

Cost Implications for Novel Therapies and Strategies in the Treatment of NSCLC: Perspectives and Clinical Updates from ASCO 2011

PROGRAM

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At the end of this activity, participants will be able to:

- Explain the impact of clinical and health economic data presented at the 2011 ASCO meeting on the care of patients with non–small-cell lung cancer (NSCLC)
- Describe how value-based cancer care is evolving in the changing US healthcare system
- Examine how all stakeholders can implement value-based care in the treatment of NSCLC

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Caroline Helwick, medical writer, has nothing to disclose. She intends to discuss investigational medications for NSCLC.

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Cost Implications for Novel Therapies and Strategies in the Treatment of NSCLC: Perspectives and Clinical Updates from ASCO 2011

By Caroline Helwick, Independent Medical Writer

Presentations from the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO) provide an ideal forum for payers grappling with reimbursement issues and benefit design for patients with non–small-cell lung cancer (NSCLC) and for pharmacists who must understand emerging treatments.

This article summarizes key clinical studies and expert discussions that describe current trends in the management of this increasingly complex and mutation-driven tumor and their cost implications. The shifting landscape in NSCLC management highlights the

need to align providers' and payers' strategies to enhance high-quality, value-based patient care.

Maintenance Therapy Extends Progression-Free Survival by a Slim Margin

Two randomized phase 3 clinical trials showed a progression-free survival (PFS) benefit for maintenance therapy with pemetrexed and gefitinib in patients with advanced NSCLC. The magnitude of the benefit, however, was modest—a gain of just 1.3 to 2.2 months in remission time, with no gain in overall survival (OS).

These studies fail to answer an

important question: is maintenance therapy superior to second-line treatment initiated once the disease progresses?

The maintenance strategy is based on 2 observations: limited benefit from 4 courses of chemotherapy and improved outcomes with second-line chemotherapy after disease progression. Maintenance therapy can involve continued treatment with the same drug, as with pemetrexed in the PARAMOUNT trial,¹ or “switch” maintenance, as in the INFORM study, which initiated gefitinib after platinum-based induction.²

The PARAMOUNT trial enrolled 939

patients with advanced nonsquamous NSCLC after they received 4 standard courses of treatment with pemetrexed and cisplatin.¹ Of these, 539 patients achieved stable disease and were randomly assigned to maintenance therapy with pemetrexed or to placebo (and best supportive care). Maintenance pemetrexed resulted in a 38% reduction in the risk of disease progression.¹

Median PFS in this group was 4.1 months versus 2.8 months for patients receiving placebo ($P = .006$), and disease control (ie, response plus stable disease) was attained in 71.8% and 59.6%, respectively, but maintenance

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therapy did not confer a quality-of-life benefit.¹

New findings from the PARAMOUNT trial “suggest that patients can still continue to benefit from the use of the same drug rather than ‘use up’ an alternative early in the course of treatment,” said lead investigator Luis Paz-Ares, MD, PhD, Seville University Hospital, Spain. “We believe the magnitude of benefit is clinically significant and may support the use of pemetrexed as maintenance therapy. This could change the standard of care for these patients, at least in terms of maintenance.”

Similarly, in the phase 3 clinical study INFORM, maintenance therapy with gefitinib (after 4 cycles of platinum-based chemotherapy) was associated with significantly superior PFS compared with placebo among 296 Chinese patients, but no difference in OS was observed.²

