About ECRI Institute

ECRI Institute (www.ecri.org), a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research to healthcare to discover which medical procedures, devices, drugs, and processes are best to enable improved patient care. As pioneers in this science for nearly 50 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. Strict conflict-of-interest guidelines ensure objectivity. ECRI Institute is designated an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality (AHRQ). ECRI Institute was a contractor to AHRQ for the National Healthcare Horizon Scanning System. ECRI Institute PSO is listed as a federally certified Patient Safety Organization by the U.S. Department of Health and Human Services.

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Introduction

What does 2017 herald for healthcare? The pressure to focus on creating high value that balances costs, quality, and outcomes continues as health system leaders wonder about what changes the new U.S. administration will bring to these ongoing initiatives and how they will have to adapt or adhere. Perhaps faster approvals of drugs and devices, but the battle about high drug costs will continue.

ECRI Institute presents its 2017 Top 10 Hospital C-suite Watch List. It includes both technologies and critical technology use issues we think should be on your radar.

Opioid addiction and opioid prescribing protocols have been in the headlines, with heightened attention on the medical and mental health aspects of addiction, the brain disorders that addiction reflects, and the dire need for more and quicker access to quality care. The 21st Century Cures Act includes funding to address some of these issues. How will your health system participate in efforts to stem the tide of addiction and its terrible toll on our communities?

Other familiar themes remain. Healthcare-acquired infections persist as a problem—though strides have been made—and new technologies to help address it continue to enter the market. We include another familiar technology for your consideration—compact ultraviolet-C LEDs. Their design and the light spectrum they emit allow more flexibility and ease of use than previous disinfectant lighting solutions.

Technology transfer among clinical service lines is evident with emerging applications for indocyanine green imaging for endoscopic procedures in oncology, such as lymph node examination during surgery.

We again look at some new technologies that will be or are being hyped that may be novel and nice to have, but are they really necessary? Do they meet your strategic goals? Decide for yourself as you read about Pepper, the first emotional interactive robot, and the new da Vinci Xi Integrated Table Motion that, going forward, will be included with the high-end da Vinci Xi robotic system.

As in years past, ECRI Institute’s experts are ready to help guide you through these tough decisions. We also welcome you to post feedback and any questions on our associated LinkedIn group, Emerging Healthcare Technologies in Patient Care. Together, we will be well prepared to face the tsunami of healthcare technology decisions!

About This Free Resource

The 2017 Top 10 Hospital C-suite Watch List is produced as an independent collaborative research project by ECRI Institute’s Health Technology Assessment Information Service and ECRIgene staff of doctoral-level researchers, medical librarians, and clinical analysts and the Applied Solutions Group, a team of experienced health technology specialists who provide on-site and customized consulting to hospitals, health systems, and ministries of health on a broad range of technology and patient-safety-related projects.
Precision medicine and the federal Cancer Moonshot initiative are driving development of liquid biopsies. Liquid biopsy is a generic term that refers to genetic testing that uses a patient’s sample of blood, plasma, serum, or urine, rather than biopsied tissue, to identify genetic variants and mutations intended to inform patient management. Liquid biopsy samples for testing are faster to obtain and less risky than needle or surgical biopsy of tissue from organs, such as the lung, liver, and heart, or from a developing fetus. With diseases like cancer that generate new genetic mutations over the course of treatment and disease progression, multiple biopsies over a long period may be needed to inform decisions about targeted therapies. Sounds great, but is it ready for prime time?

More than 40 companies and laboratories are developing and marketing these types of tests for the U.S. and international markets using various new technologies and methods. Most liquid biopsies in the United States are laboratory-developed tests from labs overseen by Medicare, but some companies are seeking FDA approval. FDA approved the first liquid biopsy for cancer in June 2016; more are anticipated. Taking note of the rapid pace of development, associated complex issues, and diffusion into clinical care, FDA cosponsored a town hall meeting with the American Association for Cancer Research in July 2016 to look at oncologic liquid biopsies. The issues that stakeholders raised clearly indicated that the science underpinning these tests has far to go to produce reliable, reproducible results that will lead to solid clinical utility. One clinical researcher from Massachusetts General Hospital at the town hall noted the tests are “multiplying like rabbits” and advised caution “about letting these drive treatment decisions.”

Related Reports:

WHAT TO DO

- Confirm whether a sound genetic test clinical utilization management process is in place for all clinicians ordering tests in your health system.
- If no effective utilization management is in place, ask your department heads in key clinical service lines that order genetic tests (e.g., clinical laboratory, oncology, cardiovascular, neurology, pediatrics, obstetrics/gynecology) to collaborate and develop a process that ensures appropriate liquid biopsy test ordering.
- Perform a value-analysis assessment to determine what new tests your health system offers and whether testing is performed internally or by an outside lab.
- Ensure that independent assessment of evidence of clinical validity and clinical utility is carried out for the tests being ordered.
- Ensure your health system has appropriate expertise to explain test results and their implications to patients.

The science underpinning these tests has far to go to produce reliable, reproducible results that will lead to solid clinical utility.
Researchers are seeking solutions to different parts of the opioid addiction problem. New genetic tests attempt to identify those at greatest risk for opioid addiction so that opioids won’t be prescribed in the first place or so the opioid that will be most effective and least harmful can be prescribed. At least two companies, Proove Biosciences and Canterbury Healthcare’s Innovative Medical Testing, now offer laboratory-developed tests for combinations of genetic variants thought to be associated with higher risk of addiction or poor response to opioids for pain relief. Addiction experts point out that because dozens of genetic variants are involved in vulnerability to addiction, testing for even 20 variants is not considered sufficient. The difficulty lies in the fact that genetics are thought to account for about half a person’s risk, and some gene variants may play a role that has not been identified yet. Thus, available tests are not thought to be ready for wide use, and many believe the science has a long way to go before a genetic test with real clinical utility is available.

