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Have We Drawn the Wrong Conclusions About the Value of Care Pathways? Is a Cochrane Review Appropriate?

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Abstract

Care pathways are used increasingly worldwide to organize patient care. However, different views exist about their effectiveness. One of the reasons for this is that pathways are complex interventions. A recent

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Cochrane review was published which reported positive results, but although the Cochrane team performed excellent work with an enormous commitment, the conclusions may be inappropriate. To fully understand the potential and problems of care pathways, it is important to define (a) exactly what we are talking about (b) whether the study methods are appropriate, and (c) whether we can properly define the outcomes.

Keywords
critical pathway, Cochrane review, clinical pathway, care process, complex intervention

Why Are We Concerned About Care Pathways?

Fifteen years ago a landmark article was published on the problems and potentials of critical pathways as a strategy for improving care (Pearson, Goulart-Fisher, & Lee, 1995), prompting immediate debate (Campbell, Hotchkiss, Bradshaw, & Porteous, 1998). Nowadays care pathways (also known as clinical pathways, critical pathways, or integrated care pathways) are in widespread use as one systematic way to design, (re)organize, and follow-up patient-focused care processes (Barbieri et al., 2009; Darer, Pronovost, & Bass, 2002; Goldmann, 2010; Hindle & Yazbeck, 2005; Kwan & Sandercock, 2004; Lemmens, Van Zelm, Vanhaecht, & Kerkkamp, 2008; Marchisio, Ferraccioli, Barbieri, Porcelli, & Panella, 2006; Ovretveit, 2010; Panella & Vanhaecht, 2010b; Trowbridge & Weingarten, 2001; Van Herck, Vanhaecht, & Sermeus, 2004; Vanhaecht et al., 2006; Vanhaecht, Panella, Van Zelm, & Sermeus, 2009).

In March 2010, the first Cochrane systematic review on the overall concept of pathways was published by Rotter et al. (2010). Previously Kwan published a Cochrane on pathways for stroke (Kwan & Sandercock, 2004). The authors of the most recent Cochrane review concluded; ''Clinical pathways are associated with reduced in-hospital complications and improved documentation without negatively impacting on length of stay and hospital costs'' (Rotter et al., 2010). Pathway advocates might use this review to persuade skeptical clinicians and managers to test the approach. Yet, while ''care pathways'' become popular in political and policy statements, there remain several important misunderstandings about their use and potential (Panella, Vanhaecht, & Sermeus, 2009; Vanhaecht et al., 2006; Vanhaecht, De Witte, Panella, & Sermeus, 2009; Vanhaecht, Sermeus, Peers, Deneckere, et al., 2010). Kinsman, Rotter, James, Snow, and Willis (2010) recently published an article on the definition of

pathways, on which the recent Cochrane review was based, to inform the debate (Kinsman et al., 2010). The definition suggested in the Kinsman et al. article and used in the Cochrane Review does not define pathways as complex interventions (Kinsman et al., 2010; Rotter et al., 2010). They even divide pathways into simple pathways and multifaceted pathways. Maybe we therefore have to be careful with the conclusions made and the discussion that is launched. It is important to define (a) exactly what we are talking about, (b) whether a new evaluation framework is necessary to study pathways, and (c) whether we can be clear about the effects of pathways.

What Are Care Pathways?

Care pathways, initially termed case management plans, critical pathways, or clinical pathways, were introduced in the United States in the late 1980s with a new finance system based on diagnosis related groups (Bower, 2009; Zander, 2002; Zander, Etheredge, & Bower, 1987; Zander & McGill, 1994). They were designed to decrease length of stay and cut out unnecessary cost while maintaining or improving the quality of care. In the early 1990s, the concept was applied in the United Kingdom, not only to increase efficiency but also to expand the use of guidelines in daily practice for clinical governance (Campbell et al., 1998; De Luc, 2000a, 2000b; De Luc & Currie, 1999; Zander, 2002). Since then, the use of pathways, largely unchanged in method or scope, has been reported in more than 20 countries (Hindle & Yazbeck, 2004, 2005; Vanhaecht et al., 2006; Zander, 2002)

A total of 84 different definitions of pathways have been described and many terms have been used in publications (De Bleser et al., 2006). A total of 10 examples of definitions of pathways from landmark articles are described in Table 1. Care pathways terms, for which the Medical SubHeading (MeSH) is still "critical pathway," range from "schedules of medical and nursing procedures" to "methods and tools" to "complex interventions" (Anderson, Anderson, & Glanze, 1994; De Bleser et al., 2006; Vanhaecht, De Witte, & Sermeus, 2007). The European Pathway Association (E-P-A) defines a care pathway 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" (Vanhaecht, De Witte, & Sermeus, 2007; Vanhaecht, Panella, Van Zelm, & Sermeus, 2010). The aim of a care pathway is to enhance the quality of care measured by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources. The E-P-A proposes the defining characteristics of care pathways as: (a) an

