
Clinical Pathways: Overview of Current Practices and Potential Implications for Patients, Payers, and Providers

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Prepared by:

Avalere Health LLC
1350 Connecticut Avenue NW
Suite 900
Washington, DC 20036



Avalere would like to thank the individuals listed below for their insights and perspectives in developing this report:

Francesca Pirog, BS

Hillary Kleiner, MPH

Borislava Marcheva, MA

Dayo Jagun, MBBS, MPH

Natalie Sweetnam, BA

Miryam Frieder, MBA, MPH

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EXECUTIVE SUMMARY

Payers and providers are increasingly implementing decision-support tools, such as clinical pathways (CPs), to improve the quality of care delivered and to control healthcare costs in the United States. In response to a greater emphasis on paying for value in healthcare, payers and providers are also beginning to link financial incentives to compliance with pathway recommendations and achievement of improved patient outcomes.

CPs are multidisciplinary care plans that provide specific guidance on the sequencing of care steps and the timeline of interventions. They often consider evidence on the benefits and harms of alternative care options and rely on clinical practice guidelines (CPGs) as a foundation. CPs often take the cost of drugs or services into account, particularly those that are deployed by payers and at-risk providers. Given the expansion of pathways and their increasing influence on patient care, Avalere undertook a study to examine their development, use of evidence to inform their design, implementation processes, and impact on the quality of care delivered, costs, and health outcomes.

Avalere's research found that providers, and third-party vendors are the principal developers of pathways (specialty society development is limited). Payers are also somewhat involved in pathway development, however they are the primary drivers of CP use (deployment). These stakeholders, particularly payers and providers, develop and adopt CPs to improve quality of care and reduce variation in treatments and costs. Overall, there is wide variation in the patterns of development, testing, and revision among pathway developers. For example, pathway developers differ in who is involved in committees that develop pathways and what sources of evidence are used. In many cases, there is limited transparency into the development and testing process.

Typically, pathway users aim to guide treatment to achieve improved health outcomes and quality of care. Providers that assume more risk (such as accountable care organizations) often use CPs as a tool to manage their risk by controlling costs and assisting providers in meeting quality metrics. Providers outside of risk-bearing arrangements focus more on improving quality of care and treatment standardization when implementing their own pathways. Payers and providers interviewed for this research report that another motivation to use of CPs is to enhance the predictability of the course and cost of care, with potential positive improvements to existing treatment variations. The available evidence on the impact of CPs is limited, but suggests that

they have the potential to reduce costs and the utilization of some healthcare services. To date, there is limited research that examines their impact on quality of care and health outcomes.

Despite these potential benefits, a number of stakeholder concerns were identified. Though physicians both develop and use CPs as part of organizational quality improvement initiatives, the physician groups interviewed expressed concern with the administrative burden of complying with multiple payer-deployed pathways. In addition, providers, patient organizations and professional societies raised questions as to whether pathways could limit treatment options, particularly with regard to tailoring care to the needs of individual patients, and hamper shared decision-making between physicians and patients regarding appropriate treatment.

A lack of transparency in current pathway practices may hinder stakeholders' ability to ensure that the development and implementation process for pathways is inclusive, relies on robust and current evidence and procedures, and supports measurement of impact. For example, patients are rarely involved in CP development or evaluation, which could affect the extent to which pathways reflect or take into consideration individual patient perspectives and needs.

As interest in value-based healthcare continues to drive use of pathways, stakeholders can work together to develop strategies to ensure pathways are operationalized to align with payer, provider, and patient needs. Strategies to enhance provider and patient communication around clinical pathways and how they may impact treatment choices are needed. Further research is required to more fully understand the impact of pathways and what the appropriate adherence thresholds should be to account for patient variation in care across conditions. In addition, developing and instituting principles or standards for CP development and deployment may be a helpful step forward. The American Society of Clinical Oncology (ASCO) is one of the few organizations that has proposed potential development and deployment standards for pathways in their payment and delivery reform proposal released March 2015, suggesting that their organization should be tasked with developing pathway appropriate use criteria.¹

INTRODUCTION

In response to rising costs in the United States (U.S.) healthcare systemⁱⁱ and efforts to shift payment and care delivery away from remunerating the quantity of care toward rewarding quality and value, payers and providers have adopted new models, such as accountable care organizations (ACOs) and other mechanisms, to better manage utilization, variations in care, and costs.

Clinical pathways (CPs) are one of the tools that payers and providers are increasingly adopting to meet these aims. CPs are defined as structured and multidisciplinary care plans used to detail essential steps and timing in the care of patients with a specific clinical problem.ⁱⁱⁱ Both payers and physicians are interested in developing CPs to address conditions with high variability in treatment patterns or outcomes, reduce costs, and decrease the use of less effective therapies or those with a higher incidence of side effects.^{iv} Payers, in particular, view CPs as a mechanism to inform providers of payment or prior-authorization policies associated with certain treatments, given that pathways are often linked to reimbursement, and a way to manage actuarial risk. CPs may also be implemented as part of broader quality improvement initiatives that aim to standardize treatment protocols around best practices and evidence-based guidelines. Physician groups interviewed indicated that they develop CPs to improve quality of care, standardize treatment options, reduce costs, as well as to preempt payer-mandated CP programs.^v Other research suggests that providers in risk-bearing agreements are most likely to develop and adopt CPs.^{vi}

CPs are typically developed by providers or third-party pathway vendors using nationally recognized guidelines, such as the National Comprehensive Cancer Network (NCCN) guidelines,^{vii} which are then modified as needed by advisory boards or committees. Some providers (e.g., Moffitt Cancer Center & Research Institute) have created CPs independently, often using clinical practice guidelines (CPGs) as a starting point and making modifications based on their own clinical experience. Payers most often implement vendor-developed programs that are likely to include preferential positioning for preferred treatments. Examples of leading vendors in the oncology CP market include eviti, Inc., ION Solutions, D3 Oncology Solutions, and PathForward. (See **Appendix A** for additional information on select CP developers).

