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The 7-phase method to design, implement and evaluate care pathways

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Abstract

Background: Care pathways, also known as clinical pathways, are used all over the world to implement and monitor patient-centered care processes in a transparent way. Care pathways are defined as a complex intervention, but there is a lack of information on how to design care pathways.

Method: Based on the experience of the Belgian Dutch Clinical Pathway Network, a 7-phase method to develop, implement, evaluate and continuously follow up a care pathway was designed. An international expert panel of the European Pathway Association validated this method.

Findings: The 7-phase method can be useful for in-hospital, primary care and cross boundary projects to improve the quality of healthcare processes. This 7-phase method includes a screening phase, a project management phase, a diagnostic and objectification phase, a development phase, an implementation phase, an evaluation phase and a continuous follow-up phase.

Conclusion: This method can offer support to multidisciplinary teams (re)designing and implementing safe, efficient, effective, person-centered, timely, equitable, continuous and integrated care processes. However, the method is no guarantee to success. The key to success is the collaboration and critical attitude of the entire multidisciplinary team when implementing pathways.

Originality: This paper is the first publication defining the detailed steps to design care pathways. The content is based on international experience and discussions within an expert panel. The method can support clinicians and healthcare managers in re-designing their processes of care.

Keywords
Care pathway, care process, clinical pathway, design, development, evaluation, implementation, person-centered care, quality

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**Introduction**

Clinical pathways are increasingly called "care pathways" because of the shift from in-hospital care to their broader cross boundary character [1-3]. They are one of the methods to implement, make transparent, standardize, optimize and organize the continuous follow up of patient-centered care processes [4-6]. Care pathways were introduced in 1987 in the United States [7]. Nowadays they are in use all over the world as a process control method for many diseases [4,8-16].

Care pathways were in the past defined as a control method for clinical care with the purpose of improving clinical outcomes, service, process, financial balance and teamwork working [12,17-20]. Apart from the change in the terminology from clinical pathways to care pathways, there grew also a broader consensus on the definition of this concept [21]. Care pathways are currently being defined as a “complex intervention” for the mutual decision-making and organization of care processes for a well defined group of patients during a well defined period [3,22]. Defining characteristics of care pathways include: (i) an explicit statement of the goals and key elements of care based on evidence, best practice and patients’ expectations and their characteristics; (ii) the facilitation of the communication among the team members and with patients and families; (iii) the coordination of the care process by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives; (iv) the documentation, monitoring and evaluation of variances and outcomes and (v) the identification of the appropriate resources. The aim of a care pathway is to enhance the quality of care across the continuum by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction and optimizing the use of resources [3,22]. Care pathways are thus described as complex interventions, also known as multi-component interventions [23-28]. These consist of several parts or components that are essential for its operation but whose active components are difficult to interpret.

An international survey on the use and prevalence of care pathways described that not all multidisciplinary teams are using a standardized approach during the development and implementation [15]. As the implementation method can be one of the active components of the complex intervention, an international team of pathway experts developed a 7-phase method which can be used in small improvement methods and in randomized and non-randomized trials to study the effect of care pathways [29].

**Method**

In 2002, an article on “Development and use of clinical pathways in health care” was published in the Belgian Medical Journal [30]. This publication described the then understanding of the concept, the definition and a 30-step methodology which inspired in the past years more than 110 organizations with more than 1250 care pathway projects in Belgium and The Netherlands who are members of the Belgian-Dutch Clinical Pathway Network (BDCPN) [31]. This network is a training initiative launched in 2000 by the Catholic University Leuven, Belgium. The 30-step methodology was based on the experience in pilot studies between 1997 and 2002 and a literature review on care pathway implementation methods performed in 2002 [2,32-41].

