



**ECRI Institute's 22nd Annual Conference on
the Use of Evidence in Policy and Practice**

Co-sponsored by the National Cancer Institute

Cancer Care Delivery in a Rapidly Changing Healthcare System

November 17-18, 2015

Omni Shoreham Hotel in Washington, DC

Cancer Care Delivery in a Rapidly Changing Healthcare System



Table of Contents

Executive Summary

Session 1: Our Changing Understanding of the Biology of Cancer

Session 2: What Is the Status of the Technologies of “Precision Medicine”?

Session 3: The Complex, Intertwined Role of Patients in Research and Care

Session 4: How is Quality Perceived and Measured when Cancer Is a Chronic Condition?

Session 5: How to Make Paying for Value Valuable

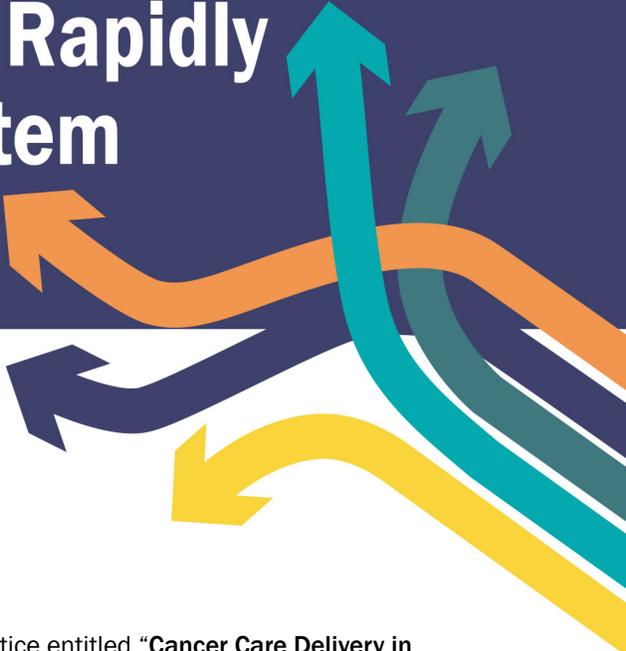
Session 6: How Do Various Integrated Delivery Systems Provide Cancer Care?

Session 7: CEO Perspectives on How Their Differing Health Systems Deliver Care Now and Are Preparing for the Future

Session 8: Looking to the Future: Legislative and Policy Perspectives

Session 9: Capstone Session: Perspectives on What We Have Learned and What We Can Do

Cancer Care Delivery in a Rapidly Changing Healthcare System



Executive Summary

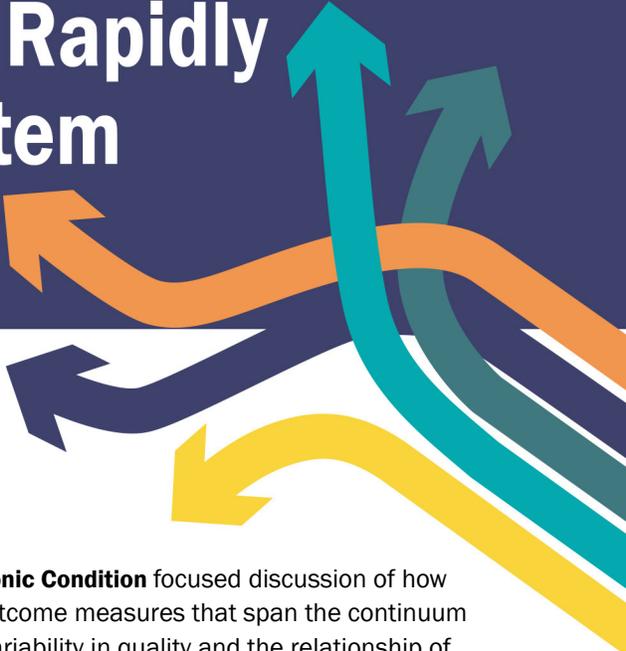
ECRI Institute's 22nd annual conference on the use of evidence in policy and practice entitled "**Cancer Care Delivery in a Rapidly Changing Healthcare System**", was held November 17-18, 2015, in Washington, DC, at the Omni Shoreham Hotel. It was organized by ECRI Institute and the National Cancer Institute (NCI), in cooperation with AcademyHealth, the Agency for Healthcare Research and Quality (AHRQ), the Bipartisan Policy Center, the Department of Veterans Affairs, *Health Affairs*, the Jayne Koskinas Ted Giovanis Foundation for Health and Policy, Kaiser Permanente, the Leonard Davis Institute of Health Economics, the Patient-Centered Outcomes Research Institute (PCORI), and the University of Pennsylvania Health System. All of the co-sponsors actively participated in creating the sessions, including identifying topics and appropriate speakers, and publicizing the conference. Key stakeholders, including both speakers and the audience, discussed the current status of key areas in cancer care delivery. The presentations and conversations focused on understanding the current state of cancer care and whether we are on the right path forward. Nine themed sessions over two days addressed cancer care delivery and health policy; how public and private policy makers, regulators, payers, providers and consumers use the evidence and make decisions when that evidence is incomplete; the status of public and private sector value-based payment initiatives for cancer care; the state of tailored and coordinated cancer care; quality measurement of cancer care; and legislative and policy initiatives currently under consideration.

Overview of Conference Proceedings

DAY ONE

- **Session 1: Our Changing Understanding of the Biology of Cancer** conveyed the current understanding of the biology of cancer. It addressed which cancers are believed to be system-based as opposed to organ-based, and the effect that has on the development of new technologies and the delivery of care.
- **Session 2: What Is the Status of the Technologies of "Precision Medicine"?** addressed U.S. Food and Drug Administration (FDA) regulation of medical devices and oncology drugs and other technologies associated with precision medicine. It also explored ways the FDA works with patients. It included perspectives on a PCORI-funded clinical trial on proton beam therapy, looking at technology from a patient-centered point of view.
- **Session 3: The Complex, Intertwined Role of Patients in Research and Care** introduced Centers for Medicare and Medicaid Services' (CMS) novel approach to requiring shared decision-making prior to patients undergoing computed tomography (CT) scanning in screening for lung cancer and how this constitutes population-based shared decision-making. It also addressed the evolving role of patients in research and cultural issues affecting the clinician-patient relationship, including those which may underlie disparities in care.

Cancer Care Delivery in a Rapidly Changing Healthcare System



- **Session 4: How is Quality Perceived and Measured when Cancer Is a Chronic Condition** focused discussion of how cancer quality is measured now, addressing whether there are useful outcome measures that span the continuum of care – specifically after the acute treatment phase. It also reviewed variability in quality and the relationship of quality to cost of newly available drugs. Finally, this session explored what underlies new approaches from payers to stimulate higher quality oncology care.
- **Session 5: How to Make Paying for Value Valuable** addressed 1) The positive and negative attributes of bundled payments for oncology; 2) How prior authorization in the private sector could be the basis for comparative effectiveness evaluations; 3) Outcomes of performance payment programs that have been completed; and 4) Issues in primary care such as treatment for those who have survived their initial cancer or patients who choose not to undergo screening.

DAY TWO

- **Session 6: How Do Various Integrated Delivery Systems Provide Cancer Care?** covered coordination of care (treatment spanning screening, diagnosis, treatment, and post-acute care), access to out-of-system care, and the value of integrated delivery systems resources such as registries and electronic health records in research-based care. Discussion included issues such as population-based outcomes, identifying high risk populations, and studies of adherence to treatment. Individual shared decision-making was also addressed.
- **Session 7: CEO Perspectives on How Their Differing Health Systems Deliver Care Now and Are Preparing for the Future** was a discussion among CEOs of three major health systems centered on how they manage their ultimate responsibility for what is encompassed by their systems, including how they attend to financial pressures, clinical pressures, and incentives, as well as how they take account of larger population-based issues and overall strategic considerations.
- **Session 8: Looking to the Future: Legislative and Policy Perspectives** was a bipartisan conversation among senior congressional aides who discussed key policy issues, legislation and prospects for legislation. It also provided a broader sense of where Congress is headed.
- **Session 9: Capstone Session: Perspectives on What We Have Learned and What We Can Do** united issues and perspectives from the previous sessions and added fresh perspectives on how to address the changing pathways for cancer care delivery.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Major Themes

UNDERSTANDING THE BIOLOGY OF CANCER

Recently, the landscape of cancer treatment has changed dramatically and our understanding of the biology of cancer has rapidly accelerated. Diagnostic advancements have changed the way that cancer is classified and characterized. Dr. Roy Herbst, from the Yale Cancer Center, pointed out that cancer biology has always informed treatment. For example, chemotherapy is based on the understanding of the biology of cancer cells, but now more than ever, new insights into the molecular biology of tumors are driving treatment. The increase in knowledge about biology has led to powerful instrumentation and analyses that identify the molecular underpinnings of cancer.

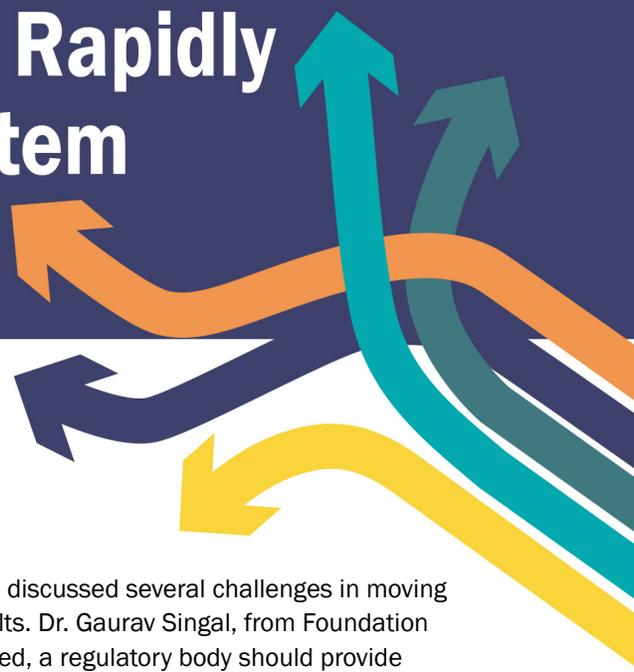
DNA sequencing has revolutionized the understanding of cancer. Dr. James Zwiebel, from the National Cancer Institute, explained that when a physician sends a sample of a patient's tumor to be sequenced, the DNA is extracted from that tissue sample, the structure and composition of those genes are reviewed to identify any mutations, and those mutations are matched against a set of genes that are believed to be associated with cancer. These mutations may be the cause of the patient's cancer growth. Furthermore, DNA encodes for RNA, which is the template for creating proteins. In cancer, a single base change in the DNA can lead to a totally different three-dimensional configuration of a protein, causing the protein to have different attributes that may drive the multiplication of cancer cells. Gene mutations also affect the normal function of other cellular processes including DNA repair pathways.

There are also potentially curative treatments becoming available that harness the innate power of the immune system. Dr. Herbst touched on immunotherapy, which exploits the specificity and memory of the immune system to shrink tumors. Dr. Gary Gilliland, from the Fred Hutchinson Cancer Center, stressed the need to look for therapies that have curative intent. Even if those therapies are expensive, there is value because patients are treated for a discrete period of time rather than treated over their lifetime. Also, even expensive curative treatments could be less expensive than the cumulative cost of conventional treatment.

PRECISION MEDICINE

The President's Precision Medicine Initiative is an innovative approach to cancer treatment that takes into account individual differences in people's genes, and their environmental and lifestyle-related risk factors. Many of the current efforts toward achieving this goal have focused on analyzing and interpreting a person's unique genetic makeup to identify genetic mutations that may be the cause of their cancer. Advancements in diagnostics provide the opportunity to deliver new investigational therapeutics based on the biology and activated pathways of an individual's cancer, which helps clinicians better predict which treatments will be the most effective. Additionally, a targeted drug focused on a single genetic mutation can be effective across multiple cancer types irrespective of organ involvement. There are still many mutations in DNA and RNA that have not been identified or for which no targeted drug currently exists. However, the number of actionable alleles and targeted therapies are rapidly increasing.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Several panelists noted that precision medicine is still in the research realm and discussed several challenges in moving forward. One challenge is to improve the reliability of molecular sequencing results. Dr. Gaurav Singal, from Foundation Medicine, Inc., noted that as testing becomes more sophisticated and complicated, a regulatory body should provide oversight to make sure results are accurate, reliable, and valid.

Another challenge is using this information to identify the subset of patients that would benefit from each therapy or combination of therapies. Dr. Singal noted that we often do not have all of the data points that we need to match patients effectively. Also concerning is that the overlapping toxicities of radiation, chemotherapy, new targeted therapies, and immunotherapies can make it impossible to combine certain therapeutics. Lastly, there are financial challenges due to the enormous investment it will take to screen patients, pay for these expensive tests, understand the biology of tumors better, and develop matched drugs.

REGULATION OF MEDICAL DEVICES, ONCOLOGY DRUGS, AND TECHNOLOGIES

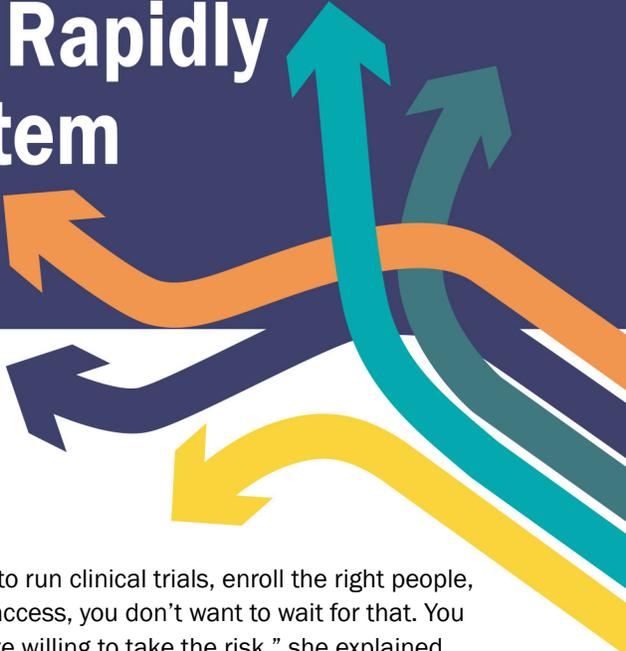
One major policy objective of the FDA is to facilitate the implementation of precision medicine. Dr. Gideon Blumenthal, from the FDA, explained the FDA's two approval pathways for drugs and biologics. The first is traditional (regular) approval, which is based on improvement in a direct measure of clinical benefit. The second is expedited approval, which includes breakthrough therapy, the newest program for drugs used to treat serious life threatening disease based on preliminary clinical evidence showing substantial improvement over other available therapies. Now more than ever, drugs are being approved based on very preliminary clinical trial results. About 40% of requests for breakthrough therapies are in oncology.

In the precision medicine era, most of the drugs and devices currently being evaluated are intended to provide more precise diagnosis or treatment, such as pharmacogenomics, companion diagnostics, next generation sequencing, tailored therapeutic devices, and mobile/wearable devices. Dr. Elizabeth Mansfield from the FDA noted that as targeted drugs and biologics are developed, companion diagnostics are needed to determine whether the patient has the right mutation or variant to be a candidate for that drug.

Although rapid approval and adoption provides patients with more access to new drugs and technologies, it is not always clear whether they are better than current treatments. As a condition of expedited approval, post-marketing studies must be conducted to confirm the clinical benefit of the therapy. The FDA has advisory committees that confirm that these requirements are met and there are financial penalties if they are not. Typically, the post-marketing studies do confirm clinical benefit. However, typical of such new programs, this program presents challenges, including how to determine the right threshold for granting a breakthrough therapy designation, what constitutes available therapy for comparison purposes, and on what basis a designation should be rescinded.

The FDA is actively engaged in managing the balance between access and certainty and between the benefit to patients now with greater certainty of exactly how a drug or technology works, which requires time. "If you want to be really certain

Cancer Care Delivery in a Rapidly Changing Healthcare System



that something works or exactly how it works, it's going to take a while. You have to run clinical trials, enroll the right people, analyze them, and you may get different results from different trials. If you want access, you don't want to wait for that. You want it now and you want to see if it works, and many patients want it now and are willing to take the risk," she explained.

EVIDENCE GENERATION & THE NEED FOR BIG DATA

Novel clinical trial designs have been developed over the last several years to help expedite the drug development process and ensure that patients receive the most appropriate therapies, including basket trials and umbrella trials. Basket trials focus on a specific gene mutation found in the tumor, regardless of where the cancer originated. One example is NCI's Molecular Analysis for Therapy Choice (MATCH) trial, a large scale trial that analyzes patient's tumors to determine whether they contain genetic abnormalities and then matches those abnormalities to known targeted drugs and treatments. The trial involves a panel of roughly 200 genes that contain abnormalities thought to drive cancer and for which there is a targeted therapy available. Currently, there are more abnormalities than there are targeted drugs. Umbrella trials test the impact of different drugs on different mutations in a single type of cancer.

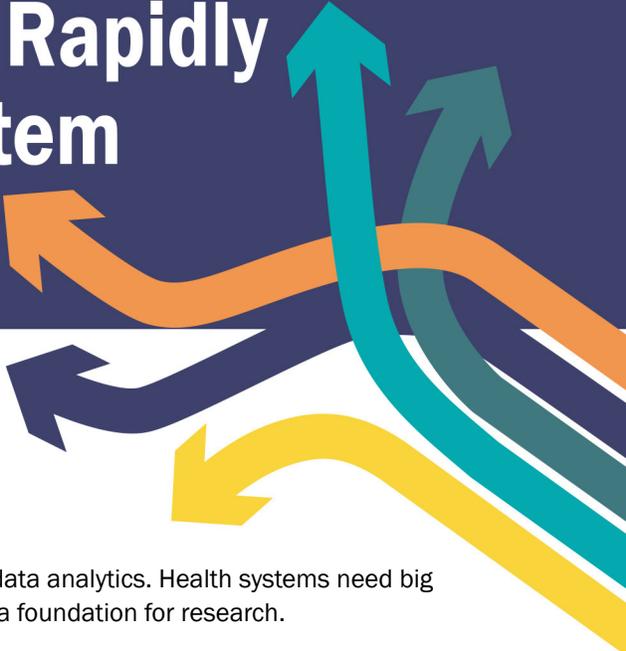
"Clinical trials need to be more scientific, smaller, and more adaptive," said Dr. Herbst. However, another challenge of cancer medicine is that as treatment improves, patients are living longer, and it takes longer to assess outcomes. This has implications on clinical trial design because outcomes may be years away. Dr. Justin Bekelman, from the University of Pennsylvania, stressed that we cannot just say we are going to do "adaptive design"; we have to think harder about what that means.

Additionally, there is a need to increase the overall number of patients who are able to participate in clinical trials, as well as to combat racial and ethnic disparities in clinical trials. Dr. Grace Ma, from Temple University and the Center for Asian Health, noted that only 2-3% of minority populations are participating in randomized controlled trials (RCTs). In order to advance precision medicine, it is critical to conduct RCTs that engage minority populations and are culturally relevant. Clinical trials also need to be more widely available so that patients can get cutting edge care without having to travel far distances in their frail state.

Although traditionally medicine has relied on the gold standard of prospective trials, especially RCTs, over the last 20 years, it has become evident that this may not be the only way to gather information. For rare cancers, it may not be possible to do RCTs. There is a need within the clinical community to learn from information outside of RCTs by developing more sophisticated methods to analyze observational data and to learn from the collective experience of treating cancer.

Registries have been integral to understanding the behavior of cancer and advancing knowledge about cancer. Historically, cancer registries have been used primarily for public health surveillance and to support research. Dr. Kenneth Kizer, from California Cancer Reporting and Epidemiologic Surveillance Program, stressed the need to take cancer registries to the next level, including more timely data that needs less cleaning and curation. He suggested that this could be improved through structured data submission, better and easier access to other relevant data through the integration of other public and

Cancer Care Delivery in a Rapidly Changing Healthcare System



private clinical databases, and active mining of the linked databases to support data analytics. Health systems need big data sources to provide a resource for quality performance, as well as to provide a foundation for research.

Linking clinical databases, electronic health records (EHRs), environmental databases, claims data, and utilization data may help get to more clinically meaningful real-time data and identify patterns of care from a quality perspective. Twenty-five years ago, the problem with merging databases and registries was technology; that is no longer a problem. Now the problems are administrative policy, political, and privacy issues. Although it is currently possible to bring databases together, it takes a long time to get Institutional Review Board (IRB) approval to link them. There needs to be a routine and easy way to link and mine databases and more resources need to be devoted to analyzing and interpreting this data. “If we can bring this data together, it has the potential to offer new insights,” Dr. Kizer noted.

THE ROLE OF PATIENTS IN RESEARCH

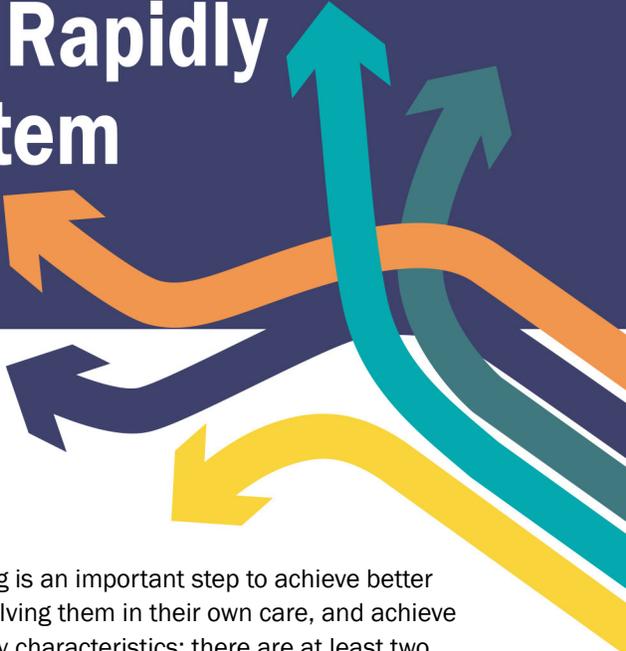
“Involving patients in research is just as important as involving patients in their own care,” said Dr. Joe Selby from PCORI. Recently, there have been significant efforts to involve patients in the research process. The Reagan-Udall Foundation was created by Congress to support the scientific mission of the FDA by advancing regulatory science and combining science, critical appraisal, and patients’ perspectives. The foundation fosters collaboration among patient groups, industry, academia, and FDA scientists to design and conduct regulatory science research. Other efforts include the FDA’s Patient Preference Initiative, which systematically elicits, measures, and incorporates patient preference information into clinical trials and device development, and the Patient Engagement Advisory Committee which ensures that the needs and experiences of patients are incorporated into the FDA’s work.

Ms. Jane Reese-Coulbourne, Executive Director of the Reagan-Udall Foundation for the FDA, explained that when they placed patients advocates on steering committees they found that patients were overwhelmed, intimidated and did not feel that they could contribute due to the technical and scientific nature of the conversation. This led the Foundation to apply for PCORI funding of the program, “Big Data for Patients,” which seeks to give patients background knowledge and an understanding of the landscape, as well as to teach the vocabulary and critical appraisal skills necessary to participate in the conversation. She stressed that patients cannot participate if they cannot follow the conversations. Understanding the diversity of the patient population and incorporating the voice of representatives from different subpopulations is another challenge.

THE ROLE OF PATIENTS IN CARE & SHARED DECISION-MAKING

Oncology care is medically complex, fragmented, and often difficult for patients to navigate. Dr. Brent James, from Intermountain Healthcare, noted that there are two ways to think about patient-centered care. The first is to organize care around the patient, rather than the physicians, technology or facilities. The second focuses on patient autonomy, patient-reported outcomes (PROs), and a co-production model that puts patients on care teams. This model is participatory and engages patients.