To date, the CPs developed have focused mainly on oncology, especially for common cancers, such as breast and lung cancer,^{viii} and those that are resource intensive to treat, such as pancreatic cancer.^{viii} However, the development and application of CPs in other clinical areas, such as cardiology,^{ix} gastroenterology,^x and immunology,^{xi} is gaining traction.

Given the expansion in CPs and their increasing influence on patient care, it is important to obtain a better understanding of their development, implementation, and impact on quality, cost, and health outcomes. Between May and December 2014, Avalere conducted primary and secondary research of existing CP programs to assess these issues in further detail. This analysis aimed to identify potential opportunities and challenges associated with the adoption of CPs.

RESEARCH APPROACH

To frame and guide the analysis, we adopted the following definition of clinical pathways:

Multidisciplinary care plans that are more prescriptive than clinical practice guidelines, providing specific guidance on the sequencing of care steps and the timeline of interventions. CPs often, although not always, factor in the cost of care in treatment decision-making.¹

Avalere then identified several key research domains of interest. **Table 1** outlines the domains and associated research questions.

Table 1: Key Research Domains and Questions

DOMAIN	KEY RESEARCH QUESTIONS
Understanding of clinical pathways	How do payers, providers, pathway developers, physicians, and patients typically understand the term “clinical pathway”?
Development processes	What are the key elements in the process of initial development and subsequent refinement of clinical pathways?
Evidence categories	How do payers, providers, specialty societies, and vendors determine what evidence categories to evaluate and include when creating clinical pathways?
Common diseases	What are the considerations in selecting specific conditions for pathway development or adoption?
Incentives and adoption	What types of incentives are used to promote the adoption of and adherence to clinical pathways?
Impact	What is the impact of using clinical pathways from the perspective of payers, physicians, pathway developers, and patients?

¹ Note: Avalere used the Cochrane Review pathway definition as a basis and refined this definition based on primary and secondary research findings.

Our research employed a multi-method qualitative study approach, based on data collected from published peer-reviewed and grey literature, publicly available reports, and semi-structured interviews with stakeholders involved in or affected by CPs. The aim of the literature review was to provide a comprehensive landscape assessment of current CP development and implementation practices. In addition, the review helped frame and inform the interviews. The interviews served to complement the literature review by examining identified key issues in further detail.

The literature review included articles published between 2008 and 2014 and focused on several leading academic journals and professional publications, including, but not limited to, *Journal of the American Medical Association (JAMA)*, *American Journal of Managed Care (AJMC)*, *Health Affairs*, *Oncology Business Review*, *Specialty Pharmacy News*, and *Drug Benefit News*. Search terms included, but were not limited to: *clinical pathways*, *clinical processes*, *care processes*, *clinical practices*, *care models and pathways*, *clinical guidelines*, *clinical algorithms*, *policies and clinical pathways*, *clinical decision support tools* or *clinical decision support aids*, and *care pathways*. Based on the search, we reviewed 48 sources to identify articles for relevancy and appropriateness to address the main research questions. In addition to these information resources, Avalere also reviewed industry newsletters and select professional society websites² to identify relevant documents, including comment letters, conference proceedings, and reports.

Based on the findings from the literature review, we developed an interview discussion guide focused on the key research domains: how stakeholders understand the term “clinical pathway”; key steps and considerations for CP development and revision; common therapeutic areas targeted for CPs; type and source of evidence used to support CP development; use of incentives to promote the use and adoption of CPs; and potential impact of CPs on the U.S. healthcare system.

Using this discussion guide, we conducted 15 semi-structured telephone interviews between May and December 2014 with individuals across several stakeholder groups, including:

- Four Provider Groups³
- Two Patient Groups⁴
- Two Pathway Developers⁵
- Three Payers⁶
- Four Specialty Societies⁷

2 The following professional societies' websites were reviewed for relevant literature: American Society for Quality (ASQ), Partnership to Improve Patient Care (PIPC), American Academy of Family Physicians (AAFP), American Gastroenterological Association (AGA), American Nurses Credentialing Center (ANCC), and the American Society for Clinical Oncology (ASCO).

3 Includes hospitals and hospital systems

4 Includes organizations representing the patient interest in the areas of oncology

5 Includes private sector organizations primarily focused on developing and marketing clinical decision-support tools

6 Includes national payer organizations

7 Includes professional societies primarily involved in the creation of clinical practice guidelines

Some interviewees played dual roles (e.g., provider groups and developers, provider groups and members of professional societies). Interviewees were identified through the literature review and consultation with experts knowledgeable in CP development and implementation.

From the literature search and interviews, we reviewed and analyzed all of the collected information for key trends across the topic domains covered in the discussion guide.

