Strategies to improve preoperative care

Lidwien Lemmens

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Strategies to improve preoperative care

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(met een samenvatting in het Nederlands)

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Contents

Chapter 1

General introduction

In the Netherlands, about 1.5 million people a year are scheduled for (any type of) surgery. The care process for elective or planned surgery can be divided roughly into 3 phases: the preoperative, the intra operative and the postoperative phase. This thesis focuses on the preoperative phase.

The preoperative phase may vary from a day - or sometimes even hours - to several months before surgery. In this preoperative period, the indication for surgery is made, the patient is screened for risk factors and co-morbidities by anaesthetists, nurse practitioners and surgeons, and admission to the hospital is organized. Furthermore, the preoperative period offers the opportunity to optimize the patients' physical condition before surgery.

The contents and organization of the preoperative period have gained increasing attention over the past decade. Several preoperative strategies have emerged to prepare patients better for surgery, aiming to minimize the risk of postoperative complications. Also, several advisory boards have issued reports on improved preoperative risk assessment and optimization of the patients' condition, to increase quality of surgical care.[1-3] One of the introduced preoperative strategies has been the implementation of an outpatient preoperative evaluation clinic (OPE clinic), run by anaesthetists and nurses. The aim of an OPE clinic is to comprehensively screen each patient scheduled for (elective) surgery for co morbidities and risk factors for intra and postoperative complications in order to optimize the patients' condition, as needed.[4-7]

Another recent development is the use of clinical pathways in hospital care, including preoperative care.[8-10] Clinical pathways are a methodology for the mutual decision making and organization of care for a well-defined group of patients during a well-defined period.[11] Clinical pathways are not only used to reduce length of stay and thereby costs, but also to increase quality of care by reducing variations in care, especially for more complex, high risk surgery.[12-15] Clinical pathways can also serve as a tool to implement interventions in the preoperative phase to (further) enhance the patients' preoperative condition. An example of such intervention emerged from the field of physiotherapy. Preoperative exercise training programs by physiotherapists have shown to decrease postoperative complications and length of stay in different surgical patient groups.[16;17]

In this thesis the implementation of two different strategies for preoperative risk-assessment and optimization are studied. The first part, studies factors that influence the implementation of OPE clinics for all types of elective surgery. The second part, evaluates the implementation of specific preoperative interventions in clinical pathways for gastrointestinal surgery. In chapter 2 to 4 the results of a nationwide study are presented aiming to define factors that play a limiting or facilitating role in the implementation of an OPE clinic in Dutch hospitals. *Chapter 2* describes the first results of this study. Based on in-depth face-to-face interviews

with 5 different professional parties from a selected sample of nine Dutch hospitals, we present the main overall factors that positively or negatively influence the implementation of an OPE clinic. *Chapter 3* describes the influence of the national guidelines of the Dutch Health Council and the Netherlands Society of Anaesthesiology on the implementation of OPE clinics in Dutch hospitals. These results are based on a survey among anaesthetists in all Dutch hospitals. *Chapter 4* includes the last part of the nationwide OPE study. This chapter describes the results of a survey among 5 professional parties in all Dutch hospitals to determine which specific factors influence the implementation of OPE clinics. Medical specialists (anaesthetists, internists, surgeons) as well as managers (members of the medical staff and board of directors) were included in this part of the study.

In chapter 5 to 8 clinical pathways for patients undergoing gastrointestinal surgery are evaluated. *Chapter 5* is a systematic review on the necessary contents and interventions of clinical pathways for gastrointestinal surgery. The medical and organizational content of these clinical pathways is described, as well as the health professionals involved. *Chapter 6* is a systematic review about currently used indicators in studies to evaluate clinical pathways for gastrointestinal surgery. The five domains of the Leuven Clinical Pathway Compass are used to categorize these indicators.[18] *Chapter 7* is a study on the feasibility of a preoperative therapeutic exercise program for patients undergoing gastrointestinal surgery to enhance their preoperative functional status. This preoperative program is an intervention lead by a physiotherapist and allows surgical patients to improve their physical condition. *Chapter 8* describes the evaluation of implementing an intervention, consisting of a preoperative multi strategy outpatient visit complemented by a therapeutic exercise program, in a clinical pathway for patients undergoing esophagectomy.

The last chapter includes the general discussion of this thesis.

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Chapter 2

Facilitating and limiting factors for implementation of an outpatient preoperative evaluation clinic: An explorative study in nine hospitals

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Abstract

Background Despite the (qualitatively and quantitatively) proven cost-effectiveness of timely outpatient preoperative evaluation (OPE), many Dutch hospitals have not implemented an OPE clinic yet. Hence, a large national study among all Dutch hospitals has recently been started to determine which factors facilitate or limit the implementation of OPE clinics.

Methods After defining the potential facilitating and limiting factors, based on extensive literature research, we empirically tested the presence or absence of these factors in 9 specifically selected hospitals (three with a complete, three with a partial and three without OPE clinic). This was done by means of face-to-face interviews with representatives of 5 different parties which are somehow involved in the implementation of OPE clinics. These parties are: the board of directors, the medical staff, anaesthetists, internists and surgeons.

Results Financing and motivation (cooperation) were mentioned as major factors influencing the implementation of an OPE clinic. Underlying problems that were mentioned were budget transfer between specialists, loss of income and turf battles. Logistic and organizational preconditions were also mentioned as important factors for the successful implementation of an OPE clinic.

Conclusion The results of this explorative study offer an overview of the likely facilitating and limiting factors for the implementation of an OPE clinic. These factors will be tested further in all Dutch hospitals. The study will eventually contribute to the definition of advices and guidelines for the successful implementation strategies for OPE clinics, and for health innovation projects in general.

Introduction

In the Netherlands more than 1.5 million people a year undergo elective surgery. A substantial part has limited or no preoperative contact with the anaesthetist. As a result, the opportunity to optimize the preoperative health status of the patient and the opportunity to prevent intra and postoperative complications is not fully utilized. Several national and international studies have shown that a timely (several weeks before surgery) outpatient preoperative screening increases the quality of care and is more cost-effective.[1-8] The Dutch Health Council (in 1997) and the Netherlands Society of Anaesthesiology (in 2003), therefore, advised to perform a preoperative screening timely before the date of surgery, and preferably in an outpatient clinic, under the responsibility of the anaesthetist.[9;10]

A recent study in 2000 has shown that only 20% of the Dutch hospitals have a so-called *complete* outpatient preoperative evaluation clinic (OPE clinic), which means that *all* elective surgical patients are screened by an anaesthetist in an outpatient clinic timely before the date of surgery.[11] The remaining hospitals either have a *partial* OPE clinic, where a part of the elective patients is screened (30%), or have *no* OPE clinic at all (50%).[11] In the latter, patients are only seen and evaluated by the anaesthetist on the day before surgery or even on the day of surgery. The question arises why such a substantial part of the Dutch hospitals has not implemented an OPE clinic, not even partially.

Implementation of an OPE clinic can be regarded as the implementation of a organizational health care innovation. Literature shows that a multitude of factors can play a role in the implementation of (guidelines for) such an innovation. Not only the means,[11-16] but also culture,[12;13;17-20] the motivation of professionals involved[13;15;16;21] and the organizational structure in a hospital[13;22;23] can contribute to the success of implementing a health care innovation like an OPE clinic.

Recently a study is started in all Dutch hospitals (financed by the Netherlands Organization for Health Research and Development). The aim is to provide a detailed overview of factors that influence, both positively and negatively, the implementation of OPE clinics. To this aim, first a questionnaire will be constructed based on the literature. This questionnaire will be tested by face-to-face interviews in nine hospitals (with and without OPE clinic) among representatives of five professional parties (phase 1, explorative phase). These parties are medical specialists as well as managers, who are involved in the execution of the preoperative evaluation or in the implementation of the OPE clinic. Then, according to the results of this first phase, a written questionnaire will be made and will be sent to representatives of the same parties in all Dutch hospitals (phase 2). The results of these written questionnaires will be analyzed and reported.

In the current article we discuss the results of phase one of the above mentioned study. The aim of phase one is to obtain an overall view, via literature and empirical studies,

of the factors and preconditions that play a major role in the successful implementation of an OPE clinic.

Methods

Literature research and construction of the questionnaires

Literature research. The studied literature consisted of studies on the (implementation) of OPE clinics,[1-8;11] as well as general literature about implementation and organizational theories.[12-25] Literature about organizational theories was chosen because implementation of an OPE clinic brings organizational changes in the preoperative phase; the anaesthetist now will be involved in the preoperative phase at an earlier stage than before. As a result, a task substitution will occur between different medical specialists. We expected to determine which major type of factors potentially play a role in the implementation of an organizational health care innovation such as the OPE clinic.

Questionnaires for interviews. Based on the results of the literature study, four questionnaires were constructed. For medical specialists and managers, as well as for hospitals with and without an OPE clinic a specific questionnaire was made. Factors that, according to literature, possibly influence the decision making and implementation process of organizational health care innovations were incorporated in questions. To prevent to be directive and to stimulate respondents to tell their own story, questions were formulated as open as possible. For example, instead of directly asking whether there were financial problems with the implementation of the OPE clinic, we asked how the financing of the OPE clinic was arranged. The final questionnaires contained (mainly) open questions about:

1) organization of the current preoperative evaluation;
2) the decision making and implementation process regarding to the OPE clinic;
3) the satisfaction with the current organization of the preoperative evaluation.

The exact content of the questionnaires can be found in the Appendix.

We defined an OPE clinic as the preoperative evaluation of *at least part* of the elective surgical patients in an outpatient clinic, under responsibility of an anaesthetist, at a time point that leaves the opportunity for the optimization of the patients' physical condition and for the authorization for surgery. The outpatient clinic did not have to be bound to a specific physical space or time point before surgery.

Face-to-face interviews

The aim of the interviews was to empirically test whether the potential limiting and facilitating factors for implementation that were found in literature were indeed perceived as such by the respondents. Furthermore, we assessed whether the chosen definition of an OPE clinic was consistent with the current practice and opinion of the respondents.

Respondents. We specifically selected 9 hospitals: 3 hospitals with a complete, 3 hospitals with a partial and 3 hospitals without an OPE clinic. If a hospital had more than one location, the interview was confined to one location, as the status of the OPE clinic could differ between locations. An exception was made for one hospital. In this hospital the managers did not know how the implementation process went at the location of choice, but they did know how it went on the other location; both locations had a complete OPE clinic. Furthermore, the hospitals consisted of 1 university and 8 general hospitals (median number of beds 602, range 365-863).

In each hospital a representative of the five parties, which were expected to play a role in the organization of the preoperative evaluation, was interviewed. These parties concerned anaesthetists, internists, surgeons, members of the medical staff and members of the board of directors. With regard to the surgeons, we chose to interview general surgeons as representatives of a large surgical specialty and ear-nose-throat specialists as representatives of a small surgical specialty. This choice was made since the impact of an OPE clinic could be different for large and small surgical specialties.

Interviews. The interviews were all performed by the same interviewer (LL). This interviewer was very experienced in interviewing medical specialists and was also the main researcher of the current study. The interviews were performed at the workplace of the respondent. As soon as an appointment was made, the questionnaire was sent to the respondents to allow them to prepare for the interview. During the interview, the respondents could tell their own story as much as possible. If necessary, additional questions were asked according to the points of attention (prompts) in the questionnaire (see Appendix). The interviews were performed from July until October 2003.

Data analysis

Based on the results of the interviews, frequencies of limiting and facilitating factors and of preconditions for successful implementation of an OPE clinic were calculated. Also several quotes of respondents were mentioned to illustrate the perceptions of the respondents regarding preoperative evaluation.

Results

Literature research

We found a multitude of factors that could play a role in the implementation of an organizational health care innovation, such as the OPE clinic. Availability of means like financial resources, space and personnel highly influence the implementation of an OPE clinic.[11-16] Motivation of the parties involved, i.e. the extent to which those involved are prepared to cooperate and change their routines, can also very much determine the success of an implementation process.[13;15;16;21] Furthermore, cultural factors like the co-existence of a 'culture of change' and the presence of 'change agents' (i.e. people who initiate and pull the implementation process) possibly play a role.[12;13;17-20] Also, the organizational structure seemed important for the implementation processes in a hospital. The number of organizational layers and the rigidness of the borders in-between also determine whether the implementation of an health care innovation will be easy or not.[13;22;23]

Response

Of the 45 encountered respondents, 40 participated in the interviews (89%). Reasons for refusal were lack of time (n=3) or not seeing the relevance of the interview (n=2). In total 8 representatives of the board of directors, 9 representatives of the medical staff, 9 anaesthetists, 7 internists and 7 surgeons (of which 4 general surgeons and 3 ear-nose-throat specialists) participated (table 1). Per hospital at least 3 respondents were interviewed.

Table 1 Respondents per type of hospital

	board of directors	medical staff	anaes-thetist	internist	surgeon	*total number of interviews*
type of hospital						
complete OPE clinic[1]	1	1	1	1	1	*5*
complete OPE clinic	1	1	1	1	1	*5*
complete OPE clinic	1	1	1	1	1	*5*
partial OPE clinic	1	1	1	0	0	*3*
partial OPE clinic	0	1	1	1	1	*4*
partial OPE clinic	1	1	1	1	1	*5*
no OPE clinic	1	1	1	0	0	*3*
no OPE clinic	1	1	1	1	1	*5*
no OPE clinic	1	1	1	1	1	*5*
total	*8*	*9*	*9*	*7*	*7*	*40*

[1] University hospital

0=refused to participate

Current organization of the preoperative evaluation

The respondents agreed to our definition of an OPE clinic, although a third of the respondents argued that not only a part but *all* elective surgical patients should be preoperatively evaluated to actually call it an OPE clinic.

Among the 3 hospitals with a complete OPE clinic there were no major differences in the organization of the OPE clinic. The 3 hospitals with a partial OPE clinic differed mainly in the type of patients that were evaluated. It concerned either patients with a higher expected length of stay, or patients above a certain age or patients of specific surgical specialties. The functioning of the OPE clinic was predominantly evaluated as positive by all respondents of these 6 hospitals with complete or partial OPE clinic. With regard to future plans, respondents mainly mentioned an electronic patient record, a walk-in outpatient clinic, and the employment of nurses and physician assistants at the OPE clinic. Two of the 3 hospitals with a partial OPE clinic indicated that they wanted to implement a complete OPE clinic.

The respondents of the 3 hospitals without an OPE clinic were predominantly negative about the current organization of the preoperative evaluation. In all 3 hospitals the decision making and planning for an OPE clinic was started. In two of the three hospitals attempts were already made. In one of the hospitals a so-called nurse-led preoperative evaluation had already started and in another hospital patients were educated by the anaesthetist according to the law on medical agreement a week before surgery. However, none of these 3 hospitals had a preoperative evaluation by or under responsibility of an anaesthetist in an outpatient clinic.

Perceptions regarding the current organization of the preoperative evaluation are expressed in the following quotations:

Respondent of hospital with complete OPE clinic: 'Until now we manage to see all patients, everything is properly recorded, the number of preoperative tests is sufficient, and not too much….'
Respondent of hospital without OPE clinic: 'The organization of the preoperative path becomes increasingly a logistical problem and limits the flexibility of the organization of the surgical unit'

Facilitating factors for the implementation of an OPE clinic

The most frequently mentioned facilitating factor was a positive attitude of other specialists than anaesthetists (i.e. mainly internists and surgeons) towards an OPE clinic (table 2). This factor was mainly mentioned by the medical specialists (12 of 17). Furthermore, 40% mentioned the importance of a board of directors that is open to change and innovations. Twenty-eight percent called a positive attitude of the anaesthetists as facilitating for the implementation of the OPE clinic. Twenty-five percent of the respondents mentioned that a complete financing of the OPE clinic would be facilitating, especially managers shared this opinion.

Two quotations illustrating the facilitating factors were:

Respondent of hospital with complete OPE clinic: 'What exceeded my expectations was that the other medical specialists in the hospital, when their first concerns whether we could do it and whether we would have an acceptable solution had gone, actually turned out to be loyal and very brotherly.'
Respondent of hospital with partial OPE clinic: 'Crucial to the start of the OPE clinic was that there was no financial blockade'

Limiting factors for the implementation of an OPE clinic
The most frequently mentioned limiting factor was financing (53%, in 8 of the 9 hospitals, table 3), especially that of the employment of (extra) anaesthetists at the OPE clinic. Insufficient cooperation of other medical specialists than anaesthetists was also repeatedly mentioned as limiting factor (28%). Two characteristic quotations regarding the limiting factors were:

Respondent of hospital without OPE clinic: 'As far as I know for this location a half fulltime equivalent is financed. The anaesthetists think this is too little and therefore don't want to start an OPE clinic because they are afraid they will get work for one fulltime equivalent'
Respondent of hospital with complete OPE clinic: 'We had some resistance from the internists. They took care of a substantial part of the preoperative evaluation and income was attached to that…'

Table 2 Facilitating factors for implementation of an OPE clinic

	number of respondents	board of directors	medical staff	anaes-thetist	internist	surgeon	hospitals with complete OPE clinic	hospital with partial OPE clinic	hospital without OPE clinic
	(n=40)	(n=8)	(n=9)	(n=9)	(n=7)	(n=7)	(n=3)	(n=3)	(n=3)
	n (%)	n	n	n	n	n	n	n	n
facilitating factors									
- positive attitude other specialists	17 (43)	4	1	6	3	3	1	3	3
- hospital/board of directors open for change	16 (40)	4	3	5	3	1	1	3	2
- positive attitude anaesthetists	11 (28)	3	2	4	2	0	2	1	2
- financing is covered	10 (25)	4	4	2	0	0	1	1	2
- introduction of a new paying system	10 (25)	3	3	3	0	1	0	3	2
- availability of supporting personnel	4 (10)	1	1	1	0	1	2	1	1
- availability of appropriate space	4 (10)	2	1	1	0	0	1	0	1
- presence of change agents	3 (8)	1	0	1	1	0	1	1	0
- agreement of division of work with other specialists	3 (8)	1	0	1	1	0	2	0	0
- mutual trust/ understanding and good cooperation	3 (8)	1	1	1	0	0	1	2	0
- providing insight into the benefits of the OPE clinic	2 (5)	1	1	0	0	0	1	0	0
- other*	6 (15)	2	2	2	0	0	2	1	2

*e.g. partner for merger already had an OPE clinic and financial crisis of the hospital

n= number of respondents

Table 3 Limiting factors for implementation of an OPE clinic

	number of respondents (n=40)	board of directors (n=8)	medical staff (n=9)	anaes-thetist (n=9)	internist (n=7)	surgeon (n=7)	hospitals with complete OPE clinic (n=3)	hospital with partial OPE clinic (n=3)	hospital without OPE clinic (n=3)
	n (%)	n	n	n	n	n	n	n	n
limiting factors									
- problems with financing	21 (53)	6	4	5	3	3	2	3	3
- insufficient cooperation of other specialists	11 (28)	2	3	3	2	1	2	2	2
- lack of appropriate space	5 (13)	1	1	2	0	1	2	1	0
- merger of hospitals	4 (10)	1	1	2	0	0	0	1	1
- lack of anaesthetists	4 (10)	0	1	2	0	1	0	1	1
- lack of supporting personnel	3 (8)	0	0	2	0	1	1	1	0
- difficulty with showing the savings of an OPE clinic	2 (5)	1	1	0	0	0	0	1	1
- other*	5 (13)	5	0	0	0	0	2	1	2

*e.g. no OPE clinic does not imply inadequate care, a vast amount of work agreements makes the administration complicated, the OPE clinic of our merger partner has to be evaluated and improved before it can be copied to our hospital

n= number of respondents

Preconditions and success factors for implementation of an OPE clinic

The financing of an OPE clinic had to be arranged in the right way (53%, in all hospitals) to make implementation of an OPE clinic successful. Furthermore, other medical specialists than anaesthetists (mainly internists) and medical staff should be cooperative (30%, table 4). Illustrative quotations regarding these preconditions were:

Respondent of hospital with complete OPE clinic: 'You should not have to ask for money every half year again'

Respondent of hospital with complete OPE clinic: 'There has to be support from the medical staff. Everybody has to be committed to it. You have to want to do it with each other'

Table 4 Preconditions and success factors for implementation of an OPE clinic

	number of respondents	board of directors	medical staff	anaes-thetist	internist	surgeon	hospitals with complete OPE clinic	hospital with partial OPE clinic	hospital without OPE clinic
	(n=40)	(n=8)	(n=9)	(n=9)	(n=7)	(n=7)	(n=3)	(n=3)	(n=3)
	n (%)	n	n	n	n	n	n	n	n
preconditions/success factors									
- availability of financing	21 (53)	7	3	5	3	3	3	3	3
- cooperation of other specialists and medical staff	12 (30)	1	4	5	0	2	3	3	1
- good work agreements and communication between medical specialists	7 (18)	1	1	2	2	1	3	1	0
- presence of enthusiastic change agents or key persons	6 (15)	2	1	2	1	0	2	1	0
- logistics must be well taken care of	6 (15)	1	1	1	2	1	0	0	3
- qualitative, medical arguments have to be prominent	5 (13)	2	2	0	0	1	1	1	1
- evaluation and improvement is necessary	4 (10)	2	1	1	0	0	1	1	1
- walk-in outpatient clinic	4 (10)	0	1	2	0	1	0	1	1
- merger of anaesthesiology departments	4 (10)	2	1	1	0	0	0	0	2
- good work agreements and communication between anaesthetists	4 (10)	1	1	1	0	1	2	0	0
- availability of supporting personnel	3 (8)	0	0	3	0	0	0	1	2
- presence of ICT	3 (8)	1	0	1	0	1	2	0	1
- solid project plan	3 (8)	0	1	1	1	0	2	0	0
- extra formation (personnel)	3 (8)	1	1	0	0	1	0	1	1
- good mutual agreement between those involved	3 (8)	1	1	0	0	1	0	2	0
- copy other hospitals	2 (5)	1	0	1	0	0	2	0	0
- cooperation of the board of directors	2 (5)	0	1	1	0	0	1	1	0
- don't let it depend on financing	2 (5)	0	1	1	0	0	1	1	0
- implement OPE clinic in phases	2 (5)	0	0	1	0	1	1	1	0
- other*	7 (18)	0	2	1	2	2	1	2	2

*e.g. implement OPE clinic in one time, support on project basis and availability of space

n= number of respondents

Discussion

We described the results of the first phase of a large national survey on the implementation of an OPE clinic in Dutch hospitals. The aim of this first explorative phase was to gain insight in the type of facilitating and limiting factors and preconditions that play a role in such implementation. Since all three types of hospitals (with complete, partial and without an OPE clinic) are studied, it can be assumed that all factors relevant for the implementation process of an OPE clinic are covered. The results show that a substantial number of factors in the financial, motivational, organizational as well as logistical domain play a role. Especially financing and motivation of the people involved seem to play a determining role. In the next phase of the study, all these factors will be empirically tested in *all* Dutch hospitals, in much more detail.

Interviews
All interviews were performed by one experienced interviewer which rules out variation in interview style. The interviewer was neither a medical specialist nor a hospital manager and was not biased with regard to the subject of the interview. The response to the interviews was significant (89%). However, it is remarkable that the non response occurred most in the hospitals with a partial or no OPE clinic and was not among the anaesthetists. This could be an indication for the lack of motivation regarding the implementation of the OPE clinic.

Facilitating and limiting factors for the implementation of an OPE clinic
The factors that were mentioned most frequently in this first phase were the financing of the OPE clinic and the motivation (cooperation) of the professionals involved. If these factors are not present in a positive sense, it appears to be almost impossible to implement an OPE clinic. Either the process stops at the (formal) decision to implement an OPE clinic or the hospital will not get past the phase of adopting the idea of an OPE clinic: the so-called adoption phase.

With regard to the financing: a previous study on the implementation of the guidelines of the Dutch Health Council regarding OPE clinics confirmed that financial problems play a limiting role.[11] Furthermore, financing is mentioned as a determining factor for the implementation of other health care innovations as well.[13;16] Our results show that the financing of (extra) anaesthetists to employ at the OPE clinic is difficult. According to the managers, the health insurers demand that the required finances for preoperative evaluation by anaesthetists must come from the budgets of the surgeons and internists. However these two specialist groups usually do not tend to agree with this budget transfer.

Motivation or the cooperation of the professionals involved as facilitating factor for innovations in health care can also be found the general literature.[13;21;23] We found that the motivation is to a large extent determined by the underlying interests of the professionals involved. There especially seems to be a turf battle between anaesthetists and internists. Internists not only consider the preoperative evaluation to belong to their competence, but they often experience loss of income as well if an OPE clinic is implemented. Surgeons seem to have difficulty to lose their influence on the planning of the surgery for the benefit of streamlining of the patient flows at the OPE clinic.

Preconditions and success factors for implementation of an OPE clinic
The current explorative study shows that if financing and motivation are present, it then depends on the organizational and logistical preconditions whether an OPE clinic can be actually implemented according to the guidelines of the Dutch Health Council and the Netherlands Society of Anesthesiology. Factors like multidisciplinary work agreements, availability of space, supporting personnel and ICT, and streamlining of patient flows, are important for a successful implementation. All these organizational and logistic factors are also found in literature.[12;16;22;24;25]

Conclusion

To illustrate the factors and actors that potentially play a determining role in the adoption and implementation of an OPE clinic we designed a theoretical model (figure 1). This model will be tested in the next phase of the study in all Dutch hospitals (chapter 3 and 4 of this thesis).

Adoption process		Implementation process	
Decision making Formal decision that an OPE clinic will be implemented	*Plan making* Planning about the content of the OPE clinic and the time line	*Realization* Starting to implement the OPE clinic	*Final result* Having a OPE clinic that meets the conditions of the national guidelines
Possible actors: - board of directors (make formal decision) - medical staff (support decision) - anaesthetists (support decision) - internists (support decision) - surgeons (support decision) - health insurance company (decide to finance)	Possible actors: - board of directors (facilitating role, set time line) - medical staff (support plans, facilitating role, set timeline) - anaesthetists (determine content of OPE clinic) - internists (support plans) - surgeons (support plans)	Possible actors: - anaesthetists (start OPE clinic) - internists (give up first outpatient visit) - surgeons (sent patients to OPE clinic)	Possible actors: - anaesthetists (start OPE clinic) - surgeons (keep on sending patients to OPE clinic)
Possible factors: - financing (money for extra employment of anaesthetists) - motivation (cooperation of actors involved)	Possible factors: - financing (money for extra employment of anaesthetists) - motivation (cooperation of involved actors)	Possible factors: - motivation (cooperation of actors involved, change agents) - organization (task substitution, personnel, space) - logistics (planning of patients flows)	Possible factors: - financing (structural financing) - motivation (motivation to further develop and improve the OPE clinic) - organization (task substitution) - logistics (walk-in outpatient clinic, electronic patient record)

Figure 1 Summary of the results

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Appendix [in Dutch]

Vragenlijst behandelaars met POS poli

1a. Vindt u de in de beschrijving gehanteerde definitie van een POS poli (zie tekst pagina 9) een juiste definitie (ja/nee)? Welke onderdelen vindt u juist of onjuist?
1b. Kent u de inhoud van de richtlijnen van de Nederlandse Vereniging voor Anesthesiologie (NVA) uit 2002 ten aanzien van de poliklinische organisatie van de preoperatieve zorg (ja/nee)?
1c. Kent u de inhoud van het rapport van de Gezondheidsraad uit 1997 over de poliklinische organisatie van het preoperatief onderzoek (ja/nee)?
2. Wat waren de belangrijkste redenen om voor de ontwikkeling en invoering van een POS poli te kiezen bij u in het ziekenhuis?
3. Kunt u beschrijven hoe het besluitvormingsproces met betrekking tot de invoering van de POS poli is verlopen? Denkt u hierbij aan: betrokken partijen, uw eigen rol, verschillende belangen van betrokken partijen, inspraakrondes, meningsverschillen, besluiten over locatie, personele bezetting en inhoudelijke invulling.
4. Kunt u beschrijven hoe het implementatieproces met betrekking tot de POS poli is verlopen? Denkt u hierbij aan: tijdstraject, betrokkenen, uw eigen rol, meevallers, tegenvallers, bevorderende factoren en belemmerende factoren.
5. Kunt u beschrijven hoe het betreffende personeel is voorbereid op de komst van de POS poli? Denkt u hierbij aan inspraakrondes, voorlichtingsbijeenkomsten, bijscholing, taakverdeling/ verschuiving?
6. Kunt u beschrijven welke rol cultuur heeft gespeeld bij het slagen van de implementatie van de POS poli? Denkt u hierbij aan: verandercultuur in het ziekenhuis, subculturen van de verschillende specialismen, de rol van sleutelfiguren/kartrekkers, groepsprocessen.
7. Heeft u inzicht in de financiering van de POS poli (ja/nee)? Indien ja, kunt u beschrijven hoe de financiering van de POS poli is geregeld? Denkt u hierbij aan: financiers, budgetten, budgetoverheveling tussen specialismen, incidentele financiering of structurele financiering.
8. Hoe vindt u dat de POS poli in zijn huidige vorm functioneert (goed/redelijk/slecht)? kunt u dit toelichten? Denkt u hierbij aan: competenties, werksfeer, meningsverschillen, openingstijden, personele bezetting, locatie, patiënttevredenheid enz.
9. Heeft er een kwantitatieve evaluatie van de invoering van de POS poli plaatsgevonden (ja/ nee)? Indien ja, op welke aspecten (bijv. doorlooptijd, complicaties, patiënttevredenheid) en wat is daar uitgekomen?
10. Indien niet aan de orde geweest: Heeft u een beeld van de tevredenheid van patiënten met betrekking tot de huidige organisatie van het preoperatief onderzoek (ja/nee)? Indien ja, wat vinden de patiënten over het algemeen van de POS poli?
11. Wat zijn succesfactoren en randvoorwaarden bij de implementatie van een POS poli? Welk advies kunt u andere ziekenhuizen geven als zij ook een POS poli willen invoeren?
12. Wat zijn de toekomstplannen met betrekking tot de POS poli in uw eigen ziekenhuis?
13. Wat zou uw beroepsorganisatie (nog meer) kunnen doen om de invoering van een POS poli in Nederlandse ziekenhuizen te bevorderen?