Table 1. Overview of 10 Different Pathway Definitions

Year	Author	Terminology	Definition
1994	Anderson, Anderson, and Glanze (1994)	Critical pathway	Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment
1995	Pearson, Goulart-Fisher, and Lee (1995)	Critical pathway	Management plans that display goals for patients and provide the corresponding ideal sequence and timing of staff actions to achieve those goals with optimal efficiency
1998	Campbell, Hotchkiss, Bradshaw, and Porteous (1998)	Integrated care pathway	Describe, for a specific clinical condition, the tasks to be carried out together with the timing and sequence of these tasks and the discipline involved in completing the task. They consist of a single multidisciplinary record which is part of the patient's clinical record together with a patient summary sheet
2000	De Luc (2000b)	Integrated care pathway	Determine locally agreed, multidisciplinary practices based on guidelines and evidence where available, for a specific patient/client group. It forms all or part of the clinical record, documents the care given, and facilitates the evaluation of outcomes for continuous quality improvement
2000	Every, Hochman, Becker, Kopecky, and Cannon (2000)	Critical pathway	A distinct tool that details processes of care and highlights inefficiencies regardless of whether there is evidence to warrant changes in those processes
2004	Kwan and Sandercock (2004)	Care pathway	In general, a care pathway can be defined as a plan of care that aims to promote organized and efficient multidisciplinary patient care that is based on the best available evidence and guidelines for a specific condition

(continued)

Table 1 (continued)

Year	Author	Terminology	Definition
2004	Degeling, Maxwell, Iedema, and Hunter (2004)	Integrated care pathways	Describe the diagnostic and therapeutic events that will appreciably affect the quality, outcomes, and cost of care. Use of integrated care pathways for systematizing care extends the evidence base, strengthens service integration, and improves clinical effectiveness, quality, and technical efficiency, as well as patients' satisfaction and clinicians' work experience.
2006	De Bleser et al. (2006)	Clinical pathways	Is a method for the patient-care management of a well-defined group of patients during a well-defined period of time. A clinical pathway explicitly states the goals and key elements of care based on evidence-based medicine (EBM) guidelines, best practice, and patient expectations by facilitating the communication, coordinating roles and sequencing the activities of the multidisciplinary care team, patients, and their relatives; by documenting, monitoring, and evaluating variances; and by providing the necessary resources and outcomes. The aim of a clinical pathway is to improve the quality of care, reduce risks, increase patient satisfaction, and increase the efficiency in the use of resources

(continued)

Table 1 (continued)

Year	Author	Terminology	Definition
2008	European Pathway Association (Vanhaecht, De Witte, and Sermeus, 2007; Vanhaecht, Panella, Van Zelm, and Sermeus, 2010)	Care pathway	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. Defining characteristics of care pathways include: (a) An explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations and their characteristics; (b) the facilitation of communication among team members and with patients and families; (c) the coordination of the care process by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients, and their relatives; (d) the documentation, monitoring, and evaluation of variances and outcomes; and (e) 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
2010	Kinsman, Rotter, James, Snow, and Willis (2010)	Clinical pathway	The intervention is a structured multidisciplinary plan of care; the intervention is used to channel the translation of guidelines or evidence into local structures; the intervention details the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol, or other "inventory of actions"; the intervention has time frames or criteria-based progression (i.e., steps were taken if designated criteria were met); and the intervention aims to standardize care for a specific clinical problem, procedure, or episode of health care in a specific population

explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations and their characteristics; (b) the facilitation of the communication among the team members and with patients and families; (c) the coordination of the care process by defining the roles and sequencing the activities of the multidisciplinary care team, including patients and their relatives; (d) the documentation, monitoring, and evaluation of variances and outcomes; and (e) the identification of the appropriate resources (Vanhaecht, De Witte, & Sermeus, 2007). The history and development process of this definition was recently published (Vanhaecht, Panella, et al., 2010). Based on this definition, a set of characteristics could be developed for screening the literature: (a) organization of care, (b) specific patient group and time, (c) goals based on evidence, (d) focus on communication, coordination, and evaluation, and (e) link with resources to (f) improve the different aspects of quality.

