

Measures That Improve Quality Must Be Nimble if Imperfect, UnitedHealthcare's Newcomer Explains

Lee N. Newcomer, MD, MHA, senior vice president for Oncology, Genetics and Women's Health at UnitedHealthcare, spoke next on "Defining and Measuring Quality Outcomes in Oncology."

Not long ago, a cancer care provider asked to measure quality would eschew attempts to take on the task, and declare that they would know quality when they saw it. That time has passed, said Lee N. Newcomer, MD, MHA, but what measurements will fill the void?

Newcomer, the senior vice president for Oncology, Genetics and Women's Health at UnitedHealthcare, said that while oncology has accepted the need for measures of quality, deciding what they will be remains a work in progress. He outlined how to get beyond "process" measurements and take on the real cost drivers.

First, in Newcomer's view, measurements used for accreditation or reimbursement are so heavily vetted that they become worthless. Second, measurements that can bring quality improvement quickly are necessarily imperfect, but perfection is not point. Changing behavior is, and he described how "organic" measurements are more valuable, as they can be changed mid-course if payers realize they are not capturing the right information.

UnitedHealthcare has created a database of information collected from its oncology providers. Newcomer said the insurer asked about the cost of a

single course of specialty drugs—and providers were asked to fill out a form requesting information on histology, disease stage, gene tests, relapses, and current status of patients with breast, colon, lung, and prostate cancers. Most providers—70%—provided the data willingly. And now UnitedHealthcare has data on 65,000 patients, which it can use to spot trends and help providers make adjustments.

"You're trying to move quickly here; you're trying to find out how you can measure changes that you make in your processes, and being inclusive gets you numbers faster," Newcomer said.

He offered this example: A hospital was told its readmission rates were too high after patients were treated for toxicity to chemotherapy. Leaving it up to the patient to call the clinic for follow-up appointments meant that many were not seen for 30 to 40 days. People got sick and had to be readmitted. After being told of the problem, the hospital worked to schedule follow-up visits 48 hours before discharge. Readmission rates are down.

"You need very instantaneous data to help people improve," Newcomer said. That data should also be transparent; the public should have the ability

to judge providers the same way payers do. Hospitals that don't release data aren't fooling anyone, Newcomer said, because payers can get it through their own means. As data collection becomes more commonplace and robust, there will be more data and more real-time assessments of quality, he predicts.

"The notion has been that patients aren't smart enough to use that data correctly; they won't risk-adjust, and I think that's bologna," Newcomer said.

Keys, he said, are for costs of care to be part of the quality equation, and for statisticians to be involved. An analysis

of a clinic's survival rates that doesn't break down data by tumor type is less valuable than one that does, for example.

Newcomer also said that as payers collect and analyze more data, it may change just who or what is held accountable for quality. "If we can now look at outcomes, and if I can, as a payer, gather data on hundreds, if not thousands, of patients with a specific clinical diagnosis treated with several different regimens, we should be comparing the chemotherapy regimens, not the doctors," he said. **EBO**



Lee N. Newcomer, MD, MHA, discussed the value of acting on near-term data, even if they are not perfect.

With Data, Access and Sharing Are Keys to Improving Quality

Following his talk, Lee N. Newcomer, MD, MHA, joined the response panel, "Challenges and Opportunities for Quality Measures in Oncology," which included Phyllis Torda, vice president, Quality Solutions Group, the National Committee for Quality Assurance; and Dennis Scanlon, PhD, professor of health policy and administration at Penn State University. Ira M. Klein, MD, MBA, FACP, chief of staff, Office of the Chief Medical Officer, Aetna, Inc, led the discussion.

Unlike the famous song, time is not on the side of payers who seek data to improve healthcare.

Time is what Lee N. Newcomer, MD, MHA, senior vice president for Oncology, Genetics and Women's Health at Uni-

tedHealthcare, described as his greatest hurdle in using numbers to drive improvements in cancer care delivery. Data collection takes too long, and then more time is needed to make sense of it before payers can use the findings.

Ira M. Klein, MD, MBA, FACP, who led the panel discussion after Newcomer's talk, asked each person to describe the biggest challenge to using data success-

fully. Like Newcomer, Klein represents a large payer, and he said that Newcomer had "understated" the challenges of deploying data in the cause of quality improvement. Klein wanted to know how Phyllis Torda, of the National Committee for Quality Assurance (NCQA), viewed Newcomer's assessment that data

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could be less than perfect but still useful in promoting quality care.

Torda, whose role for NCQA includes promoting use of electronic health records (EHRs), seemed to disagree with Newcomer when she listed “standardized data” as her greatest challenge. But then she drew a distinction between the database Newcomer had described for use within a health plan and data gathered for external uses.

“I totally agree with the value of the quality improvement process that (was) described.... Every practice should have that process in place,” Torda said. “Definitely, the bar gets higher when you get to data for accountability, data that’s going to be publicly reported. It is definitely

a balancing act between precision and getting something out there, and the small numbers issue plays into that.

“You really have to figure out where you need that precision and where it’s really not going to make that big of a difference, but it does take time to do that,” she said.

Newcomer said the key to making providers comfortable with sharing numbers and discussing performance is to separate the quality improvement process from the one used for accreditation or payment. When UnitedHealthcare initially shared information with cancer care providers on how they rated against measures from the National Comprehensive Cancer Network, reac-

tion was harsh. But that changed when UnitedHealthcare presented the caveat that “There is no blame here—zero. All we are doing, if we find a gap; it’s an opportunity.”

