

California Health Benefits Review Program

Brief: Clinical Care Pathways

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Clinical Care Pathways

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CLINICAL CARE PATHWAYS

Introduction

In response to a request from the legislature to analyze Assembly Bill 2209, Health care coverage: clinical care pathways, the California Health Benefits Review Program (CHBRP) undertook the task of preparing a brief that includes a review of the published literature and a summary of available information on the impacts of the use of clinical care pathways (CCPs). It provides a general (but not legal) definition of CCPs and then summarizes the evidence on CCPs implemented at the initiation of health plans and insurers, as well as CCPs implemented at the initiation of providers (e.g., physician groups, hospitals).

Defining CCPs

CHBRP is unaware of any standard clinical or legal definition of CCPs, and the definitions provided in the literature vary greatly. A literature review by De Bleser et al. (2006) identified 84 different definitions for clinical pathways. These definitions included broad terms such as care pathway, protocol, and guideline. A team of Cochrane Review authors reviewed the 84 definitions of CCPs and put forth several criteria that they suggested be used as a basis for development of a standardized, internationally accepted definition (Kinsman et al., 2010):

- 1) The intervention consists of a structured multidisciplinary plan of care;
- 2) The intervention is used to assist the translation of guidelines or evidence into practice;
- 3) The intervention details a set of necessary or recommended steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol, or other “inventory of actions”;
- 4) The intervention describes timeframes or criteria-based progression to proceed through the steps; and
- 5) The intervention aims to standardize care for a specific clinical problem, procedure, or episode of health care in a specific population.

These criteria may be too broad to be used to legally define CCPs as different from other utilization management techniques, but they do give an idea of the general complexity and structure of CCPs. The goals of CCPs are to simultaneously improve patient outcomes and reduce costs (Lawal, 2016). The following sections of this brief consider available evidence as to whether plan/insurer use of CCPs or provider use of CCPs meet either of these goals.

CCPs have been used to suggest treatment sequences for conditions with high variability in treatment patterns or outcomes and can apply to a variety of prevalent or high-cost conditions (Avalere Health, 2015). Cancer care has been a focus of CCPs, but they are also being developed for a variety of other conditions such as rheumatoid arthritis, hepatitis C, and inflammatory bowel disease (Avalere Health, 2015). CCPs may be developed by plans or insurers for internal use, developed by providers (hospitals, physician groups, or others) for internal use, or developed by other entities and purchased for use by plans/insurers or by providers acting independently of any plan/insurer involvement. Examples of commercially available oncology CCPs (see further descriptions by the vendors at the links, below) include:

- [Via Oncology \(http://viaoncology.com/product-portfolio/pathways-portal.htm\)](http://viaoncology.com/product-portfolio/pathways-portal.htm);
- [Cardinal Health's PathWare™ Pathways Management System \(http://www.cardinalhealth.com/en/services/physician-s-office/physicians-office-business-solutions/vitalsource-gpo/oncology-solutions/clinical-solutions/pathware-pathways-solution.html\)](http://www.cardinalhealth.com/en/services/physician-s-office/physicians-office-business-solutions/vitalsource-gpo/oncology-solutions/clinical-solutions/pathware-pathways-solution.html);
- [eviti \(http://www.eviti.com/cancer_care/products-2/\)](http://www.eviti.com/cancer_care/products-2/); and
- [McKesson's US Oncology \(https://oncology.mckessonsspecialtyhealth.com/clinical-tools/value-pathways\)](https://oncology.mckessonsspecialtyhealth.com/clinical-tools/value-pathways).

Use of CCPs by State-Regulated Health Plans/Insurers in California¹

In California, CCPs may be used in the care of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI). CHBRP surveyed health plans regulated by DMHC and health insurers regulated by CDI regarding their use of CCPs in cancer care.² Five respondents indicated that they were not using CCPs for cancer care; the other seven plans/insurers did not respond. From an online search, it appears that CCPs are applied to cancer care for some enrollees in at least one plan.³ Due to limited survey responses, CHBRP cannot estimate the exact percentages of enrollees in DMHC-regulated plans and CDI-regulated policies currently affected by plan/insurer use of CCPs in cancer care.

Approach to Analyzing the Impacts of the Use of CCPs

CHBRP conducted a review of the literature to assess the impact of the use of CCPs on health care outcomes including morbidity and mortality, as well as the impact on costs. CHBRP reviewed studies regardless of whether CCPs were implemented at the initiation of plans/insurers or providers. Studies were identified through searches of PubMed, the Cochrane Library, Web of Science, and the Cumulative Index of Nursing and Allied Health Literature. The search was limited to abstracts of studies published in English. Abstracts published from 2000 to the present were included.

