Clinical Pathways
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The Current Oncology Landscape

### Payers
- Controlling rapidly escalating cancer treatment costs
- Managing off-label prescription use
- Supporting cost-effective quality cancer care

### Providers\(^1,^4\)
- Utilizing new agents and therapies
- Incorporating evolving standards of care into practice
- Efficiently operating an oncology practice

### Patients\(^1,^5\)
- Accessing appropriate care in a timely manner
- Receiving high-quality cancer care

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1. Goldsmith M. Presented at: The Center for Business Intelligence 3rd Annual Effective Oncology Benefit Management Conference; October 6, 2008; Chicago, IL.
Significant Variation Exists in Community Oncology Practices

Concordance With Select Quality Oncology Practice Initiative Quality Indicators and Group Variation*

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Round 1 Yes (%)</th>
<th>Round 2 Yes (%)</th>
<th>Compare Round 1 vs 2 P Value</th>
<th>Variation Among Groups Range (%)</th>
<th>Variation Between Groups P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was G-CSF given per guideline?</td>
<td>24</td>
<td>50</td>
<td>0.01</td>
<td>0-88</td>
<td>0.002</td>
</tr>
<tr>
<td>Were EGFs given per guideline?</td>
<td>72</td>
<td>60</td>
<td>0.048</td>
<td>37-100</td>
<td>0.001</td>
</tr>
<tr>
<td>Was a pathology report available?</td>
<td>96</td>
<td>96</td>
<td>0.95</td>
<td>94-97</td>
<td>0.23</td>
</tr>
<tr>
<td>Was staging completed?</td>
<td>62</td>
<td>87</td>
<td>—</td>
<td>78-93</td>
<td>0.012</td>
</tr>
<tr>
<td>Was a signed consent for chemotherapy in the chart?</td>
<td>71</td>
<td>58</td>
<td>—</td>
<td>2-100</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Abbreviations: EGFs, erythroid growth factors; G-CSF, granulocyte colony-stimulating factor.

*Results using standard medical records abstraction measures based on clinical practice guidelines and consensus-supported indicators of quality care developed by 92 physicians in 7 oncology groups. Two rounds of medical chart reviews were conducted 6 months apart. The process of quality evaluation, development of the pilot questionnaire and preliminary results are reported. All types of cancer were included in the analysis.

Clinical Pathways: An Approach to Help Reduce Treatment Variability and Standardize Care

- Clinical pathways are commonly:
  - Defined as a management tool for standardizing the way an MCO network’s physicians and other health care providers treat a disease\(^1,2\)
  - Developed by oncologists to encourage the consistent delivery of value-driven, evidence-based treatment\(^1\)
  - Based on clinical guidelines or other commonly used clinical expertise\(^2\)
  - Designed to increase the predictability of care, increase treatment consistency, improve quality care, and manage costs\(^1-4\)

A 2008 Web-based survey found that 95% of providers (n=50) and 64% of payers (n=50) agreed that guidelines and pathways played a “somewhat significant” or “very significant” role in their organizations\(^5\)

Pathways

- Pathways combine evidence-based practices and clinical community consensus to develop consistent treatment approaches^1
- Pathways from many sources are being integrated into the practice of oncology^1
- Two studies of pathways showed cost advantages of on-pathway versus off-pathway treatment, with outcomes consistent with the published literature^2,^3
- Pathways may enable oncologists and oncology practices to better position themselves to participate with ACOs, PCMHs, and other stakeholders^4
- The impact of ACOs, PCMHs, and hospital VBP will likely be felt first in Medicare reimbursement, followed by private payers

Types of Pathway and Utilization Initiatives

- “Front-end” compliance programs
  - Primary focus is to support evidence-based treatment decisions made by physicians in the development of clinical pathways
  - Clinical pathways are monitored and maintained by physicians

- “Back-end” compliance programs
  - Primary focus is to track care through post-treatment claims data against multiple approved preferred treatment choices and drug margins

- Episode-of-care programs
  - Primary focus is to provide bundled payment for drugs, removing incentives for using ineffective interventions
  - Office visits, drug administration costs, radiation treatments, or lab tests are still reimbursed on a fee-for-service basis

1. Holcombe D. Presented at: 2010 Cancer Center Business Summit; October 7 and 8, 2010; Chicago, IL.
Clinical Pathway Parameters

- Most stakeholders consider a variety of inputs when developing or updating a pathway, which typically include a systematic evaluation of a drug’s attributes based on the following (in order of importance)\(^1\)
  - Efficacy
  - Tolerability
  - Costs

- When evaluating oncolytics that are perceived to be equally effective, stakeholders typically choose the drug based on the safety\(^1\)