Then there’s the problem of bad data, or data that are incomplete, such as the example Scanlon described—getting a set of claims data without complete clinical information. That’s why Scanlon finds it so essential to collaborate with payers or groups like NCQA; data can be culled from different sources and combined to yield the most complete picture. “When you can combine (tumor) registry information with the claims data, it’s powerful; a lot of questions can be answered,” Scanlon said.

Torda said this is why EHR collection must be improved. “What we are beginning to get out of EHRs is not adequate to support quality measurement, or even quality improvement,” she said. “Too much information is not in structured fields; the structured fields need to be defined, they need to be present.”

Newcomer agreed, as this will allow providers to review results from multiple payers—including, soon, the Centers for Medicare & Medicaid Services. “People recognize that it’ll be valuable information, and there are already discussions going on about how can we collaborate in a way that isn’t going to violate anti-trust, but will push the quality agenda.” **EBO**

Can Clinical Pathways Change the “Culture” in Cancer Care?

In May 2013, **Bruce A. Feinberg, DO**, of Cardinal Health Specialty Solutions, published results in *Evidence-Based Oncology*¹ showing that Cardinal’s deployment of pathways had achieved measurable savings across a diverse set of healthcare providers, with an actuary’s validation. In his talk, “An Update on Clinical Pathways,” Feinberg outlined the Cardinal philosophy, while raising an important issue: educating doctors about better quality approaches will not change behavior until they are aligned with financial incentives.

The crisis in cancer care delivery is clear: an aging population, combined with treatment advances, will create ever-rising numbers of survivors, and, with them, rising costs. **Bruce A. Feinberg, DO**, referred to well-known statistics: the number of cancer survivors will rise 30% by 2022, and cancer incidence will rise 45% by 2030. Costs of cancer care, which were \$125 billion in 2010, are expected to rise 39% to \$173 billion by 2020.²

How can oncology address “increasing innovation and increasing cost at a time of increasing incidence”?

One answer is clinical pathways, which offer a narrower range of evidence-based options from among accepted treatment choices. Feinberg said that while pathways companies may look similar from afar, this is not the case. What sets Cardinal apart, he

said, “is that we have validated savings against multiple cancers.”

He referenced results published in May 2013,¹ which showed that Cardinal’s pathways pilot with CareFirst BlueCross BlueShield, for treatment of breast, lung, and colon cancers, resulted in lower rates of emergency department visits, lower rates of hospitalization, and a 7% overall decline in hospital admissions. “There was a 15% savings to the health plan, and the doctors actually were reimbursed higher for participating,” he explained. Of greatest importance, Cardinal’s results received third-party validation by Milliman.

Even with this evidence, moving the cancer care community from the way things have been to the way they should be requires more than presenting facts. Feinberg went through several examples in which physicians have

had evidence but still failed to pursue less costly, less intrusive options, especially in end-of-life care.

He pointed to the 2012 study in *Health Affairs*,³ led by Nancy E. Morden, MD, of The Dartmouth Institute, which found an alarming intensity in end-of-life care among cancer patients whose prognosis was known to be poor; worse, this intensity of care cut across all types of settings, including leading cancer centers. More recent data are not encouraging. Feinberg noted that the Dartmouth Atlas had just reported that while hospital deaths declined 14.4%, this came as the result of a 31% increase in patients with a hospice stay of 3 days or less. This, he said, is not good news.

“I will tell you, as someone who did oncology patient care for 25 plus years, there is nothing worse you can do to a patient or a family than when they are in the active process of dying, take them or their family and move them out of that hospital bed and move them somewhere else so they can die a day later.”

Avoiding this scenario, producing better results and savings starts with engagement. The greatest challenge,

Feinberg said, is gaining physician buy-in, and taking on what he called the “culture of medicine.”

“If we don’t get to the culture of medicine, then we’re really ignoring the elephant in the room,” Feinberg said. “It’s a culture of medicine which embraces now over later, new over old, and more over less.”

He distilled the principles of change espoused by quality care advocates:

- Pay for value, not for volume.
- Ensure physician core competencies in evidence-based medicine.
- Promote patient-centered care, in which the patient is fully informed and involved in shared decision making.
- Deploy health information technology (HIT) with real-time analyses that enable the other goals.

Evidence shows that this approach works. He discussed results from the *New England Journal of Medicine* which show that early use of palliative care produces better survival rates than standard care.⁴

Echoing Berman’s keynote message, Feinberg said longer and better survival requires a better understanding of the patient’s prognosis and goals, less

Table. National Trends in Selected Measures of the Care of Cancer Patients Near the End of Life

Measure	2003-07	2010	Percent Change, 2003-2007 to 2010
Number of deaths among cancer ill patients ^a	235,821	212,322	-10.0%
Hospital utilization			
Percent of deaths occurring in hospital	28.8	4.7	-14.4%
Percent hospitalized, last month of life	61.3	62.2	1.5%
All hospital days per patient, last month of life	5.1	4.8	-5.2%
Percent admitted to ICU, last month of life	23.7	28.8	21.6%
ICU days per patient, last month of life	1.3	1.6	21.2%
Cancer treatment			
Percent receiving life-sustaining treatment, last month of life	9.2	9.4	3.1%
Percent receiving chemotherapy, last 2 weeks of life	6.0	6.0	0.7%
Supportive care			
Percent enrolled in hospice, last month of life	54.6	61.3	12.2%
Hospice days per patient, last month of life	8.7	9.1	4.3%
Percent enrolled in hospice within 3 days of death	8.3	10.9	30.9%
Physician utilization			
Percent seeing 10 or more physicians, last 6 months of life	46.2	58.5	26.8%

^aThe estimate for 2003-2007 was created by summing a 20% sample over 5 individual years.
Source: Goodman DC, Morden NE, Chang CH, Fisher ES, Wennberg JE. The Dartmouth Atlas Project. September 4, 2013.

intravenous chemotherapy in the last 60 days of life, less aggressive end-of-life care, and more and earlier use of hospice care.

