

Prescriptions for Excellence in HEALTH CARE

A COLLABORATION BETWEEN JEFFERSON SCHOOL OF POPULATION HEALTH AND LILLY USA, LLC

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Editorial

Health Reform: A Work In Progress

By David B. Nash, MD, MBA
Editor-in-Chief

It has been 5 years since we, in partnership with Eli Lilly and Company, introduced *Prescriptions for Excellence in Health Care (PEHC)*, a unique newsletter series devoted to the evolving national quality improvement agenda. Since its launch in 2007, the newsletter has been provided as a supplement to our *Health Policy Newsletter (HPN)*. This issue marks 2 important beginnings – a new 4-part series on the present and future impact of health care reform and, as *HPN* goes exclusively electronic, the debut of *PEHC* as a stand-alone publication.

Like many of our readers, I have followed the implementation of the Patient Protection and Affordable Care Act (ACA) with keen interest, some trepidation, and a certain amount of optimism. As we go to press, it is almost 2 years since the passage of this historic, game-changing legislation that promises to influence how health care is delivered and reimbursed in the United States for decades to come.

Debates continue to rage about the ACA's design, its intended effects, and whose way is best. But, lawsuits and court challenges by some states

notwithstanding, the ACA and the overwhelming majority of its provisions are here to stay.

Although the popular media tends to focus on the few hot-button issues (eg, charges of amendment violations, “death panels”), an astounding array of provisions have already gone into effect across the entire industry. In the first year alone (2010), insurers faced a variety of new requirements, such as: increased mandatory reporting of administrative data, continued coverage of adult children under their parents’ policies (until the 26th birthday), strict limits on reasons for discontinuing coverage, and free preventive screening services for adults. Nonprofit insurers were required to maintain a medical loss ratio of 85% or higher in order to take advantage of Internal Revenue Service tax benefits.

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Other provisions that went into effect in 2010 include new tax credits available to small businesses (those with 25 or fewer employees) to help with employee premium costs and the expansion of Medicare to small, rural hospitals and facilities.

In January 2011, Medicare beneficiaries began to receive free preventive care as well as a 50% discount on the cost of covered brand-name prescription drugs for the Medicare Part D coverage gap (donut hole). Grants became available to states to develop programs aimed at delaying the onset and reducing the prevalence of chronic conditions among Medicaid beneficiaries.

Hospitals, too, have begun to feel the impact of ACA as the federal government ceased making payments to states for Medicaid services related to certain hospital-acquired infections – a precursor to a reduction in Medicare payments for preventable hospital admissions scheduled to take effect in 2012.

On the policy front, the Centers for Medicare and Medicaid Services

has met its deadline for developing the CMS Center for Medicare and Medicaid Innovation, the body that will oversee testing of innovative payment and delivery models.

In the summer of 2011, we convened a symposium to get a snapshot of how various provisions of the ACA have begun to affect health care quality and population health. With presentations from a cross section of stakeholder groups, we had an opportunity to learn how things are going on the front lines, from primary care to long-term care to policy making. Three of these presentations form the basis of the articles in this issue.

The first article, “*The Role of Primary Care in Health Care Reform*,” examines 3 current ACA-related initiatives that have the potential to reinforce primary care as the foundation for assuring the success of health care reform.

Prevention plays either a starring or supporting role in many ACA provisions. The second article, “*A New Model for Integrating Clinical Preventive Medicine into Patient*

Care,” describes one residency program’s approach to improving how preventive medicine specialists are prepared to meet the expectations of health reform.

The third article is one that certainly piqued my interest. Exploring another key component of health reform, “*Leveraging Electronic Health Records in Comparative Effectiveness Research*” translates a complex sounding concept into terms that are easily understood and thought provoking.

I hope that this issue and others in this series will shed new light on some of the changes that are occurring as health care reform unfolds. As always, I welcome questions and comments from readers. I can be reached at: david.nash@jefferson.edu.

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A Message from Lilly

The Continued Evolution of Health Care Reform in the United States

By Barton R. Peterson, BS, JD

Health care reform in the United States was inevitable. In the absence of any changes to federal law, 25% of total US Gross Domestic Product would have been spent on health care by 2025. A system that provided financial incentives for services without regard for patient outcomes was bound to hit the wall. We were

spending nearly twice what the rest of the developed world spent on health care, yet measures of quality suggested that US health care was not twice as good. It was time for a fundamental reevaluation.