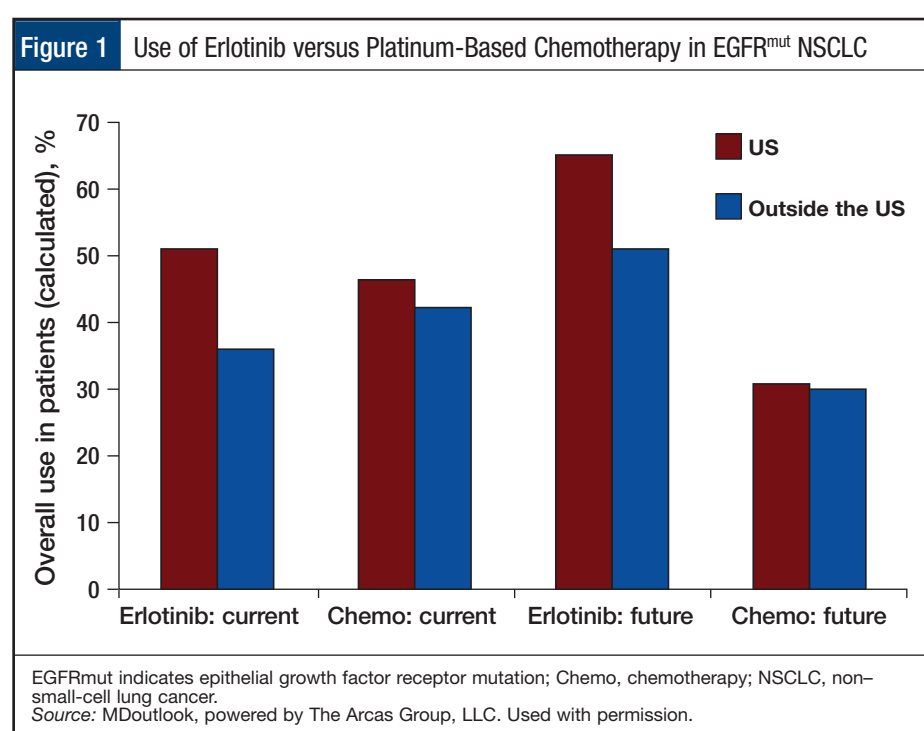
At a median follow-up of 16.8 months, median PFS was 4.8 months with gefitinib maintenance versus 2.6 months with placebo ($P < .001$), representing a 58% reduction in the risk of disease progression. Approximately one third of patients carried mutations of the epidermal growth factor receptor (EGFR), and they derived the best outcomes from gefitinib.²

Despite both studies meeting their primary end points, study discussant Martin J. Edelman, MD, of the University of Maryland Greenbaum Cancer Center, Baltimore, commented that “maintenance therapy in NSCLC is an ever-contentious issue,” suggesting that “these studies raise more questions than answers.”

He pointed out that PFS “does not necessarily predict overall survival,” and that when differences in PFS are small, quality-of-life (QOL) analyses can help define benefit. “But the quality-of-life data from maintenance studies is actually somewhat disappointing....No differences have been demonstrated, which indicates that maintenance is not necessarily cost-free in terms of toxicity,” said Dr Edelman.

The PARAMOUNT study demonstrated no improvement in QOL for maintenance therapy with pemetrexed.¹ Along with increased toxicity with continued treatment, the cost of treatment also becomes a factor. “We really need a cost-effective analysis in this era of follow-up strategies, of frequent visits and of scanning, with [a study of] early institution of second-line therapy, versus the maintenance approach,” he said.

What has been learned from PARAMOUNT, said Dr Edelman, is that “the drugs work in patients who



derive benefit from first-line chemotherapy. To date, there is no evidence that early introduction of therapy will improve survival compared with introducing second-line therapy at disease progression.”

First-Line Erlotinib Superior to Chemotherapy

Erlotinib, given as first-line treatment to patients with advanced NSCLC and EGFR mutations, substantially prolonged remissions in the phase 3 clinical trial EURTAC (European Randomized Trial of Tarceva vs Chemotherapy).³

“EGFR tyrosine kinase-activating mutations are present in 10% to 26% of NSCLC tumors and are associated with increased response to erlotinib and gefitinib. But little is known about the efficacy and safety profile of erlotinib compared with chemotherapy in EGFR-mutant Caucasian patients,” said Rafeal Rosell, MD, of the Catalan Institute of Oncology, Barcelona, Spain, who presented the findings.³

The interim updated analysis of 173 patients in the EURTAC trial showed significant efficacy for single-agent erlotinib over a standard platinum-based doublet in the up-front setting. Erlotinib reduced the risk for disease progression or death by 63%, nearly doubling the median PFS, which was 9.7 months versus 5.2 months with chemotherapy ($P < .001$). Objective response rates were 58% with erlotinib and 15% with chemotherapy.³

The death rate was also reduced by 20%, but this finding was not significant ($P = .417$),³ presumably because of high crossover from chemotherapy to an EGFR inhibitor, and because the OS data are not mature. Erlotinib was bet-

ter tolerated than chemotherapy, Dr Rosell reported.

New Class of Agents May Change Treatment for 5% of Patients with NSCLC

The novel agent crizotinib, which targets the *EML4-ALK* mutation that is found in about 5% of patients with NSCLC, is positioned to become an integral part of treatment for this NSCLC subgroup. The oral agent crizotinib is first in a class known as anaplastic lymphoma kinase (ALK) inhibitors; it targets tumors harboring rearrangements of the *ALK* gene, which is involved in growth and survival of lung tumors.

