PRACTICE MANAGEMENT AND INFORMATION TECHNOLOGY

CancerLinQ: A Rapid Learning System for Oncology

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CancerLinQ and the Future of Cancer Care

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OVERVIEW

Patients, health care providers, and payers all have a similar interest in a health care system that is both efficient and intelligent. The attributes of such a system are widely recognized: we want a system that provides widespread access to consistently high-quality, science-based medical care; we want that system to be efficient, avoiding unnecessary waste, while delivering the right treatments to the right patients in a timely fashion; we want a system that allows us to both learn from our experience and generate new knowledge that will inform future treatment options; and we want a system that is compassionate and caring. What we want from a health care system often runs up against real-life obstacles and challenges: a fragmented delivery system, varying levels (or lack of) insurance, a growing burden of regulation and paperwork, and an increasingly complex understanding of tumor biology and the therapeutic approaches derived from this biology. New challenges are on the horizon—emerging genomic and imaging technology, with their enormous cognitive and data burdens, and a looming demographic challenge, where inadequate personnel resources face an aging population and an explosion of new treatments. Not all problems have technologic solutions, but many of the issues described above have potential solutions related to information technology. ASCO’s CancerLinQ, described in this article, is an evolving attempt by the Society to improve the quality and efficiency of cancer care, while supporting education and research in the cancer field.

The explosion of knowledge resulting from advances in genomics and proteomics requires clinicians to process dozens if not hundreds of facts per clinical decision, exceeding human cognitive capacity by two to three orders of magnitude.1 The management of “big data” represents a growing challenge in the biomedical sciences. This is particularly true in oncology, where a wide variety of data elements, including existing and putative biomarkers, must be linked to individual patient data and clinical outcomes. There is an urgent need to aggregate and evaluate data elements currently captured in disparate health care settings and information systems to inform the development of “omics”-centric clinical practice guidelines.2

LIMITATIONS OF ELECTRONIC HEALTH RECORDS: THE NEED FOR A RAPID LEARNING SYSTEM

Despite the increasing adoption of electronic health records (EHRs), in part catalyzed in the United States by federal “meaningful use incentives,” lack of interoperability of most commercial systems across institutional boundaries remains a major issue. The harmonization of existing standards for vocabulary and code sets, clinical content exchange, and transport has been a major focus of the Health Information Technology Standards Committee (HITSC), the Federal Advisory Committee that makes recommendations to the National Coordinator for Health Information Technology, part of the U.S. Department of Health and Human Services (HHS).3 In oncology there is an additional concern regarding the lack of existing data standards robust enough to describe the nuances and complexity of cancer care, given its multidisciplinary and data-intensive nature. To share data between and across provider organizations for such tasks as care coordination, quality measurement, and research, data elements must be interoperable on both a syntactic (data format) and semantic (data meaning) level so that clinical meaning is preserved irrespective of the EHR supplying the data.4 ASCO is currently involved in an effort to develop a framework for oncology data exchange that utilizes the Health Level 7 (HL7) Clinical Document Architecture (CDA).5 This will be based on the existing ASCO Treatment Plan and Summary documents for breast cancer, which have been created to coordinate treatment and facilitate survivorship care.6 Creation of this standard will build on prior work, including oncology templates from the National Cancer Institute and tools from the Centers for Disease Control and Prevention (CDC) used in reporting cases to cancer registries. Standardizing the characteristics of these data elements in a structure as widely adopted and accessible as HL7 templates will improve interoperability, although the approval and adoption process can be lengthy.

The rapid learning health system (RLHS), first described by health services researcher Lynn Etheredge in 2007,7 is a technology framework that might be able to surmount some of the challenges described above regarding interoperability. In
an RLHS, multiple data sources, including elements from the delivery of routine patient care, results from clinical trials, registry information, and patient reported outcomes, are continuously aggregated into a centralized databank or separate coordinated databases. These data in turn are analyzed in an iterative process that constantly feeds back to generate new knowledge, which can then be used for routine care, clinical trial hypothesis generation, and clinical practice guidelines. Although consistent data standards are optimal for the analysis of aggregated data, true semantic interoperability is not a requirement. Furthermore, depending on the dexterity of the programming and analytic properties of the system, identical data formats across sources may not be mandatory. The power of the RLHS is in its comprehensive scope and the artificial intelligence of the software, which “learns” through the iterative aggregation and analysis of the data streams.

The Institute of Medicine suggested in 2009 that the discipline of oncology is particularly well suited for the development and implementation of an RLHS, given the effect of cancer, the complexity of the data, and the high levels of patient engagement and empowerment currently seen. There are numerous reasons why an RLHS in oncology is potentially attractive. For example, it is well recognized that most clinical trials address only a limited population or a narrowly focused clinical issue, and the generalizability of the results are often in question. An RLHS can incorporate data from a series of clinical trials with varying eligibility requirements, on-trial assessments, and therapeutic interventions to answer crosscutting questions that cannot be ascertained from the analysis of an individual trial. Likewise, data in population-based cancer registries, such as the regional registries supported by the CDC, can be linked with EHR data using rapid learning technology. In addition, a particularly exciting example where an RLHS model could advance care is in the area of genomics and personalized medicine.

**KEY POINTS**

- Patients, health care providers, and payers want a system that provides widespread access to consistently high-quality, science-based medical care. That system should be efficient, delivering the right treatments to the right patients in a timely fashion, and should allow us to both learn from our experience and generate new knowledge informing future treatments. Finally, we want a system that is compassionate and caring.
- The real-life obstacles and challenges to creating such a system include: a fragmented delivery system, varying levels (or lack of) insurance, a growing burden of regulation and paperwork, and an increasingly complex understanding of tumor biology and the therapeutic approaches derived from this biology.
- ASCO’s CancerLinQ is an evolving attempt by the Society to improve the quality and efficiency of cancer care, while supporting education and research in the cancer field.

Patient-level data, including blood and tissue biomarkers and genomic data, could be linked with outcomes data and facilitate comparative effectiveness research (CER), which in the future could affect economic outcome data and quality measurements. However, the requirements for this type of CER are steep, and to be successful, a more robust cancer informatics infrastructure must be developed, and greater linkage between institutional biorepositories must be enabled.

ASCO has chosen to undertake the development of an RLHS, entitled CancerLinQ (“Learning Intelligence Network for Quality”), as part of its core mission of promoting cancer care quality. The Board developed guiding principles for an ASCO-based RLHS at a 2011 strategy meeting. A Rapid Learning System Working Group, staffed by ASCO volunteers and supported by new ASCO staff, was created in response to the Board’s initiative later in 2011. ASCO’s vision for CancerLinQ was presented in a series of announcements beginning in the second quarter of 2012. A working prototype of CancerLinQ was unveiled at the 2012 ASCO Quality Care Symposium in a presentation by ASCO Chief Executive Officer Allen Lichter, MD.

As described below, this pilot utilized EHR data from a small collection of oncology practices, which were extracted and batch processed using a combination of an open source EHR and commercial analytic tools. This pilot project was created primarily to show a proof of principle rather than a production-ready model, but serves as the basis for ongoing and future efforts by ASCO in the RLHS universe.

ASCO’s CancerLinQ is intended to become the logical extension of ASCO’s series of quality programs and initiatives. These include the National Initiative for Cancer Care Quality (NICCCQ), which assessed breast and colorectal cancer care in selected metropolitan areas; the Quality Oncology Practice Initiative (QOPI), a practice-based quality improvement program for U.S. medical oncologists to assess their performance on a series of quality indicators against national benchmarks; the QOPI Certification Program (QCP), a 3-year certification for practices demonstrating particularly notable levels of performance for patient care quality and safety; and the ASCO Clinical Practice Guidelines. CancerLinQ is envisioned as being particularly useful in compensating for some of the inherent deficiencies of the ASCO guideline process, specifically the long-time horizon required for the integration of the systematic review of the literature and expert opinion and the limited scope of each guideline. Because the ultimate source of CancerLinQ data is a combination of real-time practice data, data from clinical trials, patient-reported outcomes, and registry data, this will enable a much more nimble process to generate high-level evidence at the point of care than the current retrospective application of practice guidelines. While ASCO’s existing guideline process will no doubt continue to play a valuable role in the assessment of evidence useful for clinical practice, it will be complemented and enhanced by outputs from CancerLinQ if the full vision of this prototyping is realized.
THE CANCERLINQ PROTOTYPE

To demonstrate the feasibility of a Rapid Learning System (RLS) in oncology, the ASCO Board of Directors commissioned a project to build an RLS prototype in early 2012. Although the prototype was not designed for full functionality, it was developed to demonstrate proof of principle for five key goals:

1. Capture and aggregate complete longitudinal patient records from any source, in any format, and make use of the data
2. Provide real-time clinical decision support based on clinical guidelines and integrate that into a demonstration EHR system
3. Measure clinical performance on a subset of QOPI performance measures
4. Explore and generate hypotheses from clinical data
5. Provide lessons learned about technical and logistical challenges of a full CancerLinQ implementation

The prototype was developed using open source software to expedite development. We used CouchDB as our operating platform, PopHealth for quality reporting, Open MRS as the Electronic Health Record, and Galileo Cosmos (not open source) for a hypothesis-generating reporting tool.

