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Comparative Effectiveness Research: The Next Big Thing?

By Tony Schueth, Editor-in-Chief

What is the next big thing in health care? There are a lot of candidates out there jockeying for position. We believe a dark horse emerging from the pack is comparative effectiveness research (CER), which will significantly raise the bar in how we define and measure quality and translate research into practice. Results will likely be used to inform payment and coverage decisions for procedures, drugs and devices. Electronic medical records (EMRs) and health information exchanges (HIEs) will provide the necessary data. In short, CER will be a high-stakes game for all stakeholders.

CER is not necessarily new. The public and private sectors for years have been investigating what is being done in health care, how much it costs, what works and what is safe. The results are not necessarily pretty. For example, there is substantial evidence that costs and practice patterns vary significantly across the country; extrapolating from that, researchers believe that as much as 30% of spending reflect medical care of uncertain or questionable value. We all know that the nation's growing, multibillion-dollar health care tab is unsustainable.

CER represents a new way of thinking and doing business. According to the Kaiser Family Foundation, traditional clinical research typically examines the effectiveness of one method, product or service at a time. Comparative effectiveness research compares two or more different methods for preventing, diagnosing and treating health conditions to determine their clinical effectiveness and, potentially, their cost-effectiveness for different populations and subpopulations. Outcomes will be evaluated using a variety of methods for obtaining and analyzing data. Findings will be disseminated so patients, payers and providers can make informed decisions based on compelling evidence. The expectation is CER will ultimately "bend the health care curve" by improving the quality and outcomes of care, reducing costs and creating value.

CER is important on many fronts, not the least of which is the significant amount of money that is now available. The American Recovery and Reinvestment Act (ARRA) included $1.1 billion in CER funding to be divided among the National Institutes of Health, the Agency for Healthcare Quality and Research, and the Department of Health and Human Services (HHS). ARRA also established the Federal Coordinating Council for Comparative Effectiveness Research (composed of federal officials), and required that HHS consider recommendations on CER priorities from both the coordinating council and the Institute of Medicine (IOM). CER also received a second cash infusion through the recent health reform legislation. The new law created the nonprofit Patient-Centered Outcomes Research Institute and the Patient-Centered Outcomes Research Trust Fund. The latter includes appropriations of $10 million for fiscal 2010, $50 million for fiscal 2011 and $150 million for fiscal 2012.

Of course, the devil is in the details for implementation. There are many unknowns that have not yet been defined, particularly the level of detail in CER measurement programs. For example, will the statin class of drugs be compared against a medical device or against each other and generics? However, we do know CER will impact on various stakeholders. Even from the get-go, we see the following:

• Pharma is likely to be significantly impacted by CER. Brand-to-brand comparisons will be easier and quicker. Results could spell either the rapid demise for lucrative products shown to be more expensive and less therapeutically effective than competitors' offerings or an increase in script writing for a particular brand if it is proven to be clinically advantageous to other therapies. Companies will be pressured to differentiate their products in various ways. CER will accelerate clinical trials management and alter interactions with relevant federal agencies. There is likely to be an increase in use of patient data registries focused on measuring clinical effectiveness and an increase in phase 4 observational trials. Certain biologics may be first to come under the CER microscope, based on recommendations last summer from the IOM.
• Payers will likely act on CER results to hold down costs. For example, if a branded drug does not appear to offer much benefit over a generic, there will be a push to cover that generic.
• CER will shorten timeframes and change the methods under which clinical trials and related studies are conducted. This is in contrast with the current system, in which prospective trials take too long, cost too much and results are obsolete before they are even known due to the pace of technological change.
• CER will more quickly provide the FDA better data for post-marketing surveillance and patient tracking and safety issues will be identified more rapidly. CER results will undoubtedly arm the FDA with information that can

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change the pace and depth of subsequent regulatory requirements for drugs, devices and procedures.
• Providers may not welcome this kind of research, worrying about such issues as clinical autonomy and potential loss of revenue from the rapid eclipse of lucrative treatments. Clinicians often are skeptical of research findings, which are not always clear-cut and compelling. Some view them as simply a vehicle to save payers money, and not provide optimal care to patients. Moreover, today's "gold standard" may be discredited or overtaken by events within five years. This has business model and malpractice implications for practitioners who do not change. On the other hand, CER holds promise for giving providers better information to make more informed clinical decisions quicker and avoid treatments that are of low value or not reimbursable.
• CER may accelerate HIT adoption, particularly for EMRs that will be the primary data sources for the research. There will be pressure on HIT vendors to create different functionalities in their products to meet the specific requirements of CER. Agreements among HIT vendors will be required to support data interoperability and effectively measure all patient interactions with the health care system. Operationalizing this could pose numerous challenges.
• HIEs and the National Health Information Network will become the new superhighways for data that fuel the CER engine. However, there will be myriad of related privacy and security concerns, as well as interoperability issues.
• No patient wants to be subjected to products or treatments that have not been proven or which provide less than optimal results. Having better information about what works best, what costs the least and what is safest will allow patients a more informed voice in their care and facilitate their engagement in the process. However, both patients and providers will need help in identifying and interpreting the available evidence from CER and factoring that into treatment options. It is likely that the use of personal health records that link to provider EMR systems can be an effective tool in providing patients with information to guide their discussions with their treating provider.

