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The impact of Clinical Pathways on the organisation of care processes.

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To my wife Skrallan

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List of abbreviations

AGREE	Appraisal of Guidelines Research and Evaluation
ASA	American Society of Anaesthesiology
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
CI	Confidence Interval
CMO	Context Mechanism Outcome
CPI	Clinical Process Innovation
CPM	Critical Path Method
CPSET	Care Process Self Evaluation Tool
CRAG	Clinical Resource and Audit Group
DRG	Diagnosis Related Group
EFA	Exploratory Factor Analysis
EFQM	European Foundation for Quality Management
EPA	European Pathway Association
ICP	Integrated Care Pathway
ICPAT	Integrated Care Pathway Appraisal Tool
IIF	Incremental Index of Fit
IOM	Institute Of Medicine
LOS	Length Of Stay
LR	Likelihood Ratio
NASA	National Aeronautics and Space Administration
NFI	Normed Fit Index

NLM	National Library of Medicine
PERT	Program Evaluation and Review Technique
QAT	Quality Assurance Template
RMSEA	Root Mean Square Error of Approximation
RQ	Research Question
SD	Standard Deviation
TKA	Total Knee Arthroplasty
UK	United Kingdom
US	United States
USA	United States of America
VAS	Visual Analogue Scale

Table of contents

Chapter 1:
General Introduction

This chapter is already published and
reproduced with the kind permission of the editor:
Vanhaecht, K, De Witte, K., Sermeus, W. The Care Process Organisation Triangle: A framework to better understand how clinical pathways work. Journal of Integrated Care Pathways, 2007, 11, 1-8.

Background

Patient safety, quality of care, and efficiency of healthcare procedures are international phenomena. In 1991, Brennan et al. (1;2) concluded that a substantial amount of injury to patients occurs due to healthcare management and that many injuries result from substandard care processes. One of the most cited reports on this topic was published in 1999 by Kohn and colleagues of the Institute of Medicine (IOM): "To err is human" (3). Later, other authors from all over the world published similar results on adverse events (4-8). The first and fundamental ethical principle in healthcare—do no harm—is now being taken seriously by a wide constituency (9). Five years after the IOM report, in 2004 Altman et al. (10) concluded that many promising efforts have been launched, but the task is far from complete.

Although adverse events are not uncommon in hospitalised patients, they are by no means inevitable (11). Even if a direct relationship is difficult to establish between variations and errors, reducing variations by standardising clinical processes is an effective tool to minimise the probability of medical errors (3).

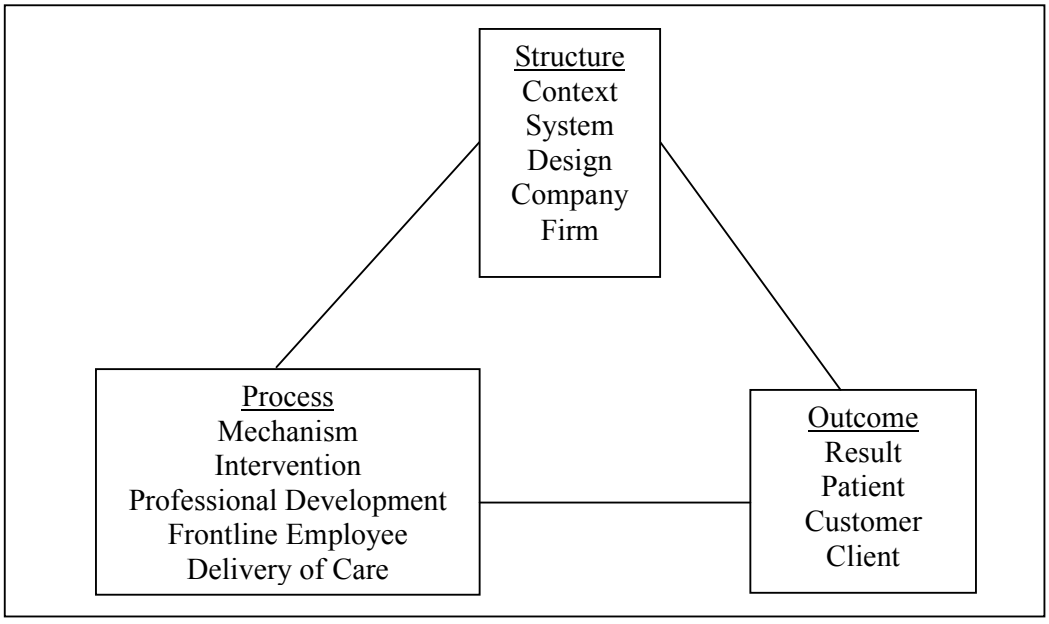
Porter et al. (12;13) stated that healthcare should change and that the purpose of healthcare systems is not to minimise costs but to deliver value for patients, which in the long run results in better health per dollar spent. Three principles should guide this change: (i) delivering value to patients should be a goal, (ii) medical practice should be organised around medical conditions and care cycles, and (iii) results—risk adjusted outcomes and costs—must be measured. With respect to this change, the role of the multidisciplinary team is to focus on the clinical process innovation (CPI) (14;15). CPIs are central to the ability of organisations to negotiate the challenges of cost containment and quality improvement, yet many CPIs have not met expectations to improve these primary processes (15). Well-organised care processes, medical conditions, or care cycles lead to appropriate outcomes if they include a structured context and a well-functioning multidisciplinary team (16). Improvement in healthcare requires the active participation of not only physicians but also all healthcare workers. Recently, Batalden and Davidoff stated: "Everyone in healthcare really has two jobs when they come to work every day: to do their work and to improve it!" (17).

The organisation of the care process

Emphasis on the evaluation and management of healthcare quality has shifted over time from structures (having the right things) to processes (doing things right) to outcomes (having the right things happen) (18). The relationship between structure, process, and outcome is also known as Donabedian's paradigm (19). Healthcare is actually seen as processes acting within systems or structures (17). The organisation of care processes receives more and more attention from clinicians and managers (3;14;16;20-22). Many care processes are undergoing change, and although every improvement involves change, not all changes are improvements. To know that change is producing improvement, we need information about what is happening (17). Different authors discuss the direct relationship between interventions or organisational changes and outcomes (18;23-26).

To better understand how clinical pathways work and to derive the different research questions, the Care Process Organisation Triangle was developed as conceptual framework. The Triangle is based on the work of Donabedian (19), Pawson & Tilley (25), Mitchell (18), Batalden (17), Heskett (23) and Teboul (24). In the following paragraph the different models will be described.

Figure 1: The care process organisation triangle (based on Donabedian and including the terminology used by Pawson & Tilley, Mitchell, Batalden, Heskett et al., and Teboul).



Based on Donabedians' paradigm, the Realistic Evaluation Configuration (25) contends that causal outcomes follow from mechanisms acting in a context (Context + Mechanism = Outcome [CMO]). The Realistic Evaluation approach offers researchers the opportunity to look at evaluation from a realistic perspective, one in which action is not happening in a laboratory environment. The questions posed are "What works, for whom, in what circumstances?" instead of "Does this work?" or "What works?" (25). The basic CMO concern is still, of course, the outcome. However, the explanation first focuses on the mechanism (e.g., the program that was introduced, known as the process in Donabedians' paradigm) and secondly focuses on the context (e.g., the characteristics of the organisation where the program was introduced, known as the structure in Donabedians' paradigm). The Realistic Evaluation Configuration has previously been used in a wide range of healthcare projects (27-29). In 1998, Mitchell et al. (18) indicated that no direct relationship exists between interventions and outcomes. Their Quality Health Outcomes Model has four components—system, intervention, client, and outcomes—and proposes bidirectional relationships among components, with interventions always acting through characteristics of the system and of the clients. In 2007, Batalden and Davidoff (17) described the linked aims of improvement: Better patient outcomes, better professional development, and better system performance lead to improvement for everyone. Healthcare organisations are professional organisations in which the multidisciplinary team occupies a central place (20). Healthcare is a type of service industry in which internal and external customers (known as employees and patients) each play a specific role (23). Heskett and colleagues (23) describe this relationship as the service triangle, which includes the firm (i.e., the hospital, which is considered to be the structure or context), the frontline employee (i.e., members of the multidisciplinary team, which are considered to be the process or mechanism), and the customer (i.e., patients, which are considered to be the outcome or result). The success of a service company depends on its ability to develop a satisfactory relationship with each of its customers. Since employees play a vital part in promoting and providing the service, during the delivery of care, it is essential that they fully understand their roles and are willing to act as required. Most of the work is designed backstage, out of the sight of the customer, but is performed front stage, creating "a moment of truth". Teboul (24) states that "service is a front stage experience". The relationship between the design of the process, the role of the involved multidisciplinary personnel, and the customers is vital within these processes (23;30). Quality, therefore, is what the customer determines (24). No matter how much care is taken in designing the structure or service on paper, in testing it, and in delivering it during the process of care, what

customers perceive is quite different from the original proposition. This means that gaps in quality can exist between the three cornerstones—structure, process, and outcome—of the service triangle (24).

If one wants to reorganise healthcare as suggested by the reports of the IOM (3;16) and more recently by Porter & Olmsted Teisberg in 2006 and 2007 (12;13), the innovation and change should be focused on care, which is the essence of a healthcare organisation (14). This means that care processes will occupy a central place and that organisations will be designed in such a way that the care processes deliver high quality and efficient care.

Previously described concepts (12;17-19;23-25) have been integrated into a paradigm specifically intended to help us understand these complex relationships: the Care Process Organisation Triangle (see figure 1). In this triangle, the relationships between care process structure, multidisciplinary team processes, and outcomes are described. Also within this triangle, gaps or chasms between these three cornerstones can occur more frequently than we thought (16;24). This Care Process Organisation Triangle—based on Donabedian (19), Heskett et al. (23), Teboul (23;24), Batalden (17), Mitchell (18), and Pawson & Tilley (25)—will be the organising concept of this dissertation.

1) The structure

In industry, processes occupy a central place in the management of a company or product line. Different methods are used to systematically plan and follow up these processes. Continuous quality improvement projects, lean management, and six sigma or process redesign are examples of methods that continuously improve the efficiency and quality of the product line. Most of the methods are based on Shewhart and Deming's principles of quality improvement (26;31). The reduction of variability is the key to quality. Decreasing this variability is the cornerstone of methods introduced by different quality gurus (32). Organisations like the European Foundation for Quality Management (EFQM) and European Quality Awards still base their process survey tools on these concepts (33;34). Also in service industries like hotels, consulting, financial institutions, and healthcare, there is an increased focus on primary processes (14;23;24;30). Hospitals are seriously analysing their operations and are currently using industrial knowledge to optimise work flow (35).

To better understand what is happening in the structure of these primary processes, transparency and standardisation are necessary. In industry, the Critical Pathway Method (CPM) and Program Evaluation and Review Technique (PERT) have been used since the

1950's to plan and standardise the structure of processes (36). CPM and PERT are used to manage complex processes in which different team members or agencies work together towards shared financial and quality goals. Until today, companies and organisations like Motorola, Boeing, and NASA are still using these methods. In 1985, this technique was translated into healthcare in the form of clinical pathways or case management plans (37).

Managers and clinicians have always searched for novel methods to improve the quality and efficiency of healthcare processes. As early as the early 1970's, concepts related to pathways were discussed and researched, but the environment for implementation was not receptive (38). In 1974, for example, Shoemaker stated the following: "Routine or patient protocols are useful means to standardise care, to facilitate completeness of services, and to evaluate both the patient's progress and the therapeutic efficacy of the program. They are also an educational tool. In essence, the development of protocols is the first step leading from anecdotal to scientific medicine (39). Protocols, routines, and other standards do not insure excellence, but sometimes they prevent disasters" (38;39).

The development, implementation, and evaluation of clinical pathways represents one of these structured care methodologies (21;40-46). Clinical pathways are nowadays being implemented in a wide range of healthcare systems, primarily to improve the efficiency of hospital care while maintaining or improving quality (37;43;45-53). The first systematic use of clinical pathways took place in 1985 at the New England Medical Center in Boston (USA) in response to the 1983 introduction of Diagnosis Related Groups (DRGs) (37;54). Typically, a reference length-of-stay (LOS) and a budget are assigned to each DRG. Clinical pathways, as a method for monitoring processes and processing time, were introduced for reducing LOS and managing costs while maintaining quality of care. In the late 1990's, more than 80% of US hospitals used at least some pathways (55). In the UK, pathways were introduced in the early 1990's (54;56). Clinical pathways, or integrated care pathways as they are called in the UK, are primarily considered to be tools for designing care processes, implementing clinical governance, streamlining delivered care, improving the quality of clinical care, and ensuring that clinical care is based on the latest research (57-60). From the late 1990's towards the beginning of the 21st century, clinical pathways were disseminated all over the world (54). Nowadays clinical pathways are used worldwide as one of the tools used to structure or design care processes and improve them within the patient-centred care concept (42;43;52;53;61). In most countries, the prevalence of pathways is still rather meagre, unless one considers the idea that the care of 60-80% of patient groups in general hospitals should be suitable for pathway use (62).

Although they have been in use for 20 years, there is still a great deal of uncertainty surrounding (i) the definition of pathways, (ii) the actual use of pathways, (iii) the dissemination and knowledge sharing of pathways, (iv) the methods used to develop and implement pathways, and (v) the effect of pathways on outcomes.

A recent literature review (63) found 84 different definitions in Medline literature published between 2000 and 2003. In the study of De Luc and colleagues (64), 17 different terms were found for this concept. Although the term mostly used is clinical pathway, the equivalent medical subheading (MeSH) term in PubMed is still critical pathway. Fifteen different entry terms are used. In 1996, the National Library of Medicine (NLM) in the USA introduced the term "critical pathway", defining it according to Mosby's Medical Nursing & Allied Health Dictionary, 4th Edition: "Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment" (65). In a international survey by the European Pathway Association (E-P-A), which included 23 countries, 13 different English synonyms were mentioned (62). The top 10 pathway characteristics that came out of this study were (i) improvement of quality of care, (ii) improving evidence-based care, (iii) multidisciplinary use, (iv) improving efficiency of care, (v) communication tool between professionals, (vi) standardisation of care, (vii) plan to manage the respondent's care, (viii) outcome oriented, (ix) use of guidelines, and (x) communication tool between patient and professional (62). Based on the literature study on definitions (63), the E-P-A survey (62), discussions on an internet forum on pathways (61), and consensus meetings of the board of the E-P-A in 2005 and 2006 (www.E-P-A.org) (62), the E-P-A defined a care pathway as: "A methodology for the mutual decision making and organisation of care for a well-defined group of patients during a well-defined period. Defining characteristics of care pathways includes: An explicit statement of the goals and key elements of care based on evidence, best practice, and patient expectations; The facilitation of the communication, coordination of roles, and sequencing the activities of the multidisciplinary care team, patients and their relatives; The documentation, monitoring, and evaluation of variances and outcomes; and The identification of the appropriate resources. The aim of a care pathway is to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources" (www.E-P-A.org) (52).

Pathways are mostly documented in a time-task matrix or Gantt Chart (45;66). In the UK, pathways are mainly used to replace or to be integrated into the patient record (67;68). A pathway for hip or knee arthroplasty can be more than 50 pages. However, a pathway for the

same procedure in the USA can be only be a few pages. The difference in use is the level of detail that is described in the pathway. With the approach used in the USA, only key interventions and outcomes are written in the pathway document. Not only the level of details in pathways is important, also the clinical conditions for which pathways are amenable are under discussion (26;66;69-72). Zander & Bower (2000) state that pathways are used for high volume, high cost, high risk and high predictable patient groups. Gittell (2002) found out that pathways also work under conditions with more input uncertainty (26).

2) The process

A second uncertainty in clinical pathways is that how they are used vary. During the delivery of care, what mechanisms do frontline employees use to organise the care? Zander and Bower (66;73) emphasise that clinical pathways represent more than written instructions in patients' records, and that the main purpose of pathways is to redesign and follow up care processes, as other structured care methodologies might do. The clinical pathway as a document is probably not its crucial factor. Pathways comprise more than just the structure of the care process. More crucial is that the entire process of care is discussed, is made explicit, and is shared by the multidisciplinary team. Although pathways were introduced in the USA with a focus on cost containment, in 1992 Berwick (74) described them as one of the methods employed to promote physician involvement in quality management. Because the process is made explicit, best practices can be discussed, timing and procedures can be planned and scheduled in a better way, desirable outcomes can be set and monitored, and capacity and resources can be provided (45). In an overview article on clinical pathways, Bandolier (51) concluded the following: "In industry, clinical pathways would be called something else. A mix, perhaps, of good practice and quality control, plus a large helping of ongoing quality improvement. After all, care pathways involve not one action, but many, often in a complex package of care. In these complex packages, it is the combining of individual interventions in a management framework suited to local needs and abilities that is the critical factor."

A third uncertainty in or weakness of clinical pathways is the variable dissemination and knowledge sharing of pathways. The international survey of the E-P-A revealed that many countries lack knowledge sharing on how care processes are organised (62). Most teams do not share their practical knowledge, sometimes even not within the same organisation. Some countries have knowledge sharing networks and use the same pathway methodology (43;52;53;62;75). In Belgium and The Netherlands, a Belgian–Dutch Clinical Pathway

Network (75) was launched in 2000 with eight participating acute hospital trusts. As of 2007, this social capital network (www.nkp.be) had 106 member organisations. In contrast to this knowledge-sharing network comprising different organisations, in most other countries, knowledge-sharing networks consist of individuals that share ideas, discuss methodologies, and share results (52;53;62). In 2004, the E-P-A was launched to help individuals build knowledge-sharing networks within and beyond the borders of the European Union. The E-P-A currently has a contact person in over 25 countries. Knowledge sharing on how multidisciplinary teams organise these care processes will become an important issue.

A fourth uncertainty in clinical pathways involves the differences in methods used to develop, implement, and evaluate a pathway. One of the most glaring weaknesses in pathway methodology is the lack of integration of the latest evidence (44;46;62;66;76-79). The development of most pathways is based on only the peer review of pathway content by the multidisciplinary team that develops the pathway. A review by Harkleroad et al. (80) revealed a variety of methods for developing and implementing a pathway. In 2003, Wood (76) wrote a systematic review on the development and implementation of integrated care pathways in which she found 20 protocols describing pathway methodologies. Even if different methods exist, in all pathway projects the goal of multidisciplinary teams is to develop well-organised care processes. Currently, most pathways are developed by healthcare professionals, with little direct input from patients. The increasing focus on patients (16) may result in a movement towards patient input (38). Within the Belgian–Dutch Clinical Pathway Network (75;81), one method used to develop, implement, and evaluate pathways is known as the 30-step scenario (78;79;82). This scenario is based on Deming's Plan-Do-Check-Act cycle for continuous quality improvement (31), on results of from literature reviews (78;80), and on national and international collaboration (66;75;81). This methodology is taught to pathway facilitators from the member organisations and is continuously updated and improved.

As stated by Degeling et al. (21), a clinical pathway represents a method to achieve a result. A pathway is a tool for empowering clinicians to strike a balance between the clinical and resource dimensions of care and between the requirements of both clinical autonomy and transparent accountability. The team's perspective is essential. Pathways provide a basis for re-establishing "responsible autonomy" as the primary organising principle of clinical work. If multidisciplinary teams, including both clinicians and managers, do not work together on the re-organisation of healthcare, all parties will continue to be driven by the distrust and related crises of confidence that pervade the field (21).

When teams improve their coordination, or relational coordination as termed by Gittell et al. (26;83), outcomes of care also improve. Recently the development and implementation of pathways, with a focus on teamwork, transparency, and coordination, was also suggested as a method for solving safety problems (84). The process or mechanism of care is therefore essential in understanding how pathways work.

3) The outcome

Besides uncertainty in the pathway definition, use, dissemination and knowledge sharing, and methodology, the impact of clinical pathways on outcomes remains rather unclear. Several reviews have indicated that clinical pathways are linked to a variety of outcomes (44-46;51;77;85-92). In 2004 and 2005, our research team presented an overview of the impact of pathways as part of an introduction on pathways published by Sermeus et al. (45) and Van Herck et al. (87). Although most results in the literature are positive, no changes, and even negative results, have also been described (45;87)

As discussed in previous reviews (45;87), the methodologies used to assess the effects of clinical pathways are often criticised because of their research designs and sample sizes. Several potential sources of bias are present. Only a few large multicentre studies with an appropriate design are available. The published studies explored the direct relationship between the introduction of a pathway and its effect on outcome. As described in the Care Process Organisation Triangle (see figure 1), the multidisciplinary process or mechanism plays a vital role in the relationship between the structure and the outcome (17;18;23-25). This mechanism, or the way the multidisciplinary team works and evaluates the organisation of a care process, is not taken into account in most of the above-mentioned pathway research. Even though a clinical pathway in some situations may not affect patient outcome, the reasons for the lack of an effect should be investigated and understood. Although many papers have been published on the outcome of pathways, most of the pathway knowledge are found in the grey literature. This situation will certainly produce a publication bias in pathway research.

The wide range of outcomes observed can be explained by differences in study design or implementation method. An obvious explanation for these differences in outcomes, however, is the great variability in how researchers define implementation of the "clinical pathway": from implementing a new patient record with minor or no changes in clinical practice (working on only the structure) to totally redesigning care given by a multidisciplinary team (working on the total process). Besides the wide variation in clinical

pathway content, all these researchers tended to use the term "clinical pathway" to describe the change they introduced into healthcare (40;45;46;51;85;90).

Conclusion

In conclusion, as gathered from this introduction, it is clear that clinicians and healthcare managers are still looking for methods to improve the safety, quality, and efficiency of their work. As in other service industries, the focus in healthcare shifts from the structure to the process to the outcome. Care processes and the organisation of care processes are receiving more and more attention from both clinicians and managers. Both the care process structure and the multidisciplinary process or mechanisms are important in understanding the impact on outcomes when care processes are changed. Methods to make these processes transparent and more standardised have been in use since the mid 1980's. One structured care methodology is clinical pathways, which are used worldwide in a wide range of settings to manage well-organised care processes. Clinical pathways seem to be under-conceptualised, with healthcare workers having very little understanding of what exactly is being implemented or what happens while introducing the pathway. Although pathways are used internationally, uncertainty exists about their concept, method, and impact.

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Chapter 2

Research questions

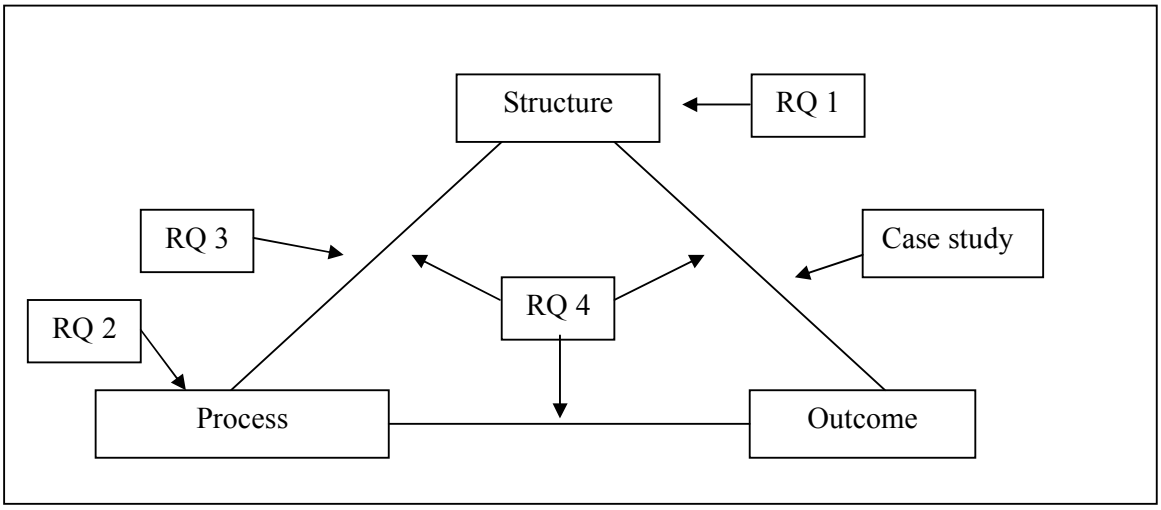
&

Overview of the dissertation

The problems described in the introduction bring us to the four main research questions of this dissertation. The four research questions will be discussed in four separate chapters. Each chapter is written as an individual publication. Chapter four also presents a case study that clarifies the development, implementation, and evaluation of a clinical pathway for total knee arthroplasty. In the final chapter, a general discussion is presented. The care process organisation triangle (structure, process, and outcome) (see figure 1 in the introduction and the figure below) will provide the link between the different chapters.

