AHRQ Healthcare Horizon Scanning System

Horizon Scanning Protocol and Operations Manual September 2015 Revision

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The U.S. Agency for Healthcare Research and Quality (AHRQ) Healthcare Horizon Scanning System is operated by ECRI Institute under contract to AHRQ, Rockville, MD (Contract No. 290-2010-0006-C). The findings and conclusions in this document are those of the authors, who are responsible for its content. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

A novel intervention may not appear in the reports simply because the System has not yet detected it or it does not yet meet inclusion criteria outlined in the following protocol. Inclusion or absence of novel interventions in the Horizon Scanning Reports will change over time as new information is collected. Therefore, inclusion or absence should not be construed as either endorsements or rejections of specific interventions.

A representative from AHRQ served as a Contracting Officer's Technical Representative and provided input during the implementation of the horizon scanning system. AHRQ does not directly participate in the horizon scanning or assessment of leads or topics, and did not provide opinions regarding potential impact of interventions.

Persons using assistive technology may not be able to fully access information in this report. For assistance, contact info@ahrq.gov.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this document.

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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 Protocol and Operations Manual. Send comments by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to effectivehealthcare@ahrq.hhs.gov.

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Introduction

Horizon scanning is an activity undertaken to identify technological and system innovations that could have important impacts or bring about paradigm shifts. In the health care sector, horizon scanning pertains to identification of 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. Health care horizon scanning has typically been performed to inform a variety of strategic planning activities. Formal or informal health care horizon scanning programs have long been used by public or private entities around the world for various purposes, including commercial planning, health service research prioritization, financial or operational planning, controlled diffusion of technologies, and provision of information to policy makers, purchasers, and providers of health care. For example, hospitals and health care facilities have used horizon scanning information to inform their 5-year technology acquisition plans to better understand how their clinical service lines might be affected or disrupted by new innovations. Third-party payer (health insurance companies and government payers) have used horizon scanning information to prepare for coverage decisions they anticipate needing to make in the future. Some, such as the EuroScan horizon scanning (or "early alert") systems, may also inform decisions regarding primary or secondary research (e.g., Health Technology Assessment).

In early 2010, the Agency for Healthcare Research and Quality (AHRQ) identified an immediate need to establish a national Healthcare Horizon Scanning System to generate information to inform comparative effectiveness research investments made through its Effective Health Care (EHC) Program. Those investments are made in 14 priority areas for which AHRQ commissions comparative effectiveness reviews and research. For purposes of horizon scanning within those priority areas, AHRQ's interests are broad and encompass drugs, devices, procedures, treatments, screening and diagnostics, therapeutics, surgery, and care delivery innovations—which are referred to generically as "interventions" in the AHRQ Healthcare Horizon Scanning System.

AHRQ has identified the following goals for its health care horizon scanning activities:

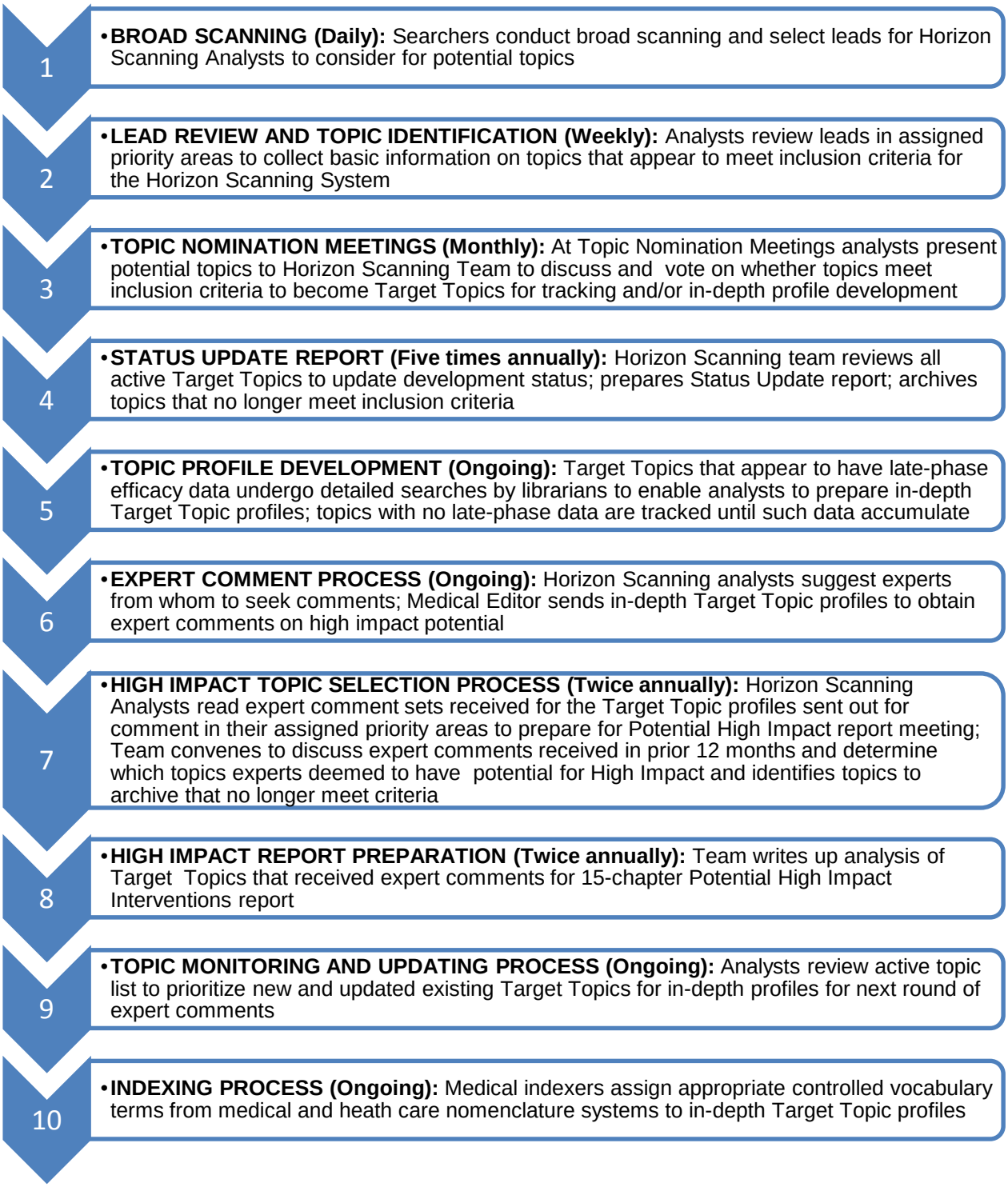
1. To create and use transparent and clearly defined processes to identify and monitor novel interventions or new uses of existing interventions in health care that might address an unmet need.
2. To develop and implement a transparent and clearly defined framework for identifying which interventions could have the highest potential impact on clinical care, the health care system, patient outcomes, and costs.
3. To evaluate components of existing horizon scanning systems and their respective protocols to identify best practices and effective methods of horizon scanning.

Prior to this initiative, no publicly available, comprehensive system existed for horizon scanning in the United States. AHRQ, therefore, implemented a horizon scanning framework and infrastructure that builds on prior private sector work to identify, monitor, and assess target interventions in health care but also includes new methods for determining potential impacts. Although some of the horizon scanning methods and procedures developed for other countries may be applicable in the United States, the ARHQ Healthcare Horizon Scanning System takes into account the unique characteristics of health care in the United States. This document outlines the basic protocol and decision processes being used in broad scanning to identify leads for new interventions, to select topics for in-depth information searches, and to identify interventions that could have the greatest potential impact in each priority area within 2 to 3

years of their availability for diffusion into clinical practice. An overview of these processes is shown in Figure 1.

In this update, we have also included the protocol for pilot rapid cost analyses of topics assessed as having potential for high impact in the moderate to high range in 2014.

Figure 1. AHRQ Healthcare Horizon Scanning System process overview



Process and Decision Algorithm for the AHRQ Healthcare Horizon Scanning System

Herein we describe the steps involved in creating and maintaining the AHRQ Health Care Horizon Scanning System. Because certain terminology is limiting in terms of what we scan for and identify, we use the generic term "intervention" to encompass drugs, devices, procedures, surgeries, care delivery innovations, diagnostics, and treatments.

Step 1. Daily Broad Scanning

To identify potential topics, ECRI Institute's Information Center has implemented a tiered scanning and search system. The center is staffed by medical librarians (also called searchers) and funnels leads to a team of horizon scanning analysts. As related leads aggregate, analysts develop specific topics. (See Step 2. Lead Review and Topic Identification.) At the outset, for the broadest level of scanning performed for each priority area, the process integrates external inputs with searching and scanning done by the Information Center. The searchers access public and proprietary resources in the health, scientific, and business spheres to scan for new developments in all facets of health care-related topics. (See Appendix A. Table A. 1) These include, but are not limited to, ECRI Institute's own research publications and the questions it receives from hospitals, health plans, and other entities that use the organization's services; blogs; aggregated news sources (e.g., PR Newswire health and science industries); repositories of peer-reviewed journals (both general medical and specialty journals) and gray literature (e.g., government-issued documents; manufacturer-issued documents; health care and medical science trade publications and newsletters; other health care information published outside the peer-reviewed journal literature). Press releases and conference proceedings from meetings of professional societies and other organizations (e.g., trade associations, industry associations) are evaluated and added to the scanning list if they are found to yield high-quality relevant information.

Resources are reviewed initially without employing a search strategy. When possible, distribution of publications is customized (for example, using RSS feeds) to send daily email updates and electronic tables of contents to Horizon Scanning team members or to allow team members to set alerts that will notify them when a new issue or new content is available. Individual resources, such as those listed in Table A. 1 and Table A. 2 are assigned to the medical librarians who are responsible for creating their own alerts and reviewing content regularly. They create a scanning schedule for resources that do not offer an updating option. Such resources are reviewed daily, weekly, monthly or quarterly depending on their publication schedule.

Items of interest are downloaded in electronic format and posted to a leads management document library. At this point, the medical librarians assign one or more "tags" to the items. The tags include the names of the 14 priority areas and 1 area designated "cross-cutting" by ECRI Institute for interventions that affect many or all priority areas (see Priority Area list below). Additional tags may be added to a lead to denote subcategories within a broad priority area (e.g., breast cancer, peripheral artery disease, type I diabetes).

Scanning of peer-reviewed medical and scientific journals is also part of the broad search in the priority areas to identify potential leads. The databases searched (see Appendix A, Table A. 3) and subject-specific search strategies tailored to each of the priority areas were developed and adapted for the syntax of each search platform (as in the example in Appendix A, Table A. 4). In

addition, librarians search for health care delivery innovations through the Centers for Medicare and Medicaid Innovations Center and an innovations journal (see Appendix A, Table A. 5).

Daily Leads Reviewed and Selected by Searchers Performing Broad Scans

Searchers use the criteria described on the following pages to guide lead selection from their broad scans. To cast as wide a net as possible, searchers err on the side of inclusion and "select" a potential lead if they are unclear as to whether it meets the inclusion criteria. The decision about whether to pursue a lead is made by the horizon scanning analyst team at a later point (see Step 2). The team undertakes preliminary general background searching as needed to further research and evaluate leads they receive.

All leads selected by searchers for consideration must pertain to one of the 14 AHRQ-defined priority areas or a cross-cutting area (see the "Priority Areas" in Table 1). The topics pertaining to most of the priority areas are fairly clear; however the priority area termed "Functional Limitations" is very broad. For purposes of horizon scanning, AHRQ has chosen to define this area using the U.S. Department of Health and Human Services definition of disability: "In general, disabilities are characteristics of the body, mind, or senses that, to a greater or lesser extent, affect a person's ability to engage independently in some or all aspects of day-to-day life." The Horizon Scanning team operationalizes this definition by considering interventions in the context of conditions that impair activities of daily living (e.g., feeding, bathing, toileting/continence, transfers, such as those from bed to chair or wheelchair,) or ambulation, dressing, or other independent activities of daily living (medication management, telephone use, leaving home without assistance, making meals, housekeeping).

