

Conference Summary

Evidence-Based Medicine /
Set Your Sights

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Preamble: Set Your Sights /

Today, evidence-based medicine (EBM) underpins numerous policy initiatives designed to increase comparative effectiveness information on technologies, promote value-based purchasing by employers, payers, and consumers, and engender accountability in healthcare delivery. These efforts at the federal, state, and local level create a marketplace of new information on the value of therapies and the need for all healthcare stakeholders to understand and engage in shaping the emerging market.

This year's EBM conference, *Set Your Sights*, identified six trends in the emerging marketplace of information.

- **Navigate the Fragmented Healthcare System:** Healthcare in the United States has been characterized as less of a system and more of a sector. Any efforts to reform the healthcare sector must keep in mind long-standing structural barriers and the lack of a national health information infrastructure.
- **Balance Patient Care with Population-Level Quality Improvement:** Efforts to generate effectiveness and safety information have traditionally focused on the population at large. However, reliance on such evidence without allowances for patient heterogeneity may hurt, rather than enhance care. Balancing population-based information and personalized medicine will become increasingly important.
- **Treat Patients and Physicians as More than an Audience:** Reform efforts imposed on, rather than devised in collaboration with providers and recipients of care, offer little promise for success. Engaging these stakeholders early on as participants and not as audiences will better guide these efforts.
- **Understand Incentives:** Programs designed to promote best practices in patient care are rapidly evolving. Policymakers and payers must better understand how to re-engineer financial incentives in place today to ensure that what is known to work for patients is adopted into practice.
- **Encourage Transparency:** Healthcare reform efforts to generate and promote value-driven healthcare will require increased transparency. Stakeholders with a vested interest in achieving reform must identify what is meaningful transparency for the public.
- **Call for Strong Leadership:** To unify existing efforts to reform healthcare through the promotion of EBM, strong leadership remains essential to charting a course for success.

Avalere Health is actively engaged in these issues through our Center on Evidence-Based Medicine. We look forward to future collaboration. Please feel free to contact Tanisha Carino, tcarino@avalerehealth.net, with any questions.



Agenda /

Welcoming Remarks: Set Your Sights

Tanisha Carino / Avalere Health

Today, EBM is more than just a buzzword; it underpins concrete policy initiatives that focus on increasing comparative effectiveness information, value-based purchasing, and accountability from health providers. The tangible business impact of these initiatives on commercial manufacturers and health plans is ever apparent. This session will describe why it is a critical time to set your sights on tangible goals within the rapidly evolving world of EBM.

The Role of EBM in Healthcare Reform

Moderator: Riaz Ali / Avalere Health

Speakers: Dan Mendelson / Avalere Health; **Tom Barker** / U.S. Department of Health and Human Services; **Scott Gottlieb** / American Enterprise Institute

Evidence-based medicine is being widely discussed as part of reforms to bring more competition and transparency to the healthcare system. This session will focus on EBM's role in medical product commercialization, the movement toward greater transparency in healthcare, and the new age of drug safety. The expert panelists also will highlight the pivotal role health information plays in accelerating the exchange of evidence to advance these trends and how various healthcare stakeholders are relying on principles of EBM to advance broader healthcare reform.

Health Technology Assessments: The Five-Year Horizon

Moderator: Stu Guterman / Commonwealth Fund

Speakers: Sean Tunis / Center for Medical Technology Policy;
Gerald W. Peden / Independence Blue Cross

There is an increased push toward centralization of health technology assessments (HTAs) in the U.S. to counter the existing decentralized approach to generating comparative evidence. Representatives from emerging HTA organizations and expert panelists will highlight their organizations' goals, efforts to date, and the challenges and limitations they must overcome in the next five years to provide comparative effectiveness research to the U.S. healthcare marketplace.

Lunch and Keynote Address: EBM and Medicare Transformation

Peter Orszag / Director, Congressional Budget Office



Impact of Coverage Policy on Payer Decision-Making

Moderator: Lauren Barnes / Avalere Health

Speakers: Perry Bridger / Avalere Health; Cynthia Rice / Juvenile Diabetes Research Foundation; Steve Pearson / Institute for Clinical and Economic Review

Medicare has started a new trend by explicitly citing evidence assessments and coverage policy to rationalize some coding and payment decisions. Commercial payers are also demanding additional evidence to refine or reconsider existing policy. As a result of these developments, stakeholders pushing for broader access to therapies have actively engaged in evidence generation, with patient groups sponsoring research to supplement existing studies, and manufacturers re-thinking their clinical research focus. This session will focus on the impact of, and response to, coverage policy development on overall payer decision-making.

