healthcare professionals. The latter, i.e. having a common language, would greatly enhance the understandability of process mining in the healthcare domain. Moreover, by having an overview of the concepts which are relevant for process mining in healthcare, it can also be determined how the current XES standard (and its extensions) can best be used to support it.

8.3.2 Present the ‘unique value proposition’ of process mining in healthcare (rc-2)

8

The introduction highlighted that, despite the potential of process mining in healthcare, only anecdotal evidence of its systematic use is available until now. To facilitate a more widespread use of process mining in healthcare, process mining needs to be clearly positioned with respect to more established methodologies and systems such as clinical decision support systems [80–82] and lean management [83,84]. Consequently, there is a need to present the ‘*unique value proposition*’ of process mining in healthcare, expressing the needs that process mining can fulfill which other methods or systems cannot [85]. A key element in the ‘unique value proposition’ of process mining in healthcare is its ability to increase transparency by providing actionable and inductive insights into end-to-end processes. Looking at end-to-end processes breaks down departmental silos and potentially even boundaries between healthcare organizations. The actionable insights, derived from real-life process execution data, can be pivotal to improve both clinical and administrative processes. To substantiate this claim, the research

community should move beyond individual case studies and develop a taxonomy of problems that process mining can tackle. In this way, a convincing set of key use cases can be composed and communicated. Moreover, for clinical processes, there is a need for research which links interventions based on process mining insights to clinical outcomes. An example of preliminary work in this direction is Vroling [54], where the impact of deviations from the clinical guidelines for colon cancer treatment on patient survival is studied [33,54]. Similarly, Chiudinelli et al. [24] study the survival probability of breast cancer patients based on their post-surgery treatment process. Relating improvement initiatives inspired by process mining to positive clinical effects will demonstrate that patients can also benefit from process mining. This is an argument that medical doctors are likely to be more susceptible to, compared to a reasoning based on efficiency gains, e.g. due to cost reductions. This, more generally, highlights the need for methods that enable a reliable assessment of the impact of interventions based on process mining outcomes [15]. Developing a substantiated ‘unique value proposition’ for process mining in healthcare also implies being transparent about the (current) boundaries of process mining. Nevertheless, this is not a plea to position process mining on an island, disconnected from other methods and techniques. In contrast, the close interconnection and complementarity between process mining and other fields such as lean management, predictive analytics, and operations research needs to be stressed. For instance: predictions regarding the expected outcome can be supported by insights in the similarity between the process of a patient who is currently being treated and the trajectory of similar patients in the past [86]. Similarly, simulation is a well-established operations research technique to investigate changes to a process before implementing them using a computer model. It has been extensively applied in healthcare [87]. Process mining can complement simulation by retrieving inductive insights about process behavior, which can be leveraged when building a simulation model [88–90].

8.3.3 Start from real-world healthcare problems (rc-3)

To enhance the usability of process mining in healthcare, it is crucial that it tackles real-world problems experienced by healthcare practitioners. This is consistent with one of the key principles of *design science research*, which is a research paradigm that centers around the design, development and scientific

study of an artifact which solves a problem [91,92]. This problem originates from a particular problem context and should be relevant, broadly recognized, and challenging to solve [92, 93]. Within the context of this paper, the problem context refers to (a particular type or set of) healthcare organizations. In process mining research, healthcare examples are commonly used to show the applicability of a technique that has been developed. However, this does not guarantee that the developed technique solves a real-world problem which is relevant and broadly acknowledged. This is especially attributed to the fact that domain-specific requirements are not explicitly considered during technique development. Researchers active in process mining for healthcare are strongly encouraged to take another perspective. They should stay up to date with the innovation within the healthcare sector. This enables them to identify relevant healthcare problems and treat them as ‘first-class citizens’. This requires an important time investment as clarifying the problem typically asks for thorough discussions with healthcare practitioners from different healthcare organizations. Moreover, during the entire research process and when reporting the results, researchers need to reflect upon the implications in healthcare and the actionable insights that can be retrieved from the analyses.

Even when researchers decide to work on a particular clinical process, a researcher needs to know and attribute central importance to the specific problems experienced by clinicians. Starting from these problems, solutions can be developed which leverage process mining to tackle the specific issues that healthcare professionals are confronted with. This also requires awareness of the particularities of the clinical process under consideration as it might influence the design of the techniques. For instance: when the process is composed of a large number of distinct activities, the mining technique might need to incorporate an additional abstraction step. Chiudinelli et al. [24], for instance, propose such an abstraction for the post-surgical breast cancer process as the prime point of interest was the temporal relation between different hospital visits and not the order of activities during one specific hospital visit.

From the previous discussion, it follows that close ties are needed between process mining researchers and healthcare practitioners. This relates to some of the core principles of methodologies such as design science research and action research, which stress the need for a close partnership with the problem context

[92]. Moreover, researchers have to be open-minded and should perceive their work as a means to an end, instead of as a goal in itself. Such a mindset is only possible when research starts from real-world healthcare problems.

8.3.4 Identify the most suitable process modeling language (rc-4)

A key asset of process mining is its ability to retrieve a control-flow model from process execution data. A process model can serve different goals such as creating a shared understanding about the process [94], and supporting the design and configuration of an information system [95]. This recommendation centers around the former, i.e. the use of a process model as a visual instrument to provide healthcare practitioners with insights in their processes. Within the context of a clinical process, the process model can e.g. visualize how the treatment process for a particular pathology takes place in practice, which can be a powerful instrument to evoke process improvement discussions. To visualize the process flow of a healthcare process, a wide variety of process modeling languages is available. A review by Figl [96] highlights that the used modeling language influences the understandability of the model. Hence, it is important to identify the most suitable process modeling language to represent the output of control-flow discovery algorithms, taking into account the specific healthcare context. In this respect, two key observations that need to be taken into account are (i) the presence of a multitude of process modeling languages available in the business process management domain, and (ii) the presence of modeling language used within the context of clinical guidelines. The first observation is that, within the business process management field, a large number of different process modeling languages is present. A distinction can be made between procedural, declarative and hybrid languages. In a *procedural control-flow model*, the model shows all possible activity flows, implying that any behavior not shown in the model is not allowed [97]. Hence, a procedural model represents the exact way in which the process can be executed, which typically enhances its understandability for domain experts [98]. Examples of procedural languages are Petri nets/Workflow nets, Yet Another Workflow Language (YAWL), Event-driven Process Chains (EPCs), Business Process Model and Notation (BPMN) [12], and directly-follows graphs [99]. In industry, the ISO-certified standard BPMN (ISO/IEC 19510) has become the *de facto* standard for process modelling [100–102]. While a

procedural approach is appropriate in structured contexts, healthcare processes are typically more variable as, e.g., a clinical process needs to be adjusted to specific patient characteristics [6,8]. When including all possible execution paths in a procedural process model, this can make the model very complex [98]. In such contexts, *declarative process modelling languages* can be useful. A declarative model consists of a set of constraint that the execution of a process for a patient should satisfy. An example of such a constraint is that ‘Execute CT-scan’ should be eventually followed by ‘CT results available’. Any behavior which satisfies these constraints is allowed [97]. Some declarative process modelling languages, such as Declare or DCR graphs, have a graphical notation, making it possible to use them for communication purposes [103,104]. However, as the control-flow is represented in an implicit way by means of constraints [105], declarative models are sometimes criticized as being difficult to understand [98]. This especially holds when a declarative approach is used to model a highly structured (part of a) process as it would require a high number of constraints [98]. Recently, researchers recognized that the procedural and declarative process modeling approach should not be treated as mutually exclusive, giving rise to *hybrid process modeling languages* [97,106]. For instance: BPMN-D is a hybrid language which extends a subset of BPMN (procedural component) with Declare constraints (declarative component). In such a hybrid model, the structured parts of the process are modelled with a procedural language and the variable parts in a declarative way. While hybrid modeling approaches could be valuable within a healthcare context, a recent review by Andaloussi et al. [98] concludes that thorough empirical work on the understandability of hybrid models and their usability for communication purposes is lacking. The second observation stressing the need to investigate the most suitable way to visualize a healthcare process is that, within the healthcare domain, distinct modeling languages are used to represent clinical guidelines. These modeling languages include Asbru [107], GLIF3 [108], and PROforma [109]. They describe a set of constructs which can be used to model guideline components such as activities that need to be executed and clinical decisions. Some languages also support additional features. For instance, Asbru also enables the incorporation of the guideline’s intentions with respect to the process and its outcomes [44]. While these modeling languages are predominantly used to embed clinical guidelines in information systems used by clinicians [44,110], they should also be considered when looking for a clear communication language as clinicians might be familiar with their notation

to a certain extent. For a more extensive overview on modeling languages for clinical guidelines, the reader is referred to the review by Peleg [44]. From these two observations, it follows that a wide range of process modeling languages are available to represent the output of control-flow discovery algorithms to healthcare professionals. Given its impact on model understandability [96], a thorough benchmarking study is required, focusing on differences between languages in terms of the insights that healthcare practitioners retrieve from the resulting models. Besides the main process modeling languages from the business process management domain, modeling languages used for clinical guidelines should also be taken into consideration as healthcare professionals might be more acquainted with them from their clinical practice. Such a comparative study should involve a wide number of healthcare professionals from distinct clinical contexts. The results of the benchmarking study will provide rich insights in the suitability of existing process modeling languages in particular clinical contexts. This will highlight whether there is a need for a novel process modeling language, potentially leveraging the strengths of several existing languages. At least, the process mining community should carefully assess the similarities and differences between the process model representations used in the process mining field and their counterparts from the clinical domain. This can lead to actionable insights targeting an increase in the understandability of process mining from a representational point of view.

8.3.5 Take into account healthcare specificities during technique development (rc-5)

Besides tackling real-world healthcare problems (Section 3.3), process mining researchers also need to take healthcare specificities into account during technique development. Consider, for instance, the fact that the flow of a clinical process can be heavily influenced by patient conditions which might not be directly related to the process under analysis. When techniques are tailored to the specific context of healthcare, this will facilitate their use in healthcare practice. For illustrative purposes, the following two healthcare specificities will be discussed: (i) the robustness for temporal changes, and (ii) the ability to focus on infrequent behavior. Many of the existing process discovery and conformance checking techniques are not suitable for analyzing healthcare processes exhibiting

such behaviors. Clinical processes frequently change over time due to a variety of factors such as advances in medicine and innovations of medical equipment. Depending on the type of change, healthcare professionals might be aware that a change happened at a particular point in time. Even when healthcare professionals know that a change took place, they might not have insights in the effects on the process or the (potentially unintended) side-effects. Process mining researchers need to be aware of the existence of temporal changes and techniques should be robust for such changes. The latter especially holds when techniques are intended to be used on event logs with a longer time horizon. Research on the notion of concept drift, which is the term used to express process changes, can be a valuable starting point [111,112]. However, compared to other contexts, where processes remain stable for extended periods of time, temporal changes should receive more attention in a clinical setting. Another example of a healthcare specificity is the need to focus on infrequent behavior. In many other application domains, infrequent behavior (such as process execution paths occurring very rarely) is not considered informative as it might distract domain experts from the main process behavior. Hence, some existing process mining algorithms filter out such infrequent behavior to obtain a more understandable process model. For instance: the premise of the heuristics miner (a control-flow discovery algorithm) is that infrequent behavior should not be included in a control-flow model [12,113]. Depending on the purpose of the analysis, infrequent behavior could be of utmost interest to clinicians as it can demonstrate the need to, e.g., change or sharpen medical protocols. Hence, process mining techniques should have the ability to highlight and analyze infrequent paths to retrieve valuable insights from them. In this respect, efforts such as Hompes et al. [114] and Mannhardt et al. [115], can be a starting point. Hompes et al. [114] use cluster analysis to discover frequent process variants, as well as exceptional paths, in a cancer treatment process. Mannhardt et al. [115] present an approach to distinguish infrequent paths from random noise using data attributes. The aforementioned examples highlight the importance of tailoring process mining techniques to the specific needs of healthcare. In this respect, interactive process mining methods are promising as they enable healthcare experts to leverage specific domain expertise to obtain useful process mining outcomes within a particular healthcare context. Some interactive approaches have already been presented, for instance to investigate the process of stroke patients at the emergency department [116], or to interactively explore healthcare processes, which is demonstrated

for the diabetes treatment process [117]. Moreover, a preliminary method to interactively perform event log cleaning within a healthcare context has recently been proposed in Martin et al. [118]. Additional pointers in the general process mining literature relate, for example, to the inclusion of domain knowledge during control-flow discovery [119,120].

8.3.6 Express the trustworthiness of process mining output (rc-6)

Since the early 1990s, evidence-based medicine reflects a paradigm in which decision-making in medicine is systematically improved by considering scientific evidence [121]. In evidence-based medicine, different degrees of trustworthiness are attributed to different types of scientific evidence. For instance, the results of a randomized controlled trial are considered as more trustworthy than outcomes of an observational study [122]. In turn, the results of a meta-analysis are considered more trustworthy than the outcomes of a single randomized controlled trial [123]. In an effort to obtain a more widespread use of process mining by healthcare practitioners, it has to meet the key standards which are applicable in the medical domain. Hence, it is important that the output of process mining techniques expresses its trustworthiness. While actions such as showing the frequency of arcs in process models and reporting the conformance metrics are valuable, a more sophisticated way to transparently express the trustworthiness of models is warranted. A starting point is identifying the key elements which influence the trustworthiness of a particular process mining result such as the number of care episodes which are included, and the data sources that have been used.

An aspect that will also greatly influence the trustworthiness of process mining output is the data quality of the event log. Consistent with the *'garbage in-garbage out'* principle, the quality of all process mining analyses ultimately depends on the quality of its input data [2]. This is highly relevant in a healthcare context, where it is not always possible to extract high-quality data from health information systems [124,125]. A case study at the Maastricht University Medical Centre showed that the three most frequently occurring data quality issues in health information systems data are missing events (i.e. events that took place, but were not logged), imprecise timestamps (i.e. timestamps recorded at the day level), and imprecise resource information (i.e. resource information not referring to a

specific staff member) [2]. Another common issue in event logs is that healthcare professionals record their actions in the health information system at a later point in time, and potentially even in batch for several patients [126]. This is highly problematic for process mining as it implies that the timestamps in the event log no longer correspond to the time at which the activity has actually took place. Besides, for instance, biasing insights in the duration of activities, it can also falsify the order of activities when activities are recorded in a different order than they were executed. In recent years, there has been an uptake in research on data quality within the process mining field. Literature focuses on the identification of data quality issues [2,126,127,61,128], and the mitigation of one or more of these issues using a particular heuristic [61,128,129,62, 130–132]. Besides the need to thoroughly assess data quality [126] and keeping a structured data quality register [133], data quality issues should also be reflected in process mining outputs. It could, for instance, be expressed that the trustworthiness of particular aspects of the output (e.g. particular connections between activities in a control-flow model) is lower due to data quality problems.

8.3.7 Provide a holistic process view (rc-7)

To anchor process mining in a sustainable way in the healthcare sector, it needs to be able to provide healthcare practitioners with a holistic process view. This can be achieved by leveraging all sources of process-related data which are available. Traditionally, process-related data originates from, for instance, a hospital information system. Besides structured fields, many entries in a hospital information system still consist of free text fields, such as the notes of clinicians [134]. Important data about the execution of the process, such as case/event attributes, can be embedded in such free text fields. To unearth insights from unstructured textual data to consider it for process mining purposes, research efforts at the boundary between natural language processing and process mining are required [135,136]. Within the context of healthcare processes, efforts such as Najafabadipour et al. [134], proposing a method to retrieve the trajectory of lung cancer patients from textual clinical notes, are promising. Epure et al. [137] consider the context of written online conversations about health-related topics to automatically identify speech intentions such as complaining or disagreeing. Gathering insights from unstructured textual data about the process will become

increasingly relevant when technologies such as conversational agents will be more intensively used in clinical processes [138,139].

Besides traditional sources of process-related data, such as a hospital information system, technological advances will make other sources of data available. One notable evolution is the *Internet of Things* (IoT). IoT refers to a network of interconnected devices, equipped with tags or sensors, which enables continuous monitoring of a particular phenomenon [140,141]. The number of IoT-applications in healthcare is rapidly increasing, as demonstrated by recent reviews such as Nguyen et al. [142] and Ahmadi et al. [143]. Examples of IoT-applications are systems to monitor patients suffering from a chronic disease from home, or an intelligent pill box to assist the elderly with their medication [142]. Another example is FibriCheck, a smartphone application which uses the phone's built-in camera to monitor the heart rate of patients and to detect atrial fibrillation [144]. Due to the increasing presence of tags or sensors in a multitude of connected devices, new sources of process-related data become available. This provides major opportunities to provide a more holistic view on the process as, e.g., treatments which are conducted at home can also be taken into consideration. Another dimension of a holistic process view involves moving beyond the boundaries of a single healthcare organization (and the data from its information systems). Within the realm of integrated care, patients should experience a continuum of care instead of fragmented care [145,146]. This implies that a care process is not confined to the hospital's walls, but also encompasses other care entities such as primary care and home health nursing. For instance: a cancer patient might visit a specialized hospital for surgery, have regular check-ups at a local hospital, and take some therapies at home supported by home health nurses. Evidently, this will pose challenges as process execution data will not only be spread over different databases of a single institution, but over a wide number of databases in several institutions. Moreover, healthcare organizations might be reluctant to share data. In this respect, blockchain is a promising technology as it facilitates data exchange among healthcare organizations [147–149]. Initial approaches on how to use blockchain data for control-flow discovery purposes have recently been proposed [150]. Great care should also be taken to protect the patient's privacy in response to international privacy regulations. Solutions can originate from privacy preservation techniques that allow distributed computations without extracting data from the healthcare organizations where it has been recorded

[151]. Despite such challenges, the cross-organizational perspective needs to be taken into consideration when moving towards holistic process mining in healthcare.

8.3.8 Need for multi-perspective approaches (rc-8)

To enhance the usability of process mining in healthcare, multi-perspective approaches are required. In process mining research, a multi-perspective approach connects several perspectives on the process, such as the control-flow, resource or time perspective [152]. This implies that a process model will not only depict the control-flow, but also, amongst others, includes information about the healthcare professional (or team of professionals) involved, and the waiting times in several stages of the process. Besides this angle on multi-perspectivism, process mining in healthcare should also have the ability to analyze a process from the perspective of different stakeholders. These stakeholders include physicians, nurses, hospital management, and the patient. Different stakeholders can have different information needs. For instance: while hospital management might be interested in the dominant process flow, physicians might be especially interested in infrequent behavior and its clinical impact. To date, process mining research attributed limited explicit attention to the patient perspective, i.e. to identify and study the patient's journey [153]. However, this constitutes a valuable direction for research as studying healthcare processes from the patient's perspective will help healthcare organizations to move towards more patient-centered care, which is considered as one of the most important determinants for care quality [154]. Considering the patient perspective can be challenging as it, for instance, involves moving beyond the boundaries of a single healthcare organization (as outlined in the previous recommendation).

8.3.9 Towards a proactive paradigm (rc-9)

Process mining mainly focuses on providing insights in a process using historical process execution data. Complementary to this retrospective paradigm, healthcare would also greatly benefit from a proactive paradigm. In a proactive setting, process mining techniques generate actionable insights which can be

brought into practice while the process is still running. This relates to the notion of process mining providing online operational support [155]. Proactive process mining can enhance the use of process mining in healthcare as it directly supports the daily operations of healthcare practitioners. For instance: process mining can add a context- and process-aware dimension to decision support systems in healthcare [156]. In this way, process mining can inform taking proactive actions when similarities are detected between treated patients or historic process states, and the current patient/state. This requires process similarity measures, where works such as Combi et al. [86] within the context of stroke can be leveraged. Proactive applications can have a trickle-down effect on the use of other techniques once healthcare practitioners are convinced of the added value of process mining. Research on the proactive use of process mining should be closely linked to existing work on predictive analytics, where the focus is on the prediction of, e.g., the onset or progression of diseases (e.g. [157,158]) or the effectiveness of a particular therapy (e.g. [159]). To further enhance their usability, proactive process mining techniques can be extended with the ability to learn from user interaction. Consider, for instance, a system which automatically raises alerts to a physician when a clinical guideline is not followed. When a particular type of alert is systematically discarded by the physician, the system could autonomously change the alert threshold or recommend the user to alter a particular setting. In this respect, principles from active learning could be leveraged [160].

