Oncology Clinical Pathways: Making Treatment Decisions in the Era of Patient-Centered, Personalized Cancer Care
June 12, 2017

Moderator:
Daryl Pritchard, Ph.D.
Vice President, Science Policy
Personalized Medicine Coalition
Today’s Agenda

1) Welcome and Introductions
2) State of Play in Oncology Care and Working Group Overview
3) Working Group Findings and Recommendations
4) Expert Panel Discussion
5) Q & A
Learning Objectives

• Inform attendees about the importance of personalized medicine in oncology care

• Promote an understanding of how oncology clinical pathways can affect patient care and provider workflows

• Discuss stakeholder perspectives on the role of clinical pathways in patient-provider decision-making

• Review potential solutions to ensure clinical pathways optimize patient care
State of Play in Oncology Care

• Cancer is a term that encompasses over 200 separate diseases.¹

• How we understand the genesis, prevention, diagnosis, and treatment of cancer is rapidly evolving.

• Advances in science show that some genetic mutations may render some cancers susceptible to targeted treatments.

Source: ¹https://www.aacrfoundation.org/Pages/what-is-cancer.aspx
Treatment is evolving from one size fits all, where some benefit and some do not...

...to an era of personalized medicine where we can identify the right treatment, for the right patient, at the right time.

Personalized medicine in cancer is becoming a reality.

<table>
<thead>
<tr>
<th>Tackle Tumors: Percentage of patients whose tumors are driven by certain genetic mutations that could be targets for specific drugs, by types of cancer.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melanoma</td>
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<td>Thyroid</td>
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<td>Colorectal</td>
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<td>Endometrial</td>
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<td>Lung</td>
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<td>Pancreatic</td>
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<td>Breast</td>
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<tr>
<td>Other gynecological</td>
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<td>Genitourinary</td>
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<tr>
<td>Other gastrointestinal</td>
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<tr>
<td>Ovarian</td>
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<tr>
<td>Head and neck</td>
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</table>

Making Treatment Decisions in an Era of Personalized Medicine

- Treatment protocols have been created to help providers make sense of rapidly evolving science, encourage evidence-based practice, and more recently, help providers identify patients who might benefit from personalized treatments.

- Clinical pathways are an example of a tool that may be used to standardize care and treatment protocols.

Clinical Pathways are a method for managing patient care based on clinical practice guidelines and other evidence, with the main goals of improving quality of care, reducing variation in clinical practice, and increasing the efficient use of healthcare resources.
Transition to Value Based Health Care

• Oncology care has been experiencing a shift from volume-based to value-based reimbursement over the last several years.

• This focus on value has driven an increased interest in payment models, including clinical pathways, and other decision-support as a means by which to maximize evidence-based care, while minimizing ineffective or costly treatments.

• The popularity of clinical pathways has been growing; a 2012 McKinsey report estimated that by 2015, 25% of oncology lives would be treated by clinical pathways.
Clinical Pathways: Benefits and Drawbacks

When designed appropriately, pathways can...

- Help providers understand and access the best available evidence and care practices
- Help providers make sense of complex science
- Increase efficiency in care
- Ensure patients receive the appropriate care at the appropriate time

If not designed appropriately, pathways can...

- Create barriers to patient choice and personalized care
- Impede access to innovative care
- Limit physician autonomy
Turning the Tide Oncology Clinical Pathways Expert Working Group

• Goal: To understand how clinical pathways can sustain innovation while enabling high-quality, patient-focused care

• Participants: Representatives from the patient advocacy, oncology care provider, biopharmaceutical industry, health information technology and payer communities

• Activities:
  • Phase I: Come to consensus around a list of best practices for clinical pathways that balances innovation with high-value care
  • Phase II: Assess how closely currently utilized pathway programs align with the list of best practices
Best Practices for Oncology Clinical Pathways
Development, Implementation and Evaluation

Table 1. Best Practices for Oncology Clinical Pathways

Development
a. The pathway developer has a clearly defined governance process that:
   i. Is supported by codified bylaws and procedures and outlines roles and responsibilities; and
   ii. Includes multi-stakeholder input from at least:
      1. Patients
      2. Actively practicing oncologists
      3. Pharmacists
      4. Others

b. The pathway does:
   i. Each clinical outcome
      ii. Reflect decision points at
   iii. Both the
   iv. The
   v. The
   vi. An
   v. An
   vi. An
   vi. An

c. The pathway provides to a patient needs
   i. Pathway develop
   ii. Pathway develop
   iii. Pathway develop
   iv. The
   v. The
   vi. The

b. The pathway design evidence and best
   i. Relevant
   ii. A

d. The pathway is used to:
   i. The
   ii. The
   iii. The
   iv. The

Implementation
a. Patients are informed when a pathway is being used to guide their care plan. At a minimum, the information should include:
   i. The purpose and expected benefits of using pathways as an approach;
   ii. Why a pathway is relevant to the patient and their treatment;
   iii. Whether participation in a pathway may limit a patient's treatment options or whether there may be alternative pathways to consider;
   iv. Whether the patient's healthcare provider may receive financial incentives for adherence to the pathway at a patient level;
   v. Additional information accessed additional details about the pathway.
   vi. Pathway details are available for clinicians and patients, including whether physicians can deviate from the pathway without penalty when it is appropriate for the patient.
   vii. Staff is given adequate training for implementing the pathways, including:
      i. Use of health information technology (HIT) systems to support pathway implementation;
      ii. Appropriately assessing whether patients meet institutionalization criteria;
   viii. Physicians can deviate from the pathway without penalty when they believe it is medically appropriate for the patient.
   ix. Providers in a clinical trial are considered on-pathway for purposes of calculating a pathway adherence rate.
   x. The pathway has a mechanism to follow patients who fail outside the pathway protocol, in order to more completely capture patient specific data, and to ensure that the pathway is not too restrictive.

