



A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care: Workshop Summary

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A FOUNDATION FOR EVIDENCE-DRIVEN PRACTICE

A Rapid Learning System for Cancer Care

WORKSHOP SUMMARY

Sharon Murphy and Margie Patlak, *Rapporteurs*

National Cancer Policy Forum

Board on Health Care Services

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Willing is not enough; we must do.”*
—Goethe



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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **James O. Armitage** of University of Nebraska Medical Center. Appointed by the Institute of Medicine, he was responsible for making certain that

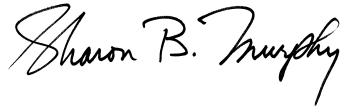
an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authors and the institution.

Preface

There is a compelling public interest to advance the evidence base for cancer treatment and control measures, and to transform the way evidence is aggregated and applied in real-time, driving the process of discovery as a natural outgrowth of patient care, to ensure innovation, quality, safety, and value. A learning health care system for cancer would take full advantage of private and public sector databases and emerging information technology, including electronic medical records, to advance clinical cancer data, both as a public utility and a point-of-care patient-centered clinical decision support system. In light of substantial public investments in health information technology and comparative effectiveness research, this workshop is both timely and topical. The promise of personalized cancer medicine and targeted therapies for cancer add further urgency to foster development of rapid learning systems to know what works and deliver higher value cancer care.

The goal of this workshop is to foster progress toward this vision for a rapid learning health care system for cancer. The workshop will examine the foundation stones upon which to build such a system and explore aspects of information technology which will enable such a system to operate seamlessly. An important aspect of rapid learning which will be examined is patient-driven, highlighting the rapidly expanding importance of partici-

patory cancer care. The impact on oncology providers and policy challenges will be examined with the aim of stimulating collaboration and action.

A handwritten signature in black ink that reads "Sharon B. Murphy". The signature is written in a cursive, flowing style.

Sharon B. Murphy
Scholar-in-Residence, National Cancer Policy Forum,
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Contents

PREFACE	xi
1 INTRODUCTION	1
2 OVERVIEW	5
3 BASIC ELEMENTS AND BUILDING BLOCKS OF A RLHS FOR CANCER	13
Cancer Registries, 13	
Grid Computing, 22	
Comparative Effectiveness Research, 27	
Guidelines and Standards for Care, 30	
Decision Tools and Models, 34	
4 A PRIVATE RLHS—KAISER PERMANENTE	37
5 PATIENT-DRIVEN RAPID LEARNING SYSTEMS	41
6 CHALLENGES AND OPPORTUNITIES	49
Implementation of EHRs, 49	
Data Quality, Completeness, and Appropriate Analyses, 53	
Harmonization and Standardization, 57	
Ensuring Patient Privacy and Portability of Medical Records, 59	

	Rapid Reporting and Translation, 61	
	Stakeholder Cooperation and Participation, 62	
	Choosing Appropriate IT, 65	
7	THE FEDERAL CHALLENGE OF RESPONDING TO THE NEED FOR A RLHS	69
8	SUMMARY	75
	REFERENCES	79
	ACRONYMS	83
	APPENDIXES	
A	WORKSHOP AGENDA	87
B	SPEAKER AND MODERATOR BIOGRAPHIES	95

1

Introduction

Evidence of what is effective in clinical practice, especially evidence of what is appropriate for specific individual patients, is often lacking. In addition, if such evidence is available, it is often not translated rapidly into standard clinical practice, nor is it followed uniformly across healthcare practices. Our current healthcare system is plagued by overuse, underuse, and misuse, leading a recent Institute of Medicine (IOM) committee to conclude there is an urgent need to “know what works” (IOM, 2008). This is problematic and challenging given the rapidity with which medical advances render standard care obsolete. A delay in translation or inappropriate care can shorten the life span of patients with life-threatening diseases. Regrettably, much of the information that could improve care is not currently collected or distributed at the point of care, despite recent advances in information technology that make this possible.

Opportunities for rapid learning, incorporating electronic health records (EHRs) and large datasets, were first identified by Etheredge and others (Eddy, 2007; Etheredge, 2007; Kupersmith et al., 2007; Liang, 2007; Lumpkin, 2007; Neumann, 2007; Pawlson, 2007; Perlin and Kupersmith, 2007; Platt, 2007; Slutsky, 2007; Stewart et al., 2007; Tunis et al., 2007; Wallace, 2007). Recognizing the importance and potential impact of rapid learning and the need to build knowledge development and application into each stage of the healthcare delivery process, the IOM Roundtable on Value & Science-Driven Health Care has conducted a series of workshops on the

“Learning Healthcare System” (IOM, 2007). These workshops have focused on various cross-cutting issues important for improving the development and application of practice-based evidence in healthcare decision making. The National Cancer Policy Forum of the IOM decided to apply the theoretical notion of a rapid learning healthcare system (RLHS) discussed in a broad sense in these workshops to cancer care, in specific.

The forum focused on cancer as a model for development of a RLHS because of the high prevalence of the disease, rising incidence in the aging population, complexity, variable outcomes, and high burden of care, as well as cancer’s life-threatening nature that highly motivates patients, their families, and healthcare providers to seek information to improve care. Despite decades of investment in the war on cancer, there is still a major unmet need in measurement of the clinical effectiveness of many cancer treatments. The rapid marketplace entry of new and often very costly healthcare technologies and treatments for cancer, which have not been evaluated completely for clinical effectiveness, has spurred a compelling public interest in advancing the evidence base for the comparative effectiveness of cancer care as rapidly as possible (IOM, 2009b). Fortunately, many of the foundational elements of a RLHS, such as cancer registries, cancer clinical trials, computer systems, academic and community cancer centers and networks, and evidence-based practice guidelines are already in place for cancer and thus offer another reason to examine cancer as a model for the development of a RLHS. There also is a long-standing successful model of a learning system in pediatric oncology, consistently trying to learn as much as possible from every patient, with standardized protocol-based treatments and systematic collection of clinical data and outcomes, resulting in a “virtuous cycle” of incorporation of what is learned into new treatment protocols that successively improve survival rates.

Although it is widely acknowledged that randomized clinical trials are the gold standard for development of clinical guidelines and that clinical and translational cancer research is essential to expanding the knowledge base in oncology, it is also recognized that dependence on expensive, time-consuming trials as the sole source of evidence is unfeasible. Moreover we need a better understanding of how diverse patient populations respond to cancer treatments in typical clinical settings. A RLHS for cancer would take full advantage of private and public sector databases and emerging information technology (IT), including EHRs, to generate and apply the evidence needed to deliver the best care for each individual cancer patient as rapidly as possible. In light of the current substantial public investments in health

information technology and comparative effectiveness research,¹ the notion of a RLHS for cancer is both timely and topical. The potential for personalized cancer medicine and targeted therapies for cancer adds further urgency to foster development of rapid learning systems to know what works and deliver high-value cancer care.

The National Cancer Policy Forum held a workshop in Washington, DC, on October 5 and 6, 2009, titled *A Foundation for Evidence-Based Medicine: A Rapid Learning System for Cancer Care*, with the aim of horizon-scanning to describe the current landscape² for rapid learning in cancer and to assess what policy and other measures are needed to foster progress and overcome obstacles to more fully develop a RLHS. This document is a summary of the conference proceedings. The views expressed in this summary are those of the speakers and discussants, as attributed to them, and are not the consensus views of workshop participants or members of the National Cancer Policy Forum.³

¹American Recovery and Reinvestment Act of 2009, Public Law 111-5, 111th Cong., 1st Sess. (February 17, 2009).

²While recognizing that there may be useful lessons from other countries' experience with rapid learning health care systems, the planning committee chose to focus the limited time available for the workshop on issues pertaining to the health care system in the United States. Thus, solutions suggested by speakers might not be equally applicable in other parts of the world.

³The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop.

2

Overview

Dr. Amy Abernethy of Duke Comprehensive Cancer Center and Lynn Etheredge of George Washington University began the workshop by giving an overview of what an ideal RLHS entails, how a RLHS might improve care, and how it differs from what is currently standard practice in cancer care. The originator of the concept of a learning healthcare system, Etheredge defined a cancer RLHS as one that generates as rapidly as possible the evidence needed to deliver the best care for each cancer patient. Such a system bridges the gap between clinical research and clinical practice “to learn as much as possible as soon as possible” by enabling the collection of data at the point of care that can then be used to inform clinical, payer, and policy decisions. “For each cancer, each stage, all the way down to each patient, we want to be able to do what physicians and patients really need, which is to be able to tell them the available treatments, their comparative effectiveness, and how to personalize their decision making. That is a long way from where we are now in terms of results,” he said.

RLHS is both patient centered and system centered, a point underscored by both Etheredge and Abernethy. Data collected at the individual patient level not only inform care for that person, but also contribute to evidence development and systemic improvements, along with other data collected system-wide using the experience of all cancer patients, as well as results of clinical trials, systematic reviews, and other relevant aggregated information. In addition, patient data can be used for large-scale evidence

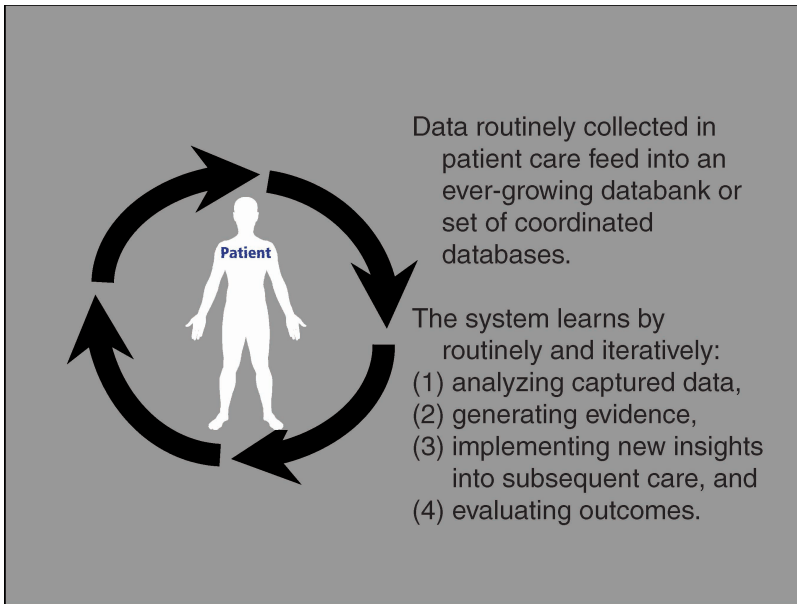


FIGURE 2-1 A patient-centered model of a RLHS.

SOURCE: Etheredge and Abernethy, 2009.

synthesis, comparative effectiveness research (CER), discovery, and evidence implementation on the health system and national levels (see Figure 2-1). Such a system is built at the patient level and scaled to the societal level.

Dr. Abernethy views the critical elements of a RLHS as being linked information, motivated individuals, and systems that are engaged to provide reliable integrated information. She expanded on the patient-centered perspective of a RLHS. “In order to have rapid-learning health care, we have to have rapid-learning health care around *patients*,” she stressed. “The care of the individual patient is informed by the care of people coming before, and his or her care also informs the care of people in the future in a circuitous way.” (See Box 2-1.)

For purposes of illustrating the way cancer care is currently delivered (i.e., in a data-poor and slow-learning environment), Dr. Abernethy discussed the care she recently gave one of her patients. This 37-year-old woman had newly diagnosed Stage IIIB melanoma. She was considering starting a family and wanted to know what adjuvant treatments might reduce her risk of death at five years, and how such treatment would affect her quality of life and ability to become pregnant. Although the National

BOX 2-1

A Rapid Learning Healthcare System

A rapid learning healthcare system (RLHS) is one that uses advances in information technology to continually and automatically collect and compile from clinical practice, disease registries, clinical trials, and other sources of information, the evidence needed to deliver the best, most up-to-date care that is personalized for each patient. That evidence is made available as rapidly as possible to users of a RLHS, which include patients, physicians, academic institutions, hospitals, insurers, and public health agencies. A RLHS ensures that this data-rich system learns routinely and iteratively by analyzing captured data, generating evidence, and implementing new insights into subsequent care.

SOURCES: Adapted from Etheredge, 2007; IOM, 2007.

Comprehensive Cancer Network (NCCN) guidelines offered three treatment options, a lack of comparative data prevented delineation of the best option for her, in terms of improving survival and quality of life. The guidelines also lacked evidence from a recently published study indicating that shorter-dose interferon therapy might be just as effective as longer-term treatment. There also was no evidence provided on how such treatments might affect fertility. As Dr. Abernethy pointed out, for this patient, “I can roughly predict her odds of surviving, but I cannot really refine that or personalize it using data from recently treated patients like her. I cannot determine which is the right adjuvant program for her, and I do not have any clue about the risk of infertility. Her mother died of melanoma, and she worries that what happens for her does not really [clinically] impact people like her in the future at all, and that was really very distressing for her.”

In contrast, if Dr. Abernethy were part of a functioning RLHS, she would continually be collecting information about how various treatment options are affecting her patients. That information would be added to such point-of-care data collected on other patients throughout the country, or even globally, as well as to data collected from clinical trials and other sources, and the aggregate information would be used for real-time analyses to determine the best treatment for her individual patients at the time care

is provided. Dr. Abernethy currently is able to access comparative clinical data only from the hospital in which she practices, and then only through laborious and slow manual methods.

Explaining the system-centered aspects of a RLHS, Dr. Carolyn Clancy, director of the Agency for Healthcare Research and Quality (AHRQ), stressed that such a system ideally would be able to produce evidence on the comparative effectiveness of cancer care options. This comparative effectiveness research would be facilitated by the data collected on each treated patient in a RLHS. Another critical aspect of a cancer RLHS is that it engages system-wide learning, using the experience of all cancer patients, not just those enrolled in clinical trials.

“Only a very small percentage of cancer patients today have their key clinical data captured for research purposes. We need to think about the potential, with our new computers and EHRs, of capturing the key data from virtually every patient and feeding that into a learning system to try to learn as much as possible,” Etheredge said. He added that such a system-wide approach would engage virtually all oncologists and cancer clinics in an active research enterprise, as opposed to the small percentage who currently participates in clinical cancer research. This data-rich system of the future would learn routinely and iteratively by linking and analyzing captured patient data, linking patient data to clinical trials and other research data, generating evidence, and implementing new insights into subsequent care (see Figure 2-2).

This RLHS is in contrast to the current system of clinical learning, in which it often takes more than five years to develop a large Phase III cancer clinical trial, accrue patients, and generate evidence (Dilts et al., 2008) and an additional 10 years before that evidence substantially changes clinical practice. Although randomized clinical trials (RCTs) are the gold standard for the development of clinical guidelines and are an essential component in expanding the knowledge base in oncology, in a RLHS the results of RCTs would be complemented by data collected internally within the healthcare system as well as external linked information, such as genomic and molecular data.

Enabling RLHS are advances in *in silico* research, which Etheredge defined as research on computerized databases. Such research brings together the extraordinary power of high-speed computing with the data-rich capabilities of large computerized databases and distributed database networks. Internet capability also enables data to be accessed by researchers around the globe. In addition, computer advances enable the complex

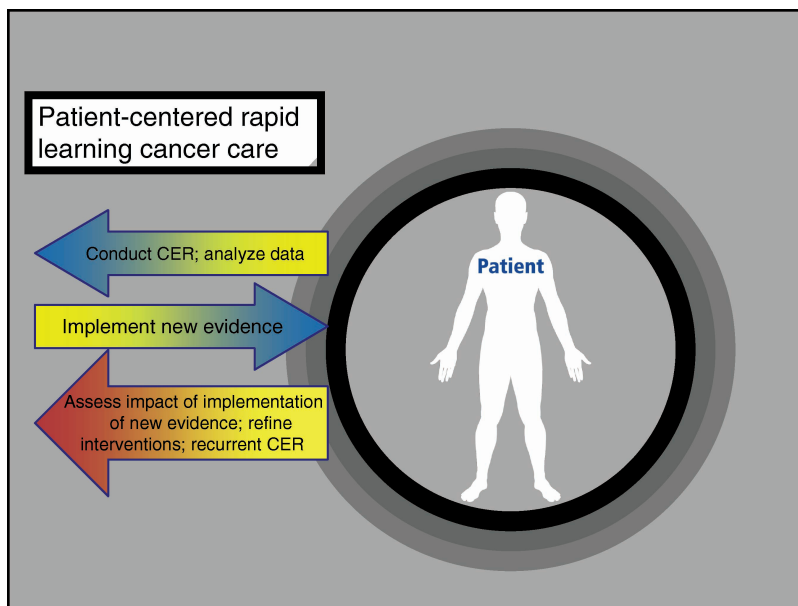


FIGURE 2-2 A rapid learning patient-centered system for cancer care encompasses information and data gleaned from patient care, continuously analyzing and implementing new evidence.

SOURCE: Etheredge and Abernethy, 2009.

genetic analyses that underlie efforts to personalize medicine. “Researchers plus high-speed computers plus great databases equal rapid learning,” Etheredge said.

Dr. Abernethy stressed that a RLHS “provides a means through which we can achieve a number of important national goals, including comparative effectiveness research, improved healthcare quality, personalized medicine, and patient-centered care.” Dr. Clancy expanded on some of these goals and added other challenges that a RLHS might help address, including concerns about healthcare spending, pervasive problems with quality of care, and uncertainty about best practices. Data collected by her agency and the Dartmouth Atlas of Health Care revealed that the quality of health care delivered in this country varied considerably by region, literally all over the map, with some regions outperforming others, and that furthermore there was a lack of correlation between the amount of Medicare spending and the quality of care received (Fisher et al., 2003a, 2003b; Hossain, 2009).

“We speculate a lot, but we urgently need to learn why that is. We are not going to achieve and sustain health reform without getting some of these answers and bringing it right back to the level of clinicians and patients,” Dr. Clancy said.

Dr. Clancy suspects that much of the variability in care stems from clinical uncertainty about best practices and treatments—knowledge gaps on the comparative effectiveness of various options that could be ameliorated by gathering more information from patients. “There is a big gap between best possible care and care that is routinely delivered just about everywhere,” she said. “We do not reward or create a space to learn from systems that are way ahead.” In theory, a RLHS should improve the uniformity and quality of care by providing such a learning space and by promulgating appropriate standards of care. “We can use this learning healthcare system approach to figure out how to make sure that we more rapidly translate those very promising advances and make sure that they get to the patients likely to benefit. At a system level we want to know with precision how well we are getting what is learned into practice,” Dr. Clancy said.

Dr. Clancy referred to the six elements of good care—care that is safe, timely, effective, efficient, equitable, and patient centered—criteria previously delineated by the IOM (2001). Quality measures for various healthcare practices and health systems can be privately or publicly reported so as to provide an impetus for improving care and a means to link payment to performance. Yet such collection and reporting of information are not consistently done because “we do not have good systems in place” to do so, she said. A system-wide approach is also vitally needed to coordinate the care that individual patients receive from a variety of specialists, Dr. Clancy added. “We are completely blind because our information systems do not connect,” she said. More collaboration and trust among providers, purchasers, and consumers will be needed to achieve more effortless and transparent information sharing with health IT, ultimately leading to transformation of the healthcare system (see Figure 2-3).

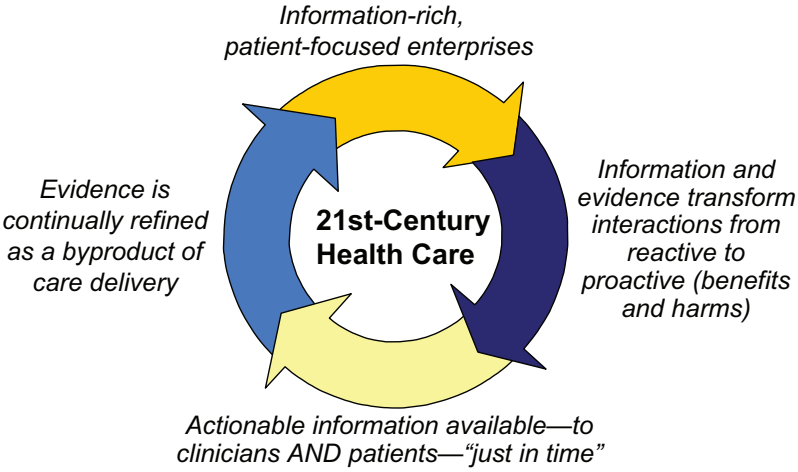


FIGURE 2-3 A vision for twenty-first century health care.
SOURCE: Clancy, 2009.

3

Basic Elements and Building Blocks of a RLHS for Cancer

For a cancer RLHS to meet the promise of evidence-based personalized medicine, it must have a number of basic elements. Some of these building blocks are already in place. This chapter will discuss cancer registries that collect patient data and the computer technology that enables these registries to link to each other and to other datasets in dispersed networks that act in concert to achieve specific tasks. Augmenting registries and computer grids are electronic health records, which could enable rapid electronic reporting and seamless capture of staging and other patient test and treatment information. Electronic networks are able to provide information exchange and feedback to providers. Other key elements of the infrastructure of an active and growing RLHS for cancer discussed in this chapter include the integration of information from clinical trials, comparative effectiveness research, evidence-based clinical practice guidelines, quality metrics, and decision support tools.

