Evidence for Clinical Utility of Molecular Diagnostics in Oncology

Lloyd Everson, MD
Vice Chairman and Founder
The US Oncology Network

May 24, 2012
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
Emergence of molecular diagnostic tests

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?

Innovations in technology are key to helping to identify biomarkers
- Requested by the FDA in drug development
- Used in multiple disease settings
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
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.
The costs of chemotherapy are rising.
Changing physician incentives

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 2008, are now projected to rise to $173 billion in 2020.4

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.”
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
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
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
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.

### Journal of Oncology Practice, January 2010

### Cost-Effectiveness of Evidence-Based Treatment Guidelines for the Treatment of Non-Small-Cell Lung Cancer in the Community Setting

**Abstract**

A retrospective study was conducted to evaluate the cost-effectiveness of Level I Pathways, which were designed to improve the efficiency of outpatient care by reducing unnecessary tests and treatments for patients with non-small-cell lung cancer (NSCLC) treated in the community setting.

**Patients and Methods**

All included patients with NSCLC meeting the criteria for participation were divided into two groups: those treated according to Level I Pathways and those treated according to usual care. A cost-effectiveness analysis was performed using a Markov model to simulate the outcomes of patients over a 1-year period.

**Introduction**

Lung cancer is the second most common cancer diagnosed in the United States and is the leading cause of cancer-related death, with an estimated 230,000 new cases and 159,000 deaths annually. Despite advancements in treatment, the overall 5-year survival rate remains low, approximately 20% of all patients diagnosed with NSCLC have an estimated 5-year survival rate.

**Results**

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.

**Conclusions**

The Proven value of Level I Pathways was supported by McKesson Specialty Health. © 2012 McKesson Specialty Health. All rights reserved.
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.
Current Level I Pathways

- Breast, CLL,
- Colon,
- Esophageal/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 ….”
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
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.
Questions?