Vragenlijst behandelaars zonder POS poli

1a. Vindt u de in de beschrijving gehanteerde definitie van een POS poli een juiste definitie (ja/nee)? Welke onderdelen vindt u juist of onjuist?
1b. Kent u de inhoud van de richtlijnen van de Nederlandse Vereniging voor Anesthesiologie (NVA) uit 2002 ten aanzien van de poliklinische organisatie van de preoperatieve zorg (ja/nee)?
1c. Kent u de inhoud van het rapport van de Gezondheidsraad uit 1997 over de poliklinische organisatie van het preoperatief onderzoek (ja/nee)?

2. Bent u tevreden met de huidige organisatie van het preoperatief onderzoek in uw ziekenhuis? (ja/nee) Kunt u uitleggen waarom u wel of niet tevreden bent?
3. Wat is de belangrijkste reden dat er momenteel geen POS poli is bij u in het ziekenhuis?
4. Wat vindt u er zelf van dat er nog geen POS poli is in uw ziekenhuis en waarom vindt u dat?
5. Heeft u een beeld van de tevredenheid van patiënten met betrekking tot de huidige organisatie van het preoperatief onderzoek (ja/nee)? Indien ja, wat vinden de patiënten over het algemeen van de huidige organisatie van het preoperatief onderzoek?
6. Aan welke voorwaarden zal voldaan moeten worden om de invoering van een POS poli in uw ziekenhuis te realiseren? Denkt u hierbij aan: financiële, organisatorische, logistieke en motivationele factoren.
7. Van wie zal het initiatief moeten komen voor de opzet van een POS poli in uw ziekenhuis en waarom?
8. Hoe zou de besluitvorming moeten lopen ten aanzien van de ontwikkeling en invoering van een POS poli? Denkt u hierbij aan: inspraakrondes, wie er bij betrokken dienen te zijn, belangen, uw eigen rol enz.
9. Stel dat besloten wordt tot de invoering van een POS poli bij u in het ziekenhuis: Wat zal dan uw eigen rol kunnen zijn bij de implementatie?
10. Wat zou uw beroepsorganisatie (nog meer) kunnen doen om de invoering van een POS poli in Nederlandse ziekenhuizen te bevorderen?

Vragenlijst bestuurders met POS poli

1. Bij wie lag het initiatief voor de ontwikkeling en invoering van een POS poli?
2. Wat waren de belangrijkste redenen om voor de ontwikkeling en invoering van een POS poli te kiezen bij u in het ziekenhuis?
3. Kunt u beschrijven het besluitvormingsproces met betrekking tot de invoering van de POS poli is verlopen? Denkt u hierbij aan: betrokken partijen, uw eigen rol, verschillende belangen van betrokken partijen, inspraakrondes, meningsverschillen, besluiten over locatie, personele bezetting en inhoudelijke invulling.
4. Heeft u zicht op het verloop van het implementatieproces ten aanzien van de POS poli (ja/nee)? Indien ja, kunt u beschrijven hoe het implementatieproces met betrekking tot de POS poli is verlopen? Denkt u hierbij aan: tijdstraject, betrokkenen, uw eigen rol, meevallers, tegenvallers, bevorderende factoren en belemmerende factoren.
5. Kunt u beschrijven welke rol cultuur heeft gespeeld bij het slagen van de implementatie van de POS poli? Denkt u hierbij aan: verandercultuur in het ziekenhuis, subculturen van de verschillende specialismen, de rol van sleutelfiguren/kartrekkers, groepsprocessen.
6. Kunt u beschrijven hoe de financiering van de POS poli is geregeld? Denkt u hierbij aan: financiers, budgetten, budgetoverheveling tussen specialismen, incidentele financiering of structurele financiering.
7. Wat zijn succesfactoren en randvoorwaarden bij de implementatie van een POS poli? Welk advies kunt u andere ziekenhuizen geven als zij ook een POS poli willen invoeren?
8. Wat zijn de toekomstplannen met betrekking tot de POS poli in uw eigen ziekenhuis?

Vragenlijst bestuurders zonder POS poli

1. Bent u tevreden met de huidige organisatie van het preoperatief onderzoek in uw ziekenhuis (ja/nee)? Kunt u uitleggen waarom u wel of niet tevreden bent?
2. Wat is de belangrijkste reden dat er momenteel nog geen POS poli is bij u in het ziekenhuis?
3. Is er naar u weet (ooit) een initiatief ontplooid, d.w.z. een aanvraag gedaan of plannen ingediend voor de ontwikkeling van een POS poli (ja/nee)? Indien ja, wanneer en door wie werd dit initiatief ontplooid? Indien nee, waarom is er denkt u nooit een initiatief ontplooid voor de ontwikkeling van een POS poli?

4. Is er naar u weet ooit getracht een POS poli in te voeren in uw ziekenhuis (ja/nee)? Indien ja, weet u waar die poging op gestrand is?
5. Aan welke voorwaarden zal voldaan moeten worden om de invoering van een POS poli in uw ziekenhuis te realiseren? Denkt u hierbij aan: financiële, organisatorische, logistieke en motivationele factoren.

Chapter 3

The effect of national guidelines on the implementation of outpatient preoperative evaluation clinics in Dutch hospitals

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Abstract

Background Preoperative evaluation performed by anaesthetists primarily aims to estimate the risk of perioperative complications and to create opportunities to optimize the patients' condition before surgery. In this study an inventory was made of the current practice of preoperative evaluation in Dutch hospitals. It was estimated how many hospitals had implemented an outpatient preoperative evaluation clinic in 2004. Subsequently, current practice was compared with the results of a previous inventory (2000). It was also evaluated to what extent the guidelines of the Dutch Health Council and the Netherlands Society of Anaesthesiology were followed.

Methods The study consisted of two phases. First, literature research was performed and pilot interviews were constructed. The interviews were conducted face-to-face with anaesthetists in a sample of Dutch hospitals. Based on the results, written questionnaires were constructed. In the second phase these questionnaires were sent to all general and academic hospitals in the Netherlands.

Results In 2004, 74% of the hospitals had an outpatient preoperative evaluation clinic, compared with 50% in 2000. The percentage of hospitals with an outpatient preoperative evaluation clinic available for *all* elective patients increased from 20 to 52%.

Conclusion The Dutch guidelines on preoperative evaluation seem to have influenced the current practice. An increase in the number of outpatient preoperative evaluation clinics was seen after the guidelines were published. The implementation of an outpatient preoperative clinic seems to warrant that anaesthetists are carrying out the activities prescribed by the guidelines. Most hospitals without a clinic aim to implement one in the future.

Introduction

Historically surgeons provided preoperative evaluation (if any) and anaesthetists played no role in this. However, due to changed insights with regard to the role of the anaesthetist, preoperative evaluation became eventually a shared responsibility of the surgeon and the anaesthetist in Dutch hospitals.[1] Many studies have since shown that preoperative evaluation performed in outpatient clinics (the so-called OPE clinics) increases quality of care and cost-effectiveness.[2-8] The implementation of OPE clinics therefore gained support from the Dutch Health Council in 1997 and the Netherlands Society of Anaesthesiology in 2002.

Their guidelines state that preoperative evaluation is a shared responsibility of the surgeon and the anaesthetist[1;9] (see Appendix): The surgeon has to provide the necessary information to allow the anaesthetist to make an assessment of the anaesthetic possibilities and risks with respect to the proposed surgical intervention in that particular patient. The anaesthetist has to evaluate the clinical information provided, take an additional patient history, and perform a physical examination (if necessary). Additional laboratory and function tests are ordered according to the indication (e.g. type and screen when there is risk for transfusion[10;11]). After the preoperative assessment, steps may have to be taken in order to optimize the patients' condition before undergoing anaesthesia and surgery. A last step of the preoperative evaluation is to educate patients about the possible anaesthetic strategies. The preoperative evaluation is preferably done in an outpatient setting.[1;9]

The primary aim of this study was to make an inventory of the current practice of preoperative evaluation in Dutch hospitals. It was estimated how many hospitals had implemented an OPE clinic in May 2004. We discuss the differences between the results of this extensive inventory and the results of a pilot study conducted in 2000.[12] The second aim was to evaluate to what extent the guidelines of the Dutch Health Council and the Netherlands Society of Anaesthesiology were implemented in current practice.

Methods

The study consisted of two phases. In the first phase a literature research was performed and interviews were constructed to explore all possible forms of preoperative evaluation. The interviews were conducted face-to-face with nine anaesthetists, drawn from nine of the hospitals out of all general and academic hospitals in the Netherlands. Anaesthetists were regarded as the medical specialists who would be able to give the most information about the organization and content of preoperative evaluation and therefore they were the medical specialists approached in this study. Based on the results of literature research and

the interviews in nine Dutch hospitals written questionnaires were made. In the second phase these questionnaires were sent to all general and academic hospitals in the Netherlands in order to address both study aims.

Phase one

Literature research. To get an impression of the recent developments in preoperative evaluation and to be able to make thorough questions for the face-to-face interviews, Pubmed and EBSCOhost® Academic Search Elite databases were used to search for literature concerning the organization, implementation and cost-effectiveness of preoperative evaluation in hospitals. The literature which was selected consisted of studies on (guidelines for) preoperative evaluation by anaesthetists and on OPE clinics.[1-7,12-17] In this, special attention was paid to the study of van Klei *et al.*, which was considered as the pilot study of the present study. In the pilot study a first indication was obtained on the effect of the Dutch Health Council guideline on preoperative evaluation and on the number of OPE clinics in the Netherlands.[12] The pilot showed that in January 2000 only 20% of Dutch hospitals had an OPE clinic in which *all* elective patients were evaluated preoperatively by or under supervision of an anaesthetist.

Literature about the most recent development regarding OPE clinics in Dutch hospitals, namely the employment of nurses substituting anaesthetists, was also taken into account.[15;17]

Implementation level and definition of OPE clinics. The responding anaesthetists were divided into three groups (respondents from hospitals with a complete, a partial or without OPE clinic), because we a-priori hypothesized the presence of potential differences in compliance to the national guidelines between anaesthetists of hospitals with a different implementation level of the OPE clinic. This was similarly done in the previously conducted pilot study by van Klei *et al.*.[12]

A 'complete OPE clinic' was defined as an OPE clinic where *all* elective surgical patients (except children) were evaluated routinely by or under supervision of an anaesthetist. The label 'partial OPE clinic' was assigned if some patient groups were excluded from preoperative evaluation by or under supervision the anaesthetist at an outpatient clinic (e.g. ASA 1 and ASA 2 patients or patients under 60 years).

Construction of open interviews. We designed two questionnaires, one for the six responding anaesthetists in the hospitals with an OPE clinic (three complete and three partial) and one for the three respondents in hospitals without an OPE clinic. We deliberately chose in this initial phase for an open rather than a well structured interview in order to allow the respondents to give more open responses (to tell their own story). The questionnaires therefore consisted

mostly of open questions concerning the current practice of the preoperative evaluation, the implementation of the OPE clinic, the satisfaction with the current practice, and future plans regarding preoperative evaluation. The respondents also documented the timing, content and personnel involved with regard to the preoperative evaluation. To double check the information given in the interviews, transcripts of the interviews were sent back to the respondents for their comments and consent.

Construction of structured (written) questionnaires. We designed two structured questionnaires based on the results of the interviews, one for respondents in hospitals with and one for respondents in hospitals without an OPE clinic. The aim of these questionnaires was to capture all items raised in the nine open interviews using structured questions, in order to verify the interview-answers across all anaesthetists of all Dutch hospitals and to enhance the data analysis. The main items were similar to those in the open interviews, but the questions were now precoded instead of open-ended. Main items were the current organization and content of the preoperative evaluation, the course of adoption and implementation of the OPE clinic, the satisfaction with the current practice, and the future plans regarding preoperative evaluation. A specific question was asked to assess whether anaesthetists had the intention to train nurses to take over some of the tasks of the anaesthetist, as this seems to be a promising new trend in the current practice of preoperative evaluation. In some items a distinction was made between the evaluation of patients operated in day case surgery, patients in short stay (expected hospital stay $\leq$ 5 days) and patients in longer stay (expected hospital stay >5 days), as the pilot interviews showed differences in preoperative evaluation between these subgroups.

Phase two

Data acquisition. The questionnaires were sent in May 2004 to the contact person of the Netherlands Society of Anaesthesiology of each solitary general or academic hospital in the Netherlands. To decide which of the two questionnaires (one for respondents in hospitals with and one for respondents in hospitals without OPE clinic) should be sent, it was (roughly) investigated by internet or by telephone whether the anaesthetist concerned worked in a hospital with or without OPE clinic. To increase response rates, non-responding anaesthetists were phoned between June and July 2004 to ask whether they received the questionnaire, had any questions and whether they intended to fill out and return the questionnaire. The last questionnaire was returned at the end of September 2004. All returned questionnaires were handled anonymously.

Data analysis

SPSS release 12.0 was used for analysis. The respondents were divided into three groups: anaesthetists from hospitals with a 'complete OPE clinic', a 'partial OPE clinic' or 'no OPE clinic'. Differences and similarities in organization of the preoperative evaluation between these three groups were listed by calculating frequencies. Subsequently, a linear regression analysis was performed to assess whether the growth of the number of hospitals with OPE clinics (dependent variable) over the years (independent variable) was statistically significant. The *t*-test was then used to compare the difference in the mean growth of the number of hospitals with an OPE clinic before and after the publishing of the national guidelines in 1997, to infer on the role of the publication on the increase in hospitals with an OPE clinic.

To analyse to what extent Dutch guidelines on the content of the preoperative evaluation were implemented, it was calculated how many anaesthetists reported to perform the activities that they should perform according to the guidelines.

Results

Response

In May 2004 there were 138 hospitals where surgery was conducted. Of these 138 hospitals 52% (n=71) had a complete, 22% (n=31) had a partial and 26% (n=36) had no OPE clinic. In total 70% of the 138 questionnaires were returned, covering 97 hospitals; 54 with a complete, 21 with a partial and 22 without an OPE clinic. Non-response was highest in hospitals without an OPE clinic (39%) and lowest in hospitals with a complete OPE clinic (24%). Fifty-six percent of the responding anaesthetists were employed in a hospital with a complete OPE clinic, 21% in a hospital with a partial and 23% in a hospital without OPE clinic.

Hospitals with a complete or partial OPE clinic

The respondents were asked how long their OPE clinic was already operational. In hospitals with a complete OPE clinic, the clinic was operational for on average 4 years. In 30%, the OPE clinic existed 5 years or longer. In hospitals with a partial OPE clinic, the OPE clinic existed on average 3 years. It took on average 1 year and 8 months years to prepare for implementation of an OPE clinic after the formal decision was made. Figure 1 shows the increase in the number of hospitals with OPE clinics over the years, which was highly significant (p-value<0.001).

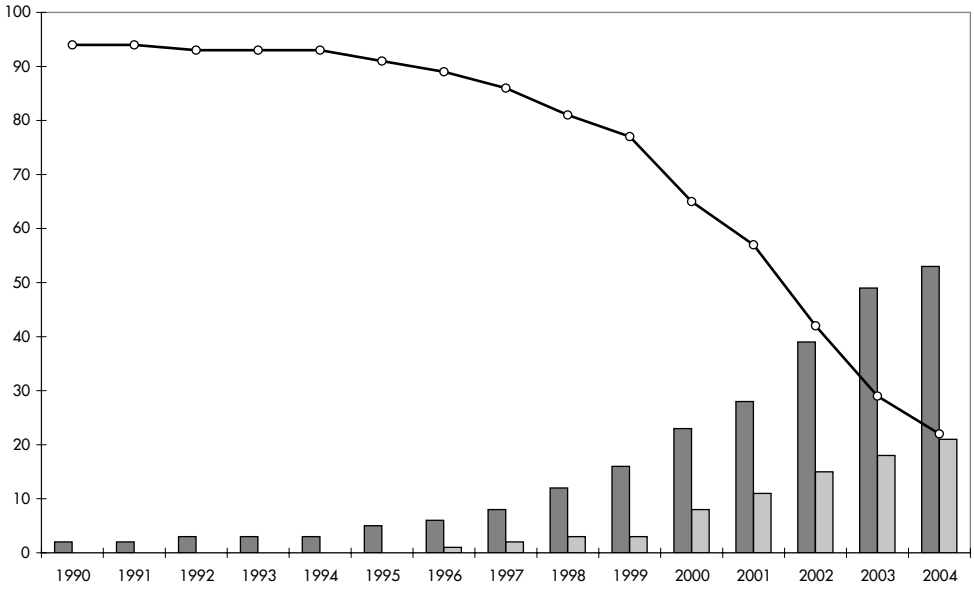

Figure 1 Distribution of the hospitals (n=97) without and with an OPE clinic over the years. Anaesthetists were asked how long the OPE clinic in their hospital was already operational. The number of hospitals is shown on the y-axis and years are shown on the x-axis. We used 1990 as starting point: two OPE clinics already existed then, one was implemented in 1982 and one in 1989. The dark grey bars show the number of hospitals with a complete OPE clinic. The light grey bars show the number of hospitals with a partial OPE clinic. The line shows the number of hospitals without OPE clinic.

The anaesthetists at the OPE clinic did not always examine patients themselves (n= 24, table 1). For example, the examination was alternatively performed by residents (n=11). In the majority of hospitals, preoperative evaluation was structured and formalised during the implementation of the OPE clinics. For example, protocols were currently present in 87% of the hospitals with a complete OPE clinic, whereas *before* implementation of the OPE clinic protocols were present at 15% of these hospitals (table 1).

The guidelines of the Dutch Health Council (1997) and the Netherlands Society of Anaesthesiology (2002) were most frequently mentioned as a reason for having implemented an OPE clinic. This reported effect of the guidelines on the implementation of OPE clinics was confirmed by the fact that after the publishing of the national guidelines the average growth of the number of hospitals with an OPE clinic per year was 8.4 (standard deviation= 4.5) whereas this was 0.71 (0.95) before the publishing of the guidelines. This difference was also highly significant (*t*-test *p*-value was 0.002).

Table 1 Organization, structure and processes of preoperative evaluation. All anaesthetists were asked how the preoperative evaluation was organized and structured in their hospital.

			complete OPE clinic (n=54)	partial OPE clinic (n=21)	no OPE clinic (n=22)
question			n (%)	n (%)	n (%)
-	are all patients that visit the OPE clinic examined by an anaesthetist?	yes	38 (70)	11 (52)	-
		no, part of the patients is not	11 (20)	10 (48)	-
		no, none of the patients is	3 (6)	0 (0)	-
-	who performs the preoperative evaluation?	only the anaesthetist	-	-	5 (23)
		only the surgeon	-	-	4 (18)
		only the internist	-	-	1 (5)
		anaesthetist or internist, or both	-	-	6 (27)
		anaesthetist or surgeon, or both	-	-	3 (14)
		internist or surgeon, or both	-	-	2 (9)
-	protocols for preoperative evaluation?	yes, present at the OPE clinic	47 (87)	20 (95)	-
		yes, already present *before* implementation of the OPE clinic	8 (15)	7 (33)	15 (68)
-	formalisation of tasks and responsibilities of the anaesthetists ?	yes, present at the OPE clinic	39 (72)	15 (71)	-
		yes, already present *before* implementation of the OPE clinic	6 (11)	5 (24)	10 (46)
-	electronic patient record	yes, present at the OPE clinic	9 (17)	5 (24)	-
		yes, already present *before* implementation of the OPE clinic	2 (4)	2 (10)	8 (36)

- = not applicable, question was not asked to these respondents

OPE clinic= outpatient preoperative evaluation clinic; complete OPE clinic= OPE clinic available for all elective patients, no patient groups are excluded; partial OPE clinic= OPE clinic not available for all elective patients; specific patient groups are excluded from the OPE clinic; no OPE clinic= no OPE clinic available at all

The most frequently reported reason for having a partial instead of a complete OPE clinic was a shortage of manpower. However, lack of finance and inadequate logistics also played a role.

Hospitals without an OPE clinic

Hospitals without an OPE clinic did not have a routine outpatient organization of the preoperative evaluation under responsibility of anaesthetists. This was most frequently caused by lack of finance. In some hospitals certain patients, selected on the basis of their medical record, were seen by the anaesthetist on the day before surgery. Sometimes, patients visited the anaesthetist at their own request.

In one third of the hospitals without an OPE clinic (n=7) anaesthetists stated that they did not perform the preoperative evaluation themselves. It was alternatively done by the internist or surgeon, or both (table 1).

Sixty-eight percent of the 22 hospitals without OPE clinic had protocols for the preoperative evaluation (table 1). In contrast, 15% of the hospitals with a complete and 33% of the hospitals with a partial OPE clinic had protocols for preoperative evaluation *before* they implemented the OPE clinic.

Table 2 Timing and content of preoperative evaluation in hospitals without OPE clinic. Anaesthetists in hospitals without OPE clinic were asked what the timing and content of the preoperative evaluation was in their hospital. Multiple answers were possible.

	day case surgery (n=22)	short stay (≤5 days in hospital) (n=22)	clinical (>5 days in hospital) (n=22)
	n (%)	n (%)	n (%)
timing			
- afternoon/evening before surgery	1 (5)	4 (18)	17 (77)
- morning of surgery	4 (18)	2 (9)	0 (0)
- just before anaesthesia induction	11 (50)	8 (36)	0 (0)
- 1 week before surgery	1 (5)	1 (5)	1 (5)
content			
- by using a patient history questionnaire	18 (82)	18 (82)	11 (50)
- on paper by using the patient record	17 (77)	17 (77)	13 (59)
- office hours by nurses	3 (14)	1 (5)	0 (0)
- by routine lab and function examination	16 (73)	16 (73)	13 (59)
- by routine physical examination	6 (27)	7 (32)	8 (36)
- no screening	1 (5)	1 (5)	1 (5)

Day-case surgery patients were evaluated just before anaesthesia induction in 50% of the hospitals. Short stay patients were less frequently evaluated just before anaesthesia induction (36%). Patients with an expected hospital stay of more than 5 days after surgery were in general evaluated on the afternoon or evening before surgery (77%, table 2). Patients were mostly evaluated by using patient history questionnaires, patient records and routine laboratory and function tests (table 2). In three hospitals patients seemed to be evaluated 'on paper' only, i.e. the risk estimation was merely based on the medical record and a written questionnaire rather than on direct contact with the patient.

Notably around two thirds of the responding anaesthetists mentioned that in their

opinion an OPE clinic has no additional value for specific patient groups, such as patients of ASA class I and II.

Activities of anaesthetists during preoperative evaluation

Table 3 shows the activities of anaesthetists during preoperative evaluation. These activities are all prescribed by the guidelines. In hospitals without an OPE clinic anaesthetists perform less of these activities during preoperative evaluation than in hospitals with an OPE clinic. For example, optimization of the patients' condition in the preoperative period was more frequently reported by the anaesthetists in hospitals with a partial OPE clinic (91%) and a complete OPE clinic (82%), compared to hospitals without an OPE clinic (59%).

Table 3 Activities of anaesthetists during preoperative evaluation. All anaesthetists were asked which of the listed activities they perform during preoperative evaluation. Multiple answers were possible.

	complete OPE clinic (n=54)	partial OPE clinic (n=21)	no OPE clinic (n=22)
	n (%)	n (%)	n (%)
- take patient history	49 (91)	19 (91)	15 (68)
- conduct physical examination	50 (93)	17 (81)	9 (41)
- request additional tests (laboratory, electrocardiogram)	49 (91)	19 (91)	12 (55)
- make a risk estimation in relation to the intended operation	52 (96)	19 (91)	20 (91)
- optimize patients' condition before surgery	44 (82)	19 (91)	13 (59)
- determine perioperative policy	51 (94)	19 (91)	20 (91)
- educate the patient (in accordance with Dutch law on medical agreement)	51 (94)	19 (91)	16 (73)

OPE clinic= outpatient preoperative evaluation clinic; complete OPE clinic= OPE clinic available for all elective patients, no patient groups are excluded; partial OPE clinic= OPE clinic not available for all elective patients; specific patient groups are excluded from the OPE clinic; no OPE clinic= no OPE clinic available at all

Future plans regarding OPE clinics

In hospitals with a complete OPE clinic, implementation of an electronic patient record keeping system (85%) and further improvement of logistical processes (74%) were frequently mentioned as future plans (table 4). All anaesthetists working in a hospital with a partial OPE clinic expressed the intention to make the OPE clinic available for *all* patients.

To reduce the actual workload of anaesthetists, about one third of the respondents expressed the intention to train nurses to take over some of the preoperative tasks of the anaesthetists at the OPE clinic (n=29). Especially anaesthetists in hospitals with a partial OPE clinic showed interest in this task substitution. In eight hospitals (n=5 with a complete and n=3 with a partial OPE clinic) nurses were already performing some of the preoperative tasks of the anaesthetist at the OPE clinic.

In the hospitals without an OPE clinic, one third of the anaesthetists (n=8) stated that an OPE clinic would be implemented within a year.

