Care Pathways in US Healthcare Settings: Current Successes and Limitations, and Future Challenges

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ABSTRACT

Objectives: Care pathways are used widely in US healthcare settings and are expected to have greater influence on quality of care and patient outcomes in the future. We conducted qualitative research to evaluate the state of care pathways and their impact in the United States.

Study Design: Targeted literature review followed by an online survey and in-person interviews.

Methods: The PubMed and Cochrane databases were searched for publications on care pathways (January 1, 2005, to July 21, 2014) to inform the subsequent surveys and interviews with payers, providers, and pathway vendors regarding care pathway design, development, and management. A targeted hand search was completed in May 2015 to supplement the earlier review.

Results: Twenty-nine publications, posters, or abstracts on specific care pathways were identified; the online survey and follow-up interviews included 26 and 18 respondents, respectively. Positive trends in current care pathways development and implementation include prioritization of high-quality evidence, enhancing the role of providers in development and implementation, and flexibility for providers to tailor treatment decisions to patients' needs. Nevertheless, there are some limitations in methodology for development and implementation, in criteria for evaluation, and in the degree of transparency surrounding these activities.

Conclusions: Our research confirms that high-quality evidence of efficacy and safety are expected to be central to future pathway development, and that physicians play a major role in development and implementation. To achieve the goals of improving quality of care while managing costs, further efforts are required regarding systematic development and evaluation, consistent implementation and compliance metrics, and transparency in implementation outcomes and financial motivators.

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Care pathways, sometimes referred to as clinical pathways or integrated care pathways, are used widely in US healthcare settings. The concept goes as far back as 1985, with roots in efforts to codify or formalize patterns of care that were initiated at the New England Medical Center in Boston, Massachusetts.[1] Although without a uniformly accepted definition, care pathways are typically characterized as a method for managing patient care based on clinical practice guidelines, with the main goals of improving quality of care, reducing variation in clinical practice, and increasing the efficient use of healthcare resources.[1-4] Care pathways are generally expected to reduce the overall costs of treatment related to the condition for which a pathway is developed.[2,3,5,6] A Cochrane systematic review of published studies that compared clinical pathways—both stand-alone and as part of a multifaceted intervention—with usual care found a reduction in in-hospital complications and improved documentation in 20 studies that compared stand-alone clinical pathways with usual care.[7]

Care pathways vary in content, implementation, and place of service. In some healthcare systems, reduction in resource use can be achieved effectively by integrating patient management across different treatment settings. In these situations, such as in the United Kingdom healthcare system, pathways may place greater emphasis on clinical flow than management of prescription drugs. In the United States, where care is often fragmented even within integrated systems, pathways tend to focus on resource use that can be controlled by choice of pharmacologic treatment. Many consider US care pathways an option for managing utilization of pharmaceuticals, particularly specialty drugs. Payers and provider networks have shown considerable interest in oncology care pathways, in large part because of wide variation in utilization and costs of oncology drugs, which continue to receive considerable attention.[6,8-15] Care pathways have been noted as an approach for managing utilization of specialty drugs, and their use in other

Take-Away Points

Care pathways are developed to manage patient care, improve quality, reduce variation, and increase efficient use of healthcare. They provide a mechanism for integrating evidence-based medicine into clinical practice. However, formal best practices to guide development, implementation, evaluation, and monitoring are needed.

- Often, pathways are implemented to manage drug utilization, particularly specialty drugs.
- Trends in development and implementation have not been investigated systematically.
- Pathways will have more influence in the future, particularly with bundled or episode-based payments.
- Research findings support implementation of standards and increased transparency in all dimensions of pathway development, implementation, and evaluation.

therapeutic areas is likely to grow[16]; for example, a care pathway has been developed in rheumatoid arthritis.[17]

Care pathways are intended to be a pragmatic translation of clinical guidelines and evidence, with specific direction for delivering care that may extend over the course of disease or continuum of care. Consequently, they have enormous potential to impact quality of care and patient outcomes. Best practices for developing clinical practice guidelines include a formal, structured process with systematic literature review, critical appraisal, multidisciplinary consultation, and grading of recommendation by evidence levels.[18,19] In the United States, the Institute of Medicine (IOM) developed 8 standards for developing clinical practice guidelines,[18,19] which address transparency, conflict of interest, development group composition, systematic review methodology, criteria for evaluating evidence quality, articulation of recommendations, external review, and updating. Care pathways, however, do not yet have published formal development standards.