There was much speculation about why the biopharmaceutical industry

jumped headlong into the health care reform debate in 2009. The industry supported what became the Affordable Care Act (ACA) despite the enormous additional expenditures it imposed on biopharmaceutical companies. Why? The simplest answer is that the system’s flaws were catching up

with it and producing results that were not in Americans' best interests – most importantly, the patients who were its intended beneficiaries.

This issue of *Prescriptions for Excellence in Health Care* comes at a very uncertain time. The US Supreme Court will decide the fate of at least the individual mandate in the ACA, if not the fate of the entire law. Regardless of how the high court rules, the 2012 elections could result in a Republican president and a Republican-controlled Congress – 2 entities that have pledged to repeal the ACA. If President Obama is reelected, he may face a Republican Congress that imposes limits on funding the implementation of certain ACA provisions. And then there are the States, which have responsibility for insurance exchanges, the expansion of Medicaid, and other critical components of the new law.

The foregoing challenges aside, it is a very good time to discuss the issues presented on the following pages. If the ACA survives, it must evolve. Even its staunchest supporters admit that. If it is repealed, it must be replaced with something else. Otherwise, we're in the same place we were 2 years ago – with millions of uninsured people, unsustainable growth in expenditures, and little to show in the way of improved outcomes and higher quality.

In the biopharmaceutical industry, there are many opinions as to what such an improved system might look like, and I have my own. The movement toward compensating those in the health care system for improved individual health outcomes is inexorable, but it will be a terribly complicated thing to do. The ACA puts a number of “toes in the water” on the subject of paying for results, Accountable Care Organizations being the most prominent. When so many different individuals and institutions are involved in the care of a single person, how do we distinguish who performed well from who performed poorly and, importantly, how do we compensate them accordingly? What about the role of the health care consumer in his or her own health? What about prevention?

I believe that the age of health care “silos” will come to an end. A system that pays only for products and services facilitates siloed providers, and vice versa. The biopharmaceutical industry provides essential innovation for the benefit of patients and value for the health care system but is compensated solely on the number of pills and vials it sells. I hope the business model for biopharmaceutical companies evolves to the point where they are seen as an integral part of producing better *individual* patient outcomes. At Lilly, our corporate vision is “Improved

Outcomes for Individual Patients.” These are not empty words. They drive the actions of our employees across the world every day.

US health care reform is closer to the beginning than the end. At least our country is now purposefully focused on real issues and real solutions. It is imperative that this focus lead to a sustainable health care system that produces better outcomes for all Americans.

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Company.*

The Role of Primary Care in Health Care Reform

By Kenneth Goldblum, MD

Few discussions on health care reform fail to mention the importance of primary care and, indeed, primary care plays such a critical role in health care delivery that any successful health care reform effort will necessarily depend on a strong primary care foundation. At the present time, that foundation is not solid enough to fulfill its role. It will need significant reinforcement if reform is to succeed.¹

For a patient experiencing a new problem, primary care is generally the first contact with the health care system. Comprehensive in nature and centered on the whole person rather than a specific disease process or organ system, primary care coordinates care given by different providers in different settings. It is continuous over time and, as such, is forward looking and prevention based.

Although health care reform is multifaceted, with different orientations depending on the context, a majority of its goals target lowered costs, improved quality and safety, better access to care, and more patient-centeredness. By its very nature, primary care supports these goals; for example, studies of geographical variation in costs in this country have shown that areas with more primary care have lower costs. On a macro scale, this is supported by data showing that countries with a higher percentage of primary care doctors also have lower costs. Outpatient quality improvement efforts have focused on primary care initiatives with specialist programs lagging behind. Moreover, newer care delivery models such as the Patient-

Centered Medical Home (PCMH) are designed in part to improve both access and patient-centeredness.

Despite the concordance between the nature of primary care and the goals of reform, primary care is ill equipped to fulfill its potential foundational role. Consider the following:

- At a mere 5% of total health expenditures, primary care is woefully underfunded. It is trapped in a fee-for-service payment methodology that reimburses visits and does not support the goals of reform.
- Primary care is fragmented, with evidence revealing that in 1 year the average Medicare patient sees 2 primary care doctors and 5 specialists working in 4 different locations.²
- Primary care is increasingly isolated as fewer and fewer primary care physicians practice in the hospital setting.
- Primary care is time challenged, with one study documenting that it would take 7.4 hours per day to provide all recommended preventive care and another revealing that it would take 10.6 hours per day to provide all recommended chronic care.³

Despite recent efforts, including those contained in the Affordable Care Act, primary care doctors remain in short supply. Market forces likely will exacerbate this problem.