8.3.10 Develop a comprehensive methodology for process mining in healthcare (rc-10)

Besides complying with the aforementioned recommendations when, e.g., developing a new process mining technique, the usability of process mining would also be enhanced by guiding healthcare organizations regarding its use. In this respect, there is a need for a comprehensive methodology for process mining in healthcare. Its comprehensive character relates to the fact that it should range from the identification of process-related questions or challenges, over the collection and preparation of process execution data, until the application of suitable process mining techniques to answer the questions or handle the challenges. Within the process mining field, the L*-methodology [12], the Process Diagnostics Method [161] and the PM2-methodology [162] provide a

high-level overview of the steps that need to be taken when a process mining analysis is performed. However, to provide more targeted support to healthcare organizations, a methodology which takes into account and anticipates upon the specificities of healthcare and clinical processes is warranted. In this respect, a starting point for the development of the methodology can be a synthesis of key use cases of process mining in healthcare. These use cases can be used to group existing techniques and to add pointers to reliable implementations which are available. The latter highlights the need to have well-documented implementations generating clear outputs. Other questions that should receive attention in the methodology include: How to construct an event log which actually captures all relevant dimensions of a healthcare process? How to handle unstructured data such as a clinician's notes in the patient's file? How to ensure that the process mining analysis provides the information that a clinician actually needs to tackle the real problems they face in daily practice? Regarding the latter, existing efforts relating to the use of interactive approaches [116,118,120,163], the use of a question-driven methodology [164], or the (Simplified) Clinical Pathway Analysis Method [165,166] constitute potential starting points. When a comprehensive methodology is in place, there will be support for healthcare organizations and clinicians during their process mining endeavors. The presence of such an instrument might also provide the required reassurance for healthcare organizations who are considering the adoption of process mining. In this way, the methodology will both enhance the usability of process mining in healthcare, and will ensure that healthcare organizations get the full potential out of the available techniques. Moreover, by providing an end-to-end view, the methodology will also highlight research challenges for the process mining community in the form of stages which are currently inadequately supported from an algorithmic or methodical point of view.

8.3.11 Summary

From the previous, it follows that process mining researchers and the research community play an important role in enhancing the usability and understandability of process mining in healthcare. While many recommendations are situated, at least for an important part, at the technical level (RC-4, RC-6, RC-7, RC-8, RC9), efforts at a non-technical level will also prove indispensable to obtain a more

widespread use of process mining. Such non-technical efforts relate to clearly communicating the value of process mining for healthcare practitioners using a standardized terminology (RC-1, RC-2), and providing the required support to healthcare organizations to use these techniques (RC-10). Moreover, researchers should have a mindset in which close collaboration with healthcare organizations is a natural reflex. Such a mindset ensures that future process mining techniques explicitly incorporate healthcare specificities and are able to tackle real-world healthcare problems (RC-3, RC-5).

8.4 Recommendations for healthcare organizations and health information systems vendors

The predominant focus of this paper is on providing recommendations to process mining researchers and the research community to enhance the usability and understandability of process mining in healthcare. However, healthcare organizations and health information systems vendors also play a key role in a more widespread use of process mining as they should provide an environment which enables a continuous use of process mining. To this end, three key recommendations are provided to shape such an environment. The remainder of this section will outline these recommendations, which are summarized in Fig. 3.

8.4.1 Invest in training opportunities for healthcare professionals (hov-1)

Currently, healthcare organizations tend to make use of external expertise when conducting a process mining project, e.g. by entering in a partnership with a university or a consulting company. However, to embed process mining in a sustainable way in healthcare organizations, it is important that internal expertise is also built up. Besides some dedicated staff members with a more extensive process mining background, a minimal level of data and process literacy at the level of healthcare professionals or hospital administrators is also required. The latter is, amongst others, important to formulate the right questions that process mining should tackle and to understand the analysis results. To this end,

healthcare organizations will need to offer training opportunities to promote healthcare analytics in general and process mining in particular. During such training sessions, clinicians should be motivated to identify process-related challenges they are confronted with in their clinical practice, as these constitute starting points for using process mining. Enhanced training will ensure that healthcare organizations will treat the available data in their health information systems as a strategic asset. This will also highlight the need to retain full control over their data, even when the maintenance of their systems is outsourced [167]. Moreover, training can help healthcare professionals to see data-driven process analysis as an opportunity to improve patient care, instead of as a threat solely focused on cost reduction or individual performance measurement.

The process mining community can be a facilitator by providing training materials for healthcare professionals in a variety of forms, including dedicated training programs, online courses² or hands-on textbooks. Moreover, as was already pointed at in Section 3.10, process mining researchers have to make sure that the techniques they develop are publicly available, deliver clear outputs, and are well-documented.

8.4.2 Promote efforts to improve the quality of recorded data (hov-2)

8

As highlighted earlier in this paper, process execution data from health information systems often suffers from data quality problems [2, 124–126]. Data quality issues, such as missing events or incorrect timestamps, impede many of the existing process mining techniques to reach their full potential. While research is being performed on the improvement of data quality using heuristics (e.g. [61,62]), this will always remain suboptimal compared to more accurate data recording at the source. To enhance the potential of healthcare organizations to benefit from process mining, efforts to improve the quality of recorded process execution data are warranted. These efforts can be situated at two levels: (i) at the health information system level, and (ii) at the level of logging attitudes and mechanisms.



Figure 3. Overview of recommendations for healthcare organizations and health information systems vendors.

At the level of health information systems, vendors could increase the process-aware character of their systems. This would cause the data to be recorded in a more process-oriented way, facilitating its use within a process mining context. Moreover, vendors could enable system configurations which require that data is, to the extent possible within clinical practice, recorded in a structured way (in contrast to, e.g., free text fields). As the input data for process mining typically originates from several information systems, healthcare organizations are encouraged to take measures to ensure that data from different sources can be correlated correctly, e.g. by using a common patient identifier. At the level of logging attitudes and mechanisms, healthcare organizations could start with raising awareness among healthcare professionals regarding the importance of accurate and timely data registration. In this respect, the intended use cases for process mining within the organization can be highlighted. These same use cases will also highlight which specific data points need to be recorded more accurately. Besides awareness creation, measures could also be taken to facilitate data registration. A commonly heard complaint is that it takes too much time to systematically login to the terminals present within each room to record certain actions. When this holds, data registration can be facilitated by, e.g., equipping the computers in the department with a badge scanning system. This will lead to more accurate and timely data registrations, without placing additional burdens on healthcare professionals. While the aforementioned measures are beneficial to enable the systematic use of process mining, healthcare organizations will probably only take such measures when they are convinced of the added value of process mining. Once this is the case, healthcare organizations and professionals

will become partners of the process mining community in the quest to improve the quality of recorded process execution data.

8.4.3 Integrate process mining functionalities in existing health information systems (hov-3)

When the community aims to achieve a more widespread use of process mining in healthcare organizations, a close partnership with health information systems vendors is required. Process mining functionalities should be integrated in existing health information systems such that healthcare professionals can seamlessly use them, ideally moving towards the concept of process-aware information systems envisaged by Dumas et al. [94]. When process mining can only be applied using a standalone tool, data needs to be exported from the health information systems to import it in this tool (potentially requiring data restructuring). This imposes significant barriers to the use of process mining for clinical and non-clinical decision support. While ensuring this seamless use is a responsibility for health information systems vendors, it is important to recognize that vendors are typically demand-driven when determining which features to add to their systems. Hence, healthcare organizations can motivate vendors to incorporate process mining functionalities by, e.g., stressing the need for data-driven process analysis functions or by incorporating it as a system requirement.

8.5. Conclusions

Despite the unique potential of process mining to retrieve data-driven insights in healthcare processes, its uptake in healthcare organizations is rather limited. Given this observation, this paper synthesized the outcomes of a two-day international brainstorm seminar on how to enhance the usability and understandability of process mining in healthcare. Based on the discussions of 18 experts, both researchers and healthcare practitioners, a set of key recommendations is specified. Ten recommendations target process mining researchers and the research community. While this was the predominant focus of the work, three additional recommendations are directed to healthcare organizations and

health information systems vendors. The recommendations to process mining researchers give rise to several research challenges. These include (i) setting up a benchmarking study to identify the most suitable process modeling language to visualize the output of control-flow discovery algorithms in healthcare, (ii) developing techniques to handle data quality issues in healthcare event logs, (iii) designing techniques which leverage different sources of process-related data, e.g. originating from IoT settings, which potentially originate from different healthcare organizations, (iv) creating process mining methods which approach healthcare processes from various perspectives and attribute central importance to the patient journey, and (v) guiding healthcare organizations in their process mining endeavors by developing a comprehensive methodology for process mining in healthcare. Besides these challenges, continued research efforts are required at the intersection of process mining and complementary techniques within areas such as predictive analytics, operations research, and machine learning. Enhancing the usability and understandability of process mining in healthcare will require continued efforts by individual researchers and the research community. Some specific topics for future work have been highlighted in the previous paragraph. However, to strengthen the relevance of process mining in healthcare and to further increase its potential benefits, researchers are strongly encouraged to carefully consider the recommendations formulated in this paper in all their research projects. This also involves developing an attitude in which, for instance, real-world healthcare problems are a starting point for research, and healthcare specificities are taken into account when developing new process mining techniques. Besides the efforts of individual researchers, the research community will also play a key role. The community can, for instance, target the development of a standardized terminology for process mining in healthcare, or ensure that sufficient training opportunities for healthcare professionals are available. These united efforts will contribute to process mining reaching its full potential as a catalyst for evidence-based process improvement in healthcare.

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9

BETTER OUTCOME AT LOWER COSTS AFTER IMPLEMENTING A CRT-CARE PATHWAY: COMPREHENSIVE EVALUATION OF REAL- WORLD DATA

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Abstract

Aims

Cardiac resynchronization therapy (CRT) requires intensive, complex, and multidisciplinary care for heart failure (HF) patients. Due to limitations in time, resources, and coordination of care, in current practice, this is often incomplete. We evaluated the effect of the introduction of a CRT-care pathway (CRT-CPW) on clinical outcome and costs.

Methods and results

The CRT-CPW focused on structuring CRT patient selection, implantation, and follow-up management. To facilitate and guarantee quality, checklists were introduced. The CRT-CPW was implemented in the Maastricht University Medical Centre in 2014. Physician-led usual care was restructured to a nurse-led care pathway. A retrospective comparison of data from CRT patients receiving usual care (2012–2014, 222 patients) and patients receiving care according to CRT-CPW (2015–2018, 241 patients) was performed. The primary outcome was the composite of all-cause mortality and HF hospitalization. Hospital-related costs of cardiovascular care after CRT implantation were analysed to address cost-effectiveness of the CRT-CPW. Demographics were comparable in the usual care and CRT-CPW groups. Kaplan–Meier estimates of the occurrence of the primary endpoint showed a significant improvement in the CRT-CPW group (25.7% vs. 34.7%, hazard ratio 0.56; confidence interval 0.40–0.78; $P < 0.005$), at 36 months of follow-up. The total costs for cardiology-related hospitalizations were significantly reduced in the CRT-CPW group [€17 698 (14 192–21 195) vs. €19 933 (16 980–22 991), $P < 0.001$]. Bootstrap cost-effectiveness analyses showed that implementation of CRT-CPW would be an economically dominant strategy in 90.7% of bootstrap samples.

Conclusions

The introduction of a novel multidisciplinary, nurse-led care pathway for CRT patients resulted in significant reduction of the combination of all-cause mortality and HF hospitalizations, at reduced cardiovascular-related hospital costs.

9.1 Introduction

Multiple randomized clinical trials have shown that cardiac resynchronization therapy (CRT) reduces symptoms of heart failure (HF), improves exercise capacity and quality of life, and reduces HF hospitalizations and mortality.¹⁻⁶ Clinical guidelines of the European Society of Cardiology and the American College of Cardiology Foundation/American Heart Association endorse these results and recommend utilization of CRT in selected HF patients.⁷⁻¹⁰ Despite guidelines and experts' consensus, variability in patient selection, implantation techniques, in-hospital management, and follow-up is observed in clinical practice.¹¹⁻¹³ To optimize benefit from CRT, thorough selection, carefully planned implantation strategy, and a comprehensive follow-up including HF treatment and device management should be reassured. Previously, a small number of studies introducing structured, comprehensive programmes to improve the use and outcomes of CRT in HF patients have shown promising results.^{14,15} However, the widespread adoption of such programmes requires it to improve outcomes without the use of extensive or highly specialized resources. Moreover, as resources and costs are becoming more important with the expanding HF population,¹⁶ evaluation of interventions should consider cost-effectiveness. In general HF care, the transition from physician-led to nurse-led care has been shown to result in a reduced risk of HF hospitalization and is a cost-effective intervention.¹⁶⁻²⁰ Moreover, studies have shown that structured aids in HF care programmes can lead to improved adherence to guidelines.^{14,21,22} We therefore developed and implemented a multidisciplinary, nurse-led, structured CRT-care pathway (CRT-CPW), with protocolized aids and advanced planning, which aims to improve outcome at reduced costs.²³ This paper evaluates whether the implementation of the CRT CPW improves outcome by reducing all-cause mortality and HF hospitalization, and whether the CRT-CPW is cost-effective.

9.2 Methods

9.2.1 Cardiac resynchronization therapy-care pathway

In 2013, three CRT expert centres experienced the need for a best practice care process design to accommodate the complex multidisciplinary care for these patients and therefore optimize outcomes. Incorporating local experiences and scientific evidence, a benchmark CRT-CPW design was designed. The design aimed to capture predictors of outcomes relevant to each individual process step, using checklists. The generic care pathway was then operationalized to fit the Maastricht University Medical Centre+ (MUMC+) organization, detailing structured planning of process steps with relevant resources needed, and responsibilities of contributors. The most important changes introduced compared with usual care at the MUMC+ were the structured planning of follow-up from implantation on and a transition of tasks from physicians to specialized HF nurses and device technicians, enabling one-stop-shop visits, to reduce unnecessary resource use and patient burden. Importantly, the care pathway did not focus on the implementation of novel tools for device implantation (e.g. quadripolar leads), enhanced patient monitoring (use of home monitoring), use of new device algorithms, or prescription of novel HF medication. The CRT-CPW involves a structured workflow with routine, pre-planned contacts led by trained HF nurses in collaboration with device technicians. Heterogeneity of care for HF patients treated with CRT was captured by the use of checklists at (1) patient referral, (2) pre-implant assessment, (3) device implantation, and (4) follow-up, used at prespecified one-stop-shop contact moments. The care pathway involved the implementation of a multidisciplinary (HF and electrophysiology) meeting discussing referrals, a one-stop-shop pre-assessment visit with an implanting physician and specialized device nurse, single-day admission for implantation, and 2 week, 3 month, 6 month, and 12 month pre-planned one-stop-shop follow-up contacts with HF nurses and device technicians. Each step was guided by the checklists to ensure dedicated optimization in every way possible. For detailed insight into the checklists and the care pathway design, we refer to a previously published evaluation of the CRT-CPW.²³ The implementation of the care pathway took place from January 2014 to September 2014. During this time, all contributors

to the different phases of the CRT-CPW were trained in the use of the checklists and on logistic and IT support changes relevant to their contributions to the CPW.

9.2.2 Data collection and analysis

The study was performed according to the Declaration of Helsinki and was approved by the Medical Ethics Committee (METC). At the time of the METC approval of the CRT-CPW study, Dutch guidelines allowed the use of de-identified patient data acquired from routine clinical care, without prior individual patient consent. All patients who underwent CRT device implantation or upgrade procedure (from any device vendor) and received follow-up care at MUMC+ were included in the current analysis. Baseline characteristics were collected by extracting data from the MUMC+ (electronic) hospital information system. HF cause was deemed ischaemic when there was clear evidence of myocardial infarction or coronary artery bypass graft (CABG) in medical history.

A retrospective data analysis of two CRT patient groups was conducted comparing the usual care group (2012–2014) with the CRT-CPW group (2015–2018). The primary outcome was the composite of all-cause mortality and HF hospitalizations. Secondary outcomes were the components of the primary outcome analysed separately and hospital-related costs of cardiovascular care after CRT implantation. Clinical outcome data were retrieved from the electronic hospital information system, linked to municipal registries on mortality. Hospitalizations were deemed HF-related when clearly described as such in discharge forms by responsible physicians. Furthermore, total hospital-related costs of cardiovascular care from 6 months before and 12 months after CRT implantation were analysed to address cost-effectiveness. To calculate the cardiac care-related costs per CRT patient, all registered care activities related to the CRT-CPW per patient such as diagnostics (echocardiography, electrocardiogram, and X-ray's), hospitalization days, cathlab procedure time, and consultations were multiplied with their respective hospital cost-price per activity. To define which care activities are CRT-CPW related, all care activities connected to cardiology DRG's within a time scope from 6 months prior to CRT device implant until 12 months after were included. These activities were retrieved from the electronic hospital information system. The hospital cost-price per care activity is based

on annual activity-based costing methodology and were provided by hospital finance department.

9.2.3 Statistical analysis

Categorical variables are summarized with counts and percentages and compared with Fisher's exact test for nominal variables and the Cochran–Mantel–Haenszel test for ordinal variables. Continuous variables are reported as mean (standard deviation), or median [interquartile range], as appropriate, and compared with Student's *t*-test or Wilcoxon rank sum test, respectively. Analyses were conducted in SAS Version 9.4 (SAS Institute Inc., Cary, NC, USA). Incidence of death, HF hospitalization, and the composite of these events are estimated using the Kaplan–Meier method. The log-rank test is used to compare event incidence between groups. Univariable Cox regression is used to obtain estimates for the hazard ratio (HR) and its 95% confidence interval (CI). Multivariable modelling of death, HF hospitalization, and the composite event was done using Cox regression. The models include group (CRT-CPW vs. usual care), sex, age, body mass index, left ventricular ejection fraction (LVEF), QRS duration, New York Heart Association (NYHA) class, left bundle branch block (LBBB), ischaemic cardiomyopathy, hypertension, atrial fibrillation, chronic lung disease, diabetes, de novo implant, therapeutic vs. prophylactic, urgent vs. elective, and CRT-P vs. CRT-D device.

Multivariable modelling of cost was done using linear regression on the natural logarithm of cost. Parameter estimates are converted to cost scale and reported as a relative, per cent-wise change per unit change of the covariate. Stratified bootstrap was used to assess robustness of and correlation between the reduction in mortality and reduction in cost associated with implementation of the CRT pathway. Five thousand samples with replacements were taken. For each sample, HR and Δcost were calculated. Results are reported with a scatter plot and summary statistics, identifying four quadrants defined by $\text{HR} < 1$ vs. $\text{HR} \geq 1$ and $\Delta\text{cost} < 0$ vs. $\Delta\text{cost} \geq 0$. Multiple imputation of missing values was performed using fully conditional specification to create 25 complete data sets.²⁴ Multivariable regression models are reported from the completed datasets, using Rubin's rule to combine the results.²⁵

9.3 Results

9.3.1 Patient characteristics

The study cohort comprised a total of 463 patients available for analysis. Data were collected from 222 patients referred for implantation of a CRT device before implementation of the CRT-CPW (usual care group) and data from 241 patients after introduction of the CRT-CPW (CRT-CPWgroup) were analysed. The two groups reflect a typical real-world CRT population, with an average age of 68 years old; more than 80% of patients were in NYHA functional class II or III. The average baseline LVEF was 30%, with an ischaemic cause of HF present in 40% of patients. Over 85% of patients were treated with an angiotensin-converting enzyme-inhibitor or angiotensin receptor blocker and beta-blocker, and over 50% with a mineralocorticoid receptor antagonist. Fourteen per cent of patients underwent an upgrade procedure from a previous device, and over 70% of patients received a CRT-ICD system. Baseline QRS duration was 158 ± 28 ms, and 50% of patients showed a baseline LBBB QRS morphology. The baseline characteristics of the usual care and CRT-CPW group patients were largely comparable (see *Table 1*). In the CRT-CPW group, atrial fibrillation and previous myocardial infarction were more prevalent (see *Table 1*).

Table 1. Baseline characteristics

Baseline characteristic	Usual care (N = 222)	CRT-care pathway (N = 241)	P-value ^a
Male, n (%)	156 (70.3%)	174 (72.2%)	0.68
Age, years ^b (mean $\pm$ SD)	68.1 $\pm$ 11.0	68.6 $\pm$ 10.3	0.66
BMI, kg/m ² (mean $\pm$ SD)	27.4 $\pm$ 5.0	27.5 $\pm$ 4.7	—
NYHA class ^c			0.11
• Class I, n (%)	6 (2.9%)	15 (8.0%)	
• Class II, n (%)	124 (59.6%)	88 (46.8%)	
• Class III, n (%)	72 (34.6%)	63 (33.5%)	
• Class IV, n (%)	6 (2.9%)	22 (11.7%)	
• Missing, n (%)	14 (6.3%)	53 (22.0%)	

Table 1. Baseline characteristics *Continued*.

Baseline characteristic	Usual care (N = 222)	CRT-care pathway (N = 241)	P-value ^a
LBBB, n (%)	117 (52.7%)	117 (48.5%)	0.51
QRS duration, ms (mean ± SD)	157.6 ± 28.4	155.9 ± 31.0	0.54
LVEF, % (mean ± SD)	28.9 ± 9.1	30.4 ± 10.1	0.089
LVESV, mL (mean ± SD)	133.2 ± 58.6	133.1 ± 58.2	0.99
Ischaemic cardiomyopathy, n (%)	90 (40.5%)	95 (39.4%)	0.85
Hypertension, n (%)	75 (33.8%)	86 (35.7%)	0.70
Myocardial infarction, n (%)	52 (23.4%)	78 (32.4%)	0.038
Atrial fibrillation, n (%)	73 (32.9%)	104 (43.2%)	0.028
Chronic lung disease, n (%)	33 (14.9%)	35 (14.5%)	1.00
Diabetes, n (%)	44 (19.8%)	56 (23.2%)	0.43
Kidney failure, n (%)	2 (0.9%)	2 (0.8%)	1.00
NT-proBNP, pg/mL (mean ± SD)	361 ± 621	354 ± 503	0.90
GFR (MDRD), mL/min/1.73 m ² (mean ± SD)	63.3 ± 28.6	59.8 ± 22.0	0.15
Beta-blocker use, n (%)	193 (86.9%)	205 (85.1%)	0.59
ACEi/ARB use, n (%)	200 (90.1%)	204 (84.6%)	0.094
MRA use, n (%)	107 (48.2%)	135 (56.0%)	0.095
ARNI use, n (%)	0 (0.0%)	5 (2.1%)	0.062
Upgrade from ICD/pacemaker, n (%)	26 (11.7%)	40 (16.6%)	0.14
CRT-D ^c , n (%)	172 (77.5%)	168 (69.7%)	0.073

Abbreviations: ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; BMI, body mass index; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; GFR, glomerular filtration rate; ICD, implantable cardioverter-defibrillator; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; MRA, mineralocorticoid receptor antagonist; NT-proBNP, N-terminal prohormone of brain natriuretic peptide; NYHA, New York Heart Association.

