Guidelines, Pathways, and Culture Change: Reports from the National Comprehensive Cancer Network (NCCN), Texas Oncology, and the US Oncology Network
Faculty

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Disclosures

Dr Hoverman and Ms McClure have nothing to disclose.
Learning Objectives

• Understand how to utilize NCCN Guidelines and Evidence Blocks in guiding treatment decisions
• Outline the evolution of pathways
• Present results of studies on the value of pathways
• Discuss moral tension and its place in care delivery
• Discuss the necessity of culture assimilation to alleviate issues of moral tension
NCCN Guidelines and Evidence Blocks in Guiding Treatment Decisions

Joan McClure, MS
The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 26 of the world's leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives.

**Mission:**
Our mission, as an alliance of leading cancer centers devoted to patient care, research, and education, is to improve the quality, effectiveness, and efficiency of cancer care so that patients can live better lives.

**Vision:**
To be the world's leader in defining and advancing high-quality, high-value cancer care.
• Guidelines: what to do and when
  – Essentially a superset of recommendations
  – Allows for patient or physician preference and clinical variability
• Pathways: what to do and when
  – Typically narrower, based on efficacy, safety, and cost
• Care plans: how to do it
  – Instructions for implementing guidelines/pathways
NCCN Guidelines®

• Cover continuum and all modalities of cancer care
• Accepted as standard for clinical care and policy in oncology in United States
• 53 multidisciplinary panels with 26-30 experts per panel
• 26,000+ hours volunteered by panel members in 2016
• 67 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) updated continuously
Multidisciplinary Panels

- Medical oncology
- Surgery/surgical oncology
- Radiation oncology
- Hematology/hematology oncology
- Bone marrow transplantation
- Urology
- Neurology/neuro-oncology
- Gynecologic oncology
- Otolaryngology
- Orthopedics/orthopedic oncology
- Pathology
- Dermatology
- Internal medicine
- Gastroenterology
- Endocrinology
- Diagnostic radiology

- Interventional radiology
- Nursing
- Cancer genetics
- Psychiatry/psychology
- Pulmonary medicine
- Pharmacology/pharmacy
- Infectious diseases
- Allergy/immunology
- Anesthesiology
- Cardiology
- Geriatric medicine
- Epidemiology
- Patient advocacy
- Palliative care/pain management
- Pastoral care
- Oncology social work

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Use of Evidence to Make Recommendations

Data from multiple studies and sources

- Ongoing process based on evolving data
- The amount of data available differs across disease sites and across clinical decisions within a disease site
- Continuous review of evidence and guideline updates are required
- New studies WILL change the standard of care over time

Expert evaluation

Distill appropriate recommendations
Evidence-based Consensus Allows Comprehensive Guideline

Continuum of disease and patient care

Evidence-based guideline

- High-level evidence exists

Evidence-based consensus guideline

- Gaps in evidence filled with expert consensus
Category 1: Based upon high-level evidence, there is uniform NCCN consensus (≥85%) that the intervention is appropriate.

Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus (≥85%) that the intervention is appropriate.

Category 2B: Based upon lower-level evidence, there is NCCN consensus (50-85%) that the intervention is appropriate.

Category 3: Based upon any level of evidence, there is major NCCN disagreement (at least 3 institutions on each side) that the intervention is appropriate.

All recommendations are category 2A unless otherwise noted.
NCCN Evidence Blocks

- Use consistent methodology and display to inform decision-making

- Measures
  - Efficacy
  - Safety
  - Quality of Evidence
  - Consistency of Evidence
  - Affordability

- More shading is better
Minimization of Bias

- Large number of panel members
- Multidisciplinary (eg, medical oncology, radiation, surgery, nursing, others) membership
- Geographic diversity
- Different philosophical views represented
- Institutional review
- External review and input: submissions, conferences/symposia, international
- Formal declaration of potential conflicts: verbal/written
Disclosure

- No industry or any other interest group funds are used to support panel meetings
- No industry representatives allowed at meetings
- Individual panel members disclose conflicts of interest at least annually
- Financial conflicts of interest published for individuals on NCCN.org
- Members are excused from deliberations when degree of conflict warrants
By far the most influential guidelines for oncology treatment decisions are those published by the National Comprehensive Cancer Network, used by 86.5% of MCOs. - The 2010-2011 Genentech Oncology Trend Report

