Protocol for Process Evaluation of evidence-based care pathways – the case of colorectal cancer surgery

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Abstract

Background and Aim Care pathways are complex interventions, consisting of multiple ‘active ingredients’, to structure care processes around patient needs. Numerous studies have reported improved outcomes after implementation of care pathways. The Structure – Process – Outcome framework and the Context – Mechanism – Outcome framework both suggest that outcomes can only be achieved through a certain process within a context or structure. To understand how and why care pathways are effective, understanding of both this process and context is necessary.

The aim of this paper is to propose a study protocol to evaluate the implementation process of evidence-based care pathways, including the influence of the context. This protocol is explained by applying it to the implementation of a colorectal cancer surgery pathway in an international setting.

Methods The Medical Research Council guidance on process evaluations for complex interventions is used as the basis for the protocol. The key components of process evaluation are Intervention, Context, Implementation, Mechanisms of Impact, and Outcomes. In process evaluations, these components are studied using quantitative and qualitative methods. Among them are patient record analysis, questionnaires, on-site visits and interviews.

Discussion To guide our methodological choices, the Medical Research Council guidance for process evaluations of complex interventions, and published protocols for process evaluations of complex interventions were used. Our protocol is now tailored for the process evaluation of evidence-based care pathways and provides researchers and clinicians methods and tools, as well as a worked example, that can be used to study the process of care pathway implementation. As

a result, healthcare professionals will be informed on context factors and implementation processes that can facilitate the implementation of care pathways, improving quality and effectiveness of care processes.

Key words

care pathways; colorectal cancer; evidence; implementation; methodology; protocol; process evaluation

Manuscript highlights

What is known about the topic?

- Care pathways are complex interventions, consisting of multiple 'active ingredients', to structure care processes around patient needs
- Evaluation of outcomes of care pathways shows mainly positive results on processes and outcomes
- The Structure – Process – Outcome framework and the Context – Mechanism – Outcome framework both suggest that outcomes can only be achieved through a certain process within a context or structure. To understand the process and context in which care pathways work, a process evaluation is necessary

What does this paper add?

- This manuscript presents a study protocol for process evaluation based on the Medical Research Council guidance on process evaluation of complex interventions
- The manuscript provides not only a protocol, but also a worked example of the process evaluation of the implementation of a care pathway in 12 hospitals in four countries, based on the E-P-A definition of a care pathway as a complex intervention
- The protocol is tailored for the process evaluation of evidence-based care pathways and provides researchers and clinicians methods and tools, to study and improve the process of care pathway implementation, but can be used to evaluate other quality improvement initiatives as well

Background

Care pathways (CP), also known as critical pathways or clinical pathways, are used worldwide as a tool to structure or design care processes around patients' needs and, by doing so, to improve quality of care.^{1,2} CPs are defined as a 'complex intervention for the mutual decision making and organisation of predictable care for a well-defined group of patients during a well-defined period'.^{3,4} Complex interventions are interventions consisting of multiple components, working interactively.^{5,6} These components, or active ingredients, are defined for CPs as: 1) A formative evaluation of quality and organisation of the care setting (including feedback of the results), 2) A set of evidence-based key interventions, and 3) Support of the development and implementation of the care pathway.⁷ In essence, a CP is not merely a tool or product, but rather a process including formative evaluation and feedback, and a strategy to implement the CP.

CPs are widely used in surgical patient groups, where they are regarded as one of the proven interventions to reduce adverse events.⁸ A meta-analysis by Song et al. on effects of pathways for patients with gastro-intestinal cancer, shows a reduction in expenditure and average length of stay (LOS), and higher patient satisfaction.⁹

CP's are used in quality improvement work with positive outcomes. However, to be able to understand the outcomes of care, it is necessary to understand *how* these outcomes were achieved. Two well-known frameworks suggest there are antecedents to outcomes. First, the 'Structure – Process – Outcome' framework on quality of care by Donabedian, implies that outcomes can only be achieved through processes within a structure.¹⁰ The Realist Evaluation Framework (Context – Mechanisms – Outcomes) by Pawson and Tilley, suggest that interventions (e.g. care pathways) are not stand-alone mechanisms, but work in different contexts, that effect outcomes.¹¹ Gaining a comprehensive insight in the effects of a CP, as well as the underlying processes, ask for a process evaluation.

