

**Payer Perspectives on Improving Usability of Effective  
Health Care Products:**

**Bridging the Gap Between Information Needs and Evidence Translation**



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# **Payer Perspectives on Improving Usability of Effective Health Care Products:**

**Bridging the Gap Between Information Needs and Evidence Translation**

**Prepared for:**

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# Introduction

For research results to be useful and relevant to decisionmakers, the active involvement of stakeholders in the research process is critical. As such, stakeholder engagement is a fundamental aspect of comparative effectiveness research (CER), and the impact of CER depends on developing effective processes for the meaningful participation of stakeholders throughout the research continuum.<sup>1,2</sup> A stakeholder in this context refers to anyone who plays a role in health care decisionmaking, including patients, clinicians, public and private policymakers and payers, and members of industry.<sup>3</sup>

The centrality of stakeholder engagement to CER has been a guiding principle of the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care (EHC) Program since its inception. Section 1013 of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act, which instructed AHRQ to conduct and support CER, mandated broad and ongoing consultation with relevant stakeholders.

In response to this mandate, AHRQ's EHC Program has created multiple mechanisms for stakeholder input and relies on ongoing consultation with stakeholders to ensure that the program responds to the most pressing issues and produces information that is useful for health care decisionmakers.<sup>4</sup> General stakeholder input is collected on an ongoing basis through topic nominations and public comment submitted via the EHC Web site. In recent years, AHRQ has specified stakeholder engagement as a core element of funding announcements, and new grantees are required to describe plans for involving stakeholders in their work. The EHC Stakeholder Group, a 20-member volunteer committee representing the full range of stakeholders, was established in 2007 and convened quarterly until July 2012 for the purpose of providing insights into stakeholder perspectives to increase the impact of the EHC Program. The John M. Eisenberg Center for Clinical Decisions and Communications Science, a component of the EHC Program responsible for translating research results into guides and tools that are useful to health care decisionmakers, regularly solicits stakeholder feedback on its products through focus groups and telephone interviews. In addition, AHRQ's Community Forum initiative, initially funded by the American Recovery and Reinvestment Act of 2009, was created to examine and systematize stakeholder engagement in the EHC Program.

AHRQ created the Evidence-based Practice Centers (EPCs) in 1997 to produce comparative effectiveness or effectiveness reviews on medications, devices, and other health care services with the goal of helping patients, physicians, policymakers, and payers make better decisions about treatments. The EPCs solicit stakeholder input at multiple points in the review process, including topic generation, development, and refinement; protocol development; future research needs development; and translation and dissemination.

EPC researchers receive stakeholder input through open invitation during public posting and comment periods, as well as through direct contact with selected stakeholders. Consultation with key informants is critical at the topic development and refinement stages to ensure the relevance and usefulness of the questions being asked. Stakeholders also participate in Technical Expert Panels to provide input during research reviews and in identifying future research needs. Recognizing that different audiences have different needs from comparative effectiveness reviews, EPC process guidelines emphasize the importance of engaging a range of stakeholders, including clinicians, patients and consumers, researchers, government agencies, industry representatives, payers, and policymakers.<sup>5</sup> However, due to issues of timeliness and cost, EPC researchers cannot engage all stakeholders at each step for every topic.<sup>5</sup> Efficiently incorporating

the most important perspectives where they are likely to have the greatest impact requires careful consideration of the evidence needs of different stakeholder groups.

Health care payers, defined here as any entity other than the patient that finances or reimburses the cost of health services, rely on comparative effectiveness reviews to help them make rational choices based on the available clinical evidence. When multiple treatments work for the same condition, information on the pros and cons of available alternatives enables payers to make more effective decisions that take into account potential variation in patient or provider treatment choices. The perspective of payers is therefore critical to the comparative effectiveness review process. Although payers have participated as key informants, there are a number of obstacles to consistently including this stakeholder group in EHC projects, such as identifying appropriate individuals to invite within often-complex organizations, and questions remain concerning the most appropriate time and method to capture their perspective. Furthermore, payers that have participated as stakeholders have often included individuals involved in other aspects of the EHC Program (e.g., the EHC Stakeholder Advisory Group) and have not represented the full spectrum of private and public health care payers.

Payers have conveyed a number of challenges related to the use of EHC reports for decisionmaking. At a 2011 meeting of the EHC Stakeholder Group and subsequent presentation at the EPC Directors meeting, private and public payers serving as stakeholders described the following challenges:

- Payers have to make policy decisions whether the evidence is good, bad, uncertain, or nonexistent. Therefore, it is problematic when researchers say, “We have no evidence.” Even in the case of very inadequate evidence, we do know some things (e.g., treatments that are unsafe, treatments that are safe but do not work).
- The causes of uncertainty need to be communicated more clearly.
- Information concerning the balance of benefits and harms needs to be more readily accessible.

As part of the Community Forum initiative, we sought to expand on previous payer input by soliciting feedback from a diverse panel of health care payers. The goals of the project were to broaden payer involvement in the EHC Program and develop recommendations regarding—

- Effective means of identifying, recruiting, and engaging payers
- Optimal points of engagement for payers in the EHC process
- Modifications or additions to EHC reports that would make them more useful for payers
- Modifications or additions to summary guides produced by the Eisenberg Center that would make them more useful for payers

# Methods

For this project we identified and recruited medical directors from several types of payer organizations and oriented them to the EHC Program and the systematic review process. We selected two EHC reports and their related summary guides, and we developed a protocol for payers to follow in reviewing the reports. Payers provided feedback on the reports and summary guides via online data collection forms, one-on-one telephone interviews, and a group discussion.