Care pathways are expected to have more influence on quality of care and patient outcomes in the future. With movement from fee-for-service to bundled payments in commercial health plans and with the Oncology Care Model being launched by CMS in 2016,[20] care pathways are expected to play a major role.[21,22] Moreover, expansion into nononcologic therapeutic areas suggests that their impact will be even broader. Current use of care pathways, and their impact on costs, patient outcomes, and quality of care in US healthcare settings, has not been characterized fully. Furthermore, because only relatively mature pathway programs have data for such assessments, trends in care pathway development and implementation across therapeutic areas and treatment settings have not been investigated systematically.

We conducted qualitative research to evaluate the current state of care pathways and their impact in the United States. First, we conducted a targeted review of published literature on care pathways, including publications in peer-reviewed journals and the gray literature. Second, we supplemented this review with primary research using online surveys and semi-structured interviews with individuals having detailed knowledge of care pathway development and implementation. Our evaluation assessed stated objectives of care pathways, processes for development, supporting evidence, application, trends in development and use across therapeutic areas, and evidence of effects on outcomes. Together, this research provides information on the ways in which care pathways are currently succeeding and where they have limitations, as well as the challenges and opportunities for enhancing their future impact.

METHODS

Targeted Literature Review

We searched the PubMed and Cochrane Reviews databases and selected conferences' websites with keywords, combining "care pathway," "clinical pathway," "treatment pathway," "critical pathway," "evidence-based," "cost," and "comparative effectiveness." We conducted targeted searches of trade journals and the websites of professional organizations, pathway vendors, payers, and large provider groups to supplement our database search for publications. Publications, posters, or abstracts were selected for further evaluation if they were published in English, dated between January 1, 2005, and July 21, 2014, and if they specifically described development, implementation, or evaluation of care pathways in US healthcare settings. Our selection criteria required that a care pathway have stated objectives defining the goals and key elements of care, including at least one of the following goals: improving patient outcomes, improving quality of care, reducing treatment variation, or reducing healthcare resource utilization.[3]

Guidance for prescribing decisions and other aspects of patient care (including processes and timeframes) was required to be based on specific disease states in defined patient populations. Additionally, a care pathway had to translate available evidence to local clinical practice,[1] or use evidence-based medicine or clinical guidelines to develop treatment recommendations.[3,4] The care pathway had to include a monitoring and evaluation mechanism.[2-4] Finally, we focused our investigation on care pathways that included criteria for the use of pharmacologic therapies. A targeted hand search was completed in May 2015 to supplement the earlier review with more recent information.

Primary Research

Subjects. Between August and November 2014, we conducted online surveys with 26 participants, based on a target of 20 to 30 respondents, followed by semi-structured interviews with 15 of those participants and an additional 3 opinion leaders, given a target of 50% follow-up interviews. This research did not include human subjects, according to the federal definition of human subject research,[23] and thus was exempt from institutional review board review.

Respondents were selected to represent a mix of health plans with commercial, Medicare (Part D, Advantage), and/or Medicaid lines of business; pharmacy benefit management organizations; healthcare providers; and commercial care pathway vendors. To capture perspectives from most US healthcare provider organizations, provider respondents were selected from small and large group practices, accountable care organizations (ACOs), and integrated health delivery systems (IDSs). All respondents were screened for involvement in the development, implementation, use, or evaluation of care pathways used to guide pharmaceutical or medical treatment decisions. The online survey and semi-structured interviews were administered only to respondents who indicated familiarity with care pathways and had at least some knowledge relevant to the sections covered by the survey. Participants were offered honoraria for survey and interview participation.

Online survey. The survey instrument consisted of 8 sections: an introduction, de-identified participant information, participant experience with care pathways, care pathway development, implementation and use, evaluation, key stakeholder agreements and relationships, and perceptions about the future of care pathways. Respondents were asked to provide answers to questions only if they indicated having at least some knowledge of the information covered in a given section (a rating of at least "3" on a 5-point scale); those who reported experience with non-oncology care pathways were instructed to respond to questions from this perspective. The total number of questions answered per respondent depended on their role and experience, to a maximum of 86 possible questions. Descriptive analyses were conducted in Excel; due to small sample sizes, statistical testing was not conducted.