- When reviewing 2 or more treatment options with similar safety profiles, stakeholders typically choose the less costly drug (looking at total costs including downstream costs)\(^1\)

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Clinical Pathway Parameters (cont)

- Oncology clinical pathways are commonly supported by scientific evidence and national guidelines such as the following organizations:\(^1\):
  - National Comprehensive Cancer Network (NCCN)
  - American Society of Clinical Oncology (ASCO)
- Clinical pathways differ from guidelines because they are designed to narrow treatment options and ultimately guide physicians to preferred treatments for every state and stage of a disease with respect to efficacy, drug toxicities, and cost\(^1,2\)
- When properly coordinated, clinical pathways may help stakeholders achieve quality health outcomes and a cost benefit\(^2\)

**Collaboration among payer and providers helps improve the likelihood of success in implementing clinical pathways\(^2\)**

Clinical Pathways Should Be Flexible Enough to Support Personalized Treatment

• Cancer care is complicated by vast differences in:
  – Diagnosis
  – Staging
  – Physician training
  – Available therapies

• Important differences also exist among patients with regard to:
  – Medical history
  – Genetics
  – Desired treatments

“Payer clinical guidelines in oncology need to allow providers sufficient flexibility in medical decision making.”

Important Considerations When Assessing Clinical Pathways

1. Oncology groups and payers can ask critical questions when examining pathways, such as
   - Who developed the pathways?
   - How were the pathways developed, and are they firmly grounded in evidence-based clinical information?
   - Do the pathways define preferred treatments for each state and stage of disease?
   - Are the pathways detailed and comprehensive?
   - Are the pathways regularly updated?
   - Are the pathways available and accessible in real time at the point of care?
   - Are mechanisms in place that hold physicians accountable to follow the pathways?
     - Can the rates at which physicians use the pathways be documented and tracked?
     - Can the patient capture rate (e.g., data/patient completeness) and reasons for going off-pathway be reported?
     - Are physicians allowed to treat with an off-pathway alternative and will outcomes, reasons, and causes for the variation be collected?

Important Considerations When Assessing Clinical Pathways (cont)

- Pathways are one component of quality-based care management
  - Quality of medical care: What should payers assess?
  - Structure\(^1-3\)
    - Are adequate facilities, equipment, medical staff, and procedures in place to deliver quality care?
  - Process\(^3\)
    - Is care in line with accepted standards of care (eg, evidence-based treatment recommendations)?
  - Outcomes\(^3\)
    - What are the valid measures of effectiveness and quality, recovery, and survival?

Health care quality can be defined as:

“The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”\(^4,5\)

Outcome Measures or Clinical Endpoints in Oncology

- Clinical trials measure the safety and efficacy (or clinical benefit) of interventions used against a disease
- Quantitative endpoints in clinical oncology studies include
  - Overall survival (OS)
  - Symptom endpoints (patient-reported outcomes)
  - Surrogate endpoints are based on tumor assessment
    - Disease-free survival (DFS); Progression-free survival (PFS); Response rate (RR); Time to Treatment Failure (TTP)

- Are these measures practical in community practice?
  - Besides OS, most of these measures are probably not practical in every-day practice
  - Measurements would not be consistent or reproducible

Outcome Measures or Clinical Endpoints in Oncology

- Measures that may ‘represent’ good/bad care (also referred to as down-stream endpoints) ~ Surrogate Markers
  - Transfusions
  - Return clinic visits
  - ER visits
  - Hospitalizations
  - Infections
  - Hydration
- Cancer care by inference
  - To conclude from certain premises or evidence

Outcome Measures or Clinical Endpoints in Oncology

- So what should be done now in community practice?
  - Demonstrating true ‘outcome’ measures in community practice will be difficult
  - Documenting the provision of ‘appropriate’ care should be the goad
  - Process measurement can document appropriate care
  - Pathways provide a mechanism to systematically apply treatment strategies with rules, allowing for appropriate care determinations
  - Until national standards for the measurement process, reproducibility, and endpoint validation are established, nationally recognized pay incentives will lag behind
  - Practices need to be able to tell a story with their clinical data on how they manage specific cohorts of patients
  - Benchmarking your pathway treatments compared to non-pathway treatments is a good place to start

The Oncology Patient-Centered Medical Home™ (OPCMH) model provides a partial solution to fragmented delivery of care\(^1,2\)

Key features of OPCMH include\(^1,3\)
- Open access, enhanced care coordination, comprehensive care, and sustained personal relationships

An oncology practice becomes the central coordinator of care throughout all phases of a patient’s treatment after a cancer diagnosis\(^1\)
- Surgery, radiation, chemotherapy, and survivorship

OPCMH represents a logical platform to build a value-oriented, outcome-based system of delivering care by addressing important challenges\(^1\)
- Cost control, quality assurance, outcome measures, and process improvement

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*Oncology Patient-Centered Medical Home™ is a trademark of the National Committee for Quality Assurance.