Differentiating between a clinical pathway and a care process is essential for this dissertation. Every patient follows a care trajectory and undergoes a care process in which the multidisciplinary team is more or less organised, coordinated, and involved. Each care process can be evaluated retrospectively. Multidisciplinary teams, including management, are responsible for organising care processes. Some of these care processes are supported by clinical pathways, that is, such care processes are discussed thoroughly and (re)designed. In designing a clinical pathway, the multidisciplinary team should endeavour to make a care process as transparent and standardised as possible. Although all patients undergo a certain care process, some patients undergo care directed by a clinical pathway while others do not.

Figure 1: Overview of the four research questions of this dissertation within the context of the care process organisation triangle (RQ= Research question).



Clinical pathways are used all over the world to make care processes transparent and to improve the efficiency and quality of care. They represent one way to describe the structure of a care process. Differences in definitions, as well as the actual use of pathways and the

methods to develop pathways, lead to confusion about which care processes are supported by clinical pathways and which are not. This brings us to the first research question, which will be discussed in chapter three: **Which instruments (known as clinical pathway audit tools) are available to measure the clinical pathway level of a care process?** This question will be answered by providing a systematic literature review of available clinical pathway audit tools. This chapter was published in the *Journal of Nursing Management.*

The goal of clinical pathways, as a structured care methodology, remains confusing. In all pathway projects, multidisciplinary teams use different methods to improve the organisation of a care process. Pathway projects analyse how care processes (also known as mechanisms) delivered by multidisciplinary teams work. Thus, the goal of clinical pathways is to manage well-organised care processes. Therefore, the second research question, which will be addressed in chapter four, is **What are the characteristics of a well-organised care process?** To address this question, we invited professionals (clinicians and managers from hospitals and primary care) and patients to participate in different focus groups to discuss this question. Based on information obtained from the focus groups, we developed a questionnaire that measures the organisation of care processes from a teams' perspective: the Care Process Self Evaluation Tool (CPSET). To be able to use the tool in different kinds of settings, the tool was validated in a multicentre study within the Belgian–Dutch Clinical Pathway Network using different patient groups. This tool defines the item "multidisciplinary team process/mechanism" in the care process organisation triangle. The second chapter describes the development and validation of the CPSET, which was published in the *Journal of Health Services Management Research.*

If pathways are indeed a method used by multidisciplinary teams to design well-organised care processes, then we need to determine whether clinical pathways actually improve the organisation of these processes. This brings us to the third research question, which is addressed in chapter three: **Do pathways improve the organisation of care processes?** A subsample of the data obtained from the validation study was used to answer this question. The care process was scored in terms of pathway implementation by clinical pathway facilitators trained by Leuven University. Using the CPSET, multidisciplinary team members involved in the care process evaluated the care process organisation. As a result, three subquestions were raised: (i) Do score differences exist among different professional groups assessing the organisation of the care process? (ii) Which care processes (no pathways,

pathways under development, and pathways in use) obtained the highest scores on the CPSET? (iii) What is the sensitivity and specificity of pathways in predicting well-organised care processes. The fifth chapter presents the results of this study, which has been *submitted for publication.*

To make the concept of clinical pathways more tangible, the sixth chapter will describe a case study on the development, implementation, and evaluation of a clinical pathway for total knee arthroplasty. This project was performed by the multidisciplinary knee team of the University Hospital Pellenberg under the supervision of Professor Dr. Johan Bellemans. Kris Vanhaecht, the project coordinator, evaluated the project. The impact of this pathway was published in *Acta Orthopedica Belgica.*

As suggested by different authors and as described in the case study on total knee arthroplasty, the goal of multidisciplinary teams is not only to improve the organisation of care processes but also to improve patient outcomes. Therefore, the fourth and last research question, which will be discussed in chapter seven, is **What is the relationship between clinical pathways, the organisation of care processes, and patient outcomes—the three cornerstones of the care process organisation triangle?**
This question was addressed by analysing the use of care pathways in a population of total joint replacement patients. To assess the relationship between clinical pathways and care process organisation, we collected data on the use of care pathways and CPSET scores for 39 care processes during the CPSET validation study. To assess the effects of clinical pathways on patient outcomes, we performed a multicentre study including 737 patients within the Belgian–Dutch Clinical Pathway Network. The seventh chapter presents the results of this final study, which has been *submitted for publication*.

The eight and final chapter of this dissertation contains a discussion of the relationship between the literature review and the answers of the four research questions in the context of the care process organisation triangle. Additionally, conclusions gained from the dissertation research and findings are provided.

Chapter 3:
Clinical Pathway Audit Tools: A Systematic Review.

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Vanhaecht K, De Witte K, Depreitere R, Sermeus W. Clinical pathway audit tools: a systematic review. J Nurs Manag 2006; 14(7):529-537.

Introduction

In 1996, the National Library of Medicine (NLM) in the USA introduced the term "critical pathway," defining it according to Mosby's Medical Nursing & Allied Health Dictionary, 4th Edition: "Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment" (1). Critical pathways, or clinical pathways, are now used throughout the world (2-5). Despite their prevalence, many issues relating to clinical pathways remain unsettled.

Firstly, terminology used in pathways varies, and how pathways are defined and developed remain unclear (6-10). Internationally, many terms are used for clinical pathways, thereby causing confusion. De Luc et al. (8) identified 17 different terms describing this concept. The most frequently encountered terms in the literature are clinical pathway, critical pathway, integrated care pathway, and care map (6;7). At present, 15 different equivalent terms exist in the NLM's medical subheading (MeSH) database. A recent literature review (7) comprising data obtained from a Medline search for articles published from 2000 to 2003 identified 84 different clinical pathway definitions.

Secondly, the impact of clinical pathways remains unclear. Several reviews have indicated that clinical pathways (6;11-22) are linked to a variety of outcomes. Even though a clinical pathway may not affect patient outcome, the reasons for the lack of effect should be investigated. The wide range of outcomes observed can be explained by differences in study design or implementation method. An obvious explanation for these differences, however, is the great variability in how researchers define the implementation of the "clinical pathway"—from implementing a new patient record with minor or no changes in clinical practice to totally redesigning care given by a multidisciplinary team. Besides the wide variation in clinical pathway content, all these researchers tend to use the term "clinical pathway" to describe the change they introduce into health care (6;11;12;15;19;23). Clinical pathways seem to be underconceptualised with very little understanding of what exactly it is that is being implemented (9). The lack of clarity in the definition and lack of uniform usage of the term clinical pathway makes it very difficult to evaluate studies that use the term and to compare the outcomes of these studies.

One way to address this problem is to check or assess whether a clinical pathway in question meets the key characteristics of clinical pathways. These checklists are called clinical pathway audit tools. In the present systematic review, we describe and compare different audit tools. Our aim is to evaluate the ability of different tools to grade different clinical pathways,

with the long-term goal of identifying a tool capable of accurately evaluating the outcome of clinical pathways.

Methods

Four search strategies were used to identify clinical pathway audit tools: (1) review the pertinent literature, (2) contact members of the Smartgroup on Clinical Pathways, (3) email board members of the European Pathway Association for information, and (4) search the internet.

In April 2005, we conducted a thorough search for literature on clinical pathway audit tools using the Ovid-Medline Database (1966–2005), Cinahl (1982–2005), and the British Nursing Index (1985–2005), and different combinations of the following text terms: clinical pathway, critical pathway, integrated care pathway, care pathway, care process, audit tool, appraisal tool, and self-evaluation tool. We found only two relevant publications (24;25); both dealt with the Integrated Care Pathway Appraisal Tool (ICPAT) (25). We also manually searched through the *Journal of Integrated Care Pathways* (2001–2005), a journal specific on clinical pathways but not currently indexed by Medline, and manually searched for pertinent references. This search revealed two additional publications: a 2003 paper by McSherry et al. on the Quality Assurance Template (QAT) – Pathway Development/Practice Standard (26) and a 2005 paper by Croucher on the Integrated Care Pathway Key Elements Checklist (27).

Next, we contacted 546 members (member status as of June 2005) of the Smartgroup on Clinical Pathways (5) (www.smartgroups.com/groups/clinicalpathways), a virtual network and discussion forum on the Internet with an international membership. The group is open to all professionals interested in clinical pathways (5). We obtained information on five additional tools from Smartgroup members (21;28-31). We also emailed the board members of the European Pathway Association (EPA; www.E-P-A.org), an international network of Clinical Pathway Networks, Clinical Pathway User Groups, Academic Institutions, Supporting Organisations, and individuals who support the development, implementation, and evaluation of clinical pathways, critical pathways, care pathways, and integrated care pathways (2). The EPA offered information on four additional tools (32-35).

Finally, in April 2005 we performed an internet Google® search using the term clinical pathway "audit tool", resulting in 990 hits. This search provided information on three additional tools (36-38). In total, 15 audit tools were found by combining the four search strategies (Table 1).

We included audit tools for detailed review if the tool (1) assessed the characteristics of clinical pathways, (2) assessed the effect of clinical pathways, and (3) used a scale to grade clinical pathways. Audit tools were excluded if the tool (1) used only subjective evaluations (e.g., "what do you think of clinical pathways?"), (2) offered general recommendations for the format or criteria of pathways, (3) described scenarios to develop, implement, and evaluate pathways, or (4) used surveys to assess the use and dissemination of pathways (Table 1).

Table 1: Inclusion and exclusion criteria for clinical pathway audit tools*

	Inclusion Criteria			Exclusion Criteria			
Tools	Pathway doc / change process	Pathway effect/ outcome	Contains scoring dimen-sion	Percep-tions only	General recom-menda-tions on format or criteria	Scenario to develop/ imple-ment/ evaluate	Survey on use and dissemin-ation
Clinical Path Assessment (33)	X	X	X				
ICPAT (25)	X	X	X				
Template for Clinical Pathway Design (32)	X	X	X				
ICP Analysis Sheet (21)	X	X	X				
ICP Evaluation Form (28)	X	X	X				
Q-A-T: Pathway Develop-ment/ Practice Standard (26)	X	X	X				

ICP Key Elements Checklist (27)	X	X	X				
Clinical Pathway Evaluation Framework (38)	X	X	X				X
Criteria For Care Pathways (34)	X	X			X		
Clinical Pathway Developme nt/Review Checklist (37)		X	X		X	X	
ICP: Evaluation (35)	X		X	X			X
Evaluation Of New ICP (29)	X		X	X			X
Critical Pathway Auditing (30)	X	X			X	X	X
Critical Pathway Format (31)	X	X			X		
Clinical Pathway Audit Guide (36)	X	X			X	X	

*n=15

Two investigators (K.V., R.D.P.) independently assessed all 15 audit tools on the basis of these seven criteria. The investigators agreed on the selection of five (25-28;33) tools for further study and agreed on the rejection of six tools. For the remaining four tools on which they could not reach consensus, a third investigator (K.D.W.) was consulted (21;32;36;38). Based on this consultation, two of the four remaining tools were included for further detailed study (21;32). In all, seven of 15 tools met the inclusion criteria: the Clinical Path Assessment (33), the Integrated Care Pathway (ICP) Analysis Sheet (21), the ICP Evaluation Form (28), the ICP Key Elements Checklist (27), the ICPAT (25), the Quality Assurance Template (QAT)–Pathway Development/Practice Standard (26), and the Template for Clinical Pathway Design (32) (Table 2). Three tools were published in the *Journal of Integrated Care Pathways* (25-27), one tool was published in the *Clinical Governance Bulletin* (32), and the remaining three tools were provided by the Smartgroup (21;28) and EPA (33). We contacted the authors of the seven tools by email or telephone to collect additional information about the development, the actual use, and the validation of these audit tools.

To further understand the content and goals of these audit tools, two investigators (K.V., R.D.P.) performed a content analysis of each tool. They identified 17 characteristics inherent to clinical pathways (Table 3). They also reviewed the eight excluded tools for additional pathway characteristics, but this examination gleaned no additional information. We used the realistic evaluation configuration (context + mechanism = outcome) (39;40) by Pawson & Tilley (39) to group the 17 characteristics (Table 3). The realistic evaluation paradigm is useful not only for evaluations that systematically track outcomes but also for evaluations that track mechanisms that produce outcomes, contexts in which the mechanisms operate, and content of the intervention (39-41).

Results

General characteristics of audit tools

The seven selected tools were published or developed between 1998 and 2005 (Table 2). Three tools were developed in England (25-27), one in the USA (33), one in Australia (32), one in Scotland (21), and one in Wales (28). The total number of domains and items in the audit tools range between 4 and 14, and 14 and 101, respectively. The reliability and content validity of only one tool has been tested (25). The other tools were developed, discussed, and/or revised by a pathway steering group or focus group. For these tools, only

face validity has been obtained. The tools use different scoring systems: (1) an ordinal scale (0 or 1 to 4) (26;33); (2) nominal scale (yes/no/not sure/not applicable) (21;25); or (3) checkbox system (yes/no) (27;28;32) (Table 2). Total scores for each tool are calculated in different ways. Most of the tools use sum scores per domain. None of the audit tools compared until now the pathway scores with patient outcomes.

Table 2: General characteristics of the seven clinical pathway audit tools selected for in-depth analysis

Clinical pathway audit tool	Reference	Country or locality of origin	Year of development	Source	No. of domains *	Total no. of items*	Validation	Scoring system	Total score	Pathway score compared with patient outcomes
Clinical Path Assessment	Bower & Zander, 2000 [33]	USA	2000	EPA	11	44	No	1–4 scale	score per domain	no
ICP Analysis Sheet	Bryson & Browning, 1999 [20]	Scotland	1998	Smartgroup	28	101	No	Yes/No/ Not Applicable	score per item	no
ICP Evaluation Form	Jones, 2002 [28]	Wales	2002	Smartgroup	5	38	No	Yes/No	score per domain	no
ICP Key Elements Checklist	Croucher, 2005 [26]	England	2005	Literature	14	14	No	Yes/No	overall score	no
ICPAT	Whittle et al., 2004 [24]	England	1999	Literature	6	99	Yes	Yes/No/ Not Sure /Not Applicable	score per domain	no

Quality Assurance Template Pathway Development/ Practice Standard	McSherry et al., 2003 [25]	England	2001	Literature	4	24	No	0–4 scale	score per domain	no
Template For Clinical Pathway Design	Mallock & Braithwaite, 2005 [32]	Australia	2005	EPA / Literature	5	20	No	Yes/No	score per domain	no

* Number of domains or items as defined by the author(s) of the tool

We describe below the seven tools we selected for in-depth discussion in this review.

1. The Clinical Path Assessment (33) was developed by the Center for Case Management (USA) in the late 1990s. Although the tool was based on expert experience and opinions, it has not been validated formally (42). The Center for Case Management has used the Clinical Path Assessment tool as a screening instrument to determine how a pathway will perform within a specific organisation (42).
2. The ICP Analysis Sheet (21) was developed by the Clinical Resource and Audit Group (CRAG) (Scotland) in 1999. Although the ICP analysis sheet was specifically prepared for the project evaluation of the CRAG study (21), it has not been validated. Moreover, it is no longer in use in its original format (43). The ICP Analysis Sheet has been used to develop an outcome-based variance analysis tool (43).
3. The ICP Evaluation Form (28) was developed by the Cardiff and Vale Trust (Wales) in 2002. Although the tool was based on the trust's experience with pathways, literature, and pathway objectives, it has not been validated formally [44]. The trust used the ICP Evaluation Form for the annual evaluation of all pathways in the trust and as a guideline for pathway development.
4. The ICP Key Elements Checklist (27) was developed by Croucher (England) in 2004 as part of master's thesis research on the quality of integrated care pathways being used in the UK National Health Service (44). The ICP Key Elements Checklist was based mainly on UK-based literature. It has not been validated. The checklist is currently being used by one trust in England (44).
5. The Integrated Care Pathway Appraisal Tool (ICPAT) (25) was been under development since 1999 by Whittle et al. (England) with the support of the Partnership for Developing Quality, West Midlands Regional Levy Board (45). It is based on a design similar to the Appraisal of Guidelines Research and Evaluation (AGREE) instrument (24;46;47). All six dimensions of the ICPAT have good internal consistency, with Cronbach's alpha ranging from 0.77 to 0.96. The inter-rater agreement is also good, with inter-class correlations ranging from 0.63 to 0.99. Most items correlate with the appropriate dimension. The ICPAT is currently being used and undergoing further development and validation (47). Future ICPAT uses include facilitating the commission of services, assessing clinical governance, guiding novice pathway developers, and developing electronic pathways (25;47).
6. The QAT Pathway Development/Practice Standard (26) was developed by McSherry et al. (England) in 2001 for a project supported by the National Health Service. It has

been used to evaluate pathway projects within and between trusts. Several dimensions of the QAT Pathway Development/Practice Standard (26) are very similar to those in the ICP Evaluation Form (28). It was adapted for use by the Determining Excellence European Framework for Quality Management Standards (48). The QAT Pathways Development/Practice Standard is no longer in use and has never been validated (49).

7. The Template for Clinical Pathway Design (32) was developed by Mallock and Braithwaite (Australia) in 2005 with the support of the Centre for Clinical Governance Research in Health, the University of New South Wales. The template was based on a literature review from a master's thesis on informatics in medicine (50). It has been used to evaluate 176 clinical pathway documents from different countries. The tool is no longer in use and has never been validated (50).

Content analysis

In addition to describing the general characteristics of the tools, we conducted a content analysis of each tool (Table 3), identifying 17 different characteristics. These characteristics are made operational by different statements or questions. Using the realistic evaluation configuration (39), we grouped three characteristics into a context category, 12 into a mechanism category, and two into an outcome category (Table 3). The number of questions for each of the characteristics and the relative number of items per characteristic are shown in Table 3. In total, 9.6% of the items were context items, 73.5% were mechanism items, and 16.9% were outcome items.

Next, we evaluated the characteristics of each tool and counted how many fall into the context, mechanism, or outcome categories. Four of seven tools contain context characteristics on organisational commitment and pathway project management. Only two tools contain perceptions about the pathway concept. All seven tools described the following mechanism characteristics: format, content, multidisciplinary involvement, and variance management. The ICPAT (25) was the only tool that focused on implementing pathways. All seven tools also addressed outcome management. Five of seven tools contained items on safety/risk management.

The ICPAT (25) and the ICP Evaluation Form (28) contain 15 of the 17 characteristics (Table 3). Whittle et al. (25) did not include operational arrangements into the ICPAT, and Jones (28) did not include implementation phase into the ICP Evaluation Form. The QAT

Pathway Development/Practice Standard (26) and the Clinical Path Assessment (33) contain 13 and 10 characteristics, respectively. The ICP Analysis Sheet (21) and the Key Elements Checklist (27) both contain 9 characteristics. The Template for Clinical Pathway Design (32) contains 6 characteristics.

Table 3: Content analysis of the seven clinical pathway audit tools*

Characteristics	CMO	Clinical Path Assessment [33]	ICP Analysis Sheet [20]	ICP Evaluation [28]	ICP Key Elements Checklist [26]	ICPAT [24]	QAT Practice Development Standard [25]	Template For Pathway Design [32]	No. of tools	Relative no. of items per characteristic (%)
Organizational commitment	C	4		1		7	1		4	3.28
Path project management	C	4		1		5	1		4	2.99
Perception about concept of paths	C	4			2				2	3.34
Format of doc.	M	4	3	5	3	13	5	5	7	15.09
Content of pathway	M	4	43	4	2	10	3	5	7	17.73
Multidisciplinary involvement	M	4	11	1	1	5	1	1	7	6.28
Variance management	M	8	2	2	1	4	2	5	7	9.99
EBM / Guidelines	M		14	2	2	7	2		5	6.97
Maintenance of pathway	M	4		2	1	15	3		5	7.02
Accountability	M	4		2		6	2		4	4.11

Patient involvement	M			1		4	1		3	1.55
Development of pathway	M			1		5	1		3	1.69
Additional support systems & documents	M		3	1		2			3	1.09
Operational arrangements	M		2	1			1		3	1.25
Implementation	M					5			1	0.72
Outcome management	O	4	21	11	1	10	1	3	7	13.61
Safety	O		2	3	1	1		1	5	3.29
Total number of items		44	101	38	14	99	24	20		
Total number of characteristics		10	9	15	9	15	13	6		

*Number of items per characteristic C M O: Context – Mechanism - Outcome

Discussion

Although vast amounts of literature exist on the effects of clinical pathways, the lack of research on the auditing of pathways is astonishing. Pathways were introduced into health care in the mid 1980s (3), but the first audit tools were developed in the late 1990s. The variability of characteristics across the seven audit tools we analysed, confirms a lack of consensus on the concept and definition of pathways (2-4;6;9;17;32). Differences in the relative number of items per realistic evaluation category (39) (context: 0-27.3%; mechanism: 57.9-87.5%; outcome: 4.2-36.8%) also indicate that a conceptual problem exists. We also found a relatively high proportion of mechanism items to context items (7:1) and mechanism items to outcome items (4:1), which is consistent with the confusion currently found in the conceptualisation of clinical pathways.

Although the ICPAT (25) was the only tool to be validated by a study published in a peer-reviewed journal, surprisingly to our knowledge, it is yet to be cited in a peer-reviewed publication examining the effect of clinical pathways. In fact, to our knowledge, none of the tools have ever been cited in peer-reviewed publications examining the effect of clinical pathways. The ICPAT seems to be the most appropriate clinical pathway audit tool, because it contains 15 of the 17 characteristics we identified during our content analysis. A limitation of this tool, however, is that it mainly evaluates the written clinical pathway (i.e., pathway document), and less so the functioning clinical pathway. Moreover, the ICPAT does not contain questions on how the care process is organised and managed. Bower (42) emphasises that clinical pathways represent more than written instructions in patients' records and that the main purpose of pathways is to redesign and follow up care processes, such as other structured care methodologies might do (42;51). Although Mallock and Braithwaite (32) generally support this premise, they concluded that developing a clinical pathway according to a set of criteria does not automatically ensure that the pathway will achieve its intended goal or that a care process will be well organised. Pathway success requires productive negotiation, agreement, a good design, and collaborative efforts by various stakeholders (32). This scenario is analogous to an orchestra needing more than a perfect music score to guarantee a perfect performance.

Despite the effort put forth in developing clinical pathway audit tools, until now audit tools contribute very little to a better understanding of which characteristics in clinical pathways affect outcome. None of the fifteen tools we reviewed has been used to grade the quality of pathways in terms of outcomes. In essence, clinical pathways still function within a

black box in that it remains unknown how each pathway characteristic contributes to pathway-related outcomes. A clinical pathway audit tool should, therefore, focus on such "key characteristics", ones that can affect patient outcome. Further research on the construct and criterion validity of clinical pathway audit tools seems necessary in order to fully understand why and when clinical pathways succeed.

Without a demonstrative impact, it is difficult to defend the implementation and continuation of a given intervention. When auditing or evaluating care processes, one needs to use a method that takes into account what the intervention (e.g., redesign of the care process or clinical pathway) actually does to change behaviours and why not every situation is conducive to that particular intervention (39;40). This is also true for clinical pathway research. A strong need exists for the systematic analysis of the effects of clinical pathways. To date, not enough is known about "clinical pathway interventions" for researchers to be able to evaluate pathway efforts. In this regard, researchers must make the development, analysis, and use of clinical pathway audit tools a priority, so that clinical pathways can be evaluated uniformly and confidently. Future research should focus on identifying the key characteristics of clinical pathways that have impact on patient outcomes.

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Chapter 4:
The development and validation of a Care Process Self Evaluation Tool.