Table 1. Priority areas

1.	Arthritis and nontraumatic joint disease
2.	Cancer
3.	Cardiovascular disease
4.	Dementia (including Alzheimer's Disease)
5.	Depression and other mental health disorders
6.	Developmental delays, attention-deficit hyperactivity disorder, and autism
7.	Diabetes mellitus
8.	Functional limitations and disability
9.	Infectious Disease, including HIV/AIDS
10.	Obesity
11.	Peptic ulcer disease and dyspepsia
12.	Pregnancy, including preterm birth
13.	Pulmonary disease/asthma
14.	Substance abuse
15.	Cross cutting

We developed sets of questions to inform searchers' and analysts' thinking about whether a lead appears to represent an intervention that is novel, innovative, relevant, and addresses a potentially important unmet need. We define "unmet need" in an extremely broad sense: 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. Interventions might be lacking entirely (e.g., treatments for Alzheimer's disease, pervasive developmental disorders, preventing preterm birth) or existing options might be less than optimal (e.g., therapy for pancreatic cancer). Unmet need also arises from conditions for which significant barriers exist to obtaining effective care, such as

heart transplantation, or conditions for which availability of certain treatments is limited by location, access, high cost, or cultural or ethnic barriers that could cause health disparities.

A frequently cited historical example of a technology that addressed an unmet need was the Zostavax vaccine for prevention of some strains of herpes zoster, the cause of shingles. Prior to Zostavax, no effective means of preventing shingles existed. Unmet need also arises from interventions to which patients have difficulty adhering, such as complex medication regimens. Thus an intervention that simplifies administration of a medication (e.g., integrating multiple medications into one medication, or formulating a medication so it has to be taken only once daily when previously, it had to be taken 3 times daily.) Unmet need also arises from a multitude of barriers to care. Thus, a care process innovation that enables better access to care for an underserved population or a population that is disproportionately affected by a condition and known to have poor health outcomes (e.g., hypertension in African Americans; diabetes in Native Americans) would be considered important because it addresses unmet needs.

We also consider whether a lead relates to an older innovation that never diffused but now appears primed for further development or diffusion because of a "tipping point," i.e., circumstances that make it ripe for development and diffusion. The sets of questions we consider are also meant to help the team filter out interventions that are very similar to interventions already available and diffused, which thus would not address an unmet need. We also provide below reasons why we ask and answer these questions when considering whether a lead should be developed into a target topic in the AHRQ Healthcare Horizon Scanning System. The five tables below (Table 2, Table 3, Table 4, Table 5, and Table 6) outline the questions we consider for Drugs, Biologics, and Devices; Screening and Diagnostic Interventions; Surgical Procedures; Behavioral Health Interventions; and Health Programs and Health Care Delivery Innovations.

Table 2. Questions considered about drugs, biologics, and devices

1. Is this a new molecular entity (drug), biologic, or device being developed for potential diffusion into the U.S. health care system AND in late Phase (3 or 4) clinical development or in Phase 2 clinical development with orphan, breakthrough, or fast-track status designation by FDA? If so, select. (Rationale: New molecular entities may be a signal of a new class of interventions intended to address a potentially important unmet need. New devices subject to a premarket application pathway may signal a new device addressing a potentially important unmet need.) Consider the following when answering this question:

- a. Is it subject to approval under FDA's Investigational New Drug, Biologics Licensing, combination-product application, or Investigational Device Exemption Premarket Approval processes? If so, select.
- b. Is it a generic drug? If so, do not select, because these are "me-too" of existing drugs.
- c. Is it subject to 510(k) clearance or De Novo pathway? If so, select only if it appears to represent some sort of relevant innovation to address a potentially important unmet need.
- d. Is this a late-phase human clinical trial of either an apparent novel intervention or a novel way to use an existing intervention, and is it capable of diffusing into the U.S. healthcare system within 3 years? If so, select. (Note: Animal and in vitro studies are excluded.) (Rationale: Clinical trials may be a signal of some new research question, or unmet need, being studied. Clinical trials also examine interventions that are not subject to regulatory pathways, such as surgical procedures.) The additional questions below help to determine if this is the case and also inform the stage of development (and expected time to adoption).
  - i. Has a trial been initiated or terminated?
  - ii. Are late-phase results being reported?
- e. Does this appear to be a different/off-label use of an available drug, biologic, or device? If so, select. (Rationale: Off-label use may signal an attempt by the clinical community to address an unmet need that is not being pursued by developers or innovators.)

Table 2. Questions considered about drugs, biologics, and devices (continued)

f. Is this a professional medical society meeting announcement? If so, should we monitor the meeting annually for new developments? (Rationale: New research about interventions in development to address unmet needs is typically presented at professional society meetings. Meeting abstracts and poster presentations presented in these venues may not appear in the peer-reviewed literature and can be a rich source of leads.)
g. Is this a product launch? (Rationale: Such announcements can signal diffusion of an intervention intended to address a potentially important unmet need. Select if it appears to address a potentially important unmet need.) Do not select if the unmet need is a small incremental (e.g., next-generation) development.
h. Is this a regulatory announcement? This includes manufacturers' announcements of intentions to file for regulatory approval/clearance as well as notices from regulatory agencies and advisory panels. (Rationale: These announcements may identify novel or relevant interventions that potentially address an unmet need.) Select if it appears to address an unmet need.
i. Is this a different delivery mode for an existing drug or device? (Rationale: Changes in formulation (e.g., from injection administered by a clinician to an oral pill) or dosing regimens (e.g., from daily dosing to once-a-month dosing) are sometimes intended to address potentially important unmet needs, such as a need to improve patient adherence or access to a therapy.) If so, select.
j. Is this being called an innovation AND is it in late phase development? If a developer refers to the intervention as an innovation, scanners may select it for further follow-up by an analyst to determine if it is truly innovative and addresses a potentially important unmet need.
k. Is this an award for an innovative product, procedure or process?

Table 3. Questions considered about screening and diagnostic interventions

1. Is this a novel screening or diagnostic intervention being developed for potential diffusion into the U.S. health care system? The following questions aid searchers in determining whether the screening or diagnostic intervention is within the areas of interest that AHRQ is not addressing through other agency initiatives:
   a. Is this a laboratory-developed test (LDT)? If so, do not select unless the developer has expressed intent to create and market a commercial test kit in the United States that can be acquired by laboratories AND the trial is in late phase development. (Rationale: AHRQ has other initiatives examining LDTs and thus LDTs are outside the scope of the Healthcare Horizon Scanning System)
   b. Is this a genome-wide association study (GWAS)? If so, do not select. (Rationale: GWAS reflects the earliest research that may one day underpin future development of an LDT or a genetic marker test kit, but these are too early for inclusion in the horizon scanning system.)
   c. Is this an available screening or diagnostic testing tool that is being used in a new way for a disease or condition to address an unmet need AND is it in late-phase clinical development? If so, select.
   d. If this is an accepted form of screening or diagnostic testing delivered in a slightly different setting, do not select.
   e. Is this a professional medical society meeting announcement about a screening or diagnostic intervention purported to address an unmet need? If so, should we monitor the meeting annually for possible leads?
   f. Is this being called an innovation AND is it in late-phase clinical development? If so, select.
   g. Is this an award for an innovative product, procedure or process that is in late phase clinical development? If so, select.

Table 4. Questions considered about surgical procedures

1. Is this a different or novel surgical approach or procedure that has potential to diffuse into the U.S. health care system within the next 2 to 3 years? Consider the following when deciding whether to select:
    a. Have signals of interest by U.S. surgeons or institutions been identified through vehicles such as meeting abstracts, editorials, commentaries, case reports, or press releases?
    b. Is this a new and different clinical indication for an existing surgical procedure? If so, select.
    c. Is this a surgical procedure that requires use of procedure-specific tools or devices in development? Consider the following when answering this question:
        i. Are the tools subject to approval under FDA's premarket notification 510(k) or Premarket Approval (PMA) application processes or combination-product process? If a PMA or a 510(k), select only if it enables some sort of relevant innovation in surgery to address an unmet need AND it is in late phase clinical trials.
    d. Is this a late phase human clinical trial (animal and in vitro studies are excluded.) on a novel surgical approach to address an unmet need? Also consider the following when deciding whether to select:
        i. Has a trial been initiated (select) or terminated (do not select unless the topic is already being tracked and a trial is subsequently terminated)?
        ii. Are results being reported? If so, select.
    e. Is this a professional medical society meeting announcement on a novel surgical approach? If so, should we monitor the meeting annually?
    f. Is this being called an innovation in surgery? If so, select.
    g. Is this an award for an innovative product, procedure or process?

Table 5. Questions considered about behavioral health interventions

1. Is this a behavioral intervention that is purported to be a markedly different or novel approach than currently exists to address an unmet need AND is it in a late phase trial? If so, select.
2. Has a trial been initiated (select) or terminated (do not select unless the topic is already being tracked and a trial is subsequently terminated)?
    a. Are results being reported? If so, select.
3. Is this a professional medical society meeting announcement that signals a markedly different or novel approach than currently exists and that purports to address a potentially important unmet need? If so, should we monitor the meeting annually?
4. Has there been a shift or tipping point in an existing, but not previously diffused behavioral health intervention? Does it appear poised to become much more widely diffused for some reason? Is it a novel combination of approaches? If so, select.
5. Is this a program launch of a different or novel program than currently exists and purports to address an unmet need? If so, select.
6. Is this intervention being called an innovation? If so, select.
7. Is this an award for an innovative product, procedure or process?

Table 6. Questions considered about health care delivery innovations

1. Is this a novel or innovative way of delivering care or a different/new combination of services being developed or adapted and implemented into the U.S. health care system that is listed in the Centers for Medicare and Medicaid (CMS) Innovations Center projects or *The Journal of Delivery Science and Innovation* or the journal *Health Management, Policy and Innovation*?

Step 2. Lead Review and Topic Identification

After searchers have collected leads from broad scanning using the above criteria, leads are uploaded to the Initial Leads List. This is a document library containing all leads identified by searchers as well as leads generated from signals ECRI Institute receives as an information provider to health care facilities, health systems, and payers inquiring about new procedures and off-label and new uses of existing technologies. ECRI Institute also receives unsolicited

suggestions from individuals and entities aware of the project and subjects those suggestions to the same criteria as the leads that searchers identify. In addition, searchers add priority area sub-classifications as shown in Appendix A, Table A. 5. Leads are then assigned to horizon scanning analysts according to the priority areas they are covering.

Initial Lead Sorting and Topic Identification

After leads are assigned to analysts by searchers, the analysts classify leads by topic class (see Table 7).

Table 7. Topic classes

- Assistive Technology
- Behavioral Therapy
- Biotechnology
- Care delivery innovation
- Complementary/Alternative Therapy
- Device
- Diagnostic
- Diet/Nutrition
- Implant
- Information Technology
- Nanotechnology
- Pharmaceutical
- Procedure
- Program
- Service
- Surgery
- Other

Upon receiving broad scanning results from ECRI's Information Center, horizon scanning analysts review the results and use the following algorithm (see Table 8) to initially assess preliminary leads and create a list of possible topics. The list includes the topic name, the intended patient population, a paragraph describing the intervention, and the unmet need it purports to address, the developer/manufacturer, and development or regulatory status. (See Step 3 Topic Nomination Meetings.)

Table 8. Algorithm for assessing and sorting leads to identify possible topics

1. Analysts sort leads by AHRQ Priority Area, Subcategory, and Topic Class.
2. Within each general sort area, the analysts group leads into "topics." Each topic corresponds to a discrete intervention (technology, service, care innovation, new use of existing intervention, new procedure/surgery etc.).
3. Analysts tag each lead with one or more identifiers (e.g., product name, manufacturer name, or program name) related to the technology, service, care innovation, new use of existing service, etc., to enable grouping and sorting of related leads.
4. Each analyst provides a brief descriptor for each lead in a "Notes" field of the Initial Leads List. For example, the analyst might include his/her rationale for topic proposal, notes on expected or potential impacts to the health care system, reasons for inclusion/exclusion, technology mechanism of action, competing technologies, etc.
5. The status of each lead is documented by analysts by choosing from a drop down list containing the following items:
    a. New – The lead was recently uploaded and has not yet been reviewed by an analyst.
    b. Reviewed – The lead has been reviewed by an analyst, but no formal action has been taken at this point.
    c. Linked – The lead has been reviewed by an analyst and linked to one or more topics.

