

NON-SYSTEMATIC REVIEW

Trial design & interpretation

Overview on the target population and methods used in care pathway projects: A narrative review

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Abstract

Background: There is evidence that the efficiency and effectiveness of care processes can be improved in all countries. Care pathways (CPs) are proposed as a method to improve the quality of care by reducing variation. During the last decades, CPs have been intensively used in practice. The objective of this study is to examine the study designs for investigating CPs, for which pathologies CPs are used and what the reported indicators to measure the impact of CPs are.

Methods: A narrative review of the literature published from 2015 to 2019 was performed.

Results: We identified 286 studies, of which 207 evaluated the impact of CPs, 33 were review articles, 29 studies described the development of a CP, 12 were study protocols and 5 opinion papers. The most frequently reported study design for studying the impact of a CP is pre-posttest ($n = 82$), followed by cross-sectional studies ($n = 50$). Oncology, cardiovascular disease and abdominal surgery are the domains with the highest numbers of studies evaluating the impact of CPs. Financial ($n = 86$), process ($n = 76$) and clinical indicators ($n = 74$) are the most frequently reported indicators while service ($n = 12$) and team indicators ($n = 6$) are less reported.

Conclusions: Based on the relative low number of identified studies compared with the number of CP projects in organisations, we conclude that the CP knowledge is not only found in the literature. We, therefore, argue that (inter)national scientific societies should not only focus on searching and spreading evidence on the content of care but also enhance their knowledge sharing initiatives on the organisation of care processes.

1 | BACKGROUND

In general, there is evidence of poor efficiency and effectiveness of care processes in all countries, including high-income countries, as (i) one in 10 patients is adversely affected during treatment, (ii) healthcare-associated infections can be expected in seven in 100 hospitalised patients and (iii) there is still a considerable proportion of patients who do not receive appropriate evidence-based

care because of unwarranted variation.¹ This implies that the quality of care patients receive is organised in a suboptimal way.²⁻⁴ Adherence to guidelines can improve the organisation of care and consequently quality of care. To improve adherence to guidelines, five strategies are necessary: (i) a checklist with interventions linked in time and space in the clinical guideline, (ii) identify barriers for using clinical guidelines and share successful implementation strategies, (iii) integrate guidelines for conditions that

commonly coexist, (iv) ensure that patients receive the recommended care and (v) create transdisciplinary teams and pool expertise from different fields.⁵

Care pathways (CPs) are a useful method to increase adherence to guidelines as they contain these five strategies. They have been used as structured care methodology since the 1990s and show to be a method to improve the quality of care.⁶ CPs are defined as “a complex intervention for the mutual decision-making and organisation of care processes for a well-defined group of patients during a well-defined period”.⁷ The ultimate goal of CPs is to improve outcomes by providing a mechanism to better coordinate care and reduce fragmentation and ultimately costs.⁸

Compared with 15 years ago, there is an increase in publications reporting the impact of CPs. Based on a study, published in 2004, 34% of the publications contained some form of evaluation.⁹ A Cochrane review by Rotter and colleagues in 2010 concluded that by implementing a CP, in-hospital complications were reduced and documentation was optimised with no impact on the length of stay and hospital costs.¹⁰ However, hospitals are not only interested in the general impact of CPs, but also in which results can be achieved by implementing a CP for a specific type of pathology. Until now, it is unclear which type of study designs are being used to study the effect of the implementation of CPs. As CPs are complex interventions, the golden standard should be cluster randomised controlled trials (cRCTs).¹¹ However, from a practical point of view, this is not always achievable, as organisations for example may differ in culture or readiness for change, or have different discharge criteria. Next, CPs mainly evaluate the effect for a specific group of patients, implying a specific set of disease-specific indicators is used in the evaluation. This implies that disease-specific indicators are reported and therefore reviews, and meta-analysis should only be performed for disease-specific groups. Next, to evaluate the impact of CPs, the focus should not only be on clinical indicators but should also include team and organisational aspects. Nowadays, there is more and more attention for value-based healthcare, also for CPs, with the focus on outcomes and costs.¹² The future of CPs lies in planning, improving expectations of patients and clinicians, pathway sharing and benchmarking.^{13,14}