## Identification of Payers

Our goal was to recruit a panel of up to nine health care payers from different types of public and private payer organizations that are likely to use comparative effectiveness reviews in making coverage and policy decisions. We began by identifying six categories of payer organizations for possible representation on the panel: Medicare Advantage Plans, Medicare administrative contractors, Medicaid managed care plans, State-administered Medicaid programs, health maintenance organizations (HMOs), and labor unions (Table 1). The private payer organizations represent a range of patient populations (e.g., Medicare, Medicaid, union members) and administrative models (e.g., fee-for-service, HMO, Taft-Hartley Fund). Although State Medicaid medical directors have a history of engagement with AHRQ, this group has a unique perspective on the use of evidence for coverage and policy decisions that warranted inclusion on the panel. For each category, a preliminary list of organizations and programs was created using a variety of publicly available sources.

With the exception of Medicaid medical directors, we sought to identify specific organizations and programs to target for recruitment that had limited prior involvement in EHC activities. We also targeted regional organizations and programs representing a range of geographic locations. Based on previous experience, we determined that medical directors would have the most relevant perspective on the use of evidence in making coverage decisions. Once a preliminary list of organizations was compiled, we identified a medical director from each and sent letters inviting them to participate in the panel.

**Table 1. Categories of health care payers**

Category	Description
Medicare Advantage (MA) Plans	MA plans are offered by private companies approved by Medicare and are among the largest providers of health care to the Medicare population. They include Part A (Hospital Insurance) and Part B (Medical Insurance) coverage. A large number of them also include Medicare prescription drug coverage (Part D).
Medicare administrative contractors (MACs)	MACs process both Part A and Part B Medicare claims for the fee-for-service benefit. The Centers for Medicare & Medicaid Services (CMS) initially awarded 15 MACs but will consolidate these into 10 MAC jurisdictions. This group can make local coverage decisions for different technologies/products independently in their specific regions.
Medicaid managed care plans	Medicaid enrollment in 2011 was 70 million and is predicted to include an additional 16 million people by 2019. A large proportion of the Medicaid population is covered through the Medicaid Managed Care program.

**Table 1. Categories of health care payers (continued)**

<b>Category</b>	<b>Description</b>
State-administered Medicaid programs	Medicaid Medical Directors advise the Medicaid Director for one or more components of a Medicaid program administered by a State, territory, or the District of Columbia. This group is responsible for making coverage decisions for a large number of Medicaid beneficiaries in the country and ensuring high-quality care under tight State budgets.
Health maintenance organizations (HMOs)	HMOs provide managed care for health insurance, self-funded health care benefit plans, individuals, and other entities as a liaison with health care providers (hospitals, doctors, etc.) on a prepaid basis. They cover care rendered by doctors and other professionals who have agreed by contract to treat patients in accordance with the HMO's guidelines and restrictions in exchange for a steady stream of customers.
Labor unions	Labor union members receive health care benefits through Taft-Hartley Health Funds. These trust funds are established through collective bargaining between a company and a union (or multiple companies and unions) to provide health and related benefits for covered employees and their families. They are subject to the provisions of the Employee Retirement Income Security Act (ERISA). Funds and their assets are managed by a joint board of trustees equally representative of management and labor.

## Identification of Reports for Review Activity

We began with several criteria for selecting EHC reports to be reviewed by the panel. First, we considered only reports that had been released within the past year. Because a key goal of the project was to determine which report formats and products are most beneficial to payers, we considered only reports for which at least one summary guide (e.g., Clinician Summary) was available. We were particularly interested in including a report for which a policymaker summary was available. These brief summaries, developed by the Eisenberg Center, are intended to highlight findings from the full report that are likely to be of interest to payers and other policymakers. Only one policymaker summary based on a systematic review had been released at the time of this study, for the review titled “Traumatic Brain Injury and Depression.”<sup>6</sup> Therefore, we selected this EHC report and its related Clinician and Policymaker Summaries to be reviewed by the panel.

We solicited input from the EHC Stakeholder Group and from Eisenberg Center staff in selecting a second report. EHC stakeholders indicated that reports of greatest interest to payers are those that are likely to have a significant financial impact and that relate to current policy decisions. Based on this input and suggestions from the Eisenberg Center, we selected the EHC report and clinician summary titled “Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness”<sup>7</sup> for review by the panel (Table 2). Diabetes and its management are of keen interest to payers, and in addition, this particular report includes quality-of-life data and observational studies.

**Table 2. Reports reviewed by payer panel**

EHC Report	Key Questions From Selected EHC Reports	Products Reviewed
Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness	<ol style="list-style-type: none"> <li>1. In patients receiving intensive insulin therapy, does the mode of delivery—multiple daily injections vs. external continuous subcutaneous insulin infusion via a pump—have a differential effect on process measures, intermediate outcomes, and clinical outcomes, and do effects differ by type1/type 2 status, age, or pregnancy status?</li> <li>2. Does the type of glucose monitoring, real-time continuous glucose monitoring (rt-CGM) vs. self-monitoring of blood glucose, have a differential effect on process measures, intermediate outcomes, or clinical outcomes (i.e., what is the incremental benefit of rt-CGM)?</li> </ol>	<ul style="list-style-type: none"> <li>• Executive summary</li> <li>• Full report</li> <li>• Clinician summary</li> </ul>
Traumatic Brain Injury and Depression	<ol style="list-style-type: none"> <li>1. What is the prevalence of depression after traumatic brain injury (TBI), and do the area of the brain injured, the severity of the injury, the mechanism or context of injury, time to recognition of the TBI, or other patient factors influence the probability of developing clinical depression?</li> <li>2. When should patients who suffer TBI be screened for depression, with what tools, and in what setting?</li> <li>3. Among individuals with TBI and depression, what is the prevalence of concomitant psychiatric/behavioral conditions, including anxiety disorders, post-traumatic stress disorder, substance abuse, and major psychiatric disorders?</li> <li>4. What are the outcomes (short and long term, including harm) of treatment for depression among TBI patients utilizing psychotropic medications, individual/group psychotherapy, neuropsychological rehabilitation, community-based rehabilitation, complementary and alternative medicine, neuromodulation therapies, and other therapies?</li> <li>5. Where head-to-head comparisons are available, which treatment modalities are equivalent or superior with respect to benefits, short- and long-term risks, quality of life, or costs of care?</li> <li>6. Are the short- and long-term outcomes of treatment for depression after TBI modified by individual characteristics, such as age, preexisting mental health status or medical conditions, functional status, and social support?</li> </ol>	<ul style="list-style-type: none"> <li>• Executive summary</li> <li>• Clinician summary</li> <li>• Policymaker summary</li> </ul>

EHC = Effective Health Care Program

## Data Collection Activities

### Introductory Webinar

During a 1-hour Webinar, we provided an introduction to the EHC Program, the EPC Program and systematic review process, and the specific products selected for the review activity.