Table 8. Algorithm for assessing and sorting leads to identify possible topics (continued)

d. Discarded – The analyst has determined that the lead is irrelevant to the horizon scanning system for any of several reasons (such as, out-of-date, pertains to animals, is a duplicate, does not meet criteria upon their further evaluation). The analyst provides a brief rationale for discarding the lead. e. Archived – The lead had previously been saved or assigned but is no longer relevant for any of several reasons. The analyst provides a brief rationale for archiving the lead (e.g., the lead is out-of-date, superseded by another lead). **6.** The analyst may then use various tags to further classify the lead (e.g., lead source, manufacturer name(s), product/intervention name(s), clinical condition, mechanism of action).

Initial Posting of Potential Topics

As analysts identify potential topics during their initial lead sorting processes, they add the topic to the potential Identified Topics List. (See Step 3 Topic Nomination Meetings.) The analysts describe topics according to the outline below (see Table 9). Part of the context for thinking about interventions is the "PICO" framework in which analysts describe the potential **P**opulation, **I**ntervention, potential **C**omparators to that intervention, and potential **O**utcomes of interest for the patient population. The horizon scanning analysts then link related leads from the Initial Leads List to the appropriate topic in the Identified Topics List to enable them to review all leads associated with each identified topic.

Table 9. Topic description outline for potential topics

1. Topic name/title **2.** AHRQ Priority Area **3.** Topic class **4.** Potential/Proposed Patient Population (including important disease stage or condition characteristics) **5.** Intervention description (including, sponsor, developer, or manufacturer) **6.** Phase of development and confirmation that it is being developed for potential diffusion into the U.S. health care system. Interventions are included only if they are in late phase development, designated orphan and fast track status, or, if not subject to FDA regulatory processes, have some data available on the target population for the intervention. **7.** Potential Comparators (to existing options for the same disease/conditions/patient population, if known at this point in the process) **8.** Potential Outcomes (i.e., potential health outcomes the intervention could address)

Topic Selection Criteria Checklist

Horizon scanning analysts consider the following criteria when proposing topics (see Table 10). These questions are considered in sequence as they determine whether they can build a case for nominating the topic for entry into the horizon scanning system. If they can build a case after going through this exercise for each potential topic, the topic is brought to a topic nomination meeting for discussion and decision making about its possible entry into the system.

Table 10. Criteria for entering topic into the horizon scanning system

1. Does the intervention purport to address an unmet need? If yes, describe the unmet need and the potential importance of this unmet need.
2. Is the intervention in late-phase development for the U.S. health care system? Or, can the intervention be adopted or diffused into the U.S. without going through a regulatory process (e.g., off-label uses, new surgery approaches, care delivery innovations, behavioral health nondrug interventions)? If yes, consider question 3.
3. Is the intervention novel, relevant, or innovative for addressing the need? If yes, consider question 4.
    a. Would adoption or implementation of this intervention potentially shift/change/disrupt any of the following? If yes, describe the intervention's potential impacts. In thinking about this, consider the following:
        i. Potential to change current treatment models
        ii. Disparities in health care among different patient populations
        iii. Paradigm shifts (e.g., in patient management, understanding disease or condition)
        iv. Care setting change
        v. Health care delivery process change
        vi. Infrastructure needs of the health care system or health facilities
        vii. Patient health outcomes and individual burden of disease
        viii. Population health outcomes and societal burden of disease
        ix. Clinician learning curve to use the intervention
        x. Patient or non-clinician caregiver to use the intervention
        xi. Costs of care for the disease or condition

Step 3. Topic Nomination Meetings

Horizon scanning analysts nominate topics for entry into the system at Topic Nomination Meetings. The issues analysts address during the nomination process are presented are in Table 11.

Table 11. Issues discussed when analysts present propose topics at topic nomination meetings

1. Rationale for proposing the topic: why the topic seems important overall
2. Brief description of the unmet need the topic addresses
3. Description of how the intervention proposes to meet the need and whether it seems to be novel or innovative
4. Stage of development of the intervention and confirmation of development for U.S. market
5. Potential outcomes/areas of impact
6. Potential existing comparators and potential comparators in development

Topic nomination meetings occur monthly or more often if needed, depending on the number of potential topics to be proposed.

Medical librarian searchers, ECRI horizon scanning analysts, the content team leader, the project manager, and other invited staff and experts participate in the discussions as analysts present "proposed topics" from their assigned priority areas to the team and invited experts. The topics are presented at a disease-specific, product-specific, procedure-specific, program-specific level. 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 Potential High Impact Interventions report (see Step 7. High Impact Topic Selection Process). In that report, some topics are rolled up to the "class" level. For example, each protease inhibitor for treatment of hepatitis C virus would be tracked individually, but the drugs would be discussed as a class if the expert comment process (see Step 6. Expert Comment Process) deemed any of the protease inhibitors to have potential for high impact. Keeping the topics granular when they are being tracked in the system is necessary because evidence

development, ongoing trials, regulatory status, and manufacturers differ by individual product, procedure, or program. For example, one company may cease development while another company proceeds to market.

To be entered into the system, topics are assigned one of these two statuses: "track only" or "advance to target." The "track-only" designation means that the intervention is in late-phase trials, but late-phase data have not yet been reported. In this case, the horizon scanning search team does not formulate detailed search strategies to perform in-depth searches for more information about the topic and analysts do not prepare in-depth written profiles for expert comment. Rather, searchers continue to identify related leads and material through their daily scanning, and they link the leads to the topic to enable analysts to follow the status of development. Once a topic is designated "advance to target," searchers devise detailed search strategies and undertake in-depth searches of public and proprietary databases to identify topic-specific information for the analysts. Analysts review and use this information to develop more detailed profiles of these topics for expert comment, complete with referenced sources.

While considering the presentations at topic nomination meetings, team members and any guest attendees with subject matter expertise consider the same questions (Table 10) that the analysts considered when deciding whether to nominate a topic. Team discussion takes place for each topic and includes an opportunity to ask questions. Medical librarians participating in the meetings conduct ad hoc searches to address questions raised during discussion. If a question cannot be resolved satisfactorily and quickly during the meeting, the topic is marked for follow-up searches by a librarian and/or the analyst proposing the topic. The results of that follow up are communicated to the team electronically. A final decision (majority vote by the team) is made on whether to enter the topic into the system, and if the topic is to be entered, its status as track-only or advance-to-target) is assigned.

All topic recommendations and their disposition are voted on and recorded. Topics must receive a majority vote to be entered into the system. If a vote is a tie, the project manager breaks the tie with an extra vote. If the project manager is absent, the content team leader has an additional vote. During the first 2 years of the system's operation, scanning criteria were most broad because they considered topics in very early phase development, and more than 1700 topics were considered with tie votes occurring less than 1 percent of the time; close votes occurred less than 5 percent of the time. When revised criteria were implemented in January 2013 to narrow the project scope to include only later phase topics, and as the system matured and fewer leads were identified that met scanning criteria, the number of topics being considered was nearly halved. The percentage of tie votes also has diminished over time as the team has gained more in-depth knowledge in all the priority areas.

Clinical interventions (i.e., drugs, devices, procedures) that are voted for advancing to target must have some preliminary late-phase efficacy and safety data available for the target population to include in the in-depth profile. Topics that are programs or care delivery innovations may be advanced to target with less data available if enough information is available to describe the care delivery innovation well, and if demonstration projects or pilot studies are underway. Profiles on the advance-to-target topics are subsequently submitted to sets of various types of experts from the health care sector. (See Step 6. Expert Comment Process.) They are asked to read the profile and offer perspectives and opinions about potential impact using a structured response form that we provide.

Step 4. Status Update Report

Five times each year (end of January, April, July, September, November), we prepare a report that is a compendium reflecting the active topics in the system and the topics that have been archived since we issued the prior Status Update report. This report is organized by priority area and consists of 15 tables—one for each priority area—in each of three sections of the report: (1) currently tracked topics; (2) new topics added since issuing the prior report; and (3) topics archived since the prior report. The topic title, intended patient population, short description of each topic, its developer, and development status, and possible comparators are listed alphabetically in each priority area. We title topics according to their current name (e.g., research names using numbers/letters evolve to generic product name, which evolves to brand name when U.S. Food and Drug Administration [FDA] approved) and the specific clinical indication for which they are intended to be used. As interventions develop, the clinical indications for which they are developed may also evolve over time, so topic titles evolve as we track and monitor topics. In the "topics archived" section of the report, we list the reason each topic was archived. Reasons include changes in development status (halted development) and timing out of the system (topics are followed for 2 years post FDA approval or, if topic is not subject to FDA approval, until signs of diffusion or lack thereof are evident—generally after 2 to 3 years of tracking).

The Status Update report captures a snapshot of a dynamic horizon scanning system at a point in time. AHRQ publishes these reports to its Effective Health Care Web site to make the material publicly available, typically within a week of report delivery.

Step 5. Topic Profile Development

After each topic nomination meeting, the content team leader adds each new "advance to target" topic into the *Horizon Scanning Production Queue* for development of a more detailed profile (topics added to the *Production Queue* are prioritized as outlined in Step 9.Topic Monitoring and Updating Process. Each of these topics is assigned to the analyst covering that priority area and to a medical librarian who creates the detailed search strategy and conducts searches. Each analyst covers the same AHRQ priority area(s) to maintain continuity and grow his or her expertise and understanding of the landscape of new developments in that priority area.

Topic-Specific Searching and Reference Management

In developing the strategies and conducting searches, medical librarians follow a protocol to decide which resources are appropriate for topic-specific searches. Parallel search strategies are created for every resource searched. The search strategy and results of the searches are recorded on a standardized data entry form that is maintained in the system. Searchers also set up topic-specific alerts to begin the ongoing monitoring process for each topic. Alerts go to the searcher for uploading into the system and assignment to the analyst covering that topic.

Members of the database management team standardize search results from public and proprietary bibliographic databases for entry into the citation (reference) management system and also manually create records in the citation management system for information retrieved from non-database sources (such as manufacturer Web sites). They then deliver these processed results electronically to the analysts' workflow system.

The database staff also process and manage the analysts' document requests. They work closely with the library staff to obtain full-text documents electronically, distribute documents

electronically to the requesting analyst, record analysts' requests, document the delivery in the citation management system, and generate reference lists based on documents selected by the analysts for inclusion in the profiles they write.

The database staff also enter every set of expert comments (Step 6. Expert Comment Process) received on a topic into the document management system, and assign a reference number to it so that analysts can reference expert perspectives (by expert category) as needed when they synthesize results of the comment process that leads to designations of topics as potential high impact (See Step 7. High Impact Topic Selection Process).

Development of Advance-to-Target Topic Profiles

After receiving topic-specific search results, the horizon scanning analyst reviews and organizes all materials, selects materials of most relevance for completing an in-depth profile, requests additional follow-up searches as needed, and begins drafting the target topic profile. Two templates are used: one for clinical interventions (drugs, devices, procedures, surgery, screening, diagnostic interventions) (see Table 12); one for care delivery innovations (Table 13). The fields of information compiled in each template are presented in the boxes below.

The analyst populates, as fully as possible, the appropriate template. While compiling the information for each profile, the analyst references each source of information so that reference lists can be generated for the profile.