How can the culture be changed? Feinberg offered the following: First, pathway compliance should be focused on the 20% of diagnoses that

are responsible for 80% of the costs. Second, reform efforts should be targeted on those behaviors with the greatest impact on cost and quality.

Physicians must be engaged intensively, he said, “but choose your battles wisely.” Patients need to be educated, too. Finally, accountability demands HIT solutions for both physicians and patients that will promote these goals while being HIPAA compliant. When it comes to getting physicians to honestly present end-of-life options, payers and practice leaders must ask, “Do they know how to have the conversation?” **EBO**

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Precision Medicine

Payer Perspectives in Genetic Counseling

Session 3, Precision Medicine, examined how care targeted at the individual can hold down costs while improving quality. This includes matching the right drug to the right patient, and genetic testing is a tool for doing that. But ordering the wrong test can be as harmful as no testing. That’s where genetic counselors can help. **Karen Lewis, MS, MM, CGC**, a medical policy and technology administrator and genetic counselor at Priority Health of Michigan, discussed the challenges and opportunities for genetic counseling and testing in oncology.

Done well, genetic counseling and testing fulfills the mission of the triple aim: better care, better population health, and lower costs. But doing it well requires understanding what tests should and should not be done, for cost and other reasons. **Karen Lewis, MS, MM, CGC**, began by noting that while genetic tests can be expensive, their costs are miniscule when compared with giving cancer patients a \$10,000-a-month therapy that will not work.

Payers who seek help from genetic counselors must realize that the field of certified counselors is fairly small—

there are only about 3000 in the United States and only 25 training programs. Payers should look for candidates with a master’s degree and board certification from the American Board of Genetic Counseling.

To deal with the rising need for its services, Lewis said, “The field has transformed itself from a face-to-face, brick-and-mortar type of service to a telephonic, telemedicine-based service.” Counselors themselves have studied whether this approach meets patient needs, “and they have seen some very positive outcomes.”

At its heart, Lewis said, “Genetic counseling is a communication process.” It combines the hard science of looking at test results and data with the social science of working with patients and families, and educating the family about what results mean.

So what is the role of a genetic counselor at a health plan? Lewis works with medical directors, developing policies on counseling and testing, reviewing requests for tests to ensure they make sense, and hearing grievances, which, ironically, is one of the best parts of her job. “It’s those outlier cases that bring to our attention things we might have missed during the normal processing,” she said. Change comes from those outliers, she said.

Genetic counselors can help a health plan bring order to a realm where tremendous opportunities for profit can lead to poor, uninformed choices by doctors and patients—especially as

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—Karen Lewis, MS, MM, CGC
Priority Health

testing incidents make their way into the media. Lewis was a counselor for 15 years before joining Priority Health, and she is alarmed when she sees the names of labs popping up that she's never heard of. "It's frightening—it's important to choose a lab where you know you're going to get a result that's clinically valid."

"The time has passed when we can just order from the most convenient lab," she said later. "We need high-quality labs, but we also need the best price and high quality together."

Inundated by heavy marketing, patients often demand the wrong test, or use home test kits that produce results

Table. Physician Confidence With Molecular Diagnostic Tests

I am confident I can...	Physicians
End Point	No.
Explain test results to my patients	46%
Identify appropriate patients for testing	45%
Understand and interpret the test results	42%
Choose the right test	35%
Choose which lab to send tests to	30%
Determine if the test is covered by insurance	24%
Determine the right insurance codes	23%

Data source: Jerry Coamey, CAHG Landmark Physician Study 2011.

they cannot interpret. "A mutation does not always necessarily lead to cancer, and we need to consider what else is going on," she said. That's why insurers are moving toward controlling when tests are ordered and encouraging counseling. Despite what some may think, the

family practitioner may be ill equipped to order, much less interpret, genetic test results (Table).

Data show high incidence of the wrong test being ordered, or of full tests being ordered even after a mutation has already been identified in the family. "Seventy-two percent of non-genetics-trained MDs rate themselves as having fair to poor knowledge regarding genetics," Lewis said.

Top issues for payers, she said, include informed consent, transparency, and better coding. And ensuring access. "You're going to have to partner, most likely, with a telephonic genetic service to get full coverage." **EBO**

Grappling With the Fallout of Genetic Testing, in Oncology and Beyond

Moving beyond the topic, "Companion Diagnostics in Targeted Treatment," the panel that followed took on the unregulated nature of testing in the wake of the June 2013 US Supreme Court ruling against Myriad Genetics, which ended the company's BRCA testing monopoly. Ira M. Klein, MD, MBA, FACP, chief of staff, Office of the Chief Medical Officer, Aetna, Inc, served as moderator for the discussion with Jan Berger, MD, MJ, president and CEO of Health Intelligence Partners, and Michael A. Kolodziej, MD, national medical director for Oncology Strategies at Aetna, Inc. Berger is also editor-in-chief of The American Journal of Pharmacy Benefits.