Three initiatives currently under way or close to starting have the potential to help improve the situation for primary care. The first of these is the PCMH, a care delivery model innovation that seeks to improve the core primary care functions of access, comprehensiveness, coordination, and quality improvement. Although it does deliver results in these areas, the data are not as robust with regard to cost reduction. The extent to which PCMH is truly able to drive change depends primarily on payers supporting the concept. In the absence of strong data on cost reduction, such payer support remains in question.

The second initiative currently affecting primary care is payment for meaningful use (MU) of electronic medical records (EMR). Legislated through the American Recovery and Reinvestment Act in 2009, final criteria for the first stage of MU were recently established, and the first wave of practices is now in the certifying process. Anecdotal evidence suggests that the criteria will represent a difficult stretch for many physician practices and therefore may not be a significant driver of change. On the positive side, the 2011 standards for National Committee for Quality Assurance PCMH certification include many of the same elements that are necessary for MU certification, so a practice that certifies as a meaningful user of EMR will be well on its way to PCMH certification as well.

The last initiative, one that begins soon, is the Medicare Shared Savings Program. Preliminary rules were

published in March of 2011, and the final rules are still pending at the time of this writing. While the term Accountable Care Organization (ACO) is used in other contexts, here it refers to a business structure of providers of traditional Medicare services who will contract with the Centers for Medicare and Medicaid Services to engage in a shared savings program. The sharing of savings is first predicated on the organization's achievement of acceptable performance levels on specific quality measures. The preliminary rules describe 65 such measures, many of which are outpatient, primary care-based measures. Five of the measures are MU measures, and there is a requirement that 50% of the ACO's primary care doctors be certified as meaningful users of EMR by the ACO's second year.

Because ACOs will be held liable for losses incurred under the Shared Savings Program, they also must be risk-bearing entities with sufficient capital – a resource not typically associated with primary care physicians. Given that participation in the ACO is entirely at the discretion of the primary care doctor, this initiative does have the potential to better fund primary care if the practitioners are able to leverage this with a strategically aligned capital partner.⁴

Although these 3 initiatives have different origins and different goals, they tie together and support each other. As noted, practices that can certify as meaningful users of EMR are well on the way to PCMH

certification, and MU certification is critical for ACO participation. PCMH certification, in turn, goes a long way toward meeting the proposed ACO quality measures. Only the ACO is a true payment methodology reform but, to the extent that the PCMH is embedded in the ACO and driving its quality, the ACO may provide the PCMH with financial support. Many themes of reform – from cost reduction to quality improvement to better patient-centeredness – run through all 3 of these initiatives.

Although each of these initiatives has the potential to improve the plight of primary care, a true bolstering of the foundational role of primary care (and thereby a true support of the delivery system as a whole) will depend on new payment mechanisms that support the goals of reform. To accomplish this will require fundamental reform that uncouples reimbursement from the individual visit and creates incentives for team building.⁵

A reimbursement system that pays for visits will continue to produce visits without necessarily improving access, comprehensiveness, safety, or quality of care. Conversely, a reimbursement system that rewards the goals of reform has the potential to address the challenges of primary care and, hence, improve the delivery system as a whole.

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References

1. Bodenheimer T. Primary care - will it survive? *N Engl J Med*. 2006;355(9):861-866.
2. Pham H, Schrag D, O'Malley AS, Wu B, Bach PB. Care patterns in Medicare and their implications for pay for performance. *N Engl J Med*. 2007;356(11):1130-1139.
3. Bodenheimer T. Coordinating care - a perilous journey through the health care system. *N Engl J Med*. 2008;358(10):1064-1071.
4. Rittenhouse DR, Shortell SM, Fisher ES. Primary care and accountable care - two essential elements of delivery system reform. *N Engl J Med*. 2009;361(24):2301-2303.
5. Baron RJ, Cassel CK. 21st century primary care: new physician roles need new payment models. *JAMA*. 2008;299(13):1595-1597.

