

# Looking at CER from the Managed Care Organization Perspective

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## ABSTRACT

**BACKGROUND:** The amount of available comparative effectiveness research (CER) is increasing, giving managed care organizations (MCOs) more information to use in decision making. However, MCOs may not be prepared to integrate this new and voluminous data into their current practices and policies.

**OBJECTIVES:** To describe ways that health care reform will affect MCO populations in the future, to examine examples of how MCOs have utilized CER data in the past, and to identify questions that MCOs will have to address as they integrate CER into future decision making.

**SUMMARY:** Unquestionably, health care reform will change the U.S. market. Millions more insured individuals will be making purchasing decisions. In addition, health care reform will mean more CER data will be available, affecting the decisions MCOs must make. In the past, MCOs may not have used CER as effectively as they could in making formulary and other policy decisions. However, there are examples that show how CER can be integrated effectively, such as Intermountain Healthcare's use of CER to create treatment guidelines, which have been shown to lower costs and improve delivery of care. In the future, MCOs will need to assess their own abilities to utilize CER, including their infrastructure of expertise, hardware, software, and protocols and processes. MCOs will also need to understand how pertinent CER is to their own needs, how it may affect benefit design, and how it will affect their customers' needs.

**CONCLUSION:** Health care reform, and the resultant growth of CER, will have significant impact on MCOs, who will need to invest in better infrastructure and new understandings of a transforming market, changing customer bases, and evolving data.

*J Manag Care Pharm.* 2012;18(4-a):S13-S16

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### What is already known about this subject

- Under health care reform, millions more insured individuals will be making purchasing decisions.
- In the past, managed care organizations (MCOs) may not have used comparative effectiveness research (CER) as effectively as they could in making formulary and other policy decisions.
- Traditionally, MCOs recognized facilities, hospitals, and physicians as stakeholders and involved them in decision-making discussions. Seldom, if ever, have MCOs involved the patient in that process.

### What this article adds

- This article suggests ways in which CER data can be used more effectively, such as in creating treatment guidelines and pathways for providers.
- MCOs will need to assess their own abilities to utilize CER, including their infrastructure of expertise, hardware, software, protocols, and processes.
- To fully utilize CER, MCOs will need to understand how pertinent the available CER is to their own needs, how it may affect benefit design, and how it will affect their customers' needs.
- MCOs must participate in CER discussions and find ways to encourage CER that will produce results useful for decision making.

Since 2009, health care reform has become one of the driving forces behind comparative effectiveness research (CER). Health care reform has also driven other changes in the marketplace, such as additional coverage being added for different treatments, and coverage being extended to people who weren't eligible for care previously. Clearly, we will continue to see changes in the market over the coming years. The challenge is in predicting how consumers and employers will react to those changes, how CER will affect the market, and how managed care organizations (MCOs) will respond to the increase in information.

Before we can understand the role of CER in a reformed market, we need to have some idea of what that market will look like and what the market will want. Figure 1 illustrates a 2009 Kaiser Commission on Medicaid and the Uninsured/Urban Institute analysis showing where U.S. adults aged 19 to 64 years currently obtain health care coverage. The analysis shows 23% of this population is uninsured, 59% obtain coverage through their employer, and 6% are in the private market (nongroup). Medicaid and other public payers make up the remaining 13%.<sup>1</sup>

By 2019 up to 32 million people will gain coverage who have not had coverage before, including large increases in the Medicaid population. The exchanges will enroll previously uninsured individuals, individuals who will lose employer-based coverage or who cannot afford employer-based coverage due to increasing costs, individuals who would otherwise have purchased health insurance in the nongroup private market, and adults above the 138% federal poverty level (FPL) who will lose their Medicaid coverage.<sup>2</sup>

