AHRQ Healthcare Horizon Scanning System

Evaluation of the AHRQ Healthcare Horizon Scanning System

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The purpose of the AHRQ Healthcare Horizon Scanning System is to conduct horizon scanning of emerging health care technologies and innovations to better inform patient-centered outcomes research investments at AHRQ through the Effective Health Care Program. The Healthcare Horizon Scanning System provides AHRQ a systematic process to identify and monitor target technologies and innovations in health care and to create an inventory of target technologies that have the highest potential for impact on clinical care, the health care system, patient outcomes, and costs. It will also be a tool for the public to identify and find information on new health care technologies and interventions. Any investigator or funder of research will be able to use the AHRQ Healthcare Horizon Scanning System to select potential topics for research.

The health care technologies and innovations of interest for horizon scanning are those that have yet to diffuse into or become part of established health care practice. These health care interventions are still in the early stages of development or adoption except in the case of new applications of already-diffused technologies. Consistent with the definitions of health care interventions provided by the National Academy of Medicine (formerly the Institute of Medicine) and the Federal Coordinating Council for Comparative Effectiveness Research, AHRQ is interested in innovations in drugs and biologics, medical devices, screening and diagnostic tests, procedures, services and programs, and care delivery.

Horizon scanning involves two processes. The first is identifying and monitoring new and evolving health care interventions that purportedly hold potential to diagnose, treat, or otherwise manage a particular condition or to improve care delivery for a variety of conditions. The second is analyzing the relevant health care context in which these new and evolving interventions exist to understand their potential impact on clinical care, the health care system, patient outcomes, and costs. It is NOT the goal of the AHRQ Healthcare Horizon Scanning System to make predictions on the future utilization and costs of any health care technology. Rather, the reports are intended to help to inform and guide the planning and prioritization of research resources.

We welcome comments on this Evaluation of the Horizon Scanning System. Send comments by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 5600 Fishers Lane Rockville, MD 20857 or by email to effectivehealthcare@ahrq.hhs.gov.

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Executive Summary

With funding from the American Recovery and Reinvestment Act of 2009 (ARRA) and the Patient-Centered Outcomes Research Institute (PCORI) Trust Fund, the Agency for Healthcare Research and Quality (AHRQ) implemented and continues to oversee the Healthcare Horizon Scanning System. The Horizon Scanning System seeks to identify, monitor, and evaluate new and emerging technologies, off-label uses, and new uses of existing technologies and services that may have a significant clinical, system, or cost impact on the provision of health care in the United States. The Horizon Scanning System is the first public horizon scanning system to focus on emerging health interventions and innovations within the unique political, regulatory, cultural, and economic context of the U.S. health care system.

The goals of this evaluation are to assess the performance of the three primary functions of the Horizon Scanning System and to discern ways to improve its processes. The evaluation used multiple methods, metrics, and data sources to address four research questions relevant to scanning for emerging health care interventions:

1. How successfully did the AHRQ Healthcare Horizon Scanning System identify and prioritize interventions for monitoring?

2. How successfully did the Horizon Scanning System monitor the selected target interventions?

3. How accurately did the Horizon Scanning System assess the potential for high-impact of the interventions?

4. How can processes for identification, prioritization, monitoring, and assessment of potential for high-impact of the interventions be improved?

Methods

We used multiple methods, metrics, and data sources to address these questions. Using Status Update Reports, which ECRI produces and AHRQ publishes on its Web site, we examined whether there were any potentially late-identified interventions the Horizon Scanning System should have identified earlier in their development. Via semistructured interviews with staff and domain experts, we received detailed input on what has worked well or was problematic across every stage of the Horizon Scanning System protocol. We also surveyed experts to aid in assessing the accuracy, completeness, and usability of the Potential High-Impact Intervention reports (also produced by ECRI and published by AHRQ). In addition to the expert survey, we also conducted a survey of stakeholders to evaluate the credibility and usability of Potential High-Impact Intervention reports. Finally, we evaluated the variability in the high-impact potential (HIP) assessments using the metric of the proportion of Potential High-Impact Interventions for which the HIP assessment was unchanged from 2013 to 2014.[a] We also

[a] HIP refers to the three subcategories (low, moderate, high) within the high-impact potential range assigned to the Potential High-Impact Interventions. Interventions with these three designations are all considered potentially high-

evaluated the usability of the HIP assessment through the stakeholder survey. These analyses were supplemented by perspectives of the Horizon Scanning System staff on the activities to collect and synthesize expert comments to develop an overall assessment of HIP.

Findings

The findings of this evaluation present evidence that the Horizon Scanning System effectively identified, monitored, and assessed the potential for high-impact of emerging health care interventions. We summarize the key findings below in Table ES.1

Table ES.1. Summary of key findings

Identification of interventions

- Of a sample of 200 interventions subject to either Medicare coverage or FDA approval, the study identified only 2 interventions that were identified by the Horizon Scanning System after the receipt of FDA approval.
- One instance was due to internal operations (a change in the criteria for a priority condition and a determination by the Horizon Scanning System analyst that the intervention failed to meet the Horizon Scanning System criteria).
- The other instance was due to the absence of public information on this intervention until attainment of FDA approval—a factor outside of the Horizon Scanning System's control.

Monitoring of interventions

- The 26 experts who provided feedback on Horizon Scanning System reports generally found no substantive inaccuracies and no missing information that they viewed as important.
- These experts indicated that the reports' descriptions of the clinical use of interventions was consistent with the prevailing view.
- A majority of the 65 stakeholders who reviewed a Horizon Scanning System report found the reports highly credible and relatively easy to understand.
- Among the stakeholders for whom the intervention was relevant to their work, most noted it was easy to find the information of interest.

Assessment of intervention potential for high-impact

- Surveys of 7 cancer experts found high agreement with interventions rated by the Horizon Scanning System as having potential for high impact. However for interventions rated in the Horizon Scanning System as having no potential for high-impact, some were assessed by responding experts as having some high impact potential.

impact interventions. Interventions assessed as no HIP are not expected to have high impact, but may still have an impact.

- A majority of the stakeholders indicated that they found the report section on the high-impact potential and summary of expert comments useful.
- Likewise, a similar proportion of the stakeholders indicated the high-impact potential rating was consistent with the other information in the reports.

Potential improvements to the Horizon Scanning System

In line with the findings above, interviews of external experts and internal staff identified several potential improvements. These included: refining the inclusion criteria for the Functional Disability and Limitations condition area, including additional information in the topic profiles, providing more guidance to experts on applying the rating scale, addressing the difficulty of assessing the potential impact of interventions on health disparities, and implementing outreach to raise the visibility of the Horizon Scanning System among the general public and experts.

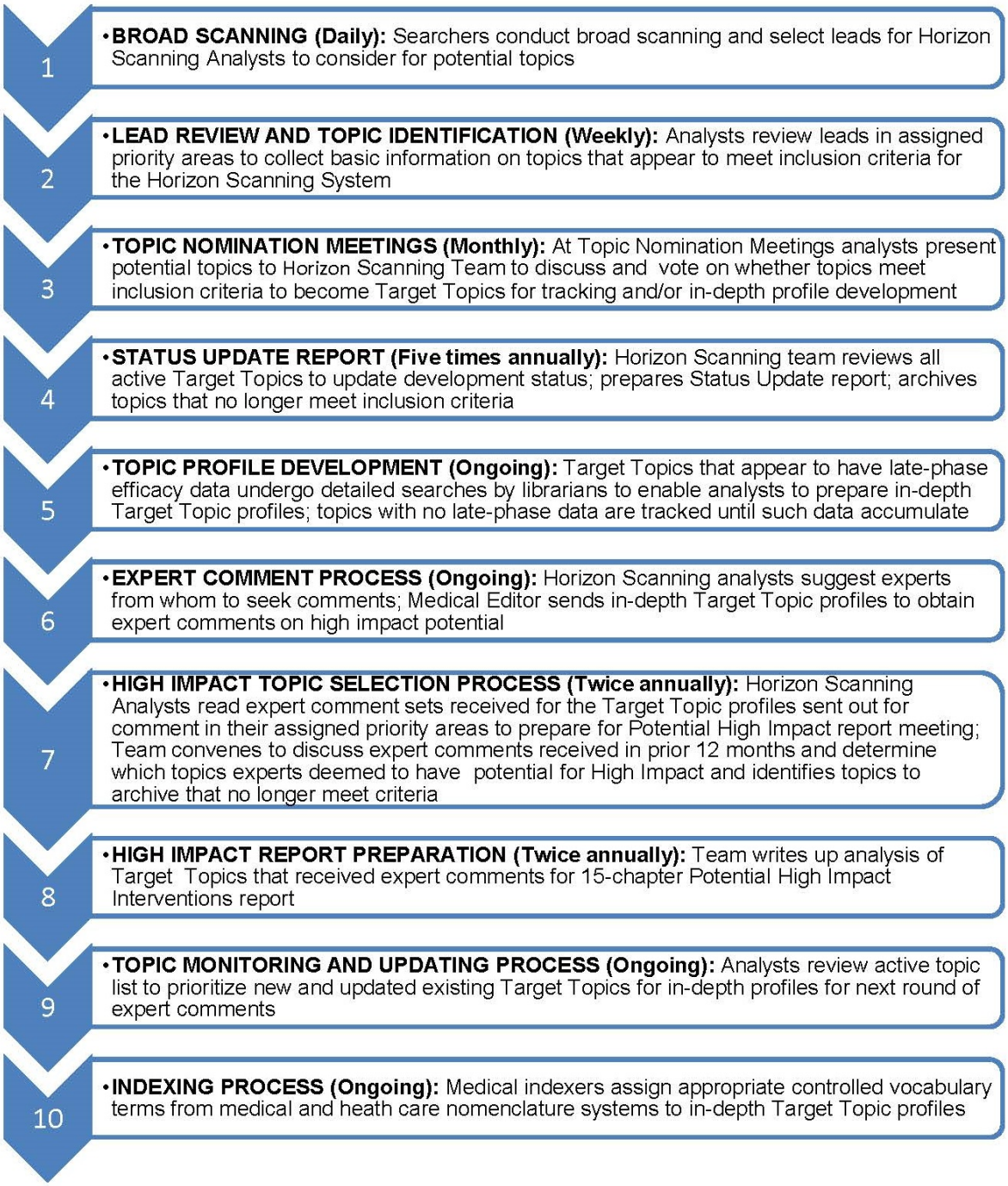
Below we present a more detailed summary of the results addressing each research question. For each question, we note which steps of the Horizon Scanning System process (outlined in Figure ES.1) are applicable. The description of the activities and the figure are drawn from the AHRQ Healthcare Horizon Scanning System: Horizon Scanning Protocol and Operations Manual.[1]

1. How Well Did the AHRQ Healthcare Horizon Scanning System Identify Emerging Health Care Interventions?

The evaluation identified minor improvements that might be made to the initial identification and prioritization of interventions as described in Steps 1 to 3 in Figure ES.1.

Identification of Interventions. For the Horizon Scanning System to be most useful to external stakeholders, relevant interventions should appear in a Status Update Report before they are approved by a Medicare national or local coverage decision, by private insurers, or the U.S. Food and Drug Administration (FDA). Of a sample of 200 interventions examined, only 2 were found to have been potentially identified after FDA approval. The first mention of these interventions in Status Update Reports followed the date of FDA approval (and thus they were potentially late-identified interventions). In one instance, the intervention had been identified by ECRI prior to FDA approval, but an ECRI analyst did not believe the intervention and associated patient population met criteria for inclusion in the Functional Limitations and Disability AHRQ priority area. In the second instance, ECRI likely would not have been able to identify the intervention through information publicly available prior to FDA approval. Thus we found only one instance where internal Scanning System processes may have resulted in an intervention not appearing in a Status Update Report prior to approval by the FDA.

Figure ES.1. AHRQ Healthcare Horizon Scanning System process overview



2. How Well Did the AHRQ Healthcare Horizon Scanning System Monitor Emerging Health Care Interventions?

There are several opportunities for improvement to consider regarding monitoring of tracked interventions, which occurs for the most part during Steps 4 and 7 in Figure ES-1.

Expert Survey Results.[b] Experts who provided feedback on Horizon Scanning System reports generally found no substantive inaccuracies and no missing information that they viewed as important. A total of 64 experts were invited to review and provide survey feedback on a Horizon Scanning System report (selected from a group of 12 reports). Twenty-six experts provided analyzable responses; none of the 26 identified any substantive inaccuracies. These experts indicated that report descriptions of the clinical use of interventions was consistent with the prevailing view of the intervention's potential role. On the question of whether reports were missing important information, 11 experts expressed that they did not have the knowledge to determine whether the reports were missing important information on this specific topic. Twelve experts responded that the reports were not missing information they viewed as important. Three experts provided examples of information that they found to be absent from the report. A secondary review by another clinician expert found that each of the three concerns expressed reflected variations in the information of interest to experts reading these reports rather than an intrinsic limitation of the reports.

Stakeholder Survey Results. Though very few stakeholder survey respondents were aware of Horizon Scanning System reports, most found the reports to be highly credible, and noted that they were relatively easy to understand. A total of 708 stakeholders were invited to review and provide survey feedback on a Horizon Scanning System report (selecting from a group of 18 Potential High-Impact Intervention reports). Of these stakeholders, 118[c] started the survey. Sixty-five of the 118 found at least one of the 18 interventions relevant to their work and completed the survey. Of these 65 respondents, 11 were aware of the Horizon Scanning System prior to participating in the survey. Eighty-two percent of respondents found the information in the reports to be highly credible, 84 percent of those who found the reports relevant reported information in the reports of interest to them was relatively easy to find, and 74 percent found the reports relatively easy to understand. Only one respondent indicated that the report reviewed was "not at all easy to understand." Similarly, only one respondent indicated that the report was "not at all useful."

[b] Because of the small number of sampled stakeholders and experts, and the low participation rate within each stakeholder group or expert condition area, these results cannot be generalized to the reference population from which the sample was selected.

[c] The stakeholder groups were patient and consumer organizations, provider professional associations, health insurance plans, Accountable Care Organization leaders, pharmaceutical and device manufacturers, researchers, and State Medicaid Agencies.

3. How Well Did the AHRQ Healthcare Horizon Scanning System Assess the Potential for High-Impact of Emerging Health Care Interventions?

Assessments of HIP of interventions proved reliable and useful to stakeholder survey respondents. Investigation of this research question for the most part addressed Steps 5 and 6 in Figure ES.1.

Variability over time in High-Impact Potential Assessments. There was variability in HIP assessments across the June 2013 and December 2014 Potential High-Impact Intervention reports. Ultimately, we cannot conclude that any Year 3 HIP assessment was incorrect absent an observation of the real-world impact of the intervention. Of the 30 interventions that were included in both the June 2013 and December 2014 Potential High-Impact Intervention reports, 15 (50%) had the same HIP assessment in both years. Six interventions (20%) were rated as having a higher HIP in the December 2014 report, whereas 9 (30%) had a lower HIP rating or had been dropped for lack of uptake or development.

Cancer Expert Survey. Because cancer interventions represent the majority of reports produced by the Horizon Scanning System, we selected a convenience sample of cancer experts to respond to a separate survey to assess the selection of Potential High-Impact Interventions by the Horizon Scanning System. Our analysis revealed that Horizon Scanning System ratings of HIP were more consistent with expert judgments for the high and moderate HIP interventions than for the interventions with no HIP. For five of the six selected interventions rated by the Horizon Scanning System as high or moderate HIP, all of the experts who provided an assessment for these interventions placed them in the top two quartiles for overall intervention impact. However, of the six selected interventions rated in the Horizon Scanning System as no potential for high-impact, two were rated by all the responding experts to be in the top two quartiles for potential impact.

Stakeholder Survey Results. We asked stakeholders to provide their perceptions of the usefulness and consistency of the section of the Potential High-Impact Intervention Reports devoted to summarizing the intervention's HIP. A majority (78 percent) of respondents indicated that they found the overall HIP section of the reports useful. Likewise, a similar proportion (71 percent) of respondents indicated there was consistency between the HIP ratings and the other information in the reports.

4. How Can the Horizon Scanning System Processes Be Improved?

Interviews with external experts and ECRI staff highlighted various opportunities for improvement, with some potential improvements applying to more than one stage of the Scanning System process. Accordingly we summarize some key lessons learned below related to potential revisions in criteria, topic profiles, use of experts, and outreach efforts.

Refine the criteria used to identify interventions of interest. Given the broad description of the Functional Limitations and Disability priority condition, staff indicated it would be helpful

to further refine the definition for this condition area. External experts and internal staff also indicated they would like additional guidance on the types of health care disparities that are relevant.

Include additional information in the topic profiles. Experts requested that Web links to additional research papers and public documents be added to the profiles. One expert also suggested that information be included on the pharmacokinetics and pharmacodynamics of the drugs reviewed.

Enhance the expert comment process. Experts noted they would like more guidance on how to respond to the question about health disparities. They also suggested it might be helpful to clarify the 4-point rating scale so that all experts would interpret the scale consistently during the process of providing ratings in response to each of the seven questions posed in the expert comment process.

Increase outreach to experts and stakeholders. Two external experts indicated they did not know how to access the finalized Horizon Scanning Reports. Internal staff agreed it would be beneficial to engage in more outreach to raise visibility among potential users of these reports.

Conclusions

Despite limitations, our evaluation provided robust insights on the core questions posed. In general, the AHRQ Healthcare Horizon Scanning System was effective in identifying emerging health care interventions relevant to AHRQ Priority Conditions. Furthermore, the Horizon Scanning System effectively monitored and reported on these emerging health care interventions, though the visibility of this effort to potential key stakeholders could be improved. Finally, the Horizon Scanning System provided a credible effort at the daunting task of assessing the potential future impact of these emerging health care interventions. In all these efforts, ECRI staff have recognized the potential value of further outreach to external experts and other Horizon Scanning System stakeholders, through professional societies and other means, to gain the additional insights needed to further enhance health care horizon scanning relevant to the complex U.S. health care system.

I. Background

Policymakers have emphasized adoption of evidence-based care as a means to address the issue of inconsistent and low-quality health care in the United States.[2] Comparative effectiveness research (CER) is integral to the growth of evidence-based care, as it provides access to research that compares the effectiveness, benefits, and harms of alternative ways to diagnose, treat, or manage a given condition. In November 2010, the Agency for Healthcare Research and Quality implemented the AHRQ Healthcare Horizon Scanning System (Horizon Scanning System) to identify, monitor, and assess emerging health care technologies and innovations to better inform CER investments of the Effective Health Care (EHC) program. The goals for the Horizon Scanning System have since evolved, and it now also serves as an information resource for the public and for private and public entities involved in decisionmaking about adoption, implementation, and coverage of new health care interventions.

ECRI Institute was awarded the contract to implement and evaluate the AHRQ Healthcare Horizon Scanning System. As a subcontractor to the ECRI Institute, Mathematica Policy Research developed and conducted the evaluation of the Horizon Scanning System, which is currently funded to operate through December 2015. This evaluation is intended to determine whether the Horizon Scanning System is implementing its functions effectively and meeting the needs of patients, clinicians, private industry stakeholders, and policymakers, and how it can be improved to better meet the needs of its diverse users. The findings of the evaluation will be useful to policymakers as they assess the Horizon Scanning System and potential changes to its operations.

A. Legislative Background and Policy

Since its authorization under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the AHRQ EHC has supported CER by (1) synthesizing research to develop evidence reports and comparative effectiveness reviews and to identify research gaps; (2) conducting new research on outcomes, comparative clinical effectiveness, safety, and appropriateness of health care products and services; and (3) disseminating the research to decisionmakers and stakeholders. The direction of EHC's research activities is informed by the input of stakeholders, who provide guidance on the identification, selection, and refinement of research interventions.

The American Recovery and Reinvestment Act of 2009 (ARRA) appropriated $1.1 billion for CER, of which $300 million was made available to AHRQ. To facilitate stakeholders' efforts to set research priorities for future EHC research, AHRQ has used this CER funding to create the initial infrastructure and implement the Horizon Scanning System. The system seeks to identify, monitor, and evaluate new and emerging technologies, off-label uses, and new uses of existing technologies and services that may have a significant clinical, system, or cost impact on the provision of health care in the United States. The Horizon Scanning System is the first public horizon scanning system to focus on emerging health interventions and innovations within the unique political, regulatory, cultural, and economic context of the U.S. health care system.

AHRQ has subsequently used funding allocated to AHRQ from the PCORI Trust Fund to continue operating and refining the Horizon Scanning System. The intent has evolved since inception and currently is to enable informed strategic planning for CER priorities and for use by

public and private decisionmakers considering the adoption and implementation of new technology. It is also a tool for the public to identify and find information on new health care technologies and interventions.

B. AHRQ Healthcare Horizon Scanning System

The Horizon Scanning System performs three functions: (1) identification and prioritization of interventions in late-phase development for tracking and monitoring; (2) monitoring of target interventions through the development of detailed information on interventions in late-phase development; and (3) assessment of potential for high-impact of target interventions through gathering and synthesizing the perspectives of experts from various areas of the health care community about the potential impact those target interventions may have on the health care system, clinical care, patient outcomes, and health care costs. This section describes the health interventions that are of interest to the Horizon Scanning System and how the functions of that system are carried out.

