



## **Clinical Pathways: barrier or benefit to patient Access and personalized medicine?**

July 2015

### **Overview**

This paper provides normative insights into the purpose of clinical pathways and explains how they are evolving in response to various dynamics in the healthcare arena. A set of criteria are delineated for defining the fundamental components of a pathway to help reduce variability in the design and implementation of such programs. It is our contention that pathways should be held to the same transparency standards as clinical guidelines and we provide a list of additional recommendations to guide the future of clinical pathways so they are aligned with broader efforts to create a healthcare paradigm grounded in shared-decision making and personalized care. The information and recommendations conveyed in this paper are meant to be broadly applicable as a reference guide. However, we often focus on oncology as a means by which to illustrate the challenges associated with certain approaches to clinical pathways that may conflict with advancements in patient engagement and precision medicine.

### **What are Clinical Guidelines?**

It is important to understand the relationship between clinical pathways and clinical care guidelines. Guidelines for the standard of care are used to improve patient health outcomes and evaluate treatment modalities for effectiveness and quality. In 2011, the Institute of Medicine defined clinical practice guidelines as recommendations intended to optimize patient care through a "systematic review of evidence and an assessment of the benefits and harms of alternative care options."

Professional societies, provider groups, and research organizations have increasingly turned to the development and implementation of clinical care guidelines to help promote evidence-based treatment for various disease processes. Such efforts are typically based on a robust, peer-review process and held to high standards for transparency. The development and use of guidelines reflects the commitment from providers to quality and consistency of clinical care. Well known examples are the clinical treatment guidelines for oncology published by the National Comprehensive Cancer Network (NCCN) and the guidelines for cardiovascular disease published by the American Heart Association and the American College of Cardiology.

### **What are Clinical Pathways?**

While clinical guidelines contain general recommendations, clinical pathways provide the detail consistent with the local structure, systems and time-frames necessary to utilize the guidelines consistently and appropriately.<sup>1</sup> Established clinical care guidelines should serve as the source for the evidence upon which a clinical pathway program is based. The latter can then work as a

tool intended to link clinical practice with available evidence in order to improve patient outcomes and maximize clinical efficiency.<sup>2</sup> Clinical pathways commonly consist of a structured multidisciplinary plan that details essential steps in the care of specific patients spanning areas like diagnostics, surgery, nutrition, medications, and discharge planning. Rather than focus on a singular area like drug selection, pathways are often based on a comprehensive continuum of care model that provides details for the management of a patient at each stage, from diagnosis to treatment to surveillance, in order to improve care continuity and coordination across multiple areas.<sup>3</sup> The ultimate goal is to help reduce unnecessary variations in care that can lead potentially to suboptimal quality or unnecessary costs.<sup>4</sup>

Properly designed and implemented pathways can help steer patients and providers to the treatment options that might optimize or personalize key variables such as efficacy and safety along with cost.<sup>5 6 7</sup> They even can help ensure that clinical trial options, if available, are always presented to patients. The available options and treatment costs for any given disease can vary widely simply depending on the facility where the treatment is delivered and the exact nature of the treatment regimen itself. Thus, most clinical pathways are developed and defined at the local or institutional level by the providers who are expected to implement them.<sup>8</sup> This approach takes into account variations in the ways providers practice medicine within their local ecosystem to ensure that the needs of their patients are met.<sup>9</sup> Some clinical pathways, however, are intended to standardize treatment protocols at a national, state, or regional scale to further reduce variations in the delivery of evidence-based care across sites, particularly in the absence of scientific merit for regional or local variability in treatment regimens.<sup>10</sup>

### **The Evolution of Pathways**

Clinical pathways have been implemented for at least the last thirty years.<sup>11</sup> The level of interest in pathways, particularly on the part of oncology practices, increased significantly following the passage of the 2003 Medicare Prescription Drug Modernization and Improvement Act.<sup>12</sup> Pathways were seen by providers as a way for them, rather than payers, to lead improvements in quality that would reduce the need for reductions in reimbursement and utilization management programs like step therapy and prior authorization.<sup>13</sup> Echoing that perspective is Glenn Balasky, former executive director of the Zangmeister Center in Columbus, OH. “In 2006, we felt it was the right thing to do to get out in front of the challenge. Pathways gave us a framework to respond to future demands from payers or other entities concerned with cost or quality of cancer care.”<sup>14</sup>