Table 4 Future plans with regard to the OPE clinic in hospitals with a complete or partial OPE clinic. Anaesthetists in hospitals with a complete or partial OPE clinic were asked what future plans they had with regard to the OPE clinic. Multiple answers were possible.

	complete OPE clinic (n=54)	partial OPE clinic (n=21)
	n (%)	n (%)
- OPE clinic available for *all* elective patients	-	21 (100)
- OPE clinic also available for children	22 (41)	13 (62)
- OPE clinic also available for semi-acute patients	24 (44)	11 (52)
- OPE clinic on all hospitals or integration of OPE clinics of all hospitals belonging to one group	11 (20)	4 (19)
- further improvement of logistical processes	40 (74)	18 (86)
- walk-in office hours (instead of office hours by appointment)	8 (15)	5 (24)
- office hours by appointment (instead of walk-in office hours)	12 (22)	10 (48)
- combination of walk-in office hours and office hours by appointment	20 (37)	14 (67)
- implementation of an electronic patient record system	46 (85)	18 (86)
- enlargement of the capacity of OPE clinic (more personnel)	29 (54)	15 (71)

- = not applicable, question was not asked to these respondents

OPE clinic= outpatient preoperative evaluation clinic; complete OPE clinic= OPE clinic available for all elective patients, no patient groups are excluded; partial OPE clinic= OPE clinic not available for all elective patients; specific patient groups are excluded from the OPE clinic

Discussion

In this study we made an inventory of the current practice of preoperative evaluation in Dutch hospitals. In 2004, 74% of the hospitals had an OPE clinic, compared with 50% in 2000. The percentage of hospitals with a complete OPE clinic increased from 20 to 52%. Main reasons for the absence of a (complete) OPE clinic were lack of finance or shortage of anaesthetic staff, or both.

A strong point of this study was the approach in phases. A literature research and open face-to-face interviews were conducted first, and based on these a written questionnaire was made. This was first done to explore all issues regarding OPE clinics and to enhance the precoding of answers for the written questionnaire. This was necessary since a reported limitation of a previous study was that alternative organizational forms of preoperative evaluation could not be fully captured with the then used questionnaire.[12]

Response

The overall response of the anaesthetists (70%) in phase two was very satisfying. The subject of preoperative evaluation and OPE clinics apparently has the interest of anaesthetists. The response was the lowest in hospitals without an OPE clinic (61%). Consequently, of more than a third of those hospitals it is unknown how the preoperative evaluation is organized and to what extent the Dutch guidelines are followed.

Organization of preoperative evaluation

Preoperative evaluation of patients by anaesthetists is in current practice increasingly organized in the form of OPE clinics. The most important reason for this trend, as mentioned by anaesthetists, are the guidelines of the Dutch Health Council and the Netherlands Society of Anaesthesiology.[1;9] The previous inventory already showed an increase in the number of OPE clinics since 1997, when the guidelines of the Dutch Health Council were published.[12] That article also predicted a further increase in OPE clinics in the future, which was confirmed by the current study. This increase was reinforced by the guidelines of the Netherlands Society of Anaesthesiology that were issued in 2002.[9]

Activities of anaesthetists during preoperative evaluation

In the current study we show that the activities prescribed by the guidelines are performed by most of the anaesthetists in hospitals with a complete or partial OPE clinic. In the hospitals without OPE clinic the guidelines are followed to a lesser extent. One of the important benefits of a thorough and timely preoperative evaluation is the opportunity to optimize the condition of patients before surgery.[13] Although this optimization is a prescribed activity by the guidelines, still not all anaesthetists perform this task.

Attitude towards the national guidelines

With regard to the attitude of anaesthetists towards the guidelines, opinions differ whether the OPE clinic should really be available for *all* patient groups. For ASA I and II patients especially, respondents do not always see the additional value of the clinic. On this point the guidelines are questioned, particularly by anaesthetists of hospitals without OPE clinic. This does not mean that anaesthetists consider preoperative evaluation unnecessary, but rather the organizational form is questioned. To stimulate the discussion of implementing a (complete) OPE clinic the results of the current study have been sent to all respondents, to facilitate comparison of their own hospital to the mean of the hospitals in their own category and to that of the other two categories.

Future plans regarding OPE clinics

The most recent development in preoperative evaluation is the employment of nurses who can take over some of the tasks of the anaesthetists.[15;17] Especially anaesthetists in hospitals with a partial OPE clinic are interested in this new trend, mainly because they often do not have the finance for employment of extra anaesthetists at the OPE clinic. Also there is a global shortage of anaesthetists.[18-21]

Conclusion

The guidelines of the Dutch Health Council and the Netherlands Society of Anaesthesiology seem to have influenced current practice of preoperative evaluation. An increase in the number of OPE clinics was seen after the guidelines were published. The implementation of an OPE clinic seems to guarantee that anaesthetists perform the necessary preoperative activities prescribed by the guidelines. Most hospitals without OPE clinic aim to implement such a clinic in the future.

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Appendix

Point of view on preoperative care of the Netherlands Society of Anaesthesiology
The anaesthetist and the surgeon are together responsible for the preoperative care.

Goal
The goal of the anaesthetical part of the preoperative care is: to let pass the anaesthesia as optimal and as safe as possible at the intended operation.

Description
The anaesthesiological part of the preoperative care includes:
1 The assessment of the health condition of the patient in relation to the intended operation.
2 Risk estimation in relation to the intended operation.
3 Optimization of the patients' condition.
4 Education of the patient or his representative.
5 To obtain informed consent (in accordance with Dutch Law on Medical Agreement).
6 To make the perioperative policy.

1 *The assessment of the health condition of the patient in relation to the intended operation.*
At the assessment of the health condition of the patient the necessary data as those of the indication for operation, patient history, physical examination, treatment by other medical specialists and laboratory and function tests are important.
To obtain one or more of these data physicians or nurses that are regarded as qualified and capable by the anaesthetist can be used if desired. The anaesthetist stays responsible for obtaining and assessing these data.

2 *Risk estimation in relation to the intended operation.*
The risk estimation in relation to the intended operation is made by the anaesthetist based upon a conversation with the patient, upon the obtained data mentioned under point 1 and upon the results of specific physical examination

3 *Optimization of the patients' condition.*
The anaesthetist takes care of the optimization of the patients' condition in relation to the intended operation. He can for this purpose request a specific consult of another medical specialist. The anaesthetist stays responsible for the decision whether the anaesthesia can be conducted, at what time and under what conditions.

4 *Education of the patient or his representative*
The anaesthetist is responsible for the education of the general and for the patient specific aspects of the intended anaesthesia and perioperative care. During this education the following should at least be addressed: anaesthesia technique, risks, complications and instructions to the patient
For the general aspects he can use capable personnel, written information and/or video recordings.

5 *Informed consent*
The consent of the patient or his representative for the agreed anaesthesia technique has to be acquired and to be written down in the medical record by the anaesthetist. Also should be recorded that was spoken about the risks, complications and the possibility that another anaesthetist than the one to whom the consent was given could conduct the anaesthesia.
The treating anaesthetist should stick to this agreement. If there is a deviation from the made agreements this should be recorded, including the reason why, in the medical record.

6 *Perioperative policy*
The anaesthetist and the operating surgeon together determine the perioperative policy with regard to preoperative admission, medication, postoperative monitoring and pain management.

NB. The Netherlands Society of Anaesthesiology shares the conclusion about the logistics and organization as put into words in the report of the Dutch Health Council of 12-2-1997: 'With regard to the logistics and organization of the preoperative evaluation, the commission thinks that the realization of an outpatient preoperative office hour for all patients is the most advisable organization.'.

As was established in the general meeting of the Netherlands Society of Anaesthesiology of December 14th 2002.

CHAPTER 4

IMPLEMENTATION OF OUTPATIENT PREOPERATIVE EVALUATION CLINICS: FACILITATING AND LIMITING FACTORS

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Abstract

Background Several studies have shown that outpatient preoperative evaluation by anaesthetists increases quality of care and is cost-effective. The aim of this study was to gain insight in the factors that positively or negatively influence the implementation of outpatient preoperative evaluation clinics (OPE clinics).

Methods After an extensive literature study and pilot interviews, we constructed written questionnaires that were sent to *all* Dutch hospitals. The respondents were members of the board of directors, members of the medical staff, anaesthetists, internists and surgeons.

Results Cooperation of anaesthetists was most frequently mentioned as facilitating factor for implementation of an OPE clinic across all medical specialists interviewed. Lack of finance was most frequently reported as limiting factor in all categories of hospitals (with a complete, partial or no OPE clinic), but significantly more often reported in hospitals without OPE clinic ($p<0.01$). Perceived benefits and disadvantages, financial rewarding system and organizational structure played a clear role in the implementation of OPE clinics.

Conclusion A variety of factors play a role in the implementation of an OPE clinic. Besides the more obvious ones, as financing and cooperation of the professional parties involved, underlying factors such as perceptions of the professionals involved, were found to be related to implementation of an OPE clinic. These underlying factors explain differences between different kinds of hospitals and between professional parties, regarding their resources and motivation to implement an OPE clinic.

Introduction

Several studies have shown that outpatient preoperative evaluation (OPE) increases quality of care and is cost-effective.[1-4] In the late nineties, the Dutch Health Council and subsequently the Netherlands Society for Anaesthesiology issued guidelines for OPE. They recommended to conduct a timely preoperative health assessment in all elective surgical patients by or under supervision of an anaesthetist.[5;6] However, a multitude of factors can play a role in the implementation of such innovations, including not only budget allocation, but also organizational structure, culture, logistics and motivation of the people involved.[7-9] This survey among all Dutch hospitals aimed to detect financial, organizational, logistical and motivational factors that influence the implementation of the OPE clinic according to five professional parties potentially involved.

Methods

The survey consisted of two phases.[10] Phase one consisted of literature study and pilot interviews, and phase two consisted of questionnaires.

Phase one

Literature study. A search in the Pubmed and the EBSCOhost® Academic Search Elite databases was performed to gain insight in the factors that could influence the implementation of OPE clinics. Search terms included: implementation, preoperative screening, organization, guidelines, hospital, strategies, surgeons and anaesthetists. Studies on OPE clinics[1-4;11-14] as well as more general literature about implementation of guidelines, innovations and organizational changes in health care[7-9;15-24] were included. Based on this literature study face-to-face interviews with mostly open questions were constructed, focusing on the current organization of preoperative evaluation, satisfaction with this organization, level and course of adoption and implementation of an OPE clinic, and perceived facilitating and limiting factors.

Interviews. All five parties that could be involved in the implementation of an OPE clinic were interviewed. These were members of the board of directors, members of the medical staff (i.e. medical specialists involved in hospital management), anaesthetists, internists and surgeons. We anticipated potential differences regarding facilitating and limiting factors in hospitals with a different level of implementation of the OPE clinic. Hospitals were divided into three categories according to their level of implementation,[10;13] that is, hospitals with a 'complete OPE clinic' (where *all* elective adult surgical patients are

preoperatively evaluated by or under supervision of an anaesthetist), with a 'partial OPE clinic' (only subgroups of patients are evaluated routinely) and without an OPE clinic. The nine selected hospitals for the interviews included three hospitals of each category.

Four versions of the pilot interviews were made.[25] Members of the board of directors and medical staff received a different version than medical specialists. Also, respondents in hospitals with OPE clinic and those in hospitals without OPE clinic received a different version. This allowed respondents to give specialty or hospital category specific information. Transcripts of the interviews were returned to the respondents for their consent.

Phase two

Questionnaires. The results of the pilot interviews lead to the construction of structured written questionnaires with multiple choice questions, again four different versions were made. Main items were: current organization of the preoperative evaluation, satisfaction with this organization, perceived benefits and disadvantages of an OPE clinic, the adoption and implementation of an OPE clinic, perceived facilitating and limiting factors, and future plans. Questions focused on organizational, logistical, financial and motivational factors. The questionnaires were sent in May 2004 to the representatives of the five professional parties in all Dutch hospitals where surgery was performed (n=138 hospitals). To increase response rates, non responders were repeatedly contacted by phone. The last questionnaire was returned in September 2004. Questionnaires were handled anonymously.

Data analysis

The answers were summarized per professional party and each category of hospital (complete, partial or no OPE clinic) and expressed as absolute values with percentages. We hypothesized differences in facilitating and limiting factors for implementation of an OPE clinic between university hospitals, general teaching hospitals and non-teaching hospitals. Therefore, analysis was also done according these three hospital types. The chi-square or Fisher's exact test (in case of >20% of cell counts <5) was performed to investigate whether frequencies of multiple choice answers differed significantly between respondent groups (p-value < 0.05 and two-tailed).

Results

Response

In 130 hospitals (94%) at least one of the five parties returned a questionnaire (table 1). Anaesthetists showed the highest (70%) and internists the lowest (35%) response. Non response was mostly due to lack of time.

Table 1 Response per category hospital per party based on 138 hospitals. Values are number of hospitals that at least returned one questionnaire.

	total response[a]	complete OPE clinic[b] (n=71)	partial OPE clinic[b] (n=31)	no OPE clinic[b] (n=36)
	n (%)	n (%)	n (%)	n (%)
at least 1 response from hospital	130 (94)	68 (96)	29 (94)	33 (92)
board of directors (n=138)	82 (59)	44 (62)	18 (58)	20 (56)
medical staff (n=138)	70 (51)	40 (56)	14 (45)	16 (44)
anaesthetists (n=138)	97 (70)	54 (76)	21 (68)	22 (61)
internists (n=138)	48 (35)	31 (42)	6 (21)	11 (31)
surgeons (n=138)	80 (58)	43 (61)	18 (58)	19 (53)

a percentages in relation to total number of hospitals (e.g. 82/138= 59%)
b percentages in relation to total number of hospitals within the categories complete, partial or no OPE clinic (e.g. 44/71=62%)

Current organization of the preoperative evaluation

Fifty-two percent of the hospitals had a complete, 22% a partial and 26% no OPE clinic (table 1). Satisfaction with the current organization of preoperative evaluation was highest among respondents of hospitals with complete OPE clinic (79%) and lowest among respondents of hospitals without OPE clinic (25%). Anaesthetists in hospitals with OPE clinic (partial or complete) worked more often on a fixed salary base compared to anaesthetists in hospitals without OPE clinic (36% versus 14%, p=0.05).

Perceived benefits and disadvantages of an OPE clinic

Improved logistics in the preoperative pathway was mentioned most frequently as benefit of an OPE clinic (overall over 80%, table 2 and 3). In university hospitals 'working more patient centred' scored the highest (94%, table 2). Anaesthetists attributed more benefits to an OPE clinic than internists and surgeons (table 3).

The majority of the respondents in hospitals with a partial (66%) or no OPE clinic (76%) stated that an OPE clinic has financial consequences for other medical specialists than anaesthetists, in contrast to a minority (42%) in hospitals with a complete OPE clinic

(table 2). However, the possible financial consequences remained the most frequently mentioned disadvantage in the latter. Respondents at university hospitals (where all staff is paid a fixed salary) reported this disadvantage significantly less (24%) than respondents in general hospitals (57% and 56%, table 2).

There were significant differences between the five professional parties regarding the perceived disadvantages (table 3). Members of medical staff, internists and surgeons more frequently stated that an OPE clinic has no surplus value for specific patient groups, e.g. ASA class I and II, than members of the board of directors and anaesthetists (p=0.01, table 3). Anaesthetists who stated that an OPE clinic has no surplus value for specific patient groups were mostly found in hospitals without OPE clinic; 68% mentioned this disadvantage, compared to 23% and 14% in hospitals with a complete or partial OPE clinic respectively (p=0.0001).

Table 2 Top 5 of perceived benefits and disadvantages in different hospital categories. Values are number of respondents. *P*-values refer to comparisons between groups.

	complete OPE clinic (n=212)	partial OPE clinic (n=77)	no OPE clinic (n=88)	*p*-value	university hospital (n=20)	teaching hospital (n=223)	non teaching hospital (n=134)	*p*-value
	n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	
benefits								
- working according to the law on medical agreement	149 (75)	65 (88)	60 (74)	*0.05*	10 (59)	167 (79)	97 (78)	*0.17*
- working more patient centred	166 (82)	59 (80)	59 (74)	*0.32*	16 (94)	169 (79)	99 (79)	*0.31*
- improvement of logistics of preoperative pathway	187 (91)	66 (89)	69 (83)	*0.14*	15 (88)	196 (90)	111 (87)	*0.77*
- improvement of provided patient record	157 (77)	60 (83)	58 (71)	*0.18*	9 (56)	168 (79)	98 (77)	*0.13*
- decrease in preoperative consults by other specialists	176 (86)	62 (82)	68 (81)	*0.49*	15 (88)	191 (87)	100 (78)	*0.09*
disadvantages								
- decrease in professional freedom for other specialists	40 (20)	18 (23)	25 (31)	*0.14*	3 (17)	52 (25)	28 (22)	*0.69*
- too labour intensive for anaesthetists	53 (27)	23 (30)	33 (41)	*0.08*	1 (6)	56 (27)	52 (41)	*0.001*
- no surplus value for specific patient groups	65 (33)	30 (39)	34 (42)	*0.32*	4 (24)	73 (35)	52 (41)	*0.27*
- has financial consequences for other specialists	83 (42)	50 (66)	62 (76)	*<0.001*[a]	4 (24)	120 (57)	71 (56)	*0.03*
- inconvenient for patients	41 (21)	14 (18)	13 (16)	*0.64*	1 (6)	40 (19)	27 (21)	*0.31*

a *p*-value= 0.0000002

Table 3 Top 5 of perceived benefits and disadvantages per professional party. Values are number (percentage) of respondents. *P*-values refer to comparisons between groups.

	board of directors (n=82)	medical staff (n=70)	anaesthetists (n=97)	internists (n=48)	surgeons (n=80)	*p*-value
	n (%)	n (%)	n (%)	n (%)	n (%)	
benefits						
- working according to the law on medical agreement	57 (74)	53 (82)	78 (83)	32 (73)	54 (73)	*0.38*
- working more patient centred	69 (87)	50 (75)	82 (86)	30 (68)	53 (74)	*0.02*
- improvement of logistics of preoperative pathway	76 (97)	58 (84)	89 (96)	35 (78)	64 (83)	*0.0005*
- improvement of provided patient record	71 (90)	53 (78)	78 (83)	24 (53)	49 (68)	*0.00002*
- decrease in preoperative consults by other specialists	62 (79)	60 (87)	89 (94)	33 (73)	62 (81)	*0.01*
disadvantages						
- decrease in professional freedom for other specialists	22 (31)	22 (32)	15 (16)	12 (28)	12 (16)	*0.03*
- too labour intensive for anaesthetists	31 (42)	22 (32)	30 (32)	7 (18)	19 (25)	*0.06*
- no surplus value for specific patient groups	16 (22)	30 (44)	30 (32)	20 (47)	33 (43)	*0.01*
- has financial consequences for other specialists	48 (63)	40 (58)	47 (51)	31 (76)	29 (38)	*0.001*
- inconvenient for patients	9 (12)	16 (23)	19 (20)	4 (10)	20 (26)	*0.09*

Course of adoption and implementation of the OPE clinic

Anaesthetists (99%), board of directors (85%) and medical staff (71%) were most frequently involved in the decision making regarding the implementation of an OPE clinic. The average period between the formal decision and the start of implementation was 20 months (SD 17 months). The most important reason for having a partial instead of complete OPE clinic was shortage of manpower (69%), followed by inadequate logistics (65%) and lack of finance (59%). In *all* 33 hospitals without OPE clinic, implementation had been discussed. In 12 hospitals a formal decision was already made to implement an OPE clinic.

Perceived facilitating and limiting factors for implementation of an OPE clinic

Cooperation of anaesthetists was most frequently mentioned as facilitating factor (table 4 and 5). In university hospitals cooperation of the board of directors (75%) and presence of change agents (63%), i.e. persons who 'pull' the implementation process, were also frequently mentioned (table 4). Anaesthetists significantly more often named availability of finance and of supporting personnel as a facilitating factor, whereas internists and surgeons significantly more often named cooperation of other specialists than anaesthetists (table 5).

Table 4 Top 5 of perceived facilitating and limiting factors in different hospital categories. Values are number (percentage) of hospitals in which this factor was mentioned most frequently by all or a majority of the respondents. If respondents in a hospital mentioned more than one factor most frequently; e.g. two factors were mentioned by all or an equal number of respondents most frequently, both factors were scored for that hospital. *P*-values refer to comparisons between groups.

	complete OPE clinic (n=68)	partial OPE clinic (n=29)	no OPE clinic (n=33)	*p*-value	university hospital (n=8)	teaching hospital (n=76)	non teaching hospital (n=46)	*p*-value
	n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	
facilitating factors (perceived as decisive)								
- cooperation board of directors	23 (34)	14 (48)	-[a]	*0.18*	6 (75)	17 (22)	11 (24)	*0.005*
- cooperation anaesthetists	59 (87)	21 (72)	-	*0.09*	8 (100)	45 (59)	27 (59)	*0.06*
- presence of change agents	30 (44)	8 (28)	-	*0.13*	5 (63)	21 (28)	11 (24)	*0.08*
- availability of finance	29 (43)	8 (28)	-	*0.16*	1 (13)	24 (32)	11 (24)	*0.40*
- availability of supporting personnel	24 (35)	11 (38)	-	*0.80*	4 (50)	17 (22)	13 (28)	*0.22*
limiting factors (perceived as an obstacle)								
- insufficient cooperation of other specialists	10 (15)	1 (3)	7 (21)	*0.12*	0 (0)	11 (14)	7 (15)	*0.50*
- lack of finance	20 (29)	11 (38)	24 (73)	*0.0002*	4 (50)	33 (43)	19 (41)	*0.84*
- lack of appropriate space	11 (16)	6 (21)	7 (21)	*0.78*	3 (38)	16 (21)	6 (13)	*0.22*
- not enough anaesthetists to employ at OPE clinic	16 (24)	9 (31)	20 (61)	*0.001*	2 (25)	27 (36)	18 (39)	*0.73*
- savings that OPE clinic can give are difficult to proof	11 (16)	2 (7)	9 (27)	*0.10*	1 (13)	14 (18)	7 (15)	*0.85*

a not applicable, question was not asked to this category of hospital

Lack of finance and shortage of anaesthetists were most frequently reported as limiting factor in all kinds of hospitals (table 4). Both factors were mentioned significantly more often by respondents from hospitals without OPE clinic. There were no differences between

university and general hospitals regarding the limiting factors. Anaesthetists significantly more often reported insufficient cooperation of other specialists than internists and surgeons (table 5). Members of the board of directors and of the medical staff reported lack of finance as a substantial problem for implementation of an OPE clinic (74% and 70% respectively).

Table 5 Top 5 of perceived facilitating and limiting factors per type of medical specialist. Values are number (percentage) of respondents. P-values refer to comparisons between groups.

	anaesthetists	internists	surgeons	*p*-value
	n (%)	n (%)	n (%)	
	(n=75)[a]	(n=37)[a]	(n=61)[a]	
facilitating factors (perceived as decisive)				
- cooperation anaesthetists	69 (97)	25 (86)	41(93)	*0.12*
- cooperation other medical specialists	22 (31)	17 (61)	24 (57)	*0.004*
- presence of change agents	39 (55)	13 (46)	24 (59)	*0.70*
- availability of finance	49 (69)	14 (48)	20 (47)	*0.03*
- availability of supporting personnel	49 (71)	11 (39)	19 (43)	*0.002*
	(n=97)	(n=48)	(n=80)	
limiting factors (perceived as an obstacle)				
- insufficient cooperation of other specialists	19 (24)	0 (0)	5 (10)	*0.003*
- lack of finance	35 (44)	10 (30)	15 (30)	*0.17*
- lack of appropriate space	16 (20)	4 (13)	10 (20)	*0.67*
- not enough anaesthetists to employ at OPE clinic	25 (33)	9 (29)	19 (40)	*0.58*
- savings that OPE clinic can give are difficult to proof	13 (16)	4 (13)	10 (20)	*0.64*

a question was only asked to medical specialists in hospitals with a complete or partial OPE clinic

Discussion

This study gained insight into the factors that influence the implementation of OPE clinics. The most important facilitating factor was the cooperation of anaesthetists and the most limiting factor was financing, especially that of extra anaesthetists to employ at the OPE clinic.

Response and limitations

Given our comprehensive approach of the literature review, followed by open interviews and extensive questionnaires, and the high participation of hospitals and respondents, we

think it is reasonable to assume that all factors perceived as important for implementation of an OPE clinic were covered.[25]

Members of the board of directors and of the medical staff were asked less extensively about facilitating and limiting factors than the medical specialists. However, the anaesthetists seem to be the most important party in the implementation of the OPE clinic and they had the highest participation rate. Internists showed the lowest response and they were the least positive about an OPE clinic, which can be explained in two ways. In some hospitals internists were historically performing the preoperative evaluation and implementation of an OPE clinic might have resulted in loss of income or professional autonomy. In other hospitals internists are hardly involved in preoperative evaluation and are possibly not interested.

Perceived benefits and disadvantages of an OPE clinic

It is well known that perceived personal benefits are highly important for successful implementation of innovations and objective data may be less important than the clinicians' perception.[26;27] Several studies have shown that an OPE clinic is cost-effective.[1-4] However money savings are often on the hospital level, and individual medical specialists could even experience loss of income and might be reluctant to support the OPE clinic despite its cost-effectiveness. Indeed, possible financial effects for other medical specialists than anaesthetists were actually the most frequently mentioned disadvantage in the current study.

Although all respondents are convinced that an OPE clinic has benefits; some groups attributed more benefits than others. Overall, respondents (including anaesthetists) in hospitals without OPE clinic reported significantly less benefits and more disadvantages than respondents in hospitals with OPE clinic. This might explain why in these hospitals an OPE clinic is not implemented yet, despite the evidence for cost-effectiveness and increase in quality of care.[26;27]

Facilitating and limiting factors for implementation of an OPE clinic

The most limiting factors for implementation are lack of finance and shortage of anaesthetists to run the OPE clinic; both are closely related. Lack of finance is a frequently reported problem with respect to implementation of innovations in health care.[8;13] In hospitals without OPE clinic anaesthetists significantly more often worked on a fee for service base. This rewarding system could effect the willingness of the anaesthetists to implement an OPE clinic, as there is no extra fee for preoperative evaluation in the Netherlands. Interestingly, cooperation of anaesthetists was mentioned more frequently as facilitating factor than the availability of finance. It seems that if the anaesthetists want to cooperate, an OPE clinic can be implemented even with limited resources. The importance of motivation and

cooperation of the professionals involved was also found in a study on implementation of an in-training-assessment programme in anaesthesia[28] and in more general studies on implementation processes in medical settings.[15;17;22]

Perceived facilitating factors differed between university and general hospitals. Differences were mostly found in the cooperation and motivation of parties involved, the presence of change agents, and the availability of personnel. Differences in financial and organizational structure between university and general hospitals may explain these findings, e.g. all medical specialists in university hospitals are paid a fixed salary and university hospitals may have a more hierarchical structure. Analysis between teaching and non teaching general hospitals showed no conspicuous differences, most likely because their structures are more alike.

Implementation of OPE clinics in the future

The percentage of Dutch hospitals with an OPE clinic increased from 50% in 2000 to 74% in 2004 and the percentage of hospitals with a complete OPE clinic increased from 20% to 52%.[10] In all hospitals without OPE clinic the implementation of such a clinic was on the agenda and negotiations had started between the professional parties. A new trend in preoperative care is substitution of specific tasks between anaesthetists and nurses.[12;29;30] This might provide a solution for the experienced lack of finance and manpower and enhance implementation of OPE clinics.

Conclusion

A variety of factors play a role in the implementation of OPE clinics. Besides the obvious factors, like financing and cooperation of the parties involved, underlying factors as perceived benefits and disadvantages, financial rewarding system and organizational structure are also related to successful implementation. These underlying factors explain existing differences between different kinds of hospitals and professional parties with regard to their resources and motivation to implement an OPE clinic.

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Appendix

Relevant questions from the questionnaire. The answers were provided with check boxes for 'yes' and 'no'.

Tables 2 and 3 were based on the following questions. These questions were formulated the same in all relevant questionnaires.

a) Which benefits does an OPE clinic have according to you?

Working according to the law on medical agreement	yes	no
Working more patient centred	yes	no
Improvement of logistics of preoperative pathway	yes	no
Improvement of provided patient record	yes	no
Opportunity to optimize patients' condition	yes	no
Enrichment of the profession of the anaesthetist	yes	no
Decrease in cancellations of surgery	yes	no
Decrease in length of stay	yes	no
Decrease in preoperative consults by other specialists	yes	no
Decrease in function tests	yes	no
Decrease in lab requests	yes	no
Decrease in X-rays	yes	no
other…		

b) Which disadvantages does an OPE clinic have according to you?