Process Evaluation

The Medical Research Council (MRC) has published guidance on process evaluation of complex interventions.^{6,12} This guidance describes and links the key functions and components of process evaluation of complex interventions. These components are *Context*, *Implementation*, and *Mechanisms of Impact*. A description of the *intervention* which is evaluated, acts as input for the framework. The output is the actual *outcome* achieved with the intervention.

The case of a Colorectal cancer surgery pathway

The process evaluation of the implementation of a CP for colorectal cancer surgery reported in this paper, is part of a quality improvement project in 12 hospitals in four European countries: Belgium, France, Germany and The Netherlands. The project runs between January 2015 and April 2018. The project is performed by the KU Leuven Institute for Healthcare Policy (www.kuleuven.be/ligb) and is guided by the European Pathway Association (E-P-A, www.e-p-a.org), an international not-for-profit organisation aiming to increase and disseminate knowledge on CPs. In the project, the 12 participating hospitals perform a baseline measurement of their care process (outcome and process indicators), improve the care process where needed by implementing or revising a CP based on ERAS guidelines,¹³ and perform an effect measurement. The hospitals are supported by the research team in a number of sessions, and are visited for a process evaluation in the summer of 2017. Ethical approval for this study was obtained by the ethical committee of the University Hospital Leuven (S57152 (ML11311)).

Aims and objectives

A care pathway consists of multiple 'active ingredients' which leave room for local adoption and adaptation. To understand if the CP was effective, it is necessary to understand how the formative

evaluation was performed, which evidence-based key interventions were adopted and adapted, and how the local implementation took place. This is where process evaluation is situated.

The aim of this paper is twofold: first it proposes a study protocol to evaluate the implementation process of evidence-based CPs. Second, it provides a worked example of the application of the study protocol to generate results that will help understand and inform future implementation of (colorectal cancer surgery) CPs. The evaluation of outcome is not described in this paper.

The specific research questions for the process evaluation of evidence-based CPs are listed in figure 1, together with a summary of the proposed research methods. The methods are described in detail below.

Methods/design

Where outcome evaluation focusses on the effect of an intervention, process evaluation investigates the process of implementing the intervention.¹² Richards and Rahm Hallberg (2015) as well as the MRC guidance suggest mixed method research to capture different elements of the evaluation of complex interventions. Both quantitative methods, such as measurement, patient file analysis to measure key process variables, as well as qualitative methods such as interviews or focus groups to capture experiences, can and should be used in process evaluations.^{6,14} The design of process evaluation of the implementation of evidence-based CPs is based on mixing quantitative with qualitative methods.

The rationale for the protocol is discussed in detail below, following the key components of process evaluation as indicated in the MRC guidance. The methods and instruments for data collection are described per component, followed by recommendations on data analysis. The proposed steps are illustrated by the process evaluation of the implementation of a care pathway for colorectal cancer surgery.

<< figure 1 >>

Data collection

Component: Intervention

To evaluate what exactly has been implemented, a process evaluation needs a thorough description of the implementation under evaluation.^{6,12} When evaluating the implementation of a CP, a description is needed of all three active ingredients: 1) Formative evaluation of the care setting, 2) Evidence-based key interventions, and 3) Support in development and implementation of the care pathway.⁷

To provide a comprehensive and transparent description of the intervention, the Template for Intervention Description and Replication (TIDieR) checklist is suggested. The TIDieR checklist is a 12-item format, developed by Hoffmann et al. in 2014.¹⁵ It is a comprehensive format that gives authors and reviewers of research papers guidance in describing the intervention that is studied.