Table 12. Clinical interventions template

1. Topic Title (intervention name and intended use[s])
2. Potential Importance of This Topic
3. Disease/Condition Description
4. Intervention Name and Description
5. Related Names for Intervention
6. Potential Competing and Complementary Technologies/Services for the Disease/Condition
7. Potential Care Setting(s)
8. Ongoing Trials and Evidence Development (Two tables are provided: 1 for ongoing trials and 1 for recently completed trials that have reported data. Results are presented in quotation marks exactly as issued by study authors from meeting abstracts, published articles, or company press releases. They do not reflect any interpretation or analysis on the part of the Horizon Scanning team.)
9. Manufacturers or Developer, and Development Status (includes regulatory information and potential indications/contraindications)
10. Anticipated Cost Per Patient (if known)
11. Potential Clinical Provider(s) and Training/Credentialing Issues
12. Potential Staffing and Infrastructure Implications
13. Potential Patient and Clinical Staff Safety Issues
14. Coverage, Coding, and Payment Status (if available)
15. Indexing/Linkages
16. References

Table 13. Care delivery innovations template

1. Topic Title **2.** Potential Importance of this Topic **3.** Background **4.** Target Population **5.** Program or Intervention Developer and Description **6.** Potential Program or Intervention Setting(s) **7.** Evidence Development and Ongoing Clinical Trials (if available) **8.** Recently Completed Trials (if available) **9.** Intended Provider(s) and Potential Training Requirements **10.** Patient Safety Issues (if applicable) **11.** Required Resources **12.** Cost, Funding, and Reimbursement Considerations **13.** Potential Competing and Complementary Programs or Interventions **14.** Indexing/Linkages **15.** References

Step 6. Expert Comment Process

Twice annually, in December and June, we prepare a 15-chapter report (1 chapter for each priority area plus a cross-cutting area) that profiles and discusses the interventions deemed through an expert comment process to have the greatest potential for high impact. We recruit experts in the health care system to provide comments and ratings on potential impacts of interventions on the basis of their subject matter expertise. The names of experts who participate are entered into our database of expert commenters. This database contains contact information and areas of expertise for about 150 experts. These experts have domain expertise in clinical or research areas, in health systems, health disparities, health care practices, health technology assessment, health services assessment, comparative-effectiveness research, health business issues, or health administration. (See additional details of expert selection below.)

During this process, we seek comment from five to eight experts from different domains of healthcare who could offer insights and opinions about a particular topic. The system accepts a maximum of eight experts for an individual topic; as topics are updated with important new information they may be recirculated for expert comment. We seek as participants researchers whose backgrounds and activities indicate broad knowledge of their fields. We obtain comments from U.S.-based experts because they are presumed to be most familiar with the U.S. health care system and better able to respond to the parameters we ask them to consider on the comment/impact rating form. Recruitment of additional experts is ongoing to expand the pool of participants. While we ask experts for their opinions about patient acceptance or adoption of an intervention, we also consider meaningful ways in which we might include patient perspectives in the future.

For each topic on which an in-depth profile has been developed, we follow an expert comment process that involves up to two phases. All topics proceed through Phase 1. Internal Expert Comment and Triage; selected topics that complete Phase 1 may also proceed through Phase 2. External Expert Comment as outlined below.

Experts selected are recommended by the horizon scanning analysts as they compile material on a topic. They identify and nominate a blend of experts from our database or suggest additional experts they have identified from the literature or who have been referred to us by other experts in our database. The horizon scanning medical editor then solicits the experts to comment on a topic and sends the topic profile and structured comment form to each expert. (See Appendix B.) The group of experts commenting on any particular topic usually differs, even among related

topics. For example, a biologic in development for many types of cancers may have some expert commentators in common for the health systems and health business perspectives, while other experts will be unique to the clinical condition (e.g., lung cancer versus liver cancer).

Each topic-specific expert is instructed to do all of the following:

1. Read the topic profile provided.
2. Score his/her impression of each parameter using a 1- to 4-point scale (definitions of each parameter are provided).
3. Provide comments and ratings with supporting rationales for each of the seven parameters listed in Appendix B.

The expert submits comments and ratings online by clicking on a "submit" button at the end of the form. The form and its content are automatically logged into a repository for all the experts' comments and ratings.

Phase 1 – Internal Expert Comment and Triage (all topics)

In Phase 1. Internal Expert Comment and Triage, each topic is sent to four or five experts chosen from among ECRI Institute's own experts (excluding the horizon scanning analysts who compiled the information on a topic). These experts all adhere to rigorous conflict-of-interest rules as a condition of employment that prohibit ownership of any drug or biotechnology or device company stock investments, or acceptance of any gifts or grants from the medical product industry. Experts submit comments and ratings using the structured review form as described above.

Once all internal expert comments and ratings have been received for a topic, analysts review comments and ratings for that topic. Topics are then placed into Group 1 or Group 2:

- **Group 1:** Internal comments and ratings indicate that the topic has potential for high impact. Topics in this group proceed immediately to Phase 2. External Expert Comment below.
- **Group 2:** Topics requiring further discussion are brought to a team meeting to determine whether external expert comment is warranted. These topics include:
    - Topics with mixed internal comments regarding potential for high impact, or
    - Topics for which internal commenters indicated that the topic has little to no potential for high impact or should be archived because additional expert insights indicate it does not meet criteria for being a novel intervention that addresses and important unmet need.

After reaching consensus regarding internal comments and ratings on the Group 2 topics, the team chooses to either send the topic out for external expert comment, or change the status of the topic from "Advance to Target" to "Track: Passive" or "Archive." If changed to "track passive," the topic is monitored until important new information emerges that would merit revisiting the topic at a team discussion to decide whether to update the profile and obtain new comments. Topics that do not proceed to Phase 2. External Expert Comment will be noted as such in the High Impact report; however, they will not be eligible for inclusion as High Impact topics.

Phase 2 – External Expert Comment

Select topics enter Phase 2. External Expert Comment in which they are sent for external expert comment if they have successfully proceeded through Phase 1. Internal Expert Comment and Triage. Two to three external experts are selected per topic from either the expert database or

a new solicitation for participation. We request CVs from all external experts in addition to the information we collect on a COI form. Management of potential COI is discussed further in a subsequent section of this protocol.

Although we seek a maximum of eight experts for each topic that undergoes Phase 1 and 2 comment processes, topics become eligible for consideration as Potential High Impact Interventions (Step 7. High Impact Topic Selection Process) after a minimum of five experts have commented on a topic, including at least one to three external (to ECRI) experts. The experts' comments remain in the database for subsequent analysis and synthesis for the next iteration of the Potential High Impact Report. In the report, we identify experts by their respective roles (e.g., clinical, research, health systems), but not by name.

Topics that have received the required set of comments are then considered with topics that have already received sets of expert comments within the previous 12 months. Some topic profiles in the system that completed the expert comment phase may be updated and reissued (Step 9. Topic Monitoring and Updating Process) to obtain updated expert comments when we become aware of important new information that could change/inform an expert's perspective. Examples include reports of new data from ongoing or completed trials that could move the development or adoption of the intervention forward.

Experts reading the compiled information and rating the potential impacts of a topic provide their independent expert opinions based on their respective knowledge about the technology/services and the health care system. No individual's comments are intended to represent an entire group or field. Individual experts' scores for the seven parameters (see Appendix B) are intended to capture qualitative perspectives in a given field/area at a given point in time.

Balancing any Potential Conflicts of Interest From Experts

It is possible, even likely, that a particularly knowledgeable expert could have an intellectual or financial conflict of interest in a topic on which he or she provides comments. Experts are asked to declare any and all potential conflicts of interest (intellectual and financial) on the structured comment form they are required to use when commenting. Those who declare potential intellectual or financial conflicts of interest for a topic are not necessarily disqualified from participating. Their views are balanced by inputs from other neutral parties, including ECRI experts. Those with vested interests in new technologies, services, and innovations typically provide critical insights and information about the areas in which they have a vested interest. Their perspectives include their vision and plans for how they intend to carry out diffusion of a technology, service, or innovation. Out of the total number of experts per topic (five to eight), we limit to two the participation of experts with potential conflicts of interest. An expert with a potential COI and relatively lesser expertise, based on our assessment of their degree of technical/scientific knowledge by looking at their curriculum vita and publications in the field, is replaced to keep the number with conflicts of interest to one or two. Equally important is identifying whether any experts represent special interests against the technology or service. If they are involved in a competing service or product, their views must also be balanced by experts without special interests and by competing interests.

Step 7. High-Impact Topic Selection Process

The purpose of the expert comment and rating process is to aid in determining which interventions have potential for highest impact on health care utilization, patient outcomes, costs,

disparities and access, infrastructure, and systems of care delivery. The parameters we use were devised based on extensive unstructured, open feedback and suggestions received from the AHRQ Healthcare Horizon Scanning System Expert Panel convened in June 2011 and from more than 40 experts who served in the initial pilot comment and ratings process of 285 topics during the first 6 months of implementation of the system (December 2010 – May 2011).

Parameter Considerations

From the pilot, we learned that having a relatively small number of broad parameters provides an opportunity for all types of experts to respond to some aspect of the parameter without imposing a burden on experts in terms of their time commitment. The parameters we use are intended to provide an opportunity for experts to explore their thinking about a topic on the aspects of most interest to AHRQ. For any given topic, some experts may be more or less expert on some aspects of the topic. For example, researchers may have less expertise about potential health systems or infrastructure impacts, but more expertise on the potential patient outcomes. The purpose of the 4-point scoring system is to serve primarily as a tool to help experts consider various aspects of the topic and to draw out their perspectives. The parameters are worded so that the scale goes in the same direction for each parameter.

How Expert Comments and Ratings Are Used To Prepare the Report

The overall potential impact of an intervention that received a set of expert comments is determined based on the comments and ratings for each topic in each AHRQ priority area. As of the June 2014 issue of the Potential High Impact Interventions report, the comment sets received on target topics had to be current within the prior 12 to 15 months for a topic to be eligible. The list of topics eligible for consideration may grow or shrink depending on the number of active and completed topic profiles and the recency of the sets of expert comments during the prior 12 to 15 months.

ECRI calculates the mean and median expert ratings for each eligible topic. Then analysts assess expert comments for each eligible topic with ratings at or above the mean and median scores for that priority area as an initial starting point. However, the comments take priority over ratings because individual experts with similar rationales may actually rate a topic differently. Thus, ratings are used only as a preliminary signal of potential impact. Furthermore, expert comments for all eligible profiles are read—including those rating below the mean or median in a priority area—to ensure that no topic with important potential is missed because of a rating anomaly.

AHRQ has requested that up to 20 topics with Potential High Impact be identified in each of the 14 priority areas. Important to note is that the eligible topics for consideration that have the highest potential impact for each priority area are relative to analysts' assessment of other topics in that priority area at that particular point in time. Some priority areas (e.g., dementia, developmental delays, substance abuse, and peptic ulcer) may have very few interventions in development that met horizon scanning inclusion criteria and few or none that merit designation as "potential high impact." Thus, the designation of potential high impact is relative to the range of interventions that have met criteria for inclusion in the AHRQ Healthcare Horizon Scanning System. Potential High Impact reports are generated twice annually and are drawn from the set of active topics that completed the expert comment and ratings process at that time or completed

expert comment process within the prior 12 to 15 months. Thus, some number of included topics can be expected to change in any given Potential High Impact Interventions report.

Step 8. High-Impact Report Preparation

Six weeks prior to delivering the June and December reports, the Horizon Scanning team and invited internal experts meet to decide which topics merit designation as having potential for high impact in the report. The analysts for each priority area present the results of the expert comment and ratings process on all topics with a full set of internal and external expert comments from the prior 12 to15 months. Analysts make recommendations on the basis of the expert comments and the team votes (majority rules) on topics to include for the report. The decisions for each topic that an analyst presents are captured on a spread sheet. The team captures the reasons for exclusion of topics, as well as changes in the included topics (additions/deletions) from the prior potential high impact interventions report to the current report.

For 4 weeks after the decision meeting, analysts write the analyses on topics that comprise the chapters in their respective priority areas. This analysis provides an overview of each priority area and all the topics considered, followed by profiles of each topic designated as potential high impact. Within the potential high impact designation are three tiers requested by AHRQ to indicate lesser and greater degrees of potential high impact. The chapters are internally reviewed by the management team, edited by a medical editor, formatted to meet AHRQ publication standards, and delivered to AHRQ for publication to AHRQ's Web site.

Step 9. Topic Monitoring and Updating Process

All topics in the AHRQ Healthcare Horizon Scanning System —whether existing as in-depth target topic profiles or existing only as tracked topics not yet written as in-depth profiles because late-phase data are lacking—are monitored by the Horizon Scanning team for new information. To do this, searchers craft strategies using keywords and controlled vocabulary terms for each searchable resource. Wherever possible, searchers create automated alerts to capture new information on an ongoing basis. These monitoring activities can change the status of topic depending on what has occurred with its development or diffusion status.

New information on topics already in the system is entered into the Initial Leads List, linked to the topic in the Identified Topics List and assigned to the appropriate analyst for review. The analyst then reviews the new information and recommends a topic for one of these possible actions, depending on the topic's current status in the system: move from track only to preparing an in-depth target topic profile; update an existing in-depth profile; or relegate topic to a lesser status (archive or track only). (See Table 14.)

