THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

# Variation in Healthcare Processes: Implications for Quality of Care

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Division of Quality Sciences

Department of Technology Management and Economics

CHALMERS UNIVERSITY OF TECHNOLOGY

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# Variation in Healthcare Processes: Implications for Quality of Care

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# ABSTRACT

The issues of quality and variation are indissociable as the knowledge of variation is one of the foundations in improving quality. Numerous studies report the existence of a great deal of unwanted variation in healthcare processes and its concomitant detrimental effects on the quality of care. Furthermore, traditional methods employed in eliminating unwanted variation, such as Statistical Process Control and Design of Experiments, remain infrequently used in the context of healthcare. The challenges in understanding and managing variation intensify as healthcare processes become increasingly complex and the uniqueness of patients becomes increasingly evident and relevant. Although variation is of utmost importance and extensively pervades healthcare process, there seems to be a gap in understanding and managing variation in ways that enable delivering care of high quality consistently over time and across patients. Thus, the overall purpose of the research substantiated in this thesis has been to increase the understanding of variation in the quality of healthcare processes.

Overall, the research discussed in this thesis followed a case study design, as it explored different aspects of understanding and managing variation in the real-life context of healthcare processes. Both quantitative and qualitative research methods were used in the investigation of five healthcare processes, each of which is accounted for in a separate appended paper. First, the study on physician scheduling at hospital departments (Paper I) suggests that available provider capacity is often in dissonance with patient demand for services and that variation in the capacity may exceed that of the demand. The study also suggests that healthcare providers exert an excessive influence over the timeliness of healthcare processes. In the paper, it is argued that increasing the knowledge of scheduling resources, centralizing resource scheduling may mitigate the

excessive provider influence on the scheduling and result in improved timeliness of healthcare processes. Second, the study on the effects of using a decision support system in tandem with the treatment of AMI patients (Paper II) suggests that effective treatments may be underused. The study shows that the use of the decision support system was associated with significant increases in physician prescription of the effective treatments recommended in clinical practice guidelines. It can thus be argued that the decision support system was effective in mitigating the risk that healthcare providers would abstain from providing the recommended care for reasons other than patient unsuitability. Third, the study aimed at identifying differences in the treatment of patients with acute chest pain with respect to patient proficiency in Swedish (Paper III) shows that the delay time from arrival in hospital to admission to catheterization lab or ward is significantly longer for non-Swedish-speaking patients. The study also shows that co-morbidities are more prevalent among non-Swedish-speaking patients. The study suggests that inequalities in the hospital treatment of non-Swedish-patients are uncommon as few statistically significant differences were found between Swedish-speaking and non-Swedish-speaking patients. It is thus plausible that the detrimental effects of non-patient related factors on the quality of delivered care are of minor importance. Fourth, the study on the effects of using the Lexis diagram in monitoring lead times (Paper IV) suggests that the diagram can be beneficial in monitoring lead times. The study also suggests that using the Lexis diagram may lead to improved staff scheduling and subsequently to reduced lead times. It is also suggested that by illustrating the developments in lead times on real-time and at the individual patient level, the use of the Lexis diagram may preclude the occurrence of excessively long lead times other than patient self-imposed waiting. It is thus expected that the use of the Lexis diagram may prevent non-patient related factors to detrimentally affect lead times in particular and timeliness of healthcare processes in general. Fifth, the study aimed at characterizing how healthcare quality data are reported in the annual reports of quality registries (Paper V), indicating that much focus is placed on comparing the delivery of care across healthcare units. The ranking of healthcare units in the annual reports is frequent and often lacks consideration of random variation. The need for considering differences in the patient casemix when comparing the performance of healthcare units, as well as the difficulties of riskadjustment, are also discussed in the paper. Concerning variation over time, the study indicates that the time series included in the reports often consists of a few highly aggregated points, which hinders an assessment of whether quality of care is stable and obscures variation over shorter periods of time.

The results illustrate the challenges in understanding and managing variation in healthcare processes, in which intervene different interested parties with potentially divergent interests who are nevertheless necessary for providing high-quality care. The results above give several indications of the existence of unwanted variation, either in the form of excessive provider influence on scheduling, deviations from recommended care for reasons other than patient unsuitability or inequalities in the treatment of patients which cannot be explained by differences in patient baseline characteristics. Such unwanted variations ought to be eliminated if variation in healthcare quality is to be reduced. The results emphasize the importance of supporting healthcare providers with tools that enable them to decide in their daily practice whether to comply with standard care or purposefully deviate from such care to accommodate the uniqueness of patients. Thus, unwanted variation ought to be eliminated at the same time as the possibility of treating patients differently based on their specific needs and wants must be safeguarded.

Keywords: understanding and managing variation, healthcare processes, quality of care

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Sincerely yours, Marco Santos Gothenburg, September 2013

# LIST OF APPENDED PAPERS

This thesis by publication consists of an executive summary and the papers enumerated below. All papers are appended in their entirety and are referred to in the text by the corresponding Roman numeral. The papers are presented in the chronological order of their production. A description of current status has been added in Table 1.

# Order Description Santos, M. and Eriksson, H. Insights into Physician Scheduling – A case study of public hospital Paper I departments in Sweden. In press in the International Journal of Health Care Quality Assurance. Santos, M., Tygesen, H. and Herlitz, J. From Average to Great – Improving guideline Paper II adherence. Accepted with revisions for publication in the International Journal of Health Care Quality Assurance. Santos, M., Ravn-Fischer, A., Karlsson, T., Herlitz, J. and Bergman, B. Is the early treatment of Paper III acute chest pain provided sooner to patients who speak the national language? In press in the International Journals for Quality in Health Care. Santos, M., Chakhunashvili, A., Plantin, A., Westerberg, K. and Bergman, B. Exploring the use of the Lexis diagram for monitoring lead times in healthcare: The illustrative case of an Paper IV outpatient referral process. Previous version presented at the 16<sup>th</sup> QMOD conference in Portorož, Slovenia. Santos, M. Data visualization in public reports of healthcare quality - A systematic review of five quality registries. Previous version presented at the 20<sup>th</sup> International Annual EurOMA Paper V Conference in Dublin, Ireland.

### Table 1 List of papers appended to the thesis

# CONTRIBUTIONS OF THE THESIS AUTHOR

The executive summary of the thesis was written exclusively by the thesis author, Marco Santos, who was also the main author in all appended papers. In particular, Paper V was single authored whereas Papers I to IV were co-authored. The table below shows in detail the contributions of the thesis author to the appended papers, according to the scale: *MS*, for tasks performed entirely by the thesis author, *Mainly MS*, for tasks performed mainly but not exclusively by the thesis author, *Shared*, for tasks performed by several authors in equitable proportions and *Others*, for tasks in which the participation of the thesis author was scant or non-existent. The abbreviation *n/a* stands for not applicable (see Table 2).

Phase	Paper I	Paper II	Paper III	Paper IV	Paper V	
Overall	Main author	Main author	Main author	Main author	Single author	
Study conception and design	MS	Shared	Shared	Shared	MS	
Data collection	MS	Shared	Others	Shared	MS	
Data analysis and	Mainly MS	Mainly MS	Shared	MS	MS	
interpretation			Sharea	1415	1415	
Manuscript drafting	Mainly MS	MS	MS	MS	MS	
Manuscript critical						
revision before	MS	Shared	Shared	Shared	MS	
submission <sup>a</sup>						
Manuscript revision after	MS	MS	MS	n/a	n/a	
submission to journal	1415	1415	1415	nyu	n, a	

<sup>a</sup> To journal or conference

# LIST OF ACRONYMS

The following acronyms have been used in the executive summary of the thesis (see Table 3).

Table 3 Acronyms	used in the	executive	summary	of the thesis

	Description		Description
ACS	Acute Coronary Syndrome	PCI	Percutaneous coronary intervention
AMI	Acute Myocardial Infarction	RCT	Randomized clinical trial
CABG	Coronary Artery Bypass Graft	RDM	Robust Design Methodology
ССМ	Cultural Competency in Medicine	RQ	Research Question
CDSS	Clinical Decision Support System	SkaS	Skaraborg Hospital
CICU	Cardiac Intensive Care Unit	SPC	Statistical Process Control
DoE	Design of Experiments	STEMI	ST segment Elevation Myocardial Infarction
EBM	Evidence-Based Medicine	SU	Sahlgrenska University Hospital
ECG	Electrocardiogram	SÄS	Southern Älvsborg Hospital
HRs	Heart Records		

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# **1** INTRODUCTION

This chapter starts by framing the thesis on the science of improvement (Section 1.1) and proceeds with a description of the background and current shortcoming in understanding and managing variation in healthcare processes (Section 1.2). The section that follows outlines the purpose and the research questions (Sections 1.3). Clarifications of the key concepts can be found in Section 1.4. The chapter ends with considerations of the scope of research and the structure of the thesis (Section 1.4 and 1.5, respectively).

#### 1.1 Exploring a Cornerstone of the Science of Improvement

Professional knowledge has long been considered the necessary and sufficient condition for delivering high-quality care. However, the increasing complexity in the delivery of care has exposed the hazards of solely relying on professional knowledge and contributed to the emergence of a stronger focus on organizations and processes (Ruiz and Simon, 2004). The need for linking "professional knowledge" to "improvement knowledge" was discussed in the influential paper by Batalden and Stoltz (1995). The authors propose a framework for "continual improvement" (Figure 1) that merges knowledge of a "subject", such as anatomy or microbiology, knowledge of a "discipline", such as nursing or pediatrics, and "values shared" with the four elements characteristic of improvement knowledge as defined by Deming (1993). This merger should occur even at the individual level as all healthcare providers ought to realize that "they have two jobs when they come to work every day, i.e. doing the work and improving it" (Batalden and Davidoff, 2007a).



*Figure 1* Continual improvement (black jointing material) requires both professional knowledge (white tiles) and improvement science (grey tiles), adapted from Batalden and Stoltz (1995).

As advocated by Deming (1993), a "system of profound knowledge" consists of four elements: (1) "knowledge of system", (2) "knowledge of variation", (3) "knowledge of psychology" and (4) "theory of knowledge". This proposition implies seeing organizations as a set of interrelated processes with a common aim, understanding that processes have common and special cause variation, understanding how new knowledge is generated within an organization, and understanding how people are motivated and work in groups or teams in an organization (Best and Neuhauser, 2005). Since "variation is present everywhere" and "it is fundamental to understand variation over time in order to recognize and use observed differences for the purpose of improvement" (Deming, 1993), the focus of this thesis is "knowledge of variation".

### 1.2 Background and Problem Areas

The issues of quality and variation are indissociable. Although quality can be improved by alternative approaches, such as through serendipity innovation<sup>1</sup>, managing variation has been playing a major role in improving quality and efficiency, as quality improvements very often go hand in hand with cost savings (Bergman and Klefsjö, 2010). Initially, managing variation essentially occurred in manufacturing settings based on a strategy of reducing variation, which has historically yielded productivity gains and enabled the creation of "swift, even flows" (Schmenner, 2001). In such settings, quality may be seen as inversely proportional to variation. The seminal work by Shewhart at Western Electric Company during the 1920s and 1930s shed light on the nature of variation and its management. The basic idea advocated by Shewhart (1931) was that processes should be brought into and maintained in a state of statistical control. In order to achieve a state of statistical control, in which processes perform at their best and are predictable within limits, identifiable causes that make a major contribution to variation should be eliminated. Once the process was under the influence of a large number of causes with a minor contribution to variation, it would display its natural variation while only more comprehensive and radical improvements would be able to improve the process. In subsequent decades, the field of quality management would release itself from the constraints of its manufacturing setting and evolve to include methods relevant to service industries, thereby identifying and fulfilling the needs and expectations of customers (e.g. Kano et al., 1984).

<sup>&</sup>lt;sup>1</sup> E.g. penicillin.

#### Introduction

In healthcare, concerns about quality have traditionally been addressed differently from concerns in industry. The focus on processes advocated by industry has by and large been substituted by a focus on people. Thus, efforts have been made to provide excellent education and training to future healthcare providers. Healthcare providers would then be granted a great deal of discretion in assessing each individual case and be expected to treat each patient in an irreprehensible way. Nevertheless, the increasing complexity in healthcare delivery and fast-changing pace of medical advancements<sup>2</sup> uncovered the deficiencies of this approach and undermined the myth of infallible healthcare providers. Shortcomings in understanding and managing variation resulted in proving care that deviated from the needs and wants of patients<sup>3</sup>. The underuse of Statistical Process Control (SPC) (Thor *et al.*, 2007)<sup>4</sup> and Design of Experiments (DoE) (Neuhauser, 2005), two methodologies foundational to understanding and managing variation, suggests that variation in healthcare processes remains poorly understood and managed. The prevalence of unjustified variations<sup>5</sup> in clinical practice is another symptom of shortcomings in understanding and managing variation.

During the 1980s, several studies reported the existence of unjustified variation in clinical practice (Wennberg *et al.*, 1987; Wennberg *et al.*, 1989). In some cases, it was possible to detect a twenty-fold range of variation in, for instance, hospitalizations for tooth extractions and pediatric admissions for gastro-intestinal diseases (Wennberg, 1984). The problem of unjustified variations remains unsolved in the U.S. (Nembhard *et al.*, 2009) and other countries. In the U.K., for instance, Appleby *et al.* (2004) argue that there are wide variations in the performance of individual clinicians and hospitals within the country's NHS. Similarly, in a study of the standardized death ratio in 183 English hospitals, Jarman (1999) claims that while differences in patients' age and severity of illness may explain some of the variation in hospital death rates, a large amount of unjustified variation between hospitals

<sup>&</sup>lt;sup>2</sup> New knowledge in areas such as genetics and the increasing resolution of new technologies have emphasized the uniqueness of every patient. The increasing heterogeneity of populations associated with citizen mobility and patient empowering also poses additional challenges to healthcare providers. Thus, the increasing heterogeneity occurs both in terms of needs and wants, i.e. both at the physiological and psychological levels.

<sup>&</sup>lt;sup>3</sup> The purpose of understanding and managing variation is to consistently provide high-quality care.

<sup>&</sup>lt;sup>4</sup> Although the authors found SPC to have wide applicability to healthcare, their search for SPC and healthcare during the 1966-2004 period yielded only 311 references.

<sup>&</sup>lt;sup>5</sup> Unjustified variations are variations that cannot be explained by differences in case-mix or randomness.

still exists after adjusting for age, sex and severity. Neither is Swedish health care immune to the problem of unjustified variations, as confirmed by Stenestrand *et al.* (2005) in a study that demonstrates that hospital therapy traditions influence long-term survival in patients with "acute myocardial infarction" (AMI). Clinical practice guidelines appeared in response to the perceptions of excessive variations in practice between physicians (Kassirer, 1993). Nevertheless, several factors hinder physician adherence to such guidelines (Cabana *et al.*, 1999). Unsurprisingly, it is still possible to find cases of "extreme variability in practice even in clinical areas in which there is strong evidence and high degree of expert consensus" (IOM, 2001, p. 13).

#### **1.3 Purpose and Research Questions**

By not attributing them to varying patient needs, wants or chance causes, unjustified variations in quality of care are symptomatic of opportunities for improvement as they may impact negatively on the quality of care. The elimination of unjustified variations in quality of care is nevertheless far from trivial as it may require both the elimination of variation in clinical practice due to healthcare-related causes, as well as the promotion of variation in clinical practice in order to accommodate the uniqueness of each patient.

The **purpose** of the research substantiated in this thesis is to increase the understanding of variation in the quality of healthcare processes.

To fulfil the purpose of the thesis, five research questions have been posed. The formulation of the questions was governed by the following criteria: relevance to understanding and managing variation, potential for healthcare quality improvement, and pragmatic aspects, such as access to the field, availability of data and alignment with the background of the thesis author.

#### 1.3.1 Research Question 1

Timeliness is one of the dimensions of quality of care (IOM, 2001) and is often indicated as a major area for improvement in Swedish healthcare (e.g. Fölster *et al.*, 2003; Health Consumer Powerhouse, 2012). Shortcomings in timeliness can have a detrimental effect in clinical outcomes and patient satisfaction (e.g. Davies, 1999; Natarajan *et al.*, 2002). Timeliness is largely affected by scheduling decisions (Jonsson and Mattsson, 2009), especially those

concerning physicians, as physicians are often the bottleneck in healthcare processes and occupy a dominant position relative to other healthcare providers (Schall *et al.*, 2004). Previous literature on physician scheduling has essentially dealt with optimizing physician capacity with respect to a specific task (e.g. White and White, 2003; Gendreau *et al.*, 2007) and has disregarded the multiplicity of tasks performed by physicians<sup>6</sup>. Despite its importance, physician scheduling remains sparsely investigated and its effect on timeliness is largely unnoticed.

**RQ1:** How can physician scheduling be improved in order to yield gains in timeliness?

#### 1.3.2 Research Question 2

Effectiveness is a dimension of quality of care (IOM, 2001) that reflects an ability to deliver care that is well-grounded in the latest research. Several studies suggest shortcomings in effectiveness as many variations in clinical practice can be found, even when comparing patient populations that are very similar (e.g. Eagle *et al.*, 2002). Such variations in clinical practice may result from a lack of adherence by physicians to clinical practice guidelines and subsequent underuse of recommended effective therapies (e.g. Edmond *et al.*, 2007; Hauptman *et al.*, 2010). Previous studies show that the use of "clinical decision support systems" (CDSSs), in particular reminder systems, may be associated with increased physician adherence to guidelines (Dexter *et al.*, 2001; Prior *et al.*, 2008). The effects of using CDSSs to entice physician adherence to guidelines (Grol and Grimshaw, 2003)<sup>7</sup>. It remains unclear whether the hypothesis that the use of CDSSs increases an adherence to clinical practice guidelines remains true in the case of Swedish patients diagnosed with Acute Coronary Syndrome (ACS).

RQ2: To what extent can the use of a CDSS affect clinical practice and quality of care?

<sup>&</sup>lt;sup>6</sup> At the hospital department level, physicians can serve at outpatient clinics, emergency departments and wards. Other tasks performed by physicians include on-call duties, research, teaching and conference attendance.

<sup>&</sup>lt;sup>7</sup> CDSSs tend to be more effective when used for managerial rather than for diagnostic purposes.

#### 1.3.3 Research Question 3

As demographic diversity increases, equity is one of the dimensions of quality of care (IOM, 2001) that has been attracting mounting attention. The outcomes of healthcare processes are affected by patient culture (e.g. Betancourt *et al.*, 2005), in general, and by patient language, in particular. For instance, patients with language barriers have been found to experience lower satisfaction while also consuming more resources (e.g. Brach *et al.*, 2005; Flores, 2006; Karliner *et al.*, 2007)<sup>8</sup>. In the particular case of Sweden, its multi-ethnical society encompasses a wide array of foreign languages (SCB, 2011). The interpreter services provided to compensate for language barriers have nevertheless been found wanting and in need of improvement (Fatahi, 2010). Suspicions that poor interpreter services may result in delays stress the importance of adequate interpreter services in treating conditions, such as ACS, in which timely care plays a vital role (Wallentin *et al.*, 2000). As ACSs remain major causes of death in Sweden (Socialstyrelsen, 2013a), lingering doubts about possible disparities in treating ACS patients with language barriers are of major concern.

RQ3: To what extent does language proficiency affect the delivery of care?

#### 1.3.4 Research Question 4

As previously described, timeliness is an important dimension of quality of care, for which the Swedish healthcare system has traditionally been criticized. Several countries, among them Sweden, have been attempting to overcome shortcomings in timeliness by defining targets for maximum waiting times (e.g. Hanning, 2005; Dimakou *et al.*, 2009). In Sweden, such initiatives have had only a limited effect on reducing waiting times (Socialstyrelsen, 2012), with the result that shortcomings in timeliness persist and alternative solutions must be found. Assuming that existing resources are sufficient to deliver timely care (Silvester *et al.*, 2004), poor timeliness is most likely caused by a mismatch between available capacity and patient demand for services. Moreover, decision support for managing waiting times may be lacking. It remains unclear whether the Lexis diagram (Lexis, 1875) might provide such decision support and contribute to reducing waiting times.

RQ4: How can the Lexis diagram be used to monitor lead times?

<sup>&</sup>lt;sup>8</sup> Healthcare providers may attempt to overcome language difficulties by making additional diagnostic tests and by reducing the requirements for the hospitalization of patients with language barriers.

#### Introduction

#### 1.3.5 Research Question 5

With respect to the quality of care, increased pressure is placed on healthcare providers to measure and report on the quality of care delivered in order to increase its transparency and accountability (Chassin *et al.*, 2010) and improve the quality of care (Nelson *et al.*, 2004). Nevertheless, measuring and reporting on healthcare quality may vary depending on whether the aim be improvement, research or accountability (Solberg *et al.*, 1997). To this end, quality registries have become increasingly popular, not only in Sweden but worldwide (e.g. Sousa *et al.*, 2006; Evans, Scott, *et al.*, 2011). Although quality registries hold promises of process improvements (Rosén and Sjöberg, 2010), they have been used mainly for research purposes (e.g. Larsson *et al.*, 2012). Consequently, there remain doubts about using quality registries for process improvement and how to bolster their use for this purpose.

RQ5: How can the use of quality registries for process improvement be enabled?

#### 1.3.6 The Relationship between Research Questions, Studies and Papers Appended

Figure 2 shows that each research question has given rise to a separate study, which *per se* resulted in a separate paper. Thus, appended Papers I, II, III, IV and V provide answers to research questions RQ1, RQ2, RQ3, RQ4 and RQ5, respectively. Considering the one-to-one relationship, research question, study and paper will be used interchangeably throughout the thesis.



*Figure 2* Relationships between research questions, studies and papers appended.

#### 1.4 Clarification of Key Concepts

The overarching concepts of this thesis are: Variation, Quality and Process. Definitions of and explanations of these concepts are provided in the theoretical framework. Specifically to the research questions, the theoretical chapter also elaborates on physician scheduling, CDSS, language barriers, Lexis diagram and quality registries.

#### 1.5 Scope of Research

All studies that comprise the thesis: (1) occurred in Swedish settings, (2) took place in healthcare settings, (3) occurred in publicly managed and financed settings, (4) concerned healthcare processes at the hospital level and (5) had an exploratory purpose. Moreover, the only patient group whose delivery of care was investigated was ACS patients (Studies 2 and 3)<sup>9</sup>. These delimitations have implications for generalizing the findings of this thesis and are discussed under Section 5.3.

### 1.6 Structure of the Thesis

This thesis consists of a seven-chapter Executive Summary and five appended papers. Concerning the Executive Summary, Chapter 1 starts by explaining the importance of understanding and managing variation and giving an historical account of the subject. As the challenges and current shortcomings in understanding and managing variation become apparent, the purpose of the thesis is introduced and decomposed into five research questions. The chapter ends with clarifications of key concepts and considerations on the scope of research. Chapter 2 includes some basic theories and concepts relevant to understanding quality of care. The chapter also elaborates on the nature of variation, as well as some tools and methods that are relevant to understanding and managing variation. Considerations of processes and process improvement have also been included. The initial part of Chapter 3 is dedicated to the overall methodological issues derived from the purpose of the thesis. Specifically, the chapter elaborates on the exploratory purpose of research, the case study design, as well as the complementarities between quantitative and qualitative research methods. It follows an account of the methods employed in the papers appended. Methodological motivations and implications for the quality of research are also provided. The chapter ends with an account of the research journey of the author. Chapter 4 describes

<sup>&</sup>lt;sup>9</sup> The remaining three studies concern processes that support delivery of care.