In an ideal world, every cancer patient would get high-quality genetic counseling before a test is ordered, said Ira M. Klein, MD, MBA, FACP, as he launched the discussion. Short of that, he asked, who should be doing the companion diagnostic testing, given the shortage of counselors and the pressing needs?

Jan Berger, MD, MJ, said she would answer from the employers' perspective, since they often are ultimately paying for the test through insurance coverage. "It is a really tough question, and there isn't a good answer," she said, comparing the situation with the one faced by doctors treating HIV patients in the 1980s. HIV was new, treatment wasn't effective, and counselors were scarce—which could mean delays in getting counseling in the face of a life-threatening illness.

Michael A. Kolodziej, MD, pointed out the many issues raised during Lewis' talk, and added a few more: "Next-gen sequencing is going to change the rules completely. We went from an argument

about whether you could have a patent on the BRCA test (the US Supreme Court said no) to a world in which there'll be a platform for under \$1000 to test for every single known hereditary susceptibility."

Besides the issues of quality and clinical utility are more basic ones, such as, "Not everybody wants to know."

Kolodziej highlighted the potential for testing costs to overwhelm payers, because the testing universe is hardly limited to patients newly diagnosed with cancer. "The population for whom this is geared is America. Just think about that for a second."

"So, you've got quality control problems, so we've got analytic validity, and then clinical validity and clinical utility," Klein said in summation. "I think that as the tests become not just for people with cancer, but for the United States, then that does open up a can of worms."

He asked, what guidance can payers give to physicians on the front lines?

Right now, Kolodziej said, not much.

There are too many testing companies, and many laboratory-developed tests are not even regulated by the US Food and Drug Administration (FDA). Until recently, codes for the tests made them impossible to track. It's beyond the reach of most payers to check on the effectiveness of every test provider.

Berger noted that even large employers who try to get good answers are stymied by the lack of agreement. However, she has seen a case where a consensus emerged to not permit employees to use flexible-spending accounts for direct-to-consumer tests such as 23andMe, because of the resulting claims for follow-up testing and procedures.

"It created a disaster," Berger said.

But, Klein asked, what is the appropriate level of consumerism?

Kolodziej noted that 23andMe president Anne Wojcicki gave an interview that essentially said, "Everybody should just do it."

"The issue with everybody should just do it is this: Who should inform them of the results? Who should counsel them about how to act on (the results) and what are the downstream effects of that?"

"Your health beliefs really come into play," Berger added.

Kolodziej wondered if every person would get their genetic results on a flash drive to hand to the doctor, and specu-

lated, "I'm sure there's an industry that's going to spring up that's going to help us interpret that, so that the doctor can get a report with added expense."

Genetic testing is not just for cancer. "The population for whom this is geared is America. Just think about that for a second."

—Michael A. Kolodziej, MD

National Medical Director, Oncology Strategies, Aetna, Inc

To which Klein asked, "What do you think about the fact that we don't measure how the test changes physician behavior?"

"We have no idea," Kolodziej concluded.

NOTE: After this panel met November 15, 2013, the FDA ordered 23andMe to halt marketing of its tests. Wojcicki issued a statement agreeing to comply with FDA regulatory review. **EBO**

The Present—and Future—of Genetic Profiling in Oncology

What will next-generation sequencing look like? How will the use of data make its way into clinical care? Jerry Conway, vice president of Reimbursement & Payer Strategy at Foundation Medicine, Inc, offered a glimpse of the future in his talk, which sparked a discussion of risk sharing between payers and pharmaceutical companies.

Cancer starts with DNA, when something goes wrong genetically. In the future, stopping cancer will mean moving beyond a tumor's anatomy and into the genetic makeup. Going from the tumor level to the molecular level is what big data and targeted therapies are all about—but how will the data make it into the physician's office?

Jerry Conway outlined how Foundation Medicine is partnering with pharmaceutical companies and with academia to approach cancer in a whole new way, one in which, he said, "Each patient's diagnosis and treatment is informed by a deep understanding of the molecular changes that drive their disease."

As Conway described it, the database Foundation Medicine is creating shows that each person's cancer is more like a fingerprint. To address that uniqueness, Foundation Medicine's quest is to assemble "huge amounts of data," and to translate it "so it makes a difference at the point of care." The goal is to gather enough data so that

when a patient's genomic profile is ordered, all those data and the current literature can be analyzed, giving providers an actionable gene on which to base treatment.

Beyond direct clinical care, the company is working with pharmaceutical companies to speed the approvals of new therapies—even resurrecting compounds that had been discarded.

Foundation Medicine's approach involves using a single test to delve into the genetic makeup of a tumor, instead of multiple tests piled atop one another. Known as FoundationOne, the company describes the test as "a fully informative genomic profile that helps physicians make treatment decisions for patients with cancer, by identifying the molecular growth drivers of their cancers and helping oncologists match them with relevant targeted therapeutic options."¹

Conway said the profile, which involves 236 suspect genes and takes 14 to 17 days, has enormous therapeutic and potentially cost-saving benefits—the profile can answer questions that

were not asked, unlike testing that looks at only 1 aspect of a tumor.