Cancer Care Delivery in a Rapidly Changing Healthcare System



As new technology and treatment options are introduced, shared decision making is an important step to achieve better care for the patient, focus on the outcomes that are important to patients by involving them in their own care, and achieve greater patient satisfaction. The model of shared decision-making has several key characteristics: there are at least two participants (the physician and the patient), both parties share information, they build a consensus about preferred treatment, and they reach an agreement regarding what treatment is implemented.

When patients engage in their own care they are more likely to be adherent to the plan and they achieve better outcomes. Panelists and audience members alike noted that shared decision-making can be challenging because many patients struggle to synthesize all of the information and options, may be overwhelmed, and may want to be relieved of the burden of making complex decisions by having the physician make those decisions for them. However, Dr. Joseph Chin, from the Coverage and Analysis Group in the Centers for Medicare and Medicaid Services, noted that “We have seen a change in the way patients approach their encounters with physicians. Many of the older beneficiaries do have that type of position, where they leave the decision making up to the physician. With the availability of data and additional information, I think patients in the younger generation are more accustomed to considering the data and actually engaging with physicians when making decisions.”

To address these issues in a heterogeneous population, several panelists stressed the need to educate patients and to tailor patient engagement to individual patients. To achieve this, several suggestions were offered including summarizing the available options, turning medical jargon into plain language, providing patients with evidence of improved outcomes where that evidence exists, making them aware of guideline-based standards of care, and including peer counseling and family involvement in decision-making. There is a need for better tools to inform and engage patients in their care and to get better at determining what is important to individual patients and families.

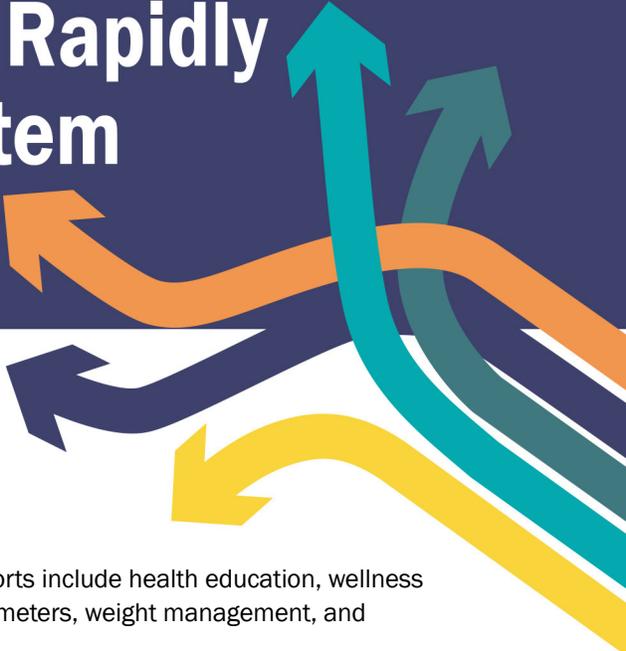
Dr. Joseph Chin explained that CMS is using a novel approach to incorporating shared decision-making by tying it to Medicare coverage determination, as was done with low-dose computed tomography for lung cancer screening. He noted that the time physicians must invest in individual patients to achieve shared decision-making is a challenge, and there is a lot of work to be done in understanding how to structure future visits and make them more efficient.

CURRENT AND FUTURE DIRECTIONS OF CANCER CARE DELIVERY

We need to recognize that people are increasingly living with cancer as a chronic condition, they are not dying quickly, as was true 20 to 30 years ago. “We need to stop having a war on cancer. We need to have a truce with cancer and learn to manage it as a chronic condition and help the public to understand that it is a chronic condition,” said Dr. Anne Geiger from NCI. Health care is shaped by how the delivery system is organized. Panelists addressed the ongoing transformation in health care delivery and cancer care.

There is an increasing focus on prevention throughout the health system. Dr. Kizer noted that some social determinants of health, such as education, food, and housing, may have more to do with improving clinical outcomes than the latest genetic therapy. “We really try to prevent the first cancer and then try to keep people healthy and prevent that second cancer,”

Cancer Care Delivery in a Rapidly Changing Healthcare System



explained Dr. Joanne Schottinger from Kaiser Permanente. Current prevention efforts include health education, wellness programs, health coaches, and interventions including activity monitors and pedometers, weight management, and aggressive tobacco cessation programs.

Large organized delivery systems have the potential to clinically integrate care, manage population health, and provide better health care value. One consistent feature of integrated delivery systems is the use of an integrated electronic health record (EHR) to improve cancer care. VistA is a single, integrated computerized patient record system that has been used throughout the Veterans Health Administration (VHA) since the late 1990s in all health care settings. Notably, the VHA was able to improve breast cancer screening rates by 10% through the integration of a system in VistA that reminds primary care providers that a patient is due for a cancer screening. Furthermore, historically, within the U.S., the rate of lung cancer resection has been lower for blacks compared to whites. Using VistA, they found no biological difference or comorbidity to explain the rate difference, and within the last two years they were able to close this gap.

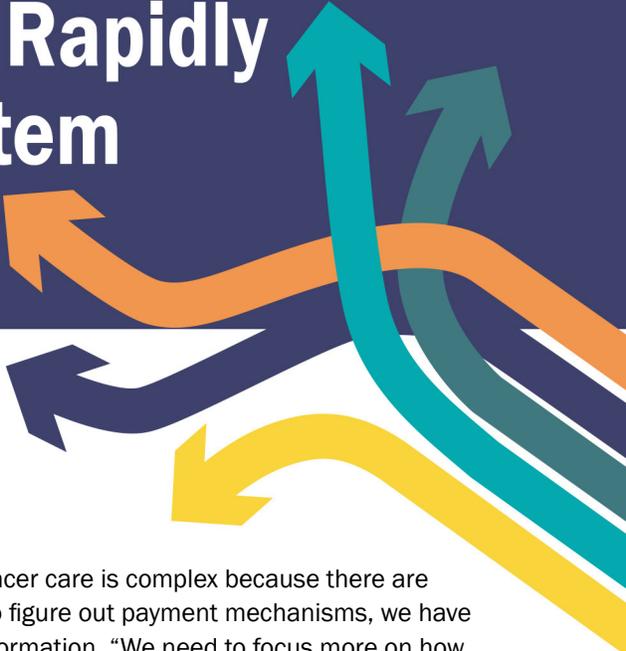
Kaiser Permanente uses HealthConnect, an integrated EHR that has been in place for about 15 years and decision support embedded within HealthConnect is used for cancer care. The system flags care gaps and those gaps are addressed by any physician regardless of the primary reason for the patient's visit. Then using a function called SureNet, results of tests and screenings are automatically sent to the appropriate specialist, thereby closing the care loop. Dr. Schottinger noted that if a patient looks at their care gaps, they are more likely to follow through with appropriate care and close those care gaps. Kaiser is trying to bring their EHR to the next level by giving patients access to their entire medical record.

Dr. Brent James, from Intermountain Healthcare, noted that integrating evidence-based best practice protocols into the workflow leads to documented improvement in mortality, significantly better patient outcomes, and higher physician efficiency. "If you rely on memory, with today's level of complexity in care delivery, you will manage to execute about 50% of the time," he explained. Treatment protocols need to be updated regularly based on the newest evidence-based tests and treatments. Panelists agreed that there is a need to vary protocols based on individual patients' needs—recognizing that there are individuals who are exceptions to guideline-based care—and honoring professional autonomy. However, Dr. James clarified, "You're not sacrificing your autonomy, you're focusing your most important resources—the trained expert mind—on that relatively narrow part of the patient's care that needs modification. It's a brilliant way of increasing productivity."

"Not all integrated delivery systems provide integrated care and integrated care is not just provided by integrated delivery systems," Dr. Kizer said. There is a need to better understand the key elements of clinical integration and how it can be achieved in diverse settings. Information mobility is critical to achieve clinical integration and we need to continue to focus on how to best integrate information across the clinical care spectrum.

Dr. Gilliland stressed the need for collaboration within the community to ensure that appropriate practices are being adopted. Dr. Kizer noted that the current "war on cancer" efforts are fragmented because we do not share goals, vocabularies, approaches, and data sets, and there is competition between centers, across geographic areas and in politics. Dr. Gilliland

Cancer Care Delivery in a Rapidly Changing Healthcare System



said, “We need to get high quality uniform practices out into the community.” Cancer care is complex because there are multiple modalities of care that can be substitutable and additive, and in order to figure out payment mechanisms, we have to figure out how to make our systems interoperable so that people can share information. “We need to focus more on how best to disseminate and apply all the new information in a coordinated and systematic manner. We will need to reconcile what uniform care and quality means as therapy becomes more individualized and personalized,” Dr. Kizer said. Another broader challenge is to bring precision medicine into play across other disease areas by adapting and applying the lessons learned from cancer science to other conditions.

MEASURING THE QUALITY OF CANCER CARE

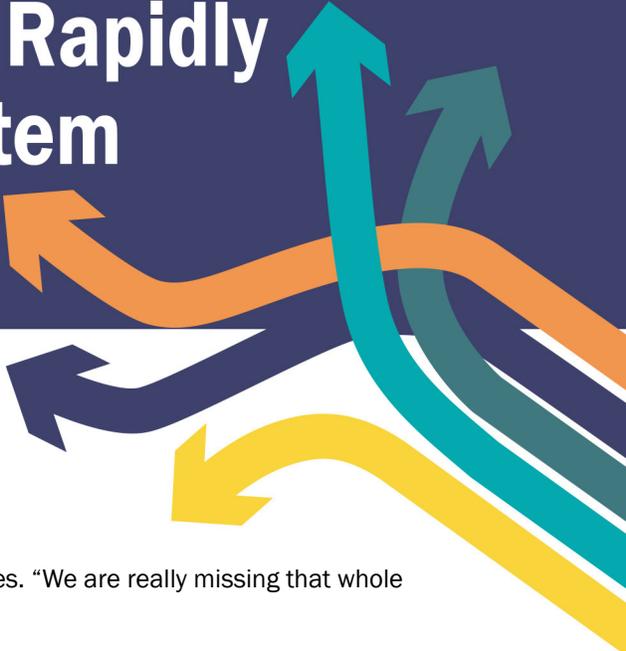
“Health care quality is getting the right care to the right patient at the right time, every time,” said Carolyn Clancy. Historically, it has been difficult to measure the quality of cancer care because of the complexity of the disease—it attacks different organs and systems, it is discovered at and progresses through different stages, and there are a variety of treatments and treatment modalities.

Panelists reviewed the current efforts at different levels of the health care system to improve the quality of cancer care through quality measurement and addressed several challenges to developing meaningful quality measures for cancer. At the government level, the Affordable Care Act (ACA) seeks to improve quality through the National Quality Strategy (NQS). The NQS addresses six priorities: 1.) Making care safer by reducing harm caused in the delivery of care, 2.) Ensuring that each person and family are engaged as partners in their care, 3.) Promoting effective communication and coordination of care, 4.) Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease, 5.) Working with communities to promote wide use of best practices to enable healthy living, and 6.) Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

Several organizations have developed measure sets that address the quality of cancer care. The American Society of Clinical Oncology (ASCO) has developed 165 ambulatory care measures for oncology medical practice. In 2012, the American Cancer Society (ACS) Commission on Cancer set new standards for cancer care which included the provision of treatment and survivorship plans, including written summaries of care and follow-up care, palliative care services, genetics services, navigation programs and psychosocial distress screenings. The Oncology Nursing Society’s (ONS) breast cancer survivorship measures, developed in conjunction with The Joint Commission, address symptom management, education, individualized goal setting and follow-up care in the ambulatory setting. The National Quality Forum has endorsed 60 measures for cancer.

However, there are currently gaps in NQF-endorsed cancer quality measures and quality measures in general, including too few validated outcome measures, too few measure of overuse, and almost no patient-centered outcome measures. Additionally, Dr. Susan Larsen Beck, of the College of Nursing at the University of Utah, noted that there is a lack of

Cancer Care Delivery in a Rapidly Changing Healthcare System



measures that address cancer as a chronic illness or focus on long-term outcomes. “We are really missing that whole period of care in terms of follow-up, except at the very end,” she said.

Panelists addressed several current challenges to developing meaningful quality measures and improving cancer care through quality measurement including the time spent measuring, integrating quality into real-time clinical care, measuring the right thing, managing quality and cost, and improving quality throughout the cancer experience. Additionally, measuring quality at the system level can be challenging because not all care rolls up into a system and there are complex attributions, particularly in non-integrated health care systems.

Evaluating the quality of cancer care is driven too much by what we can easily measure and the processes (rather than outcomes) of care. When innovations start to diffuse, it is important to be able to measure whether there is a difference in the care being provided. There needs to be further thinking about what it means to provide high quality cancer care, how we measure cancer care quality, and how quality measures drive the delivery of care and their possible unintended consequences. Performance measures affect behavior, and tying measures to incentives can cause inappropriate behaviors. Dr. Richard Roberts, from the University of Wisconsin, stressed, “You better measure what you value, because what you measure gets valued.”

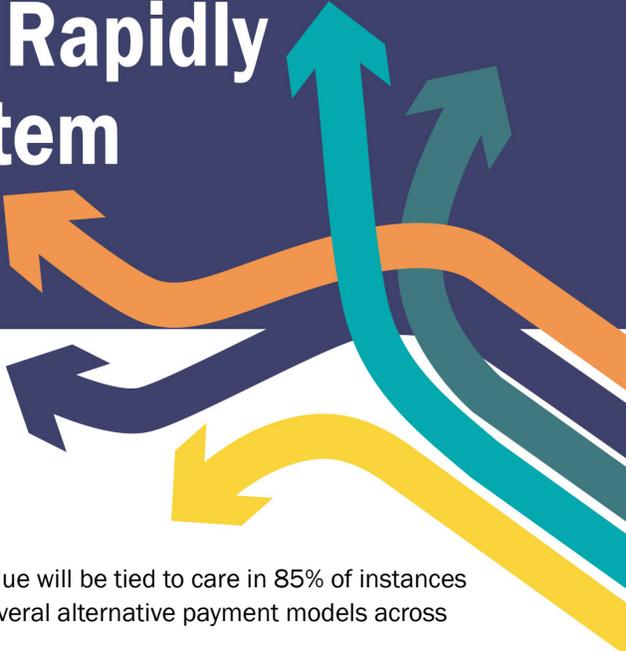
Panelists agreed that comprehensive performance measures should be part of payment initiatives and reimbursement efforts should be aligned to address affordable, patient-centered, high quality care. One of the best way to reduce cost is to improve quality. However, across regions, cost is rising without significant differences in outcomes. “There is huge opportunity for thinking about value in the oncology space,” said Dr. Lee Newcomer, from UnitedHealthcare.

COST, ALTERNATIVE PAYMENT MODELS, AND VALUE

The cost of health care compared to the gross domestic product (GDP) in the U.S. is higher than anywhere else in the world. The cost of oncology care in the U.S. is rising faster than the general cost of medical care, as reported by Institute of Medicine (IOM) in 2013. The growing cost of cancer care is not sustainable and we need to find multiple ways to increase its value. Payment system innovations are critical to achieve this.

Cancer care delivery is taking place in a dramatically changing health care system. Between 2009 and 2015, many laws were passed which affect the health care system and therefore cancer care, including the Institute for Healthcare Improvement’s Triple Aim, the Bipartisan Budget Act, the Medicare Access CHIP Reauthorization Act (MACRA), Medicare Alternative Payment Models, Medicare Pay-for-Performance, the Taxpayer Relief Act, the Budget Control Act, and the ACA. In April of 2015, the Senate passed a bill to repeal the sustainable growth rate formula (SGR), the previous physician payment formula for Medicare. This ended decades’ long payment cuts and opened the door to discussions about more effective ways of paying physicians. The current legislation replaces the SGR with an approach focused on rewarding high-performing providers while supporting alternative payment models such as Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes (PCMHs). Furthermore, HHS stated that the goal is to have 30% of care be delivered by alternative

Cancer Care Delivery in a Rapidly Changing Healthcare System



payment models by 2016 and 50% by the end of 2018. Additionally, quality or value will be tied to care in 85% of instances by the end of 2016, which will go up to 90% by 2018. The panelists discussed several alternative payment models across the public and private sectors.

Dr. Shari Ling, from CMS, described the work by CMS' Innovation Center, which is testing new care and payment models to improve quality and reduce costs, including comprehensive primary care initiatives and bundled payment efforts. She gave an overview of the Oncology Care Model-Fee for Service (OCM-FFS), an episode-based payment model for all types of cancer, targeting chemotherapy and related care during a 6-month period following the initiation of chemotherapy treatment. The model emphasizes practice transformation and focuses on total cost of care. CMS calculates a benchmark episode expenditure, and if practices fall below this benchmark they may receive performance-based payment. Payment is also tied to a range of quality measures that seek to converge cost and quality towards value.

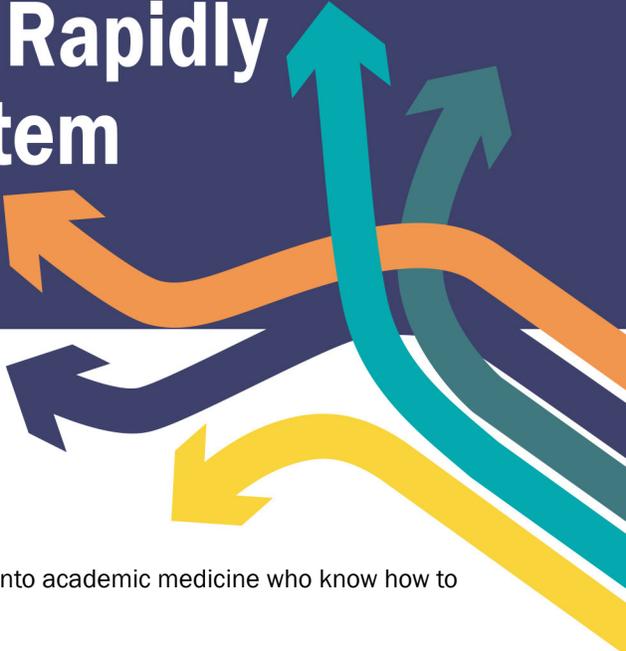
Dr. Lee Newcomer described UnitedHealthcare's two methods of performance payment, episodes and bundles. An episode payment provides a single payment for all of the services needed by a patient for an entire episode of care. This reduces the incentive to overuse unnecessary services within the episode, and gives health care providers the flexibility to decide what services should be delivered. Episode payments are gain sharing, "there is only an upside, there is no downside," he explained. Physicians can receive increased episode payment by improving their results as compared to other physicians. Episodes are limited to one specialty (medical oncology) and stratified by cancer type and tumor stage. For episodes, the payer assumes complete analytic burden and a comparison group is required for them understand how the provider performs and determine payment. In comparison, he noted "bundles are complete risk, upside and downside." United-Healthcare has one oncology bundle that addresses multi-disciplinary oncology care. One payment is made to the provider and the provider assumes all care for the patient for the next year. For bundles, the analytic burden is on the provider to understand whether they made or lost money and no comparison group is required. These approaches were designed to reward oncologists for quality patient care while simultaneously severing the link between drug selection and income.

Jennifer Malin, from Anthem, described Anthem's Cancer Care Quality Program, which focuses on improving the quality and cost of care through cancer treatment pathways. The program collects data on quality of care in real-time and provides reimbursement to oncology practices when they select a treatment regimen that is on a cancer treatment pathway.

As the demographic shifts, the population over age 65 is increasing and cancer incidence rates increase with longevity. When the Medicare program was established in 1965 there were 20 million people eligible and there were five people paying into the trust fund for every eligible person. By the end of the 2020s, there will be 80 million people eligible for Medicare and there will only be 2.5 people paying into the trust fund for every eligible person.

Dr. Steven Lipstein believes we need to create a much larger cancer care delivery platform to diversify risk. There needs to be wealth redistribution through the health care system. Part of what the ACA is intended to do is make the health system accountable for a very distributed, diverse, and large population over which we can spread the risks and total cost of providing care. "We have to get the patients the right care. To do that we are taking on a broader geography and funneling

Cancer Care Delivery in a Rapidly Changing Healthcare System



patients to appropriate care.” Mr. Muller also stressed the need to bring leaders into academic medicine who know how to think about serving broad populations.

“If you’re working in a fee-for-service context, cancer is still a significant revenue generator for health systems,” explained Dr. Gary Gilliland, from the Fred Hutchinson Cancer Center. Hospitals realize the most income from providing care to cancer patients. Cancer has an economic margin that is used to support other programs and broader aims of care, such as community-based care, care provided in emergency rooms, behavioral health, and maternity care. Payment systems have a profound effect on medicine and there is still the unanswered question of who should pay for treatments and evidence generation: the federal government and taxpayers, the device industry, commercial payers, providers and/or patients? Cancer will be an increasingly high profile political issue as the burden and cost of cancer increases with an enlarging aging population. Clinicians need to better understand political processes and there needs to be better ways to inform and engage politicians in the complex interplay of diagnostic and therapeutic advances, the cost and financing of such advances, and the care delivery system challenges in executing these advances.

Session 1: Our Changing Understanding of the Biology of Cancer

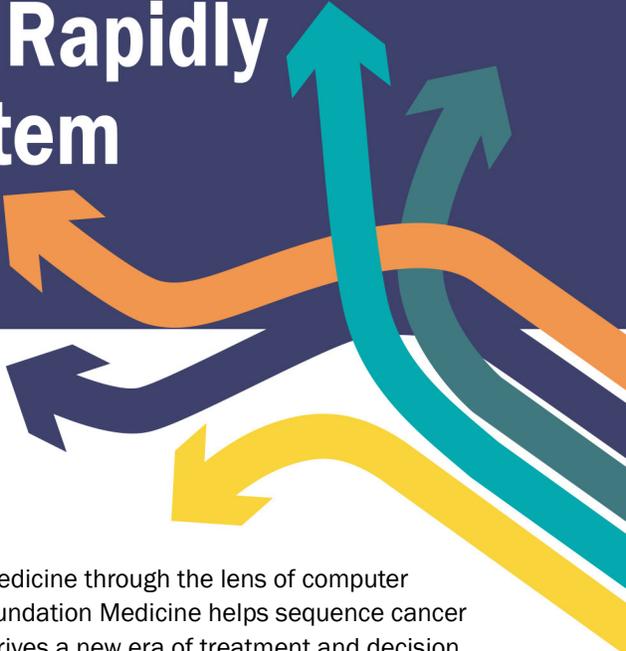
Panel: Larry Norton, Roy Herbst, Gaurav Singal, and James Zwiebel

Larry Norton, MD, Deputy Physician-in-Chief for Breast Cancer Programs; Medical Director, Evelyn H. Lauder Breast Center; Norna S. Sarofim Chair in Clinical Oncology, Memorial Sloan-Kettering Cancer Center, opened Session 1, in which panelists provided their perspectives on the current understanding of the biology of cancer and its impact on cancer care.

Roy S. Herbst, MD, PhD, Ensign Professor of Medicine (Medical Oncology) and Professor of Pharmacology; Chief of Medical Oncology, Yale Cancer Center and Smilow Cancer Hospital at Yale-New Haven; Associate Director for Translational Research, Yale Cancer Center; Translational Working Group Leader, Thoracic Oncology Program, Yale Cancer Center, specializes in the treatment of lung cancer. He stressed that there is a lot of work that needs to be done in the treatment of lung cancer. It is the number one cause of cancer death in the United States (U.S.) and is a heterogeneous disease affecting both smokers and non-smokers, and those exposed to a variety of substances.

Dr. Herbst pointed out that our understanding of biology has always informed treatment; chemotherapy is based on understanding of the biology of cancer cells, but now more than ever, new insights into tumor biology are driving treatment. Cancer care must combine targeted drug development with an understanding of patient heterogeneity and the molecular biology of an individual’s tumor. In the last 15 years there have been a number of new drugs approved targeting specific gene abnormalities, as well as new immunotherapies. There is a need for innovative clinical trial designs and a focus on tests for developing biomarkers.

