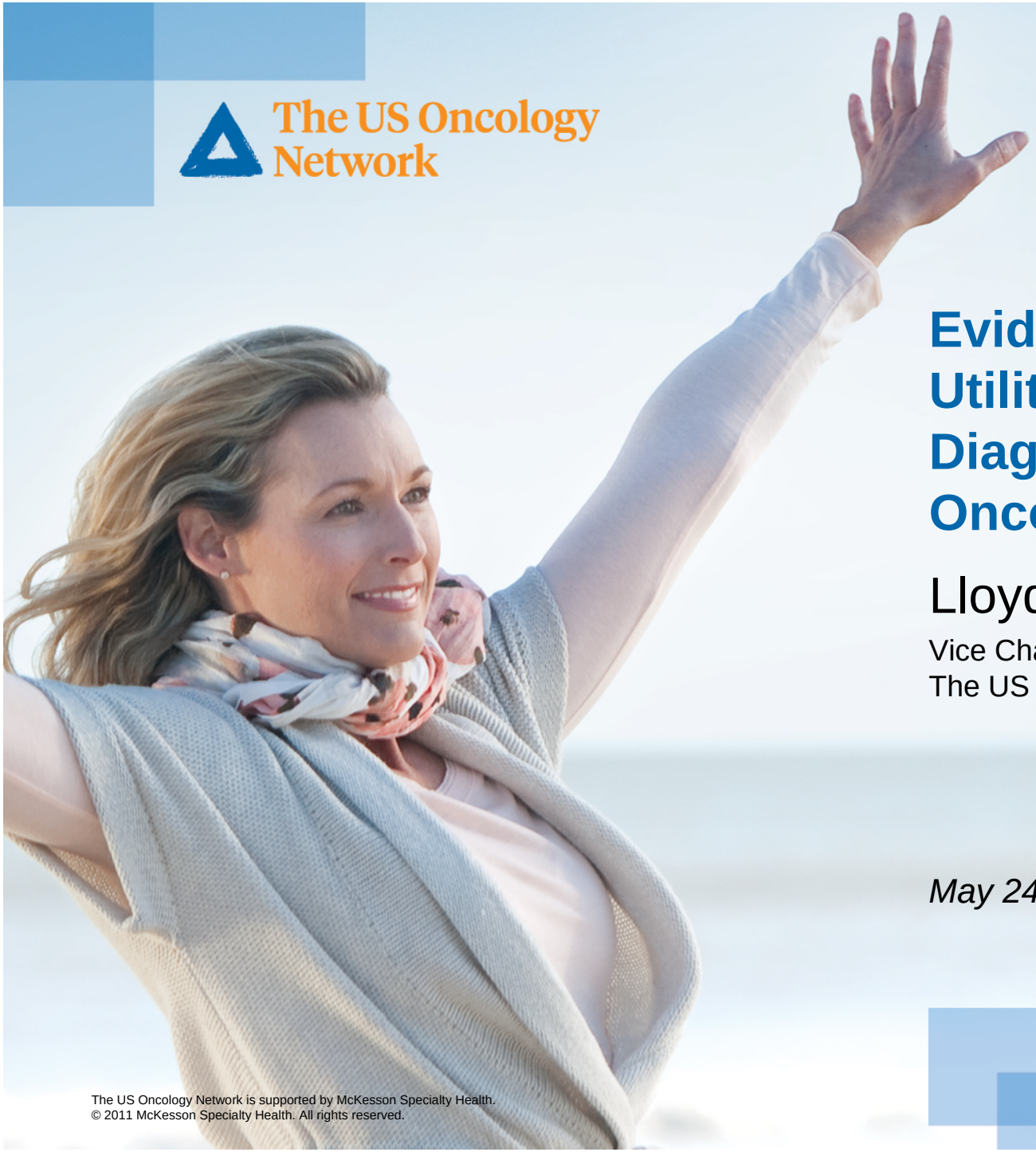

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McKesson Specialty Health

Evidence for Clinical Utility of Molecular Diagnostics in Oncology