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Introduction

Clinical pathways are being implemented in many healthcare systems, primarily to improve the efficiency of hospital care while maintaining or improving quality of care (1-7). Although clinical pathways are used worldwide (8-11), the terminology and impacts of their use are still unclear (1;3-7;12-15). Clinical pathways seem to be underconceptualised, with little understanding of what exactly is being implemented (14;16). There is a high degree of variability in how researchers define the implementation of a "clinical pathway", from implementing a new patient record with minor or no changes in clinical practice to totally redesigning care given by a multidisciplinary team. This makes it very difficult to evaluate and compare the outcomes of adopting clinical pathways. Valid and reliable clinical pathway audit tools, which measure the characteristics of clinical pathways, are needed (16).

A systematic review of clinical pathway audit tools revealed the lack of research in this field (16). The Integrated Care Pathway Appraisal Tool (ICPAT) (17) seems to be the most appropriate audit tool that has been validated and published in peer-reviewed literature (16). Like most clinical pathway audit tools, ICPAT scores the clinical pathway document in the patient record but not the organisation of the care process. As several authors have noted, clinical pathways are more than documents in patient records (2;3;16;18;19). A new document will not automatically ensure that a pathway will work or a care process is well organised. The issue is similar to an orchestra needing more than a perfect music score to guarantee a perfect performance.

The aim of our study was to develop and validate a Care Process Self Evaluation Tool (CPSET) that focuses on the actual organisation of the care process, rather than on the documentation. The main goal of the tool is to define the key characteristics of care processes / clinical pathways that are having an impact on the organisation of care processes. The ultimate goal is to be able to differentiate care processes so that the evaluation of their impacts on outcomes is facilitated.

Because clinical pathways are multidisciplinary tools to organise care processes, the development and validation of a CPSET must incorporate input from a wide range of stakeholders to ensure that the final product will meet the needs of the decision makers. A rigorous multi-step process using both qualitative and quantitative methods (20) was employed.

We sequentially investigated the content validity, face validity, construct and criterion validity and reliability of the CPSET. For each of these, the methods used and obtained results will be described.

Methods

Content Validity

For content validity, four successive phases of study were conducted. During the first phase we wanted to explore all the relevant aspects of well organised care processes. Focus groups involving various stakeholders with experience in the organisation of care were set up. In the second phase the candidate topics from these focus groups were grouped within the Realistic Evaluation framework (21) and stated as items, as a means of convergence. Cognitive testing was performed during the third phase by researchers from Belgium and The Netherlands. In the fourth phase a Delphi first round was performed to rank the items in order of importance and reduce them in number.

To identify the candidate topics of the CPSET, seven focus groups met separately between February and June 2004. Each was composed of members of one of the following stakeholder groups: clinical pathway facilitators, mainly with nursing backgrounds (n=11); medical doctors working in hospitals (n=7); allied health professionals working in hospitals (n=7); senior hospital managers (n=7); members of supporting departments such as laboratory, radiology and pharmacy (n=5); primary care professionals, including general practitioners (n=5); and patients (n=8). In total 50 persons participated. All healthcare professionals worked in organisations that are members of the Belgian Dutch Clinical Pathway Network and were experienced in the development and implementation of clinical pathways (22). The patients were contacted via the Belgian Patient Self Help Association (23). The focus group involving patients was organised in a non-clinical environment. All other focus groups took place at the Centre for Health Services and Nursing Research, Catholic University Leuven, Belgium.

An experienced moderator led the seven focus groups using a semi-structured nominal group process (24). The moderator explained the purpose and method of the group discussion. To stimulate the discussion the next question was raised: “What are the determinants of a well organised care process / clinical pathway?” Participants were given some time to think about

this question and record their thoughts in keywords. Each keyword was written on a separate sheet of paper. No suggestions or examples were given in order to obtain as many different topics as possible (divergence). The sheets were put on a blackboard by the moderator and each keyword was discussed. Within the open discussion, minimal structure was provided by the moderator. Any additional topics that came out of the discussion were added to the blackboard list. At the end of the session, digital pictures of the blackboard were taken. During the discussions, field notes were taken by an investigator. In addition to the moderator, at least two members of the research team were present as observers in each focus group. Discussion continued until all topics had been exhausted. The focus groups lasted for 90–150 minutes.

As a convergence phase, the topics obtained were grouped within the Realistic Evaluation framework (21;25), which is seen as a helpful method for clinical pathway research (16). Five members of the research team at Leuven University independently grouped the candidate topics on the three domains of this framework (21): context–mechanism–outcome (CMO) (see Box 1). During four consensus meetings in July and August 2004, lasting each three to four hours, the candidate topics were discussed, grouped on CMO by consensus and reduced in number. Topics not selected were synonyms or abbreviations of selected topics. After grouping, the five researchers reformulated the selected topics into items.

To optimise usability of the CPSET in Belgium and in The Netherlands, as there are minor language differences between the two countries, the selected items were discussed with researchers at the Dutch Institute for Healthcare Improvement during a cognitive testing phase (26;27). During two meetings in August and September 2004, four persons enunciated what they understood to be the meaning of each statement. Two Belgian research fellows, one Dutch research fellow and one hospital manager of a Dutch Hospital, who was born and raised in Belgium, participated at these meetings which lasted a total of seven hours.

A cross-sectional study was conducted in order to rank the selected items in importance, with a view to being able to reduce their number. This study was performed as a Delphi first round study. All items were presented to 241 persons from eight different stakeholder groups: clinical pathway facilitators (n=27), medical doctors (n=28), allied health professionals (n=31), senior managers (n=47), members of supporting departments (n=17), primary care professionals (n=14), nurses (n=59) and patients (n=18). The healthcare professionals were contacted via the Belgian Dutch Clinical Pathway Network (22); the Belgian and Dutch patients were contacted via the Belgian Self Help Association (23) and the

Dutch Patient and Consumers Association (28). An information letter accompanied the tool and explained the goal and method. Each item was scored [on a 1 (least important) to 10 (most important) scale] and only the 10% most important items were selected for the Alpha version* of the CPSET. For each of the eight stakeholder groups, a mean rank and Kendall's coefficient of concordance *W* were calculated using SPSS© version 11.5.1. Kendall's coefficient determines the association between all sets of rankings within a group (29). In this study *W* was calculated per CMO category separately for each of the eight stakeholder groups. To reduce the number of items within each of the realistic evaluation domains (CMO), only responses with less than 10% omissions were selected for further analysis. We subsequently retained 236 context, 232 mechanism and 227 outcome responses or 98%, 96% and 94%, respectively, of the 241 responses submitted.

Face validity

To obtain face validity the CPSET was pilot tested by six multidisciplinary teams from Belgium and The Netherlands. The face validity test of the Alpha version of the CPSET was conducted between October and November 2004. Six hospitals from the Belgian Dutch Clinical Pathway Network (22) were asked to participate with one care process of their choice. The care processes selected were: breast cancer, rehabilitation after total knee arthroplasty, total hip arthroplasty, hernia surgery, diabetes and strabismus. A clinical pathway facilitator from each hospital enrolled participants (Table 1). The patients involved had been admitted in one of the six care processes within the previous two weeks. In total 83 persons participated in this face validity test, during which the organisation of the actual care process was scored on all items of the Alpha version. All items were scored on a 1 (totally disagree) to 10 (totally agree) scale. An additional scoring category was created: "Not able to evaluate this item from my (professional) point of view". Items were removed if 20% or more of at least three of four groups of medical doctors, nurses, allied health professionals and pathway facilitators were not able to evaluate the item. In addition to scoring the care processes, the pathway facilitators were asked to evaluate the use of the tool and give feedback to the research team. The results of the pilot test were used to create the Beta version of the CPSET.

* The Alpha version of the CPSET is the first version and contains only the most important items that came out of the Delphi round. Later a Beta version was developed that includes the results of the face validity test.

Table 1: Participants in pilot testing of CPSET

	Breast cancer	Total knee rehabili-tation	Total hip arthro-plasty	Hernia surgery	Diabetes	Strabis-mus	Total
Clinical pathway facilitators	1	1	1	1	1	1	6
Medical doctors	1	3		4	1	2	11
Allied health professionals	2	2	2	2		3	11
Senior hospital managers	1	2		2	3		8
Supporting departments	2	1				3	6
Primary care				3	5		8
Nurses	2	2	2	5	4	6	21
Patients	2	2		3	3	2	12

Construct and criterion validity

To evaluate the Beta version of the CPSET for construct and criterion validity, a multicentre study was organised and data were collected between April and August 2005. The goal and methods of this phase were explained during meetings with the clinical pathway facilitators of the Belgian-Dutch Clinical Pathway Network (22). Acute hospitals and rehabilitation centres were asked to score care processes of their choice with the Beta version of the CPSET. Some of the care processes were supported by clinical pathways and others were not. In total 54 different organisations participated in this multicentre study with 142 care processes (Table 2) from 17 different clinical areas (Table 3). Each care process was scored by the medical doctor in charge, the head nurse, the most involved allied health professional and the clinical pathway facilitator. Of 528 questionnaires returned, only those (n=511) with all four parts completed (context – mechanism – outcome – three general CMO items), were submitted for further analysis.

Table 2: Demographic variables in the construct validation of the Beta version of the CPSET

Variable	Number
Number of participants	511
Number of organisations	54
Number of different patient groups	51
Number of care processes	142
Use of clinical pathways (number of surveys)	
- Pathway in use	262
- No pathway in use	126
- Pathway under development	123
Professional group (number of surveys)	
- Medical doctors	117
- Nurses	151
- Allied health professionals	111
- Pathway coordinators	132

Table 3: Questionnaires returned by participants in the validation of the Beta version of the CPSET

Clinical Area	Number of questionnaires
Abdominal Surgery	36
Cardiology and Cardio Surgery	45
Diabetes	12
Gastroenterology	4
Geriatrics	8
Gynaecology	10
Delivery	115
Maxillofacial Surgery	3
Neurosurgery	21
Neurology	42
Ophthalmology	12
Oncology	35
Orthopaedics	127
Pneumology	8
Rehabilitation	8
Urology	12
Vascular Surgery	13
All	511

The total study sample was randomly split in two parts to perform the exploratory and confirmatory factor analyses (SPSS© 11.5.1). The first part of the sample (n=251) was used for the maximum likelihood exploratory factor analysis with Varimax rotation (30) and the second part (n=260) was used to perform the confirmatory factor analysis (31;32) using LISREL© 8.5. For the confirmatory factor analysis four fit indices are reported. The first goodness-of-fit statistic is the root mean square error of approximation (RMSEA) (32;33), which has been recognised as one of the most informative criteria in covariance structure modelling. Values less than 0.05 indicate good fit and values as high as 0.08 represent reasonable fit. The comparative fit index (CFI) (32;34), which is a revised version of the normed fit index (NFI) (32;35), is reported to take sample size into account. The incremental index of fit (IIF) (32;36), which addresses the issues of parsimony and sample size that were known to be associated with the NFI, is also reported. For the CFI, NFI and IIF, coefficient values range from 0.00 to 1.00, with higher values indicating superior fit and a value of at least 0.90 required to accept a model.

The criterion validity analysis was performed by using the three general CMO items. Kendall Tau was calculated between the obtained factors and the three general CMO items to investigate the relationship between the factors and the CMO framework. As the CMO was derived from the first development phase of the study, we wanted to keep this framework within the CPSET if it proved to be consistent.

As some care processes were supported by clinical pathways (n=262 questionnaires), some had pathways in development (n=123) and some did not have pathways (n=126), this information could be used to evaluate construct validity by using a known-group technique. The hypothesis is that care processes with the support of pathways would have higher scores on the CPSET than care processes with pathways under development or without the support of pathways. For the analysis, a Kruskall Wallis Test was used.

Reliability

To obtain reliability for the CPSET, the internal consistency and intraclass correlations were calculated. As a first method of analysing reliability, the internal consistency was measured using Cronbach's alpha for each of the subscales. A second reliability test was carried out by analysing the intraclass correlation as a way of assessing inter-rater reliability. Therefore the scores of the medical doctor in charge, the head nurse, the most involved allied health professional and the clinical pathway facilitator were analysed.

Results

Content validity

A total of 373 candidate topics were identified from the following focus groups: 86 from clinical pathway facilitators, 50 from medical doctors, 64 from allied health professionals, 44 from senior hospital managers, 48 from members of supporting departments, 33 from primary carers and 48 from patients. By grouping the candidate topics within the Realistic Evaluation framework (21;25), 72 context topics, 142 mechanism topics and 34 outcome topics were selected. 125 topics were not selected because they were synonyms or abbreviations of the 248 selected ones. The investigators were careful not to drop key concepts that had been mentioned by the focus groups. Each selected topic was formulated into an item or statement describing the topic. The 248 items were each rigorously discussed in meetings involving five investigators to make them as clear and consistent as possible (26).

After conducting additional cognitive tests (26;27) at the Dutch Institute for Healthcare Improvement, 100 items (40%) were not changed but the sentence structure was edited in 123 items (50%) and the wording was changed for 25 items (10%) to improve understanding in both countries.

The statistical analysis of the data obtained from the Delphi round, to order the items according to importance, revealed that all Kendall's coefficients (*W)* were significant ($p<0.001$). Therefore, we could calculate an average rank per group. The mean rank of the 72 context items, 142 mechanism items and 34 outcome items was calculated for each of the eight stakeholder groups. The 10% most important items (context—top 7; mechanism—top 14 and outcome—top 3) of each of the eight stakeholder groups were selected for further analysis. The 248 items were hence reduced to 24 context items, 55 mechanism items and nine outcome items, which were included in the Alpha version of the tool. There was no context, mechanism or outcome item which was selected by each of the eight stakeholder groups (Tables 4 and 5). All the top items were included in the Alpha version of the CPSET.

By combining the four content validation phases (focus groups, grouping within the Realistic Evaluation framework, cognitive testing and ordering according to importance), the Alpha version of the CPSET was developed and contained 88 items.

Table 4: Content validity: consensus of top items between the stakeholder groups

	Context	Mechanism	Outcome
8 stakeholders	0	0	0
7 stakeholders	1	1	1
6 stakeholders	1	1	0
5 stakeholders	2	2	1
4 stakeholders	1	6	0
3 stakeholders	3	4	1
2 stakeholders	4	12	3
1 stakeholders	12	29	3
Total number	24	55	9

Table 5: Content validity: overview of the top two items per stakeholder group*

Stakeholder	Context	Mechanism	Outcome
Clinical pathway facilitators	Within the organisation, there is a willingness to engage in process-oriented thinking.	When (re)designing care processes, all relevant professionals are involved.	All team members are familiar with the various steps in the care process.
	The senior management stimulates the continuous improvement of care processes.	Agreements are observed.	Medical outcomes are monitored/followed up.
Medical doctors	Quality of care is the priority within the organisation.	Medical doctors are actively involved when (re)designing care processes.	Medical outcomes are monitored/followed up.
	Patient communication is considered to be important within the organisation.	Agreements are observed.	The team members stand by agreements made.
Allied health professionals	Patient communication is considered to be important within the organisation.	Time is explicitly included for allied health professionals.	All team members are familiar with the various steps in the care process.
	Quality of care is the priority within the organisation.	The (re)design of the care process is performed by a multidisciplinary team.	The team members stand by agreements made.

Senior hospital managers	Patient communication is considered to be important within the organisation.	When (re)designing care processes, all relevant professionals are involved.	Medical outcomes are monitored/followed up.
	Teams receive feedback on the outcomes of care.	Medical doctors are actively involved when (re)designing care processes.	The team members stand by agreements made.
Supporting departments	There is a clear vision of policy regarding care throughout the entire hospital	Medical doctors are actively involved when (re)designing care processes.	Within the care process monitoring/follow-up is performed to verify whether planned activities are actually performed.
	Patients are treated respectfully within the care process.	The patient record is a reliable description of the care process.	The team members stand by agreements made.
Primary care	Good cooperation exists between the hospital and primary care.	When patients are admitted to hospital, one takes the information from primary care into account.	The team members stand by agreements made.
	Primary care is considered by the hospital to be an equal partner.	Patients receive clear information on the homecare during the hospital stay.	Within the care process risks of complications are monitored / followed up systematically.
Nurses	Patients are treated respectfully within the care process.	The patient record is a reliable description of the care process.	The team members stand by agreements made.
	The team members take the patient experiences into account.	The (re)design of the care process is performed by a multidisciplinary team.	The team members feel involved in the organisation of the care process.
Patients	Patients are treated respectfully within the care process.	Patients/family are provided with candid (frank, open; straightforward) information regarding their health.	The patient record is accessible to patients.

	Quality of care is the priority within the organisation.	The patient record is a reliable description of the care process.	The team members stand by agreements made.

* The grouping is based on the original Context-Mechanism-Outcome groups of the 248 items.

Face Validity

The face validity test of the Alpha version of the CPSET yielded three main results: 1) A general satisfaction with the usability and wording of the tool although 88 items were evaluated as too many by the pathway facilitators, who advised a reduction in the number of items and the number of stakeholder groups involved in the scoring. 2) Four mechanism items were removed from the tool because the stakeholders were not able to evaluate them. 3) Three additional general questions, necessary for the criterion validation phase, were added: one on the context, "How do you score the organisation climate wherein this care process is organised?"; one on the mechanism, "How do you score the organisation of this care process?"; and one on the outcome, "How do you score the way this care process is monitored / followed-up?".

As a result, the tool was refined into a Beta version of the CPSET with 24 context items, 51 mechanism items, nine outcome items and three general CMO items.

Construct and criterion validity

The first part of the exploratory factor analysis (EFA) (30) was conducted on the context, mechanism and outcome items separately to determine the number of dimensions in each part of the tool and to further reduce the number of items per domain of the Realistic Evaluation paradigm. Factors with an eigenvalue greater than 1 were retained and items with factor loadings above 0.30 were selected. Items with cross loading differences of less than 0.15 were removed. After three rounds of EFA we obtained a context scale with items loading on one specific factor only. The context scale included three factors accounting for 66.3% of variance. For the mechanism and outcome scales, four and two EFA rounds were needed, respectively. The mechanism scale included three factors and the outcome scale included two factors, accounting for 68.7% and 76.7% of variance, respectively. In total eight factors and 33 items were retained.

The criterion validation of these eight factors with the three general CMO items was analysed. The Kendall Tau correlations (Table 6) revealed that only four out of the eight factors correlated specifically with the corresponding general CMO item.

Table 6: Discriminant and convergent validity for the first EFA round

	General context item	General mechanism item	General outcome Item
Context factor 1	0.430*	**0.437***	0.412*
Context factor 2	0.280*	**0.299***	0.178*
Context factor 3	**0.382***	0.300*	0.243*
Mechanism factor 1	0.349*	0.413*	**0.565***
Mechanism factor 2	0.396*	**0.515***	0.365*
Mechanism factor 3	0.301*	**0.396***	0.306*
Outcome factor 1	0.342*	0.412*	**0.562***
Outcome factor 2	0.425*	**0.548***	0.495*

* Kendall Tau correlation is significant at the 0.01 level (2-tailed).

Based on this information a second EFA was performed. In this second round, the 33 CPSET items were all put together in the EFA. Out of this analysis came six factors. Four of the 33 items were not retained because they cross-loaded on at least two factors. With the 29 remaining items a final EFA was performed (Table 7), yielding a five-factor solution, with an eigenvalue greater than 1, which accounted for 65% of the variance.

Table 7: Factor model with 29 items in five factors

CPSET five- factor and 29-item factor model	Moni-toring and follow-up of care process	Coordi-nation of the care process	Patient focus-ed organi-satoin	Com-munica-tion with patient and family	Colla-boration with primary care.
When (re)designing the care process quality indicators are formulated.	**0.723**				
Whether the care provided is tailored to the patient's needs is systematically monitored/followed up.	**0.718**				

Within the care process patient satisfaction is monitored/followed up systematically.	**0.712**				
The goals of the care process are described explicitly.	**0.711**				
Within the care process monitoring/follow-up is performed to verify whether planned activities are actually performed.	**0.707**				
Outcomes are systematically monitored/followed up.	**0.704**				
Variances can be monitored within the care process.	**0.700**				
Within the care process risks of complications are monitored / followed up systematically.	**0.698**				
The progress in the care process is continuously monitored/followed up and adjusted.	**0.684**				
Agreements are observed.		**0.640**			
All team members are familiar with the various steps in the care process		**0.623**			
There is an optimum timing of activities within the care process.		**0.612**			
Concrete agreements are made within the care process.		**0.592**			
Team members consider themselves to be engaged in the organisation of the care process.		**0.541**			
Patients/family are provided with candid (frank, open, straightforward) information regarding their health.		**0.513**			
Discharge is communicated in a timely manner to the patient and family so that they can take necessary measures.		**0.464**			
A patient focused vision exists within the organisation.			**0.896**		
Quality of care is the priority within the organisation.			**0.626**		
The care process coordinator has a patient focused vision.			**0.608**		
Patient communication is considered to be important within the organisation.			**0.569**		

The organisational structure is patient focused.			**0.566**		
There is a clear vision of policy regarding care throughout the entire hospital			**0.332**		
Within the care process time is explicitly provided to listen to the patient and his family.				**0.851**	
Time is explicitly scheduled within the care process for communications between healthcare professional and patient.				**0.749**	
Within the care process there is provision for sufficient time to provide information.				**0.658**	
The patient is explicitly asked for his consent with regard to the proposed care.				**0.579**	
Primary care is considered by the hospital to be an equal partner.					**0.796**
Good cooperation exists between the hospital and primary care.					**0.720**
In complex care situations consultation takes place between the physician/surgeon and general practitioner.					**0.479**

A confirmatory factor analysis (CFA) was performed on the five-factor solution with 29 items. Chi-square could not be interpreted because the study sample was larger than 200 (31). The four fit indices revealed a good fit for the CPSET: root mean square error of approximation, 0.065; comparative fit index, 0.92; incremental fit index, 0.92; normed fit index, 0.88 (31) .

The Kendall Tau correlations for the criterion validation analysis with the general CMO questions were calculated for the five-factor solution (Table 8). One factor, “patient focused organisation”, correlated highest with the general context item. Three factors, “coordination of care”, “communication with patients and family” and “cooperation with primary care”, correlated highest with the general mechanism item. The fifth factor, “follow-up of the care process”, correlated highest with the general outcome item.

Table 8: Discriminant and convergent validity for the five-factor solution

Factor	General context item	General mechanism item	General outcome item	CMO
Patient focused organisations	**0.441***	0.431*	0.411*	Context
Coordination of care	0.413*	**0.551***	0.415*	Mechanism
Communication	0.301*	**0.396***	0.306*	Mechanism
Collaboration with primary care	0.280*	**0.299***	0.179*	Mechanism
Follow-up of care	0.373*	0.431*	**0.595***	Outcome

* Kendall Tau correlation is significant at the 0.01 level (2-tailed).

An additional construct validation test was performed using the known groups technique for the surveys on care processes where pathways were in use (n=262), under development (n=123) and nonexistent (n=126). A significant difference was found in two of the five factors: "coordination of care" (p=0.000) and "follow-up of the care process" (p=0.001). Care processes with the support of pathways scored significantly higher on coordination of care than processes without pathways (p=0.001). Care processes with the support of pathways (p=0.000) and with pathways under development (p=0.001) scored significantly higher on "follow-up of care process" than care processes without pathways. Differences were not significant for patient focused organisation (p=0.144), communication with patients (p= 0.550), and cooperation with primary care (p=0.359).

Reliability

Cronbach's alpha reliability of the five factors was situated between 0.776 and 0.928. The intraclass correlations were all significant and were situated between 0.280 and 0.704 (Table 9).