Cancer Care Delivery in a Rapidly Changing Healthcare System



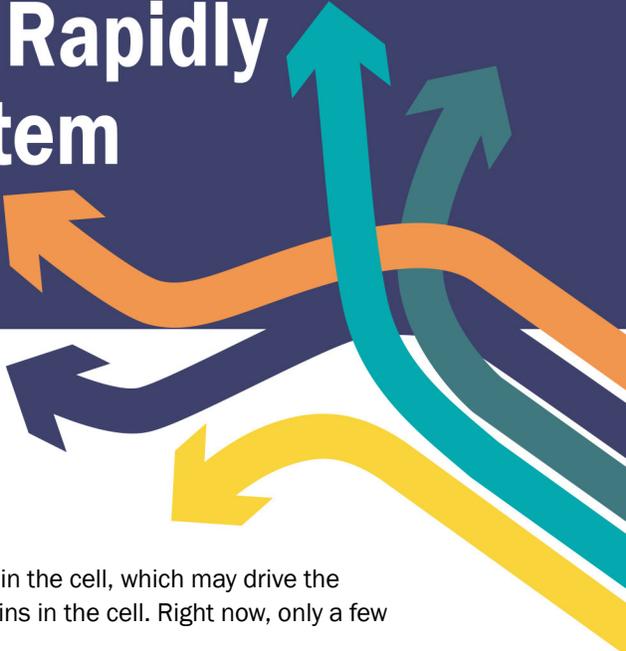
Gaurav Singal, MD, Director, Innovations Unit, Foundation Medicine, Inc., views medicine through the lens of computer science, artificial intelligence, machine learning and clinical decision support. Foundation Medicine helps sequence cancer DNA. Dr. Singal noted, “This conversation is about biology, but also how biology drives a new era of treatment and decision making.” The vision of precision medicine is emerging due to diagnostic advancements, particularly in the way cancer can be classified and characterized, and the development of many new treatment options. As the understanding of cancer continues to grow, there is a larger armamentarium with which to treat cancer, which poses the fundamental challenge of how to interpret diagnostic information and match appropriate treatments to the right patient. Often there is a lack of all of the data points needed for effective matching of treatments to individual patients. Therefore, an important focus is further development of information science. He also stressed the need for novel clinical trial designs and new sources of evidence that medicine has not traditionally used, such as real world evidence and learning from the collective experience of treating cancer.

James Zwiebel, MD, Branch Chief, Investigational Drug Branch, Cancer Therapy Evaluation Program (CTEP), National Cancer Institute (NCI), works on drug development with academic investigators and the industry to bring new investigational therapies into the clinic. Dr. Zwiebel noted, “Despite what we’ve heard about personalized medicine, it’s really in its infancy. We have a number of poster children out there where we have agents that hit their target exquisitely and lead to long, durable remissions. Unfortunately, those are few and far between. The reality is that cancer is a complex process. Cancer is evolution happening before our eyes. . . . The moment you knock out one target, another one appears.” Over the last several years the landscape of cancer treatment has changed dramatically. There has been an increase in knowledge about biology and we have powerful instrumentation and analyses to facilitate identifying the molecular underpinnings of cancer. This allows for the relatively rapid development of agents that target the identified molecular abnormalities.

He pointed out two challenges the field faces in moving forward. One challenge is to deliver new investigational therapeutics based on the biology and activated pathways of an individual’s cancer, but doing it in a way that is tolerable for the patient, specifically managing the toxicities that come with the treatments. Overlapping toxicities can make it impossible to combine certain therapeutics. A second challenge is getting reliable information from molecular sequencing. In one test recently, NCI found that several well-known laboratories did not get the same identification from the same tumor. NCI is currently working through the Molecular Analysis for Therapy Choice (NCI MATCH) trial to improve the accuracy and reliability of molecular screening results and has succeeded in obtaining the same results across four laboratories.

When a physician sends a sample of a patient’s tumor to be sequenced, the DNA is extracted from that tissue sample, the structure and composition of those genes are reviewed to identify any mutations, and those mutations are matched against a set of genes that are believed to be associated with cancer. If something is wrong with the sequence, it is called a mutation, and these mutations may be the cause of the patient’s cancer growth. Dr. Zwiebel further explained that DNA encodes for RNA, which is the template for creating a protein by stringing amino acids together. In cancer, a single base change in the DNA can lead to a totally different three-dimensional configuration of the protein; this causes the protein to gain new

Cancer Care Delivery in a Rapidly Changing Healthcare System



attributes, possibly including the loss of ability to respond to regulatory influences in the cell, which may drive the multiplication of cancer cells. There are 25 to 30,000 genes that encode for proteins in the cell. Right now, only a few identified genetic mutations have matching cancer treatments.

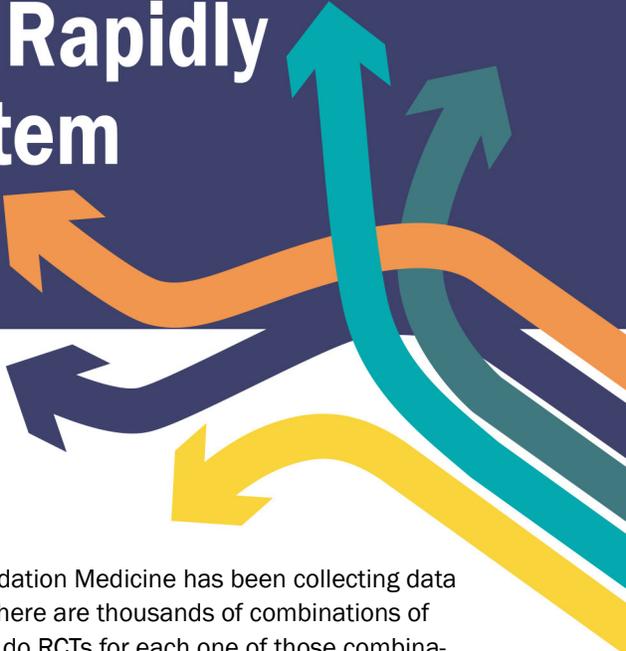
Cancer cells have an incredible ability to evolve, not in years but in weeks and months. We are learning about what drives the mutation process. Normally, our cells have capability to repair themselves. In cancer, some of the DNA repair pathways are damaged and mutations occur at greater frequency or persist. Treatments are now being developed to target the DNA repair defect.

There are a handful of markers that are so well characterized and established that treatments based on those findings are first line treatments. For example, a patient with a new diagnosis of lung cancer should be tested for 3 or 4 of the more common, known genetic abnormalities (e.g., EGFR, ALK, ROS-1) that have appropriately matched treatments, which is a major advance from a decade ago. These established tests are only being ordered about 40-50% of the time. A tremendous number of patients are still not getting the tests that guidelines recommend. "We have to make sure this gets out to people, no matter what they can afford," said Dr. Herbst. Part of the solution is education to increase patient awareness; as the patient's role in guiding their care increases, patients need to know they should be advocating for these tests. Dr. Singal added that as testing becomes more sophisticated and complicated, some regulatory body will have to provide oversight to make sure results are accurate, reliable and valid. This affects payers because they do not want to pay for a test that is not reliable or useful.

Basket trials are a new and evolving form of clinical trial design. Basket trials focus on a specific gene mutation found in the tumor, regardless of where the cancer originated. One example is the NCI-MATCH trial, a large scale signal-seeking and feasibility trial that sequences patient's tumors to determine whether they contain genetic abnormalities. The sequencing focuses on a panel of 143 genes that contain abnormalities thought to drive cancer and for which there may be an associated drug. Unfortunately, there are currently more abnormalities than there are drugs. When there is a matching treatment for an abnormality, patients are evaluated to see if they benefit from that treatment. In particular, the trial seeks to determine whether a tumor in a different cell type but with the same molecular abnormality respond to the treatment. The mutations with matching treatments are found in only a small minority of patients. While a rate of 1-5% having actionable mutations in lung cancer is a fairly large number of patients, for other tumor sites, 1-5% is exceedingly rare. The plan is that if there appears to be any activity in a new tumor cell type, the trial will expand further to test the treatment in that tumor type. It has already been shown that the same abnormality in different cell types does not always translate into a similar response. For example, while a BRAF mutation in melanoma is sensitive to treatment, but that treatment is not effective in colorectal cancer with the same BRAF mutation. However, a combination of drugs targeting the same abnormality in colorectal cancer does improve the response.

Medicine has relied on the gold standard of prospective trials, especially randomized control trials (RCTs), for decades. However, over the last 20 years, it has become evident that this may not be the only or best way to gather certain types of

Cancer Care Delivery in a Rapidly Changing Healthcare System



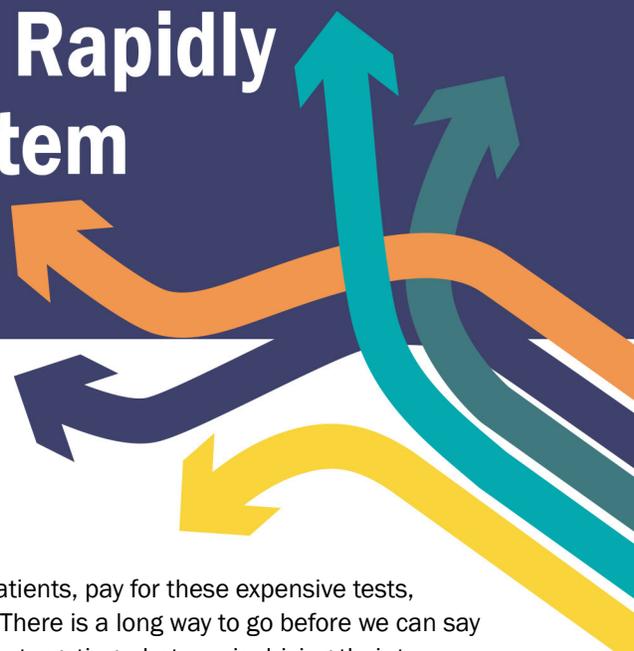
information. Another way may be to see what's happening in the real world. Foundation Medicine has been collecting data on DNA abnormalities and outcomes from the use of promising targeted drugs. There are thousands of combinations of tumor types and targets that currently exist. For rare cancers, it is not possible to do RCTs for each one of those combinations and permutations. There is a need within the clinical community to learn from information outside of clinical trials or academic medical centers, but this is a problem that has not been solved so that we can gather every piece of information that would be helpful in guiding treatment decisions. A single patient may have multiple abnormalities. Cancer cells have an incredible ability to evolve as the disease metastasizes, in fact with treatments driving that pressure on the cancer cell to evolve and survive. What we are learning is what drives the mutation process; certain genes in our cells have this incredible capability to repair themselves, but in cancer, these repair pathways are damaged, so the mutations occur at greater frequency or persist. There are ways to take advantage of the mutations. One example is BRCA, a DNA repair defect; if you induce a second DNA repair defect using an agent such as a PARP inhibitor, then the cell is more easily killed, particularly in combination with a DNA damaging agent such as chemotherapy, so we are taking advantage of the mutation. There are also other mechanisms of cancer not based on mutations – such as over-expression of proteins (e.g., HER2, estrogen receptor proteins), and many other mechanisms that add up to huge complexity. Even the so-called normal tissues around the cancer may harbor abnormalities.

Session 1: Q&A

Dr. Norton asked, “Are we overselling this?” The pathway of sequencing tumor DNA and matching a mutation to a specific agent doesn't always lead to benefit for the patient. He commented that we have to talk to the public about this because they don't understand when treatment doesn't cure the disease. Dr. Herbst noted that Yale has 15 machines sequencing 24-7 and reporting on 143 genes, but that currently they can only act upon 10 to 15 abnormalities. He also noted that it can take many weeks to get results. He commented that we know enough to do a few hypothesis-driven trials, but there is so much we don't know that it is hard to develop hypotheses. Dr. Herbst stated that “at Yale we are doing complete exome sequencing, but most of the information is stored for future research, not usable now.” There are still many mutations in DNA and RNA that have not been identified or that are not matched to treatments. We have to separate what we know now from what we need for the future. Precision medicine is still very much in the research realm.

Dr. Norton asked how the practice of medicine is going to handle the complexity of this field. Opportunities exist using traditional approaches such as the use of 1) guidelines and 2) new clinical decision support tools to help guide treatment decisions at the point of care, and 3) for clinical trials to provide structure for approaching emerging technologies. It is important to increase the number of patients that are able to participate in clinical trials; one of the challenges is how we enable patients to get cutting edge care, through clinical trials, without having them travel far distances in their frail health state. Dr. Singal stated that if we could solve that problem we could do three things, 1.) We could learn from new clinical agents in a controlled setting, like a basket trial, 2.) We could enable physicians who are not as familiar with cutting edge diagnostics and treatments to participate in this kind of care for their patients through guided protocols, 3.) We could enable patients to get this type of care independent of where they are being treated.

Cancer Care Delivery in a Rapidly Changing Healthcare System



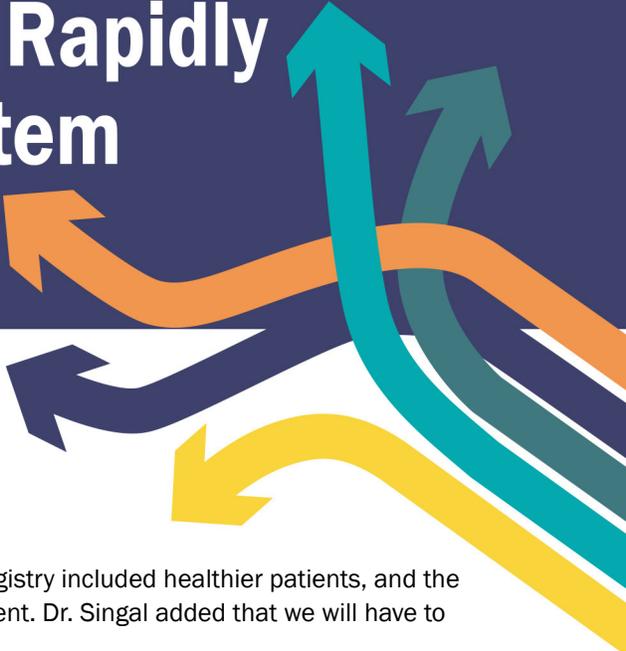
Dr. Zwiebel stressed that it is going to take an enormous investment to screen patients, pay for these expensive tests, develop more targeted treatments and better understand the biology of tumors. There is a long way to go before we can say that precision medicine is a mainstay of clinical care and we can treat patients by targeting whatever is driving their tumor. He and the other panelists agreed that we are creating undue expectations on what patients can expect now from precision medicine; the chance of finding something actionable for the individual patient are very, very low. As we learn more that will change. We need good data collection and reliable assays and many patient volunteers. How much of this is research and how much is standard of care is unclear. Without paying the community oncologist with a very busy practice to collect and submit data, how are we going to gather that information outside the clinical trial setting?

If it is true that we are going to reclassify cancer by genetic mutations rather than cell type (although not entirely clear that this is the answer) – the current economics of drug development are such that drugs for a small number of patients will not be developed. Who is going to pay for it?

The panel also touched on another major topic, immunotherapy and the relationship of cancer to the immune system. Dr. Herbst said about 200,000 patients die of lung cancer each year. Only about 15% of lung cancer patients can be helped with targeted therapy, and even those who respond eventually become resistant because of further mutations. For the other 85%, there needed to be a new paradigm. The immune therapies, initially developed in melanoma and renal cancer, turned out to be helpful in lung cancer. Dr. Herbst explained that there are ways that you can take the body's own immune system, the specificity and memory of that immune system, and not only shrink tumors but keep them smaller over time. The toxicities from immunotherapy in many cases are often less than those associated with chemotherapy. However, it only works in about 1 in 5 patients. When treating patients in real time, the challenge is identifying the subset of patients who would benefit from each therapy or combination of therapies, including radiation, chemotherapy, new targeted therapies, and immunotherapies, while managing the corresponding toxicities. Of note, the immunotherapies may work better in smokers with lung cancer than in nonsmokers and in those with mutations for which there is no targeted therapy. The bad news is that it really only works in 1 in 5 patients. The biomarker for response to immunotherapy is not a DNA mutation, but more complex than that. Dr. Zwiebel noted that at NCI, they are combining immunotherapy, targeted therapy, chemotherapy, but that they really don't know how to select patients for these expensive treatments. Dr. Singal agreed, but said that over time we will figure out the place of immunotherapy in the armamentarium of care. Unfortunately, the early attempts at combining targeted therapy and immunotherapy have demonstrated severe toxicity. We are relying extensively on empiricism – can we combine these agents with a reasonable degree of toxicity?

A representative from the American Association for the Advancement of Science, noted the frustration with traditional clinical trials, including high costs and the time it takes to enroll an adequate number of patients. She asked whether registries are being used to gain information in the cancer field. Dr. Norton responded that it may be impractical to gather data on targeted therapeutics when you're dealing with a very rare phenomenon. Both approaches are likely necessary for the future of cancer research. He noted his concern that "the experience that we get just from looking at registries, might not only be not useful, but might give us the exact wrong answer." For example, registry data initially showed that post-menopausal women

Cancer Care Delivery in a Rapidly Changing Healthcare System



taking hormone replacement therapy were healthier, but it turned out that the registry included healthier patients, and the incidence of breast cancer actually increased with the use of hormone replacement. Dr. Singal added that we will have to come up with more sophisticated methods to analyze observational data.

Dr. Lee Newcomer from UnitedHealthcare asked, “How do we begin to systematically study the multiple complex interactions and connected pathways so that we understand what we’re dealing with?” Dr. Herbst noted that for immunotherapy, we don’t even have animal models because the animals are immunosuppressed to get the tumors to grow, so we are moving to clinical trials faster than ever. “Clinical trials need to be more scientific, smaller, and more adaptive. We need to have good theoretical reasons for putting combinations together. If we try to take all these combinations to Phase 3, it will be a very tough exercise.” Dr. Norton responded that we do not yet have a universal theory for cancer biology yet; there is an organizing principle and we do not know it yet, but “we have historical precedence in other sciences for making sense of this degree of complexity.”

Katherine Treiman, RTI International, questioned what the major barriers are to patients receiving appropriate testing and increasing the reliability of the tests. Dr. Singal commented that information is a barrier and there is a need to educate patients to know that these tests are the standard of care and to empower them to ask for them. Physicians, too, need to know that these tests are the standard of care. He also noted the need for internal and external quality control in DNA sequencing to improve reliability. Dr. Singal and Dr. Zwiebel noted that sequencing is more complex than we have presented here, and this complexity increases the probability of different labs getting different results.

Anne Geiger, NCI, noted the slow uptake of estrogen receptor markers in the care of breast cancer in the past. She also commented that we have a long history of releasing screening tests, diagnostics, and treatments that were proven in a specific and small population but are then used in a large population for which there is not much evidence. She asked the panelists whether they anticipate inappropriate use of biomarker testing and treatments. Dr. Herbst responded that you have to look at the level of evidence, because if tests are used in situations where there is less data that could put a large burden on the health care system.

Dr. Fang Sun, ECRI Institute, noted that tests are being marketed for which there are currently no available agents or relevant clinical practice guidelines to guide practitioners in utilizing the results. Most cancers have a very complex genetic biology, certain cancers have been associated with multiple genes and variants, and some variants can be associated with multiple cancers. He inquired what laboratories are providing in cases of genes and types of cancer that do not have clinical guidelines to support specific testing. Dr. Singal responded that there are very few guidelines for many cancer types, and most providers are making decisions based on evidence from trials.

Christine Gunn, Boston University School of Medicine, asked about racial and ethnic disparities in clinical trials and how to combat the underrepresentation of minorities. Dr. Zwiebel responded that this is an ongoing challenge, because while there are guidelines for racial and ethnic targets for each study, ethnic and racial participation does not reflect the demographics

Cancer Care Delivery in a Rapidly Changing Healthcare System



of the country. Andrea Denicoff from NCI added that in addition to those protocols, they have a program to fund minority and underserved sites and to attempt to oversample minorities when possible.

Nivedita Misra, Kaiser Permanente, questioned where the future of guidelines is going given the increasing complexity of treatments. Dr. Herbst responded that guidelines are going to have to be in constant flux as new trials are completed and new therapies become available. He added that there is a need for guidelines to address the clinicians, regardless of discipline, who see the patients first to ensure that patients are managed optimally.

Session 2: What Is the Status of the Technologies of “Precision Medicine”?

Panel: Jeff Lerner, Elizabeth Mansfield, Gideon Blumenthal and Justin Bekelman

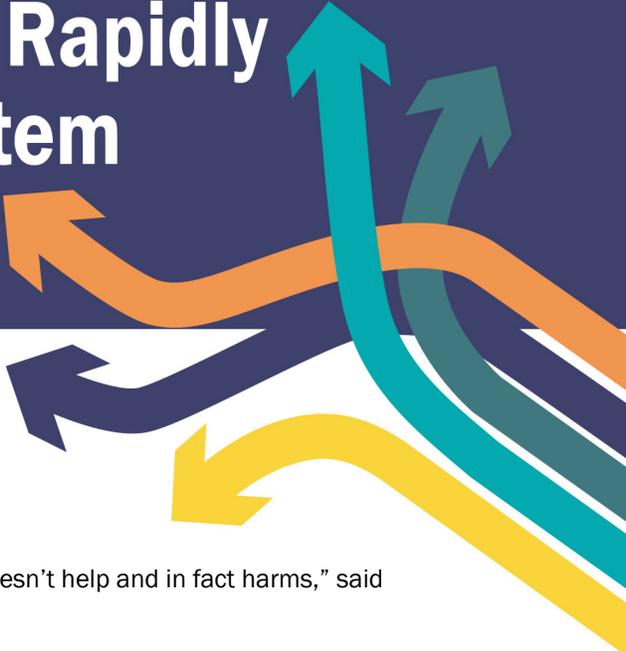
Jeffrey C. Lerner, PhD, President and Chief Executive Officer, ECRI Institute, opened Session 2, a discussion of FDA perspectives on the regulation of medical devices, oncology drugs and other technologies associated with precision medicine and the use of these cutting edge advancements in this new discipline.

Elizabeth Mansfield, PhD, Deputy Director, Personalized Medicine and Molecular Genetics, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health (CDRH) U.S. Food & Drug Administration (FDA), discussed how the CDRH thinks about precision medicine in regards to the regulation of medical devices in radiological health. In the precision medicine era, most of the devices and drugs currently being evaluated are intended to provide more precise diagnosis or treatment, such as pharmacogenetics, companion diagnostics, next generation sequencing, tailored therapeutic devices, and mobile/wearable devices.

One major policy objective of the FDA is to enable precision therapy. As targeted drugs and biologics are developed, companion diagnostics are needed to determine whether the patient has the right mutation or variant to be a candidate for that drug. In 2014, the FDA published the finalized guidance document, *In Vitro Companion Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff*, which covers the approval of companion diagnostic devices for targeted therapies, a system for matching and labeling corresponding devices and drugs, and the requirement that these are approved together.

The FDA also looks at therapeutic imaging, such as quantitative imaging biomarkers, and has helped to develop tools and methods to evaluate these markers. They are working to match patients with appropriate clinical trials and determine whether patients are responding to treatment using imaging modalities. The FDA regulates radiological therapeutic devices, including those that have greater safety and enhanced effectiveness than previous devices. For example, proton beam and stereotactic linear accelerators focus radiation on specific tissue volume and the high energy radiation exactly onto the tumor, without as much collateral damage or other organ exposure. “This is really the ‘precision’ in precision medicine,

Cancer Care Delivery in a Rapidly Changing Healthcare System



we're putting the radiation where it needs to be, and keeping it out of where it doesn't help and in fact harms," said Dr. Mansfield.