CANCER REGISTRIES

Dr. Joseph Lipscomb of Emory University described cancer registries as organized systems that use observational study methods to collect uniform data to evaluate outcomes. Cancer registration is the fundamental method in the United States by which information is systematically collected from various medical facilities about the incidence and types of

cancer, the anatomic location and extent of disease at diagnosis, kinds of treatment and outcomes. Lipscomb noted that disease registries are a core resource for a learning healthcare system. Cancer registries can be used to determine the natural history of disease, determine clinical effectiveness or cost-effectiveness, measure and monitor safety and harm, and evaluate the quality of care. Dr. Robert German of the Centers for Disease Control and Prevention (CDC) noted that state cancer registries, in specific, collect population-based data on cancer incidence, morphology, primary site, stage at diagnosis, planned first course of treatment, and outcome of the treatment and clinical management. These registries collect their information from a number of sources, including hospitals, clinics, physician offices, pathology laboratories, nursing homes, and coroner's offices. Most cancer data comes from hospitals where highly trained cancer registrars extract data from the patients' medical record and enter it into the registry's computing software for transfer to central cancer registries. Ms. Sandy Thames of CDC outlined some of the challenges and limitations of using registry data, due mainly to the time consuming, labor-intensive nature of the process of collecting cancer data, the risk of errors in extraction or transcription, the limited nature of the data set due to the expense of manually collecting and processing large amounts of information, the delay in availability of data, and the lack of completeness in reporting and follow-up of cases. In particular, no standards have been implemented for data collection and reporting from non-hospital sources which thus do not consistently report cases.

Notwithstanding the limitations, there are a number of state and national programs that actively collect and report cancer data, producing extensive surveillance of cancer incidence and mortality in this country, with the cancer data collected differing according to the mandates of the supporting agency. Beginning in the 1970s, the National Cancer Institute's (NCI's) Surveillance, Epidemiology and End Results (SEER) program has collected a non-random population-based sample of cancer incidence and survival data from a system of high-quality state and local cancer registries (NCI, 2010b). This database currently collects data from about 26 percent of the U.S. population. Since the 1990s, the CDC's National Program of Cancer Registries (NPCR) has supported statewide, population-based cancer registries from 45 states, the District of Columbia, Puerto Rico, and the U.S. Pacific Island jurisdictions. These NPCR now covers about 96 percent of the population in the United States and provides CDC the means to receive, aggregate and disseminate cancer data from state and territorial cancer registries for public health surveillance. The SEER program and the

CDC-NPCR program are complementary. SEER routinely collects patient demographics, including ethnicity, and is updated annually, providing a research resource for temporal changes in cancer incidence and mortality for segments of the population. SEER data have also been linked to Medicare claims data, thus producing a data set of over 3 million cases that contains all people in SEER found to be Medicare-eligible.

Another national registry that can provide not only valuable national cancer care data, but also feedback to providers, is the Commission on Cancer (CoC) National Cancer Data Base (NCDB), which has been in operation since 1985. The CoC is a consortium of professional organizations dedicated to reducing morbidity and mortality from cancer through education, standard setting, and monitoring the quality of care. CoC provides accreditation for hospital cancer programs throughout the country that together treat about three-quarters of cancer patients in the United States. The NCDB is not population based, but rather is an aggregation of cancer registry data from approximately 1,800 CoC-accredited institutions. It surveys and aggregates cancer patterns of care and outcomes. The CoC recently has begun using its database to monitor the performance of cancer programs in its member hospitals and provide feedback on measures that can be used as benchmarks.

CoC's database includes a number of quality management tools available to its accredited programs. These tools include a program that assesses benchmarks related to numbers of cases, stage of diagnosis, and survivals and applies National Quality Forum (NQF) quality measures for cancer care. Using these measures, the CoC has recently started to notify hospitals that fall in the bottom 10 or 25 percent of quality measures and help them develop an action plan to correct problems they may have with their data or with their care. "The CoC provides a unique national system for application because not only do we have the data collection infrastructure, but we have an existing structure for feedback and reporting for providers, which is neither the government nor the payers," pointed out Dr. Stephen Edge, chair of the CoC.

The CoC is currently piloting its Rapid Quality Reporting System (RQRS), which is a registry-based system that provides more timely tracking of care processes. Providers enter about 50 pieces of data on their patients shortly after diagnosis and then are tracked for NQF measures for specific cancers. For example, an NQF standard for hormonal therapy of breast cancer is the percentage of female patients with Stage IC through IIIC, estrogen-receptor (ER)-positive or progesterone-receptor (PR)-

positive breast cancer who were prescribed tamoxifen or an aromatase inhibitor within the 12-month reporting period. The system provides an up-to-date running track record that shows, using color-coded visuals, when providers are giving the accepted standard care and warns providers when they are approaching the time limit for such care. For the example NQF standard provided, the RQRS will inform physicians when they are approaching the one-year mark after diagnosis, the time limit for giving hormonal therapy to women with breast cancer. “This allows the registry staff the opportunity to say, ‘It has been 11 months since this person was diagnosed with breast cancer and we do not yet have the fact recorded that she got hormonal therapy,’” explained Dr. Edge, with such feedback very likely to prompt follow-up.

This more rapid system is likely to be more effective at improving quality care than traditional systems, which may not inform providers about problems in care until three years after they occur, Dr. Edge added. “There’s good evidence that implementing a tracking system actually reduces disparities and systems failures in care,” he said. RQRS does require hospitals to invest in additional support to participate, which is problematic given that hospitals are currently trying to streamline their operations, Dr. Edge noted. CoC hopes to have its RQRS available nationally by the end of 2010, he said. Presently RQRS is undergoing beta testing in about 70 CoC-approved cancer centers around the country.

However, even the best registries may not be adequate for addressing key health system questions, such as comparative effectiveness or cost-effectiveness analyses. For example, the SEER program routinely collects abundant information on cancer patients, but this program does not collect information on how patients are treated after their first course of therapy, nor does it document disease recurrence, resources consumed, provider characteristics, or patient-reported outcomes. In addition, disease registries such as SEER are not linked to product registries for specific drugs or devices or to health services registries that document specific clinical procedures, encounters, or hospitalizations. An unrealized ideal, Dr. Lipscomb claimed, would be a population-based disease registry that can serve both as a health services registry and as a product registry.

An advantage to linking registries, according to Dr. Lipscomb, is that one can then acquire more information needed to answer research questions while avoiding the costs and efforts involved in collecting another set of data that duplicates, to some degree, what is already available. “Do not gather new data unless you have to gather new data,” Dr. Lipscomb said. But it is

also the case that multiple sources of information on the same event may permit cross-validation to improve data accuracy, Dr. Lipscomb noted.

Cancer illustrates the state of the art in the creation and application of linked databases to enhance registry data. Dr. German noted that data from a cancer registry can be linked to a number of external data sources, such as a state's biostatistics or death certificates, as well as Social Security Administration data, or to the National Death Index to acquire death information about patients who die outside the state of residence. Cancer registries may also link to hospital discharge or medical claims data, such as Medicare, Medicaid, or other private insurers.

More than 200 studies have been conducted using SEER data linked to Medicare or Medicaid data or to private claims data, including studies that assess health disparities, quality of care, and cost of treatment (NCI, 2009). The SEER-Medicare database contains the more than 3 million cases in SEER that were found to be Medicare eligible, as well as a 5 percent random sample of people residing in SEER areas who have not been diagnosed with cancer to serve as controls in some studies, Dr. Potosky reported. He said that SEER-Medicare data are often used in CER because they provide longitudinal data on a large number of elderly subjects who are generally underrepresented in clinical trials. This dataset also includes patients with serious comorbidities, who would normally be excluded from cancer clinical trials.

The CoC is also exploring linking its national cancer database to administrative data, including physician records, EHRs, and billing data. In Ohio, CoC has a pilot project funded by the CDC that will enable it to link its cancer registry data with private payer claims, including those of United Healthcare and Anthem Blue Cross/Blue Shield, along with data from the Ohio Cancer Incidence and Surveillance System registry. The goal of this pilot project, which Dr. Edge is conducting along with his colleagues, is to define quality of care and identify the degree of completeness of the registry treatment data compared to care identified from claims data. This project has already demonstrated the feasibility of linking private payer claims data to the CoC database, at least in one state for one disease and one modality, and has shown a high level of agreement between the two sources of data in the surgical care of breast cancer patients. Researchers in this project plan to evaluate these same measures for lung cancer and to extend the data-linking model to other states.

State cancer registries are another useful source for researchers trying to learn what is needed to improve cancer care, especially if these registries are

extensive or extensively linked. Dr. Lipscomb discussed several advantages to having strong state-based data systems as a practical, more expeditious route to developing a national cancer data system that is also an effective learning healthcare system. He noted the ever-improving quality and capacity of state registries and the strengths of state comprehensive control plans, which increasingly call for better state data systems for surveillance and outcomes assessment. There also is a demonstrated capacity to link cancer registry data at the state level with public and private data sources. Except for the SEER-Medicare database, the ability to routinely link population-based cancer registry data with external administrative or clinical sources to create an integrated multistate or national system starts at the state level and requires collaboration across states, he noted. In particular, the process of accessing and linking confidential data is very much state-centered. Finally, he noted that the state may be the right-sized laboratory for learning, because it is large enough to reflect the complexity of mining multiple datasets that are linked together, yet small enough to avoid the chaos of managing large systems.

As an example, Dr. Lipscomb showed how the various datasets in the state of Georgia have been linked to answer a number of important cancer-related questions. These registries include the data collected by 15 counties in Georgia that are part of the SEER program and the Georgia Comprehensive Cancer Registry (GCCR), which collects data on cancer incidence for all the state's counties. GCCR has been linked to Medicare as well as to Medicaid, with Emory University researchers using the latter linked data to evaluate the impact of the Breast and Cervical Cancer Prevention and Treatment Act.¹

A new project, "Using Cancer Registry Data and Other Sources to Track Measures of Care in Georgia," sponsored and funded by the Association of Schools of Public Health (ASPH), CDC, NCI, and the Georgia Cancer Coalition, has just begun linking several sources of state data that researchers will eventually use to evaluate quality of care for patients with breast or colorectal cancer (ASPH, 2009). However the more immediate goal of this project is to show the feasibility of doing bilateral linking of multiple data registries, including public registries such as GCCR, SEER, Centers for Medicare & Medicaid Services (CMS) data on both patients and physicians, and private registries such as those of insurance companies,

¹Breast and Cervical Cancer Prevention and Treatment Act of 2000. Public Law 106-354. 106th Cong. 2nd Sess. (October 26, 2000).

and hospital discharge records. The next planned step in this project is creation of a prototype “Consolidated Georgia Cancer Data Resource” that will represent a linkage of these bilateral linked data sets with the GCCR at the hub (see Figure 3-1).

Eventually, researchers hope to expand the project to include biomarker data from state and SEER biorepositories and patient-reported outcomes, such as quality-of-life assessments, satisfaction with care, and burden of symptoms. All the datasets linked in this project will be stripped of their patient identification features, so as to preserve patient privacy, and will be subject to rigorous quality checks.

Dr. Lipscomb pointed out that researchers could potentially use the data collected in this statewide project for CER, postmarketing regulatory studies, research on quality care assessment, and other studies needed for an effective learning healthcare system. The researchers of this project also hope to eventually demonstrate reduced time lags between receipt of care and data reporting, analysis, and feedback. Two potential vehicles are available for promoting this development: the CoC’s RQRS (since 25 of the 70 beta test sites are in Georgia), and the Georgia Quality Information Exchange, an electronic network that is being established by the Georgia Cancer Coalition. The coalition’s President and Chief Executive Officer (CEO) William Todd noted that the coalition had commissioned the IOM to develop a strategy for measuring progress in cancer control that spans the continuum of cancer care from prevention, early detection, and screening, to diagnosis, staging, treatment, and palliation. Focusing mainly on breast, colorectal, lung, and prostate cancer, the coalition used the 52 measures recommended in the resulting IOM report (IOM, 2005) to plan the development of a statewide, evidence-based cancer quality measurement program (Georgia Cancer Quality Information Exchange), with the aim of improving outcomes, patient-centered care, and adherence to standards, Todd said.

The Georgia Cancer Quality Information Exchange’s initial focus is on using the benchmarks and goals the IOM recommended for its 52 metrics as the foundation for aggregating near-real-time clinical data from all of the state’s CoC-certified cancer care facilities and linked physician practices and public health data from the Georgia Comprehensive Cancer Registry and other sources (Georgia Cancer Coalition, 2009). Providers use computerized tools created by the exchange, such as its “dashboard,” to enter their patient data and see their performance relative to that of their peers in the state. Public reporting of such metrics will only be at an aggregated level. Researchers, patients, survivors, employers, payers, federal and state agen-

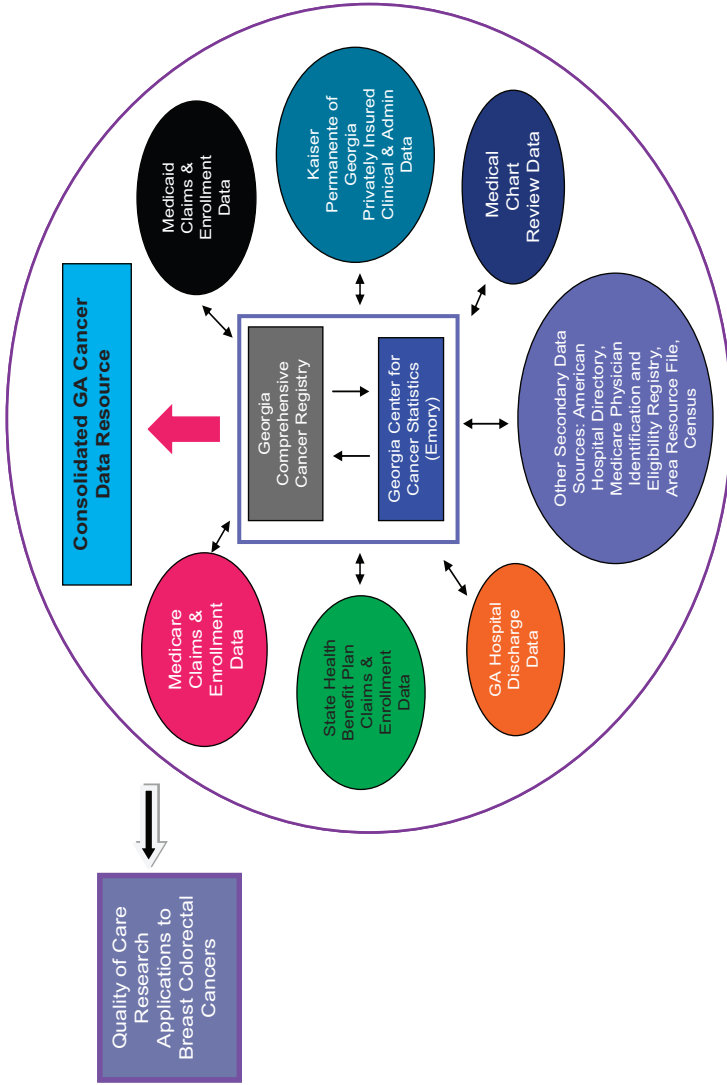


FIGURE 3-1 Linking Georgia Cancer Registry Data to public and private sources.
SOURCE: Lipscomb, 2009.

cies, and public health personnel can also use the exchange's dashboard to assess cancer care trends. Use of the dashboard can reveal weak areas that need improvement, inform ongoing cancer control planning, stimulate process improvements at participating institutions, increase adherence to the most current practice standards, and improve and make more geographically consistent patient-centered care and outcomes (Georgia Cancer Coalition, 2009).

The Georgia Cancer Quality Information Exchange, which intends to have the information technology infrastructure to accept data from all providers regardless of level of automation or technology platform, has engaged six cancer centers around the state as demonstration partners. These pilot projects revealed that many of the centers had not previously measured some of the IOM metrics because they had assumed they would perform well, when in fact the dashboard reports revealed that they performed below average in such metrics as timeliness of women's receiving a biopsy after having an abnormal mammogram or adequacy of cancer pain management. The dashboard reports led these cancer centers to alter their operations, which improved these metrics in subsequent dashboard reports, Todd reported. "Physicians thought they were managing pain well, but they really never recorded it. Now they are and there already is a big improvement," Todd said.

The exchange currently is setting up the statewide infrastructure to provide EHR interfaces and do more rapid reporting. As Todd noted, however, many cancer centers do not have EHRs. For those that do, screening reminders and alerts provided by exchange tools have led to measurable improvements in cancer care. Participation in the exchange has also boosted patient participation in clinical trials threefold, Todd pointed out. He noted that traditional cancer registry data are fairly useless to clinicians, but when such information is "married to some of the clinical information that is captured in this [exchange] system, it becomes useful in daily care."

The collection of patient-reported outcomes also will expand the usefulness of cancer registries, several speakers noted. Dr. Clancy suggested that more effort be made to gather patient-reported outcomes, not just during treatments but in between or after treatments. Such outcomes should include objective information, such as whether the doctor explained the medical care adequately or how long patients had to wait for treatment. AHRQ is currently working with NCI to develop cancer patient surveys, which should be available in 2011. Todd stressed the need to get patient-reported outcomes as close to diagnosis and treatment as possible, rather

than six months to a year later. “By weaving in the patient-reported outcomes into the movement to get patient information quicker, you could be more effective overall,” he said.

GRID COMPUTING

Computer technology will provide the platform for a RLHS. In his presentation, Dr. Chalapaty Neti from IBM provided some perspectives on how information technology can aid physicians in practice. He noted that the human cognitive capacity is limited to roughly five different facts simultaneously when making clinical decisions. Yet the current explosion in diagnostic information made possible by advances in genetics and imaging provides about 20 times that amount of facts, all of which have to be considered when making clinical decisions. The future portends an exponential increase in data. This information explosion leads to cognitive overload that risks reduced quality of care (see Figure 3-2).

Computerized systems can provide the means to manage complexity. “One of the key things information technology [IT] can do is to take this complexity that is at the point of care, and truly simplify this so that it is manageable with respect to the cognitive capacity of the care provider,” said Dr. Neti. Dr. William Stead, the chief information officer (CIO) of Vanderbilt University Medical Center, added that more can be gained by combining the human’s superior ability to identify patterns with the computer’s ability to work out various aspects of a problem and attend to such details as sending reminders to practitioners about various steps in patient care. Dr. Kenneth Buetow, leader of NCI’s caBIG[®], noted that computer grid systems enhance the capability of practitioners, but do not replace them, just like “night vision goggles do not actually see for people, they just make it so that you can see things that are present because they are displayed in a way that makes them clearer—they present the type of information that is necessary.”

Integral to a RLHS are both large- and small-scale computer systems and computer models. Computer grids are networks of computers that are dispersed geographically and work together to carry out various computing tasks involving large amounts of data and complex analyses. Both data storage and analysis are apportioned among the network of computers to accomplish these large complex tasks. Computer grids enable multiple users to access large amounts of data and conduct their own analyses in real time, because they generally have what is called an open services-oriented

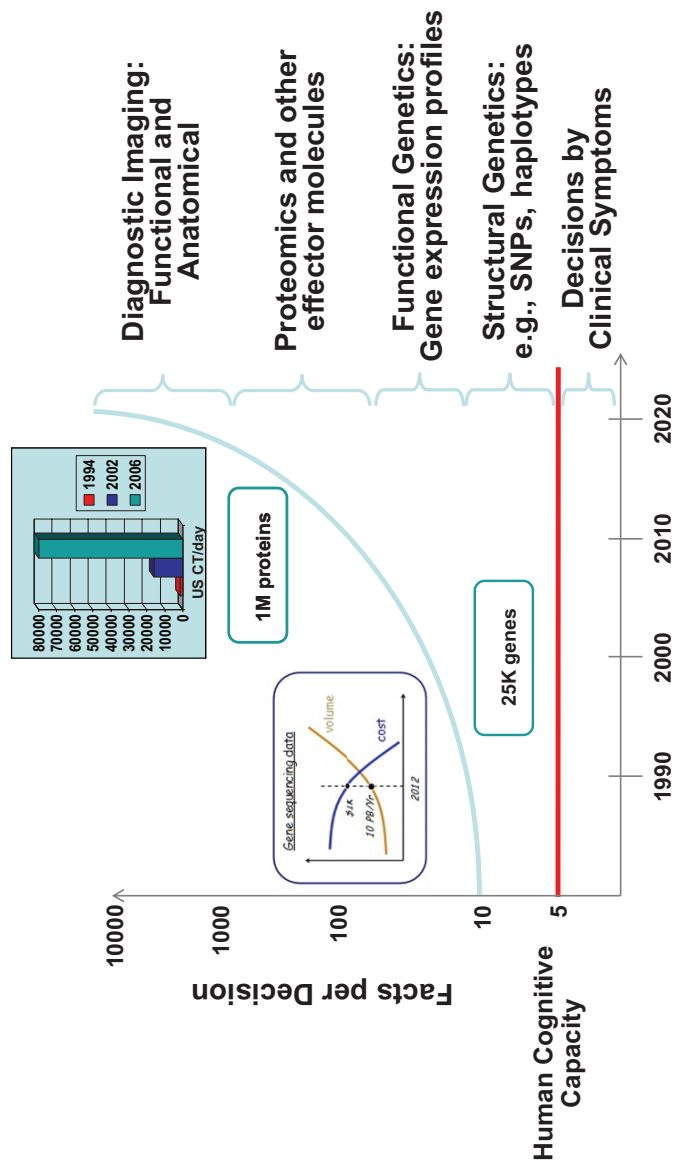


FIGURE 3-2 Challenges to delivery of individualized clinical care are data explosion and cognitive overload, exceeding human cognitive capacity. SOURCE: Neti, 2009. Adapted from Stead, 2007, p. 19.

architecture which allows applications, running as services, to be accessed in a distributed computing environment, between multiple systems or across the Internet. This allows different services and diverse applications to be run by local users on open publicly available platforms with open standards employed by central hosting services. Open platforms are software systems that allow for massive data sharing. Sometimes called cloud computing, such systems represent a new consumption and delivery model for IT services based on the Internet, where common applications can be accessed from a Web browser.