Monitoring and Evaluation
a. Monitoring
   i. Review and provider collaborate on the use of the pathway to ensure continuity, accuracy, and appropriateness of care.
   ii. There is a feedback monitoring mechanism that monitors adherence rates and shares them with the providers.

b. Evaluation
   i. Pathway developers should design their products to facilitate the measurement of relevant performance metrics focused on patients and their diseases (including the appropriate time horizon for the types of measures).
   ii. The measures should include:
      i. Patient-focused measures, such as quality of life, satisfaction, experience of care, ability to work, symptom and side effect management, and patient-defined outcomes;
      ii. Clinical measures, such as patient outcomes including mortality, complications, and adverse events;
      iii. Practice-focused measures, such as satisfaction, clinical autonomy and compliance with pathways; and
      iv. Resource use measures, such as length of stay, costs (both episodic and overall) and readmission rates.
   iii. The pathway includes a protocol to collect and measure the necessary data to improve quality of care and optimize patient outcomes.
   iv. Results are reported back to the implementing health system to inform ongoing quality improvement efforts and to the pathway developer to inform pathway maintenance.

Report available at:
www.TurningTheTideAgainstCancer.org/publications
Oncology Clinical Pathway Assessment Findings

Guy D’Andrea
Partner
Discern Health
Methodology

• Identified pathways of interest
• Conducted audit against Turning the Tide recommendations, using website, documentation and verbally reported information
• Requested interviews when contact could be identified
• Verified that pathway development process is the same for any clinical condition
### Participating Organizations

<table>
<thead>
<tr>
<th>Developer Name</th>
<th>Payer?</th>
<th>Freq licensed to others?</th>
<th>Website Review</th>
<th>Interview</th>
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</thead>
<tbody>
<tr>
<td>Anthem-AIM (includes Empire Blue Cross)</td>
<td>Y</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Alabama BCBS</td>
<td>Y</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Eviti Advisor</td>
<td>N</td>
<td>Y</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>McKesson Clear Value Plus</td>
<td>N</td>
<td></td>
<td>✓</td>
<td></td>
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<tr>
<td>New Century Health</td>
<td>N</td>
<td></td>
<td>✓</td>
<td></td>
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<tr>
<td>NCCN</td>
<td>N</td>
<td>Y</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>P4 and PathWare (Cardinal Specialty Health Solutions) - eliminated</td>
<td>N</td>
<td>Y</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Via Oncology</td>
<td>N</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Note: NCCN is a guideline developer, not a pathway developer. They were included in this assessment as a benchmark, since NCCN guidelines are frequently referenced as the source guidelines for many clinical pathways.
Macro Findings

- **Industry is in flux**: programs being added, changed, acquired or eliminated regularly.

- Pathways are **not transparent to external stakeholders**.
  - Most pathways are proprietary – only available to customers.

- Pathways **serve multiple purposes**:
  - Decision support
  - Prior authorization
  - Prior authorization and provider adherence to ’high-value’ pathways

- Pathways **can be customizable**: the same pathway can be used by different organizations for different purposes, i.e., one organization for decision support and another for prior authorization.

- Pathways **draw from foundational source guidelines** (usually NCCN) and then modify to fit specific goals or need
Key Takeaways

1) Transparency is variable during pathway development and in how companies modify pathways.

2) Pathways are supported by evidence.

3) Multiple, slightly different pathways are in use for the same condition.

4) Pathways may serve multiple purposes in various settings.

5) Pathways are administratively complex.

6) Patient role in development or implementation not discussed.

7) Developers view monitoring/evaluation as the payer or provider role.
Conclusions & Policy
Recommendations
Conclusions

**Payers** are searching for the right strategy to drive value.

**Pathway developers** offer a product that can be customized to meet different payers’ needs.

**Providers** may benefit from the clinical decision support capabilities of pathways, but may also experience administrative burden, due to multiple pathway products with different goals.

**Patients** stand to benefit from evidence-based nature of pathways, but their feedback is not included in the development, implementation or evaluation processes.

Siloed nature of our healthcare system means a lack of accountability for individual pathways, from development through evaluation.
Recommendations

Identify independent third party to serve in an accreditation or oversight capacity to be tasked with developing standard and measures for each pathway phase.

- Outline standards for how treatment regimens are assessed and selected for on-pathway inclusion
- Require stakeholder involvement, specifically patient involvement in each pathway phase
- Develop point-of-care tools or advocate for interoperability between EMRs and pathway IT portals
- Guide frequency of pathway updates that result from new scientific data, real world evidence, and pathway monitoring and evaluation data
- Establish a disclosure system whereby a patient is informed when a pathway is used to direct part of their treatment decision-making
Expert Panel Discussion

Patricia J. Goldsmith
Chief Executive Officer
CancerCare

Gilbert S. Omenn, MD, PhD
Professor, Internal Medicine
Center for Computational Medicine and Bioinformatics
University of Michigan

Kimberly Westrich, MA
Vice President,
Health Services Research
National Pharmaceutical Council
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  TurningTheTide@fkhealth.com