Table 9: Internal consistency and intraclass correlation

Factor	Cronbach's alpha	Intraclass correlation
Patient focused organisations	0.844	0.280*
Coordination of care	0.876	0.534**
Communication	0.833	0.534**
Collaboration with primary care	0.776	0.556**
Follow-up of care	0.928	0.704**

*p<0.05 **p<0.000

Discussion

When considering the outcomes of clinical pathways, not only do the mechanisms of organising care have an impact but also the context of the organisation, as suggested by Pawson and Tilley (21). The context–mechanism–outcome configuration of the Realistic Evaluation framework (21) revealed five logical key characteristics of well organised care processes. They are made measurable in the five subscales of the 29-item CPSET. The context is made operational by the factor "patient focused organisation". The importance of patient focused care in relation to clinical pathways and other methodologies for systematising care processes has been discussed in the literature over the past 10 years (3;37-40). The mechanism factors "coordination of care" and "communication with patients and family" are seen as two important characteristics of care organisation and are used in several definitions of clinical pathways (41). The need for improved collaboration between hospitals and primary care will be even more important in the near future (42-44). The involvement of primary care professionals including general practitioners in the focus groups will have produced an effect on the mechanism factor "cooperation with primary care". The fifth factor "follow-up of the care process" is defined as an outcome factor within the realistic evaluation paradigm (21). The need for continuous follow-up of the outcomes of care is seen as one of the main challenges for clinical pathways (1-4;7;45;46).

The CPSET was developed using a multi-method approach. Because the organisation of care processes is performed by multidisciplinary teams, the views of all stakeholders on the appropriate management of care had to be embedded in this tool. All stakeholders, including patients, were involved in defining the 248 candidate topics of the CPSET. In the final version of the 29-item tool, the different stakeholder groups are still well represented. Of the 29 final items, 12 items (36.4%) were in the top 10% of the patients' list, 7 items (21.2%) were top

items for medical doctors, hospital managers and primary care professionals, 8 items (24.2%) were suggested by nurses and allied health professionals, 6 items (18.2%) were suggested by representatives of the supporting departments and 11 items (33.3%) were suggested by the clinical pathway facilitators.

Although the CPSET was developed and tested for validity and reliability using a multi-method approach, the procedure had some inherent methodological limitations. In the focus groups, only Belgian people (no Dutch) were selected because sufficient candidate topics were suggested by the Belgian groups and because a research fellow from the Dutch Institute for Healthcare Improvement was continuously involved in the project. Belgian and Dutch people participated in all subsequent development and validation steps. In the construct validation phase a sample of 511 questionnaires was randomly split to perform the EFA and CFA. Although all questionnaires came out of a multi-centre study involving 54 organisations, a larger sample size would have been more appropriate. The most appropriate design would have been to use the 511 questionnaires for the EFA only and to organise a second data collection to obtain data for the CFA. This was impossible within the time frame and resources of this project and will be a consideration for additional research. Also, the involvement in the construct validation of all stakeholder groups, explicitly including patients, would be of additional value.

With respect to the reliability of the CPSET the intraclass correlation for the factor describing the "patient focused organisation" is significant but lower than for the other four factors. The different view of the professionals towards the context of the organisation, which is a proxy for the evaluation of the management team, is perhaps not a coincidence. All other factors measure the multidisciplinary teamwork and here the intraclass correlations were much higher. Based on these significant intraclass correlations, an average team score per factor would be appropriate in future research.

To determine the key characteristics of clinical pathways that have an impact on outcome indicators, an additional criterion validity test with patient outcome data would be necessary (16).

The English version of the CPSET (Table 7) was translated from the Dutch version using a forward translation to back translation method involving six people and two official English-Dutch translators. Although this is an appropriate way of translating instruments, we advise additional cross-cultural comparison and validation as a topic for future research.

An interesting question for additional research on clinical pathway audit tools would be the relationship between audit tools that measure the basic characteristics of clinical

pathways at the documentation level (such as ICPAT) and those that measure the impact of clinical pathways on the organisation of care (CPSET).

In conclusion, based on the analysis of the content validity, face validity, construct validity, criterion validity with the CMO framework, internal consistency and reliability, one can conclude that the CPSET with 29 items in five subscales [(1) patient focused organisation, (2) coordination of care, (3) communication with patients and family, (4) cooperation with primary care and (5) follow-up of the care process] is a reliable and valid instrument for measuring the organisation of the care process / clinical pathway with all stakeholders, including patients, represented. These factors are five key characteristics of well organised care processes. In future research the criterion validity of the CPSET should be further analysed to determine to what extent these key characteristics have an impact on patient outcomes.

BOX: Realistic Evaluation

The Realistic Evaluation configuration (21) contends that causal outcomes follow from mechanisms acting in a context (Context + Mechanism = Outcome (CMO)). The Realistic Evaluation approach offers researchers the opportunity to look at evaluation from a realistic perspective where the action is not happening in a laboratory environment. The question posed is "What works, for whom, in what circumstances?" instead of "Does this work?" or "What works?" (21).

The Realistic Evaluation framework or paradigm is reported to have the potential for an evaluation strategy that not only systematically tracks outcomes, but also the mechanisms that produce the outcomes, the contexts in which the mechanisms are triggered, and the content of the intervention (21;47;48). The basic CMO concern is still, of course, the outcome. But what does the explanatory work is first of all the mechanism (e.g. the program that was introduced) and secondly the context (e.g. the characteristics of the organisation where the program was introduced).

Unless programs have a demonstrable impact, it is hard to defend their implementation and continuation. In evaluation or self-evaluation, one needs a method that seeks to understand what the program (or intervention, e.g. the redesign of the care process or clinical pathway) actually do to change behaviours and why not every situation is conductive to that particular process. The Realistic Evaluation framework has been used previously in a wide range of healthcare projects (25;49-60) but not in clinical pathway research.

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Chapter 5:
Do pathways lead to better organised care processes?

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Introduction

In 1999, the Institute of Medicine recommended making care processes more transparent and organising them around patient needs (1-4). Many methods have been proposed to increase the quality, efficiency, and/or safety of care. One of these methods is clinical pathways, which are multidisciplinary tools used to (re)organise care processes (5-10). Pathways are used throughout the world in different kinds of healthcare settings (11-20). Pathways (re)organise care by standardising the care process, leading to less variation in care and more transparency on how care is performed. Pathways are methodologies that help multidisciplinary teams (re)organise their work (5;10;12;18;20-22). The decisions made during the reorganisation process are written in a time-task matrix or Gantt chart and are mostly integrated into a patient's record.

Different tools exist to evaluate clinical pathways (7). These instruments mainly evaluate the specific characteristics involved in the development of clinical pathways, not the implementation and the impact pathways have on the organisation of care processes (7;23). Although the impact of most clinical pathways is positive, confusion still exists about their safety, how they affect clinical outcomes, and how they affect the way multidisciplinary team members evaluate the organisation of care (5;7;10;17;18;20-22;24-28). We previously defined five elements of well-organised care processes (29): patient-focused organisation, coordination of the care process, communication with patients and family, collaboration with primary care, and follow-up of the care process. Because multidisciplinary teams are involved in the daily organisation of these care processes, they are ideally positioned to evaluate them.

Differentiating between a clinical pathway and a care process is essential. Every patient undergoes a care process in which the multidisciplinary team is more or less organised and involved. Each care process can be evaluated retrospectively. Some of these care processes are supported by clinical pathways, that is, such care processes are discussed thoroughly and (re)designed. Although all patients undergo a certain care process, the care of some patients is directed by a clinical pathway while that of others is not. In designing a clinical pathway, the multidisciplinary team should endeavour to make a care process as transparent and standardised as possible. Clinical pathways, however, do not guarantee that a care process will be perfectly organised (7;30). There may still be room for improvement, and bottlenecks may still occur. Also, care processes not supported by a clinical pathway could be organised in an appropriate way. Therefore, evaluating how clinical pathway methodology affects the organisation of care processes is essential.

This study has three aims: (1) to assess differences in the perception of health professionals (medical doctors, head nurses, and clinical pathway facilitators) in their evaluation of care processes, (2) to assess whether care processes supported by clinical pathways perform better than care processes not supported by clinical pathways, and (3) to assess the sensitivity and specificity of clinical pathways in predicting well-organised care processes.

Methods

In this cross-sectional multicentre study, data were collected between April 2005 and August 2005 within the Belgian–Dutch Clinical Pathway Network (29;31). The Belgian–Dutch Clinical Pathway Network is a collaborative network between the Catholic University Leuven, the Dutch Institute for Healthcare Improvement, and healthcare organisations in Belgium and The Netherlands working on the development, implementation, and evaluation of clinical pathways. Each member organisation has at least one pathway facilitator.

In the present study, we contacted pathway facilitators to select care processes to be evaluated within their organisation, even if clinical pathways were not used within their organisation. This resulted in a total sample of 142 care processes. All 142 care processes were evaluated by the pathway facilitator. If clinical pathways were used, we asked the facilitator how long they were used to direct a care process. Firstly, each pathway facilitator attended a three-day course to receive training on the concept and methodology of clinical pathways. The course was taught by the academic staff of the Center for Health Services and Nursing Research, Catholic University Leuven, and the Dutch Institute for Healthcare Improvement. Secondly, a medical doctor, a head nurse, an allied health professional, and a pathway facilitator evaluated the care process using the Care Process Self Evaluation Tool (CPSET) (see appendix 1) (29), a 29-item Likert scale used to evaluate the organisation of care processes. The CPSET has been previously tested in terms of its validity and reliability (29). The CPSET instrument has five subscales: (1) patient-focused organisation (6 items), (2) coordination of the care process (7 items), (3) communication with patients and family (4 items), (4) collaboration with primary care (3 items), and (5) follow-up of the care process (9 items). Each item is scored on a 1-to-10 scale (1= totally disagree; 10=totally agree). An average score per subscale and an overall score are calculated. For each care process, a team

score is calculated by averaging the individual scores of each team member (medical doctor, head nurse, and pathway facilitator).

For the present study, we selected care processes that received CPSET evaluations from a medical doctor, head nurse, and pathway facilitator. This resulted in a sample of 103 care processes (n=309 surveys). The 103 care processes covered 38 different patient groups in 16 clinical areas in 49 hospitals. Thirty-nine hospitals were Belgian, ten were Dutch. Twenty-five care processes had either no pathways in use or none under development, 27 had pathways under development, 23 had pathways in use for less than one year, and 28 had pathways in use for more than one year. These four groups were similar in number among the different organisations and in terms of diagnosis and clinical areas (29) (see Table 1). To study the different perceptions different healthcare professionals have about the organisation of care, we analysed 97 care processes. Six care processes were excluded, because one or more CPSET subscales were not completed.

Statistical analysis

The Friedman test was used to analyse score differences among medical doctors, head nurses, and pathway facilitators. Descriptive statistics, the Kruskal-Wallis test, and Mann-Whitney test were used to compare CPSET scores for care processes with and without pathways. To find out how sensitive and specific clinical pathways are in detecting well-organised care processes as determined by the CPSET, sensitivity, specificity, likelihood ratios, and odds ratios were calculated. For the sensitivity and specificity analysis, a cut-off score of 7, based on ROC analysis, was used. SPSS 12.0.0 and Stats Direct 2.5.6 were used to analyse the data.

Table 1: Descriptive statistics for four levels of pathway implementation

	Without pathways or no pathways under development	Pathway under development	Pathways in use less than 1 year	Pathways in use more than 1 year
Number of processes	25	27	23	28
Number of organisations (Belgium/The Netherlands)	22 (17 / 5)	23 (19 / 4)	18 (13 / 5)	19 (18 / 1)
Number of different diagnoses*	20	15	10	13
Number of clinical areas involved†	11	9	6	8

**Patient groups: acute myocardial infarction, amputation, angina pectoris, appendectomy, breast cancer, CABG, cardioversion, cataract, chemotherapy, coloscopy, COPD, delirium, diabetes, disectomy, DVT, gastric banding, heart catheterisation, heart failure, hemicollectomy, hysterectomy, incontinence, inguinal hernia, lung cancer surgery, mastectomy, memory screening, multiple sclerosis, neurostimulation, normal delivery, obesity, proctology, prostatectomy, spinal cord lesion, stoma care, strabismus, stroke, stroke rehabilitation, total hip replacement, total knee replacement, trepanation.* *†Clinical areas: bowel surgery, cardio surgery, cardiology, endocrinology, gastroenterology, geriatrics, gynaecology, neurology, neurosurgery, oncology, ophthalmology, orthopaedics, pneumology, rehabilitation, urology.*

Table 2: Differences between healthcare professionals

Average score	Medical doctor – head nurse (n=97)	Medical doctor – pathway facilitator (n=97)	Head nurse – pathway facilitator (n=97)	Difference between three groups
Patient-focussed organisation	-0.26	+0.08	+0.34*	Not significant
Coordination of the care process	0	+0.25	+0.25	Not significant
Communication with patients and family	+0.52*	+0.33	-0.19*	Significant
Collaboration with primary care	+0.29*	+0.55*	+0.26	Significant
Follow-up of the care process	+0.14	+0.45	+0.31	Not significant
Overall CPSET score	+0.13	+0.33*	+0.20	Not significant

*$p<0.05$ (Friedman Test); values represent differences between scores.

Results

Analysing the CPSET scores of medical doctors, head nurses, and pathway facilitators revealed some differences among these three groups (Table 2). A significant difference was found between the three groups only on two subscales: communication with patients and family and collaboration with primary care. Group differences were not found on the subscales patient-focused organisation, coordination of the care process, and follow-up of the care process and on overall CPSET scores.

We also analysed group differences on CPSET scores with regard to different levels of pathway implementation: (1) Group A, no pathways in use; (2) Group B, pathways under development; (3) Group C, pathways in use for less than one year; and (4) Group D, pathways in use for more than one year (Table 3).

Table 3: CPSET team scores on five subscales and overall score for different levels of pathway implementation

	Levels of pathway implementation				
	Group A	Group B	Group C	Group D	
CPSET subscale average (standard deviation)	No pathways in use (n=25)	Pathways under development (n=27)	Pathways in use less than 1 year (n=23)	Pathways in use more than 1 year (n=28)	Difference
Patient-focused organisation	7.66 (0.72)	7.79 (0.54)	8.04 (0.53)	7.78 (0.82)	(C) > (A)†
Coordination of the care process	7.42 (0.72)	7.74 (0.70)	8.19 (0.54)	7.80 (0.72)	(A)-(B)-(C)-(D)* (C) > (A)† (D) > (A)† (C) > (B)†
Communication with patients and family	6.63 (1.39)	6.96 (1.00)	7.17 (0.74)	6.75 (0.86)	
Collaboration with primary care	7.03 (0.90)	7.04 (1.17)	7.07 (0.94)	6.85 (1.00)	

Follow-up of care process	5.99 (1.20)	7.12 (1.00)	7.54 (0.76)	7.03 (1.02)	(A)-(B)-(C)-(D) * (B) > (A)† (C) > (A)† (D) > (A)†
Overall CPSET score	6.95 (0.75)	7.34 (0.69)	7.63 (0.52)	7.25 (0.62)	(A)-(B)-(C)-(D)* (B) > (A)† (C) > (A)† (C) > (D)†

*Kruskall-Wallis Test

†Mann-Whitney Test, $p<0.05$

For the first CPSET subscale, patient-focused organisation, healthcare teams that used pathways for less than one year (Group C) had significantly higher scores than teams that did not use pathways (Group A). The subscale scores of teams that had pathways under development (Group B) and teams that used pathways for more than one year (Group D) were not significantly different. For coordination of the care process, Groups B and C had significantly higher scores than Group A. Group B had significantly lower coordination subscale scores than Group C. We found no significant differences in the scores of Groups A, B, and C for the subscales, communication with patients and family and cooperation with primary care. For the fifth subscale, follow-up of the care process, Groups B, C, and D had significantly higher scores than Group A. Groups B and C had significantly higher overall CPSET scores than Group A. However, overall scores decreased significantly in Group D compared to Group C.

Table 4. Sensitivity and specificity analysis of clinical pathways on CPSET scores

	Sensitivity (95% CI)	Specificity (95% CI)	Odds (95% CI)
Patient-focused organisation	68.66% (56.16% to 79.44%)	45.45% (16.75% to 76.62%)	1.81 (0.39 to 8.05)
Coordination of the care process	72.46% (60.38% to 82.54%)	77.78% (39.99% to 97.19%)	8.92* (1.52 to 95.38)
Communication with patients and family	74.29% (56.74% to 87.51%)	39.53% (24.98% to 55.59%)	1.87 (0.65 to 5.71)
Collaboration with primary care	71.79% (55.13% to 85%)	38.46% (23.36% to 55.38%)	1.58 (0.56 to 4.61)
Follow-up of the care process	84.62% (69.47% to 94.14%)	51.28% (34.78% to 67.58%)	5.65* (1.80 to 20.36)
Overall CPSET score	77.36% (63.79% to 87.72%)	56% (34.93% to 75.6%)	4.26* (1.40 to 13.61)

*$p<0.05$

The use of clinical pathways had a significant effect on the overall CPSET score, and on the scores of the subscales coordination of the care process and follow-up of the care process. For the overall CPSET score, care processes labelled as clinical pathways enabled us to identify 77% of the well-organised care processes (sensitivity). In other words, 23% of well-organised care processes were not labelled as clinical pathways. This is not surprising, as well-organised care can be obtained by means other than clinical pathways. Indeed, 56% of the weakly organised care processes had no clinical pathway (specificity). Again, this means that 44% of the processes that were rather weakly organised were still called a clinical pathway. One implication is that just because a process may be labelled a clinical pathway, does not necessarily guarantee that it is well organised.

Although the relationship was not perfect, the odds ratio of 4.26 (95% CI: 1.40 to 13.61) indicates that having a clinical pathway led to a 4.3 times higher probability that the care process was well organised rather than weakly organised. The probability of having a well-organised care process was 1.8 times greater when the care process was supported by a clinical pathway (positive likelihood ratio (LR) = 1.76 (95% CI: 1.18 to 2.95). Having no clinical pathway decreased this probability to 40% (negative LR = 0.40 [0.22 to 0.74]), whereas having a clinical pathway increased the prevalence of well-organised care processes from 68% to 79%.

With respect to the coordination of care, a sensitivity of 72% and a specificity of 78% was found; the odds ratio was 8.92; the positive and negative LRs were 3.26 and 0.35, respectively. Having a clinical pathway increased the prevalence from 8% to 96%. For the follow-up subscale, a sensitivity and specificity of 84.6% and 51.3% were obtained, respectively. The odds ratio was 5.65 and the positive and negative LRs were 1.74 and 0.30, respectively. The prevalence of well followed-up processes increased to 63.5% (change of 13%).

No significant differences were found with subscale scores on patient-focused organisation, communication with patients and family and cooperation with primary care (Table 4). Although the relationship between clinical pathways and well-organised care processes is not perfect, it is obvious that clinical pathways seem to have a strong impact on the organisation of care.

Discussion & Conclusion

The first aim of this study was to evaluate differences on the CPSET scores among medical doctors, head nurses, and pathway facilitators. Although we found no significant differences among the three groups in terms of overall scores and subscale scores on patient-focused organisation, coordination of the care process, and follow-up of the care process, we did find a significant difference on communication with patients and family and collaboration with primary care. In future research—especially for studies that include the primary-care time frame—differences on communication and collaboration should be taken into account.

The Institute of Medicine recommends that care processes need to be reorganised around patient needs (1-4). A first step in this regard is to do a critical analysis of the actual organisation of the care process targeted to be improved or reorganised. Although analysing team scores is appropriate, analysing the scores of different professional groups (e.g., medical doctors, head nurses, pathway facilitators) or the scores of each member of a healthcare team can be useful in the search for continuous improvement. Moreover, discussing the views of each team member can help the team develop the best strategy to reorganise the care process towards excellence. Radar plots of the scores of different professional groups can provide the team with important feedback in at least three areas: (1) Subscale scores of each professional group reveal how doctors, nurses, and facilitators view a given care process; (2) subscale themes requiring the most attention are identified by analysing the differences in scores

between the subscales; and (3) score differences among the professional groups involved a given care process.

CPSET scores of care processes having different levels of pathway support revealed that the group with pathways in use for less than one year (Group C) had the highest score on all five subscales and the highest overall score. The scores increased when there was a higher level of pathway support, although the differences were not always significant. Interestingly, the scores decreased in the group with pathways in use for more than one year (Group D), although only significantly for the overall score. Even though this decrease was not significant for the individual subscales, these data do emphasize that multidisciplinary teams and managers need to follow-up closely the life cycle of a clinical pathway.

Savitz et al. (32) described the life cycle of continuous clinical process innovations, defining the criticality point as the junction between critical crossroad alternatives to further increase the change, maintain or decline. From our data, we propose that the criticality point for pathways may be around one year. Possible explanations for this decrease are the lack of continuous follow-up of the pathways and the deterioration of pathway standardisation and coordination. Another possibility is the more adequate critical appraisal by team members. Based on the transparency of a care process after a pathway is implemented, bottlenecks can be more easily followed up. This leads to more critical audits by team members, which in turn, leads to lower scores on the CPSET.

To further explore our results, qualitative studies that include interviews with team members and analysis of the (continuous) support of management after pathway implementation can be interesting. The CPSET scores can be used in pre-test versus post-test analysis of improvement methods, but will also provide interesting information for the continuous evaluation of the care process organisation. To show that introduction of a pathway to a specific care process produces an effect over time, future studies will need to use longitudinal research designs.

Our analysis of how clinical pathways affect the organisation of care processes revealed significant odds ratios for the subscale scores of coordination of the care process and follow-up of the care process, and for the overall score. To calculate the sensitivity, specificity, and odds ratios, a cut-off score of 7 was used. (Results using a cut-off level of 6 or 8 can be obtained from the authors.) The CPSET had high sensitivity but modest specificity; the latter of which reveals that other issues were also important for obtaining a well-organised care process. Based on the specificity analysis of the overall score, we conclude that other issues besides the clinical pathway probably have impact on the self-evaluation scores. Some

of these are availability of a case manager (33), competence of the professionals (34), nurse staffing levels (35), job satisfaction (36), safety culture (37), available resources (38), relational coordination (39), and availability and knowledge sharing on quality (40).

The likelihood and odds ratios emerging from this study led us to conclude that pathways, as actually used in Belgium and The Netherlands, have a significant positive impact on the coordination of care, the follow-up of care, and the overall organisation of the care process. Although the relationship between clinical pathways and well-organised care processes is not perfect, pathways have a significant impact on the organisation of care processes. However, pathway methodology does not have a significant impact on patient-focused organisation, communication with patients and family, and collaboration with primary care. This does not necessarily mean that clinical pathways have no impact on these elements of well-organised care processes, but alternatively might mean that multidisciplinary teams and pathway facilitators do not actually focus enough on these three subscale areas to significantly change CPSET scores. It would be interesting to set up an international research project on clinical pathways in different countries that use different implementation methods (11;41) and analyse the impact these methods have on the organisation of the care process.

This study focused on the effect of clinical pathways on the organisation of the care process. The organisation of the care process was measured by the CPSET, a valid and reliable instrument for evaluating the organisation of the care process from the viewpoint of a multidisciplinary team (29). One limitation of the CPSET is that it is a self-evaluation instrument: The tool measures the perceptions of the team members. For this reason, we need to be careful with generalising the CPSET results. In future research, the relationship between CPSET scores and outcome indicators needs to be analysed to determine whether there is a relationship between subjective perceptions and objective outcomes.

In most pathway research, outcome and process indicators measure the effect of a pathway. Most researchers look for a direct impact of the introduction of a pathway on outcomes without considering the team's perspective. Different authors, however, discuss the direct relationship between an intervention and outcomes: the realistic evaluation paradigm on which the CPSET is based (42), the quality health outcomes model (43), and the three quality gaps model (44), which is based on Hesketts' service triangle (45). These models all go back to Donabedians' structure–process–outcome theory (46). Donabedian describes the relationship between the structure of an organisation, the way processes are managed, and their effect on outcomes. The emphasis on evaluating quality of care has shifted from structures (having the right things) to processes (doing the right things) to outcomes (having

the right things happen) (43). Quality of a service is different from quality of a product. No matter how much care is taken on paper in designing a service, in testing it, and in delivering it, what customers perceive is quite different from the original proposition (44). The impact of a certain procedure, e.g., the implementation of a clinical pathway, can have an impact on the outcome, but as care is delivered by a multidisciplinary team— during what Teboul calls a moment of truth—the clinicians will do it with more or less success. Pathways are a part of the structure of the organisation, and teams deliver the process. Pathways are developed by task forces "back stage" but are implemented "front stage" during direct patient contact. Tebouls' conclusion is that "service is front stage" and that the perceptions of the team is therefore important (44). The teams' perception on the organisation of the care process is essential in understanding what type of impact quality improvement methodologies has on outcomes. This will not only be the case for the implementation of clinical pathways but also for the adherence to guidelines or the compliance to procedures, once the (financially sponsored) trial phase is completed. Factors like the perception of teams on the organisation of care may be used to adjust comparisons of processes and outcomes, as we actually do for case mix or severity of illness.