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**Updates Process**

- Institutional Review, including relevant supporting data
- Outside Submissions

→ Panel Meeting/teleconference → NCCN Staff Review and Update → Panel Chair Review → Panel Review

- FDA Approval
- Significant scientific publication or presentation

→ Monitoring and Review of literature

Concurrent development and production of Discussion, Compendium and Chemotherapy Order Templates

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• Use concordance of practice with NCCN Guidelines recommendations as surrogate for appropriate care
• 100% concordance is NOT the goal
• Develop benchmark concordance from care at known high-quality sites and then measure other sites to identify outliers
• Follow trends in resource utilization
Ovarian Cancer

- Adherence to NCCN Guideline improves OS for high-risk stage II and stage III colon cancer
- “These data validate the current NCCN practice guidelines for colon cancer and support the concept of guideline-based metrics that can be compared across institutions to assess the quality of cancer care and to compare the quality of cancer care among institutions.”


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• All stages
• Compliant care was associated with a 55% reduction in the hazard of death
• Compliance with NCCN Guidelines and stage-specific therapy at presentation for the treatment of patients with gastric cancer was poor
• Guideline compliance was associated with a 36% decreased odds of mortality (OR = 0.64, 95% CI 0.53-0.77, \( P < 0.0001 \))

• Patients who received compliant care had improved survival irrespective of the volume of the institution where they were treated.
Exceptions to Guideline Concordant Care

- Must use clinical judgment when applying guidelines to the individual
- Guidelines apply to about 80-85% of patients
  - Some clinical situations do not fit guidelines
  - Physical status limits desirability of concordant treatment
  - Comorbid condition is contraindication to concordant care
  - Patient may refuse guideline concordant care
- Clinical trial participation is always concordant!
• Even in the United States, access to care is limited by cost
• Healthcare debt is the most frequent cause of bankruptcy in the US
• Patients and clinicians should have the information available to make decisions based on their values and circumstances
• Different people will value different criteria
US Prescription Drug Use and Affordability

Do you currently take any prescription medicine or not?

- No: 49%
- Yes: 50%
- DK/Ref. <1%

Among the 50% who are currently taking prescription medicine:

- In general, how easy or difficult is it for you to afford to pay the cost of your prescription medicine?
  - Very easy: 48%
  - Somewhat easy: 28%
  - Somewhat difficult: 12%
  - Very difficult: 9%
  - Don't have to pay (Vol.): 3%
  - DK/Ref.: 1%

- Percent who say they or a family member have had to do each of the following because of the cost, in the past 12 months:
  - Not filled a prescription for a medicine: 25%
  - Cut pills in half or skipped doses of medicine: 18%

SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted June 2-9, 2015)
Concern has become significant about the sustainability of cost escalation
Cost to individuals is not consistent because of different payers and plans
Drugs, diagnostics, imaging, hospital, and other costs are all increasing
A variety of organizations are addressing value in different ways
Strategies to Reduce Cost of Care

• Successful solution must satisfy payer/employer and provider needs and provide high-quality care for patients
  – Narrower networks
  – Bundled payments
  – Pathways
• Pathways programs include 4 main components:
  – **Pathway development**: Pathways are developed through an evaluation of guidelines to determine which regimen is most effective, least toxic, and least costly for a particular diagnosis
  – **Compliance rate**: Target physician compliance rates with pathways are typically set between 65%-80%
  – **Reporting infrastructure**: How does the practice perform?
  – **Incentive realignment**: The goal is to decouple payment from drug choice
A cancer treatment regimen usually must first be recognized by national guidelines as an effective and recommended cancer therapy.

Recommend cancer therapies on the basis of:
  - Clinical benefit (efficacy)
  - Side effects (toxicity), especially those that lead to hospitalizations or impact on quality of life
  - Cost
  - +/- Strength of national guideline recommendations
NCCN Guidelines and McKesson Value Pathways

Characteristics

• NCCN Guidelines® are gold standard for evidence-based oncology content

• Value Pathways are a subset of the NCCN Guidelines
  – Developed with input of NCCN
  – Include consideration of quantified pharmacoeconomics

• Guidelines and Value Pathways create an evidence-based standard consistent across markets and regions

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US Clinicians Consult the Following Guidelines Regularly (N = 1,100)

