The Path not Taken? Not Anymore – the Explosion of Oncology Clinical Pathways

The Journey of ASCO’s Task Force on Oncology Clinical Pathways from Recommendations to Policy Action
ASCO’s Policy on Clinical Pathways – Future Direction
Faculty

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Disclosures

Dr. Daly: Board of Directors – Quadrant Holdings; Ownership – Quadrant Holdings; Stock – CVS Caremark, Eli Lilly, McKesson, Walgreens

Dr. Zon: Consultant – Medical Protective
Learning Objectives

• Discuss ASCO Pathways Task Force development of Criteria for High Quality Pathways

• Discuss criteria application in pathway analysis

• Discuss pathways utilization and return on investment analysis

• Describe state policy activities involving pathways
USE OF ONCOLOGY PATHWAYS

57% of covered lives are potentially impacted by pathways

5 Major Pathway Vendors

Trends in cancer care delivery – Oncology clinical pathways

Percent of Practices Reporting Compliance with a Clinical Pathway Program (ASCO)
ASCO State of Cancer Care Report, 2017

- 2014: 16%
- 2016: 58%

Genentech Oncology Trend Report
Oncologist Clinical Pathway Usage

- Currently use: 50.0%
- Planned: 39.5%
- Do not use: 10.5%

Pathways: Protecting the Patient?

- A retrospective cohort study of 981,729 women with breast cancer in the National Cancer Database from 2004-2013

- Appropriate receipt of adjuvant endocrine therapy varied significantly by age, race, geographic location, and receptor status

- Pathways potentially protect patients from under, over, and mistreatment

Pathways evolving as cornerstone of future reimbursement methodologies and quality efforts

What is Driving this Increase in Implementation of Oncology Clinical Pathways (OCP) by Payers and Providers?

1. Manage drug utilization in a world with exponential drug cost escalation

2. Avoid time-consuming prior-authorization & appeals with payers- a goal

3. Capture stage & molecular data for a more refined risk adjustment

4. Put pressure on drug prices by explicitly accounting for price when efficacy and toxicity are similar

What is Driving this Increase in Implementation of Clinical Pathways by Payers and Providers?

5. Allow providers to demonstrate their quality to key stakeholders

6. Assists cancer centers in ensuring consistency of evidence-based care among their physicians in an increasingly complex field

7. Promote accrual to clinical trials

- Payers are incentivizing oncologists to use OCP’s by offering increased reimbursement, care management fees, & shared savings.
- Some payers are also waiving prior authorization for on-pathway treatments, bestowing preferred provider status, & providing expedited claims processing.

Concerns identified by the ASCO State Affiliate Council and Clinical Practice Committee

Administrative Burden
“Caring for the pathway and not the patient”

Patient autonomy & variability

Importance of Clinical Trials

Lack of Transparency

Need for comprehensive care

Implementation concerns
Lack of analytics
Clinical Pathways Task Force established by ASCO Board of Directors – January 2015

ASCO BOARD ESTABLISHED TASK FORCE JANUARY 2015

- Better understand commercial pathways programs landscape & impact on access/quality of care
- Develop a set of recommendations to address concerns raised by stakeholders

The Pathways Task Force determined it was essential to elevate awareness and convey a cautionary note that **NO CURRENT MECHANISM** exists to assure **integrity**, **efficient implementation**, and **outcome assessment** for these care management tools.
| 1. | Pursue a collaborative, national approach to **reduce the unsustainable administrative burdens associated with the unmanaged proliferation of oncology pathways** |
| 2. | Adopt a process for development of oncology pathways that is **consistent and transparent to all stakeholders**. |
| 3. | **Ensure that pathways address the full spectrum of cancer care**, from diagnostic evaluation through medical, surgical, and radiation treatments, and include imaging, laboratory testing, survivorship, and end-of-life care. |
| 4. | **Update pathways continuously** to reflect new scientific knowledge, as well as insights gained from clinical experience and patient outcomes, to promote the best possible evidence-based care. |
| 5. | Recognize **patient variability and autonomy** and allow for physicians to easily diverge from pathways when evidence and patient needs dictate. |
| 6. | Implement oncology pathways in ways that **promote administrative efficiencies** for both oncology providers and payers. |
| 7. | Promote education, research, and access to **clinical trials** in oncology clinical pathways. |
| 8. | Develop **robust criteria to support certification** of oncology pathway programs; pathway programs should be required to qualify based on these criteria, and payers should accept all oncology pathway programs that achieve certification through such a process. |
| 9. | Support research to **understand the impact of pathways on care and outcomes**. |