In 2005, it was expected that the use of CPs will double in 5 year's time (from 20% to 40%). The use of CPs is, in general, lower than judged desirable, as much more patients are eligible for CP treatment.^{13,14} These numbers do not resonate in the published literature of the past years, suggesting there is a gap between practice-based knowledge available in healthcare organisations and research-based knowledge. Actually, we have no overview for what patient groups, how the CPs have been studied and how evaluation on CPs is performed. Therefore, the aim of this paper is to evaluate the state-of-art of the most recent CP research, to identify knowledge sharing opportunities for researchers, practitioners, scientific societies, and policy makers. Research questions are: (i) Which study designs are actually used to investigate

Review criteria

- An electronic search of literature using Medline was conducted based on keywords and MeSH terms, from January 1, 2015 to December 31, 2019.
- Enhanced Recovery After Surgery (ERAS) guidelines, fast track pathways and grey literature were excluded.

Messages for the clinic

- Most studies evaluate the impact of care pathways (CPs) for oncology patients, followed by cardiovascular diseases and abdominal surgery.
- CPs knowledge is not only found in the literature; clinicians should enhance their knowledge sharing initiatives on the organisation of care processes.

CPs?, (ii) For which type of pathologies are CPs used nowadays?, (iii) What are the indicators currently used to measure the impact of the CP?

2 | METHODS

A Medline search was conducted by exploring the following search terms: (“Critical Pathways” [Mesh]) OR “clinical pathway*” OR “care pathway*” from January 1, 2015 to December 31, 2019. Only articles including human subjects and English written articles and studies that described the impact of a CP were included. Studies that described the impact of Enhanced Recovery After Surgery (ERAS) pathways or fast track pathways and grey literature were excluded.

Results were screened on title and abstract for relevant information. This step was performed by DS, EC and RVZ. If there was no consensus, a fourth researcher (KV) was contacted. For answering the third research question “What are the reported indicators” the Leuven Clinical Pathway Compass was used to categorise the critical indicators/domains to evaluate the impact and quality of CPs.¹⁵ The Leuven Clinical Pathway Compass serves as a framework for dividing indicators into the following five domains: clinical, service, team, process and financial. Each CP should define one or more indicators for each domain.¹⁰ To answer this question, only randomised controlled trials (RCTs), case-control studies, pre-posttest studies and interrupted time series were included. Each measurement was classified in clinical, financial, process, service or team indicator.¹⁶ Data from each study were extracted using a standard protocol. For cross-sectional studies, qualitative studies, case studies and reviews we used continent, pathology, setting and year. For publications on the development of CP and study protocols, the categories were continent, pathology, setting, study design and year. For opinions/views this was continent, pathology and setting. For pre-posttest, case-control

studies, RCTs and interrupted times series we used continent, pathology, setting, study design, year, and type of indicators used.

3 | RESULTS

Our initial search strategy identified 6546 articles that were eligible for the screening phase (Figure 1). In total 5027 were excluded after applying exclusion criteria and checking for full-text availability. After full-text analysis, 286 articles were included in this study.

3.1 | RQ1: Which study designs are actually used to investigate CPs?

Out of the 286 included articles, 207 articles (72.4%) evaluated the impact of a CP, 33 (11.5%) were review articles, 29 (10.1%) articles described the development of a CP, 12 (4.2%) were study protocols and 5 (1.7%) were opinion papers.

3.1.1 | Details evaluation papers (n = 207)

Out of the 207 evaluation papers, 82 had a pre-posttest design (39.6%), 50 a cross-sectional (24.2%), 23 were case-control (11.1%), 16 were qualitative (7.7%), 15 were case studies (7.2%), 14 RCTs (6.8%) and 7 interrupted time series (3.4%) (Appendix 1 in Supplementary information). Most of the articles (n = 184, 88.9%) evaluated the impact of an in-hospital CP, while 10 articles described the impact of a CP from hospital to homecare (4.8%). The impact of an out-hospital CP was evaluated in 13 articles (6.3%).

Studies were mainly performed in North-America (n = 87, 42.0%), followed by Europe (n = 76, 36.7%), Asia (n = 30, 14.5%) and Oceania (n = 10, 4.8%). Studies in Africa (n = 2), South-America (n = 1) and Worldwide (n = 1) are less frequently performed.

3.2 | RQ2: For which type of pathologies are CPs being used nowadays?

Figure 2 gives an overview of the different main pathologies described in the evaluation papers (n = 207). Most studies evaluate the impact of CPs for oncology patients (n = 31, 15.0%), followed by cardiovascular diseases (n = 30, 14.5%) and abdominal surgery (n = 25, 12.1%). The 33 paediatric CPs were classified into the categories mentioned in Figure 2. In the next section, more details are given for the top 6 of the main pathologies.