Dr. Mansfield discussed the President's Precision Medicine Initiative, an innovative approach to improving health and treating disease that takes into account individual differences in people's genes, environments, and lifestyles. The FDA's role is to modernize and develop new regulatory strategies for next-generation sequencing that involve standards to ensure quality, open-source tools to help meet those standards, and a flexible, dynamic regulatory system. They are also trying to enable discovery and knowledge generation by aggregating clinical information in curated databases to create a "data commons" that could help inform how well tests work and be used for future research and patient care.

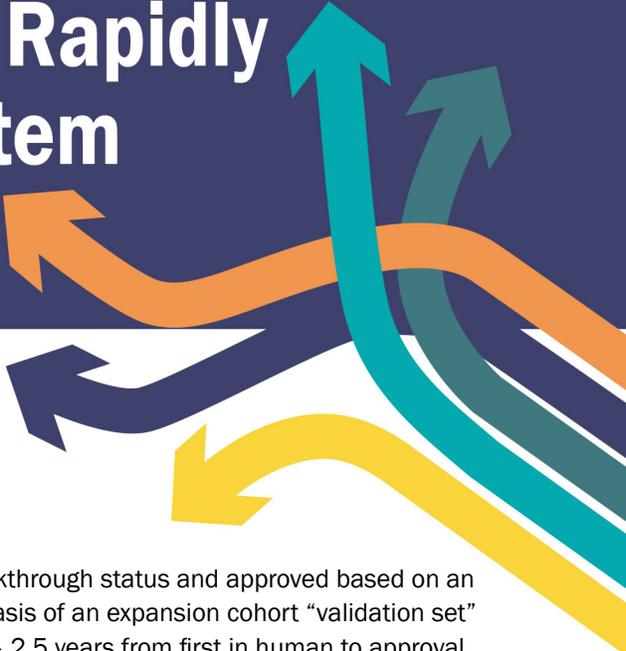
The FDA has developed several guidance documents regarding managing digital health devices that record and store information, including mobile applications. They have proactively put out guidance for developers to follow to help them rapidly develop high quality and reliable tools.

Additionally, the FDA is starting a Patient Preference Initiative to systematically elicit, measure, and incorporate patient preference information into clinical trials and device development. The FDA's Patient Engagement Advisory Committee ensures that the needs and experiences of patients are incorporated into the FDA's work in the same way that the knowledge of external experts informs the agency's work.

Gideon Blumenthal, MD, Clinical Team Leader, Thoracic and Head and Neck Oncology, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, discussed the regulation of oncology drugs. There are two approval pathways for drugs and biologics. The first is traditional (regular) approval, which is based on improvement in a direct measure of clinical benefit or an established surrogate for improved survival or quality of life. The second, accelerated approval, which was initiated in 1992 during the HIV crisis, is based on improvement in a surrogate endpoint that is reasonably likely to predict clinical benefit over available therapies. As a condition of accelerated approval, post-marketing studies must be conducted to confirm clinical benefit of the therapy. This type of approval is frequently used in oncology and, typically, the post-marketing studies do confirm clinical benefit.

The FDA has several expedited programs, including fast track, priority review, accelerated approval, and the newest program, breakthrough therapy. The breakthrough therapy designation is for drugs used to treat serious life-threatening disease, for which preliminary clinical evidence suggests substantial improvement over other available therapies. Now more than ever, drugs are being approved based on very preliminary clinical trials. About 40% of requests for breakthrough therapies are in oncology. Typical of new programs, this program presents challenges, including how to determine the right threshold for granting a breakthrough therapy designation, what constitutes currently available therapy for comparison purposes, and on what basis a designation should be rescinded. Manufacturing timelines can be a bottleneck. This has been an unfunded mandate, so this could be a resource saturation for the FDA.

Cancer Care Delivery in a Rapidly Changing Healthcare System



The lines between Phases is being blurred. For example, ceritinib was given breakthrough status and approved based on an expansion cohort in a Phase I study. Pembrolizumab was also approved on the basis of an expansion cohort “validation set” in Phase I. Novolumab and osemertinib were also approved in a very short time – 2.5 years from first in human to approval in the latter case.

The one drug/one biomarker trial paradigm is unsustainable. There are many rare variants of unknown significance (“rare is common”). The more common oncogenic drivers have been plucked – now we need to move to the rarer ones. To address the rare molecular abnormalities, the field has moved towards master protocols broadly stratified to umbrella or basket trials. Umbrella trials test the effect of different drugs on different mutations in a single type of cancer (Lung MAP). Basket trials test the effect of a drug on a single mutation in a variety of cancer types (e.g., BRAF basket trial in melanoma, colorectal cancer hairy cell leukemia, and lung cancer) Lung MAP is an example of an umbrella trial with a unique public-private partnership. The protocol has had to adapt to newly available agents and evolving standard of care. The control arms had to be reworked so that certain therapies will be tested in single arm substudies.

Dr. Blumenthal also touched on the efforts to incorporate the patient voice and patient reported outcomes into clinical trials. Efforts include validating specific patient-reported outcomes as a drug development tool and patient-focused drug development meetings.

Justin Bekelman, MD, Associate Professor of Radiation Oncology, Department of Radiation Oncology, Abramson Cancer, Perelman School of Medicine, University of Pennsylvania, talked about the adoption of advanced technology, specifically proton beam therapy, from his perspective as a practicing radiation oncologist and health services researcher. In radiation oncology, the adoption of technology has been rapid. Although this provides more access for patients to advanced technology ahead of comparative effectiveness research, it is not always clear whether it is better than current technology.

Dr. Bekelman explained the “Intervention Ladder,” concept developed in the United Kingdom (UK) to address the issue of adoption of advanced technologies. There are 8 steps of the ladder: 1.) Do nothing and monitor; 2.) Provide information; 3.) Enable choice; 4.) Guide choice through changing the default; 5.) Guide choice through incentives; 6.) Guide choice through disincentives; 7.) Restrict choice; and 8.) Eliminate choice. Each of these rungs are successively more effective in terms of how the system delivers care. On the other hand, patient choice is limited at each higher rung of the ladder. The health system is at a unique point as this relates to proton beam therapy. Proton beam therapy is a treatment that requires a massive investment (e.g., acquisition and construction-related costs); it is the most expensive medical device in the world. Therefore, the health care payer system is restricting or eliminating choice through coverage policy. However, the therapy is still at the bottom of the ladder because the comparative effectiveness data has not been generated, except in limited applications. Therefore, there is an issue applying this process.

One challenge is that different evidence generation studies look at different and sometimes conflicting primary endpoints—some more patient-centric, others more payer-centric. Another challenge of cancer medicine is that “as we get better at treating cancers, patients are living longer, and it takes longer to assess outcomes.” This has implications for clinical trial

Cancer Care Delivery in a Rapidly Changing Healthcare System



design because outcomes may be years away. When the outcome is years away, we cannot adapt until we see an outcome, unless we are willing to accept surrogate outcomes in the shorter term. Several panelists agreed that there is a need for “adaptive design” in clinical trials. Adaptive design attempts to use interim data to modify an ongoing trial without undermining its validity and integrity or introducing bias. However, Dr. Bekelman stressed that we cannot just say we are going to do “adaptive design”; we have to think harder about what that means.

Radiotherapy plays a major, curative role in the treatment of patients with breast cancer, but because of the incidental radiation to the heart, radiotherapy carries increased risks of cardiovascular morbidity and mortality. The real world effectiveness of proton beam therapy vs. photon therapy is unknown. Prior studies have been small, non-randomized and with short follow-up. The only way to determine the effectiveness of one treatment over the other is through a large, prospective, pragmatic, randomized trial in patients requiring comprehensive radiation. The Radiotherapy Comparative Effectiveness (RADCOMP) trial aims to determine the effectiveness of proton beam therapy versus photon therapy in breast cancer. This is a patient-centered and pragmatic clinical trial, which includes sites that have never participated in clinical trials. Patients and patient advocates are involved in the design and conduct of the study. The trial is randomized and assesses hard outcomes. It uses large, simple trial approaches, combining elements of the cooperative group system and long term epidemiological approaches to follow patients over time. A “radiorepository” (i.e., records of the radiation planning and delivery processes) will be used to capture treatment pathways and determine whether the trial findings can be explained in part by the quality of radiotherapy that was given during treatment. There are 25 soon-to-be operational proton beam therapy sites across the U.S. and 23 of them are part of this trial.

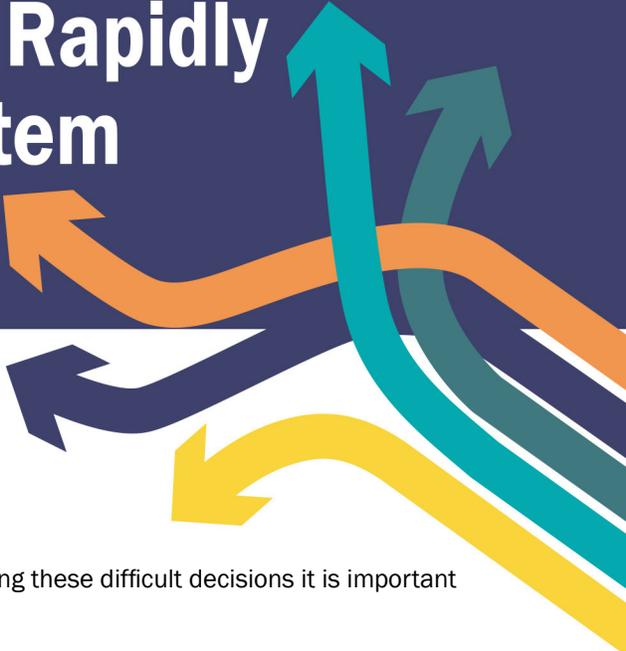
Dr. Bekelman touched on the challenge of paying for advanced technology and evidence generation for advanced technology. Should the treatments and evidence generation be paid for by the federal government and taxpayers, the device industry, commercial payers, providers and/or patients? He argued that “evidence generation for proton beam therapy requires the will and partnership of a whole community of providers, payers, patients and funders to get the evidence development done, while providing appropriate access to technology.”

Session 2: Q&A

Dr. Lerner summarized, that “it is not just the diseases and regulatory process that are changing, it’s a social change in terms of patient-centeredness and how that actually goes from being a concept to something that has to be played out in the various stages of technologies entering the health care system.”

Dr. Mansfield noted the need to balance access and certainty, between the benefit to people now with the certainty of exactly how a technology works. “If you want to be really certain that something works or exactly how it works, it’s going to take a while. You have to run clinical trials, enroll the right people, analyze them, and you may get different results from different trials. If you want access, you don’t want to wait for that. You want it now and you want to see how it works, and many patients want it now and are willing to take the risk,” she explained. The FDA is actively engaged in managing this balance. Dr. Lerner pointed out that this is taking place in a context where the FDA is under pressure to produce results

Cancer Care Delivery in a Rapidly Changing Healthcare System



faster in a more uncertain scientific world. Dr. Blumenthal added that when making these difficult decisions it is important for regulatory bodies to always think about the end user, the patient.

Peggy Eastman, *Oncology Times*, asked Dr. Bekelman whether he is concerned that there has been rapid acquisition of proton beam therapy and whether rapid adoption should be reined in until evidence is acquired. Dr. Bekelman responded that across advanced technologies there is some appropriate adoption and some adoption ahead of comparative effectiveness. Though it feels rapid, it's too soon to say that it is too rapid.

Diane Robertson, ECRI Institute, asked, "What happens when a new technology comes into the field to mitigate a long term outcome that you're assessing in an RCT?" In response, Dr. Bekelman noted that they often deal with the question of how to make sure that the results and the comparators that they are studying are relevant when the RCT is actually completed. There are two ways to think about this. One is adaptive design. The other is to query centers, and ask that if they move to a new technology they report whether it is an effect modifier—i.e., whether it mediates the relationship between the treatment and outcome. The problem is not new and each trial will individually account for this situation.

Diane Roberson questioned how the FDA is able to ensure that post-market study requirements are met for devices that are approved with this stipulation. Dr. Blumenthal agreed that this is a concern when giving accelerated approval, but the FDA does have periodic advisory committees to obtain status checks regarding these requirements and there are financial penalties if post-marketing studies are not completed.

Dr. Sharyl Nass, IOM, expressed concern that the same centers participating in the studies are advertising that they are using the latest and greatest technologies and claiming to provide better outcomes. She asked how these centers are handling the informed consent process with patients in light of such marketing. Dr. Bekelman agreed that this is a crucial issue that he deals with when enrolling patients in clinical trials and treating them with new therapies. He noted the need for funders, researchers, and physicians to address the uncertainties with patients.

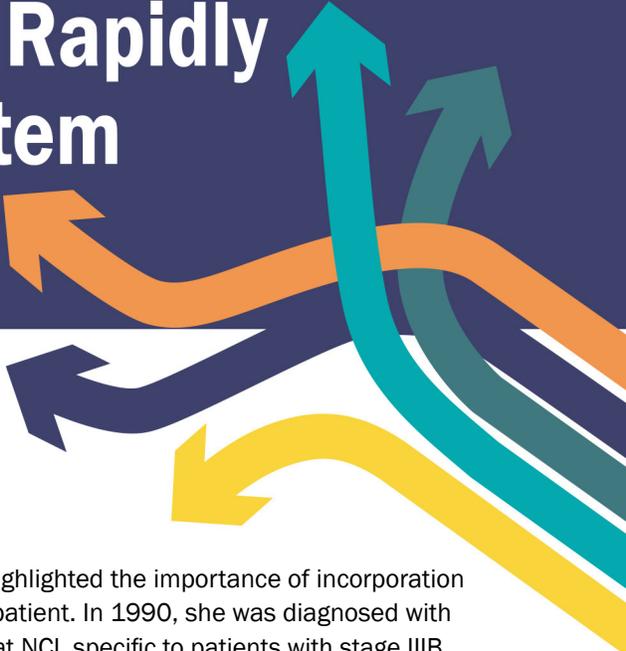
Another participant commented that there is a significant body of literature to show that patients make the wrong choices for the wrong reasons, based in part on expectations and marketing. He expressed concern about relying on the patient-centric push for regulation and reimbursement.

Session 3: The Complex, Intertwined Role of Patients in Research and Care

Panel: Joe Selby, Jane Reese-Coulbourne, Joseph Chin and Grace Ma

Joe V. Selby, MD, MPH, Executive Director, Patient-Centered Outcomes Research Institute (PCORI), introduced session 3, in which presenters addressed the patient's role in shared decision-making and the evolving role of patients in research. He noted that "involving patients in research is just as important as involving patients in their own care."

Cancer Care Delivery in a Rapidly Changing Healthcare System



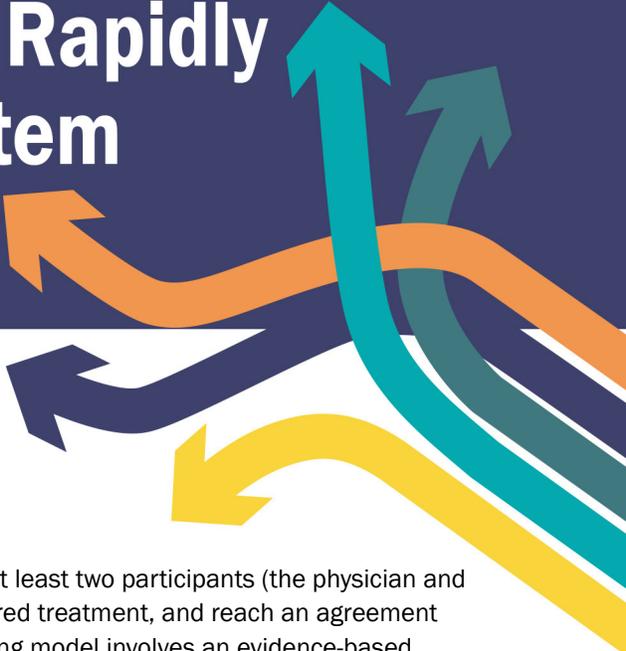
Jane Reese-Coulbourne, MS, ChE, Executive Director, Reagan-Udall Foundation, highlighted the importance of incorporation of the patient perspective in cancer treatment from her perspective as a cancer patient. In 1990, she was diagnosed with stage IIIB breast cancer and chose to be treated in a Phase 2 dosing clinical trial at NCI, specific to patients with stage IIIB and IV inflammatory breast cancer. She helped start the National Breast Cancer Coalition, with the main goal of giving patients a seat at the table to provide the patient perspective. She was also involved in starting the Reagan-Udall Foundation for the FDA, a group created by Congress to support the scientific mission of the FDA and advance regulatory science, and combine science, critical appraisal, and patient perspective. The foundation fosters collaborations among patient groups, industry, academia, and FDA scientists to design and conduct regulatory science research. When placing patients on steering committees they found that patients were overwhelmed, intimidated and did not believe that they could contribute due to the technical and scientific nature of the conversation.

This led the Reagan-Udall Foundation to seek PCORI funding for the program, Big Data for Patient Advocates, which aims to give patients background knowledge and an understanding of the research landscape, as well as to teach the vocabulary and critical appraisal skills necessary for participating in the conversation. “What our hope is at Reagan-Udall is that this will be the beginning of a series of regulatory science training programs for patient advocates,” she said, and stressed that patients cannot participate if they cannot follow the conversations. Their goal is to help patients assess information rather than be subject to commercial hype, determine what is clinically relevant, and ask questions that will elicit useful data. Ms. Reese-Coulbourne also touched on the challenge of understanding the diversity of the patient population and incorporating the voice of representatives from different subpopulations.

Joseph Chin, MD, MS, Acting Deputy Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services, gave an overview of CMS’ novel approach to incorporating shared decision-making by tying it to Medicare coverage determination. The Medicare population includes 54 million beneficiaries, which includes patients who are 65 years and older, disabled or have end-stage renal disease (ESRD). They cover 95% of the older adults in the U.S. By definition, CMS makes coverage determinations based on whether services are “reasonable and necessary” for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” In 2008, CMS received authority to add services if they were reasonable and necessary for prevention. Medicare is a defined benefit program, which delineates beneficiaries, benefit categories, providers, and settings, and decisions are focused within these constraints when determining whether to add services to Medicare.

Dr. Chin noted that recently there has been significant discussion about value in health care. The cost of health care compared to the GDP in the U.S. is higher than anywhere else in the world. He mentioned the perspective published in the *New England Journal of Medicine*, *Setting Value-Based Payment Goals – HHS Efforts to Improve US Health Care*, in which Sylvia Burwell described the goal of moving from paying for volume to paying for value in Medicare. Dr. Chin quoted Andy Slavitt, Medicare’s acting administrator, as saying “Our priority is to drive a health care system that provides better care with a smarter payment system that leads to healthier people.” From a Medicare coverage standpoint, value starts with evidence of meaningful health outcomes for the population. Medicare’s primary focus is the beneficiary.

Cancer Care Delivery in a Rapidly Changing Healthcare System



The model of shared decision-making has several key characteristics: there are at least two participants (the physician and the patient), both parties share information, they build a consensus about preferred treatment, and reach an agreement regarding what treatment is implemented. Additionally, the shared decision-making model involves an evidence-based decision aid or tool. Dr. Chin explained that shared decision-making is important for the Medicare program because as new technology and treatment options are introduced, it is an important step to reach better care for the patient, focus on the outcomes that are important to patients by involving them in their own care, and achieve greater patient satisfaction.

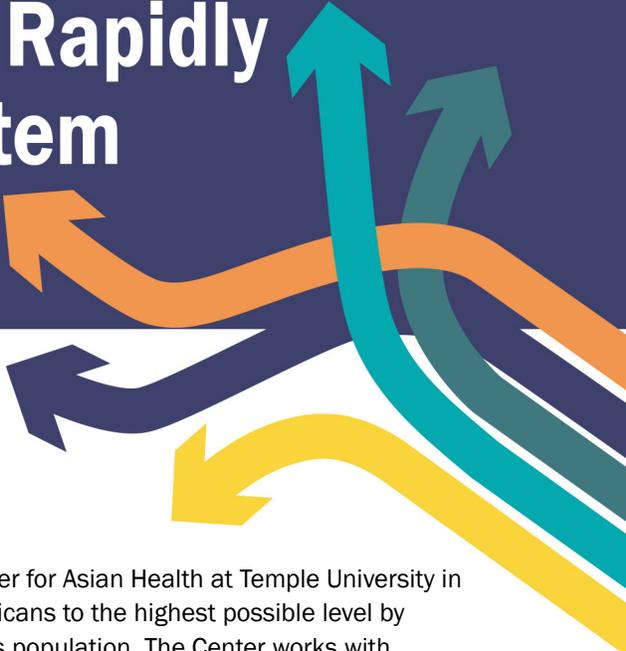
Dr. Chin used the example of lung and bronchus cancers, which are most frequently diagnosed among people aged 65 to 74, are the second most common cancer in this population, and the most common cause of cancer deaths for cancer patients. They have been monitoring evidence as it has developed and, based on the results of the National Lung Screening Trial, CMS added Medicare coverage of lung cancer screening with low dose CT for eligible beneficiaries performed at specified radiology centers. Coverage carries a requirement for an initial shared decision-making visit. This visit is an opportunity for a thorough discussion between the patient and the provider to make sure that this is the right course for the particular individual. Dr. Chin added that “shared decision-making is a new concept in Medicare from a coverage standpoint and it recognizes the role of the patient in actually determining a subsequent course of treatment and actions.” As physicians gain experience from the initial shared decision-making visits, they will be able to refine how they approach and structure shared decision-making.

Grace X. Ma, PhD, Laura H. Carnell Professor of Public Health; Director, Center for Asian Health; Director, National Asian Community Cancer Health Disparities Center; College of Public Health, Temple University; Member, Fox Chase Cancer Center, Temple University Health System, addressed the health care disparities in cancer care in the underserved Asian-American population. She introduced the concept that an individual’s health is shaped by a variety of factors, the social determinants of health, which include an individual’s social circumstances, environment, behavioral and cultural elements. These factors determine their health seeking behaviors, health services utilization, whether they participate in RCTs, and overall health outcomes.

The Asian-American population is the fastest growing racial group in the U.S. It is projected that by 2050, there will be around 40 million Asian-Americans in the U.S. This is a substantially diverse group in ethnicity as well as socioeconomic status, English proficiency, health needs, and cultural identity, beliefs and behaviors. Asian-Americans are the only U.S. population suffering cancer as the leading cause of death. Asian American women have the lowest rates of breast cancer screening and are typically diagnosed at a later stage compared to other ethnic groups. They also have the highest rates of liver and stomach cancer. Asian-Americans have the lowest level of understanding of physicians’ directions, the lowest satisfaction with care, and are less likely to receive reminders for preventive care.

Dr. Ma stressed the need to get Asian-Americans to participate more in the health care system. Statistically, only 2-3% of minority populations are participating in RCTs. In order to advance precision medicine, it is critical to conduct RCTs that engage minority populations and are culturally relevant. Dr. Ma is working with providers to raise the awareness of the

Cancer Care Delivery in a Rapidly Changing Healthcare System



needs and disparity barriers of the populations they serve. She founded the Center for Asian Health at Temple University in 2000, which seeks to raise the physical, mental, and social health of Asian-Americans to the highest possible level by identifying culturally appropriate, cost effective, and feasible interventions for this population. The Center works with community groups to educate leaders and participants, devise training programs, and play a role in providing clinical support and patient navigation. Bridging the gap between medical culture and patient culture is an important part of navigating the health care system. The full intervention spectrum of this work includes engaging health care providers, shared decision-making and engaging community leaders.

Future research directions include working across settings to develop effective and culturally appropriate interventions to reduce cancer-related health care disparities, disseminating and implementing evidence-based interventions, engaging communities in participatory research, and continuing mentorship and training of next generation population scientists.