Table 14. Examples of triggers for topic updates

1. Changes regarding United States regulatory submissions (e.g., biologic license application, new drug application, premarket approval application) including new submissions, advisory panel recommendations, FDA decision dates.
2. Start of new trials or announcement/publication of late-phase data on the topic
3. Major changes in adoption and/or implementation issues including availability of new comparators
4. Company mergers that affect product development (product development may be delayed or halted altogether)
5. Company selling of R&D rights for a product
6. Rapid increase in the volume and sources of published literature on a procedure or care innovation (e.g., uptick in reports on a surgical approach such as single incision laparoscopic surgery; uptick in gray literature on "evidence-based hospital design")
7. Changes to the intervention name (e.g., a trade name becomes available)

Topics advanced for preparing a new in-depth target topic profile are added to the Production Queue and prioritized appropriately. (See Step 5. Topic Profile Development.)

Existing topics that have an in-depth profile may be placed in the queue to be updated and reissued for expert comment when new information becomes available that the Horizon Scanning management team concludes could change perspectives. (See Table 15.) If no new information has been found through scanning activities during the previous 9 months regarding a Target Topic for which an in-depth profile has been developed, we conduct active update searches to determine whether the topic remains viable and whether new expert comments are warranted.

Table 15. Possible signals warranting updating and resending for expert comments

1. New data shed new light on an intervention, such as
   - Additional, stronger, confirmatory data that could change perspectives on potential impact
   - Safety data that could change perspectives
   - New data that are inconsistent with prior data provided to experts
   - A patient safety alert been issued that could signal a safety/efficacy change in perspectives
2. FDA issued a decision that could affect experts' perspectives, such as a Complete Response Letter from FDA to a developer/manufacturer, who then decides to continue development and initiate new trials that could change expert perspectives, or an advisory panel's negative recommendation?
3. Post-market events (within 2 years of FDA approval) occurred that could change the premarket projections of impact, such as a much slower uptake than anticipated; apparent lack of acceptance by clinicians or patients; no reimbursement; access issues; position statements by professional societies; market withdrawal of competing interventions

Monitoring and Updating High-Impact Topics

In addition to the routine monitoring discussed above, all active topics that have been included in a previous High Impact report are queued for updating and sent for expert comment if either of these following criteria apply: the topic lacks expert comments that are current within the prior 12 months; new information has become available that could affect expert ratings and comments.

Prioritizing Target Topics Under Development

Topics added to the Horizon Scanning Production Queue are prioritized for searching, profile development, and expert comment according to the schema outlined below (1 = lowest priority; 4 = highest priority). Topic prioritization is an ongoing process; therefore, analysts meet twice

each month to discuss topics as necessary to ensure that all target topics are properly prioritized according the schema outline below.

1. New topics that the team determines to have lower potential for high impact than other topics in the system (e.g., equivocal data, incremental potential benefit) and previous, active, target topics being updated that were considered for a previous High Impact report for which expert comments will be older than 12 months immediately prior to the next scheduled High Impact Report.
2. New target topics that the team considers to have higher potential for high impact than other topics in the system (e.g., strong data, Breakthrough Designation, Fast-track Status, Priority Review).
3. Previous, active, target topics currently being updated that were included in a previous High Impact report and for which expert comments will be older than 12 months immediately prior to the next scheduled High Impact report.
4. Previous, active, target topics being updated that were considered for or included in a previous High Impact report and for which new information exists (see Table 14 and Table 15above for examples) that could change experts' perspectives regardless of the recency of the prior expert comments.

Archiving Processes

During biweekly team meetings and during the process for producing the Status Update report of all interventions tracked in the system, the Horizon Scanning team also determines whether topics need to be archived (see Table 16).

Table 16. Reasons for retiring and archiving topics

1.	Product/intervention failure to meet endpoints in trials and product development ceases.
2.	Exhaustion of companies' financial resources to continue development
3.	Intervention diffusion is 2 years post regulatory approval or, if not subject to FDA regulation, has diffused beyond early adopters for the indication being tracked.
4.	Topic is no longer novel or innovative because other topics in its class have reached diffusion in the health care system, rendering the topic a "me-too" that no longer addresses a significant unmet need.
5.	Topic has completed expert comment and ratings, and experts have concluded that the topic has no potential for high impact in any of the parameters of interest to AHRQ or the entities its research supports because the intervention is not novel or innovative, or does not address an important unmet need.

Maintaining an archive accessible to end-users is important for context over the long term. An archive provides a reference source from which to draw connections about other developing, possibly related technologies; it can inform the likelihood of success and impact for a closely related technology. A technology on hold for a long period can also re-emerge, and archiving provides historical context. As such, the Horizon Status Update Report issued 5 times annually on all topics that are active in the system also includes a table of the topics archived during the previous reporting period and the reason for archiving.

The Horizon Scanning protocol enables understanding of trends over time, such as how new indications for existing technologies/services/approaches to care emerge, how groups of technology move in tandem, and how they impact the health system, clinical care, patient outcomes, and costs. Examples that illustrate this point include development of high-end imaging

technology (e.g., PET/CT) and development of minimally invasive surgery approaches with subsequent development of new technologies further enabling those approaches.

Step 10. Indexing Process

Appropriate content indexing is critical to enable end-users of the AHRQ Healthcare Horizon Scanning System to accurately and efficiently retrieve information. Controlled vocabularies, including Medical Subject Headings (MeSH), those currently used at AHRQ's Effective Health Care Web site, and ECRI's Universal Medical Device Nomenclature System (UMDNS), which has been part of the National Library of Medicine's Unified Medical Language System (UMLS) since 1992, are used to index content in the topic profiles and Potential High Impact Interventions reports produced for the AHRQ Healthcare Horizon Scanning System. Indexing terms are assigned for all topics. Indexing strategies are shown (see Table 17) with the fields used in the report templates. Such indexing would facilitate transition to a relational database in the future should AHRQ want to pursue that for the Healthcare Horizon Scanning System.

Table 17. Indexing

- Technology class
- Clinical category
- Clinical specialty
- UMDNS if applicable
- MeSH
- ICD-9
- FDA SPN
- SNOMED CT

Rapid Cost Analysis Pilot Protocol

In 2014, nearly 4 years after initiation of the horizon scanning system, AHRQ requested some exploratory and simple cost analyses be performed to illuminate the known or potential costs of new interventions that had been identified, tracked, and eventually deemed to have potential for the moderate or higher range of the high impact scale in the Potential High Impact Interventions Reports of December 2013 and June 2014. The 55 topics selected had a moderate or high designation within the high-impact-potential range. In addition, four of these topics were selected for more detailed cost analyses, which were performed by analysts from Truven Health Analytics, Inc. (Ann Arbor, Michigan).

To estimate potential costs of these new and emerging interventions, we sought to identify data on the following: prevalence of the disease or condition targeted by each intervention; actual or projected adoption of the new intervention; costs of the intervention; costs of a similar intervention for the same or another clinical indication; and costs of an alternative interventions used for the disease or condition. Of note, however, is the fact that ongoing development of two of the interventions is questionable at this time because of unexpected Phase 3 data (Symplicity renal denervation system for treatment-resistant hypertension) or financial difficulties of the company (RenalGuard device for preventing contrast-induced nephropathy). Also of note is that costs for two other interventions: a program and an infrastructure intervention could not be estimated because too many variables are associated with the interventions.

With available data, we then estimated costs of each new intervention for the estimated adoption rate, and we estimated costs of one or two of the main interventions used for the current standard of care or other alternative interventions. We also sought to determine whether the new

intervention would replace or add to existing standard of care. These simple cost analyses did not consider effectiveness of interventions in any depth, because performing systematic effectiveness reviews is not part of the horizon scanning activity. In some cases, we referred to clinical results reported in article abstracts to provide context.

These analyses also take a short-term view for the most part—estimating costs of the interventions over 1 year of adoption. The analyses do not consider how much the cost of the new interventions might be offset by replacing other interventions or other downstream effects. In a small number of cases in which others had performed and published cost-effectiveness models, we report their findings, some of which provide longer-term cost impact projections. Further details of our methods are below.

To identify data for these analyses, ECRI Institute medical librarians performed topic-specific searches for each intervention and a set of analyst-identified comparators using peer-reviewed clinical literature, business literature, public resources providing retail cost information on drugs, and proprietary databases of cost information for medical equipment and supplies that ECRI Institute collects from more than 1,500 hospitals across North America. (See Table 18). These search strategies were also used to supply ECRI subcontractor Truven Health Analytics with the source documents and information used in four Truven Health Cost Models on selected topics. ECRI Institute horizon scanning analysts and Truven Health analysts then used these search results to identify data they used to perform their analyses.

Table 18. Sources searched for cost data

Source
Embase.com®
Lexis-Nexis®
Pharma and MedTech Business Intelligence (Grey Sheet, Pink Sheet, In Vivo, Start-up, Medtech Insight)
GoodRX (drugs)
PriceGuide ECRI Database (searches for implant and consumable prices paid by hospitals)
PricePaid ECRI Database (searches for capital equipment prices paid by hospitals)
Health Technology Assessment Information Service ECRI Database (information on clinical, safety, cost, and reimbursement for health care interventions)
Cochrane (cost studies)
The Wall Street Journal
HCUP
Google
NICE (if no U.S. information found)

To identify possible costs of interventions not yet on the market in the United States, we identified existing interventions to serve as proxies for the new intervention. For example, in considering a new cardiac valve in development for a new clinical indication, we considered as a proxy the average cost of new and novel cardiac valves or devices that entered the U.S. market within the past 2–3 years. In some cases, devices have entered the European market 1 or more years before entering the U.S. market and European costs were available. Although European costs are not recognized as a direct proxy for U.S. costs, they provide some sense of pricing in industrialized countries adopting the device. For emerging pharmaceuticals or biotechnologies

that have not yet reached market and lack cost information, we used as proxies novel pharmaceuticals or biotechnologies entering the market within the past 2–3 years for the same or similar conditions. For example, we used data on the retail cost of new targeted oncology drugs over the past 4 years as a proxy for targeted oncology drugs in development.

For each topic, we also conducted searches to identify costs of one or two interventions used as the current standard of care for the clinical condition that the new intervention is intended to treat. Again, we did not attempt to calculate long-term costs and effectiveness.

Understanding potential costs also requires understanding the disease or condition prevalence (the number of patients in the target population eligible for the new intervention) and estimating what proportion of that target population might use the intervention in question. For most topics, our projections of possible cost impacts are for 1 year of the technology's use. Typically, a target population is a subset of the population with the disease or condition. Most new interventions are not adopted by 100 percent of the patient population with the disease or condition because many factors affect adoption, such as patient and clinician acceptance, access or availability, affordability, and patient preference. For some diseases and conditions, reliable prevalence information has not been collected or published. Companies also publish projections of anticipated market share and marketing plans for product launch. While these projections are typically optimistic, in the absence of information on prevalence and adoption rates, we considered this information, but with a degree of skepticism. We compared prevalence data we found with market share projections to ascertain gaps or discrepancies between what we found and what companies projected. We also tempered our adoption estimates with the expert comments we received when preparing the Potential High-Impact Interventions report about patient and clinician acceptance and adoption factors.

The types of information provided in each cost analysis are as follows:

- Brief description of the topic (full description is in High Impact report)
- Prevalence of the condition (if known or best available estimate)
- Estimated adoption rates (best available data)
- Anticipated cost per patient
- Costs of similar interventions for the same or other conditions
- Costs of alternative interventions for the disease/condition (if alternatives exist)
- Infrastructure and capital equipment costs (if applicable and available)
- Cost impact of replacement of existing interventions (if the intervention is a replacement)
- Cost impact of adding this intervention to existing interventions (if this intervention is going to be added to existing interventions)
- Potential overall cost impact (bottom line summary)

For the detailed cost analyses, Truven Health analysts created decision models reflecting management of the conditions pertinent to the four chosen topics. They identified relevant claims data in two Truven Health MarketScan® Research Databases (Commercial Claims and Encounters Database and the Medicare Supplemental Database), which include claims regardless of setting or type of service for privately insured individuals and their dependents. The MarketScan Treatment Pathways data analytics tool was used to estimate costs of existing treatments and their complications. The analysts constructed cost models using this data alongside prevalence, uptake, efficacy, and pricing estimates identified in the searches conducted by ECRI Institute librarians. Typically multiple scenarios were modeled, and sensitivity analyses were run for estimates with significant uncertainty. Model assumptions are presented in each of the four reports.