ASCO worked with the consulting firm Sapient to build the prototype in 5 months. To date, we have acquired 130,000 de-identified breast cancer cases and imported them into the system for testing. ASCO worked with several community oncology practices to obtain and de-identify data through a third-party de-identification service.

The prototype was not built to be scalable into a full RLS. However, we were successful in accomplishing the goals we identified at the beginning of the project.

Capturing Data from Any Source and Understanding the Data

Using the 130,000 de-identified breast cancer cases from five large practices and a compilation of data from 14 additional practices, we were able to import all case data regardless of the specific EHR used at the physicians’ site of practice. Using statistical functions and an artificial neural network as a model, we are now able to learn, structure, and dynamically map data fields as the data is acquired. This feature, once fully automated and scaled, will allow any practice—regardless of EHR—to participate in the full CancerLinQ project. The flexibility built into the design will allow for capture of any data including, but not limited to, billing and administrative data, pharmacy records, surgical, radiation, and hospital data, creating one of the most agile data systems in all of medicine.

Real-Time Clinical Decision Support

To demonstrate this capability we used Opener’s, an open source EHR, and converted it to have the functionality of a basic oncology EHR. Five ASCO breast cancer guidelines were translated and converted into computable statements to provide real-time clinical decision support (CDS). The system provides a CDS message when breast cancer data is entered into the EHR. The messages are a combination of adherence messages and guidance messages, which can be addressed or ignored by the physician. If a clinician wishes to see the source documents (actual ASCO guideline), direct links are embedded in the CDS message allowing for instant access.

The CDS functionality was designed and programed with scalability and flexibility in mind. To program CDS, you must start with a treatment decision tree with multiple decision nodes. Most CDS systems require an elaborate and time-intensive reprogram of the whole system when guidelines change. CancerLinQ is designed so that each decision node is created as an independent, stand-alone file. This allows ASCO to change a decision support recommendation or add new material in minutes without disrupting the rest of the decision tree.

Measuring QOPI Compliance in Real Time

Using a similar process in converting ASCO Guidelines to computable programmable statements, we also converted 10 breast cancer QOPI measures. We programed the QOPI measures into an open source software called PopHealth and demonstrated the ability to measure quality metrics in near real time. The system has the ability to provide QOPI scores on the metrics and displays the numerators and denominators for each measure.

Demonstrate the Data Can Be Explored for the Purpose of Hypothesis Generation and Learning

Once data have been processed and structured into CancerLinQ’s common data model, the data elements are available for many types of analyses and reporting mechanisms. One benefit to aggregating large volumes of clinical data is the ability to spot otherwise unknown trends. We employed the data analytics module Cosmos, which provides intuitive visualization of data allowing for easy and expedient data analytics. To run queries, one simply drops and drags data elements into the appropriate areas and runs the analysis. In seconds, a “starburst” cluster forms showing the relationships between the variables selected. To explore the relationships, one simply clicks on a variable to see the next layer of a relationship. Statistics are provided instantly and can be viewed by “hovering” over any data element. More extensive graphs and statistics are available with a click, and exporting the data set or analytics is also available. Figure 1 provides a screen shot of the tool.

As an example, breast cancer data has been sorted by stage and treatment regimen, here AC/paclitaxel. The large green circle contains the cases, and the blue labels contain the stage breakdown. By querying the case data for side effects, the upper starburst appears with each node being a separate complication. Clicking on each of those would expand that subset for further analysis. The value of such analytic tools for health care researchers, and for a Society interested in describing trends in cancer care, is obvious.
Lessons Learned

In 5 months, using open source software ASCO has been successful in building a functioning prototype of an RLS in oncology. The prototype was not designed to incorporate all functionality of an RLS. For example, we know a full-scale RLS will need to acquire data in real time, return information in real time, have the ability to scan notes using Natural Language Processing, and several other key functions. There are many challenges ahead, but the prototype provides important lessons learned; no doubt we will continue to learn from the system as it develops new functionality.

THE FUTURE OF CANCERLINQ

We continue to work closely with the ASCO Board of Directors and many ASCO committees, advisory groups, and health information technology (HIT) experts to develop the prototype and the subsequent full build of CancerLinQ. By June 2013, “lessons learned” documents will be complete, and the Board of Directors will have made decisions on how to move forward with building CancerLinQ. We anticipate the second half of 2013 will be spent preparing functional requirements, building a development team, and exploring vendors and technology for a build beginning in early 2014.

Leaving aside the real technologic challenges, many other important issues remain. ASCO is not a technology company. What relationships do we forge with such companies, allowing CancerLinQ to be both widely used (or imitated) and self-supporting? Does CancerLinQ itself become the backbone of a new Rapid Learning System or remain an important working model supplying guidance and support for others?

CancerLinQ’s ultimate success or failure will depend on its ability work in the complex health care environment. ASCO’s central role in developing CancerLinQ is based on its “honest broker” role for the many competing interests in cancer care. But ASCO is certainly not the only participant in this field. How will we interact with strategic partners in the pharmaceutical and insurance industries and in government? What roles will our sister societies play in its development? Will we develop all of the guidelines used by CancerLinQ or become a clearinghouse for guidelines developed by others?

Governance issues are at the center of many developmental issues for CancerLinQ. What principles will guide who will have access to data and at what level? How will a complex, rapidly evolving system maintain patient privacy, while being useful to physicians across multiple health care systems? How will researchers access the cornucopia of data such a system would supply? Who will decide which information is

FIG 1. Screenshot of Cosmos tool. Breast cancer data have been sorted by stage and treatment regimen, here AC/paclitaxel. The large green circle contains the cases; blue labels contain the stage breakdown. By querying the case data for side effects, the upper starburst appears with each node being a separate complication.
supplied and to whom? What role will individual physicians, and patients, play in the use of patient and practice data? CancerLinQ’s Rapid Learning System Working Group, along with ASCO staff, are already wrestling with these important governance issues.

How do we make CancerLinQ useful, rather than burdensome, to busy health care providers? Time is every physician’s most valuable asset, and, to date, information technology has arguably done little to improve the efficiency of health care delivery. CancerLinQ should access and aggregate data from multiple sources, it should support a physician’s ability to find and deliver the right treatment for the patient in clinic in real time, it should simplify interactions with payers, it should support quality initiatives and guideline information, it should support recertification, and it should serve as the backbone for clinical and translational research against the background of increasingly complex tumor biology. All of these will require not just large amounts of work, but also new modes of thought. Those new modes of thought will also change the Society itself. CancerLinQ will allow the Society to become an important node in health care’s HIT network, rather than just an interested observer. It will allow us to become a creator of health services research and allow our members to ask and answer important clinical questions. It will require us to alter how we develop guidelines, and how we use quality measures, in an increasingly fluid, rapidly evolving environment. It will, or should, change the relationship between ASCO’s membership and patients with cancer, insurance providers, and the pharmaceutical industry. It will require the energy and wisdom of our volunteers and staff to create the future of cancer care, a worthy goal for all of us.

**CONCLUSION**

There is still a massive amount of work to be accomplished to fully realize the CancerLinQ system. The prototype is an important early achievement, one step in the stairway to building a CancerLinQ system. The interest of our society’s members, and their continued support for the project, is heartening to the ASCO volunteers and staff tasked with this project. We look forward to a day when every patient and oncologist derives benefit from CancerLinQ.

**Disclosures of Potential Conflicts of Interest**

The author(s) indicated no potential conflicts of interest.

**References**

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Understanding and Surviving the Transition to Value-Based Oncology

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OVERVIEW

This paper and the three presentations it supports are drawn from the theme of the 2012 Cancer Center Business Summit (CCBS): “Transitioning to Value-Based Oncology: Strategies to Survive and Thrive.” The CCBS is a forum on oncology business innovation, and the principal question the organizers address each year is “What are the creative, innovative, and best business models and practices that are being conceived or piloted today that may provide a responsible and sustainable platform for the delivery of cancer care tomorrow?” At this moment in health care—when so much is in flux and new business models and solutions abound—the oncology sector has a solemn responsibility: to forge the business models and relationships that will help to define a new cancer care value proposition and a sustainable health care system of tomorrow for the benefit of the patients it serves to get it “right.”

Driven by economic, social, and moral imperatives, our society has to reckon with the unsustainable growth of health care spending and inappropriate variations in access to and definitions of quality health care. Health expenditures in the United States neared $2.6 trillion in 2010, over 10 times the $256 billion spent in 1980.¹ In total, health spending accounted for 17.9% of the nation’s gross domestic product (GDP) in 2010 and will account for one-fifth of our GDP by the end of this decade, potentially consuming our entire GDP by midcentury.² Cancer care accounts for one of the fastest growing segments in health care spending.

Health care purchasers are focused on reigning in their health care costs—be they private insurers, large employers, or the government (which now accounts for over one-half of all health care expenditures). All purchasers demand cost control while making sure the monies they are spending are purchasing high-quality, predictable care. Ongoing themes include reducing prices per unit of care delivered, reducing the volume of services consumed per individual, and increasing access and quality of care.