Disintegration of preoperative care	yes	no
Imposed care innovation	yes	no
Decrease in professional freedom for anaesthetists	yes	no
Decrease in professional freedom for other specialists	yes	no
Too labour intensive for anaesthetists	yes	no
No surplus value for specific patient groups	yes	no
Increase in waiting time for surgery	yes	no
Has financial consequences for other specialists	yes	no
Inconvenient for patients	yes	no
other…		

Tables 4 and 5 were based on the following questions.

a) Which *facilitating* factors played a role in the implementation of the OPE clinic and which of these were really decisive?

	a role	decisive
Cooperation board of directors	yes no	yes no
Cooperation anaesthetists	yes no	yes no
Cooperation other medical specialists	yes no	yes no
Cooperation medical staff	yes no	yes no
Presence of change agents	yes no	yes no
Multidisciplinary agreements that are made	yes no	yes no
Agreed feedbacks to attending specialists	yes no	yes no
Mutual trust and good cooperation	yes no	yes no
Availability of finance	yes no	yes no
Availability of supporting personnel	yes no	yes no
Availability of appropriate space	yes no	yes no
Introduction of a new financing system	yes no	yes no
Insight into the improvements that an OPE clinic brings	yes no	yes no
other…		

b) Which *limiting* factors played a role in the implementation of the OPE clinic and which of these were really an obstacle?

	a role	an obstacle
Insufficient cooperation of anaesthetists	yes no	yes no
Insufficient cooperation of other specialists	yes no	yes no
Insufficient cooperation of the medical staff	yes no	yes no
Insufficient cooperation of the board of directors	yes no	yes no
A merger stopped further development of the OPE clinic	yes no	yes no
Lack of finance	yes no	yes no
Lack of appropriate space	yes no	yes no
Lack of supporting personnel	yes no	yes no
Not enough anaesthetists to employ at OPE clinic	yes no	yes no
Savings that an OPE clinic can give are difficult to prove	yes no	yes no
other…		

Chapter 5

Systematic review: Clinical and organizational content of clinical pathways for gastrointestinal surgery

Provisionally accepted by Digestive Surgery as: Lemmens L, van Zelm R, Borel Rinkes I, van Hillegersberg R, Kerkkamp H. Systematic review: Clinical and organizational content of clinical pathways for digestive surgery

Abstract

Background Oncology surgery of the gastrointestinal tract is complex and infamous for its high complication rates. One of the methods for implementing interventions to optimize the patients' condition and to enhance postoperative outcome is the development and implementation of a clinical pathway. The aim of this study was to analyze the content, i.e. the interventions, of clinical pathways for digestive surgery and their effects on postoperative outcome measures.

Methods We performed a systematic review to study clinical pathways in hospital care for adult patients undergoing elective surgery of the stomach, oesophagus, pancreas, liver, colon or rectum. The MEDLINE, EMBASE and CINAHL literature databases were searched.

Results The most common interventions in the clinical pathways in this review were defined in the preoperative and postoperative phase and included: nutritional management, pain management, mobilization, education and discharge planning. The primary aim of these interventions was to enhance postoperative recovery.

Conclusion Clinical pathways for digestive surgery contain specific interventions to improve postoperative outcome. Most of these interventions are in accordance with the Enhanced Recovery After Surgery (ERAS) protocol, which is an evidence-based protocol for care after colon resections. They result in reduced length of stay without compromising other postoperative outcome measures.

Introduction

Oncology surgery of the gastrointestinal tract is known for its high complication rates.[1-4] It usually regards extensive and complex surgery. Moreover, patients are often elderly and suffer from co-morbidities.[5;6] To improve postoperative outcome, interventions are needed to improve the patients' physical condition before and after surgery. Examples of such interventions are embedded in the ERAS protocol, which stands for 'Enhanced Recovery After Surgery'. This protocol defines specific interventions in peri-operative care that are meant to improve postoperative outcome for patients undergoing colonic resection.[7;8] Other examples of interventions are a thorough preoperative screening of the physical condition of patients[9-11] and preoperative therapeutic exercise training programs.[12;13]

A method for implementing interventions to optimize the patients' physical condition and to enhance postoperative outcome is a clinical pathway. Clinical pathways are implemented in hospital care to increase the quality of care and to reduce hospital stay and costs.[14;15] Currently, clinical pathways are also used to increase the quality of care by reducing variations in care, especially for more complex surgery where the postoperative risk of complications is high.[16;17] For digestive surgery clinical pathways have become more common as well.[18]

The Department of Surgery of the University Medical Center Utrecht is in the process of designing and implementing several clinical pathways for gastrointestinal oncology surgery. The focus of these clinical pathways is on improving the patients' physical condition before and after surgery by implementing specific preoperative interventions. A systematic review was performed to study clinical pathways for gastrointestinal surgery. The aim of this study was to analyze the content of these clinical pathways and their detectable effects on postoperative outcome.

Methods

Data sources

A search was performed for the period January 2000 to November 2006 in 3 databases: MEDLINE, EMBASE and CINAHL. The following terms were searched: 'clinical pathway' combined with 'gastrointestinal', 'peri-operative', 'surgery and RCT', 'surgery and systematic review', 'gastrointestinal and fast track' or 'peri-operative and fast track'. All synonyms for these terms were included in the search as well. References had to be in English, German or Dutch. In total, 508 individual publications were found.

Study selection

All 508 titles and abstracts were individually read by two reviewers (LL and RvZ) and each reviewer made a first selection of articles that had to be studied in more detail. The two selections were compared and consensus was reached on the articles of which a full-text version had to be requested for further study. Selection criteria were the following:

1) Studies had to concern adults undergoing elective surgery of the stomach, oesophagus, pancreas, liver, colon or rectum
2) Studies had to concern clinical pathways in hospital care only
3) Studies should describe a clinical pathway implemented by the author or implemented in the hospital of the author, that is, it should not concern the content of clinical pathways of other authors
4) Studies should give a sufficient description of the content of the clinical pathway
5) Study designs had to be of sufficient quality, that is, studies should have used a control (conventional care) group
6) Studies had to report at least two of the following outcome measures which are clinically relevant: length of hospital stay, complication rates, re-admission rates or mortality

All full-text articles were read by one reviewer (LL) to decide whether the article described any medical or organizational content of the clinical pathway and whether a controlled study design with sufficient outcome parameters was used. In case of doubt, the second reviewer (RvZ) was consulted and consensus was reached. In case of more articles on the same clinical pathway, the article that had a controlled study design and reported the most elaborately on the content was selected in order to prevent duplication of studies in the review.

Data extraction

Content of the clinical pathway. One reviewer (LL) scored all content, defined as interventions, of the clinical pathways described in the included articles and discussed the scores with the second reviewer (RvZ). The content of the clinical pathways was divided into four different phases of the care process. These phases were the preoperative, intra operative, postoperative and follow-up phase. The preoperative phase refers to the care before surgery, the intra operative phase is the care during the surgical procedure (including anaesthesia), the postoperative phase refers to the phase in the hospital after surgery and the follow-up phase refers to the care after discharge. Furthermore, a distinction was made between medical and organizational interventions of the clinical pathway. The division into the four phases of care and into the medical and organizational content was discussed with a clinician (HK, an anaesthetist and medical manager) to verify the decisions made by the two reviewers. The professionals engaged in the clinical pathway were scored as well.

Outcome of the clinical pathway. Firstly, it was assessed which type of study designs were used to evaluate the effectiveness of the clinical pathway. Then, reported length of stay, complication rates, re-admissions and mortality were scored by the reviewers. It was also scored if statistically significant differences between the control group (conventional care) and the pathway group were reported.

Data analysis

Frequencies and proportions of the interventions defined, and of the health professionals involved in the clinical pathways were calculated. Interventions had to be mentioned in at least 10% of the studied clinical pathways to be included in the counts.

For the reported effects of the clinical pathways we scored the outcome as reported in the studies. Most studies calculated the mean and the standard deviation for their evaluated outcome measures. Meta-analysis was considered not appropriate for this body of literature because of the wide variety of study designs, sample sizes, patient populations and interventions.

Results

Search results

Of the 508 publications 326 were excluded, as the topic did not meet the selection criteria of adult patients undergoing elective digestive surgery (figure 1). In total 123 studies had the wrong subject for our purpose, that is, they focussed on clinical pathways in a biological or pharmacological sense or on a diagnostic or therapeutic treatment. Subsequently, 59 articles of the 508 were selected and requested full-text for further study.

The sample of articles

In total 13 articles were deemed suitable for this review on the specific content of clinical pathways for digestive surgery (figure 1).[19-31] Seven (54%) concerned studies about the evaluation of clinical pathways in the USA, two (15%) Germany, two (15%) Japan, one (8%) concerned Denmark, and one (8%) concerned Singapore.

In the 13 articles 13 clinical pathways were evaluated, that is, each article represented a study on one clinical pathway. A total of seven (54%) of the studied clinical pathways concerned colonic or colorectal resections, four (31%) pancreatic resections and two (15%) gastric resections. Resections were performed for either malignant or inflammatory gastrointestinal diseases.

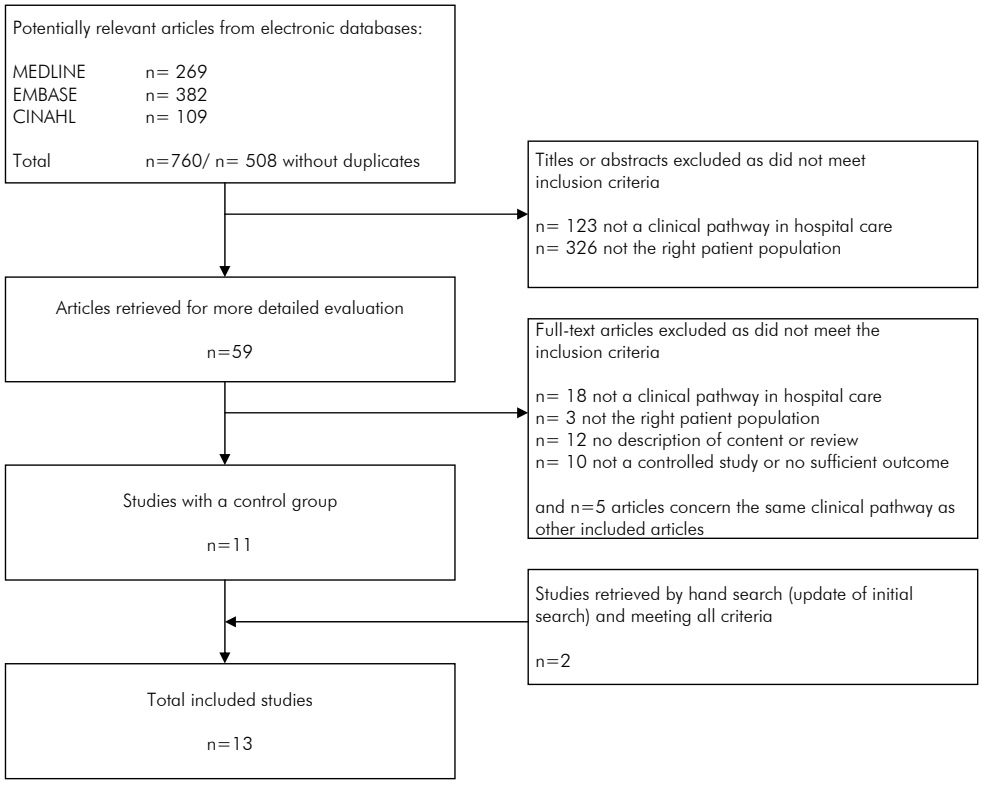

Figure 1 Systematic review flow diagram

Phases of the clinical pathway

Eleven (85%) of the clinical pathways defined interventions in the preoperative phase and seven (54%) in the intra operative phase. In all of the studied clinical pathways (100%) interventions in the postoperative phase were defined. None of the clinical pathways defined interventions in the follow-up phase.

Medical content of the clinical pathway

Most frequently defined interventions in the 13 clinical pathways were nutritional management (92%), pain management (69%), mobilization (69%), and education of patients and relatives (54%, table 1a, first column). Examples of nutritional management are: allowing clear fluids till x hours before surgery and early enteral feeding after surgery (table 1b). Pain management mostly concerns the use of epidural catheters and the use of specific pain medication. With regard to mobilization, patients are mobilized on specific time intervals after surgery, sometimes as early as in the evening of the day of surgery itself. Education of patients and relatives concerns, for example, education about the enhanced recovery program.

With regard to the interventions *per phase* of the clinical pathway: preoperatively education of patients and relatives, bowel preparation and pre medication were most frequently reported (table 1a). Pain management was most frequently defined as an intervention in the intra operative phase. Postoperatively nutritional management, pain management and mobilization were most frequently defined as intervention.

Table 1a Medical content of the clinical pathways, percentage of clinical pathways that define specific interventions in specific phase

	total (n=13)	preoperative (n=11)	intra operative (n=7)	postoperative (n=13)
intervention (with an example)	n (%)	n (%)	n (%)	n (%)
- nutritional management (see table 1b)	12 (92%)	1 (9%)	-	12 (92%)
- pain management (see table 1b)	9 (69%)	-	6 (86%)	6 (46%)
- mobilization (see table 1b)	9 (69%)	-	-	9 (69%)
- education of patient/relatives	7 (54%)	7 (64%)	-	3 (23%)
- management of urinary bladder catheter (removal on day x)	5 (38%)	-	-	5 (81%)
- drain management (removal on day x)	5 (38%)	-	-	5 (38%)
- use of naso gastric tubes (removal on day x)	6 (46%)	-	1 (14%)	5 (38%)
- laboratory tests (which tests at what time points)	3 (23%)	2 (18%)	-	1 (8%)
- use of clinical discharge criteria	4 (31%)	-	-	4 (31%)
- use of pre medication	3 (23%)	3 (27%)	-	-
- oral bowel cleaning/bowel preparation	4 (31%)	4 (36%)	-	-
- medication management (use of antibiotics)	4 (31%)	-	-	4 (31%)
- fluid management (restriction of fluids)	3 (23%)	-	1 (14%)	2 (15%)
- use of specific anaesthesia techniques/medication	2 (15%)	-	2 (29%)	-
- breathing exercises	2 (15%)	-	-	2 (15%)
- physiotherapy	2 (15%)	1 (9%)	-	1 (8%)
- stoma care/stoma siting	2 (15%)	2 (18%)	-	2 (15%)
- use of anti embolism stockings	2 (15%)	-	2 (29%)	-
- EGC (ordering of EGCs)	2 (15%)	2 (18%)	-	-

Organizational content of the clinical pathway

In total 10 of the 13 clinical pathways defined organizational content. Eight (80%) of these clinical pathways defined discharge planning as an postoperative organizational intervention.[20;23-25;28-31] Discharge planning concerned the planning of the day of discharge based on the mean length of stay or aimed length of stay for the specific type of digestive surgery. On this date (x days after the surgery) patients should ideally be sent home.

Table 1b Specification of top 3 of medical content of the clinical pathways

	type of surgery	nutritional management (n=12)
***Balcom** et al.* 2001	pancreatico-duodenectomy	-
Basse *et al.* 2004 (CP also described in Basse *et al.* 2002[32])	colonic surgery	POD0: after surgery start liquids and 2 protein drinks POD1:start normal food and 4 protein drinks POD2: normal oral intake and 4 protein drinks
Delaney *et al.* 2003 (CP also described in Delaney 2001[33])	colorectal surgery	POD0:after surgery liquids as desired POD1: non carbonated liquids, offered solid food in evening if able to tolerate oral fluids
Hirao *et al.* 2005	gastrectomy	Patient controlled diet or diet according to a schedule, not specified
Hirasaki *et al.* 2004	gastric dissection	POD0 to POD1: fasting POD2: start oral intake
Kariv *et al.* 2006	ileo-anal pouch surgery	POD0: oral liquids in evening POD1: solid food in evening
Kennedy *et al.* 2007	pancreatico-duodenectomy	POD1: start sips of water and ice chips POD2: clear liquid diet POD3: regular diet with pancreatic enzymes
Melbert *et al.* 2002	colorectal surgery	Routine early postoperative feeding, not specified
Porter *et al.* 2000	pancreatico-duodenectomy	Not specified
Raue *et al.* 2004 (CP also described in Schwenk *et al.* 2004, Schwenk *et al.* 2006[34;35])	laparoscopic sigmoidectomy	POD0: after surgery tea, yogurt: POD1 to POD3: regular hospital food
Stephen *et al.* 2002	colon resection	POD1: sips of clear liquids, excluding carbonated drinks POD2: unrestricted clear diet
Tan *et al.* 2005	major colorectal surgery	POD1 to POD2: initiation of feeds/diet
Wichmann *et al.* 2006 (CP also described in Wichmann *et al.* 2005[36])	pancreatic surgery	POD0: reduced preoperative fasting, drinks till 2 hours before surgery POD0: clear fluids POD3: solid food POD5: complete enteral nutrition

CP=clinical pathway; DBS=day before surgery, POD0= day of surgery, POD1=first day after surgery, POD2=second day after surgery, etc., - = not reported/unknown

pain management (n=9)	mobilization (n=9)	estimated/ aimed length of stay
-	-	-
POD0: thoracic epidural catheter POD1: epidural with bupivacaine and morphine add. ibuprofen, bupivacaine or opoid for breakthrough pain POD2: removal epidural, oral ibuprofen and morphine tablets for rescue analgesia	POD0: 2 hours mobilization POD1: more than 8 hours mobilization POD2: full mobilization	48 hours
POD0: intravenous patient controlled analgesia (PCA), no epidural intravenous ketorolac 30 mg/ 6hours if needed POD2: PCA removed, oral analgesia	POD0:voluntary walk POD1: encouraged to walk, sit of bed between walks, incentive spirometry	-
-	-	14 days
-	-	7 days
POD0: no epidural anaesthesia or analgesia; intravenous patient controlled analgesia (PCA)	POD0: sit in chair and walk POD1 to POD5: ambulate at least five times around nursing floor	5 days
POD0: no epidural anaesthesia or analgesia; intravenous patient controlled analgesia (PCA)	POD1: out of bed ambulating POD6 and 7: continue to increase activity levels	6 to 7 days
Optimizing pain control with liberal use of postoperative epidural analgesia, PCA and NSAIDs	Early and frequent ambulation, not specified	-
-	-	
POD0 to POD1: epidural analgesia (LA/opoid), parecoxib 40 mg i.v., avoid systemic opoids POD2: remove epidural in morning, valdecoxib POD3: oral valdecoxib	POD0: short walk, 2 hours in chair POD1: more than 8 hours out of bed POD2 to POD3: fully mobilized	3 days
POD0 to POD2: epidural catheter POD2/3: epidural removed, oral analgesia	POD0: mobilized to a chair POD1: ambulated 3 times/day	2-3 days
POD0: Postoperative analgesia, not specified	Rapid mobilization POD1 to POD2: chest and limb physiotherapy POD3 to PODx: physiotherapy and ambulation	-
POD0 to POD2: thoracic epidural catheter with Cox II inhibitors	POD0 to PODx: mobilization according to schedule, longer out of bed every day	10 days

In two clinical pathways discharge planning was even started preoperatively.[25;28] Other organizational content concerned admission on x days before surgery (10%),[23] avoidance of ICU admission (10%)[28] and the use of prewritten orders (20%).[19;26]

Reported outcome

A variety of study designs was used to evaluate outcome of the clinical pathways (table 2). One randomized controlled trial was found, three controlled clinical trials, two case control studies, one case series and six studies in which measurements were taken in the pre pathway period (control group) and post pathway (intervention group). In this last study design, either prospective or retrospective control groups were used to compare the outcome of pathway care with non pathway care, that is, conventional care.

In 11 studies the patients who were treated according to the clinical pathway showed a statistically significant shorter length of stay than patients from the conventional care group (table 2). In three studies a significant decrease in complication rate was observed and in one a significant decrease in re-admission rate was found. None of the studies showed a negative outcome of care according to the clinical pathway. In respectively two and four studies re-admission rates and mortality rates were not reported. With regard to more specific outcome coupled to specific interventions in the clinical pathway, positive effects were found regarding nutritional management (early enteral feeding, 7 out of 10 studies reported positive results) and discharge planning (5 of 8 reported a positive effect).

Professionals involved in the clinical pathway

In four (31%) of the studied clinical pathways specific interventions for surgeons were defined.[19;26;28;30] Interventions for surgeons were most frequently defined in the intra operative phase. Anaesthetists were specifically mentioned to have tasks in three clinical pathways (23%).[20;29;30] Other professionals that were mentioned were doctors or physicians, nurses, stoma therapists, physicals therapists, nurse specialists, dieticians, gastrointestinal pathologists, pharmacists and OR technicians (all mentioned once). In four (31%) of the clinical pathways it was not specified which health professionals were responsible for the interventions that were defined in the clinical pathway.[19;24;25;31]

Discussion

The selection and the sample of articles

Of the 508 articles which were found in the search, only 13 were selected as relevant for this systematic review. An explanation for this difference is that we used a very sensitive search strategy in order not to miss any studies. As a result, the majority of the articles (326

(64%)) did not meet the first criterion: adult patients undergoing elective digestive surgery.

Phases and content of the clinical pathways

Most interventions are defined in the preoperative and postoperative phase of the clinical pathways. With regard to the medical content of clinical pathways, nutritional management, pain management, mobilization, and education of patients and relatives are most frequently mentioned. These interventions are all components of the ERAS protocol.[7;8] This protocol aims to enhance recovery after colonic surgery by implementing specific interventions in peri-operative care. As a matter of fact, most interventions that are defined in the clinical pathways in this review are in accordance with this ERAS protocol.

Discharge planning is most frequently mentioned as an organizational intervention. An early planned discharge can possibly contribute to a decrease in length of stay, as personnel and patients adapt their expectations to it and act accordingly.[37-39]

Outcome of the clinical pathways

According to this review, the implementation of clinical pathways for digestive surgery can result in a decrease in length of stay in the hospital. In 11 of the 13 studies evaluating clinical pathways (85%) a statistically significant decrease in length of stay was observed.[19-29] With regard to complications rates, re-admission rates and mortality rates; these were the same[21-29;31] or lower[19;20;30] in the patient groups that were on the clinical pathway. It can therefore be argued that patients can be safely treated according to the clinical pathway, as the reported decrease in length of stay does not seem to have any adverse effects on the other three outcome measures. Two studies, however, did not report re-admission rates[23;31] and four did not report mortality.[21;23;28;31] Consequently, the results of these outcome measures are unclear.

Professionals involved in the clinical pathway

It is remarkable that surgeons and anaesthetists, although mentioned most frequently, are only mentioned to have a specific role in four (31%) and three (23%) of the studied clinical pathways, respectively, as they are the main professionals involved in surgical care. However, it is well known that medical doctors want to hold professional autonomy over their surgical and anaesthesia techniques and do not want to conform to standard operating procedures.[40] Actually, in only two of the pathways in this review specific anaesthesia techniques were defined and in none of the pathways specific surgical techniques were defined.

In four (31%) of the described clinical pathways it was not specified at all which professionals are involved. However, it can be assumed that the same professionals are involved as those who are frequently mentioned in other pathways.

Table 2 Outcome of the clinical pathways (n=13)

	type of surgery	study design	number of patients in control/ clinical pathway group
Basse *et al.* 2004	colonic surgery	pre- and post pathway measurements, the control consisted of patients from another hospital	n=130/ n=130
Delaney *et al.* 2003	intestinal or rectal resection by laparotomy	randomized controlled trial	n=33/n=31
Melbert *et al.* 2002	colorectal surgery	controlled clinical trial, surgeons decided which patients followed pathway	n=122/n=263
Kariv *et al.* 2006	ileo-anal pouch surgery	case control study	n=97/n=97
Raue *et al.* 2004	laparoscopic sigmoid-ectomy	controlled clinical trial, patients of one surgeon/ department were assigned to the pathway	n=29/n=23
Stephen *et al.* 2002	colon resection	pre- and post pathway measurements	n=52/n=86
Tan *et al.* 2005	major colorectal surgery	pre- and post pathway measurements	n=204/n=204
Hirao *et al.* 2005	gastrectomy	controlled clinical trial	n=50/n=53
Hirasaki *et al.* 2004	gastric dissection	pre- and post pathway measurements	n=20/n=23
Balcom *et al.* 2001	pancreatico-duodenectomy	retrospective case series	n=201/n=130
Kennedy *et al.* 2007	pancreatico-duodenectomy	pre- and post pathway measurements	n=44/n=91
Porter *et al.* 2000	pancreatico-duodenectomy	pre- and post pathway measurements	n=68/n=80
Wichmann *et al.* 2006	pancreatic surgery	case-control study	n=12/n=12

[1] decrease had to be significant between control and intervention group; $p<0.05$

n.s.= no significant differences found between groups

Limitations

More than half of the clinical pathways in this review concerned colon resections. Furthermore, no studies on esophagectomy and liver resection were included in this review. This may result in a limited view on the content of clinical pathways for gastrointestinal surgical procedures. However, most interventions in the pathways for colon resections are generic interventions that can be copied to pathways for other types of digestive surgery. Also, the incidence of (malignant) colon diseases is higher than the incidence of gastric, liver, pancreatic or oesophageal diseases, so it is likely that more clinical pathways are developed for colon resections.[41]

The level of description of the clinical pathways differs between articles. Some articles present complete day-to-day time task matrices, while other articles only give a

decrease in length of stay [1]	decrease in complications [1]	decrease in re-admission rate[1]	decrease in mortality rate[1]
from 10 to 3.3 days (mean) from 8 to 2 days (median)	from 45% to 25%	n.s.	n.s.
from 7.1 ± 4.8 to 5.4 ± 2.5 (mean ±SD)	n.s	n.s	not reported
from 8.2 to 5.5 days (mean)	n.s.	n.s.	n.s.
from 5.9 to 5.0 (mean) from 5 to 4 (median)	n.s.	n.s.	n.s.
from 7 to 4 days (median)	n.s.	n.s.	n.s.
from 6.6 ± 3.3 to 3.7 ± 1.5 days (mean ±SD)	n.s.	n.s.	not reported
n.s.	from 33% to 20%	from 13% to 6%	n.s.
from 21.7 ± 8.8 to 18.5 ± 5.9 days (mean ±SD)	n.s.	n.s	n.s.
from 17.5 ± 6.9 to 10.9 ± 1.9 days (mean ±SD)	n.s.	not reported	not reported
from 16.1± 0.6 to 9.5 ± 0.4 days (mean ± SE) from 9 to 6 days (median)	from 21% to 8.5%	n.s.	n.s.
from 13 to 7 days (median)	n.s.	n.s.	n.s.
from 16.4 to 13.5 days (mean)	n.s.	n.s.	n.s.
n.s.	n.s.	not reported	not reported

brief description of the clinical pathway. It is possible that interventions in clinical pathways are missed because they are not described in literature. However, it is likely that the most essential interventions of a clinical pathway are described by the authors.

Only one RCT was found, this may be due to the complex nature of the intervention, that is, a clinical pathway with multiple components of care, to be evaluated. The other study designs included in this review can be regarded as phase II studies, that is as exploratory trials in preparation of more rigorous trials, as described by Campbell *et al.* and the Medical Research Council (MRC).[42;43] Rigorous study designs to evaluate complex interventions are not only randomized controlled trials, but also clustered randomized trial as advocated by Campbell and the MRC.[42-44] As there are no such trials yet available on clinical pathways for gastrointestinal surgery, we decided to include other study designs

in our review as well. The outcome described in this review should therefore be regarded as indicative for the positive results that can be achieved with clinical pathways for gastrointestinal surgery.

None of the 13 studies report negative effects of the clinical pathway. However, this may be due to a publication bias: studies with positive results are more likely to be published than studies with negative results.