Interviews. Trained interviewers administered an hour-long semi-structured discussion guide with open-ended questions. Interviews were designed to supplement information obtained from the online survey with additional detail on selected issues. Interviews were digitally recorded, transcribed, and de-identified. Data abstraction and extraction of interview responses were conducted in parallel by 2 reviewers (SM and AK), with adjudication in rare instances of discordance.

RESULTS

Phase I: Literature Review

We identified 616 unique citations from our search of electronic databases, gray literature, and websites of care pathway vendors, payers, and major oncology provider networks. Full text review of publications was conducted for 73 citations; of these, 11 were full-length published articles, and 18 were conference abstracts and posters describing findings for studies of specific care pathways. This review was supplemented by unpublished information identified on the websites of care pathway vendors, payers, and oncology provider networks. Our goal was to identify key themes and gaps in information to inform the design of the online survey and interviews.

In our review of the literature on care pathways, we observed variation in the characterization of care pathways. Evaluations of care pathways were more frequently focused on resource use and cost, and some concerns about transparency were expressed. The extent to which care pathway development, implementation, and evaluation were documented varied, and descriptions were not standardized, although some studies described these activities in detail.[10,13,24-29] Furthermore, roles and responsibilities of key stakeholder groups in these activities were documented in some cases,[12,25] but were not always clear. Evidence documenting the impact of care pathways on quality of care, patient outcomes, and healthcare resource use is beginning to emerge; a few studies have been published, and others have been presented in conference abstracts or posters. Some studies documented pathway adherence or compliance,[12,25,28,30-36] or patient outcomes.[31,33,37-39] Most studies we identified assessed the ability of care pathways to control resource use or costs.[25,28,31,33,34,38-49] In addition to concerns about transparency in methodology associated with pathway development, concerns about lack of patient awareness of use of pathways, and implications for clinical decision making in delivery of their care, have also been noted.[50,51]

Phase II: Primary Research

Twenty-six participants completed the online survey. Ten were from payer organizations: 8 medical directors and 2 pharmacy directors representing managed care organizations, integrated delivery systems, and pharmacy benefit managers that covered a total of approximately 60 million lives. Nine were providers (1 solo/group practice, 7 hospital/clinic-based, and 1 indicated both) representing a range of specialties and practice sizes. Seven were from pathway vendors—of which 6 had experience with oncology care pathways. Nearly all payers and providers

personally had a role in the development, implementation, evaluation, or use of at least 2 care pathways (17 of 19); nearly all respondents from pathway vendor organizations had experience with more than 5 care pathways (6 of 7). Seven payers, 5 providers, 3 pathway vendors, and 3 opinion leaders completed telephone interviews. Interviewees were selected based on their depth of knowledge of care pathways, willingness to participate in a follow-up interview, and, in the case of opinion leaders, their speaking or publication record on the topic of care pathways. Detailed characteristics of primary research participants are presented in the Table.

Selection of Therapeutic Areas and Treatment Settings

The majority of survey respondents that answered questions about selection of therapeutic areas and treatment settings (67%; 14 of 21 respondents that filled out this section) indicated that selection of therapeutic areas for care pathway development is often the result of an internal selection process. Attractive candidates for care pathway development are disease states associated with a high cost of treatment or high prevalence rates, availability of multiple branded therapies, and heterogeneity in treatment patterns; high cost of care and high utilization or disease prevalence were the most commonly cited triggers for the development of a new care pathway. Over half of respondents reported that disease areas were selected based on cost of care (62%; 13 of 21) and variation in treatment patterns (57%; 12 of 21); only 33% (7 of 21) reported selection based on clinical outcomes. Heterogeneity of case mix was considered a factor in selection by 19% (4 of 21) of the respondents. In follow-up interviews, suitable features mentioned for future care pathway development included opportunities for standardization and integration of multiple treatment modalities.

Most survey respondents expected that use of care pathways would expand in the next 5 years, in both oncology (85%; 22 of 26) and other therapeutic areas (65%; 17 of 26). Beyond oncology, rheumatology, cardiology, diabetes, and multiple sclerosis were identified as therapeutic areas with the greatest expectations for uptake. When asked to rate practice settings in which care pathways are most likely to be developed (no expected increase [0] to significant increase [5]), the highest ratings were ascribed to ACOs, IDSs, and specialty practices (Figure 1).