### Criteria for High Quality Pathways

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<tr>
<th>Development</th>
<th>Implementation &amp; Use</th>
<th>Analytics</th>
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<tbody>
<tr>
<td>Expert Driven &amp; Reflects Stakeholder Input</td>
<td>Clear &amp; Achievable Expected Outcomes</td>
<td>Efficient &amp; Public Reporting of Performance Metrics</td>
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<tr>
<td>Transparent, Evidence-Based, Patient-Focused, Clinically Driven, &amp; Up to Date</td>
<td>Integrated, Cost-Effective Technology &amp; Decision Support</td>
<td>Outcomes-Driven Results</td>
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<tr>
<td>Comprehensive &amp; Promotes Participation in Clinical Trials</td>
<td>Efficient Processes for Communication &amp; Adjudication</td>
<td>Promote Research in Value and Impact of Pathways and Care Transformation</td>
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# Criteria for High-Quality Clinical Pathways in Oncology

## Pathway Development

- Expert driven
- Reflects stakeholder input
- **Transparent**
- Evidence-based
- Patient-focused
- Clinically-driven
- Up-to-Date
- Comprehensive
- Promotes participation in clinical trials

### Criteria for High-Quality Clinical Pathways

- Is there a clear, consistent process and methodology for pathway development that is transparent to all pathways users, stakeholders and the general public? Is information disclosed on:
  - The methodology used for development?
  - The strength and types of evidence used to generate consensus?
  - The specific evidence used to support the pathway recommendation (including key literature citations, guidelines or other evidence)?
  - The way in which efficacy, toxicity and cost are assessed and balanced in determining the pathway recommendation?

- Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members any other individuals or entities that contribute to the development of pathway content? Does this policy describe:
  - The nature of relationships required for disclosure?
  - The manner in which disclosure information is made publicly available?
  - The required steps for managing conflicts of interest?
  - The required steps to ensure policy adherence and enforcement?

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### 2016 AMA House of Delegates – 1st Pathways Resolution:

- That our AMA support the development of transparent, collaboratively constructed clinical pathways

Source: ASCO Task Force on Clinical Pathways, Criteria for High-Quality Clinical Pathways in Oncology, 11/2016
A pathway parable from critical care medicine

• In 2006 in *The New England Journal of Medicine*, Eichacker et al. published a commentary on the Surviving Sepsis Campaign and the drug, Xigris, arguing that these guidelines were “usurped” for “commercial purposes”

• In 2001, the FDA approved Xigris (recombinant human activated protein C or drotrecogin alfa) for the treatment of sepsis

• Approval was based primarily on a single phase 3 randomized, controlled trial – the Recombinant Human Protein C Worldwide Evaluation in Severe Sepsis (PROWESS) study – which showed a significant survival benefit

• The FDA acknowledged controversy:
  – Half of the agency’s advisory panel, pointing to methodologic and other important problems (bleeding), voted to require that a confirmatory trial be performed before approval was granted

Source: Eichacker PQ, Natanson C, Danner RL, Surviving sepsis – practice guidelines, marketing campaigns, and Eli Lilly
A pathway parable from critical care medicine

• In face of controversy, initial sales fell short of market expectations

• Per Eichacker et al., the manufacturer hired a PR firm, which launched a 3-prong strategy including: the Surviving Sepsis Campaign – treatment guidelines for sepsis
  – International experts in critical care and infectious diseases were convened to create guidelines for sepsis management; the manufacturer provided 90% of the funding

Xigris received a favorable rating in the guidelines despite persistent concerns in new studies

• The manufacturer awarded grants for implementing the Campaign, performance bundles were created based on selected recommendations from campaign guidelines, state governments were lobbied to adopt bundles

“Professional societies and other stakeholders must work together to promote...a policy that prohibits the pharmaceutical and medical-device industries from directly or indirectly funding or influencing practice standards”
– Eichacker et al., The New England Journal of Medicine, 2006

Transparent: Conflict of Interest of CPW Vendor Committees

**CPW Vendor Committee Conflicts of Interest**

- Of the different vendors, 92% of US Oncology Value Pathways voting members, 84% of NCCN Value Pathways voting members, 84% of Via Oncology Pathway chairs, and 69% of eviti medical advisory board received a 2015 general payment.

- The mean 2015 general payment to committee members ranged from $3.5K for US Oncology Value Pathways to $15.3K for NCCN Value Pathways voting members.

**Mean General and Research Payment Among CPW Committee Members, 2015**

Source: https://www.cms.gov/openpayments/
Transparent: Conflict of Interest of CPW Vendor Committees

**CPW Vendor Committee Conflicts of Interest**

- 8% of US Oncology voting members, 19% of the eviti medical advisory board, 28% of Via Oncology CPW chairs, and 42% of NCCN voting members received $10,000 or more in general payments in 2015

Source: https://www.cms.gov/openpayments/
Medicare Quality Payment Program (QPP)

Merit Based Incentive Program System
- Measures Quality, use of CEHRT, Improvement Activity and Cost.
- Peer Comparisons
- Incentives/Penalties
- Publicly Reported

Alternative Payment Models
- New Payment Mechanisms
- New Delivery Systems
- Negotiated Incentives
- Automatic Bonus

Quality Payment Program
Modernizing Medicare to provide better care and smarter spending for a healthier America.
Patient-Centered Oncology Payment Model (PCOP)