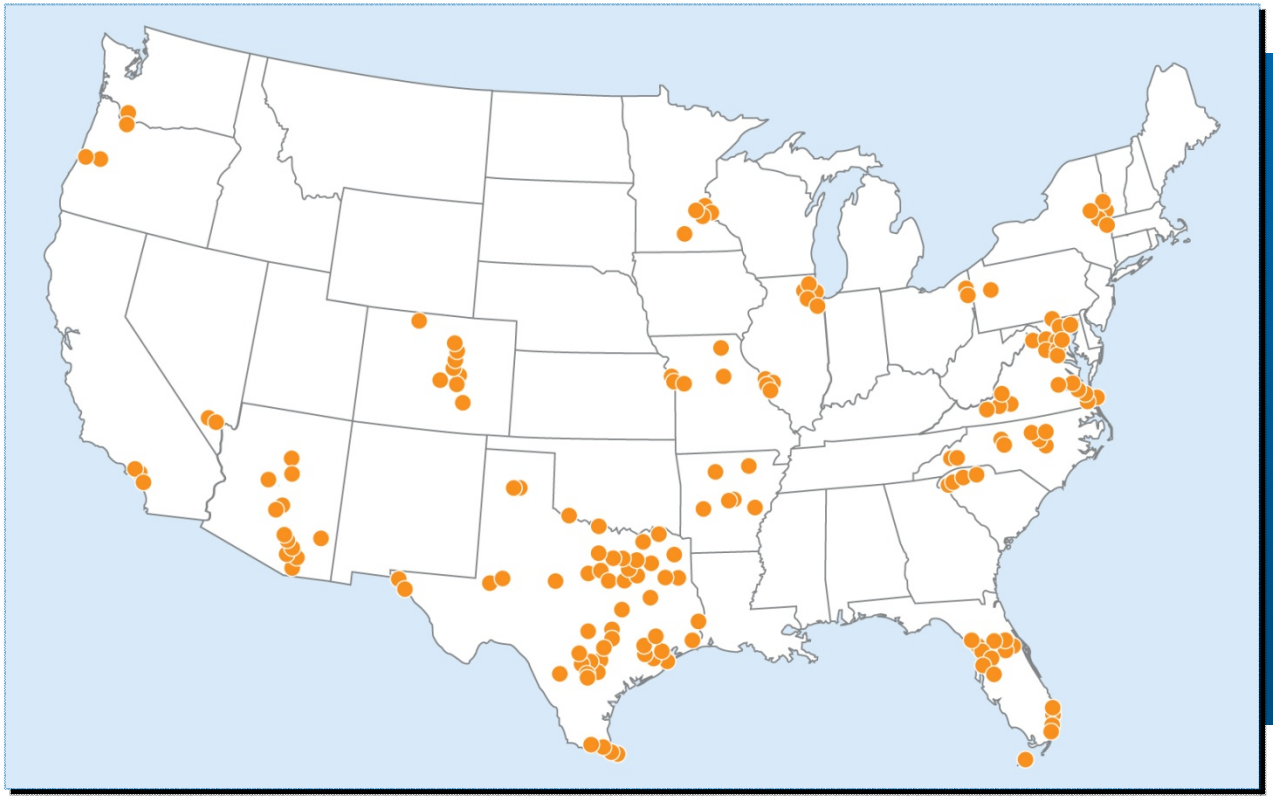
Lloyd Everson, MD

Vice Chairman and Founder
The US Oncology Network

May 24, 2012

UNITED WE HEAL

Who is The US Oncology Network?