Reforming Payment Through Pay-for-Performance: How Far Can P4P Take Us?

Moderator: Jon Glaudemans / Avalere Health

Speakers: Helen Burstin / National Quality Forum; Dennis White / National Business Coalition on Health; Blair Childs / Premier, Inc.

Advocates for payment reform argue that the current healthcare payment system does not encourage appropriate utilization of medical services and suggest a movement toward a value-based purchasing model to address possible perverse incentives. This session will explore how pay-for-performance fits into the reconfiguration of Medicare's provider incentive structure, whether the model can successfully and comprehensively address payment reform, and whether providers and payers should assume its adoption is inevitable and transferable to commercial settings.



Session #1: The Role of EBM in Healthcare Reform/

Healthcare Information Marketplace Is a Key to Improving Quality

Panelists: Dan Mendelson / Avalere Health; Tom Barker / US Department of Health and Human Services (HHS); Scott Gottlieb / American Enterprise Institute (AEI)

Highlights:

- Significant “information asymmetry” among healthcare stakeholders – mainly due to issues of transparency and availability – may directly impact the quality of care patients receive.
- Consumer involvement is necessary to drive meaningful healthcare reform, but improving consumer literacy on health issues remains critical.
- The type of cost information most useful for consumers, whether it is absolute cost or cost-effectiveness data, remains unclear.

The opening session featured a freewheeling discussion on the role of EBM both in the marketplace and in the healthcare reform movement. Tom Barker, HHS, compared the US healthcare delivery system unfavorably to the nation’s telecommunications system, noting that telecoms actually operate within a “system” and healthcare delivery does not.

“We don’t have a healthcare system, we have a healthcare sector,” Barker said, pointing out how anyone can seamlessly communicate and share information regardless of the phone service provider they choose to purchase. Healthcare has not mastered this yet, Barker said.

He outlined the “four cornerstones” of the Bush Administration’s value-driven healthcare agenda: 1) electronic health records; 2) price transparency; 3) quality transparency; and 4) incentives for consumers and providers to act on quality and cost information.

Dan Mendelson, Avalere Health, and Scott Gottlieb, AEI, agreed with Barker that the lack of interoperability and transparency, as well as the poorly aligned payment incentives, lower the value and reduce the quality of care.

Mendelson said the Administration’s four cornerstones cannot be argued against since nearly everyone agrees on the principles, but he questioned whether the Administration could do more to define and implement responsible comparative effectiveness research. “There has been relatively little new activity from the executive branch,” he said noting that Congress is likely to fill the void.

In the search for greater information, Mendelson and Gottlieb cautioned against the reliance on clinical studies whether in the pre- or post-market environment. Both heralded electronic health records as a tool necessary to ensure the proper collection and analysis of real-world clinical data. Technology-enabled data capture, according to the panel, is critical to empower healthcare stakeholders with relevant information by both assessing the comparative effectiveness of healthcare interventions and actively tracking the safety of technologies on the market.

The audience and panel also stressed that broad stakeholder involvement is needed to better define the information marketplace. While Mendelson and the panel noted the recognized gap in consumer health literacy, they agreed that without patient and provider involvement in EBM, it was unlikely that significant quality improvement would be achieved.



Session #2: Health Technology Assessments: The Five-Year Horizon/

Comparative Effectiveness: Copious Consensus, Absent Definition

Panelists: Stu Guterman / Commonwealth Fund; Sean Tunis / Center for Medical Technology Policy (CMTP); Gerald W. Peden / Independence Blue Cross

Highlights:

- Comparative effectiveness lacks a universally accepted definition.
- Patient, provider, and payer decision-makers are increasingly driving clinical and comparative effectiveness research (CER) priorities.
- CER is most useful to decision-makers for determining which patients are likely to benefit the most from a treatment, rather than making absolute decisions, like coverage or non-coverage.