### Review of Insulin Delivery/Glucose Monitoring Report

Following the Webinar, we sent panelists the first set of products for review (“Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness” executive summary, full report, and clinician summary) along with individual links to an online data collection form that directed them to different components of the products and provided space for them to record comments as they went through the materials (Appendix A).

Payers were instructed to assume that they were faced with a coverage decision concerning the effectiveness of continuous subcutaneous insulin infusion versus multiple daily injections and real-time continuous glucose monitoring (rt-CGM) versus self-monitoring of blood glucose in patients with type 2 diabetes. Overarching questions included the following: (1) Does the report contain information that would be useful for making coverage decisions? (2) Was the quality of the evidence adequately described? (3) Was it difficult to find the relevant information? (4) Would a different format make the report easier to use?

## **Telephone Interviews**

After completing the data collection form, panelists participated in hourlong, one-on-one telephone interviews conducted by the same interviewer. The interviews were recorded to allow accurate summary of the discussions. A general interview guide (Appendix B) was created, and then tailored for each interview based on payer responses on the data collection form. Discussion topics included the following: (1) Background on the panelist's organization, role, and use of evidence for decisionmaking; (2) exposure to AHRQ; (3) general impression of the Insulin Delivery/Glucose Monitoring review; (4) utility of the review for making coverage decisions; (5) relative utility of the executive summary, full report, and clinician summary; and (6) likelihood of using EHC reports and participating in AHRQ activities in the future.

## **Review of Traumatic Brain Injury and Depression Report**

For the second review, we asked panelists to provide feedback on three products from the Traumatic Brain Injury and Depression review: executive summary, clinician summary, and policymaker summary. Because a primary goal was to solicit feedback on the policymaker summary, we did not ask panelists to read the full report for this review. Panelists again provided feedback via an online data collection form (Appendix A).

## **Concluding Web Conference**

We convened a final Web conference to present key themes from the product reviews and solicit additional feedback and discussion from the panel.

# Results

## Description of Panel

We sought to recruit a group of nine payers and sent a total of 24 invitations to potential panelists representing all of the categories described in Table 1. Although nine initially agreed to participate, two panelists had to withdraw due to scheduling conflicts. The distribution of the final panel of seven health care payers is shown in Table 3. Based on the overlap of Medicare advantage and Medicaid managed care plans with large private insurers, these categories were collapsed.

**Table 3. Panel composition**

Category	Number
Large private insurers	2
Health maintenance organizations	2
State Medicaid programs	1
Medicare administrative contractors	1
Labor union benefit plans	1

## Decisionmaking Roles

Although all of the panelists were chief medical officers (CMOs) or medical directors, their role in making coverage decisions varied based on the type of organization. For example, in the case of the large private insurers, medical policy is set at the corporate level and the regional CMOs are primarily responsible for adopting and interpreting policies and guidelines, and making coverage decisions for specific members. In contrast, HMO medical directors reported that they have primary responsibility for both setting policy and making coverage determinations. Some panelists also reported serving on pharmacy and therapeutics committees, which review new and existing medications and make decisions about formulary placement, and technology assessment committees, which evaluate new and evolving technologies using an evidence-based process.

Medical directors for Medicare administrative contractors (MACs) follow national coverage determinations set by the Centers for Medicare & Medicaid Services (CMS) and issue local coverage determinations, which they review to ensure that policy meets Medicare's reasonable and necessary criteria. Our panelist in this category represented a durable medical equipment (DME) MAC, which is a carrier contracted by CMS to process claims for DME in a specific geographic jurisdiction. For labor union benefits provided through Taft-Hartley health funds, a board of trustees is ultimately responsible for all decisions about coverage and for the fiscal soundness of the health fund. The CMO makes recommendations to the board of trustees and handles appeals from patients and providers.

Panelists reported that they are faced with different types of decisions in their role as CMO or medical director. Several categories of decisionmaking and the questions they seek to answer are described in Table 4. Although payers are likely to use available evidence in making all of these decisions, the type of evidence they need and the process by which the evidence is incorporated into decisionmaking vary. For example, decisions about covered benefits or new indications may

require quick action using whatever evidence is available on the harms and benefits for a given technology. In contrast, utilization, quality, and disease management are ongoing processes that may use a wider scope in assessing the evidence. Panelists also emphasized that, in contrast to clinical decisionmaking, they must at times weigh the evidence for a population rather than individual patients.

**Table 4. Types of payer decisions**

Type of Decision	Question
Benefit decisions	Should the technology in question be a covered benefit?
New indications or applications	Should existing coverage be extended for use of a technology in a different population or for a different indication?
Utilization management	For technologies in widespread use, are they being used in ways that contribute to the overall quality and efficiency of patient care?
Medical review policies	(For Medicare administrative contractors) Are payments being made for services that meet all Medicare coverage, coding, and medical necessity requirements?
Prior authorization	What types of interventions should require prior authorization?
Formulary placement/reimbursement	At what level of the formulary should a drug be placed?
Quality and disease management	What measures of quality should be used to evaluate utilization of new technologies?