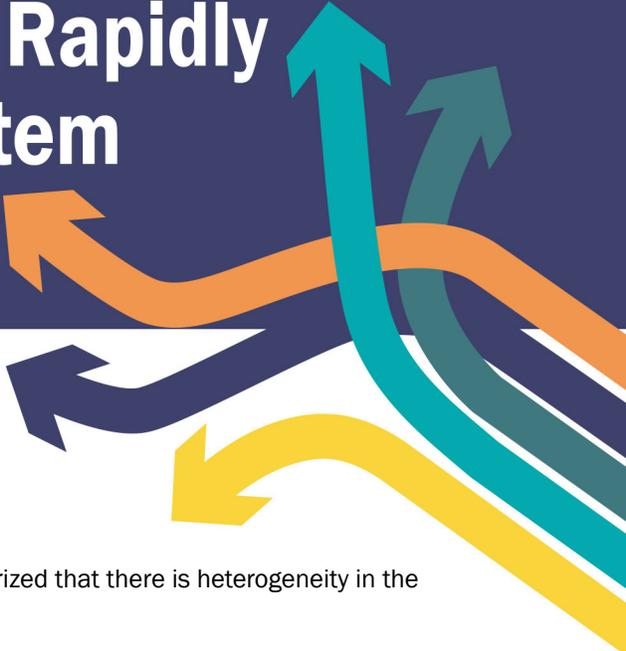
Session 3: Q&A

Dr. Selby asked the panelists how physicians should implement shared decision-making in diverse populations. Dr. Ma further questioned how we can educate patients and create shared buy-in. Dr. Chin responded that this is a good broad question about how to overcome the initial denial by patients about their risk. He said it is important to engage the patient initially to get the conversation started, and then using evidence show them they have risk factors and that the screening will lead to improved outcomes. Ms. Reese-Coulbourne added that peer-to-peer discussions has shown to be helpful in special populations and could be helpful in cancer care to help patients process information.

David Atkins, Veterans Health Administration, commented that when it comes to difficult decision making he lays out the patient's options, but most patients ask, "If this were you, what would you do?" He posited that patients may be overwhelmed and want to be relieved of the burden of making complex decisions. They struggle to synthesize all of the information and options and want the physician to make those decisions for them. "We can lay out options but the large majority simply cannot deal with it," he said. Ms. Reese-Coulbourne agreed that during one of the most stressful parts of the patient's life, it is difficult for them to digest the vast amount of complex information and make a decision. However, she suggested an iterative approach to educating patients, summarizing the available options for patients, allowing them time to digest the information, and including peer counseling and family involvement in decision making.

Dr. Atkins commented that it is a real burden to the family to think they might make the wrong decision and doctors relieving that burden is important. Dr. Ma noted the critical need to help patients understand the information and their options by turning medical jargon into plain language and developing plain language tools that are available in different languages. Dr. Chin added that it is important to provide patients with the evidence of improved outcomes, where that evidence exists. "We have seen a change in the way patients approach their encounters with physicians. Many of the older beneficiaries do have that type of position where they leave much of the decision making up to the physician. With the availability of data and additional information, I think patients in the younger generation are more accustomed to considering the data and

Cancer Care Delivery in a Rapidly Changing Healthcare System



their decisions and actually engaging with physicians,” he said. Dr. Selby summarized that there is heterogeneity in the types of decisions and growing heterogeneity in the type of patients.

A participant asked why there is counseling before the prostate-specific antigen (PSA) test or other routine screenings, rather than just performing the tests. Dr. Ma stated that PSA is not recommended for every patient, so shared decision making is particularly important. Dr. Chin added that there must be a consideration of benefits and harms prior to performing any screening test.

Michelle Sparrow, from the University of Pennsylvania Health System, provided an example of a patient visit for a cancer patient that included an explanation of options for treatment, determining the patient’s goals and joint decision making. That visit took an hour and 20 minutes. She commented that cancer care is increasingly complex and rapidly changing, and there is pressure for physicians to increase efficiency, reduce costs, increase documentation for program compliance. She asked, “How do we collectively reduce the anguish that cancer causes and protect the relationship between the patient and physician?” Ms. Reese-Coulbourne agreed that it is a challenge to provide that level of time and care for individual patients. Dr. Ma added that shared decision-making may not apply to all situations, and is most useful when there is uncertainty about benefit or potential for harms. When a choice is straight-forward, such as when it is based on an evidence-based guideline, shared decision making is less of a priority.

Elizabeth Liles, from Kaiser Permanente Center for Health Research, asked how patients who speak different languages and have different literacy levels are included in shared decision-making, particularly within a short office visit. Dr. Chin responded that, because this is new, there is a lot of work to be done in understanding how to structure future visits and make them more efficient. One way to achieve that may be to have information that would help the patient prior to the visit.

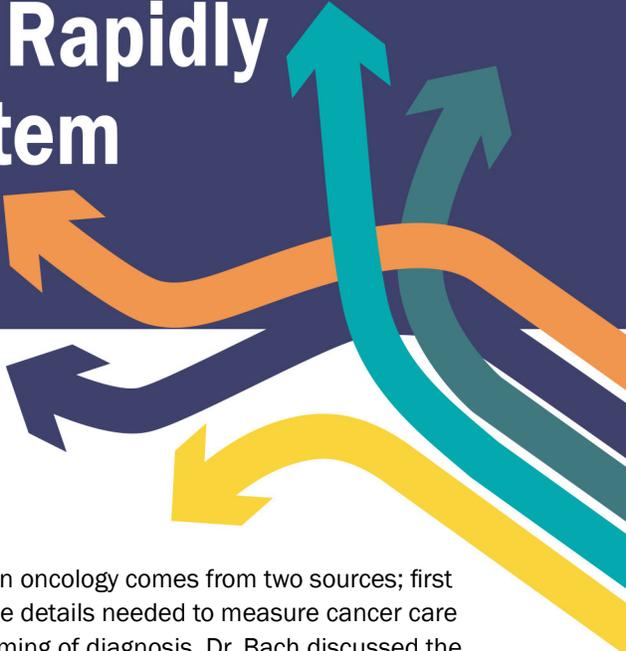
Session 4: How is Quality Perceived and Measured When Cancer is a Chronic Condition?

Panel: Lisa Simpson, Peter Bach, Susan Larsen Beck and Jennifer Malin

Lisa Simpson, MB, BCh, FAAP, President and CEO, AcademyHealth, introduced session 4, which addressed variability in quality and the relationship of quality to cost.

Peter B. Bach, MD, MAPP, Director, Center for Health Policy and Outcomes, Memorial Sloan Kettering Cancer Center, discussed the significant performance and payment differences between hospitals related to their quality of cancer care, for both Medicare and private payment plans. Other clinical conditions have accelerated ahead of cancer care with regard to the issue of performance.

Cancer Care Delivery in a Rapidly Changing Healthcare System



The perceived impediments to assessing performance and payment differences in oncology comes from two sources; first is the need to figure out who gets the attribution for the care, and second, that the details needed to measure cancer care quality cannot be pulled out of administrative claims data, such as staging and timing of diagnosis. Dr. Bach discussed the challenge of risk adjusting survival outcomes in hospitals that treat patients with cancer. Using Medicare cancer registry data, AcademyHealth found that across all cancers, hospital performance differs for 30-day mortality rates and five-year survival rates, up to 10 percentage points. However, without stage and diagnosis information, they may have misattributed patients or erred in assigning risk, causing a bias in the data. They re-did the analysis with the Surveillance, Epidemiology, and End Results (SEER) dataset which included staging and timing of diagnosis data to determine whether the performance stayed the same. After comparing the Medicare data to the SEER data they found that the absence of staging data should not affect performance rankings. They then addressed whether the performance differences could be due to the “referral center effect,” meaning performance appears better because of the migration of healthier patients. Although the phenomenon is real, and patients who travel further to hospitals have better outcomes, it was not statistically significant and not enough to bias the results.

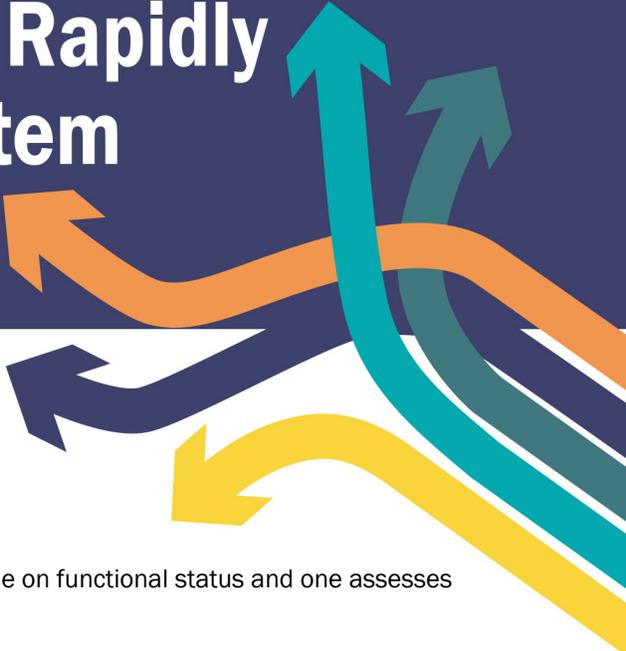
Susan Larsen Beck, PhD, APRN, FAAN, AOCN, Robert S. and Beth M. Carter Endowed Chair, College of Nursing, University of Utah, addressed the issue of how health care quality is perceived and measured as it pertains to cancer as a chronic condition. She quoted Carolyn Clancy as saying, “Health care quality is getting the right care to the right patient, at the right time, every time.” The Institute of Medicine (IOM) has defined quality as “care that is consistently safe, timely, effective, efficient, equitable, and patient centered.” She outlined the current work at different levels of the health care system to improve the quality of cancer care.

The Accountable Care Act (ACA) focuses on quality, specifically through the National Quality Strategy (NQS). The NQS is focused on six priorities: 1.) Making care safer by reducing harm caused in the delivery of care, 2.) Ensuring that each person and family are engaged as partners in their care, 3.) Promoting effective communication and coordination of care, 4.) Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease, 5.) Working with communities to promote wide use of best practices to enable healthy living, and 6.) Making quality care more affordable for individuals, families, employers, and governments by developing and disseminating new health care delivery models.

Other relevant ACA features include a focus on comparative effectiveness research, new payment models (bundled, accountable care, value based purchasing, pay-for-performance or outcomes-based), the CMS Innovations Center, the National Prevention Strategy, care coordination, and the reduction of waste, fraud and abuse in the health care system.

The National Quality Forum (NQF) has become the gold standard for endorsing measures that meets requisite criteria for being an acceptable measure of quality. NQF’s goals overlap with features of the NQS and NQF-endorsed measures have been used extensively by CMS in pay-for-performance initiatives. NQF has approved 68 measures for cancer, however, only 12 measures focus on cancer as a chronic illness and most of these address advanced cancer and end-of-life care. Only two

Cancer Care Delivery in a Rapidly Changing Healthcare System



measures are specifically focused on the period of cancer as a chronic illness, one on functional status and one assesses the presence of a treatment summary specific to radiation therapy.

The American Society of Clinical Oncology (ASCO) has also been a leader in the cancer quality measurement field, specifically in developing and measuring against benchmarks. Within ASCO's certification program, they have developed 165 ambulatory care measures for oncology medical practice. The related measure framework includes core modules, domain modules, disease modules, and care pathways. However, Dr. Beck argued that "one could make a case that we are really missing that whole period of care in terms of follow-up, except at the very end." To advance this work, ASCO took the initiative to host a collaborative quality summit in 2012 bringing together professional organizations within oncology to prioritize the work for quality measurement. ASCO is also developing a system called Cancer-LINQ, a learning intelligence network for quality. "In my opinion, I think they are really leading the field in thinking about the notion of a learning health system," Dr. Beck said. The idea is to develop an information system that provides real-time quality feedback to providers, real-time clinical decision support, and helps to look at patterns of care from a quality perspective. This will help to create big data in oncology care, which provides other opportunities for improvement.

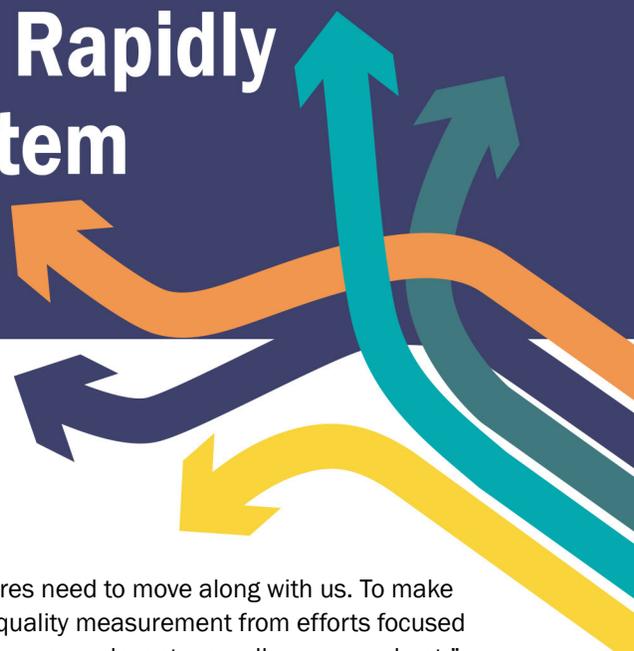
In 2012, the American College of Surgeons Commission (ACS) on Cancer set new standards for cancer care which included the provision of treatment and survivorship plans, including written summaries of care and follow-up care, palliative care services, genetics services, a navigation program and psychosocial distress screenings. "These are all new standards that are influencing the health care delivery system," Dr. Beck noted.

The Oncology Nursing Society's (ONS) breast cancer survivorship measures, developed with support of a grant and in conjunction with The Joint Commission, address symptom management, education, individualized goal setting and follow-up care in the ambulatory setting. These measures were tested in 62 clinical sites across the country and the initial results showed significant need for improvement. For example, the composite rate for symptom assessment was only 5% and for intervention was only 1.8%. The ONS and ASCO measures are based on medical record review, which Dr. Beck noted the need to move away from.

She defined challenges of measuring cancer care, which include the time spent measuring and improving quality, integrating quality into real-time clinical care, measuring the right thing, managing quality and cost, and improving quality throughout the cancer experience. Measuring quality will change with precision medicine and the learning health system, but it is unclear how.

Jennifer Malin, MD, PhD, Staff Vice President, Clinical Strategy, Anthem, further highlighted the challenges in measuring the quality of cancer care. The IOM identified several issues in cancer care currently, including that 1.) Care is often not patient-centered, 2.) Many patients do not receive palliative care, and 3.) Decisions are often not based on the latest scientific evidence. The IOM recommends a national quality reporting program with meaningful quality measures, improving the affordability of cancer care, and aligning reimbursement to reward affordable, patient-centered, high quality care. In order to achieve these goals, Dr. Malin suggested that we need an evolving continuum of quality measures, noting that "as

Cancer Care Delivery in a Rapidly Changing Healthcare System



we move from surveillance, to quality improvement, to accountability, our measures need to move along with us. To make progress on the quality and affordability of cancer care will require that we shift quality measurement from efforts focused largely on surveillance and quality improvement to accountability. They need to be more relevant, as well as more robust.”

There are currently gaps and a lack of NQF-endorsed cancer quality outcomes measures, including too few measure of overuse, and almost no patient-centered outcome measures. She also reiterated the challenge that Dr. Beck pointed out—that most of the measures that have clinical detail require chart abstraction. The other way to get to any level of clinical detail is to merge claims data with registry data, but that has proven to be fairly restricted in quality measurement because access to cancer registry data is generally limited until at least a couple of years after patients have completed treatment. Dr. Malin stressed that measures are not specific enough and scores from different facilities are often so similar that they aren’t useful for public reporting or pay-for-performance. When there are low scores, it is more often a problem with the data rather than with the quality of care. “We have to make sure if we’re going to measure and report on quality and pay people for quality, that we have good data.”

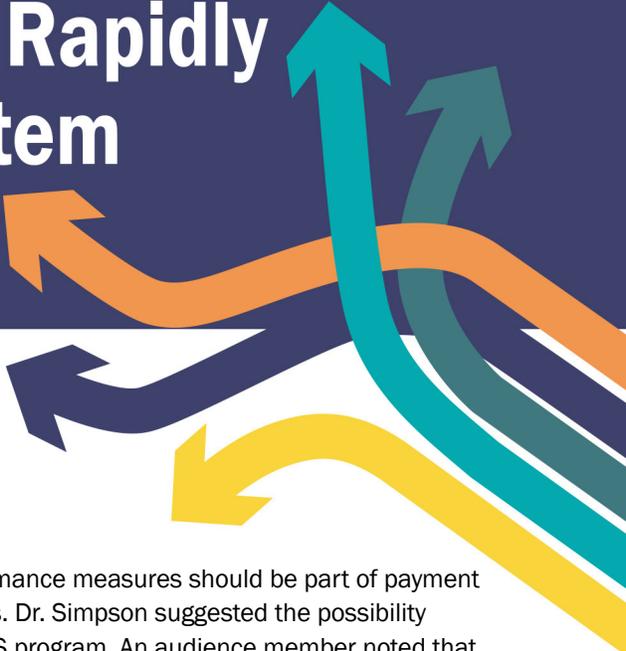
Anthem’s Cancer Care Quality Program collects data on quality of care in real-time and provides additional reimbursement to oncology practices when they select a treatment regimen that is on a cancer treatment pathway. In this program, clinical data is entered by practices through a web platform, and allows for the collection of data including cancer type, disease stage, biomarkers, performance status, and line of therapy. This data will be used along with medical and pharmacy claims to provide reports back to practices that include their adherence to treatment pathways and six evidence-based NQF-endorsed measures. The goal is to build this program to provide real-time information on mortality, length of stay, comparisons of procedures, tests, visits, service frequency, cost, and quality.

Session 4: Q&A

Dr. Simpson asked the panel to speak to the promising developments in cancer care quality improvement. Dr. Bach responded, as opposed to previous “yes/no” process measures, the move toward looking at treatment pathways is a promising development in cancer care. Dr. Malin commented that there is more attention and interest in quality improvement in oncology than ever before and agreed that one of the biggest and most systematic approaches to improving quality of care is the focus on treatment pathways. Dr. Beck noted the Journal of Oncology Practice has a feature that highlights best practices in quality improvement. Dr. Bach added that “in oncology, we have moved into the culture, of accepting that we fall short of perfect,” which is a transition from skepticism 20 years ago about the reports of quality problems in health care. There have been a number of improvements but we have a long way to go.”

Dr. Simpson asked the panelists how to address the gaps in quality measurement as well as to speak to who should be funding measurement science, specifically to understand how to design good patient reported outcome measures. Dr. Malin noted that most measures being proposed are by professional societies with interest in getting paid through quality measurement programs and “without public funding there are not going to be measures that are important to consumers and patients. We need public funding for quality measures.” Dr. Bach added that there is a need to capture more information

Cancer Care Delivery in a Rapidly Changing Healthcare System



from patients in a systematic way. Dr. Bach suggested that comprehensive performance measures should be part of payment initiatives and that there is a need for the development of true outcome measures. Dr. Simpson suggested the possibility that AHRQ fund the development of patient reported outcomes through the CAHPS program. An audience member noted that AHRQ is currently working on Cancer CAHPS.

Dr. Caroline Poplin, a primary care physician and health policy analyst with the Altarum Institute noted the concerning idea that treating patients on designated pathways may not be what the patient wants and may be in conflict with shared decision-making. She added, related to pay-for-performance, “It seems that people in measurement working with management feel that unless you reward a physician for doing the right thing, they won’t do it, that they don’t want to improve quality and they have to be forced to improve quality and that’s not very attractive.” Dr. Simpson agreed that there is “tension among measurement, accountability, quality, and physician autonomy.” Most of the time there is a gap between robust evidence of effectiveness and what practitioners are doing. In her opinion, historically, payments been incentivizing some of the wrong behaviors. Dr. Malin noted that Anthem’s program is set up in a way that they are not micromanaging physicians and that there is always room for patient choice. In the past, oncologists have made more money when they prescribed more expensive treatments. In order to provide more patient-centered services, there must be other ways of funding the practice. To combat this issue, Anthem provides a \$350/per patient/per month payment to physicians to support cancer patients and their treatment. They are working to find a balance between supporting physician autonomy, improving the transparency around quality of care, and supporting value-based practice. Dr. Bach said, “I think we have to be smart about giving as much ability to patients to make their own choices, but staying in the bounds of evidence. Walking that line is very difficult and financial incentives do play a role.” Dr. Beck added that patients also make decisions once they leave the office, and that’s an area that we have not paid enough attention to. This is a missing piece on the continuum of care: what happens when the patient leaves the office?

Dr. Simpson asked the panelists to touch on the issue of costs and the tension among quality, outcomes, and cost, particularly as this relates to expensive new therapeutics. Dr. Bach responded that he has been focused on drug prices, which account for 19% of spending in Medicare and noted that this is the only area where Medicare is not using fee schedule or an organized approach of anchoring prices. “The link between cost and quality is essentially an abstract notion with little tangible evidence that we do it in any particular way,” he said. Currently, drug prices are completely separated from any metric of quality or value. He stressed that this is an important area for focus now. We could start to arrive at prices based on the attributes of treatment, but to map that into other areas of cancer care or health care in general is complicated. Dr. Malin added that IOM’s quality and reimbursement loop is compelling because they put cost and quality outcomes are in the same bucket. “There is an inferred relationship that better quality has to cost more, and we have to stop thinking that way. We have to think about how we can improve quality and lower cost at the same time,” she said.

Dr. Simpson asked the panelists, “Five years from now, what is going to be the big advance in the quality of cancer care?” Dr. Malin said it would be transparency. Dr. Beck said that patient experience will be measured and improved in real-time.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Session 5: How to Make Paying for Value Valuable

Panel: Alan Weil, Shari Ling, Lee Newcomer and Richard Roberts

Alan Weil, JD, MPP, Editor-in-Chief, Health Affairs, introduced session 5 in which presenters addressed tying payment to quality in cancer care and the broader movement in the health care system toward paying for value and moving away from volume-based payment.

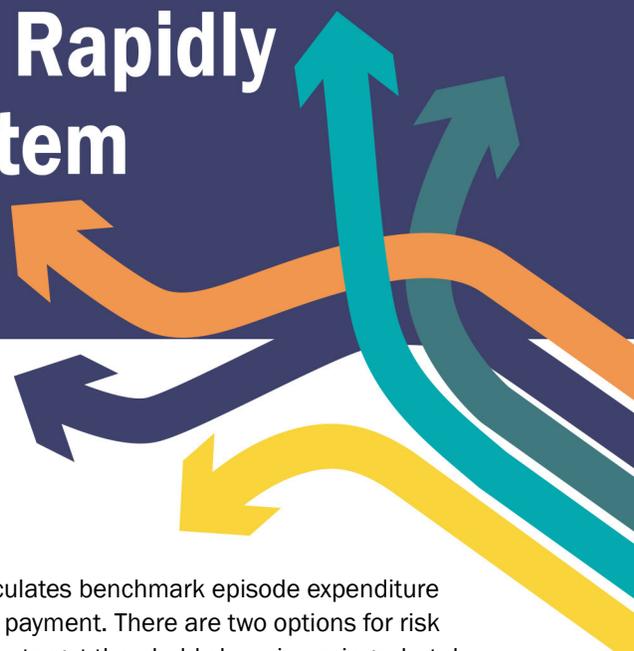
Shari M. Ling, MD, Deputy Chief Medical Officer, Centers for Medicare & Medicaid Services; Director, Center for Clinical Standards and Quality opened with the notion that the cost of oncology care in the U.S. is rising faster than the general cost of medical care, as reported by IOM in 2013. In the U.S., 1.6 million people are diagnosed with cancer each year and approximately half are Medicare beneficiaries. Across regions, cost is rising without significant differences in outcomes. However, cost significantly varies across regions, suggesting opportunities for improvement. Building on earlier comments about person-centered care and the need to consider the complexity of the cancer population, she added that “it is the person that has cancer, and the person that has cancer has many other competing conditions.” It is important to keep that in mind when delivering care; cancer as a single condition is present less than 10% of the time. Oncology care is medically complex, fragmented, and often difficult for patients to navigate.