Computer systems are usually “federated” or virtual database systems which provide an alternative to the daunting task of merging together several disparate data bases. A federated database system is a type of meta-database management system which transparently integrates multiple autonomous data base systems into a single federated database. The constituent databases are interconnected via a computer network or grid. “We have to come to the realization that the ‘Holy Grail’ of a centralized data warehouse is not going to happen,” said Dr. Neti. He said that we have to think about federated data structures, meaning the centralized link will at best be an index to where the data reside (metadata) and that there will be federated analytics, meaning that the data are not going to the place where the analytics sit, but the analytics are going to the place where the data sit. An advantage to having a federated architecture is that it preserves local control over data generated at a particular institution, which is critical to address the patient privacy issues dictated by Health Insurance Portability and Accountability Act (HIPAA) and state laws, noted Dr. Buetow, who was instrumental in creating the cancer Biomedical Informatics Grid (caBIG™) for the NCI Center for Bioinformatics and Information Technology. There are also advantages in having data reside with the people who have generated, analyzed, and aggregated it and thus have a fuller understanding of the data, he added.

A computer grid requires a high degree of interoperability among all its users, since it must be assumed that there will be proprietary and legacy IT systems at the point of care. This in turn requires a great deal of harmonization and standardization of how data are reported, represented, and integrated in the system, Dr. Neti pointed out. This necessitates the use of open platforms, open standards, and data curating to clean up and standardize data that are “dirty” from both a machine and a human perspective. There also have to be metadata management, identity management, and security to address patient privacy issues; a master patient index that

combines different data on the same patient from different repositories; and data oversight and stewardship.

As Dr. Buetow stressed, “Interoperability doesn’t just happen—these things don’t just self-assemble,” and connecting across complex heterogeneous domains requires active management, especially since, in biomedicine, terms take on different meanings in different contexts. “Just having folks adopt IT systems does not necessarily mean that the information comes together as if by magic;” rather, this depends on a well-thought-out infrastructure, user involvement, and extensive oversight and managing. “All these information sources can interact with each other because we pay time up front worrying about how information is represented and how different sources of information can be cross-connected with each other,” he said.

Dr. Buetow pointed out that users should be involved in the creation of a computer grid from the start and throughout the process of tool development to serve as advisers, developers, adopters, and disseminators to ensure functionality. Such participation is worth the investment, he added, since it accrues dividends post-development in educating the community and driving more rapid adoption of the grid. Community is critically important.

It also important that the architecture of a computer grid be flexible to accommodate changes in biomedicine so that “data can be aggregated and interpreted correctly now and reinterpreted correctly as knowledge changes,” said Dr. Stead. He suggested separating the data from the system such that the raw signal data are recorded and then later tagged with the current interpretation. In that way, “as our knowledge changes, we can rerun our interpretations of it and re-annotate it as we move forward into the future,” Dr. Stead said. Dr. Neti agreed, saying it is important to build infrastructures that allow for augmentation.

Recognizing the need to share and do large-scale analyses of the abundant data generated in the studies it supports and to connect and support the cancer community at large, NCI decided in 2003 to create caBIG, which is a shareable, interoperable information infrastructure that connects cancer researchers and practitioners (NCI, 2010a). To create caBIG, researchers developed standard rules, a unified architecture, and common language to more easily share information. The caBIG is an open-access, open-development, and open-source federated network. In other words, caBIG is open to all; the planning, testing, validation, and deployment of caBIG tools and infrastructure are open to the entire cancer community. In addition, the underlying software code for the caBIG infrastructure is

available for use and modification, and resources can be controlled locally or integrated across multiple sites. “Our role was to create the cancer knowledge cloud—a cancer information resource that leverages the power of the Internet to bring together all the various sources of information and make it accessible to consumers, practice settings, community hospitals, research hospitals, research institutions, and industry,” Dr. Buetow said. The caBIG was built with the awareness that this rich source of information would enable data aggregations, analyses, decision support, and so forth, “with the true goal of then being able to support the entire life cycle of the learning health system and convert biomedicine into part of the knowledge economy. We wanted to interconnect all the different flavors of data—whether . . . clinical data, genetic data, or imaging data, and have the rich analytic tools that users could use in their laboratory, their organization, or their institution,” Dr. Buetow noted.

An advantage that caBIG and similar computer grids offer, Dr. Stead pointed out later during the panel discussion, is that they save institutions the costs of developing *de novo* the technology needed to do complex data analyses. “One of the things that drove the creation of caBIG originally was that all the NCI-designated cancer centers were in the process of collecting molecular data in the form of microarrays. They were all creating new microarray repositories and all the data standards needed with substantial staff and IT investment. Each of them was estimating that it was going to cost somewhere between 1 [million] and 5 million dollars to create each individual system.” Instead, caBIG created the standard framework in which this information could be collected, stored, and analyzed at a cost of only 2 million to 3 million dollars, he said. “There was at least a five- to tenfold savings by having a common framework by which people could collect the information as opposed to regenerating it *de novo* each time,” Dr. Stead said.

Participants in caBIG currently include 56 NCI-designated cancer centers, 16 community cancer centers, and several cooperative groups. The caBIG is now in what Dr. Buetow calls its “enterprise phase,” which will involve more widespread deployment and adoption as well as international collaborations, with an emphasis on making the grid useful beyond the research setting by bringing in data from community settings. Along with the American Society of Clinical Oncology (ASCO), caBIG is working to develop the standards-based infrastructure for an oncology-specific EHR to enable the collection of patient data from community healthcare settings, such as physician practices and community hospitals. The caBIG has also

joined forces with academia, industry, foundations, insurers, and consumers to form the BIG Health Consortium, whose mission is to demonstrate the feasibility and benefits of personalized medicine. Through a series of projects, with an expanding number of collaborators, BIG Health will bootstrap a new approach in which clinical care, clinical research, and scientific discovery are linked.

One of caBIG's first enterprise projects, the Athena Breast Cancer Network, is to integrate diverse breast cancer data, including clinical, genomic, and molecular data, collected from 13 different sites encompassing more than 400,000 women within the University of California system, and make them accessible to end users. Grid computing will be used to standardize collection of structured data, integrating clinical and research processes including molecular profiling, starting at the point of care. Researchers will then use these data to build better models to predict risk and outcomes for low- and high-risk breast cancer patients that can be used for tailored screening and prevention strategies. In another project, caBIG is partnering with the Love/Avon Army of Women to build the first online cohort of 1 million women willing to participate in clinical trials. Leveraging Web 2.0 technology, the caBIG tools and infrastructure will facilitate the creation of this online breast cancer cohort that will match clinical researchers with individuals wanting to participate in clinical trials. In addition, Web applications enable the women to access and simultaneously review and edit their personal information. "We're hoping it will show that you can actually have a consumer-centric, patient-involved model for conducting this next-generation type of research," said Dr. Buetow. Such capacity for rapid learning is completely feasible and could galvanize the national community.

The CDC is also actively working on standardized electronic data exchange. Ms. Sandy Thames, a public health adviser with the agency, reported that CDC is working on a model electronic reporting project for cancer surveillance, linked to EHRs and harmonized with national health IT efforts at standardization and interoperability. She said CDC is also working on building a concept for how federal agencies, public health systems, providers, and consumers could be connected in a shared environment with a national public computer grid.

COMPARATIVE EFFECTIVENESS RESEARCH

Comparative effectiveness research is an essential element of a RLHS because it provides the evidence for best practices, thereby improving the

quality and consistency of care. As the IOM defines it (IOM, 2009a), and Dr. Harold Sox reported, CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and the population levels. CER involves direct, head-to-head comparisons and has a broad range of stakeholders and beneficiaries, including health services researchers, patients, clinicians, purchasers, and policy makers. In addition, unlike a lot of clinical trials research, CER studies populations representative of clinical practice.

CER tends to focus on patient-centered decision making so that tests or treatments are tailored to the specific characteristics of the patient, Dr. Sox said. As he pointed out, if a randomized controlled clinical trial shows that treatment A has a higher response rate than treatment B, 60 percent versus 50 percent, and if you did not know anything more about the patient, except that they had the condition in question, then you should prefer treatment A, even though many patients still got better on B. Yet it is possible that some patients would have actually done better on treatment B than A, and we could identify those patients in advance, both from demographic as well as clinical predictors. This sentiment was echoed by Dr. Clancy, who explained that conducting CER requires investigating not only which type of treatment is the most effective, but which type of treatment is the most effective for specific patients. “The promise of CER is that it will provide information to help doctors and patients make better decisions,” Dr. Sox said.

As Dr. Clancy reported, the AHRQ plays an instrumental role in supporting CER. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act² authorized AHRQ to conduct synthesis in research on the effectiveness and comparative effectiveness of healthcare services broadly defined as relevant to Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) beneficiaries. The agency was also charged with disseminating the information it acquires from this research to multiple stakeholders in an understandable form. It is meeting this congressional request with its Effective Health Care (EHC) Program.

After consulting with stakeholders, AHRQ has prioritized its CER research agenda, and cancer is one of its priority conditions. AHRQ has

²Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Public Law 108-73. 108th Cong. 1st Sess. (January 7, 2003).

already completed a number of cancer-related CER studies, including the comparative effectiveness of particle-beam radiation therapies and of stereotactic radiosurgery for extracranial solid tumors. “Sometimes these are systematic reviews, and sometimes we are relying on a network of research contractors that have access to very large datasets with some clinical electronic data,” Dr. Clancy said. She added, “When the facts stop, these reports stop. These are not guidelines per se, they are strictly the evidence,” and it is up to practitioners on how best to apply that evidence to their patients.

The AHRQ CER efforts have been expanded as the American Recovery and Reinvestment Act (ARRA) of 2009 included \$1.1 billion for CER, of which AHRQ was awarded \$300 million, the National Institutes of Health (NIH) \$400 million, and the Office of the Secretary of Health and Human Services (HHS) \$400 million. A Federal Coordinating Council was also appointed to coordinate CER across the federal government. With this additional funding, AHRQ plans to continue to do its evidence synthesis reviews of current research, but also to do evidence generation—new research with a focus on underrepresented populations. For this research, the agency plans to expand distributed data network models and national patient registries. Part of the allocated funds AHRQ receives will also be used to support training, research, and careers related to CER.

The American Recovery and Reinvestment Act also provided funding for an IOM study to determine the high-priority healthcare conditions and interventions to guide the spending of the portion of the ARRA funds allocated to CER (IOM, 2009a). After gathering stakeholder input, the IOM Committee on CER, which Dr. Sox co-chaired, developed a list of 100 priority topics on which CER should be conducted, which included comparing the effectiveness of dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others. The IOM top 100 priorities included several high-priority, cancer-related topics, such as comparing the effectiveness of

- Genetic and biomarker testing and usual care in preventing and treating breast, colorectal, prostate, lung, and ovarian cancer and other conditions;
- PET (positron emission tomography), MRI (magnetic resonance imaging), CT (computed tomography), and other imaging technologies in diagnosing, staging, and monitoring patients with cancer;
- Management strategies for localized prostate cancer on survival, recurrence, side effects, quality of life, and costs; and

- Management strategies for ductal carcinoma *in situ* (DCIS).

In addition, the IOM committee recommended building robust data and information systems to support CER, including clinical and administrative data networks to facilitate better use of data and more efficient ways to collect new data to inform CER. The purposes of CER and the infrastructure needed for a robust CER enterprise are actually a tight fit with the purposes and features of a RLHS. CER results will provide evidence for rapid learning, and a RLHS will provide the pathway for implementing CER. The two are synergistic.

GUIDELINES AND STANDARDS FOR CARE

In an ideal RLHS, evidence collected from point of care, clinical trials, CER, and other studies would be synthesized to create cancer care guidelines specific for various cancers with finer-grained standards specific to patient subtypes. These guidelines and standards of care would be updated continuously and widely distributed to practicing oncologists, who would be monitored and informed of their adherence to the guidelines.

Currently, the most widely recognized standards for cancer care in the United States are the guidelines developed by the National Comprehensive Cancer Network (NCCN). Established in 1995, NCCN is a network of 21 of the nation's leading cancer centers whose mission is to "positively influence and improve decisions and policies that impact the access to, availability of, and delivery of appropriate and effective cancer care," said Dr. William McGivney, who is the CEO of NCCN.

NCCN guidelines are developed by 44 multidisciplinary panels, with 20 to 30 disease-specific experts on each panel. "Our guideline panels, reviewers, and our discussions involve probably 1,500 to 1,800 oncologists," Dr. McGivney said. He added that these free guidelines are widely distributed online and via a variety of media outlets and seminars, and are updated continually, with some updates given within 48 hours of new information surfacing in medical journals or other outlets. Some guidelines are updated as frequently as four to six times a year. NCCN guidelines are used increasingly as a basis for coverage policy. NCCN also produces its own drugs and biologics compendium, which is designed to support decision making regarding the appropriate use of drugs and biologics in patients with cancer.

In addition, NCCN is currently developing chemotherapy templates to

improve the safety and effectiveness of the administration of chemotherapy and biologics in both cancer centers and community settings. These templates are especially designed to aid “community doctors who do not have the time to keep up with the numerous changes in dosing in these regimens, and the addition of new chemotherapeutic regimens, drugs, or biologics,” Dr. McGivney said.

However, as Dr. McGivney pointed out, “It is just not enough to write guidelines. It is important to actually measure whether you follow those guidelines.” The NCCN has been developing several outcomes databases to monitor and benchmark concordance with its guidelines in member institutions. “These databases describe practice patterns and outcomes of care and we feed that information back to our clinicians, our institutions, and our guideline panels,” he said. NCCN databases have been established for breast cancer, non-Hodgkin’s lymphoma, and colorectal, lung, and ovarian cancer. The most developed database in that regard is the breast cancer database, encompassing 52,000 patients from 17 NCCN institutions and 15 community cancer centers.

Each year, NCCN conducts a major analysis of the data it collects and provides participating patient-level feedback to institutions and physicians regarding concordance with the management stipulated by NCCN guidelines. “About half of participating institutions look at every patient that is not concordant,” Dr. McGivney said. The NCCN analysis evaluates concordance and the reasons given for lack of concordance, identifying issues that need to be evaluated such as variation of care across institutions. As Dr. Paul Wallace of Kaiser Permanente pointed out during a later discussion, it is important to evaluate not only concordance, but also reasons for a lack of concordance. As he noted, physicians must continually assess if the NCCN guidelines are applicable to their specific patients. If they decide the guidelines do not “fit” their patients, they must be accountable for those decisions. “There’s nothing wrong with being innovative,” Dr. Wallace said, “as long as you are accountable for it.”

NCCN has also developed analysis tools that payers can use to evaluate the quality of care of their patients based on NCCN guidelines. NCCN is also currently working with informatics firms, to develop tools that will enable the integration of NCCN guideline recommendations into EHR systems to facilitate support for physician decision making and more rapid distribution of information to clinicians. This rapid support and feedback are critical, Dr. Edge stressed later during discussion; he said that “we need to change our systems to help doctors, rather than blaming doctors for

doing something that they did five years ago. We need to reengineer the system so that it helps providers and patients.” He suggested that in addition to providing physicians with online access to NCCN guidelines, there be a way for doctors to input their relevant patient data while accessing those guidelines, to immediately assess whether they are following the guidelines properly and to provide point-of-care data that can be used to continually determine the validity of those guidelines. Dr. Edge was critical of systems that do not provide immediate feedback to physicians. Dr. McGivney concluded by noting, “We have a long way to go, but the acceptance of these guidelines by clinicians, patients, and payers has important implications for improving the healthcare system.”

Less extensive than the more than 100 guidelines put out by NCCN are about 20 clinical practice guidelines developed and distributed by the clinical practice guideline group of ASCO. ASCO has also begun rapid distribution of provisional clinical opinions to inform oncologists of new developments that affect practice (e.g., the importance of testing for KRAS gene mutations in metastatic colorectal cancer patients to predict response to anti-epidermal growth factor receptor antibody therapy).

Recently, ASCO developed its Quality Oncology Practice Initiative (QOPI), an oncologist-led, practice-based voluntary quality improvement initiative. The goal of QOPI is to promote excellence in cancer care by helping oncology practices create a culture of self-examination and improvement, said Dr. Joe Jacobson, an oncologist in practice at North Shore Medical Center and chair of the QOPI Steering Committee. QOPI shows how physicians’ processes of care (but not outcomes) measure up to standard practices stipulated by guidelines, published studies, and expert consensus. Adherence to these standard quality measures and processes, including documentation of care, chemotherapy planning and administration, pain assessment and control, end-of-life care, and symptom and toxicity management, is assessed every six months, allowing progress to be measured. Oncology practices choosing to participate are required to enter a limited number of patient datasets via a secure Web-based application. These data are collected by practice staff two times a year via retrospective chart review and data abstraction. At the close of data collection, practice reports are generated that compare practice-specific results to aggregate data.

QOPI began as a pilot program in 2002 involving 23 practices and then was opened to ASCO membership in January 2006. By the spring of 2009, 247 practices throughout the United States were actively par-

ticipating in QOPI, with more than 18,000 patient charts abstracted for 81 measures of care processes. QOPI has revealed that there has been the greatest degree of concordance for the treatment of cancers, such as breast and colorectal cancer, for which there is the best evidence base for care, Dr. Jacobsen pointed out.

Ninety-five percent of those physicians participating in QOPI report they do so because they want to know what sort of care they are providing and ways in which they can improve their care. Participation in QOPI also provides physicians with credits toward maintenance of board certification for the practice improvement module or continuing medical education (CME) credits. Some insurers have also promoted QOPI participation by reimbursing oncologists for their costs in participating. Notably, such reimbursements by Blue Cross/Blue Shield of Michigan were linked to a fourfold increase in provider participation in the program.

In the near future, QOPI plans to create registries that collect electronically transmitted patient data prospectively and in real time. An example of such a registry is the prospective breast cancer treatment registry that ASCO is currently creating with support from the Susan G. Komen for the Cure Foundation. This registry uses a Web-enabled application, based on the ASCO Breast Cancer Treatment Plan and Summary template that is provided to patients and other caregivers. De-identified data are entered into a registry in real time, and as the registry evolves, it may enable direct data transfer from EHRs.

QOPI data are also being used for quality improvement in collaborative networks, such as the NCI Community Cancer Centers Program and the Michigan Oncology Quality Consortium, which was created by Michigan Blue Cross/Blue Shield. These networks are using their QOPI data to define their best practices, which are then applied to all participating sites in their network. "The first sea change in oncology is getting oncologists to measure what they do. The next one, which is perhaps more challenging, is to get them to believe that they can improve the care they provide," Dr. Jacobsen said. He added that voluntary QOPI certification is expected to be available in 2010. Such certification will be provided to QOPI participants that achieve a minimum specified score on 28 performance measures and will also include practice site assessments for 35 chemotherapy safety standards established by ASCO in collaboration with the Oncology Nursing Society and other stakeholders.

Dr. Jacobson ended his presentation by noting that as physicians, "all of us have two jobs in life. The first is to provide care, and the second is to

improve care. We should always be thinking about how what we do could be done better.”

DECISION TOOLS AND MODELS

In addition to practice guidelines, oncologists are increasingly relying on computerized decision support tools, models, and tumor-based prognostic assessments to improve their care of cancer patients. Based on cancer registry data, clinical trials, observational studies, and genetic testing, these oncology decision-making aids are well developed for some of the more common cancers such as breast cancer, as Dr. Patricia Ganz of the Jonsson Comprehensive Cancer Center noted, and can play an important role in a RLHS. For example, the Web-based tool Adjuvant! Online[®] provides estimates of the net benefit to be expected from systemic adjuvant treatment for individual breast cancer patients according to patient-specific characteristics, such as tumor size, grade, number of involved nodes, and hormone receptor and *Her-2-neu* status (Adjuvant! Inc., 2010; Ravdin et al., 2001).

Using this information, which practitioners input directly online into the computer model, Adjuvant! Online predicts how various adjuvant treatments are likely to affect the risk of relapse and mortality, enabling oncologists and their breast cancer patients to personalize their decision making on whether to pursue adjuvant therapies. The model was developed by actuarial analysis of the San Antonio breast cancer data base and SEER data, as well as on estimates of the proportional risk reduction observed in individual randomized breast cancer clinical trials and systematic overviews of randomized adjuvant trials. Dr. Ganz pointed out that “having these kinds of tools to translate these complex scientific discoveries so they can be a part of the patient conversation is absolutely essential.” They also aid physicians, she added, who cannot easily assemble and integrate all the abundant information needed to make treatment decisions. “Most of us do not even know what the background survival rate is for a 70-year-old woman,” she said, let alone the survival statistics of a 70-year-old breast cancer patient with a number of different prognostic variables.