The approach will save money over time, he said, because better matches will occur. Right now, he said, "The data suggest that 75% of cancer treatments don't work." Foundation Medicine seeks to dramatically reduce the failure rate by allowing clinicians to create

"The data suggest that 75% of cancer treatments don't work."

—Jerry Conway

highly specific treatments, perhaps using several drugs at once.

He presented the case of a woman with inflammatory breast cancer—the same disease Amy Berman described in her keynote address—who was about to put herself under hospice care. The patient's tumors were so severe she could not turn her head. After using Foundation's test, she was able to receive a targeted treatment that afforded her 7 more months, including a stretch of quality time in which she

played tennis and danced at a wedding.

To some physicians, including a payer in the audience, the process sounded potentially expensive and perilous. Scott Ramsey, MD, PhD, of the Fred Hutchinson Cancer Research Center in Seattle, Washington, said he feared a future of "giving cocktails of multiple \$10,000-a-month drugs based on a sequence that shows multiple genomic variants" without knowing that the patient would benefit. Conway said that would amount to irresponsible use of technology, and that the data would evolve to the point of evidence-based decisions.

Ramsey called for risk sharing between payers and pharmaceutical companies. "If we're going to be able to sustain what we're doing, then we need some kind of a risk contract with pharma so that as the drug is tried in a patient that it appears indicated for, if the drug is not successful, part of that or all of that might be picked up by pharma, and in those patients where the drug is successful, that would be picked up—the entire cost of it—by the payer." **EBO**

Reference

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Next-Generation Sequencing in Oncology: Are We Ready for Prime Time?

A lively discussion followed Jerry Conway's presentation on Foundation Medicine's approach to creating genomic profiles. The payer community, represented by Lee N. Newcomer, MD, MHA, of UnitedHealthcare, Michael A. Kolodziej, MD, of Aetna, Inc, and John L. Fox, MD, MHA, senior medical director and associate vice president, Priority Health, had plenty of questions. Ira M. Klein, MD, MBA, FACP, of Aetna, Inc, moderated.

With great power comes great responsibility. That edict applies in many settings, and now, too, in genomic sequencing as it stands to transform decision making in cancer care.

Ira M. Klein, MD, MBA, FACP, put that idea out front to trigger responses from the payers, who joined Jerry Conway of Foundation Medicine to gauge whether

the advances Conway presented can deliver what they promise—and whether payers should foot the bill for data collection while the evidence rolls in.

Conway clarified that despite press reports of the cost of genomic sequencing coming down, the costs have actually flattened, due to charges from platform companies. Getting DNA ready for

sequencing is difficult and costly. "Over time, yes, I think it will be more efficient," Conway said. "Where the rubber meets the road is the enormous effort that's required to make sense of the data coming off the sequencers."

So, while the promise of next-generation sequencing is enormous, who should pay to build the knowledge base needed to help unlock the potential? Payers on the panel clearly worry that cost is headed their way.

Lee N. Newcomer, MD, MHA, of UnitedHealthcare, said too much is being made of single cases like the one Conway outlined in his earlier presentation. Providers don't grasp the limitations,

or the lack of evidence, and payers are put in a tight spot. "The need for clinical data and evidence is absolutely essential, and that's what we want from your database, but in the meantime, you can't expect the public to fund those data because the resources are too scarce," Newcomer said.

"We're not suggesting that you take 1 case study and that becomes policy," Conway responded. "There's a lot of work to be done."

John L. Fox, MD, MHA, senior medical director and associate vice president, medical affairs, Priority Health, weighed in with his concern that predictions based on genetic sequencing



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may not be the same from tumor to tumor, and that it's important to acknowledge what is not known. "When we have more and more information about what the mutations are, we have less and less information about whether or not patients are likely to respond," he said. "The real challenge is what evidence do we need to inform the decision for payers, let alone patients and physicians, about when to pull the trigger."

Michael A. Kolodziej, MD, spoke of the "leadership vacuum" in policing the scientists who use genomic sequencing to decide what drugs to try. Payers

should not bear all the burden of this research, he said, but it's so fascinating that pressure will mount for payers to fund the studies. "This is something that has got to be dealt with, and it needs to be dealt with soon, because it is so sexy," Kolodziej said.

Klein asked, given this vacuum, whether this was the right place for collaboration between payers and pharma.

Fox said that there are some clinical trials he does not mind funding, and payers know many of these costs are headed their way under the Affordable Care Act.

Newcomer followed: "What I'd love to see is the master US protocol on this concept." If sequencing shows there is an actionable gene in an unproven cancer, then payers could pick up the clinical costs while pharmaceutical companies provided the drugs.

Conway said his company cannot bear such costs by itself, but could be part of a collaborative process to do so.

After all, Klein said, the goal is to match the right treatment with the right patient—first in a study setting, and then in a traditional one.

Newcomer, Kolodziej, and Fox all had thoughts on this point. "If I could have

an ideal trial, it would be the first relapse randomized to either genomically directed or standard of care. Let's see whether the concept brings forth some kind of extra value," Newcomer said.

Kolodziej and Fox wondered whether the genomic approach should be tried earlier in a cancer's progression, not after all other options had been exhausted. Pressure is mounting from providers to do something different for those patients with a poor prognosis.