1. Health Interventions of Interest

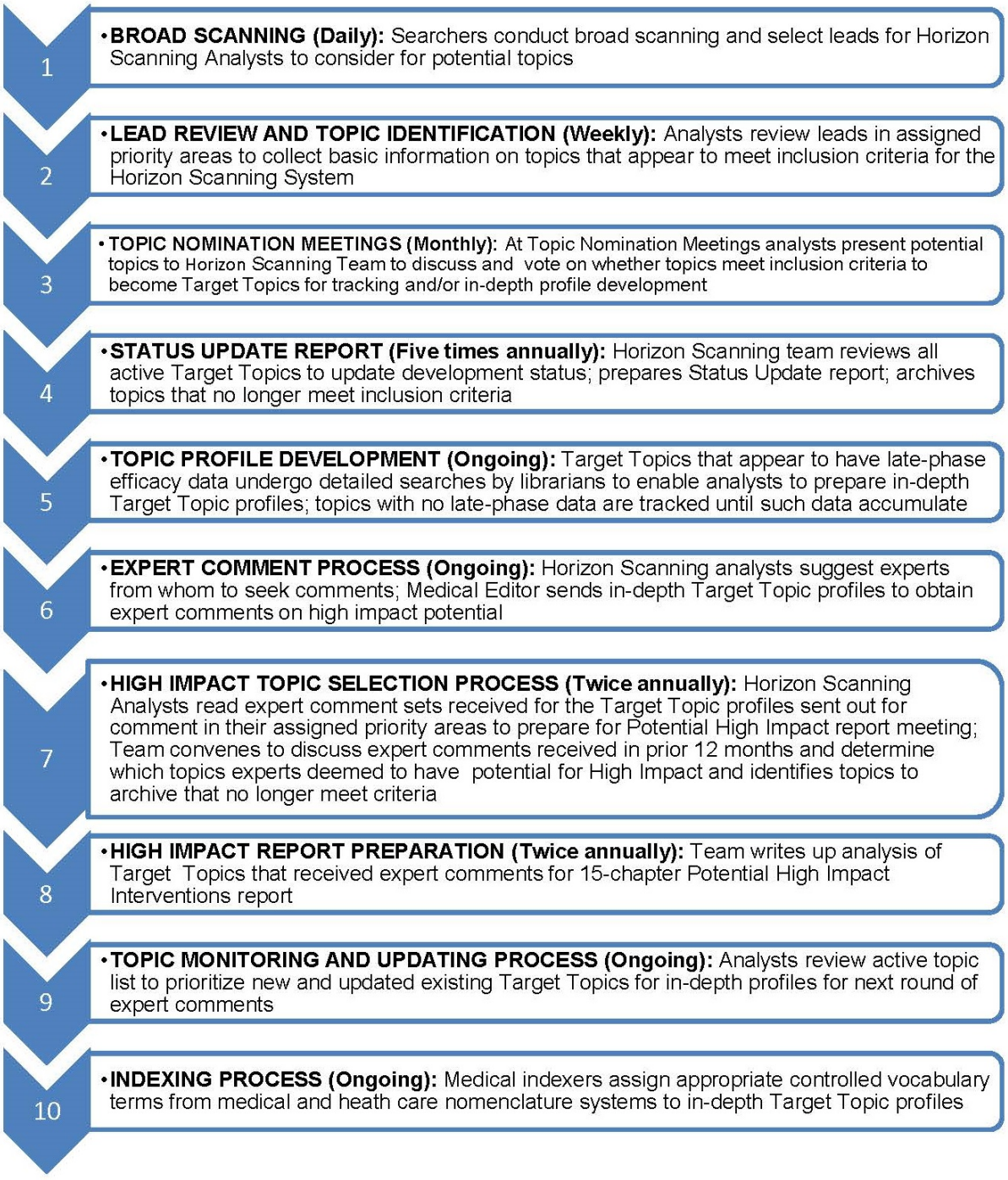
The Horizon Scanning System focuses on health interventions that address an unmet need, fall within the defined scope of health interventions, and pertain to the 14 EHC Priority Conditions consistent with the MMA.[d] For a given condition, the Horizon Scanning System defines an unmet need as any need arising from a gap in effective ways to screen, diagnose, treat, monitor, manage, or provide or deliver care for a health condition or disease. The Horizon Scanning System targets a very broad, inclusive range of health interventions, including drugs, screening and monitoring tests subject to FDA clearance or approval, medical and assistive devices, surgical techniques, therapeutic alternatives, care innovations, and systems of delivering health care.

2. Activities of the AHRQ Healthcare Horizon Scanning System

The Horizon Scanning System uses a tiered system to identify interventions for monitoring and tracking (Figure I.1). This process begins with daily, broad scanning of a variety of resources by scanners to identify leads (Step 1). A lead is any single piece of information that may link to a specific "topic." Analysts then apply defined criteria to identify those leads that are relevant to the Horizon Scanning System priority areas. These leads are posted to the Initial Leads List (Step 2) and assessed by the analysts for further consideration. Each intervention is granular; that is, it is at a product-specific, procedure-specific, program-specific level. The interventions selected by the analysts are posted to the Identified Topics List.

[d] Refer to the Glossary of Key Terms for the listing of the 14 EHC Priority Conditions.

Figure I.1. AHRQ Healthcare Horizon Scanning System process overview[e]



[e] The description of the activities and the figure are drawn from the AHRQ Healthcare Horizon Scanning System: Horizon Scanning Protocol and Operations Manual.[1] The terms *topic* and *intervention* are interchangeable. The Operations Manual is available at this hyperlink.

The analysts compile contextual information for the Identified Topics to determine which of these interventions meet the criteria to be included in the AHRQ Healthcare Horizon Scanning System and whether they should be designated "track-only" or "advance-to-target." Interventions that are designated track-only are typically in Phase III, but have not yet reported data from Phase III trials and are monitored until such data have been reported by investigators or product developers. Target interventions are those topics for which some Phase III data are available (or in the case of interventions not subject to FDA regulation, for which any efficacy or effectiveness data are available); they will be the subject of additional, detailed information searches, and development of more detailed profiles that are then sent to experts for comment. The decision to enter interventions into the Horizon Scanning System as a tracked or target topic is determined at a topic nomination meeting through a vote by the analysts, Project Manager, Content Team Leader, and Director of Information Services (Step 3). If the intervention is not voted to be added to the Horizon Scanning System, it is given the status of "identified but not tracked" or "horizon scanning criteria not met." Otherwise, upon receiving a majority vote, interventions are entered into the Horizon Scanning System and their status (track or target) is recorded.

For the target interventions, analysts prepare detailed profiles that are sent to three or four internal experts and two to four external experts for comment on their potential impact (Step 4). Experts are provided with a structured comment/potential impact ratings form and the profile draft (Step 5). They are instructed to read the intervention profiles and fill out the comment/ ratings form on potential impact in terms of seven different dimensions.

Semiannually, the AHRQ Healthcare Horizon Scanning System publishes a Potential High-Impact Interventions report for each Priority Condition. All target interventions in a given Priority Condition for which five to eight sets of expert comments have been received are considered for inclusion in the Potential High-Impact Interventions report (Step 6). Initially, comment sets received within the prior 18 months were considered; however, over time that window has been narrowed to consider only those target topics with sets of comments received within the prior 12 months. The analysts, Project Manager, Content Team Leader, Director of Information Systems, and ECRI experts review the numeric ratings and synthesize the written comments from the expert input, with expert comments taking priority over numeric ratings, to choose the interventions to include in the Potential High-Impact Interventions report.

As part of the monitoring process, all interventions in the Identified Topics List and the track and target interventions that have been added to the Horizon Scanning System are monitored daily for new information (Step 7). New information on interventions is assigned to the appropriate analyst for review, updating, and, if appropriate, revision of status. For example, new information may lead an analyst to re-propose the intervention during a topic nomination meeting. Active searches are conducted for target interventions if no new information has been generated by passive searches in the past nine months. The team uses a set of criteria to determine whether the new information warrants action (e.g., a change in status from track intervention to target intervention or a new request for comments from experts on a target intervention). During topic nomination meetings, the team uses a specified list of reasons to determine whether interventions have to be archived (i.e., monitoring is ceased) (Step 8). The final step is indexing and linking of content in all reports to support transition to a relational database should AHRQ decide to pursue that option in the future (Step 9).

3. Products of the AHRQ Healthcare Horizon Scanning System

The Horizon Scanning System produces two publicly available reports: (1) Status Updates, and (2) Potential High-Impact Interventions reports.

Status Updates

Initially the Status Update Report was prepared every 2 months (six reports/year). In January 2013, AHRQ changed to five reports (January, April, July, September, and November). AHRQ publishes the Healthcare Horizon Scanning System Status Update Report to its EHC Web site. This Status Update has three sections: Section 1 lists all interventions for which ongoing monitoring is being conducted; Section 2 lists new interventions entered in the system since the prior Status Update Report; Section 3 lists interventions archived from the system since the last report, including the reason for archiving. For each intervention in all report sections, the topic includes a title, the potential patient population, a brief description (including the developer or manufacturer and the phase of development), potentially comparable interventions, and potential health or other impacts. As explained in Chapter II, the Status Update will be the primary source of data used in assessing late-identified interventions in the evaluation.

Potential High-Impact Interventions Report

Twice a year, the AHRQ Healthcare Horizon Scanning System publishes a Potential High-Impact Interventions report for each Priority Condition. Each report contains up to 20 individual interventions deemed by expert comment processes to have potential for high-impact. The report has an Executive Summary that includes a table listing the interventions eligible for consideration for that report and which of those interventions were deemed to have potential for high-impact. A discussion summarizes briefly key information about each high-impact topic, and evolved by mid-2014 to also include a brief high-level discussion of why eligible topics were deemed to have no potential for high-impact at that time. Following the Executive Summary is a more detailed profile of each topic selected as having potential for high-impact. These profiles include the following elements:

- Intervention Overview—a description of the intervention and developer, the unmet need it purportedly addresses, development status, diffusion information (if approved for marketing), cost information (if available), and a short summary of evidence development
- Clinical Pathway at Point of This Intervention—brief discussion of how the intervention may be used in clinical care
- High-Impact Potential—an overall assessment of the HIP level (no, low, moderate, or high) and very brief summary of main expert comments
- Results and Discussion of Comments—a detailed synthesis of expert comments

These semiannual reports will be used as the basis for multiple data collection activities in the evaluation.

C. Purpose of the Evaluation

The two primary goals of this evaluation are to assess the performance of the three key functions of the Horizon Scanning System and to discern ways to improve its processes. Each function is critical to the overall performance of the Horizon Scanning System. As the first step in the scanning process, successful identification and prioritization of interventions ensures that the appropriate set of interventions will be considered for further assessment. Because the intent of the Horizon Scanning System is to inform research priorities and adoption and coverage decisions within the private and public sectors, it is important that the Horizon Scanning System provide high-quality information on target interventions. The validity of the assessment of potential for high-impact has important implications for the efficient use of future research resources devoted to CER, costs for the private and public health sectors, and health outcomes for patients. As CER will generally emphasize those interventions with high HIP, inaccurate assessment of the potential impact of interventions may lead to inaccurate identification of high-impact interventions, which in turn may result in inefficient use of research resources. As the Horizon Scanning System is relatively new, opportunities for improvements are anticipated, and some have been implemented over the duration of the system. The evaluation will identify which, if any, of these three major functions may require improvement. Identification of areas of improvement in the processes can inform specific efforts to strengthen the effectiveness of the Horizon Scanning System.

The rest of this report will describe our approach to addressing the key research questions and discuss the findings and lessons learned. Chapter II will describe the research methods, metrics, and data sources. In chapters III–V, we will present the findings. We will synthesize the findings to discuss the lessons learned in Chapter VI.

II. Methods, Metrics, and Data Sources

The evaluation uses multiple methods, metrics, and data sources to address the four primary research questions:

1. **How successfully did the AHRQ Healthcare Horizon Scanning System identify and prioritize interventions for monitoring?** Did the system identify all interventions relevant to the Priority Conditions that met the 2013 revised protocol inclusion criteria?

2. **How successfully did the Horizon Scanning System monitor the selected target interventions?** Is the information in the Potential High-Impact Interventions reports accurate and as complete as possible at the time of aggregation? Did users find the reports credible, easy to understand, relevant to their needs, and useful?

3. **How accurately did the Horizon Scanning System assess the potential for high-impact of the interventions?** How well did the system identify the Potential High-Impact Interventions and exclude lower-impact interventions? How much variability was there between the Year 3 and 4 HIP assessments for these Potential High-Impact interventions?

4. **How can processes for identification, prioritization, monitoring, and assessment of potential for high-impact of the interventions be improved?** Should any of the key elements of the protocols, such as data sources, be modified? Are there more appropriate points within the process to collect expert feedback? Should the dimensions underlying the potential for high-impact be expanded, compressed, or modified?

A. Research Methods and Metrics

1. Evaluating the AHRQ Healthcare Horizon Scanning System Identification and Prioritization Protocols

To assess the effectiveness of the Horizon Scanning System's identification process, we examined whether there were any late-identified interventions—interventions that the Horizon Scanning System should have identified earlier in their development (Table II.1). To identify late-identified interventions, we used approval data from the Food and Drug Administration (FDA), national and local coverage determination files from the Medicare Coverage Database, and publicly available coverage documents from eleven prominent private health insurers identified by ECRI and AHRQ to determine the date by which an intervention should have been identified by the Horizon Scanning System. If the date of the Status Update in which the intervention first appeared was later than the date of FDA approval or Medicare or private insurer coverage, the intervention was considered as a possible late-identified intervention.

We conducted semistructured interviews with staff and domain experts at ECRI that participate in the Horizon Scanning System across its every stage. These interviews will provide detailed input on what has worked well or was problematic during the identification process.

2. Evaluating the Horizon Scanning System Monitoring Protocol

We evaluated the monitoring protocol by assessing the accuracy, completeness, and usability of the Potential High-Impact Interventions reports (Table II.2). Accuracy and completeness were assessed by surveying a sample of domain experts who reviewed and rated a selected Potential

Table II.1. Metrics to measure success of identification and prioritization protocols

Research Goal	Metric	Definition	Measurement Details	Data Sources
How successfully did the AHRQ Healthcare Horizon Scanning System identify and prioritize interventions for monitoring?	Late-identified interventions	Number of confirmed late-identified interventions divided by the number of interventions for which we compared the date of identification by the Horizon Scanning System to the relevant comparison date	Interventions that were identified by the Horizon Scanning System about or after the time of FDA approval or Medicare or private insurer coverage	Review of FDA approval, Medicare Coverage Database, and publicly available coverage documents available via websites of eleven private insurers
	Identification and prioritization—potential process improvements	Perceptions of Horizon Scanning System staff regarding opportunities for process improvements in the identification and prioritization of interventions	Identification of opportunities for improvement in key elements of intervention identification and the prioritization process, such as lists of sources and criteria for entering interventions into the Horizon Scanning System	Key informant interviews with Horizon Scanning System staff who participate in design and implementation of the identification and prioritization of interventions

Table II.2. Metrics to measure success of monitoring protocols

	Metric	Definition	Measurement Details	Data Sources
How well did the AHRQ Healthcare Horizon Scanning System monitor target interventions?	Report accuracy	Percentage of reports with inaccurate statements regarding a target intervention	Potential High-Impact Interventions reports with inaccurate statements regarding a target intervention as judged by domain experts and confirmed by other domain experts	Survey of domain experts to rate a sample of Potential High-Impact Interventions reports Confirmation with other domain experts
	Report completeness	Percentage of intervention reports lacking important information regarding a target intervention	Potential High-Impact Interventions reports with incomplete information regarding a target intervention as judged by domain experts and confirmed by other domain experts	Survey of domain experts to rate a random sample of Potential High-Impact Interventions reports Confirmation with other domain experts
	Report usability	Relative usefulness of intervention reports to report users	Ratings of Potential High-Impact Interventions reports by their users; dimensions of ratings include credibility, ease of understanding, and relevance	Survey of stakeholders to rate a sample of Potential High-Impact Interventions reports
	Potential monitoring process improvements	Perceptions of Horizon Scanning System staff and domain experts regarding opportunities for improvements to the target intervention monitoring process	Identification of opportunities for improvement in key elements of the target intervention monitoring process	Key informant interviews with Horizon Scanning System staff and domain experts who participated in design and implementation of the target intervention monitoring process

High-Impact Intervention report on these dimensions. As we had a limited number of experts rating each report, we looked for agreement in responses between experts and confirmed these responses through short interviews with other selected domain experts, when necessary. The usability of the Potential High-Impact Intervention reports was determined by a survey that asked stakeholders to review and rate a report on three dimensions of usability, including information credibility, ease of understanding, and relevance. Interviews with the staff involved in the monitoring steps will provide additional data on which elements of the monitoring process were successfully implemented.

3. Evaluating the AHRQ Healthcare Horizon Scanning System High-Impact Potential Assessment Protocol

We used four metrics to evaluate the protocol to assess potential for high-impact (Table II.3). These analyses will draw upon multiple data sources.

We measured the accuracy of the Potential High-Impact Interventions selection by assessing its sensitivity and specificity. The sensitivity metric measures the extent to which the true Potential High-Impact Interventions were correctly included in the group of Potential High-Impact Interventions for a condition. The specificity metric is the extent to which the interventions judged as having "no high-impact potential at this time" were correctly excluded from the Potential High-Impact Interventions report. We used expert opinion to compute these two metrics. Experts assessed the potential impact of cancer interventions rated as having high or moderate HIP in the Potential High-Impact Interventions report as well as the potential impact of interventions assessed as "no high-impact potential at this time." Experts indicated the quartile into which the intervention falls among diverse emerging interventions for the given condition given the overall potential impact of that intervention. For a Potential High Impact intervention, if at least half of the experts place the intervention in the top two quartiles, we considered that intervention to be a "true" Potential High Impact Intervention. We estimated sensitivity as the percentage of the Potential High Impact Interventions that at least half of the experts ranked in the top two quartiles. For example, if among the 6 Potential High Impact Interventions being rated, at least half of the experts identified 3 interventions in the top two quartiles, the sensitivity is calculated as 3 of 6 or 50 percent. Similarly, for a non-Potential High Impact intervention, if at least half of the experts place the intervention in the bottom two quartiles, we considered that intervention to be a "true" non-Potential High Impact Intervention. We measured specificity as the percentage of non-Potential High Impact Interventions that were correctly excluded from the Potential High Impact Interventions list. For example, if among the 6 non-Potential High Impact Interventions being rated, at least half of the experts rated only 1 intervention as being in the bottom two quartiles, the specificity is calculated as 1 of 6 or 17 percent.

To evaluate the variability in the high-impact potential (HIP) assessments, we used the metric of the proportion of Potential High-Impact Interventions for which the HIP assessment was unchanged from Year 3 (2013) to Year 4 (2014).[f] We did not conduct this analysis for target interventions that have been adopted by Year 4 because the AHRQ Healthcare Horizon Scanning

[f] Because the Horizon Scanning System protocol changed in Year 3, we will use Year 3 as the baseline year for the comparison.

System will have retired these interventions from monitoring, and these interventions are unlikely to be representative of the Horizon Scanning System–monitored interventions as a whole. We reviewed the Year 3 and Year 4 Potential High-Impact Interventions reports to collect data to measure this metric.

We also evaluated the usability of the HIP assessment through the stakeholder survey. In addition to rating the overall report, stakeholders were asked specifically to rate the HIP assessment and summary of expert comments in terms of their credibility and usefulness. The analysis was supplemented by perspectives of the Horizon Scanning System staff on the activities to collect and synthesize expert comments to develop an overall assessment of HIP.

Table II.3. Metrics to measure success of high-impact potential assessment protocol

Research Goal	Metric	Definition	Measurement Details	Data Sources
How accurately did the AHRQ Healthcare Horizon Scanning System assess the potential for high-impact of target interventions?	Sensitivity of Potential High-Impact Interventions	Percentage of target interventions correctly included in the list of Potential High-Impact Interventions	List of Potential High-Impact Interventions will be ranked as in top two quartiles by domain experts	Survey of domain experts to rate the Potential High-Impact Interventions
	Specificity of Potential High-Impact Interventions	Percentage of target interventions correctly excluded from the list of Potential High-Impact Interventions	List of target interventions not identified as Potential High-Impact Interventions will be ranked as in bottom two quartiles by domain experts	Survey of domain experts to rate the target interventions that were not designated Potential High-Impact Interventions
	Variability in HIP assessment	Percentage of interventions with unvarying HIP assessments over time	For a sample of Year 3 Potential High-Impact Interventions not in use by Year 4, Year 3 and Year 4 HIP assessments will be compared	Year 3 and Year 4 Potential High-Impact Interventions reports
	Usability of HIP assessment	Relative usefulness of HIP assessments to report users	Ratings of HIP assessments in Potential High-Impact Intervention report by users; potential dimensions of ratings include credibility and usefulness	Survey of stakeholders to rate HIP assessment
	High-impact potential assessment process improvements	Perceptions of Horizon Scanning System staff and domain experts regarding opportunities for improvement in the selection and assessment of Potential High-Impact interventions	Key informant interviews to identify opportunities for improvement in key elements of the Potential High-Impact Interventions selection and assessment process	Key informant interviews with Horizon Scanning System staff and domain experts who participated in design and implementation of selection and assessment of Potential High-Impact Interventions

4. Identifying Potential Improvements to the Identification, Prioritization, Monitoring, and High-Impact Potential Assessment Protocols

We interviewed ECRI staff and outside experts who have reviewed draft Horizon Scanning System reports to identify the potential improvements that can be implemented to address the barriers and challenges faced by the Horizon Scanning System staff and external experts. Our analysis will also discuss the relative priority of the suggested enhancements.

B. Data Sources

The evaluation draws on several data sources, including the Potential High-Impact Interventions and Status Updates reports produced by the Horizon Scanning System, the FDA approval database, the Medicare coverage database, Web sites of eleven prominent private health insurers, interviews with the Horizon Scanning System staff and external experts, and surveys of domain experts, cancer experts, and stakeholders.

1. Potential High-Impact Intervention Reports

The December 2014 Potential High-Impact Intervention reports were the basis for the HIP analysis and for the stakeholder and expert surveys (Table II.4). The HIP analysis also drew on the June 2013 Potential High-Impact Intervention reports.