Oncological CPs (n = 31) are mainly developed for the following pathologies: colorectal cancer (n = 6), breast cancer (n = 5), cancer in general (n = 4), head and neck cancer (n = 2) and lung cancer (n = 2). CPs for cardiovascular diseases (n = 30) are mainly focusing on acute coronary syndrome (n = 7), cardiac surgery (n = 5), arterial fibrillation (n = 4), chest pain (n = 4) and cardiac related complications (n = 3). Abdominal surgery CPs (n = 25) are mainly for pancreatectomy/pancreaticoduodenectomy (n = 7) and appendectomy (n = 6). The respiratory diseases CPs (n = 22) are mainly related to asthma (n = 8), general respiratory illness (n = 4), pneumonia (n = 3) and chronic obstructive pulmonary disease (COPD) (n = 2). The orthopaedic pathologies (n = 18) are mainly hip fractures (n = 5), knee prosthesis (n = 3) and combination of hip and knee prosthesis (n = 2). The pathologies grouped in neurology/neurosurgery (n = 14) are mainly brain trauma (n = 3), stroke (n = 3) and dementia (n = 2).

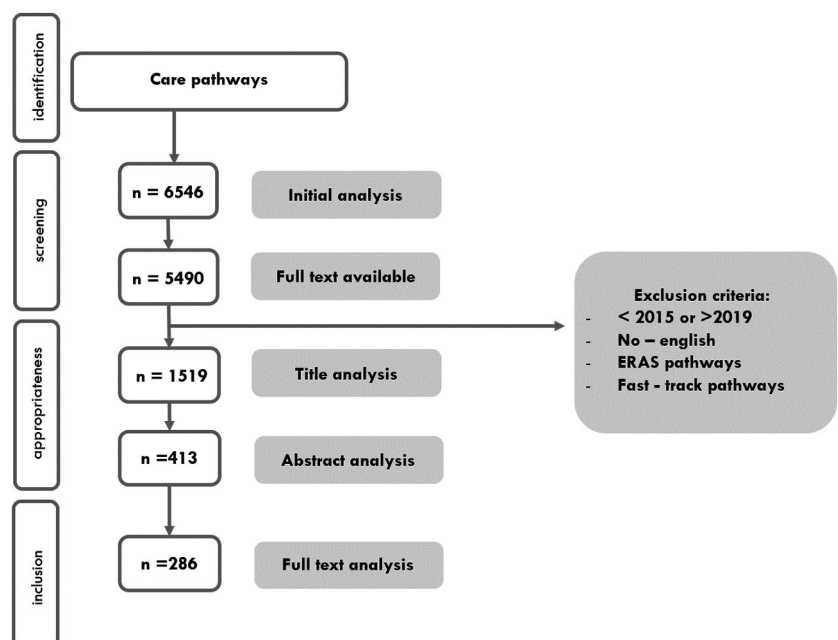


FIGURE 1 Flowchart of the article selection process

Different main pathologies (n=207)