As stated by Degeling et al. (47), a clinical pathway represents a method to achieve a result. A pathway is a tool for empowering clinicians to strike a balance between the clinical and resource dimensions of care and between the requirements of both clinical autonomy and transparent accountability. The team's perspective is essential. Pathways provide a basis for re-establishing "responsible autonomy" as the primary organising principle of clinical work. If multidisciplinary teams, including both clinicians and managers, do not work together on the re-organisation of healthcare, all parties will continue to be driven by the distrust and related crises of confidence that pervade the field (47). CPSET scores can therefore be used to evaluate the views of the multidisciplinary team before starting reorganisations or quality improvement projects. By implementing pathways, we can assume that the scores on the organisation of care processes will not only increase but also that the scores of the individual team members will be more similar. If the goal of the clinical pathway methodology is to build well organised care processes, they should not only focus on the coordination of the care process and the follow-up of the care process on which they seem already effective but also on patient-focused organisation, communication with patients and family, and on collaboration with primary care. It can be done by the adaptation of the actual pathway methodology or the inclusion of other strategies. It will be one of the main challenges for the pathway community.

Appendix 1. The Care Process Self Evaluation Tool © CZV-KULeuven, 2006

Do you agree with the following statements? Totally disagree Totally Agree

Patient-focused organisation		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
PO1	A patient-focused vision exists within the organisation.										
PO2	Quality of care is the priority within the organisation.										
PO3	The care process coordinator has patient-focused vision.										
PO4	Patient communication is considered to be important within the organisation.										
PO5	The organisational structure is patient focused.										
PO6	There is a clear vision of policy regarding care throughout the entire hospital.										
Coordination of the care process		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
COR1	Agreements are observed.										
COR2	All team members are familiar with the various steps in the care process.										
COR3	There is optimum timing of activities within the care process.										
COR4	Concrete agreements are made within the care process.										
COR5	Team members consider themselves to be engaged in the organisation of the care process.										
COR6	Patients/family are provided with candid (frank, open, straightforward) information regarding their health.										
COR7	Discharge is communicated in a timely manner to the patient and family so that they can take necessary measures.										
Communication with patient and family		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
COM1	Within the care process time is explicitly provided to listen to the patient and his/her family.										
COM2	Time is explicitly scheduled within the care process for communications between healthcare professional(s) and patient.										
COM3	Within the care process there is provision for sufficient time to provide information.										
COM4	The patient is explicitly asked for his/her consent with regard to the proposed care.										

Collaboration with primary care		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
SE1	Primary care is considered by the hospital to be an equal partner.										
SE2	Good cooperation exists between the hospital and primary care.										
SE3	In complex care situations, consultation takes place between the physician/surgeon and general practitioner.										
Monitoring and follow-up of care process		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
OP1	When (re)designing the care process, quality indicators are formulated.										
OP2	Whether the care provided is tailored to the patient's needs is systematically monitored/ followed up.										
OP3	Within the care process, patient satisfaction is monitored/followed up systematically.										
OP4	The goals of the care process are described explicitly.										
OP5	Within the care process, monitoring/follow-up is performed to verify whether planned activities are actually performed.										
OP6	Outcomes are systematically monitored/followed up.										
OP7	Variances can be monitored within the care process.										
OP8	Within the care process risks of complications are monitored/followed up systematically.										
OP9	The progress in the care process is continuously monitored/followed up and adjusted.										

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Chapter 6:
Case study on the development, implementation and evaluation of a clinical pathway for total knee arthroplasty

This chapter is already published and
reproduced with the kind permission of the editor:
Vanhaecht K, Sermeus W, Tuerlinckx G, Witters I, Vandenneucker H, Bellemans J. Development of a clinical pathway for total knee arthroplasty and the effect on length of stay and in-hospital functional outcome. Acta Orthop Belg 2005; 71(4):439-444.

Introduction

Total knee arthroplasty (TKA) is a commonly performed orthopaedic procedure. In 2000, about 9200 total knee replacements were performed in Belgium. The aims of TKA are to reduce pain and to restore a close to normal knee function. To attain these aims, TKA requires an interdisciplinary team approach. A clinical pathway (defined as a set of methods and tools underlying a multidisciplinary programme of care for a specific patient population) provides the interdisciplinary team with a tangible plan that ensures qualitative and efficient patient care and can help to achieve these aims (1).

Kim *et al* studied the recent literature on the effects of clinical pathways on hip and knee arthroplasty, and concluded that clinical pathways effectively reduce costs and length of stay in acute care hospitals without compromising patient outcomes (2). Of the 11 studies discussed in this review, nine measured complications: five studies found that pathway implementation did not affect the number of complications; whereas four studies found that pathway implementation reduced the number of complications. Although three of the studies reviewed by Kim *et al.* compared functional outcome in patients that had undergone knee arthroplasty in the presence or absence of clinical pathways, their findings were inconclusive because these studies used a wide range of measures (2). Moreover, interpretation of their findings was difficult because of substantial methodological limitations, particularly the use of historical controls and failure to account for length of stay in rehabilitation facilities (2). Despite these limitations, Kim *et al.* concluded that overall clinical pathways have a positive impact. At odds with this conclusion, however, are the findings of Mauerhan *et al.* who reported a significantly higher rate ($p=.015$) of dislocations after hospital discharge in patients undergoing total hip arthroplasty after introduction of their clinical pathway. Their pathway did decrease the length of stay from 6.6 days to 3.9 days (3).

The aim of the present study was to determine how the implementation of a clinical pathway for TKA affects length of stay and in-hospital functional outcome in a large teaching hospital in Belgium.

Patients and Methods

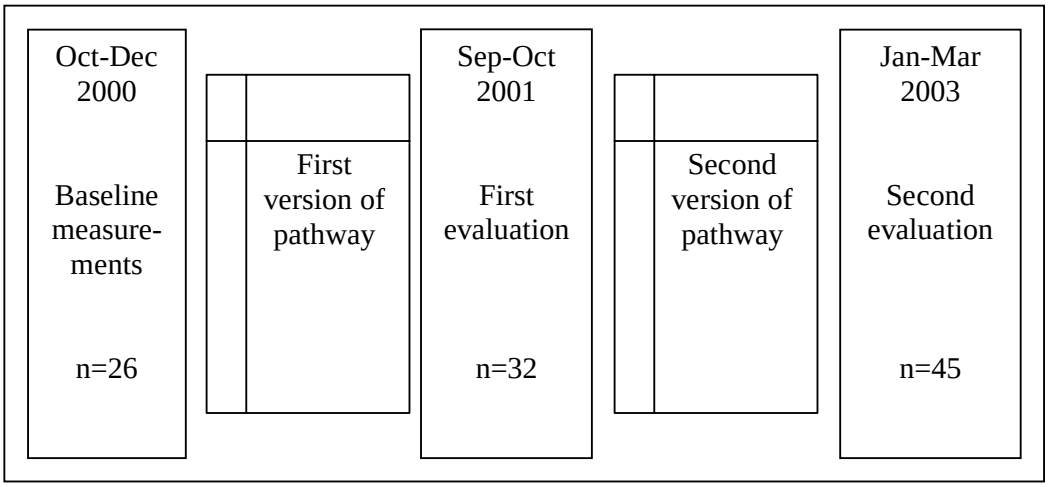
Sample

The study was carried out at the Pellenberg University Hospital, which is part of the University Hospitals Leuven in Belgium, a large system of teaching hospitals having 1850 beds. The more than 400 knee arthroplasty procedures performed annually within the Department of Orthopaedics provided us with a great opportunity to test the efficacy of our clinical pathway for TKA. The clinical pathway project began in September 2000. A total of 103 patients participated in our study; all gave informed consent to participate. All participants were Dutch-speaking patients who had never undergone a TKA procedure prior to admission to our hospital. Before implementing this pathway, a baseline measurement was performed from October 2000 to December 2000 on one group of patients (n=26; mean age=69.3 y, SD=9.43; 9 men and 17 women). We did an initial evaluation of the efficacy of the first version of the pathway from September 2001 to October 2001 on a second group of patients (n=32; mean age = 66.8 y, SD= 11.24; 11 men and 21 women). After implementation of the second version of the pathway, a second evaluation was done from January 2003 to March 2003 on a third group of patients (n=45; mean age= 64.5 y, SD= 9.76; 9 men and 36 women). Exclusion criteria included revision of the arthroplasty, mental retardation, or severe co-morbidity. We found no statistical differences between the three patient cohorts with regard to sex, age, work situation, training, or marital status.

Implementation of the clinical pathway

The clinical pathway under study in this report was developed, implemented, and evaluated according to the 30-step method developed by the Belgian-Dutch Clinical Pathway Network (www.nkp.be) (1;4-6). The project team is lead by the senior orthopaedic knee surgeon and includes the head nurse, the physiotherapist, the social worker, and the clinical pathway facilitator. The development of this pathway took nearly 6 months.

Fig. 1. — The clinical pathway intervention process.



The Clinical Pathway Intervention

The following key interventions and outcomes were defined: (1) preoperative checklist on functional and social status; (2) prophylactic antibiotics; (3) knee replacement procedure; (4) pain medication; (5) thrombo-embolic prophylaxis; (6) postoperative lab tests; (7) postoperative X-rays; (8) start of physiotherapy on postoperative day 1, including discussion of follow-up exercises; (9) pain management; (10) postoperative knee flexion; (11) patient's ability to walk various distances; (12) patient's ability to climb/descend stairs; and (13) wound status.

Two versions of this clinical pathway were used in this study (fig 1). The first version was not integrated into the patients' records, but was used as a checklist to assess the patients during each day of their hospital stay. The second version was developed after evaluating the first version of the clinical pathway. The evaluation included results on functional outcome and practical experiences. The team discovered that the amount of administrative work had doubled; thus, we attempted to integrate the clinical pathway into the patients' records in a more practical way. We also included new key interventions on pain management.

Design

A pre-experimental, interrupted, time-series design was used (fig 1). Measurements were taken three times: a baseline measurement, a second measurement taken one month after implementation of the pathway, and a third measurement taken 15 months after implementation of the pathway. The design is an extension of a one-group pre-test versus post-test design for situations having more than two observations.

Measurements

To measure the effect of the clinical pathway, six variables were defined: (1) the postoperative day 90° knee flexion was attained, (2) the postoperative day the patient could perform a straight leg raise, (3) the postoperative day the patient could walk 60 meters, (4) the postoperative day the patient could walk 200 meters, (5) the first day the patient was pain free, and (6) length of hospital stay. Pain free was defined as a pain score of less than 3 on the 0-to-10 Visual Analogue Scale, persisting for two consecutive days. The project team members scored these outcomes daily and noted these in the patients' records.

Statistical analysis

Because the data were time dependent, we used a survival analysis. The significance level was set at $p < 0.05$.

Results

Table 1. Implementation of two versions of a clinical pathway for total knee arthroplasty: effect on clinical indicators and length of stay.

Indicator	Baseline* (n=26)	First evaluation† (n=32)	Second evaluation‡ (n=45)	Log-Rank test
90° Knee flexion	9.5§	9.5	8.0	p<0.05
Straight leg raise	6.6	6.2	3.4	p<0.05
60-meter walk	9.2	7.1	5.1	p<0.05
200-meter walk	11.2	9.4	7.2	p<0.05
Pain score < 3 for two days‖	7.9	9.8	7.4	p>0.05
Length of stay	15.3	12.1	10.5	p<0.05

*Assessment performed before implementation of pathway.

†Assessment performed after implementation of the first version of the pathway.

‡Assessment performed after implementation of the second version of the pathway.

§Data represented in terms of Kaplan Meier mean survival days (i.e., postoperative days).

‖Pain measure was based on the 0-to-10 Visual Analogue Scale.

As shown in table 1, the implementation of the pathway had a significant impact on the postoperative day on which the patient could perform straight leg raises as well as on the first day patients could walk 60 and 200 meters (figs 2 and 3). Implementation of the first version of the pathway did not affect the mean postoperative day on which 90° knee flexion was attained. We noticed, however, that patients experienced a slight increase of pain intensity, but not a significant increase. On average, it took more than 9.8 days before pain intensity levels dipped below the pain score of 3 for two consecutive days. Implementation of the first version of the pathway decreased the length of hospital stay from 15.3 to 12.1 days (fig 4).

Fig. 2. — Kaplan Meier plots showing the day on which patients first walked 60 meters following total knee arthroplasty surgery. Three different groups of patients were assessed: one before implementation of the clinical pathway, one after implementation of the first version, and one after implementation of the second version of the pathway (n = 103).

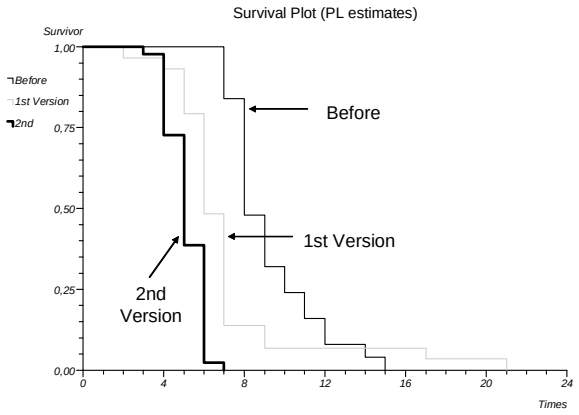


Fig. 3. — Kaplan Meier plots showing the day on which patients first walked 200 meters following total knee arthroplasty surgery (n = 103). All conventions are as in fig 2.

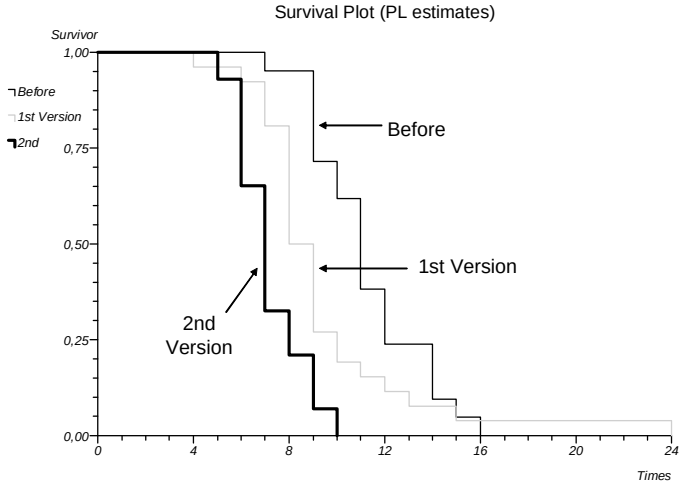
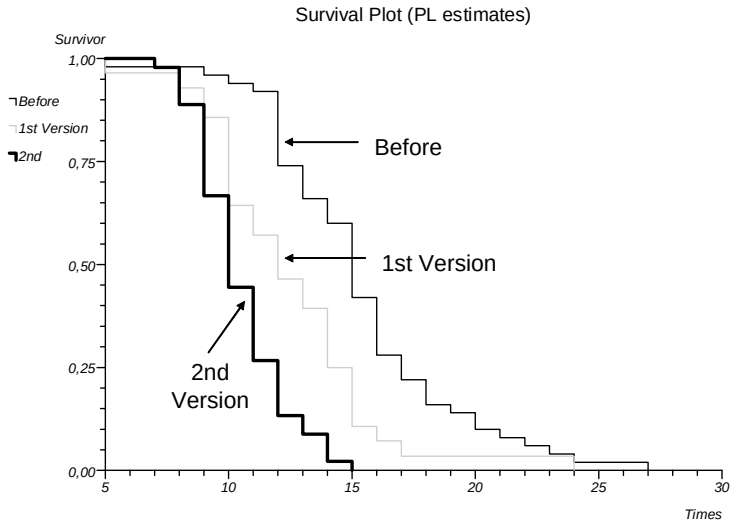


Fig. 4. — Kaplan Meier plots showing the length of hospital stay of patients following total knee arthroplasty surgery (n = 103). All conventions are as in fig 2.



Implementation of the second version of the pathway significantly advanced the mean postoperative day 90° knee flexion as well as straight leg raising and walking 60 and 200 meters was reached. The length of stay also decreased significantly. The pain score decreased to levels measured before the implementation of the pathway (table 1). Following implementation of both versions of the pathway, the mobility indicators (i.e., ability to walk 60 and 200 meters) were significantly advanced. After the implementation of the second version, all patients were able to walk 60 meters by postoperative day 7 (fig 2) and 200 meters by postoperative day 10 (fig 3). The length of stay decreased significantly from an average of 15 days before the implementation of the clinical pathway to an average of 10 days after implementation of the second version of the pathway. All of these patients were discharged 15 days after surgery; 15 days was the average length of stay of patients before the pathway was implemented (fig 4).

Discussion

The present study involved the development, implementation, and evaluation of two versions of an in hospital clinical pathway for TKA patients. Implementation of this pathway decreased length of hospital stay by 33%. Although the length of stay decreased in our study, it is still longer than that of knee arthroplasty patients that participated in previous pathway

studies, mainly in the U.S.A. (2;7-11). The length of stay of patients subjected to our second pathway is comparable to that of patients treated at 13 other hospitals within the Belgian-Dutch Clinical Pathway Network (www.nkp.be) (mean length of stay: 13.2 days; n=294) (12).

Improvement of the in hospital functional outcomes was the most important result of our study. In hospital mobility indicators improved significantly after the introduction of the pathway. Our findings are in line with those of Kim *et al.* (2). The methods we used in the present study are now being examined further by other hospitals within the Belgian-Dutch Clinical Pathway Network (6) that are in the process of developing and evaluating their own pathways for knee arthroplasty patients.

In the literature we found that in hospital clinical pathways tend to decrease total hip and knee patients' length of stay (2). This in hospital positive effect, however, can lead to negative effects such as long-term complications. This means that we have to be very careful with the interpretation of this result. The ultimate goal of clinical pathways is optimal quality and certainly not the decrease in length of stay. For example, Mauheran *et al.* found that implementation of a clinical pathway decreased length of stay but increased the rate of dislocations following hip replacement surgery (3), underscoring the need to consider the long-term effects of clinical pathways. Given the potential of negative long-term effects associated with the implementation of clinical pathways, we will have to evaluate the long-term effects of our in hospital TKA pathway in future studies. This was not possible within this study due to practical reasons. The use of both length of stay and clinical indicators to evaluate the efficacy of a clinical pathway could help in defining an appropriate length of stay for our patients in our healthcare organisation.

Our study has some inherent limitations. A risk for bias exists in the type of study design we used. First, our patient sample was small. It would have been better to have a larger sample size and to assess more patients before implementation of the first version of the pathway. The multidisciplinary team decided, however, that a pathway needed to be implemented as soon as possible. Second, because the first version of the pathway was being developed by the TKA team members at the same time that these same team members cared for the control patients, how team members cared for these patients may have been influenced, in part, by their on-going discussions about the pathway. This type of bias could have been avoided if one TKA team developed the pathway and a different team cared for the patients. The development and implementation of clinical pathways is inherently a continuously changing process in which all team members must participate. Furthermore, to utilise our team most efficiently, as well as considering our setting, we could not foresee a

more appropriate study design. Because we used the data from patients examined before pathway implementation as the control group for the first version of the pathway, randomisation was not possible.

Conclusion

The introduction of this in hospital clinical pathway for TKA in our teaching hospital reduced length of stay by 33% without affecting the short-term functional outcomes. We were not able to evaluate the long term effect of this pathway within this study. By assessing both length of stay and functional outcome, we can better determine the effectiveness of a care programme, both from the clinicians' and the hospital administrators' point of view.

Based on the findings of this clinical pathway study and the benchmarking of similar pathways by other hospitals within the Belgian-Dutch Clinical Pathway Network (6), our TKA team is currently examining the possibility of developing a short-stay pathway, which would be designed for a length of stay of 5 to 7 days. To develop this pathway the team will work closely together with the homecare teams (general practitioners, nurses and physiotherapists). In this way we will be able to evaluate the important long term effects of the clinical pathway.

We conclude that this project on the development, implementation, and evaluation of this in hospital clinical pathway for TKA had a positive impact on our hospital, our multidisciplinary TKA team, and on our patients during their acute hospitalisation.

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Chapter 7:
Does the organization of care processes affect outcomes in patients undergoing total joint replacement?

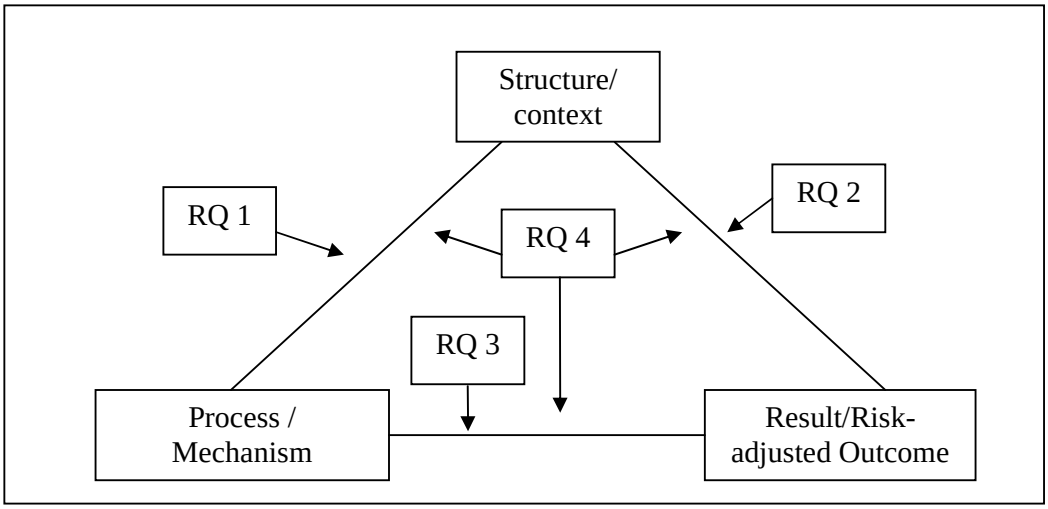
This chapter is submitted for publication as:

Vanhaecht K, Bellemans J, De Witte K, Diya L, Lesaffre E, Sermeus W. Does the organization of care processes affect outcomes in patients undergoing total joint replacement? submitted for publication 2007.

Introduction:

Length of hospital stay for patients recovering from total joint replacement surgery is decreasing throughout the world. This reduction requires more than a skillful surgeon and a perfect operative procedure. It requires a structured context, good organization and a well-functioning multidisciplinary team (1-5). The organization of care processes has been receiving more and more attention from clinicians and managers, leading to may changes in care processes. Every improvement involves change, but not all changes are improvements (6). Several authors have discussed the relationships between various organizational changes and patient outcomes (7-10). It is obvious that these relationships are more indirect than direct and involve a complex process of teamwork and coordination (2;4;11;12). This idea is presented in the care process organization triangle (Figure 1) which compromises (i) the structure of the care process, also known as the context or the design, (ii) the process or mechanism that drives the team and (iii) risk-adjusted outcome indicators or the results of the care process.

Figure 1: The care process organization triangle and the four research questions (RQ) addressed in this paper.