Dr. Ling described three vehicles of change that have been put forth by the HHS Secretary. The first is paying for value, a shift from paying for individual services or volume. The second is alternative payment models that will affect the way health care is practiced. The third is transparency – sharing information through a data-driven, evidence-based approach. To highlight how quickly the health care landscape is changing, she noted HHS’s aggressive goal that 30% of care be delivered by alternative payment models by 2016 and 50% by the end of 2018. Additionally, quality or value will be tied to care in 85% of instances by the end of 2016, which will go up to 90% by 2018.

CMS’ Innovation Center is testing new care and payment models to improve quality and reduce costs, including comprehensive primary care initiatives and bundled payment efforts. Dr. Ling gave an overview of the Oncology Care Model Fee for Service (OCM-FFS) model. The OCM-FFS is an episode-based payment model for all types of cancer, targeting chemotherapy and related care during a 6-month period following the initiation of chemotherapy treatment. The model emphasizes practice transformation and focuses on total cost of care. Practice transformation is driven by OCM’s 6 practice requirements: 1.) Provide 24/7 patient access to an appropriate clinician who has real-time access to patient’s medical records, 2.) Use an ONC-certified EHR, 3.) Utilize data for continuous quality improvement, 4.) Provide core functions of patient navigation throughout the health system, 5.) Document a care plan for every OCM patient that contains the 13 components in the IOM Care Management Plan, and 6.) Treat patients with therapies consistent with nationally recognized clinical guidelines.

OCM-FFS risk adjusts for several factors that affect episodic expenditures, including beneficiary characteristics, episode characteristics, disease characteristics, and types of services furnished. Risk adjustment after the first year may incorporate

Cancer Care Delivery in a Rapidly Changing Healthcare System



additional factors not captured by claims data, such as cancer staging. CMS calculates benchmark episode expenditure and if practices are below this expenditure they may receive performance-based payment. There are two options for risk arrangement: one-sided risk where participants who reduce expenditures below a target threshold share in savings, but do not share in the cost if they exceed the expenditure. Conversely, two-sided risk allows for greater shared savings, but participants are solely responsible for expenditures that exceed the target price. However, there is also a minimum threshold of expenditure in place to guard against the stinting of care or limiting access to needed services.

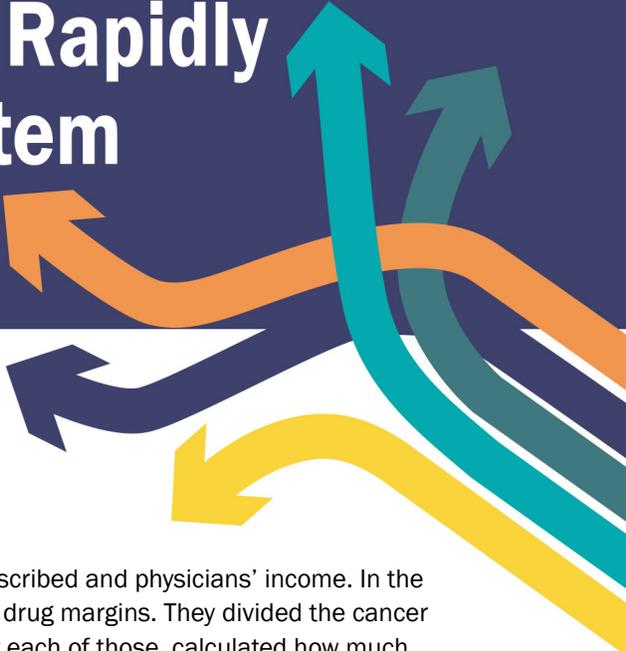
The amount of performance-based payment may be changed based on the participant's improvement on a range of quality measures that seek to converge cost and quality towards value. Preliminary quality measures reflect the NQS priorities and fall into the following measure domains: clinical quality of care, communication and care coordination, person-and care-giver-centered experience and outcomes, population health, efficiency and cost reduction, and patient safety. Monitoring and evaluation efforts are also in place that include tracking of claims data, patient surveys, site visits, analysis of quality measurement data, time and motion studies, and medical record audits.

The OCM learning system supports participants in learning from each other through an online portal allowing sharing of resources, tools, ideals, data-driven approaches to care and collaboration to explore critical topic areas in oncology. Additionally, site visits are performed to better understand how practices manage services, use evidence-based care, practice patient-centered care, and when necessary provide coaching to help practices overcome barriers to improvement.

Lee Newcomer, MD, MHA, Senior Vice President, Oncology, Genetics and Women's Health, UnitedHealthcare, talked about UnitedHealthcare's experiment in performance and value-based payment. He described their two methods of performance payment, episodes and bundles. An episode payment provides a single payment for all of the services needed by a patient for an entire episode of care. This reduces the incentive to overuse unnecessary services within the episode, and gives health care providers the flexibility to decide what services should be delivered. Episode payments are set up as gainsharing. "There is only an upside, there is no downside," he explained. Physicians can receive increased episode payments by improving their results as compared to other physicians. Episodes are limited to one specialty (medical oncology) and stratified by cancer type and tumor stage. For episodes, the payer assumes complete analytic burden and a comparison group is required for them understand how the episode performs and determine payment. In comparison, he noted "bundles are complete risk, upside and downside." UnitedHealthcare has one oncology bundle that addresses multi-disciplinary oncology care. One payment is made to the provider and the provider assumes all care for the patient for the next year. For bundles, the analytic burden is on the provider to understand whether they made or lost money and no comparison group is required. These approaches were designed to reward oncologists for quality patient care while simultaneously severing the link between drug selection and income.

UnitedHealthcare launched an episode payment pilot in 2009 focused on oncology services, rewarding physicians for improved quality and reduction in total cost of cancer care. In order to help facilitate this they provided the physicians with data to help them understand the issues and opportunities. Furthermore, the program separated the oncologist's income

Cancer Care Delivery in a Rapidly Changing Healthcare System



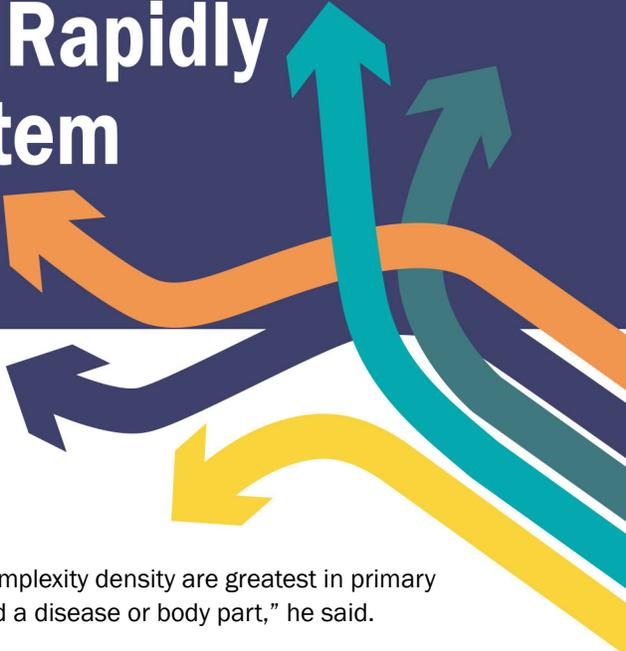
from drug sales. They completely severed the relationship between the drugs prescribed and physicians' income. In the current fee-for-service system, oncologists make about 70% of their income from drug margins. They divided the cancer types into 19 categories, determined the most appropriate treatment regimen for each of those, calculated how much money physicians would make in drug profits, and provided a frozen episode fee that covered that margin, thereby keeping the episode payments unchanged with drug changes. Performance was measured annually and episode payment was changed only with lower total cost or improved outcomes. They found that practices using episode payment cost 64 million dollars, whereas the control group cost 98 million dollars. Additionally, patients had extended access and far fewer hospitalizations.

Dr. Newcomer discussed lessons learned, and noted that the best way to reduce cost is to improve quality, collaboration trumps negotiation, and it is critical to measure success using rigorous methods. They are currently expanding this program and hope to use it nationwide. Future work continues with comparative effectiveness, specifically requiring online prior authorization that provides enough information to determine National Comprehensive Cancer Network (NCCN) guideline-recommended treatment regimens. "There is huge opportunity for thinking about value in the oncology space," he said.

Richard Roberts, MD, JD, Professor, Family Medicine, University of Wisconsin; Past President of the World Organization of Family Doctors, the American Academy of Family Physicians, and the Wisconsin Medical Society, discussed his community-based primary care perspective on how to make paying for value, valuable. Since 2008, health care has been focused on the Triple Aim: improving the patient experience of care (including quality and satisfaction), improving the health of populations, and reducing the per capita cost of health care. Dr. Roberts noted a more recent fourth aim which is to "do all of this in a way that improves morale and satisfaction of health care workers." He stressed that we are in the midst of a growing health care workforce crisis. "The challenge, when we look to bend the cost curve, is that we have a limited number of strategies," he explained. We can pay people per service, in which case we get more service or volume. We can pay per condition—such as in bundling—which may lead to less service as people look to cut corners, by person—also known as capitation—which has the same risk of potentially cutting service.

He addressed the challenges of addressing cost and quality in the primary care setting. The first challenge is the extensive time requirements. If physicians were doing all of the things that national guidelines recommend, they would spend 10.6 hours a day managing chronic conditions and 7.4 hours a day providing preventive services, this would require an 18-hour day and doesn't include the time needed to address patient agendas, acute care, and administrative issues. The other challenge is that up to 40% of the symptoms that patients present with do not fit any known diagnosis and 75% of complaints are self-limited, i.e., people will get better all by themselves. As the population ages, care is complicated by the increase in co-morbid conditions. Co-morbid conditions are present in 40% of patients, and in patients 65 years and older, 50% have at least 3 chronic conditions, and 20% have 5 or more chronic conditions. "The complexity of the patients and problems we see may surprise you," he said. The average visit addresses three to eight problems. For a specialist, it's not uncommon for the top 5 diagnostic codes to capture 90% of the diagnoses, whereas for a family doctor the top 25

Cancer Care Delivery in a Rapidly Changing Healthcare System



diagnostic codes capture only 60% of diagnoses. Total relative complexity and complexity density are greatest in primary care. “Why is that important? We need to begin to think about health care beyond a disease or body part,” he said.

Dr. Roberts discussed the United Kingdom (UK) Quality Outcomes Framework (QOF), which requires practices to report on 135 measures. Results from the QOF showed improved data capture, created more organized care pathways, and improved disease-specific care. However, the QOF agenda conflicted with the patient’s agenda, physicians lost skill, care became fragmented, the patient-physician relationship was disrupted, patients were less satisfied, care became mechanized, there was no improvement in primary prevention, and the improvements have not been sustained. “When you measure people in ways that push incentives, it can cause inappropriate behaviors,” he said and further stressed that “you better measure what you value because what you measure gets valued.

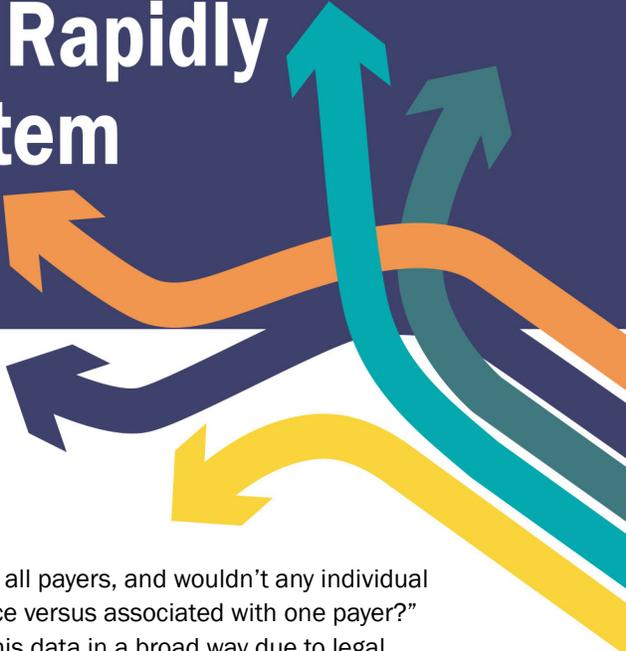
He reiterated that primary care is where most care occurs most of the time, it focuses on the patient and not the disease, is responsive to the patient’s agenda, and relies on the trusted therapeutic relationships. He noted his concern that strategies like bundling are going to affect professional satisfaction, relationships with specialists, and relationships with patients. “When you ask about value-based purchasing, what you really want to be asking is ‘whose values?’,” he said, “Patients care about how they feel and how they are treated. Let’s get that right first and the rest of it will follow.”

Session 5: Q&A

Dr. Weil expressed his concern about the level of trust that is necessary at the practice or the patient level to believe that the approach to thinking about analytics is aligned with what the practice needs to improve and what the patients need to get to the outcomes they want. He also noted that physicians express that they want to do the right thing but they are not getting paid to do the right thing. Dr. Newcomer agreed that trust is essential to the program’s success and the way you earn that trust is through total transparency, listening, and not assigning blame. The data is used to talk about what can be done to improve patient care. He stated that “If we take the approach that variation is an opportunity, it will make a huge difference.”

Dr. Weil asked the participants to reflect on the role of the learning system on improvement. Dr. Ling responded that learning and diffusion are critical parts of health care reform. By sharing lessons learned through these learning environments, better outcomes can be achieved for beneficiaries across populations. There is a learning diffusion group in the CMS Innovation Center that addresses how to share lessons learned and best practices. Additionally, there is a move towards identifying measures that matter and align incentives to best suit patient and family goals. Dr. Roberts agreed that transparency is important. “One mistake we make in our system in particular, is that we seem to think the science is better than it is,” he said. He noted the finding by John Ioannidis that the likelihood that a landmark study’s evidence will endure is only 44%. He expressed concern that “We take this ‘great evidence’ and make guidelines out of it, then make performance measures out of it, and it’s a house of cards.” He also noted the irony of telling people in the health system that “We love competition, but oh by the way, you also have to get together and share you best secrets.”

Cancer Care Delivery in a Rapidly Changing Healthcare System



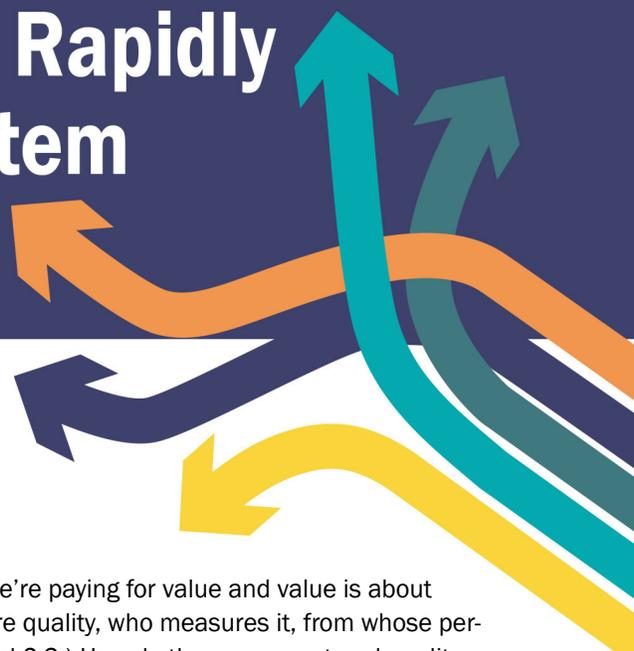
Dr. Weil asked “Wouldn’t the learning system be more robust if we had data from all payers, and wouldn’t any individual practice be able to improve more if it had its reporting back from its entire practice versus associated with one payer?” Dr. Newcomer responded, that he does not have an answer on how to combine this data in a broad way due to legal concerns. Additionally, it is difficult to standardize protocols and processes across practices because they are all different, but each should be accountable for good outcomes.

David Atkins, VA, noted that there is controversy about risk adjustment for socioeconomic status and asked whether the panelists believe incentives disadvantage practices serving disadvantaged patients. Dr. Ling responded, “Risk adjustment is a complex and thorny issue. On the one hand, for the purposes of quality reporting and value-based purchasing, the intent of risk adjustment is to permit fair comparisons. Yet, we know that there are facilities and health care providers that hit every one of the benchmarks, and are able to deliver the highest quality care despite the fact that they take care of the sickest, most disadvantaged patients. What we want is to deliver those outcomes despite all odds.” She added, “We would like to be able to achieve the highest quality of care despite socioeconomic and geographic disadvantages, but how do you do so fairly without risk adjusting away all that matters in determining what those good outcomes are?” Dr. Newcomer commented, “Within a commercial population you have a wide variation of income ranges; we didn’t see that this variation was affecting anything at all. We looked at socioeconomic status by zip code and could not find a difference.” He agreed with Dr. Ling, and further commented, “We have seen examples in all population types where excellence can be served, and that ought to be our bar no matter what.”

Katherine Treiman, RTI International, asked panelists to comment on Oncology PCMHs. Dr. Newcomer explained that oncology PCMHs came about through the acknowledgement that during the period of time of cancer care, oncologists are providing 95% of the cancer patient’s treatment, but they should be providing 100% of care. They seek to provide total care for patients through better access, weekend clinic hours, and answering calls at night. Dr. Ling reflected that there is a need for payment mechanisms that pay for time, per member, per month. This promotes conversations and coordination, and creates an opportunity to acknowledge the importance of continuity over time.

Sewit Teckie, North Shore-LIJ Cancer Institute, asked whether public-private partnerships conversations are happening around payment models. Dr. Newcomer responded that there are a series of dialogs among payers developing different models, such as Horizon, Anthem, and CMS, which compare models and address program weaknesses. “None of these systems are perfect yet,” he added. Dr. Ling commented that one of the focuses of these conversations is how to measure quality at the system level; that can be challenging because not all care rolls up into a system and there are complex attributions. If efforts are aligned, we must first determine what quality looks like, how to get to the desired outcomes, and what those desired outcomes are. Dr. Newcomer added that the three most important measures in the oncology space are 1.) A patient experience measure that addresses “How close was the outcome to the experience that was described to you the first day you came to the office?”, 2.) Survival, and 3.) Total outcomes. Process measures should drive one of these three outcomes.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Dr. Weil noted three critical themes in cancer care and payment methods, 1.) If we're paying for value and value is about delivering quality, how confident are we in our measurements, how do we measure quality, who measures it, from whose perspective, and whose values are we valuing? 2.) Who gets the money and how much? 3.) How do these payment and quality measurement models interact with this highly variable health care system into which we are putting dollars and measures?

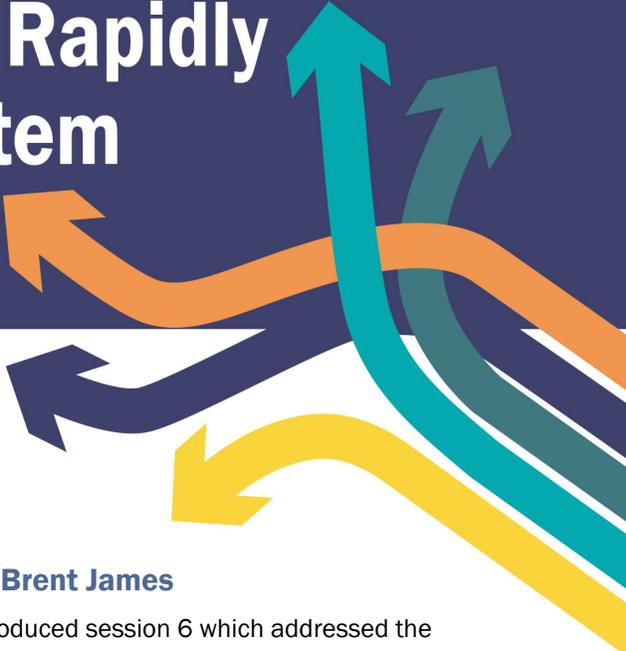
Session 6: How Do Various Integrated Delivery Systems Provide Cancer Care?

Opening:

Ann Geiger, PhD, Acting Associate Director, Healthcare Delivery Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, opened day two of the conference with an explanation of what NCI is doing to reduce the cancer burden. The Division of Cancer Control and Population Science (DCCPS) at NCI addresses genetic, epidemiologic, behavioral, social, and surveillance cancer research. The latter includes the Surveillance, Epidemiology, and End Results (SEER) Registry Program, the SEER-Medicare linked data, and efforts to collect data missing from the registry by reviewing medical records. The work of DCCPS includes research on health disparities, implementation science and cancer survivorship. The Healthcare Delivery Research Program (HDRP) is a new program (January 2015) within the DCCPS responsible for advancing innovative research to improve the delivery of cancer-related care. The program works with extramural researchers to do outcomes research (patient-focused), health systems and interventions research (on contextual factors affecting patient outcomes such as clinicians, payers, caregivers and delivery systems) and health care assessment research, which measures utilization, diffusion and population-based outcomes. Dr. Geiger noted that the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) initiative is now the Person Centered Assessment Resource (PCAR), which pulls together other patient-reported outcome measure development efforts at NIH. HDRP is involved in national level surveys, including CDC's National Health Interview Survey Cancer Control Supplement, AHRQ's Medical Expenditure Panel Survey (MEPS) Experiences with Cancer Survivorship Supplement, and surveys of oncologists. HDRP is working with ASCO to promote team-based care in oncology. The Program funds research and is particularly interested in issues such as contextual factors, processes of care, diffusion of molecularly targeted therapies, shared decision making, caregiver roles and outcomes, employment and financial burden, and overcoming disparities in care.

Dr. Geiger noted several challenges including the appropriations process, the reduction in budget over the past five years, the toughness of peer review, and setting program priorities to decide what issues to address. She ended her presentation by asking "How are our unique capacities at NCI best used to generate evidence needed to plan for care delivery in 5 to 10 years?"

Cancer Care Delivery in a Rapidly Changing Healthcare System



Panel: Carolyn Clancy, Michael J. Kelley, Joanne Schottinger and Brent James

Carolyn M. Clancy, MD, Chief Medical Officer, Department of Veterans Affairs, introduced session 6 which addressed the ongoing transformation in health care delivery and cancer care in integrated health care delivery systems. The panel addressed how current efforts leverage these emerging capabilities in regards to how patients with cancer are identified, diagnosed, staged, treated appropriately, and followed over time.

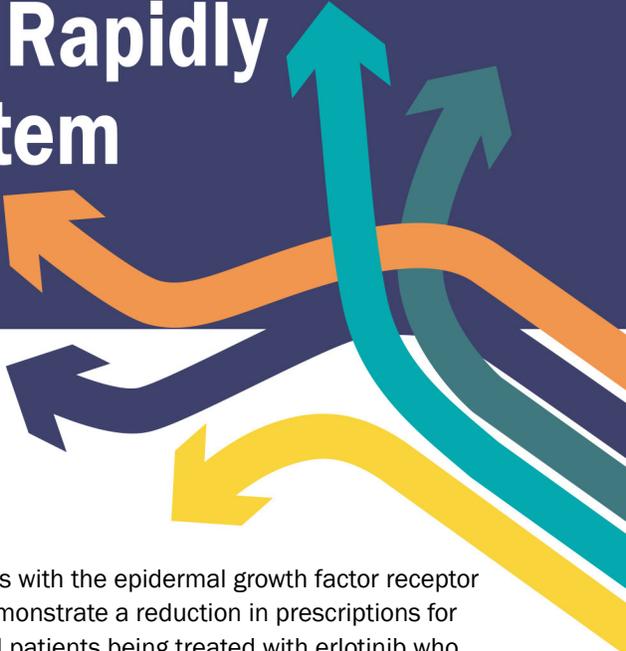
Michael J. Kelley, MD, National Program Director for Oncology/SCS/PCS; Chief, Hematology/Oncology, Department of Veterans Affairs Health Administration; Professor of Medicine, Duke University, stated that the ideal system would be a single payer system where enrollees paid little or nothing out of pocket for encounters and there is an advanced universal EHR linked to administrative data to perform health outcomes research, comparative effectiveness, quality and pharmacovigilance. He noted that health care systems can be judged against this ideal.