Conclusion

Most clinical pathways found in this review concerned colorectal surgery. Although other types of gastrointestinal cancer are less common, clinical pathways could be a valuable tool to improve the perioperative care for these patient groups as well. Most commonly, interventions in clinical pathways for gastrointestinal surgery are defined in the preoperative and postoperative phase and include: nutritional management, pain management, mobilization, education and discharge planning. The aim of these interventions is to enhance postoperative recovery and they are mainly based on the ERAS protocol. Evaluations of the clinical pathways show that a decrease in length of stay is observed without compromising other postoperative outcome measures. However, more rigorous study designs are needed to rule out adverse effects completely. In general, surgeons and anaesthetists are mentioned the most as involved disciplines in the studied clinical pathways. It seems necessary to involve these groups in the development and implementation of clinical pathways.

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Chapter 6

Systematic review: Indicators to evaluate effectiveness of clinical pathways for gastrointestinal surgery

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Abstract

Background A systematic review on clinical pathways for gastrointestinal surgery was performed. The aim was to study indicators that are used to evaluate these clinical pathways and to study which effects of clinical pathways are reported.

Methods A search was performed for the period January 2000 to November 2006 in MEDLINE, EMBASE and CINAHL. The Leuven Clinical Pathway Compass was used to categorize the indicators reported in literature.

Results Twenty-three studies were selected of which 16 were controlled studies. Studies assessed most frequently complication rates, re-admissions, mortality and length of stay. More specific indicators like time to start defecation and time to return to enteral feeding were reported as well. None of the studies reported adverse effects in any of the domains of the Clinical Pathway Compass.

Conclusion Clinical pathways for gastrointestinal surgery can enhance efficiency of care without adverse effects on outcome. Specific indicators to evaluate these clinical pathways are time to return to enteral feeding and time to defecate. Furthermore, additional to complication rates, number of re-admissions, mortality and length of stay, indicators such as the number of re-operations, pain scores and intensive care unit admission can be assessed to monitor effectiveness and patient safety of the clinical pathways.

Introduction

Clinical pathways, also known as care pathways or critical pathways are increasingly used in different kinds of healthcare settings.[1-3] Initially they were developed to reduce hospital stay and costs for high volume surgery.[4;5] Currently clinical pathways are also used to increase quality of care by reducing variations in care, especially for more complex surgery where the postoperative risk is high.[6;7]

The European Pathway Association (www.E-P-A.org) defines clinical or care pathways as follows: 'Care pathways are a methodology for the mutual decision making and organization of care for a well-defined group of patients during a well-defined period'.[8] Also, according to the Associations' definition a care pathway requires: 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. Furthermore, 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.

The effects of clinical pathways can be evaluated with different types of indicators or outcome measures that can be divided in five domains of the Leuven Clinical Pathway Compass: the 'clinical', 'service', 'team', 'process' and 'financial' domain.[9] A review on clinical pathways by Van Herck *et al.* showed that the most widely used indicators are in the 'clinical' and 'financial' domain.[10] Commonly used indicators or outcome measures in the clinical domain are complication and re-admission rates. In the financial domain they are length of stay and medical costs. Indicators in the process domain include the number of clinical examinations and analysis of deviations in the care process. In the team domain communication and satisfaction of the team members are frequently assessed and in the service domain patient satisfaction is commonly assessed.[2;10]

In this review the focus is on gastrointestinal surgery which is infamous for its substantial complication rates.[11-18] The primary aim was to study indicators that are used to evaluate clinical pathways for gastrointestinal surgery. Secondly, we summarized the reported effects of these clinical pathways.

Methods

Data sources

A literature search was performed for the period January 2000 to November 2006 in three databases: MEDLINE, EMBASE and CINAHL. The search terms were 'critical pathway' combined with one of the following terms 'gastrointestinal', 'perioperative', 'surgery and rct', 'surgery and systematic review', 'gastrointestinal and fast track' or 'perioperative and fast track'. All synonyms for these terms were searched as well. Articles had to be in English, German or Dutch. In total, 508 individual publications were found.

Study selection

Two reviewers (LL and RvZ) read all 508 titles and abstracts individually and made a first selection based on the general characteristics of clinical pathways. Both selections were then compared and consensus was reached on which articles had to be studied in more detail (full-text). Inclusion criteria were the following:

1) Studies on clinical pathways in hospital care
2) Studies among adult patients undergoing elective surgery of the stomach, oesophagus, pancreas, liver, colon or rectum
3) Studies on the evaluation of the effectiveness of a clinical pathways (all study designs); clinical pathways had to be implemented by the authors or implemented in the hospital of the authors; i.e. reviews on clinical pathways of others were excluded

The full text of 59 selected articles was considered. These were first read by one reviewer (LL) to decide whether the article described indicators for evaluation of clinical pathways. In case of doubt the second reviewer (RvZ) was consulted and consensus was reached.

Data extraction

One reviewer (LL) scored all indicators used in the selected articles, which were then discussed with the second reviewer (RvZ). The list of indicators to be scored was based on the review by Van Herck *et al.*[10] Additional indicators were listed separately and these indicators were then included in one of the five domains after consensus between the two reviewers was reached. The following indicators were scored in each domain indicators in italics are additional to those reported in the review by Van Herck *et al.*

1) *Financial domain*. influence on length of stay (LOS), influence on (medical) costs
2) *Clinical domain*. number of complications, number of re-admissions, mortality, number of admissions on intensive care unit (ICU), *time to (restart) defecation, time to return to enteral feeding, time to mobilize, pain scores, number of re-operations, discharge destination, time to remove naso gastric tube, flatus or bowel movement, pulmonary function, fatigue score, postoperative treatment with fluids, removal of bladder catheter*

3) *Service domain*. influence on patient satisfaction, *SF-36 questionnaire*
4) *Process domain*. number of clinical examinations, completeness and quality of documentation, *appropriate use of antibiotics or immunosuppressant*
5) *Team domain*. influence on team satisfaction

Data analysis
Frequencies and proportions of the indicators and the five domains of the Clinical Pathway Compass were calculated. For the reported effects of the clinical pathways (positive effect, no effect of negative effect) frequencies and proportions were calculated as well, based on the controlled studies that were included.

Results

Search results
Of the 508 publications 123 did not cover clinical pathways in hospital care, that is, they were about clinical pathways in a biological or pharmacological sense, or about a diagnostic or therapeutic treatment. Three hundred and twenty-six articles were not concerning adult patients undergoing elective gastrointestinal surgery, but concerning another type of patients or concerning another type of surgery. Finally, 59 full text articles of the 508 hits were selected (figure 1).

Retrieved articles
In total 23 of the 59 full-text articles contained any form of indicators to evaluate clinical pathway (see Appendix for details on these 23 articles). Thirty-five percent of these 23 articles evaluated clinical pathways in the USA, 17% in Denmark, 17% in Japan, 13% in Germany, 9% in the UK, 4% Israel and 4% in Singapore.

Clinical pathways were designed for patients with malignant or inflammatory gastrointestinal diseases. Sixty-seven percent described clinical pathways for colonic or colorectal resections, 17% for pancreatic resections, 13% for gastric resections, 8% for esophagectomy, 4% for liver transplantations and 4% for liver resections.

The most frequently applied study design was the quasi-experimental design with a pre- and post-test (66%), that is, a pre test is used as control group, but participants are not randomly assigned to groups (figure 1). One study was experimental (4%) and seven studies were observational (30%). Sample sizes varied from 13 to 846 subjects.

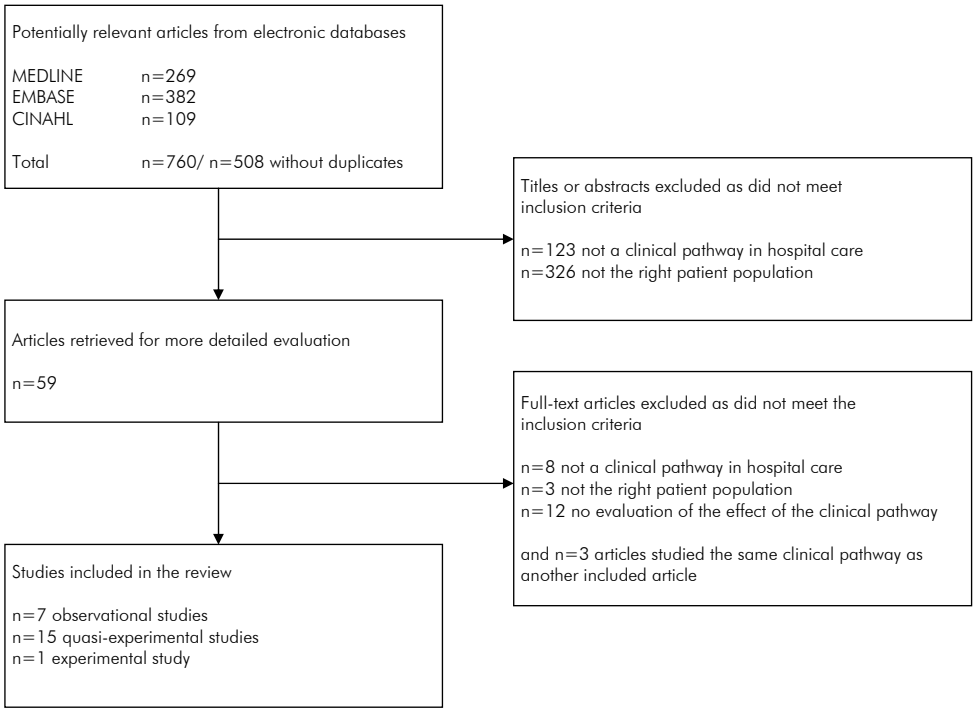

Figure 1 Systematic review flow diagram

The domains and indicators to evaluate clinical pathways

The indicators that were used to evaluate clinical pathways for gastrointestinal surgery in the literature were scored for each domain of the Leuven Clinical Pathway Compass.[9] In 96% of the 23 articles indicators in the financial domain were used and in 91% clinical outcome indicators were used (table 1). Indicators in the service and process domain were assessed in 26% and 17% of the articles, respectively. One article (4%) described indicators in the team domain as tool for evaluation of the clinical pathway.

Table 1 Domains of the Leuven Clinical Pathway Compass described in the 23 articles. Percentages are the number of articles that described indicators in that specific domain divided by the total number of articles

domain	overall percentage	references
financial	96%	[19-22;24-37;39-42]
clinical	91%	[19-22;24-37;39;40;42]
service	26%	[19;21;25;31;36;39]
process	17%	[23;24;20;35]
team	4%	[23]

In the financial domain length of stay (LOS, 91%) and medical costs (31%) were assessed (table 2). In the clinical domain the number of complications (76%) and the number of re-admissions (71%) were most frequently used indicators. In about half of the studies mortality was reported. Time to return to enteral feeding or normal diet and the time to defecate were used as indicators in one third of the studies, and in 24% time to mobilize was used. In the service domain two indicators were assessed: patient satisfaction (100%) and the SF-36 health survey (17%). Process indicators focused mainly on number of clinical examinations (75%). Other indicators were appropriate use of antibiotics or immunosuppressants and completeness and quality of documentation (both 25%). Influence on team satisfaction was the only indicator assessed in the team domain and was assessed in one article (100%).

Table 2: Indicators used to evaluate the clinical pathway in each domain. Percentages are the number of articles that described that specific indicator divided by the total number of articles in that domain.

	indicators	references
financial (n=22)		
91%	influence on length of stay	[19-21;24-28;30-37;39-42]
32%	influence on medical costs	[24;26;30-33;42]
clinical (n=21)		
76%	number of complications/ postoperative morbidity	[19;21;22;24;25;27-32;34;36;37;40;42]
71%	number of re-admissions	[19;21;24-29;31;32;34;36;37;40;42]
48%	mortality	[19;21;24;26;27;29;31;34;36;42]
33%	time to defecation	[19-22;34;37;40]
33%	time to return to enteral feeding or normal diet	[19-22;29;31;35]
24%	time to mobilize	[31;34;36;37;39]
14%	pain scores	[21;25;37]
10%	number of re-operations	[20;27]
10%	discharge destination	[26;31]
10%	number of admissions or length of stay on intensive care unit	[35;36]
10%	time to remove nasogastric tube	[21;34]
10%	flatus/bowel movement	[20;21]
10%	pulmonary function (FEV, FVC, PEF)	[21;37]
10%	fatigue score	[21;37]
10%	postoperative treatment with fluids	[21;34]
10%	removal of bladder catheter	[31;34]
service (n=6)		
100%	influence on patient satisfaction	[19;21;25;31;36;39]
17%	Quality of life (SF-36)	[25]
process (n=4)		
75%	number of clinical examinations (labs, radiology)	[24;30;35]
25%	appropriate use of antibiotics and immunosuppressant	[35]
25%	completeness and quality of documentation (compliance)	[23]
team (n=1)		
100%	influence on team satisfaction	[23]

FEV=forced expiratory volume; FVC=forced vital capacity; PEF= peak expiratory flow

Effect of the clinical pathways

The majority of the controlled studies concluded that implementation of a clinical pathway had positive effects, i.e. resulted in better outcome than conventional care in the control group (table 3). In the clinical domain 67% of the controlled studies (n=15 for that domain), scored 'no effect', that is, implementation of the clinical pathway did not lead to a change in morbidity, mortality or number of re-admissions compared to conventional care. In none of the studies a negative effect was reported.

Table 3 Reported effects of the clinical pathways. Percentages are the number of controlled studies that mention that specific effect divided by the total number of controlled studies in that domain.

domain	positive effect	no effect	negative effect
financial (n=16)	87% [21;24-35;41]	13% [22;42]	-
clinical (n=15*)	47% [21;22;29;31;34;35;42]	67% [24-33]	-
service (n=3)	67% [21;31]	33% [25]	-
process (n=3)	67% [24;35]	33% [30]	-
team (n=1)	-	-	-

*two studies reported both indicators with positive effects and with no effect in the clinical domain and the cumulative percentage therefore exceeds the 100%.

Discussion

Selection of articles

Of the 508 articles we have found, 59 were selected to read full-text. Finally only 23 were selected as relevant for this review. We have used a very sensitive search strategy, in order not to miss any publications. As a result, a majority of the articles (60%) did not concern adult patients undergoing elective gastrointestinal surgery.

The clinical pathways for gastrointestinal surgery found in this review are most frequently designed for colorectal or colonic resections. Most have a quasi-experimental design and sample size varied from smaller than 20 to greater then 800. Another review on a broad spectrum of clinical pathways in care showed similar results with regard to study design and sample size.[10]

Domains and indicators to evaluate clinical pathways

Most of the studied indicators are in the clinical and financial domain. This is consistent with the findings of other reviews on clinical pathways outside the gastrointestinal surgery

setting.[2;10] Commonly, one evaluates clinical pathways on their ability to decrease length of stay without any adverse effects on patient outcome. Therefore, besides length of stay, complication rates and re-admission rates are frequently assessed. Indicators like number of re-operations, admission on the intensive care unit and pain scores however are less often monitored.

Besides the frequently used clinical indicators such as complication rates and mortality, more specific indicators as time to defecate and time to return to enteral feeding or normal diet are reported. Time to defecate is an indicator of the return of bowel movement and therefore a useful indicator in gastrointestinal surgery. Time to return to enteral feeding or normal diet is commonly assessed in relation to clinical pathways which include fast track rehabilitation. One of the main interventions in this type of rehabilitation is an enforced or early postoperative oral nutrition.[22-25]

There seems to be limited attention for indicators in the process, team and service domain. Process indicators such as number of clinical examinations, appropriate use of antibiotics and completeness of documentation could be a good tool to monitor pathway compliance.[20;26] Indicators in the team domain could be a valuable tool to assess team satisfaction and interdisciplinary cooperation.[20] Also monitoring patient satisfaction is useful to determine whether there is (too much) pressure on patients to leave the hospital within a certain time span. In one study, 27% percent of the patients on the clinical pathway felt that they were discharged too early.[22]

Compared to the review by Van Herck *et al.* we find higher percentages of indicators in the financial and clinical domain and lower percentages in the process, service and team domain.[10] This can be explained by the fact that Van Herck reviewed a broad variety of clinical pathways in different settings, and we confined our review to hospital care and gastrointestinal surgery only.

Effects of the clinical pathways

In the majority of the controlled studies, that is, in 14 of the 16 controlled studies, a significant decrease in length of stay is found. Furthermore, these studies show no effect[19;21;27-33] or positive effects[24;29;31;34;35] on clinical outcome. This could imply that the quality of clinical care stayed at the same performance level while the efficiency was enhanced. In fact, none of the controlled studies report adverse effects in any of the domains of the Leuven Clinical Pathway Compass. However, to rule out adverse effects rigorously, one may need to monitor additional patient safety indicators such as the number of re-operations, pain scores and admissions to the ICU. This is only done in a small percentage (10-14% per indicator) of the studies[19;23;24;27;35-37].

The impact of a clinical pathway will depend on the goals of the project. When a team is only trying to improve the efficiency, we will not find improvements on clinical

quality of care or patient safety. Pathways are a method to achieve a result. They are a complex intervention to keep the structure, the multidisciplinary team process and the follow-up of the outcomes of a specific care process alive.[38]

Limitations of the review

Since the number of publications on clinical pathways for gastrointestinal surgery is low, we were not able to focus on one specific kind of gastrointestinal surgery. Although there are many similar components in clinical pathways for different types of gastrointestinal surgery, it has to be taken into account that patient groups as well as surgical procedures differ.

None of the studies we have found report negative effects of the clinical pathway. This may be due to publication bias: Studies with positive results are more likely to be published than studies with negative results. Also no longitudinal studies are performed. Hence, it is not known whether the reported positive results of the clinical pathways will sustain over time.

For practical reasons we have limited this review to studies in English, German or Dutch. However, in Japan clinical pathways are also frequently implemented into hospital care.[39] Unfortunately, many of the studies are only published in Japanese. As a result only four studies from Japan, published in the English literature, were included in this review.

Conclusion

There are many indicators that are used to evaluate the clinical pathways for gastrointestinal surgery. Besides the more common outcome measures like length of stay and complication rate, indicators such as time to return to enteral feeding or to normal diet and time to defecate are found. The literature suggests that implementation of a clinical pathway for gastrointestinal surgery can be regarded as a safe and effective method to decrease length of stay. However, more attention to indicators on patient safety is needed. Only a small percentage of the studies in this review monitor for example the number of re-operations, admissions on the ICU and pain scores. To prevent that each hospital uses their 'own set of indicators', it would be advisable that an international evidence based set of indicators is created for the evaluation of the effectiveness and patient safety of clinical pathways. Associations covering various medical disciplines and an organization like the European Pathway Association could assist in this process.[8] Such a set of indicators enables comparison of outcomes of clinical pathways between hospitals.

For a multidisciplinary team, the development of the pathway must not be the goal; clinical pathways must be seen as a complex method to achieve a result. This means

that multidisciplinary teams will have to report the changes in the organization of the care process they implemented. This information will be necessary to let the international community understand and further explore the impact of clinical pathways for gastrointestinal surgery.

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Appendix

Table with details on selected articles

First author, year of publication and journal name	Study design	Description	Study population
Andersen *et al.*, 2005, *Colorectal Disease*	O	Prospective non-randomized study, no control group	32 consecutive ileo-colic resections for Crohn's disease in 29 patients
Balcom *et al.*, 2001, *Archives of Surgery*	QE	Retrospective case series, comparison of patients in 3 periods according to the implementation of case management and clinical pathways	733 consecutive patients undergoing pancreatic resection for benign or malignant disease from April 1990 to March 2000
Basse *et al.*, 2000, *Annals of surgery*	O	Prospective after implementation of the 48-hour postoperative stay program, no control group	60 consecutive patients undergoing elective colonic resection, excluding patients with planned lower anterior resection, rectum extirpation and patients undergoing surgery for inflammatory bowel disease
Basse *et al.*, 2002, *Diseases of the Colon &Rectum*	O	Prospective study, no control group	27 consecutive patients scheduled for colostomy closure after Hartmann's procedure
Basse *et al.*, 2004, *Diseases of the Colon &Rectum*	QE	Retrospective and prospective study, the conventional care group was studied retrospectively	130 patients receiving conventional care after colonic resection in one hospital compared with 130 consecutive patients receiving multimodal, fast track rehabilitation in another hospital
Cerfolio *et al.*, 2004, *Chest*	O	Prospective after implementation of an algorithm, no control group	90 consecutive patients undergoing an elective Ivor Lewis oesophagogastrectomy by one general thoracic surgeon
Cohen *et al.*, 2003, *Transplantation Proceedings*	QE	Pre and post pathway measurements	11 patients undergoing liver transplantation prior to introduction of the clinical pathway and 14 patients after introduction of the clinical pathway
Delaney *et al.*, 2001, *British Journal of Surgery*	QE	Prospective study with a control group from another setting	60 consecutive patients undergoing complex abdominal and pelvic colorectal surgery on one colorectal service compared to patients receiving traditional care on other colorectal services during the same time period
Delaney *et al.*, 2003, *Colon & Rectum*	E	Prospective randomized controlled trial between a pathway of controlled rehabilitation and traditional postoperative care after laparotomy and intestinal resection, outcome measured at discharge and 10 and 30 days after surgery	64 patients undergoing laparotomy and intestinal or rectal resection, randomly assigned to pathway or traditional care, 31 pathway patients and 33 traditional care patients

Dy *et al.*, 2003, *Medical Care*	QE	Retrospective cohort study	a total of 10,960 admission eligible for 1 of 26 critical pathways implemented between 1990 to 1996, from 2 years before and 2 years after each pathway implementation date pathways for colon resection, distal pancreatectomy, hepaticojejunostomy, liver resection, Whipple and transhiatal esophagectomy
Hensel *et al.*, 2006, *Der Anaesthesist*	O	Prospective study, comparison with literature on conventional care for patients undergoing colon resection, no control group	208 consecutive patients, undergoing colon resection with fast track rehabilitation
Hirao *et al.*, 2005, *World Journal of Surgery*	QE	Non randomized prospective study	53 patients were in the patient controlled diet group and 50 patients were in the conventional regime group, all patients underwent distal gastrectomy for early gastric cancer
Hirasaki *et al.*, 2004, *Internal Medicine*	QE	Pre and post pathway measurements, with a retrospective control group	43 patients with early gastric differentiated adenocarcinomas up to 20mm in diameter and no ulcerations undergoing a endoscopic mucosal dissection with a insulated tip diathermic knife, 20 patients in the control group and 23 patients in the pathway group
Kawahara *et al.*, 2005, *International Surgery*	O	Prospective study after implementation of a clinical pathway, review of medical records and a 4 item structured questionnaire, no control group	52 patients undergoing laparoscopic colorectal surgery for colorectal cancer
Melbert *et al.*, 2002, *Journal of Gastrointestinal Surgery*	QE	Prospective with a control group and a telephonic survey for part of the patients about patient satisfaction	385 consecutive patients undergoing elective colon or rectal resection, 263 pathway patients and 122 non pathway patients, surgeons decided which patients followed pathway
Miller *et al.*, 2003, *Journal of Integrated Care Pathways*	O	Prospective, a pilot was started, staff satisfaction was assessed using a multiple-choice questionnaire, comparison to the results of previous pilot studies in other specialties in the same hospital and to a colorectal cancer clinical pathway in another hospital	Pilot with 13 patients with colorectal cancer in the pathway Staff satisfaction questionnaire was completed by 17 nursing staff, 4 (out of 6) doctors and 1 physiotherapist
Pearson *et al.*, 2001, *The American Journal of Medicine*	QE	Controlled prospective study with a two-year baseline period and also comparison between pathway intervention hospitals and non pathway hospitals	846 patients undergoing colectomy, 610 before pathway implementation and 263 after pathway implementation, for 68 of these patients the care was actually managed on the pathway (26%), physicians decided which patients followed the pathway
Porter *et al.*, 2000, *Annals of Surgical Oncology*	QE	Pre- and post pathway measurements	148 consecutive patients undergoing panceatico-duodenectomy, 68 patients pre pathway and 80 post pathway

Raue *et al.*, 2004, *Surgical Endoscopy*	QE	Prospective and controlled study design	52 consecutive patients underwent laparoscopic colorectal resection: 29 standard care patients and 23 fast-track patients
Stephen *et al.*, 2003, *Surgery*	QE	Pre- and post pathway measurements	138 patients undergoing colon resection, 52 patients pre and 86 post pathway, undergoing elective colonic resection by one surgeon
Tan *et al.* 2005, *Asian Journal of Surgery*	QE	Retrospective pre and post pathway measurements	408 patients, 204 pre and 204 post pathway, undergoing elective major colorectal surgery
Uchiyama *et al.*, 2002, *Surgical Endoscopy*	QE	Pre- and post pathway measurements, with a retrospective control group	281 patients undergoing laparoscopic cholecystectomy, 71 pre and 210 post pathway; 43 patients undergoing laparoscopically assisted gastrectomy with Billroth-I reconstruction, 10 pre and 33 post pathway; 45 patients undergoing laparoscopic ally assisted colectomy, 11 pre and 34 post pathway
Wichmann *et al.*, 2006, *Rozhledy v chirurgii*	QE	Prospective case-control study	24 patients undergoing surgery for pancreatic cancer, 12 patients received modified fast-track rehabilitation and their clinical course was compared with 12 age-, sex-, disease-matched control patients

O=observational study; E=experimental study; QE=quasi-experimental study

Chapter 7

Feasibility of preoperative therapeutic exercise training in patients with gastrointestinal cancer scheduled for elective surgery: A pragmatic pilot study

Submitted: Lemmens LC, de Knikker R, Kerkkamp HEM, Borel Rinkes IHM, van Hillegersberg R, Chorus AMJ, van Meeteren NLU

Abstract

Background People with cancer can suffer from fatigue, a decline in functional status and a decrease in quality of life. Due to these complaints, the physical activity level diminishes after diagnosis, and during treatment. Therapeutic exercise training has shown to be effective, during and after medical treatment, to increase functional capacity and quality of life in cancer patients. The aim of this pilot study was to, before designing a large randomized comparison, investigate the feasibility of specially designed preoperative therapeutic exercise training in patients recently diagnosed with gastrointestinal cancer and scheduled for elective surgery.

Methods Feasibility was evaluated by means of monitoring patient participation and adherence to the group training program, patient satisfaction and motivation, adverse events, and progress in cardiovascular fitness, general muscle strength, inspiratory muscle strength and inspiratory endurance.

Results Sixty-eight percent of eligible patients participated in the group exercise training program. Main reason for refusing to participate was travelling distance to the hospital. Adherence to the group training sessions was 84%. Participants were satisfied about the training program and would recommend it to others. A slight positive trend over time was observed for inspiratory muscle strength. No adverse events related to the exercise training were registered.

Conclusion The findings of this study indicate that preoperative therapeutic exercise training in patients with different severity of gastrointestinal cancer scheduled for elective surgery is feasible, appreciated, and safe. A subsequent, randomized trial, study seems justified and needed to quantify the true effectiveness of this training program.

Introduction

Patients diagnosed with cancer are known to suffer from fatigue, a decline in functional status and quality of life.[1-5] Because of these 'symptoms' patients tend to be less active and therefore the physical activity level of patients with cancer diminishes after diagnosis and during treatment.[6-8] Diminishment of activity has been demonstrated to result in losses of the functional capacity of the musculoskeletal, cardiovascular and respiratory systems.[9-11] These systems are central to achieving and maintaining functional independence. Moreover, the functional status of the musculoskeletal, cardiovascular and respiratory systems is a good predictor of postoperative outcome after a major life event like cancer surgery.[12;13] Low functional status has been shown to significantly increase hospital length of stay,[14;15] postoperative complications, morbidity and mortality rates after surgery.[14-17]

In cancer patients, therapeutic exercise training, during and after medical treatment, has shown to increase functional capacity and quality of life.[7;18-20] Furthermore, several studies showed preoperative physical therapy to be effective in increasing a patients' functional status, reducing postoperative pulmonary complications and reducing hospital length of stay, in patients who underwent a coronary artery bypass or abdominal aortic aneurysm procedure.[16;21-23] The question arises whether a specially designed preoperative therapeutic exercise program with individual home training and central group training sessions for patients, with gastrointestinal cancer undergoing elective surgery, is feasible and effective as well. Before designing a large randomized comparison, we performed a pilot study to address the feasibility of such intervention in these patients and to obtain insights in potential expected effects.[24-26]

Methods

Design, patients and setting

The present study involved an observational study in patients scheduled for surgery for gastrointestinal cancer in the University Medical Center Utrecht (UMCU), the Netherlands. In this pilot study patients that were indicated for gastrointestinal surgery were referred to a so-called Multi Strategy outpatient consult (see for detailed description below) by the oncology surgeons of the Department of Surgery of the UMCU. During this consult patients were enrolled into the therapeutic exercise training program. Both the Multi Strategy outpatient consult and training program were embedded in the preoperative phase of a clinical pathway for gastrointestinal cancer.