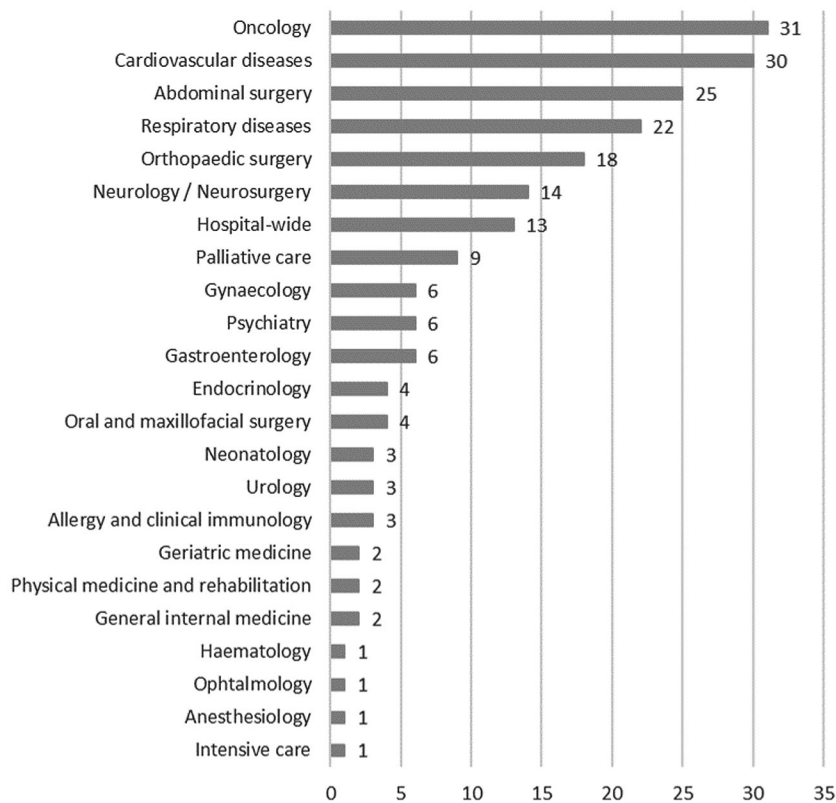


FIGURE 2 Overview of the different medical specialties where evaluation papers were performed (n = 203)

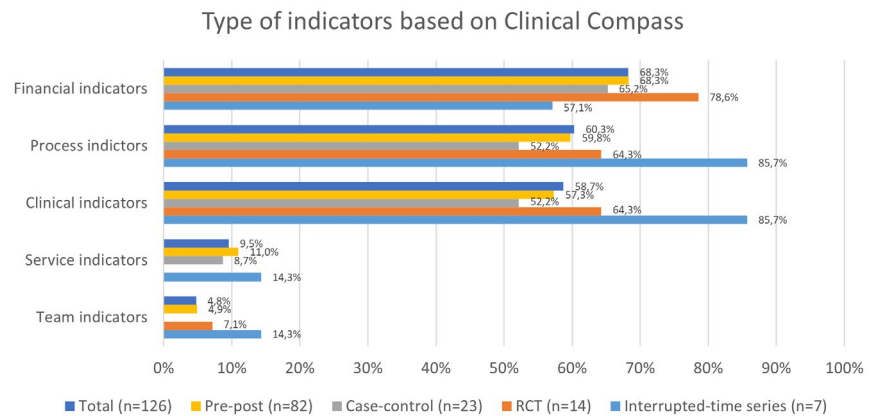
3.3 | RQ3: What are the indicators currently used to measure the impact of the CP?

For answering the research question “What are the reported indicators to measure the impact of the CP?” the reported outcomes in the articles were classified based on the Leuven Clinical Pathway Compass.¹⁶ Only case-control studies, RCTs, interrupted time series designs and pre-post studies were included for this sub-analysis (n = 126). Articles could report indicators in more than one domain of the Leuven Clinical Pathway Compass and could therefore be classified in more domains. Financial indicators were mainly measurements regarding the length of stay (n = 65) and costs (n = 28). Process indicators contain, besides adherence to pathologic specific guidelines (n = 57), also time indicators, for example, time to coronary angiography for patients with the non-ST elevated acute coronary syndrome (n = 22). Readmission rate, complication rate and mortality were clinical indicators in respectively 27, 21 and 17 articles. Service indicators were less frequently reported and were mainly measurements regarding patient satisfaction (n = 7) and quality of life (n = 3). Team indicators were mainly indicators evaluating the coordination between healthcare professionals (n = 4). In general, interrupted time series studies reported mainly process indicators (n = 6, 85.7%). In RCTs mainly financial indicators (n = 11, 78.6%), followed by process indicators (n = 9, 64.2%) and clinical indicators (n = 9, 64.2%) are reported. For pre-post studies this is, respectively, 68.3% (n = 56), 59.8% (n = 49) and 57.3% (n = 47) and for case-control studies 65.2% (n = 15), 52.1% (n = 12) and 52.1%

(n = 12), while none of the 23 case-control studies reported team indicators (Figure 3). For cardiovascular disease, team (n = 12, 40%), financial (n = 12, 40%) and service indicators (n = 10, 33.3%) were the highest reported indicators. For abdominal surgery, these were service (n = 12, 48%) and financial indicators (n = 9, 36%).