^aP-value compares old and new pathways. Tests used are Student's t-test, Cochran–Mantel–Haenszel's test, and Fisher's exact test.

^bAge is estimated from age ranges.

^cPercentages exclude missing values from denominator.

9.3.2 Outcome

The mean follow-up time in the usual care group was 62.8 ± 30.2 months, and 37.7 ± 14.9 months in the CRT-CPW group. Death from any cause or admission for HF occurred in 127 patients (57.2%) in the usual care group and 64 patients (26.6%) in the CRT-CPW group. Kaplan–Meier estimates for incidence at 12, 24, and 36 months were 14.9%, 24.8%, and 34.7% in the usual care group and 11.2%, 18.8%, and 25.7% in the CRT-CPW group, respectively (*Figure 1A*). Multivariable Cox regression model for the composite of all-cause mortality and HF hospitalization (Supporting Information, *Table S1*) shows a significant reduction of 44% (HR 0.56, CI 0.40–0.78, $P = 0.0006$) in the CRT-CPW group. Other significant predictors of the occurrence of the primary outcome were increasing age, a history of atrial fibrillation, higher functional class, and ischaemic HF aetiology.

9.3.3 All-cause mortality

Kaplan–Meier estimates for incidence of all-cause mortality at 12, 24, and 36 months were 8.1%, 17.6%, and 25.2% in the usual care group and 5.4%, 10.9%, and 18.4% in the CRT-CPW group, respectively (*Figure 1B*). Multivariable Cox regression model for mortality (Supporting Information, *Table S2*) shows that CRT-CPW group assignment was associated with a significant 40% reduction (HR 0.60, CI 0.41–0.87, $P = 0.007$) in mortality.

9.3.4 Heart failure hospitalizations

Kaplan–Meier estimates for incidence of HF hospitalizations at 12, 24, and 36 months were 8.7%, 12.7%, and 18.1% in the usual care group and 6.4%, 10.1%, and 11.2% in the CRT-CPW group, respectively (HR 0.57, CI 0.35–0.92, $P = 0.021$) (*Figure 1C*). Multivariable Cox regression model for incidence of HF hospitalizations (time to first) (Supporting Information, *Table S3*) showed that CRT-CPW treatment was associated with a significant 51% reduction (HR 0.49, CI 0.30–0.81, $P = 0.005$) in HF hospitalization rate.

9.3.5 Hospital-related costs of cardiovascular care and cost-effectiveness

The total cardiology-related hospital costs from 6 months before up to 12 months after CRT device implantation reduced significantly in the CRT-CPW group [€17.698 (14 192–21 195) vs. €19.933 (16 980–22 991), $P < 0.001$]. Multivariable linear regression analysis showed an average 9.3% cost reduction (CI -13.8% to -4.5%, $P < 0.005$; Supporting Information, *Table S4*). A bootstrap analysis of cost-effectiveness showed 90.7% of the bootstrap samples was in the dominant quadrant (*Figure 2*), indicating simultaneous clinical benefit and cost reduction for the CRT-CPW.

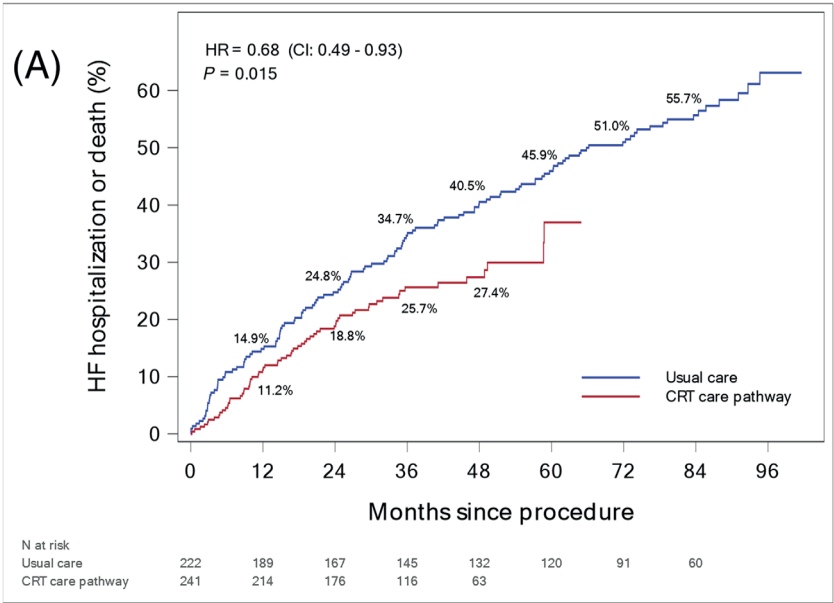
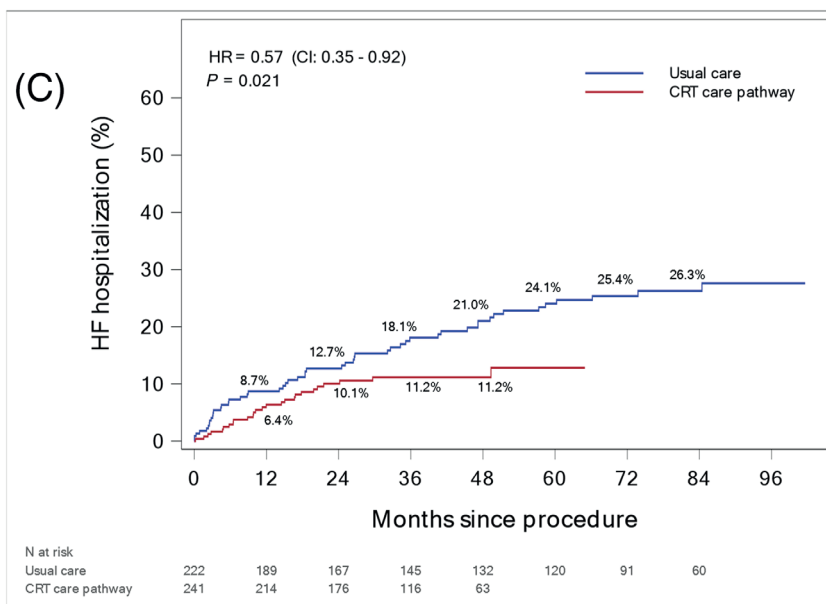
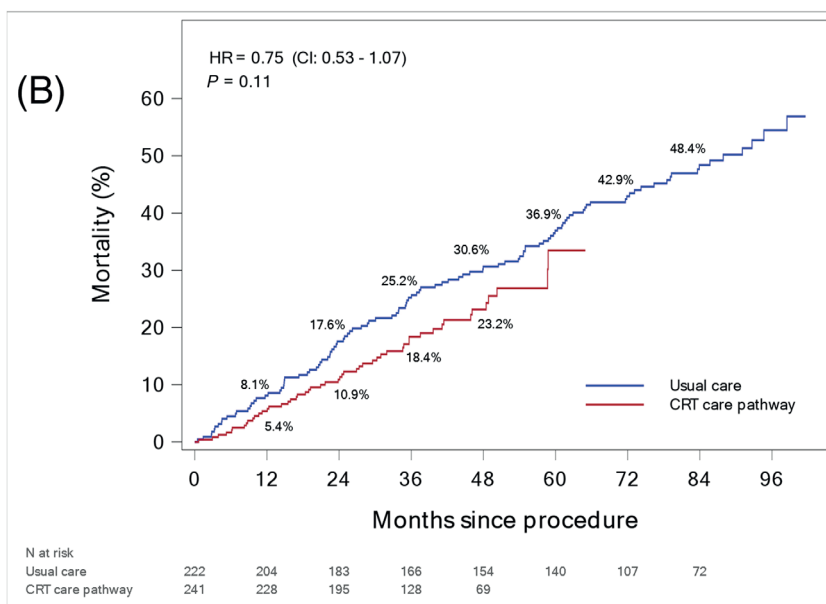


Figure 1. (a) Composite of death and HF hospitalization. Figure 1a shows the Kaplan–Meier estimates for the composite of all-cause mortality and HF hospitalization. (b) Mortality. Figure 1b shows the Kaplan–Meier estimates for all-cause mortality. The hazard ratio with 95% confidence interval with estimated mortality at selected time points, and number of patients at risk. (c) Incidence of HF hospitalizations. Figure 1c shows the Kaplan–Meier estimates for incidence of HF hospitalizations. CI: confidence interval; CRT: cardiac resynchronization therapy; HF: heart failure; HR: hazard ratio.



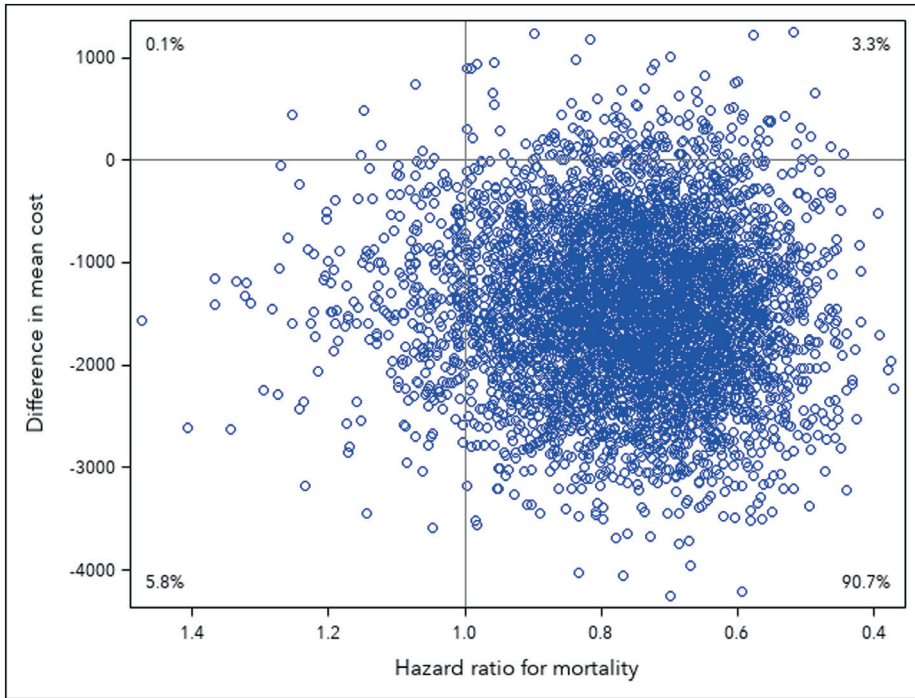


Figure 2. Five thousand bootstrap estimates of the hazard ratio for mortality and the difference in mean costs between conventional and cardiac resynchronization therapy-care pathway.

9.4 Discussion

The main finding of the current study is that the implementation of a multidisciplinary, nurse-led care pathway for CRT patients is associated with a significant reduction in the incidence of the composite endpoint of death and HF hospitalization. Furthermore, the implementation of the care pathway is associated with a reduction of care-related costs, resulting in dominant cost-effectiveness.

9.4.1 Clinical outcomes

The incidence of all-cause mortality and HF hospitalization in this study resembles that of earlier CRT studies. Patients in the CRT arm of the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial (RAFT) randomized CRT trial⁴ experienced equal event rates at 2 or 3 years of follow-up, compared with the CRT-CPW patients in the current study.

However, usual care patients experienced a significantly higher event rate. The RAFT cohort, however, included 80% of patients in HF functional class II, whereas the current cohort included ~40% of patients with functional class III or IV. Of note, baseline functional class was missing in a substantial number of patients in both usual care and CRT-CPW patient groups; this is due to the retrospective nature of the current study. In contrast to functional class, average baseline ejection fraction was higher in the current analyses (30% vs. 23%) than in the RAFT trial. As the current analysis included patients with brady-pacing indications like high degree AVB and ablate-and-pace strategy for atrial fibrillation, this included patients with baseline ejection fraction above 35%. A recent large, real-world, CRT cohort study from the UK²⁶ included over 50 000 patients implanted with a CRT device between 2009 and 2017. Even though extensive baseline data on the English CRT cohort are lacking, the real-world character likely makes it resemble the current cohort more than the RAFT trial population. All-cause mortality in this UK cohort was even slightly higher than in the usual care group in the present evaluation (28% vs. 25% at 3 years of follow-up). The higher mortality rates can be explained by a difference in inclusion period and setting, as the current analysis included patients implanted with a CRT device between 2012 and 2018 and the CRT-CPW was implemented in a tertiary referral centre in the current analyses, compared with a wide variety of centres in England.

Baseline differences between the two groups of CRT patients in the current analyses showed a higher percentage of patients with a history of atrial fibrillation and myocardial infarction in the CRT-CPW group. As recognized by guidelines, these differences are expected to reduce the effect of CRT in the CRT-CPW group.²⁷⁻²⁹ Multivariable corrections of our results show that there is no significant effect of the baseline differences on the overall effect on clinical outcomes in CRT patients. However, multivariable correction of the Cox regression analyses on all-

cause mortality revealed a significant association of CRT-CPW treatment and this endpoint. The convincing association of CRT-CPW implementation with improved clinical outcomes is likely the effect of the sum of a complete, comprehensive evaluation for both CRT device-related and HF-related opportunities for treatment

optimization, at each patient contact from patient selection up to long-term follow-up. These results confirm the observed potential for optimization in an intensive optimization programme proposed by Mullens *et al.*¹⁴ As the checklists used for post-implantation optimization of patient management were based on the programme described by Mullens *et al.*, these results extend their results to the overall CRT patient population and, moreover, establish its superiority compared with routine follow-up in these patients. The CRT-CPW however differs from the programme described by Mullens *et al.* with respect to two very important aspects. Whereas Mullens *et al.* included non-responders to CRT referred to the clinic, evaluated at a single moment in time, the CRT-CPW structurally optimizes treatment in any patient treated with CRT. Furthermore, the CRT-CPW aims to optimize treatment at each visit, from patient selection and device implantation to each contact during (long-term) followup.

The introduction of checklist-based interventions has been shown effective in the increasing guideline adherence in HF before. Fonarow *et al.* have implemented a guideline-based clinical decision support tool kit in 167 US outpatient cardiology practices in their IMPROVE HF trial.²¹ The introduction of the structured support resulted in a significant increase in guideline adherence.²¹ A consideration with respect to the results of the current study is that guidelines for HF treatment were updated during the conduction of this study. The adaptations of recommendations, especially with respect to general HF treatment, may confound the presented results. Even though baseline HF medical treatment did not significantly differ, optimization during follow-up should involve the updated medical treatment as well and may hence play a role in the improved clinical outcomes. Altman *et al.* described an optimization programme similar to the currently described CRT-CPW.¹⁵ The programme constituted a three-visit (6 month) optimization service, providing multidisciplinary, specialized evaluation and intervention, after which patients were referred back to conventional care, unless refractory symptoms or non-response persisted. After a median follow-up of 24 months, patients evaluated in this optimization programme showed

similar reductions in event rates (all-cause mortality, transplantation, or HF hospitalization) as in the current evaluation. Unfortunately, the content of the intervention(s) used in the optimization programme group was at the physician's discretion and not described in detail. The multidisciplinary team consisted of dedicated HF and EP specialists, using echocardiographic optimization. It is not clear whether dedicated protocols were used and whether specialized nurses were involved. The lack of a clear optimization protocol limits the reproducibility of these results. Moreover, the use of multiple specialists during the visits precludes its implementation in many CRT clinics. In contrast, the proposed structured CRT-CPW included protocolled optimization, guided by checklists, substituting expert experience in CRT care to ensure all possible opportunities for optimization are taken without undue burden to specialists. This enables any CRT clinic to implement the CRT-CPW using current staff and resources or even substituting physician care by nurse-led care, as shown in the current analysis.

9.4.2 Cost-effectiveness

Incidence and prevalence of HF are increasing rapidly, with healthcare programmes needing to adapt to this increased need for care and expected increase in healthcare costs.¹⁶ Cardiac resynchronization therapy optimization programmes described before did not evaluate effects on costs.^{14,15} However, the use of specialized physicians and resources (e.g. echocardiographic optimization) most likely result in additional costs, with the need of a cost-effectiveness analysis to be able to assess whether clinical results are worth the investment. In contrast, the currently evaluated CRT-CPW was not only introduced to ensure better outcomes by multidisciplinary management of HF patients eligible and treated with CRT but also to reduce the need of highly specialized care, resources, and consequently cost. The introduction of the CRT-CPW process improvement was associated with a shorter time-to-implant, shorter procedure-related length of stay, and a successful transition from a physician-led to a nurse-led care process, as was previously described in detail.²³ These process-related changes resulted in a significant reduction of costs, as shown in the current evaluation.

The current evaluation of costs involved a direct calculation of local cardiology-related costs related to resource use and healthcare consultations. These costs

are centre-specific and translation to patient-specific or societal costs may be dependent on the country-specific reimbursement systems. However, as it was associated with a significant reduction of hospitalizations, the intervention will result in reduced costs in most, if not all, healthcare systems. The difference in first-year HF hospitalizations accounts for the largest part of total cost savings in the current evaluation. However, as this cost evaluation was only possible for the period of 6 months before up to 12 months after CRT device implantation, the impact of the reduction of HF hospitalizations on costs in the current evaluation is limited. As HF hospitalizations were significantly reduced also beyond the first year after implantation, even larger cost reduction can be expected long term.

9.4.3 Future outlook

The presented CRT-CPW implementation, in contrast to previous CRT optimization programmes, allows for copying in any setting as it specifically aims to reduce resource use and transfer care from physicians to nurses. This offers opportunity for any clinic involved in care for CRT patients to adopt the presented programme to improve their CRT patient management.

9.4.4 Limitations

Even though the current evaluation of the introduced CRT-CPW provides very hopeful results, the results were derived from a single-centre implementation, and the historical comparison design does not allow for definite conclusions on superiority. As CRT and general HF therapy have evolved over time (e.g. the introduction of quadripolar leads and sacubitril/ valsartan), changes in availability of HF or device therapy may have influenced results, even though adjustment for these factors in multivariable analysis did not show any significant impact on results. Still, complete adjustment is not possible. In addition, the results need confirmation in other centres to prove reproducibility. Lastly, the use of real-world data limits data completeness. Even though endpoint collection was complete, baseline data were not available in all patients, possibly influencing baseline comparability of treatment groups. Hence, prospective, multicentre evaluation, in a (clustered) randomized controlled trial, is needed to provide definitive evidence

that a structured CRT-CPW significantly improves outcomes of CRT-treated HF patients in any setting.

9.5 Conclusions

The introduction of a structured nurse-led, multidisciplinary CRT-CPW may result in significantly better clinical outcome at lower costs. As this pathway does not require any highly specialized resources or physicians, it may be introduced in any clinic involved in CRT patient care. Still, prospective validation, ideally in a randomized controlled trial, is needed.

Supplementary materials

Supporting Information (Tables S1–S4) referred to in this chapter are available in the supplementary material of the original publication.

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10

EVALUATING TRANSCATHETER VERSUS SURGICAL AORTIC VALVE REPLACEMENT: OUTCOMES, COSTS AND CAPACITY IN THE DUTCH HEALTHCARE SYSTEM

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Abstract

Background/objectives

Transcatheter Aortic Valve Implantation (TAVI) has expanded to lower-risk patients, but adoption and reimbursement vary across healthcare systems. Evidence on long-term outcomes, hospital resource use, and costs in these populations remains limited.

Methods

This retrospective cohort study compared transfemoral TAVI and Surgical Aortic Valve Replacement (SAVR) in patients with severe aortic stenosis and low-to-intermediate surgical risk treated at a Dutch academic hospital. Primary outcomes included one-year all-cause mortality, hospital resource use, and total direct costs. Propensity score matching (2:1) was performed based on age, sex, EuroSCORE II, and baseline physical functioning.

Results

In the unmatched cohort ($n = 864$), one-year mortality was higher for TAVI (8.3% vs. 4.7%, $p = 0.065$), but four-year Kaplan–Meier survival was significantly better for SAVR (log-rank $p < 0.001$). TAVI patients were older, frailer, and had higher surgical risk. TAVI showed significantly shorter mean procedure duration (78 vs. 244 min), ICU stay (0.19 vs. 1.88 days), and ward stay (6.0 vs. 8.7 days, all $p < 0.001$), but incurred higher mean hospital costs (€32,829 vs. €25,290, $p < 0.001$). Quality of life improvement, based on the SF-36 health transition item, was comparable (mean score 2.88 vs. 2.60, $p = 0.13$). After 2:1 matching ($n = 360$), moderate imbalance remained for age and sex, while substantial imbalance persisted for physical functioning (SMD = 1.10). One-year mortality was significantly lower in TAVI (0.4% vs. 6.7%, $p = 0.001$), though no difference in four-year survival was observed ($p = 0.274$). Procedural efficiency and resource use remained more favorable for TAVI, while costs remained higher.