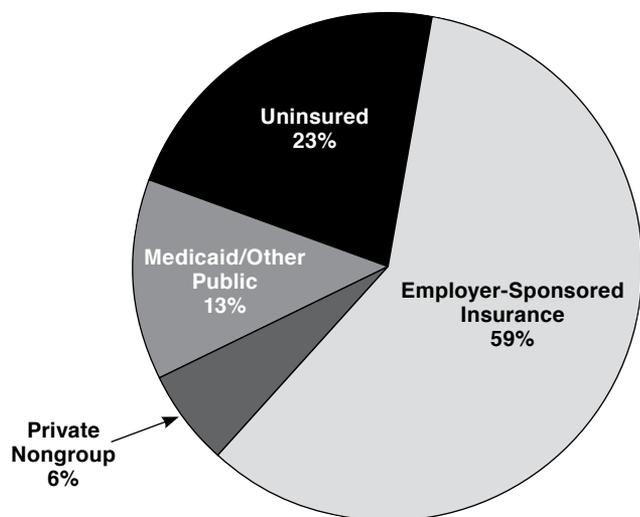
As shown in Figure 2, these estimates indicate that from 2009 to 2019, we will see an increase from 19% to almost 40% of the population making health care decisions who previously were not in the employer market (Medicaid, other public groups, and private nongroups). Another aspect of the changing market is that more groups are giving individuals a choice, even within employer-based plans, where choice may have been more limited in the past.

All of this means we must carefully consider what the consumer is going to want. At SelectHealth, we are researching and talking to patients in our market, trying to better understand what consumers want. Obviously consumers want quality products. But health insurance can be a very confusing marketplace, so they want products that are simple to understand and use. A large part of the population wants low cost and another portion of the population is willing to spend extra for value. To serve those customers, companies willing to invest in CER may be able to provide both low-cost and high-value options. Finally, will consumers be willing to compromise on the amount and type of choices they're offered?

Analyzing what employers want in health care reform reveals 3 clear goals. Employers want to contain costs, encourage healthy lifestyles, and improve the quality of care.<sup>3</sup>

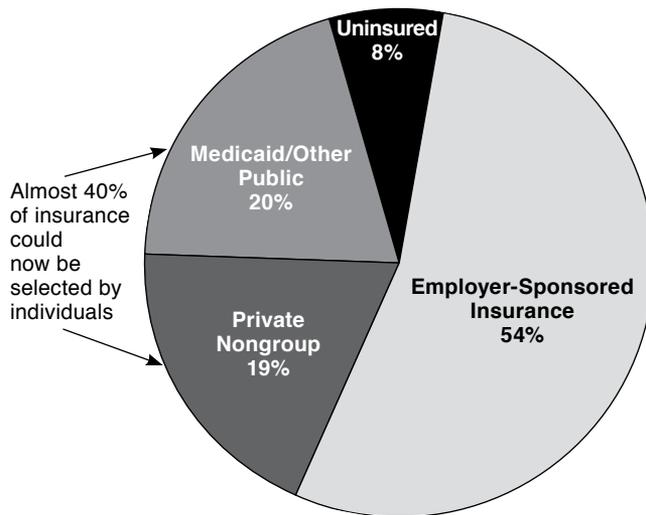
Mushlin and Ghomrawi (2010) looked at the components of health care reform that may help the health care system

**FIGURE 1** Health Insurance Coverage of 185.4 Million Nonelderly Adults, 2009<sup>a</sup>



<sup>a</sup>Source: Kaiser Commission on Medicaid and the Uninsured/Urban Institute. Health insurance coverage of 185.4 million nonelderly adults, 2009. Analysis of 2010 Annual Social and Economic (ACES) supplements to the Current Population Survey.<sup>1</sup> Adults are defined as individuals aged 19 to 64 years. Total exceeds 100% due to rounding.

**FIGURE 2** What Health Insurance Coverage of Nonelderly Adults Might Look Like After Reform<sup>a</sup>



<sup>a</sup>Source: H. Eric Cannon, SelectHealth, Intermountain Healthcare. Values are based on estimated shifts applied to existing data; total exceeds 100% due to rounding.

become more efficient and more effective.<sup>4</sup> They wrote that financial incentives, programmatic initiatives, and organizational changes could be considered “blunt instruments” that may nudge the health care system toward efficiency. On the other hand, they considered CER a “sharper tool” that could inform change and guarantee the enhanced health of the population by delivering comparative and precise information.

The Evidence-based Practice Centers (EPCs) funded by AHRQ have developed a system of grading the strength of a body of evidence when comparing medical interventions. The goal is to provide an objective assessment of the strength of evidence that decision makers can use in making their assessments. Four domains are required and include risk of bias, consistency, directness and precision.<sup>5</sup> Additional domains can be included as appropriate including dose response association, confounders, strength of association and publication bias. An overall strength of evidence grade is given as either high, moderate, low, or insufficient.