KEY FINDINGS

Stakeholders Share a Common Understanding of Clinical Pathways and Their Aims

In general, stakeholders shared a common understanding of the term “clinical pathway,” although they sometimes used different terminology, such as “care pathways,” “care protocols,” or “care modules.” The literature on CPs commonly cites the Cochrane Review’s definition: “structured multidisciplinary care plans used by health services to detail essential steps in the care of patients with a specific clinical problem”.ⁱⁱⁱ Overall, the interviewed respondents’ views of CPs align with this definition. However, they emphasized the important role of evidence in CPs to establish the best way to organize and guide treatment. Available literature and respondents also noted that CPs increasingly encompass broader care management, as opposed to focusing on a particular therapy or service.^{vii}

There was agreement on the general aims of CPs, and most of the respondents maintained that they serve as critical tools for clinicians to obtain the best treatment outcomes possible. Others noted CPs’ role in ensuring cost-effective care and potential to help drive value in the U.S. healthcare system. Interview respondents indicated that pathways do this by incorporating evidence of comparative effectiveness and cost-effectiveness. While there is a growing focus on decreasing costs, it is a secondary consideration at present to health outcomes (especially for provider-driven pathways).

Stakeholders Serve Different Roles in CP Development and Deployment

Providers and vendors are the leading entities that develop CPs. A recent survey found that of 50 oncology providers, the largest proportion of respondents (45%), developed their own CPs.^{xii} One respondent noted that hospitals in particular are increasingly developing their pathways internally. Over the last five years, the Association of Community Cancer Centers (ACCC) noted that 65% of oncology CPs were hospital-developed and implemented, followed by individual provider practices and academic medical centers.^{xiii} Vendors that develop CPs will often utilize providers recognized

as experts in a particular therapeutic area to inform and guide their CP development. A number of respondents emphasized the benefit of involving physicians in the development process, as they have deep knowledge and experience in patient care and are more likely to adhere to CPs if involved in their development.

Payers are among the primary drivers of the use of CPs (deployers) and do not typically develop pathways directly. In fact, most of the payers interviewed noted that they are not “in the business” of CP development due to their lack of knowledge in this area and concerns about potential conflicts of interest. Rather, most payers will work with a third-party vendor to establish and deploy pathway programs, as well as provide input on the financial incentives tied to pathway adherence. Anthem is among the few payers directly involved in pathway development through their subsidiary AIM Specialty Health.^{xiv}

Given the impact of CPs on patient care, we sought to understand the role of patients in CP development and deployment. There was clear consensus among those interviewed that patients are not involved currently in these processes. However, several of the respondents indicated that patients are considered in the development phase, but not substantially unless the evidence supporting the pathway considered patient-reported outcomes (PRO) data. Among the majority of experts interviewed, the lack of patient engagement was a common concern. At a minimum, experts suggested that patients should be aware of the CPs influencing their care.

Table 2 below highlights differences in CP development and deployment across stakeholder groups.

Table 2: Clinical Pathway Development and Deployment Across Key Stakeholders

STAKEHOLDER	DEVELOPMENT ^{xv}	DEPLOYMENT ^{xv}
Payers	<ul style="list-style-type: none"> • Rarely Develop CPs 	<ul style="list-style-type: none"> • Deploy vendor-developed CPs
Providers	<ul style="list-style-type: none"> • Internally develop CPs • Often serve on the subject matter expert committees that vendors use to develop CPs 	<ul style="list-style-type: none"> • Deploy CPs that are internally developed or acquired via third-party vendors • Some provider organizations also market their solutions to other providers
Vendors	<ul style="list-style-type: none"> • Focused on CP development 	<ul style="list-style-type: none"> • Commercially market but do not deploy CPs

Pathway Developers Use Different Processes to Develop, Test, and Implement CPs

CP Development Milestones. The CP development lifecycle process generally follows three phases: 1) the development stage, 2) the review and revision stage, and 3) the release and deploy stage. **Figure 1** below outlines each phase and correlated steps, however, our research encountered multiple additional sub-steps within each phase that differed by stakeholder group. While CPs often follow the phases and steps detailed below, it should be noted that many stakeholder groups we interviewed refrained from sharing details on their organizational strategy and implementation of CPs.

Figure 1: CP Development Milestones^{xvi}



CP Development. Most pathway developers interviewed begin by convening a committee of subject matter experts with varying backgrounds and expertise (e.g., physicians, nurses, pharmacists) from their organization. For vendor-developed CPs, the committee typically comprises experts from various research institutions or network providers from the collaborating payer. These committees are tasked with determining the scope of the CP (i.e., condition and population served), evidence collection and review, recommendation development, and dissemination and communication strategies. Interviewee responses regarding who participates in their pathways committees varied and included the heads of academic medical centers, as well as various cancer specialties. One large integrated delivery network stated that they leave most of their pathway development up to primary care physicians. Overall, the respondents emphasized the broad range of experts involved (“multidisciplinary teams”) and that they strive to include all parties participating in the entire care continuum for a particular therapeutic area to provide input on treatment options and new evidence. Moreover, a few payers noted that they work closely with vendors who develop their pathways throughout the CP lifecycle to create an iterative “feedback loop.” This ensures that the evidence used to develop and update the pathway is current.^v

Among the providers interviewed, those who develop CPs for their internal use tend to be more consensus-driven than vendors when developing pathways, particularly with regard to reviews of available evidence. For example, in cases where physicians do not agree on one best course of treatment, one leading oncology treatment center includes all options “on pathway.” By contrast, vendors typically have a governing body that makes the ultimate decision of what treatments to leave “on pathway.”