Said Fox, "There is going to come a point pretty quickly, I think, where the tension between these two is going to hit the public and explode." **EBO**

Stakeholder Collaboration: A Focus On The Future

Putting the "Economics" Back Into Health Economics Outcomes Research

From his vantage point as director of the Cancer Technology Assessment Group at the Fred Hutchinson Cancer Research Center in Seattle, Washington, Scott D. Ramsey, MD, PhD, sees the financial fallout of cancer care like few do. An internist and health economist, Ramsey asserts that the entire approach to clinical trials in recent years has contributed to escalating costs of drugs, and that this trend cannot continue. His talk was titled, "Where Does HEOR Fit in the Oncology Model?"

The connection between economics and healthcare is broken, at least in the United States; so, too, is the pricing model for pharmaceuticals, according to Scott D. Ramsey, MD, PhD. He began his talk by describing the futility of even trying to find a good definition of health economics outcomes research (HEOR) in the literature; in his view, clinical research has had an increasingly narrow focus on whether new cancer drugs produce a short-term benefit, with little regard paid to whether that benefit is worth it financially. This must end, he said.

"Unless we look at value, unless we look at cost, the outcomes research (OR) is somewhat pointless, because we're not going to be able to make good decisions and improve value for our patients until we take cost into account, and what we get for what we pay," Ramsey said.

Ramsey said that while some in medicine are having discussions about whether new cancer drugs are worth the price, in clinical trials, the structure often looks at end points that are favorable to the pharmaceutical companies—regardless of whether the real-world results that include price have

value for patients.

He cited a study in the *Journal of Clinical Oncology* by a Canadian team that found trials are increasingly using measures of progression-free survival (PFS), "which may or may not correlate with symptoms." The authors found that since the 1980s, when PFS was never an end point, this end point accounted for "nearly a quarter of all the trials in the 2000s."¹ In the palliative setting, the share rose from zero to 45% in that same period, he said (Table).

"If progression-free survival correlated precisely with patient quality of life or overall survival, that might make sense to me, but we know from multiple studies that that is a very inconsistent relationship," Ramsey said. "We're getting away from measuring things that I think patients value the most."

By contrast, data that show overall survival (OS) in metastatic colorectal cancer increasing from 8 to 18 months since the 1990s represent "real progress."

The problem, as Ramsey sees it, is the lack of relationship between meaningful survival results and soaring drug costs. "The costs of the drugs are increasing regardless of the incremental benefit," he said. Groups like the National Comprehensive Cancer Network

(NCCN) do not help when they equate a drug that costs \$840 a month with a few side effects to a string of oral therapies that together cost \$60,000 for a treatment course.

"What we have is a disconnect between what I think would be the ideal and what is real," he said. US drug development and approval processes differ vastly from those in Europe, which take into account what support payers are willing to provide. By contrast, the biggest US payer of all—the Centers for Medicare & Medicaid (CMS)—is politically hamstrung from negotiating directly with drug companies.

The question is: "Will the change in our payment paradigms change the health economics and outcomes research paradigm? In other words, will it

Table. How Progression-Free Survival Became the Standard Over Time

End Point	1975 to 1984		1985 to 1994		1995 to 2004		2005 to 2009	
	No.	%	No.	%	No.	%	No.	%
No. of RCTs published	47		107		167		137	
PFS/TTP as primary end point	0	0	2	2	11	7	35	26
No. of RCTs with time-to-event primary end point	11		60		125		123	
PFS/TTP as primary end point	0	0	2	3	11	9	35	28
No. of RCTs in palliative setting	34		66		101		77	
PFS/TTP as primary end point	0	0	2	3	10 of 101	9	35	45

PFS indicates progression-free survival; RCTs, random controlled trials; and TTP, time to progression. Booth CM, Eisenhauer EA. *JCO*, 2012.

make health economics more relevant? And my answer is, I'm not certain."

So far, risk sharing takes place between the payer and the patient, but

pharmaceutical companies do not accept a role. This creates no incentives to contain prices, Ramsey said.

If nothing changes, "We're going to

have to stop giving patients access; oncology practices are going to go bankrupt; patients are going to go bankrupt. It's just not a supportable system." **EBO**

Reference

1. Booth CM, Eisenhauer EA. Progression-free survival: meaningful or simply measurable? *JCO*. 2012;30(10):1030-1033.

Value-Based Pricing: The Role of Outcomes Data in Pricing Models

Data about escalating prices for cancer drugs laid the groundwork for the panel that followed, where **Michael E. Chernew, PhD**, Harvard health economist and co-editor-in-chief of *The American Journal of Managed Care*, outlined how changing the paradigm will require a different kind of shopping. **Cliff Goodman, PhD**, chaired the panel, which featured **Jeffrey D. Dunn, PharmD, MBA**, and **Kirby Eng, RPh**.

Having just heard a provocative take on how research design is driving up drug prices, **Cliff Goodman, PhD**, opened by asking **Michael E. Chernew, PhD**, whether anything he had heard offered hope for the concept of value-based pricing: the principle that says healthcare costs should be tied to their effectiveness, and drugs that offer little value should be reimbursed in a way that either pushes them out of the market or forces their makers to cut the price.

Goodman asked Chernew how the market would react to some of the ideas from the previous talk. Chernew said the answer was complicated, because it depends on "who's doing the shopping, what they are shopping on, and how effective is that shopping."