A New Model for Integrating Clinical Preventive Medicine into Patient Care

By Kevin L. Bowman, MD, MBA, MPH

The General Preventive Medicine Residency (GPMR) Program of the Johns Hopkins Bloomberg School of Public Health is one of the oldest and largest preventive medicine (PM) residency programs in the country. The mission of the residency program is as follows¹:

To prepare physicians in the theoretical, practical, and clinical knowledge and skills essential to leadership roles in the design, management, and evaluation of population-based approaches to health.

Basic to this mission are 5 key goals:

- To instill in residents the ability to synthesize clinical and population-based approaches to disease prevention and health promotion
- To view health issues on a broad continuum that ranges from local to international in perspective
- To discover and apply knowledge toward the protection of the public's health
- To provide residents with the management and epidemiologic skills needed to address the overall health needs of underserved populations
- To provide residents with the clinical skills needed to treat specific diseases that disproportionately affect underserved populations.¹

Each year, approximately 10 resident physicians enter the GPMR Program

after completing at least 1 year of clinical training in an Accreditation Council for Graduate Medical Education (ACGME)-accredited program. One student is accepted directly from medical school through the match process and completes the required clinical training at Basset Healthcare Hospital in Cooperstown, NY. Approximately half of the other 9 residents who enter the program each year have completed a partial clinical residency in another specialty (eg, internal medicine, radiology, neurosurgery) and have been in practice for some time prior to entering the program. The remaining residents have completed full clinical residencies (eg, pediatrics, family medicine, internal medicine).

Like most PM residencies, the GPMR Program is 2 years of specialty-specific training that includes graduate level course work and hands-on rotation experiences. Although some PM residencies spread the graduate course work and rotation experiences throughout the 2-year period, the GPMR Program has separated the 2 disciplines into an academic (graduate course work) year and a practicum (rotation experience) year.

During the academic year, residents have been full-time graduate students in the Master of Public Health (MPH) program at the Johns Hopkins Bloomberg School of Public Health. The school offers hundreds of classes in a wide variety of areas, and residents are encouraged to design a personalized curriculum that meets

their interests and career goals. The MPH course work has constituted about 60% to 70% of their time. The remaining time has been dedicated to typical residency activities such as journal clubs, grand rounds, and numerous educational seminars/classes on various topics (eg, problem-solving skills in public health, health advocacy, public health preparedness, quality assessment/quality improvement, budgeting and financial management, conflict management and negotiation, strategic leadership principles).

Residents have spent all 12 months of the practicum year doing elective rotations at a variety of sites to fulfill the core competencies of the residency (ie, biostatistics/epidemiology, health care management and administration, clinical preventive medicine, occupational/environmental health). The rotation sites have ranged from industry to academia to government (local, state, federal, and international) and include hospitals, managed care organizations, health departments, nongovernmental organizations, community-based organizations, pharmaceutical companies, and consulting firms. The following are examples of recent resident rotation sites:

World Health Organization

Pan American Health Organization

Centers for Medicare and Medicaid Services

Food and Drug Administration

Office of the National Coordinator on Health Information Technology

Office of the Surgeon General
 Agency for Healthcare Research
 and Quality
 Maryland State Health Department
 Maryland General Assembly
 Baltimore City Health Department
 Capitol Hill
 GlaxoSmithKline
 Booz Allen
 Discovery Channel
 The Dr. Oz Show

Until recently, the GPMR Program had no formal requirements for direct patient care in the hospital or in any outpatient setting. This policy changed as of July 1, 2011, when new ACGME requirements for PM went into effect. PM residents now are required to have a minimum of 2 months of direct patient care during each year of their residency (Figure 1).²

We sought to implement this patient care experience in an innovative way, keeping in mind 3 critical goals:

- (1) Provide value to the GPMR residents, the Johns Hopkins health care system, and our patients
- (2) Focus on prevention/chronic care rather than acute care (eg, counseling individuals on health promoting behaviors such as diet, exercise, and tobacco use)
- (3) Leverage our training in both clinical medicine and population health.

To meet these requirements while accomplishing our goals, we created a

Figure 1. ACGME Program Requirements for Graduate Medical Education in Preventive Medicine

ACGME Program Requirements for Graduate Medical Education in Preventive Medicine

Effective July 1, 2011

IV.A.6. Curriculum Organization and Resident Experiences

IV.A.6.a.(2) Residents must have educational experiences within a patient care environment that address direct clinical issues relevant to their area of concentration.

IV.A.6.a.(2).(a) Each resident must have progressive responsibility for direct patient care.