A first attempt to revise the 30 step method into a 7-phase method was prepared by researchers at Leuven University (KV, EVG, SD, WS) based on the outcomes of a study on the impact of clinical pathways on the organization of care processes [22]. The method was revised by a task force on pathway methodology of the BDCPN in 2008 and 2009. The task force consisted of the scientific team of the BDCPN and care pathway facilitators from acute hospital trusts, academic medical centers, rehabilitation centers, mental health and primary care organizations. The members of the taskforce had different backgrounds: nurses, medical doctors, quality managers and health service researchers. The 7-phase method was discussed and validated by the clinical pathway experts of the BDCPN during three consensus meetings. Between October 2009 and March 2010 the method was further peer reviewed by an international team of experts in the organization of care processes. These experts were affiliated to universities, scientific institutes and healthcare consultancy firms from Belgium, The Netherlands, Italy, Ireland, Norway and Portugal. The 7-phase method was later presented and discussed during the European Pathway Association Summer School on Care pathways in September 2010 in Italy (www.E-P-A.org) with delegates from Belgium, The Netherlands, Ireland, Italy, Norway, Portugal, Switzerland, United Kingdom and France. Nowadays it is in use in more than 15 countries and is part of the complex intervention of a cluster randomized controlled trials in the European Quality of Care Pathway Study [29].

**Results**

This 7-phase method consists of: 1) screening phase; 2) project management phase; 3) diagnostic- and objectification phase; 4) development phase; 5) implementation phase; 6) evaluation phase and 7) continuous follow-up phase (see Figure 1). This phased approach is based on the Deming cycle, better known as the "plan-do-study-act" (PDSA)-cycle [42]. Since each of the seven phases passes through a Deming cycle on itself, the 7-phases are not divided in the four main categories of Deming. The 7-phase method aims at offering a systematic approach to support a multidisciplinary team that is developing a new pathway or aims to improve an existing pathway. Each of these seven phases is discussed below and for each phase is indicated
when the phase starts, to describe the main objectives, what methods can be used and how the phase is evaluated.

Phase 1: Screening phase

The screening phase starts when the demand for a new care pathway is made or when the team feels there is a need to adapt an existing pathway. The objective of this phase is to determine whether a care pathway is the appropriate method to meet the demand. Experience within the BDCPN made clear that care pathways are not the solution for every problem concerning the organization of care processes. Sometimes a simpler intervention, such as the development of a new information brochure or protocol or organizing an additional training, can solve the problem. Care pathways can be primarily used as one of the methods to optimize care processes when problems arise on communication, coordination, transparency, standardization and monitoring of proper care for a specific patient group (safe, efficient, effective, timely, person-centered and equitable) [6,15,22,43,44]. By developing one care pathway it will not be possible to optimize the complete admission policy, the coordination between the hospital and the general practitioners or the planning of the operating room.

In the screening phase, information should be brought together about the possible ownership of the project. Therefore, first of all one checks who made the demand for the (re)organization of the healthcare process (an individual, a team, a quality steering committee, the board, an external party...). It is important to gain insight into the strength and the willingness to change and innovate of the multidisciplinary team that will possibly run the project. Methods that can be helpful at this stage are stakeholder mapping, impact analysis, questionnaires regarding teamwork – for instance the questionnaire of the Climate for Innovation Team [45] and interviews with various managers and key players [46]. In this screening phase it is also important to gain insight into the existing organization and the results of the care process. To this end, preferably readily available information is used (performance indicators, financial feedback, key figures regarding volumes, patient experiences, letters of complaint, team measures or information from visitations, accreditations or internal audits). If there is little useful information to be found in the available databases, it may be necessary to collect new data. In this phase it is recommended to do so only via some kind of quick scan, because a large data collection requires a more elaborate project structure. Possibilities for the quick scan are methods for brainstorming, the 3-blackboard method [47] or the use of the tool for self-evaluation of care process (CPSET) [48]. This validated instrument can help the team at this stage to score the existing organization of the care process in five areas: person-centeredness of the organization, the coordination within the process, the communication with patients and families, the cooperation with primary care and the follow-up of the care process. These and other sources of information should enable the team to evaluate whether a project actually should be started up and how broad or in-depth it should be implemented.

The screening phase ought to last only a few weeks. This phase can be positively evaluated if it can be explained in an objective manner whether starting up the
project is a justified choice: a) is there a need for the revision of the care process based on the current results; b) is a care pathway suitable to achieve the desired outcomes and c) is the team willing to change? The decision to start up a project should be taken by the multidisciplinary team in collaboration with the management that has to provide the necessary resources.