Dr. Abernethy stressed the importance of linking decision support tools and models directly into the information technology system. “What good is a model that we have to type [patients’ data] into—that barrier in itself is going to inhibit use. We need to start building our models into our IT systems because that system already knows that the patient is 37, so why should I have to type it in?” she said. She added that there should be a

process for vetting models, as well as algorithms that enable IT systems to match the most appropriate model to the cancer patient in question.

Dr. Edge pointed out that Adjuvant! Online is just one of several oncology decision support tools, most of which are not widely known, and he and Dr. Ganz agreed that it would be helpful if these tools and models were made available within a specific publicized clearinghouse and their comparative effectiveness was assessed. Dr. Neti raised the question of whether the Food and Drug Administration (FDA) approves decision support tools and ensures that these models are accurate and can be used effectively and appropriately in a clinical setting. Dr. Abernethy responded that the FDA is currently assessing how to evaluate these tools and how to develop an approval process for them. “I should hope that these models, in a rapid-learning world, would be dynamic and that they would grow and learn as the datasets are improving, and that we actually build into those models the iteratively updated process,” she said. “Pandora[®] learns what kind of music I want, and yet my decision support models cannot learn from my patient populations. I do not know that we have gotten sophisticated enough in our regulatory process yet to understand how we are going to deal with that. That is going to be an important piece to build into the rapid learning system,” she added.

Discussant Dr. Mia Levy also expressed concern that decision support tools may not be updated rapidly enough to enable them to be part of a RLHS. “I use these tools all the time in my practice, but some have been delayed in bringing in *Her-2-neu* status into the equation, and all these other variables that go into it,” she pointed out. Dr. Ganz agreed and noted that there needs to be a financial investment in making sure these tools and models are updated regularly and used at the bedside. She pointed out that Adjuvant! Online was developed by one researcher, who was not adequately compensated for the time he spent developing it.

Dr. Sharon Murphy of the IOM pointed out that many of the data used to develop decision tools and prognostic assessments are from clinical trials that typically do not enroll elderly patients or those with poor performance data, and thus may not be applicable to all patients. Dr. Ganz pointed out that there is some representation of all patient subsets in the observational data, such as SEER, that are used in the development of decision support tools but added that, ideally, a “rapid learning health system would collect good prospective data at the bedside that would help inform us about these decisions because we have very limited information. The person who makes it to a clinical center to go on a clinical trial is not representative of that universe.”

4

A Private RLHS— Kaiser Permanente

A few private healthcare systems are developing their own oncology-specific RLHS, including Kaiser Permanente (KP), the nation's largest not-for-profit healthcare plan, which serves more than 8 million members in nine states and the District of Columbia. With its heavy investment in health services research and health information technology, and its commitment to rapid translation and quality improvement, KP strives to be a RLHS, reported Dr. Wallace, medical director of the organization's Health and Productivity Management Programs.

"A lot of the learning [in health care] will be dependent on observational research, so plan for it," Dr. Wallace said. Such planning is proactive and prospective, he stressed, and requires determining what data need to be collected and entered in a database so at a later date one can assess what treatments or treatment processes were most effective and efficient. "There is a cost for us as a society for throwing away data not just for the patient who has a rare disease but for all patients, because if the patient in front of me is a 75-year-old woman who has a history of a heart attack, and she has bad arthritis and seven or eight other nuances, how do I decide how to best deliver her care if I do not have a database that allows me to cull out 100 people just like her to understand the appropriate nuances and choices of therapy? We can do that now and what keeps us from doing that is basically a failure to respond."

He estimated that about 80 percent of cancer patients can be treated

with standard protocols and “if we can get to the point where those 80 percent take about 30 percent of our effort, then we have a lot of time to deal with the people that need customized care.”

KP has about 200 oncologists working in at least 40 sites. To create more systematic and less variable care, the system brought together a group of its oncologists, nurses, and pharmacists from a variety of different settings to develop more than 300 standard protocols for chemotherapy and clinical trials. These protocols were evidence based, but can be personalized and modified to meet patient variability and individual needs. “We wanted to test the hypothesis that, if we do that, it will lead to appropriate variability rather than random variability for our practice population,” Dr. Wallace said.

All care is electronically documented, including not just what specific treatment is given, but its indication (e.g., whether it is curative, second-line, or palliative). To address safety concerns, there are processes built in to ensure that “when you order a drug, you have absolute confidence that it will be translated into an order that will be translated into a bar code that will correspond to the patient to whom you are giving the drug,” Dr. Wallace said. Providers are also alerted when they approach the near-maximum dose for chemotherapy, and the entire healthcare team can view a treatment plan simultaneously and enter pertinent information electronically.

Kaiser physicians are given regular reports of their cancer care and how it compares to their peers on various measures, such as hospitalization rates, clinical trial enrollments, et cetera. When there is variability within and between practices, the providers are encouraged to try to determine the cause of the variability and what best practices to follow within their office or clinic because, as Dr. Wallace noted, “if you are not using the data to facilitate that conversation, there is no learning. Rapid learning takes place both at the practice level and at the system level.” If there is variability in certain regions and/or practices, KP can focus retraining and education efforts in that area to address the discrepancy in care.

KP has just begun testing its new system for oncology care and found that between 63 and 84 percent of its standard treatment protocols were used without modification. “This means physicians can focus their time on customizing care so care is patient driven, not clinician driven,” Dr. Wallace said. Encouragingly, new developments in chemotherapy were rapidly translated in the system. Within just a week of its being published that lower-dose Avastin was as effective at treating colon cancer as high dose, that shift in treatment began diffusing through the practices that are a part of KP,

resulting in a savings of about \$200,000 per practice site (i.e., a dividend in a capitated system such as Kaiser's), Dr. Wallace reported.

KP also captures patient ethnicity and race to examine health disparities and determine patient subsets that it is failing to reach with its efforts to improve care. For example, it found that Hispanics in general, especially Hispanic men, are less likely to undergo colon cancer screening than other population subgroups, so KP is trying to target its colon cancer screening messages more appropriately to those men. Collecting data on race and ethnicity can also reveal treatment differences. "Knowing race and ethnicity of patients is part of being able to do accurate, prospective, observational research. I think that this type of capability is going to change how we are going to do things," Dr. Wallace said.

KP is also beginning to look at population health and has found that its patients in southern California were more likely to survive breast, colon, melanoma, and lung cancer at all stages than indicated in SEER data collected from patients from the same geographic area. This is worth exploring further, Dr. Wallace noted.

Dr. Wallace finished his presentation by stressing the need to design healthcare systems so that "knowledge generation is just an expected by-product of care" collected in all sites, rather than in unique sites. "We need to proactively recognize that observational studies are how we are going to build the knowledge base going forward, and plan to do that in a structured and thoughtful way," he said.

5

Patient-Driven Rapid Learning Systems

Patients are increasingly playing an active role in driving the development of a cancer RLHS, reflecting the greater participation of patients in their healthcare decision-making processes. “I have been in practice long enough to have gone from being trained as an oracle that tells people what to do, to being asked to help patients understand what the information they have collected means to them. Multiple patients demonstrated to me that they knew more about their conditions didactically than I did,” noted Dr. Wallace. “As we are thinking about generating knowledge, it is really prudent for us to think about the knowledge needed by the patient, and what the patient can help us learn,” he added.

Wide-scale use of the Internet and social networking sites and tools by patients has also fostered the rapid gathering and spread of information about various conditions, explained Susannah Fox, associate director of digital strategy for the Pew Internet and American Life Project. A 2009 survey done by this project found that 8 out of 10 adults in the United States have access to the Internet and two-thirds have broadband at home. Information seeking and reporting are also more mobile and rapid, Fox noted, as 56 percent of American adults regularly go online wirelessly with their phones, laptops, or other portable devices, the survey revealed. “There are rapid learning systems that are *ad hoc* that are going on right now, and you should be aware of them because patients are using them,” Fox said, adding that “even though there are only about 80 of us in this room today, there are

thousands of people who can follow what we are doing,” via “tweets” she had simultaneously posted on Twitter. “The Internet is moving from being a stationary, slow, desktop-based information vending machine into what is now a fast, mobile, communications appliance,” Fox added.

This information technology is enabling many different ways for people not only to consume information about health and health care, but also to contribute information, Fox said. The Pew survey revealed that 52 percent of Internet users watch videos online, more than one-third share online photos, including X-rays and other medical graphics, and one out of five Internet users with cancer uses social network sites. “The Internet is really changing people’s expectations of what should be available to them, and there is a broad uptake for social media in health,” said Fox. “We are seeing that patients are looking for stories about people who are just ahead of them on the path, and they are learning from each other. Patients are doing the data collection that you crave, and they are ready to participate and be seen as your colleagues.”

Fox pointed out that between 2006 and 2008, Pew surveys found that the proportion of American adults who responded that they, or someone they knew, had been helped by medical advice they found online went from one-quarter to nearly one-half. Only 3 percent responded in the most recent survey that they had been harmed from medical advice they found online. Fox concluded by saying, “Researchers and clinicians can take advantage of what patients are already doing outside the system and welcome them into the system.”

An online leader in gathering and disseminating information about cancer to those affected and their caregivers is the international Association of Cancer Online Resources (ACOR), the largest online social network for cancer patients. Composed of close to 200 separate online support groups and social networks for individuals with cancer, ACOR has served more than a half-million cancer patients and caregivers and currently has 60,000 members. ACOR delivers an average of 1.5 million e-mails weekly to its members, including a tremendous amount of the latest scientific information about their disorder and clinical trials in which they can participate, reported Gilles Frydman, who founded ACOR in 1995. “ACOR is not a chat room,” he said, although it does provide members with the opportunity to share their personal stories with an emphasis on medically or quality-of-life significant events. One of the goals of the organization is patient empowerment and activation, and accelerating access to relevant

information with unmatched currency, bypassing what Frydman calls the “built-in lethal lag time” of professional research publishing.

ACOR also fosters data collection from within its online cancer communities. Such data collection includes postmarketing self-reporting, as well as group-wide data collection with an emphasis on adverse event reporting. For example, the International Myeloma Foundation used ACOR’s myeloma and breast cancer listserv to conduct a survey, whose results it used for a ground-breaking postmarketing study on bisphosphonates and necrosis of the jaw. This study was published in the *New England Journal of Medicine* and led Novartis to change information about the drug on its label. Similarly, reports of kidney toxicity on the ACOR listserv by myeloma patients taking Zometa[®] led to experts’ calling for slowing the infusion time of the drug. Myeloma patients were quickly notified of this change via the listserv, and kidney problems were rapidly and dramatically reduced, Frydman reported. “We see daily conversations about side effects that are not found in FDA publications,” he said.

ACOR has also literally saved many lives and led to record-breaking clinical trial accruals, according to Frydman. For example, ACOR rapidly informed its members with gastrointestinal stromal tumors (GISTs) as soon as word got out that Gleevec[®] was likely to be effective for these tumors, leading to remarkably short accrual times for a clinical trial of Gleevec for GISTs. “Novartis told me they expected their accrual time for the trial to be three years, and it was done in just over eight months, with 18 percent of the accrued patients coming through our system,” said Frydman.

He summed up his presentation by stressing that “activated patients are the most underutilized healthcare resource. Social networks of patients suffering from a rare disease may often be the best resource for high-quality information. Network patients are inventing and shaping a better healthcare model where their input is constant and central.” However, he added that patient input requires patients’ having access to all their medical data and the option to participate in the decision-making process.

New technologies are empowering patients and patient-driven research organizations,” said Dr. Simone Sommer, president of the Chordoma Foundation, co-founded with her son Josh, who was diagnosed with a chordoma in 2005. She expressed impatience with “the slow wheels of science. Healthcare organizations and patient advocacy groups like ours are going to play a much more active role as we have the highest stakes and the greatest motivation to change the system, and we cannot wait.” Dr. Sommer added

that the speed and quality of patient care are proportional to the flow of information and urged that there be open access to medical literature, and that venues and systems be created that unite disparate researchers, patients, and physicians to accelerate the process of searching for treatments for cancers, especially rare cancers such as chordoma, where both researchers and patients are few and far between.

The need for rapid learning and global networking is most pressing for patients with rare, life-threatening diseases, such as chordoma. Dr. Sommer and her son Josh spoke about their efforts to spur such learning and networking so as to more quickly find and deliver effective treatment for chordoma. There are no approved drugs for this condition, which is generally resistant to chemotherapy. With only 300 new diagnoses per year in the United States, and 20 isolated researchers studying the condition, the main barrier the Sommers found to making progress on the disease was a lack of communication, collaboration, and coordination among stakeholders, including patients, researchers, physicians, scientists, and industry, resulting in scant evidence of progress against this rare condition.

There are few clinical studies on chordoma because of the rarity of the condition. Yet because of its fatal nature, many patients with chordoma are subjected to experimental treatments, such as off-label use of cancer drugs that are approved for other malignancies. “One oncologist described it as throwing drugs at the disease until something sticks. When there is no other option, oncologists become resourceful and, in essence, they do experiments on their patients,” Dr. Sommer said. She described this process as “learning chaotically” and added, “Every day all over the world, chordoma patients and patients with all sorts of rare cancers are being experimented on, and isn’t it a shame that those experiments are not adding to our knowledge about the disease and informing care of future patients?” She called for setting up a system in which science can use such data that are being generated but not collected. Patient networks can quickly disperse any anecdotal information about experimental treatments to their members. Dr. Sommer noted that patients learn fast but there are several shortcomings in such patient-to-patient learning. These shortcomings include survivor bias that distorts the findings. “The dataset is enriched with patients who have responded to a particular treatment because you do not hear from the patients who did not respond,” Dr. Sommer pointed out. In addition, anecdotes are not generalizable, especially for chordoma, which is a heterogeneous disease. “While these social networks and online tools are very valuable for patients to learn about new potential therapies, there is a

risk in patients' relying on these anecdotal reports and thinking that what happens to someone else should guide their own therapy, because in reality, their tumors are very different. We need to capitalize on patients' ability to talk and communicate with one another, but do it in a scientific manner, and not in a patient-to-patient manner," she said.

To further research, the Chordoma Foundation is creating a systems approach featuring a centralized chordoma biospecimen bank and patient registry that links ongoing, prospectively collected patient data to biospecimens that researchers can use in their studies. The Sommers are in the process of finalizing a contract with Ohio State University to house the biobank, which will operate on the caBIG platform (see Figure 5-1).

As Josh Sommer pointed out, chordoma patients often have several surgeries at different institutions, and no one hospital has all the tumor specimens or complete records on patients, so having a centralized repository is a valuable asset that will spur research on chordoma.

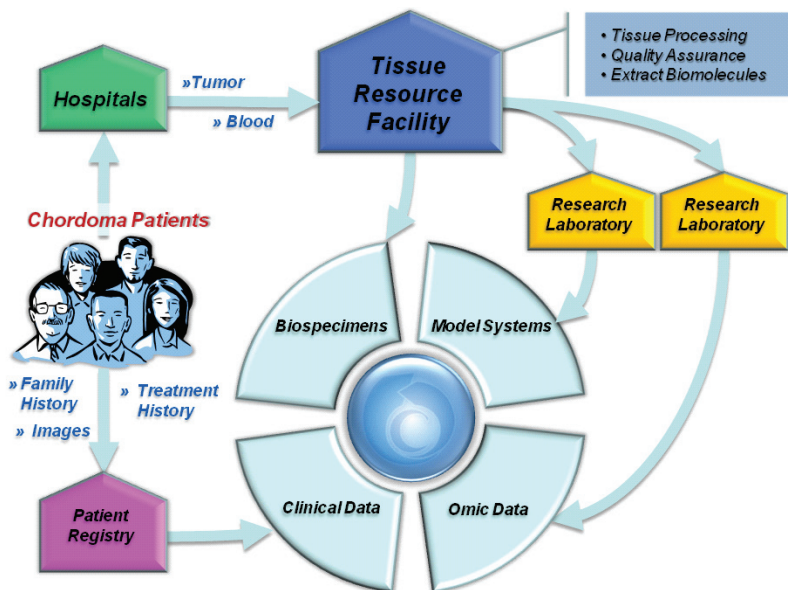


FIGURE 5-1 An example of a patient-driven rapid learning system for a rare cancer, chordoma.

SOURCE: Reprinted, with permission, from The Chordoma Association 2010. Copyright 2010 by the Chordoma Association.

Dr. Sommer ended her presentation by pointing out that patients are eager to contribute to research, but rightfully expect to benefit from results. Physicians and researchers need to respect patient privacy, as well as figure out how to quickly, safely, and ethically feed results back to patients, she said. “We need to look forward in a way that we make sure that the new frontiers include patients and their personalized health care,” Dr. Sommer said. Dr. Sommer also stressed the need for portable, longitudinal records and biospecimens tied to the patient and not to the locale and hospital, given that medical care is often done at multiple locations.

Like chordoma, amyotrophic lateral sclerosis (ALS) is a rare and fatal disease. Having his brother diagnosed with the disease spurred Jamie Heywood to create a patient online social networking site called PatientsLikeMe™ (PatientsLikeMe, 2009). The goal of this organization is to enable people to share their experiences and learn from and connect with others like them. The website provides a platform for collecting and sharing real-world, outcome-based patient data and is establishing data-sharing partnerships with doctors, pharmaceutical and medical device companies, research organizations, and nonprofits. “PatientsLikeMe is a new social contract that says if you share everything about yourself, including your DNA, your blood, your tumor, your symptoms, every drug you take, and your side effects, we will use that information in an open medical network that really begins to transform what is possible in a new way,” said Heywood.

The basic premise of PatientsLikeMe is that if enough patient-reported anecdotal information is collected, it can be turned into useful data if the right questions are asked and properly structured analyses are done on the data. PatientsLikeMe can use the information it collects to provide patients with basic predictions, such as their likely timetables of disease progression. PatientsLikeMe has created new computer analysis tools that can provide personalized predictions, based on the wealth of multivariate patient data collected on its site that are matched to individual data entered into the system by the patient requesting such predictions. These analyses strive to control patient selection bias in their careful matching process, which compares, for example, ALS patients taking the experimental treatment lithium with those ALS patients on the site who opt not to take the drug, yet have the same disease onset time, degree of disease progression, age, and so forth, as the treated group. “We integrate across every variable we know about the patients over the entire history of time we know about them, and match them to controls,” said Heywood.

A PatientsLikeMe analysis revealed that lithium was not effectively

improving symptoms or delaying disease progression in patients who took the drug, refuting preliminary evidence in the medical literature published 18 months earlier from a small group of patients suggesting it might be an effective treatment for ALS. Heywood claimed that his study had four times the power of this original preliminary study, using only patient volunteers from the “real world.” “Patient data can up-power your double-blind study because we know how to integrate the prior information about the patient’s data into the equation,” Heywood said. Random controls are not a “patient like me.” PatientsLikeMe discovered and disseminated its findings about lithium to its ALS members one year before a large-scale clinical trial testing lithium as a treatment for ALS was stopped because of futility. “They would not have released that data, via a patient press release, if we had not put our data out ahead of time,” claimed Heywood. “So not only have we begun to deliver meaningful answers ahead of time, but we have changed the expectation for the trial community to deliver data to the patient community,” he added, noting that the negative clinical trial study results were never published.

PatientsLikeMe is doing similar studies of patients with other disorders such as leukemia, Parkinson’s disease, and multiple sclerosis, and Heywood urged the medical community to fund the infrastructure needed for these observational research endeavors. “I think that we have, in medicine, failed to deliver the platform that allows the innovators that will cure disease to do it effectively,” he said, claiming that these platforms will continue to be developed by and for patients and that it would behoove the established medical research community to collaborate with such projects.

Later during discussion, Dr. John Mendelsohn, from the M.D. Anderson Cancer Center, pointed out that his center has an open records Internet site called “My MD Anderson” in which physicians and patients share information. “The website is not complete yet, but it is something that I think will improve our ability to give care,” he said. He then asked Heywood how PatientsLikeMe decided what data to collect on patients and whether such decisions were patient driven. Heywood responded that the questions asked patients are usually modified from a standard set. “We adapt existing questions because when we test them on the patients, we generally find the existing measures are not describing what the patients feel is important,” he said.

Dr. Hal Sox noted that the larger and more representative a patient population one has to work with, the more likely progress is to be made, and asked Heywood what proportions of people with the diseases tracked

by PatientsLikeMe use the site. Heywood responded that 20 percent of the ALS patients who were diagnosed in the United States within the last six months joined PatientsLikeMe. “We have about 11 percent of the U.S. ALS population in the website right now, and of those, about 60 percent are giving us what we call a clinical-trial-a-year’s worth of data.” Josh Sommer added that about one-fifth to one-quarter of all U.S. chordoma patients are represented in the Chordoma Foundation database. Heywood noted that “there is a minimum scale of about 500 patients that we find needed to get an effective dialogue going, and there appears to be a ceiling of about 11,000 to 12,000 patients within a single community that we need to figure out how to break through with our current information architecture.” Heywood implied that the high degree of dialogue that occurs on some sites limits the number of people that can effectively participate in them. Dr. Sommer also noted generational differences, with older individuals perhaps not as willing to be open and share everything online as the younger generation (e.g., on Facebook).

6

Challenges and Opportunities

Workshop speakers and discussants brought up a number of challenges to creating and implementing a RLHS (see Box 6-1).