Of the 2,257 articles found in the literature review, 34 were reviewed for potential inclusion in this brief, and 17 studies were included in this brief. The other articles were eliminated because they did not focus on the effect of CCPs on health outcomes, processes of care, or costs; were of poor quality as defined by the CHBRP protocol for evaluating the research literature;⁴ or did not report findings from clinical research studies. This brief reports the results on (1) the use of CCPs at the initiation of plans/insurers; and (2) the use of CCPs at the initiation of providers.

¹ For estimates of enrollees in state-regulated health insurance, see CHBRP's *Estimates of Sources of Health Insurance in California for 2017*, available at www.chbrp.org/other_publications/index.php.

² CHBRP regularly surveys the largest (by enrollment) DMHC-regulated plans and CDI-regulated insurers in California and a sample of DMHC-regulated plans that enroll Med-Cal beneficiaries, as these plans/insurers provide the health insurance that may be subject to state-level benefit mandates.

³ AIM Specialty Health® (AIM) is implementing the Anthem Cancer Care Quality Program including enhanced reimbursement for initial diagnosis and for ongoing care that follows certain care pathways. For more information, see <https://anthem.aimoncology.com/>.

⁴ See *Research Approach* available at www.chbrp.org/analysis_methodology/medical_effectiveness_analysis.php.

Evidence Regarding Plan/Insurer Use of CCPs

CCPs can be used by health plans and insurers in ways that are more flexible or restrictive depending on implementation goals and for a variety of purposes. CHBRP is aware of their use in educating providers and in offering financial incentives to providers for greater adherence to the recommended treatment sequence. Although plan/insurer use of CCPs may have impacts on health outcomes and costs, there is limited published evidence assessing any such impacts.

Health Outcomes

CHBRP did not identify any studies of the use of CCPs by health plans/insurers that reported morbidity or mortality. One study that used retrospective single-group, pre-test/post-test designs evaluated oncology CCPs (for breast, colon, and lung cancer in the first year of the program and five additional, unspecified malignancies in the second year) implemented by Blue Cross Blue Shield Michigan (BCBSM) in partnership with Cardinal Health Specialty Solutions (Cardinal Health), which is a vendor of oncology CCPs. The authors reported that the use of oncology CCPs was associated with lower rates of emergency room and hospital use (Feinberg et al., 2012). Although these findings suggest that implementation of oncology CCPs by health plans/insurers improves health outcomes, the study did not include a comparison group. Without a comparison group, one cannot rule out the possibility that the reductions in emergency department and hospital use were due to other changes in care delivery that occurred at the same time that the CCPs were implemented.

CHBRP concludes that there is insufficient evidence to assess the extent to which the use of CCPs by health plans/insurers impacts health outcomes. It should be noted that the absence of evidence is not the same as evidence of no impact. CCPs that are used by health plans/insurers may affect health outcomes, but the available evidence is insufficient to draw conclusions.

Cost

There are a limited number of studies that address changes in costs associated with plan/insurer use of CCPs. CHBRP identified three studies (Feinberg et al., 2012; Feinberg et al., 2013; Kreys et al., 2013) that used retrospective single-group, pre-test/post-test designs to assess payer-provider collaborative implementation of oncology CCPs. These CCPs were used by two health plans (BCBSM and CareFirst BlueCross BlueShield of Washington, DC, northern Virginia, and Maryland [CareFirst]), both in partnership with Cardinal Health.