**Phase 2: Project management phase**

To develop, implement and evaluate a care pathway, a project structure has to be set up. This second phase starts when the decision to develop a pathway has been taken. The goal is on the one hand to define the care process for which the pathway is developed and on the other hand to put together the core team and the working group. Agreements should be made on the division of tasks and the project plan, including the timing.

The pathway must be clearly defined, both regarding the patient group (inclusion- and exclusion criteria) and the time period (the start- and end point). Based on the definition of the pathway in group and time, the core team is put together. This team is limited in number, ideally five to seven people and composed of representatives of the professional groups who have direct contact with the patient population within the agreed time frame. Possibly a quality manager will be supporting this team and a representative of the management may be invited. This core team will prepare, develop and evaluate the entire project. The team is assisted by a broader working group in which several people per professional group can attend, as well as members of supporting services, the management, representatives from external organizations and preferably also a patient representative. In this phase it is important that the core team and the working group are informed on the goal of this particular initiative. The concept and methodology of the care pathways are explained in a first meeting in order to give the members a clear understanding of the potential added value, but also the limitations of care pathways, so as not to create impossible expectations. All members of the multidisciplinary team (even those not involved in the core team or working group) should be informed on the start, on the necessity and the aims of the project. The cooperation of all team members will initially be required to collect data in the third phase, but certainly in the implementation phase and continuous follow up. Besides providing information in this phase, there are specific agreements to be made about the project leadership, the various roles and the responsibilities. Drawing up a project charter or project contract can be considered. Finally, the project plan is practically developed by marking off the various tasks and assignments, carried out during the course of the project, on a timeline known as a time-task matrix or Gantt Chart, that allows to monitor the project during its course and to make adjustments where necessary. Based on this project plan also the necessary resources can be calculated and monitored.

This project management phase can be evaluated positively if the boundaries of the care process for which the pathway is developed, are clear. Furthermore, the members of the multidisciplinary team need to be aware of the why, the project approach and the desired outcomes. The members of the core team and the working group should be aware of the methodology, the responsibilities (division of tasks) and the mutual expectations. At the end of this phase, the decision to carry out this project is reconfirmed.

**Phase 3: Diagnostic- and objectification phase**

The diagnostic- and objectification phase is a very important phase of this 7-phase method. Teams who are not prepared to objectively and critically evaluate the current organization of the care process before the development of the pathway, will not be able to optimize the current organization of the care process in an objective and appropriate way. The goal of developing pathways is not to develop something new or perform a total redesign, but to understand the weaker parts of the organization and standardize them where necessary and appropriate.

This third stage in the 7-phase method starts when the preparations for the project are made and one wants to start with the evaluation of the current practice. The goal is to evaluate the current organization of the care process from four different perspectives: a) the organization and team; b) the vision of the patient and the family; c) the available evidence and legislation and d) the views of external partners (Figure 2).

The sequence in which the care process is analyzed from these four perspectives, is of less importance and can be determined by the data already available on the one hand and the reason for the start-up of the project on the other hand. In order to complete these tasks, a close cooperation between the members of the core team and the broader working group is necessary. The work on the various methods of analysis will be divided among the members.

**Own organization and team**

In this third phase, the bottlenecks and deficiencies will be further diagnosed and objectified. The current organization of the care process should be analyzed from within the own organization and the own multidisciplinary team. Here, attention is needed to determine the objectives of the care process, the analysis of the then existing bottlenecks and also determining the necessary resources to be able to organize and optimize the care process qualitatively. The targets can be set based on the results from the CPSET analysis, the five domains of the clinical pathway compass [44], the discharge or transfer criteria and the results from the 3-blackboard method [47]. The 3-blackboard method is carried out by the core team and/or the working group. This method is a consensus method to plan the activities in the care process in such a way that the objectives will be reached. The bottlenecks regarding the current organization of care are also listed and discussed during this exercise. After executing this method one obtains a list of project and process goals, a first blueprint of how the
key interventions of the care pathway can be sequenced and a list of problems and unclear aspects that need to be further investigated.