Dr. Kelley provided an overview of the VHA and addressed how the quality of oncology care in the VHA compares to the rest of the U.S. The VHA has over 9 million veteran enrollees (a minority of all veterans), 144 hospitals, 1200 outpatient sites and an established EHR. They have about 50,000 new cancer cases per year, which is approximately 3.5% of the national total. He noted that although they need to improve, the VHA objectively performs well on quality measures. In a large comparison study, looking at a number of process and outcome measures, the VHA generally performed similar to or better than care for fee-for-service Medicare beneficiaries.

VistA, a single, integrated computerized patient record system, has been used throughout the VHA since the late 1990s in all health care settings and delivers a universal record covering all aspect of patient care. Data from this EHR is used to do comparative effectiveness research. For example, breast cancer screening rates are 10% higher within, as compared to outside, the VHA because of the integration of a reminder system within VistA that reminds primary care providers that a patient is due for a cancer screening. However, he stressed that “Cancer screening by itself is not enough to result in a reduction in cancer mortality, you have to have action after the screening has been done.” The Breast Care Registry (BCR) tracks the patient’s care and includes information on mammography results, communication with the patient, follow-up, diagnosis, and care received.

Using the EHR, the VA has been able to perform a number of studies on treatment for cancer. For example, in 2004, adjuvant chemotherapy after surgical resection was adopted; they were able to document an improvement in overall survival by about 25%. Historically, within the U.S., the rate of lung cancer resection has been lower for blacks compared to whites. The open access health record system showed that there was no biological difference and no comorbidity to explain the rate difference, and within the last two years the VHA was able to close this gap. In another comparative effectiveness study using propensity score matching in Stage III NSCLC, they were able to compare two regimens, cisplatin-etoposide, and carboplatin-paclitaxel. They found equivalent effectiveness in terms of survival, but showed higher rates of hospitalizations, infections, esophagitis, acute kidney injury, nausea and vomiting with the cisplatin regimen than with the carboplatin regimen. In discussing stage IV lung cancer, Dr. Kelley noted that erlotinib was approved based on the use in any patient.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Over time, it became apparent that erlotinib was much more effective in patients with the epidermal growth factor receptor (EGFR) mutation; once EGFR mutation testing was adopted, they were able to demonstrate a reduction in prescriptions for erlotinib and in the number of patients receiving the drug. However, there are still patients being treated with erlotinib who do not have the mutation. Dr. Kelley noted that the incidence of EGFR mutation among veterans is approximately 5%, a significantly lower incidence than reported at some academic medical centers, suggesting a possible difference in the underlying biology of the patients at the VHA.

Joanne Schottinger, MD, National Clinical Lead, Cancer, Care Management Institute, Kaiser Permanente, described Kaiser's integrated health care delivery system, which includes Kaiser Foundation Health Plan, Kaiser hospitals, and the Kaiser medical groups. Kaiser covers about 10 million people in the U.S., across 7 geographic regions, which are connected by HealthConnect, an integrated EHR that has been in place for about 15 years. Kaiser strives for complete care, defined by Dr. Schottinger as "giving the right care, to the right person, every time and everywhere." She discussed cancer as a chronic condition and how Kaiser uses population management tools for chronic conditions in general.

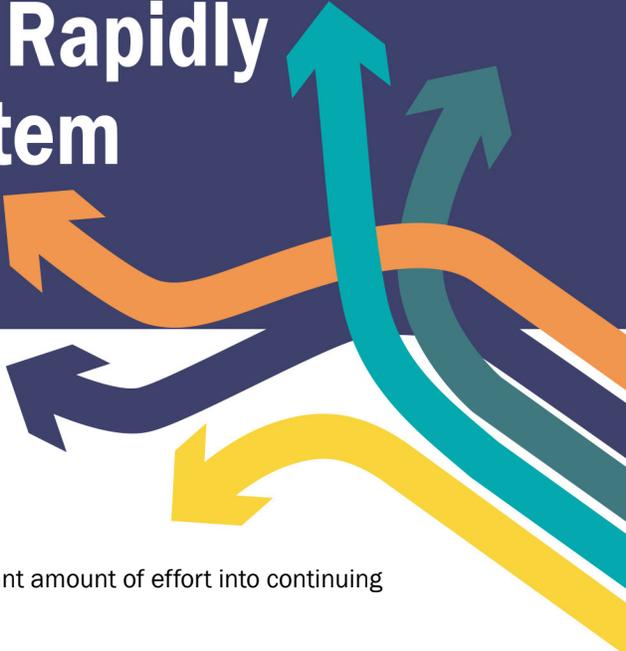
Kaiser's first function regarding chronic condition management is prevention and lifestyle. They use their EHR to support their prevention efforts, for example, they track exercise as a vital sign and recommend 150 minutes a week of exercise. Unfortunately, in the cancer population, over half of patients currently get no exercise and only 25% are getting the recommended amount. Additionally, the system's health education and wellness programs include health coaches, interventions including activity monitors and pedometers, weight management, and aggressive tobacco cessation. "We really try to prevent the first cancer and then try to keep people healthy and prevent that second cancer," she explained.

In order to address the goal of complete care, they practice proactive office encounters. Using decision support embedded within HealthConnect, care gaps are flagged and can be addressed by any physician, regardless of the primary reason for the patient's visit. Using a function called SureNet, results of tests and screenings are automatically sent to the appropriate specialist, thereby closing the care loop.

Expensive and critical medications are used in oncology care. The EHR is used to assist in medication management by showing a medication possession ratio at each visit and automatically contacting patients to refill medications. People who get those reminders do refill their prescriptions more often. Dr. Schottinger noted that 20% of patients who are prescribed oral chemotherapy drugs will discontinue them within the first two weeks because of toxicity or the inability to tolerate side effects. There is a pharmacist as part of the care team who assesses the patient within the first two weeks and helps them through any drug-related symptoms and works with the physician to assess a change in drug regimen if necessary. "All of this isn't possible without the decision support systems that we have in the electronic record," she said.

Kaiser recognizes that the field is rapidly changing. They review their chemotherapy protocols monthly and update them based on the newest evidence-based tests and treatments. They regularly perform comparative effectiveness of their cancer regimens. "We're trying to be a learning system," she said. One of the biggest issues they are facing is how to keep doctors

Cancer Care Delivery in a Rapidly Changing Healthcare System



up to date with the new tests, drugs, and technologies. They are putting a significant amount of effort into continuing medical education.

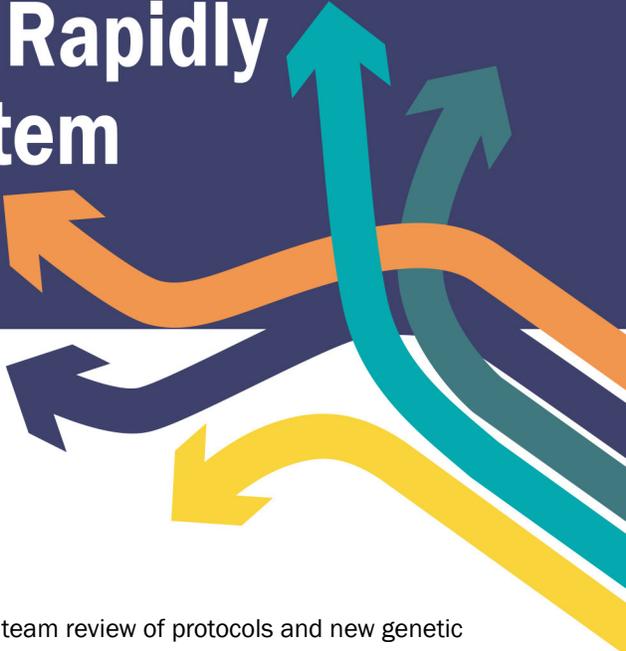
Brent James, MD, MSTAT, Executive Director, Institute for Healthcare Leadership, Intermountain Healthcare, presented his perspective from a geographically concentrated private health care system, mostly in Utah and the surrounding states including 22 hospitals and 190 freestanding clinics. Their integrated health care plan, SelectHealth, covers about 750,000 people and includes Medicare Advantage. Intermountain Health is an integrated system providing all aspects of care except for long-term care.

In the late 1980s, Intermountain Healthcare entered into a series of studies that showed a substantial variation in care at the level of the individual patient and the treatment they received, within the same health care system. Even with full access to care, some patients were not getting appropriate care. This study was the foundation of a large scale clinical quality improvement effort. He noted that in most circumstances, improving clinical outcomes reduces the cost of operations. “Quality improvement is innately a move upstream strategy, a continuum of care from population-level prevention, to screening and detection, to management of a particular condition, to some sort of outcome. It’s naturally a population health model,” he explained. The other part of quality improvement is patient-centered care. There are two ways of thinking about patient-centered care. The first is to organize care around the patient, rather than the physicians, technology or facilities. The second way of thinking about patient-centered care focuses on patient autonomy, patient-reported outcomes (PROs) and a co-production model that puts patients on care teams. This model is participatory and engages patients.

In 1991, Intermountain Healthcare developed a process management method for managing care called shared baselines. The first step is to hammer out an evidence-based best practice protocol at a patient flow level that provides a process map. Step two is to blend it into the clinical work flow through the EHR and clinical decision support so that it does not rely on clinician memory. “If you rely on memory, with today’s level of complexity in care delivery, you will manage to execute about 50% of the time,” he said. Step three is to build in a data system to derive clinical and cost outcomes. Intermountain Health has 58 big data registries that track every patient treated for common conditions, including cancers, which provide a resource for care management performance, as well as provide a foundation for research. Step four is to vary protocols based on the individual patient need, recognizing that there are individuals who are exceptions to guideline-based care, and honoring professional autonomy. Step five is to build a learning health care system by feeding data back into the learning loop. “Nearly every protocol modifies radically after you first roll it out. There is a difference between theory and reality,” he noted.

In cancer care, part of getting the right therapy to the right patient involves genomic testing. Intermountain Health supplies much of the gene sequencing and genomic tumor board services in the western U.S. By sequencing cancer, you can eliminate as many as one third of all initial courses of chemotherapy. Introducing genomic testing and precision medicine is a major cost saver because you can avoid expensive courses of chemotherapy that are predicted to fail.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Session 6: Q&A

Dr. Clancy asked Dr. Schottinger to talk more about the monthly multidisciplinary team review of protocols and new genetic information. Dr. Schottinger noted that they meet monthly and have education sessions that are driven by pharmacy and more recently pathology to keep up with the targeted therapies. She stressed that these new tests and therapies are a lot for busy oncologists to keep up with, so there is a need to devote time to education and building reminders into the EHR.

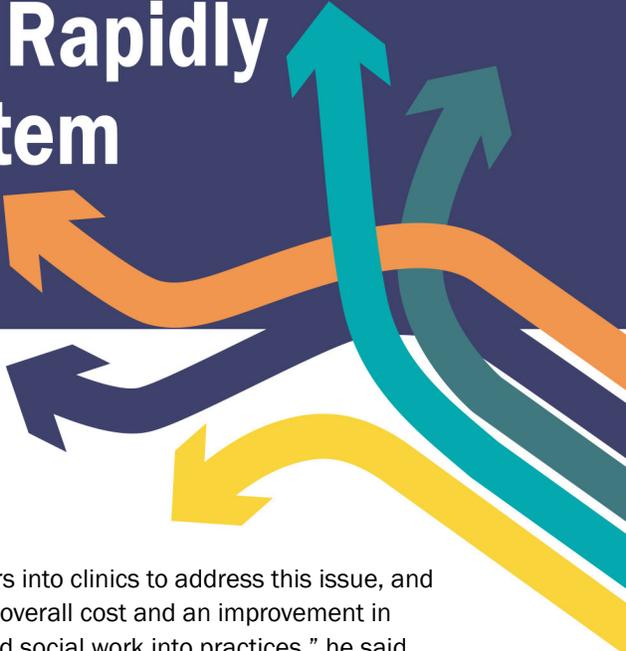
Dr. Clancy asked Dr. Kelley to discuss the VA's Million Veteran's program, a program looking at how genes affect health by collecting blood samples and health information from veterans, and to speak to how this information may be used in the future. Dr. Kelley noted that the program is targeted towards one million veterans. There are currently 400,000 veterans in the program, and so far 300,000 have been genotyped. They are first looking to determine what diseases are affecting patients. There are many different types of analyses that can be done using this information such as risk analysis, pharmacogenomics, and association with other diseases.

Dr. Kelley commented on Dr. James' statement that a very powerful way to change outcomes is to integrate processes into the patient care flow. He noted that in the VHA and outside the VHA there is resistance to doing that based on three different factors: 1.) It takes more time, 2.) Physicians think it results in less professional autonomy, and 3.) Physicians don't think there is need to do this. He asked Dr. James how he deals with this in his system. Dr. James noted that integrating these processes leads to documented improvement in mortality, significantly better patient outcomes, and higher physician efficiency. Additionally, Dr. James clarified, "You're not sacrificing your autonomy, you're focusing your most important resources—the trained expert mind—that relatively narrow part of the patient's care that needs modification. It's a brilliant way of increasing productivity."

Ed Butler, from Videris Health, asked what the evidence is behind patient engagement as a way of improving outcomes. Dr. Schottinger noted that in Kaiser's experience, if a patient looks at their care gaps, they are more likely to follow through with appropriate care and help to close those care gaps. She also noted that they are trying to bring the EHR to the next level by giving patients access to their entire medical record. The majority of patients want to engage in their own care, and when they do, they achieve a higher rate of compliance and better outcomes. However, she said, "In the quality improvement movement, I believe we're emphasizing the co-production side of it too heavily. We still have work to do around organizing processes of care. It's a balance between the two, both are important."

Linda House, from Cancer Support Community, raised the importance of patients understanding their psychosocial needs and asked how care plans can address that issue. Dr. Kelley responded that they are currently piloting this type of work in parts of the VHA, for example, including anxiety and mental health in the list of cancer symptoms as a way to screen for patients who need a plan for symptom management. In general, many veterans have significant mental health issues and that is a focus of the VA. Dr. Schottinger said they have tried questionnaires to assess patients' psychosocial wellbeing. In some areas, they have backed away from assessing, and just assume that if a patient has cancer, they need a social worker because the vast majority of people need that service. Dr. James added that with chronic diseases like cancer, at least one

Cancer Care Delivery in a Rapidly Changing Healthcare System



third of patients are depressed. They have added psychologists and social workers into clinics to address this issue, and despite not getting paid for psychological services, they have seen a reduction in overall cost and an improvement in outcomes. “The evidence shows that you need to fully integrate mental health and social work into practices,” he said.

Kirsten Sloan, from American Cancer Society Cancer Action Network, asked how patients’ needs are being addressed as they transition from oncology care back into the community and primary care. Dr. Kelley explained that in the integrated VHA system, the patient is not leaving the VHA system and primary care has access to the same EHR that includes the entirety of the patient’s records. However, they are working on improving survivorship care plans and determining what information needs to be communicated by the oncologist to the primary care physician (PCP). Dr. Schottinger responded that their PCPs have access to treatment plans and care summaries, but in some cases, patients do not move out of oncology, instead their follow-up care is provided by a PCP that is integrated into the oncology module. They are looking to integrate additional PCPs into oncology offices. Dr. Kelley added that the generation of a care plan can be facilitated by data if it is in a format that can be pulled into a template. They are working on automating this process so that the oncologist can spend less time generating the care plan.

David Wade, from Hayes, Inc., asked when it is determined that a cancer or the evolution of a cancer is appropriate for genomic sequencing. Dr. James responded that sequencing can be done for \$1,500 to \$1,800; it is a relatively low cost test that they currently do broadly for chemotherapy candidates. It is efficient, cost effective, and provides options for targeted therapies based on gene expression rather than cancer type. Dr. Kelley noted, “There has been a lot of discussions among our clinicians and pathologists about which tests to do when, and for what tumor types. That has been an ongoing discussion. The information changes very rapidly and it requires that you have a group of experts who are up to speed on this and read literature continuously.”

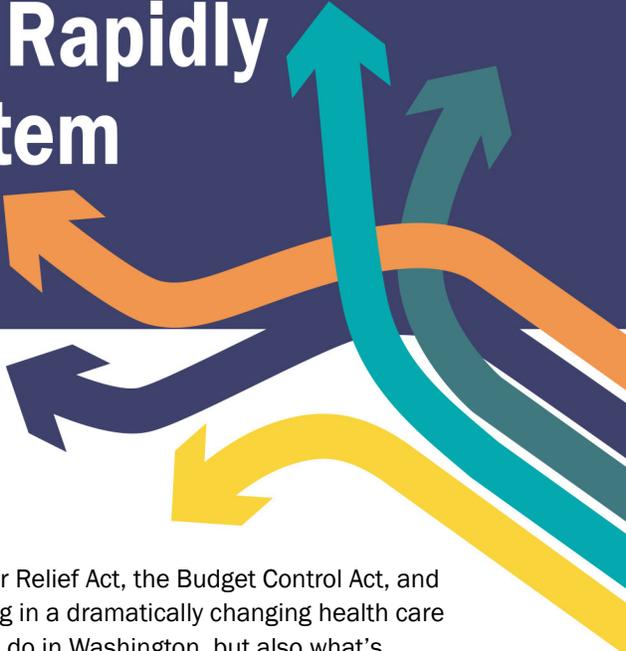
Session 7: CEO Perspectives on How Their Differing Health Systems Deliver Care Now and Are Preparing for the Future

Panel: Ralph Muller, Steven Lipstein, and Gary Gilliland

Ralph Muller, Chief Executive Officer, University of Pennsylvania Health System, opened session 7, a discussion among CEOs of major health systems about the different approaches to the delivery of cancer care, how that care is changing, and the challenges of running a health system in this environment.

Steven H. Lipstein, MHA, President and Chief Executive Officer, BJC Healthcare, discussed the ecosystem in which cancer care delivery exists today. Between 2009 and 2015, many laws were passed which affect the landscape of American health care (and therefore cancer care) and which were instrumental in the development of the ecosystem as were certain programs and models. These included the Bipartisan Budget Act, the Medicare Access CHIP Reauthorization Act (MACRA),

Cancer Care Delivery in a Rapidly Changing Healthcare System



Medicare Alternative Payment Models, Medicare Pay-for-performance, the Taxpayer Relief Act, the Budget Control Act, and the Affordable Care Act. Mr. Lipstein stressed that “Cancer care delivery is existing in a dramatically changing health care system where the math of American health care is influenced not just by what we do in Washington, but also what’s happening in the private commercial insurance sector as well.”

BJC Healthcare is part of a collaborative among health systems that serves 11 million people in Southern Illinois and Missouri. Together, these health systems add up to a 9-billion-dollar health system. Cancer care is changing dramatically and large health care systems are emerging all across the U.S. Mr. Lipstein added that in the Midwest, cancer care incidence and delivery is dispersed, which has significant care delivery implications.

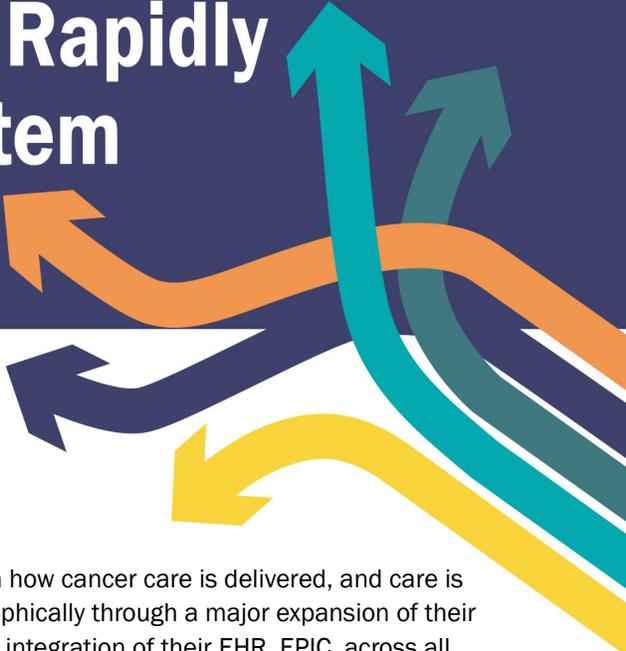
The BJC Cancer Care Collaborative aggregates data and information from each cancer center’s Survey Application Record data. Their priority areas of focus include: community health, a shared tumor board, clinical studies and multi-center trials, precision medicine, shared best practices, education resources for all staff, expedited referral channels and branding support.

Gary Gilliland, MD, PhD, President and Director, Fred Hutchinson Cancer Center Research Center, addressed challenges faced in delivering cancer care from the perspective of an academic medical center. The first challenge he addressed is that “The current rate of growth and the costs for oncology care are likely not sustainable.” We spent about 100 billion dollars worldwide for cancer care, 43 billion of that is in the U.S. alone, a 33% increase in the past 5 years. Consequently, there is a lot of research and development going on in the pharmaceutical industry focused on cancer drugs. Another challenge is the delivery of health care related to the number of practicing oncologists. Although the number of practicing oncologists has increased from 10 to 13,000 since 2004, most are concentrated in urban areas and it is difficult to get good access to care in rural areas. For example, the Fred Hutchinson Cancer Center is the only comprehensive cancer center in a five state region. That’s 27% of the land mass of the U.S. that is served by one cancer center. “We need to think about how we distribute high quality cancer care into rural areas,” Dr. Gilliland said.

Most of the advances in chemotherapy have been incremental, showing modest improvements in overall survival with more expensive treatments. He stressed the need to look for therapies that have curative intent. Even if those therapies are expensive, there is value because you are not treating people forever. There are now potentially curative treatments that are becoming available that harness the power of the immune system. Additionally, precision medicine presents opportunities and challenges related to storing sequencing data and using that data to provide analytic and decision support tools for busy oncologists. The last challenge he noted is the payer environment. “If you’re working in a fee-for-service context, cancer is still a significant revenue generator for health systems,” Dr. Gilliland explained.

Ralph Muller discussed how health care is shaped by how the delivery system is organized. Unlike Kaiser and Intermountain Health, the University of Pennsylvania Health System, BJC, and Fred Hutchinson Cancer Center do not have an integrated insurance company and must work closely with the insurer. Penn serves a geographic area about 100 miles east and west of Philadelphia, a region that has 70 hospitals. Therefore, patients may go to their local hospital prior to going to Penn. In

Cancer Care Delivery in a Rapidly Changing Healthcare System



many parts of the country there is only one local hospital. This has a big effect on how cancer care is delivered, and care is shaped by where you go first. They are attempting to serve a broader area geographically through a major expansion of their outpatient care services. The system has also invested heavily in IT, including the integration of their EHR, EPIC, across all settings. Mr. Muller also stressed the need to bring leaders into academic medicine who know how to think about serving broad populations.

Penn wants people to come to their hospital first because they make the most income from providing care to cancer patients. Cancer has an economic margin that is used to support other programs and broader aims of care, such as community-based care, emergency rooms, behavioral health, and maternity care. “Part of what we have to think about in running a cancer program, is not just what most of the focus is on today, what’s the right care for the patient, we also have to think of it in business terms of how to sustain a major academic medical center,” he said.