- >750,000 Patients Treated Annually
- Approx 1,000 Affiliated Physicians
- >1,800 Affiliated Nurses
- >350 Sites of Care
- 98 Radiation Facilities
- >200 Active Clinical Trials

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Emergence of molecular diagnostic tests

Helping oncologists predict patient responses

Innovations in technology are key to helping to identify biomarkers

- Requested by the FDA in drug development
- Used in multiple disease settings

- However, the larger questions remain:
  - Are these tests clinically useful?
  - What does this mean in terms of costs?
  - When should these types of clinical tests be moved into clinical practice?
  - What are the acceptable methodologies to collect and validly demonstrate this evidence?

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Requirements & barriers – Biomarker discovery

- Access to technology and testing methods is critical
- Potential barriers include the need for clinical validation for impactful biomarkers to be used, tested and confirmed
- Clinical decision-making using biomarkers cannot be used from setting to setting without validation of the data

Recent biomarker success examples include:

- vemurafenib in *BRAF* V600E mutant melanoma,
- crizotinib in *ALK*-rearranged non–small cell lung carcinoma (NSCLC)
- EGFR inhibitors in patients with NSCLC whose tumors harbor *EGFR* mutations

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Applying an evidence-based medicine approach to diagnostics

The use of molecular diagnostic tests and in many cases, biomarkers, will enable physicians to better predict what will happen to patients following a particular treatment.

An evidence-based medicine approach should be applied to diagnostics before bringing them into clinical practice in order to improve patient outcomes and reduce the total cost of cancer care.

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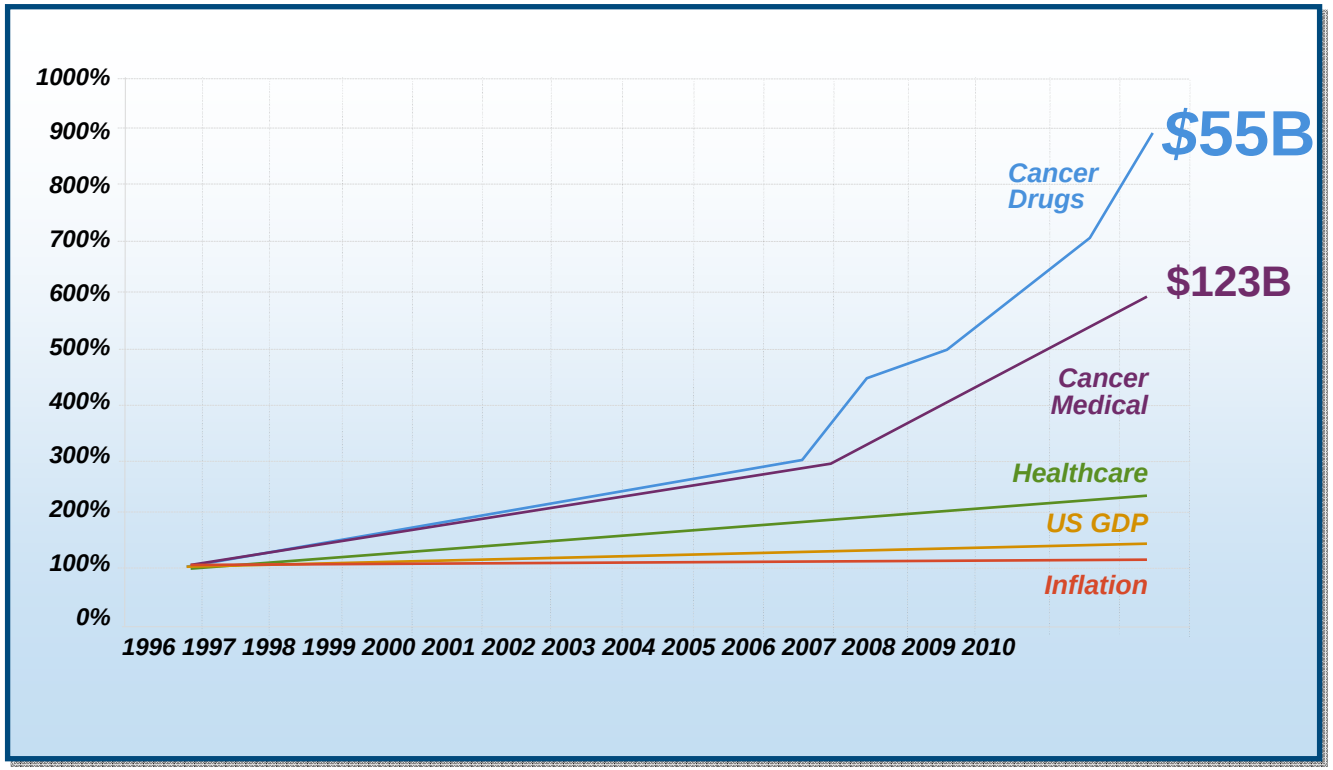
The costs of chemotherapy is rising