Conclusions

In real-world practice, TAVI offered comparable long-term survival and significantly greater procedural efficiency than SAVR, at the cost of higher initial expenses. These findings highlight the need to evaluate value beyond clinical outcomes alone, incorporating system-level benefits such as capacity gains. Reimbursement models should evolve to reflect this broader perspective on value.

10.1 Introduction

Severe aortic stenosis is a prevalent and life-threatening condition in older adults, with untreated cases facing a poor prognosis due to risks of heart failure and death [1]. Since its first clinical use in 2002, Transcatheter Aortic Valve Implantation (TAVI) has profoundly transformed the therapeutic landscape for this condition [2]. Initially reserved for inoperable or high-risk patients, growing evidence has supported the expansion of TAVI to intermediate- and low-risk populations [3,4]. This shift is reflected in the 2021 ESC/EACTS guidelines, which lowered the recommended age threshold for TAVI from 80 to 75 years, and expanded eligibility based on surgical risk rather than operability alone [5]. Large, randomized trials have demonstrated the non-inferiority of TAVI compared to Surgical Aortic Valve Replacement (SAVR) in selected low-risk cohorts [3,4]. However, these trials are typically conducted in idealized environments and may not reflect real-world constraints and variations in care delivery. In practice, healthcare systems, such as the Dutch system, operate under increasing pressure from limited intensive care capacity, procedural backlogs, and bundled-payment models that affect care pathways and financial decision-making [6–8]. At one Dutch centre, TAVI is delivered via a fast-track protocol that often avoids intensive care unit (ICU) admission and facilitates early discharge. These organizational differences have significant implications for hospital capacity, planning, and cost allocation, yet remain underrepresented in comparative studies. Most existing comparisons between TAVI and SAVR focus on short-term clinical endpoints such as mortality and stroke, with relatively little attention to differences in hospital resource utilization or cost structure [4,7,9]. Moreover, these studies often rely on multivariable adjustment to account for baseline differences between treatment

groups. While such approaches reduce confounding, propensity score matching (PSM) offers a more robust method to balance key patient characteristics and simulate randomized conditions. In this study, PSM was applied to mitigate baseline imbalances, and Activity-Based Costing (ABC) was used to derive accurate, individualized cost estimates that better reflect real-world resource consumption [6].

10.2 Methods

10.2.1 Study design and population

This retrospective cohort study included patients with severe symptomatic aortic stenosis who underwent either isolated Surgical Aortic Valve Replacement (SAVR) or transfemoral Transcatheter Aortic Valve Implantation (TAVI) between January 2017 and December 2021 at Maastricht University Medical Center+ (MUMC+), a high-volume academic center in the Netherlands. Inclusion was restricted to patients at low- to intermediate surgical risk, defined as EuroSCORE II < 9 [10]. High-risk patients were excluded due to differing treatment allocation. All TAVI procedures were performed via transfemoral access using standard institutional protocols. The study was conducted in accordance with the Declaration of Helsinki. The institutional ethics board waived the requirement for separate approval, as pseudonymized registry data were used.

10.2.2 Data collection and definitions

Baseline characteristics were extracted from electronic health records and included age, sex, EuroSCORE II [10], and physical functioning (PF) scores from the SF-36 where available. PF score served as a proxy for frailty, as formal frailty scores were only available for a subset of TAVI patients. Outcome variables included one-year all-cause mortality, operating room (OR) time in minutes, intensive care unit (ICU) and ward length of stay in days, total direct hospital costs in euros, and patient-reported quality of life (QoL) via the health transition item of the SF-36,

rated on a five-point Likert scale (1 = “much better” to 5 = “much worse”) [11]. Survival status was verified via the national civil registry.

10.2.3 Cost calculation

Cost data were derived using an institution-wide Activity-Based Costing (ABC) system [6]. Each care activity, including diagnostics, OR time, ICU and ward days, and follow-up care, was assigned a standardized unit cost. Total cost per patient was calculated as the sum of all recorded care activities during the index admission and one-year follow-up. Valve costs were included based on the hospital’s average purchase price and held constant across suppliers to avoid vendor bias. All costs were reported in euros and indexed to the 2021 level. This costing method allowed for individualized estimates of real-world resource consumption and aligned with the updated Dutch guidelines for economic evaluations, building on earlier comparative cost-effectiveness analyses [12, 13].

10.2.4 Statistical analysis – full cohort

Continuous variables were presented as mean $\pm$ standard deviation or as median and interquartile range if non-normally distributed. Categorical data were expressed as counts and percentages. Group comparisons were conducted using Student’s t-test or Mann–Whitney U test for continuous variables, and Chi-square test for categorical variables. Survival was assessed using Kaplan–Meier curves and log-rank tests, with maximum follow-up of four years. A p-value < 0.05 was considered statistically significant. Analyses were conducted using Minitab (v21.3) and Python (v3.10).

10.2.5 Propensity score matching

To control for potential confounders, propensity score matching (PSM) was performed based on age, gender, EuroSCORE II, and baseline PF score. We applied 2:1 nearest neighbor matching without replacement and without caliper, using SAVR patients as the reference group. Although caliper-based matching (0.2 SD) was

explored, this resulted in prohibitively small matched samples (e.g., $n=18$ SAVR), limiting statistical power. Despite the absence of a caliper, residual imbalance remained, particularly for PF score (SMD = 1.10), which limits the comparability of the matched groups. This matched cohort is therefore used as an exploratory sensitivity analysis rather than a definitive comparative model.

10.2.6 Multivariable Cox regression

To assess the independent association between procedure type and mortality, a multivariable Cox regression was performed in the full cohort, adjusting for age, sex, EuroSCORE II, and PF score. Hazard ratios with 95% confidence intervals were reported.

10.2.7 Ethical considerations

The study used de-identified data from patients who provided informed consent for inclusion in the Netherlands Heart Registry (NHR). No individual data were used outside the scope of quality improvement and research as per national standards. Ethics committee review was waived due to the retrospective design and pseudonymized dataset.

10.3 Results

10.3.1 Study population

A total of 864 patients met the inclusion criteria, comprising 565 patients who underwent transfemoral TAVI and 299 who received SAVR. Baseline characteristics differed significantly between groups. TAVI patients were older (mean age 78.3 vs. 65.1 years), had higher surgical risk scores (EuroSCORE II 2.71 vs. 1.56), and exhibited lower baseline physical functioning scores (21.0 vs. 60.4) compared

to SAVR patients. Additionally, a smaller proportion of TAVI patients were male (49.6% vs. 66.9%). All differences were statistically significant ($p < 0.001$).

10.3.2 Outcomes – full cohort

In the full cohort, unadjusted one-year mortality was higher in TAVI patients (8.3%) compared to SAVR patients (4.7%), though this difference did not reach statistical significance ($p = 0.065$). Procedural characteristics and resource utilization favored TAVI: ICU stay was significantly shorter for TAVI (0.19 vs. 1.88 days, $p < 0.001$), as were ward stays (6.0 vs. 8.7 days, $p < 0.001$), and procedure duration (78 vs. 244 minutes, $p < 0.001$). Total direct hospital cost was higher for TAVI (€32,829 vs. €25,290, $p < 0.001$). Quality of life improvements, assessed by the SF-36 health transition item, were similar between groups (mean scores 2.88 for TAVI and 2.60 for SAVR, $p = 0.13$) [11]. Kaplan–Meier survival analysis over a four-year follow-up showed significantly better survival for SAVR patients (log-rank $p < 0.001$).

Table 1. Full cohort comparison of baseline characteristics, clinical outcomes, health economics, and resource utilization for savr and tavi patients (2017–2021).

Variable	TAVI Median (IQR) (n=565)	SAVR Median (IQR) (n=299)	TAVI Mean (SD)	SAVR Mean (SD)	p-value ¹
Age (years)	79.0 (±8.0)	67.0 (±12.0)	78.3 ± 6.0	65.1 ± 9.8	<0.0001
Sex (% male)	–	–	49.60%	66.90%	<0.00001
EuroSCORE II	2.16 (±1.96)	1.13 (±0.85)	2.71 ± 1.69	1.56 ± 1.30	<0.0001
QOL Physical Functioning	20.0 (±20.0) (n=267)	60.0 (±35.0) (n=120)	21.0 ± 11.6 (n=267)	60.4 ± 25.0 (n=120)	<0.0001
1-year mortality (%)	–	–	8.3% ± 27.6%	4.7% ± 21.2%	0.065
Self-rated change in QoL	2.00 (1.00–3.00) (n=131)	2.00 (1.00–3.00) (n=78)	2.28 ± 1.21 (n=131)	2.10 ± 1.08 (n=78)	0.3727
Procedure time (min)	67.0 (±30.0)	230.0 (±64.0)	78.4 ± 42.3	243.6 ± 69.5	<0.0001
ICU stay (days)	0.0 (±0.0)	1.0 (±1.0)	0.19 ± 0.81	1.88 ± 3.30	<0.0001
Ward stay (days)	5.0 (±1.0)	6.5 (±4.0)	6.0 ± 2.4	8.7 ± 9.9	<0.0001
Total cost (€)	€31,034 (±2,602)	€21,034 (±7,401)	€32,829 ± 5,775	€25,290 ± 18,571	<0.0001

¹ P-values from Mann–Whitney U tests (continuous variables) and Chi-square tests (Sex, 1-year mortality).

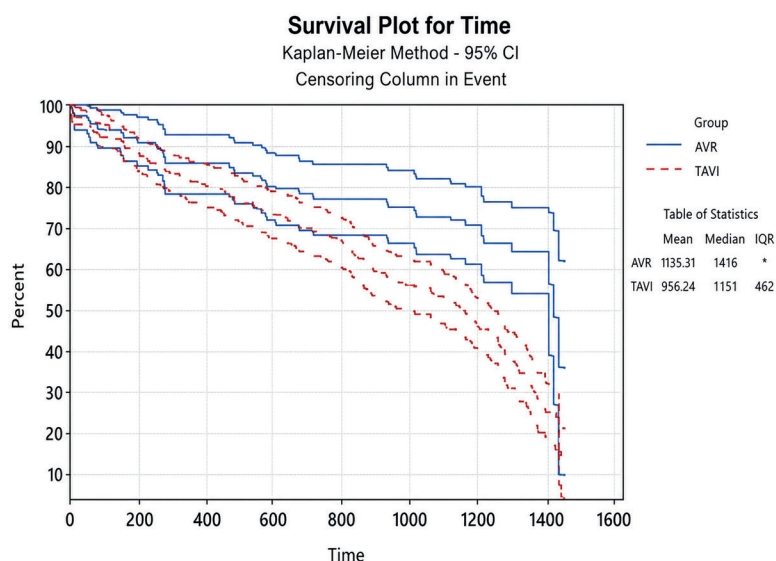


Figure 1. Kaplan-Meier Survival Comparison – Full Cohort (Max 4 years)

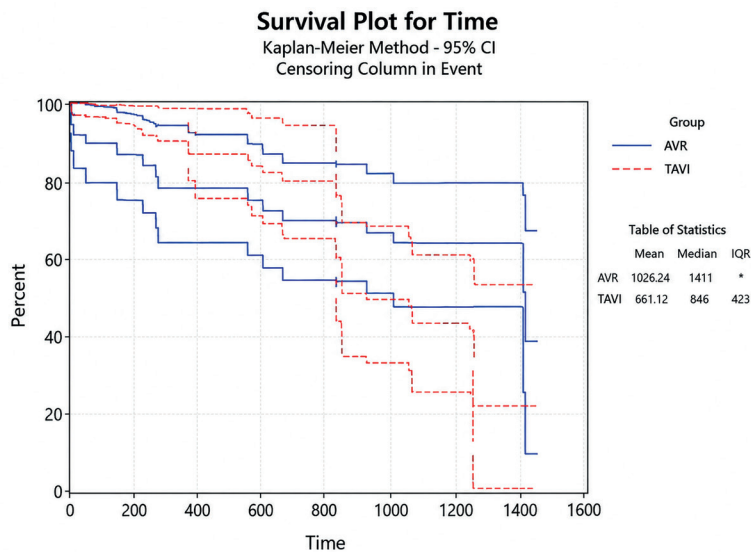
10.3.3 Matched cohort analysis

After 2:1 propensity score matching based on age, sex, EuroSCORE II [10], and baseline PF score [11], 240 TAVI patients were matched to 120 SAVR patients using nearest-neighbor matching without caliper. Although this reduced differences in age, sex, and surgical risk, substantial residual imbalance remained in PF score (SMD = 1.10). This imbalance limits the comparability of outcome estimates. In this matched cohort, one-year mortality remained significantly lower in the TAVI group (0.4% vs. 6.7%, $p = 0.001$). TAVI patients also continued to show significantly shorter ICU stays, ward stays, and procedure durations. Total cost remained higher for TAVI (€31,048 vs. €25,490, $p < 0.001$). Kaplan-Meier analysis showed no significant difference in long-term survival between the two treatment groups (log-rank $p = 0.274$). These results should be interpreted with caution due to the persistent imbalance in baseline PF [11].

Table 2. Standardized mean differences after 2:1 propensity score matching

MATCHING 2:1		
Variable	SMD	Interpretation
Age	0.301	Poor balance
Sex	0.21	Moderate balance
EuroSCORE II	0.182	Moderate balance
PF-score (QoL)	1.098	Very poor balance

Test	Chi-Square	Df	p-value
Log-Rank	17.22	1	<0.001
Wilcoxon	11.46	1	0.001



Kaplan-Meier Survival Comparison – Matched Cohort (Max 4 years)			
Test	Chi-Square	df	p-value
Log-Rank	1.2	1	0.274
Wilcoxon	0.35	1	0.556

Figure 2. Kaplan-Meier survival comparison – 2:1 matched cohort (max 4 years)

Table 3. Matched cohort comparison of baseline characteristics, clinical outcomes, health economics, and resource utilization for SAVR and TAVI patients (2017–2021).

Variable	TAVI (n=240)	SAVR (n=120)	TAVI Mean (SD)	SAVR Mean (SD)	p-value ¹
Age (years)	69.0 (5.0)	68.0 (12.0)	67.9 ± 4.6	65.6 ± 9.6	0.285
Sex (% male)	–	–	51.30%	61.70%	0.079
EuroSCORE II	1.32 (0.82)	1.10 (0.70)	1.24 ± 0.88	1.44 ± 1.21	0.837
QOL Physical Functioning	40.0 (5.0)	60.0 (35.0)	40.2 ± 7.1	60.4 ± 25.0	<0.001
1-year mortality (%)	–	–	0.4% ± 6.5%	6.7% ± 25.0%	0.001
Procedure time (min)	79.0 (2.0)	230.0 (63.0)	77.9 ± 14.1	241.2 ± 68.5	<0.001
ICU stay (days)	0.0 (0.0)	1.0 (1.0)	0.04 ± 0.21	2.23 ± 4.20	<0.001
Ward stay (days)	5.0 (3.0)	6.0 (3.0)	5.6 ± 1.6	7.9 ± 7.9	<0.001
Total cost (€)	€31,460 (±3,969)	€20,526 (±6,572)	€31,048 ± 2,822	€25,490 ± 20,858	<0.001

¹ p-values from Mann–Whitney U tests (continuous variables) and chi-square tests (sex, 1-year mortality).

10.3.4 Multivariable Cox regression

In the full cohort, multivariable Cox regression analysis demonstrated that treatment type (TAVI vs. SAVR) was not independently associated with long-term mortality after adjusting for age, sex, EuroSCORE II [10], and PF score [11]. Higher age and EuroSCORE II [10] were significantly associated with increased mortality risk, whereas PF score [11] was not a significant predictor.

10.4 Discussion

10.4.1 Summary of key findings

This study aimed to compare outcomes, resource utilization, and direct hospital costs for transfemoral Transcatheter Aortic Valve Implantation (TAVI) versus Surgical Aortic Valve Replacement (SAVR) in patients with severe aortic stenosis and low-to-intermediate surgical risk. In contrast to prior studies that focused primarily on short-term clinical endpoints, this analysis incorporated patient-reported physical functioning [11] and applied activity-based hospital costing [6] to reflect both individual- and system-level impact. After adjusting for age, sex, clinical risk [10], and functional status [11] using propensity score matching, similar mid-term survival was observed between TAVI and SAVR, but TAVI required significantly fewer hospital resources. These findings suggest that in selected patients, particularly in capacity-constrained environments, TAVI may offer a more efficient therapeutic strategy.

10.4.2 Interpretation of clinical and operational outcomes

In the unmatched cohort, TAVI patients had higher unadjusted one-year mortality than those undergoing SAVR. However, TAVI patients were also significantly older, had higher EuroSCORE II values [10], and lower physical functioning scores [11], reflecting routine clinical selection practices in which TAVI is preferentially offered to patients perceived as more vulnerable or less suitable for surgery. These

baseline differences likely explain the observed mortality difference and illustrate the risk of confounding by indication in observational studies. While statistical adjustment can partly address this, a direct comparison of crude outcomes between treatment groups with such divergent profiles must be interpreted with caution. Despite these differences, TAVI patients required significantly less hospital resources, including operating room time, ICU and ward stay. These findings suggest that the procedural and organizational advantages of TAVI persist even in higher-risk real-world patients. From a system perspective, this may support the case for broader use of TAVI where capacity constraints are a pressing concern [6].

To address baseline imbalances, propensity score matching was applied using age, sex, surgical risk [10], and physical functioning [11]. After matching, baseline characteristics were largely comparable between groups, although the SAVR group still showed slightly better PF scores [11]. While the 2:1 matching approach reduced imbalance in variables such as age, sex, and EuroSCORE II [10], the large residual imbalance in PF score ($SMD > 1.0$) limited interpretability of comparative outcomes. Attempts to apply caliper matching (0.2 SD) failed due to insufficient matched pairs. This illustrates the challenge of comparing inherently different populations in real-world observational studies, even with PSM. As such, the matched cohort analysis should be seen as an exploratory sensitivity analysis, not as a robust basis for causal inference. In this cohort, one-year mortality was significantly lower in TAVI patients, and the survival difference observed in the full cohort disappeared. These results suggest that the unadjusted survival advantage of SAVR was driven by differences in patient selection rather than intrinsic treatment effects. This highlights the importance of accounting for both clinical [10] and functional status [11] when comparing invasive interventions outside randomized settings. Interestingly, physical functioning at baseline was independently associated with treatment allocation, but not with mortality in the adjusted Cox model [11]. This implies that clinicians may appropriately factor functional status into their procedural choices, even though this factor does not necessarily predict survival. These findings support the inclusion of patient-reported outcome measures in shared decision-making processes, especially when formal frailty scoring is unavailable [11].

Our findings align with previous randomized trials, such as PARTNER 2 [14], NOTION [15], and PARTNER 3 [4], which have demonstrated non-inferiority of TAVI compared to SAVR in selected low- and intermediate-risk patients. Large-scale observational studies and national registry data have similarly reported comparable survival and complication rates between the two treatments [3,6]. However, many of these studies primarily focus on short- to mid-term outcomes, often without integrating hospital resource use or patient-reported outcomes. Our study adds to this evidence base by incorporating physical functioning and activity-based costing, offering a broader view of both patient-level and system-level impact. Recent innovations in SAVR, including sutureless and rapid-deployment valves, have shown promise in reducing operative times and improving recovery [16]. While such techniques were not used in our cohort, future comparisons should account for these developments. Moreover, recent studies have reported divergent findings regarding mid-term survival outcomes in intermediate-risk populations [17], possibly reflecting differences in patient selection, procedural standardization, and follow-up duration. These discrepancies highlight the importance of context-specific, real-world analyses to complement evidence from randomized trials.

A key strength of this study is the integration of detailed hospital-level cost data and real-world resource use. TAVI was associated with substantially shorter procedure duration, ICU stay, and total hospital stay compared to SAVR, even after adjustment for baseline differences. These findings were consistent across both unmatched and matched analyses, suggesting that the efficiency gains are inherent to the less invasive nature of TAVI rather than a by-product of patient selection. In capacity-constrained healthcare systems, such procedural efficiency may allow for increased throughput, reduced waiting times, and better use of critical care infrastructure. Despite these operational advantages, TAVI remained more expensive than SAVR in terms of total direct hospital costs. This cost gap was primarily driven by the higher price of transcatheter valves, which outweighed savings from shorter hospital stays and reduced ICU utilization. Our use of activity-based costing allowed for precise calculation of individualized resource consumption, offering more granularity than previous studies based on averaged or estimated costs [18]. These results support the notion that cost-effectiveness evaluations of TAVI should consider not only per-patient expenses, but also system-level benefits such as capacity release and workflow optimization.