Consecutive patients were included in the study if they met the following criteria: age > 18 years, elective surgery with a minimal waiting time until surgery of at least

2 weeks, and a diagnosis for gastrointestinal cancer. Eligible patients also had to be proficient in the Dutch language. Inclusion of patients started in May 2006 and ended in June 2007.

The ethical committee of the UMC Utrecht permitted us to publish data of this study as long as data of patients were presented anonymously.

Intervention

The intervention was a preoperative therapeutic exercise training program.

Enrollment of patients into the training program. During the MUlti STrategy outpatient consult (MUST), which is a multidisciplinary consult in an outpatient clinic with a nurse practitioner (acting as case manager), a physiotherapist (PT), and a dietician, the PT enrolled patients into the training program. Therefore, the PT recorded demographic variables, performed functional diagnostics (muscle strength, pulmonary and cardiovascular function), screened the patients for co-morbidities and specific contra-indications for exercise training and recorded risk factors for the development of postoperative pulmonary complications (PPC's) known from literature.[15;27-29] Patients were given oral and written information about the purpose, content, and organization of the exercise training program, which consisted of group training sessions in a central training facility *and* individual training sessions at home (see description below). Theoretically, patients started the group training sessions within a week from the MUST visit and started individual training at home right away. Patients who were not able or willing to participate in the training program were encouraged to consult a PT in their home town and were encouraged to train at home; they were regarded as non participants.

Therapeutic exercise training program. The aim of the preoperative training program was to increase the functional capacity of the (1) musculoskeletal, (2) cardiorespiratory, and (3) respiratory system in the period the patient was waiting for oncology surgery, and to avoid the risks of overtraining and adverse events. The therapeutic exercise program took place in a group under supervision of an experienced PT, as well as individually by the patient at home (both described in further detail below). The PT and the patients themselves monitored progression and goals on a weekly basis in accordance with recommendations by Glasziou *et al.*.[30]

Group training sessions. A group training protocol (two days per week for two hour sessions) was designed to train the cardiorespiratory and musculoskeletal system. The cardiorespiratory exercise training component had a moderate-to-high intensity and was based on the guidelines by the American College of Sports Medicine.[31;32] Positive effects of exercise training for increasing cardiorespiratory endurance are reported for both low-to-

moderate as well as moderate-to-high intensity exercises.[6;33;34] Exercise training consisted of two sessions of 20-30 minutes either on a stationary bike, cross trainer, row-ergometer or treadmill, as preferred by the patient. Sessions were performed on 60-85% of the Heart Rate Reserve (HRR), calculated according to the Karvonen formula: $HR_{training} = HR_{rest} + (60\text{-}85\% \times (HR_{max} - HR_{rest}))$ (HR= heart rate per minute). The advantage of this method is that the exercise training is accustomed to the cardiorespiratory condition of each individual patient.

For the exercise training of the musculoskeletal system the Physical Rehabilitation Training Systems® (PRT-systems) of the International Academy of Sports Physiotherapy were used.[35] These systems are particularly useful to load a person in a short period with the right amount of weights, without having foreknowledge of one's maximum strength. During training, emphasis is primarily on technique and repetitions and not on the weight itself. After a try-out patients exercise in the system of extensive endurance training (PRT-system B). Aim of this system is to perform three series of 20-25 repetitions with 60-90 seconds rest between series. Within each series it is evaluated when coordination starts to become lost, as a result of which individuals always exercise in maximal repetitions. When repetitions are not within the optimum bandwidth (20-25 repetitions), weight is adjusted according to a protocol. When repetitions within the 3 series fall within the optimum bandwidth without adjustment of weights, one is considered to be stable within the system. When this is the case for 2 consecutive training days, one crosses over to the system of intensive endurance training (PRT-system C). Aim of this system is performing three series of 13-20 repetitions with 90-120 seconds rest between series.

Individual training at home. At home, patients trained the respiratory and the cardiorespiratory systems. Respiratory function is trained by increasing inspiratory muscle strength and endurance using the Threshold Inspiratory Muscle Trainer (Threshold IMT; Respironics New Jersy Inc, Cedar Grove, New Jersey, USA). The Threshold IMT is a device in which patients inspire against a threshold load whereas expiration is unimpeded. Patients were instructed to train 7 days a week, one 20 minutes session per day with the IMT. Patients started exercising at a resistance equal to 30% of their maximal inspiratory pressure (PI_{max}), which is assessed weekly during group training.[16] The resistance was increased incrementally based on the rate of perceived exertion (RPE) scored on the Borg scale.[36] If the patient experienced and rated a RPE of < 5, they had to increase the resistance of the Threshold IMT incrementally by 2 cmH_2O.[16] Patients were instructed to record daily resistance levels of the IMT during training as well as their RPE-score, and complaints and adverse events in a diary.[16]

Cardiorespiratory endurance was trained according to the Dutch Health Enhancing Physical Activity guidelines.[37] Patients were instructed to engage in 30 minutes of moderately

intensive physical activity for at least 5 – but preferably all – days of the week. Examples of these activities are walking and cycling at a brisk pace, heavy household work, jogging and other strenuous forms of exercise, and climbing a flight of stairs.

Data collection

The following baseline characteristics were recorded for each patient: age, sex, co-morbidities, ASA-class,[38] risk factors for the development of postoperative pulmonary complications,[15;28] lung function, cardiorespiratory fitness, general muscle strength, inspiratory muscle strength and inspiratory muscle endurance. The ASA-class, which indicates how high the risk on complications for a certain patient for undergoing anaesthesia and surgery is, was retrieved from the medical record of the anaesthetists.

Outcomes

Feasibility of the preoperative therapeutic exercise training program

The feasibility of the training program was evaluated by means of:

1) the percentage of eligible patients that participated in the group exercise training;
2) the comparison of the baseline characteristics of participants and non participants;
3) the Physical Activity Readiness Questionnaire (PARQ) and the Fatigue Severity Scale (FSS), both described in more detail below;
4) recording of reasons for not participating in the training program (selection bias);
5) registration of the number of days between the consult at the outpatient clinic of the surgeons, the MUST visit, the first attended group training, the last attended group training and the date of surgery for each patient;
6) the scoring of available and attended group training sessions for each patient that participated in the group training, to estimate adherence; and recording of reasons for missing training sessions for patients who did participate;
7) monitoring participant satisfaction and motivation with an anonymously completed questionnaire as formerly developed and used by Hulzebos *et al.*[16;22] that was administered after the training period but before surgery.

PARQ. The Physical Activity Readiness Questionnaire (PARQ) is a self-administered questionnaire to identify persons for whom low-to-moderate physical exercise may be contraindicated.[39] It consists of 7 questions about specific medical symptoms, medication use and diseases (yes/no) that could be a contraindication for physical activity. If one or more questions were answered with 'yes' the PT checked what underlying disease there was, whether patients were treated for it and whether this treatment was an actual contraindication for participating in the training program. If necessary, the PT was able to have the patient consult a medical doctor for thorough check of the specific item(s).

FSS. The Fatigue Severity Scale (FSS) is a self-administered questionnaire to assess fatigue in patients with chronic illnesses, which can also be used for cancer patients.[40-43] It consists of 9 questions about the impact of fatigue on a persons' daily life. Answers are scored on a 7 point scale with '1' strongly disagree and '7' strongly agree. Sum scores are ranging from 9 (no fatigue) to 63 (maximum fatigue). The cut-off point used for cancer patients for 'severe fatigue' is a sum score of 42 or higher.[40-43]

Preliminary effectiveness of the preoperative therapeutic exercise training program
The potential effects of the therapeutic exercise training program were evaluated by means of:

1) recording of any adverse events that occurred during the training program;
2) changes over time in cardiorespiratory fitness, general muscle strength, inspiratory muscle strength and inspiratory muscle endurance as described in more detail below; measurements were taken once a week during a group training session.

Cardiorespiratory fitness. Cardiorespiratory fitness was measured with the Åstrand-test.[44;45] The Åstrand-test is a sub-maximal ergometer bicycle test for the evaluation of a person's maximal oxygen uptake capacity ($VO2_{max}$). The measurement error amounts to about 10% of $VO2_{max}$, making the test particularly useful for evaluating training progress of individuals or groups. Participants were instructed to cycle for 6 minutes with a pedaling frequency of 50 RPM. Heart frequency had to be over 110 beats per minute (bpm) after one minute and between 130 and 170 bpm at the end of the test.[46] Workload during the test was determined by the PT on the basis of an estimation of a person's physical fitness level. The peak oxygen uptake was estimated on the basis of workload, sex of the participant and the mean heart frequency of the 5th and 6th minute of the test and subsequently adjusted for age and weight of the participant and expressed as $VO2_{max}$ (in $mL.kg^{-1}.min^{-2}$).

General muscle strength. General muscle strength is a composite score of grip strength, elbow flexor strength and knee extensor strength. Sarcopenia (the loss of muscle strength and mass during aging) can easily be evaluated with these measures and is a good predictor of mortality, morbidity, postoperative progress and hospital length of stay.[12;47-51] Grip strength was measured with the JAMAR dynamometer (Sammons Preston Rolyan, Bolingbrook, Illinois, USA), using the measurement protocol as described by Shechtman *et al.*.[52] Grip strength was measured three times bilaterally, values were converted in Newton. The mean score of all measurements was used as outcome measure. Measurement of grip strength using the JAMAR is a reliable method and is recommended for use in clinical practice.[53;54] Elbow flexor and knee extensor strength were measured with the MicroFet2 Hand Held Dynamometer (MicroFet2 HHD; Hoggan Health Industries, West Jordan,

Utah, USA), using the make test (doctor initiated method).[55;56] Elbow flexor strength was measured according to the protocol as described by Drolet *et al.*,[57] knee extensor strength was measured according to the protocol of Wang *et al.*.[58] Patients were instructed to perform a maximal contraction (minimally 5 seconds) and were verbally encouraged. A rest period of 15 seconds was allowed between measurements.[58] Three maximal voluntary isometric contractions were measured bilaterally; the mean score of all measurements was used as outcome measure. Make tests using the MicroFet2 HHD are a reliable method for strength testing.[55]

Inspiratory muscle strength and endurance. Inspiratory muscle strength, expressed as maximal inspiratory pressure (MIP) at residual volume, was assessed with the hand-held MicroRPM (Micro Medical/PT Medical, Leek, The Netherlands). The MIP is thought to mainly reflect the inspiratory muscle force and is a useful variable to assess when respiratory muscle weakness is thought to cause a low lung volume or hypoventilation.[59;60] Inspiratory muscle strength test was standardized according to the protocol by Clanton and Diaz and the ATS/ERS Statement on Respiratory Muscle Testing.[59;61] Five consecutive attempts were recorded, considering that the two highest values did not differ more than 10%.[59] The highest value obtained after 1 second of maximum effort against the occlusion ($Pi_{max)}$ and the mean value of the 5 consecutive attempts were recorded ($Pi_{mean)}$.[16] Inspiratory muscle endurance was assessed according to the incremental threshold loading principle[62], essentially using the protocol by Hulzebos *et al.*.[16] Patients inspired through a threshold valve, starting at 30% of the MIP. Resistance was increased incrementally with 8% of the MIP every minute. The peak pressure ($P_{m\text{-}peak}$) was defined as the maximum resistance that could be tolerated for 1 minute. Inspiratory muscle endurance was expressed as $P_{m\text{-}peak}$ $/Pi_{max}$ (%).

Data analysis

Data were analyzed with Statistical Package for the Social Sciences (version 14.0; SPSS Inc., Chicago, Illinois, USA). All collected data were checked for completeness and normality with the Kolmogorov-Smirnov test.

Patient characteristics and baseline FSS and PARQ scores were analyzed using descriptive statistics. Differences at baseline between patients that participated in the training program (participants) and patients that did not participate in the training program (non participants) were analyzed with the *t*-test or the Mann-Whitney U test. *P*-values<0.05 were considered statistically significant.

Mean time intervals between attending the outpatient clinic of the surgeons, the MUST, training sessions and date of surgery were calculated for participants and non participants, and the mean number of attended and available training sessions for

participants were calculated. Differences in mean time intervals between participants and non participants were analyzed with the *t*-test or the Mann-Whitney U test.

Preliminary effectiveness of the training program was analysed by scatter plots on training outcome measures to give an indication of the variation and trends in cardiorespiratory fitness, general muscle strength, inspiratory muscle strength and inspiratory muscle endurance at different time points in the patients that underwent the training program.

Results

Patients

One hundred and fifteen patients scheduled for elective surgery were screened by the physiotherapist during the Multi Strategy outpatient consult (figure 1). Of these, 10 were excluded from further analysis as they did not have gastrointestinal cancer.

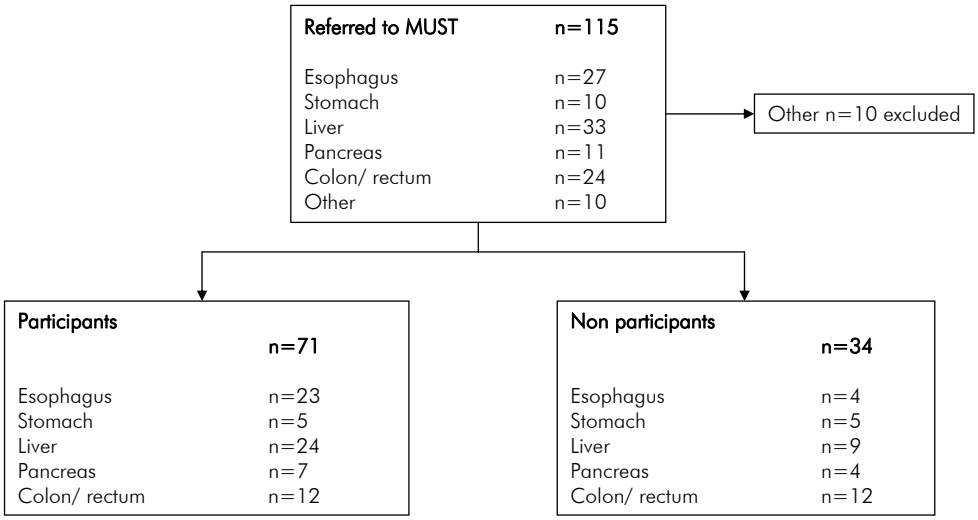

Figure 1 Flow diagram of the study participants

Feasibility of the preoperative exercise training program

Of the 105 eligible patients 71 (68%) participated in the training program, that is, participated in the group exercise training sessions and also individually trained at home with the Threshold IMT (participants). Thirty-four patients (32%) decided not to participate in the training program, they were advised to contact their local physiotherapist and to

train at home (non participants). Baseline characteristics of the patients are shown in table 1. Participants and non participants differed significantly in ASA-class and the travelling distance to the training facility. The baseline sum scores for the Physical Activity Readiness Questionnaire did not differ between participants and non participants (table 1) and both groups had a median of 1 (min-max: 1-4). With regard to the Fatigue Severity Scale participants and non participants both scored a mean sum score under the cut-off point for 'severe fatigue' (sum score of 42 or higher) and there was no statistically significant difference between the two means.

Main reason for not participating in the training program (n=34) was travelling distance (or time) between home and the training facility (44%). For 24% of the patients a reason for not participating was not recorded.

The mean (SD) number of days between the visit to the outpatient clinic of the oncology surgeons and the MUST was 14.4 (8.7) for the non participants and 10.3 (9.2) for the participants ($p = 0.003$). The mean (SD) number of days between MUST and day of surgery was 34.7 (20.3) days for the non participants and 33.6 (11.5) for the participants ($p = 0.77$).

Overall, the mean (SD) number of available group training sessions for participants from the start to the end of their individual training period was 7.7 (3.3), in which they actually attended a mean (SD) of 6.5 (3.0) training sessions. Adherence to therapeutic exercise training was estimated on 84%. Participants attended training sessions until on average 6.5 (6.3) days before their date of surgery. All participants recorded their daily Threshold IMT training in the provided diaries and the rating of perceived exertion on the Borg scale each day (100%).

Reasons for not attending group training sessions were twofold: On the one hand participants were not able to attend the sessions because of illness, because of other appointments in the hospital, or because they felt that the last training sessions were too close to the day of surgery; on the other hand the training facility was occasionally closed because of holidays or absence of the PT (due to other obligations or illness).

Forty-seven patients participating in the exercise training program returned the patient satisfaction questionnaire (table 2). Most of these patients qualified the exercise program as good to excellent and stated they were (very) motivated to participate in the group training sessions. More than half qualified the intensity of the training as heavy, but none qualified it as 'too heavy'. Two third qualified the duration of the training program as ideal, and two third reported to perceive an exercise effect. Eighty-one percent qualified training with other patients diagnosed with cancer to be (very) pleasant. All patients would advise other patients to participate in the therapeutic exercise training, and almost all would participate again themselves. Mean scores for the overall appreciation of the training program, satisfaction and motivation were 8.5 or higher.

Table 1 Baseline characteristics of the patients

	total group n=105	participants n=71	non participants n=34	*p*-value*
age (mean years ± SD)	64.6 ± 11.2	63.5 ± 10.1	67.0 ± 13.1	*0.065*
sex (% male)	60. 0	56.3	67.6	*0.268*
type of cancer (%)				*0.059*
esophagus	25.7	32.4	11.8	
stomach	9.5	7.0	14.7	
liver	31.4	33.8	26.5	
colon/rectum	22.9	16.9	35.3	
pancreas	10.5	9.9	11.8	
BMI (kg/m^2) ± SD)	25.8 ± 4.3	25.7 ± 4.0	26.0 ± 4.8	*0.495*
smoking (%)	17.1	18.3	14.7	*0.647*
COPD (%)	12.4	9.9	17.6	*0.343*
diabetes (%)	12.4	14.1	8.8	*0.541*
congestive heart failure (%)	36.5	38.0	33.3	*0.644*
ASA classification (%)				*0.046*
I	28.4	34.3	15.6	
II	61.8	60.0	65.6	
III	8.8	5.7	15.6	
IV	1.0	0	3.1	
PARQ sum score (mean ± SD; extremes 0-7)	1.0 ± 1.0	1.1 ± 0.9	0.94 ± 1.1	*0.398*
FSS total score (mean ± SD; extremes 9-63)	31.4 ± 13.8	29.9 ± 13.9	36.2 ± 12.6	*0.104*
predicted FEV_1 ± SD (%)	94.0 ± 20.4	95.9 ± 19.4	88.3 ± 22.7	*0.230*
predicted FVC ± SD (%)	97.1 ± 16.2	99.12 ± 16.3	91.1 ± 14.5	*0.075*
predicted FEV_1/FVC (%)	100.3 ± 12.3	100.9 ± 10.5	98.8 ± 16.7	*0.786*
predicted IVC (%)	93.9 ± 19.4	96.1 ± 19.7	87.3 ± 17.2	*0.082*
predicted MVV (%)	94.0 ± 20.4	96.0 ± 19.3	88.3 ± 22.7	*0.214*
cardio respiratory fitness (mean $ml.kg^{-1}.min^{-2}$ ± SD)	-	28.1 ± 5.4	-	-
general muscle strength (mean Newton ± SD)	833.6 ± 214.2	848.5 ± 217.3	799.7 ± 207.1	*0.380*
maximum MIP (mean cm H_2O ± SD)	82.4 ± 28.8	83.1 ± 27.3	81.5 ± 31.3	*0.954*
mean MIP (mean cm H_2O ± SD)	72.5 ± 26.5	72.8 ± 25.2	71.9 ± 28.6	*0.995*
inspiratory muscle endurance (mean cm H_2O ± SD)	35.0 ± 7.9	34.6 ± 8.4	36.6 ± 7.1	*0.793*
travelling distance to training facility (mean km ± SD)	30.0 ± 11.2	24.3 ± 16.5	41.8 ± 24.3	*< 0.001*

* Two-tailed ; n=number of participants; SD=standard deviation; BMI=body mass index; MIP=maximal inspiratory pressure; FEV_1=forced expiratory volume in 1 second; FVC=forced vital capacity; IVC=inspiratory vital capacity; MVV=maximal voluntary ventilation; ASA=American Society of Anaesthesiologists

Table 2 Participant evaluation of the preoperative exercise training

1.	What is your overall opinion of the exercise program?	
	Fairly good	15%
	Good	51%
	Excellent	34%
2.	How would you qualify the intensity of the exercise training?	
	Light	0%
	Ideal	43%
	Heavy	57%
3.	How would you qualify the duration of the exercise training?	
	Too short/short	15%
	Ideal	68%
	Too long	17%
4.	How would you qualify the supervision given by the physiotherapist?	
	Fairly good	7%
	Good	39%
	Excellent	54%
5.	How motivated were you?	
	Quitted prematurely	5%
	Neutral	10%
	Motivated	53%
	Very Motivated	32%
6.	Did you experience an exercise effect?	
	Yes	66%
	I don't know	32%
	No	2%
7.	How would you qualify the overall organization?	
	Fairly good	19%
	Good	59%
	Excellent	22%
8.	Would you participate again in preoperative exercise training?	
	Yes	93%
	I don't know	7%
9.	Would you advise other patients to participate in preoperative exercise training?	
	Yes	100%
10.	How would you qualify training in a group with other patients with cancer?	
	Awkward	2%
	Neutral	17%
	Pleasant	45%
	Very pleasant	36%
11.	Did you exercise more at home because of participating in preoperative exercise training?	
	Yes	31%
	I don't know	21%
	No	48%
12.	How would you rate the preoperative exercise training on a scale from 1-10 (1 = very bad, 10 = excellent)?	
	(Mean ± SD)	8.5 ± 0.86
13.	How would you rate your satisfaction with the preoperative exercise training on a scale from 1-10 (1 = very bad, 10 = excellent)?	
	(Mean ± SD)	8.6 ± 0.89
14.	How would you rate your motivation for preoperative exercise training on a scale from 1-10 (1 = very bad, 10 = excellent)?	
	(Mean ± SD)	8.6 ± 1.25

SD=standard deviation

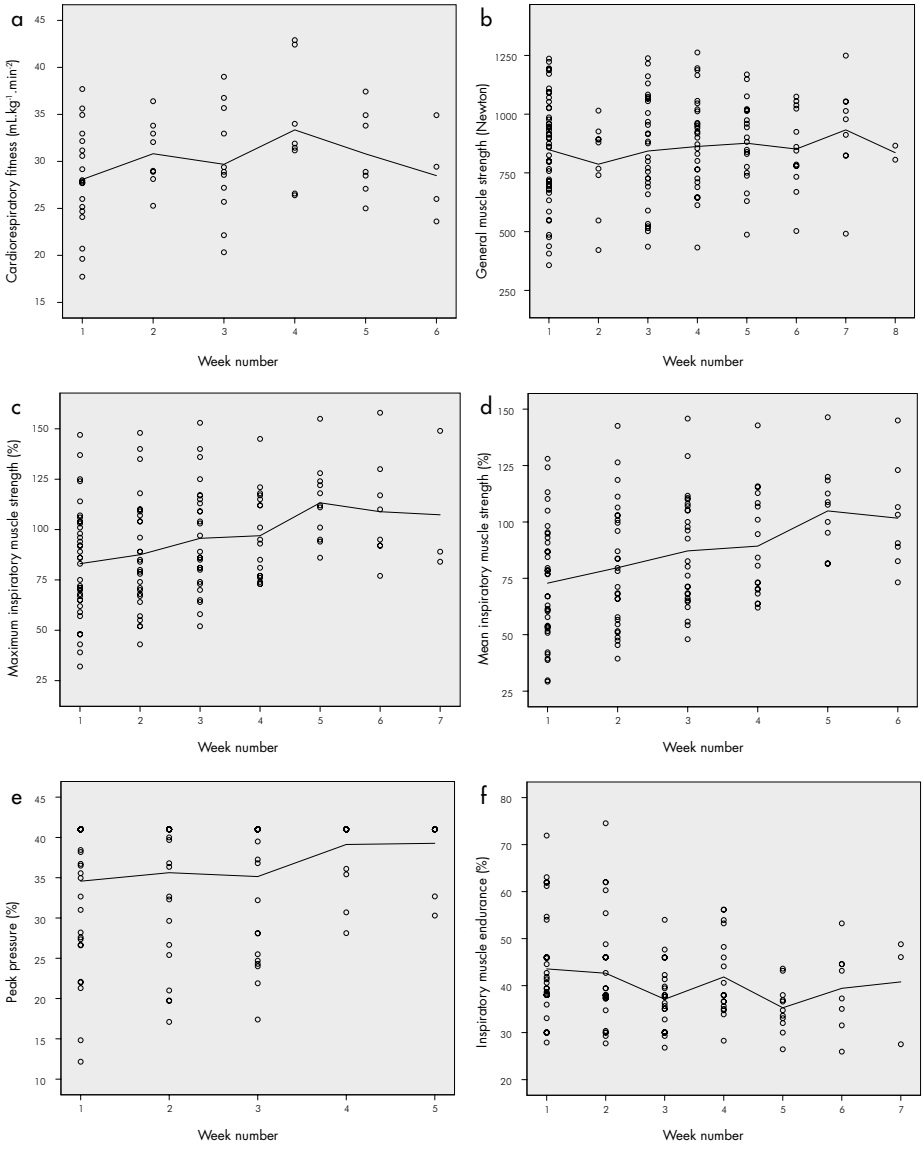

Figure 2a Cardiorespiratory fitness ($VO2_{max}$) of patients participating in the group exercise training (each dot represents a measurement of one patient; patients were measured once a week as long as they participated in the training program); *Figure 2b* General muscle strength of patients participating in the group exercise training; *Figure 2c* Maximum inspiratory muscle strength (Pi_{max}) of patients participating in the group exercise training; *Figure 2d* Mean inspiratory muscle strength (Pi_{mean}) of patients participating in the group exercise training; *Figure 2e* Peak pressure (Pm_{peak}) of patients participating in the group exercise training; *Figure 2f* Inspiratory muscle endurance (Pm_{peak}/Pi_{max})

Preliminary effectiveness of the preoperative exercise training program

One patient experienced a transient ischemic attack (TIA) during a group training session. Medical investigation by a neurologists showed that this TIA was related to a rare defect in the structure of the blood vessels in his brain. Three weeks later, after clearance by a neurologist, the patient participated in the group training sessions again.

For both the cardiorespiratory fitness (figure 2a) and the general muscle strength (figure 2b) no trend can be observed over time. For the maximal inspiratory muscle strength ($Pi_{max,}$ figure 2c) a slight positive trend was observed from the fourth measurement onwards. The mean inspiratory muscle strength (Pi_{mean}) and the peak pressure (Pm_{peak}) showed a similar trend (figure 2d and 2e). For the maximum inspiratory muscle endurance (Pm_{peak}/ Pi_{max}, figure 2f) such a trend was not observed.

Discussion

In recent years increasingly more attention is paid to the preoperative phase of surgical care and the possibilities of optimizing the patients' functional health status before surgery.[16;22;23;63] The findings of this study indicate that a preoperative therapeutic exercise training program in patients with gastrointestinal cancer scheduled for elective surgery is feasible. Patients appreciate the training program, and tolerate it well.