To be sure, there are many uncertainties about how CER can be best implemented. It is a confusing overlay on top of the voluminous requirements of ARRA. With the previously mentioned unknowns in how CER will be implemented, those stakeholders who are helping to lead the initiative to provide clarity and definition around CER will be best positioned to benefit from the final CER program definitions. Since HIT will be an instrumental component of CER measurement, organizations that understand the HIT landscape and prepared to contribute to how HIT will influence CER measurement will be advantaged.

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What's Hot in HIT?

Can You Hear Me Yet? Mobile Health Turns up the Volume

By Ed Daniels, Contributing Editor

Everyone is looking for the next "killer app." Certainly, Apple and Google have found a platform for it in the iPhone- and Android-based smart phones. Aside from changing how and when we all do our personal business, these new technologies are rapidly becoming drivers that are radically changing how we access and use health information technology (HIT).

The reason is that mobile-powered health applications, broadly termed " mHealth," are connecting the dots between HIT applications and stakeholders, particularly with patients. Just like in our personal lives, mobile health-oriented applications support wireless voice, text and e-mail communication at any time and in any location. There is interoperability with other mobile and non-mobile systems and connectivity to the Internet. But there's more—much, much more.

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n fact, mobile functionalities can be leveraged in the health care space to facilitate what Point-of-Care Partners (POCP) calls **Participatory Health.** This new paradigm coordinates the roles of all health care stakeholders – patients, providers, payers, public health agencies, pharmaceutical companies, and others – to support the patient. It shifts the central focus to and encourages the patient to be an active participant in his/her own care. Mobile technologies facilitate this new paradigm by providing real-time information among the stakeholders.

The notion that doctors and patients only communicate when the patient visits the doctor is becoming less common. Communication patterns among patients, clinicians, health plans, pharmacists and other health care providers will change rapidly. Americans are adopting more sophisticated devices and using health-oriented apps more frequently. For example, research shows that patients increasingly are using the Internet from their mobile devices to help them take immediate action on medical issues. This behavior differs from use of desktop access, by which people conduct more general research on medical conditions.

mHealth applications can help patients track their conditions and progress, monitor their medication compliance and communicate with physicians. Providers are beginning to use mobile devices to schedule visits, answer questions and electronically prescribe medications.

Health plans are using mHealth functions to better serve members. Using their mobile phones, members can connect to their insurers to search for a doctor, dentist or facility. Members also can buy insurance, view claims and peruse their personal health record. Our more innovative health insurance clients are starting to invest in this area.

More developments are also coming on the clinical side. Network carriers and application providers are linking up to give providers real-time access to a wide range of data. For example, physicians working with a mHealth provider through the Sprint network can view images and charts, including ECGs, CT scans and x-rays, directly from their mobile device. Cardiologists are alerted through their Blackberry devices. Ambulances transmit ECG data to the hospital and directly to the doctor's Blackberry.

The bottom line is that mHealth is turning up the volume and becoming a driving force in HIT adoption. The app store movement has caught fire with huge, growing consumer interest. To be sure, there are issues. For example, interfacing and interoperating with other systems is complex and risky due to errors, network limitations and security issues. However, these issues are not insurmountable and there's an added value: resolving these issues in mHealth can help solve similar issues with other applications.

POCP is closely tracking the mHealth movement, which is still in its infancy but is one of the fastest-growing segments in the health care space. We can identify new developments, applications and vendor solutions, such as niche solutions and health care verticals, which can be transformed into enterprise solutions. Because of our in-depth understanding of this volatile space, we can provide clients with custom market analysis and strategic planning. Call us or drop us a line.

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Avoiding a REC Reckoning

By David S. Green, Contributing Editor

The new regional extension centers (RECs) provide an exciting opportunity to accelerate adoption of electronic health records (EHRs) in the United States. These are new entities created through a $598 million provision in the American Recovery and Reinvestment Act. Point-of-Care Partners (POCP) offers strategic advice and management support to RECs as well as to EHR vendors, pharmaceutical companies and other organizations seeking to effectively interact with RECs. We have a few thoughts on what RECs can do that will determine whether they succeed or face an ugly reckoning.