Table II.4. December 2014 Potential High-Impact Report—Intervention Counts by Priority Condition and High-Impact Potential Rating

Priority Condition	High HIP	Moderate HIP	Low HIP	No HIP	Total
Arthritis and nontraumatic joint disease	0	0	1	0	1
Cancer	4[a]	6	8	7	25
Cardiovascular disease	0	3	1	1	5
Dementia (including Alzheimer's disease)	0	0	1	1	2
Depression and other mental health disorders	0	2	1	0	3
Development delays, ADHD, and autism	0	0	0	1	1
Diabetes mellitus	1	0	2	1	4
Functional limitations and disability	2	6	2	1	11
Infectious disease including HIV/AIDS	4[a]	1	0	2	7
Obesity	0	1	2	1	4
Peptic ulcer disease and dyspepsia	0	1	0	0	1
Pregnancy, including preterm birth	0	0	0	0	0
Pulmonary disease, including asthma	1	3[b]	0	0	4
Substance abuse	1	0	0	2	3
Total	13	23	18	17	71

[a] All 4 reports discuss the same intervention used for related, but not identical, conditions.

[b] Two of the three reports discuss the same intervention used for related, but not identical, conditions.

HIP Analysis. The HIP analysis used the Year 3 (June 2013) and Year 4 (December 2014) Potential High-Impact reports to identify the Year 3 interventions that had not been adopted by Year 4. The June 2013 report included 144 interventions across 14 Priority Conditions and the cross-cutting category. The December 2014 report included 83 interventions across 14 Priority Conditions. A total of 30 interventions from the June 2013 report were included in the December 2014 report; these 30 are the focus of the HIP analysis. We measured the variability in the HIP assessments of the Year 3 Potential High-Impact Interventions by examining the consistency between the Year 3 and Year 4 HIP assessments. For each of these 30 Potential High-Impact Interventions in the June 2013 report, we looked at the December 2014 report to determine its HIP assessment. We estimated the variability as the percentage of the Year 3 interventions whose HIP assessments remains unchanged in Year 4.

Stakeholder Survey. For the stakeholder survey, we selected 18 reports from the 71 December 2014 Potential High-Impact Intervention reports (Table II.5). Our selection strategy ensured at least one High-Impact Intervention report for each Priority Condition area (the target was two reports from each). The final number selected depended on (1) the number of reports listed for each condition across the three eligible high-impact rating categories, and (2) whether or not the intervention was discussed in more than one report. Reports for interventions rated "high" HIP were prioritized over those for "moderate" HIP interventions. If there were no "high" or "moderate" high-impact intervention reports in a Priority Condition area, then one low high-impact intervention was selected. Reports for interventions with no HIP were not eligible for selection. After excluding the Development Delays (the sole report was no HIP and ineligible) and Pregnancy (no reports were issued) Priority Conditions, we selected reports from the remaining 12. For 6 of the 12 Priority Conditions, we selected one report from each condition area. Two reports were selected from each condition area for the remaining six Priority Conditions.

Table II.5. Selected reports by condition, high-impact potential rating, and survey use

Condition	Selected Report	High-Impact Potential Rating	Selected For
Arthritis and nontraumatic joint disease	Lesinurad for treatment of hyperuricemia and allopurinol-refractory gout	Low	Stakeholder and expert surveys
Cancer	Idelalisib (Zydelig) for treatment of indolent non-Hodgkin's lymphoma	High	Stakeholder and expert surveys
	Palbociclib (Ibrance) for treatment of estrogen receptor–positive breast cancer	Moderate	Stakeholder survey
Cardiovascular disease	Percutaneous left atrial appendage occlusion (watchman) for prevention of atrial fibrillation–associated stroke	Moderate	Stakeholder survey
	Lomitapide (Juxtapid) for treatment of homozygous familial hypercholesterolemia	Moderate	Stakeholder and expert survey
Dementia (including Alzheimer's disease)	Off-label intranasal insulin for treatment of Alzheimer's disease	Low	Stakeholder and expert surveys
Depression and other mental health disorders	Off-label ketamine for treatment-resistant bipolar depression and major depressive disorder	Moderate	Stakeholder and expert surveys
	Off-label scopolamine for treatment-resistant bipolar depression and major depressive disorder	Moderate	Stakeholder survey
Diabetes mellitus	Artificial pancreas device systems for treatment of diabetes (MiniMed 530G with Enlite Low-Glucose Suspend System)	High	Stakeholder and expert surveys
Functional limitations and disability	Retinal prosthesis system (Argus II) for treatment of retinitis pigmentosa	High	Stakeholder survey
	Eliglustat tartrate (Cerdelga) for treatment of Gaucher's disease type 1	High	Stakeholder and expert surveys
Infectious disease including HIV/AIDS	Sofosbuvir (Sovaldi) for treatment of chronic hepatitis C virus infection	High	Stakeholder survey
	Xpert MTB/RIF test for simultaneous detection and drug-sensitivity testing of mycobacterium tuberculosis	Moderate	Stakeholder and expert surveys
Obesity	Liraglutide (Saxenda) for treatment of obesity	Moderate	Stakeholder and expert surveys
Peptic ulcer disease and dyspepsia	Teduglutide (Gattex) for treatment of short bowel syndrome	Moderate	Stakeholder and expert surveys
Pulmonary disease, including asthma	Lumacaftor and Ivacaftor for treatment of cystic fibrosis	High	Stakeholder and expert surveys
	Pirfenidone (Esbriet) for treatment of idiopathic pulmonary fibrosis	Moderate	Stakeholder survey
Substance abuse	Evzio for emergency treatment of opioid overdose by nonclinicians	High	Stakeholder and expert surveys

Expert Survey. To select the reports for expert review for the expert survey, we drew 12 reports from the 18 December 2014 Potential High-Impact Intervention reports selected for the stakeholder survey. This allowed us to compare expert and stakeholder perspectives on the same reports. Within the stakeholder report sample, there was only one report for six condition areas. For the other six areas, there were two reports, from which we randomly selected a report.

To select the list of 12 interventions to compute the sensitivity and specificity measures (Table II.6), we focused on the Priority Condition area of cancer—the only one with at least 12 December 2014 Potential High-Impact intervention reports. The December 2014 intervention reports covered one high HIP, six moderate HIP, eight low HIP, and seven no HIP cancer interventions. To obtain the six cancer interventions with the highest impact, we selected the sole high HIP intervention and five moderate HIP interventions. To select the no HIP cancer interventions, we randomly selected six from the seven no HIP interventions.

Table II.6. Cancer intervention selections for expert assessment of high-impact potential

Interventions
High HIP
Ibrutinib (Imbruvica) for treatment of mantle cell lymphoma
Moderate HIP
Ado-trastuzumab emtansine (Kadcyla) antibody-drug conjugate for treatment of advanced HER2-positive breast cancer
Palbociclib (Ibrance) for treatment of estrogen receptor–positive breast cancer
Pembrolizumab (Keytruda) for treatment of advanced melanoma
Radium-223 dichloride (Xofigo) for treatment of solid tumor bone metastases
Nivolumab (Opdivo) for treatment of advanced melanoma
No HIP
Anastrozole (Arimidex) for prevention of breast cancer in postmenopausal women at elevated risk of breast cancer
Ceritinib (Zykadia) for treatment of nonsmall cell lung cancer
Liposome encapsulated irinotecan (MM-398) for treatment of pancreatic cancer
Methylated Septin 9 blood test for colorectal cancer screening
Panobinostat for treatment of recurrent multiple myeloma
Ramucirumab (Cyramza) for treatment of metastatic nonsmall cell lung cancer

2. Status Update Reports

For the late-identified interventions analysis, we used the November 2014 Status Update Reports, which included 555 interventions. To efficiently carry out this task, we selected a subset of these 555. ECRI provided us with the "topic class" designation for each intervention, which we used to sort the interventions to determine whether they were subject to FDA approval, or to a national or local Medicare coverage decision, (Table II.7). For interventions we identified as under the purview of FDA approval, we sought to select up to a maximum of 50 for each of two groups: (1) interventions for which FDA approval had already been received, and (2) interventions that were most likely to receive FDA approval in the near future (those with Phase III trials complete). For interventions subject to Medicare coverage decisions, we sought to identify up to a maximum of 100.

Table II.7. Intervention topic classes, by subject to FDA approval or Medicare coverage decision status

ECRI Topic Class	FDA Approval or Medicare Coverage Decision	Databases to Search
Assistive technology	FDA Approval	Premarket Approval (PMA), 510(k), De Novo
Biotechnology[a]	FDA Approval	Drugs@FDA, Orange Book
Care delivery innovation	Medicare Coverage	Medicare Coverage Database (MCD); private insurer websites
Device	FDA Approval	PMA, 510(k), De Novo
Diagnostic	FDA Approval	PMA, 510(k), De Novo
Diet/nutrition	Medicare Coverage	MCD; private insurer websites
Implant	FDA Approval	PMA, 510(k), De Novo
Information technology	Medicare Coverage	MCD; private insurer websites
Pharmaceutical	FDA Approval	Drugs@FDA, Orange Book
Procedure	Medicare Coverage	MCD; private insurer websites
Program	Medicare Coverage	MCD; private insurer websites
Surgery	Medicare Coverage	MCD; private insurer websites

[a] Several interventions in this category were not available in any of the FDA's searchable databases; however, there was information available on non-searchable pages of the FDA's Web site which include lists of certain types of interventions—such as stem cell therapies. In these cases, we were unable to locate indications of FDA approval. For example, information on the intervention "autologous bone marrow-derived stem cell therapy (C-Cure) for heart failure" is available via the FDA Web site section named Vaccines, Blood & Biologics (http://www.fda.gov/BiologicsBloodVaccines); however, we found no information indicating whether the therapy had been FDA approved.

Among interventions subject to FDA approval, we identified 100 in the November 2014 report for which FDA approval had been received, and we identified 21 interventions with Phase III trials completed (and with no indications of FDA approval in the Status Update Report). We identified only 36 subject to Medicare coverage decisions. Because we had planned to analyze up to 200 total interventions, we expanded our overall review by adding a random sample of 43 of the remaining 398 subject to FDA approval. This resulted in a sample of 200 to analyze for the assessment of potentially delayed interventions for horizon scanning monitoring. Table II.8 below summarizes our sample by topic class, with reference to all the interventions in the November 2014 Status Update Report. Interventions designated as Pharmaceuticals make up a majority (63%) of all interventions in the November 2014 report as well as a majority in each subcategory of our sample. Biotechnology products and interventions in the Device and Implant topic classes comprise most of the rest of the interventions. Interventions in the topic classes subject to Medicare coverage decisions (Care Delivery Innovation; Information Technology; Procedure; Program; and Surgery), made up a small proportion of the interventions included in the November 2014 Report.

Table II.8. All interventions and sample interventions, by topic class

Topic Class	All Interventions (%)	Subject to FDA Approval[a]			Subject to Medicare Coverage Decision[a] (%)
		Approval Received[b] (%)	Phase III Trial Complete (%)	Sample (%)	
Assistive technology	3 (1)	2 (2)	0 (0)	1 (2)	NA
Biotechnology	69 (12)	6 (6)	2 (10)	8 (19)	NA
Care delivery innovation	3 (1)	NA	NA	NA	3 (8)
Device	36 (6)	11 (11)	3 (14)	4 (9)	NA
Diagnostic	20 (4)	4 (4)	0 (0)	2 (5)	NA
Diet/nutrition	1 (0)	NA	NA	NA	1 (3)
Implant	39 (7)	7 (7)	2 (10)	6 (14)	NA
Information technology	9 (2)	NA	NA	NA	9 (25)
Pharmaceutical	352 (63)	70 (70)	14 (67)	22 (51)	NA
Procedure	8 (1)	NA	NA	NA	8 (22)
Program	11 (2)	NA	NA	NA	11 (31)
Surgery	4 (1)	NA	NA	NA	4 (11)
Total	**555 (100)**	**100 (100)**	**21 (100)**	**43 (100)**	**36 (100)**

Source: AHRQ November 2014 Status Update Report.

[a] Our analysis sample included 164 interventions subject to FDA approval and 36 subject to Medicare coverage decisions.

[b] Interventions in this count are those for which there was an indication of the intervention having been approved by the FDA for any use, as indicated by the Status Update Report and ECRI's database. Also included in this count are interventions for which Phase III trials had been completed (in addition to an indication of FDA approval).

In Table II.9 we present the sample interventions by AHRQ Priority Conditions. We also include the Cross-Cutting condition category that contains interventions that may affect people with multiple conditions (e.g., devices designed to improve medication adherence for people with multiple chronic conditions). The condition categories of Cancer, Functional Limitations and Disabilities, Cardiovascular Disease, and Infectious Disease Including HIV-AIDS accounted for 420 of the 555 interventions (76%) in the November 2014 Status Update Report.

Table II.9. All interventions and sample interventions, by AHRQ priority condition

Priority Condition	All Interventions (%)	Sample Interventions Subject to FDA Approval[a]			Sample Interventions Subject to Medicare Coverage Decision[a] (%)
		Approval Received[a] (%)	Phase III Trial Complete (%)	Sample (%)	
Arthritis and nontraumatic joint disease	13 (2)	1 (1)	0 (0)	2 (5)	0 (0)
Cancer	202 (36)	36 (36)	3 (14)	12 (28)	4 (11)
Cardiovascular disease	56 (10)	10 (10)	3 (14)	6 (14)	0 (0)
Dementia (including Alzheimer's disease)	17 (3)	1 (1)	1 (5)	0 (0)	0 (0)
Depression and other mental health disorders	19 (3)	1 (1)	1 (5)	1 (2)	5 (14)
Developmental delays, ADHD, Autism	10 (2)	1 (1)	0 (0)	0 (0)	2 (6)
Diabetes mellitus	15 (3)	5 (5)	0 (0)	2 (5)	2 (6)
Functional limitations and disability	108 (19)	25 (25)	7 (33)	13 (30)	8 (22)
Infectious disease including HIV-AIDS	54 (10)	7 (7)	1 (5)	2 (5)	4 (11)
Obesity	8 (1)	1 (1)	1 (5)	1 (2)	1 (3)
Peptic ulcer disease and dyspepsia	10 (2)	2 (1)	2 (10)	0 (0)	1 (3)
Pregnancy, including preterm birth	5 (1)	0 (0)	0 (0)	2 (5)	2 (6)
Pulmonary disease, including asthma	18 (3)	3 (3)	1 (5)	2 (5)	2 (6)
Substance abuse	7 (1)	4 (4)	1 (5)	0 (0)	2 (6)
Cross-cutting	7 (1)	3 (3)	0 (0)	0 (0)	3 (8)
Total	**555 (100)**	**100 (100)**	**21 (100)**	**43 (100)**	**36 (100)**

Source: AHRQ November 2014 Status Update Report.

[a] Our analysis sample included 164 interventions subject to FDA approval and 36 interventions subject to Medicare coverage decisions.

After establishing our analysis sample, we set out to find potentially late-identified interventions for monitoring. We did this by comparing the date of FDA approval for interventions subject to FDA approval and the Medicare or private insurer coverage decision (in the affirmative) for interventions subject to Medicare coverage against the date the intervention first appeared in an AHRQ Status Update Report. We examined the private payer coverage date for interventions subject to Medicare coverage because these interventions may be covered by private insurers before Medicare. More specifically, for this analysis we used the publication date of the Status Update Report that first lists the intervention as the date of public reporting of identification by the Horizon Scanning System. If the relevant FDA approval or Medicare or

private insurer coverage decision date was earlier than the date of publication of the Status Update Report that first listed the intervention, then the intervention was considered potentially "late-identified" for horizon scan monitoring.

3. U.S. Food and Drug Administration Approval Database

For the late-identified interventions analysis, several databases can be searched for the approval date for interventions subject to FDA approval. We identified and reviewed the available FDA databases appropriate to the intervention (Table II.7). Below are the FDA databases we searched and descriptions of the types of interventions tracked by each.

- **Drugs@FDA.** This database contains information about FDA-approved brand name and generic prescription and over-the-counter human drugs and biological therapeutic products. It includes most of the drug products approved since 1939. Most patient information, labels, approval letters, reviews, and other information are available for drug products approved since 1998.
  [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm].
- **Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)** identifies drug products approved on the basis of safety and effectiveness by the FDA under the Food, Drug, and Cosmetic Act.
  [http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm].
- **PMA** is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices—those that (1) support or sustain human life; (2) are of substantial importance in preventing impairment of human health; or (3) present a potential, unreasonable risk of illness or injury. The PMA database can be searched by a variety of fields and is updated once a week.
  [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm].
- **Premarket Notifications – 510(k).** While Class III devices require premarket approval, Class II devices require premarket notification and submission of a 510(k) application to FDA. Medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected.
  [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm].
- **Device Classification under Section 513(a)(1) – "De Novo" Database.** This searchable database is available for some Class III devices, as amended by Section 607 of the FDA Safety and Innovation Act on July 9, 2012.
  [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm].

4. Medicare and Private Insurer Coverage Data

For the late-identified interventions analysis, interventions within the purview of Medicare coverage were checked against the Medicare Coverage Database (MCD). We did not examine the date of Medicare coverage for interventions subject to FDA approval, because CMS typically

does not approve Medicare coverage for devices or drugs that the FDA has not approved.[g] The MCD is available to search for national or local Medicare coverage decisions on interventions, such as surgical procedures, that are not subject to FDA approval.[h]

We also searched the Web sites of eleven prominent private health insurance companies identified by ECRI and AHRQ for documentation indicating coverage policies for the interventions of interest (Table II.10). In reviewing available documents, we first determined whether (1) an intervention (or service) is covered by any private insurer for the population or condition indicated in the Horizon Scanning System, and if so (2) when did that coverage become effective.

We excluded from our analysis interventions for which there were no indications they were covered by any of the insurers – i.e., no documentation was found via insurers' search engines or available coverage documents did not explicitly include language indicating the service was covered by the insurer for the population or indication named in the Horizon Scanning System. If, during the time addressed by this analysis, an insurer considered an intervention investigational, then we did not consider the intervention covered by that insurer.

For interventions covered for the indications named in the Horizon Scanning System, we then attempted to find the earliest date at which one of the eleven insurers confirmed coverage. Doing so often required reviewing histories of policy revisions and updates, though such histories are not always available. In cases where we were unable to determine a date an intervention named in the Horizon Scanning System became covered by any insurer, we did not classify that intervention as a potentially late-identified intervention.

Table II.10. Private health insurer Web sites searched

Company Name	Web site
Aetna	https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/medical-clinical-policy-bulletins.html#
Anthem	https://www.anthem.com/cptsearch_shared.html
Regence	http://blue.regence.com/trgmedpol/contents/
HealthPartners	https://www.healthpartners.com/public/coverage-criteria/
Blue Cross Blue Shield (BCBS) of Alabama	https://www.bcbsal.org/providers/disclaimer.cfm?address=/providers/policies/finalAlpha.cfm
BCBS of Massachusetts	http://www.bluecrossma.com/common/en_US/medical_policies/411.htm
United Healthcare	https://www.unitedhealthcareonline.com/b2c/CmaAction.do?channelId=016228193392b010VgnVCM100000c520720a
Cigna	https://cignaforhcp.cigna.com/web/public/resourcesGuest/!ut/p/z1/04_Sj9CPykssy0xPLMnMz0vMAfljo8zi_d0tzAw9gg083L0C3Aw8AwycPQ2Dg40NLAz0wwkpiAJKG-AAjiD9UYSUFORGGKQ7KioCAM9Hnw0!/dz/d5/L2dBISEvZ0FBI

[g] CMS (2010), Innovators' Guide to Navigating Medicare. Version 2. [https://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf].

[h] [http://www.cms.gov/medicare-coverage-database/].

	S9nQSEh/p0/IZ7_OG861HS0HGJPF0IP0CI1SS3085=CZ6_OG861HS0HGJPF0IP0CI1SS3080=LA0=Eref!QCPsitesQCPchcpQCPresourceLibraryQCPcoveragePoliciesQCPindex.page==/
Humana	http://apps.humana.com/tad/tad_new/home.aspx?type=provider
Wellmark	http://www.wellmark.com/Provider/MedPoliciesAndAuthorizations/MedicalPolicies/MedicalPolicies.aspx
Medica	https://www.medica.com/providers/policies-and-guidelines/coverage-policies

5. Interviews With AHRQ Healthcare Horizon Scanning System Staff and External Expert Contributors

We conducted interviews with the Horizon Scanning System staff and external expert contributors (1) to learn which elements of the Horizon Scanning System Protocol are working well and why; and (2) to understand which elements can be improved, how they might be improved, and the relative importance of suggested improvements. We conducted 18 interviews with employees of the ECRI Institute who work on the Horizon Scanning System and 5 with experts external to ECRI who provided feedback on interventions identified by the Horizon Scanning System (Table A.1 in Appendix A). The list of internal staff was provided by ECRI; all staff participated in the interviews. The information from the interviews with internal staff were included in this report where they augmented or clarified findings from the expert survey, stakeholder survey, interviews with external experts, and analyses of Scanning System reports.

To identify the external experts, we drew upon the list of 221 non-ECRI (external) experts who had been invited to serve or had served as a commenter on the Horizon Scanning System reports. From this list, we focused on the subset of 45 external experts who had previously provided input on the 12 reports selected for the expert survey. We reasoned that this would increase chances of prompt responses, ensure more substantive interviews (versus interviews with people who had not reviewed an advance-to-target topic profile), and allow us to triangulate the perspectives of the expert who contributed to the report and the feedback from other experts. Among this group, we identified two experts who had commented on an advance-to-target topic in five of the AHRQ priority areas: Cancer, Cardiovascular Disease, Functional Limitations and Disability, Substance Abuse, and Dementia (including Alzheimer's Disease). We chose these priority areas and associated topic profiles because they were deemed to be potentially high-impact and were subsequently published on AHRQ's Web site as such.

We set out to interview four external experts across a range of professional backgrounds, based on the information in the ECRI's list. The first group of commenters we contacted included eight people (two individuals each reviewed two reports): four clinicians or clinician-researchers; three health system administrators; and one researcher. Of the eight commenters we first contacted, three agreed to interviews. On a rolling basis, we then reached out to eight others from the subset of 45 external experts, two of whom agreed to and completed an interview.