## Sources of Evidence

Payers reported using multiple sources of evidence in making policy and coverage decisions. Frequently used sources for comparative effectiveness reviews included Hayes,<sup>a</sup> the Blue Cross Blue Shield Technology Assessment Center (BCBS TEC),<sup>b</sup> the ECRI Institute,<sup>c</sup> Delfini,<sup>d</sup> and the Cochrane Collaboration.<sup>e</sup> BCBS TEC produces 10–15 assessments per year that are publicly available on their Web site. Cochrane reviews are available by subscription to the Cochrane Library, and Hayes, ECRI, and Delfini provide access to reviews and customized analytic services to paying customers. Medicaid medical directors also have access to comparative effectiveness reviews of drugs through the Drug Effectiveness Review Project and reviews of other medical technologies through the Medicaid Evidence-based Decisions project (MED).<sup>8</sup>

All of the panelists were familiar with AHRQ and most had at some point accessed an EHC report; however, they did not consistently use EHC reports as a source of evidence. This finding is not surprising given that we sought to include payers that had limited prior involvement in EHC activities. The primary reason given for not using EHC reports more frequently was that reports produced by other organizations (e.g., Hayes, ECRI, BCBS TEC) are better aligned with their needs in terms of timeliness, clarity of recommendations, and topics:

*Other reviews are more focused on perspectives and types of issues dealt with in the commercial world—strong, practical perspective; not as esoteric as some reviews geared toward researchers.*

On the other hand, panelists indicated that they highly value EHC reviews for their comprehensiveness, methodological rigor, grounding in the evidence, and lack of bias. Payers

<sup>a</sup> [www.hayesinc.com/hayes/health-plans/comparative-effectiveness-reviews/](http://www.hayesinc.com/hayes/health-plans/comparative-effectiveness-reviews/) (accessed July 8, 2013)

<sup>b</sup> [www.bcbs.com/blueresources/tec/](http://www.bcbs.com/blueresources/tec/) (accessed July 8, 2013)

<sup>c</sup> [www.ecri.org/Pages/default.aspx](http://www.ecri.org/Pages/default.aspx) (accessed July 8, 2013)

<sup>d</sup> [www.delfini.org/](http://www.delfini.org/) (accessed July 8, 2013)

<sup>e</sup> [www.cochrane.org/cochrane-reviews](http://www.cochrane.org/cochrane-reviews) (accessed July 8, 2013)

felt that they could easily defend a coverage decision based on evidence from an AHRQ report if challenged.

## Engaging Payers in EHC Program Activities

The panelists agreed that, within payer organizations, medical directors or chief medical officers are the best target to involve in EHC Program activities. Ideally, this should include regional directors in addition to national policymakers. Regional directors are faced with day-to-day requests for coverage decisions and have evidence needs that may differ from those of payers that are focused on setting long-term policy at the national level. Panelists mentioned a number of other users of evidence within their organizations who might offer useful input, including pharmacists, nurses involved in utilization review, and full-time staff of technology assessment committees.

To identify and recruit payers to involve in EHC projects, panelists suggested networking through health plan organizations such as America's Health Insurance Plans (AHIP),<sup>f</sup> the Alliance of Community Health Plans (ACHP),<sup>g</sup> and State-based plan associations (e.g., California Association of Health Plans).<sup>h</sup> Alliances with such organizations may help in identifying payers interested in participating in EHC activities, as well as establishing channels for disseminating AHRQ products within the payer community. Panelists also suggested that AHRQ sponsor conferences with the needs of payers in mind and include content that would be valuable to health care payers.

Panelists cautioned against including “token” payers on stakeholder panels who have limited potential to influence the outcome of a review. As indicated in Figure 1, there are several points in the review process at which input from payers can have a meaningful impact on the relevance and uptake of AHRQ reviews. To start, they can provide input on which topics are most likely to be of interest to payers (e.g., those that involve a significant financial impact and relate to current or future policy dilemmas). In the topic development and refinement stage, payers can identify outcomes and subpopulations of interest. Panelists expressed particular interest in the identification of future research needs. Payers may play a role in generating evidence related to identified needs through policies such as Coverage with Evidence Development (CED). Finally, payers can contribute to developing salient messages for the payer community based on review outcomes and disseminating information about new reviews and products. Payers might also provide input during the horizon scanning phase on what is likely to be important in the near future, which is separate from the EPC process.

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<sup>f</sup> [www.ahip.org/](http://www.ahip.org/) (accessed July 8, 2013)

<sup>g</sup> [www.achp.org/](http://www.achp.org/) (accessed July 8, 2013)

<sup>h</sup> [www.calhealthplans.org/](http://www.calhealthplans.org/) (accessed July 8, 2013)

Figure 1. Points of payer engagement in the systematic review process



AHRQ = Agency for Healthcare Research and Quality; EPC = Evidence-based Practice Center

## Making EHC Reports and Summaries More Useful for Payers

### Scope of Comparative Effectiveness Reviews

Overall, panelists felt that the Key Questions for the Insulin Delivery/Glucose Monitoring and TBI and Depression reviews were appropriate and relevant. However, they noted a number of elements that would have made the reviews more useful from a payer perspective. With regard to the outcomes included in the review, payers consistently reported a need for information pertaining to resource utilization, noting a need to differentiate interventions that have an effect on certain process or outcome measures but no impact on the use of resources. Suggested measures of resource utilization included office visits, emergency room and urgent care visits, hospital admissions, additional procedures, and medications. When utilization data are not included in studies, the report should note this.

Not surprisingly, the payers on this panel consistently noted the absence of cost information as a major limitation, particularly when considering expensive technologies such as continuous subcutaneous insulin injection and rt-CGM. However, they emphasized that they are concerned with the overall cost to the health plan, not just the cost of a specific intervention. Payers were interested in different types of cost information, including cost-effectiveness, patient cost, and payer cost. A labor union benefits officer indicated that they like to consider the cost to the

patient in tandem with the cost to the plan so they can achieve an acceptable balance between the two. Panelists suggested that resource utilization may serve as a proxy for information about cost in some instances.