IMPLEMENTATION OF EHRs

Rapid healthcare learning is dependent on rapid electronic means of communication, and EHRs are a basic foundational element of an ideal RLHS. Yet it has been challenging to achieve widespread adoption of EHRs, reported Dr. Charles Friedman, deputy national coordinator of the Office of the National Coordinator (ONC) for Health Information Technology (HIT). A recent survey by his office in 2008 found that only about one-fifth of physicians' office practices have a four-component basic EHR system, with adoption skewed to larger practices. The survey also found that only about one out of ten hospitals has a basic EHR system with eight key functions fully deployed across all major clinical units.

To spur efforts to computerize the nation's health records by 2014, Congress included in its American Recovery and Reinvestment Act two sections that together are called the "HITECH" Act. These sections provided an unprecedented \$19 billion to stimulate adoption of health IT systems, to provide "meaningful use" of a nationwide interoperable EHR system (Blumenthal, 2009).

Meaningful use is an evolving concept preliminarily defined as adop-

BOX 6-1
**Challenges to Implementing a RLHS Identified by
Workshop Speakers and Participants**

- More wide-scale implementation of EHRs
- Data quality and completeness
- Harmonization, standardization, and interoperability of datasets
- Appropriate computational algorithms and statistical analyses of observational data
- Data governance
- Ensuring patient privacy and portability of data
- More rapid reporting and translation of clinical and research findings into practice
- Motivated stakeholders willing to collaborate and participate in a RLHS
- Appropriate IT that fosters clinical improvements and meaningful use
- Need for alignment of incentives and payment structures

tion of certified electronic health records, health information exchange, and quality reporting. Meaningful use will be tied to Medicare and Medicaid payment incentives and a policy process led by ONC. Initially, meaningful use will emphasize capturing and sharing data, but by 2013 a higher definition will emerge that emphasizes more advanced care processes, including sophisticated implementation of clinical decision support, which by 2015 will progress toward realization of improved outcomes through enhanced levels of technology. According to Friedman, meaningful use will likely not include the additional elements needed for a RLHS, including gridware, data stewardship, advanced intelligent methods, and means to aggregate information. Yet because these elements will eventually be superimposed on the infrastructure created by the basic elements of an EHR system it is critical that the foundation of EHRs be harmonious and compatible with the higher-level layers that will be added later.

ONC will use financial incentives to boost adoption of EHRs and will promote such adoption by creating a national system of regional extension centers to support providers in adopting and becoming meaningful users of HIT and by creating programs to enhance the number of health IT work-

ers and certify them. As Dr. Friedman pointed out, there is a widespread belief that there currently are not sufficient numbers of health IT workers to enable adoption and connection of EHR systems.

To foster connectivity of EHR systems, ONC will develop standards needed to implement information exchange and quality reporting, as well as programs to ensure privacy and security of EHRs, and will also provide grants to promote health information exchange on a state and territorial level. ONC is also working on the National Health Information Network (NHIN) to mobilize health information by creating a nationwide network of government agencies, community health centers, hospitals, laboratories, pharmacies, and community practices (see Figure 6-1).

To aid this endeavor, the ONC, through the Federal Health Architecture Program, developed an open-source computer tool (CONNECT) that enables connectivity in the NHIN. The NHIN currently consists of 24 entities that have demonstrated the ability to exchange information in real time, and the Network's capabilities are expected to be expanded in 2010.

"We are making progress on all fronts," said Dr. Friedman, "but boy do we have a long way to go." He added later during discussion that meaningful use is currently broadly defined and does not yet call for EHR modules specific to certain practice specialties, such as oncology. Discussant Suanna Bruinooge of ASCO staff pointed out that ASCO, in conjunction with the NCI Center for Biomedical Informatics and Informational Technology and the NCI Community Cancer Centers Program (NCCCP), has an initiative under way to specify the core informatics requirements, data element specifications, and EHR functions needed by practicing oncologists, paving the way for the development of oncology-specific products. "Clinical oncology involves many care processes that may or may not be reflected in the EHR products that are currently on the market," Ms. Bruinooge pointed out. She said ASCO has also been working with the Certification Commission for Healthcare Information Technology (CCHIT) to develop "a wish list of items that would be helpful to have in an EHR so as to create some interoperability between research systems and EHRs. There is a lot of looking at this in an oncology-specific sense, and hopefully that will be helpful as we are trying to create this system of the future."

Dr. Wallace pointed out that "an EHR is necessary but insufficient for supporting oncology practice," and that certain key pieces of information, such as the action plan for a given patient, are not easily captured with EHRs. "The challenge is that there are a whole variety of things that the

EHR does well but there are also things that it does not do particularly well at all,” he said.

DATA QUALITY, COMPLETENESS, AND APPROPRIATE ANALYSES

Lynn Etheredge expressed concern about the data quality in registries and other healthcare databases because “unless you have got it right at the point of entry, it is going to be useless for any other purposes, and unless you define the data, the registries, and the research plan, you will not have learned anything reliable. We have to make building a quality observational system a cornerstone for a learning healthcare system.”

Dr. Edge noted that cancer registry problems are largely related to the quality and the timeliness of the data, and he stressed the need to enhance that quality by linking cancer registry data with administrative data, including payer claims, hospital data, and data from EHRs. Such linkages can both verify and expand the data entered in registries. Dr. Stead pointed out that sets of data from multiple sources might be more statistically reliable than one integrated set of data, because that way there could be interpretation of multiple related signals rather than a single source of information. Unlike with an integrated dataset, “if you aggregate information from multiple sources and use statistical algorithms to interpret them, every new system that you add, every new source you add, actually makes the already existing algorithms more robust,” Dr. Stead said.

Dr. Potosky added that even with linked datasets, there often are data missing from cancer registries, which impedes accurate analyses. For example, in the SEER-Medicare database, cases selected for treatment are often based on nonmeasured characteristics, such as health status, that can only be acquired from patients and are not currently captured in the SEER-Medicare database. Follow-up care and treatments and new comorbidities are also not recorded. Dr. Edge noted that “engaging patients in helping us provide good data may well be a way to get around this [issue of missing data]. The problem is that there are patients who do not provide us that data, and they may be those people who we most need to get the data on.” Dr. Stead suggested that entry of data into a computer be something the clinician and patient do together, with shared records and the aid of patients’ family members. He suggested that patients enter their data at home prior to meeting with their physician, who can review and supplement or change

the data as needed, noting this as an example of the kind of change in roles and processes it will take to make technology work.

Ms. Thames noted that the reported data in cancer registries are not only incomplete, but inconsistent as well. “We do not get consistent, standardized reporting from non-hospital data sources,” she said. In addition, Ms. Thames pointed out that there often are errors in data that are entered manually. She added that cancer surveillance efforts have been limited due to the expense of manually collecting and processing large amounts of data.

Dr. Peter Bach of Memorial Sloan-Kettering Cancer Center reported a number of problems he had with data quality and completeness when he and his colleagues were engaged in the 2006 Medicare Oncology Demonstration Project, whose goal was to gather more information about patients and treatment patterns in routine cancer care. Providers were asked to include new billing codes for disease status, visit focus, and guideline adherence on claims forms. Physician practices were paid an additional \$23 for submitting these codes, and it was done on 66 percent of office visits. Yet critical information was lost because many physician offices created “cheat sheets” to simplify coding and make reporting more efficient. There was a lack of clarity on what it meant to “adhere to guidelines,” with some doctors inaccurately assuming they adhered to guidelines even if they administered another drug in addition to the drugs specified by the guidelines, for instance. “One has to be very careful of the assumptions made when one asks ‘front-line’ physicians to submit data that are analyzable,” Dr. Bach said. He added that one should probably assume that the overarching purpose of data collection will not be easy to convey and will get “lost in translation” as specialty societies, office managers, et cetera, filter what CMS conveys and what physicians see.

Dr. Janet Woodcock of the FDA added that even if EHRs are implemented more widely, “the electronic database is only as good as the data put into it, which are only as good as the people’s understanding of what enterprise they are engaged in.” She suggested more training of community cancer physicians in data collecting and analysis techniques and clinical research. She suggested that the key to acquiring quality data from community practices is by buttressing them with a supportive infrastructure. “You need trained clinical personnel who go to the community and assist the investigators in getting this work done. If you want quality data you have got to help build quality in,” Dr. Woodcock said. She suggested developing structured, convenient, and brief training for community practitioners,

central administrative support to handle clinical trial paperwork, and computerized support of trial documentation. She called for systematized data collection by people who have enough support to do it properly. She suggested creating a broad network of well-supported community-based investigators with central administrative support, noting “you are going to have to support learning” in order to have a learning health system. She said this would require expansion and reconfiguring of the existing clinical research structures in the United States.

Detailing what information needs to be collected, as Kaiser Permanente does, is not sufficient if providers do not provide that information in a standardized way. Dr. Wallace pointed out that many oncologists, including those who have EHRs, do not extensively document the care they provide to their patients, nor do they standardize it, and without such standardization and documentation there is no learning from the care. For example, he noted that although it is standard to give CHOP (cyclophosphamide, hydroxydaunorubicin, vincristine, and prednisolone) chemotherapy to patients with non-Hodgkin’s lymphoma, there is tremendous variability in the way CHOP is administered (e.g., variability in dosages and interval, and whether cytokines are administered concurrently). “If you have 30 different oncologists, you probably have at least 30 different versions of CHOP,” Dr. Wallace said. “Such variability based on provider [as opposed to patient] nuance is unsafe and compromises our ability to learn,” he added. This variability may be alleviated to some degree by ASCO’s QOPI Program, which recently developed standard chemotherapy treatment plans and summary forms for physicians to document patients’ chemotherapy regimens and responses to treatment, Dr. Jacobsen reported.

Dr. Sox suggested that to counter the problem of missing data, outcomes, and unmeasured confounders in the datasets taken from the records of actual patient care, data-gathering protocols should be established that detail what data physicians need to enter into the record and when, as well as systematic follow-up to ensure there are no missing data. To avoid the problem of confounding by indication, he suggested documenting why one treatment was chosen over another and having more patient-reported outcomes.

Once quality data are collected, they have to be properly integrated, analyzed, and applied. Several speakers pointed out that the observational data collected from clinical practice have numerous potential analytical flaws that must be addressed. For example, Dr. Potosky described a study that assessed the effectiveness of adjuvant chemotherapy for elderly colon

cancer patients by comparing those that received it to age-, stage-, and comorbidity-matched controls using SEER-Medicare data. In this study, the treatment appeared to be more effective than no adjuvant therapy, but as Dr. Potosky pointed out, probably healthier patients were given the treatment, and thus they were not comparable to the control group used in the study. When randomized controlled clinical trial data have the same findings as those generated in observational studies, Dr. Potosky said, it may validate those findings from observational studies, but sometimes there are no controlled clinical trials that are comparable. In addition, observational studies using cancer registry data may not consider certain variables that foster a selection bias. One such study that assessed the death rates of prostate cancer patients who were treated versus the mortality of those who underwent watchful waiting found those who were treated fared better, Dr. Potosky reported. However this study neglected to assess prostate-cancer-specific deaths, and when those were determined, there were no statistically significant differences between those treated and the control group. There can also be bias due to differential access to care when using claims data.

Some of the statistical shortcomings of observational claims data can be overcome using certain analytical techniques, such as instrumental variable analysis (IVA), Dr. Potosky pointed out. This technique is used in social science and economics studies when randomization is not a feasible practice and can overcome some unknown biases. IVA requires finding a variable that is correlated with the treatment of interest while being (or assumed to be) not causally related to the treatment. The instrumental variable can be used to balance treatment groups. For example, whether the patient resides in an area with high or low use of the tested treatment is a dichotomous instrumental variable posited to be highly correlated with whether or not the patient receives the treatment but not correlated with the outcome of the treatment. Dr. Potosky concluded by noting that “using SEER-Medicare data to assess the effectiveness of cancer treatment is perilous and potentially misleading. We have to be careful.” He recommended confirming findings of studies using claims data with prospective trials when possible and, if not, then via targeted studies that collect detailed data to assess or account for biases.

Mindful of the dangers of acting on conclusions based on invalid data, Dr. Sox suggested that “we build on analytic guidance systems, so that if I were to sign into a national dataset, I would be at least somewhat informed about good analytic practice. We really need to require basic statistical skills

before people get access to the data, as well as independent clinical epidemiology and statistical review before people act on findings—in other words, do not follow your nose until you know the shortcomings of the data, their implications for statistical validity of the analysis, and the potential for error in applying the conclusions to the patients.” Dr. Sox also suggested that there be some sort of transparent, unbiased peer review prior to researchers’ communicating their results to colleagues. Discussant Amy Guo of Novartis Oncology Health Economics noted that the International Society of Pharmacoeconomics and Outcomes Research currently has a task force to develop a guidance on observational studies and how to interpret them. Dr. McGinnis suggested that the National Cancer Policy Forum engage more explicitly on what represent reliable data. However, Dr. Bach cautioned that if too much time is spent planning for observational research, not enough progress will be made. “Some of the activity needs to be pushed forward while the quality of that activity is backed up,” he said.

HARMONIZATION AND STANDARDIZATION

Many speakers talked of the need for harmonization and standardization of both what data are reported and how they are integrated into computer systems. Dr. Neti stressed the need to have appropriate reporting standards so that the data collected can be used not only for evidence-based decision support and health care tailored to individual patients, but also to generate data that can be used for CER. The right type of data needs to be reported to categorize patients and their outcomes and to enable comparisons. “I don’t think we have thought this through completely and we need to put a lot of time and effort into thinking about this,” he said. He added that standard nomenclature that accurately represents the context of data is also critical for the computer analyses needed for CER. Dr. Buetow added that “in biomedicine, context is critical. The same observation of the same word used in a different place means very different things in different biomedical contexts.”

Some data collection standards have been established, but inconsistencies in these standards hamper connectivity and the completeness and usefulness of the data. Ms. Thames called for harmonizing existing cancer registry standards with those generated by the Integrating the Healthcare Enterprise (IHE) and Healthcare Information Technology Standards Panel (HITSP) so that cancer surveillance data can be connected to national health IT efforts. Ms. Thames pointed out that there are no standards for

data collection, transmission, and reporting of cancer patients that have been implemented for non-hospital sources. This is problematic given that patients are increasingly acquiring more of their cancer care outside of hospitals at free-standing radiotherapy treatment centers, physician practices, or other settings. A CDC-led working group will test implementation of electronic reporting from provider offices to registries and will try to “move the cancer registry community forward in using consistent standards for electronic provider reporting to improve completeness, timeliness, and quality of cancer registry data,” Ms. Thames said. Efforts are also under way to link cancer registry data to insurance claims data, state all-payers claims data, hospital discharge data, and provider office billing data. Other CDC initiatives have focused on standardization and harmonization of public health records. For example, CDC’s collaboration with IHE has led to international standards for reporting anatomical pathology for public health records.

In discussion, Dr. Abernethy raised the issue of whether there should be data governance at the local, national, and/or global level. Data governance encompasses a convergence of a set of processes relating to data quality, data management, business process management, and risk management. Data governance is necessary to ensure that data connected in networks can be trusted and that there is accountability for poor low data quality. With data governance, there can be positive controls over the processes and methods used by participating data stewards in computerized networks. “The more we think about developing datasets that are highly interoperable, we also have to think about the data governance that goes along with that,” Dr. Abernethy said. Drs. Stead and Neti agreed that data governance is a major issue that must be tackled in computer networks.

Dr. Stead noted that the life span of useful data may be shortened due to changing medical paradigms that may change the current interpretation of data, as well as advances in computer science that may provide new ways of extracting meaningful and useful knowledge from existing data stores. To avoid that problem, he suggested designing information and workflow systems to accommodate disruptive change and archiving data for subsequent reinterpretation in anticipation of future advances in biomedical knowledge or computer applications. “In 1970 there were two types of diabetes. By the mid-90s there were four, and now it is well over twenty depending on what you elect to count. To have actually recorded the raw observation in one of those diabetes terms would have been very lousy compression. It would have been like taking a picture with a one-megapixel camera instead of a sixteen-

megapixel camera,” he said. Consequently, Dr. Stead suggested recording raw data, as well as having IT vendors supply IT systems that permit the separation of data from applications and facilitate data transfers to and from other non-vendor applications in shareable and generally useful formats. “We need to redefine interoperable data as data that can be assembled and interpreted in light of current knowledge and reinterpreted as knowledge advances,” he said.

ENSURING PATIENT PRIVACY AND PORTABILITY OF MEDICAL RECORDS

A major challenge in developing and implementing EHRs, computer grids, and other components of a RLHS is ensuring patient privacy and conformity to HIPAA rules, yet enabling portability of patient records, given that patients are increasingly being cared for at multiple institutions and access to patient data is needed for statistical analyses. With the proper computer hardware and software it is possible to de-identify patients or hide certain data items when patient data are used in the statistical analyses done by researchers. Computer platforms such as caBIG and cancer registries such as SEER have that capability to protect patient privacy, as do the EHR systems used by many institutions. However these automatic controls that shield patient identity or prevent the sharing of patient information can hamper the connectivity of a RLHS, as well as make it difficult for patients to share their medical information with multiple institutions.

Dr. Buetow stressed that “if we really want to share data in HIPAA-compliant forms, we actually have to know what the data are. The bottom line is that there is all this discussion and excitement that we will just segment data and decide what pieces can be shared and what pieces have to be consented or de-identified.” Yet as he pointed out, if it is not precisely known what is contained in each data field, it is not possible to appropriately consent a patient to have the data be shared or de-identified. “We need to define how we can ultimately combine and share the data, because we can then be quite explicit with the people providing us with the data, who will use it and under what circumstances. In the absence of definition, you just cannot do that,” Dr. Buetow said. He suggested that access controls for computer grids require definition of data.

Frydman pointed out that protecting patient privacy was a major concern of ACOR. All of its online communities have closed archives to avoid potential employers’ searching their site for medical information about

job applicants and other such invasions of patient privacy that concern its members. “All of our content has been hidden in a quiet spot of the deep Web never to be found until we find some solution [to these privacy issues],” said Frydman.

Heywood pointed out that privacy limits the amount of meaningful individual data that can be used in statistical analyses. “There will be a contest between what these closed networks can do versus what a fully open network can do, and if we can capture 20 percent of the patients with a disease in a fully open network, the power of the value of that openness will destroy all the other datasets, just in terms of being usable,” Heywood said.

However, Dr. Sommer countered, “I do not think it is realistic to actually think that we are going to get the entire population receptive to sharing their data with everybody openly. We really need to have a dialogue of how do you create that safe, honest broker—that place where genomic and other data can be housed in a safe manner, and you can get the value of what you are doing without it having to be open.”

Dr. Mendelsohn pointed out that transparent data will drive the cost of care down, while driving the quality of care up. “We need to convince Congress of this because HIPAA is inhibiting research. We are not going to get transparent data until we begin to define vocabularies and agree to share data,” he said.

Dr. Sommer underscored the need for portable patient data, pointing out that chordoma patients often have multiple surgeries at multiple institutions and surgeons often cannot acquire the records of prior surgeries. Similarly, oncologists cannot access the prior chemotherapy records of their patients. She called such lack of record sharing a tragedy that impedes quality care. Specifically, she noted the frequent difficulties she had in bringing her son’s imaging files to other institutions that were unable to read them because they used different data formats. She stated that in her experience, up to 30 percent of images from one institution cannot be read by another unless provided in standard DICOM (Digital Imaging and Communications in Medicine) format. Consequently, imaging done at one institution had to be duplicated at another. “There must be portability of patient records,” Dr. Woodcock responded, “because there is an issue of radiation exposure when all these films have to be repeated. There should be a convergence on national standards on how it is done.” Dr. Bach agreed that portability of patient records is critical. Heywood added that some patients are even denied their medical records when they request them, and this should not be allowed.

Commenting on lost learning opportunities due to a lack of access to patient data, Dr. Victor Vikram of NCI added that there be consideration of how to use the electronic oncology records of the 500,000 to 600,000 radiation oncology patients each year, who receive some of the most expensive interventions undertaken in cancer patients, that are just sitting in radiation facility files. He suggested this information might be useful.

RAPID REPORTING AND TRANSLATION

Ideally, a RLHS would have rapid reporting of the clinical information it gathers, which will be an advantage for patients, clinicians, and researchers trying to quicken efforts to improve care, but some questioned the value of such rapid reporting unless it is accompanied by efforts to ensure the reliability of the information reported.

There are significant delays in the availability of cancer registry data, pointed out Ms. Thames. “The time gap between the diagnosis of cancer and when the data are made available for analysis can be more than two years,” she said. Dr. Potosky added that the time lag between acquiring the data and being able to analyze them for the linked Medicare-SEER database is about four years. Dr. Edge called for modernizing cancer registries by having more rapid case ascertainment so the data can be used for rapid quality management. Many of the CDC endeavors that Ms. Thames discussed aim to promote more rapid reporting of data by encouraging more standardized, machine-readable electronic health records.

To promote rapid reporting and awareness of research findings, Dr. Sommer suggested that there be open access to medical literature based on studies that are federally funded. This literature should be available to the public because the taxpayers have paid for the studies, she said. She also called for time limits for the review of journal articles that ensure more timely publication so that patients do not have to wait for results.