Levers are in play to accomplish these goals. Large payers are qualifying narrower networks of providers based on cost and measures of quality and then using the payers’ clout to steer patients into those networks. To participate in the network and derive the benefit of patients being directed to them, practices have to report real care data on the populations of patients they serve and accept lower reimbursement for the volume of patients presented. Other levers focus on patients and employees. Higher shared costs and copays force patients to adhere to the narrower networks. Benefit design shifts from contracts that detail covered benefits to those that define an employer’s economic contribution. The employee is then responsible to go to a market and purchase insurance with the employer contribution and their own money. Higher out-of-pocket premiums, higher deductibles, and copays will all cause patients to be more “careful” in utilizing health care services. This is the basic design of the government’s health exchanges. Private companies are already creating “private exchanges” with the overall goal to shift cost to the employee or patient. In addition, employers are adopting care management schemes that incentivize healthy behaviors. These levers will work together to lower reimbursements to providers and decrease utilization.

Ultimately, purchasers wish to unify the health care value chain and transform its structure to incentivize the creation of care systems that assume risk for the care of a patient population. As individual physicians, we introduce much duplication of service and variability in care simply by the orders we write. The resulting cost effects are amplified by fragmentation of care in separate specialty silos. To break down these silos and prompt coordination of care, purchasers narrow their provider networks and seek systems that can care for a large population of patients. These efforts are working as systems are beginning to amass. These systems are created in varied ways, including large health care systems acquiring physicians, hospitals, and insurers; insurers purchasing physician practices and hospital systems; and physician groups purchasing hospitals and insurers. The “end” of each of these consolidations is an integrated health care system. The goal is for a system to provide all the care a population needs, and to
do so at a predictable cost while transparently meeting quality metrics. These systems face many challenges: there must be a team-based culture (something that is not widespread in medicine), a presence of data analytic capabilities to guide the “management” of care decisions, and a governance that can hold all providers in the system accountable to quality and cost. Thus armed, the system can take on “costs risk” for the population. This risk is the heart of value-based reimbursement.

A tension for medical practices trying to prepare for the shift from volume-based reimbursement to value-based models is to find the proper balance between two polar transition strategies: whether to embrace the change and invest in the transition ahead of reimbursement changes (thereby guaranteeing a period of revenue loss while waiting on payment reform) or seek contracts that recognize value-based reimbursement and then scramble to figure out how to deliver it (making transition investments on the fly thereby guaranteeing financial stress as the practice struggle to manage the risk with the value-based contracts). Either way, oncology practices (indeed all practices) are going to struggle with change.

How to prepare? How to survive? There are no absolutes. A truism is that all practices and markets are facing very similar questions, but every market is distinct enough that there are no universal solutions. The following are other truisms:

- Embrace change. To survive, every practice will have to transform to differing models of care and develop partnerships. No practice will exist alone.
- Know your market—not only other oncology practices but also who are large employers, how will demographics change, what are pressures on local and state governments, what is the health of the hospital/health care systems, who is the primary care system aligned with, etc.
- Get bigger, either through collaboration, partnerships, consumption, or being consumed. How does your practice fit in a “system” world?
- Measure data. Adopt quality and efficiency measures in practice, use the information to drive, and demonstrate improvement.
- Rather than focusing on individual patient transactions, begin to understand the populations you serve. Segment your practice populations and standardize care.
- Prepare to manage risk.

Presentations at the 2012 CCBS emphasized many aspects of these truisms. Two transitional models of care were discussed at length, both of which can help practices transition into a future of risk-based reimbursement. The Oncology Patient–Centered Medical Home (OPCMH) employs a framework of practice improvement, increased communication, standardization, and population management into a transformative practice model. The OPCMH model may be a perfect segue into a larger entity, the accountable care organization (ACO)–essentially taking those same principles and applying them across diverse practices and often including a hospital in the mix.

**THE OPCMH: RISKY OR REVOLUTIONARY?**

Amid the dynamism of health system restructuring, community-based oncology practices and institutionally based cancer programs have a significant opportunity to lead positive change. This overview presents how the drive to create a business case for quality in cancer care led to the development of the OPCMH model and how you can prepare your practices to focus on the essential demand for improved quality and value, irrespective of future payment models (episode-based or bundles) or the organizational structure of the parties adopting it (ACOs, hospital system/payer hybrids, independent practices, clinically integrated networks, large, single tax identification number networks, etc). OPCMH is presented as a physician-driven, patient-focused value proposition that can really make a difference for patients, oncologists, and the cost of health care.

**Foundational Activity**

Mirroring our health care system in general, the delivery of cancer care is often fragmented—fraught with deficiencies in communication, coordination, and accountability. The PCMH model has emerged as a partial solution to the fragmented delivery of primary health care. Similarly, the OPCMH model of cancer care may serve as a framework for oncologists as it promotes a value-based agenda that facilitates physician accountability, encourages clinical integration between like-minded cancer care providers, enhances communication and coordination of care with primary care PCMH or ACO models, and collaborates with payers while maintaining a focus on patient needs and evidence-based

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**KEY POINTS**

- Driven by economic, social, and moral imperatives, our society has to reckon with unsustainable growth of health care spending; this will require fundamental change in how medicine is practiced.
- Each practice must develop its business case for quality and value that will sustain it through the transition from fee for service to value-based models of care.
- Improved models of cancer care delivery need to be broadly achievable and applicable to oncology practice regardless of the setting of care (e.g., private-, institutional-, or academic-based practice).
- The oncology medical home model of care demonstrates a reduction of the “cancer spend” by 7% to 13% through the implementation of structured care management and communications processes.
- Within the context of an accountable care organization, common areas of focus that effect oncology cost and quality are compliance with evidence-based, cost-effective pathways and drug regimens, reduction of emergency room visits and hospital admissions, and a disciplined approach to end-of-life care.
care. Consultants in Medical Oncology and Hematology (CMOH)—a nine-physician, hematology oncology practice outside Philadelphia—began to make the business case for quality in cancer care in 2003.

There is important, necessary foundational activity in the majority of cancer programs and practices to redesign the delivery of care and drive consistency and quality while reducing unnecessary resource utilization. Gosfield and Reinertsen, in their 2003 white paper, “Doing Well by Doing Good: Improving the Business Case for Quality,” noted, “Because of the centrality of the doctor–patient relationship to the delivery of health care services, improved quality of health care will not achieve its full potential unless physicians are enthusiastically engaged in such efforts.” They defined a number of barriers to the business case for quality as well as notorious “time stealers” that distract physicians from their work and need to be navigated throughout their workday. Gosfield and Reinertsen demonstrate that there is “considerable consistency among both the barriers to a business case for quality and those forces which steal time from the doctor–patient relationship. Many are the same problems viewed from different perspectives. To engage physicians for quality, permit broader and deeper applications of science, and provide patients-centered care, basic aspects of the physician work environment must change.” They proposed five core principles to guide new approaches to the way care is delivered, four of which are within the clinician’s domain. These five core principles include Standardize, Simplify, Make Clinically Relevant, Engage Patients, and Fix Accountability at the Locus of Control. In attempting to make our business case for quality, we modified the core principles slightly and added a sixth.

1. Streamline and standardize the processes of care (reducing valueless variation in the way care is delivered).
2. Simplify payment and administrative systems (outside of the physician’s clinical domain).
3. Minimize clinically irrelevant physician activity (allowing physicians to focus more time on making complex medical decisions and maintaining personal relationships with patients and their families).
4. Place patient education, needs, and preferences at the center of the health care delivery equation (patient centeredness, access, engagement, coordination, direction, communication, etc.).
5. Fix accountability at the patient–physician locus (organize a care team and redefine job responsibilities with physicians bearing ultimate accountability for the execution of care).
6. Commit to ongoing, data-driven, continuous process improvement (measuring performance metrics that drive patient- and payer-centric outcomes).

Principles 1 and 3 are partially addressed by internally agreeing to standardize actions within the practice and fully implementing an oncology-specific electronic medical record. Patient centeredness is not a cultural shift for most cancer care providers, but it has to be infused into the execution of every aspect of care delivery. All of the above principles require the capability of collecting and reporting real-time performance data to the physician-led care team to drive desired outcomes. This required the creation of physician-centric software support, that was designed to match the process of care, workflow, decision making, documentation, and communication necessary to enhance the consistency of care delivered to a population of complex hematology oncology patients.

Our customized software overlay, Iris, allows us to streamline and standardize care, track multiple disease management data points in patients with comorbid conditions, and facilitate the identification and measurement of potential complications of therapy and disease.

These efforts supported a business case for quality and led to CMOH’s submission of a Physician Practice Connections-PCMH application to the National Committee for Quality Assurance (NCQA) in 2009. To facilitate the practice’s transformation, a technology, advisory, and service optimization company, Oncology Management Services (OMS), was formed. We labeled this practice model OPCMH.

