

# 2011 FALL IDN SUMMIT

## PEER-TO-PEER LEARNING EXCHANGE RESEARCH REPORT

### Comparative Effectiveness Research and Healthcare Value

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## Introduction

A unifying theme in the Accountable Care Act of 2010 is that in order to achieve the goal of patient-centered, cost-effective care, the payment system must reward the value of healthcare services delivered, not the volume. Value is an undercurrent in each of the new programs created by the reform law, including value-based purchasing, accountable care organizations, medical homes and bundled payments.

Add to those changes the reform law's planned \$155 billion in cuts to hospital payments and mounting pressure on reimbursement coming as a result of the deficit reduction law approved by Congress in August 2011, and it is clear that hospitals and healthcare systems must start looking seriously at every avenue to rein in costs and charges for care.

To achieve that end, hospital leaders, supply chain professionals and value analysis teams need better scientific evidence to help guide future spending decisions for medical devices, physician preference items and drugs. They also need to be able to effectively evaluate differing approaches to care for each condition, such as surgery versus drug therapy.

It is a daunting challenge. For a variety of reasons, clinical evidence may not be utilized as the principal foundation of treatment choices and other healthcare decisions made by hospital administrators, physicians and patients. And despite a century's worth of scientific and technological advances in medicine, there is only limited clinical evidence to rely on.

"We have 6,000 drugs, 4,000 medical and surgical procedures and 13,600 possible diagnoses that can be brought to bear on medical cases. No industry in the world has had the challenge of being able to deliver that level of services efficiently," Atul Gawande, MD, a surgeon at Brigham and Women's Hospital in Boston, a Harvard Medical School professor and author of the book *The Checklist Manifesto*, told the American Hospital Association's leadership meeting in July.

New medical technologies, often dispersed after little study, are an important driver of increased healthcare costs. One example: robotic surgery is now in widespread use despite the absence of robust, conclusive evidence supporting its clinical superiority compared with far less expensive laparoscopic/endoscopic approaches.

Healthcare Reform and earlier legislation address the need to establish a firmer scientific basis for determining the clinical value and cost-benefit of devices, drugs and interventions through comparative effectiveness research (CER). This approach is designed to help determine if a medical technology works and is safe; how well it compares to other approaches; how it is best used; and, ultimately, its clinical value as established by well-designed clinical trials.

## How Comparative Effectiveness Compares

Most clinical research is still focused on whether a medical device is safe, or how a drug compares with a placebo or, at best, against a competing drug. Rarely is a drug therapy compared to other types of interventions, such as surgery. There is even less evidence about whether expensive, new medical devices are really better than what is already on the market.

Drugs and devices are regulated by the Food and Drug Administration before market entry, but surgical innovators work with little external oversight and few regulatory requirements for evidence collection before disseminating new procedures. Some procedures and services undergo evaluation by the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel to obtain a dedicated code for insurance billing purposes. In other cases, providers elect to submit claims under an existing CPT code for a similar service. Payers say it can be difficult to detect when a clinically significant new variation of a diagnostic test or clinical procedure enters the market.

In a white paper titled, "The Value of Evidence," Winifred S. Hayes, PhD, president and CEO of health technology research and consulting firm Hayes, Inc., and Susan A. Levine, DVM, PhD, senior vice president for health technology research at Hayes, write that examples abound regarding the premature adoption of health technologies that ultimately prove to be not only ineffective, but also harmful.

According to the paper, examples of technologies that were adopted into practice without sufficient evidence and that caused serious harm to patients, including death, are:

- High-dose chemotherapy and bone marrow/stem cell transplant for advanced breast cancer, which did not make patients live longer and had more serious side effects than standard-dose chemotherapy.
- The arthritis drug Vioxx, which was linked to increased risk of heart attack and sudden cardiac death and later withdrawn from the market.
- Bone morphogenetic protein, which has been widely used in spinal fusions but now appears to cause abnormal bone growth, leg pain, increased risk of infection and in men, risk of sterility.

There are a few examples of change in procedure following long-term, large scale clinical trials. The use of hormone replacement therapy in post-menopausal women, for example, dropped dramatically after evidence of its adverse effects was released. But such instances are rare exceptions to the rule.