One way to design the structure of a care process is to implement clinical pathways (3;13-19). Clinical pathways are used to standardize care processes and to make them more transparent (17;20;21). Pathways are currently used worldwide in different settings (22-28). In

orthopedics, for example, the process reengineering method is commonly used (5;29-38). The review by Kim et al. (29) on the effect of clinical pathways on hip and knee arthroplasty concluded that pathways appear to successfully reduce costs and lengths of stay in acute care hospitals, without compromising patient outcomes. Although the average effect is significant, some clinical pathways seem to work while others do not. One explanation is that the wide range of interventions used are all classified under "clinical pathways" (3;39;40). A more probable and important explanation is team dynamics. Care is still an intangible service that is consumed at the same time as it is produced. Care represents front-stage work produced during what Teboul (8) calls a moment of truth, when a care provider has contact with patients. Designing a clinical pathway may be an important factor, but real-life implementation and acceptance by interdisciplinary and interprofessional teams might be the crucial component. The team's perception of care processes organization is therefore important (3;8;39;40). Although pathways lead to better organized care processes in general (3), the relationships between the three cornerstones of the care process organization triangle – how clinical pathways organize the structure, how team dynamics affect care process organization and how pathways and team dynamics affect risk-adjusted patient outcomes – is not yet clear.

The goal of this paper is to analyze the relationship between these three cornerstones in total joint replacement cases. This brings us to the four research questions (Figure 1) that were addressed in this study: (i) What is the relationship between the use of clinical pathways and the organization of care processes? (ii) What is the relationship between clinical pathways and risk-adjusted patient outcomes? (iii) What is the relationship between the organization of care processes and risk-adjusted patient outcomes? (iv) What is the relationship between clinical pathways, the organization of care processes, and risk-adjusted patient outcomes?

Materials and Methods

Data were collected in a cross-sectional multicenter study of 39 care processes involving 737 consecutive patients that received a total joint arthroplasty. The study was conducted between April 2005 and August 2005 within the Belgian-Dutch Clinical Pathway Network (40;41). The Belgian-Dutch Clinical Pathway Network is a collaborative network between the Catholic University Leuven, the Dutch Institute for Healthcare Improvement, the Catholic University Louvain, and healthcare organizations in Belgium and The Netherlands working on the development, implementation and evaluation of clinical pathways (41).

The 39 care processes on hip (n=21) and knee (n=18) arthroplasty were scored by pathway facilitators in cases that used clinical pathways. Thirty processes were supported by pathways and nine were not supported by clinical pathways. The organization of care process was measured by the Care Process Self Evaluation Tool (CPSET) (3;39;40). This instrument has five subscales: (i) patient-focused organization (6 items); (ii) coordination of the care process (7 items); (iii) communication with patients and family (4 items); (iv) collaboration with primary care (3 items); and (v) follow-up of the care process (9 items). The scale has been validated within a sample of 142 care processes (40). Each item of the CPSET is scored on a scale from 1 (totally disagree) to 10 (totally agree). An average score per subscale and an overall score is calculated. The team score of each care process represents the average of individual scores of a medical doctor, head nurse, physiotherapist and pathway facilitator (3;40).

To define the outcome indicators and the in- and exclusion criteria a peer review meeting was organized. Twenty-two hospitals were represented by 46 people in different fields (13 orthopedic surgeons, 12 nurses, 5 physiotherapists, 11 clinical pathway coordinators and 5 hospital managers). The panel decided to use the following inclusion criteria: total joint replacements (hip or knee) having an American Society of Anesthesiology Score (ASA) of 1 or 2. Exclusion criteria were fractures, revisions of a joint replacement and an ASA of 3 or 4. During this peer review meeting, a set of outcome indicators was defined. For this study the following data were collected for all patients: the length of hospital stay, the elapsed number of days when a patient could first walk 50 meters, the amount of pain and the elapsed time-to-discharge. The mobility indicator, walking 50 meters, was evaluated by the physiotherapist. Pain was scored on a visual analogue scale and the average pain score over the first five days after the joint replacement was calculated. The elapsed time-to-discharge indicator was computed as the difference between the day patients were ready for discharge and the actual day of discharge. Patients were defined as ready for discharge if they could walk 50 meters and if their surgical wound was dry. Next to these outcome indicators, risk adjustment data on gender, age, type of operation, and ASA score were used. Written informed consent was obtained from all patients.

The study included 737 consecutive patients, 31.3% of which were male. Average age of patients was 67.52 years (SD=10.46), and 55.8% of patients were scored with an ASA of 1. All patients were monitored during the entire hospital stay.

Statistical Methods

SPSS 12.0.0, SAS v.9.1, and Stats Direct 2.5.6 were used to analyze the data. Kaplan Meier survival plots were used to describe the time-dependent indicators. Mann-Whitney tests were used to analyze the CPSET score differences between processes that used pathways and those that did not.

Simple and multiple regression models with multilevel structure were used because we counted 39 different care processes used for the 737 patients participating in our study. Multilevel techniques have increasingly been adopted to deal with hierarchically structured data (42;43). The multilevel regression model assumes that the dataset is hierarchical, has one dependent variable that is measured at the lowest level, and has more than one explanatory variables that is measured at the same and higher levels (42;43). This model enables the estimation of variances at different levels. In the present study, we assumed that patient outcomes depended on care process organization. Thus, our dataset had a two-level structure: patient level (length of stay, mobility, pain, discharge indicator, age, gender, procedure and ASA score) and care process level (use of clinical pathway and CPSET score). The patient level was nested within the care process level. The care process level was used because the intraclass correlation of the four outcome indicators ranged between 0.23 and 0.47 for the care process level. The patient outcomes were risk-adjusted for age, gender, ASA score, and type of arthroplasty. As the outcome variables had a skewed distribution, they were log transformed.

Results

Descriptive statistics

Patients supported by clinical pathways had an average length of stay of 9.42 days (95% CI: 9.14-9.70), whereas patients not supported by clinical pathways had an average length of stay of 12.03 days (95%CI: 11.28-12.78) (Figure 2). Patients supported by pathways were able to walk 50 meters after a mean of 4.48 days after surgery (95%CI: 4.33-4.63), whereas those not supported by pathways were able to walk 50 meters after a mean of 4.50 days (95% CI: 4.27-4.74) (Figure 3). The mean elapsed time-to-discharge was 4.37 days (95% CI: 4.14-4.60) for patients supported by pathways and 6.89 days (95% CI: 6.26-7.52) for those not supported by pathways (Figure 4). The mean pain intensity over the first five days

after arthroplasty was 2.66 (95% CI: 2.53-2.79) for patients on pathways and 3.27 (95% CI: 2.96-3.57) for those not on pathways.

Figure 2: Kaplan-Meier plot of length of stay for processes with (bold) and without clinical pathways.

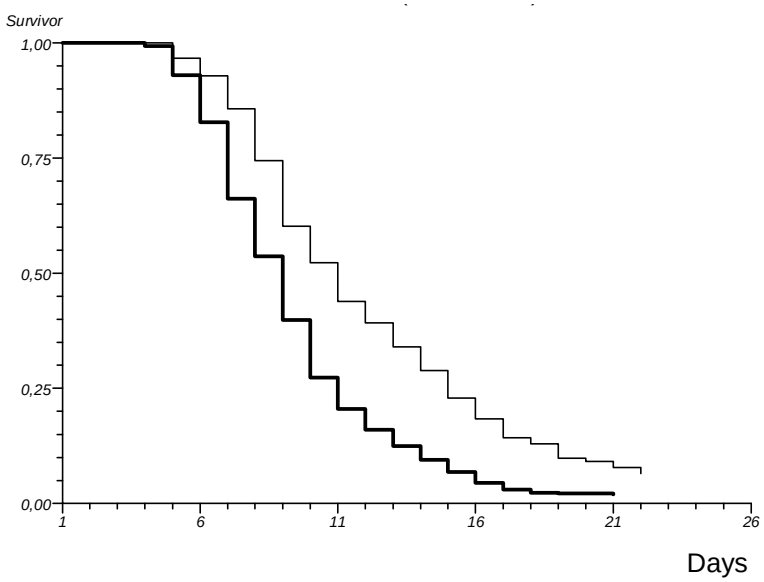


Figure 3: Kaplan-Meier plot of patients' ability to walk 50 meters for processes with (bold) and without clinical pathways.

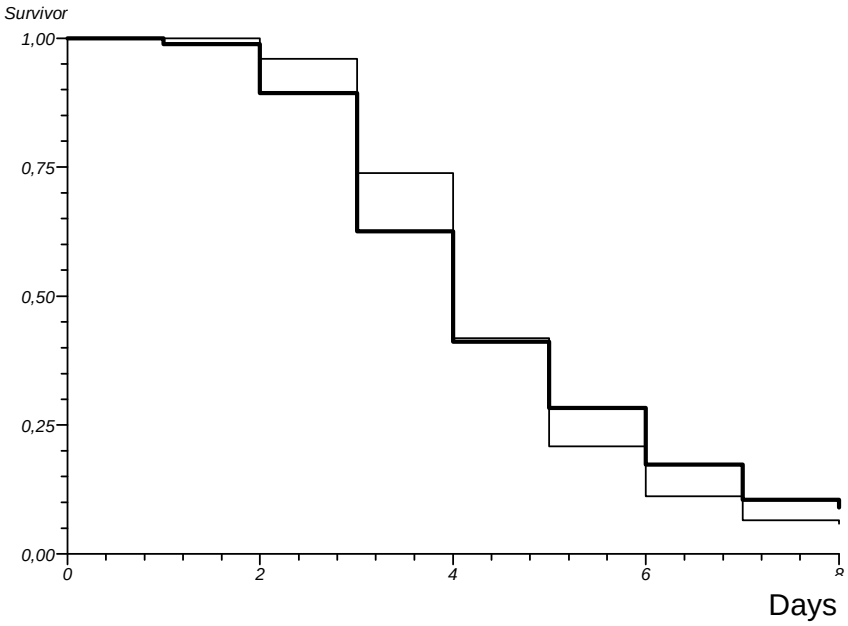
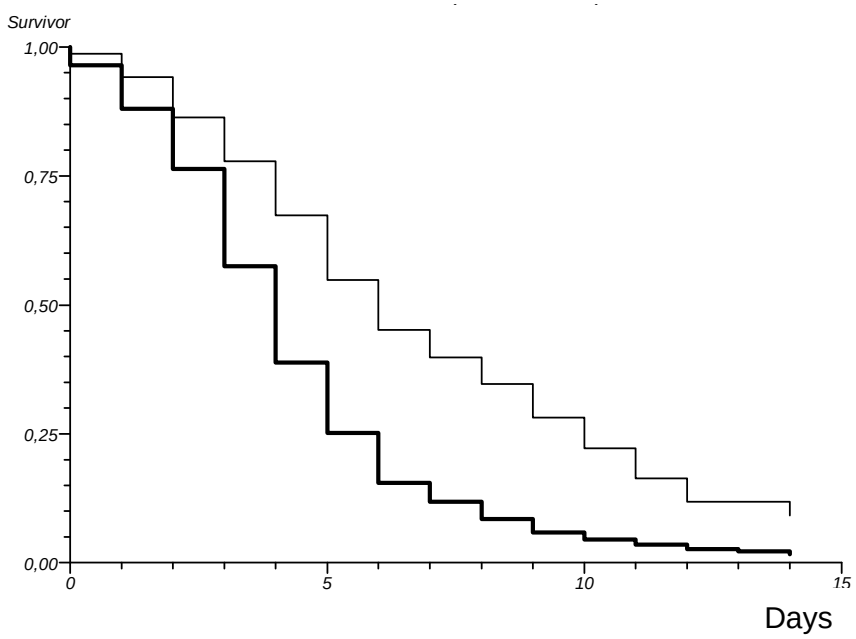


Figure 4: Kaplan-Meier plot for elapsed time-to-discharge for processes with (bold) and without clinical pathways.



Relationship within the care process organization triangle

The analysis of the relationship between clinical pathways usage and care process organization revealed that care processes in knee and hip arthroplasty that are supported by clinical pathways scored significantly higher on the coordination of the care process (p= 0.001), communication with patients and family (p= 0.001), cooperation with primary care (p=0.049), follow-up of the care process (p= 0.011) and the overall CPSET score (p= 0.002). The only non-significant difference observed was between clinical pathway usage and patient-focused organization (p= 0.515).

Analysis of the relationship between clinical pathway usage and risk-adjusted patient outcomes showed that two of four risk-adjusted indicators were significant (Table 1). Patients managed by care processes that were supported by clinical pathways had a significantly lower mean length of stay (p=0.014) and less mean elapsed time-to-discharge (p=0.003). The P value for the difference in mean pain was 0.052. No statistically significant differences were found for the mobility indicator (i.e. ability to walk 50 meters) (p=0.994).

Table 1. Simple regression model taking into account the multilevel structure of the effect of clinical pathways on risk-adjusted outcomes.

	Length of Stay (days)		Walk 50 meters (days)		Average pain score (VAS)		Elapsed time-to-discharge (days)	
	Estimate (SE)	P value	Estimate (SE)	P value	Estimate (SE)	P value	Estimate (SE)	P value
CPW	-0.225 (0.092)	0.014*	-0.001 (0.114)	0.994	-0.179 (0.092)	0.052	-0.348 (0.114)	0.003*

CPW = Clinical pathway SE= standard error VAS= Visual analogue scale
* Significant

Table 2. Simple regression model taking into account the multilevel structure of CPSET subscales on risk-adjusted outcomes.

	Length of stay		Walk 50 meters		Average pain score		Elapsed time-to-discharge	
	Estimate (SE)	P value	Estimate (SE)	P value	Estimate (SE)	P value	Estimate (SE)	P value
Patient-focused organization	0.044 (0.052)	0.404	0.115 (0.058)	0.049*	0.026 (0.052)	0.621	-0.061 (0.067)	0.365
Coordination	-0.045 (0.065)	0.491	0.034 (0.076)	0.651	0.030 (0.064)	0.639	-0.165 (0.081)	0.041*
Communication	-0.108 (0.033)	0.001*	-0.106 (0.040)	0.008*	0.000 (0.037)	0.996	-0.120 (0.045)	0.008*
Collaboration with primary care	-0.011 (0.050)	0.826	0.012 (0.058)	0.835	0.018 (0.051)	0.718	-0.080 (0.064)	0.211
Follow-up	-0.035 (0.046)	0.439	0.013 (0.053)	0.807	-0.003 (0.045)	0.944	-0.078 (0.058)	0.181
Overall CPSET score	-0.069 (0.06)	0.254	-0.011 (0.071)	0.883	0.016 (0.060)	0.789	-0.160 (0.074)	0.032*

SE= standard error * Significant

The simple multilevel analysis of the relationship between the overall CPSET scores and CPSET subscores and risk-adjusted patient outcomes, revealed some significant relationships (Table 2). Higher scores on patient-focused organization were associated with a longer period before patients were able to walk 50 meters. Better coordination was related to decreased elapsed time-to-discharge. Higher score on the communication subscale were linked to lower lengths of stay, being able to walk 50 meters sooner and shorter elapsed time-to-discharge. Higher overall CPSET scores were associated with a significantly shorter elapsed time-to-discharge (Table 2).

Table 3. Multiple regression model taking into account the multilevel structure on the determinants of risk-adjusted outcome indicators.

Outcome indicator ➔ Determinant	Estimate (SE)	P value
Length of stay		
➔ Use of clinical pathway	3.184 (0.911)	0.001*
➔ Coordination	0.396 (0.103)	<0.001*
➔ Communication	-0.127 (0.036)	<0.001*
➔ Use of clinical pathway * coordination	-0.437 (0.119)	<0.001*
Walk 50 meters		
➔ Patient-focused Organization	0.156 (0.051)	0.002*
➔ Communication	-0.131 (0.037)	<0.001*
Pain		
➔ Use of clinical pathway	-0.179 (0.092)	0.052
Elapsed time-to-discharge		
➔ Use of clinical pathway	3.356 (1.265)	0.008*
➔ Coordination	0.257 (0.138)	0.063
➔ Use of clinical pathway * coordination	-0.484 (0.167)	0.004*

* is significant pathway*coordination= interaction effect

Length of stay was significantly determined by the use of clinical pathways, coordination and communication with patients and family. A significant interaction effect was found between the use of clinical pathways and coordination ($p<0.001$) (Table 3 and Figure 5). The elapsed number of days until patients could first walk 50 meters was significantly linked to the patient-focused organization ($p=0.002$) and communication with patients and family ($p<0.001$). As observed in the simple regression model, in the multiple regression model higher scores on patient-focused organization also positively correlated with mobility. Reported pain was not significantly determined by only one factor, although the P value for the use of clinical pathways was 0.052. Elapsed time-to-discharge is significantly determined by the use of clinical pathways and coordination. A significant interaction was found between coordination and the use of clinical pathways was found ($p=0.004$) (Table 3 and Figure 6).

Figure 5: Interaction effect of coordination and use of clinical pathways on risk-adjusted length of stay.

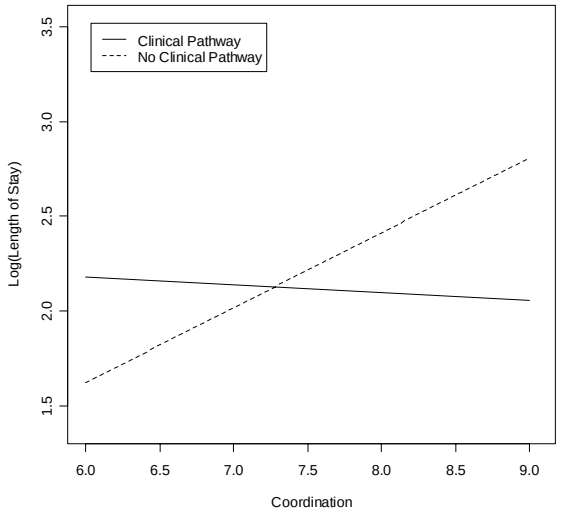
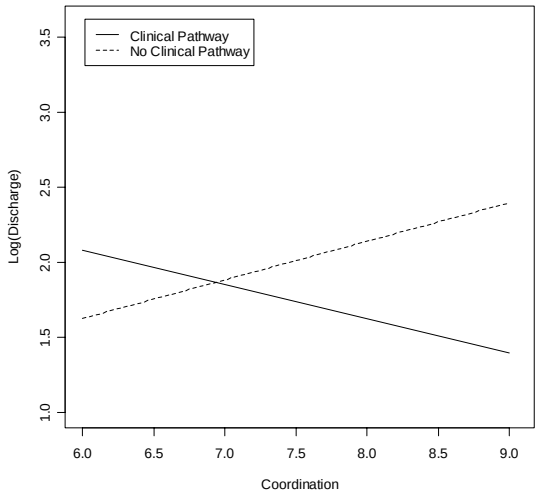


Figure 6: Interaction effect of coordination and use of clinical pathways on risk-adjusted elapsed time-to-discharge.



Discussion

In this large multicenter study of 39 care processes and 737 consecutive patients, we demonstrated the dynamics within the care process organization triangle in total joint replacements (Figure 1). The findings of this study are important for clinical orthopedic teams that are reengineering their care processes, for managers pushing these teams to further increase their efficiency, and for orthopedic researchers. The importance of focusing on processes, as suggested in the literature (1;44;45), became clear during the analyzis of the

intraclass correlations at the patient and care process levels. At the care process level, the intraclass correlation (variance partitioning) for length of stay, walking 50 meters, pain and elapsed-time-to discharge was 0.45, 0.47, 0.22 and 0.30 respectively. This indicates that part of the outcome is determined by decisions made at the individual patient level but also on the care process organizational level. For length of stay and walking 50 meters, almost of the variance is explained on the care process level which means that this is highly influenced by policy decisions. The intraclass correlation for pain and elapsed-time-to-discharge is much lower, indicating that individual patient characteristics are more involved in decision making. This finding could be very important for clinical orthopedic researchers because care process levels and care process organization are not always considered to be factors that affect clinical outcomes.

The use of clinical pathways as a way to structure the care processes had a positive impact on the opinion of team members on the care process organization and on risk-adjusted patient outcomes. Four out of five CPSET subscales received significantly higher scores from teams involved in care processes supported by pathways than from teams involved in care processes not supported by pathways. The only subscale that was not significantly affected by pathway usage was patient-focused organization. The effect of one pathway on an orthopedic unit may not be strong enough to affect how the team views the entire organization. In 2007, Vanhaecht et al. found differences in the coordination of the care process and the follow-up when clinical pathways were used. (3). In the present study of joint replacement teams, additional differences on communication with patients and family and collaboration with primary care were found.

The use of clinical pathways was associated with significantly shorter length of stay and elapsed time-to-discharge. The impact on the average pain score was marginally significant ($p=0.052$). No difference was found on the mobility indicator, walking 50 meters. Other authors that found comparable results stated that clinical pathways improve the efficiency without compromising clinical outcomes (29). With respect to the elapsed time-to-discharge indicator, we think pathways lead to more appropriate discharges. The elapsed time-to-discharge indicator is not only seen a proxy for cost or “hotel function”, but recently it is also seen as a safety indicator (46). Pathways can lead to more appropriate discharge management, but only if they include evidence-based clinical discharge criteria. Decreasing the length of stays without clinical follow-up can have adverse effects (47). With an average elapsed time-to-discharge of 4.37 days, which could have been maybe be further decreased only if clinical outcomes were followed up in primary care. These findings point to the

increasingly important roles of general practitioner, nurses, and physiotherapists in primary care. Communication and coordination mechanisms between hospital and primary care in our healthcare system should be further researched.

The effect of the patient-focused organization on the mobility indicator, walking 50 meters, was unexpected. Higher scores on patient-focused organization were associated with a longer elapsed time before patients could walk 50 meters. Although this result was unexpected but should draw our attention when using jargon like "patient-focused joint replacement programs". Perhaps lengths of stay are decreasing in an inappropriate way, and patient-focused care means that we need to give patients more time to rehabilitate. In this case, increasing a patient's rehabilitation time translates to increased mobility. Further research should therefore also include service indicators like patient satisfaction to understand the patients' views toward rehabilitation.

The direct relationship between clinical pathways and risk-adjusted outcomes is important and has been demonstrated in different studies (29). The added value of the present multicenter study is that it provides new information on the effect of pathway usage on the organization of the care processes. Our data provide information necessary for healthcare workers to implement appropriate care processes in orthopedic units. Simple and multiple regression analyses with multilevel structure revealed that communication with patients and family is one of the primary CPSET subscales that is related to risk-adjusted outcomes. Using simple regression analysis, we found that this subscale had a significant impact on length of stay, walking 50 meters and elapsed time-to-discharge. The impact of communication with patients and family is not always viewed as important in orthopedics. Our study results indicate that orthopedic teams should focus on communication principles if they want to improve their patient outcomes. Additional research is necessary to further analyze the impact of communication.

Coordination of the care process was only significantly related with elapsed time-to-discharge in the simple regression analysis ($p=0.041$) and not with other risk-adjusted outcomes. Multiple regression analyses revealed a relationship between use of clinical pathways, coordination of the care process and communication with patients and family and length of stay. The elapsed time-to-discharge was determined by the use of pathways and the coordination subscale. A significant interaction effect, also described in literature as mediation effect (48;49), was found between the use of clinical pathways and coordination of the care process. This relationship is not surprising because pathways are in theory mainly used to manage care processes (15;20;23;29;39). The interaction effect is an important finding

for clinicians and hospital managers. As the implementation of clinical pathways is sometimes only perceived as the introduction of a new patient record, an appropriate implementation translates to improved coordination within the care process (39). This finding is supported by the work of Gittell et al. who stated that higher relational coordination, an indicator that can be used to measure the multidisciplinary mechanism, is associated with improved outcomes in hip and knee arthroplasty patients (11;50). Clinicians and managers should therefore use clinical pathways as a way of improving multidisciplinary teamwork and coordination.

Implementing a clinical pathway is not a goal as such but only a way to achieve a goal (17). These goals must be predefined by both orthopedic teams and managers. The statistical interaction effect shows that only working on coordination, without implementing a clinical pathway, had no significant effect on elapsed time-to-discharge (estimate=0.257 (SE=0.138), p=0.063) but did have a significant effect on length of stay (estimate=0.396 (SE=0.103), p<0.001). As shown in Figure 5 and 6, the slope of the regression line was positive when pathways were not used. Only coordination relative to clinical pathways had the expected impact on the outcome indicators. Indeed, clinical pathways are a main determinant of improving the coordination of multidisciplinary teams. Our finding led us conclude that teams that do not use pathways are less aware of how their care process functions.

