Ever been surprised by an authorization request for a new procedure or technology you’d never heard of? Like cardiac stents to treat multiple sclerosis? Or autologous mesenchymal stem cells for yet another orthopedic indication? Or fecal transplantation for Crohn’s disease? Ever been surprised by a request for a costly new targeted drug that got FDA approval months sooner than indicated in the formal PDUFA schedule for FDA decisions?

No doubt, you would like to minimize surprises like these. Yet how can your organization keep up with developments of hundreds of new and emerging drugs, devices, and procedures? Doing so requires expansive resources and a large team working daily to pore over hundreds of information feeds — trade journals, clinical literature, proprietary databases, company SEC filings, medical conference abstracts and posters, and other resources — resources that most managed care medical policy and authorization teams don’t have. Read on to learn about free new publicly available resources that can help your organization keep up. Enter health care horizon scanning.

Knowing what’s coming down the pike this year or next is critical for planning. Health care horizon scanning, an early warning system, is intended to do just that. Horizon scanning is a process to identify and track emerging health care technologies and services in clinical stages of research and development or very early adoption. Its purpose is to identify, filter, and prioritize new and emerging health technologies and services for myriad decision makers. Health plans, health systems, and health policymakers can use the information outputs from horizon scanning to understand possible impacts of new technologies and services on health outcomes, the health care system, care delivery, utilization, and costs. The information is key for strategic planning. The strategic planning may pertain to any of the following:

- Public and private payers’ need to know which topics to slate for future medical policy making, including new interventions that may be disruptive or signal marked changes in patient care delivery
- Public and private research entities’ need to set priorities for comparative-effectiveness research to compare new technologies to existing technologies
- Public and private hospitals and health sys-

**Value of this program**

Payers using this kind of information typically use it to plan agendas for new and updated medical policies so that their policies remain as timely as possible. For example, they can use the reports to take note of when a new device or drug is going to be approved and coincide review of their medical policies with that anticipated approval. If they expect a lag between an approval and their development of a medical policy on the topic, they can at least alert staff members who are performing case review about the new approval. They can also use the information on off-label uses to determine whether they should conduct internal or external literature reviews to underpin a new or expanded medical coverage policy.

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tems’ need to create well-informed technology (drug, device, procedure) adoption plans and clinical service line plans
- Companies’ planning needs for their research and development programs to address unmet health care needs
- Investors’ need to research developing technologies and services in which to invest

Is health care horizon scanning new?

No, but in the United States, at the national level, comprehensive health care horizon scanning is a relatively recent endeavor. In December 2010, the U.S. Agency for Healthcare Research and Quality (AHRQ) created an infrastructure to support these activities, initially to aid in setting priorities for research agendas. However, many other public and private entities (e.g., governments, payers, health systems, venture capitalists, technology developers) in other countries have engaged in formal and informal health care horizon scanning activities for years or even decades for one or more of the purposes described above.

For example, in Europe, an entity known as EuroScan has 20 government-funded members performing horizon scanning in their respective countries. Other examples include three U.S. agencies — the Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) — that have conducted limited forms of horizon scanning at various times over the last two decades.

These horizon scanning initiatives have differed markedly according to their intended purpose. For example, CMS utilized information provided by ECRI Institute to identify important new interventions that could affect the over-65 population. FDA’s Centers for Devices and Radiological Health has convened expert panels of independent private (e.g., including ECRI Institute) and public sector forecasting experts periodically to gauge expert opinion about the horizon of new medical devices and their potential impact. AHRQ’s approach is arguably the broadest of any public sector initiative. This was evidenced during an international expert panel meeting convened by ECRI Institute in June 2011 on behalf of the AHRQ horizon scanning initiative. More than 30 experts from public and private horizon scanning efforts and users of horizon scanning outputs participated to provide feedback to AHRQ about its initiative, as well as to describe their own initiatives. The meeting clarified differences in approaches, clinical areas covered, types of technologies covered, and the time frame of scanning. Each of these entities develops its own criteria for scanning, including different time frames for the horizon (e.g., one year, two years, five years) and subject areas to be covered.