The interviews ranged from 15 to 75 minutes.[i] The protocol lists the questions we planned to ask each respondent (the interview protocol is in Appendix A). Generally, the number of questions and interview duration were related to each respondent's involvement with the Horizon Scanning System. Analysts, the Project Manager, and the Content Team Leader were asked the largest number of questions.

Using contact information from the Project Manager, we emailed each potential respondent to explain the general goals of the evaluation, to review the specific goals of the interview, and to schedule a time to conduct the interview. Interviews with the staff members were conducted over the telephone. Of the five external experts, three completed the interview over the telephone, and the other two responded to the questions by email.

6. Stakeholder Survey

The stakeholder survey provides data, supplementing that collected from the expert survey, to measure how well the AHRQ Healthcare Horizon Scanning System monitored and assessed the potential for high-impact of target interventions (see Appendix B for the survey instruments). The stakeholder survey was designed to collect information to evaluate the usability of the overall Potential High-Impact intervention reports and the specific report sections that include the High-Impact Potential assessment (figure), summary, and synthesis of expert comments (this part of the report is referred to as the Overall High-Impact Potential section in the survey).

Instrument Design for Stakeholder Survey

To design the stakeholder survey, we conducted cognitive testing with two examples of external stakeholders to explore the dimensions of usability. After refining the instrument based on the cognitive-interview data, the instrument was pretested with six individuals representative of the stakeholder categories of interest. The pretest focused on the format, the ease or difficulty of answering the questions, respondents' understanding of the questions, and the time required for completing the questionnaire.

Stakeholders were asked to select a report from among 18 December 2014 Potential High-Impact intervention reports to review and provide feedback on. If none of the reports were relevant, the stakeholder was screened out of the survey. The survey included questions on the credibility, ease of finding and understanding the information in the report, and usefulness of the overall report. The survey also asked about the credibility and usefulness of the Overall High-Impact Potential section, as well as questions about the HIP rating. Finally, respondents were asked to provide information about themselves, their work, how they looked for information about emerging health care interventions, and their general knowledge about the AHRQ Healthcare Horizon Scanning System.

[i] Rather than ask project leaders about particular functions of the Horizon Scanning System, we limited our questions to those involving the main functions of the Horizon Scanning System and allowed project leaders to tell us what has been working and what has not in the Horizon Scanning System. For these interviews, we typically allotted 5–20 minutes.

Selection of Stakeholder Survey Sample

The sample frame for the stakeholder survey consisted of the key groups that are most likely to use and find the Horizon Scanning System reports relevant. The stakeholder groups include (1) patient and consumer groups; (2) provider groups; (3) health care organization leaders/decisionmakers; (4) health insurance plans and payers; (5) industry members; including pharmaceutical and device manufacturing companies; (6) government policymakers; and (7) researchers. To compile the sample frame, we first identified the organizations and then the appropriate type of staff member to contact within the organization, e.g., executive director, medical/research director, or principal investigator. To identify the organizations in the first two stakeholder groups (patient and consumer groups, provider groups), we reviewed the Encyclopedia of Associations, 48th Edition[3] and focused on those associations or groups that represent providers able to bill for Medicare-covered services, as they would be the most likely users of CER information and would more frequently make health care decisions of interest to policymakers. We used the 2011 Federal Register (for providers) to guide selection of organizations to include in the frame, as those associations are relevant to key stakeholder groups. To identify associations and organizations that represented patients and consumers (in contrast to those that were grant-making organizations or service-delivery organizations), we reviewed the brief descriptions of the organizations in the Encyclopedia (and, when necessary, consulted organizational Web sites).

For health care organization leaders/decisionmakers, we compiled our frame from the list of Medicare Accountable Care Organizations. We used the membership list of America's Health Insurance Plans, a trade association for payers, to identify the sample frame for the payers group. To identify industry organizations, we used the membership lists of Pharmaceutical Researchers of America, Advanced Medical Technology, and Biotechnology Industry Organization. Government policymakers were represented by the State Medicaid directors. We used the list of ARRA CER research grantees and the PCORI comparative clinical effectiveness awardees to develop the sample frame for the researcher group.

From the sample frame of 2,017 organizations, we first selected a sample of 700 using a stratified random sampling approach with explicit stratification on the stakeholder type. A minimum of 100 organizations were to be selected from each category. Since the Medicaid agency category had fewer than 100, all these cases were selected, which left 44 that had to be selected to reach 700 in the selected sample. These were allocated proportionally to the other categories based on their frame sizes. We then drew an additional independent sample of 90 organizations, 15 for each category, except for the Medicaid agencies, for release in waves of five if needed to obtain more completes. After the stakeholder sample selection, we conducted Web site searches for the 790 to identify the targeted respondent within each organization and their contact information. However, after excluding the 81 international organizations, closed organizations, and organizations for which we could not obtain contact information, we determined that we needed to release both the initial sample and additional sample at the start of the fielding period for a total of 708. Table C.1 in Appendix C presents the total counts and initial sample selection for each stakeholder group.

Administration of Stakeholder Survey

The stakeholder survey was fielded as a Web survey over three months from April 2015 through July 2015. The sample members received multiple follow-up contacts during the field period, including reminders by email, mail, and telephone.

Of the 708 stakeholder organizations we attempted to contact, 65 participated in the survey and provided a sufficient amount of information to be considered a respondent, while an additional 53 did not find any of the reports to be relevant and were screened out from the rest of the survey. The overall completion rate for the survey was 9.2 percent. Response varied by stakeholder group. The number of responses ranged between 11 and 14 per group for the Medicaid agencies, health insurance plans, researchers, and provider associations. The remaining three stakeholder groups provided 5 or 6 responses each. Completion rate ranged between 5 and 10 percent across the stakeholder groups, except for the Medicaid agencies, which had a 27 percent completion rate. Generally, within each group, a similar percentage of the sample did not find the reports relevant to their work. The exceptions are the organizations involved with health insurance coverage—Medicaid agencies and health insurance plans, where a much lower percentage of the sample could not identify a relevant report on which to provide feedback. Table C.2. in Appendix C presents a breakdown of the number of responses for each stakeholder group. Because of the small number of sampled stakeholders and the low participation rate within each group, we do not plan to present weighted estimates that account for selection probabilities and nonresponse, and will instead present only unweighted results. This means that the results cannot be generalized to the reference population from which the sample was selected. Also, because stakeholders in different groups were sampled at different rates, unweighted results are shown separately by stakeholder group and not combined.

7. Expert Surveys

The sample for the expert surveys was drawn from a sample frame of 221 non-ECRI (external) experts who had been invited to serve or had served as a commenter on the Horizon Scanning System reports. After we excluded the 23 experts who had contributed to any of the reports we selected for the expert survey, the remaining 198 represented the sample frame.

To gather the information to measure how well the Horizon Scanning System monitored and assessed the potential for high-impact of target interventions, we conducted two separate surveys: one to domain experts across the 12 conditions to collect information to evaluate the accuracy and completeness of the Potential High-Impact Intervention reports, and the second to cancer experts to collect data to measure the sensitivity and specificity of the selection of the Potential High-Impact Interventions. These expert surveys were pretested with a clinician to make sure the concepts and survey questions were clear and to confirm the expected completion time.

Instrument Design For Expert Surveys

For the domain expert survey, respondents reviewed a Potential High-Impact Intervention report in their area of expertise and provided feedback on its accuracy and comprehensiveness. Any respondent who indicated that the report included inaccuracies, was missing important information, or was not consistent with the prevailing view at the time it was compiled (December 2014) was asked to provide an example of the issue. We also collected information

about the experts, to confirm their area of expertise, affiliations, and potential conflicts of interest. For the cancer expert survey, respondents were asked to rank 12 emerging and new health interventions, based on its overall impact potential. Respondents were not asked to provide a justification for their assessment. The actual HIP rating by the Horizon Scanning System for these 12 interventions were not presented in the survey.

Selection of Domain Expert Survey Sample

For the domain expert survey, we selected a total of 60 experts (5 for each of the 12 Priority Conditions). While 165 of the 198 experts had been classified as an expert for one Priority Condition, 33 were considered experts across multiple Priority Conditions. Therefore, it was necessary to assign the multi-area experts to one Priority Condition. To maximize the number of experts available for selection in each condition area, we first calculated the number of one-area experts in each condition area. Among the condition areas a multi-area expert was knowledgeable in, the expert was assigned to the area with the lowest number of one-area experts. Table C.3 in Appendix C presents the distribution of the sample frame, after assignment of the multi-area experts to one Priority Condition. After each expert had been assigned to a Priority Condition, we randomly selected five experts from each Priority Condition. The remaining unselected experts would serve as backup selections as needed during data collection administration.

During the course of the field period, additional sample was released to compensate for four experts for whom we could not obtain the contact information or who indicated the report was not related to his or her expertise and thus was not relevant. Each of these experts was replaced by a randomly selected expert in the same condition area.

Selection of Cancer Expert Survey Sample

After exclusion of the 5 cancer experts that were randomly selected for the expert survey, we selected a convenience sample of 22 experts for the cancer expert survey.

Administration of Domain Expert Survey

The domain expert survey was fielded over three months, from April 2015 through July 2015. It was administered primarily as a Web survey, but sample members were also offered the option to complete a hard-copy survey in the last month of the field period.

For the domain expert survey, we received 26 responses for a 41 percent completion rate (Table C.4 in Appendix C). Among the respondents, all completed the Web survey, and none completed the hard-copy survey. Pulmonary disease and substance abuse experts had the highest completion rate (80.0%). No response was obtained from cardiovascular disease experts, and only one response was received from the obesity experts. In terms of the industry area of expertise, the majority of the respondent group were clinical experts (Table C.5 in Appendix C).

Because of the small number of sampled experts and the low participation rate within each condition group, we do not plan to present weighted estimates that account for selection probabilities and nonresponse, and will instead present only unweighted results. This means that the results cannot be generalized to the reference population from which the sample was selected. Also, because experts for different conditions were sampled at different rates, unweighted results are shown separately by condition and are not combined.

Administration of Cancer Expert Survey

The cancer expert survey was administered from April through July. The experts could complete the survey by Web, hard copy, or email. We contacted 22 cancer experts on a rolling basis and received seven responses.

III. How well did the AHRQ Healthcare Horizon Scanning System Identify Emerging Health Care Interventions?

This chapter presents the findings of the late-identified intervention analysis and Horizon Scanning Staff perspectives on the identification and prioritization processes to address the question of how well the Horizon Scanning System performed the function of identifying emerging interventions.

A. Late Identification of Interventions

In our analysis sample of 200 interventions from the November 2014 Status Update Report, 36 were subject to Medicare coverage decisions. Of these, none received national or local Medicare coverage prior to publication of the November 2014 report. For these 36 interventions, we identified four which are covered by at least one of the eleven prominent private health insurers included in this analysis. None of the private insurer websites documented that the relevant service was covered by the insurer prior to the publication of the Status Update Report preceding the earliest date the intervention became privately covered.

Of the 164 interventions in our analysis sample of interventions subject to FDA approval from the November 2014 Status Update Report, we identified 33 that had been approved prior to publication of the report. Of these potentially late-identified interventions, we identified two whose first mention in Status Update Reports followed the date of FDA approval (and thus were potentially late-identified interventions).

In Table III.1 we list the two interventions—Tasimelteon (Hetlioz®) and Evzio® (naloxone HCl injection)—that were published in Status Update Reports after FDA approval. These two interventions are in the Pharmaceutical topic class and cover two AHRQ Priority Conditions: Functional Limitations and Disability and Substance Abuse.

Table III.1. Late-identified interventions

Intervention	Topic Class	Priority Condition	FDA Approval	First Status Update
Tasimelteon (Hetlioz) for treatment of non–24-hour sleep-wake disorder	Pharmaceutical	Functional Limitations and Disability	01/31/2014	04/30/2014
Evzio for emergency treatment of opioid overdose by nonclinicians	Pharmaceutical	Substance Abuse	04/03/2014	07/31/2014

The late identification of such interventions could arise from the internal/operational factors detailed below but also from external factors outside the control of the Horizon Scanning System. For example, the Horizon Scanning System could not have identified these interventions earlier than it did because the fact that an intervention was being developed for FDA consideration had not been made public. Examples of internal/operational issues that could result in late identification of an intervention include failed identification by scanners, failure of the

analyst to categorize an intervention as relevant to one of AHRQ's Priority Conditions, or difficulties applying the criteria used by analysts to advance an intervention for consideration by the topic nomination committee. Finally, the topic nomination committee could vote against the addition of the intervention to the list of topics tracked in the system. Our analysis of available information and discussions with the Horizon Scanning Staff suggest that these two interventions may reflect both external and internal factors.

FDA granted Tasimelteon orphan drug status in 2010. In discussions with the Content Team Leader, we learned that the Horizon Scanning System had identified leads for Tasimelteon in 2013—well before FDA approval—but because the scope of the project had changed in 2013, the analyst determined that the topic no longer met AHRQ criteria for inclusion. At that time, the definition of what to include in Functional Limitations and Disability also narrowed considerably, and the analyst interpreted sleep disorders as no longer meeting the inclusion criteria for this condition. During a subsequent quality control check of leads for topics, and discussion among the Horizon Scanning System managers, it was decided that this topic still met the criteria, and the intervention was formally entered into the system as an active topic, had a profile drafted, and was sent out for expert comment. Thus, this example of late identification reflects internal Horizon Scanning System operational factors, perhaps attributable to varying interpretations of changes in the scope of the project and how they would apply to the broad category of Functional Limitations and Disability.

Our Web searches on Evzio produced no information dated prior to April 3, 2014, when FDA approved it. Interviews with Horizon Scanning System staff confirmed that the System had not identified a lead for this topic until FDA approval was announced; the approval occurred unusually quickly at FDA—the application was submitted in December 2013 and was approved in April 2014. They believe the Horizon Scanning System failed to pick up Evzio for two reasons: (1) the developer is a small, privately held company that issues little information about its pipeline; and (2) it changed its name in January 2014 (from Intellijject to Kaleo), and the companies (by either name) never made a press release about Evzio until it was approved. Thus, this appears to be an example of late identification of an intervention due to external factors, reflecting the general challenge posed by privately held companies that issue little information about specific products in their development pipeline. The Horizon Scanning System may have no opportunity to obtain such information in advance, since FDA responsibility to protect proprietary information is clear: "FDA will not publicly disclose the existence of an application or abbreviated application before an approval letter is sent to the applicant . . . unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged."[j]

B. Horizon Scanning System Interviewee Perspectives

As noted, the identification process involves two stages: the topic identification and topic prioritization processes. To expand on the findings from the delayed identification analysis, we present relevant comments from our interviews with ECRI staff on what can be improved in this stage of the Horizon Scanning System.

[j] 20 C.F.R. Part 314.430.

Topic identification and prioritization process. Interventions for potential inclusion in the Horizon Scanning System are first identified via a scanning process carried out by the medical librarians. Once they identify "initial leads," analysts review them for the purpose of determining whether an intervention or topic might be nominated for entry into the Horizon Scanning System. An earlier version of the Horizon Scanning System protocol called for the scanning team to cast a very wide net in identifying interventions: scanners searched for interventions (subject to FDA approval) in early Phase II development. In mid-2013, AHRQ asked that the focus be narrowed, and scanners now search for interventions in Phase III development (in addition to products with FDA "orphan" or "fast track" status). Scanners also search for interventions not subject to FDA approval (e.g., surgical procedures, behavioral health services, care delivery innovations).

Following broad scanning and population of the Initial Leads List, analysts identify potential topics and add the topic to the potential Identified Topics List. Analysts ensure that leads are pertinent to one of AHRQ's 14 priority areas (in addition to those that are pertinent to multiple priority areas, i.e., "cross-cutting" areas) and then determine whether to nominate a topic for inclusion in the Horizon Scanning System. In deciding whether to nominate a topic, analysts rely on a set of criteria and questions developed by ECRI[k] as well as their store of knowledge on a given type of intervention. At topic nomination meetings, analysts present their "case" for including a topic in the Horizon Scanning System, and staff vote on whether to enter it into the Horizon Scanning System as track-only (topic is relevant and in Phase III, but Phase III data are unavailable) or advance-to-target (Phase III data are available, and topic is relevant), or not to enter the topic.

Need for additional guidance to determine an intervention's relevance to the Functional Limitations and Disability AHRQ priority area. As discussed above, the late identification of the intervention Tasimelteon (Hetlioz®) may have arisen during the topic prioritization process, with an analyst judging that the intervention did not meet the updated inclusion criteria for the Functional Limitations and Disability AHRQ priority area. The difficulty in applying the inclusion criteria for this priority condition area was echoed by the staff. Several interviewees suggested there might be additional refinements to these criteria, including more specific definitions for what constitutes functional disabilities and limitations to be included in the Horizon Scanning System. Someone also suggested that classifying rare conditions with debilitating effects by organ system might help remove some judgement from the process of determining whether an intervention is relevant to this priority area.

[k] See Table 10 in ECRI's *Horizon Scanning Protocol and Operations Manual*.[1]

IV. How well did the AHRQ Healthcare Horizon Scanning System Monitor Emerging Health Care Interventions?

This chapter presents the findings from the domain expert and stakeholder surveys and the perspectives of the external experts and Horizon Scanning System staff on the monitoring process to address the question of how well the Horizon Scanning System performed the function of monitoring emerging interventions.

A. Expert Survey

All but one of the experts who reviewed any of the 12 reports said either that the reports did not contain inaccuracies or that he or she did not know whether they contained inaccuracies (Table IV.1). None of the 26 experts who reviewed and provided feedback on a single report (from a group of 12 reports) (1) indicated that the reports contained an inaccuracy, or (2) provided a confirmed example of an inaccurate statement. Fourteen experts indicated that the reports did not contain inaccuracies, and the other 11 did not know whether they included inaccuracies. One expert responded that the report did include inaccuracies, but the example provided reflected an editing issue rather than incorrect information about the intervention.[l]

Only 3 of 26 of the experts who reviewed reports indicated that potentially important information was missing. Twelve experts indicated that the reports were not missing important information, and another 11 expressed that they did not have the knowledge to make that determination. Three experts provided examples of potentially important information that they found to be absent from the report—one set of comments about the Ketamine report and two sets of comments about the Evzio report.[m] A secondary review by a clinician expert on use of comparative effectiveness information indicated there was no pattern suggesting inherent incompleteness of reports. Each of the concerns expressed reflected variations in the information of interest to experts reading the reports (and thus the challenge of succinctly summarizing information on any emerging health care intervention of potential high-impact) rather than an intrinsic limitation of the reports.

[l] The expert said, "Benzodiazepines do not provide antidepressant treatment for bipolar depression, though they are commonly used for symptoms. Wording suggests antidepressant efficacy being placed after a statement about antidepressants for unipolar depression."

[m] An expert who reviewed the report on the intervention *Off-Label Ketamine for Treatment-Resistant Bipolar Depression and Major Depressive Disorder* noted that it "should include information about the ketamine-like investigational drugs, such as AZD 6765, efficacy and safety."

An expert who reviewed the report on the intervention *Evzio for Emergency Treatment of Opioid Overdose by Nonclinicians* said, "The expert opinion does not help provide any type of decision making information for this device, such as potential population reach, I am unclear as to whom the overall audience is for this document."

Finally, another expert who reviewed the report on the intervention *Evzio for Emergency Treatment of Opioid Overdose by Nonclinicians* noted, "Cost comparison (Evzio is 6 times the cost of nasal Narcan) available only in English."

Table IV.1. Expert perspectives on report quality

Measures of Information Quality	Number of Reports	Percentage of Total Reports
Reports reviewed	12	100
Contains inaccurate information	0	0
Missing important information	0	0
Does not reflect prevailing view	0	0
Contains inaccurate information, is missing important information, or does not reflect prevailing view	0	0

Similar to responses to the questions on whether reports contained inaccuracies or were missing information, the group of respondents who reviewed one of the 12 reports either (1) did not know whether the reports described clinical use of the interventions as being consistent with the prevailing view at the time they were compiled, or (2) indicated that the reports described clinical use as being consistent with the prevailing view. Seventeen experts agreed that the reports described clinical uses that were consistent with the prevailing view at the time of the compilation of the report. Two experts indicated the descriptions of clinical use were not consistent with the prevailing view; however, one did not provide an example, and the example the other cited reflected an editing issue.[n] Six experts responded that they did not know, and one did not provide a response.

B. Stakeholder Survey Findings

Of the 708 organizations contacted for the stakeholder survey, 118 representatives responded, with 65 finding at least one of 18 interventions relevant to their work and providing feedback on a report (Table C.2 in Appendix C). The other 53 representatives indicated that none of the interventions were relevant to their work and did not proceed to the survey. Though the numbers are small, there are some interesting observations across stakeholder groups. Among Medicaid directors, 14 of 16 respondents found at least one intervention relevant to their work. Similarly, 12 of 13 health plan representatives reported at least one intervention as being relevant to their work. Conversely, only 6 of 15 patient/consumer organization respondents and 11 of 28 researchers found at least one intervention relevant. Among provider professional associations, 11 of 23 respondents found at least one intervention relevant, and 6 of 12 ACO leadership respondents found at least one intervention relevant. Among and drug and device manufacturer respondents, 5 of 11 respondents found at least one intervention relevant to their work.

Relatively few stakeholder survey respondents (11 of 65) were aware of the Horizon Scanning System prior to participating in the survey (Table C.6 in Appendix C). Four of the respondents aware of the Horizon Scanning System were State Medicaid directors, and three were researchers. Ten of 11 respondents had heard of the Horizon Scanning System via AHRQ publications or its Web site. Four respondents became aware of the System via government agencies other than AHRQ, and three heard of it through work colleagues.

[n] The expert noted that "attempts that resulted in failure to auto-inject (because of insufficient pressure) were described as successful attempts."