Feasibility of the preoperative exercise training program

The exercise training program seems to be feasible. Of the 105 eligible patients, two third participated in the exercise training program, that is, attended group training sessions and individually trained at home. The adherence to the group training sessions was high (84%) and the reasons for patients missing training sessions, e.g. having another appointment in the hospital, being ill, or feeling the last training session was too close before surgery, seemed legitimate. Patients especially appreciated the group training sessions and would recommend it to other patients. No adverse events related to the exercise training were registered. Most frequently mentioned reason for not participating to the training program was travelling distance. Patients that did not participate in the program actually lived on average almost double the distance from the training facility compared with patients that did participate.

Preliminary effectiveness of the preoperative exercise training program

In patients that followed the training program, a slight positive trend in the inspiratory muscle strength was observed from four weeks training onward. This progress is likely due to training at home using the Threshold Inspiratory Muscle Trainer (Threshold IMT), which

results in improved respiratory function and thus increased inspiratory muscle strength. Hulzebos *et al.*, found similar effects of training with the Treshold IMT (combined with deep breathing exercises) in patients undergoing Coronary Artery Bypass Grafting (CABG).[16] However, in contrast to the study of Hulzebos *et al.*, no training effect was found on inspiratory muscle endurance. A possible explanation is the 'ceiling effect' of the Threshold IMT, as it is originally designed for patients with COPD, who would normally score lower values of inspiratory endurance. Hulzebos *et al.* specifically trained patients with obstructive lung problems and we did not; in fact we probably trained a younger and fitter group of patients. We observed that many of our patients reached the maximum resistance of the Threshold IMT before they were exhausted.

Although, the physiotherapist consistently observed progress in weight lifts and increases in repetitions in series and sets of exercises, in most patients no positive trends were seen in the weekly measurements of general muscle strength and cardiorespiratory fitness. Not even the trend generally seen by only repeating such performance-test measurements regularly.[64;65] This leaves ample room for speculation on the intensity, frequency and duration of the training. Wisløff *et al.*, for example, showed for heart failure patients that a highly intensive aerobic interval training program had a superior cardiovascular effect over moderate continuous training.[66] This might be the case for our patient group as well, meaning that we have to adjust the intensity of the training program. It can also be argued that we have prevented a (further) decline in functional status where we looked for positive trends. The training would then have contributed to maintaining the functional status these patients started with when enrolled in the training program. Further investigation, however, seems legitimate either way, as several patients did show a positive trend in general muscle strength and cardiorespiratory fitness on an individual base, and of these the determinants for their success should be known, as well as its consequences on the postoperative course of recovery.

Limitations

As this was a pragmatic study, it reflects the daily practices of hospital care and subsequently organizational problems were encountered. We were not able to perform all measurements for all patients participating in the group training sessions. Furthermore, patients did not have the same number of training sessions available, as this was dependent on the number of days between their MUlti STrategy outpatient consult (MUST), their first training session, the availability of the training sessions, and the date of surgery. Although better compliance to the timeline of the clinical pathway, in which the MUST and the training program were embedded, would solve a part of this problem, it will probably be impossible and even medically undesirable to actually standardize the waiting time before surgery to warrant that each patient has the same number of training sessions available.

Due to study design, the limited number of patients and the medical heterogeneity of the patient group the results must be considered as indicative for the effects that can be achieved by implementing preoperative exercise training for patients with gastrointestinal cancer. Furthermore, the preoperative exercise training program was implemented as part of a multidisciplinary outpatient consult (the MUST) with a nurse practitioner (acting as case manager), physiotherapist and dietician and embedded in a clinical pathway. Therefore, it can never be estimated which aspect of the integrated intervention is truly responsible for any observed effect. This attribution problem has to be addressed in a proper manner.

Recommendations regarding the training program

Some issues need to be addressed regarding the feasibility and further optimization of the training program. Non participants belonged significantly more often to a higher ASA class, which indicates more co morbidity and less physical fitness. This implies that these non participating patients are likely to benefit more from the group exercise training than patients that were currently participating. To be able to enrol a higher percentage of patients, measures should be taken to include all eligible patients, including those with higher ASA class, and the exercise training program should be made available at local physical therapy practices as well. This would make it less strenuous for patients to participate in the training program, as they don't have to travel to a central training facility first to attend the group training sessions. With regard to the availability of the group training sessions, reasons for cancellation like absence of the physiotherapist and patients having to visit the hospital for other appointments should be addressed, to maximize the number of available and attended training sessions.

Recommendations regarding the outcome measurement and study design

With regard to measuring changes in the inspiratory muscle endurance, it would be advisable to develop a Threshold IMT with a threshold of 90 mm H_20 instead of the current 41 mm H_20 to be able to correctly measure the effect of the training program for patients that don't have pulmonary co morbidities.

The grip strength, elbow flexor strength and knee extensor strength, although these outcome measures are advocated by many authorities as good measures of general muscle strength,[12;47-51] possibly were not able to reflect the effect of the exercise training of the muscoskeletal system in a right way. Therefore, alternatives should be considered.

Patients with a higher risk profile might benefit more than those without co-morbidity. Hulzebos and colleagues have demonstrated the relative success of such a stratification approach, an approach most experienced physiotherapists would opt for.[16] On the base of a proper risk stratification tool those patients with a high risk profile should thus be included in future studies.

In this pragmatic pilot study we chose to monitor all outcome measures once a week. Glaziou *et al.* , however, showed that treatment monitoring is a very complex intervention and should preferably consist of five different phases according to the phases of the treatment the patient is experiencing.[30] He also advocated that time intervals of measurements should vary within these five phases. These advices should be taken into account when setting up a future trial. A randomized controlled trial or a cluster randomized controlled trial[67;68] would be the next step in determining the exact effects of the exercise training program on the preoperative functional status of the patients and its subsequent effects on postoperative outcome.

Conclusion

This study showed the feasibility of an exercise training program for patients with gastrointestinal cancer awaiting surgery. A subsequent, preferably randomized, study seems justified and needed to quantify the true effectiveness of this training program.

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Chapter 8

Implementation of a clinical pathway for esophagectomy with a preoperative multi strategy outpatient clinic

Submitted: Lemmens LC, de Knikker R, van Meeteren NLU, Moons KGM, Kerkkamp HEM, Borel Rinkes IHM, van Hillegersberg R

Abstract

Background The effect of the implementation of a clinical pathway (CP) for esophagectomy, with a MUlti STrategy outpatient consult and a therapeutic exercise training (MUST) in the preoperative phase, was evaluated. We hypothesized that this CP with MUST would result in better postoperative outcome, especially with respect to length of stay and pulmonary complications.

Methods An observational before and after study was performed. Patients of the MUST group were included prospectively and patients of the conventional care group (reference group) retrospectively.

Results Twenty patients were included in the MUST group and 40 patients in the reference group. The length of stay (LOS) on the intensive care unit (ICU) decreased significantly after implementation of the CP with MUST (*t*-test, $p<0.05$). After adjustment the ratio between means was 5.22 (95% CI: 2.59-10.55). The adjusted ratio between means for the total LOS (cumulative for all wards) was 1.43 (95% CI: 1.00-2.04). The most frequently observed pulmonary adverse event in the reference group was pneumonia (35%). In the MUST group the number of patients with pneumonia was 15%. The adjusted RR for pneumonia was 0.18 (95% CI: 0.03-0.81). Patients were satisfied about the CP with MUST.

Conclusion The effect of the implementation of the CP with MUST is positive in terms of improved postoperative outcome after esophagectomy.

Introduction

Clinical pathways or care pathways are a 'working method' in hospitals for the multidisciplinary decision making and organization of care for a well-defined group of patients during a well-defined period.[1] Their aim is to provide the right care, to the right patient at the right time by the right health professional. Clinical pathways are also a useful tool to implement new evidence based guidelines and perioperative interventions into hospital care, which are designed to increase quality by reducing variations in care.[2;3] At first, clinical pathways were designed for high volume and low complex surgery, such as total hip or knee surgery. Currently, clinical pathways are also used to increase quality of care for more complex surgery.[4-6] Esophagectomy is an example of such a complex surgical procedure with a high risk of adverse events, especially pulmonary complications.[7-9]

Furthermore, several recent studies have shown that preoperative interventions aiming to optimize the functional status of patients undergoing CABG surgery and upper abdominal surgery, result in reduced complication and mortality rates, and also in reduced length of hospital stay.[10-12]

We, therefore, implemented a preoperative multi strategy outpatient consult combined with an additional therapeutic exercise training program, both aiming to optimize the patients' pre and postoperative condition, into a clinical pathway for patients undergoing esophagectomy. The effects of using a multidisciplinary clinical pathway in these patients have been studied before, but not with addition of a substantial preoperative care component similar to ours.[3;13] We hypothesized that such an extended clinical pathway results in reduced postoperative adverse (notable pulmonary) events and length of stay.

Methods

Design, setting and patients

The present study involved a before and after study in patients scheduled for esophagectomy because of esophageal carcinoma in the University Medical Center Utrecht (UMCU), The Netherlands. The UMCU is a 1000-bed teaching hospital affiliated with the Utrecht University. It has a regional function with regard to performing esophagectomies, i.e. candidate patients from adherent (non academic) hospitals are all sent to the UMCU to undergo esophagectomy. The reference group included patients that underwent esophagectomy in the UMCU from January 2002 to August 2004, according to care as usual in that period. In January 2006 a clinical pathway for these patients was introduced (see below for detailed description). The index group thus included patients that underwent

esophagectomy between July 2006 and June 2007 in which this clinical pathway was applied as care as usual.

In each period, consecutive patients were included at their first visit for esophageal carcinoma at the outpatient clinic of the department of surgery, run by gastro-intestinal oncology surgeons. Patients were excluded if they were a priori not deemed suitable for surgery (e.g. patients with metastasis already detected before surgery).

In both periods, all esophagectomies were performed by 4 experienced gastro-intestinal oncology surgeons. Three different surgical techniques were used, either robot-assisted (Da Vinci™, Intuitive Surgical, Inc, Sunnyvale, California, USA) thoraco-laparoscopic esophactomy, open transhiatal esophagectomy or open transthoracic esophagectomy.[14-16]

The ethical committee of the UMC Utrecht permitted us to publish data of this study on our request as long as data of patients were presented anonymously.

Conventional care (reference group)

Patients operated in the period from January 2002 to August 2004 received conventional preoperative care, i.e. preoperative care according to the needs of the patients as determined by the practicing physicians. Patients were not systematically subjected to any clinical pathway or (multidisciplinary) interventions to enhance their functional status before surgery.

Intervention (index group)

Patients operated from July 2006 until June 2007 systematically underwent preoperative care according to the implemented clinical pathway. Specified tasks of all involved professionals had to be fulfilled at designated time points. A time-task matrix served as a blueprint for the preoperative pathway (see Appendix for details).

In brief, all patients visited, approximately one week after their visit to the surgical outpatient clinic, a multidisciplinary outpatient clinic for a so-called MUlti STrategy consult (MUST). During this consult patients were consecutively screened by a case manager (a nurse practitioner specialized in oncologic care), a dietician and a physiotherapist. They informed and advised patients about their diet, physical exercise and expected recovery. The physiotherapist also screened patients for known risk factors for postoperative pulmonary complications and enrolled them into preoperative therapeutic exercise training. Here, patients trained in groups (2 times a week) and individually at home (7 times a week) and were monitored by the physiotherapist. Patients trained on average 4 weeks, until they went for surgery. At home, patients trained the respiratory function by increasing inspiratory muscle strength and endurance using the Threshold Inspiratory Muscle Trainer (Threshold IMT; Respironics New Jersy Inc, Cedar Grove, New Jersey, USA). The exact training protocol was previously described[10-12;17]

Outcome parameters

The following outcome parameters were measured in each patient: (1) length of hospital and ICU stay; (2) adverse events, (3) re-admissions and (4) re-interventions.[18;19]

1) Total length of in hospital stay (LOS) was calculated in days as date of discharge minus date of admission. For the three patients that were transferred to another care institution for further rehabilitation, the waiting time for their admission to this care facility was subtracted from the total LOS, as waiting lists for these care institutions can substantially influence in hospital LOS. LOS was also separately calculated for the intensive care unit (ICU). Length of stay on the ICU reflected the total number of ICU days and could concern one or more ICU admissions (in case of readmission to the ICU during the same hospital stay).
2) The occurrence (yes/no) of any adverse event including death, myocardial infarction, arrhythmias, anastomotic leaks, wound abscesses, chylothorax, anastomotic stricture, thrombus in a large blood vessel, sepsis or a pulmonary adverse event. Pulmonary adverse events included atalectasis, respiratory insufficiency, pulmonary edema, pneumo thorax, pleural empyema, Acute Respiratory Distress Syndrome (ARDS), pleural effusion, exacerbation of COPD, and pneumonia.[20] Pneumonia was also scored separately, as it is one of the most common pulmonary adverse events after esophagectomy, and had to be confirmed by either X-ray or bacterial culture.
3) Re-admission was defined as re-admission to the UMCU within 30 days of discharge to home. Patients transferred to other care institutions for rehabilitation were not considered as re-admitted.
4) Re-interventions were defined as any additional surgical procedure performed after the initial esophagectomy.

Finally, in patients in the index (MUST) group we measured satisfaction using a questionnaire designed by the researchers for the current study. The questionnaire was sent 30 days after discharge. Main items concerned satisfaction about the (social) treatment by the health care professionals, the communication with and between the professionals, the timing and completeness of patient information, and their experiences with the MUST.

Confounders

Although there were no reasons to assume that patients in the reference period were substantially different from patients operated in the index period, we measured and adjusted several potential confounding factors, also because the number of study subjects in this initial pilot study was relatively small. These confounders included age, gender, ASA class, pulmonary co-morbidity, smoking, BMI, diabetes and type of surgery.[7;21] Due to small numbers ASA class was dichotomized to ASA I versus ASA II/III/IV. Pulmonary co-morbidity included COPD and asthma. Type of surgery was categorized as thoraco-laparoscopic

esophagectomy versus open esophagectomy (including both transhiatal esophagectomy and transthoracic esophagectomy). The latter two procedures were combined as they are considered evenly more invasive than a thoraco-laparoscopic procedure and as they have comparable outcome.[14;15]

Data analysis

SPSS release 16.0 was used for the statistical analysis. We first compared the index and reference group on the potential confounding factors using the Fisher's Exact test for categorical variables or the *t*-test or Mann-Whitney test for continuous variables that were normally or non-normally distributed, respectively. As length of stay was not normally distributed we applied a log-transformation and compared the difference in mean log(LOS) between both treatment groups using the unpaired *t*-test. Subsequently, multivariable linear regression on the log(LOS) was used to adjust this mean difference for potential confounders. With regard to the dichotomous outcomes (adverse events, re-admissions and re-interventions) the relative risk with 95% confidence interval was calculated. Multivariable logistic regression analysis was then used to adjust the association between intervention and outcomes for potential confounders and subsequently transformed to adjusted Relative Risk (RR) using the formula of Zhang *et al.*.[22]

Results

Patients

Twenty patients were included in the index (MUST) group and 40 in the conventional care or reference group. Patient characteristics of both groups are summarized in table 1. In the MUST group significantly more patients underwent robot-assisted thoraco-laparoscopic esophagectomy. Furthermore, groups also slightly differed, though not significantly, for gender and pulmonary co-morbidity.

Postoperative outcomes

Length of stay. LOS on the ICU was significantly lower in the MUST group compared to the reference group (table 2). After adjustment for above mentioned confounders the ratio between two mean log(LOS) was 5.22 (95% CI: 2.59-10.55), implying that the mean LOS on the ICU was five times shorter in the index group. For total LOS, this adjusted mean ratio was 1.43.

Table 1 Distribution of the patient characteristics and potential confounders across both groups.

	conventional care (n=40)	MUST (n=20)	*p*-value
	n (%)	n (%)	
- age (in years)	63 (±9.1)[1]	62 (±9.0)[1]	*0.74*
- male gender	26 (63%)	14 (75%)	*0.33*
- ASA I	15 (38%)	9 (45%)	*0.58*
- pulmonary co morbidity	4 (10%)	4 (20%)	*0.42*
- smoking	9 (23%)	3 (15%)	*0.49*
- diabetes	4 (10%)	2 (10%)	*1.00*
- BMI (in kg/m^2)	26 (±4.0)[1]	25 (±2.8)[1]	*0.58*
- robot-assisted thoracolaparoscopic esophagectomy	14 (35%)	15 (75%)	*0.02*

[1] mean (±SD)

Table 2 Comparison of length of ICU and hospital stay (in days) between both groups.

		ICU	total
		(days)	(days)
conventional care (n=37)	median (25th; 75th)	8.5 (3.0 - 27.25)	26.5 (16.25 - 40.75)
	geometric mean (95% CI)[1]	8.93 (5.95 - 13.39)	27.62 (22.76 - 33.53)
MUST (n=20)	median (25th; 75th)	1.0 (1.0 - 2.0)	18.0 (13.0 - 25.0)
	geometric mean (95% CI)[1]	1.69 (1.12 - 2.55)	20.50 (15.79 - 26.61)
ratio between	unadjusted	5.28 (2.80 - 9.94)	1.35 (1.03 - 1.86)
geometric means	adjusted[2]	5.22 (2.59 - 10.55)	1.43 (1.00 - 2.04)

[1] geometric mean: Exp (natural log of mean length of stay)
[2] ratio adjusted for type of surgery, pulmonary co morbidity and gender
ICU=intensive care unit

Adverse events. The number of patients with any adverse event was 55% in the MUST group compared to 80% in the conventional care group: adjusted RR = 0.60 (95% CI: 0.23-0.99, table 3). For pulmonary adverse events this was 65% and 45%, respectively (adjusted RR = 0.55; 95% CI: 0.20-1.04). For pneumonia the adjusted RR was 0.18 (95% CI: 0.03-0.81) in favor of the MUST group. In the conventional care group 6 patients died during admission; in the MUST group no patients died.

Table 3 Comparison of complications, re-admissions and re-interventions across both groups.

	n (%)	crude RR (95%CI)	adjusted RR (95%CI)[1]
any adverse event			
- conventional care	32 (80%)	1.0	-
- MUST	11 (55%)	0.69 (0.45 - 1.05)	0.60 (0.23 - 0.99)
pulmonary adverse events			
- conventional care	26 (65%)	1.0	-
- MUST	9 (45%)	0.69 (0.41 - 1.18)	0.55 (0.20 - 1.04)
pneumonia			
- conventional care	14 (35%)	1.0	-
- MUST	3 (15%)	0.43 (0.14 - 1.32)	0.18 (0.03 - 0.81)
re-admissions			
- conventional care[2]	4 (12%)	1.0	-
- MUST	2 (10%)	0.85 (0.15 - 3.39)	0.59 (0.09 - 3.06)
re-interventions			
- conventional care	8 (20%)	1,0	-
- MUST	5 (25%)	1.25 (0.47 - 3.33)	1.21 (0.36 - 2.86)

[1] RR adjusted for type of surgery, pulmonary co morbidity and gender

[2] Readmission was not scored for patients that died during the first admission (n=6)

Re-admissions and re-interventions. In the index group 10% of the patients were re-admitted within 30 days after discharge compared to 12% in the conventional care group, yielding an adjusted relative risk of 0.59 (table 3). For re-interventions these numbers were 25% and 20%, respectively (adjusted RR = 1.21).

Patient satisfaction

Patients in the MUST group were in general satisfied about the way they were treated (socially) by the health care professionals (table 4). The communication between the case manager and surgeon as well as between different health care professionals was perceived as good by almost two third of the patients. Although the timing was perceived as good, about a third of the patients experienced a hiatus in the provided information. Information that was lacking varied from information about home care to information about social support after hospital discharge. Patients were satisfied about the MUST and perceived it as meaningful. They did not mind the extra visits to the hospital for the training.

Table 4 Perceived satisfaction of the patients in the MUST group.

	MUST (n=14)
patients that….	n (%)
general questions about received care	
- perceived the contact with the case manager (NP) as good to excellent	13 (93%)
- perceived the contact with the surgeon as good to excellent	11 (79%)
- perceived the time and attention that was paid to his/her feelings as good	11 (79%)
- perceived the communication between the case manager (NP) and the surgeon as good	9 (64%)
- perceived the communication between different health professionals as good	9 (64%)
- agreed that the information was given at the right moment	14 (100%)
- did not miss anything in the information given	9 (64%)
specific questions about the MUST intervention	
- was satisfied to very satisfied with the MUST	13 (93%)
- did not make a problem of the necessary extra visits to the hospital	13 (93%)
- perceived the MUST with training as meaningful	14 (100%)

Discussion

The findings of this study indicate that for patients scheduled for esophagectomy, a clinical pathway including an outpatient preoperative Multi Strategy consult complemented by therapeutic exercise training, can result in a decrease in length of stay on the intensive care unit and in the number of adverse events. Furthermore, patients are satisfied about undergoing this specific preoperative care.

Postoperative outcome

Various studies in other surgical patient groups have shown that preoperative therapeutic exercise training, not implemented in a clinical pathway, enhances the patient's functional status before surgery and thereby improves postoperative outcome.[10-12] Furthermore, other studies showed that preoperatively screening and intervening on nutritional status and preoperatively providing advices on expected recovery, can improve the patients' condition and thereby postoperative outcome.[23-26] Hence, in the present study we combined all the above aspects (instructions for exercises and training by a physiotherapist, dietary advises of a dietician and guidance and education regarding postoperative recovery from a case manager specialized in oncology care) and implemented them into the preoperative phase of a clinical pathway for patients undergoing esophagectomy. With this multifaceted preoperative intervention, we found a significant decrease in length of stay on the intensive

care unit of about five times compared to conventional preoperative care. Given the multidisciplinary approach of our intervention it can never be sure which aspect is largely responsible for this decrease, but given the results of other studies, it is likely due to the intensive preoperative therapeutic exercise training which results in a better functional status of the patient.[10;11]

Pulmonary adverse events are a major problem in esophagectomy.[8;9] With the implementation of our clinical pathway extended with the preoperative multi strategy consult and exercise training, the number of patients with pneumonia decreased significantly, yielding an adjusted risk ratio of 0.18 (95% CI: 0.03-0.81). This is likely due to the preoperative exercise training using the Threshold Inspiratory Muscle Trainer (Threshold IMT), which results in improved respiratory function and thus increased inspiratory muscle strength and endurance. Hulzebos *et al.*, found similar effects of training with the Treshold IMT on the incidence of pneumonia in patients undergoing Coronary Artery Bypass Grafting.[10]

Recent reviews show that only a limited number of studies on clinical pathways assessed patient satisfaction, despite the fact it is a valuable indicator of the perceived service by patients.[18] Generally, the patients' opinion about our intervention is very positive. However, the communication between the surgeon and the case manager and between other health care professionals can still be improved, as well as the completeness of the information that has been provided to patients. Prompted by this finding, we have now implemented written information for patients and guidelines on communication for health care professionals in the clinical pathway.

Limitations

As this study should be considered as an initial or pilot study, several issues require additional attention. Due to the limited number of patients and despite the sometimes large effects, the results must be considered as indicative for the effects that can be achieved by implementing a clinical pathway added with a multi strategy consult and preoperative exercise training. A larger study is needed to quantify the effects with more precision. Furthermore, for this initial study we explicitly used (given available number of patients undergoing this complex surgery each year) a before-after study rather than a parallel randomized design. With such design, changes in care over time and differences in patient characteristics between the two groups may always confound the observed results. Although we tried to overcome this as much as possible using adjusted analysis for each study outcome, we recommend that a multi-center parallel-randomized study is the advocated design for subsequent evaluations. A larger study may also allow insights to which specific subgroups benefit most from the multi strategy approach. Finally, we explicitly chose to study a multifaceted preoperative intervention. Using such a pragmatic study approach it can never be told which aspect

of the intervention is truly responsible for the observed effects. This was not out intention. If one would like to study separate aspects of our intervention, one should make the two study groups alike to the other aspects of the intervention.

Conclusion

The effects of the implementation of a clinical pathway for esophagectomy including a multidisciplinary outpatient consult and training in the preoperative phase are promising in terms of improved postoperative outcome and decreased length of ICU stay.

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Appendix

Table A Description of the preoperative phase of the clinical pathway for esophagectomy

professional	first outpatient clinic visit	MUST visit
case manager (NP)	• meets patient • informs patient about MUST outpatient clinic • informs patient about OPE clinic	• informs patient about type of surgery • informs patient about diagnostic tests • informs and advises patient about possible side effects of surgery • informs patient about expected recovery
surgeon	• medical examination • evaluates test results • discusses test results and planned treatment with patient • informs patient about MUST clinic • informs patient about OPE clinic • enters patient for surgery	
physiotherapist		• screens physical condition of patient • informs patient about training program • enrolls patient into training program
dietician		• screens on malnutrition • informs and advises patient about diet • starts dietary intervention if necessary
anaesthetist		

NP= nurse practitioner; MUST= Multi strategy outpatient consult; OPE= outpatient preoperative evaluation

OPE clinic visit	second outpatient clinic visit	day of surgery
	• informs patient about type of surgery • informs patient about diagnostic tests • informs and advises patient about possible side effects of surgery • informs patient about expected recovery	
	• evaluates diagnostic tests, informs patients about results • informs patient about treatment plan	• performs surgery • informs family after surgery
• screens patient for risk factors for anesthesia • informs patient about anesthesia techniques		• receives patient • performs anesthesia

Chapter 9

General discussion

In this thesis the implementation of two different strategies for improving preoperative care are studied. One concerns the implementation of outpatient preoperative evaluation clinics (OPE clinics, chapter 2 to 4) and the other concerns the implementation of specific preoperative interventions in clinical pathways for gastrointestinal surgery (chapter 5 to 8). Both strategies aim to preoperatively optimize the patients' condition before undergoing surgery, to improve postoperative outcome. First, we start with a very brief overview of our results on the implementation of the two strategies. Then, we discuss the implications for the future of preoperative care.

Outpatient preoperative evaluation clinics

It has been proven that an OPE clinic is cost-effective and improves quality of care.[1-4] Accordingly, two Dutch national guidelines were issued, in 1997 and 2002, regarding the preferred organization and content of preoperative evaluation.[5;6] We found that the national guidelines may have been positively influencing the implementation process of the OPE clinic, as anaesthetists were found to be motivated to conform to these guidelines (chapter 2 and 3). Moreover, when the anaesthetists were motivated sufficiently to implement an OPE clinic according to these guidelines, an OPE clinic could be implemented even with limited resources (chapter 2 and 4). Most of the Dutch hospitals nowadays have implemented an OPE clinic.[7-9]

Clinical pathways for gastrointestinal surgery

Until now there are few international studies on the content and effectiveness of clinical pathways for gastrointestinal surgery (chapter 5 and 6). The focus of the clinical pathways for gastrointestinal surgery described in literature is mostly on improving intra and post operative care to enhance postoperative outcome, thereby following the Enhanced Recovery After Surgery (ERAS) protocol (chapter 5).[10] Preoperative interventions that can improve postoperative outcome, like physical exercise training and reduced preoperative starving, are studied in a very limited number of studies. Furthermore, indicators used in studies for evaluation of the effectiveness of clinical pathways for gastrointestinal surgery are often limited to the obvious outcome measures like length of stay and complication rates. Whereas process outcome measures and patient satisfaction would be valuable indicators as well (chapter 6).

The preoperative outpatient MUlti STrategy consult (MUST) with additional therapeutic exercise training, as we embedded in a clinical pathway for esophagectomy to improve postoperative outcome, is a local initiative which is still struggling for a place in regular care. Our pilot study indicates that for patients undergoing esophagectomy the Multi Strategy consult with additional exercise training is feasible (chapter 7) and the mean length of stay on the intensive care unit and pulmonary complication rates may be

decreased (chapter 8).