Discussant Dr. Mia Levy questioned how fast dissemination should be of information that may be of questionable quality. Dr. Sox pointed to the rigorous process that some journals use to review their articles prior to publication. This process includes authors interacting with statisticians and editors. This is an intense, expensive, and sometimes protracted effort that few journals can afford to do right, he said. “The public really looks to journals to evaluate research for them, and that is a public good that journals do,” Dr. Sox said. He then went on to question whether such rigorous review will be carried out in a RLHS where “individuals are working on their comput-

ers at home and then translating [findings] into practice,” without a rigorous statistical review. “I am trying to make you worried about the quality of the evidence that you are getting through that process,” Dr. Sox said.

Dr. Wallace responded that “historical principles are still the right ones about peer review, patient protection, and generalizability. The challenge is that the context could change pretty dramatically. Our orthopedists would argue that the 300 of them meeting monthly is peer review, whether it has been actually published externally or not. Generalizability is redefined when you have access to clinicians and to tools that allow you to dive into a population database and learn. There are a lot of options for how things can be brought forward and a lot of different ways to learn.”

STAKEHOLDER COOPERATION AND PARTICIPATION

Although a RLHS in theory may provide numerous benefits, putting it into practice can be fraught with difficulties, particularly when it comes to the system’s human components. “Whenever you go to buy some technology, you ought to go out to lunch with an anthropologist because the major failures and our major write-offs are when we get enthralled by the electrons and lose track of how people do their work,” said Dr. Wallace. Dr. Buetow concurred, noting that “culture eats strategy for lunch.” Changing culture so that it will be more adapted to a computerized RLHS is a major challenge that cannot be ignored. Buetow pointed out that the culture of academic biomedical research has traditionally been focused on a competitive system of individual investigators and institutions. There can also be competition and a lack of collaboration between stakeholder groups such as patients, physicians, academic researchers, government agencies, payers, and industry. “You are going to have to encourage people to pound their swords into plowshares a lot of the time, and that is not necessarily a trivial undertaking,” he said. “It can be facilitated with technology, but let’s not assume that it just evaporates in the presence of good will.”

Based on what he learned creating caBIG, Dr. Buetow warned that ignoring cultural barriers can cripple such large-scale efforts and that there must be commitment from all levels of participating organizations. “You need engagement all the way from those guys that install printers up to the boardroom if you actually want to be able to do this kind of work,” Dr. Buetow said. Also needed is a willingness of stakeholders to collaborate and join together as a motivated community that drives and directs the

changes needed to make large-scale improvements in the healthcare system, he added.

Dr. Buetow pointed out that much of what prevents data sharing is not technical, but reflects the segmentation of stakeholders into silos by discipline, geography, and sector or reflects concerns about being recognized and/or rewarded for intellectual capital. Establishing new kinds of collaborative activity between and among those silos is critical, using IT as the electronic “glue” to enable each constituency to achieve its organizational goals. He noted later during discussion that cultural factors, including data access issues, have been the main impediments to making computerized healthcare databases compatible across government agencies, such as the Department of Veterans Affairs, the Department of Defense, the CDC, and the NIH. “There aren’t natural tendencies for these groups to play together—you do not get funding for using somebody else’s system,” he said. However, Dr. Buetow struck a note of optimism by pointing out that as various government organizations and other healthcare stakeholders increasingly recognize the benefits of cooperating to achieve the common goal of a RLHS or its subcomponents, they are working more effectively together. The CDC and NCI, in specific, are starting to leverage common architectural frameworks to facilitate interconnectivity, Dr. Buetow said.

The needs of point-of-care physicians also must be addressed for a RLHS to be effective. Dr. Clancy stressed that in order to implement a vision of a RLHS, we have to be able to answer the most pressing question of providers, which is, What’s in this for me? “This question has got to be paramount in our minds at all times. If people are not getting something back for it, if clinicians do not see that this is worth their while, we are going to fail,” she said and added, “Better to collect two data elements that people find incredibly valuable, than to lay out this amazingly complex vision for what could be but does not have anything to do with real life and the needs of patients and their providers.” Although health information technology is a big part of a RLHS, “the electrons are the easiest part of this,” Dr. Clancy said.

Dr. Ganz suggested one incentive for providers participating in a RLHS is the ability to streamline and standardize. The capacity to provide high-quality information for clinicians will ultimately make physician practices more efficient, and the use of decision support tools and their ilk can simplify the discussions doctors have with their patients. Dr. Abernethy added that “there is great hunger in the community oncology sector about how to make this work. They see it as improving practice efficiency and patient

satisfaction—as really helping them figure out how to do the best thing,” Dr. Clancy agreed that “what motivates most people who are providing care is actually making it better. The only reason physicians, for the most part, will participate with energy and enthusiasm is if it actually makes their jobs easier by making the right thing to do the easy thing to do. That is something people get real excited about.”

Dr. Bach noted a major barrier to instituting a RLHS is the fact that the focus of most practicing physicians is to treat their current patients adequately. There is little interest, let alone room in their busy schedules, to gather information that might be useful for future patients, he claimed. “It will be hard to get buy-in that downstream learning is valuable. Today’s care is about today’s patient and today’s bill,” Dr. Bach said, adding that physicians who do a lot of clinical trial work may be more amenable to gathering more patient data.

Heywood suggested making physician reimbursements dependent on keeping detailed records on the care provided to patients. He pointed out that shorthand notations of care, such as CHOP, can have variable interpretations and that variability impedes analyses in computerized databases of the outcomes of treatments and whether some treatments are more effective than others. “We should make a rule that says that if you cannot provide patients a computable accurate history of what was done to them, they then have the right to challenge payment for such services,” Heywood said.

Others at the conference pointed out that the inadequate training community physicians often have in regards to clinical research limits their adequate participation. “Physicians think about an ‘*n* of 1’ experience in terms of decision making, and they have been brainwashed a little bit to look at randomized clinical trials as the gold standard that leads to drug approvals. They have no conception of population-based findings and observational data and their limitations and opportunities,” said Dr. Ganz. She suggested more physician postgraduate learning in this regard, perhaps within the institutions in which they are training. “We have to school a generation of physicians, nurses, and other healthcare providers who are actively engaged in understanding how they can make use of all of this,” Dr. Ganz said.

Dr. Woodcock countered that it is difficult to get already overtaxed medical schools to fit anything more into their curriculums. Mr. Etheredge called for more physician training in the use of decision support tools and models and a better understanding of how they work. Dr. Woodcock disagreed. “I’m a real advocate of modeling, but the average physician tells us,

‘just give us the answer,’” she said. She noted that the FDA always tries to simplify what information it provides in drug or diagnostic labels, because “doctors’ lives are so busy.” Dr. McGinnis opined that the upcoming generation of physicians will be able to access algorithms online in the process of care, but probably will not be interested in understanding how models are built, so more effort should be put in vetting the models and getting universal acceptance of them rather than teaching conceptual understanding.

CHOOSING APPROPRIATE IT

Technology can both help and hinder clinical improvements, Dr. Stead noted in his presentation, and pointed out that IT isn’t used as effectively as it could be to aid clinicians. Dr. Stead chaired the National Research Council (NRC) report *Computational Technology for Effective Health Care*, which revealed significant shortcomings in how health IT was put into practice (NRC, 2009). For example, the committee noted that patients’ medical records, even when computerized, were so fragmented in some institutions that there often were five different members of a care team, each examining the same patient’s records on their individual computers, who were unable to integrate such information electronically.

In addition, Dr. Stead pointed out that although care providers spend a great deal of time electronically documenting what they did for patients, much of this documentation occurred after the fact for regulatory, legal, or billing and business purposes, often merely mimicking paper-based forms. In some cases, IT applications actually increased the time providers spent on administrative tasks as opposed to providing direct patient care. With few exceptions, because the data collected were not used to provide clinicians with evidence-based decision support and feedback, or to link clinical care and research, clinicians generally did not see these electronic data as being useful to improve their clinical care.

About 90 percent of how healthcare IT is used today focuses on applying techniques for automated repetitive actions, which are only applicable on small-scale systems, according to Dr. Stead. Little attention is given to the more important tasks of boosting connectivity of people and systems, data mining, and decision support, and “where we do these other things, we bolt them onto an automation core so our ability to do data processing automation kind of work becomes the rate-limiting step. It will not work and we have to rebalance our portfolio to use the other techniques,”

Dr. Stead said. A possible framework for future healthcare IT is depicted in Figure 6-2.

Dr. Stead suggested that rather than having data entered by clinicians into computer systems, intelligent sensors could create an automatic self-documenting environment of the medically significant content of the interactions of providers with their patients. IT systems could then use this content, along with other relevant clinical information, to model a virtual patient and suggest and support holistic care plans used by multiple decision makers.

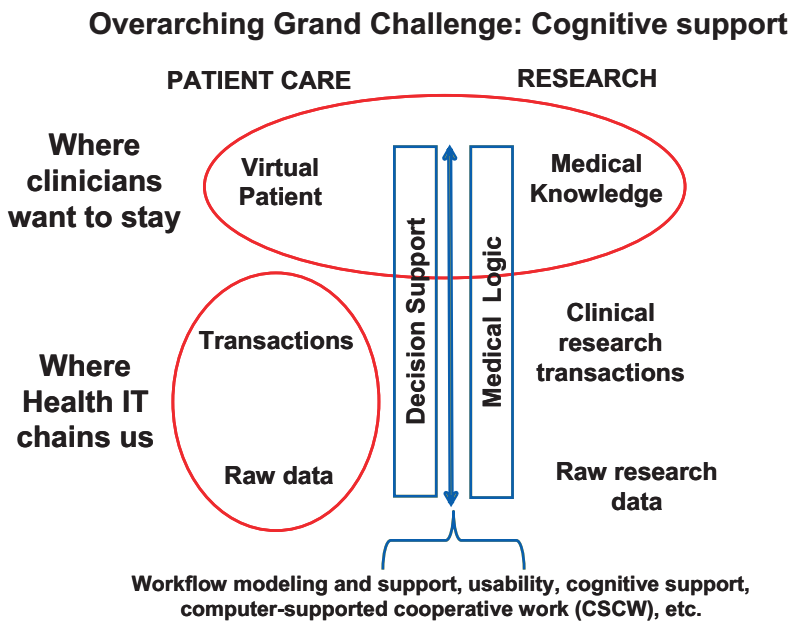


FIGURE 6-2 The virtual patient—component view of systems-supported, evidence-based practice.

NOTE: Mapping from medical logic to cognitive decision support is the process of applying general knowledge to a care process and then to a specific patient and his or her medical condition(s). This mapping involves workflow modeling and support, usability, cognitive support, and computer-supported cooperative work and is influenced by many nonmedical factors, such as resource constraints (cost-effectiveness analysis, value of information), patient values and preferences, cost, time, and so on.

SOURCE: NRC, 2009.

TABLE 6-1 Paradigm Shift Necessary for More Successful Computational Technology for Effective Health Care

Old	New
One integrated set of data	Sets of data from multiple sources
Capture data in standardized terminology	Capture raw signal and annotate with standard terminology
Single source of truth	Current interpretation of multiple, related signals
Seamless transfer among systems	Visualization of the collective output of relevant systems
Clinician uses the computer to update the record during the patient visit	Clinician and patient work together with shared records and information
System provides transaction-level data	System provides cognitive support
Work processes are programmed and adapted through nonsystematic work-around	People, process, and technology work together as a system

SOURCE: Stead, 2009.

Summarizing his approach to helping people think about electronic health records based on his experience, Dr. Stead contrasted old and new ways of thinking, highlighting the paradigm shift needed (see Table 6-1).

7

The Federal Challenge of Responding to the Need for a RLHS

Healthcare advances are often fostered by federal policy and led by federal agencies. As Dr. Wallace noted, policies that limit smoking in public places have substantially impacted tobacco use rates, and “if you want to make major changes in population health, it is not just the healthcare system [you need to focus on], but public policy.” Etheredge called on the HHS to lead the effort to create a RLHS for cancer. HHS is the umbrella organization for a number of federal agencies that determine healthcare policy for cancer, including FDA, NIH, NCI, the Cancer Clinical Trials Cooperative Groups, NCI-designated National Cancer Centers, AHRQ, CDC, CMS, and ONC. “If HHS does not lead, the chaotic state of adult cancer care will likely continue, or get worse,” said Etheredge.

He expanded that statement by noting that one HHS agency in specific, CMS, which runs both Medicare and Medicaid, is the largest payer for cancer care in the country. Between 5 and 10 percent of Medicare’s budget is spent on cancer care, “so it will be good to get those incentives aligned with the kind of quality we want and the kind of learning system we want,” Etheredge said. “In a sense we are running a large national experiment through Medicare by paying for tens of billions of dollars of cancer care, but we never collect any data, and we know it is of very uncertain quality,” he added. He called for using the purchasing power of Medicare to support the healthcare learning agenda and better-quality cancer care.

In his discussion of how Medicare could further the development of

a cancer RLHS, Etheredge outlined a series of steps CMS could take to influence and support a learning agenda for cancer care, including the following:

- Cover new cancer therapies subject to evidence development reporting requirements to learn as rapidly as possible about their best use for personalized care.
- Require expanded reporting of cancer clinical data and quality measures to national cancer registries, and withhold payment to providers until after such information is submitted and passes review.
- Fund and set standards for EHRs, with Medicare cancer care modules for Medicare patients.
- Shift Medicare cancer payments from paying for anything and everything that is done to “pay for performance” in “preferred provider” contracts, thereby paying more for effective, high-quality care, as measured by guidelines. This would incentivize participation in learning healthcare networks.
- Inform Medicare patients and physicians about cancer CER, best practices, and quality performance. By posting information on the Web, patients can choose the best cancer providers and treatments.
- Use innovation funds to support new models and incentives for patient-centered, high-quality care.

As Etheredge noted, much of the national funding for EHR subsidies will be from Medicare so it makes sense that this agency should set the standards for those systems. “It would be a huge travesty to have Medicare paying for EHRs and not be able to have the meaningful use requirements include reporting the data that we need to advance the quality and the information base of Medicare cancer care,” Etheredge said. He emphasized the need for an organized, coherent national cancer strategy in which “HHS is going to put all of the pieces together rapidly” to advance to a new era of evidence-based health care. Yet it can be challenging to carry out some of these Medicare objectives, noted Dr. Bach, who detailed the difficulties Medicare had with its coverage with evidence development (CED) program in which additional data are gathered in the course of care. This program may withhold payment for a specific treatment or diagnostic unless the intervention is accompanied with data physicians submit for their patients that receive the intervention. Within this program, Medicare may also agree to pay for an intervention, but it will pay providers more if

they submit more patient data. There are two types of CED that have been implemented. One type is dependent on treated patients being enrolled in clinical trials of the intervention being given. Another type of CED is registry based, in which coverage is given only if physicians provide additional information about the patients given the diagnostic or treatment. For example, Medicare's coverage of PET scans for many oncology indications initially was not guaranteed unless ordering physicians provided information to the National Oncologic PET Registry on patients' clinical status and expectations and potential responses in light of PET scan results. The analysis of registry data on 23,000 scans revealed that about one-third of clinical decisions are altered by PET results, and nearly three-quarters of biopsies are avoided by using PET (Hillner et al., 2009). The findings led Medicare to lift the CED requirement and cover PET scanning for all of the indications that were examined.

Dr. Bach noted a number of lessons that were learned and challenges that were insufficiently met with Medicare's first CED experiences. The registries used for CED are not housed at Medicare, but rather with a third party, for a number of reasons, and this has been a major impediment. "There is no such thing as a disinterested third party," Dr. Bach said, and it was also challenging to update funding for such registries. The ethics of the human testing that occurs in registry-based CED also is not straightforward, he added. Another limitation of this approach to foster learning is that there is no ability for Medicare to fund analyses or efforts to acquire follow-up data, Dr. Bach noted. He also pointed out that CMS was rightfully criticized for oversampling in its observational clinical studies, noting that the large sample sizes available in certain registries and other databases strictly speaking are not needed to study certain simple issues, especially if there is high prevalence of an event being assessed. "Why do you need 23,000 patients to figure out if a PET scan changed therapy?" he asked, pointing out that inefficiencies and excessive costs occur when overly large sample sizes are used in clinical research. The agency was also accused of not asking the right questions (e.g., it should have asked whether outcomes rather than clinical decisions were affected by PET scans).

Medicare's CED that uses clinical trials also has had some challenges. "We got tremendous pushback from manufacturers because, in many cases, the sponsors were about to launch the trials anyway and they did not like the inefficiencies," Dr. Bach said. In addition, there were problems with adequately blinding participating patients because the copayments were so

much higher for the tested treatment so patients were aware of which treatment they were receiving.

Medicare also has had problems with its 2006 Oncology Demonstration Project, in which physicians were paid \$23 to submit additional information, such as cancer stage, treatment adherence to guidelines, and the focus of the visit. As described previously, because of basic misunderstandings or lack of awareness of what was being asked of them, physicians often did not enter the required information properly, which limited the usefulness of the data, Dr. Bach noted.

The FDA is another key federal agency with a major role to play in fostering a nationwide RLHS because its approval of drugs and devices is needed for these products to enter the market. “We set the standards required for medical products to get on the market. This is a real hard incentive,” said Dr. Woodcock, who is the director of FDA’s Center for Drug Evaluation and Research. She added that the evidence of safety and effectiveness FDA requires for medical interventions is not the only evidence needed to show that these products are truly safe and effective in clinical real-world settings over the long term. Dr. Woodcock also pointed out medical products and uses for which there are no FDA-generated evidence requirements. These products and uses include procedures, certain laboratory-developed tests, and off-label uses of interventions, which are common in oncology and often lack a formal evidence base. In addition, because cancer is a life-threatening disease, the FDA has granted many “accelerated” approvals for cancer treatments that enable them to enter the market without meeting FDA’s more rigorous requirements for safety and effectiveness but require manufacturers to verify that these standards are met in the postmarket arena by conducting ongoing clinical trials. Until that verification is achieved, FDA can restrict the distribution of medical products. FDA also plays a role in evidence dissemination by regulating what sponsors can say about their product on the label.

The FDA Amendments Act, which was passed in 2007, enables the FDA to require postmarket studies and surveillance activities from sponsors. It may require all patients or only a subset of patients receiving a medical treatment to be enrolled in a registry to assess safety issues of the treatment. In addition, FDA conducts its own postmarket surveillance of product safety, an activity that has recently been enhanced with its newly launched Sentinel initiative. This initiative is intended to help FDA more rapidly learn about safety outcomes from distributed healthcare data of

up to 100 million patient records collected from a network of federal and private data sources.

Dr. Woodcock noted that these efforts to collect more postmarket safety and effectiveness data are not sufficient, and there needs to be more of a bridge between the development realm of clinical trials and the healthcare realm. As she pointed out, “One day drugs are unapproved and investigational, and CMS does not pay for them, and then the next day they are approved and you can use them for anything. If you designed a rational system that would not be it, because there is a continuum of learning and we really do not have the opportunity to match use according to knowledge—the level of evidence that there is about a drug.”

There also needs to be more effective translation of new science to the clinic, Dr. Woodcock stressed, and given the unacceptable time and effort to do clinical trials, she added, “The current paradigm of how we do trials and execute them and get results limits our capacity in this country.” She called for more widespread community participation, as discussed earlier, to narrow the gap between research and practice and to accelerate learning.

The FDA and Medicare wield tremendous regulatory power in health care, but they are just two of several federal agencies that can spur the development of a cancer RLHS. If federal agencies cooperated, even more could be accomplished, Etheredge noted. He envisions such cooperation, coupled with collaborations with the private sector, leading to the establishment of a three-year national research plan for “learning as much as possible as soon as possible” about the best use of new technologies for personalized cancer care. This could be achieved if such a program was hinged to FDA approvals or Medicare payments for new drugs or devices. In addition, Medicare’s coverage with evidence development, along with similar incentives from private payers, could generate the data for the much-needed CER studies. A national data registry system or clearinghouse for CER data is also needed, along with effective means to disseminate the CER results to patients and physicians, Etheredge said. With the collaboration of all HHS agencies, “we have the ability to move forward with a system that could capture a lot of learning very quickly, and help inform physicians and patients,” he added.

8

Summary

A summary of the workshop was provided by Dr. Michael McGinnis, who is a leader of IOM's initiative on evidence-based medicine. He began his summary by noting that traditional linear learning has to be replaced by the rapid network learning that typifies the current computer-driven world. "We live in a network world in which we can gain information in a much more rapid fashion, and we can vet that information in a much more rapid fashion too. So it is clearly fundamentally important we move our learning process in health care considerably into the twenty-first century with the development of a learning healthcare system," he said. This is a system in which learning is a natural by-product of the care process and is applied as a routine part of the care structure, Dr. McGinnis added. It's also a system where there is a global collection of data from multiple sources—the "notion of a global clinical data trust, the theoretical notion that eventually we would be able to capture data not just from one institution or another or from Kaiser or Mayo or Harvard or the VA, but from many institutions globally"—that will tremendously accelerate the learning process. Patients have the potential to be leaders in moving this learning process along, Dr. McGinnis said, and need to be vital partners in that respect because they are clearly motivated.

There are barriers and challenges in developing the appropriate level of confidence going forward, including justifiable concerns about how reliable observational data can be. Dr. McGinnis raised the question, How do we

understand exactly when we have arrived at a credible and an appropriate lesson in the learning process to apply it to patient care? It is also important to structure the data-gathering process to anticipate, plan for, and execute the collection of data in a systematic fashion to capture the lessons learned and feed those lessons back into the learning enterprise to improve the system's performance, he said.