Ross Camidge, MD, PhD, of the University of Colorado, Denver, remarked in an interview, “Knowing that ALK-positive patients respond to crizotinib—you can take this to the bank.” He said that the data show a “consistency of message” and form the basis for confirmatory registration studies that will compare crizotinib with chemotherapy. These will “nail down where the drug fits in the treatment paradigm for what is essentially a new disease—ALK-positive lung cancer,” he said.

Crizotinib nearly doubled OS among ALK-positive patients with NSCLC in an update of a phase 1 study reported at ASCO 2011 by Alice T. Shaw, MD, PhD, of Massachusetts General Hospital, Boston.⁴ The study involved 82 heavily pretreated patients with the ALK fusion gene who received crizotinib after tumor progression.

The objective response rate was 57%, the disease control rate was 87%, and more than 90% of the tumors regressed in the ALK-positive group

who received crizotinib. The survival rate was 74% at 1 year and 54% at 2 years. Median OS has not yet been reached, because more than half of the 82 subjects are still alive. Side effects with crizotinib were generally mild and transient, although unusual visual effects were common.⁴

By comparison, the OS rate among ALK-positive control patients receiving standard chemotherapy was 44% at 1 year and 12% at 2 years; median OS was 6 months. The median OS was similar for ALK-positive patients who received chemotherapy and for patients lacking the ALK rearrangement, Dr Shaw reported.⁴

In a separate presentation, Dr Camidge reported on a combined analysis of these 82 patients plus the first 19 ALK-positive patients who received crizotinib.⁵ After a median follow-up of 11 months, median PFS was 10 months and OS has not been reached; 79% of the patients remain alive, yielding a survival probability of 90% at 6 months and 81% at 1 year, Dr Camidge said.⁵

Accelerated approval for crizotinib in ALK-positive NSCLC has been sought from the US Food and Drug Administration in conjunction with the ongoing confirmatory phase 3 program.

Crizotinib nearly doubled OS among ALK-positive patients with NSCLC in a phase 1 study reported at ASCO 2011.

Mutation Testing Poised for Routine Use

Based on the results of mutational testing through the new Lung Cancer Mutation Consortium, Ramaswamy Govindan, MD, Washington University, St. Louis, said EGFR testing is ready to be clinically applied in lung cancer and that *EML4-ALK* (the target of crizotinib) fusion testing is not too far behind.

Dr Govindan was the invited discussant of a presentation by Mark G. Kris, MD, of Memorial Sloan-Kettering Cancer Center, New York. The Consortium evaluated 1234 patients with stage IV adenocarcinoma for 10 known mutations using standard multiplexed assays and fluorescence in situ hybridization.⁶

Driver mutations were identified in 54% of adenocarcinomas—most often KRAS (22%), EGFR (17%), and *EML4-ALK* rearrangement (7%). Less com-

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mon were alterations in *BRAF*, *PIK3CA*, *HER2*, Met amplification, *MEK1*, *NRAS*, and *AKT1*.⁶

“While an individual mutation may be rare, having a mutation of some kind that is actionable is very common in adenocarcinoma,” Dr Kris said. Mutation identification allowed *EGFR*-positive patients to be selected for erlotinib and patients with other mutations to be referred to clinical trials of other targeted agents.

The collaborative effort represents the revolutionary changes taking place in the management of lung cancer and the potential for personalized treatment, Dr Kris added.

Oncologists Plan to Use More Targeted Agents

Oncologists who treat NSCLC plan to rely more on erlotinib therapy and less on platinum-based chemotherapy in advanced disease, according to results of a survey conducted immediately after ASCO 2011—the MDOutlook ASCO 2011 Quick Poll—facilitated by the Arcas Group.⁷

The survey showed that approximately 50% of patients with mutations of *EGFR* now receive erlotinib, and about 45% receive chemotherapy. However, survey respondents anticipated prescribing erlotinib for 65% of their patients in the next year and reducing the use of platinum-based chemotherapy by 15% (Figure 1).⁷