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the empirical setting of this thesis. *Chapter 5* summarizes the main findings of the papers appended. *Chapter 6* discusses the integration of the papers appended and how these papers relate to the ultimate objective of the thesis. The chapter also discusses the limitations of the research reported in this thesis and ends with some practical and theoretical implications of the research conducted. Finally, *Chapter 7* outlines some conclusions and reflections about understanding and managing variation in healthcare processes.

# 2 THEORETICAL FRAMEWORK

This chapter encompasses theories that are relevant in light of the purpose of the thesis. The theoretical aspects discussed essentially deal with the definition and assessment of quality of care (Section 2.1), the nature of variation and its management (Section 2.2.). Clarifications of the variation concept can be found in the next section (Section 2.3), which is followed by a section dedicated to the definition and improvement of processes (Section 2.4). A brief description of various methods and tools relevant to understanding and managing variation follows (Section 2.5). The chapter proceeds with more detailed explanations on the quality dimensions most directly impacted in the papers appended (Section 2.6).

### 2.1 Definition and Assessment of Quality

This section starts by giving an account of different definitions of quality and their evolution over time. The multidimensional character of quality is also discussed. A description of the factors affecting healthcare quality that need to be considered in its assessment follows.

#### 2.1.1 Definitions of Quality

Over time, quality has been defined in several ways. Initially, quality was defined as the ability to meet product specifications, but its definition evolved in such a way as to highlight the importance of meeting the needs and expectations of customers. Specifically, quality has been defined as "conformance to specifications" (Gilmore, 1974), "conformance to requirements" (Crosby, 1979), "fitness for use" (Juran and Gryna, 1993) and more recently as the "ability to satisfy, and preferably exceed, the needs and expectations of the customers" (Bergman and Klefsjö, 2010). The emphasis on the customer when defining quality is also present in Deming (1986), who states that "quality should be aimed at the needs of the customer, present and future". Montgomery (2004, p. 4) claims that "quality is inversely proportional to variability" and that "quality improvement is the reduction of variability in processes and products".

In the specific case of healthcare services, the definition of quality has been controversial for a long time (Legido-Quigley *et al.*, 2008). An influential definition is proposed by the U.S. Institute of Medicine, according to which "quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Lohr, 1990, p. 21). The Institute of Medicine also proposes that quality of care be considered from the perspective of six complementary and synergistic quality dimensions<sup>10</sup> (IOM, 2001, p. 41). Accordingly, healthcare processes should be: (1) "safe", i.e. injuries to patients should be avoided, (2) "effective" i.e. the provision of services should be based on scientific knowledge, (3) "patient-centered", i.e. services should be provided with respect for and responsiveness to individual patient preferences, (4) "timely", i.e. delays should be reduced, (5) "efficient", i.e. waste should be avoided and (6) "equitable", i.e. differentiated care motivated by personal characteristics of patients should be avoided (Figure 3). The definition of quality of care proposed by the Institute of Medicine has been criticized, for instance for being technocratic and resulting from a professional rather than a consumer view of quality (Berwick, 2009). According to this author, although the model distinguishes six dimensions, only safety and effectiveness are primary, which means that "in the end, 'timeliness' and 'patient-centeredness' are on the defensive as aims unless evidence shows that they affect health". Despite the criticism, the six-dimensional model has been disseminated to and adopted by other healthcare organizations (Socialstyrelsen, 2006).



Figure 3 The quality dimensions proposed by the Institute of Medicine (2001).

The decomposition of quality into several dimensions undertaken by the Institute of Medicine parallels that by Parasuraman *et al.* (1988), who identified the dimensions of service quality to include "reliability", "assurance", "tangibles", "empathy" and "responsiveness".

<sup>&</sup>lt;sup>10</sup> "aims for improvement", in the original source.

A parallel can also be drawn to the dimensions of product quality proposed by Garvin (1987), i.e. "performance", "features", "reliability", "conformance", "durability", "serviceability", "aesthetics" and "perceived quality".

#### 2.1.2 Assessment of Quality of Care

In the specific case of healthcare quality, Avedis Donabedian emerges as an iconic figure in defining and assessing quality (Best and Neuhauser, 2004a). According to Donabedian (1988), since "good structure increases the likelihood of good process, and a good process increases the likelihood of a good outcome", the quality of care can be measured by evaluating "structures", "processes" and "outcomes" (Figure 4). The author defines structures as "the attributes of the settings in which care occurs", processes as "what is actually done in giving and receiving care" and outcomes as "the effects of care on the health status of patients and populations". Examples of indicators of each kind include: (1) access to CT<sup>11</sup> scans, (2) the proportion of patients with AMI who undergo Percutaneous Coronary Intervention (PCI) and (3) returning to the operating theatre within 48 hours, respectively.



Figure 4 The framework for quality of care proposed by Donabedian (1966).

The pros and cons of using quality indicators are discussed by Willis *et al.* (2007), who claims that the criteria of "sensitivity and specificity", "validity" and "reliability" are of major importance in selecting and developing quality indicators. The same author discusses the advantages and disadvantages of "process measures" and "outcome measures" and asserts

<sup>&</sup>lt;sup>11</sup> CT stands for "Computed Tomography", a medical imaging procedure that uses X-rays to produce tomographic images or "slices" of specific areas of the body.

that, despite their meaningfulness from a patient perspective, outcome measures tend to occur over a longer period of time and be influenced by many factors not related to healthcare processes, such as nutrition, environment and lifestyle. Besides Donabedian, Nightingale and Semmelweis should also be credited for emphasizing the causal link between the process of delivering care and achieved outcomes. Dating from the mid-18<sup>th</sup> century, the works of Nightingale (Neuhauser, 2003) and Semmelweis (Best and Neuhauser, 2004b) showed the tremendously positive effect of hygiene, a process characteristic, on improving outcomes, such as mortality. Another major advocate of the causal link between processes and outcomes was Codman (Neuhauser, 2002). After the writings of Donabedian in the 1960s, the concept of process became increasingly popular and pervaded the literature on healthcare quality improvement to an increasing extent, even though the concept of process often appeared under alternative designations, such as "critical pathways "(Pearson *et al.*, 1995).

#### 2.2 The Nature of Variation and its Management

Shewhart and Deming were two of the most influential figures of the quality movement, see Best and Neuhauser (2005; 2006). Shewhart pioneered the use of statistics in understanding and managing variation in manufacturing settings and established the dual nature of variation. According to Shewhart (1931; 1939), it is possible to distinguish "assignable-cause variation", i.e. variation that originates from an "assignable cause"<sup>12</sup>, from "common-cause variation"<sup>13</sup>, i.e. variation that originates from a "common cause"<sup>14</sup>. Assignable causes of variation can be identified and ought to be eliminated (Bergman and Klefsjö, 2010) as the aim should be to achieve a condition under which variation is attributable exclusively to common causes. When a process has achieved such a state, it is said to be "in statistical control" or "stable and predictable". In the words of Shewhart, "a phenomenon will be said to be controlled when, through the use of past experience, we can predict, within limits, how the phenomenon may be expected to vary in the future" (1931, p. 6). The importance of understanding and managing variation is manifest in Deming's writings as well (1993), in which the author argues in favour of the necessity of creating a "system of profound

<sup>&</sup>lt;sup>12</sup> Also called *special cause*.

<sup>&</sup>lt;sup>13</sup> Also called *natural variation* or *noise*.

<sup>&</sup>lt;sup>14</sup> Also called *chance cause*.

knowledge" encompassing "appreciation for a system", "knowledge about variation", "theory of knowledge", and "psychology".

"Control limits"<sup>15</sup> denote the range of a process that is stable and predictable and ought not to be confused with "specification limits"<sup>16</sup>. A process may be in statistical control and still vield an unacceptably high fraction of defective items, i.e. items the quality characteristic of which lies outside the specification limits. Deming (1993) argues that there is no logical connection between control limits and specification limits, as control limits reflect what the process is and what it will do tomorrow, whereas specifications limits describe how the product should perform to meet customer expectations<sup>17</sup>. It is important to notice, however, that the predictability of future performance requires the process to be in a state of statistical control. In other words, "a process that is not in statistical control has no definable capability: its performance is not predictable" (Deming, 1993, p. 99). With regards to specification limits, Taguchi (1986) proposes that all deviations from the "target"<sup>18</sup> result in a loss and that since small deviations are probably of minor importance and associated with minor losses, such losses follow a quadratic pattern. This view contrasts with the "traditional view" of no incurred loss, as long as the parameter of interest is kept within specification limits (Figure 5). Despite criticism of the symmetry and ease of determination of the "loss function", Deming (1993) advocates that "the most important use of a loss function is to help us change



**Figure 5** To the left: the traditional view of no losses incurred, as long as the parameter of interest lies within specification limits. To the right: the view proposed by Taguchi, who argues that all deviations from the target result in a loss, and that such losses follow a quadratic pattern. USL and LSL stand for upper and lower specification limits, respectively.

<sup>&</sup>lt;sup>15</sup> Also called "natural process limits"

<sup>&</sup>lt;sup>16</sup> Also called "tolerance limits"

<sup>&</sup>lt;sup>17</sup> Some authors refer to this as the "voice of the process" as compared to the "voice of the customer".

<sup>&</sup>lt;sup>18</sup> The "target" is the aimed value of the quality characteristic and lies within the specification limits.

from a world of specifications (meeting specifications) to a continual reduction of variation about the target, through the improvement of processes" (p. 217).

## 2.3 Clarification of the Concept of Variation

In order for "variation" to exist, there must be at least two entities, for instance individual patients or groups being compared to each other or to a target. Variation expresses the natural condition of things to be different from each other or to depart from a pre-established target. In statistical terms, variation is synonymous with dispersion or spread and can be quantified by statistics, such as the range, the absolute deviation, the standard deviation, the variance and the inter-quartile range (e.g. Altman, 1991)<sup>19</sup>.

There is a panoply of terms synonymous with variation which tends to be used in a specific context with a certain connotation. Terms such as variety and diversity usually have a positive connotation, whereas deviation and disparity tend to be perceived negatively. Other terms that may be equated to variation include change, modification, mutation, alteration, shift, departure, discrepancy, divergence, dispersion, spread, difference and fluctuation. In this thesis, the variation concept is used in a broad sense<sup>20</sup>.

The concepts of difference, unjustified variation and disparity differ depending on the underlying causes. Differences in quality of care may be caused by justifiable causes, such as differences in patient baseline characteristics or randomness, or by unjustifiable causes. After correcting for the effect of justifiable causes, differences in quality of care become narrower and unjustified. However, unjustified variation<sup>21</sup> cannot be directly attributed to healthcare providers as it may be caused by legislation and other "non-random", "non-patient", "non-provider" related causes. Unjustified variations become provider-related only after correcting for the effect of contextual causes which cannot be managed by healthcare providers (Figure 6). In the context of equity, a disparity is synonymous with unjustified variation, whereas discrimination is synonymous with provider-related unjustified variation (IOM, 2003).

<sup>&</sup>lt;sup>19</sup> The author uses the term "variability".

<sup>&</sup>lt;sup>20</sup> Both in the sense of unwanted variations as well as wanted variations, i.e. variety, variatio delectat.

<sup>&</sup>lt;sup>21</sup> Also called unwanted or undesirable variations.



**Figure 6** Decomposition of the difference in observed quality of care in two entities according to its causes and ability of healthcare providers to control it, adapted from IOM (2003).

### 2.4 Definition and Improvement of Processes

The origins of "process improvement" can be traced back to the works of Shewhart (1931), who contributed to shifting the focus from controlling product characteristics to controlling the characteristics of the process itself<sup>22</sup>. Other prominent advocates of process improvement within the quality field include Ishikawa (1985), Deming (1986) and Juran (1989). Over time, a focus on processes has become a tenet of quality improvement (Dean and Bowen, 1994; Bergman and Klefsjö, 2010) and has pervaded several improvement programs, e.g. "Total Quality Management" (Hackman and Wageman, 1995), "Lean Production" (Womack et al., 1990) and "Six Sigma" (Schroeder et al., 2008). The initial statistical aspects of process control were supplemented by issues related to human resources management during the 1980s and 1990s (Dale et al., 2000), leading to the initial "process control" being substituted by "process management" and similar terms. There are several definitions of the process concept, which share, nevertheless, a number of common features. According to Palmberg (2009), the various definitions of the process concept revolve around the ideas of: (1) input and output, (2) interrelated activities, (3) horizontal structure, (4) value to the customer, (5) resource consumption and (6) repeatability. In this thesis, processes are defined as "networks of activities repeated in time and aimed at creating value to external or internal customers"

<sup>&</sup>lt;sup>22</sup> This led to the development of statistical methods such as SPC and DoE.

(Bergman and Klefsjö, 2010). The "p-diagram" (Phadke, 1989) provides a graphical representation of a process showing the "output" being influenced by a number of parameters, which can be classified into: (1) "input", i.e. parameters set by the user or operator to attain the desired outcome, (2) "controllable parameters", i.e. parameters that can be specified freely by the designer<sup>23</sup> and (3) "uncontrollable parameters", i.e. causes of variation that cannot be controlled<sup>24</sup> by the designer and that may cause the output to deviate from the target<sup>25</sup> (Figure 7). Uncontrollable parameters are often related to environmental, manufacturing and customer use conditions<sup>26</sup>.



Figure 7 Illustration of a generic process

The establishment of a process-oriented organization has been found to be associated with numerous positive effects. It may, for instance, enable the development of a common language within the organization, bolster cooperation, strengthen the focus of the organization on its customers, reduce costs as well as lead times, promote standardization and holism, and enhance learning abilities (Forsberg *et al.*, 1999; Garvare, 2002). Despite promises of high yield, the establishment and improvement of processes is replete with difficulties, e.g.: (1) identifying the main processes of an organization (Biazzo, 2002), (2) controlling processes that have grown boundless and inefficient (Garvin, 1988) and (3) overcoming potential power struggles between function and processes may be more easily said than done (Hellström *et al.*, 2010). Organizational ability to accomplish such improvement should therefore be seen as a continuum rather than a dichotomous variable (Hellström and Eriksson, 2008).

<sup>&</sup>lt;sup>23</sup> E.g. choice of materials.

<sup>&</sup>lt;sup>24</sup> For either economical or technical unfeasibility.

<sup>&</sup>lt;sup>25</sup> Alternative terminology: "output", "response", or "quality characteristic"; "parameter" or "factor"; "input" or "signal factor"; "controllable parameter" or "control factor"; "uncontrollable parameter" or "noise factor".

<sup>&</sup>lt;sup>26</sup> Uncontrollable factors are expected to vary randomly with possibly known distribution parameters (e.g. mean and variance) but unknown values in a specific situation, e.g. room temperature and wear due to aging.

Despite the profusion of terms and definitions<sup>27</sup>, "process improvement" can be condensed into the ideas of shifting focus from function to interlinked processes, creating customer value-adding activities, and monitoring and improving performance (Benner and Tushman, 2003). Five steps may be distinguished in process improvement (Figure 8): (1) "organizing for improvement", the purpose of which is to ensure success by building leadership, understanding and commitment, (2) "understanding the process", the purpose of which is to understand all the dimensions of the current business process, (3) "streamlining"<sup>28</sup>, the purpose of which is to improve the efficiency, effectiveness, and adaptability of the process, (4) "measurements and control", the purpose of which is to implement a system to control the process for on-going improvement and (5) "continuous improvement", the purpose of which is to implement a continuous improvement process (Harrington, 1991).



Figure 8 The five steps in process improvement (Harrington, 1991).

#### 2.5 Methods and Tools for Understanding and Managing Variation

There is a wide array of methods and tools used for understanding and managing variation. Although the methods and tools described below may not be explicitly addressed in the papers appended, their inclusion in this section serves the purpose of completeness. This section starts by giving an account of SPC and DoE, two methods fundamental to understanding and managing variation. Subsequent methods, such as Six Sigma and Robust Design Methodology (RDM), are also addressed. The inclusion of Six Sigma owes its existence to several healthcare applications of the method, some of which have yielded admirable results. The account on RDM is deemed necessary as it offers an alternative view of understanding and managing variation. Other methods and tools owing their relevance to

<sup>&</sup>lt;sup>27</sup> Terms akin to "process improvement" include "process control", "process orientation", "process management", "process re-engineering" and "value chain management".

<sup>&</sup>lt;sup>28</sup> As an approach, "process improvement" should be interpreted in a broad sense and not strictly as "streamlining" the process.

Study 2 include "clinical practice guidelines", "checklists" and CDSSs. For their relevance to Study 5, "clinical quality registries" and "league tables" have been included<sup>29</sup>. A brief description of the "Lexis diagram" (Study 4) is also provided.

#### 2.5.1 Statistical Process Control

Based on the ideas of Shewhart about variation, SPC (Montgomery, 2004) aims at identifying assignable causes of variation and eliminating them as rapidly as possible. An important remark concerning the distinction between "assignable" and "common causes of variation" is made by Lillrank and Kujala, who emphasize the relativity of the distinction<sup>30</sup> and conclude that "the very foundation of objective, scientifically grounded SPC appears to be a social construct" (2006). Explanations of the dual nature of variation and its management additional to those given in Section 2.2, can be found in Nolan and Provost (1990), Berwick (1991) and Batalden and Stoltz (1995). Berwick (1991) claims that the idea of controlling variation strikes fear into healthcare professionals, who commonly argue that "this matter of quality control may be fine for manufacturing, but I am a physician and I don't make widgets", or "medicine isn't like making cars, as the product is not uniform and every patient is different"<sup>31</sup>. Regardless of the fears of and criticism from healthcare providers, SPC has been found to have broad applicability to healthcare processes (Thor et al., 2007). However, the authors caution that the application of SPC is, "paradoxically, both simple and difficult at the same time" and that "its power hinges on correct and smart application, which is not a trivial task" (ibid.). Some authors advocate the complementarity of SPC and Randomized Control Trials (RCTs) (Bowen and Neuhauser, 2013) and explain that SPC is mostly suitable for healthcare managers, whereas RCTs are suitable for clinical researchers. The authors argue that RCTs give little guidance on which patients that benefit most or least from the treatment and that statistically significant RCTs can even be hurtful for some

<sup>&</sup>lt;sup>29</sup> Although there are other methods and tools that can be useful to understanding and managing variation, they were excluded because of their less conspicuous connection to either understanding and managing variation in general or to the scope of the papers appended in particular. This is the case of "Design for Six Sigma", "Variation Risk Management", "Lean Production", RCTs, "Experience-Based Design", "Focused Factories" and "Hospital Accreditation".

<sup>&</sup>lt;sup>30</sup> The authors consider the distinction to be relative as it depends on the "level of knowledge of an actor", "economic means" and "where system boundaries are put".

<sup>&</sup>lt;sup>31</sup> The punctuation in the quotes has been changed.

patients. Furthermore, besides RCTs, it is important to understand the context and the key determinants of variation (ibid.).

The "control chart" is a frequently used tool within SPC. It allows the graphical monitoring of quality characteristics over time and the detection of plotted measurements that lie outside the predefined limits calculated based on previous observations (Ogrinc et al., 2012)<sup>32</sup>. Although control charts enable detecting the existence of assignable causes of variation, they provide no guidance for identifying the cause<sup>33</sup> (Chakhunashvili, 2006). Control charts should be designed in order to signal the occurrence as soon as possible of an assignable cause of variation, keeping the rate of occurrence of false alarms as low as possible. Frequently, both the location and variability of quality characteristics need to be monitored. The range of control charts available is immense. Examples of using control charts in improving healthcare processes can be found in Carey and Lloyd (1995), Alemi and Neuhauser (2004), Mohammed et al. (2008), Peden and Rooney (2009), and Ernst et al. (2010). On the differences between healthcare and industry applications of control charts, Woodall (2006) claims that in healthcare applications, the use of attribute data is much more prevalent and that there is a much greater use of control charts based on counts or time between failures. Moreover, the author associates healthcare applications of control charts with a greater necessity of risk-adjusted outcomes, a reduced emphasis on sampling, and the impossibility of rapidly restoring in-control status. When comparing the performance of healthcare providers, some authors advocate the use of control charts in lieu of leagues tables (Mohammed et al., 2001; Mohammed et al., 2008).

#### 2.5.2 Design of Experiments

The origins of DoE are often traced back to the works of British biologist and statistician Ronald Fisher in the 1920s and 1930s. A great deal of the author's pioneering work dealt with agricultural applications of statistical methods, which, over time, were expanded to other applications. Prior to the formalization of the DoE method achieved by Fisher, there were relevant experiments that deserve mentioning. An example is the case of the controlled experimentation on scurvy undertaken by Scottish military surgeon James Lind on board the

<sup>&</sup>lt;sup>32</sup> An interesting metaphor provided herein equates using a control chart to driving on a road with good visibility forward, as well as backward by means of a rear mirror.

<sup>&</sup>lt;sup>33</sup> To identify the cause, one can resort to root cause analysis, quality control tools or DoE.

HMS Salisbury in 1747<sup>34</sup>. In the experiment, 12 sailors suffering from scurvy were divided into six groups, each of which received a different supplement to the basic and common diet for a two-week period. The supplements were potential cures empirically selected rather than rationally derived. Methodologically, Lind's feat involved working with groups that were as similar as possible while maintaining them throughout the experiment under similar conditions (Hughes, 1975).

"Design of experiments" or "experimental design" (Box et al., 2005; Montgomery, 2013) is the body of knowledge on conducting experiments in such a way that a minimum of resources yield a maximum of information about a process. The basic approach of DoE consists of creating disturbances in a process and then studying the reactions taking place in the process. In the context of DoE, the experimenter faces problems related to: (1) the complexity resulting from a large number of variables affecting an outcome, (2) the inevitable experimental error and (3) the potential confusion between correlation and causation. There are three basic design strategies, to which the experimenter may resort: (1) randomization, i.e. to avoid systematic errors, the order of tests in the experiment may be randomly determined, (2) replication, i.e. to obtain more precise results, each test may be independently repeated, and (3) blocking, i.e. the experimental material can be apportioned to become more homogenous than the aggregate material, thus obtaining greater precision. A diversity of designs is encompassed by DoE. Factorial design, for instance, is a subset of DoE, which, contrary to one-factor-at-a-time design, allows factors to be changed at the same time and is, therefore, suitable for studying potential interactions of factors. Finally, despite the strong orientation of DoE towards statistical techniques, appropriate subject matter knowledge and experience play an essential role.

#### 2.5.3 Six Sigma

Six Sigma (Harry and Schroeder, 1999; Magnusson *et al.*, 2003) originated with the improvement programs run by Motorola during the 1980s and by General Electric during the 1990s. Essentially, Six Sigma is a methodology that aims at reducing variation in process outputs to a level of 3.4 defects per million opportunities<sup>35</sup>. Six Sigma projects are strongly

<sup>&</sup>lt;sup>34</sup> Later described by James Lind in "A treatise of the scurvy", published in 1753.

<sup>&</sup>lt;sup>35</sup> This level corresponds to a process variation equal to one-sixth of the half-width of the tolerance interval, allowing for a 1.5 standard deviation shift for long-term variation of the process mean.

based on statistical tools and are typically conducted according to the DMAIC cycle, i.e. Define-Measure-Analyse-Improve-Control. To be able to meet the challenging requirements of Six Sigma projects: (1) process variation may be reduced, (2) the process mean may be centered or (3) tolerances may be relaxed (Harrington and Trusko, 2005).

Despite the fact that manufacturing continues to be the focus of Six Sigma initiatives, demonstrable results have also been seen in service-focused environments (Sehwail and DeYong, 2003). There are nevertheless differences that need to be considered when applying Six Sigma to healthcare settings since the "delivery of patient care is largely a human process, and the causes of variability are often more subtle and difficult to quantify" (ibid.). Woodard (2005) argues that "the future of Six Sigma is promising" and that "Six Sigma, when implemented with vigor and dedication, can be used to effectively eliminate variation of quality in healthcare". For Harrington and Trusko (2005), "the Six Sigma approach is in its infancy in the healthcare industry".