Although this study produced significant results, we must carefully interpret our findings due to methodological limitations. First of all, the scores on the CPSET represent opinions of team members. Thus, future research would benefit from implementing external audits based on the CPSET items. The present cross sectional study could be improved by using a longitudinal design. Also the outcome indicators selected for this study could have limitations, even though they were defined by a large task force that included representatives from all clinical disciplines and management. Indeed, long-term outcomes need to be included in future research studies. One of the main methodological limitations of the current study is that all participating organizations were member of the Belgian-Dutch Clinical Pathway Network (41), and as such, interested in improving the organization of care processes. As a result, only nine care processes were not supported by clinical pathways. Including care processes from hospitals outside of this quality improvement network could bolstered our results. In future research, we advise including other indicators to define the structure of the organization (use of case managers, nurse staffing level or the level of evidence used in the process); the multidisciplinary mechanism (use of relational coordination measures, competence or job satisfaction); and long-term outcome indicators (mortality, infection or dislocation rates). Qualitative research methods, including interviews with orthopedic teams,

could lead to a better understanding of what is exactly happening while care processes are undergoing improvement.

Based on the results of this large multicenter study, we conclude a relationship exists between the organization of care processes and in-hospital, risk-adjusted patient outcomes in hip and knee arthroplasty. The use of clinical pathways positively affects the organization of care process and in-hospital patient outcomes. Clinical pathway facilitators must act to improve coordination of care process and communication with patients and family. These findings indicate that the method used to develop, implement, and evaluate pathways needs to be revised. This study also revealed that clinical pathways are an appropriate method to improve coordination within multidisciplinary teams. The findings of this study should inspire both clinicians and managers to further improve the organization of orthopedic care processes toward excellence.

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Chapter 8:
Overall Discussion

Introduction

The organisation of care processes has received increasingly more attention from both clinicians and managers. Although the effect of clinical pathways on patient outcomes is thoroughly described in the literature, consensus on their efficacy and effectiveness is still equivocal. Therefore, there is a growing need for determining why clinical pathways sometimes work and why they sometimes do not. The care process organisation triangle was used as an organising concept and for formulating the different research questions addressed in this dissertation.

Detailed discussion for each research question and the case study was presented in previous chapters. In this overall discussion, the first part will discuss the main results of the study based on the three cornerstones of the care process organisation triangle: structure, process, and outcomes. Next, the impact of the study on the definition of clinical pathways and on pathway methodology will be discussed. The chapter concludes with a consideration of methodological limitations and suggestions for further research.

Main results based on the structure–process–outcome triangle

1. Structure

Clinical pathways are viewed as a way of standardising and making processes more transparent. Reducing variability by standardising clinical processes is an effective tool for reducing the probability of medical errors (1). Decreasing variability is one of the main outcomes in process reengineering methods and in clinical pathways (2-4). In our search for clinical pathway audit tools (5), we found seven audit tools that measured or described the characteristics of a well-developed pathway. The Integrated Care Pathway Appraisal Tool (ICPAT) (6) was determined to be the best. Interestingly, the ICPAT is not further used to differentiate care processes with and without clinical pathways in this dissertation. The decision to withdraw the ICPAT from use originated mainly from the clinical pathway facilitators in hospitals. As the ICPAT was used more and more for evaluating clinical pathways with regard to structure and quality of clinical pathway documentation, many realized that clinical pathways would be useful for much more. This notion is much discussed in the literature. Champions of expanding the domain of clinical pathways are Karen Zander and Kathy Bower (7), early developers of the clinical pathway concept. In 1992, Donald

Berwick (8), chief executive officer of the Institute for Healthcare Improvement in Boston, one of the leading institutes in the field of healthcare management and quality, described a pathway as a way to make care processes more explicit, and secondly, as a way of discussing practices involving clinicians, certainly physicians, in quality management. The first use of pathways can be thought of as a way of structuring a process. Bohmer (9) also described pathways as a method for effecting multidisciplinary teamwork.

As reported by Shoemarker in 1974, healthcare teams in that era were not in the mindset to use more protocol-based care or standardised care (10). Presently, multidisciplinary teams are aware of the complexity of care and that care can only be well organised if professional cooperation exists. Well-organised care requires more than just implementing protocols or working only on the structure of the care process organisation triangle. Mallock and Braithwaite (11) generally support this premise, concluding that developing a clinical pathway according to a set of criteria does not automatically ensure that the pathway will achieve its intended goal or that a care process will be well organised. Pathway success requires productive negotiation, agreement, a good design, and collaborative efforts by various stakeholders (11). This scenario is analogous to an orchestra needing more than a perfect music score to guarantee a perfect performance.

In the present study, there are some definite indications that pathways are more than the implementation of a document or a change in the structure of an organisation (12-14). Our study shows that, even during the development phase of the pathway, CPSET scores change (13). Specifically, the decrease in CPSET score we measured after one year of implementation also suggests that the organisation of care processes is under continuous change. If the implementation of pathways were simply the implementation of a new document, then we would only find changes in the organisation of care during or after the implementation phase.

2. Process

As previously discussed, clinical pathways are mainly used as a way to manage well-organised care processes (7-9;11). What teams understand about well-organised care processes in the context of clinical pathways has not been described in the literature. By developing and validating the Care Process Self Evaluation Tool (CPSET), we defined five characteristics of well-organised care processes (12). A well-organised care process is a process organised within a patient-focussed organisation, one that is well coordinated by a

multidisciplinary team with respect to cooperation with primary care and that pays attention to communication with patients and family. The process is not only managed but also followed up continuously.

The five characteristics of well-organised care processes were defined and validated by using both qualitative and quantitative methods, including more than 890 healthcare professionals, researchers, and patients. Although a large and diverse group of people involved in care organisation took part in the validation of these characteristics, one still has to be careful in using and interpreting these characteristics. Moreover, other dimensions of well-organised care processes may also exist. What constitutes good care processes depends on perspective and time. There was no definite consensus among the different participants of the focus groups assessing the most important characteristics of a well-organized care process. We speculate that this disagreement could also indicate that the concept is not stable yet and may change with time. The final CPSET items and subscales represent the best compromise among the different views of various stakeholders involved in the focus groups. For the final items, the most important topics of all professional groups and patients are still represented. The CPSET is not an instrument that measures care process organisation from one professional groups' point of view, but it measures the views of a mix of different healthcare professionals and patients. In the development and validation process, we focussed on non-disease-specific care processes within hospitals. The CPSET is certainly not an instrument that covers the entire cross-organisation perspective of well-organised care processes. The tool was developed with respect to the Belgian and Dutch healthcare context, and using the CPSET in other healthcare systems and in other languages may require more than only a linguistic translation.

To validate the CPSET, we used the Realistic Evaluation paradigm (15) developed by Pawson and Tilley in 1997. This paradigm is highly related to Donabedians' structure–process–outcome concept, as described in the introduction of this study. The subscales of the CPSET are related to the context–mechanism–outcome dimensions of Pawson and Tilley. The first subscale, patient-focussed organisation, is related to the context of the care process (12). The other subscales—coordination, communication, and cooperation with primary care—are related to the mechanism and the follow-up of the outcome dimension. With respect to our results on how clinical pathways affect well-organised care processes, we found clinical pathway usage had no impact on patient-focussed organisation (13). This relationship also was not observed in our muliticentre study on joint arthroplasty (14). Even though the concept of patient-focussed or patient-centred care is widely discussed in the literature, it's discussion

relates mostly to patient satisfaction; very little information can be found on scales measuring this specific concept (16;17). Pearson relates patient-focussed organisation to trust in physicians and describes this as "many theories but few measures and little data" (18). Within the CPSET, this subscale dealing with patient-focussed care refers to the organisation by which the care process takes place. The items in this subscale measure the way the entire organisation is patient focused. The literature suggests the use of additional indicators to measure the impact of patient-focussed organisation on patient outcomes (19;20). It would be interesting to determine whether organisations that implement more pathways score higher on this subscale than organisations that do not use pathways.

The coordination subscale measures how the team views the transparency of the care process, the timing of the activities, the agreements and interactions among team members, their relationship to patients, and the management of patient discharges. One point of dispute is whether this subscale measures coordination alone or measures multidisciplinary teamwork. In the validation study (12), the study on how pathways affect the organisation of care processes (13), and the multicentre study on joint replacement (14), this subscale was found to be very important and sensitive for pathways and outcomes. The interaction effect we found with the use of clinical pathways on joint replacement patients (14) led us to conclude that the coordination mechanisms in clinical pathways requires much added attention. Indeed, this concepts needs to be further studied if we are to understand how this concept affect outcomes. The interaction effect shows that clinical pathways represent important tools to develop and improve coordination mechanisms. With respect to length of stay and elapsed time-to-discharge, we observed that teams without pathways scored higher on coordination if their patients had an increased length of stay or elapsed time-to-discharge (14). One way to further explore this relationship is to correlate scores of this subscale with scores on relational coordination, a measure developed by Gittell et al. in 2000 (21).

The communication subscale focuses on the communication of the team with patients and their family. The content of this subscale is highly related to the patient-focussed care concept. In orthopaedic care processes, we found that the use of clinical pathways is related to higher scores on the communication subscale. The communication subscale was related to better patient outcomes. In relation with pathways and coordination, communication with patients and family was found to be a significant determinant of length of stay in joint arthroplasty. The need for optimal communication with patients and family for all patients may become even more important, given the fact that patient expectations continue to increase (22). To further improve the communication between the multidisciplinary team and

patients, in conjunction with the actual focus of healthcare on patient safety and shared decision making, we will need to be further develop and integrate communication mechanisms and methods in the basic training of all healthcare professionals (1;23).

We found significantly higher scores on the cooperation with primary care subscale when pathways were used in orthopaedic care processes (14). No significant relationships were found between this subscale and patient outcomes (14). This finding is not supported by other researchers, who found a significant relationship when the coordination of care between hospital and primary care was improved (24). Porter and Olmsted Teisberg also emphasised the need for healthcare workers to focus more attention on this relationship and to open up care processes to care cycles that cross the continuum of one organisation (25).

The final subscale of the CPSET is follow-up of the care process. We found a significant difference between the follow-up of care processes supported by pathways and those not supported by pathways (13;14). No significant relationship was found between scores on the follow-up subscale and patient outcomes in joint replacement (14). This subscale also only measures the team's evaluation of how the care process is followed up. A high score does not guarantee that the process is followed up by appropriate indicator sets and evidence-based and validated instruments (1).

Although the effects of CPSET subscale concepts on outcomes were only analysed for joint replacement patients, we think the CPSET is valuable for documenting care process improvement projects. As in most improvement projects and accreditation models, self-evaluation is one of the first steps (26). The CPSET could be used in the accreditation of care processes. Next to the self-evaluation by the involved disciplines, an external evaluation or audit based on the five subscales of the CPSET could be performed. Walkthroughs and on-site visits with interviews of involved clinicians, managers, primary care workers, and patients would provide interesting information for validating the self-evaluation scores of the team. In this model of accreditation, we advise using peer review as one of the main methodologies. The multidisciplinary audit teams should include healthcare professionals, pathway facilitators, and managers. Opening up these teams to professionals from primary care and preferably also to patient representatives would be a main improvement for this kind of accreditation. In the field of disease-specific accreditation, the CPSET could be revised in two ways: (i) Specific items could be added for specific populations, and (ii) the scoring could be changed into scoring categories in which each category is detailed at different levels or in goals that should be obtained.

In addition to using the CPSET in pathway research, the CPSET could be used in general clinical research. An important discussion point in clinical research is the difference between efficacy and effectiveness (27). Even when evidence in the literature is very clear, it may still be very difficult to introduce these new methods into daily practice (27). In general, trials testing the efficacy of a particular intervention are of a explanatory nature, the aim of which is to establish a causal relationship (28). In trials investigating effectiveness, a more pragmatic approach is taken with the aim of assessing an intervention in routine clinical practice (28). Today, care processes are not always used at the decision level in clinical research, and certainly care process organisation is not taken into account. Therefore, we recommend using care process characteristics to explore the effect of, for example, new treatments or management programmes to help us in understanding the effectiveness of such interventions.

The CPSET could also be useful when randomising patients to different units. The organisation of care processes in these units could influence the response variables. Oakley et al. (29) discuss the use of process evaluation in randomised controlled trials, stating that complex interventions are health service interventions that are not drugs or surgical procedures but have many potential "active ingredients". A complex intervention combines different components into a whole that is more than the sum of its parts. Randomised controlled trials are the most rigorous way to evaluate the effectiveness of interventions, regardless of their complexity. Because of their multifaceted nature and dependence on social context, complex interventions pose methodological challenges and require adaptations to the standard design of such trials. Oakley et al. added that process evaluation can help to distinguish between interventions that are inherently faulty (failure of an intervention concept or theory) and those that are badly delivered (implementation failure). Process evaluations are especially necessary in multisite trials, where the "same" intervention may be implemented and received in different ways (29).

In addition to the structure of care processes, variables other than clinical pathway usage should be included in future research. Other characteristics describing the process or mechanism in the care process organisation triangle could also be included. As already mentioned, coordination mechanisms can be measured by the relational coordination concept (21). Other possible variables are team effectiveness, multidisciplinary communication, teamwork, or even job satisfaction, although we doubt that job satisfaction is sensitive enough for this research context.

3. Outcome

Pawson and Tilley (15) concluded that the basic context–mechanism–outcome concern is still, of course, the outcome. Well-organised mechanisms acting in well-structured contexts lead to appropriate outcomes. Outcomes must be continuously followed up with evidence-based, risk-adjusted outcome indicators (25). To fully understand these outcomes, knowledge of the mechanisms and structures are important.

In this study, we analysed the impact of pathways and the organisation of care processes on four outcome indicators in joint arthroplasty patients (14). The use of clinical pathways led to significantly decreased length of stay and elapsed time-to-discharge. There was no impact on the mobility indicator, and the impact of pathways on average pain was not significant ($p=0.052$). Although we conducted a multicentre study of 39 care processes and 737 patients, the sample had limitations. All care processes were managed within organisations that are members of the Belgian–Dutch Clinical Pathway Network. Thirty of the care processes under study had clinical pathways and only nine did not. More than 75% of the care processes were already reengineered, thus causing possible bias. A second source of results bias is that one year before the multicentre study was performed, the same organisations participated in a benchmarking study on quality and efficiency indicators on joint replacement. All the member organisations, as well as the ones that did not implement pathways, had access to the benchmark data and could have possibly used the data to improve their outcomes, even without implementing a pathway.

In this study, other response variables that are more appropriate for pathway usage and care process organisation could have been used. Indicators like perceived quality of care, patient satisfaction, information need or other more clinically focussed measures would have added value. The patient-perceived quality-of-care questionnaire by Chou and Boldy (30) measures patients' satisfaction in relation to teamwork, coordination, information needs, etc. Although this scale could be useful, it needs further validation before it is used in clinical pathway research.

In the multicentre trial, we found that the significant determinants for length of stay was use of clinical pathways, coordination, and communication with patients and family (14). Elapsed time-to-discharge was determined by use of clinical pathways and coordination. For both outcomes, a significant interaction effect between use of pathways and coordination was found. Pain was not significantly determined by any of the measured variables, and the mobility indicator was determined by patient-focussed organisation, although in an

unexpected direction, and by communication. Higher scores on length of stay and elapsed time-to-discharge from teams that did not use pathways positively correlated with the scores on coordination. Therefore, reverse causality is one of the topics we need to discuss. Lower length of stay and lower elapsed time-to-discharge could cause higher coordination. Teams could adapt their coordination, and coordination would then be the dependent variable. When we analysed the CPSET items, reverse causality in this study was not really possible. For example, a high CPSET score means that the team agrees that the care process is well coordinated, but a high coordination subscale score does not mean that there is a need for more coordination.

High coordination scores with long lengths of stay and long elapsed time-to-discharge can lead us to conclude that some teams are unaware of their low performance. When performance scores and CPSET scores are represented in a two-dimensional graph, results can be categorised into four groups: unaware of low performance, aware of low performance, unaware of high performance, and aware of high performance (31) (Figure 1). Depending on which quadrant of the awareness of performance diagram a team belongs, different models of change need to be used by the clinical pathway facilitator. This needs further investigation because the CPSET represents only one mechanism indicator within the care process organisation triangle.

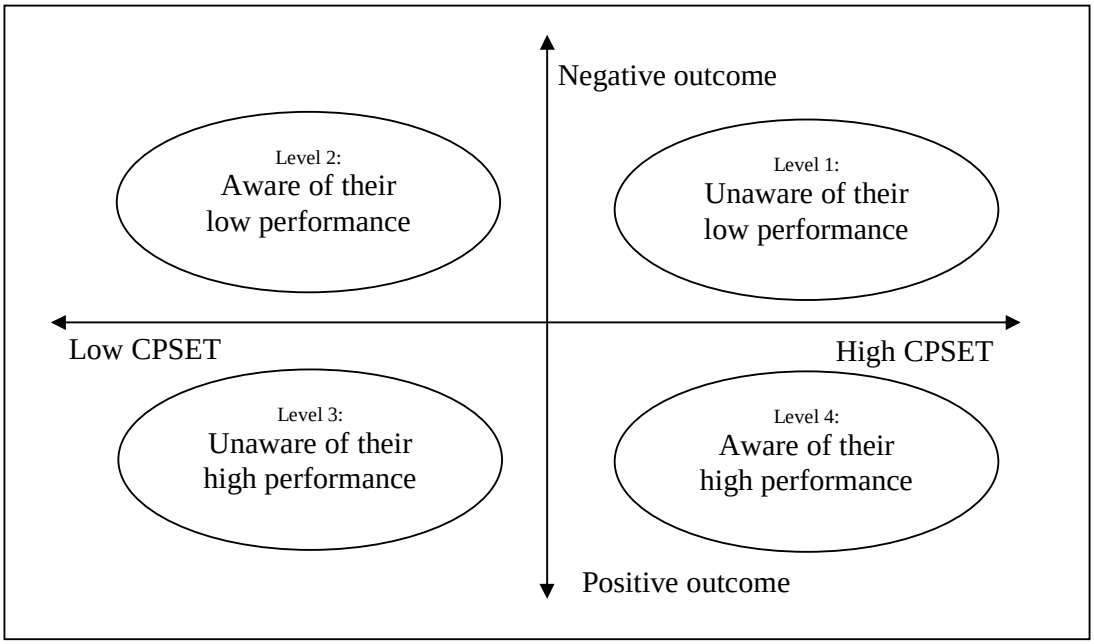

Figure 1: Awareness of performance diagram

The outcome indicators by which teams are compared should be the most important clinical indicators for a given population. Standard sets of outcomes, as used by the Joint Commission (www.jointcommission.org), or the standard set of indicators for 20 high-volume populations by the Center for Case Management (7), could serve as valuable starting points. An important point of discussion will be the cut-off point used for the outcomes. Since this diagram should be used to bring teams to a higher level of performance, mean and median scores should not be used but evidence-based outcomes per indicator should. If possible, available data should be used such as administrative minimum datasets, because measuring clinical indicators in a multicentre study is difficult and time-consuming for healthcare personnel. In our multicentre study, only joint arthroplasty patients were included. Thus, we can describe only the impact of clinical pathways and the organisation of care processes on patient outcomes relative to this patient group. Although we did not include other patient groups, we expect that the results for other surgical patients with planned admissions will be comparable. For other patient groups, like patients with chronic diseases or chemotherapy patients with several admissions, outcomes can be determined by other CPSET dimensions. The search for sensitive outcome measures will not be easy. Would service outcomes be more sensitive to CPSET score differences than only clinical outcomes or length of stay? Bohmer (9) concluded that less tangible improvements exist in much of the available pathway research and that these improvement are not always measurable.

4. Relationships within the care process organisation triangle

The organising concept and conceptual framework we used for this study was the care process organisation triangle based on the work of Pawson and Tilley (15) and related to the work of Donabedian (32), Heskett et al. (33), Teboul (34), Batalden et al. (35), and Mitchell et al. (36). This framework allowed us to define four main research questions and to analyse the relationships between clinical pathways, organisation of care processes, and risk-adjusted patient outcomes. In our report, the terminology of Donabedians' structure–process–outcome (32) was used, since all frameworks (15;33-36) are mainly based on Avedis Donabedians' model, which is the most well-known model in healthcare quality management.

One of the main problems with the care process organisation triangle is the position of the patient. In this study, patients were only viewed as outcome. In complex interventions like the implementation of clinical pathways (29;37;38), patients can be viewed as more than only an outcome. Moreover, more than only patient outcomes needs follow-up. Patient

characteristics and expectations may lead to adjustments of the process, the organisational outcomes, and even the structure. In further research on the organisation of care processes, we recommend using additional structure characteristics. In addition to analysing clinical pathway usage, the use of other structured care methodologies, like protocols, guidelines, and case management, should also be analysed. In addition to these structures, other items to be included in these analyses are information on the method used to develop pathways; information on the hospital structure, staffing level, competency of the team, and safety culture; use of information and communication technologies; level of evidence in the process; and use of other continuous quality improvement methods. Not only patient outcomes but also process outcomes (teamwork, coordination, job satisfaction) and organisational level outcomes (financial goals, manpower, governance outcomes) will need to be included. Teboul (34) stated that service is a front-stage experience and that healthcare is all about service. Therefore, we should further integrate the different organisational models. Heskett and Teboul (33;34) defined company, frontline employees, and clients. Maybe each of these three dimensions needs to be described in detail in terms of their structure, process, and outcome. These dimensions should be included in a model for further research. This is only one model, but as Deming described it: “Some models can be quite useful”.

As already mentioned, the implementation of clinical pathways has all the characteristics of complex interventions (15;29;37;38), as documented in the *British Medical Journal.* Complex interventions are those that include several components, those that have been made up of various interconnecting parts, or those that have been built up from a number of components that may act both independently and interdependently (37;38). Many health service activities should be considered complex (38). The evaluation of complex interventions is difficult because of problems in developing, identifying, documenting, and reproducing the intervention (37). The Medical Research Council of the United Kingdom defined five phases in research dealing with complex interventions (37): (i) the preclinical theoretical phase, which explores the relevant theory to ensure the best intervention and hypothesis is chosen and to predict major confounders and strategic design issues; (ii) the modelling phase, which identifies the intervention components and the underlying mechanisms by which these components will influence outcomes (this will provide evidence about the predictability of how components and mechanisms relate to and interact with each other); (iii) the exploratory trial, which describes the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative; (iv) the definitive randomised controlled trial, which compares a fully defined intervention with an

appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power; and (v) the long-term implementation phase, which determines whether others can reliably replicate your intervention and results in uncontrolled settings over a longer term). Campbell et al. (37) recommended a parallel approach that combines preclinical and modelling phases with the goal of understanding the problem, intervention, and evaluation. Based on the results of a first exploratory trial, researchers must conclude whether organising and investing time and money in a randomised trial is worthwhile. In 2007, Campbell et al. recommended conducting simultaneously the first three phases to better understand the problem, intervention, and evaluation (38).

As discussed in the introduction of this dissertation, most of the literature on the effect of pathways is positive. However, negative and no effects are also reported. Defining clinical pathways as a complex intervention may help the pathway community and clinicians in solving these problems (15). In this study, we included the first three phases of the complex intervention research model as suggested by Campbell et al. (38). The care process organisation triangle was used to model theoretical knowledge. A multicentre exploratory non-randomised trial was performed. We found that the use of clinical pathways and the organisation of care processes have an impact on outcomes in joint arthroplasty patients. The interaction effect between the use of clinical pathways, coordination of the care process, and communication with patient and family on length of stay, should inspire us to conduct further research. Based on the complex intervention research model, we now can start with describing the possibility of a randomised trial. As already suggested, other factors within the structure and process, as well as patient characteristics and expectations of the care process organisation diagram, will also need to be analysed (Figure 2). Controlling for all of these covariates will be nearly impossible because the implementation of clinical pathways is an intervention in real care within complex healthcare organisations—including complex professionals, complex patients and family—that cannot be performed under laboratory conditions.

Overall methodological limitations of the study

A limitation of the process component of the triangle is manifested in the name of the CPSET: “care process *self evaluation* tool”. Team members use the CPSET to relate their subjective opinions on care process organisation, and opinions can sometimes be wrong.