Providers as Key Stakeholders

Respondents consistently identified providers as the critical group involved in activities associated with care pathway development and implementation. Providers were viewed as taking increasingly prominent roles in care pathway development initiatives, in addition to acting as gatekeepers to successful adoption. Physician resistance was the most commonly cited barrier to care pathway expansion and uptake, and nearly all respondents reported that physicians could choose whether a patient is treated on-pathway.

Evidence Considerations in Care Pathway Development

Most respondents that answered questions about evidence considerations—86% (18 of 21) and 81% (17 of 21)—reported that treatment guidelines and randomized clinical trials, respectively, are key data sources for care pathway development (Figure 2). Peer-reviewed publications and consensus guidelines, compendia, and medical societies were the most frequently mentioned sources of evidence during interviews. Interview respondents identified the quality of efficacy-reporting studies as the most important consideration for inclusion in care pathway development, followed by data on safety or tolerability, with costs considered only after evaluating efficacy. Nevertheless, in survey responses, 81% (17 of 21), 71% (15 of 21), and 57% (12 of 21) identified medical (nonpharmaceutical) costs, pharmaceutical costs, and healthcare resource use, respectively, as measures that are considered in care pathway development. In interviews, some respondents noted that lower-cost options are likely to be placed on the pathway if there are therapeutic alternatives available and there is little to no perceived clinical differentiation among them. Some participants noted the importance of assessing the overall value of treatment, taking into account outcomes and health resource utilization, especially in the context of safety and tolerability assessment.

Processes or practices in pathway development are not commonly reported, codified, or documented, and the reported degree of methodological rigor applied to care pathway development varies greatly. In survey responses, 81% (17 of 21) reported grading evidence quality when evaluating studies used to inform development of a care pathway. Meta-analysis, adjustments for patient characteristics, and indirect comparison of interventions were reported by 62% (13 of 21), 48% (10 of 21), and 43% (9 of 21), respectively; however, many noted that the approach is not typically systematic or applied consistently. In the absence of high-quality data, respondents reported widely varying approaches and levels of rigor in pathway development. Decision making, without direct comparative studies, relies on consensus, best practices, clinical judgment, or indirect comparisons.

Table. Characteristics of Primary Research Participants

Payers									
		Lines of Business			Size (covered lives)			Implemented Care Pathways for Providers Affiliated With	
Current Title/Role	Organization Type (geographic coverage)	Commercial	Medicare (Part D/ Advantage)	Medicaid	Small (<1m)	Medium (1-5m)	Large (>5m)	ACO	IDS
Medical director	**MCO (national)**	•	•	•		•		•	•
Medical director	**MCO (national)**	•	•	•			•	•	
Medical director	MCO (regional)	•		•	•			•	•
Medical director	MCO (regional)	•	•	•		•			•
Medical director	**IDS**	•	•	•		•		•	•
Medical director	**IDS**	•	•		•			•	•
Medical director	**PBM**	•	•		•			•	•
Medical director	IDS	•	•	•	•				•
Pharmacy director	**MCO (regional)**	•	•			•			
Pharmacy director	**PBM**	•	•	•			•		•

Providers							
	Practice Setting(s)		Practice Size		Practice Affiliated With		% Patients Treated With Care Pathways
Current Title/Role	Solo/ Group	Hospital/ Clinic-Based	Physicians, n	Unique Patients per Month	ACO	IDS[a]	
Associate chief medical officer		•	11-25	51-100	•		26-50
Chief medical officer / chief of quality		•	1-5	1-10			26-50
VP patient care services and CNO		•	26-50	11-50			1-10
Executive director	•		11-25	101-250			91-100
Senior pharmacy and admixture manager		•	11-25	101-250			51-75
Practicing physician, cardiology		•	6-10	>250			51-75
Practicing physician, infectious disease		•	11-25	101-250			11-25
Department head, rheumatology	•	•	6-10	101-250			11-25
Practicing physician, physiology		•	>100	51-100	•		26-50