The transparency of the development process is fairly inconsistent across developers. While providers are generally more willing to discuss their CP development processes, vendors and payers are considerably less open. For instance, some provider organizations, including the Children’s Hospital of Philadelphia, University of North Carolina (UNC) School of Medicine, and University of Pittsburgh Medical Center (UPMC), have published information publicly about their development processes.^{xvii,xviii,xix} One professional society noted that it can be difficult to have a pre-specified process, because it often depends on the nature of the issue and the structure of the developing body.

CP Review/Revision. Once CPs are developed, there is no uniform testing and validation process across developers. CPs designed by more sophisticated provider groups and vendors are tested thoroughly. One regional ACO in the Northeast has developed a virtual ward to test and validate its CPs prior to operationalization. In addition, prior to large-scale implementation, the Children’s Hospital of Philadelphia tests their proposed CP and associated decision-support tools for feasibility, usability, and areas for improvement. This may require that the CP be tested in a single practice or care site with manual data collection and frequent feedback from frontline caregivers.^{xix} The original group of collaborators may or may not be involved in pathway revisions, which may hinder consistency in the CP iteration process.

CPs are typically refined on a periodic basis, as often as every three to six months, or following the emergence of groundbreaking evidence or an important change in clinical practice. For example, one provider organization in the Northeast revisited its diabetes CP following changes to statin guidelines in 2013. Oncology-related CPs, especially those for chemotherapy, are typically updated more frequently to account for the rapidly changing data included in oncology studies.^v

Electronically enabled clinical pathways may facilitate more timely consideration of emerging evidence. One provider group noted that making frequent updates to account for new information has been greatly improved by integrating CPs into electronic healthcare record (EHR) systems.

CP Release/Deployment. Once CPs are developed, the release/publication of them is often in tandem with the review phase. Provider-led CP developers may utilize internal communication infrastructure to publicize the tool among their physicians and/or hold organizational meetings to discuss the pathway's details. Because the pathway vendor business model functions on a client/contract basis, vendor pathways are generally only released to clients who have subscribed to the service (typically through some sort of online portal). Pathways are not typically made publicly available, though one payer (Anthem) has published its oncology pathways. The COME HOME model, a Center for Medicare & Medicaid Innovation (CMMI)-funded community oncology medical home model, has also publicly published its 11 pathways programs.^{xx}

CPs Typically Reference Guidelines, but Expert Opinion Also Plays an Important Role in Pathway Development

CPGs often serve as the foundation of pathway development. Most of the respondents rely on CPGs produced by specialty societies (e.g., NCCN for oncology), where available, given that they are based on an evidence review and are well respected. Other sources of information used in the development process include Cochrane Reviews, information from health technology assessment organizations, and specific data from randomized control trials (RCTs) and cohort and case studies, although respondents mentioned a preference for CPGs based on methodological rigor.^v Some developers may consider efficacy, toxicity, and costs of therapies as differentiators, however, provider preference is not excluded.^{xxi}

Very few CP developers consider evidence beyond peer-reviewed clinical trials, such as observational or retrospective studies and non-peer-reviewed clinical trials data. However, some groups, such as academic medical centers, are more likely to take into account emerging information, due to their relationships with the Principal Investigators of clinical trials within their institutions. Among payers, those directly involved in CP creation through subsidiary organizations are more likely to consider emerging clinical trial data.^v

Expert opinion also assumes an important role. Several of the respondents indicated that expert opinion is sometimes used to supplement CPGs in pathway development or to tailor vendor-generated guidelines. This process may involve changes to better reflect standard practice or the specific needs of the user and their patient populations. One leading CP vendor stated that while they use CPGs for 20-25% of their order sets, 50% of them are based on “what makes sense.”^v The NCCN expressed concern at a recent public event that developers citing CPGs deviate from these recommendations.^{xiii}

CPs Are Most Prevalent for High-Incidence and High-Cost Conditions

Most CPs in use today are focused on oncology, but they are increasingly being developed for other high-cost and/or high-prevalence conditions such as rheumatoid arthritis,^{xi} hepatitis C,^{xxii} and inflammatory bowel disease.^x

Oncology CPs have historically focused on high-incidence and high-prevalence malignancies, such as breast, colon, prostate, lung, and certain types of hematologic cancers.^{vii} CPs are also being developed for cancers with low incidence rates, but high treatment costs. For example, while Anthem initially created CPs for breast, colon, and lung cancer only, they recently released pathways for follicular lymphoma, marginal zone lymphoma, as well as pancreatic cancer.^{viii} Similarly, the COME HOME model participants have developed pathways for many common cancer types like colon, breast, and non-small cell lung cancer, however the participants have also developed pathways for rarer cancer types like neuroendocrine lung, pancreatic, and thyroid cancer.^{xx} While most oncology CPs initially focused on the administration of drugs (both medical and pharmacy benefit drugs), some pathway developers, notably providers, have started to broaden their reach to include the expanded continuum of care, including end of life/palliative care, surveillance, imaging, and supportive care.^{vii} Overall, the use of CPs in oncology is expected to increase. One study found that approximately 15% of oncology “lives” were treated according to CPs in 2010, which is expected to rise to 25% in 2015, as more payers and providers establish pathways programs.^{xv}

Some developers of oncology CPs are beginning to expand to other high-impact therapeutic areas. For example, pathways for hepatitis C^{xxii,xxiii} and ST-segment elevation myocardial infarction (STEMI) have been implemented or are currently in progress.^{ix} The respondents interviewed confirmed the expansion of CPs to other therapeutic areas, namely cardiology, gastroenterology, and immunology.