Appendix A. Scanning and Searching Resources

Table A. 1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
ACM TechNews 2, 3, 4, 8	Digital newsletter published 3x weekly; Summarizes current news on established and emerging areas of computer science, trends in information technology, and related science, society, and technology news. Links directly to source article		X				X	X
AdvaMed 2, 3, 4, 5, 8	Advocacy group for medical device industry. News, information on issues & advocacy efforts, case studies on various technologies AdvaMed SmartBrief, is a daily e-mail summarizing top medical technology news		X		X		X	X
Advances in Pharmacy ASHP Daily Briefing 2, 3	Daily email briefing summarizing key medical and health care news from the previous 24 hours. Targeted to health-system pharmacists			X	X			
AHA Emerging Science Series 1	Online forum for late-breaking clinical trials, key updates of previously presented trials, late-breaking science, new analyses or substudies, major bench-to-bedside breakthroughs and more	X	X	X	X	X		
AlphaGalileo 3	Distributor of news releases and other information from science, health, technology, the arts, humanities, social sciences and business	X	X	X	X	X		X
American Laboratory 2, 3, 4,5, 8	Digital monthly publication focused on the practice of analytical chemistry. Industry news and information about scientific instrumentation in analytical/ bioanalytical chemistry, basic research, applied spectroscopy, chromatography, petrochemicals and material science	X	X		X		X	X
American Medical News 2,4,5	News publication for physicians published by the American Medical Association covering information on political/regulatory issues, the medical profession, public health, the medical marketplace and practice management.					X	X	X

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
JAMA Internal Medicine 1, 4, 5, 7, 9	Bi-monthly peer-reviewed journal from the American Medical Association. Publishes original medical research targeted to internists practicing as generalists or medical subspecialists	X	X	X	X	X	X	X
Aunt Minnie Insider 2,6, 11	Aggregates information on radiation therapies and technologies		X			X	X	X
BioPhotonics 2, 3,5, 7, 8	Monthly digital magazine reporting on developments and techniques in photonics relevant to medicine / biotechnology. Feature articles and industry, product and business news	X	X					X
BizJournals 2,4, 5, 7	Digital weekly business newspapers from 41 major US cities	X	X	X				X
BMJ 1, 2, 4, 5,6, 7, 9	Digital weekly journal. Publishes original medical research to improve patient outcomes and influence the debate on health care. Continuously updated Web site	X	X	X	X	X	X	X
Business Week 2, 3, 5, 6	Weekly magazine that reports on international business, financial and investment news	X	X	X		X	X	X
CADTH Health Technology Update & CADTH Issues in Emerging Technology 1, 2,4,8	*HTU*: Digital newsletter from the Canadian Agency for Drugs and Technologies in Health; reports on new/ emerging health care technologies in Canada; provides updates/ links to recent Canadian health technology assessments, recommendations, and clinical practice guidelines; *Issues in Emerging Technology*: bulletins describing emerging drug and non-drug technologies not yet used or widely used in Canada; Health Canada's approval is usually anticipated within six to 18 months	X	X	X	X	X	X	
California HealthCare Foundation (CHCF) 1, 4	A nonprofit grant making philanthropy focused on clinical outcomes and quality of life, reducing barriers to efficient, affordable health care, promoting transparency and accountability and implementing health reform in California.					X	X	

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
CancerNetwork 1, 2, 6, 8 , 9	Website that aggregates medical information on cancer treatment including original medical research and news updates	X	X	X	X	X	X	X
Cardiology Today 1, 2, 4, 8, 9	Information source for cardiovascular medicine professionals; reports on emerging technologies, techniques and medical therapies, and clinical, therapeutic, industry and socioeconomic issues	X	X	X		X		X
Cardiovascular Update 1, 2	E-newsletter from the Mayo Clinic reports on cutting-edge diagnostic and therapeutic techniques offered in their subspecialty clinics	X	X	X		X		X
The Center for Medicare & Medicaid Innovation (the CMS Innovation Center) 1, 4	CMS project that identifies, develops, supports, and evaluates innovative models of payment and care service delivery for Medicare, Medicaid and CHIP beneficiaries using an open, transparent, and competitive process						X	
Circulation 1, 2, 4, 5, 7, 9	Peer-reviewed journal from the American Heart Association that publishes original medical research related to cardiovascular issues	X	X	X	X	X	X	X
Clinica 2, 4, 6, 8	E-newsletter updated daily; reports on the international devices and diagnostics industries; includes abstracts of relevant scientific research	X	X	X		X	X	X
Clinical Care Options 9, 11	Online medical education programs, technologies and guidelines for HIV, hepatitis/ gastroenterology, hematology/ oncology	X	X	X	X	X	X	X
CMS Coverage e-mail updates 10	E-mail notification of new NCDs or MEDCAC meeting announcements	X	X	X	X	X		
CMS Updates to Coverage Pages 8, 10	Updates to coverage delivered via email	X	X	X	X	X	X	
Commonwealth Fund 1, 4	A private foundation that promotes a high performing health care system, particularly for society's most vulnerable by supporting independent research on health care issues and making grants to improve health care practice and policy.						X	

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
Diabetes Technology & Therapeutics 1, 4, 5, 7	Monthly journal that publishes scientific research on new devices, drugs, drug delivery systems, and software for managing patients with diabetes	X	X	X	X	X		X
Diagnostic Imaging 2, 6, 8 11	Digital newsletter and Web site providing news and information about radiology		X			X	X	X
ECRI Institute Health Technology Forecast database 1, 2, 8, 11	Profiles with impact radars, conference reports, news briefs about drugs, devices, procedures in late-phase development	X	X	X	X	X	X	X
ECRI Institute Health Technology Trends 2, 4, 5, 8	Monthly newsletter about new developments in health care technologies, processes of care, and factors affecting diffusion and adoption of new interventions	X	X	X	X	X	X	X
ECRI Institute Hotline Responses 1, 4, 8	Researched responses to questions from ECRI Institute member hospitals, health plans, and other subscribing organizations about efficacy and effectiveness of health care technologies, services, and factors affecting diffusion and implementation	X	X	X	X	X	X	X
EurekAlert! 3	American Association for the Advancement of Science (AAAS) portal for press releases from universities, medical centers, journals, government agencies, corporations and other organizations engaged in research	X	X	X	X	X	X	X
European Radiology 1	Peer reviewed journal that publishes original scientific research and reviews in radiology		X			X	X	X
F1000Posters 1	Open repository for posters and slides from scientific conferences	X	X	X	X	X		
FDA Advisory Committee Alerts 12	Email notification from the FDA when advisory committees are scheduled to discuss drugs, devices	X	X	X				
FDA Approval Alerts 12	Email notification from the FDA when drugs, devices and biologics and food additives are approved	X	X	X				
FDA Device Daily Bulletin 12	Daily e-newsletter reporting on FDA regulatory, legislative and business news developments in the medical device industry		X					

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
FDA Drug Daily Bulletin 12	Daily e-newsletter reporting on regulatory, legislative and business news developments in the pharmaceutical industry			X				
FDA Orphan Drug Designation Database 12	A database of drugs that have received orphan drug status.	X		X				
Fierce Markets Network 2,4,8,10	Series of daily email newsletters on a range of health care topics including biotechnology, devices, pharmaceutical, health information technology and reimbursement issues	X	X	X		X		
Forbes 2,4,8	Biweekly business news magazine	X	X	X	X	X	X	X
Fortune 2,4,8	Biweekly news magazine focusing on political, economic and social issues related to business	X	X	X	X	X	X	X
The Gray Sheet 2,4,8	Weekly newsletter reporting on regulatory, legislative and business news relating to the medical device industry		X					X
GenomeWeb 2,3,4,8	GenomeWeb is an independent online news organization covering the scientific and economic ecosystem spurred by the advent of high-throughput genome sequencing	X	X		X	X		
Health Affairs 1, 4, 5, 6	A monthly peer-reviewed journal of health policy thought and research exploring health policy issues of current concern in both domestically and internationally.						X	
HealthCare: The Journal of Delivery Science and Innovation 1	Journal promoting cutting edge research on innovation in health care delivery, including improvements in systems, processes, management, and applied information technology					x	x	
Health Imaging & IT 2,4,11	Online newsletter covering news and business issues related to imaging technologies		X			X		X
Health Leaders Media 2, 5, 5, 8	Information on management trends, innovations, market strategies, and organizational development for health care executives and professionals						X	

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
Healthcare IT News 2,4,8,10	Monthly newsletter includes new technologies, IT strategies and tactics, statutory and regulatory issues, as well as provider and vendor updates. Published in partnership with HIMSS		X				X	X
iHealthBeat 2,4,	Online newsletter reporting technology's impact on health care		X				X	X
Imaging Economics 2, 3, 4, 8	Monthly magazine providing information on the development, diffusion, acquisition, and utilization of imaging technology.to radiologists, radiology administrators, and executives		X			X	X	X
iMedicalApps 4, 6, 8	An independent online medical publication written by a team of physicians and medical students who provide commentary and reviews of mobile medical technology and applications		X			X	X	
Institute for Healthcare Improvement 1, 4	An independent not-for profit-organization focusing on motivating and building the will for change; identifying and testing new models of care in partnership with both patients and health care professionals; and ensuring the broadest possible adoption of best practices and effective innovations.						X	
In Vivo 2, 4, 8	Monthly business resource for the biopharma, medtech, and diagnostics industries. Covers future industry trends, key industry developments, research and development of drugs and pharmaceuticals and regulatory issues	X			X		X	X
International Journal of Healthcare Technology and Management 1, 11	Bimonthly, peer-reviewed journal covering technology assessment and management, innovation and new product development		X				X	X
JAMA 1, 2, 4, 5	Weekly, peer-reviewed journal covering all areas of medical research	X	X	X	X	X	X	X
Journal of Clinical Psychiatry 1, 2	Peer-reviewed journal publishing medical research in all areas relating to mental health. Also covers newest advances in the diagnosis and treatment of mental disorders		X	X		X	X	X

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
Journal of Health Services Research and Policy 1, 4	Peer-reviewed journal covering the ideas, policies and decisions shaping health services throughout the world. Examines current issues in health care policy and research	X	X	X	X	X	X	X
Journal of Medical Devices 1, 2	Quarterly peer-reviewed journal focusing on applied research and the development of new medical devices that improve diagnostic interventional and therapeutic treatments. It provides special coverage of novel devices that allow new surgical strategies, new methods of drug delivery, or possible reductions in the complexity, cost, or adverse results of health care		X					X
Journal of Pediatrics 1	International, peer-reviewed journal of pediatric research. Geared toward the clinician. Covers the latest developments in pediatric medicine	X	X	X	X	X	X	X
Kaiser Family Foundation publications 1,2, 4, 5	A leader in health policy and communications, the Kaiser Family Foundation is a non-profit, private operating foundation focusing on the major health care issues facing the U.S., as well as the U.S. role in global health policy. Kaiser develops and runs its own research and communications programs, sometimes in partnership with other non-profit research organizations or major media companies	X	X	X	X	X	X	
LabMedicine 2	Monthly publication of the American Society for Clinical Pathology. Covers current and future trends in clinical laboratory medicine	X			X			X
Lancet 1,4,5	Weekly, peer-reviewed journal that publishes clinical trials results, research and analysis in all fields of medical research	X	X	X	X	X	X	X
Managed Care 2, 4, 10	A guide for health plan executives and physicians on capitation and other health insurance and delivery issues	X	X	X		X	X	

