

Clinical Pathway Audit Tools: A Systematic Review

Kris Vanhaecht, Karel De Witte, Walter Sermeus (2007). The impact of clinical pathways on the organisation of care processes. PhD dissertation to obtain the degree of Doctor in Social Health Sciences. Faculty of Medicine, Catholic University Leuven. ISBN 9789081222211
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Introduction

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

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

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

One way to address this problem is to check or assess whether a clinical pathway in question meets the key characteristics of clinical pathways. These checklists are called clinical

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pathway audit tools. In the present systematic review, we describe and compare different audit tools. Our aim is to evaluate the ability of different tools to grade different clinical pathways, with the long-term goal of identifying a tool capable of accurately evaluating the outcome of clinical pathways.

Methods

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

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

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

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

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

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

Tools	Inclusion Criteria			Exclusion Criteria			
	Pathway doc / change process	Pathway effect/ outcome	Contains scoring dimension	Perceptions only	General recommendations on format or criteria	Scenario to develop/ implement/ evaluate	Survey on use and dissemination
Clinical Path Assessment (33)	X	X	X				
ICPAT (25)	X	X	X				
Template for Clinical Pathway Design (32)	X	X	X				
ICP Analysis Sheet (21)	X	X	X				
ICP Evaluation Form (28)	X	X	X				

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Q-A-T: Pathway Develop- ment/ Practice Standard (26)	X	X	X				
ICP Key Elements Checklist (27)	X	X	X				
Clinical Pathway Evaluation Framework (38)	X	X	X				X
Criteria For Care Pathways (34)	X	X			X		
Clinical Pathway Developme nt/Review Checklist (37)		X	X		X	X	
ICP: Evaluation (35)	X		X	X			X
Evaluation Of New ICP (29)	X		X	X			X
Critical Pathway Auditing (30)	X	X			X	X	X
Critical Pathway	X	X			X		

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Format (31)							
Clinical Pathway Audit Guide (36)	X	X			X	X	

*n=15

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

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

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Results

General characteristics of audit tools

The seven selected tools were published or developed between 1998 and 2005 (Table 2). Three tools were developed in England (25-27), one in the USA (33), one in Australia (32), one in Scotland (21), and one in Wales (28). The total number of domains and items in the audit tools range between 4 and 14, and 14 and 101, respectively. The reliability and content validity of only one tool has been tested (25). The other tools were developed, discussed, and/or revised by a pathway steering group or focus group. For these tools, only face validity has been obtained. The tools use different scoring systems: (1) an ordinal scale (0 or 1 to 4) (26;33); (2) nominal scale (yes/no/not sure/not applicable) (21;25); or (3) checkbox system (yes/no) (27;28;32) (Table 2). Total scores for each tool are calculated in different ways. Most of the tools use sum scores per domain. None of the audit tools compared until now the pathway scores with patient outcomes.

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

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

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

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

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

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

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6. The QAT Pathway Development/Practice Standard (26) was developed by McSherry et al. (England) in 2001 for a project supported by the National Health Service. It has been used to evaluate pathway projects within and between trusts. Several dimensions of the QAT Pathway Development/Practice Standard (26) are very similar to those in the ICP Evaluation Form (28). It was adapted for use by the Determining Excellence European Framework for Quality Management Standards (48). The QAT Pathways Development/Practice Standard is no longer in use and has never been validated (49).
7. The Template for Clinical Pathway Design (32) was developed by Mallock and Braithwaite (Australia) in 2005 with the support of the Centre for Clinical Governance Research in Health, the University of New South Wales. The template was based on a literature review from a master's thesis on informatics in medicine (50). It has been used to evaluate 176 clinical pathway documents from different countries. The tool is no longer in use and has never been validated (50).

Content analysis

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

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

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The ICPAT (25) and the ICP Evaluation Form (28) contain 15 of the 17 characteristics (Table 3). Whittle et al. (25) did not include operational arrangements into the ICPAT, and Jones (28) did not include implementation phase into the ICP Evaluation Form. The QAT Pathway Development/Practice Standard (26) and the Clinical Path Assessment (33) contain 13 and 10 characteristics, respectively. The ICP Analysis Sheet (21) and the Key Elements Checklist (27) both contain 9 characteristics. The Template for Clinical Pathway Design (32) contains 6 characteristics.

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

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

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

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

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Discussion

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

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

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

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

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

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