- NCCN Guidelines: 96%
- American Society of Clinical Oncology (ASCO): 52%
- American Cancer Society (ACS): 32%
- Other cancer-related guidelines: 18%
- American College of Radiology (ACR): 9%
- Society of Surgical Oncology (SSO): 6%
- Association of Community Cancer Centers (ACCC): 6%
- Cancer Care of Ontario (CCO): 2%
- National Oncology Alliance (NOA): 1%
Clinical Pathways Used by Medical Oncologists

Percentage of Medical Oncology Clinics

N = 98

- Via Oncology: 4%
- Value Pathways Powered by NCCN: 14%
- Anthem: 1%
- Homegrown Pathways: 6%
- Adhere to NCCN Guidelines: 57%
- Do Not Use Pathways: 3%
QUESTION: Would providing decision support displaying alternative acceptable treatment regimens reduce the number of denials and the cost of care for chemotherapy prior authorization?

United Health Care, Evicore, and NCCN built and tested a digital version of the NCCN Guidelines offering all recommended treatment options when the physician reached a decision node

1 year pilot by United Health Care using practices in Florida with 4,272 eligible cases

Newcomer, Weininger, Carlson, JOP2016
Clinical Decision Support for Preauthorization

Findings:

- 20% reduction in chemotherapy drug cost trends compared to US as a whole during the trial period
- 1% of requests denied because they did not meet NCCN recommendations
- Practice financial counsellors did not have sufficient expertise to implement
- Prior authorization tools with real-time updates decrease costs and denials but require clinical expertise to implement
Pathways, Moral Tension and Culture

J. Russell Hoverman, MD, PhD
Texas Oncology’s Vision Statement

TOPA’s vision is to be the pre-eminent oncology and hematology group in the southwest as manifested by high standards for patient satisfaction, recognition as providers of exceptional value in oncology care and participation in clinical research and treatment protocols developing innovative approaches in the science of oncology and hematology.
Pathways 1.0

- Physician behavior can change
- Costs could be addressed without affecting survival
- A platform, not a program
- Recommendations only
- Last century technology, claims and paper based
- Two pathways, adjuvant breast cancer, metastatic lung
Texas Oncology Quality Oversight Committee (1999) members felt the principle of drug choice should conform to the following priorities in order of importance:

- Outcomes
- Toxicity
- Patient Costs
- Margin
DOONESBURY

YOU'RE NOT ACCEPTING THE ACCOUNT? MIKE, BELLWOS COULD FIRE YOU!

I KNOW...

BUT I'M FACED WITH A MAJOR MORAL DILEMMA HERE, MARCIA...

IF I DO THIS CAMPAIGN, I'M AN ACCOMPlice TO PEDDLING A DRUG THAT CLAIMS OVER 300,000 LIVES A YEAR!

ON THE OTHER HAND, WE REALLY NEED A NEW WASHER-DRYER. I'D GO WITH THE WASHER-DRYER.
Cost Effectiveness of Evidence-Based Treatment Guidelines for the Treatment of Non-Small-Cell Lung Cancer in the Community Setting

By Marcus A. Neubauer, MD, J. Russell Hoverman, MD, Michael Kolodziej, MD, Lonny Reisman, MD, Stephen K. Gruschkus, PhD, MPH, Susan Hoang, PharmD, Albert A. Alva, MEd, Marilyn McArthur, MS, Michael Forsyth, RPh, Todd Rothermel, and Roy A. Beveridge, MD

Kansas City Cancer Center, Overland Park, KS; Texas Oncology, Austin; US Oncology, Houston, TX; New York Oncology Hematology, Albany, NY; Aetna Informatics; and Aetna, Hartford, CT

Abstract

**Purpose:** The goal of this study was to evaluate the cost-effectiveness of Level I Pathways, a program designed to ensure the delivery of evidence-based care, among patients with non-small-cell lung cancer (NSCLC) treated in the outpatient community setting.

**Patients and Methods:** We included patients with NSCLC initiating a chemotherapy regimen between July 1, 2006, and December 31, 2007, at eight practices in the US Oncology network. Patients were characterized with respect to age, sex, stage, performance status, and line of therapy and were classified by whether they were treated according to Level I Pathways guidelines. Twelve-month cost of care and overall survival were compared between patients treated on Pathway and off Pathway. A net monetary benefit approach and corresponding cost-effectiveness acceptability curves were used to evaluate the cost-effectiveness of Level I Pathways.