The prevalence of defects in healthcare varies greatly. For instance, it is estimated that the treatment of depression is running below the 2-sigma level<sup>36</sup>, whereas deaths caused by anaesthesia during surgery hover around a 5 to 6 sigma level (Chassin, 1998; Ettinger, 2001; Harrington and Trusko, 2005). The success in reducing deaths caused by anaesthesia<sup>37</sup> is attributable to "a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines, and other systematic approaches to reducing errors" (Chassin, 1998). Allen *et al.* (2010) provide an example of the application of the DMAIC cycle for improving a hospital discharge process. The DMAIC cycle has also been applied to streamline the diagnosis for chest pain (Kumar and Thomas, 2010). Additional information on the application of Six Sigma to healthcare settings can be found in Trusko *et al.* (2007) and Lifvergren *et al.* (2010).

#### 2.5.4 Robust Design Methodology

Understanding and managing variation has hitherto been essentially described as finding and eliminating assignable causes of variation. However, another approach can be distinguished that aims not at finding or eliminating assignable causes of variation, but at

<sup>&</sup>lt;sup>36</sup> About 58% of patients with depression are not being detected or adequately treated.

<sup>&</sup>lt;sup>37</sup> In the 1970s and 1980s, deaths related to anesthesia occurred at rates of 50 to 100 per million, whereas anesthesia deaths may currently be as rare as 5 per million cases.

minimizing their detrimental effect on important quality characteristics. Chakhunashvili (2006) compares the two approaches, i.e. the "variation reduction model" and the "variation insensitivity model", and discusses their integration. The author adds that the latter approach may be particularly useful when assignable causes of variation remain unknown or their elimination unfeasible, on the grounds of costs or other factors.

Taguchi (1986) distinguishes between "on-line" and "off-line" quality control methods, with the former referring to efforts applied during the production phase and the latter referring to efforts during the design phase. Thus, Chakhunashvili (2006) argues that SPC and RDM are complementary methods, as SPC deals mainly with production, whereas RDM is primarily applicable to the upstream design phase. RDM can be defined as undertaking systematic efforts to increase the robustness of a process, i.e. increasing the characteristic of a process to be insensitive to uncontrollable parameters, thus contributing to the attainment of outcomes that are more stable (Arvidsson and Gremyr, 2008)<sup>38</sup>. Becoming insensitive to causes of variation that cannot be managed by means of SPC may sometimes be the only feasible alternative to further decreasing process variation (Chakhunashvili, 2006).

Due to the influence of uncontrollable parameters, variation in the output of processes is unavoidable (Figure 7). The basic tenet of RDM is to use controllable parameters to reduce the detrimental influence of uncontrollable parameters in the output. As relationships between parameters and outcomes may be nonlinear, different parameter combinations may yield different variations in outcomes. Thus, the basic approach of RDM is to exploit nonlinear relationships to find a parameter combination that yields the smallest variation in output and uses linear relationships to shift the outcome towards the target (Phadke, 1989). In contrast to normal operating conditions, uncontrollable parameters can be controlled in a laboratory environment. However, even in experimental situations, there are uncontrollable parameters that cannot be controlled, i.e. random uncontrollable parameters (Clausing, 1998). As mentioned in Section 2.3, uncontrollable parameters are often related to environmental, manufacturing or customer use conditions. RDM can also be found in the literature under the designation "Taguchi Methods" or "Quality Engineering". Explanations of the essence of Taguchi's ideas can be found in Hunter (1985) and Kackar (1989). RDM is

<sup>&</sup>lt;sup>38</sup> The referred authors use the terms "product" instead of "process" and "noise factors" instead of "uncontrollable parameters".

further addressed in the doctoral theses of Arvidsson (2003), Gremyr (2005) and Hasenkamp (2009).

#### 2.5.5 Clinical Practice Guidelines

"Clinical practice guidelines"<sup>39</sup> can be defined as "systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services, and outcomes" (IOM, 1992, p. 27). Several studies have reported low rates of adherence to clinical practice guidelines, a problem that, according to Eagle *et al.* (2003) needs to be confronted by healthcare providers since "professional societies play a critical role in moving from guideline development to application". This existence of a wide gap between science and practice is corroborated by McGlynn et al. (2003), who found that adults in the United States received 55% of recommended care. Similarly, Lenfant argues that "enormous amounts of new knowledge are barreling down the information highway, but they are not arriving at the doorsteps of our patients" (2003). The barriers to physician adherence to guidelines include a lack of familiarity, a lack of awareness, a lack of agreement, a lack of motivation, as well as patient and environmental factors (Cabana et al., 1999). Referring to the specific case of central-line insertion, Spear (2005) adds that "guidelines are generic to all hospitals and do not take into account the idiosyncratic factors of patient, place, and worker that are the root causes of individual infections". In a similar vein, Rasmussen (2003) argues that guidelines do not take into consideration the provider from a socio-technical point of view. Redfern and Christian (2003) highlight the need for managing change, as "successful implementation [of guidelines] is a function of the relation between the nature of evidence, organizational context and mechanisms for facilitating the process of change". Berwick (2003) stresses the importance of compatibility between an innovation and the "values, beliefs, past history, and current needs of individuals" if innovations are to be rapidly disseminated.

Despite widespread promulgation, these guidelines have had a limited effect on changing physician behavior (Lomas *et al.*, 1989). Davis and Taylor-Vaisey (1997) investigated different strategies for promoting adherence to guidelines and found that "reminder systems", "academic detailing" and "multiple interventions" were the most effective. Grol and Grimshaw (2003) found that "reminders" and "computerized decision support" are most effective in promoting guideline adherence. Along the same lines, van Achterberg *et al.* 

<sup>&</sup>lt;sup>39</sup> Along this thesis, *clinical practice guidelines, practice guidelines* and *guidelines* are used interchangeably.
(2008) argue that "strategies such as reminders, DSS [decision support systems], IT [information technology], etc. may encourage implementation of evidence and innovations". In a recent systematic review, Prior *et al.* (2008) found that "effective implementation strategies included multifaceted interventions, interactive education and clinical reminder systems" and that "didactic education and passive dissemination strategies were ineffective".

Drawing on the views of healthcare professionals on clinical practice guidelines, Davis *et al.* (2007) claim that managers and policy-makers look favorably on increased standardization and uniformity between healthcare professionals whereas the latter are "less enthusiastic about moves towards greater codification and transparency in clinical practice" (p. 23). The views on clinical practice guidelines also diverge among healthcare professionals, as claimed by McDonald *et al.* (2005), who assert that "doctors rejected written rules, instead adhering to unwritten rules of what constitutes acceptable behaviors for members of the medical professionalism and criticized doctors for failing to comply with guidelines". On the perceptions of healthcare providers towards these guidelines, Tunis *et al.* (1994) argues that "many respondents [internists] anticipate that guidelines may threaten physician autonomy, figure in disciplinary actions against physicians, and decrease satisfaction with the practice of medicine" and that "many also believe that guidelines may increase health care costs, and few expect defensive medical practices to decrease".

Guidelines differ in terms of the degree of recommendation and generalizability. Based on the strength of the underlying evidence and the degree of homogeneity of patients, Sanderlin and AbdulRahim (2007) explain that guidelines are given different degrees of recommendation. They add that guidelines based on more stringent inclusion and exclusion criteria are less generalizable to an entire population and that the application of guidelines requires consideration of the patient disease burden, patient values and context and other practical barriers to guideline implementation.

### 2.5.6 Checklists

According to Emerton *et al.* (2009), "the origins of checklists lie in the aviation industry, where technological advancement surpassed a pilot's capability to remember all the procedures necessary to fly a new advanced plane". The complexities of intensive care are

thoroughly described in Gawande (2007), who further emphasizes the prevalence and injurious effects of central-line infections<sup>40</sup>. To reduce such infections, a checklist was introduced in connection with the MHA Keystone ICU project (Pronovost *et al.*, 2006). The authors who implemented this "simple and inexpensive intervention" found that "there was a reduction in the rate of catheter-related bloodstream infection of 66% at 16 to 18 months after implementation" (ibid.). Several other checklist initiatives have resulted in improvements. De Vries *et al.* (2010) report the case of a multidisciplinary surgical safety checklist, the use of which was associated with "reductions in complications and mortality among adults undergoing general surgery in hospitals that have a high baseline standard". In another study, Haynes *et al.* (2009) found that the "introduction of the WHO Surgical Safety Checklist into operating rooms in eight diverse hospitals was associated with marked improvements in surgical outcomes". More precisely, "postoperative complications fell by 36% on average, and death rates fell by a similar amount" (ibid.).

The positive effects associated with using checklists are stressed by various authors. Bates (2002) claims that checklists can enhance patient safety, as in the case of nosocomial hypoglycemia, a situation in which "checklists can be very useful and should be more widely used". By the same token, de Vries *et al.* (2010) state that checklists may lead to "improved outcomes by improving teamwork, communication, and attitudes towards quality and safety". Trucco and Lorenzi (2010) argue that checklists can serve the purposes of real-time control, benchmarking and monitoring over time, help assessing risks, and act as sources of information for improvement work. Goldmann (2011) emphasizes the high potential of checklists as devices for collecting data. Advantages and disadvantages of using checklists are discussed by Birkmeyer (2010), who argues that "checklists seem to have crossed the threshold from good idea to standard of care". However, the same author cautions against perceiving checklists as a panacea, since "for example, they will not eliminate the variation in the surgeon's inherent skill and the proficiency conferred by procedure volume and experience" (ibid.).

Although checklists hold the promise of high yield, their introduction in practice seems to be replete with difficulties. In agreement, Bosk *et al.* (2009) state that "even if based on rigorous evidence, [checklists] have never penetrated medicine in the way they perhaps ought to have" and add that "the reasons for this are primarily social and cultural". The authors

<sup>&</sup>lt;sup>40</sup> Also called "catheter-related bloodstream infections".

proceed in arguing that "checklists are weak interventions" in the sense that "they are simple reminders of what to do, and unless they are coupled with attitude change and efforts to remove barriers to actually using them, they have limited impact" (ibid.). Conversely, Haynes *et al.* (2009) consider that, in their study, the introduction of a checklist proved to be "neither costly nor lengthy". Despite abundant evidence of the positive effects of checklists, little is known about how to develop them effectively. Hales *et al.* (2008) share this view and add that "checklist development should not be static, but an ongoing process involving expert groups, up-to-date literature, and feedback from the intended users, as well as the target audience".

## 2.5.7 Clinical Decision Support Systems

Berlin et al. (2006) argue that "CDSSs are highly variable in design, function, and use", which may explain the lack of consensus on the definition of CDSSs. A common definition is provided by Wyatt and Spiegelhalter (1991), who define medical decision aids as "active knowledge systems which use two or more items of patient data to generate case-specific advice". Similarly, Sim et al. (2001) define CDSSs as "software designed to be a direct aid to clinical decision-making, in which the characteristics of an individual patient are matched to computerized clinical knowledge base and patient-specific assessments а or recommendations are then presented". CDSSs can be either active or passive depending on whether the information is generated automatically with no preceding request (Toth-Pal, 2007). CDSSs can be applied to many different types of clinical tasks, such as "alerts and reminders", "diagnostic assistance", "therapy critiquing and planning", "prescribing decision support systems", "information retrieval" and "image recognition and interpretation" (Coiera, 2003).

In general terms, CDSSs are associated with "improved patient safety", "improved quality of care" or "improved efficiency in health care delivery" (Coiera, 2003). In a review of the evidence of the effects of CDSSs on clinician performance and patient outcomes, Johnston *et al.* (1994) concluded that "strong evidence suggests that some CDSSs can improve physician performance". In agreement, Classen (1998) claims that "the ability of CDSSs to affect clinical practice and health care quality is enormous". More specifically, Hunt *et al.* (1998) argue that "CDSSs can enhance clinical performance for drug dosing, preventive care, and other aspects of medical care, but not convincingly for diagnosis". Previous systematic reviews have demonstrated the greater effectiveness of CDSSs in hospital compared with ambulatory care

(Pearson *et al.*, 2009) and for the management of acute rather than chronic conditions (Sintchenko *et al.*, 2007). However, the effects of CDSSs on patient outcomes and costeffectiveness remain unclear (Johnston *et al.*, 1994; Hunt *et al.*, 1998). CDSSs appear to increase adherence to guidelines (Johnston *et al.*, 1994; Shiffman *et al.*, 1999; Sim *et al.*, 2001). This idea is also defended by Classen (1998), who argues that CDSSs "can transform oftenignored guidelines into dynamic programs that offer real-time patient-specific management advice". CDSSs, in particular computerized physician order entry, have the ability of decreasing the rate of medical errors, thus promoting patient safety. In a study conducted by Bates *et al.* (1998), the use of a CDSS was found to be associated with a decrease in serious medical errors from 11 to 5 events per 1,000 patient-days. Information technology should, however, not be perceived as an elixir for all ills associated with medical errors, a view conveyed by Bates *et al.* (2001), according to whom "although information technology can help reduce errors [...], it can also cause errors".

Payne (2000) distinguishes three characteristics of a successful CDSS: (1) "giving patientspecific recommendations", (2) "saving time" and (3) "[being] incorporated into workflow". In a study undertaken by Varonen et al. (2008), it was found that "physicians had relatively positive attitudes towards the idea of CDSS". The same study allowed the authors to identify several facilitators and barriers to using CDSSs. The major facilitators identified were simplicity, ease of use, flexibility and reliability of the CDSS. Conversely, the authors identified practitioner concerns about the physician-patient relationship, practitioner previous experiences of poor healthcare information systems, and practitioner concerns about professional autonomy. Concerning the broader category of computer systems, O'Connell et al. (2004) argue that "among factors that may affect user satisfaction with computer systems are gender, age, and computer sophistication or familiarity with technology". These authors also highlight the importance of user satisfaction for the successful implementation of computer systems, "since successful implementations generally require satisfied users, understanding what factors affect satisfaction can improve chances of a system's success" (ibid.). The importance of adapting CDSSs to the needs of healthcare providers is also stressed by Classen (1998), who argues that "local customization of CDSSs is necessary to fit local practice patterns, local standards of care, and local workflow issues".

Concerning the dissemination of CDSS, Wong *et al.* (2000) consider it limited and explain that "several factors continue to inhibit their [CDSSs'] widespread diffusion, including the organizational turmoil [...], and the lack of uniform data standards". As reasons for the failure of many CDSSs, Coiera (2003) indicates: (1) dependence on other information systems, (2) poor human interface design, (3) poor fit into the routine process of care, and (4) reluctance or computer illiteracy of some healthcare providers. Commercially available CDSSs have been found to vary widely in their capability (Wright *et al.*, 2009). Recent reviews of the factors impacting the uptake of CDSSs and the characteristics of effective CDSSs are provided by Moxey *et al.* (2010) and Bates *et al.* (2003), respectively.

### 2.5.8 Clinical Quality Registries

"Clinical quality registers" are a particular subset of clinical registers and aim to "improve the safety or quality of health care provided to patients by [systematically] collecting key clinical information from individual healthcare encounters which enable risk-adjusted outcomes to be used to drive quality improvement" (ACSQHC, 2008). The system or organization governing a register is known as the "registry" (ibid.). The development of new clinical quality registries gains international momentum as "in addition to providing information on the safety and efficacy of treatment, data from registries can also be used to determine whether patients have timely access to care, and whether care is delivered in line with best practice and evidence-based guidelines" (McNeil et al., 2010). According to Evans et al. (2011), clinical quality registries yield benefits for patients and physicians, as they "improve outcomes by engaging clinicians using credible data and fostering competition, enable the improvement of physician practice and contribute to advancements in epidemiology". Concerning the target of clinical quality registries, they should primarily focus on "high-cost areas of medicine with known or suspected variation in processes or outcomes that may indicate inappropriate care or inefficient use of limited resources" (Evans, Scott, et al., 2011). On the relationship between registries and RCTs, Gitt et al. (2010) argue that they are complementary, as "registries can identify novel associations, generating hypotheses for future RCTs" at the same time as "registries have an important role in validating trial findings in groups that are excluded or under-represented". In addition, due to the heightened risk of unforeseeable confounders resulting from the non-random allocation of patients to treatments, the authors caution against findings from prospective registries. Evans et al. (2011) praise registries for their "increasingly important role as a stimulus for quality improvement", owing to the provision of high-quality data and analyses that are respected by clinicians.

#### 2.5.9 League tables

Adab *et al.* (2002) write that "league tables are an established technique for displaying the comparative ranking of organizations in terms of their performance". Concerning league tables, several authors forewarn of the need of case-mix adjustment as even "small differences in case-mix can have significant effects on 'crude' measures of outcome" (Leyland and Boddy, 1998). Salem-Schatz (1994) expresses concern about using crude measures and informs that in a specific study "three quarters of the physicians identified as statistical outliers [...] were no longer identified as such with use of a case-mix-adjusted measure". Similarly, rankings of hospitals by death rates have been found to be sensitive to adjustments for the severity of disease, which makes comparison of crude death rates potentially misleading (McKee, 1997). Hence, the author recommends studying differences in death rates in a collaborative rather than confrontational way. Control charts are suggested as alternatives to league tables, as the former avoid stigmatization of poor performers and stress the need of continuous improvement (Adab *et al.*, 2002). The need for case-mix adjustment is also emphasized by Orchard (1994), who, however, considers case-mix adjustments to be costly and nontrivial.

### 2.5.10 The Lexis Diagram

The Lexis diagram was initially proposed in the 19<sup>th</sup> century by German statistician and economist Wilhelm Lexis for the purpose of monitoring over time the longevity and number of individuals within a given geographical area (Lexis, 1875). The Lexis diagram is a coordinate system with calendar time as the abscissa and age as the ordinate. Each individual is represented by a line segment of unit slope as both axes increase over time. The line segments are anchored by the abscissa according to the birth date of the individuals and terminate with their death or migration out of the geographical area under examination (see Figure 9). Lexis diagrams are commonly used as graphical representations of events that occur in calendar time and age, such as the incidence of death or disease. Thus, the diagram is useful for describing mortality and morbidity (Keiding, 1990; Cohen and Naumova, 2011).



*Figure 9* A typical Lexis diagram of ten individuals of varying longevity. At time T, the geographical area of interest is populated by seven individuals whose longevity varies from approximately 5 to 45 years.

#### 2.5.11 Differing Perspectives on Understanding and Managing Variation

Although clinical researchers, healthcare managers, and individual patients share a willingness to improve the quality of care, their perspective on how to understand and manage variation differs (Bowen and Neuhauser, 2013). Associated with each perspective, there are methods and tools that are especially suitable for answering the type of question that interests each stakeholder. Thus, RCT, randomization, risk-adjustment are key words for the clinical researcher, whereas monitoring process and outcomes, best practices and benchmarking are key words for healthcare managers. As patients are mainly interested in evaluating and understanding the variation in outcomes of their own health, "N-of-1 trials" and longitudinal factorial designs may be preferable. Each stakeholder brings a different perspective, set of methods and tools that are often complementary. Table 4 was extracted from Neuhauser *et al.* (2011) and illustrates the different perspectives of clinical researchers, healthcare managers, and individual patients. Other authors have stressed the differences between clinical research and practice with regard to variation.

Davidoff (2009), for instance, claims that "medicine is therefore ambivalent about the influence of heterogeneity on outcomes" and that "determining effect sizes by merging outcome data from groups of study participants obscures the reality that clinical interventions rarely work for everyone and under all circumstances". Moreover, the author claims that: (1) the promises of "personalised medicine" resulting from the explosion in molecular genetics and (2) the increasing awareness of the importance of contexts in improving the quality of care, will contribute to "bringing the focus of clinical evidence back down from the homogenised 'outer space' of controlled trials to the ground level of individual patient experience, with its inherent variability" (Davidoff, 2011).

**Table 4** Meaning of variation to managers, researchers and individual patients: questions, methodsand time frames. This table was originally reproduced in Neuhauser et al. (2011).

Role	Question	Methods	Time frame	Variation
Health managers	Are we getting better?	Control charts	Real-time, months' variation	Creating stable processes, learning from special cause
Clinical and health-service researchers	Other things equal, does A cause B?	RCT, regression models	Not urgent, years	Eliminate special-cause variation, test for significance, focus on mean values
Individual patient (and provider)	How can I get better?	Longitudinal, factorial designs	Days, weeks, lifelong	Help in understanding the many reasons for variation in health

# 2.6 Further Explanations of Selected Quality Dimensions

This section builds on the six-dimensional model of quality of care presented in the initial section of the chapter. Under this heading, further explanations are given on the quality dimensions that were most directly addressed in the papers appended, i.e. Timeliness (Papers 1 and 4), Effectiveness (Paper 2) and Equity (Paper 3).

#### 2.6.1 Timeliness

Shortcomings in timeliness appear under many forms in the literature, e.g. delays, waiting times, queues and waiting lists. Although timeliness may be subordinate to other dimensions of quality of care (Burge *et al.*, 2004; Conner-Spady *et al.*, 2008), shortcomings in timeliness almost invariably impact negatively on the satisfaction of both patients and healthcare providers (Murray and Berwick, 2003; Lukas-Vandeusen *et al.*, 2004). Furthermore,

shortcomings in timeliness appear to be symptomatic of the existence of inefficiencies in healthcare processes (Lacy et al., 2004; Garg et al., 2010). Although some studies were unable to find a detrimental effect of poor timeliness on postoperative outcomes (Ray et al., 2001; Mahon et al., 2002; Légaré et al., 2005), much evidence exists on the harmful effects of waiting (Davies, 1999; Natarajan et al., 2002; Sobolev et al., 2003; Légaré et al., 2005; Sobolev et al., 2006; Hodge et al., 2007; Prentice and Pizer, 2007; Sobolev et al., 2008; Valente et al., 2009). There is also evidence of poorer postoperative outcomes after a prolonged wait for surgery (Davies, 1999; Hodge et al., 2007). The pernicious effects of poor timeliness are elegantly expressed by Mahon et al. (2002), who asserts that "the wait's impact is borne by individual patients and society through the effects of pain, reduced function, lost productivity and the need for medical therapies (e.g., analgesics) and community resources". For some authors, waiting lists are inevitable (Black, 2004) and they do more than serve bureaucratic functions (Lewis et al., 2000). Several advantages may be associated with waiting lists (Davies, 1999; Brown et al., 2002; Black, 2004), for instance by: (1) ensuring a steady demand for healthcare resources, (2) permitting an interesting mix of cases, (3) providing a period for the spontaneous resolution of symptoms and (4) allowing time for reconsideration of or preparation for a procedure. Lewis et al. (2000) note that waiting time is a better indicator of shortcomings in timeliness than the length of waiting lists, and Hodge et al. (2007) argue that reported waiting times are substantially underestimated in their current definition. Various governments have attempted to promote timeliness in the delivery of care by instituting national maximum waiting time guarantees and targets (Hanning, 1996). These appear to contribute to reducing waiting times (Dimakou et al., 2009), albeit at the risk of distorting clinical priorities (Appleby et al., 2005).