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
MDLinx 1, 2, 11	Daily aggregate of medical articles and research from peer-reviewed journals and news media	X	X	X	X	X	X	X
Med Tech Insight 2, 4,	Newsletter providing business intelligence and insight in the medical technology industry; analyzes current markets and future trends in the industry, including technologies, clinical applications, key players, and start-up companies		X			X		
MedGadget 2,3, 4, 6, 8	Internet journal of emerging medical technologies		X					X
Medical Device Daily 2, 9, 10	Covers new product developments, company news, regulatory activity, legislative actions, strategic alliances, sales and mergers and market updates		X			X		X
MedicalPhysicsWeb 2, 4, 5, 6, 8	Website and "scientific Web community" from IOP; provides access to information on biomedical physics; provides links to relevant original research		X			X		X
Medpage Today [Includes conference coverage] 2, 4,5, 6, 9, 11	Targeted to physicians. Provides a clinical perspective on breaking medical news read by consumers. Co-developed by MedPage Today and The University of Pennsylvania School of Medicine, Office of Continuing Medical Education, each article alerts clinicians to breaking medical news, with summaries and actionable information enabling them to better understand the implications	X	X	X	X	X	X	X
Medscape 1, 2, 9, 11	Resource for Physicians: medical journal articles, MEDLINE, medical news, major conference coverage drug information	X	X	X	X	X	X	X
MIT Technology Review 2, 4, 5, 6, 7, 8	Magazine providing information on emerging technologies & impact on business & society	X	X					X
Neurology 1,4,5	Journal of the American Academy of Neurology (AAN).	X	X	X	X	X		X
Neurosurgery 1, 2	Official Journal of the Congress of Neurological Surgeons. Reports on research in neurosurgery and the latest science, technology, and medicine		X			X		X

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
New England Journal of Medicine 1, 2, 4, 5, 7, 9	Peer reviewed medical journal featuring current research information, reviews and articles for biomedical science, internal medicine and clinical practice	X	X	X	X	X	X	X
NHS HTA publication update	Email alert outlining new research publications as well as research agendas covering devices and technology							X
Obesity 1,2,4,5	Official journal of The Obesity Society. Publishes peer-reviewed research and cutting-edge reviews, commentaries, public health and medical developments relating to obesity		X	X		X		X
Oncology 1, 2, 4, 5,	Peer reviewed research journal. Purpose is to advance clinically-relevant knowledge of cancer, and improve the outcome of prevention, diagnosis and treatment. Publishes clinical studies translational laboratory findings, mini-reviews and controversial topics in oncology; also focuses on rapid peer-review and subsequent publication of short reports of Phase 1 and Phase 2 clinical cancer trials	X	X	X	X	X		X
Orthopedics 1, 2, 4,5,	Peer-reviewed journal that offers in depth information on research on orthopedics; is part of OrthoSuperSite.com	X	X	X	X	X		X

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
OrthoSuperSite.com 1, 2, 4, 6, 7, 8, 9	Website offering access to all varieties of information on orthopedics from scientific and medical research to industry news	X	X	X		X		X
Pain Research and Management 1	Official journal of the Canadian Pain Society. Peer reviewed journal publishing original research and review articles pertaining to pain management		X	X	X	X		X
Pharmacy & Therapeutics 1, 2, 8, 10	Journal for pharmacy and therapeutics decision-makers			X		X		
Pink Sheet 2,4,8	Weekly newsletter reporting on regulatory, legislative and business news relating to the pharma industry			X				X
PLoS Medicine 1, 2, 4, 6	Peer-reviewed open access journal that publishes medical research	X	X	X	X	X	X	X
PlosCurrents 1, 4, 5	Open-access publications for the extremely rapid communication of new research findings currently covering Huntington's disease, genomic testing and influenza.	X		X	X			
Psychiatric News 2, 4, 5, 7	Bimonthly newspaper of the American Psychiatric Association (APA); the principal and official means of communication between APA and its members about policies, politics, and legislative and judicial issues plus clinical and research news affecting psychiatry		X	X		X		
Psychiatric Times 1, 2, 4, 5, 6, 11	Monthly psychiatric magazine from UBM Media		X	X		X		
Radiotherapy and Oncology 1, 5	Peer-reviewed journal covering radiation oncology	X	X			X		X
Robert Wood Johnson Foundation 1, 4	A philanthropy that funds and produces knowledge, new ideas and expertise to improve health and health care.					X	X	

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-Label Use
Start-up 2, 8	Monthly. Profiles new product companies, identifies the hottest technology areas, reviews funds flowing into private companies and investment trends, and reports on university tech transfer licensing. Industries covered: pharmaceuticals, biotechnology, medical equipment & devices, and in vitro diagnostics			X				X
TEC Assessments 1	Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC) provides evidence-based reports on health care technology assessment in the areas of diagnosis, treatment, management and prevention of disease	X	X	X	X	X	X	
Telemedicine and e-Health 1,2,8	Covers all aspects of clinical telemedicine practice, technical advances, medical connectivity, enabling technologies, education, health policy and regulation and biomedical and health services research dealing with clinical effectiveness, efficacy and safety of telemedicine and its effects on quality, cost and accessibility of care, medical records and transmission of same		X			X	X	X
The New York Times 2, 3, 4, 5, 7	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X
theheart.org 2, 3, 4, 5, 9	Daily information on caring and prevention of disorders of the heart and circulation from Medscape	X	X	X	X	X	X	X
Therapeutics Daily 2, 8	Daily news and information focusing on the development, sales, and marketing of major therapeutic categories - Cardiovascular, Oncology, Pain & Inflammation, Central Nervous System, and Infectious Disease	X	X	X	X	X	X	X
UroToday 1, 2	Online newsletter that aggregates original research and news about developments in various urinary cancers and diseases	x	x	x		x		
Wall Street Journal 2, 4, 5, 6, 7	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X

Table A.1. Medical Web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI medical librarians and/or horizon scanning analysts (continued)

Key to Resource Type:

1: Original research and scientific reviews;
2: News;
3: Press Releases;
4: Commentary;
5: Editorial;
6: Blogs;
7: Letters;
8: Product information;
9: Education/ CME;
10: Coverage Decisions;
11: Conference reports;
12: Regulatory

Table A. 2. Meeting abstracts reviewed for leads

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
1	Advanced Technologies & Treatments for Diabetes (ATTD) 1, 11	Annual meeting presenting research and analysis into the latest developments in diabetes-related technology		X			X		
2	Alzheimer's Association International Conference (AAIC) 1, 11	Annual meeting presenting research on Alzheimer's disease	X	X	X	X	X	X	X
3	American Academy of Neurology (AAN) 1, 11	Annual meeting presenting neurologic research	X	X	X	X	X	X	X
4	American Association for Thoracic Surgery (AATS) 1, 11	Annual meeting presenting advances in cardiothoracic surgery		X			X		
5	American College of Neuropsychopharmacology (ACNP) 1, 11	Annual meeting presenting brain, behavior, and psychopharmacology research	X	X	X	X	X	X	X
6	American College of Rheumatology (ACR) 1, 11	Annual meeting presenting rheumatological research	X	X	X	X	X	X	X
7	American Diabetes Association (ADA) 1, 11	Annual meeting presenting diabetes research	X	X	X	X	X	X	X
8	American Epilepsy Society 1, 11	Annual meeting presenting research on epilepsy	X	X	X	X	X	X	X
9	American Heart Association (AHA) Scientific Sessions 1, 11	Annual meeting presenting heart disease research	X	X	X	X	X	X	X
10	American Psychiatric Association (APA) 1, 11	Annual meeting covering the scope of psychiatric diseases and care		X	X		X	X	X
11	American Society for Bone and Mineral Research (ASBMR) 1, 11	Annual meeting presenting research on bone and mineral metabolism	X	X	X	X	X	X	X

Table A.2. Meeting abstracts reviewed for leads (continued)

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
12	American Society of Clinical Oncology (ASCO) 1, 11	Annual meeting presenting cancer research	X	X	X	X	X	X	X
13	American Society of Clinical Oncology (ASCO) Breast Cancer Symposium 1, 11	Annual ASCO supplemental symposium focusing on breast cancer research	X	X	X	X	X	X	X
14	American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium 1, 11	Annual ASCO supplemental symposium focusing on gastrointestinal cancer research	X	X	X	X	X	X	X
15	American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium 1, 11	Annual ASCO supplemental symposium focusing on genitourinary cancer research	X	X	X	X	X	X	X
16	American Society of Hypertension (ASH) 1, 11	Annual meeting presenting hypertension research	X	X	X	X	X	X	X
17	American Society of Nephrology: Kidney Week 1, 11	Annual meeting presenting kidney disease research	X	X	X	X	X	X	X
18	American Society of Therapeutic Radiation Oncology (ASTRO) 1, 11	Annual meeting presenting research on radiation therapy for cancer	X	X	X		X	X	
19	American Thoracic Society (ATS) 1, 11	Annual meeting presenting research on pulmonary diseases, critical illnesses and sleep-related breathing disorders	X	X	X	X	X	X	X
20	American Urological Association (AUA) 1, 11	Annual meeting presenting research on urological diseases	X	X	X	X	X	X	X

Table A.2. Meeting abstracts reviewed for leads (continued)

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
21	Annual American Society of Hematology (ASH) Annual Meeting and Exposition 1, 11	Annual meeting presenting research on blood diseases	X	X	X	X	X	X	X
22	Annual Meeting of the American Academy of Optometry (AAOpt) 1, 11	Annual meeting presenting optometric research	X	X	X	X	X	X	X
23	Conference on Retroviruses and Opportunistic Infections (CROI) 1, 11	Annual meeting presenting research into infectious diseases	X	X	X	X	X	X	X
24	Digestive Disease Week (DDW) 1, 11	Annual meeting presenting digestive disease research	X	X	X	X	X	X	X
25	Embase Conference Coverage 1, 11	Newsfeed of abstracts indexed by Embase covering over 4700 biomedical conferences	X	X	X	X	X	X	X
26	EpiCongress 1, 11	Annual meeting presenting the use of epigenetic research for disease prevention, diagnosis and therapy	X		X	X			
27	European Association for the Study of Diabetes (EASD) 1, 11	Annual meeting presenting diabetes research	X	X	X	X	X	X	X
28	European Association for the Study of the Liver (EASL) 1, 11	Annual meeting presenting research on diseases that affect the liver	X	X	X	X	X	X	X
29	European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 1, 11	Annual meeting presenting research on multiple sclerosis	X	X	X	X	X	X	X
30	European League Against Rheumatism (EULAR) 1, 11	Annual meeting presenting research on rheumatic diseases	X	X	X	X	X	X	X

Table A.2. Meeting abstracts reviewed for leads (continued)

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
31	European Meeting on Hypertension and Cardiovascular Protection (ESH) 1, 11	Annual meeting presenting hypertension and cardiovascular research	X	X	X	X	X	X	X
32	European Respiratory Society (ERS) Congress 1, 11	Annual meeting presenting research on respiratory diseases	X	X	X	X	X	X	X
33	European Society for Medical Oncology (ESMO) 1, 1	Annual meeting presenting cancer research	X	X	X	X	X	X	X
34	European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 1, 11	Annual meeting presenting gastrointestinal cancer research	X	X	X	X	X	X	X
35	European Society of Cardiology (ESC) Congress 1, 11	Annual meeting presenting cardiology research	X	X	X	X	X	X	X
36	European Society of Cardiology's (ESC) Acute Cardiac Care 1, 11	Annual meeting presenting research on treatments of acute cardiac conditions	X	X	X	X	X	X	X
37	Heart Rhythm Society (HRS) 1, 11	Annual meeting presenting research on cardiac rhythm disorders	X	X	X	X	X	X	X
38	IDWeek 1, 11	Annual meeting presenting infectious disease research	X	X	X	X	X	X	X
39	International Conference and Exhibition on Rheumatology and Therapeutics 1, 11	Annual meeting presenting research on rheumatology	X	X	X	X	X	X	X
40	International Conference on Alzheimer's Drug Discovery 1, 11	Annual meeting on drugs to treat Alzheimer's disease			X				X

Table A.2. Meeting abstracts reviewed for leads (continued)

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
41	International Conference on Antiviral Research (ICAR) 1, 11	Annual meeting presenting antiviral research	X	X	X	X	X	X	X
42	International Congress of Parkinson's Disease and Movement Disorders 1, 11	Annual meeting presenting research on Parkinson's and other movement disorders	X	X	X	X	X	X	X
43	International Congress on Infectious Diseases (ICID) 1, 11	Biennial meeting presenting research on infectious diseases	X	X	X	X	X	X	X
44	International Diabetes Federation's (ISF) World Diabetes Congress 1, 11	Annual meeting presenting diabetes research	X	X	X	X	X	X	X
45	International Meeting for Autism Research (IMFAR) 1, 11	Annual meeting presenting autism research	X	X	X	X	X	X	X
46	International Society for Minimally Invasive Cardiothoracic Surgery (ISMICS) 1, 11	Annual meeting presenting research on cardiothoracic and cardiovascular surgery		X			X	X	
47	International Urogynecological Association (IUGA) 1, 11	Annual meeting presenting urogynecological research	X	X	X	X	X	X	X
48	Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) 1, 11	Annual meeting presenting research on antimicrobial agents and infectious diseases	X	X	X	X	X	X	X
49	Medicine 2.0	Annual meeting on the use of social media, mobile apps and the internet in medicine		X			X	X	
50	National Comprehensive Cancer Center (NCCN) Annual Congress: Hematologic Malignancies 1, 11	Annual meeting presenting hematologic cancer research	X	X	X	X	X	X	X