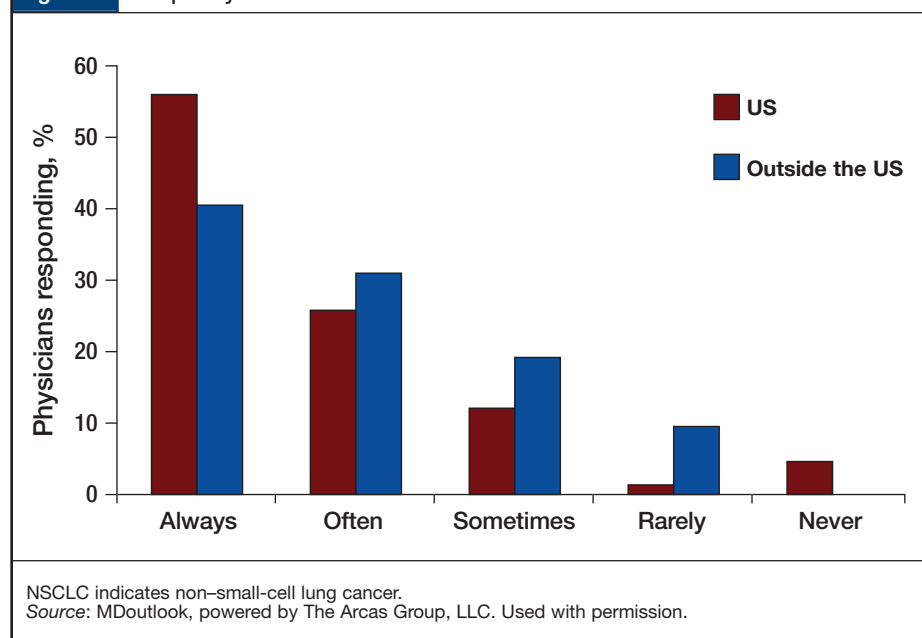
The oncologists also indicated high interest in crizotinib therapy for patients with the *EML4-ALK* gene rearrangement. More than 55% of the respondents predicted that they would “always” prescribe crizotinib to this mutation subgroup and 25% said they would “often” prescribe the new drug (Figure 2).⁷ The respondents also expected to start integrating c-Met inhibitors, especially in the setting of NSCLC resistant to *EGFR* inhibitors.

Novel Agents Show Encouraging Activity New *EGFR* Inhibitor Comparable with Gefitinib

Icotinib, an *EGFR* inhibitor manufactured in China, was found to be as active and effective as gefitinib in patients with advanced NSCLC and *EGFR* mutations who had received previous treatment.⁸ In the noninferiority randomized ICOGEN trial of 395 patients, icotinib was comparable to gefitinib in PFS, OS, and QOL, but it was better tolerated than gefitinib.⁸

The median PFS was 137 days for icotinib versus 102 days for gefitinib, and median OS was 419 days and 467

Figure 2 Frequency of Crizotinib Use in the Treatment of *ALK*-Positive NSCLC



days, respectively. As expected, patients with *EGFR* mutations had preferential benefit over those with wild-type *EGFR*, with responses observed in more than 50% of this group compared with 5% of patients without the mutation.⁸

Also showing promise was the Met inhibitor MetMab (an antibody to c-Met) combined with erlotinib in a study of 137 previously treated patients.⁹ Met gene expression is associated with a worse NSCLC prognosis.

Among patients with the Met mutation, the combination (compared with erlotinib alone) extended median PFS to 2.9 months compared with 1.5 months with erlotinib alone ($P = .04$), and extended median OS to 12.6 months versus 3.8 months ($P = .002$). A phase 3 trial of this combination will begin later in 2011.⁹

Second-Generation Hsp90 Inhibitors in the Pipeline

Geoffrey Shapiro, MD, PhD, of Dana Farber Cancer Institute, Boston, reported encouraging results for the heat shock protein 90 (Hsp90) inhibitor ganetespib from an open-label phase 2 trial of 96 patients who received previous treatment for advanced NSCLC. The median PFS was 24.1% by week 16.¹⁰

Ganetespib provides potent Hsp90 inhibition and better safety than first-generation compounds. The dose-limiting hepatic and ocular toxicity, which has complicated the development of other Hsp90 inhibitors, is absent. “Ganetespib showed promising clinical activity as a single agent, especially in tumors harboring the *ALK* rearrangement,” Dr Shapiro noted.

Surash S. Ramalingam, MD, of Emory University, Atlanta, commented on the Hsp90 inhibitor pipeline. Despite a strong biologic rationale for these drugs, he said, there have been many hurdles in drug development, primarily involving formulation issues, dose-limiting hepatic toxicity, and less than robust efficacy. The second-generation compounds, including ganetespib, are structurally different and more potent than the first-generation agents and have a favorable safety profile that facilitates their use in combination.