Healthcare professionals have been the leaders in pathway development for the past decade, just as they have been in the creation of the clinical guidelines on which they are typically based. Providers have routinely collaborated with insurance companies and other stakeholders to design and implement pathways. In some cases, healthcare providers are paid incentives by insurance companies to participate in pathway programs or share in the cost savings they may generate.<sup>15</sup>

However, there exists a concerted and growing effort on the part of some health plans to either standardize pathways or create their own.<sup>16, 17</sup> Early indications suggest that when payers create their own pathways, it is likely to be through internal processes that lead to a less robust pathway design that places greater emphasis on cost control than typically found in the creation of provider-sponsored pathways and guidelines.

This development begs several important questions about the future of pathways:

- 1) What should be the standard elements of a clinical pathway and the process for developing them?
- 2) Should the same level of transparency be expected in the creation of pathways as is typical for the creation of the clinical guidelines on which the former are based?
- 3) Who will primarily drive the process of cancer care generally and pathways more specifically in the future?
- 4) What right do patients have to know about the various forces that are acting to define and/or limit their treatment options and define their payment obligations?

### **Fundamental Components of a Pathway**

The impact of clinical pathways on hospital resources and patient outcomes remains unclear, an ambiguity driven partially by confusion among researchers and healthcare workers over what constitutes a clinical pathway.<sup>18</sup> In 2010, a team of Cochrane Review authors proposed a set of objective criteria by which to identify clinical pathways from the literature. A subsequent review of these criteria concluded that they “can be used as a foundation for the development of a standardized, internationally accepted definition of a clinical pathway.”<sup>19</sup> The Cochrane review identified at least five characteristics that define a clinical pathway:

1. Delineates a structured, multidisciplinary plan of care that spans multiple categories of care;
2. Channels the translation of guidelines or evidence into local structures;
3. Details the steps in a course of care or treatment in a plan, pathway, algorithm, guideline, protocol or other inventory of actions;
4. Provides time-frames of criteria-based progression (i.e. steps taken when designated criteria were met);
5. Standardizes care in a specific population for a specific clinical problem, procedure or episode of care.<sup>20</sup>

In addition, clinical pathways should be detailed, evidence-based, and have defined treatment regimens that include the names of the drugs, dosing levels, and schedule for administration.<sup>21</sup> Another important component is the transparency of the process by which the pathways are developed. We contend that pathways should be evaluated against their ability to meet the following transparency standards used by groups like NCCN when developing clinical guidelines.

- 1) Disclosure of the pathways development process including evidence evaluation.

The process used to develop the pathway and the evidence on which it is based should be clearly defined and disclosed so that an independent review of the data or its analysis can be conducted.

2) Disclosure of the participants involved in the process.

Knowing the background and experience of those responsible for creating the pathway is important to analyzing the credibility and reliability of the end product and identifying potential bias.

3) Involvement of other stakeholders with relevant experience in the pathway topic.

A diversity of perspectives including, but not limited to, providers, scientists, payers, and patients is necessary to insure that a pathway is truly multi-disciplinary and reflects the needs of all key groups impacted by its implementation.

4) Management of conflict of interest

Decisions about pathways must be made in an objective manner without the influence of conflicting interests. The financial relationships of the individual participants and of the convening entity should be disclosed based on a comprehensive policy for the management of potential conflicts of interest.

5) Ongoing and continuous evidence review

Pathway content and the evidence on which it is based should be reviewed and updated on a continuing and regular basis (e.g., preferably quarterly but at least annually) to ensure that the recommendations take into account the most current evidence. Any updates or changes should be immediately disclosed including the rationale for and literature supporting the change(s).