To see how CER can be used as a sharper tool in the future, it may help to look at an example of how we’ve used CER data in the past.

### How Have We Used CER with Diabetes Medications in the Past?

A 650-page report first published by the Agency for Healthcare Research and Quality (AHRQ) in 2007 and updated in 2010 analyzed CER data for oral diabetes medications for adults with type 2 diabetes. The report showed that most diabetes

medications (metformin, thiazolidinediones, sulfonylureas, and repaglinide) reduce hemoglobin A1c by a similar amount (about 1%).<sup>6</sup> The report found that metformin as monotherapy was more effective at reducing A1c than were DPP-4 inhibitors as monotherapy. Most metformin combinations were more effective than metformin monotherapy. The report also found a limited ability to draw conclusions on the glucagon-like peptide (GLP)-1 analogs and agonists because the evidence was graded as either low or insufficient. Researchers found that metformin consistently promoted weight loss, acarbose promoted weight loss or was weight neutral depending on the study, and low-density lipoprotein (LDL) cholesterol levels decreased with metformin or second-generation sulfonylureas, along with many other findings.

Another AHRQ report from 2008 reviewed insulin analogues, showing that premixed insulin analogues are better at lowering both A1c values and postprandial glucose than long-acting insulin analogues.<sup>7</sup> But, the long-acting analogues cause less weight gain and less hypoglycemia. Comparing premixed insulin analogues with noninsulin medications, 3 categories showed moderate strength of evidence indicating that the premixed were probably better, while in 2 categories the noninsulin medications performed better.<sup>7</sup> Each of these characteristics form part of the therapy decision that should be incorporated when treating diabetes in an individual patient.

But, have we really used these data to inform our formulary decisions? An analysis of SDI’s Spring 2009 *Managed Care Formulary Drug Audit* could be expected to show that HMOs’ placement of subsets of antidiabetic agents in preferred positioning might vary based on the available CER data. For

example, the data showed that pioglitazone raises triglycerides less than rosiglitazone.<sup>7</sup> But in looking at where health plans across the country have positioned those, they were almost equal in 2008 (pioglitazone placed in preferred positioning by 100% of HMOs, and rosiglitazone placed in preferred positioning by 98% of HMOs).<sup>8</sup>

Discrepancies such as these point out that managed-care plans may not be doing all we can to use the CER data and guidelines in meaningful ways when it comes to positioning products within a formulary. Despite this, there are examples of how MCOs have used CER data to drive how guidelines are established.

One of the predominant ways Intermountain Healthcare has used available CER data is in the development of disease management programs, called clinical programs, that provide tools and information to help practitioners deliver care in a consistent and integrated way. Practitioners must have access to the data and understand how to apply that data operationally, so Intermountain has designed clinical programs to guide and define new disease management systems and integrate them into routine care throughout the Intermountain system. Each disease management system includes an evidence-based care process model, patient education materials, clinical support materials to make care delivery easier, and a data measurement and reporting process to analyze practice patterns. Reducing variability in the process of care allows assignment of outcomes to a causal treatment variable. In other words, Intermountain's main goal is to reduce the variation within treatment, thereby producing better outcomes.

While Intermountain's formulary may not vary much from other MCOs as far as positioning, CER data have been incorporated in developing Care Process Models (CPMs). CPMs are evidence-based guidelines for common and chronic conditions. The CPM teams have tried to ensure all the products are available within the formulary, and then they have taken it a step further within the clinical pathways to define exactly where each product might be used. For example, in the treatment of diabetes, the CPM recommends starting with metformin. If control is not obtained then another agent can be added, depending on the specific needs of a patient. Sulfonylureas or insulin might be added as low-cost options. In a patient who needs some weight loss, the options might include a DPP-4 inhibitor or a GLP-1 agonist.<sup>9</sup>

Can the use of CER data lead to high-quality, cost-effective care in the treatment of diabetes? Intermountain has proven that its diabetes clinical program is associated with improved performance in diabetes clinical measures.<sup>10</sup> Intermountain CPMs have helped control costs and improve care.