To make a diagnosis regarding the own organization and the team, many analysis- and quality techniques can be used. The following techniques are often used: file analysis, process mapping, prospective measurement, document analysis and surveys of various team members [49]. These can be complemented by the following techniques: organizing a focus group with members of the treatment team, the use of questionnaires concerning coordination and communication within the team, establishing discipline-task matrices or the creation of value stream maps, Ishikawa diagrams or a failure mode and effects analysis (FMEA) [49,50]. Furthermore, an analysis is to be made of how the team is currently structured in terms of leadership, composition, allocation and coordination mechanisms [50].

Vision of patient and family

Next to the evaluation of the care process from within the organization and its team, we can only speak about person-centered care if patients and their families are also involved in the (re)design of the care process. This can be done by organizing interviews or focus groups or by conducting surveys regarding patient satisfaction, expectations and preferences [49,51]. Another frequently used method is to perform a walkthrough, also known as "shadowing", in which a patient is followed (shadowed) by a care provider through (or part of) the care process. This way the organization gets a picture of how the patient or family member passes through and experiences the care process. Patient associations can also contribute to the analysis of the existing care process or the communication of important pillars for good care from the perspective of the patient.

Available evidence and legislation

State-of-the-art care pathways should be based on the latest available international standards. Although evidence is not available for all activities in the pathway, certainly key interventions (these are interventions with the most impact on patient outcomes) are to be supported by international standards, local protocols or clinical expertise [52]. The same applies for the outcome indicators that need to be monitored.


Besides evidence, the adjustment of care pathways to the current legislation is of importance. We think of legislation on care pathways and care programs or directives from regional or federal government.

External partners

As a fourth pillar, the current organization of the care process needs to be evaluated from the perspective of external partners (primary or secondary care). Although organizations think in terms of lines and silos [53], for a patient the care process runs by definition cross-boundary through these lines or organizations, especially for chronic populations [54]. In addition, the development of various networks between hospitals and/or other healthcare organizations offers an opportunity. External partners, from primary or secondary care, can join in evaluating and
optimizing the current organization of the care process. For the analysis, in addition to interviews also questionnaires about coordination and cooperation can be used to make more objective data available.

This third of the seven phases, the diagnostic and objectification phase, has to deliver objective information and acts as a basis for evaluation in which from each of the four perspectives objective information about the current organization and outcomes of the care process are available (Figure 2). Based on this, the team can redesign and improve the care process.

**Phase 4: Development phase**

This fourth phase starts when the necessary information from the diagnostic and objectification phase is available and can be discussed within the core team. In this phase, the pathway is developed based on the objective information and the predetermined objectives of the screening and the diagnostic and objectification phase. Here the available resources and the opportunities for operational implementation of the pathway should be taken into account [55-58].

During this phase the team will possibly have to redefine the patient group and the time frame based on the knowledge from the diagnostic and objectification phase. The key interventions necessary to meet the process objectives, with references to the literature, guidelines or internal protocols, are marked on a time scale. Bower and Zander formulated this as follows: "you first have to identify your goals and then plan the activities to achieve those predefined goals" [47]. The ideal design of the care process will be adjusted during the development phase by taking into account the feasibility based on the possibilities for the team and the available resources, which were diagnosed and objectified during the third phase.

During this development phase the pathway gets not only designed, but also practically developed. The arrangements concerning the organization of the care process are best brought forward and standardized as part of the patient record, with or without electronic support. Based on the definition of the pathway as a complex intervention, the goals and key interventions are specified and attention is paid to the communication between team members and with patients and families. The roles and the sequence of the activities are coordinated, the results and deviation from the key interventions are documented, monitored and evaluated. Also, the justified resources are identified to make all of this possible. This requires agreements to be entered (e.g. through the establishment of service level agreements) between the core team, the management, the supporting services and, if necessary, external partners. The impact of the (re)design of this care process on other care processes outside of the scope of this project should be discussed.