Of the 51 of respondents who had not known of the Horizon Scanning System, 31 (61%) replied that they looked at information about emerging health interventions at least once a week, while 8 of 11 respondents (73%) who had known of the System did so (Table C.7 in Appendix C). Only one respondent who had not known of the System reported never having looked at information about emerging health interventions. When looking for information about emerging interventions, 54 of 62 respondents (87%) across both groups said that they rely on the peer-reviewed literature. Responses were similar across both groups, with professional associations, government agencies, technology assessment organizations, and colleagues being sources for which respondents rely on for information about emerging interventions.

Eight of the 11 respondents who had heard of the Horizon Scanning System reported using the associated reports (Table C.8 in Appendix C). Six reported using them to keep up to date on emerging health technologies in general: two Medicaid directors, one drug and device manufacturer representative, one representative of a provider professional association, and two researchers. Three respondents reported using the reports specifically to identify or prioritize topics for research: two Medicaid directors and one representative of a provider professional association. A State Medicaid director indicated using System reports to inform research funding decisions; the reports influenced research funding decisions "to a slight extent."

At the beginning of the survey, respondents were asked to rate the relevance of the intervention they selected to their work. Respondents rated the relevance of the intervention on a scale from 1 (not very relevant) to 5 (very relevant). Of the 65 respondents reporting at least one intervention as being relevant to their work, 28 confirmed the intervention as being very relevant (Table IV.2). Those rating reports as a "5" on this scale were health plan representatives (10), Medicaid directors (6), provider professional association representatives (6), patient/consumer group respondents (3), and researchers (3). Of the 17 respondents rating reports as a "4" on the "relevance" scale, four were Medicaid directors, four were drug and device manufacturer representatives, three were ACO leaders, three were researchers, two were health plan representatives, and one was a patient/consumer group respondent.

Most of the 65 respondents rated the reports as quite credible. Fifty-three respondents rated the reports as either "4" or "5" on the "credibility" scale; 11 rated them as a "3," and one rated a report as a "2." Of the 26 respondents who rated reports as "very credible," six were Medicaid directors, six were from provider professional associations, five were health plan representatives, four were researchers, three were ACO leaders, and two were patient/consumer organization respondents.

Table IV.2. Stakeholder perspectives on usability of reports

Dimensions of Usability Full Report	Number	Percentage of Total Respondents
Relevance to work		
5 (Very relevant)	28	43.1
4	17	26.2
3	13	20.0
2	4	6.2
1 (Not very relevant)	3	4.6
Credibility of report		
5 (Very credible)	26	40.0
4	27	41.5
3	11	16.9
2	1	1.5
1 (Not at all credible)	0	0.0
Ease of finding information interested in (of those who find the report relevant)		
5 (Very easy to find)	16	27.6
4	33	56.9
3	7	12.1
2	1	1.7
1 (Not at all easy to find)	1	1.7
Ease of understanding report		
5 (Very easy to understand)	28	43.1
4	20	30.8
3	13	20.0
2	3	4.6
1 (Not at all easy to understand)	1	1.5
Overall usefulness of report		
5 (Very useful)	22	33.9
4	24	36.9
3	15	23.1
2	3	4.6
1 (Not at all useful)	1	1.5

As with the previous set of responses on the credibility of the reports, most respondents indicated that information of interest was easy to find. Of the 58 respondents who rated the reports as a relevance of "3" or higher, 49 rated them a "4" or "5" on the question about ease of finding information of interest. Seven rated them a "3," and one indicated that it was "not at all easy to find" information of interest in the report. Of the 16 respondents rating information of interest being very easy to find, four were Medicaid directors, four were from provider professional associations, four were researchers, three were health plan representatives, and one was an ACO leader. The one respondent who indicated that information of interest was "not at all easy to find" was an ACO leader.

Tracking closely with the scale on ease of finding information of interest were the responses rating the ease of understanding the reports. Forty-eight of 65 respondents replied that the reports were easy to understand (rating of "4" or "5" on this scale), and only one indicated that a report was "not at all easy to understand." This respondent, an ACO leader, rated the report a "3" on the "relevance to their work" scale and a "2" on "overall usefulness of the report." There were 13

respondents who rated the reports a "3" on this scale. The 48 respondents rating reports as a "4" or "5" comprised Medicaid directors (11), health plan representatives (11), representatives of provider professional associations (9), researchers (8), drug and device manufacturer representatives (4), ACO leaders (3), and patient/consumer respondents (2).

Finally, most respondents rated the reports as being useful. Forty-six of 65 respondents rated the reports a "4" or "5" on the scale for "overall usefulness." Fifteen assigned the reports a rating of "3" on the "overall usefulness" scale. One respondent representing a provider professional association indicated a report was "not at all useful"; of note this respondent rated the report as a "2" on the "relevance to their work" scale. Those 46 respondents rating the reports as a "4" or "5" on the "overall usefulness" scale comprised Medicaid directors (12), health plan representatives (10), representatives of provider professional associations (8), researchers (5), ACO leaders (4), drug and device manufacturer representatives (4), and patient/consumer respondents (3).

Most stakeholder respondents (51 of 62, or 82%) said they were "somewhat" or "very" likely to access or use the Horizon Scanning System in the future (Table IV.3). Thirty-two of 62 respondents (52%) reported being "somewhat likely" to use or access reports, and 19 of 62 (31%) reported being "very likely" to do so. Of the 11 respondents who had known of the Horizon Scanning System, 5 indicated they are "very likely" to use or access it in the future, while 4 reported they were "somewhat likely" to do so. Two respondents who had known of the System indicated they were "not very likely" to access or use it in the future. Among the 51 respondents who had not known about the Horizon Scanning System, 14 indicated they were "very likely" to access or use it, and 28 indicated they were "somewhat likely" to do so in the future.

Table IV.3. Likelihood of using the AHRQ Healthcare Horizon Scanning System

Likelihood of Accessing or Using the AHRQ Healthcare Horizon Scanning System Reports	Had Known of AHRQ Healthcare Horizon Scanning System Number (Percentage of Total Responses)	Had Not Known About AHRQ Healthcare Horizon Scanning System Number (Percentage of Total Responses)	Total Number (Percentage)
Very likely	5 (45.45)	14 (27.45)	19 (30.65)
Somewhat likely	4 (36.36)	28 (54.9)	32 (51.61)
Not very likely	2 (18.18)	7 (13.73)	9 (14.52)
Not at all likely	0 (0)	2 (3.92)	2 (3.23)
Total	11 (100)	51 (100)	62 (100)

C. Horizon Scanning System Interviewee Perspectives

We note below a few findings from our interviews with external experts and ECRI staff relevant to our survey findings above.

Profile Development Process. Profile development is an ongoing process, involving medical librarians (in this role referred to as *searchers*) who develop and conduct targeted searches and

analysts who review material as well as independently perform searches on topics. After topic nomination meetings, each new "advance-to-target" topic is entered into the "production queue" for development of a more detailed profile. Analysts use two templates to develop and complete profiles for advance-to-target topics: one for clinical interventions (drugs, devices, procedures, surgery, screening, diagnostic interventions); and one for care delivery innovations.[o] For topics included in the Target Topic database, analysts review database entries generated by the automated searches and update topics to reflect the new information. Analysts update topics and may request a formal search update at any time.

Cost information can be difficult to provide. As noted above, one expert survey respondent commented that the Evzio report was missing information about the cost comparison with nasal Narcan. Internal staff noted that while the criteria on costs of the intervention are straightforward, finding good information addressing the criteria can be difficult. For example, interviewees perceived cost estimates from trade publications may be "way off" or otherwise unrealistic. Interviewees also noted the criteria for payment or reimbursement are often difficult to address. Interviewees said it is difficult to identify sources providing timely updates on reimbursement for some interventions.

Increase awareness of the Scanning System. From the stakeholder survey we learned relatively few respondents were aware of the Horizon Scanning System prior to participating in the survey. Similarly, two external experts we interviewed were unsure where to find the finalized reports on their own (despite the fact that the reports are publicly available via AHRQ's Web site). ECRI staff interviewees also expressed awareness regarding the potential limited visibility of the work to relevant stakeholders; two noted that were additional resources to be available, there could be additional efforts to make the reports more visible to stakeholders.

[o] See tables 12 and 13 in the most recent Horizon Scanning Protocol and Operations Manual.[3]

V. How Well Did the AHRQ Healthcare Horizon Scanning System Assess the Potential for High-Impact of Emerging Health Care Interventions?

This chapter presents the findings from the cancer expert and stakeholder surveys, analysis of the variability in the HIP ratings, and the interviews with the external expert contributors and Horizon Scanning System staff to address the question of how well the Horizon Scanning System assessed the potential for high-impact of emerging interventions.

A. Cancer Expert Survey

For the small set of seven expert respondents, the Horizon Scanning System ratings of HIP were more consistent with expert judgments for the high and moderate HIP interventions than for the no HIP ones. For five of the six selected interventions rated by the Horizon Scanning System as high or moderate HIP, all the experts who provided an assessment of the overall potential impact for these interventions placed them in the top two quartiles for overall impact (Table V.1). The exception is Radium-223 dichloride (Xofigo). The single expert who assessed this intervention placed its overall potential impact in the bottom two quartiles. Of note is that for each of these six interventions, at least four of the seven respondents reported that they did not know (could not assess) its relative potential impact. The "don't know/not sure" responses were not included in the analysis of the results. The sensitivity rate for the Potential High-Impact interventions was 88 percent with 5 of 6 interventions classified as potential high-impact. (See Chapter II for a description of how the sensitivity and specificity metrics were calculated). Because of the low number of respondents, we also calculated the agreement rate among all the observations of overall potential impact; this was 13 of 14 observations, or 93 percent.

Of the six selected interventions rated as no HIP in the Horizon Scanning System, at least half the experts who provided assessments placed four interventions in the lower two quartiles of overall potential impact. The other two interventions, Anastrozole and Methylated Septin 9 blood test, were assessed by all the experts who ranked them to be in the top two quartiles. As with the high and moderate HIP interventions, a minimum of four experts indicated they were unable to assess the overall potential impact for each of the no HIP interventions. The specificity rate for the non-Potential High Impact interventions was 67% with 4 of 6 interventions classified as not having potential for high-impact. The agreement rate among all the observations was 54 percent (7 of 13 observations).

The survey did not ask respondents to provide a justification or rationale for their ratings of the overall potential impact of the interventions. Nor did the survey process highlight to respondents circumstances where their assessment of overall impact of an intervention was different from the HIP assessment presented in the Horizon Scanning System. Accordingly we cannot offer any specific insights in those instances where we observed differences in HIP assessment by the small number of responding experts relative to the HIP rating in the Scanning System reports.

B. Stakeholder Survey

Sixty-three respondents selected one of the 18 potential high-impact interventions as being relevant to their work and answered survey questions regarding usability of the overall HIP section of the report they viewed.[p] Of these respondents, 44 (70%) indicated that the overall HIP section of the report was credible, with 23 rating it as "very credible" (Table V.2). Those 44 respondents rating this section as a "4" or "5" on the "credibility" scale were made up of Medicaid directors (12), health plan representatives (8), representatives of provider professional associations (7), researchers (6), ACO leaders (5), patient/consumer respondents (5), and drug and device manufacturer representatives (1). One respondent indicated that this section of the report was "not at all credible," and 15 rated it a "3" on the credibility scale.

Table V.1. Measures of sensitivity and specificity of high-impact potential rating

	Number of Experts Ranked Intervention as in—				
	Top Quartile (large impact)	Second Quartile (medium impact)	Third or Fourth Quartile (small impact)	Not Sure/ No Opinion	Total Expert Responses
High- or moderate-HIP interventions					
Ado-trastuzumab emtansine (Kadcyla) antibody-drug conjugate for treatment of advanced HER2-positive breast cancer	0	3	0	4	7
Ibrutinib (Imbruvica) for treatment of mantle cell lymphoma	1	2	0	4	7
Nivolumab (Opdivo) for treatment of advanced melanoma	3	0	0	4	7
Palbociclib (Ibrance) for treatment of estrogen receptor–positive breast cancer	0	1	0	6	7
Pembrolizumab (Keytruda) for treatment of advanced melanoma	3	0	0	4	7
Radium-223 dichloride (Xofigo) for treatment of solid tumor bone metastases	0	0	1	6	7
No-HIP interventions					
Anastrozole (Arimidex) for prevention of breast cancer in postmenopausal women at elevated risk of breast cancer	1	1	0	5	7
Ceritinib (Zykadia) for treatment of nonsmall cell lung cancer	0	1	1	5	7

[p] The overall HIP section of the report includes the High-Impact Potential assessment (figure), summary, and synthesis of expert comments.

Liposome encapsulated irinotecan (MM-398) for treatment of pancreatic cancer	1	0	2	4	7
Methylated Septin 9 blood test for colorectal cancer screening	1	0	0	6	7
Panobinostat for treatment of recurrent multiple myeloma	0	1	2	4	7
Ramucirumab (Cyramza) for treatment of metastatic nonsmall cell lung cancer	0	0	2	5	7

When asked to describe the usefulness of overall HIP section of the reports, 49 of 63 respondents (78%) indicated they found this section useful. The 49 respondents rating this section as a "4" or "5" on the usefulness scale included 13 Medicaid directors, 9 health plan representatives, 9 representatives from provider professional associations, 6 researchers, 5 patient/consumer representatives, 4 ACO leaders, and 3 representatives of drug and device manufacturers. Eleven respondents rated this section of the reports a "3" on the overall usefulness scale. One respondent indicated that the overall HIP section of a report was not at all useful; this respondent, a representative of a provider professional association, rated the overall usefulness of the report as "not at all useful" ("1" on the scale) and rated it a "2" on the "relevance to their work" scale.

Table V.2. Dimensions of usability of overall high-impact potential section of report

Dimensions of Usability	Number	Percentage of Total Respondents
Credibility of section		
5 (Very credible)	23	36.5
4	21	33.3
3	15	23.8
2	3	4.8
1 (Not at all credible)	1	1.6
Overall usefulness of section		
5 (Very useful)	18	28.6
4	31	49.2
3	11	17.5
2	2	3.2
1 (Not at all useful)	1	1.6
Consistency between HIP rating and information		
5 (Very consistent)	24	38.1
4	21	33.3
3	12	19.1
2	5	7.9
1 (Not at all consistent)	1	1.6

Finally, respondents were asked to rate on a scale of 1 to 5 the consistency between the HIP rating and the information given in the reports they reviewed. Forty-five of 63 respondents (71%) indicated there was consistency between the HIP ratings and the information contained in the reports by rating reports as a "4" or "5" on this dimension. These 45 comprised Medicaid directors (13), health plan representatives (9), researchers (7), provider professional association representatives (5), patient/consumer respondents (4), drug and device manufacturer

representatives (4), and ACO leaders (3). Twelve respondents rated consistency between HIP ratings and information in the reports as a "3." One respondent indicated that the consistency between the HIP ratings and the information in the report was "not very consistent."

C. Variability in High-Impact Potential Assessments

Of the 30 interventions that were included in the June 2013 and December 2014 Potential High-Impact Intervention reports, 15 (50%) had the same HIP assessment in both years (Table V.3). Six (20%) were rated as having a potentially high HIP in the December 2014 report, whereas 9 (30%) had a lower rating or had been dropped for lack of uptake or development. Two of the 30 interventions in the June 2013 High-Impact Potential set of reports were dropped for further development by their developer by December 2014; both these interventions had been rated previously as low HIP.

Table V.3. Change in high-impact potential assessments for 30 sampled interventions

HIP Assessment June 2013	Unchanged from June 2013 to December 2014	Higher HIP Rating December 2014	Lower HIP Rating December 2014	Archived Because Little Uptake or No Potential for High-Impact by December 2014	Archived Because Developer Dropped Indication by December 2014
High HIP	3	NA	2[a]	0	0
Moderately high HIP	8	0	2	2	0
Low HIP	3	2	1	0	2
No HIP	1	4[b]	NA	0	0
Total	**15**	**6**	**5**	**2**	**2**

[a] One intervention changed by more than 1 high-impact category.

[b] Two interventions changed by more than 1 high-impact category.

Among the limitations of this analysis is that in most cases the Year 4 (2014) assessment of potential high-impact does not provide a real measure of the actual impact of the intervention for patients. The possible exception to this caution is those interventions for which the developer has ceased pursuit of approval for this indication. Of course, even then, the manufacturer might reevaluate this judgment at some future date. Two interventions (both rated low HIP in June 2013) were in this status in December 2014.

Otherwise, we can observe variability in ratings only between the two years. One would need to observe the ultimate health system and clinical impact of a target intervention in order to assess how accurately the Horizon Scanning System assessed its potential impact in June 2013. Therefore, we cannot conclude that the Year 3 assessment was incorrect absent an observation of the real-world impact of the intervention.

D. Horizon Scanning System Interviewee Perspectives

Below we summarize findings from our interviews with external experts and ECRI staff regarding the processes associated with experts rating the potential impact of advance-to-target intervention topics.

Expert comment process. As ECRI analysts develop profiles on a topic, they identify experts who might comment on the potential impact of an advance-to-target topic. After the departure of the subcontractor that maintained a database of experts, ECRI built a new database that now contains information on approximately 170 external experts. Analysts choose potential experts from this database or suggest experts identified from the literature. For each advance-to-target topic, experts comment on and rate the potential impact of each intervention on the health care system. Because of regulations from the Federal Office of Budget and Management (OMB) under the Paperwork Reduction Act (PRA) of 1995, at most nine experts can comment on any given topic; typically, five to seven experts offer comments.[q]

Topic profiles presented to experts generally provide information sufficient for rating and commenting on interventions. Experts (both at and outside ECRI) receive topic profiles that are prepared with the templates discussed in Chapter IV. While they suggested some improvements to the profiles (which we discuss below), each expert found the information to be comprehensive and helpful in rating interventions. Experts noted that the profiles were well organized; one commented in particular on the helpfulness of the information presented on clinical trials.

However, some experts expressed that the topic profiles might include additional information for the purpose of allowing experts to more effectively address questions in the structured comment form. We heard a few requests specific to intervention topic classes for additional information in the reports. For example, an external expert with a doctorate in pharmacology expressed interest in receiving more information in the profiles on the pharmacokinetics and pharmacodynamics of the drugs reviewed (but noted the availability to ECRI of this information may be limited by pharmaceutical companies protecting certain "trade secrets"). One external expert suggested providing Web links to additional published papers and public information on the intervention in the topic profiles.

The shortened length of the expert comment and rating form is appropriate and useful for rating the potential impact of an advance-to-target topic. Most interviewees (both internal and external experts) reported the current length of the comment form to be appropriate (it had been reduced from 20 questions down to 7). One external expert said that while some aspects of the comment form may not apply to every type of intervention, the important thing is that the form is "adaptable" and "succinct"; the interviewee noted that this made participation easier and facilitated useful comments across many types of interventions.

The 4-point rating scale enables more informative ratings of potential impact. The original comment form included a 10-point (versus the current 4-point) rating scale for each of the seven questions. Most interviewees said they are comfortable with the 4-point scale, one

[q] For more information on the PRA, see [http://www.hhs.gov/ocio/policy/collection].

adding that it is useful because it facilitates more definitive ratings. A more neutral rating was possible with the 10-point scale, which made it more challenging to determine whether to include an intervention in a Potential High-Impact report.

There were several suggestions to specify more clearly what each rating means. While most interviewees are comfortable with the 4-point scale, concerns were expressed about occasional lack of agreement between experts' ratings and the associated comments. Various interviewees suggested the comment forms could include more explicit directions about what each rating means when responding to the seven questions.

Interviewees expressed difficulty addressing the health disparities criteria. External reviewers we interviewed mentioned the disparities parameter as being one that might be tailored or clarified based on the intervention as they said it was often difficult to rate. One interviewee gave the example of interventions aimed at a rare disease, Gaucher's, as being difficult to rate on the disparities parameter because it affects so few people. One expert said that "trying to gauge [impact on health disparities] is somewhat of a dart-throwing exercise" and noted that not everyone is an expert on population health analysis. This person suggested directing questions on disparities to people with relevant expertise. Several external experts noted there was sometimes not enough information in the profile to permit a response to the comment form question about the potential effects of an intervention on health disparities.

The health disparities criteria also posed issues in the earlier stages of the Scanning System. During the prioritization process, when considering bringing a topic to a nomination meeting, analysts must address whether, following adoption of an intervention, the intervention will result in health care disparities. Some analysts claim that this criterion is too broadly defined and can be difficult to address. Consistent with the experts' view, analysts also said more specificity for this criterion would be helpful for purposes of obtaining useful expert feedback.

Suggestions to improve outreach to external experts. The current process of recruiting new experts involves analysts sending a list to ECRI's expert review coordinator, who then contacts the recruits (usually via email). One analyst wondered whether in some cases having analysts contact recruits directly would increase response and participation rates. Another interviewee suggested additional expert recruitment strategies, such as reaching out to professional societies. This person also suggested recruiting in some way via AHRQ's Web site. These comments are relevant to those made by an external expert, who noted that communication with ECRI to review a particular topic report "feels haphazard" and that invitations might "be missed." ECRI interviewees also suggested that it may be an improvement for analysts to reach out to experts directly, perhaps via phone and email, when they are developing advance-to-target topic profiles.

VI. Conclusions

In November 2010, AHRQ implemented its Horizon Scanning System to identify, monitor, and assess emerging health care technologies and innovations to better inform CER investments of the EHC program. The Horizon Scanning System was also to serve as an information resource for the various members of the public involved in decisionmaking about adoption, implementation, and coverage of new health care interventions. This evaluation was designed to assess this Horizon Scanning System as the first of its kind serving U.S. decisionmakers, and learn how it might be improved to better meet the needs of its diverse potential users.