4 | DISCUSSION

The aim of this review was to evaluate: (i) which study designs are used to investigate CPs, (ii) for which type of pathologies CPs are used, (iii) Which are the reported indicators to measure the impact of the CP. During the past five years, CP research mainly resulted in evaluation papers (n = 207), followed by 33 review articles and 29 articles describing the development of a CP. Study protocols and opinion papers were less frequently published. Of the evaluation papers, 40.3% reported a pre-posttest design (n = 82) and 24.2% reported cross-sectional studies (n = 50). RCTs were less frequently published (n = 14). CPs are mainly evaluated in the domains of oncology (n = 31), cardiovascular diseases (n = 30) and abdominal surgery (n = 25). The focus of studies regarding CPs is mainly in-hospital. The reported outcomes are predominantly length of stay (n = 65) which is classified as a financial indicator based on the Leuven Clinical Pathway Compass,¹⁶ adherence to pathology specific guidelines (n = 57) as process indicator and readmission (n = 27) as clinical indicators. Service (n = 12) and team indicators (n = 6) are less reported.

FIGURE 3 Type of indicators based on Clinical Pathway Compass domains

We found an increase in the proportion of publications including some form of evaluation. In 2004, this was 34%, while in our study this amount has risen to 72%. However, it is hard to compare the impact of different studies as in most papers, CPs were used without specifying or defining what was actually developed and implemented.^{9,15} To understand the impact of CPs, as CPs are complex interventions, one must include the context in which the CP was developed and implemented. The question still remains if cRCTs are the most appropriate way to study CPs, as they are considered the gold standard to study the effect of complex interventions.¹¹ cRCTs are the highest possible design, however, this is not always achievable because of the fact that the context is hard to uniform and the implementation of a CP never stops. Pre-posttest are not the most recommended way as the time for follow-up is too short. Interrupted time series designs are more recommended as they enable to study the impact of a CP for a longer time period and evaluate each of the active components in a different time period. This is necessary to better understand how and under which circumstances CPs are working. Ideally, a process evaluation of the CP should be performed as well as an effect evaluation. Some form of process evaluation was only found in 3 of the included publications. To study the impact of CPs, the primary outcomes should also be uniform and well defined. On the other hand, sample size calculations should be performed based on power analyses to make correct conclusions. We observed that this was performed more often in the stronger designs.

Within each main pathology, there is a wide variation of included pathologies where a CP was developed and implemented. The main pathology oncology was the most frequently reported in our review. This is in contrast with the 2010 Cochrane review from Rotter et al, which included no oncological CPs.¹⁰ A possible explanation for this difference might be the used definition of CP, leading to different inclusion criteria in our study compared with the Cochrane review. The present review contains a relatively low number of orthopaedic and abdominal surgery CPs. This is because of our exclusion criteria as studies reporting and evaluating the impact of ERAS guidelines or fast track pathways were excluded. This implies that there is also a conceptual diversity of CPs.^{9,14,15,17}

Financial indicators are the indicators that are reported most frequently for follow up in CP research. This is in line with the growing attention for value-based healthcare, in which value is

defined as quality over cost.¹² CPs are developed to increase the quality of care, however, only 58.7% of publications included clinical indicators to evaluate their care process. To improve the quality of care, clinical indicators should be included in each CP. The main focus of CP evaluation is financial, process and clinical indicators. A pitfall of this is that organisations focus on the standardisation of their care process but forget the patient. This can lead to less patient-centred care.¹⁸ Last, healthcare providers should use the CP in daily practice. Although there is evidence that CPs increase the organisational level of care processes and decrease the risk of burnout,¹⁹ less attention is given to this type of indicators (eg, adherence). In general, to improve the quality of care, when CPs are developed, indicators in each of the 5 domains of the Leuven Clinical Pathway Compass should be defined and followed up. The frequencies in which clinical outcomes, service and team indicators are reported in this review were lower compared with a study published in 2004.⁹ Compared with a recent review, our results are lower for team and service indicators while for the other domains our results are much higher.¹⁵ On the other hand, length of stay, readmission, complications and mortality are still the most commonly reported outcome indicators. Length of stay is an indicator reporting a significant reduction after the implementation of CPs.¹⁰ However, from patient and healthcare provider perspectives, it is necessary that hospitals pay more and more attention to service and team indicators, which is unseen during the past 5 years. First, the ultimate goal of CPs is to reduce fragmentation of care or team while simultaneously improving team and patient satisfaction.⁸ Moreover, this is in line with the expansion from triple aim to quadruple aim.¹⁹ Besides patient experiences, improving population health and reducing costs were included in triple aim. However, to improve patient outcomes, the focus of an organisation should not only be on improving adherence to clinical guidelines but also on improving the wellbeing of their healthcare professionals, which is linked with a higher quality of care.²⁰ This leads to quadruple aim, where improving the work-life balance of health care providers is added to the triple aim.²¹ Measuring team indicators gives organisations very useful information as teams should be involved in the whole process of CPs development and implementation. In this way, high-performing teams can be built.²² Healthcare professionals are responsible for performing the CPs.