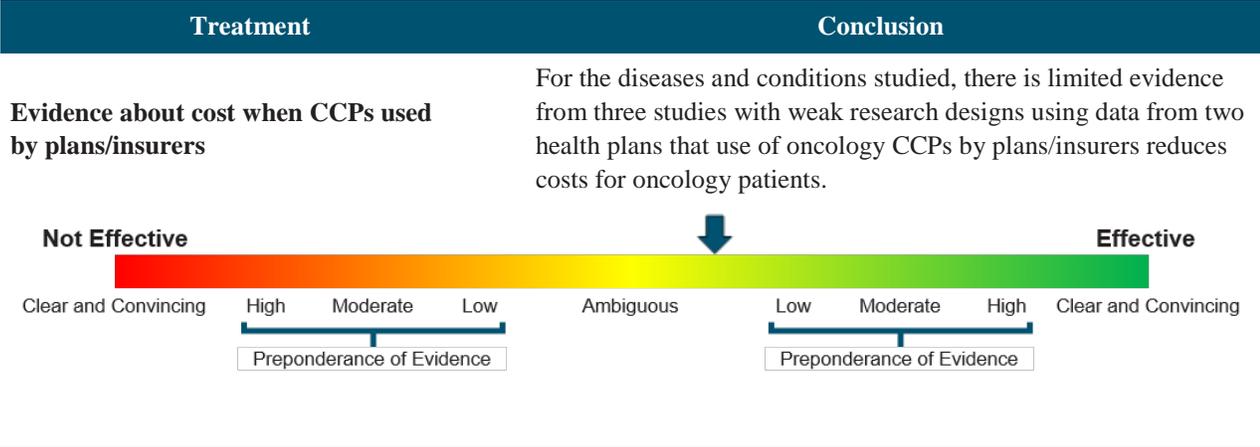
One study reported that oncology CCPs implemented by BCBSM in partnership with Physician Resource Management (an oncology consulting firm) and Cardinal Health were associated with cost savings resulting from reduced variation in chemotherapy regimens, conversion from brand drug regimens to generic regimens when equally effective, and conversion from more expensive to less expensive brand drug regimens (Feinberg et al., 2012).

Two studies (Feinberg et al., 2013; Kreys et al., 2013) analyzed data from CareFirst on the impact of oncology CCPs (for breast, lung, and colorectal cancers) that it developed in partnership with Cardinal Health in 2008. The two studies used different samples of patients from this insurer. One study reported a 15% savings on cancer-related claims costs, noting that cost savings were

accompanied by greater reductions in variability of drug combinations used as first-line treatments (Feinberg et al., 2013). The study noted potential sample bias due to motivated participating providers; thus, their findings may represent a high estimate of potential savings. A second study reported substantial chemotherapy cost savings and a significant decrease in hospitalization costs when CCPs were used (Kreys et al., 2013). CHBRP did not find any more recent studies reporting cost results for this insurer or any other insurer in the published literature.

Weak study designs are a key limitation of these three studies; the absence of a comparison group in these studies limits CHBRP’s confidence that the changes observed are due to the CCPs and not to other factors that changed at the same time. The evidence of cost impacts when CCPs are used by plans/insurers is summarized in Figure 1. Due to the small number of studies and the limited number of conditions/diseases studied, the results may not be generalizable.

Figure 1. Plan/Insurer Use of CCPs: Cost Summary



Evidence Regarding Provider Use of CCPs

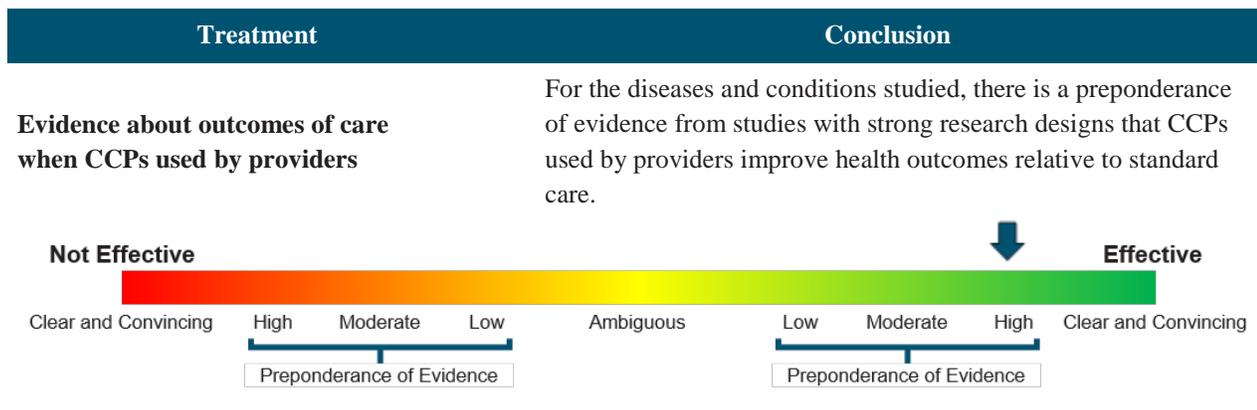
In addition to their use by health plans, CCPs can be used by providers (e.g., physician groups, hospitals) for purposes such as education about best practices or for quality improvement initiatives. This section considers the evidence as to whether provider use of CCPs improves health outcomes and/or lowers costs. CHBRP assumed that unless studies specifically mentioned plan/insurer involvement in provider use of CCPs, plans/insurers were not involved.