A. How Well Did the AHRQ Healthcare Horizon Scanning System Identify Emerging Health Care Interventions?

The first step of the horizon scanning process is identification and prioritization of interventions to ensure that the appropriate set of interventions will be considered for further assessment in the Horizon Scanning System. We judged the identification of an intervention to have been delayed from the perspective of the AHRQ Healthcare Horizon Scanning System if it was first included in a Status Update Report after the time of FDA approval for interventions subject to FDA approval or Medicare or private insurer coverage for interventions subject to Medicare coverage. From among the 200 interventions in the November 2014 Status Update Report we considered, we identified only 2 (1%) whose first mention in Status Update Reports followed the date of FDA approval (and thus were potentially late-identified interventions). These were Tasimelteon (Hetlioz) ®) for treatment of non–24-hour sleep-wake disorder and Evzio® (injectable naloxone) for emergency treatment of opioid overdose by nonclinicians.

The late identification of such interventions could arise from internal/operational lapses in the Horizon Scanning System or from external factors outside Horizon Scanning System control (such as lack of publicly available information regarding the intervention). Our investigation of these two instances suggest both factors may have been in play.

As noted, in the instance of Tasimelteon for treatment of non–24-hour sleep-wake intervention, the analyst did not judge Tasimelteon for non–24-hour sleep-wake problems as meeting the criteria for inclusion in the Functional Limitations and Disability area of AHRQ priorities. By the time this intervention was reclassified as relevant to the Horizon Scanning System, FDA had approved the intervention. In the second instance, Evzio was developed by a small private corporation that does not appear to have made any public announcement of its interest in developing this product prior to application to the FDA for review. Furthermore, the time from FDA application to FDA review and approval was quite short. Therefore, this appears to be an example of late identification of an intervention due to external factors, reflecting the general challenge posed by product development by privately held companies that may issue very little public information about their development pipeline.

Thus each of these two instances may offer only limited insights regarding how the Horizon Scanning System might achieve an even lower rate of late identification of an intervention. Nonetheless, our interviews with ECRI staff offer a potential enhancement in the process of target identification. In particular, interviewed staff noted that additional guidance might be

helpful to staff responsible for determining an intervention's relevance to the Functional Limitations and Disability AHRQ priority area (as in the Tasimelteon example above).

Understandably, our interviews did not identify a potential solution to the thorny problem of obtaining information on interventions kept confidential by their developers. FDA responsibilities to protect proprietary information are clear: "FDA will not publicly disclose the existence of an application or abbreviated application before an approval letter is sent to the applicant . . . unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged."[r] There might be advantages to discussions between AHRQ and FDA to consider how closer communication between the Horizon Scanning System and those at the FDA involved in assessment of new interventions could provide the most timely information possible in the Horizon Scanning System consistent with current regulations. Nonetheless, it may be inevitable that there continue to be occasions when innovations in drug delivery like Evzio cannot be noted by the Horizon Scanning System until after public announcement of FDA approval.

Various issues related to evaluating the potential impact of interventions on health care disparities were noted by interviewees as a potential challenge at several stages of the Horizon Scanning System process. This might represent its own topic for further exploration and refinement in future Horizon Scanning System efforts.

B. How Well Did the AHRQ Healthcare Horizon Scanning System Monitor Emerging Health Care Interventions?

The next step in the horizon scanning process is monitoring identified interventions. The information in the Potential High-Impact Interventions reports should be accurate and as complete as practicable. Various potential users of the reports should find them informative (e.g., relevant to their work, useful, easy to understand, and credible). Of course AHRQ as the primary audience of the reports has been integrally involved in the initial design of the Horizon Scanning System as well as its redesign. Therefore, we chose to not seek additional formal input from AHRQ. Instead, we sought the perspectives of experts familiar with the Horizon Scanning System generally regarding their view of one report not previously reviewed by them (but otherwise representative of Horizon Scanning System reports). We also sought the perspective of the types of stakeholders who are likely to be interested in, and potentially to make use of, information on emerging health care interventions. We identified these as patient/consumer organizations, provider professional associations, health insurance plans, Accountable Care Organization leaders, pharmaceutical and device manufacturers, State Medicaid agencies, and researchers.

Among Horizon Scanning System "outside" experts surveyed, no respondent identified substantive inaccuracies in the Horizon Scanning System report they reviewed (chosen by them from a group of 12 representative reports). However, on the question of whether reports were missing important information, 11 (of 26) responding experts expressed they did not have sufficient specific knowledge to give an answer. Most respondents who reported sufficient

[r] 20 C.F.R. Part 314.430.

expertise did not identify the report reviewed to have important information missing. However, three experts provided examples of information that they found to be absent from the report. Review of these examples by another clinician expert found that in each case, the concern expressed may reflect idiosyncratic variation in the information of interest to the specific expert reading the report. Thus, this survey finding may simply reflect the ongoing challenge of succinctly summarizing information on any emerging health care intervention of potential high-impact.

Of the 708 stakeholders contacted for the survey, 118 started the survey to review the 18 interventions to determine whether any of them were relevant to their work. A little over half the 118 stakeholders (65) found at least one of the 18 to be potentially relevant and completed the survey. Perhaps not surprisingly, this varied across stakeholder types. The large majority of Medicaid director and health plan representatives found at least one intervention report relevant to their work. Patient/consumer organization respondents were the stakeholder group least likely to find an intervention report relevant.

Relatively few (11) of the 65 survey respondents were aware of the Horizon Scanning System prior to participating in the survey. While we do not know how many of the 53 who could not find a relevant report were aware of the Horizon Scanning System, it is possible that low stakeholder awareness contributed to the low (17%) rate of participation from many representatives of stakeholder organizations potentially interested in health care horizon scanning.

Among those respondents who found at least one intervention relevant to their work, the large majority found the information in the reports to be credible and easy to understand. Only one respondent (an ACO leader) indicated that the report reviewed was "not at all easy to understand," and one respondent (representing a provider professional association) indicated that the report reviewed was "not at all useful."

The findings from our expert and stakeholder surveys suggest opportunities for improvement in the broader public utility of the Horizon Scanning System's monitoring of emerging interventions. While domain experts reviewing representative reports did not identify important inaccuracies, they differed on whether additional information might be helpful, highlighting the challenge of succinctly summarizing any emerging health care intervention of potential high-impact. The lack of visibility of the Horizon Scanning System to potential stakeholders may impose its own limitations to continued improvement of the reports. Therefore, additional formal outreach to key stakeholders could aid further development by increasing the visibility and use of the Horizon Scanning System, thus providing additional feedback on the most useful types of information. For example, engaging relevant key stakeholders through organizational meetings and other communication vehicles could increase visibility of Horizon Scanning System reports, as well as expand opportunities to obtain stakeholder-specific feedback.

The fact that the Horizon Scanning System has as its focus a subset of health care interventions, (those relevant to AHRQ Priority Conditions) could impose its own limitation on use of the System by different potential stakeholders. However key stakeholder groups (e.g., health plan representatives and Medicaid directors) found topics relevant to their work listed among the limited sample of 18 interventions used in the survey. Our surveys of outside experts

and stakeholders did not address the question of the optimal breadth and depth of topics monitored by the Horizon Scanning System. Discussion with Horizon Scanning System staff highlighted the advantages in efficiency offered by a narrower scope of conditions scanned. Interviewees reported that narrowing project scope made it easier for staff to become expert in identifying and prioritizing emerging interventions. Accordingly, another topic that might be explored further through engagement with Horizon Scanning System stakeholders might be the relative benefits of alternative approaches to scanning both the range of conditions and the types of interventions the Horizon Scanning System monitors.

C. How Well Did the AHRQ Healthcare Horizon Scanning System Assess the Potential for High-Impact of Emerging Health Care Interventions?

A particular challenge of any horizon scanning system is determining the potential impact of an emerging health care intervention. The AHRQ Horizon Scanning System approaches this challenge by obtaining input from 5 to 8 experts drawn from "front-line clinical specialists, generalists, and health systems and health administration professionals working in all sizes of health systems and settings"[1]). Horizon Scanning System staff then review and synthesize the numeric impact ratings and written comments from the experts to select the interventions to include in the Potential High-Impact Interventions reports.

To assess how well this approach succeeded in assessing the potential for high-impact of interventions, we used several approaches. First, we compared the consistency of the HIP assessments from the June 2013 and December 2014 Potential High-Impact Intervention reports. Of the interventions included in both the June 2013 and the December 2014 Potential High-Impact Intervention reports, half (50%) had the same HIP assessment in both years. Twenty percent had a higher HIP rating in the December 2014 report, whereas 30 percent had a lower HIP rating (or had been dropped for lack of uptake or development). Of course, inconsistency between time periods in the Horizon Scanning System HIP categorization of a specific intervention does not necessarily reflect a problem in the Horizon Scanning Systems' process for assessing the potential for high-impact of interventions. The entire purpose of ongoing research is to clarify the potential value of health care innovations. Furthermore, a more recent subjective assessment by experts of "potential" impact does not provide a measure of the actual future impact of innovations. Indeed, even interventions that the developer has ceased to pursue further might be reinvestigated in the future and re-emerge as a high-impact innovation. Only quantitative information collected over time would provide information on the actual health system and clinical impact of a target intervention relative to the potential impact predicted by the Horizon Scanning System in the June 2013 report. Without this information, we cannot conclude that any June 2013 assessment was incorrect.

We also surveyed a small sample of cancer experts to explore the question of consistency of Horizon Scanning System HIP ratings with those of independent experts. This effort uncovered additional challenges to assessing the Horizon Scanning System ratings of the HIP of interventions. While the System ratings were relatively consistent with expert judgments for the high and moderate HIP interventions, ratings for the six no HIP interventions were not. Indeed, two of these no HIP interventions were rated by all the responding experts to be in the top two quartiles of potential impact (instead of the lower two quartiles). While only one to two experts

rated these no HIP interventions, this finding may reflect the challenge inherent in obtaining reliable subjective assessments from experts on the abstract concept of potential impact of an emerging health care innovation. As the survey did not present the Horizon Scanning System ratings nor ask respondents to provide a justification or rationale for their ratings of the overall potential impact of the interventions, we cannot offer any specific insights in those instances where we observed differences in expert respondents' HIP assessments relative to the HIP ratings in the Scanning System reports.

Despite these potential limitations of the Horizon Scanning System approach to rating the HIP, the large majority of stakeholder respondents indicated they found the overall HIP section of the reports to be useful. Indeed, most found the HIP section credible, with reasonable consistency between the HIP ratings and the other information in the reports.

Our interviews documented Horizon Scanning System staff's awareness of the challenge of using expert ratings to develop reliable and informative assessments of the HIP of innovations. For example, interviewees noted that the expert comment and rating form might be improved by providing more context about the purpose of the Horizon Scanning System (an issue that was also reflected on comments by at least one expert in our surveys). There was general support for the simpler feedback tool and the more concise, 4-point rating scale used by the Horizon Scanning System in recent years. However, some experts suggested that opportunities remained to clarify the specific constructs being rated. In particular, interviewees noted the challenge understanding how to determine the potential for emerging innovations to reduce disparities in care.

D. Specific Opportunities for Horizon Scanning System Improvement

As noted above, interviews with external experts and ECRI staff highlighted various opportunities for improvement, with some potential improvements applying to more than one stage of the Horizon Scanning System process. Accordingly we summarize some key lessons learned below related to potential revisions in criteria, topic profiles, use of outside experts, and outreach efforts.

Refine the criteria used to identify interventions of interest. Given the broad description of the Functional Limitations and Disability priority condition, staff indicated it would be helpful to further specify the definition for this condition area. While these clarifications can help staff better identify interventions that meet the Horizon Scanning System criteria, it would also be helpful to document the interventions that do not meet the criteria. Internal staff and external experts also indicated they would like additional guidance on the types of health care disparities that are relevant.

Include additional information in the topic profiles. Experts requested that Web links to additional research papers and public documents be added to the profiles, to allow them the ability to read these documents in-depth. One expert asked for information on the pharmacokinetics and pharmacodynamics of the drugs reviewed.

Enhance the expert comment process. Staff made several suggestions about how to improve the utility of expert input, including emphasizing the importance of providing input on the potential impact of an intervention and modifying questions to require a more specific response, such as asking experts to provide a time line of adoption. Experts noted they would like more guidance on how to respond to the question about health disparities. They also suggested there be clarification of the 4-point rating scale so that all experts would interpret the scale consistently during the process of providing ratings in response to each of the seven questions posed in the expert comment process.

E. Limitations

As noted earlier, there are a variety of limitations to our sources of data. For example, our interviews with the volunteer outside experts and ECRI staff reflect the insights of a limited number of people with an ongoing commitment to the Horizon Scanning System. Nonetheless, these interviews collected insights from highly knowledgeable individuals who were able to articulate vivid examples of system improvements over time, and thus reflect on additional enhancement opportunities. Similarly, survey respondents (both experts and stakeholders) were a small and (given the low response rate) not necessarily representative sample of the universe of possible perspectives. Nevertheless, the surveys documented the views of a highly relevant cross-section of domain experts and potential users of Horizon Scanning System reports.

An additional limitation is the lack of an independent "gold standard" by which we might assess how successfully the Horizon Scanning System identified and prioritized interventions as having potential for high impact. In planning our evaluation we considered six other publically available scanning systems: the National Horizon Scanning Centre (NHSC); the Australia and New Zealand Horizon Scanning Network (ANZHSN); the Canadian Agency for Drugs and Technologies in Health Environmental Scanning Program (CADTH); the SorTek Program of the Basque Office for Health Technology Assessment (OSTEBA); the Italian Horizon Scanning Project (IHSP); and the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA). We had initially planned to use two of these comparison networks (e.g. NHSC and the National Horizon Scanning Unit (NHSU) of the ANZHSN) to find interventions that the AHRQ Horizon Scanning System identified but failed to prioritize, that is, interventions that other scanning networks suggest should have been labeled as Potential High Impact by the Horizon Scanning System. However, because of substantial differences in the criteria used by the networks for prioritizing interventions, we determined we could not conduct a valid comparison of prioritization. For example, one of the seven criteria by which impact is assessed in the Horizon Scanning System is the potential to affect health disparities; neither the NHSC nor the NHSU considers disparities as part of prioritization. Criteria for both the NHSC and NHSU include cost; "potential impact on health care costs" is also addressed as part of the Horizon Scanning System impact assessment but pricing of innovations in the US can be quite different than in other countries, with attendant effects on relative potential impact. Another important issue is that the different scanning approaches have different criteria for the stage of development of the intervention. The Horizon Scanning System identifies interventions in Phase III, but international networks may target interventions at an earlier point in development. Furthermore, due to regulatory differences, the same intervention may be in different stages of development across various countries. These and other differences in the criteria used for prioritization

precluded comparison of prioritization between the Horizon Scanning System and the NHSC and NHSU.

F. Summary

Despite these limitations, our evaluation provided robust insights on the core questions posed. In general, the AHRQ Healthcare Horizon Scanning System was effective in identifying emerging health care interventions relevant to AHRQ Priority Conditions. Furthermore, the Horizon Scanning System effectively monitored and reported on these emerging interventions, though the visibility of this effort to potential key stakeholders could be improved. Finally, the Horizon Scanning System provided a credible attempt at the daunting task of assessing the potential future impact of these interventions. In all these efforts, ECRI staff have recognized the potential value of further outreach to external experts and other Horizon Scanning System stakeholders, through professional societies and other means, to gain the additional insights needed to further enhance health care horizon scanning relevant to the complex U.S. health care system.

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Glossary of Key Terms

Diffusion	Point in time by which the AHRQ Healthcare Horizon Scanning System should identify interventions addressing unmet need
EHC	AHRQ's Effective Health Care program, which funds individual researchers, research centers, and academic organizations to work together with the AHRQ to produce effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers
FDA	U.S. Food and Drug Administration
High-Impact Potential (HIP)	Potential, based on expert input, for interventions to have significant impact on an unmet health need in terms of health outcomes, disparities, cost, and/or health care practice or delivery. Subcategories within the high-impact potential range assigned to the Potential High-Impact Interventions include low, moderate, and high; all of these interventions are all considered potentially high-impact interventions. Interventions assessed as no HIP are not expected to have a high impact but may still be judged to have some potential for impact.
Intervention	Individual health care technology that is tracked and monitored by the AHRQ Healthcare Horizon Scanning System. For example, if several candidates in a new class of drugs or devices are in development at the same time, each one is tracked individually during its journey through the system until consideration for the semiannual Potential High-Impact Interventions report. Interventions are also referred to as topics in the AHRQ Healthcare Horizon Scanning System Protocol and Operations Manual.
Late-identified intervention	Intervention deemed in the evaluation to have been identified by the Agency for Healthcare Research and Quality (AHRQ) Healthcare Horizon Scanning System too late in its development cycle
Lead	Article or other information found by a medical librarian during broad scanning as part of the AHRQ Healthcare Horizon Scanning System
Potential High-Impact Interventions	Interventions deemed on the basis of expert input to have the capability to have a large impact on some capacity of health care. A maximum of 20 interventions per Priority Condition can receive this distinction.
Potential High-Impact Interventions report	Report produced twice a year for each Priority Condition including up to 20 interventions labeled as Potential High-Impact Interventions. For each intervention, the report includes a description of the intervention and clinical pathway, an assessment of the High-Impact Potential category, and a synthesis of experts' perspectives.
Priority Conditions	Fourteen medical conditions identified by the EHC that have been given priority for research: arthritis and nontraumatic joint disorders; cancer; cardiovascular disease, including stroke and hypertension; dementia, including Alzheimer's disease; depression and other mental health disorders; developmental delays, attention-deficit hyperactivity disorder, and autism; diabetes mellitus; functional limitations and disability; infectious disease, including HIV/AIDS; obesity; peptic ulcer disease and dyspepsia; pregnancy, including preterm birth; pulmonary disease/asthma; and substance abuse

Target intervention	Intervention for which regular searches are conducted for new information and which undergoes profile development, expert comment, and consideration for inclusion in the Potential High-Impact Intervention report if a minimum of five sets of expert comments are collected. Target interventions are typically in the later (Phase III) stages of development with safety and efficacy data. These interventions are also referred to as advance-to-target interventions.
Topic	See *Intervention*; health care technology that is tracked and monitored by the AHRQ Healthcare Horizon Scanning System
Topic nomination meeting	Meeting with analysts, the Project Manager, the Content Team Leader, and the Director of Information Services during which the group discusses and votes on topics that have been nominated by an analyst as potential target interventions
Track-only intervention	Intervention for which regular searches are conducted for new information but which does not undergo profile development and expert comment. Track-only interventions are typically in late-phase development unless FDA grants a status of breakthrough, accelerated approval, fast-track, and/or orphan product.
Status Update	Report produced by the AHRQ Healthcare Horizon Scanning System five times a year that lists all interventions that are tracked (both track-only and target interventions), archived, or identified but not tracked
Unmet need	Any need arising from a gap in effective ways to screen, diagnose, treat, monitor, manage, or provide or deliver care for a health condition or disease.

Sources: AHRQ Healthcare Horizon Scanning System: Horizon Scanning Protocol and Operations Manual (2013).

Appendix A. Interviews

Table A.1. Horizon Scanning System interviewees

Horizon Scanning System Role	Number of staff in this role	Number of staff interviewed
Project Manager	1	1
Content Team Leader	1	1
Project Director	1	1
Analyst	6	6
Leads Manager	1	1
Searcher	12	2
Scanner	12	2
Internal Expert	4	2
External Expert	170*	5
Director of Information Services	1	1
Expert Review Coordinator	1	1

* ECRI's Expert Review Coordinator told us there are approximately 170 external experts in the current database.

INTERVIEW PROTOCOL

GENERAL INTRODUCTION AND BACKGROUND

We appreciate you taking the time to speak with us today. Before we begin, let me introduce myself and explain what we will be doing. My name is **[NAME],** and I work for Mathematica Policy Research, a social policy research firm. We are conducting an evaluation of the Healthcare Horizon Scanning System, which we will refer to as the "horizon scanning system." As part of the evaluation we are talking with a variety of people who participate in the horizon scanning system in order to:

- Learn which elements of the horizon scanning system protocol are working well and the reasons why they are working well; and
- Understand which elements of the horizon scanning system protocol can be improved, how they might be improved, and the relative importance of suggested improvements.

The results of our discussion will be synthesized in a final report. Only general themes that emerge from our discussions will be reported. We will not attribute specific comments or quotes to named individuals.

We expect this discussion to take about **[NUMBER]** minutes. Do you have any questions before we begin?

I. STAFFING

Before we ask questions about the horizon scanning process, we'd like to know more about the positions staffed on the system, the roles associated with each position, and recruiting processes. (Project Director [PD], Project Manager [PM])

1. Can you tell us the number of staff at each position? (*If necessary, recite positions*).
2. Is there high turnover among any positions? If so, why?
3. What are your strategies for recruiting staff with the necessary knowledge and qualifications?

II. SCANNING AND LEAD SELECTION

I would like to start by talking about scanning and lead selection. (Searcher [Se], Scanner [Sc], Leads Manager [LM], Analyst [A], PM, Content Team Leader [CTL])

1. Please give us one or two examples of how scanning and lead selection is working well. (*Prompt: For example, what specific sources or types of sources produce particularly high quality information?*) (Se, Sc, LM)
2. Do you track the usefulness of the sources scanned/searched? If so, how do you measure usefulness and how often do you do so? (PM, LM, A, CTL, Se/Sc)
3. How often do you reassess or update the list of sources? How often do you drop sources that are not useful and add sources? How do you identify new sources to scan/search? (*Prompts: Are there any examples of interventions that were difficult to identify using the current list of sources? What specific sources or types of sources regularly fail to produce useful information? What additional sources or types of sources are needed?*) (Se, Sc, LM, A)

Prompt for Searchers/Scanners, Analyst, and Leads Manager regarding the potentially delayed intervention, Evzio for emergency treatment of opioid overdose by non-clinicians: Have you found ways to address problems associated with identifying potential interventions under FDA consideration but for which little if any information is available due to the proprietary nature of product development? Do large and small developers vary in the amount of information that is public prior to FDA consideration? Are all agents subject to FDA approval announced as under consideration prior to the FDA determination? If so, what might be the shortest timeframe between FDA publicly indicating an agent is under consideration and approving the agent? If not, what challenges does that pose to identifying potential targets and entering these for tracking?