IV.A.6.a.(2).(b) Each resident must have progressive responsibility for the management of health and provision of health care for a defined population, as specified for their area of preventive medicine.

IV.A.6.d.(2) Residents must have a minimum of two months of direct patient care experience during each year of the program.

Source: Preventive Medicine Residency Review Committee. Preventive Medicine Program Requirements. http://www.acgme.org/acWebsite/downloads/RRC_progReq/380_preventive_medicine_PRs_07012011.pdf. Accessed September 18, 2011.

new curriculum (clinical program) that will expose residents to the different ways preventive care can be delivered and integrated throughout an entire health care system.

Beginning in September 2011, GPMR residents will spend one half day per week for 2 years in a Johns Hopkins Community Physicians (JHCP) clinic, the primary care outpatient clinics at Johns Hopkins. Residents also will work with Johns Hopkins HealthCare, the health plan of Johns Hopkins that administers health care services across several different product lines. Through didactic sessions, online modules, and working directly with physicians, health coaches/educators, and care managers, residents will learn how to assess disease risk, practice evidence-based behavioral counseling and risk factor reduction, apply shared decision-making strategies to generate self-management tools for patients, set up collaborative referrals

to health care professionals, and utilize team-based management skills for lifestyle-related conditions.

Residents also will learn about broader concepts of health care delivery and population management such as Patient-Centered Medical Homes (PCMHs), Accountable Care Organizations, meaningful use of electronic health records, disease registries, and performance measurement/outcomes evaluation (eg, utilizing health risk assessments and administrative, pharmacy, and laboratory claims data). Residents will spend a portion of their time seeing patients and providing preventive care, and a portion of their time working on projects to improve safety, quality, population management, and/or operations in a JHCP clinic, multiple clinics, or across the entire Hopkins health care system. Some residents will work in a National Committee for Quality Assurance-recognized PCMH.

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Indeed, the landscape of medicine is changing and, at Johns Hopkins, we want to be ahead of the curve. We used the new ACGME requirements as an opportunity to create a new model that better integrates preventive medicine into patient care. We wanted this new model to provide value for the residents, value for the Johns Hopkins health care system, and above all, value for the many patients through our planned interactions. We believe this new model does that because of its

focus on promoting healthy behaviors through preventive care at multiple levels of the health care system.

We look forward to sharing our experiences in the future and welcome questions and feedback from readers.

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References

1. Johns Hopkins General Preventive Medicine Residency Program. Mission statement. <http://www.jhsph.edu/gpmr/mission.html>. Accessed October 31, 2011.
2. Preventive Medicine Residency Review Committee. Preventive Medicine Program Requirements. http://www.acgme.org/acWebsite/downloads/RRC_progReq/380_preventive_medicine_PRs_07012011.pdf. Accessed September 18, 2011.

Leveraging Electronic Health Records in Comparative Effectiveness Research

By Andrew Masica, MD, MSCI and Ashley Collinworth, MPH

Comparative Effectiveness Research (CER) has been identified as a key component of US health care reform. The Institute of Medicine defines CER as “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 delivery of care” for the purpose of allowing “consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”¹

CER ultimately seeks to provide pragmatic knowledge that can be applied toward delivering “the right treatment to the right patient at the right time.”² Achieving this goal in a complex health care environment will require robust, accessible data sources capable of providing detailed patient-level information in a time- and cost-efficient fashion. Electronic health records (EHRs) are well suited to fill that need, but current technical aspects and methodologies of using these

systems as research tools are at an early stage of development.

The Federal Coordinating Council for CER (established by the American Recovery and Reinvestment Act of 2009, which also included a \$1.1 billion appropriation for CER) advocated a strategic framework² that reflects the importance of EHRs in the CER enterprise. As shown in Table 1,

the core components of CER outlined by the Council are strongly influenced and enhanced by EHRs, particularly those with functionalities that allow interoperability and data exchange.