Despite a growing number of high-profile proposals for increasing the national CER capacity, Gerald Peden, Independence Blue Cross, said the reality is that comparative effectiveness “has not really been defined yet.” Sean Tunis, CMTP, suggested that this ambiguity has led numerous and diverse healthcare stakeholders to a consensus on the need to establish a centralized CER entity. “When there is universal agreement on a topic, you generally have not defined it enough,” remarked Tunis.

To lend some meaning to the CER debate, Tunis defined CER as a set of analytic tools that allow for the comparison of one treatment – drug, device, or procedure – to another treatment on the basis of risks, benefits, and, potentially, cost. The panel agreed that these tools include: systematic reviews of existing literature, decision models based upon existing information, retrospective analysis of administrative data, and prospective comparative studies.

Panelists also identified issues in the CER debate where “battle lines will be drawn.” Chief among these is the research priority-setting process, largely because different decision-makers require different sets of research questions and study designs to inform their decision-making. Because the intent of CER is to inform decision-making, patients, providers, and payers are all seeking to be more involved in the design of research questions and study protocols, to ensure they produce utilizable findings. Peden said decision-makers want to know what technologies are best for which patient and are driving the research agenda to meet this need. The panel agreed that stakeholder involvement early and throughout the CER generation and dissemination process will be vital to its success. Other “battle line” issues included whether an entity should be charged with conducting prospective head-to-head CER trials and whether cost-effectiveness analyses should be explicitly included in the CER agenda.

Stu Guterman, Commonwealth Fund, noted that CER can help forge a high-performance health system by informing value-based benefit design and differential copayments. Panelists agreed that, in this manner, stakeholders could use comparative and cost-effectiveness information to make value-based decisions about healthcare technologies in a politically viable way, despite the common opinion that cost-effectiveness implies rationing and binary yes-or-no coverage decisions.



Lunch Keynote Address: EBM and Medicare Transformation

CBO Head Views Comparative Effectiveness Research as a Solution to Growing Healthcare Expenditures

Speaker: Peter Orszag / Congressional Budget Office (CBO)

Highlights:

- Investing in CER offers a potential opportunity for a significant decrease in future health expenditures and an increase in value.
- Comparative effectiveness will only be useful if coupled with a realignment of incentives to correspond to high-value care.
- The real opportunity for CER to generate savings is tied to the adoption of new technology.

CBO Director Peter Orszag, in the keynote lunch address, said CER offers one of the best potential methods for reducing the nation's spiraling healthcare costs. However, he cautioned, today we "woefully under-invest in comparative effectiveness research."

CER, combined with realigned payment incentives, could produce a substantial reduction in healthcare costs and increase in value, Orszag said. "Payment systems should correspond to what works and what doesn't work," because "we get what we provide incentives for." Specifically, Orszag called for change in financial incentives to encourage delivery of high-value healthcare. He noted that a lack of evidence leads to variation in the provision of care due to ambiguity about the service's appropriateness, resulting in increased utilization and higher cost. Further, he asserted, the higher costs that result do not produce improvements in health outcomes.

Regardless of the potential entity's structure, he noted that the evidence base should be largely comprised of non-randomized clinical trial evidence. High-quality data, perhaps gathered through electronic health records, would provide a rapid source that a CER entity could use to assess treatments and outcomes.

He noted that savings would not begin to accrue immediately, as it would take time to get a CER entity started, to undertake research, and to change Medicare to a fee-for-value rather than a fee-for-service entity. However, because healthcare cost is the "single most important factor driving the nation's long-term fiscal imbalance," the creation of an appropriately organized and focused CER entity would offer significant long-term savings. Orszag said CBO plans on issuing factors to consider when organizing a CER entity this calendar year.

Finally, Orszag argued that one of the primary drivers for the growth rate in healthcare cost is the introduction and adoption of new technology that may or may not be worthwhile. While new technology should be utilized when appropriate, its use in patients that do not derive additional health benefits simply serves to increase healthcare spending. Consequently, the US healthcare system needs to more appropriately tie incentives to the use of better technologies, while reducing the incentives to use those that are less effective, Orszag said. Currently, payers are unable to design such incentive systems because they do not know which treatments are worthwhile.