Quality-of-life (QOL) measures were included in the Insulin Delivery/Glucose Monitoring review, and panelists felt it was important to include these in EHC reviews. One regional medical director of a large private insurer noted that impact on QOL, as well as functionality and productivity, are becoming increasingly important in payer evaluations. QOL also has implications for adherence to treatment, which is another outcome important to payers.

Panelists also indicated that they would like more information regarding certain subpopulations. For example, a MAC noted that the Insulin Delivery/Glucose Monitoring report lacked a focus on elderly and disabled populations and was therefore of limited utility for payers who cover Medicare populations. Representatives from a labor union benefits plan indicated that their members are largely urban, low-wage earners and minorities. They suggested that if there is a lack of evidence for this specific population, the gap in research should be reported.

Finally, panelists generally supported the inclusion of observational studies in reviews, noting that such studies can help them understand the actual impact of an intervention. However, they indicated that observational data should be clearly delineated from findings from randomized controlled trials and interpreted cautiously.

## Content of EHC Reports

Panelists highlighted several categories of report content that are particularly important to payers. First, they emphasized that strength-of-evidence (SOE) information is critical in interpreting review findings. One payer commented that SOE is valuable in framing how decisions are made—for example, in providing explanations to physicians when coverage for a particular intervention is not supported by existing evidence. Panelists had no problem with the SOE scale used in AHRQ reviews (Appendix C), but some commented that it would be beneficial if all organizations that develop systematic reviews use the same scale. Other SOE scales that panelists referenced included those developed by Hayes, Delfini, and MED. Payers typically prefer an SOE format, such as in the clinician summary, that allows them to quickly scan to determine whether the evidence is strong enough to warrant further consideration. Panelists also indicated that the forest plots included in the full report are an effective means of conveying the strength and consistency of the evidence.

The panel reported that the lack of clear recommendations in AHRQ reports poses a challenge. Payers are interested in recommendations that indicate (1) which services have proven benefit compared to other options and for whom, (2) which have no proven benefit, (3) which are unsafe for a given application or population, and (4) how they will impact resource use.

One panelist noted:

*The summary conclusion for AHRQ reports is often that either alternative is acceptable, and it comes down to patient or clinician acceptance, but health plan perspective would be “minimal difference so not medical necessity”; health plan perspective is, “Is there a significant, measurable clinical superiority of something that is very different financially?”*

Several panelists also commented on the importance of information about research gaps and future research needs. If the evidence is inadequate, they want to know what steps need to be taken to fix it. A Medicare contractor was particularly interested in a level of specificity that would allow them to recommend what types of CED studies are needed to address evidentiary gaps.

## **Review Products and Formats**

### **Executive Summary**

Panelists consistently commented on the length of the executive summary (ES). At 30 pages (without references), they felt the ES for Insulin Delivery/Glucose Monitoring, in particular, was too long. Some commented that the 10-page ES for the TBI and Depression report was also too long. As noted by one panelist:

*The ES should be high level and succinct, and tell you where you need to go to find more information. You don't need to include methods in ES; brief introduction and results should be sufficient.*

In commenting on the presentation of evidence in the Insulin Delivery/Glucose Monitoring ES, most indicated that the right content was included in the evidence tables (e.g., outcome, strength of evidence, number of studies/number of good-quality studies, and main findings). However, several panelists suggested that a format with less narrative that is easier to scan for key points would be preferable. For the ES discussion section, suggestions included reducing the amount of detail, including a more structured reporting of future research needs, and moving the “Implications” to the beginning of the section.

### **Full Report**

Most of the panelists reported that, at least for the two reports they were asked to review, the information contained in the ES would typically be sufficient for their evidence needs and reviewing the full report would probably not be necessary. However, they emphasized that having access to the full report is critical. More specifically, panelists indicated that the full report is important for devising restrictive policy that they would have to defend in administrative court; determining inclusion/exclusion criteria when writing their own policy; ensuring that summary conclusions are validated by the results; and finding out more about studies referenced in the ES that are particularly relevant.

### **Clinician Summary**

Reactions to the clinician summary were generally favorable. Payers liked the “Clinical Bottom Line” in particular because it allowed them to quickly scan the evidence to determine if and where they needed to dig deeper. As mentioned above, they found the SOE format effective and liked that, for both reviews, they could see at a glance that the SOE for the majority of the evidence was low. Panelists also indicated that the “Gaps in Knowledge” section is valuable for payers. References were the key element cited as missing from the clinician summary.

## **Policymaker Summary**

As indicated above, the policymaker summary was a primary focus of feedback for the TBI and Depression review. Several panelists struggled with why this specific review was selected as the subject of a policymaker summary to target guidance for payers and other policymakers. The policymaker summary underscores that frequent screening for depression is warranted after TBI, but that evidence regarding depression treatment for this population is limited. Payers noted that they would not challenge requests for repeat depression screening, given the low cost associated with screening and that, given the lack of information about treatment options, the policymaker summary contains little that would be useful to them in making coverage decisions. Some panelists also commented that the “Key Policy Implications” are not supported by the evidence included in the review and are therefore conjecture. Payers appreciated the brevity of this product and the fact that it included key references.

## Discussion

In this activity, we sought a better understanding of the evidence needs of health care payers, their preferences for the conduct and presentation of comparative effectiveness reviews, and strategies for expanding payer involvement in the EHC Program. The results are limited by the number and variety of payers involved in the activity, and those who agreed to participate may have a higher level of familiarity with the EHC Program than those who declined. Results are also limited by the focus on only two comparative effectiveness reviews. However, we believe many of the findings are generalizable to a larger payer audience and to other comparative effectiveness reviews.