There are many misconceptions about the genesis and management of queues in healthcare. Silvester *et al.* (2004) shed light on the subject by formulating four hypotheses on the formation of queues: (1) demand is greater than capacity, (2) demand and variation are out of phase, (3) queues enable full utilization of resources and (4) queues inhibit patients from seeking care. The argument of insufficient capacity as the cause of poor timeliness is refuted by several authors who claim that "lack of capacity is typically not a major issue" (Silvester *et al.*, 2004), "in many cases, delays are not a resource problem" (Haraden and Resar, 2004) and that "14 outpatient specialty clinics show statistically significant improvement in reducing delays without adding capacity" (van der Voort *et al.*, 2010). Likewise, some authors recall that the constancy of waiting times and length of waiting lists in many healthcare

organizations contributes to rebutting the claim for additional resources since a shortage of capacity would lead to indefinitely growing queues (Brasted, 2008; Pandit et al., 2010). For Silvester et al. (2004), "the primary reason for waits is variation and a mismatch between capacity and demand". Resulting imbalances cause peaks and valleys that pose problems for both staff and patients. According to Pierskalla and Brailer, (1994) "the valleys create a situation of excess contracted labor. The peaks create congestion and, because of difficulties in finding appropriately trained personnel on short notice at typical wages, they can lead to patient dissatisfaction, lower quality and higher operating costs". Consistent with this view is that of Walley et al. (2006), who advocate that "delays are mostly caused by a lack of attention to variation". In a similar vein, Harper and Gamlin (2003) argue that matching supply to demand offers the possibility of efficiency gains with no need for extra resources. Evidence of the negative effects of excessive variation in capacity is reported by Wijeysundera et al. (2010), who found that "These disparities<sup>41</sup> are partially explained by variations in supply of both procedural capacity and physician services, most notably in elective and semi-urgent patients". Also Hashimoto and Bell (1996) caution against the risks of excessive variation in capacity and argue that the efficiency of operations is reduced when too many providers are available. Brasted advocates waiting lists to be seen from a broader perspective as they may be viewed as "accounting artefacts arising from mismatched capacity and demand, social constructs or a form of resource management" (2008). In contrast to the "traditional" and "carve-out", models such as "open access"<sup>42</sup> resting on the premise "do today's work today" have been adopted by many primary and specialty care clinics (Murray and Tantau, 2000). The successful application of open access to different primary and specialty care clinics (Murray et al., 2003; Lukas-Vandeusen et al., 2004; Pickin et al., 2004; Schall et al., 2004; Dixon et al., 2006) suggest that "the principles of advanced clinic access are robust across settings and types of clinics" (Schall et al., 2004).

# 2.6.2 Effectiveness

Effectiveness refers to the provision of care for which there is an evidence base (IOM, 2001, p. 47) and requires continuous efforts to avoid both "underuse" and "overuse" by healthcare providers. As defined by Chassin (1997), "underuse is the failure to provide a service whose

<sup>&</sup>lt;sup>41</sup> I.e. regional disparities in access to coronary angiography after accounting for clinical need.

<sup>&</sup>lt;sup>42</sup> Also called "advanced access" or "same-day scheduling".

benefit is greater than its risk" and "overuse occurs when a health service is provided when its risk outweighs its benefit". The movement of Evidence-Based Medicine (EBM) has as its ultimate purpose to promote effectiveness in the delivery of care. Coined by Guyatt, EBM appears in the literature for the first time in 1992 (Guyatt, 1992) and has its modern roots in the influential work of Cochrane originally published in 1972 (Cochrane, 1999). EBM is commonly defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett et al., 1996). Evidence, clinical expertise and patient are the three components essential to EBM, the practice of which is described by Sackett et al. (2000) and Porzsolt et al. (2003). In the context of EBM, studies are evaluated based on levels of evidence from Level I to Level V. The highest level, Level I is reserved for large RCTs with clear-cut results (Sackett, 1989). The problem attributed to EBM is the gap between generic clinical practice guidelines and decisionmaking concerning individual patients at the moment of care delivery (Eddy, 2005). Similarly, Davidoff (2000) claims that "the medical profession falls far short in its efforts to make the critical link between the huge body of information hidden away in the medical literature and the information needed at the point of care". In an examination of the differences and similarities between EBM and process improvement<sup>43</sup>, Glasziou et al. (2011) argue a need for integrating the two approaches and claim that such a combination would enable "doing the right things right". Critics of EBM call it "old wine in new bottles", "old hat", "cookbook medicine" and view it as a new form of managerialism. The critics adduce arguments of: (1) questionable ethics, (2) high cost and time demands, (3) experimental character and subsequent limits to generalization, (4) conflicts of interest and medical ghostwriting and (5) enforcement of the logic of empiricism and quantitative research. Morse (2006) discusses some political aspects associated with EBM, which the author considers to be "an oppressive movement" that fosters the use of quantitative research methods and illegitimatizes other research methods and types of medical reports other than RCTs. Morse proceeds in arguing that "qualitative research does contribute to a reduction in morbidity and mortality without the cost in dollars and lives that are necessarily incurred in evidencebased inquiry" and that qualitative researchers address "confusing and chaotic problems that are too difficult to tackle quantitatively".

<sup>&</sup>lt;sup>43</sup> "Clinical Quality Improvements", in the words of the original author.

## 2.6.3 Equity

The aim of equity can be discussed both at the population and individual levels. At the population level, "the goal of the healthcare system is to improve the health status in a manner that reduces health disparities among particular subgroups" (IOM, 2001), whereas at the individual level, "the availability of care and quality of services should be based on individuals' particular needs and not on personal characteristics unrelated to the patient's condition or to the reason for seeking care" (ibid.). Inequities can be found with respect to patient gender (Perelman *et al.*, 2010), race/ethnicity (Fiscella *et al.*, 2000), age (Horton *et al.*, 2011), income (Judge *et al.*, 2010), education (Do and Eggleston, 2011), disability (Ward *et al.*, 2010), sexual orientation (Wang *et al.*, 2007) and residence location (Sibley and Weiner, 2011). Semantic differences between "health disparities", "health inequalities" and "health inequilities" are discussed by Carter-Pokras and Baquet (2002). In the landmark report "Unequal Treatment" (IOM, 2003), a "difference" is considered a "disparity" if it resides on grounds other than clinical appropriateness or patient preferences.

Cultural Competency in Medicine (CCM) is an approach aimed at reducing disparities. As claimed by Brach and Fraser (2000), CCM can "improve the ability of health systems and their clinicians to deliver appropriate services to diverse populations, thereby improving outcomes and reducing disparities". Some authors warn that "if we ignore culture, we will perpetuate and exacerbate the differential outcomes and unequal distribution of disease burden present today" (Kagawa-Singer and Kassim-Lakha, 2003). One of the earliest definitions of CCM is provided by Betancourt et al. (2002), for whom CCM "describes the ability of systems to provide care to patients with diverse values, beliefs and behaviors, including tailoring delivery to meet patients' social, cultural, and linguistic needs". Situations abound in which CCM is required to deliver effective care. For illustrative purposes, Betancourt (2004) mentions the cases of an Italian son asking the physician not to inform his mother of her diagnosed cancer and a Chinese father treating his asthmatic daughter with herbal remedies in tandem with prescribed inhalers. Betancourt (2003) distinguishes between three conceptual approaches to medical education focusing on attitudes, knowledge and skills, all of which are necessary but insufficient for the effective management of cross-cultural situations. Several authors forewarn, however, of the risks of stereotyping (Tervalon and Murray-García, 1998; Kleinman, 2004). Besides more culturally competent healthcare providers, if it is to become institutionalized, CCM must be addressed

at a system level. Brach and Fraser (2000) have thus identified nine major CCM-promoting techniques: (1) interpreter services, (2) recruitment and retention policies, (3) training, (4) coordinating with traditional healers, (5) use of community health workers, (6) culturally competent health promotion, (7) including family/community members, (8) immersion into another culture and (9) administrative and organizational accommodations. Despite major advancements, further investments in CCM are hindered by a lack of evidence of its cost-effectiveness (Betancourt *et al.*, 2005) and unclear relationship between CCM and EBM (Hasnain-Wynia, 2006). According to the latter authors, the integration of CCM and patients, whereas CCM promotes the same discretion.

# 3 RESEARCH METHODOLOGY

This chapter starts with some ontological and epistemological considerations on quality and processes (Sections 3.1 and 3.2, respectively), followed by an exposé on the general research design employed in the thesis, i.e. case study approach (Section 3.3). The following sections provide some theoretical insights into case selection and an account of the selection of cases in practice (Section 3.4 and 3.5, respectively). Methodological considerations can be found in Section 3.6. Thereafter, the methods employed are described, both in terms of data collection and data analysis (Sections 3.7). The quality of research is discussed in the next section (Section 3.8). Finally, some comments on the research journey of the author have been included (Section 3.9).

# 3.1 Ontological Considerations

Given the previous definitions of processes, it is possible to conclude that they do not physically exist except as mental constructions depicting sets of activities. The existence of "objective" and "subjective" elements can be found: (1) upstream of the process, i.e. in incoming patients, (2) in the process itself, as well as (3) downstream of the process, i.e. in outcomes delivered. *Upstream of the process*, there are objective elements such as patient age, sex, location of thrombolysis, residence and yearly income, as well as subjective elements such as patient perceptions of a reasonable waiting time and patient attitudes towards involvement in clinical decision-making. *In the process itself*, there are objective elements, such as performing PCI on patients, time to hospitalization and prescribing aspirin on discharge, as well as subjective elements such as conflicting interests among healthcare providers, collegiality among physicians and emotional support provided to patients. *Downstream of the process*, there are objective elements such as mortality, occurrence of rehospitalization and bleedings, as well as subjective elements such as experiencing pain and patient satisfaction.

With respect to quality, Shewhart (1931) distinguished between the existence of objective elements dealing with an "objective reality independent of the existence of man" and subjective elements dealing with "what we think, feel, or sense as a result of the objective reality" (p. 53). Consistent with this view is the decomposition of quality into "quality of design" and "conformance with specifications", as suggested by Juran and Gryna (1993, p. 4). In a similar vein, some authors emphasize the importance of considering factors other than physiological ones. For instance, Sawatzky and Naimark (2009) stress the need for

including "a broader scope of physiological and psychosocial parameters to predict the outcomes of CABG [Coronary Artery Bypass Graft] surgery". Likewise, Foote et al. (2004) claim that the feelings of dependence, anxiety and powerlessness experienced by patients during a waiting period need to be managed rather than ignored. The authors add that "operations research and health economic approaches are essentially irrelevant to the patient concerns" and that "patients are not in fact 'work-in-progress' but have to live with waiting on a waiting list" (ibid.). Ontology deals with questions concerning the nature of existence and being. Ontology discusses whether social phenomena and their meanings exist independently of social actors or whether they are continually being accomplished by social actors (Bryman and Bell, 2007). These perspectives are in line with the ontological positions of objectivism and constructivism, respectively. As discussed previously, healthcare processes comprise both objective and subjective elements. Hence, it is advisable to follow a middle position between the constructivist and objectivist ontological positions, such as critical realism (Bhaskar, 1989), according to which "social phenomena are produced by mechanisms that are real, but that are not directly accessible to observation and are discernible only through their effects" (Bryman and Bell, 2007, p. 628).

# 3.2 Epistemological Considerations

Whereas ontology addresses questions related to the nature of existence, epistemology addresses questions related to the nature of knowledge. Epistemology discusses whether knowledge is objective, generalizable and in essence context-free or whether it is rather subjective, particular and context-dependent (Bryman and Bell, 2007). The former perspective is associated with positivism and the latter with interpretivism (ibid.). The positivistic position is characterized by a belief in science built on facts, whereas the interpretivist position conceives reality as built by multiple realities, often said to be subjective. The positivistic and interpretivist positions prevail in the realms of natural science and social science, respectively. Healthcare processes contain many elements akin to the social sciences, which are less suitable to being studied merely according to the canons of positivism. In agreement, Smith asserts that "there is a clear difference between studying physical matter or biological species and studying thinking, creative, interacting, unpredictable human beings" (1998, p. 139).

With respect to quality improvement, Batalden and Davidoff maintain that "learning to deliver care therefore means going beyond conceptual knowledge ('knowing what') to the

acquisition of working knowledge ('knowing how')" (2007b). Both "knowing what" and "knowing how", i.e. "episteme" and "techne" are necessary forms of knowledge (Batalden et al., 2011). The same authors allude to the multiple social components of healthcare, such as "human performance, professional behavior and social change" (ibid.), which stress the importance of the context in quality improvement and helps explain why excellent mathematical models may not be accepted. Epistemological differences result in methodological differences. Quality improvement initiatives are often combined into bundles of activities that can together produce improved results over time, which is why it makes no sense to pull these components apart to study them from a reductionist perspective, e.g. by means of RCTs (Neuhauser and Diaz, 2007). The authors add that quality improvement focuses on the implementation of RCT findings and deals with improvement over time, hence requiring reference to concurrent comparisons. In a similar vein, Berwick (2008) argues against the tyranny of RCTs and claims that RCTs have limitations that make them unsuitable for learning about how to improve. According to the author, "these methods [i.e. SPC, time series analysis, simulations, factorial experiments, ethnography, and anthropology] are not compromises in learning on how to improve; they are superior [to RCTs]" (ibid.).

# 3.3 Research Design

There are several types of research design, among them are case studies (Bryman and Bell, 2007). The term case study is often employed despite the difficulties of providing a univocal definition (Ragin, 1992). For instance, Eisenhardt (1989) defines a case study as a "research strategy which focuses on understanding the dynamics present within single settings" (p. 554) and claims that "cases may be chosen to replicate previous cases or extend emergent theory, or they may be chosen to fill theoretical categories and provide examples of polar types" (p. 537). Thomas (2011) argues that "case studies are analyses of persons, events, decisions, periods, projects, policies, institutions, or other systems that are studied holistically by one or more methods" (p. 513). According to Yin (1994), a case study can be defined as "an empirical enquiry that investigates a contemporary phenomenon within its real life context" (p. 13). Concerning the applicability of case studies, Yin (1994) argues that case studies are most appropriate when "how" and "why" questions are being posed, when the investigator has little control over events, and when the focus is on contemporary phenomena within some real-life context. Moreover, case studies are suitable for studies

with an exploratory purpose, when the main purpose is not to find a causal relationship but to obtain additional knowledge and add understanding about such a relationship. A review of case study definitions is provided by Thomas (2011).

In general, case studies are becoming increasingly popular within management research because of their ability to investigate little-known and complex phenomena, such as organizations (Gummesson, 2000). Moreover, organizations place increasing importance on learning from unique events. In other words, "organizations attempt to experience history more richly, to formulate more interpretations of that experience, and to supplement history by experiencing more of the events that did not occur but could have" (March *et al.*, 2003). In the field of quality improvement, where case studies are currently underutilized (Baker, 2011), an increased use of case studies is recommended.

Palmberg (2009) discusses the use of case studies from a positivistic versus an interpretivist perspective. The author concludes that from a positivistic perspective, greater importance is placed on collecting data guided by theory, prioritizing the number of cases rather than studying them in depth, formulating precise definitions, conforming to an initial plan and conducting research in a linear fashion. Conversely, the interpretivist perspective values researcher pre-understanding more than existing theories and advocates a flexible research process. Thus, in lieu of departing from known theories, proceeding with data collection and analysis and terminating with refinements to this theory, the interpretivist perspective favors a research approach in which loosely defined concepts are used pragmatically in studies, the design of which emerges with time and which fluctuates between theory and data in an iterative manner.

Since the research substantiated in this thesis had the overall exploratory purpose of increasing the understanding of variations in the quality of current healthcare processes, a phenomenon that in many regards remains poorly understood, it was designed as a case study. Due to limited possibilities of deliberately inducing changes in healthcare processes to study the effects of such changes on quality, the research aimed at studying variations in quality without intruding into the normal *modus operandi* of healthcare processes. Besides the exploratory research purpose and the real-life focus, the complexities involved in understanding and managing the quality of healthcare processes served to strengthen the case study design.

# 3.4 Case Selection in Theory

This section contains some considerations about the criteria for selecting case studies, the different types of case study purposes, the definition of case study unit of analysis and the varieties of case study design.

### 3.4.1 Criteria for Case Study Selection

There are several factors to take into consideration when choosing a case to study. For instance, Siggelkow (2007) advocates that the uniqueness of the case is the key to its compelling nature. The author considers a purely descriptive case to be "a hard sell" and advises the researcher to have a "talking pig", which is likely to deter any potential accusations of non-representativeness of the case. By the same token, Eisenhardt (1989) argues that cases should be chosen for theoretical and not for statistical reasons. The possibility of providing a rich and deep understanding of the phenomenon under study is another important criterion, meaning that access to the field is of utmost importance (ibid.). Consequently, it may be advisable to study cases that are highly accessible in order to spend the majority of time with such cases. Thomas (2011) differentiates between the criteria of "exemplary knowledge", "key-ness" and "outlier-ness"<sup>44</sup> for selecting a case and, in contrast to Yin, rejects selecting a case for its representativeness or typicality. Yin (2009) maintains that a single case study may be chosen because it is a "critical case", an "extreme" or "unique case", a "representative" or a "longitudinal case".

### 3.4.2 Types of cases study purposes

The classification of case studies according to their purpose varies by author. In 1994, Yin would classify the purpose<sup>45</sup> of case studies according to: (1) explanatory, (2) descriptive and (3) exploratory, which would later be refined into (1) explanatory, (2) descriptive, (3) illustrative and (4) enlightening (Yin, 2009). Other authors classify the purpose of case studies as: (1) explanatory, (2) descriptive, (3) exploratory and (4) predictive (Marshall and Rossman, 1995). Gummesson (2000) elaborates on these purposes and states that exploratory and descriptive cases have traditionally been given low status and are primarily viewed as ancillary to other methods. According to Marshall and Rossman (1995), exploratory and

<sup>&</sup>lt;sup>44</sup> In my opinion, the criterion of "exemplary knowledge" relates to the previous criterion of good access to the field, whereas the criterion of uniqueness covers both the key and deviant cases suggested by Thomas.

<sup>&</sup>lt;sup>45</sup> The author uses the term "application".

descriptive case studies build rich descriptions of complex circumstances that have been unexplored in the literature, while explanatory studies show relationships between events and the meaning of these events. The purpose of each case study in this thesis will be discussed according to the most recent classification suggested by Yin (Table 5).

Table 5 Purposes of case studies according to Yin (2009).

Explanatory	Descriptive	Illustrative	Enlightening				
To explain the presumed	To describe an	To illustrate certain	To enlighten those				
causal links in the real-life	intervention and the	topics within an	situations in which the				
interventions that are too	real-life context in	evaluation, in	intervention being				
complex for the survey or	which it occurred	descriptive mode	evaluated has no clear,				
experimental strategies			single set of outcomes				

# 3.4.3 Definition of Case Study Unit of Analysis

According to Yin (2009), the definition of the case study unit of analysis often poses problems. Nevertheless, a correct definition is essential to identify the theoretical field to which the case is expected to contribute and to distinguish the data relevant to the case from the data external to the case, i.e. the context. Possible units of analysis include decisions, individuals, organizations, processes, programs, neighborhoods, institutions, and even events (ibid.). Thomas (2011) considers the term unit of analysis susceptible to doubt and maintains that a case study must comprise two elements: (1) a practical, historical unit, i.e. the "subject" and (2) an analytical or theoretical frame, i.e. the "object"<sup>46</sup>. The object can thus be seen as the theoretical, scientific basis that delimits the subject. In other words, the object constitutes an analytical frame within which the case is viewed and which the case exemplifies. However, the definition of the object is less straightforward than that of the subject and can be aided by posing the question "What is this a case of?" (ibid.).

### 3.4.4 Varieties of Case Study Design

Yin (2009) identifies four varieties of case study design depending on: (1) whether a single or multiple cases are being studied and (2) whether one or several units of analysis are being studied. The four varieties of case study design are shown in Figure 10. Single-unit of analysis designs are preferable when no logical subunits can be identified, but they pose the

<sup>&</sup>lt;sup>46</sup> Because of its importance to U.S. resistance to putative Communist expansion (the object), the author gives the example of a case aimed at studying the Korean War (the subject).

risk of having the study conducted at too general a level. Multiple-case designs can be used for common cases to obtain more compelling evidence at the expense of additional resources (ibid.). The author also stresses that the use of multiple-case designs should follow a replication and not a sampling logic.



### Figure 10 Varieties of case study designs

# 3.5 Case Selection in Practice

This section elaborates on the individual cases encompassed in the thesis. For each case study, the subject and object are differentiated and a motivation for the case study design is provided. The descriptions of the individual case studies are systematized in Table 5.

### 3.5.1 Study 1

To answer RQ1, a case study was designed for the purpose of studying current practices of physician scheduling (subject) because of their potentially detrimental effects on the timeliness of delivered care (object). Due to the scarcity of previous research on physician scheduling at the hospital department level, the purpose of the case study was deemed to be enlightening. As the object appeared to be coherent, the study followed a holistic design. Since physician scheduling is a common process found in all hospital departments, the study was designed to involve multiple cases in order to strengthen the evidence produced. In total, 13 hospital departments where investigated following a complementary logic. The hospital departments included in the study offered good access to the field and provided opportunity of gaining "exemplary knowledge". More details on the selection of hospital departments and potential sampling biases are provided later. To pay heed to economy of space, the 13 hospital departments investigated will not be described in Chapter 4. In summary, the case study was designed to be a "holistic multiple-case" study.

### 3.5.2 Study 2

To answer RQ2, a case study was designed for the purpose of studying the use of a CDSS (subject) because of its potential effects on clinical practice and quality of care (object).

Because the investigated relationship is fairly well understood, the purpose of the case study was deemed explanatory. The CDSS investigated had been developed at the Cardiac Intensive Care Unit (CICU) of the Southern Älvsborg Hospital (SÄS) and was called the Heart Records (HRs). The investigation of the HRs was supported by the "key-ness" and "outlier-ness"<sup>47</sup> of the HRs and a guarantee of good access to the field. The HRs were used in the treatment of ACS patients. As the object appeared to be coherent, the study followed a holistic design. Since the HRs were exclusive to the SÄS CICU, there were no possibilities of including multiple cases. In summary, the case study was designed as a "holistic single-case" study. A description of the SÄS CICU is included in the description of the empirical setting (Chapter 4). Further details on the HRs and the SÄS CICU are available in the paper appended.

### 3.5.3 Study 3

To answer RQ3, a case study was designed for the purpose of studying the care of patients with language barriers (subject) because of their potential effects on equity (object). Given that some previous studies support the proposition of the existence of disparities in the care of patient with language difficulties, the purpose of the case study was considered descriptive. The case study was thus aimed at describing the current care received by these patients and identifying differences relative to patients with no language barriers. The patient group investigated consisted of ACS patients treated at CICU of the Sahlgrenska University Hospital (SU). In this case, both good access to the field and high practical importance could be expected. As the object appeared to be coherent, the study followed a holistic design. Considering the extensiveness of the variables to be investigated and the prudency of economy of resources, no additional cases other than the SU CICU were investigated. In summary, the case study was designed to be a "holistic single-case" study. Descriptions of ACSs and the SU are included in Chapter 4. Further details on the SU CICU are provided in the paper appended.

### 3.5.4 Study 4

To answer RQ4, because of the potential effects of the Lexis diagram on lead times in particular and timeliness in general (object), a case study was designed for the purpose of

<sup>&</sup>lt;sup>47</sup> The "key-ness" of the HRs rested on the initial suspicion of the success of the HRs, whereas the "outlier-ness" rested on the fact that no other CICU than that at the SÄS used the HRs.

studying the use of the Lexis diagram in an outpatient referral process (subject) The purpose of the case study was deemed to be illustrative since it aimed at illustrating how the Lexis diagram could be used in monitoring lead times. The surgery department of the Skaraborg Hospital (SkaS) was the hospital department investigated. The investigation of the outpatient referral process at the hospital guaranteed good access to the field and was deemed suitable for the purpose of illustrating the use of the Lexis diagram in monitoring lead times. As the object appeared to be coherent, the study followed a holistic design. Considering the introductory character of the study, no additional cases other than the outpatient referral process at the SkaS surgery department were investigated. In summary, the case study was designed to be a "holistic single-case" study. The SkaS surgery department is included in the description of the empirical setting (Chapter 4) and details on the outpatient referral process are provided in the paper appended.