10.4.3 Costs

Although TAVI was more resource-efficient, it had higher initial costs. The average cost per patient was €32,829 for TAVI compared to €25,290 for SAVR. This difference mainly reflects the higher price of transcatheter valves and delivery systems [13]. While savings in operating room time and hospital stay partially compensated for these costs, they did not fully close the gap within the one-year follow-up period. Longer-term trends suggest convergence: TAVI patients tend to have fewer or shorter readmissions, reducing downstream expenses such as those associated with surgical complications like wound infections [13]. This is consistent with findings from studies such as PARTNER 3, where cumulative costs at two years are nearly equal between TAVI and SAVR [4]. Over a lifetime, TAVI could be more cost-effective because of similar survival rates and delayed complication-related costs [13]. Dutch guidelines for economic evaluations, updated in 2022, advise a minimum five-year follow-up to capture long-term costs and outcomes [14]. However, reimbursement decisions often fall short of these standards, reinforcing short-termism in procurement. Part of the cost difference is driven not only by technology prices but also by limited reimbursement coverage for TAVI in lower-risk groups, which leaves hospitals to absorb initial costs [8]. As a result, hospitals are forced to absorb the higher upfront costs of TAVI, despite its operational advantages. This situation highlights a broader system-level misalignment. Reimbursement decisions are typically driven by short-term financial considerations. In contrast, the value of TAVI, particularly its efficiency and long-term impact, only becomes fully apparent when assessed over multi-year horizons [15, 16]

10.4.4 Health policy and reimbursement implications

These findings have broader implications for healthcare delivery and policy, particularly in systems facing increasing procedural demand, workforce shortages, and limited surgical capacity. TAVI's ability to reduce ICU and ward utilization while maintaining comparable clinical outcomes may allow hospitals to treat more patients within existing infrastructure. This could be especially relevant in countries where surgical wait times contribute to excess mortality, as has been observed in the UK and parts of the Netherlands. However, current reimbursement

frameworks do not adequately reflect the value of such procedural efficiencies. In the Dutch system, reimbursement for TAVI in low- and intermediate-risk patients remains formally constrained by the national reimbursement criteria set by Zorginstituut Nederland, despite a recent amendment to the clinical indication guideline by the Netherlands Society of Cardiology (NVVC), which lowered the age threshold from 80 to 75 years [19]. As a result, hospitals are often required to absorb higher upfront procedural costs despite potential downstream system-level benefits. These structural misalignments may delay adoption of high-value innovations. Moreover, current cost-effectiveness evaluations often overlook opportunity costs, such as forgone treatments for other patients when surgical resources are blocked. As Persson and Tinghög have argued, ignoring these opportunity costs can lead to suboptimal policy decisions [20]. A more integrated reimbursement model that incorporates both clinical outcomes and system-level efficiencies, such as bundled payments or shared savings contracts, could help align incentives across providers and payers. In the Dutch context, such models would support broader access to TAVI for appropriate patients, while also enabling hospitals to operate more efficiently and sustainably.

10.4.5 Future research and patient selection

Careful patient selection remains essential as indications for TAVI continue to expand. Decisions should weigh anatomical suitability, comorbidities, life expectancy, and patient preferences. Although five-year data on TAVI durability are reassuring [4], long-term outcomes beyond ten years, particularly in younger patients, remain uncertain. As such, TAVI should be offered selectively in younger low-risk individuals until more robust evidence becomes available. Future studies should evaluate TAVI and SAVR across diverse settings, accounting for differences in hospital infrastructure, surgical techniques, and care pathways. More comprehensive assessment of patient-centered outcomes, including functional recovery, freedom from reintervention, and sustained quality of life, is also needed [21]. In our study, baseline physical functioning was an important determinant of treatment allocation, yet it did not predict mortality, suggesting its role in shared decision-making rather than risk stratification. Health-economic models should further explore how system-level efficiencies, such as freed ICU or OR-capacity, can be quantified and linked to broader value creation [22]. Particularly in systems

with limited surgical capacity and short-term reimbursement horizons, these factors must be incorporated to fully capture the societal value of structural heart interventions. In addition, future research should investigate how the replacement of SAVR procedures with TAVI may influence the length and duration of surgical waiting lists. Reductions in waiting times could result in earlier symptom relief and improved quality of life for patients awaiting treatment. Understanding the downstream effects of this shift, including the potential economic value of earlier intervention, would provide valuable insights for both clinical planning and health policy evaluation. Future research should explore alternative matching strategies or causal inference methods, such as instrumental variable analysis or inverse probability weighting, to better control for confounding. Moreover, larger datasets with richer baseline information may facilitate more robust adjustment and improve balance in key outcomes such as baseline QoL.

10.4.6 Limitations

Several limitations of this study must be acknowledged. First, the retrospective single-center design introduces potential selection bias and limits generalizability to other populations or healthcare systems. Although we used propensity score matching to reduce confounding, residual bias from unmeasured factors such as anatomical complexity or social support cannot be excluded. Second, frailty was assessed indirectly through physical functioning scores from the SF-36, as formal frailty scales were only available in a subset of patients. Third, patient-reported outcomes were only available in 23% of the cohort, raising the possibility of response bias. The patients who completed follow-up may differ systematically from those who did not, potentially limiting the interpretability of the QoL results. Fourth, while Kaplan–Meier survival was reported with up to four years of follow-up, all other outcomes, including costs and quality of life, were limited to one-year post-procedure. Fifth, our analysis only included hospital-based care episodes captured within the study center; any admissions or complications treated at other institutions were not included. Sixth, although we did not separately analyze complication rates such as pacemaker implantation, such events were reflected in the recorded healthcare utilization and costs if they occurred within one year and within the same hospital. Seventh, our institutional protocol allows most TAVI patients to bypass ICU admission entirely, which may

not be generalizable to other centers. This site-specific policy likely contributed to the observed resource savings and must be interpreted in that context. Eighth, the study period included the years of the COVID-19 pandemic, which may have influenced both procedural outcomes and mortality [23]. Pandemic-related constraints, particularly on ICU capacity, further underscore the potential value of TAVI as a lower-impact intervention in times of systemic pressure. Ninth, the cost analysis focused on direct hospital costs and did not include indirect costs such as patient productivity losses or societal opportunity costs. As such, the total economic impact of each treatment strategy may be underestimated. Despite these limitations, the consistency of our findings across adjusted and matched analyses, and their alignment with published randomized trials, support the validity and practical relevance of the results.

10.5 Conclusions

For patients with severe aortic stenosis at low to intermediate surgical risk, this study confirms that TAVI is an equally effective alternative to SAVR in terms of one-year survival and symptom improvement. However, beyond clinical outcomes, TAVI offers clear operational advantages, including shorter procedure times, reduced ICU utilization, and shorter hospital stays. These efficiency gains are especially valuable in capacity-constrained health systems. Although initial procedural costs for TAVI remain higher, our findings highlight the importance of assessing value beyond per-patient costs alone. Broader system-level effects, such as opportunity costs and increased care capacity, must be factored into value assessments [15–17]. Current reimbursement and procurement practices in the Netherlands, which emphasize short-term budgetary control, fail to capture these longer-term benefits and may thus hinder innovation adoption. To fully realize the potential of interventions like TAVI, reimbursement policies should better align with multi-year value-based care principles. Structural reforms, including longer-term contracts, bundled payment models, or shared savings arrangements, could incentivize investments in interventions that deliver system-wide value over time.

Future efforts should focus on improving patient selection, reducing device costs, and integrating system-level value measures into both clinical and policy decisions. Until such changes are realized, hospitals already equipped to perform TAVI should leverage its demonstrated efficiency to improve outcomes for both individual patients and the healthcare system at large.

Author contributions

Conceptualization, S.S., P.H., A.L., F.v.M. and J.M.; methodology, S.S., P.H., A.L., F.v.M. and J.M.; validation, S.S., A.L., R.Z. and J.M.; formal analysis, S.S.; investigation, S.S. and P.H.; data curation, S.S., A.L., S.K., and J.M.; writing, original draft preparation, S.S. and P.H.; writing, review and editing, S.S., P.H., A.L. and R.Z. visualization, S.S.; supervision, S.K., R.Z., F.v.M., M.J., and J.M. All authors have read and agreed to the published version of the manuscript.

Institutional review board statement and informed consent

The study was conducted in accordance with the Declaration of Helsinki. Ethical review and approval were waived by the Institutional Review Board (or Ethics Committee) of Maastricht University Medical Centre+ due to the retrospective, observational nature of this study using pseudonymized data collected as part of routine clinical practice. Only data from patients who provided informed consent to participate in the Netherlands Heart Registration (NHR) registry, including agreement for their data to be used for research aimed at improving quality of care, were included.

Data Availability Statement: The data supporting the findings of this study are not publicly available due to privacy and ethical restrictions, in line with the informed consent provided by patients participating in the Netherlands Heart Registry (NHR), which allows data use exclusively for research aimed at improving quality of care.

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Conflicts of interest

S. Schretlen is appointed as a PhD candidate at CARIM, Maastricht University, and is employed by Medtronic. His role at Medtronic is non-commercial and unrelated to device sales. All other authors declare no conflicts of interest.

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11

DISCUSSION AND CONCLUSION



11.1 The implementation gap: from strategic intent to operational reality

As outlined in Chapter 1, this dissertation is grounded in the observation that healthcare systems face a persistent gap between strategic value-based ambitions and operational execution in daily clinical practice. Rather than re-evaluating Value-Based Healthcare (VBHC) as a normative reform model, this dissertation reflects on why value-based ambitions do not automatically translate into routine practice, despite widespread outcome measurement and strategic commitment.

The findings of this dissertation confirm that the implementation gap in Value-Based Healthcare is not only a practical problem, but also a scientific one. Previous reviews have shown that VBHC implementation often remains partial, with organisations introducing elements such as outcome measurement or multidisciplinary team structures without achieving coherent integration of care processes, data systems, and improvement routines (Van Staalduinen et al., 2022; Khalil et al., 2025; Douglas et al., 2025). At the same time, Lean Six Sigma and related improvement approaches can improve operational performance, but are often insufficiently connected to patient-relevant outcomes and organisational learning (McDermott et al., 2022). The empirical chapters in this dissertation illustrate how this separation plays out at the meso-level of hospital departments and care pathways. They show that value improvement requires more than either strategic outcome measurement or isolated process optimisation. It requires a structured connection between data quality, process redesign, clinical ownership, outcome evaluation, and iterative learning. The Value Improvement Roadmap developed in this dissertation addresses this specific meso-level gap by integrating these elements into a coherent framework for value-oriented operational improvement.

Instead of claiming system-wide transformation, it presents a realist synthesis of data-driven improvement initiatives conducted in Dutch secondary and tertiary hospital settings between 2018 and 2025. In these initiatives, structured improvement support was embedded in routine practice, providing methodological continuity to assist clinical teams in translating data into concrete process changes rather than stand-alone analyses. The initiatives emerged from

local clinical and operational challenges and shared a focus on structured process optimization at the meso-level of healthcare delivery.

In this dissertation, the meso-level is defined as the organizational level at which care delivery is actively coordinated, governed, and improved through multidisciplinary routines that hold shared accountability for process design and operational performance across professional roles and, characteristically, across departmental boundaries (Ferland et al., 2001; Vijverberg et al., 2022). Analytical units at this level include clinical pathways, service lines, or formally chartered improvement teams with delegated authority for workflow redesign, data collection, and iterative improvement, yet without strategic control over hospital-wide IT architecture, budgeting frameworks, or macro-level reimbursement policy. This demarcation explicitly excludes the micro-level of individual clinician–patient encounters and the macro-level of system governance. Consequently, whereas institutional roadmaps such as EUHA primarily address organization-wide enabling architecture, the Value Improvement Roadmap developed in this dissertation specifies how value ambitions are translated into actionable routines and sustained improvement cycles within meso-level governance structures.

The overarching observation emerging from the empirical studies is that strategic intent alone is insufficient to change clinical practice. Resource constraints generate a structural paradox: they increase the urgency of value creation while simultaneously limiting the organizational capacity for sustained adaptation and improvement. Across the studied initiatives, a consistent pattern emerged: the main barrier to improvement was rarely a lack of ideas about how care processes could be better designed. More often, teams lacked protected time, sufficient capacity, and organizational capability to translate improvement ideas into sustained practice.

A substantial share of professional effort was absorbed by non-value-adding work, such as administrative burden, rework, repeated cancellations, duplicated diagnostics, and unplanned delays. This kept teams focused on resolving immediate operational issues rather than redesigning underlying processes. As a result, strategic value ambitions could coexist with persistent operational friction at pathway level, even when senior leadership expressed strong commitment. Sustained improvement requires operational capabilities

that render care processes sufficiently visible, measurable, and manageable to support improvement and adaptation. In this dissertation, operational excellence is not understood as efficiency in itself, but as a set of organizational capabilities, including process transparency, multidisciplinary governance, data literacy, and iterative improvement routines, that enable care processes to be redesigned and sustained over time. To structure these insights, this chapter introduces the Value Improvement Roadmap as a middle-range, theoretically transferable learning architecture for building sustained improvement capability at the meso-level under conditions of structural constraint.

11.2 Synthesis: the value improvement roadmap as an extended Structure-Process-Outcome (SPO) framework

To move beyond isolated improvement initiatives and support coherent learning across care pathways, this dissertation synthesizes its empirical findings into the Value Improvement Roadmap. This synthesis adopts a realist, retroductive perspective by identifying recurring mechanisms and contextual conditions across heterogeneous improvement initiatives conducted at the meso-level of hospital care. The Value Improvement Roadmap does not replace organizational strategy but specifies how strategic value ambitions become operationally actionable and governable at the meso-level. Rather than aggregating results, the synthesis explains how strategic value ambitions were translated into operational practice under real-world conditions.

11.2.1 Empirical synthesis of improvement mechanisms

The empirical chapters in this dissertation describe improvement initiatives carried out in different clinical domains, organizational settings, and time periods. Although these initiatives were not planned as part of a single prospective research program, they share a clear focus on data-driven process improvement at the meso-level of hospital care. This common focus makes it possible to reflect across cases and identify recurring mechanisms that help explain how value-oriented improvement was achieved in practice.

The synthesis follows a realist logic and therefore concentrates on mechanisms rather than outcomes alone. Across the initiatives, several recurring patterns were observed. First, sequencing mattered: initiatives that first stabilized care processes and clarified roles created the conditions for meaningful use of data, whereas initiatives that started with measurement alone struggled to achieve lasting change. Second, governance embedded in daily work proved critical. Standardized decision rules and shared accountability within multidisciplinary teams reduced unwarranted variation more effectively than retrospective performance monitoring. Third, data quality problems consistently reflected unstable processes rather than purely technical shortcomings. Improvements in data usability typically followed process redesign and stabilization, rather than preceding them.

In addition to these operational patterns, a consistent social mechanism emerged across cases. Structured multidisciplinary dialogue around a shared care pathway and shared data supported collective understanding of how care was actually delivered. Bringing clinicians, nurses, planners, and managers together to jointly interpret process variation helped make implicit operational knowledge explicit and strengthened shared ownership of change. In several initiatives, this collective diagnosis created alignment and momentum even before specific technical interventions were implemented.

These mechanisms did not operate in isolation. Their effects depended on contextual conditions such as baseline performance, data infrastructure maturity, leadership engagement, and organizational urgency. Table 1 summarizes this empirical synthesis by linking each study to its dominant Lean Six Sigma phases, the primary mechanism identified, and the context in which it operated. Together, these recurring mechanisms form the empirical foundation for the Value Improvement Roadmap developed in this dissertation.

Table 1. Mapping of empirical chapters to Lean Six Sigma phases, tools, and value improvement mechanisms

Chapter	Focus	Lean Six Sigma Phases	Specific Tools	Primary Value Improvement Roadmap Phase	Mechanism Identified (Roadmap Contribution)	Contextual Conditions
3	CABG Cancellations	D-M-A-I-C	SIPOC, VSM, Pareto, 5 Why, Gemba, Kaizen, SPC	C + D	Sequencing Mechanism: Process flow must be stabilized before data-driven control becomes meaningful	High baseline cancellation rate; Board-level overtime approval
4	CRT Pathway	D-M-A-I-C	VSM, SIPOC, Task Matrix, Standard Work, Checklists	C	Task Reallocation Mechanism: Protocolized task redistribution enables cross-disciplinary flow and continuity	Pre-existing nurse specialists; Vendor grant funding
5	Heart Team	D-M-A-I-C	CTQ Flowdown, FMEA, Poka-Yoke, Visual Management	B + C	Governance Mechanism: Standardized decision protocols reduce unwarranted variation in multidisciplinary decision-making	Merger urgency; Pre-existing Heart Team culture clash
6	Low Back Pain	D-M-A-I-C	Demand-Capacity Analysis, Triage Logic, Pathway Redesign	B + C	Transferability Mechanism: Intermediate care models enable scaling of process redesign across care boundaries	Provincial funding flexibility; GP engagement network

Table 1. Mapping of empirical chapters to Lean Six Sigma phases, tools, and value improvement mechanisms *Continued.*

Chapter	Focus	Lean Six Sigma Phases	Specific Tools	Primary Value Improvement Roadmap Phase	Mechanism Identified (Roadmap Contribution)	Contextual Conditions
7	Surgical Review	Pre-DMAIC	Systematic Review, Evidence Gap Mapping	A + B	Evidence Threshold Mechanism: Improvement tool selection should be guided by systematic evidence rather than expert preference	Limited quality-improvement evidence base in cardiac surgery
8	Process Mining	M-A-I	Discovery, Conformance Checking, Variant Analysis, Data Quality Audit	A	Data Quality Mechanism: Data quality deficits plausibly reflect limitations in process control rather than solely IT constraints	Heterogeneous IT systems; Clinical documentation variation
9	CRT Outcomes	D-M-A-I-C	KPI Dashboards, Funnel Charts, Bootstrap Analysis	D	Feedback Mechanism: Sustained value creation requires embedded monitoring beyond project closure	Historical control design; Real-world data limitations

Table 1. Mapping of empirical chapters to Lean Six Sigma phases, tools, and value improvement mechanisms *Continued.*

Chapter	Focus	Lean Six Sigma Phases	Specific Tools	Primary Value Improvement Roadmap Phase	Mechanism Identified (Roadmap Contribution)	Contextual Conditions
10	TAVI vs SAVR	M–A (evaluation-focused)	Resource Mapping, Variance Analysis, Capacity Modeling	D	System Value Mechanism: Meso-level improvements require system-level governance to address inter-departmental resource shifts	Post-COVID resource competition; System-level perspective

11.2.2 Conceptual integration: from empirical mechanisms to the value improvement roadmap

The Value Improvement Roadmap integrates the empirically identified mechanisms into a coherent conceptual framework. Its theoretical foundation builds on the classic Structure–Process–Outcome (SPO) model by Avedis Donabedian (Donabedian, 1988), which conceptualizes healthcare quality as the result of interactions between organizational structures, care processes, and outcomes. While Value-Based Healthcare frameworks predominantly emphasize outcomes, and operational improvement methodologies such as Lean Six Sigma primarily target processes, the Roadmap explicitly foregrounds the structural conditions required to connect these domains in a sustained and learnable manner.

In doing so, the Roadmap extends the SPO logic from a static evaluative model to a dynamic learning framework. Structural conditions such as data maturity, governance routines, and role clarity are treated not as background variables but as active enablers of process redesign and outcome improvement. This conceptual integration reflects the empirical observation that outcomes become actionable only when supported by stable processes and enabling structures.

Notably, the structural phases identified through this synthesis align closely with the consensus roadmap recently published by the European University Hospital Alliance (Cossio-Gil et al., 2022). Although the empirical work in this dissertation preceded the publication of the EUHA framework, the overlap in identified requirements such as data infrastructure and multidisciplinary governance provides convergent theoretical validity for the findings. A crucial distinction, however, concerns the level of analysis. Whereas the EUHA roadmap focuses on institutional-level architecture, the Value Improvement Roadmap developed in this dissertation functions as an operational backbone for the meso-level, where care delivery is coordinated and improved in daily practice.

11.2.3 The value improvement roadmap as an extended SPO framework

The Value Improvement Roadmap should be read as an iterative organizational learning framework rather than a linear implementation checklist. Viewed from this perspective, the Value Improvement Roadmap can be interpreted as a pathway from open-loop improvement, in which tools generate local feedback, towards more closed-loop value improvement, in which data, governance, process redesign, outcomes, and financial feedback are increasingly integrated at the meso-level. Although the phases are presented in a pragmatic sequence, improvement efforts in hospital practice cycle between data interpretation, process redesign, and outcome evaluation through recurring feedback loops. Governance and shared ownership at the level of clinical pathways function as enabling conditions across all phases, shaping how insights are translated into action and sustained over time. In practice, shared ownership proved strongest when ‘value’ was articulated in locally meaningful terms that resonated with daily clinical work, rather than framed primarily as abstract performance targets. Across the studied initiatives, linking process redesign to tangible improvements for patients, professionals, or workflow reliability helped translate strategic value ambitions into actionable commitment at pathway level. In this roadmap, ‘insights’ refers to sensemaking and analysis at pathway level, supported by tools such as dashboards. ‘Scaling’ denotes principle-based adaptation and dissemination across contexts, rather than direct replication, as performance depends on local structures, processes, and governance.

This section elaborates on the Structure, Process, and Outcome domains of the Value Improvement Roadmap illustrated in Figure 1, linking each domain to the empirical mechanisms identified across the case studies.