Thus pathways are complex or multicomponent interventions which include many potential "active ingredients" where the whole of the intervention should be considered more than the sum of its parts (Berwick, 2008; Medical Research Council, 2000; Medical Research Council (MRC), 2002; Panella, Marchisio, Demarchi, Manzoli, & Di Stanislao, 2009; Panella, Marchisio, Gardini, & Di Stanislao, 2007; Vanhaecht, De Witte, & Sermeus, 2007). Pathways are more than only a document in the patient record but a way to organize and standardize multidisciplinary care for patient groups using well-known quality improvement methods. Ovretveit (2002) states that a useful way to develop multidisciplinary teams is for them to develop a pathway, and that pathway development should be viewed as part of a strategy to develop interprofessional cooperation. This will not only be the case for in-hospital teams but developing and maintaining cross-boundary care pathways will be an important challenge for clinicians, healthcare managers, and policymakers (Panella & Vanhaecht, 2010a).

How Should We Evaluate Pathways?

Active ingredients of a complex pathway intervention include the information on the evidence-based key interventions, the information on the organization and design of the care process, and the phase-by-phase approach to develop, implement, evaluate, and follow-up the pathway (Panella, Marchisio, Barbieri, & Di Stanislao, 2008; Panella et al., 2007; Vanhaecht, Sermeus, Peers, Deneckere, et al., 2010). Research design for evaluating the effectiveness of complex social interventions remains controversial. In the case of care pathways, there are sometimes different

interventions classified under the same term. Further, as well as defining the general effectiveness of a pathway, the mode of implementation and the conditions needed for its success require analysis, emphasizing the complexity of the subject (Goldmann, 2010; Ovretveit, 2010; Panella, Brambilla, Marchisio, & Di Stanislao, 2008; Panella, Marchisio, et al., 2008; Panella et al., 2007, Panella, Vanhaecht, & Sermeus, 2009; Panella & Vanhaecht, 2010b; Vanhaecht, Sermeus, Peers, Deneckere, et al., 2010).

Pathways describe processes, and in the planning of a pathway, identification, and resolution of process "bottlenecks" frequently occurs. However, what works for one organization may not work for another, because of subtle differences in these processes and bottlenecks. One overall solution will not fit for every organizational challenge and the ingredients or components of the complex intervention will differ from project to project. Organizations are also different in their readiness for and capacity to change—these are often referred to as context issues, which influence implementation and effectiveness (Goldmann, 2010; Ovretveit, 2010).

These features present challenges to evaluating pathways. The evaluation design will depend on for whom the evaluation is performed and the questions to be answered (Ovretveit, 2002). Appropriate methods can be a formative or a summative evaluation (Scriven, 1991). In formative evaluations, a team is interested in understanding if their pathway works, which was implemented in their specific context using their approach. In this type of evaluation, quality improvement and analysis methods are frequently used. In summative evaluation one is performing research to understand if "pathways" work. The Medical Research Council advises cluster randomized controlled trials (cRCT) to study complex interventions like care pathways, stroke units, or other multicomponent interventions (Medical Research Council, 2000). This approach has proved useful in assessing pathways for specific patient populations (Panella, Brambilla, et al., 2008; Panella et al., 2009). The first international cRCT's on pathways are currently being performed for patients with (a) chronic obstructive pulmonary disease (Vanhaecht, Sermeus, Peers, Decramer, et al., 2010) and (b) proximal femur fracture patients (Deneckere et al., 2010; Vanhaecht, Sermeus, Peers, Deneckere, et al., 2010). Within cRCT designs one challenge is to standardize the intervention. In pathway research the pathway process or quality improvement cycle carried out is part of the intervention and should therefore be standardized. Hawe, Shiell, and Riley (2004) suggest the key is to decide which aspect to standardize, and that in complex interventions, the function and process of the intervention should be standardized and not only the components (Hawe et al., 2004).

One challenge certainly for non-RCT designs is to describe and explain context influences. Pawson and Tilley (1997) define that an action is causal only if its outcome is triggered by a mechanism acting in a context (context + mechanism = outcome) (Kazi, 2003; Pawson & Tilley, 1997). They argue that programs are effective only insofar as they introduce the appropriate ideas and opportunities (the mechanism) to groups in the appropriate social and cultural conditions (the context or the environment) (Berwick, 2008; Grol, Berwick, & Wensing, 2008; Pawson & Tilley, 1997). This realistic evaluation paradigm has already been used in pathway research and was recently suggested as one method for evaluating some quality improvement interventions (Vanhaecht, De Witte, Depreitere, et al., 2007; Vanhaecht, Sermeus, Peers, Decramer, et al., 2010; Vanhaecht, Sermeus, Peers, Deneckere, et al., 2010). In the context of care pathways, the mechanism involves the active ingredients described above, but the fine-tuning of the intervention will be based on the bottlenecks and in the context of the organization and multidisciplinary team involved. In the international cRCT studies of pathways, a set of team indicators and organizational factors are quantified to understand the context (Deneckere et al., 2010). The process and outcome indicators provide data to understand if pathways work, but the team indicators and context variables will be of help in understanding why and how they work (Deneckere et al., 2010). This information on the context and the change process is critical to the ability of others to adapt the findings of a study to their own setting (Berwick, 2008; Goldmann, 2010). An effective pathway in one place may be ineffective in another without this key knowledge.