That should change dramatically as a result of governmental action. The Agency for Healthcare Research and Quality (AHRQ) was established in 2003 in part to conduct evaluations on comparative effectiveness of products and services. In 2009, the Obama Administration's economic stimulus package allocated \$1.1 billion for CER, particularly alternative treatments for the same disease. Then, the Affordable Care Act authorized creation of the nonprofit Patient-Centered Outcomes Research Institute (PCORI) to identify comparative effectiveness research priorities, establish a research agenda, adopt methodological standards and administer a federal trust fund dedicated to CER.

PCORI is really just getting started, with its first executive director, Dr. Joe V. Selby, MD, MPH, formerly director of research at Kaiser Permanente. Its grants and contracts are to begin in September 2011. Taking into account AHRQ, the National Institutes for Health and PCORI, estimates are that \$210 million in grant money for CER will be available through the end of 2012.

One of the challenges for PCORI is simply to clarify what treatments are in development or use. An effort like this, such as the planned "registry of registries" proposed by AHRQ, would help ensure that CER evaluations of alternative therapies do not systematically omit some interventions and that all relevant therapies are evaluated. Such a registry could help mitigate claims, for example, by proponents of surgical treatments for a condition that their approach would have been found just as effective if it had been included in the study.

Another challenge is to define a valid clinical trial and good science in CER. Study design, sample size, appropriate patient population, study execution, data reporting, use of statistics and ability to replicate the study are key. Adequate study controls are essential to exclude confounding variables, prevent unintentional bias and allow evaluation of the actual impact of the health technology that is the focus of the study.

Finally, evidence, once established, has to be translated into best practices, especially for approaches to managing the most costly and most common diseases, such as congestive heart failure, acute myocardial infarction and diabetes.

### **ACOs and Value-based Purchasing**

One of the biggest drivers of CER is the development of accountable care organizations (ACOs), networks of care providers, suppliers and, sometimes, private insurers that share responsibility for providing and coordinating care to Medicare fee-for-service beneficiaries. Under the new law, an ACO would agree to manage the healthcare needs of a minimum of 5,000 Medicare beneficiaries for at least three years. The idea is that physicians and hospitals will work together to coordinate care for patients, avoiding unnecessary tests and procedures while cutting costs and improving quality.

To achieve these goals, ACOs are required to implement evidence-based medicine, or clinical practice guidelines and processes. The guidelines and processes must cover diagnoses with "significant potential" for the ACO to achieve quality and cost improvements, taking into account the circumstances of individual beneficiaries. All ACO participants and suppliers/providers must agree to abide by these guidelines and processes, and will be evaluated for their compliance.

Healthcare Reform mandates that ACOs must be able to show that the procedures they use are based on comparative data, which is where CER comes into play.

Other aspects of reform will also advance the use of CER. As just one example of many, the Obama Administration has now finalized a new measure of hospital performance called "Medicare spending per beneficiary" that will soon become part of the Hospital Inpatient Value Based Purchasing Program. Hospitals are to be held accountable not only for the cost of the care they provide, but also for the cost of services performed by doctors and other health care providers in the 30 days after a Medicare patient leaves the hospital. If a hospital's costs are out of line with national averages, its payments will be reduced for all charges submitted to Medicare. Numerous studies have documented widespread variability in costs of care, even with common surgical procedures such as stent implantation. Whether or not ACOs are the model of care that eventually wins out, it is clear that the federal government is moving toward pay for performance and wants to see evidence used to guide clinical pathways.

### **Limits of Use**

A 2010 study by the National Institute for Health Care Reform found concerns among health services researchers and clinicians about whether providers using CER to make treatment decisions will be able to wade through all the ambiguity. Specifically, it states, "They may not know whether previous CER study results remain relevant, particularly if a new product with competing claims has entered the market. They may doubt whether the CER findings based on early use of a treatment truly apply to particular clinicians or facilities with extensive experience in more recent refinements. They may wonder whether the findings apply only to the specific disease stage and patient population described in the study or can be extrapolated to a broader range of clinical indications and patients."

That finding points out the need to quickly disseminate updated findings to clinicians and physicians, likely through a nationally interconnected health information system.