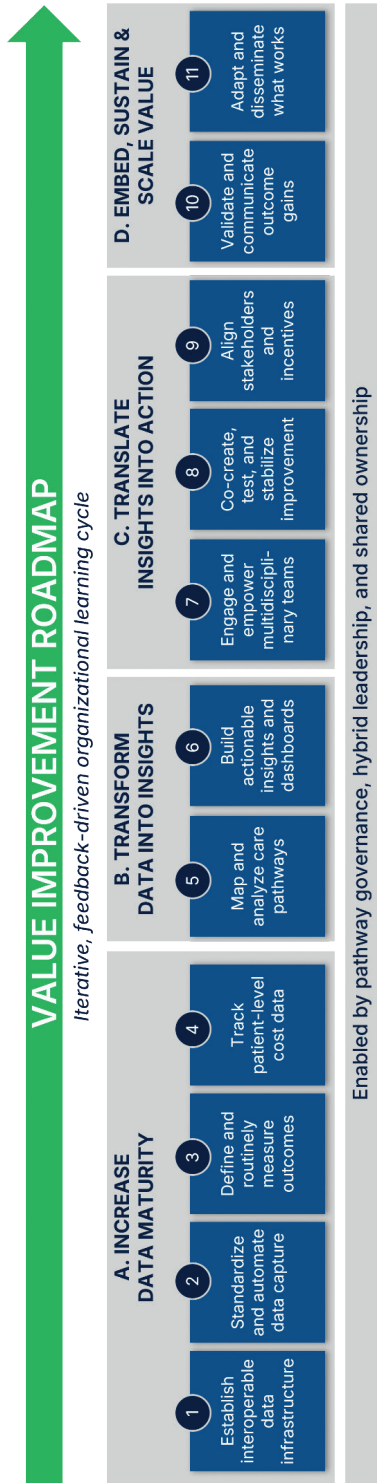


Figure 1. The Value Improvement Roadmap as an iterative, learning-oriented organizational framework linking structure, process, and outcomes at the pathway level. Value is understood as patient-relevant outcomes in relation to costs and capacity.

Within this roadmap, *Structure* refers to the organizational and informational prerequisites required to initiate value-oriented improvement. Across the empirical studies, limitations in data completeness and standardization consistently constrained the ability to evaluate performance. Chapter 8 demonstrated that without reliable registration at the source, attempts to reconstruct care pathways remain fragmented and analytically weak. Conversely, Chapter 9 showed that when data maturity is actively addressed through structured pre-assessment routines, meaningful analyses of costs, outcomes, and capacity become feasible. Together, these findings position data maturity not as a passive technical prerequisite, but as an active organizational design challenge that must be deliberately developed.

The *Process* domain constitutes the operational backbone of the roadmap. The empirical chapters show that structured process analysis, supported by Lean Six Sigma methodologies, enabled clinical teams to translate value ambitions into daily routines. Chapters 3 and 4 illustrate that care pathways are often characterized by unwarranted variation and operational disruptions. By stabilizing processes through role clarification, standard work, and flow redesign, these initiatives created conditions under which outcome measurement became actionable rather than merely descriptive. This supports the interpretation of well-designed and stabilized operations as a central enabling mechanism for value-based care.

The *Outcome* domain retains the core Value-Based Healthcare emphasis on measuring results that matter to patients, while explicitly broadening the evaluative lens to include resource use and capacity implications. The comparative evaluation of TAVI versus SAVR in Chapter 10 illustrates that improvements in clinical outcomes cannot be interpreted in isolation from their organizational consequences. Systematic feedback of multidimensional outcomes to clinical teams supports feedback, informs refinement of process design, and guides adjustments to structural conditions. In this way, the roadmap operationalizes the Structure–Process–Outcome triad as a continuous organizational learning cycle, rather than a static or linear assessment model, thereby creating the conditions for sustained integration in practice.

11.3 Empirical conditions for integration

While the Value Improvement Roadmap provides a structured framework for integration, the empirical studies in this dissertation reveal three conditions that determine whether this structure translates into sustained value in practice. These conditions concern the evolution of data intelligence, the role of hybrid leadership, and the alignment of financial incentives. Together, they explain why similar improvement tools yield different results across contexts.

11.3.1 From retrospective insight to actionable intelligence

A consistent empirical observation across the studies is that the availability of data alone does not lead to improvement. As demonstrated in Chapter 8, healthcare organizations often possess extensive volumes of process data. However, these data frequently remain unusable due to fragmentation, inconsistent registration, and limited standardization. This dissertation conceptualizes this tension as a Data Quality Paradox: data are widely collected, but often not structured well enough to reliably reconstruct care processes and support learning.

What initially appeared as methodological limitations in data completeness emerged as empirical findings in their own right, revealing underlying organizational learning barriers. The inability to reconstruct care processes reliably reflects underlying organizational routines and workarounds that impede data-driven improvement. In this sense, data quality problems are not merely technical deficiencies but manifestations of insufficient process control.

A related mechanism observed across the initiatives was that making process variation visible at pathway level often shifted discussions from anecdotal explanations to shared root-cause analysis. Even preliminary visualizations based on imperfect data helped teams to objectify bottlenecks that had previously been normalized as ‘how things are’, thereby creating urgency and focus for redesign rather than debate. In several cases, this early use of imperfect data did not hinder improvement but instead stimulated reflection on definitions and registration practices, allowing data maturity to develop in parallel with process stabilization.

Across multiple cases, the temporal sequence of events suggests a plausible enabling role for structured process design and stabilization. Where Lean Six Sigma principles were applied to stabilize workflows and standardize definitions, improvements in registration quality followed. For example, in the CABG pathway (Chapter 3), the introduction of standard work and explicit decision rules preceded measurable improvements in data consistency. This indicates that Phase A of the Roadmap, increasing data maturity, is not a passive prerequisite but an active design challenge that can be addressed through targeted process optimization.

This observation has implications for emerging applications of Artificial Intelligence in healthcare. AI models depend on historical data that reflect existing care processes. Where those processes are unstable or inconsistently documented, advanced analytics risk reinforcing existing inefficiencies. From this perspective, stable and well-defined care processes can be understood as a plausible precondition for the responsible use of predictive analytics, rather than merely a tool for short-term efficiency gains.

11.3.2 The human factor: hybrid leadership

Beyond technical conditions, the empirical studies consistently highlight the importance of human dynamics. This dissertation nuances technocratic interpretations of Value-Based Healthcare that emphasize metrics and dashboards by showing that improvement is also a socially constructed learning process. The analyses of the Heart Team (Chapter 5) and the nurse-led CRT pathway (Chapter 4) indicate that successful interventions depend on hybrid leadership arrangements that combine strategic direction with professional autonomy.

In the more successful cases, responsibility for redesigned processes was shared across professional roles. In the CRT pathway, for example, the checklist was jointly owned by a cardiothoracic surgeon and a heart failure nurse. This shared stewardship supported psychological safety, enabling teams to surface errors and variation without fear of blame (Edmondson, 2018). Such conditions allowed Lean Six Sigma tools to function as enablers rather than control instruments.

Process waste in the form of rework, administrative burden, and unplanned rescheduling imposed not only operational costs but also a cognitive load on professionals. It diverted time and attention away from value-adding clinical activities and reduced the space for reflection and proactive improvement. This reactive workload helped sustain underlying structural problems rather than resolving them.

Across initiatives, teams consistently reported stronger engagement when process redesign could be connected patient-relevant outcomes and reduced preventable workload. When these benefits became visible in daily work, improvement was no longer seen as an abstract management goal, but as something that directly mattered to professionals and patients.

These findings suggest that while Lean Six Sigma provides methodological structure, its effects are mediated by leadership practices that shape motivation, trust, and engagement. Data and technology function most effectively when embedded in such social conditions, supporting rather than substituting professional judgment.

11.3.3 Value alignment and financial reality

The third condition concerns the alignment between value creation and financial incentives. The outcome and capacity analyses in Chapters 9 and 10 show that process improvements can generate value by reallocating constrained resources, such as reduced ICU utilization or shorter length of stay. However, these gains do not automatically translate into incentives for the units that generate them. This misalignment also shapes professional and managerial behaviour. When the units investing time and effort in pathway redesign experience negative or neutral financial feedback, improvement efforts can become rationally unattractive despite clinical success. In such settings, local decision-making is guided by short-term budgetary signals rather than by system-level value creation, weakening incentives to sustain or scale operational improvements.

The comparative evaluation of TAVI versus SAVR (Chapter 10) illustrates this tension. Higher upfront material costs associated with minimally invasive procedures were offset by gains in procedural efficiency and reduced hospitalization. Yet in siloed budgeting systems, the department bearing the costs does not necessarily benefit from the released capacity. Similarly, the CRT pathway analysis (Chapter 9) showed that investment in specialized nursing reduced downstream hospitalizations, benefiting payers and patients but potentially reducing hospital revenue under volume-based reimbursement.

These observations indicate that the sustainability of operational improvement depends not only on technical success but also on governance arrangements that recognize and redistribute value across organizational boundaries. Without mechanisms that align meso-level improvement efforts with financial feedback, the incentives to maintain redesigned processes remain fragile. Within the Value Improvement Roadmap, this tension becomes most visible in Phase D, which concerns the embedding and realization of value following operational improvement. Although this dissertation does not design a reimbursement model, it shows that without explicit internal financial governance at the care pathway level, operational improvements are often not rewarded and may even generate negative financial incentives, such as budgetary corrections or capacity reductions. Under such conditions, improvement efforts can become rationally unattractive for clinical teams, undermining the sustainability of value creation.

A potential governance response lies in internal value-alignment mechanisms, such as shared savings arrangements or reinvestment pools, that allow departments generating capacity gains to retain part of the value created. While this dissertation does not evaluate such models empirically, the empirical patterns indicate that without explicit financial alignment, even well-designed improvement initiatives are unlikely to be sustained over time.

11.3.4 Synthesis: empirical conditions mapped to the value improvement roadmap

Taken together, the three empirical conditions identified in this section can be directly mapped onto distinct phases of the Value Improvement Roadmap. First, the evolution from retrospective insight to actionable intelligence primarily relates to the Structure domain and Phase A of the roadmap. The Data Quality Paradox demonstrates that data maturity is not a technical precondition but an outcome of deliberate process optimization. Without stabilized workflows and standardized registration, higher-order learning and evaluation remain unattainable. Second, hybrid leadership emerges as a critical enabling condition within the Process domain, particularly in Phases B and C, where care pathways are designed, redesigned, and embedded into routine practice. The empirical cases show that process redesign succeeds only when professional autonomy and managerial structure are deliberately combined within shared governance routines. Third, the alignment of financial incentives becomes most salient in the Outcome domain and Phase D of the roadmap. Even when processes are optimized and outcomes improve, sustainability depends on whether released capacity and generated value are recognized and redistributed within existing financial structures. Together, these conditions illustrate that the roadmap functions not as a linear implementation checklist, but as a recursive organizational feedback system.

11.4 Methodological reflections: limitations as empirical findings

Interpreting the findings of this dissertation requires positioning its methodological design in relation to the type of knowledge it aims to generate. The empirical chapters predominantly employ observational and quasi-experimental approaches. While these designs limit definitive causal inference, they were deliberately chosen to examine how improvement unfolds within the complexity of routine hospital practice and to identify plausible generative mechanisms rather than isolated effects. The methodological choices reflect the central research objective: to understand conditions, mechanisms, and constraints of

value-oriented improvement under real-world circumstances rather than to test isolated interventions under controlled conditions.

11.4.1 Ecological validity and realist synthesis

A primary strength of this research lies in its high ecological validity, meaning that the observed mechanisms reflect routine organizational practice rather than experimental conditions. Unlike randomized controlled trials (RCTs), which often abstract away from routine practice to maximize internal validity, the studies in this dissertation were embedded within the operational reality of functioning hospital departments (Damschroder et al., 2009). Interventions were implemented under everyday conditions, including staffing constraints, legacy information systems, and competing clinical priorities. As a result, the findings provide a realistic account of both the potential and the limitations of value-oriented improvement in settings that closely resemble routine practice elsewhere.

Methodologically, this dissertation adopts a realist synthesis of improvement programs. This theory-driven approach aligns with realist evaluation traditions that seek to explain what works, for whom, and under which circumstances in complex systems (Pawson & Tilley, 1997; Rycroft-Malone et al., 2012). Rather than testing the effectiveness of isolated interventions, the synthesis integrates evidence across multiple initiatives to identify recurring mechanisms and the contextual conditions that enable or constrain value-based improvement.

Because the interventions were embedded in routine practice and focused on real-world improvement, experimental or randomized designs were neither feasible nor appropriate. Withholding structured process improvements from a control group would have delayed or denied demonstrably beneficial changes to routine care. Moreover, improvement initiatives often evolved iteratively in response to emerging insights, further limiting the applicability of fixed prospective designs.

The realist synthesis approach enabled the identification of recurring patterns across heterogeneous clinical domains, ranging from high-complexity cardiovascular interventions to high-volume low back pain management. By

analyzing improvement initiatives conducted over an extended period, this dissertation moves beyond disease-specific findings and demonstrates that the integration of strategic value ambitions with operational Lean Six Sigma execution follows broadly similar mechanisms across different levels of clinical acuity.

The researcher's active participation in several improvement initiatives introduces a potential risk of interpretive bias. At the same time, this embedded role facilitated access to organizational processes, decision-making routines, and granular operational data that would have been difficult to obtain through more detached research designs. This dual role is therefore treated not only as a limitation but also as an analytical resource for understanding improvement dynamics as they unfold in practice.

11.4.2 Contextual transferability: beyond the academic center

All empirical work in this dissertation was conducted in Dutch secondary and tertiary hospital settings operating within a specific regulatory, reimbursement, and governance context. Several studies were situated in academic hospitals. These environments are characterized by high organizational complexity, dual professional hierarchies, fragmented legacy information systems, and competing mandates for care delivery, research, and education.

Conducting improvement initiatives in this context can be interpreted as a stringent test of the proposed Value Improvement Roadmap. The empirical finding that structured process optimization and data-driven improvement could be implemented under these conditions suggests that the identified mechanisms are not dependent on unusually favorable organizational circumstances. Instead, they appear robust under conditions of structural complexity and limited managerial control.

This does not imply statistical generalizability of specific interventions or effect sizes. Rather, it supports contextual transferability of the underlying principles. In particular, conditions such as data discipline at the source, hybrid clinical-managerial leadership, and stabilization of core care processes emerged as enabling mechanisms across cases. These conditions are not inherently

specific to academic hospitals and may be expected to apply, with appropriate adaptation, in general and teaching hospitals where decision-making lines are often shorter and operational focus is more concentrated. Accordingly, the Value Improvement Roadmap should be interpreted as a set of transferable design principles for hospital-based value improvement at the meso-level, consistent with a middle-range learning framework, rather than as a universal or context-free implementation blueprint.

11.4.3 Limitations: causal inference and the data quality paradox

The primary methodological trade-off associated with the high ecological validity of this dissertation is a limitation in causal inference. The empirical studies were observational or quasi-experimental in nature. Consequently, observed improvements in outcomes, efficiency, or capacity cannot be attributed unambiguously to the implemented interventions with the same level of statistical certainty as in randomized controlled trials. Confounding factors, including secular technological developments, organizational improvement effects, or unmeasured changes in patient case-mix, may have contributed to the observed patterns.

At the same time, similar patterns observed across multiple independent cases make the proposed mechanisms plausible explanations for the observed changes. While causal claims remain bounded, the recurrence of similar process–outcome relationships across heterogeneous contexts supports the interpretation that the identified mechanisms are meaningful under routine conditions.

A second limitation concerns the reliance on routinely collected hospital data. In several chapters, analyses were constrained by incomplete event logs, inconsistent coding, and limited system interoperability. These issues were not purely technical. In many cases, inconsistent data reflected variation in how care was delivered and documented. Difficulties in reconstructing care pathways therefore pointed to gaps in process standardization and governance, rather than to shortcomings of the data systems alone.

This observation reinforces a central conclusion of the study. Without deliberate investment in the Structure phase of the Value Improvement Roadmap, including standardized workflows, clear ownership of registration practices, and embedded control routines, the potential for data-driven improvement remains limited. Data maturity should therefore be understood not as a technical endpoint, but as an organizational capability that must be actively developed to enable sustained learning and value creation.

11.4.4 Reflection on the doctoral candidate's contribution and research development

The empirical studies in this dissertation were conducted in close collaboration with clinical teams. The doctoral candidate operated from the dual position of embedded researcher and external improvement lead, drawing on expertise in Lean Six Sigma and data-driven process improvement. This role provided access to organisational processes, implementation dynamics, decision-making routines, and operational data that would have been difficult to obtain through a more detached research design.

This collaborative model is reflected in the authorship structure. In several publications, the doctoral candidate shares first authorship with a clinical co-author. This shared authorship reflects complementary contributions: the clinical co-authors provided domain expertise, clinical validation, and access to patient data and clinical workflows, while the doctoral candidate contributed methodological design, improvement methodology, implementation support, data analysis, interpretation, and manuscript preparation.

Reflecting on the dissertation as a whole, the doctoral candidate's individual contribution lies not only in the execution of individual studies, but particularly in their methodological and conceptual integration. Across the empirical chapters, the candidate applied and adapted Lean Six Sigma, process analysis, and data-driven evaluation methods to clinical settings. In the overarching chapters, these empirical insights were brought together into a coherent synthesis linking Value-Based Healthcare, operational improvement, and organisational learning at the meso-level of hospital care. The Value Improvement Roadmap represents the

primary intellectual contribution of this dissertation, developed under supervision and grounded in the empirical studies included in the thesis.

The research trajectory also reflects the progressive development of an independent research profile, from collaborative improvement projects in the early chapters to sole first authorship and corresponding authorship in Chapter 10, and from empirical case studies to the theory-building synthesis in Chapter 11. A key lesson from this trajectory is that structured improvement methods are necessary but not sufficient for sustainable change in healthcare. Lean Six Sigma, process analysis, and data-driven evaluation provide discipline and analytical rigour, but their impact depends on how they are introduced and embedded in clinical practice. Across the studies, improvement required attention to local context, respect for professional routines, patience in building shared understanding, and trust-based relationships with clinical teams.

The embedded researcher position also requires critical reflection. Close involvement in improvement practice may create a risk of overemphasising the contribution of the improvement approach or underestimating contextual factors. This risk was mitigated by review of the synthesis by co-authors of the empirical studies, comparison across different clinical contexts, and explicit attention to findings that did not fully support the expected improvement logic, including financial misalignment in the TAVI versus SAVR study and governance tensions in the Heart Team study.

11.5 Implications for practice and governance

The findings of this dissertation have implications for how hospital organizations govern, prioritize, and operationalize value-oriented improvement as an ongoing feedback process at the meso-level of care delivery. Rather than prescribing fixed solutions, these implications specify organizational conditions under which the integration of strategic value ambitions and operational improvement is more likely to be sustained. Each implication aligns with a specific phase of the Value Improvement Roadmap and addresses a recurrent barrier observed across the empirical studies. Across all three domains, a central tension emerges: resource

constraints increase the urgency of improvement while simultaneously limiting the organizational capacity required to invest in process redesign.

11.5.1 To hospital boards: digital ambitions and operational readiness

For hospital boards and executive leadership, the findings offer a cautionary perspective on digital transformation strategies. There is widespread enthusiasm for Artificial Intelligence and advanced analytics as solutions to capacity and quality challenges. However, the empirical evidence in this dissertation indicates that such investments yield limited value when underlying care processes remain unstable or poorly standardized.

The Value Improvement Roadmap positions data maturity and process stability as prerequisites for digital maturity. Before algorithms can optimize patient flow or predict demand, the flow itself must be made visible, consistent, and controllable. Across the studied cases, this required comparatively low-tech interventions such as standardized registration at the source, clear ownership of data definitions, and structured process control using Lean Six Sigma routines.

From a governance perspective, effective digital transformation depends less on technology acquisition and more on prior investment in data literacy, operational improvement capability, and sustained improvement governance. Digital tools are most effective when they support human decision-making within stable and observable care processes. Within the Value Improvement Roadmap, they function primarily as learning amplifiers, increasing the speed and scope of feedback.

11.5.2 To clinical leaders: cultivating hybrid leadership

For clinical leaders, the findings underscore that value-based improvement is fundamentally relational and organizational work. Successful initiatives relied on hybrid leadership models in which clinical authority was combined with active engagement in process design and improvement governance.

The empirical cases demonstrate that improvement efforts were most effective when clinical leaders co-owned redesigned workflows, performance indicators, and feedback routines. In the CRT pathway and Heart Team cases, shared stewardship over checklists and decision protocols fostered psychological safety and reduced unwarranted variation. This enabled professionals to surface errors and inefficiencies without fear of blame.

These findings challenge the perceived trade-off between efficiency and quality. Operational excellence and professional responsibility proved mutually reinforcing when improvement routines reduced administrative burden and stabilized daily practice. In this configuration, VBHC provides strategic direction, while Lean Six Sigma offers the operational methods required to translate that direction into routine care. Hybrid leadership is therefore not an optional soft skill, but a structural condition for sustained adaptation and value creation at the meso-level.

11.5.3 To financial governance: addressing the wrong pocket problem

A third implication concerns financial governance. Across the evaluative studies, process improvements generated value by freeing scarce capacity through reduced length of stay, fewer complications, or avoided admissions. However, these gains were often not reflected in local financial incentives due to siloed budgeting and reimbursement structures.