During the last decades, they have been confronted with more and more tasks. Not all teams are ready for change and it is necessary to take this into account when a CP is developed. On the other hand, studies have shown that implementation of a CP leads to better team outcomes.²² From this point of view, these team indicators are equally important as reporting financial, process and clinical indicators. It can be a way to understand how the team is involving and detect other problems in an early stage.

Although patient satisfaction was already part of triple aim,²³ only a few studies include this as an outcome measurement. This is remarkable for a patient-centred and multidisciplinary concept as CPs. In general, more and more attention are given to patient-reported outcomes (PROMS) and patient experienced outcomes. These (validated) measures should result in more involvement of patients during the development and implementation of CPs but also on reported outcomes (service indicators). PROMS include patient satisfaction and quality of life.²⁴ Team and patient indicators are also connected. When healthcare professionals felt that they are working within a psychological safety environment, they indicate that the given care would result in higher patient satisfaction.²⁵ As mentioned in the introduction, there is a vast amount of CP projects implemented in healthcare organisations. However, only a small proportion of these projects are thoroughly evaluated and even less are published. This implies that there is publication bias in publishing CP research and a gap between practical knowledge and the literature. The knowledge of CPs is not only found in the literature but is found in the organisations itself or in knowledge-sharing networks. In Belgium and the Netherlands, a knowledge sharing network, the Belgian-Dutch Clinical Pathway Network (www.nkp.be) is active. In 2019, 44 member organisations (34 in Belgium and 10 in The Netherlands) implemented 853 CPs, 246 CPs were in development phase and 28 CPs were planned to be developed and implemented. Only 4 of them have been published.²⁶⁻²⁹ Other knowledge-sharing network are, for example European Pathway Association (www.e-p-a.org) or the Japanese Society for Clinical Pathways (www.jsccp.gr.jp).

Several study limitations should be reported. First, despite the search strategy, other relevant research can be missed, for example grey literature or care protocols which are CPs (according to the E-P-A definition) but are not labelled as CPs. Second, our study does not include ERAS guidelines or fast track pathways, as it is debatable whether these are similar to the definition of CPs. Including these articles would make the comparison with previous CP reviews less meaningful. Last, we could not attempt a statistical meta-analysis because of the heterogenous research context, study designs and as it was not always clear what the active components of the studies were. Nonetheless, our review provided valuable insight in the current status of CP research.

Future research should include what was implemented and under which circumstances. The culture of the organisation, the readiness of the team for change, teamwork, etc can provide more insight to understand why and under which circumstances CPs are working or not. This should include (i) specify which changes, teams

or organisations want to achieve, (ii) how this will be achieved by showing the method, rationale or theory for the improvement, (iii) motivation and capability of the organisation and (iv) context within which the improvement work is occurring.³⁰ On the other hand, research should also focus on how organisations include patients and team members in the development and implementation of their CPs. As service and team indicators are equally important as clinical, process and financial indicators. In the future, (inter) national scientific societies should follow the chosen path of developing guidelines that includes not only the necessary clinical context but also organisational aspects. For pathologies that imply surgery, the focus should also be ERAS. Organisations should not choose between ERAS or CPs, but ERAS can be an added value of CPs.

5 | CONCLUSION

CP research mainly focuses on the impact of CPs on a specific pathology by using pre-posttest design studies. To improve the quality of care, in general, more attention should be given to clinical outcomes and patient and team aspects. Over 70% of the included papers reported an evaluation of the impact of CPs. However, less strong study designs were used and only a relatively small number of CP projects is actually published. This implies that there is still a large publication bias. The future of CPs is knowledge sharing. This should not only be performed by (inter)national CP networks. It should be set as a high priority on the agenda of (inter)national scientific societies, as CPs can be the linking pin between the content and the organisation of the care process, and thereby enhance the value of healthcare.

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Not applicable

DISCLOSURES

Not applicable.

AUTHORS' CONTRIBUTIONS

DS, EC, RVZ and KV conducted the literature search and data analysis. DS, EC, RVZ and KV drafted the manuscript. WS, MP and ABP revised the manuscript. All authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the Supporting Information section.

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