In addition to costs and disease prevalence, CP developers consider if there are any outstanding clinical questions, the time to develop the CP, and the level of supporting evidence available when deciding which CPs to pursue.

Use of Financial Incentives Is Common to Promote Adherence to CPs and Achieve Patient Outcomes

Because one goal of pathway programs is to standardize care, measuring compliance is an important piece of CP implementation. Most of the organizations interviewed aim to achieve around 80% compliance with the CPs that they deploy, which aligns with existing evidence on the issue.^{vii} Respondents maintained that this rate provided enough flexibility to allow physicians to tailor care for different patients, such as those with comorbidities, and their individual circumstances.

Many organizations deploying CPs use various financial and non-financial incentives to foster compliance, however, financial incentives are most commonly used by payers. For example, Anthem's Cancer Care Quality Program provides a \$350 bonus payment per patient per month, as well as a \$350 new patient fee, for adhering to pathways.^{xxiv} Others tie financial incentives to use of an EHR system, which can include CP recommendations, and/or requirements to meet a certain frequency of a "preferred pathway" to organize care. Other financial incentive arrangements that have been implemented include payments for filling out care plans using pathways tools, rewards for generic drug use, and additional evaluation and management services for pathway participants.

Respondents noted that some payers and provider groups are offering financial rewards for not only compliance to CPs, but for improved quality of care and patient outcomes. For example, Aetna provides shared savings with CP vendors and/or provider practices using pathways if more efficient, effective care is achieved, such as reduced emergency visits and inpatient stays.^{xxv} (See **Appendix B** for more detail on financial pathway incentives).

Non-financial incentives are also employed, typically by provider groups and, to a lesser extent, payers. One regional hospital system in the Northeast includes physician compliance rates in annual performance reviews to encourage CP compliance.^v Another provider organization reported on clinical outcomes from CP-guided and non-CP-guided care plans to show their impact and better inform physician treatment decisions. One payer interviewed noted that they often partner or consult with leading academic medical centers (e.g., MD Anderson) to enhance physician compliance, as providers hold these institutions in high regard and look to them to inform practice. Many of the respondents emphasized the importance of physician buy-in to attaining adherence.

One of the key themes arising from the interviews is the importance of a robust EHR (or other technology) infrastructure to support CP implementation and compliance. A few of the respondents indicated that CP users prefer to use an automated pathway to provide guidance to physicians at the point of care. In addition to EHRs, applications ("apps") were identified as useful. Respondents also indicated that the integration of pathways programs into EHRs and claims processing systems can often be difficult and resource intensive.

There Is Limited Evidence on the Impact of CPs—Pilot Studies Indicate Potential for Improved Quality of Care and Reduced Costs

Overall, the evidence on the impact of CPs on care delivery and costs is limited. The preliminary evidence suggests that CPs have the potential to reduce costs and enhance select areas of care quality (see **Appendix C** for a summary of leading CP programs

and the results of their pilots). In particular, evaluations of CP pilots reported reduced hospital readmissions, emergency room visits, chemotherapy dosing errors, and annual treatment costs. For example, a recent study found that CPs reduced overall and post-operative length of stay for a number of surgical procedures, including total knee arthroplasty, appendectomy, total laryngectomy, cholecystectomy, carotid endarterectomy, gastrectomy, inguinal hernia repair, and colon surgery.^{xxvi} Another study examined the impact of different CPs on door-to-balloon time and found that those patients who were on STENU CP, bypassed admission in the cardiac ward and had shorter door-to-balloon times.^{ix} Research on oncology CPs found reductions in cancer-related costs and in-patient hospital admissions and average per patient inpatient days.^{xxvii,xxviii,xxix} For example, Cardinal Health and CareFirst BlueCross BlueShield oncology pathways demonstrated an \$8M in cost savings and a 15% and 7% decrease in cancer-related costs and patient hospital admissions, respectively, following implementation.^{xxvii} Improved management of toxicities and drug regimens were also reported by select programs (see **Appendix C**).

Notably, there is a paucity of evidence on CPs' influence on patient outcomes. The longer time horizon required to measure patient outcomes, such as overall survival, quality of care, and patient experience, in addition to the challenges surrounding cohort data analysis, contribute to the limited availability of results. The lack of transparency and reporting of program results also limits the evidence base on CPs across all potential areas of impact. However, a few respondents noted that they are in the process of assembling outcomes data or intend to do so in the near future.

The particular focus or aims of the CP may influence how impact is defined. CPs can focus on drug treatment costs only, or attend to the broader continuum of care. For example, vendor- and payer-led pathways (e.g., Anthem's oncology pathways) primarily guide drug treatment choice,^{xxx} and do not encompass the full spectrum of care. Alternatively, academic medical centers are likely to develop CPs that span the entire spectrum of patient care, including post-acute and palliative care.

CPs Offer Varying Benefits and Challenges to Healthcare Stakeholders

CPs introduce a number of potential benefits and challenges across different stakeholder groups (see **Table 3**). For physicians, CPs have the potential to guide patient care using evidence-based recommendations and to improve health outcomes, but also have the potential to narrow or limit physician choice in their treatment decisions.^{xxxi} CPs may be a mechanism for physicians to meet and advance organizational quality improvement initiatives or achieve performance targets (and associated incentive payments)

established by payers. However, physicians may be required to comply with multiple payer-deployed CPs, creating administrative burden as well as the potential for higher variability of outcomes within a patient population due to differences across CPs.