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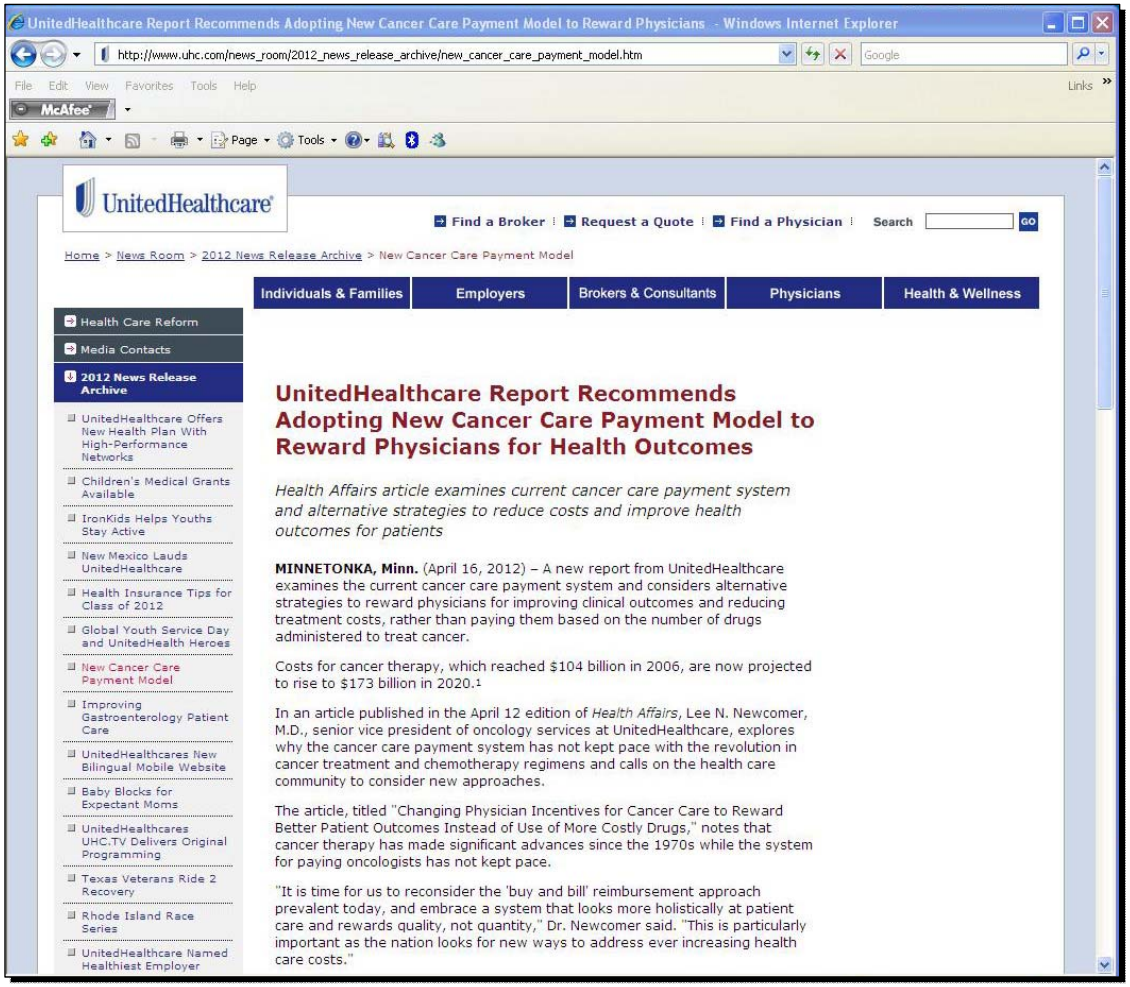
Changing physician incentives