The TIDieR checklist was used to describe the complex intervention with its three active ingredients in the colorectal cancer surgery CP project. The formative evaluation of the current care process is the first active ingredient. It consisted of a baseline measurement of outcome and process indicators, including protocol adherence. The rationale behind this complex intervention is that providing feedback to a clinical team on their current performance, will show the areas for improvement and will spark a shared ambition to improve performance. The results were presented in a feedback report and two feedback sessions were organised. First, a feedback session per country was organised (n=4). The goal of these meetings was to share general findings, and to encourage the exchange of knowledge. Second, all but two of the participating hospitals (n=12) were visited to give on-site feedback to the interdisciplinary team. The two hospitals that were not visited already had extensive experience in working with CPs, and decided an on-site visit was not necessary. These teams only received the full feedback report. The results

of the formative evaluation have been published by Van Zelm et al. (2017). The main conclusions were that protocol adherence was low (44% on average) and that there is considerable variation within and between teams.¹⁶ In eight out of ten of the visited hospitals, the results were accepted by the teams as 'benchmark', showing room for improvement. One of the teams questioned the results, and in one case the results were even rejected during the feedback session. In this particular case, the head of abdominal surgery presented his own data to challenge the information given during the feedback session.

The second active ingredient of the complex intervention, the list of evidence-based key interventions, was shared with the participating hospitals after the feedback sessions. The hospitals received the main clinical recommendations from the research literature.¹⁷ Based on this summary, a proposal for a time-task matrix was developed. This matrix summarizes the key interventions on a day-to-day time frame in a so called model pathway.¹⁷ The model pathway contains 27 interventions which the local teams can use as guidance to develop or adapt their own CP. There are nine interventions in the preoperative phase (e.g. patient education, no prolonged fasting, carbohydrate loading), ten in the perioperative phase (e.g. avoidance of salt and water overload, no use of nasogastric tubes), and eight in the postoperative phase (e.g. early mobilisation and early oral nutrition, no use of opioids).

The third active ingredient, development and implementation of local CPs, started with a second three hour on-site training session in which the goals for improvement of each individual hospital, based on the formative evaluation, were discussed in a multidisciplinary team meeting. Following that, the rationale behind the model pathway was explained and discussed. The session ended with practical considerations for the use of the model pathway in daily practice.

All sessions used a standardised format, and were led by the same person (RvZ). In all sessions in the French speaking hospitals, RvZ was supported by DA. Although the project language is English, support of a bilingual person proved crucial to assure good communication. After the

second on-site session, each hospital followed its own course in adapting and implementing the pathway, based on local context, barriers and facilitators. The number of interventions in the model pathway and the fact that teams can place their own focus on which areas to improve and how to do that, underline the 'complex' nature of this intervention.

The intervention as summarised above is described in more detail in the TIDieR checklist.¹⁵ The completed TIDieR checklist can be obtained from the corresponding author.

Component: Context

Process evaluation studies the context to understand how it affects the implementation of a complex intervention.^{6,12} Implementation of CPs is a form of quality improvement. An emerging framework to study the role of context in quality improvement, is MUSIQ.^{18,19} This Model for Understanding Success In Quality (MUSIQ) is developed as conceptual model to understand and optimise contextual factors affecting the success of a quality improvement project. The model defines 25 factors, which are divided in the following categories: external environment; organisation; quality improvement support and capacity; microsystem; quality improvement team; miscellaneous.^{18,19}

To understand the context in which the colorectal cancer surgery CP is implemented, general characteristics of each participating hospital were collected (total number of beds, number of beds allocated for colorectal cancer surgery, number of annual colorectal cancer surgery patients, teaching / non-teaching hospital, and the composition of the clinical team). Next to these general aspects, the concepts from MUSIQ^{18,19} were used to develop an interview topic guide (see next section).