This fourth phase, in which the care pathway is developed, will be positively evaluated if the pathway is multidisciplinary prepared and is designed for a specific patient group during a defined time frame in the form of a time-task matrix in the (electronic) patient record with a clear starting point and end point. The final and intermediate objectives are clear and the key interventions - if possible supported by evidence - were made visually, making deviations of the pathway easier to be followed. A reporting system to monitor all of this is prepared. The care pathway has to be approved by the core team after consulting the working group and is best presented for external review to, for example, the antibiotics committee, the laboratory, the hospital hygiene service, the quality and safety committee, etc. Developing a patient version of the pathway is desirable in order to involve the patient and the family closely with the subsequent operational implementation of the pathway and the organization and follow up of the care process. This way the patient’s and the team’s expectations can be linked.

**Phase 5: Implementation phase**

When the pathway is fully developed, the implementation phase can commence. The goal is to prepare the use of the pathway in daily practice by informing all team members and to test the pathway for a predetermined period. Afterwards the pathway can, after any final adjustments, be implemented for daily use.

During this phase, an implementation plan will be drawn up, in which the division of roles between the members of the core team is important [59,60]. It should be agreed who will act as contact person in case any problems occur. Feedback on the practical usability and communication problems when using this pathway should be centrally monitored. Before testing the pathway, information sessions should be organized for all team members who will use the pathway. During these sessions it will be indicated why this pathway was developed and what the main changes compared to the previous way of working are. How the pathway is used and how users will communicate deserves special attention. It should also be determined whether additional training sessions are required in terms of substantive changes (new medical, nursing and paramedical activities) or if special attention is needed regarding the indicators to be followed up.

The Center for Case Management (www.cfcm.com) advises to test the care pathway on a limited group of patients [61]. The rule of thumb here is to test for three weeks in the case of a low-volume population and to test on ten patients if it concerns a high-volume population. During this period, members of the core team need to be available to follow up on problems and to adjust the team members in the first use when needed.

Based on initial experiences, the pathway is adjusted where necessary. The feedback from this test phase is included in a report. Possibly some details in the reporting system need to be optimized. The core team evaluates the test phase based on feedback from team members and decides whether or not the pathway is put into service. If major problems/bottlenecks are noted, it may be necessary to collect additional information or to obtain the advice of other clinical disciplines or the management.

This implementation phase can be evaluated positively if the pathway was explained and tested and if, based on the first experiences and after consultation within the core team, it was decided whether or not to use the pathway in
daily practice [59]. At the end of this phase the pathway is implemented into daily practice and the pathway document is used to guide the team in managing the care process for a specific patient.

**Phase 6: Evaluation phase**

After the pathway has been implemented, it will be evaluated. In this phase will be investigated whether the bottlenecks in the organization of care, which were present before the implementation of the pathway, were eliminated. The usability is also evaluated. In addition, the compliance with respect to the key interventions (in the form of process indicators) and the intermediate and final outcomes of care (outcome indicators) are examined. This first thorough assessment is best performed two to three months after the implementation.

As in the diagnostic and objectification phase, analyses are made from four perspectives (Figure 2). The techniques presented during the third phase, can also be used here. In addition, variance tracking and analysis, i.e. the deviations in the newly developed care pathway in comparison with the detailed operational pathway, is a necessary exercise. For each key intervention is monitored in what percentage of patients this key intervention was carried out according to plan [26,27]. Furthermore, there is specific attention for achieving the intermediate and final outcomes of care, for example, in the form of obtained discharge criteria [12,62-64]. The results may be randomly or continuously followed up, depending on the practical possibilities for the team and organization [50]. The results are monitored through dashboards, runcharts or statistical process control [49,65]. In this evaluation phase the CPSET can be used again to see how the team feels about the new organization of care [48].

The evaluation phase concludes the project approach and passed off positively if a thorough evaluation was conducted from four perspectives and if objective data are available that can be statistically verified. Because of this, the difference between the results from the diagnostic and objectification phase and the evaluation phase become objective and the results can be submitted to the full multidisciplinary team and the management of the organization. Based on these results, the decision is made to continue using and continuously monitor the pathway or to make specific adjustments.