UnitedHealthcare Report Recommends Adopting New Cancer Care Payment Model to Reward Physicians - Windows Internet Explorer

http://www.uhc.com/news_room/2012_news_release_archive/new_cancer_care_payment_model.htm

UnitedHealthcare

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  - New Mexico Lauds UnitedHealthcare
  - Health Insurance Tips for Class of 2012
  - Global Youth Service Day and UnitedHealth Heroes
  - New Cancer Care Payment Model
  - Improving Gastroenterology Patient Care
  - UnitedHealthcares New Bilingual Mobile Website
  - Baby Blocks for Expectant Moms
  - UnitedHealthcares UHC.TV Delivers Original Programming
  - Texas Veterans Ride 2 Recovery
  - Rhode Island Race Series
  - UnitedHealthcare Named Healthiest Employer

UnitedHealthcare Report Recommends Adopting New Cancer Care Payment Model to Reward Physicians for Health Outcomes

Health Affairs article examines current cancer care payment system and alternative strategies to reduce costs and improve health outcomes for patients

MINNETONKA, Minn. (April 16, 2012) – A new report from UnitedHealthcare examines the current cancer care payment system and considers alternative strategies to reward physicians for improving clinical outcomes and reducing treatment costs, rather than paying them based on the number of drugs administered to treat cancer.

Costs for cancer therapy, which reached $104 billion in 2006, are now projected to rise to $173 billion in 2020.[1]

In an article published in the April 12 edition of *Health Affairs*, Lee N. Newcomer, M.D., senior vice president of oncology services at UnitedHealthcare, explores why the cancer care payment system has not kept pace with the revolution in cancer treatment and chemotherapy regimens and calls on the health care community to consider new approaches.

The article, titled "Changing Physician Incentives for Cancer Care to Reward Better Patient Outcomes Instead of Use of More Costly Drugs," notes that cancer therapy has made significant advances since the 1970s while the system for paying oncologists has not kept pace.

"It is time for us to reconsider the 'buy and bill' reimbursement approach prevalent today, and embrace a system that looks more holistically at patient care and rewards quality, not quantity," Dr. Newcomer said. "This is particularly important as the nation looks for new ways to address ever increasing health care costs."

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Applying evidence-based medicine with standardization

Pathways

Evidence-based treatment guidelines that provide a precise, clinically proven approach to cancer care.

- Developed by physicians in The US Oncology Network
- Level I Pathways support physicians in making treatment decisions to provide a consistent platform for delivering, documenting, and reporting high-quality, evidence-based care
- Use of biomarkers goes hand and hand with following evidence-based medicine, as seen with Level I Pathways

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Levels and grades of evidence

Levels of Evidence

- Level I - randomized controlled trials: THE GOLD STANDARD
- Level II - Single-arm, uncontrolled trials
- Level III - Case Studies
- Level IV - Observation, Expert opinion

Grades of Evidence

- A - based on randomized, controlled trials (Level I evidence)
- B - based on several Level II, III, IV studies
- C - based on Level II, III, IV evidence, but is inconsistent
- D - no empirical evidence to support

The US Oncology Network Pathways are Level I Pathways

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Key guiding principles in Pathways development