**Not All Pathways are Created Equal**

The reaction to pathways has been mixed, particularly on the part of medical oncologists.<sup>22</sup> Some resist it as a “cookie-cutter” approach that can interfere with the true practice of medicine, which involves personalizing a care plan to the individual.<sup>23</sup> Others support it as an important tool for driving standardization of care in a way that reduces errors and costs while increasing efficiency based on the best available evidence.<sup>24</sup> The extent to which pathways promote or impede personalized medicine depends greatly upon the design of the pathway and the extent to which it is deployed in a manner that supports clinical judgment. Thus, pathways should be evaluated based on how they are put to use in a clinical setting. A pathway program that is meant to drive coverage decisions for an individual patient treatment

will operate differently from one that seeks to create quality at an aggregate level while maintaining flexibility and clinical judgement at the individual treatment level. To some extent, the variation in design is related to differences in the groups responsible for creation of a pathway. For example, the methods by which the pathway is developed and the preferred concepts on which it is based are likely to differ when the program is driven by a group of providers as opposed to a payer.

Pathways can be designed to enable treating physicians to navigate their patients through various healthcare decisions, including clinical trials, based on different safety and effectiveness profiles as well as cost considerations leading to clinical decisions that meet the unique needs of an individual patient. A pathway that serves as a comprehensive decision support tool rather than a predetermined outcome can help make sure that at various points along the care continuum the patient receives evidenced-based interventions.<sup>25</sup>

On the other hand, a clinical pathway may serve, either intentionally or not, to limit the need for clinical judgment and customization through rigid standardization based on the “average” patient. Some pathways, for example, consist solely of a pre-determined “checklist” of drug regimens from which the prescribing physician is incentivized to select for 80 to 90% of patients.<sup>26</sup> Such a limited approach to a pathway more closely resembles common utilization management techniques like step therapy or “fail first” requirements. These practices are utilized by payers to regulate how a patient gets a medication, particularly those that are expensive, in an effort to control cost.

Cost containment should not be the primary goal of clinical pathways. However, cost considerations are a necessary component of discussions related to treatment selection. The rising cost of prescription drugs, particularly in oncology, is a topic of much discussion and debate. The United States spent roughly \$37 billion on cancer drugs in 2013.<sup>27</sup> However, the cost of oncology and other drugs is only a small fraction of overall healthcare costs. According to 2013 CMS figures, spending on prescription drugs accounts for around 9% of overall healthcare spending in the US with more than 50% attributed to hospital care combined with physician and clinical services.<sup>28</sup> Any attempt to utilize pathways as a cost containment strategy needs to focus across multiple aspects of care and not just one component, like drug treatments, in order to minimize the impact such a pathway may have on patient access to a variety of therapeutic options, especially in an era of precision medicine.

### **Patient Access Issues**

There exists a growing concern among some physicians and patient advocacy groups regarding the use of clinical pathways designed by payers that include payments to physicians to induce the use of a limited set of drug therapies preselected by the payer.<sup>29</sup> When providers elect to administer therapies that diverge from a payer’s clinical pathway, the latter is likely to deny coverage or require prior authorization and take time to review the provider’s chosen course of treatment regimen. Not only can such delays in physician-recommended treatment threaten patient health and impose unnecessary costs on the system, they also waste providers’ time, effort and resources and can lead to higher physician fees. Such review procedures can

discourage providers from prescribing treatments that deviate from the pathway even when there exists medical reason to do so and the patient is fully informed of their various treatment options. Studies have shown that access restrictions in oncology increase the likelihood that providers will alter their treatment decisions. A 2009 study<sup>30</sup> in *Health Affairs* estimated that prior authorization requests alone utilized about 20 hours of work on behalf of physicians, nurses, and office staff per week for a given medical practice. The burdens on providers who choose to appeal access restrictions on behalf of their patients are a significant annoyance, a hindrance to the provider-patient relationship and potentially harmful to optimal patient care. While their request for prior authorization moves through the various stages of appeal and denial, the patient's health may deteriorate further and ultimately require more invasive treatment, including hospitalization.