Components: Implementation and Mechanisms of Impact

To study the implementation, process evaluation focusses on “what” (fidelity, dose, adaptations, reach) is implemented, and “how” it is implemented (process).^{6,12} When the intervention under evaluation is a CP, this means first establishing to what degree the interventions from the model pathway have been implemented, and if each intervention is implemented in part (e.g. not in full dose, not consistently over time) or in full (prescribed dose, timing, et cetera). Second, how the interventions were implemented, and who was involved.

For this purpose, a mix of quantitative and qualitative methods is used, such as questionnaires to study the level of implementation, interviews with involved professionals, direct observation and audit, and measurement of protocol adherence. The overview of facilitators and barriers to pathway implementation (Evans-Lacko, 2010), or the evaluation of pathway implementation (Deneckere, 2012) can serve as input to develop the evaluation questions.^{20,21}

Process evaluation also tries to understand the mechanisms of how the intervention works, and to identify any unexpected events or consequences.^{6,12} For this purpose, the same qualitative data as collected to evaluate the implementation process is used.

To measure the level of implementation of the CP for colorectal cancer surgery, a questionnaire was sent to the local study coordinator of the participating hospitals. The questionnaire is a self-evaluation tool, using a five-point anchored scale, to assess the level of implementation (0% - 100%) of each key intervention as described in the model pathway. The anchors, short and concise explanations of the ratings, provide a common frame-of-reference for users of the scale, improving interrater reliability and reducing rating errors.^{22,23} The anchors from the EFQM (translated as Kwadrant in Flanders) self-evaluation compass²⁴ were used as basis for the questionnaire. The EFQM self-evaluation compass is focussed on quality and organisation of care, making the anchors highly applicable for the process evaluation of a CP, although translation was necessary. After translation, the anchors were ranked from ‘no implementation’ to ‘full

implementation', and a draft of the questionnaire was developed, which was tested in a hospital not participating in the study. After this test, the questionnaire was approved for use during a consensus meeting with the research team. Per level of implementation, the anchors are defined as follows: (0%) "Little or no evidence of implementation, not really, usually not"; (25%) "Some evidence of implementation, not systematically, sometimes, more often not"; (50%) "Demonstrable, reasonably planned or systematic"; (75%) "Obvious, systematic, almost complete, all relevant staff"; (100%) "Example for others, imbedded in daily practice, regular evaluation of practice". The full questionnaire can be obtained from the corresponding author.

The implementation process of the colorectal cancer surgery pathway was studied using semi-structured interviews during on-site visits to the hospital. Purposive sampling was used to select the interviewees. This is a non-probability sampling technique, in which known characteristics of the population are used to construct the sample. The goal is to select information-rich cases.^{25,26} Interviews were conducted in all participating hospitals with a medical doctor (surgeon or gastroenterologist), a nurse from the clinical ward or a clinical nurse specialist, and a quality officer or care pathway facilitator who supported the project. This sampling is comparable to a previously published process evaluation in colorectal surgery.²⁷ In our evaluation, we are looking for overall saturation across the participating hospitals, not saturation per case, to draw overarching conclusions. With this purposeful sample, we include not only the local 'champions', but also clinical team members, reducing the risk of bias.

If during analysis it becomes apparent that specific topics are underrepresented in the data, additional interviews with involved professionals in the participating centres are conducted. All interviews were audio recorded and transcribed verbatim.

To develop our interview topic guide, an overview of implementation influencing factors was created. First, more generic studies on implementation of CPs and quality improvement were

used to identify implementation influencing factors (both barriers as well as facilitators).^{20,21,28}

Second, a number of studies on implementation of an enhanced recovery protocol for colorectal cancer surgery was used to identify specific factors for this CP.^{27,29,30} Next to these studies, the MUSIQ concept^{18,19} was added to identify relevant contextual factors (see 'Context').