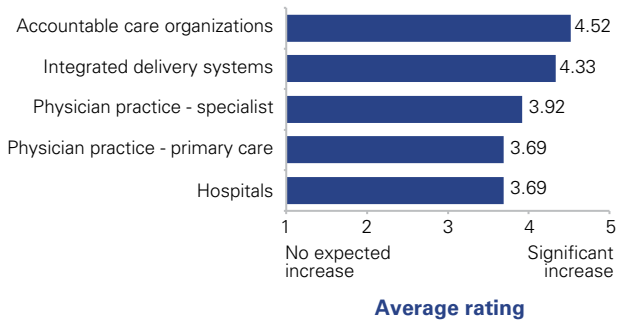
Pathway Vendors		
Current Title/Role	Organization Type	Care Pathway Experience
CEO	Affiliated with wholesale distributor	Oncology pathways
Affiliate, professor of medicine[a]	Affiliated with wholesale distributor	Oncology pathways
Director of sales	Affiliated with wholesale distributor	Nononcology pathways
Director of pharmacy and clinical services	Affiliated with wholesale distributor	Oncology pathways
Vice president and general manager	Affiliated with wholesale distributor	Oncology pathways
Project director	Affiliated with PBM	Oncology pathways
Director of client integration	Independent	Oncology pathways
Chief consultant	Independent	Oncology and nononcology pathways

ACO indicates accountable care organization; CEO, chief executive officer; CNO, chief nursing officer; IDS, integrated delivery system; m, million; MCO, managed care organization; PBM, pharmacy benefits manager.
[a]Did not participate in online survey. Fifteen survey respondents participated in the interviews (see names in bold). Only 1 interviewee (1 vendor) who was interviewed did not fill out the survey. Opinion leaders interviewed (3) are not listed in the tables.
Bold indicates participation in qualitative interviews.

Implementation of Care Pathways

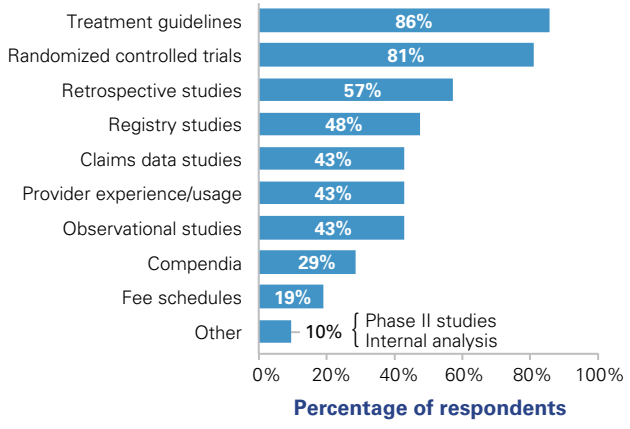
Electronic medical record systems were reported to be the most commonly identified mechanism for implementing care pathways. Web portals or websites are also common, particularly for health plan care pathways. Meetings and seminars, e-mail communication, and paper publica-

Figure 1. Expected Increase in Care Pathway Use



Source: Online survey of 26 stakeholders (payers, providers, and vendors) who influence or are affected by care pathways (see Methods section). Vendor/payer survey Q68, provider survey Q85, question: *"Do you expect the use of care pathways (oncology- and/or non–oncology-related) to increase in any of the settings listed below?"*

Figure 2. Key Data Sources for Care Pathway Development



No respondents reported "none of the above" or "do not know."
Source: Online survey with stakeholders (base: payers, providers, and vendors who rated their level of experience/knowledge related to development of care pathways as 3, 4, or 5 [N = 21]) who influence or are affected by care pathways (see Methods section). Vendor/payer survey Q25, provider survey Q39, question: *"In developing a care pathway, different types of evidence or information may be used to develop the clinical algorithm. Please indicate which of the following types of evidence or information are typically used to develop the clinical algorithm."*

tions also effectively disseminate information and serve in physician education.

Most survey respondents (92%; 23 of 25 respondents who rated ≥3 as their level of experience and knowledge regarding pathway implementation) reported that physicians had multiple treatment options on care pathways for a given diagnosis. Deviating from these options is possible but often requires prior authorization. Interviewees reported that some deviation is expected, primarily due to patient heterogeneity, but deviation was associated with financial disincentives. Failing to meet compliance targets may also result in administrative hassle, potential exposure of performance statistics to other practices, and follow-up inquiry or monitoring. Provider responses regarding pathway effect on treatment decisions were mixed: some viewed them as altering their treatment decisions, while others felt validated.