#### 3.5.5 Study 5

To answer RQ5, a case study was designed for the purpose of studying quality registries (subject) because of their potential use for process improvement (object). Since the case study aimed at describing current quality registries with respect to relevant process improvement characteristics suggested in the literature, the purpose of the case study was deemed descriptive. The subject was further delimited to focus exclusively on the annual reports issued by the quality registries. This delimitation was based on the need to pay attention to an economy of resources and the fact that annual reports represent a main form of feedback from quality registries to healthcare practitioners. As the annual reports are publicly available, the investigation of annual reports also guaranteed good access to the data. Since the object appeared to be coherent, the study followed a holistic design. To increase the reliability of findings, a multiple-case design was preferred. The focus on Level I quality registries made it possible to keep the set of cases fairly homogenous. The implications of focusing on Level I quality registries are discussed later. In total, five Level I quality registries were investigated, each of which represented a specific case, following a replication logic. In summary, the case study was designed to be a "holistic multiple-case" study. Details on Swedish quality registries are provided in the description of the empirical setting (Chapter 4) and further information on specific quality registries can be found on their respective websites.

# 3.6 Methodological Considerations

Several authors discuss the benefits and challenges of combining quantitative and qualitative research methods. Grønmo (2006) defends the idea that a phenomenon can possess both quantitative and qualitative characteristics and that "qualitative and quantitative data are hence not antagonistic but complementary types of data" (p. 20, free translation). Moreover, "research based on the combination of qualitative and quantitative data can contribute to a more comprehensive understanding of the social phenomena under study" (ibid.). By the same token, Flick (2009) claims that "a linking of both approaches [qualitative and quantitative research] is often necessary and useful for pragmatic reasons" (p. 460). Similarly, Malterud (2001) argues for methodological diversity in the traditionally positivistic bastion of medical research. The author claims that "we need to prevent methodological separatism and supremacy if the field of medical knowledge is to be expanded, not just strengthened or divided" and that the "responsible application of qualitative research methods is a promising approach to broader understanding of clinical realities" (ibid.).

Although quantitative and qualitative research methods can be used complementarily, it is important to be aware of the differences between these approaches. In this regard, Lee (1998) argues that "qualitative research may be well suited to the pursuit of questions of description, interpretation, and explanation" and that "qualitative research may not be well suited to the examination of questions of prevalence, generalizability, and calibration" (p. 64). Flick (2009) provides the example of chronic mental illness that can be studied using both quantitative and qualitative research methods depending on whether the purpose is to investigate the frequency and distribution of such disease in the population or the subjective experience of this disease. Qualitative research methods are suitable when the aim is to gain an understanding of a complex problem and when the questions asked are "What is it about?", "Why?" or "What does it imply?" (Kvale and Brinkmann, 2009). In the words of Miles and Huberman (1994), qualitative research methods can provide "richness and holism" and have a "strong potential for revealing complexity" (p. 10). Quantitative and qualitative research methods can be combined in a variety of designs. With reference to Creswell, Lee (1998) argues that the blending of qualitative and quantitative research follows one of three general designs: "two-phase design", "dominant-less dominant design" and "mixed-methodology design" (p. 11). Analogous designs for the combination of quantitative and qualitative research methods are proposed by Grønmo (2006, p. 210) and Flick (2009, p. 25).

The research report in this thesis employs both quantitative and qualitative methods. In agreement with Cassell and Symon's (1994) advice to "count the countable"<sup>48</sup>, quantitative methods were employed whenever deemed suitable. Similarly, Lee (1998) adds that "in virtually every qualitative study, opportunities arise for the researcher to collect at least some quantitative data" (p. 143), which the author considers often ignored or underutilized. Several authors advocate case studies that combine both quantitative and qualitative methods (e.g. Eisenhardt, 1989; Miles and Huberman, 1994; Flyvbjerg, 2011). Furthermore, the use of both quantitative and qualitative methods seems to be consistent with the critical realist position assumed in this thesis. Table 6 shows a summary of the methods employed in this thesis.

<sup>&</sup>lt;sup>48</sup> In this regard, it is also relevant recalling the quotation usually credited to Einstein that "not everything that counts can be counted, and not everything that can be counted counts".

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Table 6 Characteristics of the case studies included in the thesis.

Study 5	How can the use of	quality registries for	process improvement be	enabled?	Descriptive	Quality registry, in	particular annual reports		Effects on the usability	for process improvement	Holistic multiple-case	Level I quality registries		Quantitative		Data collected by means	of an abstraction form			Data collected by means	of an abstraction form	
Study 4	How can the Lexis	diagram be used to	monitor lead times?		Illustrative	Use of the Lexis diagram	in an outpatient referral	process	Effects on lead times		Holistic single-case	West Sweden, SkaS,	Surgery department	Mainly qualitative		Interviews, data	extracted from hospital	databases		Interviews, data	extracted from hospital	databases
Study 3	To what extent does	language proficiency	affect delivery of care?		Descriptive	Care of patients with	language hinders		Effects on equity,	disparities	Holistic single-case	West Sweden, SU, CICU,	ACS patients	Quantitative		Data were extracted from	the medical records, etc.			Data were extracted from	the medical records, etc.	
Study 2	To what extent can the	use of a CDSS affect	clinical practice and	quality of care?	Explanatory	Use of a CDSS, in	particular the HRs		Effects on clinical practice	and quality of care	Holistic single-case	West Sweden, SÄS, CICU,	ACS patients	Mainly quantitative		Data were extracted from	the national quality	registry database,	interviews	Data were extracted from	the national quality	registry database, interviews
Study 1	How can physician	scheduling be improved	in order to yield gains in	timeliness?	Enlightening	Physician scheduling	current practices		Detrimental effects on	timeliness	Holistic multiple-case	13 Swedish public	hospital departments	Qualitative		Interviews and	documents			Interviews and	documents	
	Research	question			Purpose	Subject			Object		Design	Sample		Research	strategy	Data	collection	methods		Data	collection	methods

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# 3.7 Data Collection and Analysis

The descriptions provided below greatly coincide with the methodology sections of the five appended papers. For each study, an account is given on the methods used for data collection and analysis.

### 3.7.1 Study 1

To answer RQ1 within the boundaries of the case study previously discussed (Table 5), both interviews and document have been used to collect the data. However, the research question was formulated after the data had been collected and in such a way that existing data could be used to adequately answer the research question. The data had previously been collected for quality improvement initiatives, for which the main author of the study played the role of a consultant assisting healthcare departments in improving the timeliness of their services by focusing on improving physician scheduling. At the moment of the data collection, the purpose was very similar to that resulting from the research question, i.e. providing a description of shortcomings in current physician scheduling practices. After the data had been collected, the quality improvement initiative proceeded, but at the moment of the formulation of the research question, no further contact existed between the main author of the study and the hospital departments. The 13 hospital departments investigated covered seven different specialties including dermatology, internal medicine, obstetrics & gynaecology, ophthalmology, orthopaedics, paediatrics and surgery. These hospital departments had in common the willingness to participate in quality improvement initiatives aimed at improving physician scheduling. Thus, risk of selection bias could not be definitely ruled out.

Whenever feasible, it is preferable to observe behaviors rather than asking participants about their perceptions. However, in the case of physician scheduling, it is difficult to observe how the process unfolds since it occurs discontinuously and since some of the aspects of the process cannot be observed, for instance the resolution of conflicts and the trade-offs between different interests. Hence, qualitative interviews (Kvale and Brinkmann, 2009) were adequate to collect the data for the present study. The interviews were unstructured without any guidance of a theoretical model. Only the main author of the study was involved in these interviews, in which only individuals involved in the production of physician schedules were consulted. Interviewing other stakeholders such as physicians, nurses and patients seemed irrelevant as they might only address the outcomes of physician scheduling rather than current practices and their shortcomings. The identification of relevant potential interviewees was made by the head of each hospital department. At the request of interviewees, some interviews were conducted in group settings. On an average, about two hours of interviewing were spent in each hospital department. A simple interview guide was used to ensure that all areas previously considered by the researcher were covered during the interviews. All interviews took place in the work environment of the interviewee. Notes were taken during the interviews without the help of tape recordings. During the interviews, the staff at the hospital departments provided copies of the documents necessary for physician scheduling and print-outs of the different schedule templates used at the hospital department. In some cases, these documents were discussed during the interviews.

The data used in this study were analyzed according to a "summarizing qualitative content analysis" approach (Flick, 2009, p. 325). Both authors were involved in the analysis of the data. After reading the interview notes, all relevant statements were entered into a spread sheet file (data reduction). In the following step, one or more codes were attached to each statement. The passages concerning the same code were put together (meaning condensation). Similar codes were clustered and gave rise to new categories. This method of data analysis was akin to the method proposed by Miles and Huberman (1994), according to whom there is an initial step of data reduction, followed by data display and, finally, drawing conclusions. In our analysis, no major importance was placed on data display. Instead, the most frequent categories were identified and reported in the paper.

### 3.7.2 Study 2

To answer RQ2 within the boundaries of the case study previously discussed (Table 5), both quantitative and qualitative data were collected. The qualitative data served the ancillary purpose of discussing probable factors that enabled the development and introduction of the HRs to the hospital department in agreement with the SQUIRE recommendations (Ogrinc *et al.*, 2008) of investigating both quantitative effects and qualitative aspects related to change management. The qualitative data were collected in two semi-structured interviews, in which the main author of the study interviewed the physician in charge of the development and introduction of the HRs. Notes were taken during the interviews and the data analysed according to the "summarizing qualitative content analysis" approach described for Study 1. The final version of the paper was checked and approved by the interviewee. It was agreed

that the interviewee would figure among the co-authors in the early stages of the study. The use of the HRs was measured at a dichotomous level. The effects of the use of the HRs on clinical practice and quality of care were operationalized by using the quality criteria monitored by the RIKS-HIA quality registry (see description in Chapter 4). The quality criteria were measures of physician adherence to guidelines, reflecting whether the physician provided the therapies recommended in the guidelines or not. As the staff at the intervention CICU only reported data on the five indicators originally monitored by RIKS-HIA, not all quality criteria monitored by RIKS-HIA database by the physician in charge of the development and introduction of the HRs since he was entitled to access the database. This study was thus observational and retrospective. No assessment of the data quality was conducted as it was known that RIKS-HIA performs such assessments and assumed that data from the RIKS-HIA database were of high quality. The data showed the annual number of patients who received the recommended therapies. The data collected were divided into two groups, i.e. the intervention CICU versus the remaining regional CICUs.

The data were analysed by the main author of the study under the guidance of a statistician. The statistical analyses were bipartite and investigated the short-term and the long-term effects of using the HRs. To estimate the short-term effects of the intervention, differences in guideline adherence between 2004 and 2002 were calculated (2003 was the year of introduction of the HRs). The effect of the intervention was calculated as the difference in change scores between intervention CICU and the control group. These differences were tested by using  $\chi^2$  tests of independence (Altman, 1991, p. 241)<sup>49</sup>. Confidence intervals for the estimated effects were calculated by means of one-sample t-tests (Altman, 1991, p. 194), which tested the estimated effect in a sample size which was the minimum of the 2002 and 2004 sample sizes. In the investigation of the long-term effects of the intervention, weighted averages of guideline adherence at the intervention CICU versus the control group were calculated for the 2004-2008 period. The differences between proportions were tested using the  $\chi^2$  tests of independence. To obtain odds ratios (Altman, 1991, p. 268)<sup>50</sup> and confidence

<sup>&</sup>lt;sup>49</sup> More details about this test on <u>http://udel.edu/~mcdonald/statchiind.html</u>.

<sup>&</sup>lt;sup>50</sup> In a mundane example of using odds ratios, let use assume that female applicants are accepted in 75% of the cases (the odds of success equal 3), whereas male applicants are accepted in 50% of the cases (the odds of success equal 1). In this case, the odds ratio equal to 3 meaning that the odds of female students being

intervals, logistic regressions (Altman, 1991, p. 351) were conducted with guideline adherence as the dependent variable and the use of HRs and year as the independent variables. To check on the possibility of a relapse at the intervention CICU, simple binary logistic regressions were performed with guideline adherence as the dependent variable and year as the independent variable. To study the changes in guideline adherence in the control group compared to the intervention CICU during the same period, the proportion of the control group that would have received the recommended therapy given guideline adherence in the control group similar to that of the intervention CICU was calculated for each year. This variable was used as an independent variable in simple binary logistic regressions with year as the dependent variable. All significance tests were two-sided and the statistical significance was set at the 0.05 probability level. All analyses were made using the IBM SPSS® Statistics 19 software package.

### 3.7.3 Study 3

To answer RQ3 within the boundaries of the case study previously discussed (Table 5), data were collected by a group of nurses on a number of variables deemed important to the delivery of care. The variables included patient baseline characteristics and process and outcome indicators. The variables were selected by two experienced physicians and nurses who would collect the data from hospital multiple databases. Several meetings were held to define the variables to be collected and to create a common procedure for data collection. The nurses collected the data by filling out a form. Subsequently, the data contained in the forms were saved digitally and cleaned by a statistician. The retrospectively collected data corresponded to one-fourth of the annual population of patients with chest pain or symptoms suggestive of ACS. The patients included in the study sought care between mid-September and mid-December 2008 and amounted to 2,588 visits. The research question was formulated after the data had been collected and led to the definition of five primary quality indicators, all of which dealt with delays in the delivery of care. The data were analysed by a statistician using SAS/STAT® statistical software. The results of this analysis are available in the paper appended. For educational purposes, the main author of the study replicated the statistical analysis by using the IBM SPSS® Statistics 19 software package. The patient language barrier factors was operationalized by the dichotomous "need of interpreter"

accepted is 3 times larger than the odds of male students being accepted. An odds ratio is not the same as the proportions of success ratio.

variable, which resulted in the creation of "Swedish-speaking" and "non-Swedish-speaking" patient groups.

With respect to statistical analyses, the difference in the median ages of the two groups was tested by means of the non-parametric Mann-Whitney U-test (Altman, 1991, p. 194). This test is suitable for situations in which the assumption of normal distribution is less tenable<sup>51</sup>, as in the case of age and other variables for which there are physical thresholds. As statistically significant differences in age were found between the two groups and that health status was strongly correlated with age, subsequently calculated P-values had to be adjusted for age. To test differences in proportions between the two groups, e.g. the prevalence of previous diabetes adjusting for age differences, the Cochran-Mantel-Haenszel test (Cochran, 1954)52 was used. This test allows for examining the relationship between two variables, making allowance for variation in a third variable (Altman, 1991, p. 270). For the continuous variables examined, i.e. the five delay variables of greatest interest to the study, differences in median delays between the two groups were tested adjusted for age by means of stratumadjusted Kruskal-Wallis tests (SAS, 2000, p. 1315). Thereafter, the originally continuous delay variables were dichotomized by the median (Royston et al., 2006; DeCoster et al., 2009). This lowering of the measurement level was made because some threats to the quality of the time values had been identified. The dichotomized times were used as dependent variable in a multiple logistic regression (Altman, 1991, p. 351). The independent variables inserted into the regression model were belonging to groups, i.e. "Swedish-speaking" and "non-Swedishspeaking", and relevant patient baseline characteristics. To identify the relevant baseline characteristics, logistic regressions were performed with baseline characteristic as the dependent variable and group belonging as the independent variable, as well as logistic regressions with baseline characteristics and delay as the dependent variables. Baseline characteristics with a univariate P<0.2 with both group belonging and delay were considered relevant. All tests were two-sided at the 5% significance level.

#### 3.7.4 Study 4

To answer RQ4 within the boundaries of the case study previously discussed (Table 5), the researchers conducted two rounds of semi-structured interviews with two practitioners

<sup>&</sup>lt;sup>51</sup> The t-test is the alternative test when the distribution can be assumed to be normal.

<sup>&</sup>lt;sup>52</sup> This expansion of the tradition  $\chi^2$  test is explained <u>http://udel.edu/~mcdonald/statcmh.html</u>.

knowledgeable about the outpatient referral process and current monitoring of lead times at the hospital department investigated. The informants were interviewed separately. Two researchers were present at the interviews, which took about one hour. The purpose of the first round of interviews was to characterize the outpatient referral process and current management of lead times. In a second round of interviews, the researchers explained the rationale behind the Lexis diagram, presented a Lexis diagram of the lead times previously collected and gathered the impressions of the interviewees of the potential benefits and challenges of using the Lexis diagram to monitor lead times. Interviews are suitable for describing, clarifying and elaborating on perspectives and meanings of the world experienced by individuals (Kvale and Brinkmann, 2009), which justifies the use of interviews to collect practitioner perceptions of benefits and challenges of a tool that can be used in their daily work. To produce the Lexis diagram presented in the second round of interviews, the main author of the study created a spreadsheet file able to produce Lexis diagrams and entered the lead times previously collected by another researcher. These data had been collected in connection with a quality improvement initiative and corresponded to 84 referrals received during an 11-week period. Since the study had an illustrative purpose, the interviews were neither recorded nor transcribed and the interviewees promised to verify the final version of the paper.

The data in the interview notes were analyzed by the main author of the study according to the "summarizing qualitative content analysis" approach described under Study 1. The final version of the paper was checked and approved by the interviewees. By suggestion of the main author of the study, the interviewees were included among the co-authors of the study after the interviews had been concluded. The initial design of the study included a pilot study, in which the Lexis diagram would be tested in practice during a short period. However, after the pilot study had been postponed at the request of practitioners, the main author of the study decided to reduce the scope of the study and evaluate the effects of the Lexis diagram based on practitioner perceptions of its potential use.

### 3.7.5 Study 5

To answer RQ5 within the boundaries of the case study previously discussed (Table 5), the researcher started by converting the principles for data reporting that support process improvement found in the literature (e.g. Shewhart, 1931; Solberg *et al.*, 1997) into a set of variables with predefined values. The resulting abstraction form was tested and revised.

Assuming an economy of resources and that the characteristics of the annual reports remain almost unaltered from year to year, the 2012 annual reports were alone investigated. Furthermore, as the textual information in the annual reports was expected not to add substantial new and relevant information besides that displayed in the charts, it was disregarded. It was also assumed that practitioners who might engage in process improvement primarily read and react to charts rather than to text. Furthermore, the coding of the textual information seemed subjective, which might increase the risk of researcher bias. The five annual reports of Level I quality registries contained 636 charts in total, each of which was coded according to the abstraction form transferring data entered into a spreadsheet file.

The data were analyzed by calculating simple statistics, such as percentages for the separate annual reports and weighted averages for the annual reports combined. As the purpose was not to compare the annual reports among themselves but to provide a general characterization of the annual reports altogether, differences between them were disregarded.

# 3.8 Quality of Research

This section contains some initial considerations on the definition and assessment of quality of research in general. The latter part of this section is dedicated to discussing the quality of the research conducted in each study.

### 3.8.1 Defining and Assessing the Quality of Research

Ultimately, research aims at uncovering the "truth" of the surrounding world. Scientific statements should thus have a correspondence to objective reality, as well as being relevant and complete in relation to the question posed (Kvale and Brinkmann, 2009). Several indicators can be used to assess the quality of research and, ultimately, the degree of truth inherent in scientific statements. Such indicators include "reliability", "validity", "generalization", "construct validity", "internal validity", "external validity", "predictive validity", "concurrent validity", "content validity", "ecological validity" and "replicability" (Lee, 1998; Grønmo, 2006; Bryman and Bell, 2007; Yin, 2009). Some authors argue that qualitative research should be evaluated according to its own quality criteria. Such an author is Malterud (2001), to whom the caliber of qualitative research should be evaluated in terms of "relevance", "validity" and "reflexivity". Alternative criteria for assessing the quality of qualitative research may, however, vary across researchers. For instance, Lincoln and Guba (1985) propose the criteria of "trustworthiness" and "authenticity", with the former decomposed into the sub-criteria of "credibility", "transferability", "dependability" and "confirmability". An explanation of these criteria is provided in Table 7. The need for special indicators to assess the caliber of qualitative research is grounded in the idea that quantitative and qualitative methods are different in nature. Whereas quantitative methods are often associated with statistical generalization, distance to the subject, selection and precision, qualitative methods tend to be associated with analytical description, closeness to subject, sensitivity and relevance (Grønmo, 2006). Some authors maintain that the quality of research should be assessed on the basis of a common set of quality criteria irrespective of the nature of research (e.g. Mason, 1996). This is the case with Lee, (1998), who argues that "although the traditions of qualitative and quantitative research certainly differ, I would agree that the ideas of reliability and validity apply equally well to both" (p. 146). The quality of the research of this thesis, irrespective of being quantitative or qualitative, will be discussed based on the criteria proposed by Yin (2009), i.e. "construct validity", "internal validity", "external validity" and "reliability". These four criteria are examined in Table 8.

**Table 7** Description of the criteria suggested by Lincoln and Guba (1985) for assessing the caliber of qualitative research.

**Credibility:** Degree of agreement with canons of good practice and match-up between researcher understanding and the social world. It can be improved by, for instance, prolonged engagement in the field, triangulation, negative case analysis, member checking and peer debriefing.

**Frustworthiness** 

**Transferability:** Degree of generalization of findings across social settings. It can be improved by providing "thick descriptions", i.e. descriptions that are rich enough to allow readers to make a judgment on the transferability of findings to other settings or contexts.

**Dependability:** Degree of traceability of the research process. It can be improved by keeping accurate and comprehensive documentation and by peer auditing.

**Confirmability:** Degree of researcher objectivity, i.e. *bona fide* action and freedom from biases based on researcher personal values or theoretical inclinations. It can be improved by exercising reflexivity and by using auditors.

Authenticity: Degree to which the research conducted contributes to increasing: fairness, member understanding of their social environment, member appreciation of other member perspectives, member willingness and ability to act.

### *Table 8* Description of the criteria suggested by Tin (2009) for assessing the quality of research.

**Construct or Measurement Validity:** Degree to which measures represent the concepts they should represent. It deals with the correctness of the operational measures employed.

**Internal Validity:** Degree of validity of inferences about cause based on research findings. This is mainly an issue for explanatory studies as it deals with establishing a causal relationship, whereby certain conditions are believed to lead to other conditions, as distinguished from spurious relationships.

**External Validity:** Degree of validity of inferences about the generality of the research findings. It deals with defining the domain to which study findings can be generalized.

**Reliability:** Degree of repeatability of the study and stability of findings. Reliability is a necessary but not sufficient condition for validity.

#### 3.8.2 Study 1

In this study, the interviews were complemented by document analysis, which represents a form of triangulation of methods (Patton, 2002) that strengthens the reliability of findings. Documents and templates provided were, moreover, discussed during the interviews, which allowed for clarification of possible misunderstandings. Documents and templates can, thus, be perceived as primary data without any risk of distortion in the interpretation of documents as is customary for secondary data. In this regard, Grønmo (2006, p. 193) warns that the risks of qualitative content analysis are affected by the researcher's background, perceptions and limited contextual understanding. Social desirability and memory biases are common in inquiry situations, such as interviews (Kvale and Brinkmann, 2009). Social desirability bias seems nevertheless to be irrelevant in this study since scheduling tends to be perceived as a mere support process, beyond the core medical competence of healthcare professionals. This may have enhanced the free description of the current process and its shortcomings. Another factor contributing to low social desirability bias was the open format of the interviews. Since the interviews focused on activities performed regularly rather than as episodic events by the interviewees, the problem of memory bias was of minor concern. By collecting the data in the natural setting of the interviewees with only minor interference in daily operations, the reliability of findings was strengthened. Likewise, the involvement in the data analysis of an outside researcher was beneficial from a reliability point of view. Eisenhardt (1989) argues that "investigators who have not met the informants and have not become immersed in case details may bring a very different and possibly more objective eve to the evidence", which corroborates the point above. As the study was exploratory, unstructured interviews seemed acceptable. Nevertheless, the use of a theoretical model for guiding data collection might have rendered the findings less dependable on the researchers involved. Similarly, reliability might have been improved by recording and transcribing the interviews, which, however, might have dissuaded potential interviewees from participating or prevented them from freely giving their testimonials. As the data had already been collected when the research question was formulated, recording the interviews was unfeasible. Conversely, the continued collaboration with the interviewees after the interviews had been completed contributed to increasing the understanding of the research problem. The methods employed in this study, i.e. interviews and document analysis, have limitations in terms of construct and external validity (Lee, 1998, p. 152). The external validity of findings was strengthened by the number of hospital departments. According to Firestone (1993), the generalizability, i.e. external validity of findings, can be strengthened by providing "thick descriptions", purposeful sampling to achieve theoretically relevant diversity and replication of cases through multiple sites. The interview notes and data analysis performed have been saved either physically or digitally. Peer feedback was obtained by submitting the paper to a relevant scientific journal.