Chernew said Massachusetts' health-care reform experience, which is considered a prototype for what will come under the Affordable Care Act (ACA), has shown that "when you made the providers bear risk for medical care, they shopped unbelievably well. They changed a little bit of practice patterns, but boy, they sent people to the lowest cost providers, because now when they spent extra money to send a person to an expensive provider, that was coming out of their profit."

Enforcement came not from individual doctors, but from practice groups that figured out low-cost structures. This is trickier in oncology, Chernew said, because the "death panel" notion makes it politically more difficult to deny therapies.

However, he said, if some expensive drugs with marginal benefit relative to their cost are placed on a "fourth-tier

formulary" where they are rarely prescribed, the market forces will take over.

But, Goodman asked, "Is it the patient who's doing the shopping or the oncologist?"

Echoing Scott Ramsey, MD, from the prior talk, Chernew said it depends on how one spreads the risk. A pure patient-centered model—with no provider risk—would allow out-of-pocket costs to drive all care. Conversely, bundled payments can put too much burden on the doctors. "What we're trying to do now—exactly what Scott said—is we're spreading the risk so both are doing shopping in very particular ways." Chernew said pricing models have to allow for innovation, or it won't happen.

Goodman then turned to **Kirby Eng, RPh**, who, as director of oncology pharmacy management at CVS Caremark, would know whether being a big player in the market helps create leverage. According to Eng, it creates surprisingly little. What's helping more are competing therapies within individual forms of cancer, because that allows market forces to work.

Jeffrey D. Dunn, PharmD, MBA, was asked to explain how his firm, VRx, tries to control costs. He described VRx as a combination of a traditional pharmacy benefits manager (PBM) and a negotiator with third-party administrators, that also offers medication therapy management. Dunn said he agreed with Ramsey's assessment that economics needs to find its way back into outcomes research. "This concept of value-based pricing or cost-effectiveness—whatever you call it—is not a new concept. I think part of the challenge is that what the FDA requires of pharmaceutical compa-

nies is not what we, as payers, need and it's not what providers need. There's a total disconnect there."

He added: "I really think the payment reform concept is going to be crucial, and the risk concept ... is going to be crucial, because right now it's really the payers that hold the risk, and to some extent, the patients because they're paying co-pays, and providers a little bit...."

"At the end of the day, we're the ones paying for the drugs," Dunn said. It's time to find a risk-sharing role for drug companies, because payers are in a position where it's hard to deny coverage based on marginal effectiveness. "If we say no right now, we're going to be on the front page of the newspaper and we're going to be killed, but if we could get help (in risk sharing), then we're going to be in a much better situation."

"Part of the challenge is that what the FDA requires is not what we, as payers, need."

—**Jeffrey D. Dunn, PharmD, MBA**

VRx Pharmacy

By its nature, oncology care presents a tougher management challenge than, say, diabetes care. But costs are rising to the point where payers will have little choice but to limit options.

"We're going to pick 3 or 4 drugs based on value, and we're not going to reimburse for other drugs. We've done that in RA—rheumatoid arthritis—and we've done that in multiple sclerosis," Dunn said. With oncology, "It's much harder; we can't say no right now, like I said, but

that's where we need the help with the providers and other folks to say no, and if we can say no and only cover certain drugs, then it will give us different leverage."

"So, oncology drugs are really expensive," Goodman said, "but they're kind of getting a free ride right now, right?"

Said Dunn, "They have."

Chernew said that before patients heard, "no," they would hear, "yes, but," that exception processes would exist, and there would be hurdles to get drugs off formularies. Gaining the ability to say "no" will be essential to establishing leverage in setting drug prices, but who gets to say it and how remain unsettled.

Patients might not have enough information. Physicians seem to be the ones to say no, but "Most physicians didn't get into medicine to say no in particular areas. So, we are struggling," Chernew said. An educated patient like Amy Berman is rare.

Dunn agreed. "The role of insurance, just by definition, is not to pay for experiments. At the same time, we don't want to just say no just for saying no.... We want to say yes to appropriate utilization."

Goodman asked Eng to weigh in on how a large pharmacy could shape the landscape.

"We are under extraordinary pressure by our clients—again, health plans as well as employers—to start looking at ways to start bending that trend. That's across all specialty therapies," Eng said.

It's going to be up to every stakeholder to create change, because no 1 player can act alone. "This cannot be done in a silo or a vacuum," he said, and "Pharma has to be involved."

"I think this is going to be anywhere from the next 2 to 5 years, and I think, again, it's going to be driven a little bit by the patients themselves and then as an extension of that, the employers, because it's estimated that specialty trends in general are going to double our PMPM

(per patient, per month) pharmacy spend in the next 4 years.”

Goodman asked each expert to look ahead: If, in 10 years, costs have flattened, what will have been done right?

“My fear is that in 10 years, we could probably give these exact same talks and nothing will have changed,” Dunn

said. “We need to figure out how we take advantage of biosimilars and generics. Right now we are totally unprepared, as payers, to deal with those.”

Eng said, assuming healthcare reform takes hold, he would like to see consumers evaluate cancer care the way they compare other products.

Chernew concluded, “The answer is we pushed risks down to providers and to patients to get the market to shop better. That’s what we have done, through some combination of this risk notion. We’ve made groups accountable.... What I believe will probably happen, if we do things right, is through aspects of per-

sonalized medicine and some of the things we saw (today), we will see markets for some of these drugs shrink.