- Review the evidence
- Flexibility of choice
- Find the balance point that maximizes patient benefit but maintains accountability for healthcare expenditures
- Ensure flexibility to participate in clinical trials
- Integrate with workflow
- Keep current

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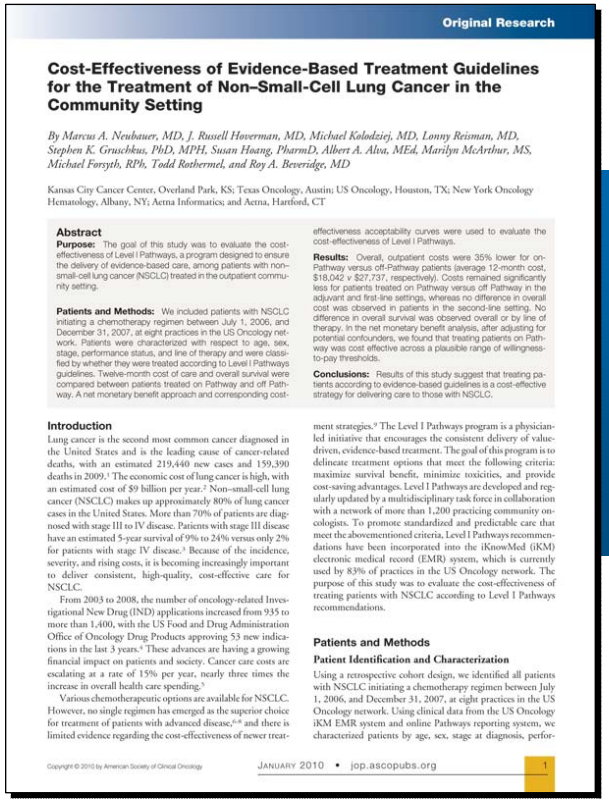
Proven value of Level I Pathways

- *Journal of Oncology Practice,* January 2010



Original Research

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 v $27,737, respectively). Costs remained 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.

Introduction

Lung cancer is the second most common cancer diagnosed in the United States and is the leading cause of cancer-related deaths, with an estimated 219,440 new cases and 159,390 deaths in 2009.[1] The economic cost of lung cancer is high, with an estimated cost of $9 billion per year.[2] Non–small-cell lung cancer (NSCLC) makes up approximately 80% of lung cancer cases in the United States. More than 70% of patients are diagnosed with stage III to IV disease. Patients with stage III disease have an estimated 5-year survival of 9% to 24% versus only 2% for patients with stage IV disease.[3] Because of the incidence, severity, and rising costs, it is becoming increasingly important to deliver consistent, high-quality, cost-effective care for NSCLC.

From 2003 to 2008, the number of oncology-related Investigational New Drug (IND) applications increased from 935 to more than 1,400, with the US Food and Drug Administration Office of Oncology Drug Products approving 53 new indications in the last 3 years.[4] These advances are having a growing financial impact on patients and society. Cancer care costs are escalating at a rate of 15% per year, nearly three times the increase in overall health care spending.[5]

Various chemotherapeutic options are available for NSCLC. However, no single regimen has emerged as the superior choice for treatment of patients with advanced disease,[6-8] and there is limited evidence regarding the cost-effectiveness of newer treatment strategies.[9] The Level I Pathways program is a physician-led initiative that encourages the consistent delivery of value-driven, evidence-based treatment. The goal of this program is to delineate treatment options that meet the following criteria: maximize survival benefit, minimize toxicities, and provide cost-saving advantages. Level I Pathways are developed and regularly updated by a multidisciplinary task force in collaboration with a network of more than 1,200 practicing community oncologists. To promote standardized and predictable care that meet the abovementioned criteria, Level I Pathways recommendations have been incorporated into the iKnowMed (iKM) electronic medical record (EMR) system, which is currently used by 83% of practices in the US Oncology network. The purpose of this study was to evaluate the cost-effectiveness of treating patients with NSCLC according to Level I Pathways recommendations.