Once implemented, reimbursement for care pathways is typically fee-for-service or fee-per-patient. Over half of the survey respondents who answered questions about financial incentives in the context of care pathway implementation (68%; 13 of 19 respondents who rated ≥3 as their level of experience and knowledge regarding financial incentives [or penalties] tied to physician use of care pathways to make treatment decision) reported that qualifications for reimbursement are most commonly tied to compliance, with target rates reported to be 75% to 80%. The proportion of eligible patients maintained on-pathway was considered the key measure of compliance (92%; 12 of 13), and therefore, that of reimbursement. Nevertheless, reimbursement policies may also consider quality of care (77%; 10 of 13), cost savings (38%; 5 of 13), physician satisfaction (23%; 3 of 13), and hospital length of stay (23%; 3 of 13).

Evaluation of the Impact of Care Pathways

Systems or processes for evaluating performance of care pathways were reported by nearly all survey respondents who answered questions about evaluation of care pathways. Most respondents (95%; 18 of 19 respondents who responded to questions in the survey section on "evaluation") indicated that compliance rate was the most commonly used metric; 68% (13 of 19) reported the use of quality metrics (Figure 3). Physicians generally receive data on their compliance with care pathways through periodic (quarterly) reports that detail their performance metrics. Provider feedback on care pathways may be included in the evaluation of care pathway performance on an ad hoc basis. During interviews, a few respondents noted that a significant amount of negative feedback on a pathway, pushback, or widespread deviation from a pathway could trigger further investigation and potentially lead to modification of a pathway.

Health plans are typically responsible for monitoring care pathways, according to 58% (11 of 19) of all respondents (payers, providers, and vendors) who answered questions in this section, while 47% (9 of 19) and 37% (7 of 19) reported that providers and care pathway vendors, respectively, play a role. In response to follow-up questions, half (50%; 8 of 16 respondents [including payers,

providers, and vendors] who answered "yes" to the initial question) indicated that compliance is measured for any patients entering a practice rather than patients selected for on-pathway treatment, implying that true pathway adherence may be underestimated, since the entire practice patient population would serve as the denominator in a compliance measure, but only patients who are eligible for and treated on the pathway are counted in the numerator. Two respondents of 16 (13%) reported measuring compliance only among patients with specific diseases or conditions, or using varying measurements. Some interviewees noted specifically that outliers or deviation from pathways that resulted in significant variation from target adherence rates, most often quoted as 75% to 80%, would trigger follow-up investigation. None of the respondents indicated that medically appropriate deviation from pathway recommendations was precluded.

Interviewees reported limited knowledge of the impact of care pathways on patient outcomes or quality of care, and whether the impact might be sustainable. Among respondents familiar with care pathways research, several voiced doubts about the meaningfulness of patient outcome studies, citing a lack of proven results and concerns about limitations of available data. Data availability, level of detail collected, and analytic methods were identified repeatedly as challenges in conducting robust analyses of performance.

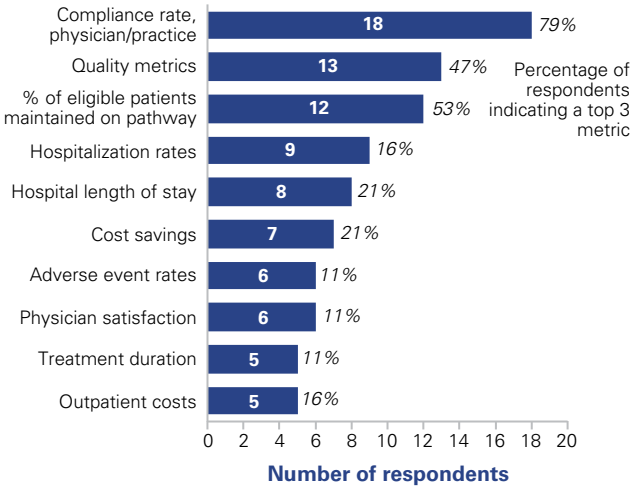
Transparency and Disclosure

Although most respondents indicated that some aspects of the care pathway development process may be documented, access to this information remains limited to internal stakeholders with direct involvement. Transparency surrounding implementation was perceived as similarly limited—in part because the proprietary nature of many pathways limits public disclosure. Most healthcare providers who responded to the survey (80%; 4 of 5), all of whom use care pathways, indicated that patients are not informed or directly educated about the use of care pathways; voluntary opt-out by patients was reportedly in the form of declining treatment, not through a formal mechanism. Several respondents noted that patients may have trouble understanding the care pathways or have a negative response if the concept is not sufficiently explained.