EHRs also help address the disconnection between the vast amount of health care data that are available and our ability to access and organize those data in a way that is meaningful

Table 1. Relationships between the Comparative Effectiveness Research (CER) Strategic Framework and Electronic Health Records (EHRs)

CER Activity/Investment	EHR Support of Activity/Investment
Research Content	<ul style="list-style-type: none"> • End product of investigators applying EHRs effectively • Accelerated research production time frame
Human and Scientific Capital	<ul style="list-style-type: none"> • Human resources to extract and configure electronic data • EHR appropriate study design and analysis methodologies • Hardware/software that facilitates research
Data Infrastructure	<ul style="list-style-type: none"> • Longitudinal patient registries • Development of distributive data networks
Dissemination and Translation	<ul style="list-style-type: none"> • Clinical decision support embedded into EHR workflows

for CER. More than ever before, health care is “information rich,” as interactions between clinicians and patients produce a myriad of data points including diagnoses, laboratory results, images, interventions, and responses to treatments.³

Historically, it has been difficult to use data collected as a part of routine patient care to perform research efficiently because the material of interest often was buried in paper charts or archived records and scattered across the siloed care sites. This incongruity has hampered the development of evidence to determine which intervention(s) works best for individual patients. EHRs offer a potential mechanism to identify and compile relevant clinical information for the full spectrum of patients across the continuum of care, to structure that data, and to enable appropriate comparisons of treatments from a single source.

Until the recent movement toward widespread EHR implementation, the type of original research (excluding systematic literature reviews) that would satisfy criteria as a CER study would necessitate undertaking a clinical trial, conducting costly and time-consuming manual audits of paper charts, or relying on administrative data, which may be inaccurate and lacking in granular clinical information.

Although randomized controlled trials (RCTs) have long been considered the gold standard for comparing efficacy, these types of studies are performed in highly controlled environments in which patients are selected based on strict inclusion criteria and in which treatment adherence is closely

monitored. Research regulations, study logistics, and negative perceptions of research in certain populations often make it difficult or impossible to include certain subgroups (eg, children, pregnant women, the elderly, minorities, people with multiple chronic conditions, those with rare diseases) in clinical trials.⁴ Thus, the results of RCTs often have limited generalizability to an affected patient population, whereas a central tenet of CER is to determine what works in “real world” settings.⁵ Lastly, RCTs are expensive and cannot be modified easily to include additional patient data over time or account for emerging care improvements.

EHRs also have a clear advantage over purely administrative data sources in retrospective studies, as they contain access to discrete, longitudinal observations (eg, blood pressure measurements, serial laboratory tests) that can be used to strengthen statistical models pertaining to the outcomes of interest.⁶

Early experience using EHRs as tools in CER has shown some promising results,⁷ but methodological and practical challenges must be addressed to leverage these systems to their full potential. Current EHRs are designed for frontline patient care delivery rather than for research. As such, EHR data quality is subject to the idiosyncrasies of daily practice operations (eg, patients skipping appointments with resultant long intervals between observations, variations in provider behavior) and does not match the quality of data garnered from clinical trials.

Likewise, treatment decisions in practice generally are determined by patient- and provider- specific factors rather than randomly, so observational studies

relying on EHR data need analytic techniques that account for confounding.

Another major obstacle in use of EHRs for CER is missing data. This issue stems largely from the relative immaturity of these systems and the recording of information in inaccessible “free text” fields, rendering it essentially lost to the researcher without manual chart review. With the exception of a few early adopter health care delivery organizations, most EHR patient populations have accrued less than 5 years of data. This can reduce the available sample size when retrospectively evaluating the associations between interventions and outcomes in chronic diseases because new user designs (wherein only those patients with an incident disease diagnosis captured in the EHR are eligible for the cohort) are optimal for these types of studies to minimize bias.⁸

Finally, the lack of standardization among vendors has hampered data-sharing efforts between sites. With disparate EHRs, a significant amount of data transformation and configuration are required for systems to exchange information.⁹

Applied solutions to the aforementioned challenges are actively being pursued by the CER and medical informatics communities. With a wide variety of uses, natural language processing (NLP) appears to be an extremely potent tactic to access data trapped in EHR free text fields, and the Agency for Healthcare Research and Quality (AHRQ) currently is funding a grant to create a common NLP platform that can interface with EHR data to conduct CER.¹⁰ Statistical methods, such as propensity scoring and inverse probability weighting,^{11,12} have been

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used successfully to help counter potential confounding in observational studies using EHR data.

The “Meaningful Use of EHRs” incentive program and plans for electronic reporting of Centers for Medicare and Medicaid Services Core measures has heightened the emphasis on standardization of EHR data element specifications, and data-sharing consortiums between systems, intended to support CER, also are developing independently.¹³ Pooling data among multiple sites will resolve sample size problems and facilitate procuring CER information on subgroups.