AHRQ adopted a general set of definitions of “new” and “emerging.” These definitions had
been previously developed by the International Information Network on New and Emerging Health Technologies (EuroScan), the international collaboration of agencies that share information on new and emerging drugs, devices, procedures, programs, and health care settings. The definitions are:

- **New technologies**: technology in the adoption phase that has been available for clinical use for a short period
- **Emerging technologies**: technology not yet available for use in the health care system (e.g., pharmaceutical products in Phase II and III trials)
- **Established technologies with new indications**
- **Technologies that are part of a group of developing technologies that may as a whole have an impact**

AHRQ also defined 14 clinical priority areas of interest across scores of disease states for which it would scan. In addition to its broader coverage than most other horizon scanning entities, another way the AHRQ system differs from most other horizon scanning programs is its publication of the explicit processes used in its system to provide transparency to users of the information. The Protocol and Operations Manual, first published in 2011, has undergone revision as the system has matured and AHRQ refined some of its areas of interest, including the horizon time frame (from seven+ years, to zero to three years from perceived clinical availability). This manual articulates the processes for the three main activities that constitute horizon scanning activity:

- Identifying technologies/topics of interest
- Monitoring/tracking their development
- Assessing their potential impact

Generally, the AHRQ system places high importance on technologies, interventions, and processes of care that may have potential to address significant unmet health care needs. Unmet need is defined broadly and not limited by the size of the patient population addressed by the intervention.

The team performing the work consists of more than 20 full-time staff members, including master’s level medical librarians and analysts with diverse backgrounds (clinical or basic science research, public health, clinical care) who review possible leads for new topics from hundreds of resources, assess whether they meet the inclusion criteria specified in the protocol, and then discuss and decide whether to enter them into the scanning system to monitor.

Topics that are furthest along in development are selected for writing detailed profiles. These profiles are then sent out to experts from a variety of clinical, research, and health systems backgrounds who provide comment and opinions on the potential impacts of the technology or intervention.

The horizon scanning team uses the expert comments to determine which topics bubble to the top as having the most and least potential for high impact. This process helps to determine which topics to keep monitoring in the system and which to archive. Additional criteria for archiving topics are provided in the protocol.

AHRQ routinely publishes two main outputs: Status Update Reports and Potential High Impact Reports.

**Status Update Reports** include a table for each priority area that lists topics being tracked in that area. Each topic listed includes a brief description of the intended patient population, unmet need, intervention/product description, developer, development status, potential comparators, and potential health impacts. The report also includes a section on topics that have been archived from the scanning system and why. The Status Update is published five times a year.

**Potential High Impact Reports** are published twice a year for each priority area. They present an executive summary of an entire priority area, plus detailed profiles of the topics that emerged as having potential for high impact.

**Evidence development**

While these reports do not analyze the clinical evidence, they do present the current state of evidence development. Comments are sought from five to nine experts for each topic; topics are updated as important new information emerges. The content in the Potential High Impact Reports changes as topics move through the system and as tracking concludes or opinions change.

For managed care, this report, published in early July and January of each year on AHRQ’s Effective Health Care Web site, can offer early signals of
important new technologies, procedures, and programs.

Since December 2010, more than 16,000 leads have been uploaded into the system and reviewed by analysts, from which about 1,900 topics have been initially identified and moved through the system. The just-published, latest Status Update report contains 480 identified interventions, 435 of which have been monitored for two months to three years, and 45 new topics added since the prior Status Update report in July. The team archived 25 topics from monitoring over the past two months (since the last update report). Three reasons account for the majority of archived topics:

- Expert commenters saw no high-impact potential at this time for the parameters of interest to AHRQ.
- Companies halted development for lack of funding or trials did not meet endpoint.
- Topics that had been tracked met criteria for archiving because they have diffused since tracking started, have shown no movement at all in over two years of tracking, or are two years past approval by the U.S. Food and Drug Administration.

The latest report shows that four priority areas constitute 70% of the interventions (including programs) being tracked. Cancer-related interventions have accounted for more than 30% of topics in the system since its inception.

Three other priority areas contain the next largest proportions of topics in the system and have since inception: functional limitations and disability (16%), cardiovascular diseases (10%), and infectious diseases (9%).

Areas in which a relative paucity of interventions are in development, given the significant unmet needs and burden of illness in these areas, are dementia/Alzheimer’s disease, depression and other mental illnesses, developmental delays (autism spectrum disorder, ADHD), pregnancy and childbirth, and substance abuse, which account for 4% or fewer (in each priority area) of the total topics tracked. One reason appears to be lack of understanding of the basic biology and pathogenesis regarding certain disease states.

In terms of overall categories of interventions, about 70% of topics pertain to a pharmacy and biotechnology (e.g., drug, vaccine, biologic) — and this includes drugs in development as well as novel off-label uses. About 18% of topics pertain to external or internal devices and prostheses. About 4% are technologies intended to screen, diagnose, identify risk, identify blood markers or gene mutations, or monitor a disease state (e.g., test kits, imaging modalities). About 3% of topics are surgeries and procedures.

### Articles and websites cited

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