CPs offer payers the opportunity to attain cost savings by reducing unnecessary care (e.g., re-hospitalizations, emergency room visits) and increasing use of less expensive treatment, such as generic drugs, or preferred products. In addition, payers can deploy CPs as a tool to improve and measure provider performance and the achievement of quality improvement targets. However, the payers interviewed highlighted the difficulty in obtaining physician buy-in and, to a certain extent, full compliance with a given pathway, especially among physicians who view evidence-based treatment algorithms as “cookbook medicine.” Other noted challenges included the high cost of integrating technology to support implementation of CPs and supporting analysis, and the availability of baseline data on outcomes and provider performance to measure success.

If pathways are developed based on robust evidence and include some flexibility to tailor treatment to certain circumstances, CPs can benefit patients by ensuring they receive appropriate care and are aware of their care continuum. However, realizing these benefits requires patient education on CPs and knowledge that their physician is consulting a CP to guide their care, which has been notably limited to date. One respondent noted that their organization found that 75% of patients were unaware of CPs and the role in their care. There are also concerns, particularly among patient advocacy groups, that greater adoption of payer-driven CPs that employ financial incentives may negatively impact patient choice and reduce access to innovative treatment options.^{xiii}

Value-based payment has heightened the demand for and use of CPs, thereby increasing business opportunities and market share for CP vendors. However, the vendors interviewed identified a couple of challenges, particularly that physician buy-in and participation in development can be difficult, as well as the resources and time required to keep up with rapid changes in care and the supporting evidence. As one vendor noted, “Development is one thing, but maintenance of CPs is truly where costs and resource use come into play.”

For other stakeholders, such as biopharmaceutical and diagnostic companies, pathways present new communication challenges. To the extent that manufacturers wish to share evidence of the benefits of their treatments outside of the Food and Drug Administration (FDA)-approved labeling, including information about medically accepted unapproved uses of products, FDA rules regarding communications by manufacturers may limit the ability of manufacturers to communicate this information. If a new treatment or clinically accepted use is not placed appropriately into a pathway, it could have implications for uptake and reimbursement of the therapy.

Table 3: Benefits and Challenges of Pathway Implementation

STAKEHOLDER GROUP	BENEFITS	CHALLENGES
Patients	<ul style="list-style-type: none"> • Potential to improve patient outcomes • Reduce variability of care • Improve process of care to reduce risk of adverse events or unplanned interventions 	<ul style="list-style-type: none"> • Lack of patient involvement in pathway development • Lack of communication to patients by providers and payers that they are receiving pathway-driven care • Could negatively impact patient choice, and reduce access to innovative treatment options
Payers	<ul style="list-style-type: none"> • Attain cost savings from reduced unnecessary care (e.g., re-hospitalizations, emergency room visits) and increased use of less expensive treatment, such as generic drugs • Use CPs as a tool to improve provider performance and achieve quality targets 	<ul style="list-style-type: none"> • Lack of provider buy-in and 100% compliance • High cost of integrating technology to support implementation of CPs and supporting analysis, and the lack of baseline data on outcomes and provider performance to measure success
Providers	<ul style="list-style-type: none"> • Improve patient outcomes by standardizing care • Mechanism for physicians to meet and advance organizational quality improvement initiatives • Benefit financially if CPs are linked to financial incentives—CPs may increase receipt of shared savings, bonuses, and monetary rewards for meeting performance and quality targets 	<ul style="list-style-type: none"> • CPs have the potential to narrow or limit physician choice in their treatment decisions • May be required to comply with multiple payer-deployed CPs, creating administrative burden as well as the potential for variability of outcomes due to potential differences across different CPs within a patient population
Vendors	<ul style="list-style-type: none"> • Heightened demand for and use of CPs, thereby increasing business opportunities and market share 	<ul style="list-style-type: none"> • Physician buy-in and participation in development can be difficult • Keeping up with rapid changes in care and the supporting evidence is resource and time intensive

DISCUSSION

The use of CPs is set to grow given ongoing developments in the broader healthcare system, including new payment and delivery models that seek to reward value over volume, investments in evidence development on the value of healthcare services and treatments, expanding initiatives to improve quality of care, and growing implementation of EHRs and other health information technology platforms.

Our research highlighted a number of limitations that need to be addressed to ensure CPs meet their aims while avoiding unintended consequences.

Variable Evidence Standards. Currently, there appears to be limited consistency across evidentiary standards used in CP development. While most pathway developers first consider CPGs, expert opinion also plays a pivotal role in pathway development. Consequently, pathways may be guiding specific treatment regimens when there is lack of conclusive evidence or when there is variation in the interpretation of existing clinical evidence and subsequent treatment recommendations. Such inconsistencies may stymie progress toward one of the main goals of CPs—to standardize care around evidence-based practices.

Need for Maintenance. Pathway developers noted that CPs are typically refined on a periodic basis, as often as every three to six months, or following the emergence of groundbreaking evidence or an important change in clinical practice. However, in some clinical areas like oncology, the pace of science necessitates frequent updates to pathways if they are to align with current evidence. Ensuring that the most current evidence is reflected in CPs is a common challenge reported across stakeholders, due to time and resource constraints.