“Therefore, there is a resurgence of interest in these compounds,” Dr Ramalingam said. More than a dozen are in various stages of development, of which the most active in solid tumors are ganetespib, retaspimycin, and AUY-922.

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Ganetespib and retaspimycin have produced “robust anticancer effects,” with tumor regression or disease stabilization seen in almost all *ALK*-positive patients, Dr Ramalingam noted. “Hsp90 inhibitors have entered the therapeutic algorithm for *ALK*-positive disease,” he concluded. “In the historically disappointing development of Hsp90 inhibitors, it is my belief that we have reached an important and exciting turning point.”

Chemoimmunotherapy with Toll-Like Receptors

The toll-like receptor (TLR)-2 agonist mycobacterium w (Cadi-05) looked promising in a study presented by Chandra Belani, MD, of Penn State Hershey Cancer Institute, Hershey, PA. Mycobacterium w works best when combined with paclitaxel and cisplatin as chemoimmunotherapy; this regimen was evaluated in 121 patients.¹¹

Chemoimmunotherapy led to higher response rates and disease control rates than chemotherapy alone. The median PFS was 199 days with the combination versus 97 days with chemotherapy alone, representing a 31% risk reduction ($P = .052$). Although OS was similar at 208 days versus 196 days, respectively, a survival benefit was observed among the subset of patients with squamous-cell carcinoma: median OS was 229 days with chemoimmunotherapy versus 172 days with chemotherapy, representing a 46% risk reduction ($P = .031$).¹¹

In addition, in the analysis of patients who completed all 4 cycles, median PFS was 253 days with chemoimmunotherapy versus 157 days with chemotherapy, a 57% risk reduction ($P = .001$), and OS was 299 days versus 233 days, respectively, for a 36% risk reduction ($P = .043$). For patients with squamous-cell carcinoma who completed 4 cycles, median OS reached 364 days with chemoimmunotherapy versus 254 days with chemotherapy alone, representing a 60% reduction in risk of dying ($P = .041$), Dr Belani reported.¹¹

“The addition of Cadi-05 to paclitaxel and cisplatin improved OS and PFS in the prespecified subset of patients completing 4 cycles, and its efficacy was better in patients with squamous-cell carcinoma than with adenocarcinoma,” Dr Belani concluded.

Raffit Hassan, MD, of the National Cancer Institute, said that several immunotherapy approaches for NSCLC were moving forward, including vaccines and TLR agonists, such as mycobacterium w. “Hurdles remain, and no agent has been approved,” Dr Hassan said, “but recent randomized phase 2 trials show hints of activity, leading to phase 3 trials.”

The vaccines in phase 3 trials are belagenpumatucel-L (Lucanix), L-BLP25 (Stimuvax), and the MAGE-A3 vaccine, which showed OS benefits (or trends) in phase 2 trials.

TLR agonists, by contrast, have been disappointing in phase 3 trials, although mycobacterium w is showing

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promise, he said.

“The results of the ongoing phase 3 trials will be important to validate immunotherapy as a valid option in lung cancer,” Dr Hassan concluded.

Future of Some Once-Promising Agents Uncertain

Several investigational agents, however, turned in disappointing results. One of these is motesanib, which inhibits a number of tumors. When combined with chemotherapy in the randomized, placebo-controlled phase 3 MONET (Motesanib NSCLC Efficacy and Tolerability) 1 clinical study of 1090 patients with advanced nonsquamous NSCLC, motesanib—which was once considered a promising drug for NSCLC—did not improve OS over chemotherapy alone.¹²

The vascular-disrupting agent vadmecan has also failed to improve efficacy versus chemotherapy alone in a global phase 3 clinical trial of front-line treatment in 1299 patients.¹³

Aggressive Care at End of Life Still Common, Expensive

The practice of overly aggressive care at the end of life has been recognized as a concern. A study presented at last year’s ASCO showed that OS in patients with NSCLC was actually compromised, not improved, by chemotherapy administered in the final months.¹⁴ However, the message that aggressive end-of-life care is unwarranted is still falling on deaf ears, ASCO studies suggested.