Prompt for Searchers/Scanners and Analyst regarding the potentially delayed intervention, Tasimelteon (Hetlioz) for treatment of non-24-hour sleep-wake disorder: [If applicable]: Can you talk a bit about the history of this intervention – how it came to be identified, removed, etc.? Was it on the Identified Topics List and then removed? Do you know which particular AHRQ criteria might have caused the analyst to categorize the topic as no longer meeting AHRQ's inclusion criteria? Do you know what specific change(s) to the definition of the Functional Limitations and Disability area led to the analyst to conclude it no longer fell within this condition area? Did changes to the definition, and which ones, make it more difficult to determine whether new leads fit within this area? When the definition of the Functional

Limitations and Disability area changed, did this affect any of the interventions that had been classified in this area prior to this change? Under the new definition for the Functional Limitations and Disability area, would non-24-hour sleep-wake disorder make it on a leads list for that priority area? If it's not clear it would be included in the Functional Limitations and Disability area, do you have any suggestions regarding how to make this decision easier?

4. What suggestions do you have for how to improve the questions intended to help identify leads? (horizon scanning system protocol pp. 7–9) (*Prompts: What questions should be added or removed? What suggestions do you have for making the questions easier to apply? Would providing additional guidance to scanners about assigning leads to priority areas be helpful?*) (Se, Sc, LM)
5. Questions regarding determining whether the lead pertains to one of the 14 AHRQ-defined priority areas or the crosscutting priority area (Se, Sc, LM, A, PM, CTL)

a. Do **[you (Sc)/scanners; Se (LM, CTL, PM)]** have difficulty determining whether leads should be assigned to a priority area, including the crosscutting priority area? If so, what kinds of difficulties do you/they encounter? And in what situations? (Se, Sc, LM, PM, CTL)

b. Do **[you (A)/analysts (CTL, PM)]** have difficulty determining whether interventions should be assigned to a priority area, including the crosscutting priority area? If so, what kinds of difficulties do you/they encounter? And in what situations? If so, any suggestions regarding how one might address these difficulties in future? (A, PM, CTL)

Probe regarding potentially delayed intervention, Tasimelteon (Hetlioz) for treatment of non-24-hour sleep-wake disorder (CTL, PM): What about Tasimelteon (Hetlioz) for treatment of non-24-hour sleep-wake disorder? Under the new definition for the Functional Limitations and Disability area, would non-24-hour sleep-wake disorder make it on a leads list for that priority area? If it's not clear it would be included in the Functional Limitations and Disability area, do you have any suggestions regarding how to make this decision easier?

6. From the Protocol and Operations Manual we learned scanners are to err on the side of being inclusive. Is the daily volume of leads generally manageable? (*Prompts: Do leads from multiple sources present problems such as presenting information that is contradictory? What is the percentage of leads that become topics that are developed?*) (Se/Sc, A, LM)

III. DEVELOPMENT OF INTERVENTIONS

Now I would like to talk about development of interventions and determination of which interventions are brought to the topic nomination meeting. (A)

1. Does the algorithm you use to assess and sort leads for the purpose of identifying potential topics work well (Table 8, p. 10 of Protocol and Operations Manual)? (A, PM, CTL)
2. How would you improve the criteria for entering interventions into the horizon scanning system? (Table 10, p. 11 of Protocol and Operations Manual) (A)

3. How often are you unsure about whether an intervention should be dropped or proceed to a vote during a topic nomination meeting? (A)
    a. What do you do when you are unsure? (*Prompts: What is the process? Is there a set process? What changes, if any, should be made to that process?*) (A)
    b. How many of the identified topics move to a topic meeting?

IV. TOPIC NOMINATION MEETINGS AND PROFILE DEVELOPMENT FOR TARGET INTERVENTIONS

Now I would like to talk about topic nomination meetings and profile development for target interventions (A, PM, CTL)

1. What aspects of the topic nomination meetings and voting work well? (A, PM, CTL)
2. How many topics are covered during a regular monthly topic nomination meeting? What precipitates holding more than one meeting during a given month? (A, PM, CTL)
3. How many meetings does it usually take to get a vote on a topic? (A, PM, CTL)
4. How many of the topics that are presented get voted as track-only, advance-to-target, or dropped? (A, PM, CTL)
5. Is it difficult to get appropriate staff members and experts to attend topic nomination meetings? If so, how is this addressed? (A, PM, CTL)
6. In the topic nomination meetings, how are the criteria for entering a topic into the scanning system (Table 10, p. 11) addressed? (*Potential prompts: Do team members and invited guests review the analyst's responses to the criteria for entering a topic into the scanning system prior to the actual topic nomination meeting? Are the criteria explicitly addressed during the meeting?*) (A, PM, CTL)
7. What other suggestions do you have for improving the meeting aspects of the topic nomination process? (*Prompts: What changes, if any, would you make to the length and frequency of the meetings? Should meetings be restricted to specific priority areas? If yes, what changes would you make? What changes, if any, would you make to who attends the meeting? Would you add additional attendees? If yes, who and what types of attendees would you add?*) (A, PM, CTL)
8. What ideas do you have for improving communication among searchers and analysts? (LM, A, Director of Information Services [DIS], PM, CTL,)
9. What ideas do you have for improving communication among analysts and the database management team (or reference management team)? (A, PM, CTL, Reference Manager [RM])
10. Please discuss any challenges that have arisen when developing an intervention profile for an intervention that advances to target. (A, CTL, PM)
    a. How have **[you (A)/analysts (Se, CTL, PM)]** responded to these challenges? (A, CTL, PM) (*Prompt: What challenges have you faced with conducting searches for the advance-to-target interventions?*)
    b. What changes, if any, would you make to the templates used to develop target intervention profiles to make them more useful? (Horizon scanning system protocol Tables 12 and 13, p. 14) (A)

c. How often do you have to make specific requests or follow-up data requests to the database management team? (A)

11. What happens to topics that are not entered into the Scanning System? Are they kept in the Leads and Topic Lists? What is the process for searching? How often might they be reconsidered in future Topic Nomination meetings? (A, CTL, PM)

Prompts, for Searcher/Scanner tasked with tracking potentially delayed intervention, Evzio for emergency treatment of opioid overdose by non-clinicians: How did Evzio come to be entered into the Scanning System? Are there ways it might have been identified prior to FDA approving its use?

Prompts, for Searcher/Scanner tasked with tracking potentially delayed intervention, Tasimelteon (Hetlioz) for treatment of non-24-hour sleep-wake disorder: How did Hetlioz come to be entered into the Scanning System? Are there ways it might have been identified prior to FDA approving its use?

V. EXPERT INPUT AND DETERMINATION OF POTENTIAL HIGH-IMPACT INTERVENTIONS

Next I would like to talk about expert comment process and determination of Potential High-Impact Interventions. (A, PM, CTL)

I would like to talk about the expert review process. (E, Expert Review Coordinator [PRI])

1. How many experts are contacted to get the target of 5-8 responses? Is the selection random or do you tend to use the more responsive experts? Do you contact all the selected experts at once or use a staggered process? (PD, PM, PRI)
2. Please provide a couple of examples of how the process of identifying experts and gathering comments is working well. (A, PM, CTL)
3. In what ways can selection of experts be improved? (*Prompts: Should changes be made to address the balance of reviewer categories (e.g., health systems, clinical research)? If yes, how so? Should more or fewer experts be contacted on the first pass? If more or fewer, please say more about that.*) (A, PM, CTL)
   a. What improvements, if any, should be made to the process of identifying and balancing conflicts of interest? (A, PM, CTL)
4. In what ways can communication with experts be improved? (A, PM, CTL, Expert [E], PRI)
5. How would you describe the amount of information that you **[provide (A)/receive (E)]** on an intervention that **[experts (A)/you (E)]** are asked to review? (*Prompt: Is it adequate, too much, or too little information? Do you have any suggestions for improving this process or the resulting reports on high-impact interventions?*) (A, E)
6. What suggestions do you have for improving the Horizon Scanning intervention comment form? (*Prompt: Should parameters be added, deleted, or revised? Are changes needed to the four point rating system?*) (horizon scanning system protocol pp. B1-B3) (A, PM, CTL, E, PRI)

7. What suggestions do you have for improving the process of reviewing expert comments and comparing comments with ratings? (*Prompts: How difficult is it to handle topics where experts provide similar comments but different ratings? How many people are involved in reviewing the comments and assigning ratings?*) (A, PM, CTL)
8. My final question is about the Potential High-Impact reports. Have you had a chance to review at least one of those reports? (E)
    a. If so, what suggestions do you have about ways to improve the Potential High-Impact reports? (*Prompts: Do you think the information should be framed differently? Was there sufficient clinical context? How might the Potential High-Impact rating be explained more clearly?*) (E)

VI. INTERVENTION ARCHIVING, MONITORING, UPDATING, AND REASSESSMENT OF POTENTIAL IMPACT

Now let's talk about intervention archiving, monitoring, updating, and reassessment of potential impact. (A, DIS, Se)

1. What lessons have been learned from automated daily searching on "track-only" and "advance-to-target" interventions? (*Prompts: Are some triggers for updates of interventions more commonly identified than others? (horizon scanning system protocol Table 14, p. 18) If yes, what are those? How can communication between searchers, analysts, and reference managers be improved?*) (A, DIS, Se)
2. For track-only interventions, have you encountered problems associated with sources that are issued on a monthly or quarterly basis? For example, does the time lag in these types of publication schedules cause problems identifying late-phase data in a timely manner? How do you address these types of publication schedules? (A, DIS, Se, Sc)
3. What lessons have been learned from active searching on "advance-to-target" interventions? (*Prompt: How could lessons from active searching be used to improve automated daily searching?*) (A, DIS, Se)
4. What lessons from automated searches and active searches could be applied to improve scanning for leads? (A, DIS, Se)

VII. OVERARCHING AND MISCELLANEOUS QUESTIONS

We're almost done. Thanks so much for talking with us. (A, PM, CTL)

I have [one (A, PM, CTL)/three (PD)] overarching question[s] for you. (A, PM, CTL, PD)

1. The three main functions of the horizon scanning system are: (1) identification and prioritization of interventions for tracking and monitoring; (2) development of detailed content on target interventions and acquisition of expert opinions about the potential impact of the interventions; and (3) synthesis of perspectives of experts. Which of these functions should receive more resources? Which should receive less resources? (A, PM, CTL, PD)
2. What steps or activities of the horizon scanning system have been the most successful? (*Prompts: Scanning? Intervention nomination meetings? Gathering expert reviews?*

Review of expert comments and scores? Creation of the Potential High-Impact reports? Automated searching and intervention monitoring?) (PD)

3. What steps or activities of the horizon scanning system have been the least successful? (*Prompts: Scanning? Topic nomination meetings? Gathering expert reviews? Review of expert comments and scores to determine potential high impact interventions? Automated searching and intervention monitoring?*) (PD)

Those are all the questions I have. Do you have any final thoughts about the AHRQ Healthcare Horizon Scanning System that you'd like to share with us?

Thanks again for taking the time to talk with us today. We really appreciate your input. Have a good day. Good-bye.

Appendix B. Surveys

Form Approved
OMB No. 0935-0229
Exp. Date 12/31/2016

MATHEMATICA
Policy Research

HEALTHCARE HORIZON SCANNING SYSTEM STAKEHOLDER SURVEY

Sponsored by the Agency for Healthcare Research and Quality (AHRQ)

Conducted by Mathematica Policy Research

INSTRUCTIONS

The Agency for Healthcare Research and Quality (AHRQ) is sponsoring this survey as part of the **evaluation of the AHRQ Healthcare Horizon Scanning System**. Mathematica Policy Research, an independent social policy firm, is conducting the survey for the evaluation. The survey will help AHRQ assess the Potential High Impact Interventions Report series issued by the AHRQ Healthcare Horizon Scanning System.

Thank you for taking the time to complete the survey. The purpose of the survey is to solicit your feedback on an AHRQ Healthcare Horizon Scanning System report. As part of the survey, we will list reports on 18 health care medications, devices, and processes and ask you to select a report on a topic that is most relevant to your work. We will ask you to read and provide feedback on this report. Your participation and input is very important. It should take you about 30 minutes to read the report and complete this survey.

Please be assured that:

- Your participation in the survey is voluntary. However, we hope that you will participate and answer as many questions as you can.
- Your answers will be used for study purposes only. All responses will be combined and data will be reported in the aggregate. No names of individuals or organizations will be used in any reports.

If you have difficulty or questions when completing this survey, please call 855-743-8476 toll free or click here Contact@HorizonScanningSurvey.org to send an email.

You can find more information about the survey if you click on this link: Frequently Asked Questions sheet.

Below is a list of reports on 18 health care medications, devices, and processes. We will ask you first to identify the intervention report that is most relevant to your work for you to provide feedback on.

- **To browse the reports, please click on the intervention name to open the report in another window.**
- **Once you have selected the report you will provide feedback on, please read the report, and keep the report on hand as you complete the survey. You may also print the report.**
- **You will have an opportunity to view and print this report at any time in the survey.**
- **Please return to the survey window to continue the survey.**

1. Artificial Pancreas Device Systems for Diabetes (MiniMed 530G with Enlite Low-Glucose Suspend System)
2. Eliglustat Tartrate (Cerdelga) for Gaucher's Disease Type 1
3. Evzio for Opioid Overdose by Nonclinicians
4. Idelalisib (Zydelig) for Indolent Non-Hodgkin's Lymphoma
5. Intranasal Insulin for Alzheimer's Disease
6. Ketamine for treatment-resistant Bipolar Depression and Major Depressive Disorder
7. Lesinurad for Hyperuricemia and Allopurinol-Refractory Gout
8. Liraglutide (Saxenda) for Obesity
9. Lomitapide (Juxtapid) for Homozygous Familial Hypercholesterolemia
10. Lumacaftor and Ivacaftor for Cystic Fibrosis
11. Palbociclib (Ibrance) for Estrogen Receptor–Positive Breast Cancer
12. Percutaneous Left Atrial Appendage Occlusion (Watchman) for Atrial Fibrillation–Associated Stroke
13. Pirfenidone (Esbriet) for Idiopathic Pulmonary Fibrosis
14. Retinal Prosthesis System (Argus II) for Retinitis Pigmentosa
15. Scopolamine for treatment-resistant Bipolar Depression and Major Depressive Disorder
16. Sofosbuvir (Sovaldi) for Chronic Hepatitis C virus infection
17. Teduglutide (Gattex) for Short Bowel Syndrome
18. Xpert MTB/RIF Test for Simultaneous Detection and Drug-Sensitivity Testing of Mycobacterium Tuberculosis

A0. Please indicate which intervention report you will provide feedback on in this survey.

MARK ONE ONLY

1 ☐ Artificial Pancreas Device Systems for Diabetes (MiniMed 530G with Enlite Low-Glucose Suspend System)

2 ☐ Eliglustat Tartrate (Cerdelga) for Gaucher's Disease Type 1

3 ☐ Evzio for Opioid Overdose by Nonclinicians

4 ☐ Idelalisib (Zydelig) for indolent non-Hodgkin's lymphoma

5 ☐ Intranasal Insulin for Alzheimer's Disease

6 ☐ Ketamine for treatment-resistant Bipolar Depression and Major Depressive Disorder

7 ☐ Lesinurad for Hyperuricemia and Allopurinol-Refractory Gout

8 ☐ Liraglutide (Saxenda) for Obesity

9 ☐ Lomitapide (Juxtapid) for Homozygous Familial Hypercholesterolemia

10 ☐ Lumacaftor and Ivacaftor for Cystic Fibrosis

11 ☐ Palbociclib (Ibrance) for Estrogen Receptor–Positive Breast Cancer

12 ☐ Percutaneous Left Atrial Appendage Occlusion (Watchman) for Atrial Fibrillation–Associated Stroke

13 ☐ Pirfenidone (Esbriet) for idiopathic pulmonary fibrosis

14 ☐ Retinal Prosthesis System (Argus II) for Retinitis Pigmentosa

15 ☐ Scopolamine for treatment-resistant Bipolar Depression and Major Depressive Disorder

16 ☐ Sofosbuvir (Sovaldi) for chronic hepatitis C virus infection

17 ☐ Teduglutide (Gattex) for Short Bowel Syndrome

18 ☐ Xpert MTB/RIF Test for Simultaneous Detection and Drug-Sensitivity Testing of Mycobacterium Tuberculosis

0 ☐ None of these topics is relevant to my work **GO TO A00**

IF A0=1-18, GO TO A1

A00. Thank you for your willingness to complete this survey. Please take a moment to indicate to us why none of these topics are relevant to your work.

❍ In general, assessments of the potential impact of health care interventions are not relevant to my work 1

❍ The health conditions relevant to my work are not included in this list 2

❍ Other

Specify [ ]

GO TO END

A. FEEDBACK ON THE OVERALL REPORT

The first few questions are about your opinion of the overall report on [INTERVENTION NAME].

A1. Please rate the relevance of the intervention of [INTERVENTION NAME] to your work.

Not very relevant 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very relevant

A2. Please rate the credibility of the report. By credibility, we mean how much confidence you had in the correctness of the information in the report.

Not at all credible 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very credible

IF A2 = 3 OR 4 OR 5 OR MISSING, GO TO A3**. ELSE GO TO A2a.**

A2a. What part(s) of the report did you find not credible?

[ ] NOT CREDIBLE CONTENT

IF A1 = 1 OR 2, GO TO A4. ELSE GO TO A3.

A3. Please rate how easy it was to find the information you were interested in.

Not at all easy to find 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very easy to find

A4. Please rate how easy it was to understand the report.

Not at all easy to understand 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very easy to understand

IF A4 = 1 OR 2, GO TO A4a. ELSE GO TO A5.

A4a. What part(s) of the report did you have difficulty understanding or find confusing?

[ ] DIFFICULT TO UNDERSTAND CONTENT

A5. Please rate the overall usefulness of the report.

Not at all useful	1 ❍	2 ❍	3 ❍	4 ❍	5 ❍	Very useful

IF A5 = 1 OR 2, GO TO A5a. ELSE GO TO A6

A5a. Why was this report not useful to you?

[ ] REASON WHY REPORT IS NOT USEFUL

A6. Semi-yearly, the AHRQ Healthcare Horizon Scanning System reports on up to 20 interventions with the highest potential impact in a condition area. Do you agree that in the area of [AREA CONDITION], [INTERVENTION NAME] should have been included in the Potential High Impact Interventions report series?

SELECT ONE ONLY

- ❍ Yes 1
- ❍ No 2
- ❍ Don't know 3

IF A6=2, GO TO A6a. ELSE GO TO A7.

A6a. Please explain why you do not think [INTERVENTION NAME] should have been included in the Potential High Impact Interventions series.

A7. Please provide any additional comments about the overall report that you would like to share.

[ ] ADDITIONAL COMMENTS

B. FEEDBACK ON THE OVERALL HIGH IMPACT POTENTIAL SECTION

Questions B1 – B3 are about the last sections of the report that begin with Figure 1. We will call this part of the report the *"Overall High Impact Potential"* section. This section includes the overall high impact potential arrow graphic (Figure 1), summary comments adjacent to the arrow graphic, and the "Results and Discussion of Comments."

B1. Please rate the credibility of the information in the "Overall High Impact Potential" section of the report, which begins with Figure 1 and continues to the end of the report. By credibility, we mean how much confidence you had in the correctness of the information.

Not at all credible 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very credible

IF B1 = 1 OR 2, GO TO B1a. ELSE GO TO B2

B1a. What part(s) of the "Overall High Impact Potential" section did you find not credible?

[ ] NOT CREDIBLE CONTENT

B2. Please rate the overall usefulness of the "Overall High Impact Potential" section of the report, which begins with Figure 1 and continues to the end of the report.

Not at all useful 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very useful

IF B2 = 1 OR 2, GO TO B2a. ELSE GO TO B3

B2a. Why was the "Overall High Impact Potential" section of the report not useful to you?

[ ] REASON WHY SECTION IS NOT

B3. Please provide any additional comments about the "Overall High Impact Potential" section of the report that you would like to share.

[ ] ADDITIONAL COMMENTS

These next questions are about Figure 1 (overall high impact potential rating).

B4. Please rate how consistent Figure 1 (overall high impact potential rating) was with the information in the entire report.

Not at all consistent 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very consistent

IF B4 = 1 OR 2, GO TO B4a. ELSE GO TO B5

B4a. Please provide the reason(s) why you think Figure 1 (overall high impact potential rating) was inconsistent with the information in the entire report.

[ ] INCONSISTENCY BETWEEN RATING AND REPORT INFORMATION

B5. Please rate the overall usefulness of Figure 1 (overall high impact potential rating).

Not at all useful 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5 ❍ Very useful

IF B5 = 1 OR 2, GO TO B5a. ELSE GO TO B6

B5a. Why was Figure 1 (overall high impact potential rating) not useful to you?

[ ] REASON WHY RATING IS NOT USEFUL

B6. Do you agree with the overall high impact potential rating reflected in Figure 1?

SELECT ONE ONLY

- ❍ Yes 1
- ❍ No 2
- ❍ Don't know 3

IF B6= 2, GO TO B6a. ELSE GO TO C1

B6a. Please explain why you do not agree with the overall high impact potential rating reflected in Figure 1.

[ ] REASON WHY DISAGREE WITH OVERALL HIGH IMPACT POTENTIAL RATING

C. ABOUT YOU

The last questions are about you.

C1. Please identify your role in the health care field.