### **Pathways and Personalized Medicine**

Advances in understanding of the human genome are making possible the use of targeted therapies that are selected with genomic profiling. New medications that target a patient's particular genetic form of disease represents an emerging treatment model referred to as personalized medicine, which can be understood as a focus on treatment that is highly individualized to the patient. While this type of therapy represents the future of medicine, it may be incompatible with clinical pathways that are not thoughtfully constructed, or don't take into account detailed patient characteristics. Richard Schilsky, MD, chief medical officer of the American Society of Clinical Oncology stated that clinical pathways can drive everyone toward getting the same treatment, while "precision medicine wants to drive toward everyone getting unique treatment."<sup>31</sup> Pathways grounded in a "cookie cutter" approach that attempt to standardize treatment for large patient segments without respect to the emerging realities of personalized medicine risk eliminating a dynamic and potentially powerful series of treatments. Moreover, providers are expressing concern with the potential dilemma that might arise when the pressure to follow a payer's limited set of predetermined pathway options that emphasize cost containment conflicts with the provider's clinical judgment about the best treatment option based on the individual's unique circumstances.<sup>32</sup>

### **NPAF Position on Transparency and Patient Engagement**

We believe that pathway development should be owned and led by providers with specific clinical experience and expertise in the disease area that is the subject of the pathway. The providers who must live by the pathways are in the best position to determine how to translate guidelines into their institutional structures.<sup>33</sup> Kathy Lokay, President of Via Oncology, believes that "if the payers are calling the shots on which pathways to buy/hire, I don't know how an oncology practice can cope in that world....I think we want practices picking the pathways they like and feel the most comfortable with."<sup>34</sup>

Local design and control also helps prevent pressure to have multiple pathways from different sources deployed in the same provider ecosystem. Competing pathways within the same practice could lead to variability and inconsistency in the patient care experience, which are exactly the types of issues pathways are intended to reduce. For example, if multiple payers

were to create different clinical pathways, then different patients with the same disease in the same hospital system might receive different care experiences based on their payer's pathway.<sup>35</sup> As stated by Brian J. Bolwell, chairman of the Cleveland Clinic's Taussig Cancer Institute: "We generally don't like to practice by insurance company. We practice by patient."<sup>36</sup>

Because patients rarely possess the comprehensive medical knowledge necessary to evaluate their available options, they rely upon their care team's expertise to guide them through a decision-making process that elucidates their personal values and goals and then identifies a treatment plan that truly reflects the patient's individual perspective. Relevant considerations for such patient-centered care include efficacy, quality of life, toxicity, convenience and cost, which may vary according to patient age, comorbidities, life circumstances, personal finances and religious beliefs, as well as individual values and goals.<sup>37</sup> With the changing demographics and the long-standing disparities in incidence and mortality rates for diseases like cancer, it is prudent that information provided to patients be presented at a literacy level that permits understanding and in the patient's language of choice.<sup>38</sup>

Patients place great value in having a sense of trust and mutual respect with their treating physician as they move through this process. We seek to protect this relationship from attempts by those who might benefit financially from the outcome to influence the physician's treatment recommendations in the form of kickback arrangements to the physician or their practice. Thus, we are very concerned that pay-to-prescribe incentives linked to a narrow list of "on-pathway" therapies might short circuit the shared decision-making process and limit patient access to viable treatment options that are "off-pathway" and subject to utilization management protocols or high coinsurance.

Certain pharmaceutical and device companies are required, in the interest of transparency, to disclose publicly their payments to physicians and teaching hospitals as part of the Physician Payments Sunshine Act. The same approach could be taken with insurance companies that stand to benefit financially by influencing treatment selection by offering extra payments to physicians who place a patient on a drug therapy pre-determined by the insurer.

We believe that, at the very least, patients should have the right to know when their physician is participating in such a program. Patients need to know not only how options on pathways were chosen but what other alternatives are also viable according to guidelines but not listed in the pathway. This approach insures that patients know the "on- and off-" pathway treatment options that exist for their diagnosis and to have an honest consultation with their physician about the various risks, benefits, and costs associated with each. Also patients should know the process of selecting a guideline choice outside the pathway. It is also important for access to clinical trials to serve as a cornerstone option in pathways and guidelines.

If reasonable clinical evidence exists to support one drug treatment regimen over others based on what is going to provide the best approach for the patient, then healthcare professionals should be trusted to follow the evidence without an extra financial inducement to do so. Such is their obligation and duty to the patient; a responsibility they take very seriously. Pathways, as well as the guidelines on which they are based, should be designed to help guide that process.