OPCMH

In 2010, CMOH became the first oncology practice recognized by the NCQA as a level III PCMH. The model is straightforward and built on the previous focus on quality by ASCO, the National Comprehensive Cancer Network (NCCN), American College of Surgeons, National Quality Forum, Institute of Medicine, and NCQA. At the time of cancer diagnosis, the practice assumes the primary responsibility for the coordination of all related services for patients requiring evaluation and active treatment of their oncologic and hematologic conditions. Responsibility of care delivery continues through all necessary therapy—including surgery, radiation therapy, and chemotherapy—and extends into the survivorship phase of care. The practice does not assume the management of non-oncologic medical issues from the patient’s primary care physician, necessitating the maintenance of an intense level of communication between the practice and the primary care team.

The growing national attention focused on this model has, in large part, stemmed from CMOH’s success in effectively reducing unnecessary resource utilization. CMOH has seen positive results since 2007. Particular areas of improvement in care are shown in Fig. 1.

Phone Triage System

Enhanced patient engagement has resulted in a dramatic increase in timely clinical phone calls to CMOH’s triage system. Trained nurses use customized symptom management algorithms to address clinical issues, and every clinical call is tracked, recorded, and analyzed. In 2011, over 80% of all clinical calls resulted in the management of symptoms at home. Approximately 10% of clinical calls resulted in an unscheduled office visit within 24 hours. Four percent of clinical calls resulted in emergency room (ER) evaluations.
NCCN Guideline Compliance
Compliance is enhanced by construction of standardized care plans within the electronic medical record.

ER and Admissions
CMOH has lowered emergency department visits by 68% and hospital admissions per patient treated with chemotherapy per year by 51%. CMOH has also seen a 22% reduction in outpatient visits per patient per year in the general (hematology and oncology) patient population and a 12% reduction in outpatient visits per patient per year in the chemotherapy subpopulation (2008–2011).

Unscheduled Visits
With improved patient engagement and expanding patient access to the clinical staff, the number of unscheduled office visits within 24 hours of a clinical call doubled by 2010. Interestingly, that number of unscheduled visits declined in 2011 possibly because of increased consistency and effectiveness of routine office visits.

Goals of Therapy and End-of-Life Care
Performance status serves as the focal point of patient-centered care. It is the basis for decision making on the day of chemotherapy administration and is used longitudinally as a guide to update goals of therapy and the initiation of end-of-life care discussions and timely hospice referrals. Endpoints measured in the last 8 weeks of life include ER, intensive care, and hospital admissions; chemotherapy administration; radiation therapy; and hospice enrollment and duration.

Documentation Turnaround Time
Progress notes serve as a universal document relevant to referring physicians; co-managing radiation and surgical oncologists; cardiologists, etc.; telephone triage nurses; patient and family members; precertification specialists; payer medical directors; chemotherapy nursing staff; covering physicians within the practice; and ER physicians. The document continues to serve as a survivorship care plan template for those patients completing adjuvant therapy.

The aggregated economic savings for CMOH’s payers are substantial and serve as the business case for quality and value in cancer care. The magnitude of the savings—estimated at 7% to 13% of the total cost of cancer care—is a reflection of the cost of caring for a concentrated population of clinically vulnerable, older, chronically ill patients with multiple comorbid conditions and unique psychosocial needs. CMOH demonstrated that the processes of improving the delivery of cancer care and reducing unnecessary use (waste) are intertwined; they are one and the same.

The Business Case for Payer Collaboration
As the cost of cancer care is rising at an unsustainable rate, payers and government programs are looking for solutions. Other current “oncology management” solutions available to payers are transitional at best. These solutions tend to focus...
on chemotherapy costs, which account for approximately 22% of the total amount spent on cancer care (I. Klein, Aetna Medical Director, personal communication, November 2010). This narrowly focused approach only partially advances the quality-of-care agenda and does not advance the value proposition from the patient service and disease management perspective.

The OPCMH model of cancer care looks beyond chemotherapy drug pathway compliance. Practices with these capabilities will be positioned to become future providers of choice, capable of transitioning to value-based payment models.8

Payers have acknowledged the value of, and responded favorably to, primary care PCMH efforts. The recent emergence of the NCQA Patient-Centered Specialty Practice Recognition program is expected to provide a framework for improving care delivery ad coordination and provide independent objective verification of a specialty practice’s commitment to continuously improving quality and service while reducing unnecessary utilization of resources. Payers are responding favorably to this structure.

OPCMH is potentially transformational. Focused on the essential demand for improved quality and value and irrespective of the payment model or the organizational structure of the parties adopting it, OPCMH is flexible enough to accommodate whatever payment changes may come in the future.

**ONCOLOGY’S FIT IN AN ACCOUNTABLE CARE WORLD**

**Accountable Care Backdrop**

Accountable care has entered the health care mainstream and it is not likely to fade away like similar initiatives in integrated health care in the 1990s. There are currently 254 Medicare-designated ACOs as of January 2013 with at least another 200 or so commercial/non-Medicare ACO-like programs in place nationally.9,10

The objective of accountable care is expressed in terms of the “triple aim,” that is, to improve the experience individual care, to improve the health of populations, and to reduce health care costs per capita (or at least reduce the escalation in costs).

Accountable care is founded on principles of patient-centered and coordinated care—drawing from the same principles that underpin the PCMH. Early accountable care initiatives, such as the Medicare Physician Group Practice Demonstration, were principally primary care oriented.

The primary care orientation to accountable care focuses on management of chronic health impairments, such as diabetes, hypertension, asthma, chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF). The expectation is that by virtue of active monitoring and early intervention and through coordination of specialist care, outcomes will improve and overall health care costs will be reduced.

But what is the magnitude of cost savings that can be achieved solely through primary care–focused efforts? Early results have been less than encouraging. One study conducted by the Dartmouth Institute for Health Policy and Clinical Practice identified an overall cost savings of $114 per Medicare beneficiary for participants in the Medicare Physician Group Practice Demonstration.11 Another recent study reported in *Health Affairs* showed little savings produced from primary care–oriented efforts associated with diabetes management.12

Could ACO cost savings be greater if high-cost specialties, such as oncology, were provided an incentive to contribute to ACO cost savings? After all, oncology costs associated with a Medicare patient attributed to a Medicare ACO are going to be charged against the ACO shared savings pool anyway. So why not bring oncologists into the mix?

**Are ACO Leaders Thinking About Oncology?**

We wanted to better understand where oncology fits in this new paradigm. What are accountable care leaders actually thinking with regard to including or excluding oncology in their ACO plans? We set out in search of answers in the 2012 Annual Industry Survey of the CCBS with our research survey, “Oncology’s Fit in an ACO World.”

We conducted our research during from June through August 2012 through semi-structured phone interviews with ACO executives. The study was funded by the Health Care Industry Team at the national law firm of Foley & Lardner and by HillCoHealth, a health policy advisory firm. During the course of the research, 64 direct interviews were conducted. The demographics of the interviewees are described in Fig. 2.

**Key Survey Findings**

Inquiry 1: Are oncologists participating in ACO shared savings? Surprisingly, 18 of 40 Medicare ACOs (45%) indicated that specialists—oncologists included—would participate in some manner in distributions from the ACO’s shared savings pool, but the methodology and timing for including them had not yet been determined. So interviewees seemed to be aware of the potential for tapping into cancer cost savings, but the “how” and the “when” and “how much” are still largely a work in progress.

This finding correlates with a prevalent theme of those interviewed during the survey: in the overall scheme of things, cancer care was a secondary priority (after conditions such as CHF, COPD, diabetes, and asthma) because of oncology’s relative low incidence, high cost, and complexity (i.e., multiple different cancer types, multiple primary sites, and high variation in treatment approaches and regimens). Therefore, it was not currently a top priority for ACO leadership. But because oncology care accounts for as much as 10% of total health care spend, ACO leadership usually recognized that they will need to tackle cancer care costs at some point.
Inquiry 2: Should we limit participation solely to Medicare? We asked the Medicare ACOs whether they had or were planning ACO relationships with commercial/non-Medicare shared savings programs or other alternative payment arrangements. We found that 22 of 40 Medicare ACOs (55%) were also in relationships with commercial/non-Medicare programs and another 17% were in talks with commercial/non-Medicare plans.

This finding would seem to indicate that despite the government-mandated primary care focus of Medicare ACOs, there is significant activity taking place within the commercial health insurance sector where there may be greater opportunity to test oncology savings opportunities.

In fact, our survey identified a number of commercial/non-Medicare programs with an oncology-specific focus that characterized themselves as an “oncology medical home,” “oncology ACO,” or “accountable cancer care organization.” (See the “Who Are the Oncology Accountable Care Pioneers?” section.)

Inquiry 3: How can oncologists achieve substantial savings? Three primary areas of focus were identified for achieving savings in cancer care:

1. Compliance with evidence-based, cost-effective pathways/drug regimens;
2. Reduction of ER visits and hospital admissions by proactively managing side effects through care coordination among providers and 24/7 access, typically to a triage nurse; and
3. Reduction end-of-life care expenses, particularly in the last 15 to 60 days of life, through early end-of-life planning and timely use of palliative and hospice care services.