One in 5 Patients Receives Aggressive End-of-Life Care

This appears true even at institutions of the National Comprehensive Cancer Network (NCCN). In an analysis of patients with metastatic NSCLC treated at NCCN institutions, almost 20% of patients received aggressive end-of-life chemotherapy or treatment in the intensive care unit (ICU).¹⁵

Investigators identified 1092 patients with metastatic NSCLC who received treatment at 8 NCCN institutions between 2007 and 2010.

Aggressive end-of-life care was defined as (1) the initiation of a new chemotherapy regimen within 30 days of death, (2) the receipt of chemotherapy within 14 days of death, or (3) any ICU admission within the last 30 days of life. The analysis revealed that¹⁵:

- 18.9% of patients received aggressive end-of-life chemotherapy or care in an ICU
- 10.7% started a new chemotherapy regimen in the last 30 days of life

- 11.8% received chemotherapy during the last 14 days of life
- 3.2% were admitted to the ICU in the last 30 days of life
- 43% of patients with poor performance status received aggressive end-of-life chemotherapy
- 34% of patients receiving aggressive chemotherapy were starting their first and only treatment line
- 37.5% of patients receiving an EGFR inhibitor as their final treatment were still using the drug 14 days before death
- 48% of patients receiving chemotherapy in the last 14 days of life were taking erlotinib.

“This is a higher rate than I was hoping for,” said lead author Kathleen Bickel, MD, from the University of Michigan Comprehensive Cancer Center, Ann Arbor. “And this is recent data. It’s not patients treated 10 years ago.”

OS in patients with NSCLC was actually compromised, not improved, by chemotherapy administered in the final months.

Early Palliative Care Reduces Intravenous, but Not Oral, Drug Use

Early initiation of palliative care resulted in a 2.7-month (30%) survival benefit and QOL improvements in the randomized study by Temel and colleagues that was presented last year at ASCO 2010.¹⁴ A secondary analysis examined the reasons for this finding and was presented at ASCO 2011.¹⁶

“Palliative care services are traditionally delivered late in the course of disease, when their benefits may be limited. Ideally, they should be integrated throughout the course of illness and in tandem with life-prolonging treatment,” said lead investigator Joseph Greer, PhD, Massachusetts General Hospital Cancer Center, Boston.

Within 8 weeks of a metastatic NSCLC diagnosis, 151 patients were assigned to early palliative care integrated with standard oncology care (regular meetings with a palliative care specialist) or to standard care (ad hoc palliative care upon request).¹⁶ Although the early palliative care intervention did not result in less use of oral chemotherapy, other benefits were obvious, he reported.

Patients in the early palliative care group were significantly less likely to

receive intravenous (IV) chemotherapy, and, although about 70% of patients in each arm entered hospice, the patients who received early palliative care enrolled earlier and spent almost 3 times as many days under hospice care ($P = .004$).¹⁶

IV chemotherapy was administered within 60 days of death to 25% of the palliative care group versus 45% of patients receiving standard care ($P = .01$); within 30 days of death in 10% versus 25%, respectively ($P = .07$); and within 14 days of death in 2% and 10% ($P = .06$). Less use of IV chemotherapy in the early palliative care arm had no detrimental effect on survival.¹⁶

The use of oral agents, however, did not differ between the 2 groups. Oral agents were prescribed within 60 days of death to 28% of patients who received early palliative care and 22% of the standard care group; within 30 days in approximately 20% per arm; and within 14 days in 10% per arm.¹⁶

The more frequent use of oral drugs might be the result of a “clinical compromise” or may reflect that they can be started while patients are enrolling in hospice, Dr Greer suggested, but the reasons for their frequent use in the palliative care setting must be determined.

The bottom line is that early integration of palliative care means that the timing of final chemotherapy will probably be more appropriate and that patients will access hospice services sooner, he said, “which are key measures of quality end-of-life care.”

End-of-Life Care More Expensive than Biologics

An analysis of the total cost of managing patients with advanced NSCLC yielded a few surprises, showing that the most costly segment was end-of-life care, and targeted agents were responsible for only a modest portion of the active treatment costs.¹⁷

Investigators from the University of Texas Health Science Center at San Antonio used the PharMetrics claims database of 5847 patients to characterize the direct cost of treating patients with advanced NSCLC between 2000 and 2009.

