Oncology Clinical Pathways: What’s the Endgame?

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Faculty Disclosures

- Received consulting fees from Merck, Amgen and Thorne Research
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- Receive research funding from BMS

Objectives

- Describe the processes in the development of an oncology clinical pathway
- Identify the impact oncology pathways will have on practice including benefits, disadvantages, barriers and measures of success
- Discuss how oncology pathways will impact patient care

A Clinical Pathway

A task-oriented, step-wise management tool for standardizing a specific disease care plan

Benefits of Clinical Pathways

- Allows the use of evidence-based medicine
- Excellent tool for resource utilization control
- Encourages the use of national guidelines and helps to establish standards of care
- Can set a framework for continuity of care

Benefits of Clinical Pathways (Cont.)

- Can account for variations in patient care
- Establishes a database on care patterns
- Allows for measurement of endpoints and/or outcomes
- Should maintain or improve quality of care
Concerns With Clinical Pathways

- Discourages personalized care and appropriate clinical judgment
- Risk of litigation (with use or without)
- May limit response to unexpected changes in a patient’s condition
- May stifle innovation and progress (ie., new drug development)
- Could see exploitation (ie., financial)

Clinical Pathways Barriers

- Physician reluctance to change
  - It’s just ‘cook-book’ medicine
- Existence of guidelines
- Time and resources
- Buy-in by all parties (administration, payers)
- May not work well with all medical scenarios

Clinical Pathways: Systematic Review

- Design: Systematic review and meta-analysis
- Evaluation: (these are hospital-based)
  - Patients managed according to clinical pathway vs usual care
  - Impact on patient outcomes, length of hospital stay and hospital cost
- Twenty-seven studies met inclusion criteria

Randomized Controlled Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Setting</th>
<th>Sample size</th>
<th>Country</th>
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<tbody>
<tr>
<td>Aizawa 2002</td>
<td>TURP</td>
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<td>Japan</td>
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<tr>
<td>Brook 1999</td>
<td>Mechanical ventilation</td>
<td>Medical ICU</td>
<td>321</td>
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<td>Delaney 2003</td>
<td>Laparotomy and Intestinal Resection</td>
<td>Surgical / Rehabilitation</td>
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<td>Dowsey 1999</td>
<td>Hip and knee arthroplasty</td>
<td>Orthopedic unit</td>
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<td>Stroke Rehabilitation</td>
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<td>Coronary Care unit</td>
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<td>Girgis 2000</td>
<td>Atrial fibrillation</td>
<td>Emergency and Pediatrics wards</td>
<td>110</td>
<td>USA</td>
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<tr>
<td>Kim 2002</td>
<td>Arterial reconstruction</td>
<td>Emergency Department</td>
<td>18</td>
<td>USA</td>
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<tr>
<td>Kijas 2003</td>
<td>Gastroenterology</td>
<td>Gastroenterology</td>
<td>85</td>
<td>Japan</td>
</tr>
<tr>
<td>Kijas 2007</td>
<td>Mechanical ventilation</td>
<td>Medical &amp; Surgical ICU</td>
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<td>USA</td>
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<tr>
<td>Matos 2008</td>
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<td>Roberts 2007</td>
<td>Chest Pain / possible MI</td>
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<td>Bauer 2006</td>
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<td>936</td>
<td>USA</td>
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<td>Cobb 2006</td>
<td>Asthmatic children</td>
<td>Pediatric unit</td>
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<td>Copley 2002</td>
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<td>Kamper 2006</td>
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<td>62</td>
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<tr>
<td>Rotter T, et al. Cochrane Database of Systematic Reviews 2010, Issue 3. Article No.: CD006632</td>
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Length of Stay

<table>
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<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
</tr>
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<tbody>
<tr>
<td>Length of stay (in days)</td>
<td>Mean difference (95% CI)</td>
</tr>
<tr>
<td>Aizawa 2002</td>
<td>-2.88 (-3.58, -2.18)</td>
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<tr>
<td>Brook 1999</td>
<td>-1.38 (-1.69, -1.07)</td>
</tr>
<tr>
<td>Delaney 2003</td>
<td>-0.80 (-1.08, -0.52)</td>
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<td>Dowsey 1999</td>
<td>-0.70 (-1.00, -0.40)</td>
</tr>
<tr>
<td>Girgis 2000</td>
<td>-0.41 (-0.59, -0.23)</td>
</tr>
<tr>
<td>Kijas 2003</td>
<td>-0.28 (-0.46, -0.10)</td>
</tr>
<tr>
<td>Kim 2002</td>
<td>-0.14 (-0.34, 0.06)</td>
</tr>
<tr>
<td>Kijas 2007</td>
<td>-0.13 (-0.43, 0.17)</td>
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Cost