Barriers to Pathway Uptake

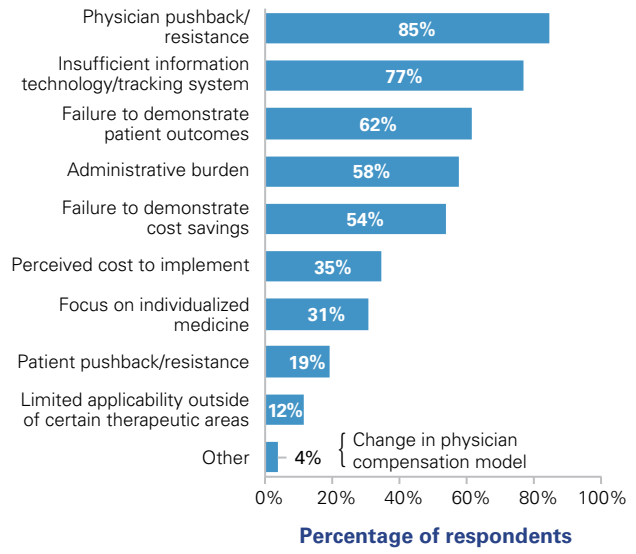
Among all survey respondents, 85% (22 of 26) indicated that physician pushback is the largest barrier to the expansion of care pathways (Figure 4). Insufficient tracking systems and administrative burdens rank high for most

Figure 3. Commonly Used Evaluation Metrics in the Evaluation of the Impact of Care Pathways



No respondents reported "none of the above."
Source: Online survey with stakeholders (base: payers, providers, and vendors who rated their level of experience/knowledge related to evaluating care pathway performance as 3, 4, or 5 [N = 19]) who influence or are affected by care pathways (see Methods section). Vendor/payer survey Q43, Provider survey Q60, question: *"Which of the following metrics (if any) are typically used to evaluate care pathway performance? For the metrics that you selected, please indicate the 3 most important metrics when it comes to evaluating care pathway performance."*

Figure 4. Potential Barriers to Pathways Expansion



Source: Online survey with stakeholders (base: all payers, providers, and vendors [N = 26]) who influence or are affected by care pathways (see Methods section). Vendor/payer survey Q69, Provider survey Q86, question: *"What do you see as potential barriers to the expansion or uptake of care pathways?"*

respondents. Additional barriers are failure to demonstrate results or cost savings.

DISCUSSION

Generally, care pathways appear to provide a good mechanism for integrating evidence-based medicine with real-world clinical practice, with the goal of using high-quality evidence for pathway development and affording physicians flexibility in implementation. Our research indicates that development efforts have prioritized high-quality clinical studies and guidelines as sources for determining clinical management and treatment choices. In this context, data on treatment efficacy and safety are prioritized over cost when determining the best treatment options. Cost considerations, however, remain a major focus in guiding pathway development, particularly in selection of therapeutic areas, and they are dominant in the absence of clear differentiation among alternative treatment options. Nonetheless, physicians wield substantial influence on care pathway development and implementation, reflecting the emphasis on clinical considerations. Furthermore, developers appear to recognize the need to provide flexibility in treatment decision making to account for differences in patient characteristics or needs, and heterogeneity of treatment effect.

However, several concerns associated with current care practices remain. Variation in development and implementation methodology persists, given the lack of standardization or policy on best practices. Wide variation in approaches to pathway development and evidence requirements, particularly when high-quality data are not available, impedes the practice of medicine based on the best available evidence. This finding is consistent with increasingly high-profile criticism of attempts to reduce variation in care,[52] requiring the establishment of industry best practices across all therapeutic areas and treatment modalities, in order to ensure that evidence quality is characterized using appropriate criteria and evaluation is systematic. Recommendations for care pathways in oncology,[51] and the IOM initiative on standards for clinical practice guidelines, may serve as valuable starting points.[19,53] After the IOM standards were disseminated, evaluation studies were conducted, and they provided valuable insights into the extent to which activities associated with evidence evaluation and guideline development adhered to the best practices that had been codified.