“That will necessitate higher price for particular drugs, but the goal in economics is not to focus on the price per dose; it’s to focus on the value you get in your insurance premium.” **EBO**

Redefining the Role of Industry in Contemporary Healthcare

So, just how can pharmaceutical companies adapt to a changing environment? Are they the source of the problem, or have they simply responded to US Food and Drug Administration mandates? Why should community oncologists care how drugs get created and approved? Sorting it out were John L. Fox, MD, MHA; Bo Gamble; and Cliff Goodman, PhD.

At the outset, **Cliff Goodman, PhD**, asked panelists to distill what lessons pharmaceutical companies could take from what they had heard. **Bo Gamble**, of the Community Oncology Alliance, began by saying that everyone at Patient-Centered Oncology Care 2013 gets the message: The time has come to pay for quality, and everyone must be on board.

What will drive change, Gamble said, is for that message to filter out to those who don’t get it. “A lot of the providers don’t and a lot of the payers don’t; certainly the patients don’t,” he said. Many providers don’t grasp that reform is an “evolutionary” process; it’s not something they can assign to a single time slot in each week.

Goodman then asked **John L. Fox, MD, MHA**, on behalf of payers, whether pharmaceutical companies—and the life sciences industry generally—are ready for change.

Fox said he often feels he has to be an ambassador of sorts for drug companies when he deals with providers or employers. It’s an uncomfortable spot, but it highlights a disconnect. He’s starting to see manufacturers develop patient navigation tools that do not steer consumers to a particular product, but it’s not commonplace. And the reason is obvious: right now, payers, providers, and patients bear the risk.

It’s time, he said, for “mutual accountability...for making sure the right patients are on the right therapy. Today the risk is ours alone, as a payer. Pharma really doesn’t have any skin in the game in ensuring that the right patients are on the right drugs.”

Does that mean, Goodman asked, that drugs should not be reimbursed if they don’t have certain health outcomes?

Essentially, Fox said, yes. “There should be a minimum threshold for improvement. That would be ideal, as a starting point, to say we’re not going to bring anything to the market that’s a bunt single. We want to bring a double to market or a home run, but if it’s going to be a bunt single, I don’t want that.”

Gamble agreed, saying there should be a “comprehensive view” of drugs that make it to the market. With drug prices so high, it’s not easy for community oncology practices to transition to value-based care.

“The thing about healthcare is, it’s been totally about utilization,” Gamble said. “You come in, you consume, you get a bill. There’s been no accountability, and we’re saying ‘No, think differently about everything you do.’ Think about quality, think about value. Prove it.”

Fox said there’s too much focus on which drug will be best for a condition, without asking about factors that affect whether it works—such as side effects and whether the patient can afford it.

“But,” Goodman interjected, “the life sciences companies have been oriented over the decades—many decades—toward getting some kind of regulatory approval based on certain biomarkers or some sort of end points. Have they been in the business of adherence and medication management and whether or not your drug reduces readmissions?”

“No, but they need to be,” Gamble said. “We’re also asking the practices to gear

up for that, we’re asking the patients to gear up for that....It needs to look like the Angie’s List of healthcare; what is the quality and the value component here?”

Goodman asked Fox whether healthcare reform would change the life sciences industry. “If they’re just cranking out molecules—some that you can swallow, some that have to be injected—is that still a viable long-term approach given the healthcare demand and the things for which you intend to pay?”

“My only job is to produce a drug; if it’s everybody else’s job to make sure the patients take it and to get the best possible outcomes, then that’s not a partnership, that’s not mutual accountability.”

—**John L. Fox, MD, MHA**
Priority Health

Fox said what payers want to see are drugs that help people live longer, with good quality of life. Today’s attitude, he said, is “My only job is to produce a drug; if it’s everybody else’s job to make sure the patients take it and to get the best possible outcomes, then that’s not a partnership, that’s not mutual accountability. Yet, how do we define what mutual accountability looks like?” Other diseases,

typically chronic diseases, have support programs that go beyond making sure patients take their medicine.

Goodman asked if anyone in the pharmaceutical industry wanted to respond.

One respondent said what’s needed is a uniformed, structured approach. To one individual, incremental benefit may be a huge benefit, depending on the person’s circumstances. What is success? When do you abort a trial?

Fox said what this points to is “patient-relevant outcomes.” The oncology community—including drug makers—must ask patients what is more important: living longer, or living longer without chemotherapy? Is the answer different from what it is for an oncologist?

Tom Morrow, MD, of Genentech, said the work of drug companies has brought cancer care forward; many cases that had no hope now can become chronic conditions.

Overall survival is a hard standard, because it’s not measurable. “Can we do overall survival when we have control of the patient over a period of time that they’re willing to put themselves under our control?” Progression-free survival is the FDA goal.

Goodman said Genentech was “one of the most innovative companies.” Did more need to be done with payers? Morrow said Genentech has a fleet of staff who work with payers, but drug makers need “really close definitions of what they want.” Drug development still takes 10 years—which is a huge investment of time and money.

Fox ended this way: “One of my favorite quotes is from Indira Gandhi, and she said it’s hard to shake hands with a clenched fist, and I don’t think that we’ll solve this problem without collaboration. I think it’s one, however, that has to be around shared accountability.” **EBO**

Teva

Teva