Given that several federal agencies are sponsoring CER (eg, AHRQ’s Effective Health Care Program, National Institutes of Health, and the recently formed Patient-Centered Outcomes Research Institute) as well as the interests of industry in this area, the pace of innovation surrounding use of EHRs in CER likely will be brisk.

Even though EHRs are viewed as a part of larger systemic changes to drive health care improvements,³ expectations surrounding EHRs in CER must be pragmatic. EHRs should

be promoted as powerful tools that can facilitate CER efficiency rather than as a singular solution. The broad rollout of EHRs across US health care delivery organizations affords a window of opportunity to deploy these systems in a way that will help reach the vision of CER as a valuable resource for informed health care decision making.

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References

- Institute of Medicine of the National Academies. *Initial National Priorities for Comparative Effectiveness Research*. Washington, DC: Institute of Medicine; 2009.
- Federal Coordinating Council for Comparative Effectiveness Research. Report to the President and Congress. <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>. Accessed September 17, 2011.
- D’Avolio LW, Farwell WR, Fiore LD. Comparative effectiveness research and medical informatics. *Am J Med*. 2010;123(12 suppl 1):e32-e37.
- Etheredge LM. Creating a high-performance system for comparative effectiveness research. *Health Aff (Millwood)*. 2010;29(10):1761-1767.
- Slutsky JR, Clancy CM. Patient-centered comparative effectiveness research: essential for high-quality care. *Arch Intern Med*. 2010;170(5):403-404.
- Sullivan P, Goldmann D. The promise of comparative effectiveness research. *JAMA*. 2011;305(4):400-401.
- Pace WD, Cifuentes M, Valuck RJ, Staton EW, Brandt EC, West DR. An electronic practice-based network for observational comparative effectiveness research. *Ann Intern Med*. 2009;151(5):338-340.
- Ray WA. Evaluating medication effects outside of clinical trials: new-user designs. *Am J Epidemiol*. 2003;158(9):915-920.
- Kudyakov R, Bowen J, Ewen E, et al. Electronic health record use to classify patients with newly diagnosed versus preexisting type 2 diabetes: infrastructure for comparative effectiveness and population health management. *Popul Health Manag*. Epub ahead of print August 31, 2011.
- Agency for Healthcare Research and Quality Grants On-line Database. Grant Summary: Enhancing Clinical Effectiveness Research with Natural L. http://gold.ahrq.gov/projectsearch/grant_summary.jsp?grant=R01+HS19828-01. Accessed September 17, 2011.
- Toh S, García Rodríguez LA, Hernán MA. Confounding adjustment via a semi-automated high-dimensional propensity score algorithm: an application to electronic medical records. *Pharmacoepidemiol Drug Saf*. 2011;20(8):849-857.
- Curtis LH, Hammill BG, Eisenstein EL, Kramer JM, Anstrom KJ. Using inverse probability-weighted estimators in comparative effectiveness analyses with observational databases. *Med Care*. 2007;45(10 suppl 2):S103-S107.
- Dartmouth-Hitchcock. High value healthcare collaborative expands. <http://www.dartmouth-hitchcock.org/news/newsdetail/59724/>. Accessed September 17, 2011.

Key Health Reform Web Sites

Starting in 2010 and continuing through 2014, the Affordable Care Act will be implemented, increasing access to affordable health care for individuals, families, seniors, and businesses. The following links to time lines illustrate implementation of the legislation.

<http://www.whitehouse.gov/healthreform/timeline>

The implementation time line below from the Kaiser Family Foundation is an interactive tool designed to explain how and when the provisions of the health reform law will be implemented over the next several years.

<http://healthreform.kff.org/timeline.aspx>

Electronic Health Record Incentive Program

The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs will provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals as they adopt, implement, upgrade, or demonstrate meaningful use of certified EHR technology.

<http://www.cms.gov/ehrincentiveprograms/>

Medicare Shared Savings Program

The Medicare Shared Savings Program provides incentives for participating health care providers who agree to work together and become accountable for coordinating care for patients. Providers who band together through this model and who meet certain quality standards based upon, among other measures, patient outcomes and care coordination among the provider team, may share in the savings they achieve for the Medicare program. The higher the quality of care providers deliver, the more shared savings the providers may keep.

https://www.cms.gov/sharedsavingsprogram/05_News.asp