### How Will CER Affect MCOs?

Every MCO will need to conduct its own introspective review and ask what it must do to be in a position to use the growing volume of CER information. At every level, individuals need to be educated, understand how the research was done, determine how it applies to their population, and identify how it applies in different demographics. Taking it further, we must also ask: where have we used comparative effectiveness in the

past, where would we like to use it in the future, and what will it take to accomplish that? Some of these questions will be difficult, with implications that will need to be managed carefully. For example, if observational data tells us a particular therapy doesn't work as well as others in certain populations, how do we handle patients who are already using that therapy successfully?

As more individual consumers begin making purchasing decisions, we'll have to ensure that those individuals are choosing our organizations and putting their money and their support behind us, or we won't remain viable. So how will we incorporate those patients and individuals into our decision making? In the past, our stakeholders clearly have included facilities, hospitals, and physicians, and we as MCOs have involved them in these discussions and in making decisions. Seldom, if ever, have we involved the patient in that process. But in a reformed market, the individual will play a greater role in health care decisions and will have a greater need to be engaged. How do we disseminate more information to them? The Institute of Medicine recommends that consumers should have involvement in CER. Kreis et al. (2012) surveyed 17 organizations conducting or commissioning systematic reviews and found that 7 of them involve consumers at a programmatic level, through one-time consultation or on ongoing collaboration.<sup>11</sup> They conclude that an assessment of which approaches are most effective is required to further define the most appropriate involvement of consumers in CER.

At a basic level, we need to work at building the infrastructure to incorporate CER. Within each of our organizations, we will need to develop the expertise, the hardware, the software, and the protocols to use this new and growing volume of data. The Center for Medical Technology Policy held a CER summit in November 2010, and one of the issues that resulted was the need for consistent data standards in data generation and utilization.<sup>12</sup> The availability of data allowing comparisons is critical to CER. Hirsch et al. (2011) describes examples of the data infrastructure needed to support various CER methods, some of which are already slowly developing.<sup>12</sup> For example, to support meta-analysis and guideline development, we will need standardized data collection in clinical trials to allow comparisons across trials and practices, and strengthened national registries that incorporate data from clinical practice. The integration of patient-reported outcomes will require development of patient-accessible platforms in which data can be directly entered and integrated into electronic health records (EHRs), as well as interfaces that allow clinicians and researchers to track data in real time. And coverage with evidence development will require the development of integrated EHRs that allow a range of outcomes to be assessed, and expedited analysis in clinical trials by relying less on manual aggregation of data.<sup>12</sup>

As we design the infrastructure and operational systems to adjudicate the claims made from CER analyses, how does that affect benefit design? Will there still be a role for an open formulary or are we going to be looking at more closed formularies based on the evidence?

## Conclusions

As we evaluate CER and its many impacts on the U.S. health care system, it's clear that many different stakeholders will have different agendas and needs for the data that will be generated and analyzed. Several years ago, Sean Tunis, MD, discussed how the funding for CER could affect the ability of MCOs to use that research. He said "If the money goes through the usual channels and is primarily controlled by the academic community and the existing research infrastructure, it's going to be a large volume of answering questions that don't matter to decision makers."<sup>13</sup> Several health plans across the country have recognized the need for more involvement and are starting find ways to create collaboration. For example in the fall of 2011, Pfizer and Humana announced a partnership to improve health care delivery to seniors. Researchers and health care experts from both organizations will be brought together to study key issues and deliver interventions to reduce inefficiencies in the management of chronic conditions such as pain, cardiovascular disease and Alzheimer's disease.<sup>14</sup>

From a managed care perspective, the key as we start doing more and more CER is to ensure we are asking questions that are relevant to us as MCOs and are producing results that we can actually use to make decisions. If it isn't relevant to us, it really won't provide any value for us.

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## DISCLOSURES

This supplement was sponsored by PIM and StrataMed through an educational grant from Novo Nordisk. Eric Cannon received compensation from PIM for participating in the live continuing education activity on which this article is based and for writing the article. Cannon reports a consulting relationship with Novo Nordisk.

## ACKNOWLEDGEMENTS

The author thanks Kelley J. P. Lindberg, BS, for writing assistance in preparation of this manuscript.

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