The input (facilitators, barriers), from these studies were categorised in the five elements of the MRC guidance by RvZ and DA. This created a rich matrix (see appendix 1), which was used as basis for the draft topic list.

Similar items from the matrix were grouped in topics. For each topic 1 or 2 example questions were formulated. The draft was circulated for commenting in the research team and then tested by RvZ and DA in a pilot interview in a hospital with extensive experience in working with CPs, but not participating in the project. Based on this test, the topic list was finalised in a research team meeting. The final topic list can be obtained from the corresponding author.

Finally, a retrospective patient record analysis was performed to measure the protocol adherence. This is the percentage of key interventions described in our model pathway a patients receives.¹⁷ The local study coordinator was instructed to collect from the patient record which interventions the patient received. This was done for 20 randomly selected patients admitted between December 1st 2016 to May 31st 2017. This timing allowed the participating hospitals 6 months for the actual implementation of the CP.

Data analysis

For the analysis of process evaluation data, the MRC guidance gives a number of recommendations.^{6,12} These recommendations are not specific for any type of complex intervention under evaluation, so can also apply to the evaluation of CPs. For the analysis of quantitative data, descriptive statistic on measures such as fidelity, dose, and reach can be used. More detailed modelling can be used to explore if and how the implementation process varies in

different contexts. The analysis of qualitative data should give insight in mechanisms through which the intervention brings about change and in the contextual factors. Preferably, qualitative data collection and analysis is an iterative process, occurring at the same time. The main recommendation is to use a mixed method approach: qualitative and quantitative analysis should complement each other. The MRC guidance recommends to 'where possible, initially analyse and report process data before trial outcomes are known to avoid biased interpretation'.^{6,12}

The qualitative data in the process evaluation of the colorectal cancer pathway was analysed using a specific type of thematic analysis, referred to as the framework method, or framework approach.³¹⁻³³ This method consists of a data management stage (familiarisation with the data, construction of initial thematic framework, indexing and sorting of data ('coding'), review of data samples, data summary and display), followed by an abstraction and interpretation stage (description of emerging categories, relationships between categories, and explanation of patterns found).³³ To improve the clarity and transparency of the qualitative findings, the results of the interviews will be reported in accordance with the Consolidated criteria for reporting qualitative research (COREQ) checklist.³⁴

The protocol adherence will be reported as proportions, with median and interquartile range (IQR). Differences between the baseline and effect measurement will be analysed using Chi-square test. Correlation and regression analysis will be performed to analyse the relation between context, implementation, and mechanism factors versus adherence.

The process evaluation data (on context, implementation, and mechanisms) are analysed before the analysis of data from a separate outcome evaluation. When both analyses are complete, an integrated analysis of process and outcome data will be performed to answer the overarching

research questions 8 and 9 (figure 1). The final report of the process analysis will be based on the MRC guidance for process evaluations of complex interventions⁶, and the RAMESES II reporting standards for realist evaluations.^{6,35}

Discussion

The purpose of process evaluation is not to show an effect of the complex intervention under investigation, but rather to gain a comprehensive insight in the context, implementation process and mechanisms and how this works interactively to produce the outcomes. This can inform practitioners and policy makers on future quality improvements. Using both quantitative and qualitative methods to collect a variety of data as outlined in our protocol, enables us to answer the questions *how* the care pathway worked, and *why* or under what circumstances it worked. We believe that a process evaluation of a CP following our protocol and answering the research questions as listed in figure 1, generates a thorough understanding of the implementation process, mechanisms, and context factors.. To guide our methodological choices, we have stayed close to the MRC guidance for process evaluations of complex interventions and earlier protocols for process evaluations of complex interventions.^{12,14,36-38} In our experience, the MRC guidance is very applicable to evaluate this quality improvement initiative. Especially the distinction in implementation (what and how) proves useful to get a good understanding of the actual implementation activities, actors and results. The description of 'Context' in the MRC guidance, is somewhat limited.