CCPs are often designed to improve clinical health outcomes through standardizing the care delivered by clinicians or in institutions, and/or received by patients. There is substantially more published, peer-reviewed literature on the use of CCPs by providers than on their use by health plans/insurers, but these systematic reviews and studies typically focused on one disease or condition. CHBRP considered two sets of outcomes in its review: (a) health outcomes, including both physiological measures and patient-reported outcomes; and (b) process of care outcomes, including treatment adherence, accuracy of diagnoses, and accuracy of treatment plans.

Health Outcomes

CHBRP found two systematic reviews and one randomized controlled trial (RCT) that assessed the use of CCPs by providers to reduce morbidity or mortality. One systematic review of RCTs found that the use of CCPs with post myocardial infarction patients (with or without left ventricular dysfunction and/or heart failure) reduced the incidence of heart failure and other cardiac complications including myocardial infarction (Amin, 2006). Another systematic review that included two cluster RCTs, one RCT, one interrupted time series study, and three retrospective cohort studies concluded that care pathways for treatment of heart failure decreased mortality rates in heart failure patients (Kul et al., 2012). One RCT reported improved functional status and reduced pain in hip and knee arthroplasty patients with degenerative joint disorder for up to 12 months post-operatively (Gooch et al., 2012). The evidence on changes in health outcomes associated with provider use of CCPs is summarized in Figure 2.

Figure 2. Provider Use of CCPs: Health Outcomes Summary

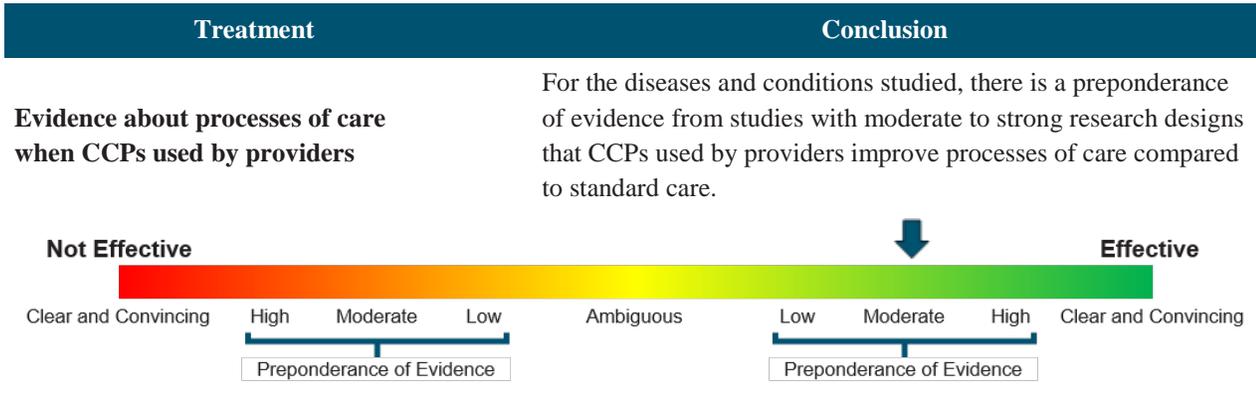


Processes of Care

CHBRP found four studies that examined the effect of CCPs on processes of care. One cluster RCT in the UK comparing care with the use of a clinical pathway to standard care for children presenting to the emergency department with acute asthma and wheezing found that the use of the pathway was associated with a statistically significant 30% reduction in the total number of prescribing errors, improved rates of discharge with a care plan in pediatric acute asthma patients, and a modest reduction in the length of stay when discharge criteria were adhered to (Cunningham et al., 2008). Another cluster RCT in Italy found that in hospitals with CCPs, patients with cancer had a higher probability of receiving potentially appropriate medications (Costantini et al., 2014). An RCT conducted in Australia that tested pathology-focused CCPs found a reduction in unnecessary laboratory tests (Board et al., 2000).

Finally, a prospective cohort study of patients in China admitted to the hospital for newly diagnosed breast, colon, or rectal cancer compared outcomes for two cohorts treated according to clinical pathways and one cohort that received standard care. The study found significant improvement in compliance with standard preoperative care processes in the cohorts treated according to CCPs (Bao et al., 2016). The evidence on changes in processes of care associated with provider use of CCPs is summarized in Figure 3.