### 3.8.3 Study 2

In terms of construct validity, operationalizing the quality of care using the indicators proposed by RIKS-HIA may raise objections as it is questionable that total adherence to recommended therapies would be desirable. Still, considering the current situation, in which adherence to recommended therapies is far below desirable levels, an increase in the score of the indicator can be assumed to represent an increase in the quality of care. It was assumed that all physicians at the intervention CICU use the HRs in tandem with the delivery of care. Still, it is not possible to rule out the possibility that some physicians at the intervention CICU fill out the HRs after the care has been delivered. The data extracted from the RIKS-HIA database are assumed to be of high quality, i.e. to be in accordance with electronic patient records and, ultimately, physician practice. The quality of the data reported to the Riks-HIA lies beyond the scope of this study and is discussed elsewhere (RIKS-HIA, 2005 p. 7). Concerning the reliability of findings, the collection of the data from the RIKS-HIA database was conducted by a a single author, which, on the one hand, enabled uniformity of data collection, but on the other hand increased the risks of researcher bias. As the interviewee/data collector was among the authors of the study, there might have been some distorting effect on the interview data that cannot be definitively excluded. However, the interviews played a secondary role to the purpose of the study. The primary data, i.e. the quantitative data collected from the RIKS-HIA database, was, however, objective and less vulnerable to such distorting effects. The reliability of findings was increased by performing the statistical data analysis under the guidance of an experienced statistician. Another tactic employed to increase reliability was respondent validation. The internal validity of the findings was strengthened by using a control group for assessing the effects of the HRs, which permitted removing the influence of time-dependent factors, such as technological advancements. Random assignment of patients was unfeasible as patients were allocated to the intervention CICU or the control group on the basis of their location of residence and range of necessary healthcare services. This erodes the internal validity of the study as the
effects estimated can thus be confounded (Bryman and Bell, 2007, pp. 38-73) with the effects of variables other than the use of HRs that distinguish the intervention CICU from the control group. The composition of the control group also merits further attention since it results in a trade-off between internal and external validity. The more similar the units included in the control group, the higher the internal validity, something that nonetheless prevents generalization to units dissimilar from those included in the control group, i.e. the study has lower external validity. Considering the differences that exist between regions in Sweden, the authors wanted the intervention CICU to be compared to other regional units. However, the data extracted from the RIKS-HIA database did not discriminate between the units in the control group, which is why correcting for possible differences in the baseline characteristics of units could not be made. During the evaluation period, the HRs were exclusively available at the intervention CICU and no demonstrations of the HRs outside the intervention CICU were made whatsoever. The interviewee also mentioned that during the evaluation period, remaining regional units showed no interest in the HRs. Thus, the risk of contaminating the control group seemed negligible. It can be argued that the introduction of the HRs induced changes in the behavior of physicians, who became more conscientious and judicious because they felt they were being observed or put to a test. By studying the longterm effects of the intervention, the present study circumvents potential reactivity biases (Mayo, 1933; Grønmo, 2006 p. 51-52) as behavioral changes instigated by the awareness of being observed tend to disappear over time as individuals relapse into old habits. Regarding the external validity, Shojania and Grimshaw (2005) argue that it is important to describe contexts clearly, which is often not the case in quality improvement research. To bolster "case-to-case transition" (Firestone, 1993), some contextual features of the change initiative were provided, as well as details about the intervention CICU. The data collected and analyses performed were saved digitally. Peer feedback was obtained by submitting the paper to a relevant scientific journal.

### 3.8.4 Study 3

Concerning reliability, efforts were made to clearly instruct data collectors to keep the data collection as uniform as possible. However, no measurement was made of inter-data collector consistency. The abstraction form used for data collection was pre-tested. With respect to construct validity, the discriminatory factor investigated in this study, i.e. language proficiency, was considered dichotomous and was operationalized as the need for

an interpreter. This may raise controversy as language proficiency can be perceived as a continuous variable and as the need for an interpreter may depend on factors other than the language proficiency of patients. The risk of misclassification cannot be definitively ruled out. The selection of variables that operationalized the delivery of care was made by experienced practitioners, some of whom possessed deep theoretical knowledge about the patient group. This knowledge served to increase the construct validity of the findings, which were, however, threatened by shortcomings in the quality of delay values. These concerns were assuaged by considering the fact that shortcomings in the quality of delay values affected both groups similarly and thus played only a minor role in calculating the differences in time between the two groups. Bryman and Bell (2007) argue that "in terms of reliability, validity, replicability, and generalizability, the comparative study is no different from the cross-sectional design" (p. 68). With respect to external validity, the authors maintain that the external validity of cross-sectional research designs is strong, especially if "the sample from which data are collected has been randomly selected" (ibid., p. 58). In this study, all patients who sought care during the three-month study period were included in the analysis. The authors also claim that the internal validity of cross-sectional designs is typically weak and that "cross-sectional research designs produce associations rather than findings from which causal inferences can be unambiguously made" (ibid., p. 58). Since differences between Swedish-speaking and non-Swedish-speaking patients may in fact be caused by other factors, for instance lifestyle and nutritional habits, this is a noteworthy comment. To improve internal validity, the findings were adjusted for differences in age and disease severity between the two patient groups, i.e. Swedish-speaking and non-Swedishspeaking. Multiple testing might be a threat to internal validity as it increases the probability of appearance of false positives. The statistical analyses were performed by an experienced statistician and were replicated, which strengthens the reliability of findings. The retrospective collection of data affected the internal validity of the study and rendered it more vulnerable to the potentially distorting effects of missing data, a problem that was nonetheless compensated for by an unobtrusiveness in daily operations and decreased reactivity bias. The problem of missing data affected mainly variables such as smoking habits but was negligible for the "Swedish-speaking" versus "non-Swedish-speaking" grouping variable, for which as few as 2% of the data were missing. The data collected and the statistical analyses performed were saved digitally. Peer feedback was obtained by submitting the paper to a relevant scientific journal.

### 3.8.5 Study 4

The quality of the lead times collected was of minor importance in this study as they were merely used for illustrative purposes. Nevertheless, the authors considered it beneficial to produce Lexis diagrams based on lead times that were familiar to interviewees. The principal methods for collecting data were qualitative interviews. At the expense of not being able to capture collateral but relevant insights, the interviews could have been more structured by using a theoretical model to guide data collection, such as the five criteria for enabling the adoption of innovations proposed by Rogers (1995). To mitigate the risk of social desirability bias, the authors sought impartiality when presenting the Lexis diagrams and interviewing the practitioners. Any risk of social desirability deriving from the inclusion of the interviewees among the co-authors can be ruled out as this was decided at the end of the study and after the interviews had been completed. The risk of memory bias was deemed low as the interviewees were asked about something in which they were recurrently involved. To reduce the risk of misunderstandings, the final manuscript was sent to the interviewees for validation of case descriptions and findings. The relevant data, e.g. lead times collected and interview notes, were saved digitally, as were the files used for producing Lexis diagrams and for analyzing the data. Peer feedback was obtained by presenting the study at a relevant scientific conference. The generalizability of results may not be particularly high considering that only one case was studied and that only two practitioners were interviewed twice. The study was aimed at exploring the use of the Lexis diagram for monitoring lead times and for giving indications whether the subject should be further investigated. By studying other cases and testing the use of the Lexis diagram in daily practices, the generalizability of future studies will be higher than in this initial study.

### 3.8.6 Study 5

According to Bryman and Bell (2007), the quality of the documents can be assessed in terms of "authenticity", "credibility", "representativeness" and "meaning". As the study focuses on the characteristics of data reporting in annual reports, not the quality of data reported, only the criterion of representativeness was relevant to the purpose of this study. Notwithstanding the aforementioned, considering the requirements imposed on Level 1 National Quality Registries, the annual reports were expected to score high on authenticity, credibility and meaning criteria. Documents may be difficult to access, which was not the case as the annual reports were publicly available over the Internet. It remains unclear

whether the findings of this study can be generalized to annual reports of lower level quality registries, annual reports of quality registries in other countries and mechanisms for reporting healthcare quality data other than written annual reports. The research method employed, i.e. content analysis (Grønmo, 2006), yields the benefits of transparency and concomitant objectivity in data collection. The method also yielded the benefit of unobtrusiveness to the authors of the annual reports, which permitted ruling out any risks of reactivity bias. A major disadvantage of content analysis is usually its inadequacy in answering why-type questions, something that was not the case in this study that aimed at characterizing features of charts in annual reports. The limited understanding of the context by the researcher is a frequent criticism against using documents as data sources. However, context understanding was unnecessary for the purpose of the study. Another criticism deals with coder subjectivity and subsequent threats to internal reliability. The data were collected by a single author, which, on the one hand, enabled uniformity in data collection but on the other hand increased the risks of researcher bias. The involvement of additional researchers would have allowed assessing inter-researcher consistency and strengthening reliability. To mitigate the risks of researcher bias, efforts were made to unambiguously define the codes used in the abstraction form. In order to promote intra-coder reliability, data collection occurred over a brief period. Issues related to internal validity and external reliability were deemed irrelevant to this study. The data collected by means of an abstraction form, as well as the file used for calculating the statistics reported, were saved digitally. Peer feedback was obtained by presenting the study before a relevant scientific conference.

### 3.9 Considerations on the Research Journey

This section contains some personal views on truth, science and progress, as well as clarifications of my interest in healthcare processes, quality improvement and research. This section also describes my research journey, including the initial conditions of my Ph.D. studies and the unfolding of these studies until the Licentiate Degree and thereafter. I will allow myself to be more personal than in the remainder of this thesis and I hope not to be perceived as preaching as that has not been my intention.

### 3.9.1 Personal Views on Truth, Science and Progress

This thesis is the terminus of a five-year-long journey moulded by compromises between "wants" and "cans" and speckled with moments of both enjoyment and frustration. Ad astra per aspera<sup>53</sup>, as the ancient Romans would say, although equating the completion of Ph.D. studies to reaching the stars is clearly exaggerated. Since all science is a human construction, erected by fallible and inevitably biased human beings, a description of my research journey and background is important for the sake of transparency and credibility. Science is nonetheless quite an impressive construction that has allowed humans, by standing on each other's shoulders<sup>54</sup>, to go<sup>55</sup> from creating fire by rubbing flint stones together (Stapert and Johansen, 1999) to the recent production of human heart tissue from human pluripotent stem cells implanted in a decellularized mouse heart (Lu et al., 2013). The fallibility and inevitable biases of researchers result in a distortion of the "facts" that supposedly reflect a reality exogenous to mankind and governed by the immutable laws of nature. The results can be particularly disastrous when the fallibility and inevitable biases of individual researchers are magnified by political forces (Gould, 1996; Seidelman, 1996; Dejong-Lambert and Krementsov, 2012), fear and uncontested obedience to authority (Milgram, 1963). Regardless of underlying motives<sup>56</sup> and intentionality, the distortions in the understanding of reality render truth unattainable and leave researchers with the consolation of being able to produce nothing but imperfect theories and models, which can nevertheless be useful in certain contexts. To me, researchers are doomed to looking at shadows and can never come

<sup>&</sup>lt;sup>53</sup> In English, "through difficulties to the stars".

<sup>&</sup>lt;sup>54</sup> The aphorism "standing on the shoulders of giants" is well documented in Isaac Newton's writings but its origins can be traced back to Antiquity.

<sup>&</sup>lt;sup>55</sup> The alternatives "to evolve" or "to develop" still raise my doubts from a biosphere perspective.

<sup>&</sup>lt;sup>56</sup> E.g. researcher intellectual and sensory limitation, selective perception, ideological biases.

out into the sunlight of the absolute truth (Plato, 360 BC)<sup>57</sup>. At best, researchers can aim at increasing the resolution of those shadows. The unattainability of truth may exert a discouraging effect on researchers, who, in the face of disillusion, need to recalibrate their aspirations. A feasible aspiration for researchers, as specimens of an intrinsically curious and unfulfilled species, is to go one step further in the never-ending quest for knowledge, which will hopefully contribute to progress that benefits all human beings (e.g. Blomkamp, 2013), as well as the preservation of nature and its biodiversity (Guggenheim, 2006). The primacy of the useful truth over the unreachable absolute truth is made well manifest in quality improvement, the epistemological foundations of which rest on pragmatism (Mauléon and Bergman, 2009).

### 3.9.2 Background and Methodological Preferences

I have a background in engineering, more specifically in mechanics and production management, which, to some extent, explains my preference for quantitative research methods. Notwithstanding this background, I am an advocate of methodological eclecticism as different methods serve different purposes<sup>58</sup>. Besides knowledge of specific methods, this implies that one should be able to select the methods that are best suited to solving the problem at hands. In fact, I see statistics as a theory like any other, which is useful in helping to understand and manage the variation that inevitably pervades all aspects of life. Furthermore, I have to agree with Collins that "statistical testing is more a matter of faith than an ultimate criterion of truth" (1984, p. 335). It is also important to remember that statistics can be misused and that such misuse may have horrific consequences (e.g. Gould, 1996). When using statistics, there are several fallacies lurking (Anscombe, 1973; Bergman, 2012), such as confusing correlation with causation<sup>59</sup> (e.g. Aldrich, 1995; Lawlor *et al.*, 2004), neglecting problems of mass significance<sup>60</sup> (e.g. Bland and Altman, 1995; Perneger, 1998) or

<sup>&</sup>lt;sup>57</sup> An animation of Plato's cave is available at <u>http://www.fakenation.info/platoscave</u>.

<sup>&</sup>lt;sup>58</sup> As one of my colleagues once said, if the only tool one can handle is a hammer, then one will see nails everywhere.

<sup>&</sup>lt;sup>59</sup> An example of spurious correlation is that between drinking coffee and increased risk of lung cancer, as the correlation is confounded by smoking. Time and size are frequent confounding factors. Not only the existence but also the direction of a causal relationship needs to be investigated.

<sup>&</sup>lt;sup>60</sup> E.g. on an average, it is expected that one of every 20 independent hypothesis tests on the same data be significant at the 5% significance level purely due to chance. See also Holm-Bonferroni and Šidák methods.

extrapolating correlations at the group level to correlations at the individual level (Robinson, 1950). Another important aspect is discussed by Ziliak and McCloskey (2008) and deals with the risks of tyranny of the P-value and the subsequent subordination of practical significance to statistical significance.

### 3.9.3 Personal Motivations

Several times I have been questioned about my interest in healthcare processes. I usually recall Spear's reflection on the achievement of outstanding results by average people at Toyota and on what should be possible to achieve in a system, such as the healthcare system, replete with brilliant people (Spear, 2006). I am deeply convinced that the quality of the care delivered can be significantly improved, for the benefit of patients, at the same time as it is possible to improve work conditions for the benefit of healthcare providers. I am also convinced that, for the benefit of the society, the pursuit of quality will, overall, be associated with cost savings. Despite the enormous potential for improvement, the complexities involved in the delivery of care and the difficulties of achieving change render the healthcare system a most challenging field. My interest in healthcare processes is also grounded in my belief that all citizens have the right to receive high-quality care and thus being able to live a better life. As the "give and take" usually go hand in hand, citizens who feel happy about their lives will tend to share their well-being with the surrounding environment. Thus, delivering high-quality care plays an important role in society, not only for patients in particular, but also for society and environment at large. The philanthropic view previously expounded may reflect more of a wish than a reality. Finally, my interest in healthcare processes rests on the idea that healthcare greatly impacts the economic growth of countries and that economic growth is accompanied less prosperous countries emulating socially developed Western societies. Swedish healthcare can, in particular, contribute to preserving, and preferably further promoting, the social advancements that have occurred in Swedish society over the past decades, as well as to disseminating those advancements to societies outside Sweden.

Although I recognize that the sound use of resources is an important and worthy aim, my interest in quality has little to do with potential immediate cost savings associated with quality improvement. My interest rests mainly on my perception that quality improvement initiatives can promote both customer satisfaction and sustainable development (e.g. WCED, 1987). The quest for customer satisfaction relates to the previous idea of enjoying and sharing

a good life, whereas the pursuit of sustainable development relates to my idea that we human beings are responsible for assuring the liveability of the planet for future generations and for preserving nature and its biodiversity. Although the relationship between quality and sustainable development can be discussed from different vantage points, quality improvement can, in an immediate way, result in enhanced product reliability and reduced consumption. By translating the idea of product reliability to healthcare, quality improvement might be able to contribute to strengthening both primary and secondary prevention and to reducing the prevalence of curative care. In my opinion, quality improvement can play an essential role in maintaining the health of citizens and keeping them away from hospitals.

Finally, I would like to comment on my motivations for engaging in research and pursuing a doctorate. The date of filling the application that led to my enrollment as a Ph.D. student was not the first time I considered engaging in research. Even after an initial frustrated attempt, in which I was told to lack the background to complete Ph.D. studies in the quality sciences, I persisted in learning more about quality improvement and understanding the whys of questions that intrigued me. Before starting my Ph.D. studies, I was aware that, in the role of consultant, I would be expected to produce something of value to practitioners and that the role of a Ph.D. student would pose other demands, including a contribution to theory. At the end of five years, I have a better understanding of the roles played by Ph.D. students. I would argue that, as a Ph.D. student, one is required to possess the curiosity and resourcefulness of a detective, the reporting accuracy and completeness of a journalist, as well as the theoretical inclination and critical thinking of a scholar. In a well-known metaphor, Newton described the endeavors of a researcher as that of a youngster playing in search for a smoother pebble or a prettier shell than the ordinary ones, on the shore of the great ocean of truth laying in front all undiscovered<sup>61</sup> (Brewster, 1855). In a similar vein, Kvale and Brinkmann (2009) depicted a researcher as an ore searcher, who diligently seeks nuggets of knowledge. I prefer, however, the alternative metaphor presented by Kvale and Brinkmann, in which the researcher is equated to a traveler who constructs knowledge along

<sup>&</sup>lt;sup>61</sup> Original quote of Newton: "[...] like a boy playing on the sea shore, and diverting myself in now and then finding a smoother pebble or a prettier shell than ordinary, whilst the great ocean of truth lay all undiscovered before me" (page 490).

a journey. In my opinion, science is, indeed, a journey and not only a destination<sup>62</sup> (Gummesson, 2000).

### 3.9.4 The Foundational Research Project

At the beginning of my Ph.D. studies, it was expected that the "Acute Chest Pain: A Study of Variation, Quality, Safety and Cost at a University Hospital" project, henceforth the "acute chest pain project", would form the basis of my research, at least until earning the Licentiate Degree, which should happen within two to three years after the initiation of my studies. The project was financed under the auspices of the Vinnvård Research Program<sup>63</sup> and aimed at eliminating unwanted variations in the treatment of acute chest pain, thus yielding gains in access to correct treatment, quality of care and costs. In this collaboration between Chalmers University of Technology and the SU, it was expected that the project would lead to actual improvements in treating acute chest pain patients. I was to be actively engaged mainly during the improvement part of this allegedly action research project. At the time I took up my Ph.D. studies in September 2008, the variables relevant to the characterization of the current treatment of acute chest pain had been defined and data collection initiated.

### 3.9.5 The Ph.D. Studies until the Licentiate Degree

In the beginning of my Ph.D. studies, I allocated much time to the Ph.D. education curriculum. As time passed, the pressure for producing publications increased. While waiting for the collection of data from the acute chest pain project to be completed, I proceeded to use the data on physician scheduling that I had previously collected while working as a consultant (Study 1). Not only were the data readily available but the subject was also of major importance with respect to the timeliness of healthcare delivery. Another possibility of an interesting and relevant study emerged when I was recommended to investigate the CDSS that had been developed at the SÄS and that apparently had produced resounding improvements in the quality of cardiac care at that hospital (Study 2). Once the collection of the data from the acute chest pain project had been completed, I was able to access the data to conduct Study 3. The three studies above formed the core of the Licentiate thesis, which I presented by the end of 2011.

<sup>&</sup>lt;sup>62</sup> Original quote: "science is a journey, not a destination" (p. 90).

<sup>&</sup>lt;sup>63</sup> <u>http://www.vinnvard.se/</u>.

### 3.9.6 The Ph.D. Studies after the Licentiate Degree

Besides Study 3, there were other studies conducted within the acute chest pain project (Ravn-Fischer et al., 2012; Thang et al., 2012; Ravn-Fischer et al., 2013). Although various opportunities for improvement were identified as a result of these studies, the project did not proceed to the improvement phase as initially expected. This thwarted my role in the project, which essentially turned into a medical research project. Nevertheless, I found my collaboration with the research team of the SU throughout the project to have been both enjoyable and enriching. After concluding my participation in the acute chest pain project, I initiated a study jointly with practitioners at the SkaS on monitoring lead times (Study 4). Two major reasons for conducting the study were the access to the field that it enabled and its relevance from the perspective of timeliness. The initial design of the study included an *in loco* test of the proposed Lexis diagram and a quantitative assessment of the effects of using the Lexis diagram on lead times. The test was postponed by practitioners more than once. After several unsuccessful attempts at testing the Lexis diagram in daily practice, I reduced the initial scope of the study and became contented with collecting pre-test practitioner perceptions of the potential benefits and challenges of using the Lexis diagram for monitoring lead times. Under the pressure of completing the Ph.D. studies within five years, I gained a great deal of independence while conducting Study 5, which resulted in a singleauthor literature review.

Figure 11 illustrates the time frame of my five-year research journey. The figure shows some important milestones, such as the presentation of the Licentiate thesis and the defence of the doctoral thesis. During the course of five years, I made the study visits and attended the conferences shown in the figure. Each study is associated with a bar that indicates approximately the starting and end points of the study. The figure excludes departmental duties, such as teaching and course administration. With the benefit of hindsight, I regret not having started my writing earlier and lacked the perspicacity to assess the circumstances for conducting my studies. I also find it unfortunate that I allowed the "cans" to predominate over the "wants" and the thesis to be more scattered than I had wished. Conversely, I am glad that I had the perseverance necessary to complete this thesis along a journey of much learning and several fruitful collaborations.

# **Research Methodology**



time as Ph.D. student, nor the curricular part of the Ph.D. studies;<sup>c</sup> Doctoral thesis defence;<sup>d</sup> The data used in Study 1 were collected prior to the initiation of the Ph.D. studies;<sup>e</sup> The data collected referred to care delivered during Sep-Dec 2008 and were collected retrospectively by others, to which I gained access in Apr 2010;<sup>f</sup> The data collected referred to care delivered during Mar-Jun 2011 and were partly collected by others in a retrospective fashion, to which I gained access in Jan 2012.