Social desirability requires caution (31). Teams may score the organisation of a care process higher than they should. Important in this respect is how scores are used. Social desirability may not be so problematic if scores are used within the multidisciplinary team alone to find bottlenecks in the actual organisation. We have to be cautious, however, if scores are used to give feedback to the general management of an organisation or even for external evaluation. Even though in the information letter we explicitly requested teams to evaluate the care process critically, social desirability could have influenced the scoring, as the teams knew the scores would be transferred to Leuven University for research purposes.

Another limitation is the set of outcomes measured in this study, which were all in-hospital outcomes. It would have been better to measure also the impact of clinical pathways and the organisation of care processes on long-term outcomes: indicators like readmission rate, infections, joint dislocation rates, quality of life, and long-term mobility. The most important outcome indicator—mortality—was not measured in this study.

The most inherent limitation of this study is the multiple use of the CPSET data. The data obtained in the validation study (12) was used for two other studies (13;14). It would have been more appropriate to address each research question by measuring care process organisation in different data sets. However, this was not possible because of time and resource constraints.

In addition to the multiple use of the data, the data were obtained in a cross-sectional multicentre study. Longitudinal data would have enabled us to analyse CPSET scores over time, permitting a more in depth analysis of the criticality point. Although the multicentre study presented us with many opportunities, because of the multicentre design we did not analyse several other covariates, such as those related to the structure of the care process. As suggested by Campbell et al. (37), we did not qualitatively analyse all of the participating hospitals.

An important point of discussion is the research setting: the Belgian–Dutch Clinical Pathway Network. Most of the people involved in the development and validation of the CPSET were professionals working within Belgian–Dutch Clinical Pathway Network member organisations. The multicentre study on joint arthroplasty was performed in only Network hospitals. From a purely scientific point of view, this is a limitation. Outcomes could have been different in many ways if non-Network hospitals were included in our study. For example, the Network could have influenced the results of the impact of clinical pathways on the organisation of care processes, in which we found significant odds for coordination and follow-up (13). Within the Network, pathways are mainly viewed as methods to

systematically plan and follow up patient-focussed care programmes. Another but opposite example is provided by our multicentre study on joint replacement. If non-Network organisations that had no experience with pathways for other patients groups were included in our study, the impact of clinical pathways and the organisation of care processes could have been more explicit (14). With respect to the limitations of the Belgian–Dutch Network setting, we believe that this setting has provided us with much more opportunities than problems. If the Network did not exist, it would have been nearly impossible to have more than 890 people involved in the development and validation of the CPSET. To motivate 142 multidisciplinary teams, including physicians, head nurses, paramedics, and pathway facilitators, to validate a newly developed tool as the CPSET would not have been easy. The multicentre study of 39 care processes and 737 patients would have been much more time- and resource-consuming without the help of study nurses that were closely involved in the daily care of these patients.

A final limitation is that the data were obtained two years ago in 2005. When we examine the progress made in the conceptualisation and methodology of clinical pathways during the last two years, certainly with respect to the inclusion of primary care, we need to be careful when translating these results to managerial implications.

The impact on practice: a revised definition of care pathway

The European Pathway Association (E-P-A) developed a definition of care pathway based on a literature review of pathway definitions (39), an E-P-A survey (40), discussions on an internet forum on pathways (41), and consensus meetings of the board of the E-P-A in 2005 and 2006 (www.E-P-A.org) (40). Based on the literature search described in the introduction of this dissertation and the findings of this study we recommend revising this definition as follows:

> A care pathway is a ~~methodology~~ *complex intervention* for the mutual decision making and organisation of care *processes* for a well-defined group of patients during a well-defined period. Defining characteristics of care pathways include: (i) An explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations *and their characteristics*; (ii) the facilitation of the communication *among the team members and with patients and families*; (iii) the *coordination of the care process* by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives; (iv) the documentation, monitoring, and evaluation of variances and outcomes; and (v) the

identification of the appropriate resources. The aim of a care pathway is to enhance the quality of care *across the continuum* by improving *risk-adjusted* patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources.

The impact on practice: a revised methodology for the development, implementation, and evaluation of pathways

In addition to a revised definition of care pathway, we propose revising the methodology used to develop, implement, evaluate, and continuously follow up a pathway based on the findings and the limitations of this study. Pathways are a way of continuously improving care processes. (Figure 2).

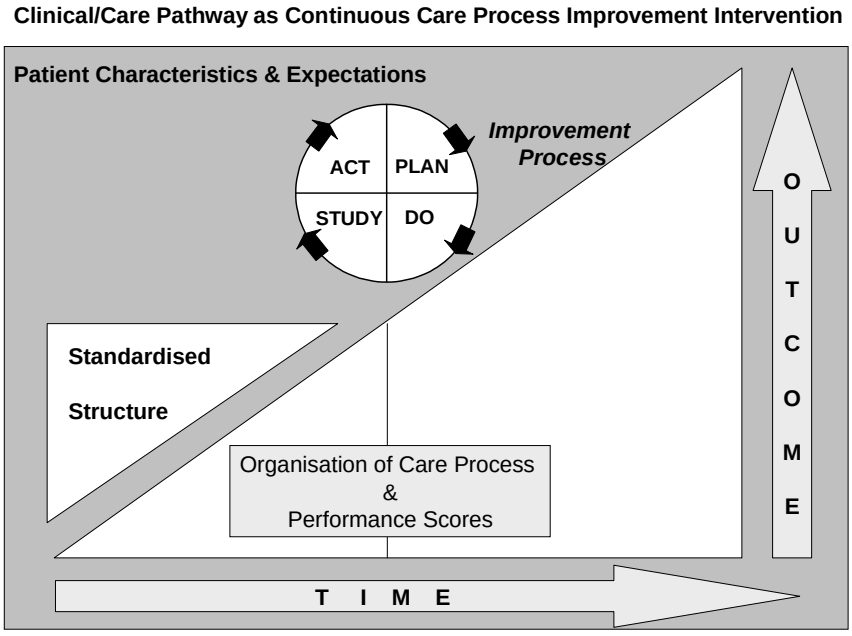

Figure 2: The pathway as a continuous care process improvement intervention

The CPSET should be used in the plan phase of pathway development to analyse the organisation of the care process from the teams' point of view. Goals and bottlenecks could be defined based on the results and certainly on the differences in scores between different professionals. The CPSET can also be used later on in the development process as part of the

analysis of the actual organisation (i.e., during Demings' do phase (42)). Based on the findings of the criticality point, the CPSET can be used to analyse continuously the organisation of the care process on a yearly basis. The CPSET scores should be mainly used to help multidisciplinary teams to improve their organisation of care processes.

During the development of care pathways, more attention should be given to the coordination of the care process. The roles and sequencing of evidence-based activities should be clearly defined. The process owner or the person who coordinates the process should be named and his/her role should be clearly defined.

When analysing the actual organisation of the care process, communication with patients and family should be incorporated. We recommend that pathway developers interview patients and their family, getting their advice on how to further improve the pathway. Team members should be aware of patient expectations and characteristics, and the findings must be integrated into the new structure. The list of activities should include a specific time to discuss the patient's health status and to give the patient information.

In all pathway projects, primary care professionals should be designated a specific role. Also, when a pathway is implemented in an in-hospital only situation, pathway personnel should communicate with primary care professionals, asking their advise on how to improve the pathway. If cooperation with primary care is one of the characteristics of well-organised care processes, then primary care professionals must be part of all pathway development teams.

The continuous follow-up of the care process needs more attention. The findings of the criticality point indicate that we need to make sure that pathways are in continuous development. Besides the CPSET, evidence-based, pathway-specific indicators should be followed up, and outcomes need to be reported to the members of the multidisciplinary team and management. This will be the only way of keeping pathways alive, so they will continue to have impact on how much care process organisation is patient focussed.

Suggestions for further research

One of the most important issues for further research is to develop new audit tools based on the Belgian-Dutch context and pathway concept. Based on the new pathway definition, researchers must further develop and validate these tools to audit (i) the pathway document; (ii) the evidence base of the pathway content; (iii) the criteria for pathway-specific indicators; (iv) the methods used to develop, implement, evaluate, and continuously follow up

the pathway; and (v) the organisation of the care process. These audit tools should focus on the interdependency and connectivity of the different parts of the intervention, as pathways are categorised under the concept of complex interventions.

Today, questions are being raised about the accreditation of care processes or certification of clinical pathways. New audit tools could facilitate this accreditation or certification process. Tool availability would also have a direct impact on the quality of pathways, as teams can use a tool as a checklist when developing and improving a pathway. The characteristics of an instrument used to score a pathway document could be partially based on ICPAT subscales and further developed by a task force of the Belgian–Dutch Pathway Network. A literature study, including the grey literature, should be performed when analysing how the concepts, methods, and results of clinical pathways have evolved during the last 2 or 3 years. New clinical pathway audit tools should be validated and tested in a multicentre setting.

In further research, the CPSET should be used in longitudinal studies or interrupted time-series designs to analyse the impact of clinical pathway implementation. In this way, the CPSET could become part of the dependent variables in pathway research. When pathways are implemented, not only do we expect higher CPSET scores but certainly also less variation between the scores of the disciplines involved. Certain teams may have lower CPSET scores after the implementation of a care pathway. Two reasons could account for our findings from the study on the impact of pathways on care process organisation, in which teams with pathways in use for longer than one year have lower CPSET scores (13). One reason is that lower scores mean that the care process is poorly organised. Indeed, a care process organisation that is continuously improved should translate to high CPSET scores. Another reason is that teams that use pathways for long periods become more critical, discover more bottlenecks, and are willing to accept constraints. In both cases, a lower CPSET score should alert managers, clinicians, and pathway facilitators, prompting them to bring the team together to discuss the actual organisation of a care process. Also the unexpected positive correlation we found between length of stay and coordination of teams not using pathways needs further research.

Two of the most important steps in further CPSET development are developing a revised version that is scored by patients and developing a version that is used for care processes across the continuum of one organisation. Who else are more involved in care processes than patients? Although patients participated in the development and face validation of the CPSET, they did not participate in later phases of CPSET development. Practical

reasons must be overcome, because patient viewpoints are necessary to further understand and improve the organisation of care processes. The viewpoint of patients on coordination mechanisms have already been described in the literature (24). Scoring the CPSET from patients' point of view will require additional testing. Patient representative groups, such as those who were involved in the initial CPSET focus groups, could be used to further analyse the ability of patients to understand the wording of revised CPSETs and to test the validity and reliability of these revisions. Patients should also be involved if the CPSET will be used to assess care processes across the continuum of one organisation. The revision of the CPSET for use in primary care or across borders should not start from the beginning, because primary care professionals participated in the initial focus groups and in the reduction phase of the first set of items.

Last but not least, we recommend that our multicentre research of clinical pathways on patient outcomes be replicated in patient populations other than joint arthroplasty patients.

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Chapter 9:

Overall Conclusion and Managerial Implications

Clinical/care pathways are currently used internationally in different kinds of settings to manage and improve care processes. Well-organised care processes are organised in a patient-focussed manner, which is well coordinated by a multidisciplinary team with respect to cooperation with primary care and which pays attention to communication with patients and family. The process is not only managed but also continuously followed up.

The organisation of care processes can be measured by the CPSET. This 29-item instrument was developed and validated with the support of more than 890 healthcare professionals from hospitals and primary care and patients. The tool was validated in a multicentre study that included 142 care processes.

In a study including 103 care processes, we found that processes that are supported by a clinical pathway have significantly higher scores on coordination of care (odds ratio: 8.92), follow-up (odds ratio: 6.65), and overall CPSET (odds ratio: 4.26). Not all care processes supported by a clinical pathway are well organised and the use of a clinical pathway does not always lead to well-organised care processes.

A large multicentre study of 39 care processes and 737 joint replacement patients revealed that clinical pathways lead to higher scores on coordination of care, communication with patients and family, cooperation with primary care, follow-up of the care process, and overall CPSET. In this population, clinical pathways improved risk-adjusted outcomes. Length of stay in joint replacement patients was determined by the use of clinical pathways, coordination of care, and communication with patients and family. The elapsed time-to-discharge was determined by the use of clinical pathways and coordination of care. For both outcomes, a significant interaction effect was found between clinical pathways and coordination of care.

The development and implementation of clinical pathways involve more than just standardising the structure of a care process. The clinical pathway as a structure represents only one way of standardising improvements made within a multidisciplinary team process to achieve more appropriate outcomes. The clinical pathway method is a complex intervention that should be performed by a multidisciplinary team, management, primary care professionals, and patients.

No matter how much care is taken in designing the structure or service on paper, in testing it, and in delivering it during the process of care, what customers perceive is

sometimes quite different from the original proposition. Therefore, processes should be centralized and continuously followed up.

Based on our literature study and the findings and limitations of the studies described in this dissertation, we propose five main recommendations for healthcare managers, clinicians, and policy makers:

1) Investing in care processes means investing in the coordination of care, communication with patients and family, cooperation with primary care, and continuous follow-up of the care process, all within a patient-focussed organisation.
2) Clinical pathways have impact on the organisation of care processes and on patient outcomes but not all clinical pathways are well organised. The actual definition and methodology have therefore been revised.
3) Patient expectations and characteristics should be further analysed and integrated into actual pathways.
4) The Care Process Self Evaluation Tool or CPSET is a validated instrument that can help teams and management clarify their perspective on the actual organisation of care. This tool should always be used in cooperation with evidence-based performance indicators. Teams that work with clinical pathways have a more logical view of how their care processes are organised.
5) Clinical pathways represent more than the development and implementation of a new document or structure for a care process. Pathways are complex interventions that keep the structure, process, and outcome alive. They must be used as a method to achieve a result.

Summary

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Samenvatting

Summary

Clinicians and healthcare managers give more attention to the organisation of care processes. One of the methods to organise care processes is clinical pathways. Clinical pathways are used worldwide in different kind of settings. Many publications describe positive effects of their implementation. Pathways are mainly used as a tool to improve the quality and efficiency of care processes. Therefore the question was raised: "What is the effect of clinical pathways on the organisation of care processes?" The study consists of four phases.

In a first phase, a literature study was performed on instruments to describe differences in clinical pathways. Seven clinical pathway audit tools were analysed. The Integrated Care Pathway Appraisal Tool was evaluated as the best tool available. Because of limitations in these audit tools, it was decided to use during the next phases of the study the implicit knowledge of the pathway facilitators to score if a clinical pathway was present.

Secondly, a mix of qualitative and quantitative methods was used to define the characteristics of well organised care processes. In total more than 890 clinicians and healthcare managers from hospitals and primary care, and patients participated in the different phases to describe these characteristics. Based on the characteristics a new tool was developed and validated to measure the organisation of care processes: The Care Process Self Evaluation Tool (CPSET). This 29 item instrument has 5 subscales: (i) the patient focused organisation, (ii) the coordination of the care process, (iii) the communication with patients and family, (iv) the collaboration with primary care and (v) the follow-up of the care process. The tool was validated in a multicenter study including 142 care processes within the Belgian Dutch Clinical Pathway Network.

Thirdly, in a study with 103 care processes we found out that clinical pathways have a significant positive impact on the coordination of care and the follow-up of the care process. Not all clinical pathways are well organised and not all well organised care processes are supported by clinical pathways.

Fourthly, in a multicenter clinical trial including 39 organisations and 737 consecutive patients with total joint replacement, the relations between the use of clinical pathways, the organisation of care processes (CPSET scores) and risk adjusted patient outcomes were analysed. Organisations using clinical pathways had significant higher scores on four out of five subscales of the CPSET. Only the patient focused organisation subscale was not significant. Clinical pathways lead to significantly lower length of stay and elapsed time-to-discharge. The communication with patients and family came out as one of the most

important CPSET subscales for this patient group. The length of stay was significantly determined by the use of clinical pathways, the coordination of the care process and the communication with patients and family. The elapsed time-to-discharge was significantly determined by the use of clinical pathways and the coordination of the care process. A significant interaction effect between the use of clinical pathways and the coordination of the care process was found for both risk adjusted in-hospital outcomes.

We can conclude that clinical pathways are one of the main methodologies to organise and coordinate care processes but the methodology needs to be further improved. It is a complex intervention which has to be developed and continuously followed up by a team including clinicians, healthcare managers and patients.

Based on this study we propose five main recommendations for healthcare managers, clinicians and policy makers: (i) Investing in care processes means investing in the coordination of care, communication with patients and family, cooperation with primary care, and continuous follow-up of the care process, all within a patient-focussed organisation. (ii) Clinical pathways have impact on the organisation of care processes and on patient outcomes but not all clinical pathways are well organised. The actual definition and methodology have therefore been revised. (iii) Patient expectations and characteristics should be further analysed and integrated into actual pathways. (iv) The Care Process Self Evaluation Tool (CPSET) is a validated instrument that can help teams and management to clarify their perspective on the actual organisation of care. This tool should always be used in cooperation with evidence-based performance indicators. Teams that work with clinical pathways have a more logical view of how their care processes are organised. (v) Clinical pathways represent more than the development and implementation of a new document or structure for a care process. Pathways are complex interventions that keep the structure, process, and outcome alive. They must be used as a method to achieve a result.

Samenvatting

Zorgverleners en managers geven meer aandacht aan de organisatie van zorgprocessen. Eén van de methoden om zorgprocessen te organiseren is klinische paden. Klinische paden worden wereldwijd gebruikt in tal van omgevingen. De meeste literatuur beschrijft de positieve effecten van hun implementatie. Klinische paden worden voornamelijk gebruikt om de kwaliteit en efficiëntie van zorgprocessen te optimaliseren. Daarom werd volgende onderzoeksvraag geformuleerd: “Wat is het effect van klinische paden op de organisatie van zorgprocessen?” Het onderzoek bestaat uit vier fasen.

In een eerste fase werd een literatuurstudie uitgevoerd naar instrumenten die het onderscheid in klinische paden beschrijven. Zeven audit tools werden geanalyseerd. De Integrated Care Pathway Appraisal Tool werd geëvalueerd als het best beschikbare instrument. Omwille van beperkingen van deze audit tools werd beslist om in de volgende onderzoeksfasen de impliciete kennis van de klinisch pad coördinatoren te gebruiken om de aanwezigheid van een klinisch pad te scoren.

De tweede fase bestond uit kwalitatieve en kwantitatieve onderzoeksmethoden om de karakteristieken van goed georganiseerde zorgprocessen te definiëren. In totaal namen meer dan 890 patiënten, clinici en managers uit de eerstelijn en ziekenhuizen deel aan deze onderzoekfase. Op basis van de beschreven karakteristieken werd een nieuw instrument ontwikkeld om de organisatie van het zorgproces te meten: de ZorgProces ZelfEvaluatie Tool (ZPZET). Dit instrument bevat 29 items onderverdeeld in 5 subschalen: (i) de patiëntgerichtheid van de organisatie, (ii) de coördinatie van het zorgproces, (iii) de communicatie met patiënten en familie, (iv) de samenwerking met de eerstelijn en (v) de opvolging van het zorgproces. Het instrument werd gevalideerd in een multicenter onderzoek in 142 zorgprocessen uit het Belgisch Nederlands Netwerk Klinische Paden.

In een derde fase werd in een studie met 103 zorgprocessen de significante impact van klinische paden beschreven op de coördinatie en opvolging van het zorgproces. Niet alle klinische paden waren goed georganiseerd en niet alle goed georganiseerde zorgprocessen werden ondersteund door een klinische pad.

Een vierde onderzoeksfase beschrijft een multicenter onderzoek met 39 organisatie en 737 opeenvolgende patiënten die opgenomen werden voor prothesechirurgie. Hierin werd de relatie tussen het gebruik van klinische paden, de organisatie van het zorgproces en patiënten outcomes, gecorrigeerd voor verschillende risicofactoren, onderzocht. Organisaties die klinische paden gebruikten hadden een significant hogere score op vier van de vijf subschalen

van de ZPZET. Enkel de subschaal patiëntgerichtheid van de organisatie was niet significant hoger. Klinische paden leiden tot significant kortere verblijfsduur en wachttijd tot ontslag. Communicatie met patiënten en familie is één van de belangrijkste ZPZET subschalen voor deze patiëntenpopulatie. Verblijfsduur werd significant gedetermineerd door het gebruik van klinische paden, de coördinatie van het zorgproces en de communicatie met patiënten en familie. De wachttijd tot ontslag werd significant gedetermineerd door het gebruik van klinische paden en de coördinatie van het zorgproces. Een significant interactie-effect werd ontdekt tussen het gebruik van klinische paden en de coördinatie voor beide outcomes.

We kunnen concluderen dat klinische paden een van de belangrijke methoden zijn voor de organisatie en coördinatie van zorgprocessen maar de methodologie dient verder verbeterd te worden. Het is een complexe interventie die ontwikkeld en continu opgevolgd dient te worden door een team van clinici, managers en patiënten.

Op basis van deze studie worden vijf aanbevelingen gedaan voor clinici, managers en beleidsverantwoordelijken: (i) Investeren in zorgprocessen betekent het investeren in de coördinatie van zorg, de communicatie met patiënten en familie, samenwerking met de eerstelijn, continue opvolging van het zorgproces en dit binnen een patiëntgerichte organisatie. (ii) Klinische paden hebben een impact op de organisatie van zorgprocessen en outcomes maar niet alle klinische paden zijn goed georganiseerde zorgprocessen. De huidige definitie en methodiek werden hierdoor aangepast. (iii) Patiëntenverwachtingen en kenmerken zouden verder geanalyseerd en geïntegreerd moeten worden in de huidige paden. (iv) De Zorgproces ZelfEvaluatie Tool (ZPZET) is een valide instrument dat teams en het management kan helpen bij het beter begrijpen van de huidige organisatie van het zorgproces. Dit instrument dient altijd gebruikt te worden in combinatie met op evidence-based performantie indicatoren. Teams die werken met klinische paden hebben een logischere kijk op de organisatie van hun zorgproces. (v) Klinische paden zijn meer dan de ontwikkeling en implementatie van een nieuw document of structuur van het zorgproces. Klinische paden zijn complexe interventies die de structuur, het proces en de resultaten van zorg in beweging houden. Zij dienen gebruikt te worden als een methode om een bepaald doel te bereiken.

Curriculum Vitae Kris Vanhaecht

Kris Vanhaecht, born on February 26, 1974 in Vilvoorde, is a registered nurse (1995) and holds a masters degree in nursing sciences from the Katholieke Universiteit Leuven (1998). During his masters training, he was involved in the pilot study on clinical pathways in Belgium (1997-1998) with a study on the effect of a clinical pathway for the diagnosis and staging of lymphoma. In April 2000 he participated in an intensive workshop on implementing strategies for managing care at the Center for Case Management in Boston. He holds a postgraduate degree in operations management from the Leuven Graduated School for Business Studies (2002).

After his masters' studies, he worked as research fellow for the WISECARE project, a European funded healthcare informatics project on outcome evaluation in oncology in 10 European countries. When the Belgian Dutch Clinical Pathway Network started in 2000, he became deputy coordinator of the Network under the supervision of Professor Dr. Walter Sermeus. From 2000-2003 Kris was deputy coordinator of the Belgian Dutch Clinical Pathway Network. Together with Professor Sermeus he further developed the concept and methodologies to develop, implement and evaluate clinical pathways. In 2003 he started his PhD study on the impact of clinical pathways on the organisation of care processes. Kris worked as pathway facilitator (orthopedics, ear-nose-throat, ophthalmology and rehabilitation) within the University Hospitals Leuven. Nowadays he is research fellow at Leuven University and is involved in the management of Zorgnet Brussels, a virtual organisation to improve the management and follow-up of care processes between hospitals and primary care.

In 2004, together with Professor Massimiliano Panella of the University of Eastern Piemont, he launched the European Pathway Association (www.E-P-A.org). Kris is co-chairman of this association with representatives in more than 25 countries worldwide.

Kris is married to Skröllan Tack. Skröllan is a dermatologist working in Lummen and Heusden-Zolder. They expect their first child in November 2007.

More information: www.krisvanhaecht.be

"Everyone in healthcare really has two jobs
when they come to work every day:
to do their work and to improve it."

Batalden, P.B & Davidoff, F., 2007