Incorporating the input of multiple stakeholders, including payers, into the already tight timeline for comparative effectiveness reviews is an ongoing challenge for the EHC Program. Determining how payer input can be efficiently collected and when it is likely to have the greatest impact is critical. Provided EHC researchers are cognizant of issues that are routinely important to payers (e.g., cost, resource utilization, subpopulations, QOL, observational studies), it may not be essential to involve payers in every review. Researchers should consider the potential impact of review findings on payer decisionmaking in determining the optimal level of input. With regard to the optimal point of engagement, involving payers at the topic development and refinement stage is likely to increase the utility of comparative effectiveness reviews for coverage and policy decisions, particularly for topics that are of special interest to payers. When time and resources for obtaining payer input are limited, one strategy might be to target outreach to payer groups for input on Key Questions during the public comment period. For reviews already in process, payer input regarding the presentation of findings is likely to result in reports that are more useful for this stakeholder group. One possible approach is to present a summary of review findings to payers during the peer review phase, and solicit input regarding what information would be most useful to them and how it should be presented.

The need for timely information to address coverage decisions was a recurring theme in our interactions with the panel. Some payers expressed frustration at the length of time required for completion of AHRQ systematic reviews and raised the possibility of shortening the timeline. At the same time, they indicated that the value of AHRQ reviews is their thoroughness and rigor, and that other, commercial, services provide the quick turnaround they sometimes need. Accepting that the EHC Program cannot fill every evidence need of every stakeholder group, one conclusion is that it should focus on what it does best—producing comprehensive comparative effectiveness reviews that do not compromise methodological rigor in the interest of quick turnaround.

The potential role of other AHRQ products in addressing payers' needs also warrants further consideration. For example, payers may not be aware that “topic suggestion dispositions” are posted for all nominated review topics. Payers seeking evidence for a particular topic may find it useful to identify, in addition to available reviews, reviews that were suggested but not conducted due to lack of available evidence. Disposition reports are available on the EHC Web site and are searchable by nomination year and keywords. The Healthcare Horizon Scanning System monitors emerging health care technologies and innovations and creates an inventory of those that have the highest potential for impact on clinical care, the health care system, patient outcomes, and costs. The payers we spoke with were not aware of the Horizon Scanning program, but may find this product valuable in anticipating future coverage requests and identifying topics that are the most relevant and technologies for which additional evidence will be needed.

Technical briefs are another AHRQ product with potential value to health care payers. In contrast to comparative effectiveness reviews, technical briefs address emerging topics for which a systematic review may be premature. The goal of a technical brief, as described by one EHC researcher, is to find out what we do not know about a particular topic and why we do not know it. This may involve taking a topic for which there is a lot of “hype” and grounding it in the reality of existing evidence. This goal is consistent with the need our panel expressed to understand what areas lack evidence. Moreover, the intended 6- to 9-month timeframe for the preparation of technical briefs is in keeping with payers’ need for rapid information, particularly when existing evidence for a topic is limited.

The need to increase general outreach to payers regarding the EHC Program is a key finding from this project. Although health care payers are important consumers of evidence, the payers on this panel had limited knowledge and awareness of AHRQ products. Direct outreach to individual payers (i.e., via email notifications) may not be ideal given the volume of communications they receive. Partnering with payer organizations to raise awareness about the range of AHRQ research products and their potential utility for payers is one potential strategy.

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# Appendix A. Review Protocol

*Review Protocol (Responses collected through online data form with unlimited text entry)*

## **Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness**

For purposes of this review, please assume that you are faced with a coverage decision for your organization involving the following questions: (1) How effective is external continuous subcutaneous insulin infusion (CSSI) compared with multiple daily injections (MDI) in patients with type 2 diabetes, and (2) How effective is real-time continuous glucose monitoring (rt-CGM) compared with self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes. Assume that this report is the primary source of clinical evidence relevant to the coverage determination(s).

In reviewing this report, please consider the following overarching questions:

- I. Does the report contain information that would be useful for making coverage decisions?
  - II. Was the quality of the evidence adequately described?
  - III. Was it difficult to find the relevant information?
  - IV. Would a different format make the report easier to use?
- 

## **Executive Summary**

*Please begin by reading the executive summary (ES) and responding in as much detail as possible to the following:*

1. The **Key Questions** that guided this systematic review are presented on pages ES-3–4. Please comment on the extent to which the questions address issues that are important to you as a payer. What modifications to the Key Questions would make the review more useful for coverage decisions?
2. The **analytic framework and outcomes measures** for the review are presented on pages E-4 and E-5. Please describe your reaction to the choice of populations, interventions, comparisons, and outcomes included in the review, noting any alterations that would make the review more useful for coverage decisions.
3. **Tables** summarizing the evidence relevant to each of the Key Questions begin on page E-10. After reviewing these tables, how readily can you draw conclusions about the key findings from this review? What additional or different information would make the tables more useful? What changes to the format of the tables would make them easier to read and interpret?
4. The **Discussion** section of the ES begins on page ES-26. Does this section adequately describe the key findings and implications from this review?
5. Based on your overall review of the executive summary, what questions are raised that you feel could be answered in the summary but were not? Is enough information provided in the ES to obviate the need to review the full report? What changes to the content or format of the ES would make it more useful? What information is included in the ES that is *not* useful?

## **Full Report**

*Now we would like your feedback on the full EPC report. Although you may not choose to read the report from start to finish, please consider how useful the information in each section of the report would be for making coverage decisions, and whether a different format for presenting the information would make the report more useful.*

The Methods section, beginning on page 9, describes the process for determining which studies were included in the review, rating the quality of evidence for each study, synthesizing the data, and rating the overall body of evidence for each comparison. Please comment on the clarity of these descriptions and whether there is sufficient detail for interpreting the review findings.