SELECT ONE ONLY

- ❍ Federal or state staff ..... 1 GO TO C1a
- ❍ Clinical/health care provider 2
- ❍ Administrator of institutional health care service provider 3
- ❍ Private third-party health care payer/insurance 4
- ❍ Health care product (medication/device) manufacturer 5
- ❍ Consumer or patient representative 6
- ❍ Researcher ..... 7 GO TO C1_1
- ❍ Other 8

Specify ☐

IF C1 = 1, GO TO C1a. IF C1 = 7, GO TO C1_1. ELSE, GO TO C2

C1_1. What is your research area?

Specify ☐

GO TO C2

C1a. What is the primary focus of your work?

SELECT ONE ONLY

- ❍ Health care insurance/payment policy/ coverage of services 1
- ❍ Safety of drugs, biologics, and/or medical devices 2
- ❍ Research on effectiveness of medications/devices/care processes 3
- ❍ Clinical care/ improving quality/patient centeredness of care 4
- ❍ Other 5

Specify ☐

C2. In the past 12 months, how often did you look at information about emerging or new health interventions? Please do not include the report on [INTERVENTION NAME] you reviewed for this survey.

By emerging or new health interventions, we mean new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, behavioral health interventions, health care delivery innovations, and public health and health promotion activities intended for use in the U.S. health care system.

SELECT ONE ONLY

- ❍ Daily 1
- ❍ Several days a week 2
- ❍ Once a week 3
- ❍ Once a month 4
- ❍ Less than once a month 5
- ❍ Never ..... 6 GO TO C4

NO RESPONSE ..... M

IF C2 = 6, GO TO C4. ELSE GO TO C3.

C3. In the past 12 months, how much did you rely on each of the following sources for information about emerging or new health interventions? Please do not include the report on [INTERVENTION NAME] you reviewed for this survey.

By emerging or new health interventions, we mean new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, behavioral health interventions, health care delivery innovations, and public health and health promotion activities.

SELECT ONE RESPONSE PER ROW

	NEVER RELY	RARELY RELY	SOMETIMES RELY	HEAVILY RELY
a. Peer reviewed journals.	1 ☐	2 ☐	3 ☐	4 ☐
b. Clinical/pharmaceutical reference textbooks and compendia	1 ☐	2 ☐	3 ☐	4 ☐
c. Colleagues.	1 ☐	2 ☐	3 ☐	4 ☐
d. Drug and device manufacturers.....	1 ☐	2 ☐	3 ☐	4 ☐
e. Health care businesses.	1 ☐	2 ☐	3 ☐	4 ☐
f. Insurance companies.....	1 ☐	2 ☐	3 ☐	4 ☐
g. Government agencies.....	1 ☐	2 ☐	3 ☐	4 ☐
h. Professional associations.	1 ☐	2 ☐	3 ☐	4 ☐
i. Technology assessment organizations.	1 ☐	2 ☐	3 ☐	4 ☐
j. Listservs and blogs.	1 ☐	2 ☐	3 ☐	4 ☐
k. Mass media.....	1 ☐	2 ☐	3 ☐	4 ☐
l. Other *Specify* _____	1 ☐	2 ☐	3 ☐	4 ☐

C4. Prior to receiving this survey, have you ever heard of the AHRQ Healthcare Horizon Scanning System?

SELECT ONE ONLY

- ❍ Yes..... 1
- ❍ No ..... 2 GO TO C5

IF C4 = 1, GO TO C4a. ELSE GO TO C5.

C4a. Prior to receiving this survey, where did you hear about the AHRQ Healthcare Horizon Scanning System?

MARK ALL THAT APPLY

- ❍ AHRQ publications or Web site 1
- ❍ Work colleagues 2
- ❍ Peer reviewed journals 3
- ❍ Other professional publications (newsletters) 4
- ❍ Other government agencies 5
- ❍ Drug and device manufacturers 6
- ❍ Insurance companies 7
- ❍ Listservs and blogs 8
- ❍ Mass media 9
- ❍ Other: please specify _____ 10

C4b. Prior to receiving this survey, have you used the information or reports produced by the AHRQ Healthcare Horizon Scanning System?

SELECT ONE ONLY

- ❍ Yes 1
- ❍ No ..... 2 GO TO C5

IF C4b = 1, GO TO C4c. ELSE GO TO C5.

C4c. Prior to receiving this survey, how have you used the information or reports produced by the AHRQ Healthcare Horizon Scanning System?

MARK ALL THAT APPLY

- ❍ Inform research funding decisions 1
- ❍ Identify or prioritize topics for research ..... 2 GO TO C5
- ❍ Keep up to date on technologies to help my patients ..... 3 GO TO C5
- ❍ Inform investment or business decisions ..... 4 GO TO C5
- ❍ Keep up to date on emerging health technologies in general ..... 5 GO TO C5
- ❍ Other: please specify _____ ..... 6 GO TO C5

IF C4c=1, GO TO C4d. ELSE GO TO C5.

C4d. To what extent have the information or reports produced by the AHRQ Healthcare Horizon Scanning System influenced your research funding decisions?

SELECT ONE ONLY

- ❍ Not at all 1
- ❍ To a slight extent 2
- ❍ To some extent 3
- ❍ To a great extent 4

C5. In the future, how likely is it that you will access or use the reports produced by the AHRQ Healthcare Horizon Scanning System?

SELECT ONE ONLY

- ❍ Very likely 1
- ❍ Somewhat likely 2
- ❍ Not very likely 3
- ❍ Not at all likely 4

D. THANK YOU

Thank you for completing this important survey.

D1. Please provide your contact information. We will only contact you if we have any questions about the answers you provided on the survey.

	NAME
	TELEPHONE
	EMAIL ADDRESS

Thank you for completing the survey!

If you have any questions about the survey, contact Mathematica toll free at 855-743-8476 or by email at: Contact@HorizonScanningSurvey.org.

Form Approved
OMB No. 0935-0229
Exp. Date 12/31/2016

MATHEMATICA
Policy Research

HEALTHCARE HORIZON SCANNING SYSTEM DOMAIN EXPERT SURVEY

Sponsored by the
Agency for Healthcare Research and Quality (AHRQ)

Conducted by
Mathematica Policy Research

INSTRUCTIONS

The Agency for Healthcare Research and Quality (AHRQ) is sponsoring this survey as part of the **evaluation of the AHRQ Healthcare Horizon Scanning System**. Mathematica Policy Research, an independent social policy research company, is conducting the survey for the evaluation. **We ask you to participate in this survey to provide feedback on the reports produced by the Healthcare Horizon Scanning System on emerging health care technologies.**

Thank you for taking the time to complete the survey. Your participation and input is very important. It should take you about 10-20 minutes to read the report and complete this survey.

The survey asks for your feedback on the report on [**INTERVENTION NAME**] that we sent you. You can also access the report through the report link below and throughout the online survey.

Please be assured that:

- Your participation in the survey is voluntary. However, we hope that you will participate and answer as many questions as you can.
- Your answers will used for study purposes only. All responses will be combined and data will be reported in the aggregate. No names of individuals or organizations will be used in any reports.

Before you begin the survey, please:

- Make sure you have read the report.
- Have the report in front of you so you can refer to it easily. If you do not have the report available, please click on this link [INTERVENTION REPORT LINK] to access the report.
- Answer the questions to the best of your knowledge. We ask you to not conduct any research on the content or subject of the report but to provide us your immediate perceptions of the report.

If you have difficulty or questions when completing this survey, please call (855) 743-8476 toll free or click here Contact@HorizonScanningSurvey.org to send an email.

You can find more information about the survey if you click on this link: Frequently Asked Questions.

SECTION A: POTENTIAL HIGH IMPACT REPORT

The first few questions are about the overall report on [INTERVENTION NAME]. Please answer based on the information about [INTERVENTION NAME] that was available when the Potential High Impact report was developed in December 2014.

A1: Based on the information available in December 2014 about [INTERVENTION NAME], does the report contain any inaccuracies?

SELECT ONE ONLY

1 ☐ Yes
0 ☐ No → GO TO A2
d ☐ Don't know → GO TO A2

A1a: Please provide an example of an inaccurate statement from the report.

A2: Based on the information available in December 2014 about [INTERVENTION NAME], is the report missing any important information?

SELECT ONE ONLY

1 ☐ Yes
0 ☐ No → GO TO A3, PAGE
d ☐ Don't know → GO TO A3, PAGE

A2a: Please provide an example of important information that was missing from the report.

A3: This question is about the section of the report titled "Clinical Pathway at Point of This Intervention." Based on the information available in December 2014 about [INTERVENTION NAME], does this section accurately reflect the prevailing view at that time about how [INTERVENTION NAME] may be used in clinical care?

SELECT ONE ONLY

1 ☐ Yes → GO TO A4

0 ☐ No

d ☐ Don't know → GO TO A4

A3a: Please explain how this section does not accurately reflect the prevailing view on how this intervention may be used in clinical care.

A4: Please provide any additional comments about the report that you would like to share.

SECTION B: ABOUT YOU

These last questions are about you.

B1: What is your area of expertise in the health care field?

SELECT ONE ONLY

1 ☐ Government policy and regulation

2 ☐ Clinical expertise

3 ☐ Insurance

4 ☐ Manufacturing or marketing of health care products

5 ☐ Financial performance or investment outlook

6 ☐ Health systems

7 ☐ Other *(specify)* _____

B2: Please disclose below your academic, professional, and manufacturer affiliations.

B3: Please disclose below any potential intellectual or financial conflicts of interest, such as research in progress, consulting arrangements, or other financial involvements with companies related to technologies, services, or programs evaluated in the report.

☐ I have no conflicts of interest → GO TO END (PAGE 6)

B4: Do you consult for developers or manufacturers that do or would compete with this intervention?

1 ☐ Yes

0 ☐ No → GO TO END

B4a: If yes, please specify the nature of your consultation below.

Thank you for completing the survey!

Form Approved
OMB No. 0935-0229
Exp. Date 12/31/2016

MATHEMATICA
Policy Research

HEALTHCARE HORIZON SCANNING SYSTEM CANCER EXPERT SURVEY

Sponsored by the
Agency for Healthcare Research and Quality (AHRQ)

Conducted by
Mathematica Policy Research

INSTRUCTIONS

The Agency for Healthcare Research and Quality (AHRQ) is sponsoring this survey as part of **the evaluation of the AHRQ Healthcare Horizon Scanning System**. Mathematica Policy Research, an independent social policy research company, is conducting the survey for the evaluation. **The survey will help AHRQ assess the Potential High Impact Interventions report series issued by the AHRQ Healthcare Horizon Scanning System.**

Thank you for taking the time to complete the survey. Your participation and input is very important. It should take you about 20 minutes to complete this survey.

The survey asks for your assessment of the overall potential impact of a set of 12 emerging and new health interventions.

Please be assured that:

- Your participation in the survey is voluntary. However, we hope that you will participate and answer as many questions as you can.

- Your answers will be used for study purposes only. All responses will be combined and data will be reported in the aggregate. No names of individuals or organizations will be used in any reports.

Please answer the questions to the best of your knowledge.

If you have any difficulty or questions when completing this survey, please call (855) 743-8476 toll free or click here Contact@HorizonScanningSurvey.org to send an email.

You can also find more information about the survey if you click on this link: Frequently Asked Questions.

SECTION A: OVERALL POTENTIAL IMPACT ASSESSMENT

A1: This question is about your assessment of the overall potential impact of 12 emerging and new health interventions in the area of cancer.

- **We define overall potential impact as the potential for high impact on U.S. health care when considering all the factors below:**
  - **Potential importance of the unmet need it intends to address**
  - **Potential to improve patient health**
  - **Potential to affect health disparities**
  - **Potential to disrupt the health care delivery system**
  - **Potential for acceptance/adoption by patients and clinicians**
  - **Potential impact on health care costs**
  - **Overall potential to fulfill the unmet need**

- **We define emerging and new health interventions to include new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, behavioral health interventions, health care delivery innovations, and public health and health promotion activities intended for use in the U.S. health care system.**
- **Please think about all of the emerging and new health interventions with which you are familiar in the cancer area and consider the overall potential impact of each of these interventions on U.S. health care.**
- **Then, for each of the interventions listed below, select the quartile you would rank the intervention in terms of its overall potential impact on U.S. health care when compared to Phase III emerging and new health interventions in the cancer area.**

SELECT ONE PER EACH ROW

	In terms of overall potential impact, relative to all emerging and health interventions in cancer area, this intervention would be in the…			
	Top Quartile (i.e., large impact relative to other emerging health interventions)	**Second Quartile** (i.e., medium impact relative to other emerging health interventions)	**Third or Fourth Quartile** (i.e., small impact relative to other emerging health interventions)	**Not Sure/ No Opinion**
a. Ado-trastuzumab emtansine (Kadcyla) antibody-drug conjugate for advanced HER2- positive breast cancer	1 ☐	2 ☐	3 ☐	4 ☐
b. Anastrozole (Arimidex) for prevention of breast cancer in postmenopausal women at elevated risk of breast cancer	1 ☐	2 ☐	3 ☐	4 ☐
c. Ceritinib (Zykadia) for nonsmall cell lung cancer	1 ☐	2 ☐	3 ☐	4 ☐

SELECT ONE PER EACH ROW

	In terms of overall potential impact, relative to all emerging and health interventions in cancer area, this intervention would be in the…			
	Top Quartile (i.e., large impact relative to other emerging health interventions)	**Second Quartile** (i.e., medium impact relative to other emerging health interventions)	**Third or Fourth Quartile** (i.e., small impact relative to other emerging health interventions)	**Not Sure/ No Opinion**
d. Ibrutinib (Imbruvica) for mantle cell lymphoma	1 ☐	2 ☐	3 ☐	4 ☐
e. Liposome encapsulated irinotecan (MM-398) for pancreatic cancer	1 ☐	2 ☐	3 ☐	4 ☐
f. Methylated Septin 9 blood test for colorectal cancer screening	1 ☐	2 ☐	3 ☐	4 ☐
g. Nivolumab (Opdivo) for advanced melanoma	1 ☐	2 ☐	3 ☐	4 ☐
h. Palbociclib (Ibrance) for estrogen receptor–positive breast cancer	1 ☐	2 ☐	3 ☐	4 ☐
i. Panobinostat for recurrent multiple myeloma	1 ☐	2 ☐	3 ☐	4 ☐
j. Pembrolizumab (Keytruda) for advanced melanoma	1 ☐	2 ☐	3 ☐	4 ☐
k. Radium-223 dichloride (Xofigo) for solid tumor bone metastases	1 ☐	2 ☐	3 ☐	4 ☐
l. Ramucirumab (Cyramza) for metastatic nonsmall cell lung cancer	1 ☐	2 ☐	3 ☐	4 ☐

Thank you for completing the survey!

Appendix C. Tables

Table C.1. Initial frame and selection counts by stakeholder group

Stakeholder Group	Count of Frame	Initial Selection Count	Selection of Additional Sample	Total Sample Selected	Final Sample Size
Patient consumer organizations	143	103	15	118	105
Provider associations	360	108	15	123	120
Health insurance plans	405	109	15	124	115
Accountable Care Organizations	233	105	15	120	94
Pharmaceutical and device manufacturers	325	107	15	122	95
Medicaid agencies	56	56	0	56	52
Researchers[a]	495	112	15	127	127
Total	**2017**	**700**	**90**	**790**	**708**

[a] Sample member is an individual, not an organization.

Table C.2. Distribution of stakeholder survey respondents by stakeholder group

Stakeholder Group	Total Released	Total Respondents Who Provided Feedback on Reports	Percentage of Total Released	Total Respondents Who Did Not Find Reports Relevant	Percentage of Total Released
Patient consumer organizations	105	6	6	9	9
Provider associations	120	11	9	12	10
Health insurance plans	115	12	10	1	1
Accountable Care Organizations	94	6	6	6	6
Pharmaceutical and device manufacturers	95	5	5	6	6
Medicaid agencies	52	14	27	2	4
Researchers[a]	127	11	9	17	13
Total	**708**	65	9	53	7

[a] This sample included individuals, whereas the other stakeholder groups included organizational entities.

Table C.3. Distribution of domain expert survey sample frame

Priority Condition	Number of External Experts Classified as an Expert in One Priority Condition	Number of External Experts Classified as an Expert in More Than One Priority Condition	Number of External Experts Available for Random Selection After Assignment to Condition Area	Number of Experts Selected
Arthritis and nontraumatic joint disease	5	3	8	5
Cancer	62	0	62	5
Cardiovascular disease	24	3	27	5
Dementia (including Alzheimer's disease)	4	4	8	5
Depression and other mental health disorders	13	1	14	5
Diabetes mellitus	4	3	7	5
Functional limits and disability	28	2	30	5
Infectious disease including HIV-AIDS	11	3	14	5
Obesity	3	4	7	5
Peptic ulcer and dyspepsia	4	2	6	5
Pulmonary disease, including asthma	3	4	7	5
Substance abuse	4	4	8	5
Total	**165**	**33**	**198**	**60**

Table C.4. Distribution of expert survey respondents by condition area of expertise

Condition Area of Expertise	Number Released	Number Responded	Percentage of Released
Arthritis and nontraumatic joint disease	6[a]	2	33
Cancer	6[a]	2	33
Cardiovascular disease	6[a]	0	0
Dementia, including Alzheimer's	5	3	60
Depression and other mental health disorders	5	2	40
Diabetes mellitus	5	2	40
Functional limitations and disability	6[a]	2	33
Infectious disease, including AIDS-HIV	5	2	40
Obesity	5	1	20
Peptic ulcer disease and dyspepsia	5	2	40
Pulmonary disease, including asthma	5	4	80
Substance abuse	5	4	80
Total	**64**	**26**	**41**

[a] A sample member indicated the report was not relevant to them and was replaced by another expert.

Table C.5. Distribution of expert survey respondents by industry area of expertise[a]

Condition Area of Expertise	Government Policy & Regulation	Clinical Expertise	Health Systems	Manufacturing or Marketing of Health Care Products	Other	Not Specified	Total Respondents
Arthritis and nontraumatic joint disease		1				1	2
Cancer	1	1					2
Cardiovascular disease							0
Dementia, including Alzheimer's			1		1	1	3
Depression and other mental health disorders		2					2
Diabetes mellitus		1		1			1
Functional limitations and disability		2					2

Condition Area of Expertise	Government Policy & Regulation	Clinical Expertise	Health Systems	Manufacturing or Marketing of Health Care Products	Other	Not Specified	Total Respondents
Infectious disease, including AIDS-HIV		1			1		2
Obesity						1	1
Peptic ulcer disease and dyspepsia		2					2
Pulmonary disease, asthma		2	1		1		4
Substance abuse		2	1		1		4
Total	**1**	**14**	**3**	**1**	**4**	**3**	**26**

[a] There were no respondents with expertise in the areas of insurance and financial performance or investment outlook.

Table C.6. Stakeholder respondents who have heard about the AHRQ Healthcare Horizon Scanning System

	Number of Respondents	Percentage of Respondents Who Have Heard of Horizon Scanning System
Heard of AHRQ Healthcare Horizon Scanning System	11	100
Heard of AHRQ Healthcare Horizon Scanning System from—		
AHRQ publications or Web site	10	90.91
Work colleagues	3	27.27
Peer-reviewed journals	1	9.09
Other professional publications (newsletters)	1	9.09
Other government agencies	4	36.36
Drug and device manufacturers	1	9.09
Insurance companies	1	9.09
Listservs and blogs	1	9.09
Mass media	0	0.00
Other	2	18.18

Table C.7. Stakeholder searching for and using information about emerging health interventions

Use of Information About Emerging Health Interventions	Had Known of AHRQ Healthcare Horizon Scanning System Number (Percentage of Total Responses)	Had Not Known About AHRQ Healthcare Horizon Scanning System Number (Percentage of Total Responses)	Total Number (Percentage)
How often looked at information about emerging health interventions in past 12 months:			
Daily	2 (18.18)	3 (5.88)	5 (8.06)
Several days a week	2 (18.18)	14 (27.45)	16 (25.81)
Once a week	4 (36.36)	14 (27.45)	18 (29.03)
Once a month	2 (18.18)	9 (17.65)	11 (17.74)
Less than once a month	1 (9.09)	9 (17.65)	10 (16.13)
Never	0 (0)	2 (3.92)	2 (3.23)
Total	**11**	**51**	**62**
Relied sometimes or heavily on source for information about emerging health interventions:			
Peer-reviewed journals	11 (100)	43 (84.31)	54 (87.10)
Clinical/pharmaceutical reference textbooks and compendia	6 (54.55)	18 (35.29)	24 (38.71)
Colleagues	10 (90.91)	40 (78.43)	50 (80.65)
Drug and device manufacturers	2 (18.18)	22 (43.14)	24 (38.71)
Health care businesses	6 (54.55)	20 (39.22)	26 (41.94)
Insurance companies	4 (36.36)	15 (29.41)	19 (30.65)
Government agencies	11 (100)	42 (82.35)	53 (85.48)
Professional associations	9 (81.81)	43 (84.31)	52 (83.87)
Technology assessment organizations	8 (72.73)	23 (45.10)	31 (50)
Listservs and blogs	3 (27.27)	11 (21.57)	14 (22.58)
Mass media	3 (27.27)	7 (13.73)	10 (16.13)
Other	0 (0)	4 (7.84)	4 (6.45)

Table C.8. How AHRQ Healthcare Horizon Scanning System reports have been used

	Number	Percentage of Respondents Who Have Used Reports
Used AHRQ Healthcare Horizon Scanning System reports	8	100
How reports were used:		
Inform research funding decisions	1	12.5
Identify or prioritize topics for research	3	37.5
Keep up to date on technologies to help my patients	0	0
Inform investment or business decisions	0	0
Keep up to date on emerging health technologies in general	6	75
Other	1	12.5
Not used AHRQ Healthcare Horizon Scanning System reports	3	27.27
Extent that reports have influenced research funding decisions		
To a great extent	0	0
To some extent	0	0
To a slight extent	1	100
Not at all	0	0
Total	**1**	**100**