They divided the study period into a “preperiod” (2000-2002), “transition period” (2003-2005), and “current period” (2006-2009) to account for the move from standard chemotherapy to the introduction of the newer agents pemetrexed, tyrosine kinase inhibitors (TKIs), and biologics.¹⁷

The mean costs of various segments of care over the study period were¹⁷:

- Total cost: \$162,134 per patient (for

≥5 months of therapy)

- Cost per patient per month (PPPM): \$10,284
- Cost related to diagnosis, PPPM: \$9162
- Active mean treatment cost, PPPM: \$10,141
- End-of-life cost, PPPM: \$18,033

PPPM costs were similar in all 3 periods: \$8662 in the preperiod, \$10,578 the transition period, and \$10,141 in the current period. Newer agents accounted for 16% of active treatment, including pemetrexed (5%), TKIs (6%), and biologics (5%). In total, newer agents accounted for just 4% of the overall cost.¹⁷

Cost of Treatment Highly Variable

Researchers from McKesson Specialty Care Solutions in South San Francisco, CA, evaluated adherence to national treatment guidelines for NSCLC and chemotherapy costs in the adjuvant and first-line metastatic settings among community oncology practices.¹⁸

The most costly segment was end-of-life care, and targeted agents were responsible for only a modest portion of the active treatment costs.

A total of 811 adjuvant and 2761 metastatic regimens were administered by 333 practices in 41 states. National guidelines recommended 26 adjuvant and 67 metastatic regimens. The rate of guideline adherence was significantly higher with the metastatic regimen than with the adjuvant regimen. In both treatment settings, carboplatin-containing regimens were given more often than cisplatin-containing regimens.¹⁸

Based on Medicare reimbursement rates for 3 months of treatment, the costs varied for the top 5 regimens in the adjuvant and metastatic settings. A standard course of therapy in the adjuvant group ranged from \$2803 (for carboplatin and etoposide every 3 weeks) to \$7362 (for carboplatin and paclitaxel every 4 weeks).¹⁸

Metastatic regimens ranged from \$3297 (for carboplatin and paclitaxel every 3 weeks) to \$29,322 (for carboplatin, paclitaxel, and bevacizumab every 3 weeks).¹⁸

“A large number of unique regi-

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mens were administered in the metastatic group, and costs for the top 5 regimens varied considerably," the investigators observed. ■

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COMMENTARY

Addressing Cost and Quality Issues in Novel Treatment Strategies for Non-Small-Cell Lung Cancer: Where Is Our Focused Factory?

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Evidence-based medicine and a focused clinical orientation are key elements to delivering the right care at the right time to the right person. The recent findings reported at the 2011 American Society of Clinical Oncology annual meeting regarding the use of novel therapies and strategies in the treatment of non-small-cell lung cancer make achieving these goals harder than ever.

Each year, treatment approaches become more complex and variable, and translating protocols that demonstrate positive outcomes into daily community practice seems more difficult than ever.

Beyond the waste and nonbeneficial care for those not well-matched for treatment, we face the additional problem of sizing and comparing treatment efficiencies within a disease state. How would experts in process control and quality improvement from other industries handle this issue?

Oncology care in the United States



We are in dire need of decision support and data storage tools that address oncologists' needs in real time. We also need reporting that helps us all learn what is the most effective and efficient care at an aggregate level.

today reflects 2 dramatic contrasts. Although admirable in its application of molecular biology (the pinnacle of science), oncology care is still very nonsystematic and inconsistent in the way new discoveries and practices are being incorporated into the patient care realm.

If data are the drivers of quality improvement, how do we collect and measure that quality information in real-life cancer care? A universal oncol-

ogy care data repository does not exist today. Without the regular application of agreed upon gold standard National Comprehensive Cancer Network-derived pathways, the typical community oncology practice, even if verbally espousing commitment to best practices, is practicing "mass inspection" for quality rather than building quality into the product in the first place.

Academic oncology practices should also not be given a pass on this

issue, because quality is more than a glossy advertising campaign.

We are in dire need of decision support and data storage tools that address oncologists' needs in real time. We also need reporting that helps us all learn what is the most effective and efficient care at an aggregate level.

Without this, we will never know who might be better served with maintenance therapy, when to use erlotinib, and how we can apply companion diagnostic testing (to detect mutations in, for example, epithelial growth factor receptor, EML4-ALK, heat shock protein 90, and toll-like receptor 2) to the right patients so that they may benefit from more targeted agents.

Finally, the application of aggressive end-of-life care will surely decline when all treating oncologists have more data-linked confidence in the "best care options." When this happens, we will have our "focused factories," and the gods of process control will be smiling down upon us. ■