It is known that early results of savings achieved from the OPCMH model with similar areas of focus have demonstrated a 7% to 13% reduction in the cancer spend. What savings might be had within an ACO with oncologists adopting similar areas of focus?

Doing the Math: Oncologist Contribution to ACO Economics

We examined the potential economic effect of incorporating oncology into the ACO shared savings mix. The following are our assumptions:

1. The cancer incidence rate for the Medicare age cohort (> age 65) is 2,100 per 100,000 population (i.e., 21 per 1,000 Medicare patients in an ACO).\(^\text{13}\)
2. The average cancer costs per Medicare patient (> age 65) are between $45,000 to $110,000 in any given ACO annual shared savings reconciliation period depending on type and stage of cancer and phase of care.\(^\text{14,15}\)
3. The average cancer costs per 1,000 Medicare population is therefore $1,680,000 (21 x $80,000 rounded to $1.7 million).
4. The average 10% savings (range 7% to 13%) are because of oncologists practicing the principles of an oncology medical home or oncology ACO.
5. Applying the 10% savings rate times $1.7 million cancer spend per 1,000 creates $170,000 savings per 1,000 Medicare patients in a Medicare ACO. This equates to $170 savings per Medicare patient in a Medicare ACO.
6. The national median caseload of Medicare patients treated annually by primary care physician is 250.\(^\text{16}\)
7. We assumed an “average size” ACO includes approximately 55 primary care physicians treating approximately 17,000 Medicare patients. This is consistent with the average number of Medicare patients attributed to the Medicare ACOs interviewed in our survey.
8. Applying the cancer cost savings per 1,000 Medicare population of $170,000 to an “average size” ACO population of 17,000 Medicare patients yields approximately $2,890,000 annual cancer cost savings to the ACO shared savings pool (17 x $170,000).

Figure 3 summarizes the economic proposition for including oncology care in an ACO.

Who Are the Oncology Accountable Care Pioneers?
During our survey, we found several organizations that have stepped up and taken the lead in oncology-specific accountable care and associated payments redesign. The list of oncology-specific pioneers includes the following:

1. Consultants in Medical Oncology & Hematology with an OPCMH in Drexel Hill, PA;
2. Wilshire Oncology Medical Group, Anthem Blue Cross with a medical oncology home in Southern California;
3. Baptist Health South Florida, Advanced Medical Specialties, Florida Blue Cross with an oncology ACO in Miami, FL.
4. Innovative Oncology Business Solutions with an oncology medical home (Come Home) Center for Medicare & Medicaid Innovation Challenge grant in New Mexico (with six participating oncology practices nationwide);
5. Priority Health Oncology Medical Home initiative in Michigan;
6. United Healthcare with five clinical pathways pilot sites;
7. Aetna-Texas Oncology/Innovent Oncology;
8. Michigan Blue Cross with a pathways program;
9. CareFirst Blue Cross with a pathways and medical home initiative in Maryland; and
10. Harvard Pilgrim Health Plan with an oncology medical home demonstration pilot in Boston, MA.

Based on our 2012 research survey findings, we believe that by including oncologists in the accountable care enterprise, there will be substantial cost savings over and above what would otherwise achieved in an ACO solely focused on primary care efforts. Assuming an “average size” ACO of 17,000 attributed Medicare beneficiaries, such an ACO could experience an additional $2.9 million contribution to its shared savings pool.

However, to achieve the cost benefits, the oncologists to be included in the ACO enterprise need to be ones that are delivering cancer care services in a cost-conscious and accountable manner (e.g., those practicing in an oncology medical home or oncology ACO construct).

The Dartmouth study found a $114 savings per Medicare patient from primary care–focused efforts. Our analysis shows potential for an additional $170 savings per Medicare patient associated with oncology-focused accountable care management of the patient with cancer. Although these are generalized projections based on the Dartmouth study and our survey results, it would appear that an oncology component of an ACO functioning under the principles of accountable cancer care could match or outstrip the savings derived from all of the primary care–oriented efforts combined, that is, $114 compared with $170 per Medicare patient attributed to the ACO. Based on these observations, the economic

**FIG 3. The economic proposition for including oncology care in an ACO.**

Abbreviations: ACO, accountable care organization; PCP, primary care physician.
proposition for involving oncologists in ACO arrangements is compelling and certainly appears worthy of consideration.

CONCLUSION
This paper reviews three broad themes reviewed in the 2012 CCBS meeting. Health care cost and the social imperative to provide better health care for the money spent demand a transformation of how we provide care. These changes will affect the very structure of the health care delivery system. OPCMH and oncology integrated ACOs are two examples of these structural changes. Oncologists should be proactive in assessing these examples, evaluating their practice settings, and seeking information on how to begin their transformation journey.

The CCBS is a thought leadership group focused on business innovations in community oncology. It explores business, legal, financial, and market developments and spotlights the most advanced thinking of industry leaders pertinent to emerging best models and practices for succeeding in the rapidly evolving market of community cancer care. The 2013 CCBS will be held October 24 and 25 in Chicago, IL, and will continue to present ideas on how oncology can successfully adapt to change.

Disclosures of Potential Conflicts of Interest

Relationships are considered self-held and compensated unless otherwise noted. Relationships marked “L” indicate leadership positions. Relationships marked “I” are those held by an immediate family member; those marked “B” are held by the author and an immediate family member. Relationships marked “U” are uncompensated. Authors marked with an asterisk (*) are participants in ASCO’s Disclosure Management System Pilot; their disclosure is not limited to subject matter under consideration in this article and includes payments to themselves, an immediate family member (i), and/or their institutions (Inst). For information on the pilot program, or to provide feedback, please visit coipilot.asco.org.


References

PRACTICE MANAGEMENT AND
INFORMATION TECHNOLOGY

Implementation of ePrescribing
and ICD10 Diagnosis Coding

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Perspectives on Electronic Prescribing and Terminologies

David Liebovitz, MD

OVERVIEW

Electronic medical records provide potential benefits and also drawbacks. Potential benefits include increased patient safety and efficiency. Potential drawbacks include newly introduced errors and diminished workflow efficiency. In the patient safety context, medication errors account for significant patient harm. Electronic prescribing (e-prescribing) offers the promise of automated drug interaction and dosage verification. In addition, the process of enabling e-prescriptions also provides access to an often unrecognized benefit, that of viewing the dispensed medication history. This information is often critical to understanding patient symptoms. Obtaining significant value from electronic medical records requires use of standardized terminology for both targeted decision support and population-based management. Further, generating documentation for a billable encounter requires usage of proper codes. The emergence of International Classification of Diseases (ICD)-10 holds promise in facilitating identification of a more precise patient code while also presenting drawbacks given its complexity. This article will focus on elements of e-prescribing and use of structured chart content, including diagnosis codes as they relate to physician office practices.

With the signature of President Obama in 2009, the Health Information Technology for Economic and Clinical Health Act (HITECH) became law. The focus of HITECH was to stimulate adoption of electronic medical records and encourage creation of infrastructure to enable interoperability of medical records. The ensuing Meaningful Use subsidy program offered maximum Medicare subsidies of $44,000 for eligible providers and discharge volume-based subsidies to hospitals. These incentives and additional regulatory changes—including requirements for standardized terminology usage such as the upcoming change to ICD-10—have impacted clinical workflow significantly and will continue to do so in coming years. It is worth considering two important subjects in this context: e-prescribing and use of standardized terminology within medical records, including diagnosis coding.

E-prescribing has been deemed a worthy goal for several reasons. In particular, the improved aspects of safe prescribing and patient and physician practice convenience are especially noteworthy. In the context of prescribing safely, it is important to note that 7,000 patients die each year from prescription errors, although improved safety using electronic orders has been better demonstrated for in-patient care than for ambulatory care.1,2 In an oncology context in particular, patients are often especially vulnerable, and risk factors for adverse drug events are often present. Efforts are underway to improve systems and approaches designed to minimize preventable adverse drug events.3 Systems that can mitigate these risks are highly desirable, and e-prescribing, implemented with decision support, can mitigate some of these risks.4

Access to past prescriptions from other practices, a potentially unappreciated benefit, may follow when e-prescribing is fully implemented. Of note, there are freestanding e-prescribing solutions apart from an EHR in which selected criteria for isolated e-prescribing incentives may be met outside of meeting full Meaningful Use criteria. However, to realize the full benefits of e-prescribing and increased benefits from a patient safety perspective in the future, incorporating e-prescribing within a fully functional EHR is required. Within this scenario, consider the case of a patient who is completely new to a practice. Further, assume health information exchanges (HIEs) are not fully functional in the community, which is often the case given financial impediments to successful ongoing HIE business models.5 Then in this case, one would presume the medication section for a new patient record would be blank. However, if a practice subscribes to the SureScripts Medication History service, a list of dispensed medications drawn from community pharmacies and the claims histories from payers and pharmacy benefit managers appear populated with medication names and dates. At the present time the “sig” information (e.g., one tablet daily) is not yet populated given lack of requirements for discrete data elements from all source systems; however, the unit dose of a medication and the number of doses dispensed is available. Thus, in practice, the regimen may often be inferred. Further, EHR vendors now routinely provide the ability to “convert” these pharmacy-processed prescriptions into
the “home medications” section of medical records. Although some manual entry to populate the sig information is required, this initial list may provide a critical starting point when patients are not completely sure of their medications.