1. Beginning on page 15, the results of the systematic review are presented using a variety of formats. How important were each of the following to your understanding of the evidence in this report?
  - a. Narrative description of key comparisons and strength of evidence with each subpopulation
  - b. Narrative description of study designs, outcomes, and population characteristics
  - c. Forest plots showing between group differences and pooled relative risks
  - d. Tables of magnitude of effect and overall strength of evidence for each comparison within each subpopulation
2. Consider the tables showing overall magnitude of effect and strength of evidence for each Key Question and subpopulation (Tables 7, 14, 16, 21, 26, and 27), what different or additional information would make these tables more useful?
3. Are the causes of uncertainty in the body of evidence adequately described? If not, what different or additional information is needed?
4. The discussion section begins on page 101. Do the summary of key findings, limitations and implications help you to draw conclusions from this report? Why or why not? What different or additional information would make this section more useful?
5. How important are each of the following Appendices to your interpretation of this report?
  - a. Detailed electronic database search strategies
  - b. Forms
  - c. List of devices
  - d. List of excluded articles
  - e. Evidence table
6. In what ways did reviewing the full report add important information or clarity to the information presented in the executive summary? What elements of the full report could be added to the executive summary to make it more useful as a stand-alone document?
7. How clear is the use of terminology in this report? What terms need to be better defined?

### **Clinician Summary**

**Although this summary guide was developed specifically for use by clinicians, it contains information and is presented in a format that may be useful to payers as well. Please review and respond to the following questions.**

1. How relevant is the content of the summary to payer decisionmaking?
2. What changes could be made to this guide to make it more useful for payers?
3. In what ways is the presentation of results superior or inferior to the results presentations in the executive summary and full report?
4. Would a summary guide such as this be sufficient for your evidence needs or would you still need to review the full report?

*Review Protocol (Responses collected through online form with unlimited text entry)*

### **Traumatic Brain Injury (TBI) and Depression**

For this review we would like for you to focus on three documents: (1) policy brief, (2) clinician guide; and (3) executive summary. The full report is included for your reference, but does not need to be systematically reviewed. We are interested in the relative utility of the three documents for your decision making needs, with regard to both content and format. Your thoughts on the policy brief are of particular interest as it was developed with the information needs of payers and other policymakers in mind.

***For purposes of this review, please assume that you are faced with a coverage decision for your organization involving the following question: When should patients who suffer traumatic brain injury be screened for depression, with what tools, and in what setting?***

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### **Executive Summary**

***Please begin by reading the executive summary (ES) and responding in as much detail as possible to the following:***

6. The **Key Questions** that guided this systematic review are presented on page ES-3. Please comment on the extent to which the questions address issues that are important to you as a payer.
7. The ES for this report is significantly shorter than for the Insulin Delivery/Glucose Monitoring report (10 pages vs. 30 pages). Are there elements missing from this ES that would make it more useful to you in the context of making coverage decisions (analytic framework, evidence tables, etc.)? Is this the appropriate length for an ES?

Why or why not?

8. The ES for this report presents the evidence in narrative form only. Please comment on the usefulness of this approach. Do you prefer that the evidence, even if limited, be presented in table format?
9. The **Discussion** section of the ES is on page ES-10. Does this section adequately describe the key findings and implications from this review?

### **Policy Brief**

1. Would the policy brief be useful to you in making coverage decisions about depression screening following TBI? Please explain.
2. Would you consider the “Key Policy Implications” important in making coverage decisions? Why or why not?
3. What information is missing from the policy brief that would make it more useful to you as a payer?

4. What if any additional information from the ES do you think should be included in the policy brief?

**Clinician Guide**

1. Would the clinician guide be more or less useful to you than the policy brief in making coverage decisions? Please explain.
2. Do you prefer the format of the clinician guide or the policy brief? Please explain.
3. What information is included in the clinician guide that you would want to see included in the policy brief?
4. What information is missing from the clinician guide that would make it more useful to you as a payer?

# Appendix B. Interview Guide

*Interviewer guides were tailored based on responses on the first data collection form.*

## **I. Goals and logistics:**

- The goals of our conversation today are to:
  - Gain a better understanding of the sources and types of information that you and your organization use in making coverage decisions
  - Determine how well the systematic reviews produced by AHRQ, and specifically the Insulin Delivery/Glucose Monitoring EPC report, meet your evidence needs
  - Discuss ways in which AHRQ might alter or add to their systematic review products to make them more useful to you as a payer
- Your responses will be combined with those of the other panelists in providing feedback to AHRQ and we will not link your name to any individual responses in reporting on this project
- We would like to record our conversation, if it is okay with you, so that we can make sure our notes are complete. We will not share the recording with anyone outside of CMTF and will delete it once we are confident that the interview has been fully documented.

## **II. Background:**

*The next few questions may sound familiar as some of them were included in the pre-webinar survey, but since that survey did not include identifiers, I'd like to take a minute to go through them again now.*

- How long have you been with (ORGANIZATION)?
- What position did you hold before coming to (ORGANIZATION)?
- What role do you play in making coverage decisions for (ORGANIZATION)?
  - Administrative jurisdiction?
  - What types of decisions?
  - Who else is involved?
  - Volume of decisions?
  - Complexity of decisions?

## **Exposure to AHRQ**

- In what capacity have you been exposed to AHRQ before?
- Have you ever been a stakeholder for AHRQ?
- Before this project, were you familiar with the EPC program?
- What sources of systematic reviews do you use in making coverage decisions? Which do you use most commonly?
  - AHRQ
  - Cochrane
  - Hayes
  - BCBS TEC
  - NICE
  - ECRI
  - CADTH
  - PBAC
- If has used reviews from AHRQ:
  - Which ones?

- Overall impression?
- How do they compare to reviews produced by other sources?
- If has not used AHRQ reviews:
  - Any particular reason? (didn't know about them, not timely, too cumbersome, etc.)
- What mechanisms do you think might be effective for AHRQ to make more payers aware of its review products?