**Phase 7: Continuous follow-up phase**

If the results of the pathway were positive, the pathway is continued to be used in daily practice. It is nevertheless important to continuously follow up its use and results. In other words, the pathway must be kept alive and adjusted where necessary. As pathways are clinical process innovations, the possible criticality point where the improvement slows down or decreases needs to be tracked [66,67].

To continuously follow up the pathway, agreements must be made on who or which team will take this task on. The role of the physician, head nurse, care manager, service line manager, quality coordinator or staff member will depend on the organizational structure and the available resources. Apart from the continuous evaluation through variance analysis and process and outcome indicators, it is necessary that the team reconsiders the pathway every six months concerning its content. In this multidisciplinary discussion, possibly with members of the core team that coordinated the previous phases, will be investigated whether the key interventions in the pathway are still applicable [6]. New evidence, standards, clinical expertise or organizational changes may be reasons to make adjustments. During these consultations, the functioning and usability are also discussed. At least once a year an objective measurement is carried out in which both process and outcome indicators are monitored. Here, the clinical as well as the service, team, process and financial results are looked at [44], if possible, for example, through an electronic system or an exit poll in which for each patient a limited amount of data are monitored and the pathway is not randomly, but continuously followed up.

The pathway is continuously followed up according to the 7-phase method if at least every six months a substantive discussion is held, including the evaluation of the use of the pathway and if at least once a year an objective evaluation of the organization of the care process is carried out. Continuous follow-up supported by ICT is, however, recommended. Based on the results it can at any time be decided to adjust the pathway concerning its contents where necessary, to start up a project to further optimize the results or to (re)define the indicators to be monitored.

**Discussion and Conclusion**

The 7-phase methodology was developed to support multidisciplinary teams in the development, implementation, evaluation and continuous monitoring of the organization of a care process. The method was designed by a team of researchers, clinicians and managers to design care pathways as complex interventions. Although the method is in use internationally and validated by an international team of experts, it is not a ‘magic bullet’. The development of care pathways without the cooperation of the medical doctors involved is doomed to fail. Not only their clinical expertise, but also their daily responsibility and involvement in developing, implementing and continuously follow-up of the care process, proved to be crucial in the past ten years. A staff member or quality assistant can be appointed to support the team so the doctor and his multidisciplinary team can concentrate on the content and only a minimum of meeting time should be spent.

The seven phases are put into practice through the use of different quality techniques and tools. In this article, only a few examples of methods were indicated and it is up to the organization to determine whether other techniques and tools can be used in one or several phases.
The 7-phase method is not a standing order that should be used from phase one to seven. It is only a guideline or roadmap to support teams when developing and implementing care pathways. Each care process, each multidisciplinary team and each organization is unique, so the timing and interpretation of the individual phases may need to be adjusted [68]. That is also why care pathways do not always lead to improvements and why we still need to be careful with being overenthusiastic about their potential [69]. The logic of the Deming cycle throughout the seven stages, however, must be retained [42].

Care pathways are defined as complex interventions [3]. The 7-phase method as such also meets the characteristics of a complex intervention in which each phase on its own constitutes an active component of the entire intervention (Figure 3).

Each of the seven phases has a specific contribution to the state-of-the-art implementation and monitoring of a well-organized care process, but the combined action between the seven phases forms a high added value. Each of the seven phases contains a number of pitfalls such as an excessive measurement during the screening phase, when in the diagnostic and objectification phase one keeps performing measurements and analyses without optimizations or when during the development phase one tries to optimize every tiny problem before one wishes to put the pathway into action and by doing so completely demotivates the team. Pathways can be a method to bring teams together [68].

The 7-phase method is not a universal remedy and not every pathway that is developed according to this method, will automatically lead to success [5,70]. Predetermining a limited number of achievable goals is a crucial factor in the phased approach, which aims to help a multidisciplinary team across the boundaries of an organization in the search for a safe, efficient, effective, patient-centered, timely, fair, continuous and integrated care process. The collaboration and critical attitude of the entire multidisciplinary team led by the responsible physician is certainly one of the keys to success.

**Conflict of interests**

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