The analyses of TAVI versus SAVR and CRT pathway redesign illustrate a recurring wrong pocket problem. Departments that incurred upfront costs for innovation did not directly benefit from downstream capacity gains or cost avoidance elsewhere in the system. In the absence of explicit internal financial alignment, such dynamics may unintentionally generate negative financial feedback, causing clinically successful improvements to be experienced as financially unattractive or even penalizing.

From a governance perspective, this suggests that hospitals require internal mechanisms that recognize and redistribute value across organizational

boundaries. One feasible approach is the creation of internal value-sharing arrangements, in which a portion of released capacity or cost savings is earmarked for reinvestment at the meso-level that generated the improvement, while the remainder supports system-wide sustainability. Such mechanisms do not require changes to external reimbursement models but enable alignment between clinical effort, operational improvement, and financial feedback.

Without addressing this misalignment, operational excellence initiatives are unlikely to be sustained. Financial governance ultimately determines whether the value created through process improvement is fed back into the organization to support continued learning and reinvestment.

11.6 Future perspectives

This dissertation contributes to the operationalization of Value-Based Healthcare at the meso-level of hospital care. At the same time, the Value Improvement Roadmap should be viewed as an evolving middle-range framework rather than a finished model. Its further development requires empirical testing across longer time horizons, richer data domains, and broader organizational contexts.

First, the Value Improvement Roadmap should be prospectively evaluated as a design framework. Future studies should examine whether deliberate application of its phases and mechanisms supports value-oriented improvement across different hospital settings. Such evaluation would require quasi-experimental, stepped-wedge, or mixed-methods designs, with explicit attention to mechanism activation, contextual adaptation, and sustainability over time.

Second, longitudinal research is needed to assess the durability of improvement effects. While the retrospective synthesis suggests that structured improvement interventions can generate measurable gains in outcomes, efficiency, and capacity, the long-term stability of these effects remains uncertain. Organizational routines may gradually erode when external facilitation diminishes or leadership priorities shift. Future studies should therefore examine whether redesigned pathways remain embedded over extended periods, and which governance routines help

sustain improvement. Relevant factors include feedback cycles, accountability structures, clinical ownership, and leadership mandates that support adherence to standardized processes.

Third, future research should further develop the Roadmap's data dimension. This dissertation demonstrates the importance of data maturity for learning, but patient-reported outcome measures were only partially integrated due to limitations in routine data availability. Future studies should examine how PROMs can be embedded into operational feedback loops in ways that support decision-making without increasing administrative burden. This requires attention to the balance between registration effort and informational value, as well as digital solutions that enable selective capture of the patient perspective during routine care. In addition, the Data Quality Paradox identified in this dissertation requires further empirical testing. The proposition that stable, well-defined care processes are a precondition for reliable advanced analytics, including artificial intelligence, should be examined across settings with different levels of digital maturity.

Fourth, the relationship between the Value Improvement Roadmap and established implementation science frameworks warrants further theoretical development. Frameworks such as CFIR identify determinants of implementation success, including leadership engagement, implementation climate, available resources, and inner setting (Damschroder et al., 2009; Damschroder et al., 2022). The Value Improvement Roadmap complements this perspective by specifying how such determinants may operate at pathway level, particularly through hybrid leadership, clinical ownership, data maturity, and iterative feedback. Its iterative learning logic also aligns with the Dynamic Sustainability Framework, which emphasises ongoing adaptation as a condition for sustained implementation (Chambers et al., 2013).

Fifth, future research should examine the transferability of the Roadmap beyond hospital departments and care pathways. Value creation increasingly spans organizational boundaries across the full cycle of care. Relevant contexts include coordination between hospital-based multidisciplinary teams and primary care, as well as post-acute and rehabilitative phases of care. As healthcare systems evolve towards networked delivery models, the Roadmap's principles of

standardized data exchange, shared process ownership, and aligned governance are likely to become increasingly important, but also more difficult to implement.

Taken together, these future directions suggest that future research should not only examine whether value-based improvement works, but also under which organizational conditions improvement remains possible despite ongoing operational pressure.

11.7 Conclusion

The central argument of this dissertation is that the sustainability of healthcare systems does not depend on a single silver-bullet solution. Rather, it relies on the deliberate integration of strategic intent and operational execution. Value-Based Healthcare articulates the *why* of value creation, while structured improvement methodologies such as Lean Six Sigma provide the *how*.

By synthesizing evidence from both cardiovascular care and low back pain, this dissertation demonstrates that the proposed approach is applicable across clinically distinct domains. Doing so requires a shift from viewing healthcare delivery as a series of isolated clinical events to understanding it as an integrated process that can be measured, managed, and continuously improved. The Value Improvement Roadmap developed in this thesis offers a structured middle-range learning framework for this transformation by operationalizing the classic triad of structure, process, and outcome into a dynamic improvement system.

The implications of this research extend beyond individual hospitals. Healthcare systems face the dual risk of becoming increasingly unaffordable and inaccessible. Given that a substantial share of healthcare expenditure is attributable to waste, reducing inefficiencies through structured problem solving carries clear societal relevance. This dissertation shows that reducing waste and stabilizing processes generates value beyond efficiency gains alone, by freeing capacity and resources for further transformation. Mature data infrastructures and reliable care pathways create the conditions under which advanced analytics, including Artificial Intelligence, can be explored responsibly in future care delivery. Organizations

that have developed operational control and improvement capability are better positioned to navigate such transitions in a controlled manner.

In this light, the operational excellence advocated in this work represents a critical stepping stone toward a more sustainable future. At the meso-level of hospital care, the integration of operational improvement capability and value-based ambition is contingent on data maturity, hybrid leadership, and aligned incentives. While the Value Improvement Roadmap provides a structured framework, its effectiveness ultimately depends on governance choices that protect the human dimension of care. Sustainable healthcare is therefore not built by choosing between efficiency and humanity, but by designing systems in which well-designed operations create the organizational space for human care to flourish.

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A

APPENDICES

Impact

Summary & Samenvatting

Author Contributions per Chapter

List of Publications

Acknowledgements

Curriculum Vitae



IMPACT

Bridging the gap between strategy and execution

Healthcare systems face a persistent mismatch between rising demand, constrained resources, and increasing expectations regarding quality and outcomes. In the Netherlands, this urgency is reflected in policy ambitions around appropriate care, regional collaboration, and digital transformation, for example in the Dutch Integraal Zorgakkoord (Integrated Care Agreement). While value-based healthcare provides a compelling strategic orientation, healthcare organizations continue to struggle with translating these ambitions into stable routines at the level where care is actually delivered: the care pathway and the department.

The primary scientific and societal impact of this dissertation lies in addressing this implementation challenge. By synthesizing improvement initiatives conducted in Dutch secondary and tertiary hospital settings between 2018 and 2025, this work develops the Value Improvement Roadmap as an empirically informed learning framework at the meso-level. Rather than introducing a new normative model, the Roadmap operationalizes existing value principles by linking structure, process, and outcomes into iterative learning cycles. Across heterogeneous clinical contexts, process stabilization, data-driven feedback, and aligned governance repeatedly appear to be associated with fewer operational disruptions, better outcomes where measurable, improved experience of care, and more appropriate use of resources. This consistency across domains suggests that the underlying mechanisms are not context-specific but reflect general organizational capabilities that enable value creation under routine conditions.

Scientific contribution

The primary scientific contribution of this dissertation lies in the development of the Value Improvement Roadmap as a middle-range, theory-building framework. The framework addresses a documented gap in the literature: the

limited operational integration of Value-Based Healthcare strategy and Lean Six Sigma execution at the meso-level of hospital care. To the author's knowledge, few existing frameworks explicitly combine four elements at this level: structural prerequisites for data quality, operational methods for process redesign, the outcome orientation of VBHC, and enabling conditions for sustained learning within hospital departments and care pathways.

Three specific scientific contributions can be distinguished. First, the dissertation formalises the Data Quality Paradox: the observation that data quality in hospital settings is not only a technical property of information systems, but also an organisational outcome of process stability. This challenges a purely technology-driven view of digital transformation and has implications for the sequencing of analytics and AI investments in healthcare. Second, the dissertation operationalises the wrong-pocket problem at care-pathway level, showing how value created through process improvement can be structurally misaligned with departmental financial incentives. Third, the convergence between the Value Improvement Roadmap and the independently developed EUHA roadmap provides external conceptual support. Despite different methodological origins, both frameworks identify data governance, multidisciplinary leadership, and iterative improvement as important conditions for value-based care. A key distinction is that the EUHA roadmap operates mainly at institutional level, while the Value Improvement Roadmap specifies how these conditions can be operationalised at the meso-level, where care delivery is coordinated in daily practice.

Impact on patient value and the experience of care

At the patient level, the impact of this work becomes visible through the reduction of avoidable disruptions in care delivery. In the redesigned Coronary Artery Bypass Grafting (CABG) pathway, improved logistical coordination and standardized pre-operative processes were associated with a reduction in last-minute cancellations from 19 percent to 10 percent. At the same time, average waiting time decreased from 71 to 46 days. These changes were not accompanied by additional resources

or technological investments, but resulted from better alignment between planning, preparation, and execution.

These operational improvements had direct implications for how patients experienced care. Fewer cancellations translated into greater predictability and continuity, reflected in a doubling of the Net Promoter Score from 14 to 28 percent. From a system perspective, the same redesign was associated with approximately 95 additional procedures per year and an estimated 600 hospital bed-days freed annually. These figures illustrate a simple but important mechanism: when routine processes are reliable, care becomes less disruptive for patients and more efficient for organizations.

The findings are not presented as definitive causal proof in a randomized sense. Rather, they illustrate a plausible mechanism under routine conditions, in which reduced operational variability lowers the likelihood of delays, rework, and unnecessary patient burden. What patients experience as clear communication, timely decisions, and compassionate attention is framed in this dissertation as “High Touch” care, enabled not by more resources, but by operational discipline.

Addressing the capacity and workforce challenge

Beyond individual pathways, the societal relevance of this work lies in its implications for healthcare capacity and workforce sustainability. Several cases demonstrate how redesigning care pathways can relieve pressure on scarce resources while maintaining or improving quality.

In an intermediate-care setting for low back pain, the introduction of a structured triage pathway reduced inappropriate referrals by 55 percent. As a result, 84 percent of patients could be safely managed in primary care, with 96 percent correctly triaged according to predefined criteria. This illustrates how pathway-level redesign can prevent unnecessary hospital utilization while improving alignment between patient needs and care setting.

Similarly, the nurse-led Cardiac Resynchronization Therapy (CRT) pathway shows how task redistribution within a clearly governed pathway can contribute to both workforce relief and clinical performance. Observational analyses indicated an association between pathway redesign and a lower composite endpoint of mortality and heart failure hospitalizations, with a hazard ratio of approximately 0.56 after adjustment for observed baseline differences. In parallel, total costs were reduced by around 9.3 percent, with bootstrap analyses indicating cost-effectiveness dominance in the majority of iterations. Read as observational findings, these results suggest that role clarity, standardized follow-up, and early identification of non-responders can create conditions for better outcomes while reducing pressure on specialist capacity.

The comparative analysis of Transcatheter Aortic Valve Implantation (TAVI) versus Surgical Aortic Valve Replacement (SAVR) further illustrates how innovation interacts with organizational constraints. TAVI was associated with a substantial reduction in intensive care utilization, with average ICU length of stay decreasing from 1.88 to 0.19 days per patient. However, these capacity gains coincided with higher procedural costs, approximately €32,829 versus €25,290 per case. This empirical contrast illustrates the so-called wrong pocket problem: value created at the system level may not align with financial incentives at the departmental or reimbursement level. Without internal financial governance mechanisms that recognize and redistribute value, hospitals may have weak structural incentives to adopt high-value innovations, even when they reduce overall system strain.

Laying the foundation for digital transformation and responsible AI

This dissertation also contributes to ongoing debates on digital transformation and artificial intelligence in healthcare. Drawing on process mining analyses, it introduces what is termed the Data Quality Paradox: advanced analytics promise insight and prediction, yet depend fundamentally on stable processes and consistent data registration that are often underdeveloped in routine care.

In Chapter 8, attempts to reconstruct care pathways revealed substantial fragmentation and missing data when processes were unstable or poorly standardized. Without reliable registration at the source, analytical reconstructions remain incomplete and vulnerable to misinterpretation. The argument advanced here is not against digital innovation, but for sequencing capability development. Process stability and standardized data capture are not merely downstream technical issues, but foundational organizational prerequisites. Within this perspective, the Value Improvement Roadmap functions as a readiness framework, helping organizations prioritize stabilization and learning before investing in advanced analytics or AI applications.

Societal valorization and dissemination

To facilitate responsible dissemination and maximize societal impact, the Value Improvement Roadmap has been translated into educational formats such as workshops and training activities for clinical leaders, improvement professionals, and multidisciplinary care teams. These activities are explicitly positioned as knowledge translation rather than additional empirical validation. They are designed to build improvement capability in alignment with the mechanisms and conditions identified in this dissertation, with a strong emphasis on local adaptation rather than one-size-fits-all implementation.

Formal evaluation of the effectiveness of these educational formats falls outside the scope of this work and represents a logical next step for future research. Their inclusion here underscores the intention to ensure that the insights generated in this dissertation actively contribute to learning and capability development within healthcare organizations.

Concluding reflection on impact

Taken together, the findings indicate that meaningful improvement in hospital care under conditions of sustained resource constraints depends less on

isolated projects or standalone technological investments, and more on the purposeful development of organizational capabilities. Across multiple clinical domains, process optimization was repeatedly associated with fewer disruptions, better outcomes where measurable, improved experiences for patients and professionals, and more efficient and better-targeted use of resources.

By articulating how value-based ambitions can be translated into routine practice at the meso-level, this dissertation demonstrates that high-quality, accessible, and sustainable care is not primarily a matter of doing more, but of organizing existing resources more reliably and intelligently. In a period of ongoing workforce shortages and financial pressure, the Value Improvement Roadmap offers a scientifically grounded yet pragmatic pathway for healthcare organizations seeking to turn the promise of value-based care into everyday reality.

SUMMARY

Background and problem definition

Healthcare systems face a growing mismatch between expanding medical and technological possibilities and the capacity to deliver care sustainably in routine practice. Persistent workforce shortages, rising costs, constrained physical capacity, and increasing organizational complexity limit accessibility, timeliness, and coordination of care. In response, Value-Based Healthcare (VBHC) has emerged as a dominant strategic framework, emphasizing the optimization of patient-relevant outcomes relative to costs.

Despite widespread adoption, the implementation of VBHC in daily clinical practice remains challenging. A structural gap persists between strategic intent and operational execution. While VBHC articulates what constitutes value and why care delivery should change, it provides limited guidance on how care processes should be redesigned and improved. In parallel, operational improvement approaches such as Lean Six Sigma (LSS) are frequently applied in isolation, with a primary focus on efficiency, often weakly connected to patient outcomes and value-based evaluation.

Objective and methodology

This dissertation examines how the strategic principles of VBHC and structured operational improvement approaches can be coherently integrated at the meso-level of hospital care, defined as departments and care pathways. The objective is to understand the mechanisms and contextual conditions under which such integration is associated with sustainable patterns of change in outcomes, efficiency, and organizational learning.

The research adopts a retroductive, realist-informed synthesis of improvement initiatives conducted between 2018 and 2025 in Dutch top-clinical and academic hospitals, including Maastricht UMC+ and Amsterdam UMC. Donabedian's

Structure-Process-Outcome framework provides the analytical foundation, complemented by an organizational learning perspective to examine how data-driven feedback supports continuous improvement over time.

Findings

Part I: operational improvement in clinical practice

The studies in the first part suggest that structured process improvement can stabilize care delivery and improve accessibility under conditions of resource scarcity. In the coronary artery bypass grafting pathway, application of Lean Six Sigma was associated with a 50% reduction in surgical cancellations and a 35% reduction in waiting times, alongside improved patient satisfaction. Redesign of the cardiac resynchronization therapy pathway into a nurse-led model resulted in shorter length of stay and more efficient use of physician capacity, without compromising clinical quality. Analysis of multidisciplinary Heart Team meetings showed that structured triage and agenda management are important to safeguard decision-making quality in complex academic and merger settings. Beyond hospital boundaries, implementation of an intermediate (1.5-line) care model for low back pain reduced unnecessary hospital referrals through improved triage and collaboration between primary and secondary care.

Part II: data-driven evaluation and learning

The second part examines longer-term patterns of change and system-level implications. Long-term follow-up of the redesigned CRT pathway showed that process improvements were associated with lower mortality, fewer heart failure hospitalizations, and reduced costs. These findings suggest plausible mechanisms through which operational improvements may be associated with improved clinical outcomes when embedded and sustained.

In contrast, comparative evaluation of transcatheter versus surgical aortic valve replacement revealed misalignment between clinical value and financial incentives. Although TAVI generated substantial capacity gains through reduced ICU use and shorter hospital stays, these benefits were not consistently captured by the departments incurring higher material costs under existing reimbursement structures.

The application of process mining highlighted limitations in data quality, leading to the formulation of the Data Quality Paradox: although hospitals collect large volumes of data, insufficient process standardization limits their reliability and usefulness for steering, learning, and advanced analytics. Well-defined and stabilized care processes emerged as a critical enabling condition for data-driven learning.

Synthesis: the value improvement roadmap

Synthesizing these findings, this dissertation introduces the Value Improvement Roadmap as a middle-range, theoretically transferable operational learning model for value-based improvement under resource constraints, extending the Structure–Process–Outcome model into a cyclical learning perspective. The roadmap distinguishes four interconnected phases: increasing data maturity, transforming data into insights, translating insights into action, and embedding and scaling value.

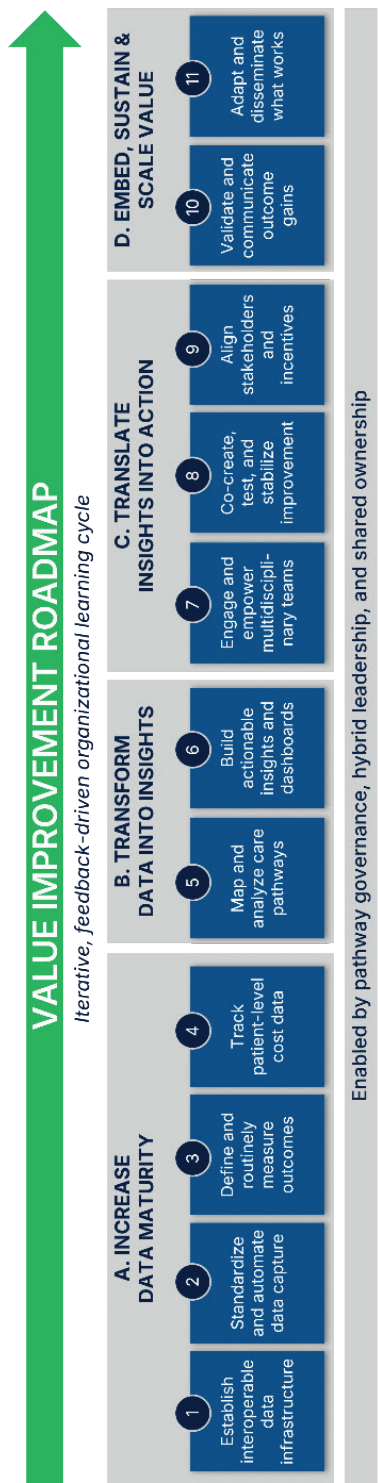


Figure 1. The Value Improvement Roadmap as an iterative, feedback-driven organizational learning framework at the meso-level of hospital care, integrating structure, process, and outcomes to support sustainable value creation under resource constraints.

Three recurring mechanisms underpin successful integration of VBHC and operational improvement. First, operational discipline is a prerequisite for data intelligence, as standardized processes generate data of sufficient quality to support evaluation and learning. Second, hybrid leadership is required, characterized by shared stewardship between physicians and nurses over both clinical and operational outcomes. Third, explicit internal financial governance at the care pathway level is necessary, as operational improvements are otherwise often not rewarded and may even generate negative financial incentives, preventing released capacity and efficiency gains from being translated into realized value across the care cycle. Figure 1 summarizes this synthesis by visualizing the Value Improvement Roadmap as an iterative, meso-level learning framework linking structure, process, and outcomes in routine hospital care.

Conclusion

This dissertation argues that improving the sustainability of healthcare systems does not depend on a single reform or technological solution, but on the systemic integration of strategic intent and operational execution. VBHC provides direction by defining value, while Lean Six Sigma offers a structured approach to realizing this value in daily practice. By stabilizing processes and reducing waste, healthcare organizations can create capacity for continuous improvement and learning. Operational excellence thus functions not as an end in itself, but as a foundational condition for safeguarding the human element of care (High Touch) within an increasingly data-driven and technologically advanced healthcare environment (High Tech).

SAMENVATTING

Achtergrond en probleemstelling

Gezondheidszorgsystemen worden geconfronteerd met een toenemende spanning tussen groeiende medische en technologische mogelijkheden enerzijds en beperkte capaciteit in personeel, financiële middelen en tijd anderzijds om zorg duurzaam te organiseren in de dagelijkse praktijk. Aanhoudende personeelstekorten, stijgende kosten, beperkte fysieke infrastructuur en toenemende organisatorische complexiteit zetten de toegankelijkheid, tijdigheid en samenhang van zorg onder druk.