Are We Making the Appropriate Conclusions?

The recent Cochrane review of pathways studies concludes that pathways decrease complications without a negative impact on the organization (Rotter et al., 2010). Although this Cochrane review used the appropriate methods and tools and the team performed excellent scientific work using the Cochrane methodology, there may be some bottlenecks. The question is: Is a Cochrane review of generic pathways either possible or appropriate? Possible? Perhaps. Appropriate? We think perhaps not.

Our concern relates not to whether the study was appropriately performed or if the correct statistical methods were used, but to the feasibility of the review research question and the appropriateness of the primary studies included. We do not have a poor appreciation of the level of detail of this Cochrane Library review nor the commitment of the review team, and are

aware of the difficult methodological requirements for complex interventions of the Cochrane Effective Practice and Organisation of Care (EPOC) group. But one of the authors of this discussion paper (MP) already informed the EPOC group of these possible pitfalls when the protocol for this review was published. The European Pathway Association even gave the authors of the review the floor at two international conferences to present the results of the review before they were published. The main author was already informed about the main critical suggestions described in this discussion article by several members of an international expert panel during a workshop about research on pathways back in May 2009.

As we have described above, pathways are complex interventions thus, if the publications reviewed in the Cochrane study do not describe in sufficient detail either the intervention or context, or how the study draws this boundary, we contend it is difficult to compare the findings (Barbieri et al., 2009; Berwick, 2008; Goldmann, 2010; Pawson & Tilley, 1997). Additionally, dividing pathways into simple and multifaceted interventions is difficult to understand as pathways as such are complex interventions.

When including different clinical topics in the meta-analysis the effect size of the intervention (between pathways) for different patient groups needs to be defined. Cochrane reviews and meta-analysis of pathways should therefore only be performed for disease-specific groups (Barbieri et al., 2009). For example, it might be possible to define the set of core, evidence-based key interventions for each pathology and measure the compliance, for example, the number of patients who received the appropriate antibiotic prophylaxis (Goldmann, 2010). These process indicators are suitable for meta-analysis. In defining the effect of pathways on outcome indicators there is a need for risk adjustment and multilevel analysis and thus large sample sizes. Multicenter studies are needed to obtain this larger sample and information on the context of the involved organizations and the mechanisms used will be necessary before the conclusions can be fully understood (Vanhaecht, Sermeus, Peers, Deneckere, et al., 2010).

If you implement a pathway in a team that is already performing well, you may not identify much improvement. A poorly performing team may, on the other hand, be greatly improved by the implementation of a new pathway. Pathways would not make the best much better, but will show their maximum effect in teams, or situations where care is considered or proven to be suboptimal. Unfortunately, even though they are the most likely to benefit, teams with a low level of coordination, poor multidisciplinary communication, and adverse outcomes, will probably not be the biggest fans of either standardization or transparency. Publication bias is

therefore an important consideration as we try to interpret the pathway literature. Appropriate articles should always report the intervention in the manner suggested by the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines or the Medical Research Council (Davidoff, Batalden, Stevens, Ogrinc, & Mooney, 2008; Medical Research Council, 2000).

Conclusion

There is some evidence that appropriately developed and implemented pathways can improve the quality and safety of healthcare, but we have to be careful with overall conclusions. Pathways are complex or multicomponent interventions so one needs to be careful in generalizing results. Simply taking over implementation strategies from one organization to another, with different contexts and change mechanisms, could be inappropriate. Both scientific and practical knowledge would be enhanced by the descriptions of both the intervention and the context, as suggested by the SQUIRE reporting guidelines. Understanding the development, change, and implementation process in a particular context is critical to support multidisciplinary teams in their search for excellence. Multidisciplinary teams should invest in the organization of care processes. Care pathways are one of the methodologies to make it happen in daily practice. Although the results of the impact of pathways, as published in recent literature, is promising, clinicians and managers should evaluate each of their individual projects to make sure patient and organizational outcomes are improved because the outcome will depend on the different components of the complex intervention.

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