Table A.2. Meeting abstracts reviewed for leads (continued)

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
51	Neuroscience – Society for Neuroscience (SFN) Annual Meeting 1, 11	Annual meeting presenting neuroscience research	X	X	X	X	X	X	X
52	North American Cystic Fibrosis Conference 1, 11	Annual meeting presenting research on cystic fibrosis	X	X	X	X	X	X	X
53	Radiological Society of North America (RSNA) 1, 11	Annual meeting presenting research on the use of radiology in medicine		X		X	X	X	
54	San Antonio Breast Cancer Symposium (SABCS) 1, 11	Annual meeting presenting breast cancer research	X	X	X	X	X	X	X
55	SLEEP 1, 11	Annual conference on sleep medicine		X	X		X	X	X
56	Society for Cardiovascular Angiography and Interventions (SCAI) 1, 11	Annual meeting covering cardiac catheterization and angiography	X	X		X	X	X	
57	The American Association for Cancer Research (AACR) 1, 11	Annual meeting presenting cancer research	X	X	X	X	X	X	X
58	The American College of Cardiology (ACC) 1, 11	Annual meeting presenting research on cardiovascular medicine	X	X	X	X	X	X	X
59	The Endocrine Society's Annual Meeting and Exposition (ENDO) 1, 11	Annual meeting presenting research on hormones and the clinical practice of endocrinology	X	X	X	X	X	X	X
60	The European Association of Percutaneous Cardiovascular Interventions (EuroPCR) 1, 11	Annual meeting presenting cardiovascular research	X	X	X	X	X	X	X

Table A.2. Meeting abstracts reviewed for leads (continued)

	Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics/ Biotech	Devices	Drugs	In Vitro Diagnostics	Procedures/ Therapies	Process	Off-Label Uses
61	The European Atherosclerosis Society (EAS) Congress 1, 11	Annual meeting presenting atherosclerotic disease research	X	X	X	X	X	X	X
62	The Liver Meeting: American Association for the Study of Liver Diseases 1, 11	Annual meeting presenting research on diseases of the liver	X	X	X	X	X	X	X
63	The Obesity Society's Annual Scientific Meeting 1, 11	Annual meeting presenting research on obesity	X	X	X	X	X	X	X
64	Transcatheter Cardiovascular Therapeutics (TCT) 1, 11	Annual meeting presenting research on cardiovascular therapies	X	X	X	X	X	X	X
65	World Congress of Cardiology (WCC) 1, 11	Biennial meeting presenting cardiology research	X	X	X	X	X	X	X
66	World Congress on Diabetes & Metabolism 1, 11	Annual meeting presenting diabetes research	X	X	X	X	X	X	X
67	World Stroke Congress 1, 11	Biennial meeting presenting research on stroke prevention and treatment	X	X	X		X	X	X

Key to Resource Type:

1: Original research and scientific reviews;
2: News;
3: Press Releases;
4: Commentary;
5: Editorial;
6: Blogs;
7: Letters;
8: Product information;
9: Education/ CME;
10: Coverage Decisions;
11: Conference reports

Table A. 3. Databases to be searched

Resource	Biologics/ Biotechnology	Devices	Drugs	In Vitro Diagnostics	Procedures	Process
Embase	X	X	X	X	X	X
EuroScan	X	X	X	X	X	X
Healthcare News, current (Lexis-Nexis)	X	X	X	X	X	X
PRNewswire*	X	X	X	X	X	X
PsycINFO	X	X	X	X	X	X
PubMed/Medline	X	X	X	X	X	X

Table A. 4. Example of an initial Embase filter for broad exploratory search of a priority area

Set number	Concept	Search Statement
1	Stroke (part of cardiovascular priority area)	*stroke/ or (stroke or cerebrovascular accident or brain attack).ti.
2	Publication types likely to yield content for Healthcare Horizon Scanning System	conference paper/ or feasibility study/ or preliminary communication/ or trend study/
3	Keywords likely to yield content for Healthcare Horizon Scanning System	Advances.ti. or development$.ti. or emerging or feasibility or (first adj2 class) or (first adj2 man) or future or horizon or investigational or new.ti. or novel or pilot or pipeline or (proof adj2 principle) or translational or trend$
4	Combine sets	1 and (2 or 3)
5	Limit	4 and (human/ or humans/)

Table A. 5. Initial leads list by AHRQ priority area

00 Unclassified
01 Arthritis and nontraumatic joint disease Examples of subcategories: Arthritis, Gout, Spine, Neck, Ankle, Knee, Hip, Elbow, Wrist, Finger
02 Cancer Examples of subcategories: Biliary, Breast, Colon, Kidney, Liver, Lung, Ovarian, Pancreas
03 Cardiovascular disease Examples of subcategories: Aneurysms, Arrhythmias, Coronary Artery Disease, Heart Failure, Peripheral Vascular Disorders, Stroke, Varicose Veins
04 Dementia (including Alzheimer's) Examples of subcategories: Alzheimer's, Frontotemporal, Lewy body, Vascular dementia
05 Depression and other mental health disorders Examples of subcategories: Anxiety disorders, Bipolar disorder, Major Depressive Disorder, Eating Disorders, Obsessive Compulsive Disorder, Post-traumatic Stress Disorder, Schizophrenia
06 Developmental delays, attention-deficit hyperactivity disorder, and autism Examples of subcategories: Attention Deficit Disorders (ADD, ADHD), Autism Spectrum Disorders, Developmental Delays
07 Diabetes mellitus Examples of subcategories: Type 1, Type 2, Metabolic Syndrome
08 Functional limitations and disability Examples of subcategories: Degenerative Disorders (e.g., MS, ALS, Muscular Dystrophy); Endocrine Dysfunction, Congenital Metabolic Disorders, Pain, Burns, incontinence and Elimination Disorders; Sensory Conditions (e.g., Vision Disorders, Hearing disorders, Vertigo, Pain)

Table A.5. Initial Leads List by AHRQ Priority Area

09 Infectious disease including HIV-AIDS Examples of subcategories: Bacterial (TB, Meningitis), Fungal, Viral (HIV, HBV, HCV, HPV, Influenza), Hospital-acquired infections (MRSA, C.Diff)
10 Obesity
11 Peptic ulcer disease and dyspepsia Examples of subcategories: Bowel diseases (e.g., Inflammatory Bowel, Crohn's), Gastroesophageal Reflux (GERD), Motility Disorders
12 Pregnancy, including preterm birth Examples of subcategories: Premature Infants, Fetal Surgery, Contraception, Fertility & Infertility
13 Pulmonary disease, asthma Examples of subcategories: Chronic Obstructive Pulmonary Disease, Cystic Fibrosis, Emphysema
14 Substance abuse Examples of subcategories: Alcohol, Cocaine, Opioids, Tobacco
15 Cross cutting Examples of subcategories: Diagnostic imaging, general care delivery innovations

Appendix B. Horizon Scanning Structured Comment Form

[Topic Title and Unique Identifying Number] (Each form is for a specific topic)
All fields denoted with an asterisk * must be completed in order to submit this form.

EXPERT's CONTACT INFORMATION
Expert's Name *
Job Title *
Academic, Professional, and Manufacturer Affiliations *
Preferred mailing address *
Email address *
Telephone *
Fax
Best times to reach you

CONFLICTS OF INTEREST DISCLOSURE

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 this draft. *

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

Yes No

If yes, please describe the nature of your consultation below.

HORIZON SCANNING TOPIC COMMENT FORM

Please use the guidance below to rate the potential of [topic title] for each of the 7 parameters described. Please provide your rationales for each rating. These parameters are intended to serve as anchoring points for considering the overall potential impact of the intervention or program. Your rationales will provide critical perspectives.

1. **For [Horizon Scanning topic, ####], Potential Importance of the Unmet Need it Intends to Address***

Consider here only whether a gap exists in health care needs that [Horizon Scanning topic] could potentially address and how important you think that gap is. (Do not limit to the size of the population affected; other considerations include magnitude of purported benefit; whether other options exist and the benefits and harms of those options.) Provide your rationale. *****

1	2	3	4
Not important	**Small importance**	**Moderate importance**	**Very important**

Rationale: *****

2. For [Horizon Scanning topic, ####], Potential to Improve Patient Health*

Consider the scientific and/or clinical validity of the developer's claims and purported benefits for [Horizon Scanning topic]. Are the claims sound? Does the underlying theory/concept and the preliminary data reported by investigators thus far support the claim? How convinced are you about its potential to improve patient outcomes? What gaps between the theory or claims and early data concern you the most? Provide your rationale. *****

1	2	3	4
None	Small	Moderate	Large

Rationale: *

3. For [Horizon Scanning topic, ####], Potential to Affect Health Disparities*

Do you think this intervention could potentially affect health disparities? We define disparity as a climate in the health care system that creates differences in access to, use of, and quality of care such that it affects health status or patient-oriented health outcomes. In what ways, e.g., would it increase or decrease disparities and access? *

1	2	3	4
None	Small	Moderate	Large

Rationale: *

4. For [Horizon Scanning topic, ####], Potential to Disrupt the Healthcare Delivery System*

What potential do you think [Horizon Scanning topic] has to disrupt how patients are managed and how clinicians and health systems approach the condition/disease/problem? Issues to consider include: care process changes when it is implemented; length of patient stay; numbers of patients that can be treated; amount of care that needs to be delivered; amount of care that can be avoided; shift in care setting from inpatient to outpatient or to home care or one department to another; change in infrastructure needs, such as physical resources (e.g., facility expansion or contraction, impact on use of shared resources within a facility or health system, capital equipment acquisition or obsolescence, expenditures or savings), and staffing resources (e.g., increases/decreases, staffing mix required, patient throughput handled by staff). Provide your rationale. *

1	2	3	4
No disruption	Small disruption	Moderate disruption	Large disruption

Rationale: *

5. For [Horizon Scanning topic, ####], Potential for Acceptance/Adoption by Patients and Clinicians*

Consider factors that could affect willingness to use [Horizon Scanning topic], such as, but not limited to, convenience/ease of use and learning curve to use it, ease of acquisition, ease of compliance, degree of invasiveness, degree of physical and mental capacity required for use, anticipated side effects, risks, adverse events. Please also highlight any potential controversies you foresee [Horizon Scanning topic] generating. Provide your rationale.

By Clinicians*

1	2	3	4
No acceptance	Low acceptance	Moderate Acceptance	Wide Acceptance

Rationale*

By Patients*

1	2	3	4
No acceptance	**Low acceptance**	**Moderate Acceptance**	**Wide Acceptance**

Rationale:*

6. For [Horizon Scanning topic, ####], Potential Impact on Healthcare Costs*

How might [Horizon Scanning topic] affect costs of care for the intended patients and health care system? Please note how you expect costs to change and for whom (e.g., patients, payers, health care facilities). Do you anticipate that any of the potential changes in cost would generate controversy? What kind of controversy? Provide your rationale.*****

1	2	3	4
None	**Small impact**	**Moderate Impact**	**Large impact**

Rationale:*

7. For [Horizon Scanning topic, ####], Overall Potential to Fulfill the Unmet Need?*

Given your considerations about all the parameters you have responded to, what do you think is the overall potential of [Horizon Scanning topic] to fulfill the unmet need(s) it purports to address? Provide your rationale.*****

1	2	3	4
None	**Small**	**Moderate**	**Large**

Rationale:*

Additional Comments (Please limit to 1000 characters):

Note: All fields denoted with * must be completed in order to submit this form. If the form does not advance to a 'confirmation page' when the 'Submit' button is clicked, please scroll up and complete any remaining blank fields indicated by ‘response required’ text.