POCP believes RECs can help correct the historically weak rate of EHR adoption in the US. In our opinion, there is no excuse for the fact that while 98% of primary care physicians (PCPs) in Denmark use EHRs, EHR adoption among PCPs in the US has only recently crept up to 28%. If RECs can achieve their goal of 100,000 providers becoming meaningful users of EHRs by 2011, the $598 million investment will have been well spent. However, there is a dark side looming that RECs need to avoid. According to our math, 100,000 providers at an average EHR cost of $45,000 per provider translate to $4.5 billion in EHR-related buying decisions. These, in turn, will be intentionally and strongly influenced by the RECs. That is a lot of money, and it means that RECs are already and will continue to be swarmed with all kinds of attempts to influence their recommendations. We won't go into the details of what is happening in this article, but the potential for illegitimate influence is significant. What should be done about it? If you are an REC manager interacting with vendors, you need to follow the "60 Minutes Rule," which is, "if my actions and conversations were revealed in detail in the blogosphere or on TV, I would be able to comfortably explain and defend my policies and behavior and that of my staff."

The Office of the National Coordinator for Health Information Technology (ONC), which is funding and overseeing all of this, believes your REC should "help providers select the highest-value option — the option that offers the greatest opportunity to achieve and maintain meaningful use of EHRs and improved quality of care at the most favorable cost of ownership and operation, including both the initial acquisition of the technology, cost of implementation and ongoing maintenance and predictable needed upgrades over time." ONC also notes that RECs should "offer unbiased advice on the systems and services best suited to enable the priority primary care providers to become meaningful users of EHRs. Regional centers will avoid entering into business arrangements creating an actual or apparent conflict of interest."

That's a great statement, but in the next breath ONC states that federal funding isn't going to be enough and partnerships with private industry will be needed to ensure sustainability. That means RECs need to derive revenue from their partners but still avoid conflicts – a challenge for even the most well-intentioned REC manager.

If you are an honest, well-intentioned REC manager, how do you objectively select from among the 300+ EHR vendors and at the same time create a revenue stream that will make your organization sustainable in the long term? How do you do this while avoiding even the appearance of back-room dealing, financial kickbacks and unfair influence?

Based on our interactions with several RECs and many more EHR vendors and consultants who would like to be given a fair opportunity, here are some specific suggestions:

1. Establish a public comment period and solicit a wide range of input regarding your EHR selection criteria. Request input via your Web site along with other means.
2. Consider this input as you develop your selection criteria. Once finalized, post the criteria on your Web site.
3. Solicit proposals from the broadest possible range of EHR vendors.
4. Make your selection of a "short list" of recommended vendors in a systematic, objective manner using your criteria and the "60 Minutes Rule."
5. Make your short list public on your Web site. Include a structured process for dealing with appeals from vendors that have not been selected. Include a place where vendors that would like to be considered in the next cycle can ask to be included.
6. Establish a periodic review process by which new vendors can be considered and existing vendors are subject to replacement.

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We believe that with an open process like this, vendors, providers and state and local governments will develop faith and trust in RECs as fair and trusted advisors. Once this happens, RECs will be able to take their place as collaborative participants in the drive toward quality improvement throughout our health care system.

eMedication Management

Judgment Day for ePrescribing of Controlled Substances

June 1 is the go-live date for ePrescribing of controlled substances, according to the new rules just created by the Drug Enforcement Administration (DEA). We are closely monitoring its implementation. Preliminary reports indicate that things may get off the ground slowly. Few vendors appear to be able to meet the new, specific requirements, although we believe that eRx Network and DrFirst will be heavily advantaged due to their participation in a recent pilot program. One of the biggest barriers is uncertainty regarding credentialing entities for non-institutional providers. To date, we have seen virtually no movement in this area. Who will be stepping up to perform similar vetting for ePrescribing hardware and software is unknown because criteria and processes are still being sorted out at the federal level. Stay tuned.

Company News

POCP Launches New Web Site

Point-of-Care Partners (POCP) is pleased to announce the launch of its new Web site. In addition to presenting an updated and more attractive picture of POCP, we have updated some sections to provide more information about us. For example, the grey box on the upper right-hand corner of the Web site highlights five of our main customer groups. When you click on that hyperlink, you not only see a description of what we generally do for those companies, we also provide a list of case studies that provide details on the situation, solution and results. We have also updated the "Our Team" summary information and respective team bios to highlight some of the projects different team members are working on. Check it out and let us know what you think: www.pocp.com.