**Results:** Overall, outpatient costs were 35% lower for on-Pathway versus off-Pathway patients (average 12-month cost, $18,042 vs $27,737, respectively). Cost savings were significantly less for patients treated on Pathway versus off Pathway in the adjuvant and first-line settings, whereas no difference in overall cost was observed in patients in the second-line setting. No difference in overall survival was observed overall or by line of therapy. In the net monetary benefit analysis, after adjusting for potential confounders, we found that treating patients on Pathway was cost-effective across a plausible range of willingness-to-pay thresholds.

**Conclusions:** Results of this study suggest that treating patients according to evidence-based guidelines is a cost-effective strategy for delivering care to those with NSCLC.
12 Month Cumulative Cost by Pathway Status

Neubauer, Cost-Effectiveness of Evidence-based Treatment Guidelines for the Treatment of NSCLC in the Community Setting, JOP, 6:1.
Overall Survival by Pathways Status

<table>
<thead>
<tr>
<th>Pathway status</th>
<th>3 month</th>
<th>6 month</th>
<th>9 month</th>
<th>12 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients (n = 1,409)</td>
<td>0.82</td>
<td>0.64</td>
<td>0.53</td>
<td>0.46</td>
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<tr>
<td>On pathway (n = 1,095)</td>
<td>0.82</td>
<td>0.65</td>
<td>0.53</td>
<td>0.45</td>
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<tr>
<td>Off pathway (n = 314)</td>
<td>0.80</td>
<td>0.64</td>
<td>0.54</td>
<td>0.46</td>
</tr>
</tbody>
</table>

Log-rank $P = .867$

Neubauer, Cost-Effectiveness of Evidence-based Treatment Guidelines for the Treatment of NSCLC in the Community Setting, JOP, 6:1.
On-Pathways vs. Off-Pathways Cost and Utilization Patterns

1. Cost = Inpatient + Outpatient + Prescription Drug costs incurred from index date + 15 months
2. Inpatient and Outpatient costs include chemotherapy paid under medical benefit

Milliman Analysis of Medstat 2007, 14 million commercially insured lives, 104,473 cancer patients, Milliman Health Cost Guidelines 2009, Chemotherapy patients exclude patients on chemotherapy hormone therapy only.
Pathways 2.0

- Prospective approval
- Electronic medical record based
- Pathways adherence about 75%
- Exception process not streamlined and can be bypassed
- 21 diseases as Level One Pathways within US Oncology
Value

Value Formula

\[ V = \frac{O}{C} \]
Relative Value

RV1 = O1/C1
RV2 = O2/C2
RV3 = O3/C3
Subjective Data

- Relative value may be determined by subjective value, assessable only by the patient.

- True value to the patient cannot be determined unless subjective values are explored.
Financial Toxicity

- Expenses for average Medicare patient with cancer averages 25% of household income
- Bankruptcy 2.5x more common after a cancer diagnosis
- Bankruptcy itself is a predictor of higher mortality
- Those with limited reserve reported significantly increased pain…greater symptom burden…and poorer QOL

Value Drivers

- Outcomes
- Toxicity
- Patient Costs
- Margin
Pathways – Perverse Incentives

• Market Dynamics (Volume vs Value)
• Margin directly proportional to cost of drug
• Institutional Discounts (e.g. 340b)
Pathways - Aligned Incentives

• Payer pathways and employer (not necessarily for providers)

• Value-based payments (payers, employers, providers)

• Overarching goal of better, cost-effective care
Arguments for Margin Weight

- **Mission:** (No margin, no mission)
  - Outreach, charity care
  - Teaching
  - Research

- Keeping doors open (drug financial risk, bad debt)

- Expanding services

- Lifestyle

- The demands of the patient (and/or family) sitting in front of you
### Aetna Medicare Advantage Y2 Financial Results

<table>
<thead>
<tr>
<th></th>
<th>Chemotherapy and Supportive Care</th>
<th>Inpatient</th>
<th>ER</th>
<th>Total</th>
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<td><strong>Benchmark Cost</strong></td>
<td>$11,420,791</td>
<td>$3,925,662</td>
<td>$305,247</td>
<td>$15,651,701</td>
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<td><strong>Actual Cost</strong></td>
<td>$9,081,351</td>
<td>$3,323,072</td>
<td>$281,140</td>
<td>$12,685,563</td>
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<tr>
<td><strong>Savings Percent</strong></td>
<td>20.48%</td>
<td>15.35%</td>
<td>7.90%</td>
<td>18.95%</td>
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</tbody>
</table>