In reactie op deze ontwikkelingen is Value-Based Healthcare (VBHC) uitgegroeid tot een dominant strategisch kader, waarin het maximaliseren van patiëntrelevante uitkomsten in verhouding tot de benodigde kosten centraal staat.

Ondanks brede adoptie blijkt de implementatie van VBHC in de dagelijkse klinische praktijk echter complex. Er bestaat een structurele kloof tussen strategische ambities en operationele uitvoering. Terwijl VBHC definieert wat waarde is en waarom zorg moet veranderen, biedt het beperkte handvatten voor hoe zorgprocessen concreet herontworpen en verbeterd kunnen worden. Tegelijkertijd worden operationele verbeterbenaderingen zoals Lean Six Sigma (LSS) vaak geïsoleerd toegepast, met een sterke focus op efficiëntie, maar zwak verbonden met patiëntuitkomsten en waarde-georiënteerde evaluatie.

Doel en methodologie

Dit proefschrift onderzoekt hoe de strategische principes van VBHC en gestructureerde operationele verbeterbenaderingen coherent geïntegreerd kunnen worden op het mesoniveau van ziekenhuiszorg, gedefinieerd als afdelingen en zorgpaden. Het doel is inzicht te verkrijgen in de mechanismen en contextuele voorwaarden waaronder deze integratie samenhangt met duurzame patronen van verandering in uitkomsten, efficiëntie en organisatorisch leren. Het onderzoek

hanteert een retroductieve, realist-informed synthesis (theoriegedreven synthese) van verbeterinitiatieven die zijn uitgevoerd tussen 2018 en 2025 in Nederlandse topklinische en academische ziekenhuizen, waaronder Maastricht UMC+ en Amsterdam UMC. Het Structure–Process–Outcome (SPO) model van Donabedian vormt het analytisch fundament, aangevuld met een perspectief op organisatorisch leren om te onderzoeken hoe datagedreven feedback continue verbetering ondersteunt.

Bevindingen

Deel I: operationele verbetering in de klinische praktijk

De studies in het eerste deel suggereren dat gestructureerde procesverbetering kan bijdragen aan het stabiliseren van zorgverlening en het verbeteren van toegankelijkheid onder omstandigheden van schaarste. In het CABG-zorgpad werd toepassing van Lean Six Sigma geassocieerd met een reductie van 50% in operatieve annuleringen en 35% kortere wachttijden, evenals verbeterde patiënttevredenheid. Het herontwerp van het CRT-zorgpad naar een verpleegkundig geleid model ging samen met een kortere opnameduur en efficiënter gebruik van artsencapaciteit, zonder verlies van klinische kwaliteit. Analyse van multidisciplinaire Heart Team-besluitvorming liet zien dat gestructureerde triage en agendabeheer belangrijk zijn voor het borgen van besluitkwaliteit in complexe academische en fusiecontexten. Buiten het ziekenhuis leidde implementatie van een 1,5-lijns zorgmodel voor lage rugklachten tot minder onnodige ziekenhuisverwijzingen door verbeterde triage en samenwerking tussen eerste en tweede lijn.

Deel II: datagedreven evaluatie en leren

Het tweede deel richt zich op langere termijn patronen van verandering en systeemimplicaties. Langetermijnfollow-up van het herontworpen CRT-zorgpad liet zien dat procesverbeteringen geassocieerd waren met lagere mortaliteit, minder ziekenhuisopnames voor hartfalen en lagere kosten. Deze bevindingen

suggereren plausibele mechanismen waarlangs operationele verbeteringen samenhangen met betere klinische uitkomsten wanneer zij structureel worden ingebed.

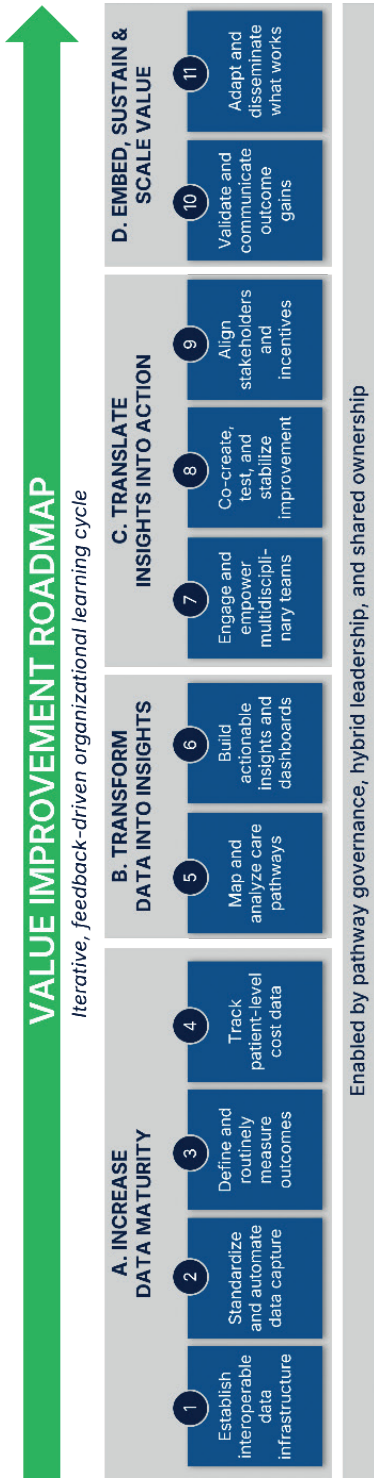
De vergelijking tussen transkatheter- (TAVI) en chirurgische aortaklepvervangende toonde een misalignment tussen klinische waarde en financiële prikkels. Hoewel TAVI substantiële capaciteitswinst opleverde door minder IC-gebruik en kortere opnames, werden deze voordelen niet consistent gerealiseerd binnen de afdelingen die geconfronteerd werden met hogere materiaalkosten onder bestaande bekostigingsstructuren.

Toepassing van process mining bracht beperkingen in datakwaliteit aan het licht, leidend tot de formulering van de Data Quality Paradox: hoewel ziekenhuizen grote hoeveelheden data verzamelen, beperkt onvoldoende processtandaardisatie de betrouwbaarheid en bruikbaarheid voor sturing, leren en geavanceerde analyses. Gestabiliseerde en goed gedefinieerde zorgprocessen kwamen naar voren als cruciale randvoorwaarde voor datagedreven leren.

Synthese: de Value Improvement Roadmap

Op basis van deze bevindingen introduceert dit proefschrift de Value Improvement Roadmap als een theoretisch overdraagbaar leermodel op mesoniveau voor waardegedreven verbetering in zorgorganisaties, waarmee het Structure–Process–Outcome model wordt uitgebreid met een cyclisch leerperspectief. De roadmap onderscheidt vier onderling verbonden fasen: het vergroten van datamaturiteit, het vertalen van data naar inzichten, het omzetten van inzichten in actie, en het borgen en opschalen van waardecreatie.

Drie terugkerende mechanismen blijken bepalend voor succesvolle integratie van VBHC en operationele verbetering. Ten eerste zijn goed georganiseerde en stabiele zorgprocessen noodzakelijk voor data-intelligentie, omdat gestandaardiseerde processen data van voldoende kwaliteit genereren voor evaluatie en leren. Ten tweede is hybride leiderschap vereist, gekenmerkt door gedeeld eigenaarschap van artsen en verpleegkundigen over zowel klinische als operationele uitkomsten.



Figuur 1. De Value Improvement Roadmap als iteratief, feedback-gedreven leermodel op mesoniveau van ziekenhuiszorg, waarin structuur, proces en uitkomsten worden geïntegreerd ter ondersteuning van duurzame waardecreatie onder omstandigheden van schaarste.

Gedeeld eigenaarschap verwijst naar multidisciplinaire zorgpadteams, waarin artsen, verpleegkundigen, management en data-ondersteuning gezamenlijk prioriteiten bepalen, prestaties monitoren en verantwoordelijkheid dragen voor continue verbetering. Ten derde is expliciete (interne) financiële governance essentieel. Dit proefschrift laat zien dat operationele verbeteringen zonder dergelijke governance regelmatig niet worden beloond en in sommige gevallen zelfs leiden tot negatieve financiële prikkels, waardoor duurzame verbetering onder druk komt te staan. Figuur 1 vat deze synthese samen door de Value Improvement Roadmap te visualiseren als een iteratief leermodel op mesoniveau dat structuur, proces en uitkomsten in de ziekenhuiszorg met elkaar verbindt.

Conclusie

Dit proefschrift betoogt dat de duurzaamheid van gezondheidszorgsystemen niet afhankelijk is van één enkele hervorming of technologische oplossing, maar van de doelbewuste integratie van strategische intentie en operationele uitvoering. VBHC biedt richting door waarde te definiëren, terwijl Lean Six Sigma een gestructureerde aanpak biedt om deze waarde in de dagelijkse praktijk te realiseren. Door processen te stabiliseren en verspilling te reduceren, kunnen zorgorganisaties ruimte creëren voor continu verbeteren en leren. Operationele excellentie is daarmee niet enkel een doel op zich, maar fungeert als fundamentele voorwaarde voor het borgen van het menselijke aspect van zorg (High Touch) binnen een steeds meer datagedreven en technologisch geavanceerde zorgomgeving (High Tech).

AUTHOR CONTRIBUTIONS PER CHAPTER

This dissertation is based on eight empirical studies conducted in collaboration with clinical teams across multiple hospital settings. The following statement describes the specific contributions of the doctoral candidate, S. Schretlen (SS), to each chapter, in accordance with the principles of the CRediT Contributor Roles Taxonomy.

Chapter 1: General Introduction

Chapter 1 was written by SS. The chapter frames the research problem, positions the dissertation within the literature on Value-Based Healthcare, Lean Six Sigma, data-driven learning, and hospital-level implementation, and formulates the overarching research question and sub-questions.

Chapter 2: Methods and Design

Chapter 2 was written by SS. The chapter describes the methodological approach of the dissertation, including the retroductive, realist-informed synthesis strategy, the study settings, the analytical framework, and the logic through which findings across the empirical chapters are integrated.

Chapter 3: Reducing Surgical Cancellations (BMJ Open Quality, 2021)

SS initiated and led the Lean Six Sigma improvement project. SS contributed to the study design, data collection, data analysis, interpretation of findings, and manuscript preparation. SS and P. Hoefsmits contributed equally as first authors. S. Kats, J. Maessen, and H.R. Zandbergen contributed to interpretation and critically reviewed the manuscript. G.G. van Merode provided methodological oversight.

Chapter 4: Streamlining the CRT Care Pathway (BMJ Open Quality, 2021)

SS co-initiated this study with A.M.W. van Stipdonk. SS designed the process mining and Lean Six Sigma methodology, contributed to data extraction, led the analytical work, interpreted the operational findings, and had a leading role in manuscript preparation. A.M.W. van Stipdonk contributed clinical domain expertise, ensured clinical validity, and facilitated access to patient data and clinical workflows. In the published article, the clinical co-author is listed first. The equal contribution statement reflects that both authors fulfilled a first-author role, with complementary responsibilities.

Chapter 5: Optimising Heart Team Decision-Making (BMJ Open Quality, 2023)

SS initiated and led the Lean Six Sigma project. SS contributed to the study design, data acquisition, quantitative analysis, interpretation of findings, and manuscript preparation. P.C. Hoefsmit and SS contributed equally as first authors. N.J. Verouden contributed clinical context and interpretation. H.R. Zandbergen supervised the study and critically reviewed the manuscript.

Chapter 6: Preventing Unnecessary Hospital Visits for Low Back Pain (Nederlands Tijdschrift voor Pijn en Pijnbestrijding, 2022)

SS co-initiated this study and led the analytical design, data collection, and data analysis. SS contributed substantially to the interpretation of findings and manuscript preparation. D. Branje contributed clinical context and clinical validation. Both authors contributed equally as first authors. N. de Meij and J. van Zundert provided clinical oversight. J. Muris and P. Willems contributed to interpretation and manuscript review.

Chapter 7: Reviewing Quality Improvement in Cardiac Surgery (Journal of Clinical Medicine, 2022)

SS contributed substantially to the research design, theoretical framing, classification logic, interpretation of findings, and manuscript preparation. P.C. Hoefsmit led the systematic search and screening process. SS co-designed the search strategy and classification framework, contributed to data analysis, and co-wrote the manuscript. H.R. Zandbergen supervised the study.

Chapter 8: Enhancing Process Mining in Healthcare (Artificial Intelligence in Medicine, 2020)

This chapter emerged from an international expert consortium. SS contributed from his expertise in data-driven process improvement in healthcare settings. SS co-authored the manuscript and contributed to the practical recommendations for applying process mining in healthcare. Within this dissertation, the chapter broadens the methodological foundation by introducing an internationally validated perspective on process mining and its usability in healthcare improvement.

Chapter 9: Improving Patient Outcomes with the CRT Care Pathway (ESC Heart Failure, 2022)

SS co-initiated this study and led the analytical design, data collection, and data analysis, including the cost and resource-use evaluation. SS had a leading role in interpretation of findings and manuscript preparation. A.M.W. van Stipdonk contributed clinical expertise and co-interpreted the results. In the published article, the clinical co-author is listed first. The equal contribution statement reflects that both authors fulfilled a first-author role, with complementary responsibilities.

Chapter 10: Assessing TAVI and SAVR: Outcomes, Costs and Capacity (submitted)

SS is sole first author and corresponding author. SS was responsible for conceptualisation, study design, methodology, data curation, formal analysis, interpretation, visualisation, and manuscript preparation. This chapter demonstrates independent scientific leadership and represents the most recent and methodologically comprehensive empirical component of the dissertation.

Chapter 11: Discussion and Conclusion

Chapter 11 was written by SS. This chapter presents the retroductive synthesis of findings across all empirical chapters and introduces the Value Improvement Roadmap as the integrative framework of the dissertation. The framework represents the doctoral candidate's primary intellectual contribution, developed under supervision and informed by the empirical studies included in this dissertation.

Impact Paragraph, Summary, and Samenvatting

The Impact Paragraph, Summary, and Samenvatting were written by SS.

Role of the supervisory team

The supervisory team contributed primarily at the level of the research programme, rather than to every individual publication. Prof. dr. M.J. Jacobs, as Medical Director of the Heart and Vascular Centre at Maastricht UMC+, initiated the Lean and VBHC strategy within which several studies were conducted, and contributed directly and substantively to Chapter 10. Prof. dr. G.G. van Merode provided methodological direction and supported the scientific coherence of

the research programme from an operational excellence perspective. Dr. H.R. Zandbergen co-authored several publications and supported the connection of the research programme to clinical settings in Amsterdam UMC. In accordance with ICMJE criteria, authorship of individual publications was reserved for those who contributed directly to the execution and reporting of the study concerned.

Relation to other dissertations

Some chapters are also included in related clinical dissertations. In the present dissertation, these studies are interpreted from the perspective of operational improvement, data-driven evaluation, and value-based integration. This interpretive synthesis and the resulting Value Improvement Roadmap are specific to this dissertation.

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*Branje, D., ***Schretlen, S.**, Brouwer, B., de Meij, N., van Zundert, J., Muris, J., & Willems, P. (2022). Het reduceren van onnodige ziekenhuiszorg voor patiënten met lage rugpijn: Implementatie van een 1.5-lijnpoli. *Nederlands Tijdschrift voor Pijn en Pijnbestrijding*, 41, 5–9.

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*Van Stipdonk, A. M. W., ***Schretlen, S.**, Dohmen, W., Knackstedt, C., Beckers-Wesche, F., Debie, L., Rocca, H. B., & Vernooy, K. (2022). Better outcome at lower costs after implementing a CRT-care pathway: Comprehensive evaluation of real-world data. *ESC Heart Failure*, 9, 2518–2527. <https://doi.org/10.1002/ehf2.13958>

Submitted for Publication

Schretlen, S., Hoefsmit, P. C., Lux, A., Kats, S., Zandbergen, H. R., van Merode, G. G., Jacobs, M. J., & Maessen, J. G. Evaluating transcatheter versus surgical aortic valve replacement: Outcomes, costs, and capacity in the Dutch healthcare system.

* *Shared first authorship*

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Het dankwoord! Eindelijk een hoofdstuk zonder wetenschappelijke taal, geen referenties naar anderen, geen geworstel met zinsconstructies en geen methodologie. Gewoon lekker opschrijven wat ik zelf graag wil zeggen, zonder verantwoording! Wat een weelde. Daar ga ik even goed gebruik van maken. Ga er dus maar even voor zitten en pak er een boek bij, het liefst dit boek.

Een proefschrift schrijven. Ik wist jarenlang zeker dat ik daarvoor niet in de wieg was gelegd. Mijn bachelor- en masterthesis waren een worsteling, en mijn aard dat het altijd nog wat beter kan helpt ook niet om iets af te ronden. Had ik er tijd voor? Nee. Kreeg ik ervoor betaald? Nee. Maar toch heb ik het gedaan. Niet om de 's' van 'drs.' te deleten. Niet omdat Caroline ook gepromoveerd is. En ook niet om mijn carrière een boost te geven.

Waarom dan wel, zul je je afvragen? Noodzaak, passie, impact en uitdaging!

- 1) **Noodzaak:** In een tijd waarin defensie, onderwijs en gezondheidszorg allemaal strijden om dezelfde euro, zijn we er in de zorg samen voor verantwoordelijk om die euro optimaal in te zetten voor het verbeteren van gezondheidsuitkomsten. Daar is nog veel te winnen. Mijn proefschrift laat zien hoe dat kan en biedt daarvoor een roadmap.
- 2) **Passie:** Ik vind Value-Based Healthcare een waanzinnig interessant onderwerp. Ik heb er zelfs m'n werk van gemaakt. Voor velen is gezondheid het belangrijkste in hun leven. Daar kom je eigenlijk pas achter als je erdoor in de steek wordt gelaten. Maar het systeem is niet houdbaar. Het wordt steeds duurder, en er zijn vooral steeds meer mensen nodig om de zorg te leveren. Tegelijkertijd weet iedereen dat het zorgsysteem vol zit met verspilling: wachten, dubbel werk, fouten, miscommunicatie etc. Dat leidt tot frustratie bij patiënt en zorgprofessional. Hoe mooi is het om samen met de zorgprofessionals te werken om die frustratie te reduceren, om meer tijd te creëren, om voor betere uitkomsten te zorgen en om klachten te vervangen door complimenten. De zorg verdient een positieve benadering en er is nog zoveel te bereiken! Door mijn lessons learned te delen, dus door te publiceren

wat wel en niet werkte, hoop ik anderen te inspireren om te verbeteren, zonder dat ik er zelf bij betrokken ben.

- 3) **Impact:** In mijn werk als consultant is Powerpoint je beste vriend. Projecten beginnen met een kick-off presentatie, en eindigen met een eindpresentatie. Maar dat is niet de taal die in (academische) ziekenhuizen wordt gesproken. En als je impact wil maken, moet je de juiste taal spreken. Ik vond het daarom tijd om die taal te leren. Om mijn gepresenteerde projecten en verbeteringen wetenschappelijk te onderbouwen en door onafhankelijke experts te laten reviewen. Want pas als iets gepubliceerd is, krijgen inzichten de geloofwaardigheid die nodig is voor bredere adoptie.
- 4) **Uitdaging.** Ik wilde mezelf uitdagen. Kan ik mezelf motiveren om iets te doen wat buiten mijn comfort zone ligt? Maar ook artsen en bestuurders bleven me uitdagen. Michael Jacobs: “Stijn, hoe kunnen we onze VBHC-lessen vastleggen?” Frits van Merode: “Stijn, zou je daar niet eens een proefschrift over schrijven?”. Reinier Zandbergen: “gast, dit resultaat moeten we (lees: jij) publiceren!” Ik zag ervan af, totdat men zei: “Dat gaat niet meer gebeuren”, “ik denk niet dat jij dat kan”. Toen ben ik aan de slag gegaan, met de hiervoor genoemde heren als mijn promotoren.

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CURRICULUM VITAE

Stijn Joppe Schretlen (1981) is a Managing Consultant at Medtronic Integrated Health Solutions and an accredited Lean Six Sigma Master Black Belt (American Society for Quality). He obtained his Master's degree in Health Policy, Economics and Management from Maastricht University in 2008. During his studies, he conducted research on the impact of market mechanisms and reimbursement systems on healthcare delivery.

Following graduation, he worked as a consultant and project manager for several consulting firms and hospitals, specializing in healthcare process improvement, Lean Six Sigma, and healthcare financing. Since joining Medtronic in 2011, he has led more than 100 improvement projects in collaboration with hospitals across Europe, with a particular focus on the Benelux. Throughout his career, he has trained and coached more than 1,000 healthcare professionals in Lean Six Sigma and Value-Based Healthcare.

In addition to his professional activities, he serves as a guest lecturer in the master's programme at Maastricht University and regularly presents at international conferences on Value-Based Healthcare, data-driven innovation, and public-private partnerships in healthcare.

His doctoral research at Maastricht University focuses on operationalizing Value-Based Healthcare by combining data-driven process optimization with rigorous outcome evaluation. Through this work, he aims to provide healthcare organizations with a practical roadmap for translating the principles of Value-Based Healthcare into measurable and sustainable improvements in patient outcomes, care delivery, and resource utilization.