Transparency. There is limited public information around the CP development process, incentive structures, and, the degree of flexibility clinicians have to adopt treatment plans that deviate from the pathway to meet patients' needs. Our research found limited available information on how CPs are constructed to favor one treatment option over another and the evidence base employed for making these determinations. Furthermore, patients are often unaware that their physicians participate in CPs and therefore may be more likely to offer particular treatments supported by the pathway. Consequently, patient advocacy organizations raised concerns that patients may not be aware that their care is based on CPs and that their physician may be incentivized to follow or recommend a CP-guided treatment plan, which may or may not be appropriate to specific patients. Such practices could potentially hinder treatment choice and shared decision-making between patients and their care providers.^{xxxii,xxxiii} More education and training for providers on communicating with patients about use of CPs is needed, so that patients are aware of them and can discuss any concerns about their treatment.

As CPs become more common, the establishment of standards or best practices for evaluating evidence could mitigate some of these issues. To aid this aim, further research is needed on the comparative limitations and benefits of various pathway treatment algorithms. Initiatives focused on quality measurement and CPG development may offer valuable best practices for pathways stakeholders to consider, particularly with regard to the transparency and consistency of the development process. The National Quality Forum (NQF) and the Institute of Medicine (IOM) offer guidance on quality measure and CPG development, respectively. The NQF uses consensus-based processes and standards for stakeholders to follow, while the IOM suggests that patient input be included in the guideline development process.^{xxxiv} Specialty societies are also considering best practices for pathways. For example ASCO is proposing that it should be tasked with developing pathways appropriate use criteria.ⁱ

Transparency could also potentially be enhanced through the establishment of a pathway endorsement organization similar to the NQF that would foster consensus and vet potential requirements or best practices for CPs.

Compliance Requirements. Variability in pathway program requirements can be challenging for physicians, who are being asked to adhere to multiple different program designs. For example, an oncology group working with multiple private payers could be responsible for complying with a number of different pathway programs when treating patients. Many programs target an 80% compliance rate to allow for appropriate deviation from established pathways. Several respondents emphasized that some variability in pathway compliance should be accommodated to account for the introduction of new technologies, expanded indications, or emerging evidence on benefits and costs. Further research is needed to understand these divergences and reasons underlying them, as well as what the appropriate compliance rates should be for different therapeutic areas with different care processes.

One of the provider advocacy organizations interviewed stated that there has been a considerable increase in “home grown” CPs among their member physician groups, with the goal to preempt payer-led CP initiatives. These “home grown” pathways may offer practices more flexibility to address the needs of their patients, however, there is also a need to ensure that these pathways meet basic standards.

Quality of Care and Patient Access. As physicians are increasingly incentivized to use payer-mandated CPs to reduce inappropriate treatment variation, improve quality, and reduce costs,^{xxxv} specialty societies and physician and patient advocacy organizations have raised questions as to whether CPs inhibit a physician’s ability to tailor care plans to unique patient needs, especially for those conditions with wide variability in disease manifestation and patient experience.^{xxxv} Nevertheless, linking CPs to health and

quality outcome targets was considered appropriate and needed to ensure health and economic benefits are realized, especially with the growing movement toward value-based healthcare.

Current evidence and the collective experience of the respondents demonstrate that both financial and/or quality-based incentives can drive clinical decision-making, which underscores the importance for stakeholders to use such incentives in a way that aligns with sound clinical judgment and patient needs. To meet this need, future CP programs should incorporate quality as well as clinical and PRO measures to substantiate their benefits and limitations on health and quality outcomes. As interest in value-based healthcare grows, it would be prudent to also collect and assess evidence on the economic implications of CPs.

Patient engagement in CP development or evaluation, which is currently rarely done, is another area where pathway developers and deployers could enhance current processes. Greater patient involvement would help address stakeholder concerns regarding potential impacts of CPs on quality of care and patient and provider choice. It is important for CPs to be flexible enough to allow for shared decision-making between providers and patients, so that patient-specific characteristics, needs, and preferences can be incorporated into treatment plans. CP developers and deployers may look to organizations such as the IOM that have developed guidance on how to involve patients in care decisions through shared-decision-making mechanisms.^{xxxvi}

Although, the use of CPs is expected to expand, many programs are currently operating on a pilot basis and have not been widely implemented. This offers an opportunity for stakeholders to come together to identify and discuss best practices and strategies to harness the potential benefits of CPs, while mitigating their possible risks. Greater stakeholder collaboration could also help improve the transparency of CP development and implementation.