# Figure 11 Time frame of my Ph.D. studies.

# 4 EMPIRICAL SETTING

Overall, the research accounted for in this thesis followed a case study design. The description of the case study provided in this chapter is necessary for understanding the extent to which the findings of this research may be generalized to other settings. As all studies were conducted in Swedish healthcare settings, the first section of this chapter briefly portrays Sweden as a country and its healthcare system. In particular, the SÄS, the SU and the SkaS are described (Studies 2, 3 and 4 respectively). This chapter also draws on the timeliness of healthcare delivery in Sweden, which is often indicated as the Achilles' heel of the Swedish healthcare system. Moreover, the studies on physician scheduling and on lead times (Studies 1 and 4) are especially important concerning the timeliness of healthcare delivery. This chapter also includes a section devoted to the highly lethal ACSs, of which acute chest pain is usually a symptom (Studies 2 and 3). The chapter ends with an account of some healthcare quality databases and reports and additional information on Swedish quality registries (Studies 2 and 5).

### 4.1 Sweden and the Swedish Healthcare System

Sweden is an OECD<sup>64</sup> country that allocates nearly 10% of its gross domestic product to the provision of healthcare services (WHO, 2013), which amounts to nearly SEK 374,000 per capita. Sweden has been facing a demographic increase over recent decades and has a current population of about 9.6 million, of which about 20% has foreign background. Average life expectancy at birth is approximately 80 years for men and 84 for women. Currently, citizens 80-year-old or more represent circa 5% of the entire population. According to the latest estimates, the unemployment rate in the 15-74 year range hovered around 9% in June 2013 (SCB, 2013)<sup>65</sup>.

### 4.1.1 Organization

Swedish health policy is a national responsibility that rests with the Government and Parliament. Overall, the Swedish healthcare system is regulated by the Health and Medical Services Act (Ministry of Health and Social Affairs, 1982), the purpose of which is to contribute to good health and equitable care for all citizens. The act emphasizes the

<sup>&</sup>lt;sup>64</sup> Organization for Economic Cooperation and Development (<u>www.oecd.org</u>).

<sup>&</sup>lt;sup>65</sup> The figures indicated in this paragraph concern 2011 or 2012 unless indicated otherwise.

importance of prevention and establishes that healthcare quality has to be systematically and continuously improved and assured. The system is supervised by National Board of Health and Welfare<sup>66</sup>. Operationally, the Swedish healthcare system is highly decentralized and is primarily operated by 21 counties and regions and 290 municipalities. The municipalities are responsible for all health services associated with residential care, excluding physician services and can enter into contracts with the county councils to provide home care. The system is overwhelmingly tax-financed, with patient fees<sup>67</sup> accounting for less than 3% of revenues. Overall, private providers account for about 10% of healthcare services delivered. About one of four primary care centers is privately managed. A more detailed description of the Swedish healthcare system can be found in a report published by the Swedish Association of Local Authorities and Regions<sup>68</sup> (SALAR, 2005).

### 4.1.2 Relevant Healthcare Providers

Studies 2, 3 and 4 were conducted at specific hospitals, all of which are part of the West Sweden region<sup>69</sup> (see Figure 12). The region was formed in 1999 and operates 17 hospitals and 121 healthcare centers. About 1.6 million inhabitants live in the region, the largest city of which is Gothenburg.

The SkaS<sup>70</sup> provides specialized care at the Borås and Skene sites to a population of about 285,000 inhabitants. The intervention investigated in Study 2 took place at the CICU of Borås<sup>71</sup>, which provides care to patients with cardiac diseases, e.g. AMI, angina pectoris, arrhythmia and heart failure. The treatments provided include PCI, CABG, pacemaker and postoperative care after heart valve surgery. At the time of the intervention, there were about 20 beds at the Borås CICU. Two specialist and two junior physician positions were shared among six specialists and the nearly 20 junior physicians that served the ward for over a year. The SU<sup>72</sup> is one of seven university hospitals offering medical education in Sweden. The hospital provides emergency and basic care to the 630,000 inhabitants of the Gothenburg

<sup>&</sup>lt;sup>66</sup> In Swedish, "Socialstyrelsen" (<u>http://www.socialstyrelsen.se/english</u>).

<sup>&</sup>lt;sup>67</sup> I.e. out-of-pocket expenses.

<sup>&</sup>lt;sup>68</sup> In Swedish, "Sveriges Kommuner och Landsting" (<u>http://english.skl.se/</u>).

<sup>&</sup>lt;sup>69</sup> In Swedish, "Västra Götalandsregionen" (<u>www.vgregion.se/en</u>).

<sup>&</sup>lt;sup>70</sup> In Swedish, "Södra Älvsborgs Sjukhus", abbreviated SÄS (<u>http://sas.vgregion.se/Sodra-Alvsborgs-Sjukhus/</u>).

<sup>&</sup>lt;sup>71</sup> <u>http://sas.vgregion.se/sv/Sodra-Alvsborgs-Sjukhus/SAS-/Kliniker-och-enheter/Hjart--lungklinik/HIA/</u>

<sup>&</sup>lt;sup>72</sup> In Swedish, "Sahlgrenska Universitetssjukhuset", abbreviated SU (<u>http://www.sahlgrenska.se</u>).

region. It also provides highly specialised care to the 1.6 million inhabitants of the West Sweden region, of which circa 15% are born abroad<sup>73</sup>. The SkaS<sup>74</sup> provides specialized care at the Falköping, Lidköping, Mariestad and Skövde sites. The surgery department investigated in Study 4 is one of two comprising the hospital group and embraces three of the four sites previously mentioned. The surgery department has a service area of circa 185,000 inhabitants and its services include emergency surgery, day care surgery, inpatient surgery, inpatient care, and outpatient clinic appointments. Not all services are available at all sites. Annually, departmental staff performs about 3,300 surgical procedures and provides approximately 9,500 outpatient clinic appointments.



**Figure 12** The map on the extreme right shows the location of Sweden in Europe. The darkened area in the middle map corresponds to the West Sweden region. The map on the left shows the location of the three hospitals relevant to this thesis.

### 4.1.3 Timeliness of Swedish healthcare

As in several other European countries, the healthcare system in Sweden faces challenges resulting from population aging, demographic growth, increased ethnic diversity, technological advances<sup>75</sup>, increased complexity of healthcare delivery and the growth of cross-border care, to name a few. By 2060, it is estimated that a population of 11.6 million will live in Sweden and that 9.6% will reach the age of 80 or older (SCB, 2013). Health

<sup>&</sup>lt;sup>73</sup> The figures in this paragraph concern 2011 and were obtained from Statistics Sweden databases.

<sup>&</sup>lt;sup>74</sup> In Swedish, "Skaraborgs Sjukhus", abbreviated SkaS (<u>www.vgregion.se/Skaraborgs-sjukhus/</u>).

<sup>&</sup>lt;sup>75</sup> E.g. information systems, innovations in genomics, biotechnology and nanotechnology.

### **Empirical Setting**

expenditures in Sweden have been increasing over time and cost-containment demands have thus been imposed on healthcare managers and providers (Anell, 2005). Although the Swedish healthcare system seems to excel in medical outcomes at reasonable cost (e.g. SALAR, 2005; 2009), it is often criticized on the grounds of its low productivity (e.g. Fölster *et al.*, 2003) and lengthy waiting times (e.g. Health Consumer Powerhouse, 2012). Despite misspellings, free market propaganda and hyperboles, Hogberg (2007) gives a factual account of the successive reforms undertaken in Sweden and their effects on waiting times.

In an attempt to reduce Swedish waiting times, national guarantees on maximum waiting times have been created, the first of which was introduced in 1992. The current guarantee dates from 2005 and states that: (1) patients should be able to get into contact with primary care on the day of their first attempt, (2) if a physician visit is deemed necessary, patients should be able to see the primary care physician within seven days, (3) if the patient is referred to a specialist, patients should be able to see the specialist physician within 90 days and (4) the delay between treatment decision and treatment initiation should not exceed 90 days<sup>76</sup>. Accordingly, the current maximum waiting time guarantee is associated with the 0-7-90-90 number series (Figure 13). It is also stated in the guarantee that if both physician and

patient agree, deviations from the previously indicated specification limits are permissible. The guarantee is applicable to all patients and excludes acute care, which should be provided as soon as possible. The guarantee exclusively concerns specification limits for waiting times and gives patients no entitlement to receive care.

**Figure 13** Number series commonly associated with the current Maximum Waiting Time Guarantee.

In an early assessment of the effects of the "maximum waiting time guarantee", Hanning (2005) argued that the positive effects of the guarantee were temporary and based on rationalization, the introduction of new technology, and stricter prioritization. Furthermore, the guarantee was found to have contributed to empowering patients and slowing the expansion of treatment indications, notwithstanding its failure to reduce regional differences. As long waiting times persisted, it was decided that SEK 1 billion<sup>77</sup> would be

<sup>&</sup>lt;sup>76</sup> More information can be retrieved from the SALAR database "Väntetider i vården" (<u>www.vantetider.se</u>), which has been used for monitoring waiting times across Sweden since 2000.

<sup>&</sup>lt;sup>77</sup> SEK 10<sup>9</sup> were made available and became known as "Kömiljarden".

injected into the Swedish healthcare system during the 2009-2011 triennium in order to eradicate excessive waiting. According to the report aimed at evaluating the effects of this extraordinary expenditure (Socialstyrelsen, 2012), no unequivocal answer on the success of the initiative may be provided. The report cautions against the risk of crowding-out as the improved timeliness for newly incoming patients may have been achieved partly at the expense of patient groups not contemplated in the guarantee, such as patients waiting for follow-up visits. Towards the end of 2011, it was decided to repeat the initiative for the following triennium.

### 4.2 Acute Chest Pain

This section is dedicated to acute chest pain, a symptom that is usually considered a medical emergency as it may be a symptom of a life-threatening disease such as heart attack, also called AMI, or simply myocardial infarction (MERCK, 2011). Both Studies 2 and 3 concern patients with ACSs. The initial part of this section provides general explanations on the classification, management and predictors of acute chest pain and ACSs. Conversely, the considerations made in the latter part of the section are specific to the Swedish healthcare context and concern mortality and morbidity, relevant quality registries, quality indicators and clinical practice guidelines. Some of the data used in Study 2 were extracted from the quality registry described hereafter. The quality indicators described below were used in Study 2 to evaluate the effects of the CDSS implemented. In Study 3, the data used were extracted from hospital databases and coincide to a large extent with the data sent by the hospital to the quality registry.

### 4.2.1 Classification of acute chest pain

Albeit alarming, acute chest pain is not necessarily a symptom of heart disorder. As depicted in Figure 14, there are several disorders other than cardiovascular ones that are associated with acute chest pain, e.g. pulmonary disorders, upper gastrointestinal ailments, problems of chest wall structures and psychological disorders. "Cardiovascular disorders" are those that affect the heart or blood vessels. These disorders are usually divided into "cardiac disorders"<sup>78</sup> and peripheral blood vessel disorders. Cardiac disorders affect the heart and blood vessels that supply the heart muscle, whereas peripheral blood vessel disorders affect

<sup>&</sup>lt;sup>78</sup> Alternatively, "heart disorders".

the blood vessels of the arms, legs and trunk<sup>79</sup>. Disorders that affect the blood vessels

supplying the brain are called cerebrovascular disorders, e.g. stroke. Cardiac acute chest pain can be a symptom of an ACS or other disorders that do not necessarily result from a sudden blockage in a coronary artery. The sudden blockage in a coronary artery causes either "unstable angina" or "acute myocardial infarction", depending on the location and amount of blockage. Patients afflicted by unstable angina do not present signs of heart attack on their Electrocardiograms (ECGs) or blood tests, but have a high risk of suffering an AMI. Blood tests and ECGs can be used to detect AMI. From an ECG it is possible to verify whether the AMI has produced an elevation of the ST segment, i.e. whether an ST-segment Elevation Myocardial Infarction (STEMI) has occurred.



Figure 14 Classification of acute chest pain

### 4.2.2 Pathogenesis and Diagnosis of Acute Coronary Syndrome

ACS is a condition in which the blood supply to the heart muscle is partially or completely blocked. If the blood supply to the heart muscle (myocardium), which is irrigated by the coronary arteries, is interrupted (ischemia) for more than a few minutes, heart cells will die (necrosis) and the death of heart tissue from reduced or obstructed blood supply ensues (AMI). Since half of deaths due to a heart attack occur during the first three or four hours after symptoms begin, ACS is a medical emergency. The sooner treatment begins, the better the chances of survival. Diagnosing AMI depends on several criteria, including: laboratory parameters (e.g. troponin levels), location of pain or discomfort (e.g. chest, arms, jaw, back, or abdomen), occurrence of other symptoms (e.g. dyspnea, nausea or cold sweat) and ECG-findings. A more precise description of the diagnostic criteria of AMI is provided by Ravn-Fisher (2013, p. v). More information about ACSs is available in Wallentin *et al.* (2000).

<sup>&</sup>lt;sup>79</sup> Except the blood vessels that supply the heart.

### 4.2.3 Diverse Considerations

Differences concerning AMI with respect to sex are many. Women tend to be older when having their first AMI and their previous history of diseases tends to differ from that of men. Biological differences result in more diffuse symptoms and differences in the localization of pain for women. Not only sex, but also socio-economic status and education level are associated with the risk of cardiovascular disease. Moreover, lower socio-economic status and lower education level are both associated with an increased risk of cardiovascular disease. Since several decades, it has been established that the treatment of heart diseases by specially trained staff is associated with lower mortality. Over time, the patients admitted to the care units in which this specially trained staff works<sup>80</sup> have become older and less severely ill. The use of ambulance transport for hospital admission for patients with ACS has been found beneficial as appropriate therapies can be initiated sooner and the emergency department visit can be bypassed by taking the patient directly to the catheterization lab. The body of knowledge on the treatment of ACSs has dramatically increased during recent years, which has contributed to a significant decrease during the last decade in the incidence and mortality of AMI. References supporting these considerations can be found in Ravn-Fisher (2013).

### 4.2.4 Mortality and Morbidity in Sweden

Mortality associated with cardiovascular diseases, in which AMI is included, has been decreasing over time in Sweden, as well as in many other industrialized countries. Cardiovascular diseases, however, remain a leading cause of death in Sweden. Of the nearly 90,000 deaths that occurred in Sweden during 2011, all causes included, almost 40% were due to cardiovascular diseases, with women and men being affected at around the same rate (Socialstyrelsen, 2013a). In 2011, about 32,000 incident cases of AMI were registered, of which 9,000 resulted in death from AMI as the underlying or contributing cause (Socialstyrelsen, 2013b). Figure 15 illustrates the annual all-cause mortality and incidence of AMI in Sweden. Reports on the mortality and morbidity associated with AMI are annually compiled by the Swedish registers of Cause of Death and RIKS-HIA.

<sup>&</sup>lt;sup>80</sup> Usually called, "cardiac intensive care unit".

Annual all-cause mortality Figure 15 Annual all-cause mortality and incidence of AMI in
Sweden in 2011. The black icons correspond to the annual
deaths from AMI as the underlying or contributing cause. Each
icon represents 1,000 individuals and figures are approximated
to the nearest thousands.

### 4.2.5 The Swedish National Quality Registry RIKS-HIA

The Swedish national quality registry RIKS-HIA<sup>81</sup> aims at developing acute coronary care in order to decrease mortality and morbidity and increase the cost-effectiveness of coronary care. The RIKS-HIA has been accepted as a national quality registry since 1995. All patients admitted to intensive coronary care at participating hospitals are reported to the RIKS-HIA using a case record form including data on admission, hospitalization and discharge. In 2009, the four separate quality registries within coronary care merged into a single national quality registry called SWEDEHEART<sup>82</sup>. The data reported to RIKS-HIA may be used for either longitudinal or cross-sectional studies. In fact, comparative annual reports (RIKS-HIA, 2011; SWEDEHEART, 2011) have been published, giving an account of acute cardiac care delivered, the characteristics and development of AMI and patient outcomes. The reports allow comparisons across participating units and the calculation of a quality index based on a number of quality indicators.

<sup>&</sup>lt;sup>81</sup> I.e. Registry of Information and Knowledge about Swedish Heart Intensive Care Admissions.

<sup>&</sup>lt;sup>82</sup> I.e. Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies.

### 4.2.6 The RIKS-HIA Quality Indicators and Quality Index

The quality index established by the RIKS-HIA in 2005 is currently based on nine quality indicators, each of which assesses the adherence to national guidelines with respect to some highly prioritized interventions. Reporting healthcare units receive  $0, \frac{1}{2}$  or 1 point depending on the fraction of patients who receive care in accordance with national guidelines. The maximum number of points that a reporting healthcare unit can be awarded is nine. Details on the calculation of the quality index and on the nine quality indicators are provided in the annual reports published by RIKS-HIA. Figure 16 shows some of the quality indicators currently included that were used in Study 2 as well as in other projects (Carlhed *et al.*, 2006).

$\left( \right)$	Performance of coronary angiography in non-STEMI patients
	Prescription of Lmw-heparin or performance of PCI within 24 h in non-STEMI patients
	Prescription of Lipid-lowering therapy after AMI at discharge
	Prescription of ACE-inhibitor/A2-blocker treatment after AMI at discharge
	Prescription of Clopidogrel after AMI in non-STEMI patients at discharge

Figure 16 Some quality indicators of cardiac care (SWEDEHEART, 2012).

### 4.2.7 The Swedish National Guidelines for Cardiac Care

The quality indicators previously discussed are based on the Swedish national guidelines for cardiac care issued by the National Board of Health and Welfare (Socialstyrelsen, 2008a). Besides ACSs, there are other groups of cardiac disease contemplated in the guidelines, e.g. arrhythmias, heart failure, heart and valve defects and congenital heart disease. Each recommendation is associated with a 1 to 10 indicator according to the degree of importance. The recommendations cover prevention, diagnosis, treatment and recovery. There are three types of recommendations: (1) ranked recommendations, (2) "don't do it" recommendations and (3) "research" recommendations. Treatments of documented ineffectiveness or increased risk for complications or secondary effects are labelled "don't do it". Treatments associated with insufficient or conflicting evidence are treated as "research". The economic and organizational consequences of recommendations are expressed as cost per quality-adjusted life years. Most recommendations represent cost savings or are cost-neutral. In the final chapter of the national guidelines there are recommendations on communication,

participation and co-decision to deliver high-quality care. Concerning the prioritization of treatments, as patient needs and abilities to benefit from a treatment should govern the choice of treatment, the guidelines advocate that prioritization should be indicated on the basis of a patient's biological rather than chronological age. In the clinical situation, individual judgement of patient life expectancy and quality of life is necessary (Socialstyrelsen, 2008b).

### 4.3 Swedish Quality Registries

The emergence and dissemination of quality registries is consistent with the perspective that measurement is a necessary pre-condition for improving healthcare quality (e.g. Nelson *et al.*, 2004). There are currently a vast number of organizations that regularly publish reports of healthcare quality in Sweden. International comparisons with respect to healthcare between Sweden and other countries can be found both at the global (e.g. OECD, 2012; WHO, 2012)<sup>83</sup>, as well as the European level (e.g. European Commision, 2012; Health Consumer Powerhouse, 2012). At the national level, annual reports compare the quality of care delivered by different counties and regions that comprise Sweden (e.g. SKL and Socialstyrelsen, 2012)<sup>84</sup>. There are also reports on the quality of care at regional levels (e.g. VGR, 2012).

Sweden has a long established tradition of measuring healthcare quality and can thus be considered a forerunner in developing and using quality registries (Sousa *et al.*, 2006). It has been claimed that quality registries have the potential of becoming "gold mines" to Swedish healthcare and that further investments at the national level would be necessary to strengthen the use of quality registries (Rosén and Sjöberg, 2010). Annually, Swedish quality registries are evaluated and classified into one of four categories: "Candidate for national quality registry" (28 registries in 2013), "Level 3 national quality registry" (50 registries), "Level 2 national quality registry" (21 registries) and, finally, "Level 1 national quality registry" (6 registries) attributed to the most highly developed quality registries. The six quality registries awarded in 2013 with Level 1<sup>85</sup> included: the "National Prostate Cancer

<sup>&</sup>lt;sup>83</sup> "Organisation for Economic Co-operation and Development" and "World Health Organization", respectively.

<sup>&</sup>lt;sup>84</sup> This report series is called "Öppna Jämförelser" and are produced by SALAR.

<sup>&</sup>lt;sup>85</sup> Complete list of registries and candidates in each category at <u>www.kvalitetsregister.se/register</u>.

Register<sup>"86</sup>, "National Diabetes Register<sup>"87</sup>, SWEDEHEART<sup>88</sup>, "Swedish Stroke Register<sup>"89</sup>, "Swedish Hip Arthroplasty Register<sup>"90</sup> and "InfCare HIV<sup>"91</sup>. The evaluation criteria deal with such factors as registry organization and infrastructures, registry relevance and coverage, registry use in research, linkages to other databases and providing feedback. For instance, Level 1 national quality registries are required to be conducive to good to excellent conditions for systematic local process improvement and for providing feedback supportive of process improvement<sup>92</sup>. A brief description in English of the 56 national quality registries existing in Sweden in 2007 can be found in a catalogue published by SALAR (2007). The number of national quality registries has been increasing and currently totals 77 registries and 28 candidates.

<sup>&</sup>lt;sup>86</sup> In Swedish, "Nationella prostatacancerregistret" (<u>http://www.roc.se</u>).

<sup>&</sup>lt;sup>87</sup> In Swedish, "Nationellt kvalitetsregister" (<u>https://www.ndr.nu</u>).

<sup>&</sup>lt;sup>88</sup> <u>http://www.ucr.uu.se/swedeheart/</u>

<sup>&</sup>lt;sup>89</sup> In Swedish, "Riks-Stroke" (<u>http://www.riks-stroke.org</u>).

<sup>&</sup>lt;sup>90</sup> In Swedish, "Svenska Höftprotesregistret" (<u>http://www.shpr.se</u>).

<sup>&</sup>lt;sup>91</sup> <u>http://infcare.se/hiv/sv/</u>

<sup>&</sup>lt;sup>92</sup> Complete list of requirements for each category can be found at <u>www.kvalitetsregister.se/register</u>

# 5 MAIN RESULTS

This chapter reports on the main results of the five studies previously described. For a more detailed discussion of results, the reader is referred to the individual papers appended to this thesis.

### 5.1 Study 1

The main results of this study are presented in the first appended paper that shed light on the various intricacies that pervaded physician scheduling in the hospital departments investigated. The paper showed that physician scheduling required the coordination of patients, physicians, non-physician staff, rooms and equipment and that it could be described as a six-step process. Several scheduling aspects were identified as problematic: (1) an overreliance on memory, (2) uncoordinated resources, (3) redundant-data entry, (4) lacking follow-up data, (5) mismatches between demand and capacity, (6) highly varying physician availability, (7) uninformed vacation and leave requests and (8) conflicting stakeholder interests. It was suggested that the shortcomings in physician scheduling identified may have resulted from excessive fragmentation, lacking decision support and scarce learning opportunities.

### 5.2 Study 2

The main results of this study are presented in the second appended paper that showed that the intervention investigated, i.e. introduction of a CDSS, was associated with increases in guideline adherence ranging from 16 to 35 percentage points, depending on the therapy recommended. Figure 17 shows the pre-intervention and post-intervention rates of guideline adherence at the intervention CICU and in the control group. The association between guideline adherence and the use of the CDSS remained statistically significant over the fiveyear period subsequent to the introduction of the CDSS. During the same period, no relapses occurred at the intervention CICU. The differences in guideline adherence between the intervention CICU and the control group, however, diminished over time. The paper added evidence of the ability of CDSSs to change clinical practice and promote guideline adherence. The paper also added evidence of the ability of CDSSs to improve healthcare quality, as the effects of using the CDSS were evaluated according to quality criteria considered to be underused quality criteria in the treatment of AMI.