Neubauer et al  J Clin Oncol 2016;34:abstr#6505
# Aetna Medicare Advantage Y2 Financial Results

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<tr>
<th>Condition</th>
<th>Age Band</th>
<th>Members</th>
<th>Case Months</th>
<th>IP Cost / MM</th>
<th>ER Cost / MM</th>
<th>CRDC / MM</th>
<th>Control IP Cost / MM</th>
<th>Control ER Cost / MM</th>
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<th>IP Savings</th>
<th>ER Savings</th>
<th>CRDC Savings</th>
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<td>Multiple Myeloma</td>
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<td><strong>2Y Total - All Cohorts</strong></td>
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<td><strong>415</strong></td>
<td><strong>2139</strong></td>
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Texas Oncology, Aetna unpublished data.
The New Delivery System

- Total cost of care
- The patient is the center
- Multiple touches needed to understand and act upon patient choices and values
- Care becomes team based
1. Provide **24/7 patient access** to an appropriate clinician who has real-time access to patient’s medical records

2. Use an **ONC-certified EHR and attest to Stage 2** of Meaningful Use by the end of the third model performance year

3. Utilize data for **continuous quality improvement**

4. Provide core functions of **patient navigation**

5. Document a **care plan** that contains the **13 components in the Institute of Medicine** Care Management Plan

6. Treatments consistent with **nationally recognized clinical guidelines**

*Practice reported or attestation*
The IOM Care Management Plan Elements

1. Relevant patient information
2. Diagnosis, specific tissue information, relevant biomarkers, and stage
3. Prognosis
4. Treatment goals
5. Initial plan for treatment and proposed duration
6. Expected response to treatment
7. Treatment benefits and harms, including common and rare toxicities
8. Information on quality of life and a patient’s likely treatment experience
9. Who will take responsibility for specific aspects of a patient’s care
10. Advance Directives (Care Plan)
11. Estimated total and out-of-pocket costs of treatment
12. A plan for addressing a patient’s psychosocial health needs
13. Survivorship Plan
Corporate culture refers to the beliefs and behaviors that determine how a company’s employees and management interact and handle outside business transactions.
Corporate Culture

• Culture is the set of processes in an organization that affects the total motivation of its people.

• Positive – play (enjoy work), purpose, potential

• Negative-Emotional pressure, economic pressure, inertia

The most sensitive positive determinate of corporate culture is role satisfaction.

The next most important is the identity of an organization, which includes its mission...
The Mission and Vision statements of a successful organization will reinforce the moral inclinations of its employees and reduce moral tension.

Good companies will hire employees consistent with the mission and vision statements.

As a rule, employees must feel they can “do well by doing good.”
Texas Oncology’s Vision
– To be the first choice for cancer care

Texas Oncology’s Mission
• To provide excellent, evidence-based care for each patient we serve, while advancing cancer care for tomorrow.
OUR CULTURE

Doing the Right Thing
WHY IS THIS IMPORTANT?

For our PATIENTS

For each OTHER

For our COMMUNITIES
Corporate History

- 1993  American Oncology Resources (AOR)
       Physician Reliance Network (PRN)
- 1999  Two companies merge to form US Oncology
- 2006  US Oncology goes private
- 2011  US Oncology acquired by McKesson Specialty Health/Mckesson
Our mission is to provide comprehensive pharmacy solutions…
Together with our customers and partners, we are creating a sustainable future for health care. Together we are charting a course to better health.
USON, McKesson Specialty Health, McKesson

**OCM** – supports 15 practices

**MIPS** – Supports 15 practices
Comment From a New OCM practice

You are not the same company that tried to recruit us 2 years ago.
Harder Times Ahead?
Recent Troubles

• “Bad debt soars for Baylor, THR and Methodist hospital….,” $1.9 billion in uncompensated care in 2016. Dallas Business Journal

• “MD Anderson starts 2017 fiscal year with massive losses….,” Houston Chronicle
MAKE CANCER CARE GREAT AGAIN
Questions?