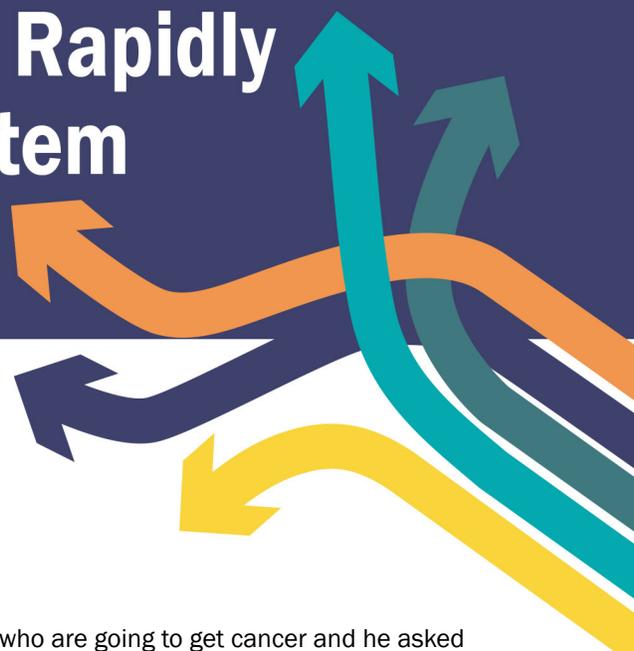
Dr. Muller asked the panelists to elaborate on the difference between running a focused cancer center and a broader health care system.

Dr. Gilliland noted one advantage of a freestanding cancer center is that they have opportunities to develop novel and innovative therapies, particularly to focus on cutting edge therapies that have curative intent. They have in-house capabilities for DNA sequencing and patient stratification based on mutation analysis. As that space expands, they are looking towards developing analytic tools to support those efforts. He noted that one challenge is sharing this work with the community to ensure that they have adopted appropriate practices. Dr. Gilliland said, “We need to get high quality uniform practices out into the community.”

Mr. Lipstein noted that the context in which cancer care exists is largely episodic. The way health care delivery is currently set up, it’s largely at the request of and initiated by the patient, and has a beginning and an end. The other way they are thinking about expanding the care delivery concept, is a continuing care model with care being initiated by the providers, and in this context there is a shared insurance function for the patient or shared financial risk for total cost of care for the patient.

Dr. Muller stated that “The Affordable Care Act could just as easily be called the Accountable Care Act, because in many ways it tries to shape and focus on affordability but also the accountability for populations.” He stressed the need to determine who is really accountable for the care of a population. When you have an integrated system, there is accountability for health care. However, when you have a system where there are separate insurers and providers, it’s different. One percent of the patients in the country incur 20% of the costs and 5% of the patients incur 50% of the total cost of health care. There is currently a very focused expenditure of health care resources. In working with insurers, when we reduce readmission, mortality, and infection rates, the savings from that goes back to the insurance company. Yet we (the academic medical centers) make big investments for community health and behavioral health and those savings go back to the insurance company. How long can this system be sustained when the savings go back to the insurance companies? “The system is incredibly complex inside this country and we have to move towards bundling, episodic payments, and longitudinal payments,” he said.

Cancer Care Delivery in a Rapidly Changing Healthcare System



Session 7: Q&A

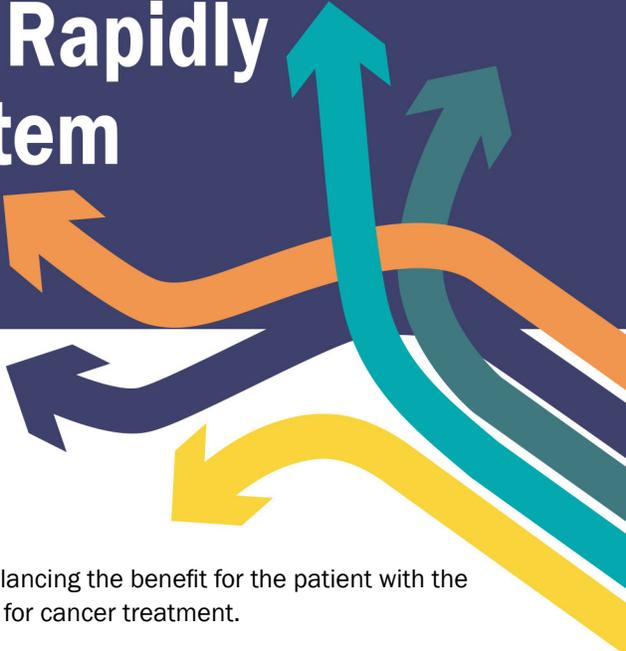
Dr. Lerner noted that the demographic shift is leading to more and more people who are going to get cancer and he asked the panelists how they are going to address this issue within their systems. Mr. Lipstein responded that when the Medicare program was established in 1965 there were 20 million people eligible and there were five people paying into the trust fund for every eligible person. By the end of the 2020s, there will be 80 million people eligible for Medicare and there will only be 2.5 people paying into the trust fund for every eligible person. “That means that the government is going to have to go to fixed cost budgeting at some level. Fixed cost budgeting means determining how much the government can afford to spend for every person on Medicare and then figuring out how to disperse that money,” he explained. There will be a doubling of the population over age 65 and cancer incidence rates increase with longevity. Dr. Lipstein believes we need to create a much larger cancer care delivery platform to diversify financial risk. There needs to be wealth redistribution through the health care system. He explained that part of what the ACA is intended to do is make us accountable for a very distributed, diverse and large population over which we can spread the risks and total cost of providing care.

Dr. Muller asked Dr. Gilliland, who has been a leader in precision medicine, where he thinks this new discipline is going in the next couple of years and how it can be paid for in this complex environment so that it can be advanced. Dr. Gilliland responded that “precision medicine is a very exciting area of investigation.” Although, currently, there are relatively few actionable alleles based on targeted therapies, they hope this will rapidly increase. In response to how to pay for precision medicine, he noted that value and cost effectiveness must be demonstrated, adding that over time the cost of the tests should come down. Another challenge is that as whole genome sequencing becomes available, there will be information available on actionable alleles even if you are not looking for them. This poses an ethical question of responsibility when determining whether to do anything about those findings. He also noted that oncology could be viewed as the low-hanging fruit and the larger challenge is how to bring precision medicine into play across other disease areas.

Sewit Teckie, commented on Dr. Muller’s statement that income from cancer care subsidizes other care, and asked how long that could continue. Mr. Lipstein responded that it is not just a function of cancer care subsidizing other services. Inside the American health care system, challenges include the cost shift among payers, insurance companies negotiating discounts, and a shift towards cost transparency.

Larry Norton, Memorial Sloane Kettering, noted that “If we just follow guidelines, we are going to have high level mediocrity and frankly, be more expensive.” He asked the panelists to comment on how to approach the important concept of ‘wise judgement’. Mr. Muller responded that “We have to get the patients the right care. To do that we are taking on a broader geography and funneling patients to appropriate care.” He also noted that payment systems have a profound effect on medicine. Mr. Lipstein commented that in bundled payment and oncology care models, the provider is given a specific amount of money and they have to use their own judgment to use that wisely, but there is pressure from the patient and pressure from the payer. “The policy wizards believe that what people want is more health care value for the dollar, what people tell you they want is more health care,” he said. Dr. Gilliland added that 10% of patients receive chemotherapy in the last 14 days

Cancer Care Delivery in a Rapidly Changing Healthcare System



of life. “We need to be thoughtful about how and when we give chemotherapy, balancing the benefit for the patient with the need to simply do something,” he said. This is one way to reduce the cost of care for cancer treatment.

Session 8: Looking to the Future: Legislative and Policy Perspectives

Panel: Janet Marchibroda, Karen Fisher, and Wade Ackerman

Janet Marchibroda, Director, Health Innovation Initiative, Executive Director, CEO Council on Health and Innovation, Bipartisan Policy Center, introduced session 8 in which senior congressional aides discussed key policy issues, legislation, and prospects for legislation.

Karen Fisher, Senate Finance Committee (Ranking Member Ron Wyden, D-OR), works with Medicare/Medicaid jointly with the Health, Education, Labor and Pensions (HELP) committee to deal with issues of coverage for the ACA, alternative payment models, and meaningful use in health care IT. She noted that the Senate tends to be bipartisan and both sides are working together to address issues of accountability, value and payment.

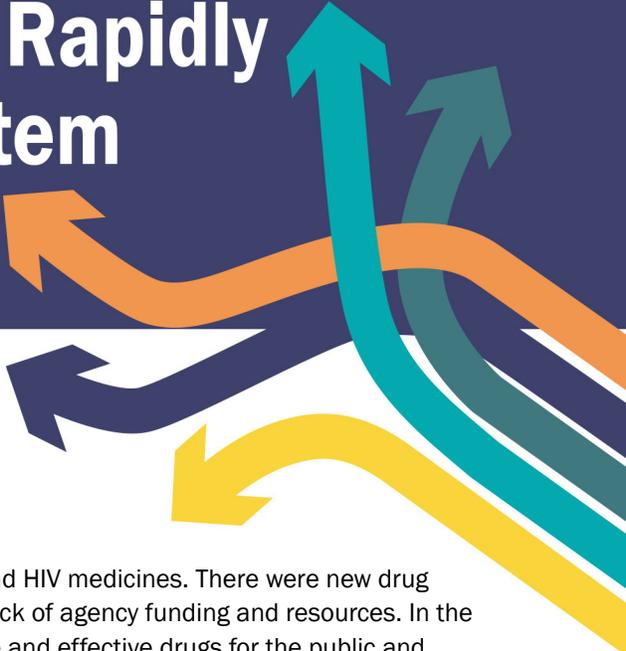
Current discussions are addressing where the health care system is moving and how to get to high quality health care while ensuring value for the Medicare program. Ms. Fisher stressed that there are a lot of opportunities to better improve care. Ms. Fisher noted that over the last five years Medicare’s gross per capita spending has been the lowest in its history. However, she agreed that there will be challenges with the number of people paying into the trust fund as compared to the number of people on Medicare, as well as the higher incidence of disease due to the aging population.

In April of 2015, the Senate passed a bill to repeal the sustainable growth rate formula (SGR), the previous physician payment formula for Medicare. This ended decade long payment cuts and opened the door to discussions about more effective ways of paying physicians. The current legislation replaces the SGR with an approach focused on rewarding high-performing providers while supporting alternative payment models such as ACOs and PCMHs.

For cancer care, they are looking at new ways to deliver and pay for cancer care including oncology bundles and ACOs for oncology. She noted that cancer care is complex because there are multiple modalities of care for which there are substitutes and also some are additive. So it is complex to figure out payment mechanisms, and we have to figure out how to make our systems interoperable so that people can share information. She also stressed the need for the community to work together to address care coordination issues.

Wade Ackerman, Senate HELP Committee (Ranking Member Patty Murray, D-WA), works primarily on FDA issues, particularly on the approval pathways for new treatments and technologies. The FDA has a critical and central role in reviewing new drug applications and is also involved early on in the research and development process.

Cancer Care Delivery in a Rapidly Changing Healthcare System



The current FDA processes are in part a result of the drug lag of the 1980s around HIV medicines. There were new drug applications sitting for a long time and not being approved, an issue caused by lack of agency funding and resources. In the early 1990s, the industry and Congress got involved to help speed access to safe and effective drugs for the public and reduce cost to the industry. The Prescription Drug User Fee Act (PDUFA) was created by Congress in 1992 and authorizes FDA to collect fees from drug companies for the service of reviewing their application. This program must be reauthorized every five years, and as of 2012, it is in its 5th reauthorization. For each reauthorization, stakeholders including patient groups, consumer groups, and organizations outside of the FDA meet to determine priorities and performance goals. In 2012, Congress authorized a similar program for generic drugs, called the Generic Drug User Fee Amendments (GDUFA). Additionally, in 2011 there was a drug shortage crisis with over 2,000 drugs in shortage. In 2012, Congress provided the FDA with additional tools to manage and mitigate drug shortages.

Congress has been engaging stakeholders to determine if there are additional policies or tools that could be put into place to promote rapid drug and device development in the health care space. One current focus is on incorporating the patient perspective into the drug development and regulatory review process. The 21st Century Cures Act pass through the House in July of 2015 and includes this as a focus, as well as removing barriers to increased research collaboration, advancing personalized medicine, modernizing clinical trials, and removing regulatory uncertainty for the development of new medical applications.

Session 8: Q&A

Robert Crane, ECRI Institute's Board of Directors, asked for the panelists' perspective on CMS's Innovations Center.

Ms. Fisher responded that from the Democratic perspective, they are very happy with the center. The center has funded and tested many models with rapid evaluation and turn around, including ACOs and bundled payments.

Dr. Norton commented that "If the floor is wet, you can buy more pails or make them more efficient, but you can also fix the roof." He asked what the government is doing about providing funding for the science of health care delivery. Mr. Ackerman stated that within the Medical Innovations Project, they are looking at addressing EHR interoperability. He also stressed the need for NIH and NCI to have significant funding. Additionally, he noted emphasis on revolutionizing the clinical trial process by leveraging EHRs to design trials to get information disseminated and assess whether treatments and interventions are working, or working for sub-populations. The Senate is working to ensure that agencies have the tools and resources they need to advance science and health care delivery. Karen Fisher added that payment system innovations are critical. The finance committee is supportive of innovations that add value to the health care system. One issue we need to make sure keeps coming along relates to quality measures, so we can really tell that the care being delivered is maintained as high quality and measures are meaningful. When innovations come in, we need to be able to measure whether there is a difference in the care being provided.

Cancer Care Delivery in a Rapidly Changing Healthcare System



A participant asked whether they are working on legislation to accelerate the approval of drugs approved in the European Union. Mr. Ackerman responded that the FDA issued a report last year, which included 3rd party independent research from the UK that showed that the FDA is leading the world in drug approvals and the speed of drug approvals.

Jean Silver-Isenstadt, National Physicians Alliance, noted that as the FDA moves towards more rapid innovation and post-market evidence generation, there is risk of public harm because people do not understand this breakthrough approval process. People tend to put confidence in anything that is FDA approved leading to hype, enthusiasm and uptake, and it is not easy to pull things off the market if they are harmful. Mr. Ackerman agreed that those are important points but stressed that FDA approval means today what it has always meant, that safety and efficacy are maintained.

Session 9: Capstone Session: Perspectives on What We Have Learned and What We Can Do

Panel: Jeff Lerner, Ann Geiger, and Ken Kizer

Jeffrey C. Lerner, PhD, President and CEO, ECRI Institute, opened the capstone session, during which panelists shared their perspectives of what they had learned from the conference and how to address the changing pathways for cancer care delivery.

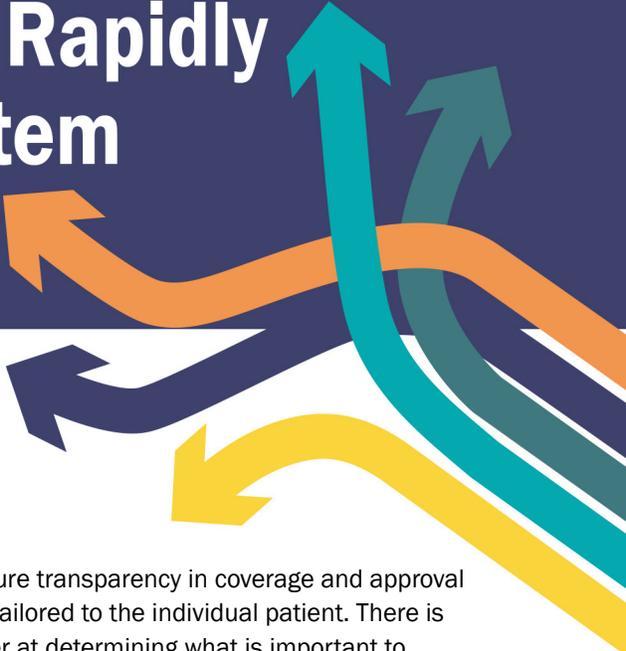
Panelist included:

- **Ann Geiger, PhD**, Acting Associate Director, Healthcare Delivery Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute
- **Kenneth W. Kizer, MD, MPH, Director**, California Cancer Reporting and Epidemiologic Surveillance Program; Distinguished Professor, University of California, Davis, and Director, Institute for Population Health Improvement, UC Davis Health System

Panelist discussion:

Dr. Kizer emphasized that cancer will soon be the nation's leading cause of death and the most expensive health condition. He addressed eight observations that stood out from the discussions and associated actions needed. 1.) He observed that our understanding of the biology of cancer is rapidly accelerating and cancer care is becoming ever more complex and will be in perpetual flux for the foreseeable future. "We need to focus more on how best to disseminate and apply all the new information in a coordinated and systematic manner. We will need to reconcile what uniform care and quality means as therapy becomes more individualized and personalized," he said. 2.) There is a tension between access and coverage. Finding the right balance between having equitable access to new technologies and having reasonable assurance that the technologies are effective and worth their cost will continue to be a challenge. Clinicians and investigators have to

Cancer Care Delivery in a Rapidly Changing Healthcare System

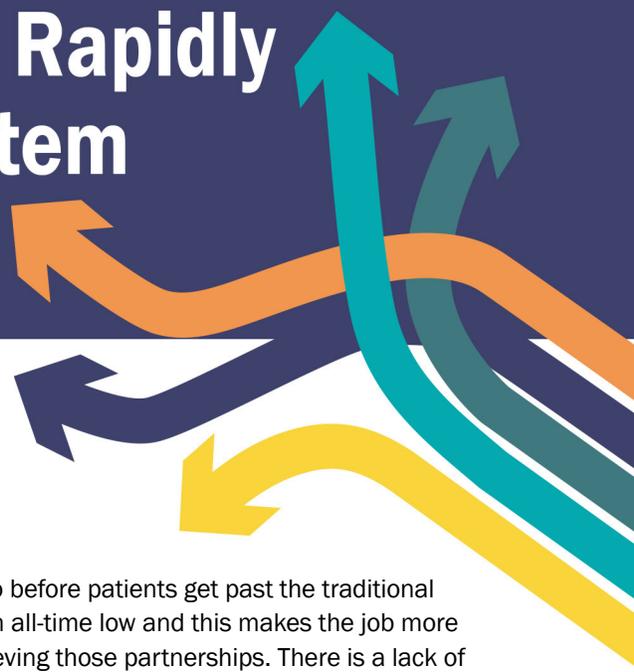


demonstrate how new technologies add value. Payers and regulators need to ensure transparency in coverage and approval processes. 3.) Patient engagement in decision making is imperative but must be tailored to the individual patient. There is a need for better tools to inform and engage patients in their care and to get better at determining what is important to individual patients and families. 4.) The lessons learned from understanding the causes of, and best ways to care for, cancer may be broadly applicable. “We need to think about and find more systematic ways of harvesting, adapting, and applying the lessons learned from cancer science to other conditions,” he said. 5.) Evaluating the quality of cancer care is driven too much by what we can measure and the processes of care. We need to think further about what it means to provide high quality cancer care and how we measure cancer care quality. We need to better understand how quality measures drive the delivery of care and their possible unintended consequences. Performance measures affect behavior and not always in a positive way. 6.) Large organized delivery systems have the potential to clinically integrate care, manage population health, and provide better health care value. However, integrated care and integrated delivery system are not the same. “Not all integrated delivery systems provide integrated care and integrated care is not just provided by integrated delivery systems,” he said. We need to better understand the key elements of clinical integration and how it can be achieved in diverse settings. Information mobility is critical to achieve clinical integration and we need to continue to focus on how to best integrate information across the clinical care spectrum. 7.) Cancer will be an increasingly high profile political issue as the burden and cost of cancer increases. Clinicians need to better understand political processes and we need better ways to inform and engage politicians. 8.) The growing cost of cancer care is not sustainable and we need to find multiple ways to increase its value.

Dr. Kizer also discussed the topic of population-based cancer registries. Registries have been integral to understanding the behavior of cancer and advancing knowledge about cancer. Historically, cancer registries have been used primarily for public health surveillance and to support research. He stressed the need to take cancer registries to the next level, including more timely data that needs less cleaning and curation through structured data submission, better and easier access to other relevant data through the integration of other public and private clinical databases, and to actively mine the linked databases to support data analytics. “If we can bring this data together, it has the potential to offer new insights,” he noted. Although it is currently possible to bring databases together, it takes a long time to get Institutional Review Board (IRB) approval to link databases. There needs to be a routine and easy way to link and mine those databases. More resources need to be devoted to analyzing and interpreting this data. Additionally, linking clinical databases, EHRs, environmental databases, claims data and utilization data may help get to more clinically meaningful real-time information.

Dr. Geiger identified three themes from the discussions. 1.) The understanding of the biology of cancer and cancer treatments are rapidly growing. We need to recognize that people are increasingly living with cancer as a chronic condition, they are not dying quickly as was true 20 to 30 years ago. “We need to stop having a war on cancer. We need to have a truce with cancer and learn to manage it as a chronic condition and help the public to understand that it is a chronic condition,” she said. 2.) “The evidence for what we need to be doing is more uncertain than we’d like to admit,” she noted. There is a tendency to assume our science is more advanced than it really is. There is no perfect study and evidence is not available for everyone. The benefits of treatments and diagnostic approaches tend to be overstated while the harms are understated. Furthermore, more patients than we realized are ill-prepared to synthesize this information and participate in shared deci-

Cancer Care Delivery in a Rapidly Changing Healthcare System



sion-making. Shared decision-making is a great idea but we have a long way to go before patients get past the traditional view of clinicians telling patients what to do. Additionally, scientific literacy is at an all-time low and this makes the job more difficult. 3.) We need partnerships. However, there are several challenges to achieving those partnerships. There is a lack of a common understanding of the challenges, and the challenges vary depending on different perspectives. Groups such as patients and payers do not have shared, mutually beneficial goals. There is disagreement regarding the extent to which cost should be taken into account. Lastly, there are many streams of data but necessary data are missing from those sources. She questioned whether the higher quality of care in integrated systems is due to the shared understanding of challenges, more common goals, consistent ideas about how much cost matters, and that it is easier to partner within the system. She noted the need to translate those features into non-integrated systems.

Bob Griss, Institute of Social Medicine & Community Health, noted that Dr. Kizer's comments raised questions of prevention that have not been addressed in the technology of treatment. He questioned why the government is not doing more to integrate data and make use of it to support policy changes and regulations. Dr. Kizer commented that he implemented the tobacco control program in California in the 1980s, and as a result of that program, tobacco use rates have dropped disproportionately to other states. This had to do with increasing tax on tobacco products. This was fiercely opposed but it passed because enough evidence was provided to the public about the impact and cost of tobacco. He agreed that some social determinants of health, such as education, food, and housing, may have more to do with improving clinical outcomes than the latest genetic therapy. Dr. Geiger added, "We knew in the 1950s that tobacco caused lung cancer, that's roughly 60 years ago, and still 20% of people smoke." With tobacco, you have to get people to stop doing something. Factors that contribute to cancer prevention, such as nutrition and physical activity, are more complex because you have to get people to do more complicated behaviors that require a lot of choice.

Jean Owen, Owen Consulting, asked Dr. Kizer how he deals with IRB and regulatory requirements when linking state registry data with other forms of research data. Dr. Kizer responded that linking state registry data with private EHRs has a different set of issues than linking state databases. He noted that one of the things they would like to explore is linking the state cancer registry, genetic disease registry, immunization registry, and data on newborn birth defects. Twenty-five years ago, the problem with doing this was technology; that is no longer a problem. Now the problems are administrative policy, political, and privacy issues.

Dr. Norton commented that his takeaway from this discussion was that current "war on cancer" efforts are fragmented because we do not share goals, vocabularies, approaches, and data sets, and there is competition among centers, across geographic areas and in politics. He asked whether the panelists have suggestions for dealing with this issue. Dr. Geiger responded, "I don't know how you do it unless you centralize health care. There has to be somebody or some group who has the power and will to get people to the table and get them to commit to making changes. We do have a common enemy but we do not have an army assembled." Not having a single payer system and not wanting government in health care creates barriers. Dr. Kizer said that "the war on cancer has been only modestly more successful than the war on drugs." He posited that the private sector can only be brought together if something is spearheaded by the government.