Session #3: Impact of Coverage Policy on Payer Decision-making

Evidence Generation Evolves to Meet the Needs of Payers, but Questions Remain

Panelists: Perry Bridger / Avalere Health; Cynthia Rice / Juvenile Diabetes Research Foundation (JDRF); Steve Pearson / Institute for Clinical and Economic Review (ICER)

Highlights:

- Payers are becoming more savvy consumers of healthcare, demanding evidence at all steps in a technology's life cycle.
- The clinical research enterprise is evolving to answer payers' questions with tailored studies and tools for their interpretation.
- In light of the population-versus-individual evidentiary tension, payers will need to be creative in how they apply evidence to benefit design.

The previously straightforward path of reimbursement for medical technologies following FDA approval is becoming increasingly complex, as payers are becoming more savvy consumers of healthcare. As such, payers are demanding evidence throughout a technology's life cycle, and the clinical research enterprise is evolving to meet these needs.

Steven Pearson, ICER, along with Perry Bridger, Avalere Health, and Cynthia Rice, JDRF, discussed the evolving impact of evidence on payer decision-making. Bridger noted that all payers want unbiased evidence on which to base reimbursement decisions, and public and private payers have taken steps toward incorporating such evidence into their processes (coverage, coding, and payment). Patient groups, such as JDRF, are taking a proactive role in funding the evidence base required by payers.

A key lesson learned, noted Rice, is that organizations undertaking research should seek advice from health plans in the design of their clinical trials, in order to ensure the information gathered will meet payer needs. She added that payers were very receptive to meeting with JDRF and saw no reason why this model could not be replicated in other disease areas.

Once the evidence has been generated, however, payers require tools to assist in the evaluation of such evidence. ICER attempts to make evidence assessments more principled through the use of an Integrated Evidence Rating, which compares technologies for a particular medical condition on the dual axes of comparative clinical effectiveness and comparative value.

The panelists noted that the nation's healthcare system is unlikely to accept traditional binary decisions for individual coverage based upon population-level evidence. Therefore, payers will need to be creative in how they apply evidence to benefit design, with new evidence and interpretive methods as tools to start the conversation.



Session #4: Reforming Payment Through Pay-for-Performance: How Far Can P4P Take Us?

Pay-for-Performance: Solution to 'Toxic' Payment System?

Panelists: Helen Burstin / National Quality Forum (NQF); Dennis White / National Business Coalition on Health (NBCH); Blair Childs / Premier, Inc.

Highlights:

- P4P initiatives may help serve as a bridge from the current fee-for-service model to value-based purchasing and payment reform.
- Meaningful performance assessment requires properly developed, aligned, and standardized measurement across providers and care settings.
- Pay-for-performance (P4P) may result in relatively more positive gains in quality improvement compared with pay-for-reporting programs for hospitals based on data from the Premier Hospital Quality Incentive Demonstration.

P4P initiatives are expanding in both the public and private sector. While originally designed as a way to encourage quality improvement, healthcare leaders are now viewing these programs as a potential bridge to larger healthcare payment reform.

“We’ve known what to do for years [to improve quality], yet we haven’t embedded [quality metrics and data collection] in processes of care, decision support, and ways to get data in real time,” according to Helen Burstin, NQF. Today, Burstin reported, NQF is attempting to better prepare for the growing importance of P4P by developing quality metrics with an eye toward their use in P4P initiatives. She expects that eventually standardized quality metrics will work in tandem with health information technology and electronic health records to allow for quality data collection.

However, improving quality through P4P initiatives is not only a goal for the future, according to Blair Childs, the Premier Inc. Hospital Quality Improvement Demonstration (HQID), it is happening today. Childs presented data from the HQID to show that hospitals with P4P incentives improve patient care and outcomes. “On a patient-by-patient basis, [there is a] clear correlation between quality improvement and patient outcomes,” he said. In addition, data were presented demonstrating that Premier P4P hospitals showed significant quality improvement over pay-for-reporting hospitals.

Building on the demonstrated success of the Premier P4P initiative, Dennis White, NBCH, discussed the problems with the current payment system and how P4P and value-based purchasing may offer opportunities for payment reform. Currently, NBCH works with employers and other healthcare purchasers to implement HHS’ Value-Driven Health Care initiative. White believes that the current “P4P structure is a bridge to much more fundamental reform” of our “toxic system of payment by transaction.” To White, P4P helps to begin to create a system that compensates providers based on the outcomes across episodes of care rather than transactions at points of care.