End-of-Life Care

• Organizations such as the National Quality Forum (NQF) and NCCN have developed preferred practices and performance measures for palliative and end-of-life care[^1][^2]
  – Includes the coordination of multiple specialists
• More than 1 million people die each year without access to palliative and end-of-life services[^3]
• Medicare paid for over 83% of all hospice care in 2009[^4]
  – The median time in hospice is 17 days[^5]

Pay-for-Performance (P4P)

• Also known as P4P or VBP, this payment model rewards physicians, hospitals, medical groups, and other healthcare providers for meeting certain performance measures for quality and efficiency
• P4P can be integrated into pathways programs
• P4P seeks to generate cost-efficiencies through
  – Evidence-based, high-quality care
  – Health information technology
  – Outcomes measurement
  – Clinical/financial analytics
  – Patient support

Abbreviation: VBP, value-based purchasing. Also called VBR, value-based reimbursement.
Characteristics That May Improve the Likelihood of Clinical Practice Guidelines Program Success

- Development of the clinical practice guidelines (CPGs), which include clinical pathways
  - Should include all local users who are given the opportunity to critique them

- Dissemination of the CPGs
  - Should go beyond publication in a journal and include vehicles such as specific mailing and educational conferences

- Implementation of the CPGs
  - Should be accomplished through patient-specific reminders
  - Must be readily available for reference
  - Physician should be prompted to use it

- Accountability for process and outcomes
  - Considered the most important aspect of clinical practice guidelines program success
  - Can take the form of peer pressure, financial incentives, or administrative reward or sanction

Potential Benefits and Pitfalls of Clinical Pathways*

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Pitfalls</th>
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<tbody>
<tr>
<td>Payers</td>
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<tr>
<td></td>
<td>– Help reduce treatment variability and</td>
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<td></td>
<td>increase predictability of outcomes</td>
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<tr>
<td></td>
<td>– May reduce the costs of care</td>
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<td></td>
<td>– May help reduce precertifications</td>
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<tr>
<td>Providers</td>
<td>Payers</td>
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<tr>
<td></td>
<td>– Cautious not to be accused of limiting</td>
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<tr>
<td></td>
<td>care</td>
</tr>
<tr>
<td></td>
<td>– Concerns over physician acceptance</td>
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<tr>
<td></td>
<td>– Compliance difficult to monitor</td>
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<tr>
<td></td>
<td>– Difficult to prove savings</td>
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<tr>
<td>Patients</td>
<td>Providers</td>
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<tr>
<td></td>
<td>– Don’t want to be limited in treatment</td>
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<tr>
<td></td>
<td>options</td>
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<tr>
<td></td>
<td>– Savings typically don’t come back to</td>
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<td></td>
<td>the physicians</td>
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<tr>
<td></td>
<td>– May be locked into the pathway contract</td>
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*The information presented is consistent with the clinical experience of key opinion leaders.
Questions
Survivorship and Chronic Care

- Survivorship and chronic care are part of the national healthcare continuum-of-care priority\(^1,2\)
- The number of cancer survivors has more than tripled—to almost 10 million—over the past 30 years, and survival rates are increasing\(^3\)
- Guidelines for survivorship and chronic care are included in accreditation standards established by the Commission on Cancer, representing 30% of all hospitals and more than 70% of newly diagnosed cancer patients annually\(^2\)
- Primary care physicians seldom receive explicit guidance from oncologists\(^4\)

Episodes of Care

- This payment model reimburses for an “episode of care” by bundling payments to groups for the full cost of care for each cancer patient.
- The payer may freeze drug margins in an episodes-of-care model, which would replace the buy-and-bill approach.
- The payer may continue to pay for drug costs, office visits, and administration fees on a fee-for-service (FFS) basis, allowing for inflation.
- In an episodes-of-care model, quality and outcomes are closely monitored.

References


Goldmann F, Graham EA. *The Quality of Medical Care Provided at the Labor Health Institute, St Louis, Missouri*. St Louis, MO: Labor Health Institute; 1954.

Goldsmith M. Navigating the oncology care maze: evidence based medicine as a pathway for payers, providers & patients. Presented at: The Center for Business Intelligence 3rd Annual Effective Oncology Benefit Management Conference; October 6, 2008; Chicago, IL.