However this endeavor has numerous challenges, Dr. McGinnis pointed out, including legal, regulatory, fiscal, and professional. He reiterated the potential of regulatory agencies, such as Medicare and the FDA, to spur the development of a cancer RLHS. Medicare has the ability to “transform our mind-set about the way in which every clinical encounter ought to add to the learning process,” he said, and added that it is encouraging that the FDA, which has traditionally limited itself to the premarket domain, “is now working hard to engage the postmarket domain. So we have the right perspectives, insights, and inclinations on the part of the leadership to act on some of the exciting activities that we heard about in the course of the meeting.”

He then described six basic elements of the continuous learning process:

1. Capturing the experiences of every clinical encounter
2. Developing consensus and guidelines based on the experiences that have been captured
3. Validating the various guidelines that have been developed
4. Delivering care based on those guidelines
5. Ensuring that care is standardized and harmonized, while controlling variation that allows for innovation and the generation of new information
6. Creating natural feedback loops so the results captured are evaluated and fed back into the system for learning and improvement purposes

Because the modern network approach to learning is nonlinear, as opposed to the more traditional linear approach, “one of our biggest challenges is to force ourselves to look specifically at those intersecting dynamics, at each of those points in the feedback process and ensure that the elements necessary for the success of the activities at each of those points are given consideration,” Dr. McGinnis said.

Dr. McGinnis provided some take-home messages, noting that we

have the capacity to gather large amounts of data and use the EHR in a fashion that is systematic, sensitive, and appropriate. “The three Rs of learning now are not reading, writing, and arithmetic, but research-ready records so that we are thinking ahead about the kinds of information that are needed to ensure the learning process.” He pointed to the need we have as a society to give much more energy and attention to the processes of care and the adaptive dynamics in those processes. “If we are going to develop the incentives that will change the state of play on the front line, we have to spend a lot more time understanding those [care delivery] dynamics,” Dr. McGinnis said. He also emphasized the importance of improving the value of health care, since we live in a world that is starkly constrained in terms of resources.

Dr. McGinnis agreed with the need for public policy changes and noted that nongovernmental groups could also “take ownership of the learning obligation.” “You have in the cancer community the patients, the providers, and the motivations to serve as the leading edge of progress and to engage decision makers in an explicit exploration of the issues, opportunities, and responsibilities when it comes to improving access to data, which is a fundamental issue for a learning healthcare system. With the passionate testimony that you have all witnessed firsthand of patients with whom you deal, you really have the opportunity to lay out in a much more compelling fashion than any other professional discipline, how shared decision making can make a difference in the learning process and turn the process of exploration [of a RLHS] into a process for action,” Dr. McGinnis said.

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Acronyms

ACOR	Association of Cancer Online Resources
AHRQ	Agency for Healthcare Research and Quality
ALS	amyotrophic lateral sclerosis
ARRA	American Recovery and Reinvestment Act
ASCO	American Society of Clinical Oncology
ASPH	Association of Schools of Public Health
caBIG™	Cancer Biomedical Informatics Grid
CCHIT	Certification Commission for Healthcare Information Technology
CDC	Centers for Disease Control and Prevention
CED	coverage with evidence development
CER	comparative effectiveness research
CHOP	cyclophosphamide, hydroxydaunorubicin, vincristine, and prednisolone
CME	continuing medical education
CMS	Centers for Medicare & Medicaid Services
CoC	Commission on Cancer
CSCW	computer-supported cooperative work
CT	computed tomography

DCIS	ductal carcinoma <i>in situ</i>
DICOM	Digital Imaging and Communications in Medicine
EHR	electronic health record
FDA	Food and Drug Administration
GCCR	Georgia Comprehensive Cancer Registry
GIST	gastrointestinal stromal tumor
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIT	health information technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HITSP	Healthcare Information Technology Standards Panel
IHE	Integrating the Healthcare Enterprise
IOM	Institute of Medicine
IT	information technology
IVA	instrumental variable analysis
KP	Kaiser Permanente
MRI	magnetic resonance imaging
NCCCP	NCI Community Cancer Centers Program
NCCN	National Comprehensive Cancer Network
NCDB	National Cancer Data Base
NCI	National Cancer Institute
NHIN	National Health Information Network
NIH	National Institutes of Health
NPCR	National Program of Cancer Registries
NQF	National Quality Forum
NRC	National Research Council
ONC	Office of the National Coordinator
PET	positron emission tomography

ACRONYMS

85

QOPI	Quality Oncology Practice Initiative
RCT	randomized clinical trial
RLHS	rapid learning healthcare system
RQRS	Rapid Quality Reporting System
SEER	Surveillance, Epidemiology and End Results

Appendix A

Workshop Agenda

A FOUNDATION FOR EVIDENCE-DRIVEN PRACTICE: A RAPID LEARNING SYSTEM FOR CANCER CARE

Monday and Tuesday, October 5 and 6, 2009
Keck Center of the National Academies
500 Fifth Street, N.W.—Room 100
Washington, DC 20001

AGENDA

Monday, October 5, 2009

7:30 a.m. **Registration and Hot American Breakfast**

8:00 a.m. **Welcome, Introductory Remarks: What Is a Learning
Health Care System?**

Sharon Murphy, *Scholar-in-Residence, Institute of
Medicine*

**Description of a Learning Health Care System from
Differing Perspectives: The Societal and the Patient
Level**

Lynn Etheredge, *Consultant, Rapid Learning Project,
George Washington University*

Amy Abernethy, *Associate Director for Population
Sciences, Information Technology (IT), and Informatics,
Duke Comprehensive Cancer Center*

8:30 a.m.

Keynote Address

Carolyn Clancy, *Director, Agency for Healthcare Research and Quality*

A learning health care system: a framework for knowing what works and developing the infrastructure needed for developing evidence from medical practice to better inform decisions regarding delivery of effective high-quality care for the patient.

9:20 a.m.

New Approaches to Organization and Uses of Cancer Registries: Local, State, and National Experience

Moderator: Robert German, *Associate Director for Science, Division of Cancer Prevention & Control, Centers for Disease Control and Prevention*

Georgia Cancer Quality Information Exchange

William Todd, *President & CEO, Georgia Cancer Coalition*

Strengthening State Cancer Registry Data by Linking to Public and Private Data Sources

Joseph Lipscomb, *Professor of Public Health, Emory University*

Reengineering the Cancer Data Infrastructure for Quality Evaluation and Care Management: The National Cancer Database Model

Stephen Edge, *Chair, Department of Breast Surgery, Roswell Park Cancer Institute*

SEER Medicare Data Linkage

Arnold Potosky, *Director of Health Services Research, Lombardi Comprehensive Cancer Center*

10:30 a.m.

Ten-Minute Coffee Break

- 10:40 a.m. **Panel Discussion, Questions**
 German, Todd, Lipscomb, Edge, Potosky
- How close are we to aggregating and integrating state and national cancer datasets?
 - How can we systematically improve cancer care by supporting rapid cancer data exchange and quality monitoring?
 - What are the opportunities and obstacles to development of a common cancer dataset?
 - How can information be linked from provider organizations to large private and public payers?
 - Can we identify best practices to guide the development of consistent high-quality cancer reporting?
- 11:00 a.m. **Open Source, Open Access Platforms: Cloud Computing for Cancer Data Sharing and Evidence Generation**
Moderator: Chalapathy Neti, *Executive Architect Information Agenda for Healthcare, IBM*
- Major Issues Impacting the Likelihood of Success of Large-Scale Efforts at Data Sharing and Data Integration for Fast-Track Evidence-Based Medicine**
 Chalapathy Neti, *IBM*
- 11:15 a.m. **The Cancer Biomedical Informatics Grid**
 Kenneth Buetow, *Director, Center for Biomedical Informatics and Information Technology, National Cancer Institute*
- 11:45 a.m. **National Program of Cancer Registries: Advancing E-Cancer Reporting and Registry Operations (NPCR-AERRO)**
 Sandy Thames, *Public Health Advisor, Division of Cancer Prevention & Control, Centers for Disease Control and Prevention*

12:00-1:00 p.m. *Lunch Break*

1:00 p.m. **Implications of the NRC Report on Computational Technology for Health Care**

William Stead, *Associate Vice Chancellor for Strategy/Transformation, CIO, Vanderbilt University Medical Center*

1:30 p.m. **Panel Discussion/Questions**

Buetow, Neti, Stead, Thames

Issues of Interoperability and Platform Integration

- What are some of the biggest impediments for IT adoption and large-scale data sharing in cancer care? Lack of perceived value? Lack of appropriate standards? Privacy concerns?
- What are the key change drivers to catalyze the transformation toward a learning cancer care system?
- What is the role of payment structures and incentives?
- Do we need new entities in the ecosystem to enable the transformation? If so, what is their nature?

1:45 p.m. **Information Infrastructure for Rapid Learning and Comparative Effectiveness Research (CER)—The Federal Role in Promotion of Information Tools for Transformational Change**

Moderator: Sharon Murphy, *Scholar-in-Residence, Institute of Medicine*

Health Information Standards for Meaningful Use of EHRs and Oncology Learning: What's Needed?

Charles Friedman, *Deputy National Coordinator for Health Information Technology, Department of Health and Human Services*

CER: Opportunities to Improve Decision Making About Cancer Care and Prevention

Harold Sox, *Editor Emeritus, Annals of Internal Medicine, American College of Physicians of Internal Medicine*

2:25 p.m. **Panel Discussion/Questions**

Friedman, Murphy, Sox

2:45 p.m. *Fifteen-Minute Break*

3:00 p.m. **Patient-Centered Rapid Learning for Cancer Patients: The Health 2.0 Movement**

Moderator: Paul Wallace, *Medical Director for Health & Productivity Management Programs, The Permanente Federation, Kaiser Permanente*

Research on e-Patients and the Use of Social Media for Health

Susannah Fox, *Associate Director, Digital Strategy Pew Internet Project*

Pioneering Online Communities for Cancer Patients: 13 Years of Shared Learning

Gilles Frydman, *President & Founder, Association of Cancer Online Resources*

Patient Driven Research for a Rare Cancer: Lessons Learned from Chordoma

Simone Sommer and Josh Sommer, *Co-founders of the Chordoma Foundation*

Learning Directly with the Patient to Inform Care and Build Knowledge

Jamie Heywood, *Co-founder and Chairman, patientslikeme.com*

4:00 p.m.

Panel Discussion/Questions

Fox, Frydman, Heywood, Sommer, Sommer, Wallace

- What are the key knowledge gaps for cancer patients today?
- How has this changed from five years ago?
- How should this change in the next five years?
- How do you see that change occurring?

4:30 p.m.

Adjourn for the Day

Tuesday, October 6, 2009

8:00 a.m.

Breakfast

8:30 a.m.

A View of the Future/Transforming Rapid Learning for Cancer from Concept to Reality

The Experience of Two Oncologists with Two Different Patients: Clinical Vignettes Revealing the Realities and the Possibilities

Amy Abernethy, Associate Director for Population Sciences, Information Technology, and Informatics, Duke Comprehensive Cancer Center

Patricia Ganz, Director, Division of Cancer Prevention & Control Research, Jonsson Comprehensive Cancer Center

9:00 a.m.

Impact of a Rapid Learning System for Cancer on Oncology Providers and their Practices—How to Close the Gap in Translation and Dissemination
Moderators: Patricia Ganz and Amy Abernethy

National Comprehensive Cancer Network (NCCN) Guidelines and Outcomes Databases

Bill McGivney, CEO, National Comprehensive Cancer Network

**American Society of Clinical Oncology-Quality
Oncology Practice Initiative (QOPI)**

Joseph Jacobsen, *Department of Medicine, North Shore
Medical Center*

**Kaiser-Permanente Oncology-Specific Care
Management Systems**

Paul Wallace, *Medical Director for Health & Productivity
Management Programs, The Permanente Federation,
Kaiser Permanente*

10:00 a.m.

Panel Discussion/Questions

Abernethy, Ganz, Jacobsen, McGivney, Wallace

10:30 a.m.

Fifteen-Minute Break

10:45 a.m.

**The HHS-wide Policy Challenges of Responding to
the Needs for Rapid Cancer Learning**

Moderator: Lynn Etheredge, *Rapid Learning Project,
George Washington University*

**HHS Leadership in Stimulating Rapid Learning:
Medicare and Cancer Care**

Lynn Etheredge, *George Washington University*

**Lessons from the CMS: Coverage with Evidence
Development and the Oncology Demonstration
Project**

Peter Bach, *Associate Attending Physician, Memorial
Sloan-Kettering Cancer Center*

**The FDA's Role in Facilitating Rapid Learning for
Cancer**

Janet Woodcock, *Food and Drug Administration*

**A Rapid Learning Health Care System for Cancer:
Overview and Workshop Summary of Opportunities
and Practical Needs**

Michael McGinnis, *Institute of Medicine*

12:00 p.m.

Panel Discussion/Questions

Bach, Etheredge, German, McGinnis, Woodcock

- What new HHS initiatives are needed for a rapid learning health system for cancer care?
- What are the future challenges for each of the HHS health agencies and for HHS leadership?
- What has been learned from previous experience and from this workshop that can inform and shape new national cancer policies?

12:30 p.m.

Adjourn for the day

Appendix B

Speaker and Moderator Biographies

Amy P. Abernethy, M.D., is associate director, Population Sciences, Information Technology (IT), and Informatics, Duke Comprehensive Cancer Center; associate professor of medicine, Duke University School of Medicine; and an active clinician in both outpatient and inpatient oncology. As senior fellow with the Duke Center for Clinical Health Policy Research, home of the Duke Evidence-based Practice Center, she conducts technology assessments, evidence reviews, and studies of elements of the evidence system including compendia quality and methods, conflict of interest, payment policy, and clinical trial enrollment. She participates in national initiatives, such as caBIG[®] (Cancer Biomedical Informatics Grid) and BIG Health, aimed at improving current biomedical research methods and infrastructure. Dr. Abernethy founded and directs the Duke Cancer Care Research Program (DCCRP), which is developing a new model of combined clinical-research inquiry in oncology and IT-based methods to support it.

Peter B. Bach, M.D., MAPP, was formerly senior adviser to the administrator on healthcare quality and cancer policy with the Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services. Currently, he is an associate attending physician with Memorial Sloan-Kettering Cancer Center. Dr. Bach received his bachelor's degree in English and American literature from Harvard College, his medical degree from

the University of Minnesota, and his master of arts degree in public policy from the University of Chicago, where he was also a Robert Wood Johnson clinical scholar. He completed his clinical training in internal medicine, pulmonary, and critical care at the Johns Hopkins Hospital. Dr. Bach's main research interests are assessment and improvement of the quality of cancer care. He has focused particularly on improving the quality of care for early-stage lung cancer and has a broader research interest in racial disparities in cancer care and outcomes.

Kenneth H. Buetow, Ph.D., has focused for more than 20 years on understanding the role of genetics in complex human diseases such as cancer and on applying sophisticated informatics technologies to solve major biomedical challenges. In his current role of National Cancer Institute associate director responsible for bioinformatics and information technology, he initiated and oversees the caBIG program, a groundbreaking initiative built to connect the entire cancer community in a "World Wide Web" of biomedical research. Dr. Buetow also serves as the director of the NCI Center for Bioinformatics and Information Technology (NCI CBIIT), which is responsible for maximizing the interoperability and integration of NCI research. He is also chief of the Laboratory of Population Genetics (LPG), where his group applies genomics to increase our understanding of the genetics of complex phenotypes. In addition to serving on the governing and advisory boards for numerous government organizations, academic institutions, and scientific and medical societies, Dr. Buetow has published more than 160 scientific papers. His recent honors and awards include the Editor's Choice Award from Bio-IT World (2008), the Federal 100 Award (2005), the NIH Award of Merit (2004), and the NCI Director's Gold Star Award (2004). Dr. Buetow received a B.A. in biology from Indiana University in 1980 and a Ph.D. in human genetics from the University of Pittsburgh in 1985.

Carolyn M. Clancy, M.D., a clinical researcher and a practicing internist, was named director of the Agency for Healthcare Research and Quality (AHRQ) on February 5, 2003. Previously, she directed AHRQ's Center for Outcomes and Effectiveness Research. From 1984 to 1990, Dr. Clancy was an assistant professor of medicine and director of the Medical Clinic at the Medical College of Virginia, and currently she is associate clinical professor at George Washington University's Department of Medicine. Her health services research priorities include issues such as quality, access, and the

impact of delivery system changes. Her medical specialties include primary care medicine and women's health. Dr. Clancy has authored and coauthored six medical books, published widely in peer-reviewed medical journals, presented multiple research papers at academic conferences, and spoken to diverse audiences and the media on healthcare issues. She serves on the editorial boards of the *Journal of General Internal Medicine*, the *American Journal of Public Health*, and the *Journal of Evaluation in Clinical Practice*, and she is a senior associate editor for *Health Services Research*. Dr. Clancy holds a B.S. degree, magna cum laude, in math and chemistry from Boston College (1975) and an M.D. from the University of Massachusetts School of Medicine (1979). Her postdoctoral training includes the Kennedy Institute of Bioethics Intensive Course at Georgetown University in 1989; the Stanford Faculty Development Program in Clinical Teaching in 1988; and the Henry Kaiser Family Foundation Fellow in General Internal Medicine from 1982 to 1984 at the Hospital of the University of Pennsylvania.

Stephen B. Edge, M.D., FACS, is professor of surgery and oncology at the Roswell Park Cancer Institute and the State University of New York at Buffalo. Dr. Edge attended medical school and trained in surgery at Case Western Reserve University School of Medicine. After a fellowship in surgical oncology at the National Cancer Institute, he served as assistant professor of surgery and surgical oncology at the University of Virginia. In 1992, he moved to Roswell Park Cancer Institute, where he continues to serve as chief of the Breast Service and professor of surgery and oncology. Dr. Edge is active in breast cancer research, in techniques of surgery, and in sentinel lymph node biopsy. He is also active in efforts to define and improve the quality of cancer care for breast and other types of cancer. His work involves research with large cancer registry programs and linking those registries to other sources of cancer treatment information. He is the chair of the Commission on Cancer of the American College of Surgeons. He is the past chair of the American Joint Committee on Cancer (AJCC) and is the editor-in-chief of the 7th edition of the *AJCC Cancer Staging Manual* published in 2009. He also is on the Board of Directors of the National Comprehensive Cancer Network and is a member of the NCCN Breast Cancer Practice Guideline Panel.

Lynn Etheredge is a health economist and independent consultant working on healthcare and social policy issues, currently with the Rapid Learning Project at George Washington University. His career started at the White

House Office of Management and Budget (OMB). During the Nixon and Ford administrations, he was OMB's principal analyst for Medicare and Medicaid and led its staff work on national health insurance proposals. He returned to OMB as a senior career executive and headed its professional health staff in the Carter and Reagan administrations. He was a coauthor of the Jackson Hole Group's proposals for healthcare reform and a co-founder of the Health Insurance Reform Project at George Washington University. During the last several years, Lynn has authored policy studies about Medicare reform, quality of care, consumer health information strategies, health insurance and flexible benefits tax credits, Medicaid, and public policies for the baby boom generation's retirement. He is author of more than 70 publications and is a graduate of Swarthmore College.

Susannah Fox is associate director of Digital Strategy, at the Pew Internet and American Life Project. She leads the project's health research and oversees its digital strategy. Some of her recent reports include *The Social Life of Health Information*, *Twitter and status updating*, and *Generations Online* in 2009. Fox is the former editor of the website for *U.S. News & World Report* magazine. She has also worked as a researcher for RealNetworks and for the Harwood Group. Fox graduated from Wesleyan University with a degree in anthropology.

Charles P. Friedman, Ph.D., is deputy national coordinator for health information technology in the Office of the Secretary for Health and Human Services. In this capacity, he serves as the chief operating officer of the Office of the National Coordinator (ONC) for Health Information Technology, working to build collaborations in the public and private sectors and maintain cohesion across the programs that ONC undertakes. In addition, Dr. Friedman is ONC's lead for planning and communication activities, as well as its initiatives relating to clinical decision support. Prior to joining ONC, Dr. Friedman was associate director for research informatics and information technology at the National Heart, Lung, and Blood Institute of the NIH. Friedman first came to NIH in 2003, in the role of senior scholar at the National Library of Medicine, where he coordinated its research program in bioinformatics, was the library's informatics training officer, and served as NLM's representative to informatics programs in the NIH Roadmap. From 1996 to 2003, Dr. Friedman was professor and associate vice chancellor for biomedical informatics at the University of Pittsburgh. After receiving his Ph.D. in education, he spent more than 19

years on the faculty at the University of North Carolina (UNC). In 1985, he established the Laboratory for Computing and Cognition at UNC, and in 1992, he started UNC's medical informatics training program. He is a past president of the American College of Medical Informatics and was the 2005 chair of the Annual Symposium of the American Medical Informatics Association. He currently serves as associate editor of the *Journal of the American Medical Informatics Association*.

Gilles Frydman is a pioneer of medical online communities. He obtained a bachelor of science at the Hebrew University in Jerusalem & Rehovot (Israel), majoring in animal biology. After working on various government research programs involving telecommunication technology, he became a pioneer in using computers and communication technologies to optimize the care received by cancer patients worldwide. He is the founder, in 1995, of the Association of Cancer Online Resources, the largest online social network for cancer patients, composed of close to 200 separate online support groups for individuals with cancer. ACOR has served over a half-million cancer patients and caregivers. He serves on a number of advocacy and advisory committees in support of patient-centered computing and consults with major internet based corporations. His most recent projects are all related to the ways in which online virtual environments can be used to facilitate and improve health care, particularly for people suffering from rare and deadly conditions.