There are several important limitations of the currently accepted system of e-prescribing. It is possible that the dose may have changed since the pharmacy processed the prescription. For example, the physician may have told the patient to take one tablet instead of two as had been dispensed, or, in fact, the medication may have been stopped entirely. An additional important limitation is that some items may be lacking for some patient groups. For example, some state Medicaid systems do not share prescription information with the Surescripts network. Further, if a patient were to pay cash and not process the transaction through a pharmacy benefit manager, the medication may not appear within the list. Another important note is that physicians may, at times, be surprised that medication lists are already available to the physician. An additional limitation is that at the time of e-prescribing, the specific pharmacy must be designated. Although this enables prescriptions to be picked up on a patient’s way home from a physician appointment, many patients prefer to price shop among a number of pharmacies. A system that provided for holding prescriptions in abeyance until a pharmacy was selected by the patient could address this limitation. Given this limitation, though, patients may still prefer paper-based prescriptions to allow for price shopping comparisons.

The linkage from the EHR to the Surescripts medication history occurs through the patient’s insurance information, which includes payer and/or a designated pharmacy benefit manager. This linkage provides additional workflow benefits to physicians and convenience benefits to patients. The practice workflow benefits ensue in that patients will be less likely to call back asking for a less expensive alternative medication. Guidance to the physician occurs during the process of e-prescribing in which formulary designations specific to the patient’s coverage appear and facilitate the optimally chosen medication from a financial perspective when efficacy factors are equivalent. Physicians, though, who may be accustomed to prescribing just one or two drugs within a given class of medications may need to become more familiar with a wider array of alternatives. From a patient perspective, there would thus be less often a need to request the pharmacist call back to request a lower priced alternative since the patient’s physician would have this information during the initial prescribing process.

Proceeding along the ambulatory practice workflow for e-prescribing, there are several clear patient safety improvements that become possible with e-prescribing. These include context-specific warnings for weight-based dosing, renal function–based dosing, drug–drug interactions, drug–allergy interactions, drug–problem list interactions, and guidance for potentially indicated but not yet prescribed medications. However, at the current state of medication prescribing decision support, it is important to realize that the decision support is neither comprehensive nor always applicable to given patient care scenarios. In fact, it is even possible to introduce new errors of a type never seen with paper-based prescribing. An example here would be when a physician cannot find an order with the specific preferred regimen listed as an available option and then orders something related and includes a free text comment to override the order details. Unfortunately, this approach introduces substantial risk that the comments will be ignored and the unintended order processed instead.

Given the potential benefits, a Medical Electronic Prescribing Incentive Program began January 1, 2009. This program, mandated through legislation, has begun to issue payment penalties since January 2013. The enrollment requirements are relatively simple and include use of a certified eRx system with reports on how often eRx is being used for prescriptions. Report metrics are then assessed relative to the specific criteria applicable to the reporting period and appear on the Centers for Medicare and Medicaid Services website. For example, the eRx requirements specify that at least 10% of Medicare Part B charges consist of codes specified in the eRx measure. Further, multiple reporting avenues exist. These include use of the eRx measure on Medicare Part B claims, participation in a qualified registry of patients, or submission directly from a qualified EHR or through use of a “qualified data submission vendor” as an intermediary. Further, a group practice reporting option would allow aggregate reporting. Details for both e-prescribing and Meaningful Use criteria continue to evolve. Key websites to monitor are listed in Table 1.

Given these potential benefits and drawbacks, it would be prudent for practices to set a series of goals to maximize the value of the workflow changes required by e-prescribing. Table 2 lists a few example options. To ensure realization of potential benefits, practices should set specific goals. In addition,

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**TABLE 1. Electronic Prescribing and Meaningful Use Incentive Websites**

<table>
<thead>
<tr>
<th>Incentive</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meaningful Use Incentives (CMS)</td>
<td><a href="http://go.cms.gov/VQoQmR">http://go.cms.gov/VQoQmR</a></td>
</tr>
<tr>
<td>Electronic Prescribing Incentives (CMS)</td>
<td><a href="http://go.cms.gov/V1LbxO">http://go.cms.gov/V1LbxO</a></td>
</tr>
</tbody>
</table>

Abbreviation: CMS, Centers for Medicare and Medicaid Services.

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**KEY POINTS**

- Electronic prescribing offers financial incentives and patient safety benefits.
- Usage of the dispensed medication history for patients may improve medication safety.
- Use of structured terminology facilitates quality metrics and decision support.
- Claim transmission using ICD-10 is required starting October 1, 2014.
TABLE 2. Potential Benefits to Monitor and Seek to Achieve with ePrescribing

<table>
<thead>
<tr>
<th>Potential Benefit</th>
<th>Measure for Possible Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced staff time processing refills</td>
<td>Number of faxes sent and received</td>
</tr>
<tr>
<td>Decreased pharmacy callbacks for clarification</td>
<td>Number of messages left for physicians</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Number of complaints regarding prescriptions</td>
</tr>
</tbody>
</table>

approaches to maximize efficiency, such as setting pharmacy “favorites” in the system for nearby pharmacies would likely be a significant timesaver.

For electronic medical records to yield significant benefits across a population of patients, functionality to cluster similar patients and identify key clinical events and any outliers is required to ensure all patients receive a care standard. In this context, tracking variables such as diagnoses, medications, and test results in a consistent manner is required. To exchange clinical information across practice sites and track services provided and adherence to quality-of-care standards, consistent documentation schemes are required with specific values that may be compared and exchanged within and across practice sites. Specific terminologies exist across these various clinical dimensions. In the context of medications, many proprietary terminologies exist among vendors of medication content for medical record systems. RXNorm, however, is an accepted normalized list of drugs (e.g., First Databank, Micromedex, MediSpan, Gold Standard, and Multum) mapping across all proprietary references. This mapping may then facilitate both information exchange and tracking for quality measures. The National Provider Identifier identifying specific physicians is another example of standardization allowing for transactions and reporting. In another example of standardization of key clinical record events, collaboration among the Office of the Surgeon General and the National Human Genome Research Institute has led to the formation of an online family history tool for submitting and tracking these clinical elements (https://familyhistory.hhs.gov). In addition, for the problem list, Meaningful Use requirements specify SNOMED CT should be used, and certified EHR systems now incorporate this mapping either explicitly or as the default problem list terminology. Of note, the terminology used for diagnosis codes and therefore for billing purposes and various quality measures is now changing from ICD-9 to ICD-10. One might inquire why not switch from ICD-9 directly to SNOMED CT for billing if it is already in use for problem lists. As it happens, a transition from ICD-9 to ICD-10, despite the substantial changes listed in part below, will be much easier for systems and coding personnel to learn to use given similar design and implementation context. Further, for claims processing to occur, the transition to ICD-10 is now mandated for October 1, 2014, as part of the HIPAA code set.

To clarify the distinction between problem lists and diagnoses as typically used within electronic medical records, problem lists refer to ongoing medical issues, whereas diagnosis codes refer to the conditions managed during a given encounter, such as an outpatient visit. The conversion from ICD-9 to ICD-10 will greatly increase the number of available codes. Although many differences are accounted for by laterality (left vs. right), many new concepts also appear. These additional concepts will better address coverage for conditions and authorization for services, better ensure referral requirements are met, and assist with claims adjudication. Further, the enhanced specificity of the ICD-10 codes can better ensure quality measures are tracked accurately, which is important given a continued emphasis on pay for performance incentives. For example, ICD-10 has the potential to better identify coded patients for matching to quality-based metrics across a practice to ensure eligible patients receive appropriate health maintenance interventions and that the ineligible patients are appropriately excluded. Case mix adjustment is thought to become more accurate with this enhanced specificity as well.

Additional background on the ICD terminology is helpful to consider when appreciating the substantial work effort required for this code set conversion. Not only physicians and medical record systems need to adapt; practice management systems and billing processes need to be modified and the changes implemented overnight. ICD-9 was published in 1977 and further modifications were applied and effective April 1, 1989, when ICD-9 was formalized as the code set used for Medicare reimbursement. More recently in 1996, ICD-9 codes became the established standard for almost all

TABLE 3. Useful ICD-10 Reference Sources for Practice Adoption

<table>
<thead>
<tr>
<th>Site</th>
<th>Notes</th>
<th>Shortcut Link for Easy Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Medical Association</td>
<td>Background, frequently asked questions</td>
<td><a href="http://bit.ly/amaicd10">http://bit.ly/amaicd10</a></td>
</tr>
<tr>
<td>American College of Physicians</td>
<td>General coding information along with International Classification of Diseases (ICD)-10 specific content</td>
<td>acponline.org/running_practice/payment_coding/coding/</td>
</tr>
</tbody>
</table>
U.S. medical claims. Even before this in 1992, the ICD code was revised by the World Health Organization to the ICD-10 version and is now used in more than 100 countries. The United States is the only industrialized country that has not yet adopted ICD-10. A clear-cut and compelling reason for adoption is that the numbering system of ICD-9 (mostly numeric with 3–5 digits) makes new concepts difficult or impossible to add. This has been addressed with ICD-10 (3–7 characters and alphanumeric for many additional combinations possible). Important clinical contexts are now addressed as well, for example, disease severity, specific fracture details, whether the service provided was an initial assessment, public health exposure scenarios, and reasons for non-adherence to regimens.