Patients and Methods

Patient Identification and Characterization

Using a retrospective cohort design, we identified all patients with NSCLC initiating a chemotherapy regimen between July 1, 2006, and December 31, 2007, at eight practices in the US Oncology network. Using clinical data from the US Oncology iKM EMR system and online Pathways reporting system, we characterized patients by age, sex, stage at diagnosis, perfor-

The study found that, with no change in survival outcomes, overall outpatient costs were 35% lower for those patients treated according to Level I Pathways.

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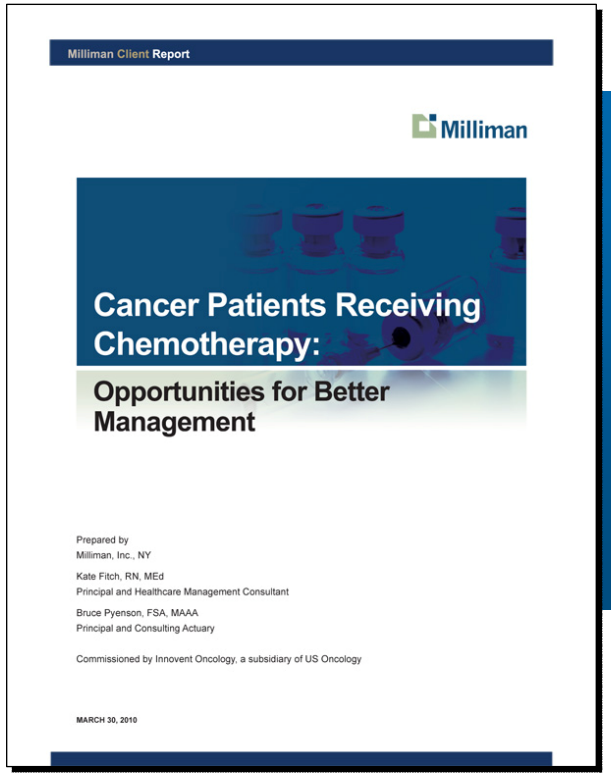
Proven value of Level I Pathways

- *Journal of Oncology Practice* and the *American Journal of Managed Care,* May 2011



Treating colon cancer patients "On-Pathway" resulted in significant cost savings in a payer claims database. Clinical outcomes in an "On-Pathway" colon cancer population were consistent with outcomes in previously published data. Total cost savings per patient of more than 30%: $53,000 per patient for the treatment of adjuvant colon cancer, and $60,000 per patient for the treatment of metastatic colon cancer.

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Current Level I Pathways

- Breast, CLL,
- Colon,
- Esophogeal/EGJ,
- Gastric,
- Head & Neck (3),
- Hodgkin's Lymphoma,
- Multiple Myeloma,
- Non-Hodgkin's Lymphoma (3),
- Non-Small Cell Lung,
- Ovarian, Pancreatic,
- Prostate, Rectal,
- Small Cell Lung,
- Supportive Care (4)

Note: many of these pathways – ie. Breast and GI – incorporate bio-marker parameters during the decision process …."

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Benefits of Level I Pathways

- Reduces variation in patient care
- Improves predictability of costs for health plans
- Promotes evidence-based medicine
- Offers up-to-date clinical tools to practices for documentation and reporting
- Prepares oncologists to succeed in pay-for-performance relationships
- Demonstrates fiscal responsibility to patients and payers

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Utilizing diagnostics to uncover clinical validations for treatment

Evidence-based approach

- Ensure the evidence points to a change in clinical decision-making or therapy

Importance of diagnostics

- Diagnostics can help to uncover biomarkers and other clinical validations for treatment

Control Costs

- Goal needs to remain to reduce overall costs and have an evidence-based medicine approach.

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Questions?

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