### **NPAF's Recommendations for Clinical Pathways**

Based on the clinical expertise of our Scientific Advisory Committee and our nearly twenty years of experience helping hundreds of thousands of patients overcome administrative and financial barriers to care through Patient Advocate Foundation (our sister organization), the National Patient Advocate Foundation (NPAF) strongly believes that clinical pathways should:

- Support shared decision making and be process-driven to allow patients to express their preferences for how to individualize their care leading to a personalized treatment plan;
- Include discussion and consideration of clinical trial options as a required pathway element;
- Be developed by physician scientists and other members of the care team and/or the professional societies that represent them with expertise in the clinical area covered by the pathway and have clear mechanisms for involving patient advocates throughout the pathway development process;
- Be based on principles of transparency in design and execution;
- Focus on improving patient health outcomes and quality by providing feedback and measurement components to evaluate whether or not the pathways are improving quality of care;
- Be based on efficacy and safety as the main considerations in their design by focusing on clinical effectiveness and toxicity data as the primary variables while incorporating relevant personalized/precision determinants of effectiveness;
- Allow for differences in the clinical and biological characteristics of individual disease processes;
- Exclude the use cost as a factor to limit the initial set of choices in the pathway, but instead enable patients and their providers to consider cost information when selecting among those options identified during the process as the best available to them based on evidence.

Furthermore, patients whose conditions are well managed by their current treatments should not be shifted to pathways or utilization management techniques if they happen to change some aspect of their interactions with the healthcare system like a change in plan, site of care, or network. Continuity of care for patients whose disease is well managed is crucial to good health.

Patients need to have confidence and faith that pathways will not simply be a hidden tool to steer them to a limited range of treatment options pre-selected by their insurance provider. Ultimately, the process needs to be designed so treatment protocols are optimized and



personalized for each patient according to the physician’s clinical judgment. That is, after all, what medicine is all about.

<b>Table1. Guidelines for Clinical Pathway Design and Development</b>	
Fundamental elements of a Clinical Pathway	<ol style="list-style-type: none"> <li>1. Delineates a structured and multidisciplinary plan of care that spans multiple categories of care</li> <li>2. Translates guidelines or evidence into local structures</li> <li>3. Details the steps in a course of care or treatment in a plan, pathway, algorithm, guideline, protocol or other inventory of actions</li> <li>4. Includes time-frames of criteria-based progression</li> <li>5. Standardizes care in a specific population for a specific clinical subject for a specific clinical problem, procedure or episode of care</li> </ol>
Transparency Standards for Clinical Pathways Development	<ol style="list-style-type: none"> <li>1. Process used to develop pathway is disclosed and replicable including the criteria applied for evidence selection</li> <li>2. Participants involved in the pathway development process are disclosed</li> <li>3. The development and review process involved representatives for all relevant stakeholders with experience in the clinical area covered by the pathway Including patients</li> <li>4. Adherence to an established COI policy</li> <li>5. Pathway content and the evidence on which it is based should be reviewed and updated on a continuing basis</li> </ol>
NPAF recommendations for Clinical Pathways	<ol style="list-style-type: none"> <li>1. Pathways should support shared decision making and be process-driven to allow patients to express their preferences for how to individualize their care leading to a personalized treatment plan</li> <li>2. Include discussion and consideration of clinical trial options as a required pathway element</li> <li>3. Pathways should be developed by physician scientists and/or the professional societies that represent them with expertise in the clinical area covered by the pathway and have clear mechanisms for involving patient advocates throughout the pathway development process</li> <li>4. Pathways should be based on principles of transparency in design and execution</li> <li>5. Pathways should focus on improving patient health outcomes and quality by providing feedback and measurement components to evaluate whether or not the pathways are improving quality of care</li> <li>6. Pathways should be based on efficacy and safety as the main considerations in their design by focusing on clinical effectiveness and toxicity data as the primary variables while incorporating relevant personalized/precision determinants of effectiveness</li> <li>7. Pathways should allow for differences in the clinical and biological characteristics of individual disease processes</li> <li>8. Pathways should not use cost as a factor to limit the initial set of choices in the pathway, but instead enable patients and their providers to consider cost information when selecting among those options identified during the process as the best available to them based on evidence</li> </ol>

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Published ahead of print on June 22, 2015 available at

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