In conclusion, use of e-prescribing and adoption of a growing number of standards—such as the especially complex change to ICD-10 by October 1, 2014—constitute significant practice changes with significant clinical and workflow effects. Understanding the potential benefits of these changes will allow practices to set relevant practice-focused goals and thereby ensure not only compliance with mandated guidelines but also tangible benefits to practice operations. References to assist with the ICD-10 conversion process are listed in Table 3.

Disclosures of Potential Conflicts of Interest

The author(s) indicated no potential conflicts of interest.

References

PRACTICE MANAGEMENT AND INFORMATION TECHNOLOGY

The Affordable Care Act: Legislative Update and What to Expect in Oncology

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OPPORTUNITIES FOR ONCOLOGY IN THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

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OVERVIEW

The Patient Protection and Affordable Care Act (ACA) contains within it three significant legislative constructs: to enhance access to health care, improve quality, and decrease cost. Also known as the Triple Aim, these three simple, yet monumental, goals have been the object of actions to date as well as future implementation efforts. This article will identify sections of the legislation that would directly provide areas of opportunity to improve health and achieve the triple aim for the oncology profession.

On March 21, 2010, the Patient Protection and Affordable Care Act (ACA) was signed into law by President Barack Obama, and on June 28, 2012, the United States Supreme Court validated the constitutionality of the legislation, including one of the more controversial elements that detailed the individual mandate. Some of the highlights of the legislation include provisions that would allow young adults to continue coverage on their parents’ insurance plans until the age of 26, prohibit the denial of coverage to individuals with pre-existing conditions, provide incentives for the expansion of Medicaid, improve the quality of care, and implement significant changes to the delivery system to increase innovation in health care.

Lack of access to medical care has been a multifaceted problem faced by patients in the United States. Access, or lack thereof, can affect the entire spectrum of care, starting with preventive screenings, to diagnosis, and then to treatment. A recent study found that two-thirds of patients newly diagnosed with cancer were unable to schedule appointments with oncologists, regardless of whether they had insurance.2 The study cited several factors that prevented or delayed the patient from obtaining access to an oncologist, including limited resources at the oncology facility, a patient’s failure to provide medical records, failure to meet referral requirements, and failure to connect with the appropriate scheduling staff.

Furthermore, issues of rising cost exacerbate other systemic problems. In 2007, it was estimated that 62.1% of all bankruptcies were related to medical bills; 92% of those bankruptcies were medical debts that exceeded $5,000 or 10% of pretax family income.3 Cancer treatment is an often cited source of rising out-of-pocket expenses for patients, and the financial jeopardy that they may face when starting treatment influences what type of care they choose and when they choose to start it. A recent study reinforces this point: 35.3% of uninsured, 4.0% of Medicaid, and 8.3% of privately insured nonelderly adults with chronic conditions including cancer delayed or refused medical care because of the overwhelming costs.4 Provenge, a cellular immunotherapy drug treatment for prostate cancer that was approved by the Food and Drug Administration (FDA) in April 2010, illustrates some of the cost challenges in cancer. Treatment is roughly $31,000 per session and requires a series of three treatments to be most effective.5 The financial effects of these types of costly drug therapies is evident; Part B medications, which include a large number of drugs used to treat cancer, cost Medicare $3 billion in 1997, increasing to $11 billion per year in 2004.6 In 2010, Medicare spent approximately $19.5 billion on Part B drugs. Table 1 features the top 10 greatest drug costs of Medicare Part B in 2010, which accounted for nearly 45% of the year’s Part B spending. Of the 10, seven are used in cancer treatment therapies.

The traditional fee-for-service payment system that the majority of the health care system operates in is not the ideal model to follow when the goal is to reduce health care spending. Physicians are generally reimbursed by volume, which can lead to misaligned incentives, often rewarding higher volume rather than higher value. In addition, a hefty source of cancer care spending is paid for chemotherapy drug sales, which includes a margin, currently 6% for Medicare and variable for some commercial payers, that oncologists are paid in addition to the average sales price for the drug.8 This drug margin accounts for 22% to 25% of total net revenue, and, though over time the drug margin percent has gone down and chemotherapy administrative payments have decreased, overall costs continue to rise.9 Below, we highlight aspects of
the ACA that touch on access, cost, and quality with a view to the future of oncology and the possibilities in health care.

INCREASED ACCESS TO PREVENTION, DIAGNOSTICS, AND TREATMENT

The Congressional Budget Office (CBO) estimates that the ACA provisions will expand coverage to an additional 32 million Americans by 2019.10 The majority of the expansion is through the Medicaid program, which will now cover childless adults as well as the establishment of health insurance exchanges, which will offer an insurance option for individuals and families who are either unemployed, in small businesses, or are not offered insurance through their employer.

Elimination of Cost Sharing

As of September 23, 2010, the ACA requires all new or renewing private health plans to cover the costs of 45 preventive services, a list that was developed under the guidance of the U.S. Preventive Services Task Force (USPSTF). The ACA eliminates any copays, deductibles, and any other variation of cost sharing from the patient. Important covered services related to cancer care include colonoscopy screening, pap smears, and mammograms.11 When identifying and prioritizing health service recommendations, USPSTF assigns one of five letter grades (A, B, C, D, or I) to each of its recommendations. Those that earn a score of A or B will be fully covered by insurers under the ACA.

Medicare “Donut Hole”

In conjunction with the increased rates of cost sharing for services, cost sharing for cancer treatment drugs is also a major threat to a patient’s financial security. The “donut hole” refers to the gap in coverage that occurs when a beneficiary exceeds a certain monetary threshold for drug coverage. Once they reach that maximum, patients are expected to cover 100% of their drug costs until they reach “catastrophic protection” and their coverage will be effective once again. The maximum and minimums are routinely adjusted to account for inflation. By 2020, the ACA is aiming to close the gap by providing discounts to generic drugs, subsidizing name-brand drugs, and raising the initial coverage limit to meet the coverage-gap threshold.12

Essential Health Benefits

In an effort to standardize new insurance programs across the nation, the ACA identified a list of services that were

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**TABLE 1. Top 10 Medicare Part B Expenditures in 2010**

<table>
<thead>
<tr>
<th>2010 Rank by Total Medicare Expenditures</th>
<th>Brand Name(s)</th>
<th>Drug Description</th>
<th>Condition(s) Treated</th>
<th>Total 2010 Expenditures for Medicare Beneficiaries (Dollars in Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Epogen/Procrit (ESRD use)</td>
<td>Epoetin alfa, ESRD a</td>
<td>Anemia in patients with ESRD</td>
<td>$2,000</td>
</tr>
<tr>
<td>2</td>
<td>Rituxan</td>
<td>Rituximab injection</td>
<td>Cancer, rheumatoid arthritis</td>
<td>1,302</td>
</tr>
<tr>
<td>3</td>
<td>Lucentis</td>
<td>Ranibizumab injection</td>
<td>Wet AMD</td>
<td>1,180</td>
</tr>
<tr>
<td>4</td>
<td>Avastin</td>
<td>Bevacizumab injection</td>
<td>Cancer; wet AMD</td>
<td>1,130</td>
</tr>
<tr>
<td>5</td>
<td>Remicade</td>
<td>Infliximab injection</td>
<td>Various autoimmune disorders</td>
<td>900</td>
</tr>
<tr>
<td>6</td>
<td>Neulasta</td>
<td>Injection, pegfilgrastim 6 mg</td>
<td>Prevent infection in chemotherapy patients</td>
<td>888</td>
</tr>
<tr>
<td>7</td>
<td>Aranesp (non-ESRD use)</td>
<td>Darbepoetin alfa, non-ESRD</td>
<td>Anemia in chemotherapy patients</td>
<td>504</td>
</tr>
<tr>
<td>8</td>
<td>Epogen/Procrit (non-ESRD use)</td>
<td>Epoetin alfa, non-ESRD</td>
<td>Anemia in chemotherapy and HIV patients; prevent blood loss in surgical patients</td>
<td>443</td>
</tr>
<tr>
<td>9</td>
<td>Alimta®</td>
<td>Pemetrexed injection</td>
<td>Cancer</td>
<td>394</td>
</tr>
<tr>
<td>10</td>
<td>Taxotere.</td>
<td>Docetaxel injection</td>
<td>Cancer</td>
<td>387</td>
</tr>
</tbody>
</table>

Total | **$9,128**

Abbreviations: ESRD, end-stage renal disease; AMD, wet age-related macular degeneration.