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<tr>
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<tr>
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<tr>
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</tr>
<tr>
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<td>-3.01 (-2.70, -3.31)</td>
</tr>
<tr>
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<td>-2.75 (-3.04, -2.46)</td>
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</tr>
<tr>
<td>Kim 2002</td>
<td>-2.57 (-2.91, -2.22)</td>
</tr>
<tr>
<td>Kijas 2007</td>
<td>-2.51 (-2.86, -2.15)</td>
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<td>Total cost (difference)</td>
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Why Cancer Clinical Pathways?

- Cancer is second leading cause of death in US
- Direct cancer medical costs nearing $100 billion
- Cancer drugs are expensive and their cost is rising faster than other drug categories
- Variation in cancer disease management can exceed 100%
- Availability of national guidelines

Causes of Death in US

- Heart Disease: 27%
- Cancer: 23%
- Chronic lower respiratory disease: 5%
- Accidents: 5%
- All other causes: 34%

Variation in chemotherapy during the last two weeks of life

- Orange: 11%
- Red: 3%

Cost of Lung Cancer Treatment

- Cost varies from patient to patient

Expected sales growth rate of oncology medicines vs. the pharmaceutical industry as a whole

- Oncology sales growth rate: 10%
- Pharmaceutical industry growth rate: 3%
Cancer Treatment Guidelines

Oncology Clinical Pathways

- Defined as a set of treatment standards that should be used in some orderly fashion and consist of:
  - Diagnostics
  - Disease treatment (drug specific)
    - Should include chemotherapy and supportive care
    - Establish set regimen recipes
    - Set regimens to be used by line of therapy
  - Additional disease treatment
    - Surgery, radiotherapy
  - End-of-life care

Ellis PG. Oncol Times 2010;32:46-47.

Oncology Clinical Pathways (Cont.)

- To date, most active pathways have focused on the disease treatment phase of cancer care
- Oncology pathways should combine evidence-based medicine and practicing physician consensus to develop best approach
- Have mainly been applied in the oncology outpatient treatment setting


Oncology Clinical Pathways (Cont.)

- May support better participation with accountable care organizations (ACO’s) and other managed care programs.
- Two published pathway studies show cost savings using strict pathways versus no pathway, with outcomes consistent with published literature.


Oncology Pathway Parameters

- Oncology pathways should be evidence-based and supported by scientific evidence and nationally recognized guidelines:
  - National Comprehensive Cancer Network (NCCN)
  - American Society of Clinical Oncology (ASCO)
- Pathways are designed to narrow treatment options and guide physicians to preferred treatment strategies
- When managed properly, pathways should maintain or enhance health outcomes and offer a cost benefit (i.e., cost-effective care)


Oncology Pathway Parameters (Cont.)

- Stakeholders should consider a variety of inputs when picking regimens for a specific pathway
  - Efficacy
  - Tolerability (toxicities)
  - Cost and reimbursement
- Once regimens are selected and standardized, they can be put in order by line of therapy
  - The number and type of regimens available in each line of therapy will indicate how restrictive or more lenient the pathway is.

Durin JD. Mening Clin. 2010;18(S4).
Pathway Development & Implementation

The pathway is evidence-based and formulated by representative physicians.

All affected physicians and healthcare professionals are given the pathway to review, and are expected to critique.

Guideline should be readily available for reference and caregivers should be prompted to use. Follow-up and updating must be built into process.

All caregivers must be accountable, typically rewarded through maintaining or increased reimbursement.

Available Oncology Clinical Pathways

- **National NCCN**
  - These are overall macro guidelines that represent ‘clinical practice’
  - Are updated frequently
  - Generally discuss all available treatments, do not provide ‘best practice’ or take cost into consideration
- **McKesson/US Oncology**
  - Currently, have been in-network (US Oncology) specific (applied across the US)
  - Promote relatively restrictive ‘level 1’ pathways
    - Have a ‘preferred’ regimen(s)(generally based on cost), then restrict other choices
    - Have demonstrated cost saving and improved outcome

Available Oncology Clinical Pathways (Cont.)