Like any study design, this protocol comes with strengths and limitations. For the quantitative data collection and analysis, these have been discussed in a previous paper.¹⁶ For the qualitative data collection and analysis in our protocol, a strength is the use of proven methods and conceptual frameworks, tested in previous CP research, such as semi-structured interviews with direct involved staff.^{21,27-30} Adding the MUSIQ concept^{18,19} to help understand the role of context

in the implementation, is a new and promising approach. The MRC guidance recommends to evaluate 'contextual factors', without specifying these factors. We used the MUSIQ concept to distinguish 4 levels of context: the external context, organizational context, the clinical microsystem, and the quality improvement team. This helps in a more detailed understanding of contextual factors on different levels, with a focus on quality improvement. We recognize that broader contextual factors such as political forces, socio-economic status etcetera, can influence the intervention. To effectively study this influence, larger samples are necessary. Based on the proposed sample size, we cannot extrapolate with regard to these factors. This is a limitation of our design.

Another strength is that our research methods are flexible, in order to collect the right data at the right time, as suggested in previous published protocol papers.³⁷ This flexibility, especially in the hospital visits, gives us the opportunity to shift our focus if new, unexpected themes emerge. In contrast with previous published studies with average interview length ranging between 20 and 33 minutes,^{27,29} our interviews are planned to take 45-60 minutes, allowing flexibility to discuss multiple topics and to achieve depth in data collection. All hospital visits will be conducted by two researchers (RvZ together with EC or DA), to allow for immediate reflection and briefing. We acknowledge that this is a resource intensive approach. However, we believe that using two researchers and have sufficient time to achieve depth are necessary to have a trustworthy and comprehensive data collection.

Our approach uses mixed methods and the analysis of both quantitative and qualitative data, which can be challenging. Several authors suggest to deploy a multidisciplinary research team, with specialists from different backgrounds.^{14,31,32} Therefore, we added a public health specialist, a statistician, and colorectal surgeons to our research team for the integrated analysis .

Although the study protocol is tailored for the process evaluation of evidence-based CP's, we believe it has a broader application. It can be used in any quality improvement initiative in which a (new) standard is introduced, accompanied by formative evaluation and implementation. For example the introduction of a safe surgery checklist, or a new diagnostic procedure, We believe that the same research questions and methods as listed in Figure 1 can be applied. In fact, we suggest to use the study protocol for future research, which can be used to refine the protocol. First, the protocol can be used for a process evaluation of a CP in a single center setting. This can give insight in the applicability on a smaller, local scale. Second, the protocol can be used for process evaluations of other quality improvement initiatives than development and implementation of CP's. This will give valuable insight in the range of applicability.

Conclusion

This paper presents a protocol for process evaluation of the implementation of an evidence-based care pathway, and illustrates this protocol with the case of a colorectal cancer surgery pathway. The protocol is developed in accordance with recommendations for the design, execution, and reporting of process evaluations as outlined in methodologic literature and previously published protocols. The paper gives researchers and clinicians methods and tools to use for studying the process of CP implementation.

The process evaluation of the colorectal cancer surgery pathway will provide insight in how a CP as a complex intervention works. It will help in understanding the context factors, processes and mechanisms that played a role in the development and implementation of the CP. Combined with information on the outcomes of implementation, these results can inform healthcare professionals, managers and policy makers on strategies for effective implementation of CPs, improving quality and effectiveness of care processes.

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Figure legend*Figure 1. Protocol for process evaluation of care pathways - overview*

Left: process evaluation questions and methods per concept from MRC guidance on process evaluation of complex interventions

Right: application of the methods in colorectal cancer surgery care pathway process evaluation

†TIDieR: Template for Intervention Description and Replication¹⁵

#MUSIQ: Model for Understanding Success In Quality^{18,19}

§COREQ: Consolidated criteria for reporting qualitative research³⁴