Patricia A. Ganz, M.D., is professor of health services in the School of Public Health and professor of medicine in the David Geffen School of Medicine at the University of California at Los Angeles (UCLA). Dr. Ganz received her M.D. from the UCLA School of Medicine in 1973 and completed postdoctoral training in internal medicine and medical oncology at the UCLA Medical Center. She has been on the faculty of the School of Medicine since 1977 and joined the faculty of the School of Public Health in 1992. Dr. Ganz has devoted the past 25 years to the study of quality-of-life outcomes in cancer and other chronic diseases. Dr. Ganz is also director of the Division of Cancer Prevention and Control Research of the Jonsson Comprehensive Cancer Center at UCLA and leads a large research group that applies the scientific disciplines of public health (epidemiology, health services, behavioral sciences, biostatistics) to research on the prevention, detection, treatment, and supportive care of cancer. Dr. Ganz is associate editor of the *Journal of Clinical Oncology*, the journal of the National Cancer

Institute, and is a member of the editorial board of the Cochrane Breast Cancer Group. In 1999 she was named an American Cancer Society Clinical Research Professor and in 2007 she became a member of the Institute of Medicine.

Robert R. German, Dr.P.H., M.P.H., currently serves as the associate director for science for the Centers for Disease Control and Prevention's (CDC's) Division of Cancer Prevention and Control. Bob's experience in cancer surveillance and research has included a field assignment as a CDC epidemiologist in the West Virginia Breast and Cervical Cancer Screening Program, a CDC project officer for CDC's National Program of Cancer Registries, work on the United States Cancer Statistics series, and the lead scientist for CDC's patterns of cancer care studies and for its cancer mortality study. His work in cancer has focused on prostate cancer and the quality of cancer registry data. He received his Dr.P.H. in epidemiology in 2004 from the University of South Carolina and his M.P.H. in 1991 from Emory University.

James Allen Heywood is co-founder and chairman of PatientsLikeMe™. A Massachusetts Institute of Technology engineer, he entered the field of translational research when his brother Stephen was diagnosed with amyotrophic lateral sclerosis (ALS) in 1998 at the age of 29. Heywood brought an expertise in design, information technology, modeling, and industrial processes to the problems of helping patients develop treatments and manage diseases. Heywood is also the founder of the ALS Therapy Development Institute (ALS TDI), the world's first nonprofit biotechnology company and served as its chief executive officer from 1999 to 2007. Heywood co-founded PatientsLikeMe in 2004 with his youngest brother, Benjamin, and his friend Jeff Cole. Currently, he serves as chairman, where he provides the scientific vision and architecture for its patient-centered medical platform. Heywood is a frequent speaker, media pundit, and active investment adviser. His work has been profiled in the *New Yorker*, *New York Times Magazine*, *Business Week*, *60 Minutes*, *Science*, and *Nature*, as well as in Pulitzer Prize winner Jonathan Wiener's biography *His Brother's Keeper* and the Sundance award-winning documentary *So Much So Fast*.

Joseph O. Jacobson, M.D., is the chairman of the Department of Medicine at North Shore Medical Center (NSMC) and an associate clinical professor at Harvard Medical School. He is board certified in internal

medicine, medical oncology, and hematology and holds an M.S. (clinical effectiveness) from the Harvard School of Public Health. He has an active clinical practice. Dr. Jacobson's focus as a department chair and as a practicing medical oncologist has been to identify means to both measure and improve patient care and safety. He was among the founding members of the American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative. Dr. Jacobson is currently the immediate past chair of the ASCO Quality of Care Committee and the chair of the Quality Oncology Practice Initiative Steering Committee. He serves on the editorial board of the *Journal of Clinical Oncology* and is an associate editor for the *Journal of Oncology Practice*. He is the co-chair of the Partners Healthcare Quality Oncology Leadership Group.

Joseph Lipscomb, Ph.D., is professor of health policy and management and Georgia Cancer Coalition Distinguished Cancer Scholar at the Rollins School of Public Health at Emory University. He is also a co-leader of the Cancer Control and Population Sciences Program at Emory's Winship Cancer Institute. From 1999 until arriving at Emory in 2004, he was chief of the Outcomes Research Branch at the National Cancer Institute. He is a member of the Steering Committee for the Georgia Comprehensive Cancer Control Plan. He serves on national committees to improve cancer outcomes and quality at both the American College of Surgeons' Commission on Cancer and the American Cancer Society. He has published widely on a variety of topics in health economics and outcomes research, including patient-reported outcomes assessment, quality-of-care evaluation and improvement, and the theory and practice of cost-effectiveness analysis. He received his Ph.D. in economics from the University of North Carolina at Chapel Hill in 1975 and a B.A. in mathematics from Vanderbilt University in 1970. From 1975 until joining the National Cancer Institute, he was on the faculty at Duke University.

Michael McGinnis, M.D., is a physician, epidemiologist, and long-time contributor to national and international health programs and policy. An elected member of the Institute of Medicine (IOM) of the National Academies, he has since 2005 also served as IOM senior scholar, leading its initiative on evidence and value-based health care. From 1999 to 2005, he was senior vice president and founding director of the health group at the Robert Wood Johnson Foundation (RWJF). Previously, and unusual for political and policy posts, he held continuous appointment through the

Carter, Reagan, Bush, and Clinton administrations at the Department of Health and Human Services, with policy responsibilities for disease prevention and health promotion (1977-1995). Programs and policies conceived and initiated by Dr. McGinnis include the *Healthy People* process setting national health objectives (1979-present), the U.S. Preventive Services Task Force (1984-present), the *Dietary Guidelines for Americans* (with the U.S. Department of Agriculture, 1980-present), the Public Health Functions Steering Group and the Ten Essential Services of Public Health (1994-present), the RWJF Active Living family of programs (2000-present), the RWJF Young Epidemiology Scholars Program (2001-present), and the RWJF Health and Society Scholars Program (2002-present). His research interests are in the determinants of health and the rational allocation of social resources. Dr. McGinnis has taught (in visiting or adjunct capacities) at George Washington, UCLA, Princeton, and Duke universities. He is a graduate of the University of California at Berkeley, the UCLA Medical School, and the John F. Kennedy School of Government at Harvard.

William T. McGivney, Ph.D., is chief executive officer of the National Comprehensive Cancer Network—an alliance of 21 of the world’s leading cancer centers. Prior to joining the NCCN in 1997, Dr. McGivney was director of the Division of Health Care Technology at the American Medical Association from 1982 to 1991. In 1991, Dr. McGivney joined Aetna Health Plans, where he worked until 1997 as vice president for clinical and coverage policy. In 1991, in collaboration with Grace Powers Monaco, he established the first formal independent outside review process. This process was used as the model for the passage of the Knowles-Friedman Act in California in 1996, the first of many states to mandate that health plans offer an outside review option. Dr. McGivney, a recognized expert in coverage policy and in drug and device regulatory policy, was awarded the Food and Drug Administration’s (FDA’s) Commissioner’s Medal of Appreciation in 1989. He has served on numerous national boards and committees including the United Network for Organ Sharing (UNOS) Board of Directors, the Board of the Patient Advocate Foundation, and the Medicare Coverage Advisory Committee. He earned his undergraduate degree from Boston College and his Ph.D. from the University of North Carolina at Chapel Hill. He completed a postdoctoral fellowship at Harvard Medical School.

Sharon B. Murphy, M.D., joined the IOM as a scholar-in-residence in October 2008, coming to the District of Columbia from Texas where she

was the inaugural director of the Greehey Children's Cancer Research Institute and professor of pediatrics at the University of Texas Health Science Center at San Antonio from 2002 to 2008. From 1988 to 2002, Dr. Murphy was chief of the Division of Hematology-Oncology at Children's Memorial Hospital in Chicago and professor of pediatrics at Northwestern University School of Medicine where she also led the program in pediatric oncology at the Robert H. Lurie Cancer Center. From 1974 to 1988, Dr. Murphy was on the faculty at St. Jude Children's Research Hospital in Memphis. A pediatric oncologist and clinical cancer researcher, Dr. Murphy has devoted her career to improving cure rates for childhood cancer, particularly childhood lymphomas and leukemias. She was chair of the Pediatric Oncology Group from 1993 to 2001. She has been recognized for her achievements by the Association of Community Cancer Centers (2001), the Distinguished Service Award for Scientific Leadership from the American Society of Clinical Oncology (2005), and the Distinguished Career Award from the American Society of Pediatric Hematology and Oncology (2009). The author of more than 220 original articles, reviews, and book chapters, Dr. Murphy has also served on numerous editorial boards, including *Cancer Research*, *Clinical Cancer Research*, and the *Journal of Clinical Oncology*. She has been a member of the boards of directors for the American Cancer Society, the American Association of Cancer Research, the American Society of Hematology, and the American Society of Clinical Oncology and has been an adviser to NCI and FDA. She earned her bachelor of science degree from the University of Wisconsin (1965) and her medical degree, *cum laude*, from Harvard Medical School (1969). She completed postdoctoral training in pediatrics at the University of Colorado (1969-1971) and in pediatric hematology and oncology at the University of Pennsylvania (1971-1973).

Chalapathy Neti, Ph.D., is currently the associate director, Healthcare Transformation, at IBM Research. Prior to this role, he was an executive architect in the information agenda organization, IBM Software Group. Prior to his assignment in IBM Software Group, Dr. Neti was a senior manager for information analysis and interaction technologies at IBM Research. Prior to the senior management role, he held various senior technical and management positions including the CTO of IBM's digital media business, manager of audiovisual speech technologies, and technical roles in rich media analysis (speech, audio, and video) and mining. He has been with IBM since 1990. Dr. Neti received his Ph.D. in biomedical engineering from the Johns Hopkins University (1990) and B.S. from the Indian Insti-

tute of Technology, Kanpur (1980). He has more than 20 years of advanced R&D experience and has authored more than 50 articles (conference and journal) in various fields related to biomedical informatics, medical imaging, speech and video analysis, computational neuroscience, and VLSI (very large scale integration) design. He has 16 patents and several pending. He is an active member of IEEE (Institute of Electrical and Electronics Engineers, the world's leading professional association for the advancement of technology), a former member of IEEE Multimedia Signal Processing Technical Committee (2001-2004), and an associate editor of *IEEE Transactions on Multimedia* (2002-2005).

Arnold L. Potosky, Ph.D., a professor in the Department of Oncology, is director of Health Services Research at the Georgetown University Medical Center (GUMC) Lombardi Comprehensive Cancer Center (LCCC), Cancer Control Program where he was appointed in September 2008. Dr. Potosky earned his Ph.D. in health services research from John Hopkins University in 1994 and was a health scientist at the National Cancer Institute from 1987 to 2008, where he helped develop a national research program focusing on cancer-related health services and outcomes research. Dr. Potosky has conceived and implemented multisite national studies of cancer care quality and effectiveness, including the Prostate Cancer Outcomes Study (PCOS) and the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS), a multisite national study of 10,000 recently diagnosed lung and colorectal cancer patients. He conducted the initial linkage of the Surveillance, Epidemiology and End Results (SEER) Program-Medicare database in 1991 and developed methods for assessing costs, comorbidity, and outcomes using the linked data. Dr. Potosky's research at Georgetown continues his earlier work on the dissemination of cancer prevention and treatments; comparisons of outcomes according to patient, provider, and delivery system factors; assessing patient-reported outcomes and complications; and evaluating the comparative effectiveness of cancer-directed therapies in observational studies.

Josh Sommer is executive director of the Chordoma Foundation, which he co-founded with his mother, Dr. Simone Sommer, after he was diagnosed with a clival chordoma in 2006. He believes that patients should play an active role in bringing about treatments for their own conditions, and that patients represent a largely untapped source of funding, energy, and know-how in the treatment development process. Josh was a freshman at

Duke University studying environmental engineering when he was diagnosed with chordoma. Soon after his diagnosis, Josh joined the lab of Dr. Michael Kelley, a Duke oncologist studying the genetic basis of chordoma, and the only federally funded chordoma researcher. His research in Dr. Kelley's lab included cell line characterization, gene-expression microarray analysis, candidate gene knockdown using RNA interference, and in vitro drug screening. To support his work in the lab, Josh switched majors to a self-designed bioengineering curriculum focused on modeling and solving biological "problems" that lead to disease. After finishing his junior year in May 2008, Josh was awarded a two-year Echoing Green fellowship for social entrepreneurs, and subsequently has taken a leave of absence from Duke to lead the Chordoma Foundation with Dr. Simone Sommer. To complement his work for the Chordoma Foundation, Josh has joined Duke's Program on Global Health and Technology Access as a Fellow in Strategic Philanthropy and Health. In addition, Josh continues to participate in research in Dr. Kelley's lab, and helps coordinate collaborations with a network of chordoma researchers at other institutions around the world. In school Josh received numerous honors and awards including the *USA Today* All-USA Academic First Team Award, Prudential Spirit of Community Award, Coca-Cola Scholarship, and AXA Achievement National Award.

Simone Sommer, M.D., M.P.H., is president of the Chordoma Foundation, which she formed in February 2007 after her only child, Josh, was diagnosed with a chordoma in 2006. The Chordoma Foundation is an innovative nonprofit organization uniting patients, doctors, and scientists to accelerate the development of effective treatments and ultimately a cure for this neglected form of cancer. Under her direction, the Chordoma Foundation has launched a coordinated international research effort that has invigorated the field of chordoma research. Dr. Sommer and her son Josh, who is now an Echoing Green Social Entrepreneur fellow, take an active role in every aspect of the research process by formulating research priorities, recruiting the best researchers, initiating new projects, brokering collaborations, and breaking down barriers to progress. Dr. Sommer is a graduate of George Washington University School of Medicine. She completed her internship at Duke University Medical Center and completed a residency and faculty development fellowship in family medicine at the University of North Carolina in Chapel Hill. Dr. Sommer also holds a master's degree in public health in epidemiology from the University of North Carolina School of Public Health. She was formerly associate clinical professor at the

University of North Carolina, Department of Family Medicine and previously served as medical director of the Guilford County Health Department Infectious and Chronic Disease Prevention Program. She is past president of Sommer Health Services of Greensboro, North Carolina.

William W. Stead, M.D., is associate vice chancellor for health affairs and chief strategy and information officer at Vanderbilt University Medical Center. He also serves as chief information architect for the university and as director of the Informatics Center. Dr. Stead received his B.A. and M.D. degrees from Duke University where he also completed specialty and subspecialty training in internal medicine and nephrology. As a faculty member in nephrology, he was the physician in the physician-engineer partnership that developed the Medical Record (TMR), one of the first practical electronic medical record systems. He helped Duke build one of the first patient-centered hospital information systems (IBM's PCS/ASDS). He came to Vanderbilt in 1991 to work out how to link information to workflow to help people make better decisions at an enterprise scale. His team has shown how to translate techniques from the science of biomedical informatics into novel approaches to information infrastructure that reduce costs to implement and barriers to adoption. The resulting enterprise-wide electronic patient chart and communication and decision support tools promote his current focus on system-supported, evidence-based practice and research leading toward personalized medicine. Dr. Stead is McKesson Foundation Professor of Biomedical Informatics and professor of medicine. He is a founding fellow of both the American College of Medical Informatics and the American Institute for Engineering in Biology and Medicine and is an elected member of both the Institute of Medicine of the National Academies and the American Clinical and Climatological Association. He was the first recipient of the Lindberg Award for Innovation in Informatics and the 2007 recipient of the Collen Award for Excellence in Medical Informatics. He was the founding editor-in-chief of the *Journal of the American Medical Informatics Association* and served as president of the American Association for Medical Systems and Informatics and the American College of Medical Informatics. He served as chairman of the Board of Regents of the National Library of Medicine, as a presidential appointee to the Commission on Systemic Interoperability, and as chair of the National Research Council (NRC) Committee on Engaging the Computer Science Research Community in Health Care Informatics. He is a member of the Council of the Institute of Medicine and Tennessee's eHealth Advisory Council.

Sandy Thames is a public health adviser with the Cancer Surveillance Branch, Division of Cancer Prevention and Control, at the Centers for Disease Control and Prevention. She is the lead on the National Program of Cancer Registries-Advancing E-cancer Reporting and Registry Operations (NPCR-AERRO) (formerly the Model Electronic Reporting Project), which is developing a consensus model for cancer surveillance. She serves as the liaison to the CDC Public Health Information Network-National Electronic Disease Surveillance System informatics activities. Ms. Thames also participates on the Healthcare Information Technology Standards Panel and the Healthcare Information and Management Systems Society Integrating the Healthcare Enterprise workgroups that are focused on moving forward the development of a standardized electronic health record and the secure exchange of standardized patient information across the healthcare community. She has been with the CDC since 1989.

William J. Todd has been president and CEO of the Georgia Cancer Coalition since 2003. His 38-year career has focused on healthcare and technology management in Georgia. He was the founding president of the Georgia Research Alliance in 1990, nurturing the independent not-for-profit organization that has helped build Georgia's reputation as a center for discovery and invention and fostered major advances in science, medicine, and technology. He founded Encina Technology Ventures in 2000. His career began at Emory University hospitals, clinics, and medical school, where he held a variety of administrative posts over two decades, ultimately serving as assistant vice president for medical administration at the Robert W. Woodruff Health Sciences Center. A 1971 graduate of the College of Management at Georgia Institute of Technology, Todd attended the Institute for Educational Management at Harvard University. In 2000, he received an honorary doctor of science degree from the University of Ulster in Northern Ireland. Todd is board chairman of the Georgia Tech Alumni Association and a board member of the Georgia Chamber of Commerce, the American Cancer Society, and the Georgia Tech Foundation.

Paul Wallace, M.D., is medical director for health and productivity management programs in Kaiser Permanente's (KP's) national Permanente Federation. He leads work to extend KP's experience with population-based care to further develop and integrate wellness, health maintenance, and productivity enhancement interventions. He is also active in the design and promotion of systematic approaches to comparative effectiveness

assessment and accelerated organizational learning. He was previously the executive director of KP's Care Management Institute (CMI) from 2000 to 2005 and continues as a senior adviser to CMI and to Avivia Health, the KP disease management company established in 2005. Dr. Wallace joined KP in 1989 and has participated in KP's program-wide New Technology, Research, Guidelines, and Diversity Committees. Board certified in internal medicine and hematology, he previously taught clinical and basic sciences and investigated bone marrow function as a faculty member at the Oregon Health Sciences University. Dr. Wallace is currently a member of the IOM Board on Population Health and Public Health Practice. He has previously served on the Committee on Performance Measurement and Standards Committees for the National Committee for Quality Assurance (NCQA), the National Advisory Council of AHRQ, the Medical Coverage Advisory Committee for CMS, and the Medical Advisory Panel for the Blue Cross and Blue Shield Technology Evaluation Center. Wallace is a graduate of the University of Iowa School of Medicine and completed further training in internal medicine and hematology at Strong Memorial Hospital and the University of Rochester.

Janet Woodcock, M.D., is the director, Center for Drug Evaluation and Research (CDER), at FDA. She previously served as FDA deputy commissioner and chief medical officer, as well as FDA deputy commissioner for operations and chief operating officer. Dr. Woodcock has led many cross-agency initiatives while at FDA. She introduced the concept of pharmaceutical risk management in 2000 as a new approach to drug safety. She has led the Pharmaceutical Quality for the 21st Century Initiative since 2002. She spearheaded an initiative on pharmacogenomics that has led to unprecedented agency-industry interactions on pharmacogenomics use in drug development. Over the last three years, she has been leading FDA's Critical Path Initiative, which is designed to improve the scientific basis for medical product development. Dr. Woodcock was director of the CDER from 1994 to 2005. Dr. Woodcock also oversaw initiatives to automate submission and review of applications and adverse event reports. Under Dr. Woodcock's leadership, CDER's regulatory decision making was made more open and transparent to the public. Changes included publishing CDER's regulatory procedures and policies, developing more than 100 technical "guidances" that describe regulatory standards, providing an unprecedented degree of participation of consumer and patient representatives in FDA processes, and creating an extensive CDER website that includes drug reviews and

consumer information. Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER). Dr. Woodcock has earned numerous awards, including the Gary Neal Prize for Innovation in Drug Development (American Society for Clinical Pharmacology and Therapeutics [ASCPT], 2009), a Presidential Rank Meritorious Executive Award, the Nathan Davis Award from the American Medical Association (1999), the Roger W. Jones Award for Executive Leadership from American University (2000), the Public Health Leadership Award (2004) from the National Organization for Rare Disorders (NORD), the VIDA Award from the National Alliance for Hispanic Health (2005), the Leadership Award in Personalized Medicine from the Personalized Medicine Coalition (2005), the Public Service Award from the American Association for Cancer Research (2006), the Indispensable Person of the Year Award from the Alliance for Aging Research (2007), the Distinguished Service and Leadership Award from the Food and Drug Law Institute (2008), and the Distinguished Career Award from the Drug Information Association (2008). She has also received three HHS Secretary's Distinguished Service Awards and the HHS Asian-Pacific Network Achievement Award (2001) and six FDA Commissioner's Special Citations. Dr. Woodcock received her M.D. from Northwestern University Medical School in 1977. She received her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco.