The Transformation of Oncology Payment

www.asco.org/paymentreform
PCOP Implementation and Possible Role of Pathways

- **Role of Pathways**
  - Quality Measures
    - Pathway Compliance Quality Metric
  - Financial Impact
    - Two sided risk equation
    - Cost assignment and measurement
    - Integrate pathways into resource utilization (drugs)
- **EHR Technology and Data Requirements**
  - Pathways as a surrogate for stage, bio/molecular/genomic marker data submission (reduces data submission)
Leveraging High-Quality Pathways to Measure Resource Use in MIPS

• A fair and appropriate methodology for measuring Resource Use for oncologists is critical
• Pathways feasible alternative to episodes of care:
  – Can determine whether a provider adhered to a clinically appropriate course of care
  – Provide a mechanism to assess the quality and cost of care provided
  – Already being used by payers

• Pathways potentially underpin utilization management strategies
• High quality pathways delivering high quality care can help manage the overall cost of care for patients. Many payers are already using pathways, but ASCO is suggesting both a way to improve UM strategies, as well as improve the use and effectiveness of pathways
Frequently asked: Return on Investment?

- Optimize patient outcomes (QOL-Survival-Financial-Equitable)
- Maximize the value of the dollar spent
- Health care system
- Assist providers in proving value to payers resulting in reimbursement benefit
- Optimize practice efficiencies and reduce administrative costs/resources
- Assure most recent scientific and real world evidence is basis for intervention selections
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<th>Return on Investment?</th>
<th>Patient, Provider, Payer and Employer</th>
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<tr>
<td><strong>Decrease ED/Hosp</strong></td>
<td>Clin abstracting simplified</td>
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<td><strong>Decrease in medical errors</strong></td>
<td>Emerging Best Practices</td>
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<td><strong>Decrease EOL costs</strong></td>
<td>QOL Improvement</td>
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<td><strong>Improve triage nurse efficiencies</strong></td>
<td>Pre cert eliminated</td>
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<tr>
<td><strong>Improve chair time management</strong></td>
<td>Improve Clinical Research Accrual</td>
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<tr>
<td><strong>Improve work flow</strong></td>
<td>Decrease admin work</td>
</tr>
<tr>
<td><strong>Improve patient flow</strong></td>
<td>Supportive care optimized</td>
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Needed Strategies to Enable and Maximize Return on Investment

• Pathway program analysis- quality, patient outcomes, financial perspectives
• Verbiage to assist providers in contract discussions with payers
• Integration with EHRs to populate reportable data
The Future Of Pathways
Provider, Payer and Employer Perspective

Value Based Pathways
To Support Value Based Reimbursement and Care Regardless of Payer
The Future of Pathways
Patient Perspective

Patient Centric
Value Based Care
“Right Care”

Education, Information, Transparency

Clinical Pathways Congress
Clinical Pathways: State Advocacy

- The State Affiliates have raised serious concerns with the development and use of pathways
- ASCO developed a model bill as a resource to State Affiliates and is offering advocacy assistance
- The focus of the model legislation:
  - Improving pathways development
  - Addressing practice burden
  - Legislation in California and Connecticut
“For the purposes of this section, the phrase ‘clinical pathways for oncology’ shall refer to a detailed protocol for delivering cancer care, including but not limited to anticancer drug regimens, for specific patient presentations, including the type, stage and molecular subtype of disease”
**Future Direction**

*The Oncology Clinical Pathways Act of 2017 (AB 1107)*

- “The bill would prohibit a plan or health insurer from, among other things, developing and implementing a CPW that discourages patient access to clinical trials” or “interferes with the independent clinical judgement of a provider”

- The bill would “ensure that each oncology clinical pathway is evidence-based...developed by a group of actively practicing physicians with clinical expertise...”

- “Review and update, as new therapies emerge, but not less than annually.”

- “Provide to contracting providers, upon request, all of the following:
  - The names, qualifications, institutional affiliations, and any conflicts of interests of the physicians and other individuals who conducted the research, developed the analysis, and assessed oncology CPW”
The Oncology Clinical Pathways Act of 2017 (AB 1107)

• “The American Society of Clinical Oncology is pleased to support your legislation, the Oncology Clinical Pathway Act of 2017 (AB 1107), as a critical first step towards ensuring that the process for developing oncology clinical pathways is consistent and transparent.” – Daniel F. Hayes, ASCO President

• “Anthem Blue Cross must respectfully oppose your AB 1107, as amended, regarding oncology care pathways. AB 1107 unnecessarily targets care management tools used by health plans and insurers.” - Michael Prosio, Regional Vice President

• The California Association of Health Plans, representing 49 public and private organizations that collectively provide health coverage to more than 28 MM Californians, has regrettably taken an OPPOSE position on Assembly Bill 1107, which unnecessarily seeks to regulate voluntary clinical guidelines developed by health plans” – The California Association of Health Plans

• The bill was held in the appropriations committee and no further action will occur this year
Questions?