Figure 3. Provider Use of CCPs: Processes of Care Summary

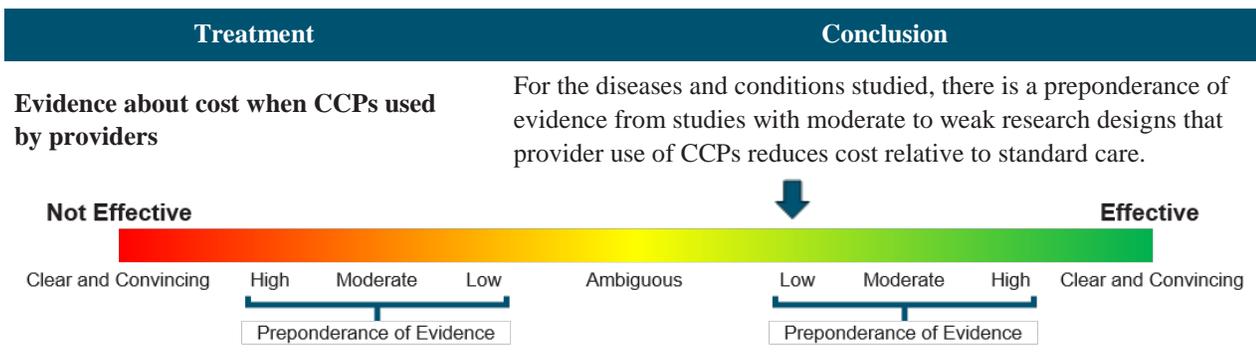


Cost

While there is more research evidence on the cost impacts of provider use of CCPs than plan/insurer use, the literature is not extensive. One systematic review of joint arthroplasty clinical pathways (Van Herck et al., 2010) included retrospective and prospective cohort studies examining cost impacts of CCPs. This review reported that three studies found significant cost savings ranging from \$800 to \$3,000 per patient (Van Herck et al., 2010).

CHBRP identified two other individual studies of weak design reporting lower cancer care costs associated with use of CCPs by providers. One national retrospective cohort study of about 1,400 patients with non-small-cell lung cancer treated in the outpatient setting found 35% lower costs for patients treated on-pathway vs. those treated off-pathway with no offsetting effects on survival (Neubauer et al., 2010). The other retrospective cohort study focused on colon cancer and reported lower overall costs for patients treated according to CCPs with no decrease in patient survival (Hoverman et al., 2011). It should be noted that due to the weak study designs, whether the lower costs were related to the use of CCPs or to changes in other factors could not be determined. The evidence on cost savings associated with provider use of CCPs is summarized in Figure 4.

Figure 4. Provider Use of CCPs: Cost Summary



Discussion

As various stakeholders in the health care system continue to engage in efforts to improve quality of care, reduce treatment variability, and manage costs, there may be increased use of CCPs designed to achieve these goals. However, documentation in the published literature of their impacts when used by payers/insurers is quite sparse. To date, it appears that CCPs are used by payers/insurers for educational purposes or to offer incentives for adherence to the pathway; CHBRP found no published evidence of payers/insurers requiring adherence to CCPs or reducing payments if providers used treatments not on the pathway.

Multiple issues complicate the assessment of the effectiveness of CCPs. The first issue relates to the portion of a physician's practice affected by any specific CCP used by a plan/insurer. When providers are paid by several plans/insurers that use different CCPs for a specific condition, the possibility of conflicting CCPs could substantially diminish any positive effects. By contrast, when a CCP for a specific condition is used by a group of providers, it has the potential to be consistently implemented for all patients in the practice or group for whom the CCP is applicable.

A second complicating factor in assessing the effectiveness of CCPs is that published studies of plan/insurer use of CCPs are much more limited and have focused on oncology in the outpatient setting, where treatment often spans several months or longer. By contrast, published studies of provider use of CCPs are more variable in the diseases and conditions studied and the length of a treatment episode. The heterogeneity of the studies limits the generalizability of the findings, and the available evidence is insufficient to conclude that CCPs are more effective when implemented at the initiation of providers than at the initiation of plans/insurers.

Conclusions

The evidence on the impacts of CCPs on health outcomes, processes of care, and costs tends to be condition-specific, so study results cannot be generalized beyond the diseases/conditions studied. For plan/insurer use of CCPs, there are very few published studies, and the evidence is insufficient to assess the impacts on health outcomes. There is limited evidence from three studies with weak research designs using data from two health plans showing reduced oncology costs for oncology patients, and there is insufficient evidence to draw conclusions about cost impacts when CCPs are used for other conditions. For provider use of CCPs, there is stronger evidence from higher-quality research studies that their use leads to improved health outcomes and improved processes of care. There is also evidence from studies with moderate to weak research designs that provider use of CCPs lowers costs. The available evidence is insufficient to conclude that CCPs are more effective when implemented by providers than by plans/insurers.

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from six University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis.

CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature.

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CHBRP assumes full responsibility for the brief and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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