**Figure 17** Effects of the introduction of a CDSS on the guideline adherence rates of four recommended therapies. Pre-intervention rates (year 2002) and post-intervention rates (year 2004) are shown both at the intervention CICU (dark bars) and in the control group (light bars). Bar width is proportional to the number of patients in each group.

### 5.3 Study 3

The main results of this study are presented in the third appended paper that showed that three of the four delay times investigated were longer for non-Swedish-speaking patients. However, only the association between poorer language proficiency and longer delay time from arrival in hospital to admission to catheterization lab or ward was found to be statistically significant (see Table 9). The paper also showed that non-Swedish-speaking patients had a higher probability of being hospitalized (64% versus 54%, P<0.001) and that they had a higher prevalence of co-morbidities and risk factors compared to Swedish-speaking patients, e.g. diabetes, hypertension, AMI, PCI and stroke.

Table 9 Delays in minutes for all hospitalized patients [overall median]: median (n=sample size).

Delay variable	Swedish- speaking	non-Swedish- speaking	P <sup>a</sup>
Arrival in hospital to admission: PCI-lab or ward [216]	211 (n=1155)	254 (n=123)	0.002
$1^{st}$ physical contact to $1^{st}$ electrocardiography [13]	13 (n=1073) <sup>c</sup>	17 (n=119) <sup>b</sup>	0.43
1 <sup>st</sup> physical contact to 1 <sup>st</sup> aspirin [78]	81 (n=286) <sup>b</sup>	61 (n=34) <sup>b</sup>	0.43
Arrival in hospital to coronary angiography [1819]	1806 (n=202) <sup>b</sup>	2631 (n=21) <sup>b</sup>	0.45

<sup>a</sup> Adjusted for all baseline variables with univariate *P*<0.20 for association with both group belonging and delay

<sup>b</sup> 5-10% missing

<sup>c</sup> 10-25% missing

### 5.4 Study 4

The main results of this study are presented in the fourth appended paper that argued that the Lexis diagram could be used to monitor lead times, thus complementing the reporting of waiting times imposed by the national maximum waiting time guarantee in force in Swedish healthcare. Prior to any test in daily practice, the practitioners interviewed expected the Lexis Diagram to contribute to a more holistic view of processes, a more precise measurement of lead times, in addition to enhancing the ability of practitioners to react on time while the

referral was still active in the system. Further, the diagram was expected to motivate improvements in staff scheduling by increasing knowledge of the number of referrals currently active in the system. However, the results pointed to the risk of clutter, rendering the Lexis diagram inadequate for displaying lead times over lengthy periods, as well as to the risk of distorting clinical priorities by placing excessive emphasis on time. It was also suggested that there might be obstacles to fitting the Lexis diagram neatly into current operations.

Figure 18 illustrates how a Lexis diagram used for monitoring referral lead times might look on the specific date of May 31. The figure shows that during the May 24 to May 31 week (horizontal axis), seven referrals would have been closed (line segments with markers) and that on May 31, 37 referrals would be active in the system (line segments intersecting the vertical line on May 31), with total time ranging from about 1 to 63 days (vertical axis).



*Figure 18 Example of a Lexis diagram used for lead times monitoring.* 

### 5.5 Study 5

The main results of this study are presented in the fifth paper appended showing that synchronic variation, i.e. variation over time, was represented in 40% of the charts, whereas diachronic variation, i.e. geographical variation, was illustrated in about 45% of the charts. Percentages or proportions were used in about four of five charts. In 75% of the cases in

which synchronic variation was displayed (see Table 10), the healthcare units were ranked and an internal comparator used, usually a national weighted average. League tables represented 75% of the charts displaying synchronic variation. Guidance on distinguishing random variation from assignable cause variation was provided in fewer than 25% of the charts. Concerning the charts that displayed diachronic variation (see Table 10), the number of time periods displayed ranged from 3 to 10 in half of the charts, whereas 25% of the charts displayed only two time periods. The vast majority of the charts that displayed diachronic variation, 86%, reported annual values. Less aggregated data, e.g. quarterly or biannual, were reported in about 1% of the charts. No control charts were found among the charts examined. The results concluded that the annual reports issued by quality registries lack both the level of detail and consideration of random variation necessary to being systematically used in process improvement.

**Table 10** The characteristics of charts displaying synchronic variation (n=255, all quality registries included) are shown in the left table, whereas the table on the right shows the characteristics of charts displaying synchronic variation (n=289, all quality registries included).

Charts displaying synchronic variation			
Variable	%		
WITH RANKED PROVIDERS			
TYPE OF COMPARATOR			
Internal to the data	71		
External to the data	3		
CONSIDERATION OF CHANCE			
Outliers clearly indicated	9		
Provision of confidence intervals	12		
Provision of Interquartile ranges	3		
TYPE OF CHART			
League table	75		
Funnel plot	1		
Other (e.g. maps, radar charts)	25		

Charts displaying diachronic variation				
Variable				
NUMBER OF TIME PERIODS DISPLAYED				
Тwo	24			
Between 3 to 10	52			
More than 10	24			
FREQUENCY OF CHARTING				
Shorter than one year	1			
One year	86			
Longer than one year	13			
TYPE OF CHART				
Run chart	66			
Other	34			

# 6 DISCUSSION

Unjustified variations are expressions of the existence of causes that are allowed to persist in the delivery of care despite their detrimental effect on the stability and predictability of the quality of care and subsequent impossibility of consistently delivering high-quality care. It is therefore necessary to increase the understanding of the causes affecting the quality of care, their effects on the quality of such care and how their management can be improved. Each of the research questions formulated at the beginning of this thesis has been addressed in separate papers. Papers I to V provide answers to research questions RQ1 to RQ5, respectively. This chapter starts with a discussion of the common themes in the papers appended concerning understanding and managing variation in healthcare processes. A discussion on the implications for quality of care and the limitations of the research conducted follows.

## 6.1 Understanding and Managing Variation

It is possible to distinguish three steps in understanding and managing variation in the quality of care. First, it is necessary to detect differences in the quality of care delivered. Second, the differences detected must be understood, i.e. the causes of such differences need to be identified. Third, actions need to be taken in order to eliminate or neutralize the causes identified (Figure 19).



*Figure 19* The three steps in understanding and managing variation (adaptation from Chakhunashvili, 2006)

### 6.1.1 Understanding Variation – Detecting Differences

Quality of care can be evaluated in terms of infrastructure, process or outcome indicators (Donabedian, 1966). Therefore, differences in such indicators can be used for improving the quality of care. In Paper II, only process indicators were investigated in order to assess the effects of the HRs on the quality of care, e.g. the performance of coronary angiography. In Paper III, both process and outcome indicators were investigated, e.g. the delay from hospital admission to arrival at the PCI lab and in-hospital survival, respectively. In Paper IV, the quality indicator investigated dealt with process lead times. The operationalization of the quality of care in remaining papers is less explicit. Paper I aimed at identifying opportunities for improvement that might increase timeliness within the approach of no additional resources allocated, i.e. timeliness was operationalized as a match-up between capacity and demand. In Paper V, no specific quality indicator was investigated, other than the suitability for process improvement.

Once a quality indicator has been chosen, it is necessary to detect differences in the quality indicator that may signal variation in the quality of care attributable to healthcare managers and providers. For this purpose, groups and patients can be compared among themselves or in relation to a target with respect to the quality indicator selected. In Paper III, two groups of patients were compared following a cross-sectional approach that allowed identifying synchronic variation. In Paper II, differences were studied both over time, i.e. before and after the introduction of the HRs, as well as between different groups, i.e. intervention CICU and control group. Paper II thus gave indications of both diachronic and synchronic variation. In Paper IV, differences in the quality indicator were studied over time, i.e. before and after the fictitious introduction of the Lexis diagram, not at the level of quantitative data, but at the level of practitioner perceptions. In Papers I and V, the approach was slightly different as the current state of affairs, i.e. current physician scheduling practices and current visualization of data in annual reports, was compared to a target. In Paper I, the target of how physician scheduling practices should look like was idealized by practitioners, whereas in Paper V, the target of how data should be reported was derived from the literature.

### 6.1.2 Understanding Variation – Identifying Causes

After detecting an "interesting" difference, it becomes necessary to identify its causes. In interventional studies, the cause is known beforehand, such as in Papers II and IV. Depending on the design of the study, however, the risk of confounding factors must be

### Discussion

examined. For instance, in Paper IV, we might ask ourselves the question whether the Lexis diagram itself would lead to the perceived improvements in lead times or whether the mere visualization of lead times in a diagram would have this effect. In Paper II and IV, the causes of variation investigated were the use of the HRs and the potential use of the Lexis diagram. In Paper III, the cause of variation is explicitly stated and deals with patient language proficiency. In Paper V, the causes of variation that affect the usability of quality registry annual reports were collected from the theory and include factors such as the display of quality indicators over time and the level of measurement of quality indicators. In Paper I, the causes were distinguished based on the shortcomings identified by the interviewees. Table 11 systematizes the quality indicators studied for each paper, the approach followed in identifying difference, the level at which the differences were described and, finally, the causes that may explain the differences detected.

RQ	Quality indicators investigated (Y)	Approach	Level	Causes (X)
RQ1	Match capacity-demand	Differences between current state and ideal "target"	Perceptions	Culture of entitlement Use of CDSS Scheduling knowledge
RQ2	Provision of recommended treatment	Differences across time and groups	Quant	Use of a the HRs
RQ3	Delay to treatment initiation Transport mean to hospital	Differences across groups	Quant	Patient language proficiency
RQ4	Lead time	Differences across time in the same unit	Perceptions	Use of the Lexis diagram
RQ5	Use of QR for process improvement	Differences between current state and theoretical "target"	Quant	Display of quality over time Ranking of units Level of measurement

Table 11 The papers appended in the context of detecting and identifying variation

### 6.1.3 Managing Variation

The nature of the cause identified plays a key role in its management. Thus, if no cause could be assigned to the difference detected, it may be assumed that the difference might be attributable to chance causes. These causes cannot be eliminated and the basic recommendation is to refrain from acting on the process. If a cause has been found, it should be eliminated or neutralized, relating to the "variation reduction" and "variation insensitivity" models, respectively (Chakhunashvili, 2006). In Paper II, the differences detected resulted from the use of the HRs, which had a beneficial effect on clinical practice and the quality of care. The HRs as a cause disrupted the stability of the quality of care delivered at the intervention CICU and in the West Sweden region and should therefore be eliminated. As Shewhart (1931) claimed, it is of utmost importance to achieve a state of stability, a requirements for being able to predict, within limits, how a process will behave in the future. Such elimination would not necessarily mean going back to the old process. It would not mean that in the name of stability, the use of the HRs should be suspended. Since the use of HRs had a positive effect on the quality of care, the stability of the process should be restored by accepting the use of these HRs at the intervention CICU, as well as in remaining regional CICUs. By doing this, the stability of quality delivered would be restored at the same time as the quality of delivered care to ACS patients in the region would be improved. In the hypothetical case that the HRs were to have a detrimental effect on the quality of care, their use should be suspended in order to restore the stability of quality and return to the previous levels of quality of care.

Up to this point, we have been discussing causes that can be eliminated. However, this may not always be the case. In fact, in many cases in which the cause is related to the patient, it cannot be eliminated. Let us assume that, when comparing Swedish-speaking patients to non-Swedish-speaking patients, differences had been found in some delay times. Let us also assume that such delays could be attributable to lower patient language proficiency. In such a case, the elimination of the cause would mean refusing treating patients with lower language proficiency or sending them for a language course before they would be eligible to receive care. Certainly, neither of these alternatives would be acceptable. Since the cause cannot be eliminated, measures should be taken for the purpose of accommodating the cause and achieving similar outcomes to those situations in which the cause were not present. This means that, when a cause cannot be eliminated, the variation originated by the cause needs to be met with a variation introduced into the process.

In summary, stability is a requirement for being able to predict and control the future behavior of healthcare quality. However, stability *per se* must not be equated with highquality processes. The creation and maintenance of stability in ways that bolster quality depend on the actions taken by managers. Managing variation starts with the detection of differences that are somehow considered promising, suggesting that something extraordinarily good or bad has been occurring. These differences detected must then pass the test of random variation. After establishing that special cause variation has been

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detected, the underlying special cause should be identified. Thereafter, the degree to which the identified cause may be affected by healthcare staff should be assessed. In the cases of causes that can hardly be affected by the members of healthcare staff, changes should be made to the standard healthcare process in order to achieve similar process outcomes. In the cases of causes that can largely be affected by healthcare staff members, we may pose the question whether the special cause has indeed resulted in a quality gain or loss. If the special cause were to result in a quality gain, the "good outlier" should be eliminated by making it the new standard. If the special cause resulted in a quality loss, the "bad outlier" should be eliminated by making it comply with the current standard. A stable state is temporary until a new special cause occurs. The performance of the process needs therefore to be continuously monitored.

### 6.2 Current State of Affairs

The papers appended suggest the existence of a great deal unjustified variation. For instance, in Paper I there are indications that physician available capacity widely varies over time and that such variations affect detrimentally the timeliness of the care delivered. The pervasiveness of variation originated by internal causes is consistent with some previous studies (e.g. Strum 2000). In Paper II, the increases in guideline adherence subsequent to the introduction of the HRs, allow us to speculate as to why physicians were not adhering to guidelines (Cabana *et al.*, 1999). Irrespective of the specific cause, the causes of low adherence to guidelines by physicians were most likely internal and could not be explained by differences in patient baseline characteristics or effects of chance causes. The culture of entitlement suggested in Paper I may also lead to the occurrence of unjustified variations. To eliminate unjustified variations, it may therefore be necessary to strengthen the focus on patient needs and wants, if necessary to the detriment of the needs and wants of healthcare providers. Not only a culture of entitlement, but also physician collegiality and commitment to individual and professional autonomy, may give rise to unjustified variations and limit quality progress (Leape and Berwick, 2005).

An aspect that pervades the research reported in this thesis deals with the necessity of acquiring decision support for healthcare providers in their daily practices. In Paper I, the lack of such support is suggested to be a possible cause of the shortcomings identified. In Paper II, the support provided to physicians by means of the HRs resulted in quality improvements. Paper IV explored the use of another potential decision support system

resulting in preliminary practitioner impressions that were positive. Possibly, if better decision support were available to healthcare providers, a great deal of the unjustified variations that exist in the current delivery of care would disappear owing to the ability of decision support systems to bridge practitioner knowledge gaps and promote the standardization of work processes.

An important aspect to consider when comparing two groups is whether "apples" are being compared to "apples" or to "oranges", meaning that differences in patient baseline characteristics need to be considered to avoid the risk of having "good apples look bad" (Salem-Schatz *et al.*, 1994). The problem of case-mix adjustment is that it is never perfect (Iezonni, 2003), which always leaves some room for manoeuvre to those healthcare providers who, justifiably or not, attempt to explain a position in a ranking below expectations. To avoid such oftentimes fruitless discussions, it may be advisable to divert the attention from comparing between units to comparing the unit itself over time. In this way, each unit would be its own control and much of the discussion about the shortcomings in case-mix adjustment would be avoided. This would mean placing a greater focus on change scores, which could possibly press all units to improve, even those units that appear in the inconspicuous middle of league tables. Among the papers appended, case-mix adjustment was employed in Paper III.

A relevant finding in Paper V suggests that random variation is poorly represented when reporting healthcare quality data. This lack of assistance in distinguishing between chance cause variation and assignable cause variation may contribute to fruitless discussions about differences in rankings. Moreover, it is also unreasonable that a unit would end up at the bottom of a ranking when its deviation from the overall average is only due to chance. Albeit appealing, league tables pose several risks (Adab *et al.*, 2002) and should therefore be replaced by, for instance, funnel plots or control charts (Spiegelhalter, 2005). Control charts (Alemi and Neuhauser, 2004; Woodall, 2006) are particularly useful in distinguishing variations caused by chance from those caused by assignable causes. In this regard, control charts are superior tools compared to run charts (Perla *et al.*, 2011). Despite the vast applicability of control charts to healthcare settings (Thor *et al.*, 2007) and their ability to complement RCT (Neuhauser and Diaz, 2007), control charts remain underused, which is consistent with the findings in Paper V. Once it has been established that the difference

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detected is unlikely to be attributable to chance causes, we can proceed with the identification of assignable causes.

A collateral finding in this thesis is the poor quality of data routinely collected. For instance, in Study 3, the variable "patient smoking habits" was deleted from the data due to the pervasiveness of missing data. In this regard, it is relevant to recall that data of good quality is essential to the improvement of processes. Accurate and precise measurements are of utmost importance, as advocated by Harrington (1991), who said "If you cannot measure it, you cannot control it, you cannot manage it, you cannot improve it" (p. 82).

Another aspect of concern regarding the data collected deals with the level of measurement. Many variables are measured on a dichotomous scale (Woodall, 2006), which disregards dispersion. Although the incidence of AMI is measured dichotomously, AMIs vary a great deal in severity (Killip III and Kimball, 1967), which, of course, is taken into consideration when treating a specific patient. The overwhelming use of percentages in reporting healthcare quality data (Paper V) is a symptom of the pervasiveness of the dichotomous measurements in healthcare processes, which *per se* leads to goals being expressed as percentages, e.g. the percentage of patients waiting less than 90 days to see a specialist doctor. Setting goals as percentages is, however, unfortunate as it is possible to obtain improvements expressed in percentage goals pose the risk of crowding-out effects, i.e. a target may be perceived as a "magical threshold", which once surpassed, condemns a patient to oblivion by healthcare providers.

### 6.3 Limitations

The methodological limitations of the research conducted have been discussed elsewhere in this thesis and will not be addressed here. The section aims at discussing the limitations resulting from the delimitations imposed on the thesis. All studies were conducted in Swedish healthcare settings and focused on the delivery of care in publicly managed and financed hospitals. Moreover, the only specific patient group investigated was ACS patients. The healthcare sector differs from other sectors in many ways, such as the vital importance of its services, its organizational and power structures (Glouberman and Mintzberg, 2001a; Glouberman and Mintzberg, 2001b) and its underdeveloped processes (IOM, 2001). The context-specificity of the thesis reduces the generalization of findings to sectors other than

healthcare. Even within the healthcare context, it may be unreasonable to generalize the findings to non-hospital settings, especially at a more concrete level (Neuhauser and Diaz, 2007). Nevertheless, there are some overarching ideas that may also be applicable to nonhospital settings. These ideas include the need for matching capacity against demand, the need for clinical practice support, the comparison of groups to identify differences in quality used for improvement and the need of paying more attention to variation, not only to average values. With regard to the diagnosis specifically addressed, this diagnosis is characterized by its criticality for survival, fast pace of medical advancements and vital importance of the timely delivery of care (Wallentin et al., 2000). These factors need to be considered when generalizing the findings to other diagnoses. For instance, if the practice guidelines were stable, the introduction of a CDSS, such as the HRs (Paper II), may be less pressing. Finally, the question of generalization to hospitals other than publicly managed and financed hospitals remains. These hospitals are driven by other values and tend to focus on aspects of healthcare delivery that are more correlated with patient satisfaction, such as waiting times. It seems therefore unlikely that these private hospitals would share shortcomings similar to those reported in this thesis (Paper I). Moreover, it sounds plausible that hospitals that are not publicly managed primarily aim to achieve earnings and growth, rather than focusing on equity questions (Ellis, 1998), an issue addressed in Paper III.

# 7 CONCLUSIONS

This section outlines the major conclusions that can be drawn from the research reported in this thesis. The section ends with some considerations about the practical implications of the research conducted and opportunities for further research.

### 7.1 Concluding Remarks

The research reported in this thesis aimed at exploring the phenomenon of variation in healthcare processes. The research followed a case study overall design, in which both quantitative and qualitative methods were employed. The research conducted concluded that much variation pervades healthcare processes. A great deal of variation in healthcare processes in fact originates from healthcare managers and providers, who do not play the negligible role that is oftentimes ascribed to them. Another conclusion deals with the harsh conditions faced by healthcare providers in delivering care. There are a number of opportunities for assisting healthcare providers in the delivery of care that is today increasingly complex and fragmented. Reminder systems are an example of decision support that can contribute to improving the quality of care. The findings also suggest the need for improved monitoring of healthcare processes, which should preferably occur in real-time.

As a result of the research reported, it is possible to infer that in order to consistently deliver care of high quality, healthcare managers and providers need to be skillful at detecting unjustified variation, making sense of such variations and undertaking appropriate action. Both the approaches of elimination and accommodation of assignable causes of variation need to be employed in delivering care that is free from detrimental internal causes and that takes into consideration the uniqueness of each patient. The research conducted concludes that much focus is placed on ranking units and on studying quality in a cross-sectional fashion. Similarly, a strong focus is placed on average values at the expense of dispersion. This disregard of dispersion is conspicuous in the overwhelming use of percentages. Among the lessons learned from this research is the need for better understanding of random variation and the need for improving the quality of data routinely collected.

### 7.2 Practical Implications

The papers appended have several concrete implications for practitioners. It is thus advisable to direct efforts towards improving physician scheduling (Paper I). The evidence produced strongly indicates that the HRs should be disseminated to other CICUs (Paper II). Practitioners are also recommended to improve interpretation services and the quality of data collected on each patient (Paper III). Concerning the Lexis diagram, practitioners are urged to test the diagram in their clinical practices and direct their efforts towards real-time monitoring of processes (Paper IV). With respect to the quality registry annual reports, the data visualized in the reports should be presented differently if the reports are to be used to a larger extent for process improvement (Paper V).

On a more general level, practitioners are requested to support the work of healthcare providers to a larger extent by, for instance, creating reminder systems. It may also be advisable to undertake measures to strengthen the position of the patient as a customer and to restrict the culture of entitlement whenever it does not directly benefit patients. With respect to the uniqueness of patients, practitioners should identify patient subgroups that are somewhat homogenous in their needs and wants in order to design processes aimed at fulfilling and preferably exceeding the needs and wants of such patient groups. Simultaneously, individual practitioners should be given a certain amount of discretion in deviating from standard processes in order to meet the needs and wants of specific patients. Another implication of this research deals with the need of monitoring processes in real-time, for which the currently underused control charts can be a tool *par excellence*. Finally, the focus on ranking healthcare providers on the basis of absolute values of quality should be dampened and substituted by a focus on improving all units, which "compete" for the highest improvement rates.

### 7.3 Further Research

The processes investigated in the thesis had a defined scope, which might be interesting to extend into further studies. The papers appended focused exclusively on: physician scheduling (Paper I), effects of the HRs on guideline adherence (Paper II), disparities in hospital care (Paper III), practitioner perceptions on the potential use of the Lexis diagram (Paper IV) and quality registry annual reports (Paper V). In the continuation of the papers appended, a number of studies might be of future interest, such as: investigating nurse
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scheduling and its interconnectedness with physician scheduling, investigating the effects of the HRs on other quality indicators, investigating disparities in non-hospital care, investigating the effects of the actual use of the Lexis diagram and investigating quality registry mechanisms other than annual reports.

The purpose of this research was exploratory and essentially aimed at generating hypotheses for subsequent testing. Thus, some of the qualitative evidence produced should be complemented with quantitative evidence. For Paper I, for instance, it would be relevant to study the contribution of healthcare-related causes to the variation in the timeliness of delivered services. In the continuation of Paper II, it would be interesting to investigate why it has taken so long for the HRs to be disseminated to other units. This would increase the understanding of why assignable causes of variation are allowed to persist in healthcare processes. With regard to understanding and managing variation, researchers are recommended to investigate why two commonly used methodologies, such as DoE and RDM, remain rarely used in improving healthcare processes. Researchers are also recommended to investigate the contextual features that enable or hinder the elimination of assignable causes of variation in healthcare processes.

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