APPENDIX A

Prominent Pathway Developers

DEVELOPER	STAKEHOLDER GROUP	TYPES OF PATHWAYS
Innovent Oncology (subsidiary of McKesson) and US Oncology ^{xxxvii}	Vendor	<ul style="list-style-type: none"> • Focus on chemo administration for breast, colorectal, hematologic, lung, ovarian, pancreatic, and prostate cancers
P4 Pathways (owned by Cardinal Health) ^{xxi,xxxviii}	Vendor	<ul style="list-style-type: none"> • Focus on chemo administration for breast, colorectal, lung, ovarian, prostate and renal cancers, B-cell non-Hodgkin's lymphoma, and multiple myeloma • Also includes drugs for supportive care (anemia, neutropenia, and anti-emesis) • Separate pathway for rheumatoid arthritis drugs
Via Oncology (owned by University of Pittsburgh Medical Center) ^{xxxix}	Provider/ Vendor	<ul style="list-style-type: none"> • Includes the entire spectrum of cancer treatment across bladder, breast, colorectal, esophageal, gastric, head and neck, lung, ovarian, pancreatic, prostate, renal, skin, testicular and uterine cancers, CML, MDS, myeloma, and lymphomas • Also includes radiation oncology
eviti ^{xl}	Vendor	<ul style="list-style-type: none"> • For all cancer types—pathways include entire spectrum of cancer care (surgery, chemotherapy, and radiation oncology)
AIM Specialty Health (subsidiary of WellPoint)	Payer	<ul style="list-style-type: none"> • Focus only on drug use for breast cancer, endocrine therapy, central nervous system cancer, colorectal cancer, diffuse large B-cell lymphoma, follicular lymphoma and marginal zone lymphoma, melanoma, myeloma, non-small cell lung cancer, ovarian cancer, pancreatic cancer, small lymphocytic, lymphoma/chronic, lymphocytic leukemia
Moffitt Cancer Centers ^{xli}	Provider	<ul style="list-style-type: none"> • Entire spectrum of cancer care
Kaiser ^{xlii}	Provider	<ul style="list-style-type: none"> • Entire spectrum of care, mostly focus on care provided in hospital (not just cancer)
American Gastroenterological Association ^{x,xliii}	Professional Society/ Provider	<ul style="list-style-type: none"> • Focus on use of biologic drugs for inflammatory Crohn's disease • Also developed hepatitis C screening and evaluation pathway

CML: Chronic myelogenous leukemia; MDS: myelodysplastic syndrome

APPENDIX B

Examples of Pathway Incentive Payments

PAYER	INCENTIVES
Large national payer ⁸	<ul style="list-style-type: none"> Provides \$1,000–\$2,000 per physician per quarter for following CP-driven care
Aetna	<ul style="list-style-type: none"> Implemented a shared savings model to incentivize compliance^{xxv}
Blue Cross Blue Shield (BCBS) of Alabama	<ul style="list-style-type: none"> Rewards \$100 to each physician for each care plan they fill out using the eviti tool^{xiii}
BCBS Michigan, Physician Resource Management, and P4 Pathways	<ul style="list-style-type: none"> Partnered to develop a pathways program that provided each physician participant a \$5,000 payment for the first year of the pathways program to cover any extra costs involved and to provide a financial incentive to participate and meet approved compliance thresholds Reimbursement rate for several generic therapies associated with the specific CPs was increased (13 drugs were modified in 2010) Reimbursement for evaluation and management codes were also increased (10%) for pathway program participants as a result of compliance in year one^{xiv}

8 Note: this information is blinded since it came from interview findings.

APPENDIX C

Select Results from CP Programs⁹

CP SPONSOR OR IMPLEMENTING ORGANIZATION	DATE OF IMPLEMENTATION	CP DISEASE FOCUS	RESULTS
Via Oncology, subsidiary of the University of Pittsburgh Medical Center (UPMC), and UPMC ^{xiv}	Nov 2005	Oncology (17 types of cancers)	2006 to 2009: <ul style="list-style-type: none"> • 1% increase in annual treatment costs in CP group vs. 6-7% increase in annual treatment costs in control group • Reduced chemotherapy error and improved management of toxicities
Cardinal Health and CareFirst BlueCross BlueShield (CFBCBS) ^{xxvii}	Aug 2008	Oncology (breast, lung, colon)	2007 to 2010: <ul style="list-style-type: none"> • \$8M in cost savings in CP group • 15% decrease in cancer-related costs in CP group • 7% decrease in hospital admission in CP group
Innovent Oncology, subsidiary of US Oncology ^{xxix, xxviii} and Aetna	June 2010	Oncology (breast, lung, colon)	2010 to 2012: <ul style="list-style-type: none"> • 12% decrease in costs • \$506,481 total savings • 1.2 inpatient days vs. 2.1 prior to program launch • 10% ER visits in CP group vs. 14% in control group

⁹ While most studies reporting CP program results attempted to isolate the effect of CPs from other organizational initiatives, it is likely that some of the reported outcomes could have been driven by parallel.

Select Results from CP Programs⁹

CP SPONSOR OR IMPLEMENTING ORGANIZATION	DATE OF IMPLEMENTATION	CP DISEASE FOCUS	RESULTS
Cardinal Health and Aetna ^{xlvi,xi}	July 2010	Oncology (breast, lung, colorectal)	2010 to 2012: <ul style="list-style-type: none"> • 18.3% decrease in chemotherapy costs in CP group vs. 3.8% increase in control group • \$7,037 in drug cost savings per patient per year in the CP group • 0.8% decrease in average ER admissions in CP group vs. 8.5% increase in control group
P4 Pathways and Aetna ^{xxviii,xlvii}	July 2011	Oncology (breast, lung, colon)	2011 to 2012: <ul style="list-style-type: none"> • Number of distinct drug regimens used reduced by 28% • 11% increase in generic-only drug utilization in CP group
Cardinal Health and CFBCBS ^{xlvi}	Feb 2012	Rheumatoid Arthritis	2012 to 2013: <ul style="list-style-type: none"> • 8% decrease in biologic agent use in CP group following disease-modifying antirheumatic drug (DMARD) as first-line treatment

⁹ While most studies reporting CP program results attempted to isolate the effect of CPs from other organizational initiatives, it is likely that some of the reported outcomes could have been driven by parallel.

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Contact Us

Avalere Health

1350 Connecticut Ave, NW Suite 900

Washington, DC 20036

202.207.1300 | Fax 202.467.4455

www.avalere.com