- **UPMC/Via Oncology**
  - Based off of UPMC Institutional pathways
  - Implemented by Horizon BCBS
  - These are also relatively restrictive pathways
- **Cardinal Health/P4 Healthcare**
  - Utilized by several state BCBS’s (ie., CareFirst, Michigan)
  - Generally less-restrictive (more treatment options)
  - Provide monetary incentives for use
  - Have demonstrated cost savings

Oncology Pathway Results

- **US Oncology: NSCLC ‘Level 1’ pathway evaluation**
- **Retrospective, 1409 patients**
- **12-month cost of care on vs. off pathway**
  - Evaluated:
    - Outpt/Acute care/Hospice visits
    - Chemotherapy/supportive care
    - Laboratory
    - Other
  - Chemotherapy and supportive care drugs accounted for most of the decrease ~ 22% and 23%, respectively
- **Survival was equivalent**

US Oncology ‘Level 1’ NSCLC Pathway

- **Metastatic: (Squamous cell)**
  - **First-Line**
    - Carboplatin/paclitaxel
    - Vinorelbine (poor PS)
    - BSC
  - **Second-Line**
    - Docetaxel
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Twelve-Month First-Line Cumulative Costs

Twelve-Month Second-Line Cumulative Costs

Categorized Costs

Oncology Pathway Results

Survival

Median Overall Survival
Claims Analyzed Costs


Breast Cancer
• Adjuvant breast
  - Low risk
  - High Risk
  - Her2Neu Positive
• Metastatic Breast
  - Her2Neu Negative
  - Her2Neu Positive

Colorectal Cancer
• Adjuvant Stage IB, II, IIIa
• Stage III unrestricted
• Stage IV
  - 1st line
  - Maintenance therapy after 1st line
  - 2nd line
  - 3rd line
  - 4th line and further

Non-Small Cell Lung Cancer (NSCLC)
• Adjuvant Colon (stage II and III)
• Metastatic Colon
  - 1st line
  - 2nd line
  - 3rd line

Small Cell Lung Cancer (SCLC)
• Initial
• Failed prior therapy
• 3rd Line

CareFirst/P4 Pathways

CareFirst/P4 NSCLC Pathway
- Metastatic: NSCLC
  - First-Line
    - Carboplatin + paclitaxel/docetaxel
      - + bevacizumab (non-squamous)
    - Platinum + pemetrexed (non-squamous only)
    - Platinum (carbo/cis)/gemcitabine (squamous only)
    - Erlotinib (EGFR (+) only)
  - Second-Line
    - Any non-cross resistant regimen from first-line
    - Docetaxel
    - BSC
  - Third-Line
    - Erlotinib
    - BSC

Oncology Pathway Results

- 46 sites, representing 4,713 patients and 78,821 claims were reviewed
  - Breast (50%); Lung (28%); colon (22%)
- Compliance by site:
  - Chemotherapy ~ yr +1 (83%) yr +2 (54%)
  - Supportive care ~ yr +1 & +2 (74%)
- Actual cost savings: (projecting no cost increases)
  - Using the yr -1 through yr +2 time frame
  - Drugs $657,000 (2.5% + over 3 yrs)
    - Chemotherapy $349,000
    - Supportive care $1,006,000
  - Hospitalization $2,935,000 (57% ↓ over 3 yrs)
  - Total actual cost savings ~ $2,278,000

So Where Do We Go From Here?

• With the systematic application of resources with rules (i.e., pathway), we are then able to collect the data generated from a specific cohort of patients (will have to be something more than claims data), we then can start to look at endpoints, outcomes and cost, and compare different resource applications (i.e., comparative effectiveness)
• But, that's another lecture...

Self-Assessment Questions

• In the Rotter’s Cochrane Systematic Review of the value of clinical pathways, length of stay was not significantly different between pathway’s and ‘usual care’ of patients
  – A. True
  – B. False
• Which of the following is true concerning pathways in oncology practice
  – A. Most available pathways are consensus-based
  – B. Pathways are designed to narrow treatment options
  – C. Are routinely used in VA hospitals inpatient units
  – D. NCCN pathways are ‘best practice’ in nature

Self-Assessment Questions

• In the US Oncology colon cancer pathways study published by Hooverman looking at on/off pathway use, the data showed:
  – A. A statistical difference in DFS
  – B. Overall survival was not statistically different
  – C. The difference in adjuvant treatment cost was $10,200
  – D. The difference in metastatic cost was not significant