### **III. Review of Insulin Delivery/Glucose Monitoring Report**

#### **A. Overall Impressions**

- How would you rate the overall clarity of the report?
- How would you rate the overall usefulness of the report for making coverage decisions?
- Would this report substantively improve your ability to make decisions about these topics given the other sources you use? Why or why not?

#### **B. Utility Of Content For Coverage Decisionmaking**

→ *Let's start with the question:*

*For people who are on tight glucose control, how does continuous subcutaneous insulin injection (CSII) compare with multiple daily injections (MDI) in improving patient outcomes (specifically, HBA1c, hypoglycemia, hyperglycemia, weight and patient quality of life)? How does this vary by type 1 and type 2 status? By age? By pregnancy status?*

- Have you ever considered covering CSII for glucose control in diabetics?
  - If yes, what is your coverage policy for CONTINUOUS SUBCUTANEOUS INSULIN INJECTION (CSII)?
- What are your biggest concerns about the evidence regarding the effectiveness of CSII for type 2 diabetics? What about the other patient subgroups listed?
  - Did this report address those concerns?
- Would you have had the right information in this report to have made an informed coverage decision for type 2 diabetics? If not, what else would you have liked to see?
- What else could the authors have done to better address your concerns?

→ *Now, let's turn to the question:*

*For patients using intensive insulin therapy, does the type of glucose monitoring—that is, real-time continuous glucose monitoring versus self-monitored blood glucose control—have a differential impact on process measures, intermediate outcomes and clinical outcomes (specifically, frequency of adjusting insulin therapy, adherence to therapy, frequency of allied health visits, HBA1c, hyperglycemia, weight gain, hypoglycemia) and on micro-vascular and macrovascular complications, QOL, mortality, and pregnancy outcomes? How does this vary by type 1 or 2 status? Age? Pregnancy status? Insulin delivery?*

- Have you ever considered covering rt-CGM for diabetics?
  - If yes, what is your coverage policy for rt-CGM?
- What are your biggest concerns about the evidence regarding the effectiveness of rt-CGM for type 2 diabetics? What about the other patient subgroups listed?
  - Did this report address those concerns?
- Would you have had the right information in this report to have made an informed coverage decision for type 2 diabetics?
  - If not, what else would you have liked to see?

- What else could the authors have done to better address your concerns?
- What content is absolutely essential for you to use for coverage?

### C. Clinician Summary

*Turning now to the clinician summary...*

- Is there anything missing from the clinician guide that you would need for making a coverage decision? What?
- Does the clinician guide contain the same type of information a payer would need as a clinician? If not, how should it be modified?
- You indicated that the CS is 95% as useful as the longer report:
  - What details from the full report would make the CS more useful as a stand-alone source of evidence for payers?
- The conclusion of the clinician guide states, "...some studies suggested that CSII was superior to MDI for glycemic control in adults with type 1 diabetes." In the Clinical Bottom Line area, it shows the strength of evidence was low and the results were heavily influenced by one study. How would you treat this information if you were making a coverage decision? Would you like to have the specific study or study referenced in this guide?
- The summary in the clinician guide states that rt-CGM in the form of sensor augmenting pumps was superior to SMBG in lowering HBA1c, but does not discuss other aspects of the review. Is this relevant for making a coverage decision? What other statement would you like to see in the summary?
- Probes
  - Would you need to know that this was only for type 1 diabetics?
  - Would you need to know there was no evidence on effects on micro and macrovascular disease?
  - Would you need to know more about mortality – although included in the review, this was not mentioned in the guide?
  - Would you need to know more about quality of life?
- How useful do you find the strength of evidence rating provided in the clinician guide?
- Did you understand how the authors developed this? Did you need more information about their methods?
- Are you familiar with alternative ways to present the strength of clinical evidence? What are these? Do you find them more or less useful than what is used in this report?

### D. Executive Summary

*Now turning to the executive summary:*

- Was there any information in the ES that would have been helpful to have in the clinician guide?
- Strength of evidence was presented on the second page of the guide, but embedded in the summary results of the structured abstract. Which would you find more useful?
- A statement that SOE for outcomes other than HBA1c were low or insufficient for sensor pump augmented rt-CGM was in the structured abstract for the ES, but not in the clinician summary
- You suggested that the **tables** are too detailed for an ES:

- Looking at Table D on page ES-17 which presents the evidence for CSII versus MDI in adults with type 2 diabetes:
  - Which components are essential?
  - Which are not necessary for the ES?
  - Would a different format make this table easier to use? Such as in the clinician summary? Tables you have seen in other reviews?
- You mentioned the level of detail in the **Discussion** section as well:
  - What information would you consider most critical for the discussion section with regard to this particular coverage decision?

#### **E. Full Report**

*Now turning to the full report, different evidence tables are presented.*

- Table 16 on page 59 presents evidence for CSII versus MDI in adults with type 2 diabetes:
  - Is this table more useful to you than the table in the ES? Why or why not?

#### **F. Future Use**

- Based on this review, would you likely use AHRQ CER Reviews for Future Decisions? Why or why not?
- Do you know the best way to find out about these reviews and when they are published?
- Payers did not serve on the advisory panel, although they sometimes do for these reports. Do you feel having a payer presence right up front would have substantively altered the approach taken by the authors to this work? In what way? What about the way in which the evidence was presented?
- Based on this most recent experience, would you likely be interested in serving as a stakeholder on the EPC review panels? Why or why not?

# Appendix C. Strength-of-Evidence Scale

AHRQ Strength of Evidence		
<b>High:</b>	● ● ●	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
<b>Moderate:</b>	● ● ○	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
<b>Low:</b>	● ○ ○	Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
<b>Insufficient</b>	○ ○ ○	Evidence either is unavailable or does not permit a conclusion.