Because evaluation methodology and metrics for assessing care pathways have not been standardized, the true impacts of pathways on patient outcomes, on quality of care, on medical care resource use, or on cost of treatment are not yet fully known. To date, most published analyses have focused on frequently used treatments, healthcare resource utilization, and costs. They have covered relatively limited time frames, and few have provided insight on the impact of care pathways on quality of care. Several respondents in our research voiced doubts about the ability to collect and analyze data beyond compliance and resource use, largely due to challenges associated with integrating data from different sources, which are typically administrative claims and electronic medical records.

The most serious concern about the state of care pathway development and aspects of implementation is lack of transparency. Interviewees substantiated recent public calls for transparency, and they echoed concerns about the absence of development standards and inconsistent application of methodologies in care pathway development.[50,51] Some payers have disclosed treatment options, compliance measures, and reimbursement associated with their care pathways[12,13,22,25]; however, information about development and implementation has been relatively limited. In 2012, the National Comprehensive Cancer Network convened a policy summit to discuss use and implementation of care pathways, and in 2014 the American Society of Clinical Oncology's Payment Reform Workgroup included high-level guiding principles for developing and using oncology care pathways as part of its recommendations for payment reform.[11,54] To our knowledge, however, no other medical professional associations have yet made similar recommendations. Similar concerns about disclosure of research and evaluation methods in other areas of healthcare have resulted in heightened scrutiny and public attention. Calls for greater transparency and documentation emerged after inconsistencies between stated and actual practice were identified in a review of the 6 major US drug compendia, which use similar methods and are subject to the same evidence limitations as care pathway developers.[53]

Lack of transparency may also foster greater potential for conflict of interest. Our research found that selection of therapeutic areas is driven primarily by financial considerations rather than quality of care, and the selection process is not typically discussed outside an organization. Provider feedback confirmed that use of care pathways remains mostly undisclosed to patients, as previously noted in recent publications exploring this issue.[50,51] Incentive structures, which tie payment to care pathway compliance directly, may discourage deviation from on-pathway treatment options.

This research was conducted using a sample of respondents with varying backgrounds and experience with care

pathways, limiting the ability to cross-validate responses. There was little variability in respondents' knowledge and opinion; survey/interview responses were generally consistent across respondents and differed by experience and background in expected ways. Nevertheless, our findings should be interpreted as directional—particularly those findings related to new developments and trends in care pathway development, implementation, and evaluation, which are evolving.

CONCLUSIONS

As care pathway use expands in the US healthcare system, we expect high-quality evidence of efficacy and safety will be central to future pathway development, and physicians will play a major role in its development and implementation. In light of our findings, there are several options for improving current practices. First, a unanimously supported initiative is needed to create best practices that guide pathway development, implementation, and evaluation and monitoring. Best practices must require disclosure of methods used to develop a care pathway and evaluate evidence used in the process; they must also be clearly documented. These objectives may best be accomplished with an effort similar to development of standards for clinical practice guidelines, spearheaded by the IOM. Any such effort should ensure that concerns about intellectual property are addressed; certification programs or review boards may offer solutions. Second, given the potential for care pathways to affect patient outcomes and quality of care directly, within a specific pathway and broadly, consistent methods for collection and analysis of data are needed to support critical evaluation of care pathway performance against the goals of improving quality of care and efficient allocation of resources. Data collection should include measures of compliance with pathways, resource use, and patient outcomes, including functional status and quality of life. Other programs, particularly those that address quality of care, may offer existing approaches and measures to leverage.

As with clinical practice guidelines, best practices or standards can provide a natural framework for evaluating care pathway performance. Third, transparency in all elements of pathway development, implementation, and evaluation should be adopted and endorsed. Specifically, the development approach, and underlying evidence, as well as the roles, responsibilities, and potential conflicts of interest in the development efforts should be clear. Finally, patients should have access to disclosures, including whether treatment plans follow a care pathway, whether the clinical practice in which care is being delivered is subject to pathway-related incentives, and information about development and impact of pathways, should they wish to review it.

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