The study also found concern that strict adherence to CER could hinder innovation. "Comparative effectiveness research guidance will not be issued in the form of revealed truths. The findings of CER studies likely will raise as many questions as they answer, and their results will be open to constant questioning and reinterpretation. As one health services researcher said, 'I've been involved

in health services research for 35 years, and the more I do the humbler I get. I think there's a sense out there that the answers are hidden. They maybe have to be dug out, but when we get them, we've got them. The world doesn't work that way.' ”

The Accountable Care Act took pains to ensure that risks to innovation from CER are minimized. For example, the law explicitly bars the PCORI from mandating coverage, reimbursement or other policies for any public or private payer. And, the institute is specifically directed to ensure that “research findings not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations.”

## **Resistance to Change**

In many ways, comparative effectiveness research flies in the face of almost every prevailing trend in healthcare – to date, of course. Americans love the latest and greatest devices, including robotic surgery, proton beam therapy, the newest CT scanners, MRIs when X-rays would do – you name it.

Consumers are easily influenced by simplistic and misleading ad campaigns, and go into hospitals and medical practices to demand full body imaging even when evidence mounts that it doesn't increase the number of treatable tumors discovered.

Many physicians and clinicians have a lack of understanding about what constitutes high-quality evidence, and there is insufficient knowledge about how to apply evidence to healthcare decision making. Physicians are used to calling the shots and deride evidence-based practice as “cookbook medicine.” There are tests ordered on a huge scale solely to help prevent lawsuits. And there continue to be conflicts of interest among physicians, some of whom take benefit financially or otherwise from device-makers and pharmaceutical manufacturers, doing little in return except to use the products in their practices.

There are some solutions to this resistance. Widespread information on CER will be made available to providers and patients through the work of a number of government and private sector organizations. “Improving the infrastructure to collect and share data to the point where providers can submit data passively, without additional effort, can help payers and researchers gather more information about innovative therapies without limiting patients' access,” according to the National Coalition for Health Care Reform. “For example, data warehouses that collect information from multiple electronic health records could become repositories of tremendously valuable research data. Such approaches will need to address patients' privacy concerns in a meaningful way because many will be uncomfortable with the idea of their health care data being used in research.”

## **Role of the Supply Chain**

The healthcare supply chain has a pivotal role, both as gatekeeper and facilitator, in new technology acquisition, utilization and dissemination. With the kind of stresses about to be placed on reimbursement, the supply chain department should gain new muscle in working with physicians to find ways to hold down the costs of medical devices. The top health system leadership must make it clear that supply chain leaders have the full support of the C-suite in this endeavor.

Unfortunately, there is not a lot of expertise at the hospital level among supply chain leaders on how to gather and critique available scientific evidence. The large, integrated systems, such as Kaiser Permanente, Intermountain Healthcare and Geisinger Health System, have departments staffed by top experts who evaluate current CER on an ongoing basis. The large group purchasing organizations provide technology assessment, and consulting and research firms such as Hayes have a long history of providing hospital clients with detailed analyses of clinical evidence of competing technologies. Still, evidence-based cost-benefit analyses are few and far between in the private sector.

And the job is getting even more complex. In a white paper on comparative effectiveness, medical editor Josh Feldstein and Elizabeth Brooks, PhD, of the MarCom Group International, write, “To meet the need for a tool for evaluating the value of different medical devices and pharmaceuticals, economists have proposed development of highly rigorous economic models, known as value analysis models or VAMs. These models, which can be customized for different audiences, allow comparative data to be reviewed by key stakeholders. Ideally, independent teams of expert health economists are engaged by a pharmaceutical or medical device firm to generate comparative product analytics and VAMs in a hands-off manner. Such VAMs are then litmus-tested via a peer-reviewed process to validate their objectivity. Increasingly, leading-edge health economics firms are slowly emerging capable of providing these critically important services. Over the coming year or two, this area will grow and VAMs will become increasingly available.”

For supply chain professionals, VAMs provide the underpinnings for value-based purchasing as a means of improving a facility's bottom-line performance while enhancing patient care. VAMs should look well beyond the purchase price or cost of an individual item, Feldstein and Brooks assert. With the focus on accountable care across the continuum, a health system must determine the way costs are incurred over an entire episode of patient care and whether and how these costs can be attributed to specific products. “VAMs allow assessment of a wide variety of variables that affect patient outcomes and cost, such as (but not limited to) duration of hospital stay, risk of infection, operating room time, nursing time, complication and AE rates, switching costs, etc. – in short, the entire scope of a product's impact.”

This model has promise, but hospitals must be wary of influence from manufacturers, even with peer review. The key to these comparisons is first determining whether the competing technologies are clinically equivalent.