However, our feasibility study showed that, although patient satisfaction and the adherence to the group training sessions are high, the process, that is, the compliance to the timeline of the clinical pathway, is still not optimal (chapter 7). Additionally, randomized studies are needed to validly quantify the effects of the Multi Strategy consult with therapeutic exercise training with sufficient precision (chapter 7 and 8).

The future of preoperative care

Integrating the OPE clinic and a Multi Strategy consult with additional exercise training
In our study, patients on the clinical pathway for esophagectomy were screened four times by four different health professionals, that is, by the anaesthetist at the OPE clinic and by the nurse practitioner, the dietician and the physiotherapist at the MUST. Based on our results and the literature, we believe that a next step in the improvement of the preoperative care process is enhanced integration of the four screening moments. This could ultimately lead to one single screening moment performed by one health professional collecting all relevant information for the other health professionals involved as well. This can be achieved by using a protocol for the preoperative evaluation that consists of valid screening instruments for not only medical condition, but also for physical functional status, nutritional status and psychosocial status. A nurse practitioner acting as a case manager or an anaesthesia nurse could perform this screening and register the results of the screening into a shared multidisciplinary electronic medical record (both after elaborate training by an anaesthetist). This integrated preoperative screening could be embedded into the clinical pathway for esophagectomy and would be less aggravating to the patients, as they are only screened once at the OPE clinic. Moreover, it would result in a thorough screening, as all important aspects of a patients preoperative condition are directly covered. Subsequently, as more information on the patients' condition is accumulated, more tailored interventions to improve the preoperative condition of these patients are possible.

Clinical pathways as a framework for implementation of new interventions in care
In our opinion, clinical pathways should be regarded as a method to improve the quality of hospital care. Clinical pathways are a useful tool to streamline the care process in all phases of perioperative care. It forces health professionals to reconsider their role and their actions in the care process, and adapt them to current insights in medicine. Furthermore, it becomes apparent which duplicates and gaps exist in the current care process.[11;12] When clinical pathways are implemented, they provide a framework in which new evidence based guidelines and health care interventions can be incorporated.

In our study the clinical pathway for esophagectomy facilitated the implementation of the Multi Strategy consult with additional exercise training into the preoperative care process, as it provided a solid framework in which all steps of care were already defined. Furthermore, all professional parties necessary to successfully implement the MUST already worked together in the clinical pathway and were aware of their specific role in the care process. We think that for gastrointestinal surgery, and also for other types of complex surgery such as cardiothoracic surgery, preoperative as well as intra operative and postoperative interventions to improve postoperative outcome, could be best implemented in an existing clinical pathway or as part of a developing clinical pathway. However, especially when implementing new interventions within a clinical pathway, one should be aware that a clinical pathway itself is merely the vehicle to lead to improved care and thus improved patient outcome.

Indicators for evaluation of interventions in clinical pathways

Constant monitoring of the implementation process, care process and postoperative outcome should warrant that any (new) intervention embedded in a clinical pathway for any type of surgery, is improving quality of care without comprising patient safety. Indicators as defined in the Leuven Clinical Pathway Compass and as found in our review (chapter 6) are useful for this aim.[13] In our opinion, besides the more surgery specific indicators such as time to return to enteral feeding and time to defecate, indicators such as length of stay, mortality, complication rates, the number of re-operations, intensive care admissions and pain scores should be monitored more consistently when implementing new interventions. Moreover, team satisfaction and process indicators, like the number of clinical examinations, or appropriate use of adjuvant therapies, can provide useful information with regard to the effectiveness of the implementation process.[14]

When deciding on the set of indicators to evaluate the effectiveness of interventions implemented in a clinical pathway one should think about the study design for evaluation as well. Without a well chosen comparative, preferably randomized, study design, the monitoring of the chosen indicators will not provide the information needed or one will make false assumptions about the effectiveness of the implemented interventions.

Multidisciplinary guideline for preoperative care

Not only patients undergoing esophagectomy or other gastrointestinal surgery will profit from multidisciplinary preoperative care, but any type of surgical patient. To guarantee that every patient is thoroughly prepared for undergoing surgery, by screening and optimizing his or her preoperative condition, development of a multidisciplinary guideline for preoperative care in general would be advisable. Momentarily, a national multidisciplinary guideline for preoperative care for all surgical patients is developed by several national

scientific institutions on quality of health care under guidance of the Dutch Institute for Healthcare Improvement (CBO). However, this specific national guideline focuses more on the organizational aspects and competences of preoperative care and less on specific medical content. Therefore, parallel to this merely organizational guideline of the Dutch Institute for Healthcare Improvement, a guideline on the preferred (medical) content of preoperative care may be developed. Ideally, it includes modules for each element of the preoperative care process, such as a screening module, a physical therapeutic module and a dietary module, as we studied in this thesis. This modular approach can facilitate the implementation process, as it allows health care professionals to select and implement only those modules that are relevant for a specific type of surgical patient or even a specific individual patient.

For the outpatient preoperative evaluation clinics, we found that the national guidelines issued by the Dutch Health Council and the Netherlands Society of Anaesthesiology had a positive effect on the implementation process (chapter 3). Therefore, we expect that a multidisciplinary national guideline on the preferred medical content of preoperative care, which is developed in cooperation with all health care professionals involved, will also have such positive effects on the adaptation of hospitals.

Conclusion

In this thesis various strategies to improve preoperative hospital care are discussed. To be able to achieve further improvements in preoperative care, one should think carefully about integrating elements of the different preoperative strategies, like the outpatient preoperative evaluation clinic and Multi Strategy consult with additional exercise training. The latter however, has yet only been tested in a pilot study in gastrointestinal surgery patients. It first requires a more rigorous evaluation in a larger randomized study. The implementation of these integrated preoperative strategies can subsequently be facilitated by making use of clinical pathways and/or national multidisciplinary guidelines. Furthermore, the effects of this implemented integrated preoperative care should be constantly evaluated by using the right set of indicators and rigorous study designs.

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Summary

About 1.5 million Dutch people are scheduled for surgery each year. The care process built up around surgery can be divided into 3 phases: the preoperative, the intra operative and the postoperative phase. The contents and organization of the preoperative phase have gained increasing attention over the past decade. Several strategies have emerged to evaluate and optimize patients before surgery, aiming to minimize the risk of intra and postoperative complications (chapter 1, general introduction). In this thesis the implementation of two different strategies for preoperative risk-assessment and optimization was studied. These two strategies were outpatient preoperative evaluation clinics (OPE clinics) run by anaesthetists, and specific preoperative interventions embedded in a clinical pathway for gastrointestinal surgery.

Preoperative evaluation performed by anaesthetists primarily aims to estimate the risk of perioperative complications and to create opportunities to optimize the patients' condition before surgery. A nationwide study among all Dutch hospitals was conducted to determine the current content and organization of preoperative evaluation and to determine which factors facilitate or limit the implementation of OPE clinics. First, after defining the potential facilitating and limiting factors, based on extensive literature research, we empirically tested the presence or absence of these factors in nine specifically selected hospitals (three with a complete, three with a partial and three without OPE clinic) (chapter 2). This was done by means of face-to-face interviews with representatives of five different parties involved in the implementation of OPE clinics. These parties were: the board of directors, the medical staff, anaesthetists, internists and surgeons. Financing and motivation (cooperation) were mentioned as major factors influencing the implementation of an OPE clinic. Underlying problems that were mentioned were budget transfer between specialists, loss of income and turf battles. Logistic and organizational preconditions were mentioned as important factors for the successful implementation of an OPE clinic as well.

Based on the results of the interviews, a written questionnaire was developed on the current organization of preoperative evaluation and on the influence of the national guidelines on the implementation process of OPE clinics. The respondents were, again, members of the board of directors, members of the medical staff, anaesthetists, internists and surgeons. The written questionnaire was send to all Dutch hospitals in 2004. Subsequently, current organization was compared to the results of a previous inventory (2000). Finally, we evaluated to what extent the guidelines of the Dutch Health Council and the Netherlands Society of Anaesthesiology regarding the organization of preoperative evaluation (issued in 1997 and 2002, respectively) had been implemented (chapter 3). In 2004, 74% of the hospitals had an outpatient preoperative evaluation clinic, compared with 50% in 2000. The percentage of hospitals with an outpatient preoperative evaluation clinic available for *all* elective patients increased from 20% to 52%. The Dutch guidelines on

preoperative evaluation seem to have influenced the current practice. An increase in the number of outpatient preoperative evaluation clinics was seen after the two abovementioned guidelines were published. The implementation of an outpatient preoperative clinic seems to warrant that anaesthetists are carrying out the activities prescribed by the guidelines. Most hospitals without a clinic aimed to implement one in the future.

Another part of the written questionnaire that was used in the national survey of chapter 3, investigated the factors that positively or negatively influence the implementation of OPE clinics (chapter 4). Cooperation of anaesthetists was most frequently mentioned as facilitating factor for implementation of an OPE clinic across all medical specialists interviewed. Lack of finance was most frequently reported as limiting factor in all types of hospitals (i.e. with a complete, a partial or no OPE clinic present), but significantly more often reported in hospitals without an OPE clinic ($p<0.01$). Besides these more obvious factors, underlying factors like perceptions of the professionals involved and organizational structure, were found to be related to implementation of an OPE clinic. These underlying factors explain differences between different kinds of hospitals and between professional parties, regarding their resources and motivation to implementing an OPE clinic.

In the second part of the thesis, perioperative interventions embedded in clinical pathways for gastrointestinal surgery and their outcome were evaluated. The focus was on the preoperative interventions of clinical pathways. First, the medical and organizational content, that is, the interventions, of clinical pathways for digestive surgery and their effects on postoperative outcome measures were studied in a systematic review (chapter 5). The MEDLINE, EMBASE and CINAHL literature databases were searched. The most common interventions in the clinical pathways in this review were defined in the preoperative and postoperative phase and included: nutritional management, pain management, mobilization, patient education and discharge planning. The primary aim of these interventions was to enhance postoperative recovery. Most of these interventions were in accordance with the Enhanced Recovery After Surgery (ERAS) protocol, which is an evidence-based protocol for care after colon resections. They resulted in reduced length of stay without compromising other postoperative outcome measures. However, we concluded that more rigorous study designs should be used to evaluate the effectiveness of clinical pathways.

A second systematic review on clinical pathways for gastrointestinal surgery was performed, to review which indicators are commonly used to evaluate the effectiveness of clinical pathways for gastrointestinal surgery, and to study the effects of clinical pathways on these indicators (chapter 6). The Leuven Clinical Pathway Compass was used to categorize the indicators reported in literature. It was found that clinical pathways for gastrointestinal surgery can enhance efficiency of care without adverse effects on outcome. Specific indicators to evaluate these clinical pathways were time to return to enteral feeding and

time to defecate. Furthermore, additional to complication rates, number of re-admissions, mortality and length of stay, indicators such as the number of re-operations, pain scores and ICU admission can be assessed to monitor effectiveness and patient safety of the clinical pathways.

Besides the two systematic reviews, two pilot studies were performed on preoperative interventions embedded in clinical pathways for gastrointestinal surgery. In the first, a specially designed preoperative therapeutic exercise training program for patients with gastrointestinal cancer scheduled for elective surgery was implemented and evaluated (chapter 7). The aim was to investigate the feasibility of this training program, before designing a large randomized trial. People with cancer can suffer from fatigue, a decline in functional status and a decrease in quality of life. Due to these complaints, the physical activity level diminishes after diagnosis, and during treatment. Therapeutic exercise training has shown to be effective, during and after medical treatment, to increase functional capacity and quality of life in cancer patients. Feasibility of the specially designed exercise training program was evaluated by means of monitoring patient participation and adherence to the training program, patient satisfaction and motivation, adverse events, and progress in cardiovascular fitness, general muscle strength, inspiratory muscle strength and inspiratory endurance. Sixty-eight percent of the eligible patients participated in the training program. Main reason for not participating was travelling distance. Adherence to the group training sessions was 84%. Patients were satisfied about the training program and would recommend it to others. A slight positive trend over time was observed for inspiratory muscle strength. No adverse events related to the exercise training were registered. The findings of this study indicate that preoperative therapeutic exercise training in patients with gastrointestinal cancer scheduled for elective surgery is feasible. Patients appreciated the training program and tolerated it well. A subsequent, preferably randomized, study seems justified and needed to quantify the true effectiveness of this training program.

In the second pilot study, the effect of the implementation of a MUlti STrategy outpatient consult and therapeutic exercise training (referred to as MUST) embedded in the preoperative phase of a clinical pathway for esophagectomy, was evaluated (chapter 8). We hypothesized that this entire preoperative strategy would result in better postoperative outcome, especially with respect to length of stay and pulmonary complications. A before-after study was performed. Twenty patients were included in the MUST group and 40 patients in the conventional care (reference) group. The length of stay on the intensive care unit decreased significantly after implementation of the clinical pathway with the Multi Strategy outpatient consult and additional therapeutic exercise training (*t*-test, $p<0.05$). After adjustment, the MUST group had a five times shorter length of stay on the intensive care unit than the conventional care group (adjusted ratio between geometric means:

5.22 (95% CI: 2.59-10.55)). Also, the patients in the MUST group had a 1.43 times shorter total length of stay in the hospital than the reference group (95% CI: 1.00-2.04). The most frequently observed pulmonary adverse event in the reference group was pneumonia (35%). In the MUST group the number of patients with pneumonia was 15%. The adjusted risk ratio for pneumonia was 0.18 (95% CI: 0.03-0.81), indicating that the MUST group had significantly less chance of developing pneumonia postoperatively than the reference group. Patients were satisfied about the Multi Strategy outpatient consult and additional therapeutic exercise training. In conclusion, this pilot study indicates a positive effect of the implementation of a (preoperative) clinical pathway combined with a Multi Strategy outpatient consult and additional therapeutic exercise training in terms of improved postoperative outcome after esophagectomy. A larger, parallel randomized design is needed to quantify the effectiveness of this strategy with sufficient precision.

One should carefully think about how to improve preoperative care to an even greater extent in the future (chapter 9, general discussion). Elements of the different preoperative strategies, such as the outpatient preoperative evaluation clinic and the Multi Strategy consult with exercise training can be integrated. Clinical pathways and/or national multidisciplinary guidelines can be a tool in facilitating the implementation process of these integrated preoperative care interventions. Furthermore, the effects of this integrated preoperative care should be constantly evaluated by using the right set of indicators and, preferably randomized, study designs.

SAMENVATTING

Per jaar ondergaan ongeveer 1,5 miljoen Nederlanders een operatie. Het zorgproces rondom de operatie kan in 3 fasen worden ingedeeld: de preoperatieve fase, de intra-operatieve fase en de postoperatieve fase. De inhoud en organisatie van de preoperatieve fase is in het laatste decennium steeds meer in de belangstelling komen te staan. Verschillende strategieën zijn ontwikkeld om patiënten voor de operatie te evalueren en te optimaliseren, met als doel het risico op postoperatieve complicaties te verkleinen (hoofdstuk 1). In dit proefschrift staan twee strategieën voor preoperatieve evaluatie en optimalisatie centraal. Deze twee strategieën zijn preoperatieve screeningspoliklinieken (POS poli's) en specifieke preoperatieve interventies die in een klinisch pad voor gastro-intestinale chirurgie zijn ingebed.

Preoperatieve evaluatie (of screening) uitgevoerd door anesthesisten heeft als doel het risico op complicaties tijdens en na de operatie in te schatten en mogelijkheden te creëren om de conditie van de patiënt te optimaliseren voor de operatie. Een grote nationale studie onder alle Nederlandse ziekenhuizen is uitgevoerd om te bepalen wat de huidige inhoud en organisatie van de preoperatieve evaluatie is en om te bepalen welke factoren de implementatie van de POS poli bevorderen of belemmeren. Nadat eerst op basis van uitgebreid literatuuronderzoek potentiële bevorderende en belemmerende factoren waren gedefinieerd, werd de aan- of afwezigheid van deze factoren in negen speciaal geselecteerde ziekenhuizen empirisch getoetst (drie met een volledige, drie met een gedeeltelijke en drie zonder POS poli; hoofdstuk 2) Dit werd gedaan door middel van face-to-face interviews met vertegenwoordigers van vijf verschillende partijen die betrokken zijn bij de implementatie van POS poli's. Deze partijen waren: de raad van bestuur, de medische staf, anesthesisten, internisten en chirurgen. Financiering en motivatie (of medewerking) werden genoemd als belangrijke factoren die de implementatie van een POS poli beïnvloeden. Onderliggende factoren die werden genoemd waren budgetoverheveling tussen specialisten, inkomensverlies en domeinstrijd. Logistieke en organisatorische randvoorwaarden werden daarnaast als belangrijke factoren voor de succesvolle implementatie van een POS poli genoemd.

Op basis van de resultaten van de interviews werd een schriftelijke vragenlijst ontwikkeld over de huidige organisatie van de preoperatieve evaluatie en over de invloed van de nationale richtlijnen op het implementatieproces van de POS poli. De respondenten waren wederom leden van de raad van bestuur, leden van de medische staf, anesthesisten, internisten en chirurgen. De schriftelijke vragenlijst werd in 2004 naar alle Nederlandse ziekenhuizen gestuurd. Vervolgens werd de huidige organisatie van de preoperatieve evaluatie vergeleken met een eerder inventariserend onderzoek uit 2000. Tot slot, werd geëvalueerd in welke mate de richtlijnen van de Gezondheidsraad en de Nederlandse Vereniging voor Anesthesiologie ten aanzien van de organisatie van de preoperatieve

evaluatie (uitgegeven in respectievelijk 1997 en 2002) waren geïmplementeerd (hoofdstuk 3). In 2004, bleek 74% van de ziekenhuizen een POS poli te hebben, vergeleken met 50% in 2000. Het percentage van ziekenhuizen met een POS poli voor alle electieve patiënten groeide van 20% naar 52%. De nationale richtlijnen ten aanzien van de preoperatieve evaluatie lijken de huidige praktijk te hebben beïnvloed. Een stijging in het aantal POS poli's werd gezien nadat de twee richtlijnen werden gepubliceerd. De implementatie van een POS poli lijkt te waarborgen dat anesthesisten de activiteiten die voorgeschreven worden door de richtlijnen uitvoeren. De meeste ziekenhuizen zonder POS poli stellen zich ten doel één in de toekomst te implementeren.

Een ander gedeelte van de schriftelijke vragenlijst die werd gebruikt in de nationale studie van hoofdstuk 3 onderzocht de factoren die de implementatie van POS poli's positief of negatief beïnvloeden (hoofdstuk 4). Medewerking van de anesthesisten werd het meest genoemd als bevorderende factor voor de implementatie van een POS poli door alle groepen geïnterviewde specialisten. Gebrek aan financiering werd het meest frequent genoemd in alle type ziekenhuizen (met volledige, gedeeltelijk of zonder POS poli), maar significant vaker in ziekenhuizen zonder POS poli ($p<0.01$). Naast deze meer voor de hand liggende factoren werden onderliggende factoren zoals de percepties van de betrokken specialisten en organisatiestructuur gevonden als zijnde gerelateerd aan de implementatie van een POS poli. Deze onderliggende factoren verklaren verschillen tussen de verschillende soorten ziekenhuizen en tussen de professionele partijen, ten aanzien van hun middelen en motivatie om een POS poli te implementeren.

In het tweede deel van dit proefschrift werden peri-operatieve interventies ingebed in klinische paden (zorgpaden) voor gastro-intestinale chirurgie en hun uitkomsten geëvalueerd. De focus lag op preoperatieve interventies in klinische paden. Eerst werden de medische en organisatorische inhoud, dat wil zeggen de interventies, van klinische paden voor gastro-intestinale chirurgie en hun effect op de postoperatieve uitkomstmaten bestudeerd in een systematische review (hoofdstuk 5). De literatuurdatabases MEDLINE, EMBASE en CINAHL werden doorzocht. De meest voorkomende interventies in de klinische paden voor gastro-intestinale chirurgie in deze review waren gedefinieerd in de preoperatieve en postoperatieve fase en bestonden uit: voedingsbeleid, pijnmanagement, mobilisatie, patiënteneducatie en ontslagplanning. Het primaire doel van deze interventies was om het postoperatieve herstel te verbeteren. De meeste van deze interventies waren in samenspraak met het protocol voor verbeterd herstel na de operatie (ofwel het ERAS protocol), dat een evidence based protocol voor de zorg na een colonresectie is. De interventies resulteerden in een verkorte ligduur zonder daarbij de andere postoperatieve uitkomstmaten negatief te beïnvloeden. De conclusie was echter dat meer kwalitatief hoogwaardige studies opgezet moeten worden om de effectiviteit van klinische paden te kunnen evalueren.

Een tweede systematische review naar klinische paden voor gastrointestinale chirurgie werd uitgevoerd om in kaart te brengen welke indicatoren gewoonlijk gebruikt worden om de effectiviteit van klinische paden voor gastro-intestinale chirurgie te evalueren en om het effect van klinische paden op deze indicatoren te bestuderen (hoofdstuk 6). Het Leuvens Klinisch Pad Kompas werd gebruikt om de in de literatuur gerapporteerde indicatoren te categoriseren. Het bleek dat klinische paden voor gastro-intestinale chirurgie de doelmatigheid van de zorg kunnen vergroten zonder dat dit negatieve effecten heeft op de uitkomstmaten. Specifieke indicatoren om deze klinische paden te evalueren waren: tijd tot terugkeer naar enterale voeding en tijd tot eerste stoelgang. Verder, kunnen naast het aantal complicaties, het aantal heropnames, mortaliteit en ligduur, indicatoren zoals het aantal heroperaties, pijnscores en opnames op de intensive care worden bepaald om de effectiviteit en patiëntveiligheid van klinische paden te bewaken.

Naast de twee systematische reviews werden ook twee pilot studies uitgevoerd naar preoperatieve interventies die ingebed werden in klinische paden voor gastrointestinale chirurgie. In de eerste pilot studie, werd een speciaal ontworpen preoperatief therapeutisch trainingsprogramma voor patiënten met gastro-intestinale kanker die gepland stonden voor een operatie geïmplementeerd en geëvalueerd (hoofdstuk 7). Het doel was om de haalbaarheid van dit trainingsprogramma te onderzoeken voordat een groot gerandomiseerd onderzoek zou worden ontworpen. Mensen met kanker kunnen aan vermoeidheid lijden, aan een daling van hun fysiek functioneren en aan een daling in de kwaliteit van leven. Door deze klachten neemt de lichaamsbeweging af na de diagnose en tijdens de behandeling. Therapeutische training heeft bewezen effectief te zijn, gedurende en na behandeling, om het fysiek functioneren en de kwaliteit van leven van kankerpatiënten te vergroten. De haalbaarheid van het speciaal ontworpen trainingprogramma werd geëvalueerd door middel van het registreren van de deelname aan het trainingsprogramma en de aanwezigheid bij de groepstraining sessies, patiënttevredenheid en motivatie, negatieve bijeffecten en de vooruitgang in cardiovasculaire conditie, algemene spierkracht, (in)ademspierkracht en respiratoir uithoudingsvermogen. Achtenzestig procent van de in aanmerking komende patiënten deed mee aan het trainingsprogramma. De belangrijkste reden om niet te deel te nemen was reisafstand. Het aanwezigheidspercentage bij de groepstraining sessies was 84%. Patiënten waren tevreden over het trainingsprogramma en zouden het aan anderen aanraden. Een licht positieve trend werd gezien in de (in)ademspierkracht. Er werden geen negatieve bijeffecten gerelateerd aan het trainingsprogramma gevonden. De bevindingen van deze studie vormen een indicatie dat preoperatieve therapeutische training voor patiënten met gastro-intestinale kanker die gepland staan voor een operatie haalbaar zou zijn. De patiënten waardeerden het programma en doorstonden het goed. Een vervolgstudie, bij voorkeur gerandomiseerd, lijkt valide en is nodig om de werkelijk effectiviteit van het trainingsprogramma te kwantificeren.

In de tweede pilot studie werd het effect van de implementatie van een MUlti STtrategisch poliklinisch consult en additionele therapeutische training (ook wel MUST genoemd) ingebed in de preoperatieve fase van een klinisch pad voor oesophagusresecties geëvalueerd (hoofdstuk 8). De hypothese was dat deze preoperatieve strategie de postoperatieve uitkomsten zou verbeteren, in het bijzonder de ligduur en het aantal pulmonale complicaties. Een voor- en na studie werd uitgevoerd. Twintig patiënten werden geïncludeerd in de MUST groep en 40 patiënten in de conventionele zorggroep (referentiegroep). De ligduur op de intensive care afdeling daalde significant na de implementatie van het klinisch pad met het Multi Strategisch poliklinisch consult en bijbehorend trainingsprogramma (*t*-test, *p*-waarde<0.05). Na correctie had de MUST groep een vijf keer zo korte ligduur op de intensive care afdeling dan de referentiegroep (gecorrigeerd ratio tussen de geometrische gemiddelden: 5,22 (95% BI: 2,59-10,55)). Ook hadden de patiënten in de MUST groep een 1,43 zo korte totale ligduur in het ziekenhuis dan de referentiegroep (95% BI: 1,00-2,04). De meest voorkomende pulmonale complicatie in de referentiegroep was longontsteking (35%). In de MUST groep was het aantal patiënten met longontsteking 15%. Het gecorrigeerde relatieve risico voor longontsteking was 0,18 (95% BI: 0,03-0,81), wat aangeeft dat de patiënten uit de MUST groep een veel kleinere kans op de ontwikkeling van een longontsteking hadden dan de mensen uit de referentiegroep. Patiënten waren tevreden over het Multi Strategisch poliklinisch consult met bijbehorend trainingsprogramma. Concluderend is er een indicatie dat met de implementatie van een klinisch pad met daarin een preoperatief Multi Strategisch poliklinisch consult met trainingsprogramma een positief effect behaald kan worden, dat wil zeggen verbeterde postoperatieve uitkomsten, na een oesophagusresectie. Een grotere, parallel gerandomiseerde, studie is nodig om de effectiviteit van deze strategie met de nodige precisie te kwantificeren.

Men moet goed nadenken over hoe men de preoperatieve zorg verder nog kan verbeteren (hoofdstuk 9). Elementen van verschillende preoperatieve strategieën, zoals de POS poli en het Multi Strategische poliklinisch consult met bijbehorend trainingsprogramma, kunnen geïntegreerd worden. Klinische paden en/of nationale multidisciplinaire richtlijnen kunnen een goede methode zijn om het implementatieproces van deze geïntegreerde preoperatieve interventies te faciliteren. De effecten van deze geïntegreerde interventies moeten vervolgens continue geëvalueerd worden door de juiste set van indicatoren en bij voorkeur gerandomiseerde studie designs te gebruiken.

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Curriculum vitae

Lidwien Charlotte Lemmens was born on November 29th in 1973, in Amersfoort in the Netherlands. After graduating high school at the 'Hooghe Landt College' in Amersfoort, she started her Biology study at the University of Utrecht in 1992. She graduated in 1997 and started working as a field worker for the Netherlands Institute for Health Services Research (NIVEL) collecting data for the chronic patient panel project. In 1998 she became a junior researcher at MRC Health Care (MRC Gezondheidszorg). She spent three and a half years on marketing research for pharmaceutical companies. In 2002 she started working for the Centre for Prevention and Health Services Research of the National Institute for Public Health and the Environment (RIVM) as a researcher at an one-year project on integrated care for people with chronic diseases. In March 2003 she started working for the Department of Perioperative and Emergency Care at the University Medical Center in Utrecht (UMCU). She participated as a researcher in two consecutive projects. The first project was a study on the implementation of outpatient preoperative evaluation clinics in Dutch hospitals and the second was a study on clinical pathways for patients with gastrointestinal cancer. She worked at the UMCU for five years and finished her work with the current thesis (promotores: prof. dr. K.G.M. Moons and prof. dr. H.E.M. Kerkkamp). From January to May 2008 she worked for the NIVEL. Currently, she is working at the RIVM again, doing research on disease management for chronic diseases and on the recognition and treatment of depression in diabetes patients in general practice.

She lives with her husband Niek and her two rabbits in Houten.