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**KEY POINTS**

- Cancer treatment can have a financially devastating effect on patients and their families.
- The Patient Protection and Affordable Care Act (ACA) increases a beneficiary’s access to and coverage for prevention, diagnostics, and treatment by closing the “donut hole,” eliminating cost sharing, and standardizing essential health benefits.
- The ACA includes legislation that eliminates a payers’ ability to rescind or deny coverage to individuals that are sick or have a pre-existing condition.
- Major steps are being taken to improve the quality of health care; the ACA provides funding and support for programs including the Physician Feedback Program, the Physician Quality Reporting System, and the Patient-Centered Outcomes Research Institute.
- Bundled payments, patient-centered medical homes, and accountable care organizations have great potential to spark clinical transformation and payment reform in the oncology profession.
declared as Essential Health Benefits. Medicaid and other insurance plans that wish to participate in the exchange must cover the following services by 2014: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. These essential benefits include many clinical treatments for cancer as well as preventive services that can mitigate the devastation of cancer.

Clinical Trials for Treatment of Cancer
A barrier to the participation in clinical trials had been the exclusion of coverage for routine medical costs. With supportive legislation from the ACA, insurance companies are no longer allowed to deny a patient coverage or discriminate against them for routine medical costs while the individual is participating in clinical trials.

LEGAL PROTECTIONS FOR PATIENTS WITH CANCER Spending Caps
Beginning January 1, 2014, the ACA will eliminate spending caps that health plans have traditionally set on their beneficiaries for services that are considered Essential Health Benefits. Before this provision, health plans were able to set an annual or lifetime limit on what they would spend on a beneficiary’s covered benefits. Once a beneficiary met the maximum dollar amount, he or she would be forced to bear the costs out of pocket completely.

Coverage Protection
While the U.S. health care system struggles to recruit individuals that are not currently enrolled in an insurance plan, there is an equal struggle to provide and maintain care for those individuals that are currently enrolled. Too often was the case where beneficiaries were contributing to a health plan only to have their coverage rescinded once they were diagnosed with an illness. Congruent to that, if individuals wished to enroll in a new health plan, insurers had the authority to deny coverage to individuals based on their medical history and any pre-existing conditions. To combat these loopholes and eliminate opportunities where an individual could be left vulnerable to lack of health care, the ACA includes legislation that eliminates a payers’ ability to rescind or deny coverage to individuals that are sick or have a pre-existing condition. The controversial individual mandate that requires all individuals to purchase health care coverage will help alleviate the financial risk of this expansion.

QUALITY OF CARE
The quality of our country’s health care has been average at best,14 which is a motivating factor for a majority of the ACA provisions related to health care quality. Variation in cancer care has also been similar—in a study by Kahn and colleagues, adherence to quality measures was less than 85% for 18 of the 36 breast cancer measures, and large variation across metropolitan statistical areas was observed for several quality measures.15 Several highlights of programs aimed at improving the evidence base and quality care are included below.

Physician Feedback Program
In an effort to collect more robust data on quality measures and promote transparency, the ACA developed the Physician Feedback Program that will provide comparative performance information to Medicare fee-for-service physicians. Along with access to data on the average care and costs of other physicians’ Medicare patients, physicians will receive reports and data analysis on their reported quality data as well. Oncologists will eventually receive such reports, providing further foundations for quality improvement activities.

Physician Quality Reporting System
To further underscore the importance of quality reporting, the ACA will support the Physician Quality Reporting System (PQRS) program from 2011 to 2014 to encourage physician participation. The PQRS leverages incentive payments and payment adjustments for eligible physicians that contribute quality information, and, similar to the reporting system that hospitals follow, the data reported will be made available to the public. Starting in 2015, the program has the authority to impose payment adjustments (a payment penalty) if a physician does not adequately meet the reporting requirements or does not meet quality standards. There are several measures related to breast and prostate cancer treatments as well as care planning measures for pain management.

The American Society of Clinical Oncology (ASCO) has found value in quality improvement programs and clinical registries similar to those that the ACA supports. In 2006, ASCO launched the Quality Oncology Practice Initiative (QOPI), an oncologist-led quality improvement program that uses quality measures, clinical data, and oncology physician collaboration to improve cancer care, including prevention, diagnosis, and treatment. QOPI unites more than 1,000 practice sites and contains more than 100,000 patient records. In addition to improving oncology care, QOPI provides oncologists with a unique set of data to reference for potential opportunities in scientific and health services research. Recent legislation has provided a pathway for registries and participation in QOPI to potentially qualify for PQRS payments.

Patient-Centered Outcomes Research
The nonprofit Patient-Centered Outcomes Research Institute (PCORI) established by the ACA will lead and fund projects related to comparative effectiveness research, research methodology, and patient-centered outcomes research. In December of 2012, PCORI announced 25 research projects...
that they would support, three of which are cancer focused. Studies on patient-reported outcomes data to improve patient and clinician understanding and end-of-life care for children with cancer have been approved, and information will be disseminated broadly by the Agency for Healthcare Research and Quality (AHRQ).

**PAYMENT REFORM AND INNOVATION**

Built on the foundation of the Centers for Medicare and Medicaid Services (CMS), The Center for Medicare and Medicaid Innovation (CMMI) was developed to act as a conductor for creative and strategic problem-solving. CMMI encourages and supports innovative models that show potential for cost savings and delivering quality care. Parts of CMMI’s efforts include implementing a payment model that moves away from the traditional fee-for-service system and toward value-based purchasing and patient-centered medical homes (PCMH).

**Bundled Payments**

In an effort to reward providers for delivering high quality care over high volume of care, the ACA introduced the bundled payment initiative, which is supported by CMMI. In the current system, Medicare reimburses providers for the number services they perform and not based on the episode of care. The bundled payment initiative would provide reimbursement based on the episode of care and encourages collaboration and coordination among health care providers. Although not specifically identified in the ACA, bundled payments could be a bright spot for oncology reform. Private payers have also joined in the effort, reinforcing that public payment reforms are often complemented by private efforts. For example, United Health Care has partnered with five medical oncology practices across the United States and will pay a flat fee that will cover standard treatment for certain cancers over a period of 6 to 12 months, with the flexibility to renew payments in the case of cancer recurrence.16 On December 10, 2012, CMS announced that it was looking into other bundled payment systems for oncology services, in particular, the way that cancer drugs are reimbursed under Part B.17

**Patient-Centered Medical Homes**

A PCMH is a health care setting that focuses on improving health care quality and accessibility. In a PCMH, patients are managed by a primary care physician team that develops relationships with each patient and closely monitors them throughout their treatment to ensure they are receiving coordinated and comprehensive care. The same principles were applied in an oncology setting: Consultants in Medical Oncology and Hematology (CMOH) became the first oncology PCMH. Located near Philadelphia, Pennsylvania, this practice comprised of nine physicians reduced hospital admissions per patient treated with chemotherapy per year by 51% and reduced the length of stay by 21%.18 Following in CMOH’s footsteps, CMMI is investing $19 million over 3 years to develop and expand an oncology PCMH in other parts of the nation. The program will begin in New Mexico at the New Mexico Cancer Center and will expand to six other practices in the following 6 months. The program will cover those patients with public or private insurance that are affected with breast, lung, or colorectal cancer.

**Accountable Care Organizations (ACOs)**

ACOs are a network of doctors, hospitals, and other health care providers that work together to deliver coordinated, quality care for a given population of beneficiaries within a benchmarked financial goal. If an ACO can deliver care for a population at or below the benchmark goal, then the providers will “share” in the savings with Medicare, which is in contrast to the status quo where providers who save the system money do not receive any of those savings. To ensure that care is not compromised, there are also benchmark quality measures that must be maintained to receive any shared savings. The inclusion of ACO language in the ACA is an important policy shift. Unlike the other efforts that are part of CMMI or pilots/initiatives, ACOs are a technical change in Medicare payment, which means that the concept of shared savings is a permanent one. In an ACO, patients are attributed to a doctor, generally a primary care doctor, but could be an oncologist if the oncologist provides the plurality of services for a beneficiary. On December 10, 2012, CMS Medicare Chief Jonathan Blum announced that CMS was exploring the option of having specialists, instead of primary care physicians, form ACOs and lead these demonstrations.19 Given the activity in the Oncology Medical Home space, an oncology-centered ACO could be the next step.

**LOOKING AHEAD**

Facing a cancer diagnosis is extremely challenging. Facing a cancer diagnosis without the security of health care coverage makes it exponentially challenging, but the coverage that the ACA guarantees will make the experience more tolerable. When working with a complex patient population that has accelerating cost growth, unsustainable reimbursement rates, and struggles with stabilizing profit margins, a holistic approach is required to successfully reform the system. Although there is great uncertainty in how elements of the ACA will play out in the upcoming years, there is certainly great opportunity for oncology specialists to find support in the legislation, capitalize on these opportunities, and accelerate the transformation of the U.S. health care system. The most important challenge for oncologists will be navigating all the changing aspects of payment and regulations, while maintaining and building on the reputation for clinical excellence that millions of our patients have come to expect when preventing, diagnosing, and treating cancer.
Disclosures of Potential Conflicts of Interest

The author(s) indicated no potential conflicts of interest.

References