## A HEALTH SYSTEM CASE STUDY

Freeman Health System, a 404-bed, three-hospital system in Joplin, Mo., has created a system for analyzing clinical technology purchases that has allowed it to save over \$300,000. Known as the Intranet Supply Utilization Review Process, or iSURP, the program is led by a committee made up of key system stakeholders, including clinicians, physicians, finance, risk management, purchasing, infection control and education. iSURP serves as a gatekeeper for Freeman's supply formulary, ensures that the hospital system stays in compliance with all vendor contracts and measures the cost impact of any new purchasing decisions.

Bob Essner, Freeman's director of materials management, and Estella Ramirez, the clinical coordinator in that department, are tasked with coordinating the flow of information to the committee and ensuring that all appropriate information is available to determine whether or not the product should be added. They create a packet of information for potential new purchases that includes product information, pricing, clinical data and other pertinent information. They also communicate with hospital staff to indicate whether a product has been approved or denied. Added to the packet recently is evidence from clinical trials information that was untainted by manufacturers' hype or physician preference. "We had come to the point where we knew we needed clinical evidence in the review package. We weren't comfortable assuming that the physicians and vendors were always right," Essner says.

Freeman subscribed to the Hayes Knowledge Center, an online source of evidence-based health technology assessment reports from Hayes, Inc. "We are changing our culture to focus on evidence-based outcomes," Essner says. "Mentioning Hayes gets our clinical staff to pay attention to this key change."

### Conclusion

Rising healthcare costs, Healthcare Reform and payment policies in both the public and private sector mean that all stakeholders, from patients to providers to policymakers will have to integrate evidence into decisions about acquiring, using and paying for new health technologies.

According to Hayes, "Making this paradigm shift to evidence-based decision making will require a number of changes, such as: adding evidence evaluation and application to educational curricula; ensuring open and candid discussion about the need for, and the benefits of, an evidence-based approach to healthcare delivery, including consideration of cost-effectiveness; physician leadership in integrating evidence into all models of patient care and educating patients about the practice and value of evidence-based medicine; and the commitment of payers and policymakers to incorporating evidence into policies and guidelines."

There are still big questions remaining, not the least of which is how providers stay afloat financially while making the switch from reimbursement for volume of services to managing the health of populations utilizing a set amount of dollars.

But consider this: according to the Centers for Medicare and Medicaid Services, national health spending is expected to grow 5.8% per year for the period 2010 through 2020, reaching 8.3% in 2014, much higher than the expected gross domestic product. As a result, the healthcare share of the gross domestic product is projected to increase from 17.6% in 2009 to 19.8% by 2020. According to the most recent Medicare trustees report, expenses for Medicare in 2010 were \$523 billion and exceeded program income by \$37 billion.

In other words, every available cost control measure – including comparative effectiveness research – is going to have to be employed if healthcare has any chance of remaining sustainable not just in the long run, but in the very near future.

### Questions for Discussion

1. What are the biggest roadblocks to greater use of comparative effectiveness research in purchasing decisions in your organization?
2. What are the limitations of using data from clinical trials in evaluating surgical procedures versus other kinds of interventions such as drug therapy?
3. Has the threat of even greater Medicare and Medicaid funding reductions helped enhance the power of value analysis teams/supply chain department in influencing purchasing decisions?
4. Will accountable care organizations and other forms of clinical integration drive greater use of clinical research in making purchasing decisions?
5. How can you as a supply chain professional help drive the paradigm shift to integrating clinical evidence into everyday healthcare practices?

## Further reading

- MarCom Group International white paper: Value-Based Purchasing and Comparative Effectiveness Research: Why the Pharmaceutical, Biotechnology, and Medical-Surgical Device Industries Should Embrace the Coming Market Evolution.
- Hayes, Inc. white paper: The Value of Evidence.
- Hayes, Inc. case study: Freeman Health System Drives Culture Change and Significant Cost Avoidance with Hayes Evidence-Based Health Technology Assessments.
- National Institute for Health Care Reform white paper: Comparative Effectiveness Research and Innovation: Policy Options to Foster Medical Advances

## Webinar Held:

### **Comparative Effectiveness Research and Healthcare Value**

Moderated by Winifred Hayes, President & CEO, Hayes Inc

Wednesday, Aug. 24, 2011 2:00 PM EDT

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