Researchers at the University of Massachusetts are developing biosensors worn like wristwatches to determine relapse episodes in those addicted to opioids who are under treatment. The sensors detect certain physiologic characteristics indicative of opioid use, such as changes in skin temperature, electrodermal activity, and movement. Medication formulations are also in late-phase development that may aid addiction treatment. Examples include RBP-6000 and CAM2038, which provide slow-release monthly injections of buprenorphine (rather than daily treatment) to enhance adherence to substance-abuse treatment regimens. RBP-6000 developer, Indivior, anticipates FDA approval in late 2017; CAM2038 developers, Braeburn Pharmaceuticals and Camurus, expect to submit a marketing application to FDA in 2017.
WHAT TO DO

Opioid addiction is pervasive in all socioeconomic classes; all racial and ethnic populations; all urban, suburban, and rural areas; and among more- and less-educated populations.

▶ Ensure you have a process in place so that clinicians don’t order genetic tests for opioid addiction risk that have little evidence to support their clinical utility.

▶ Ensure evidence-based guidelines and clinical-decision-support tools about appropriate opioid prescribing and prescribing of naloxone tools to manage possible overdoses have been well-implemented in your health system.

▶ Participate in or lead initiatives with public services, including emergency response teams and the courts, for coordinated responses to overdoses, illicit use, and addiction treatment.

▶ Develop treatment protocols that integrate the medical and mental health teams treating affected patients.

▶ Offer education sessions to the communities your health system serves about the neurology and science of addiction, where to find help, and what effective treatment programs look like.

The difficulty lies in the fact that genetics are thought to account for about half a person’s risk, and some gene variants may play a role that has not been identified yet.
Any type of major surgery, especially abdominal surgery, can severely stress the body and increase the risk of complications and mortality. Patients with suboptimal presurgical health have an even higher risk of surgical complications and poor outcomes, resulting in longer hospitalizations and higher mortality risk. Some major research universities have piloted programs to improve outcomes and cut costs. The University of Michigan conducted a successful pilot, called the Michigan Surgical and Health Optimization Program (MSHOP). The initiative is poised to diffuse nationwide to reduce complication risks and costs in major abdominal surgery. The program combines a web-based advanced risk-assessment algorithm and interactive patient coaching, emphasizing diet monitoring, exercise, ways to improve lung function, and stress reduction before surgery.

Published data from MSHOP show the pilot reduced average hospital stays by two days (from six to four days) and average hospital costs by about $2,300 per major abdominal surgery patient. The pilot’s success led to expansion in late 2016 to 40 other Michigan hospitals through a $6.4 million grant from the U.S. Centers for Medicare & Medicaid Services to determine whether the results can be replicated across the state. Results are expected by 2018. MSHOP developers also worked with Prenovo, a startup company formed to offer the approach to hospitals outside Michigan. Prenovo claims to deliver scientifically validated solutions that reduce costs by 25% and improve patient outcomes. Its web-based solution, Prenovo Prepare™, is intended to engage patients preparing for surgery and recovery beyond the clinical setting. The company says on its website that 80% of patients enrolled in the program stay engaged with it. According to the company, the platform is intended to enhance “the patient-provider relationship with evidence-based teaching tools for shared decision-making.”

Duke University has also implemented its own presurgery preparation program, POET (Perioperative Enhancement Team), to improve outcomes and lower costs. POET, described in a recent Wall Street Journal article, targets elective major surgery patients with diabetes, anemia, malnourishment, complex pain syndromes, and poor exercise tolerance.

Related Report:

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WHAT TO DO

Surgery department heads should look at these new protocols and assess whether they can be adapted to the patient populations treated in your health system.

- Determine your typical case mix in each surgical specialty.
- Identify the patient populations you treat that are at greatest risk of poor postsurgical outcomes.
- Specify the resources needed to implement an improved presurgery preparation plan for each surgical specialty (general surgery, cardiothoracic surgery, neurosurgery, gastrointestinal surgery, orthopedic surgery).
- Choose one surgical specialty to pilot the protocol, and collect detailed cost and outcomes data.
- Review results, and determine whether the pilot protocol implemented is scalable in your health system.
Right-sizing Your Hospital: Is It Time to Refresh Your Purchasing and Implementation Processes?

When it comes to making the right decision about which new infrastructure to build or capital equipment to buy, many healthcare leaders fear making the wrong decision, or making choices that don’t meet operational, financial, and strategic goals years down the road. One multimillion-dollar mistake can cost a career, not to mention the viability of the health system.

A recent ECRI Institute Special Report, Planning the Hospital of the Future, noted that little information exists to accurately predict inpatient cases 20 years into the future in major service lines. But decisions made today will affect new hospital plans, space redesigns, capital investments, and staffing decisions at least that far into the future. For example, the report notes that coronary artery disease and heart failure prevalence will increase by 2030 (46% for heart failure). However, that does not necessarily translate to increased inpatient admissions even for these serious chronic conditions. Some technologies profiled in the 2016 Top 10 Hospital C-suite Watch List (e.g., PCSK9 inhibitors and telehealth technologies like CardioMEMS™) could enable patients with coronary artery disease or heart failure to be managed well outside the acute care setting. While some chronic diseases may see reductions in hospitalization because of new home care monitoring technologies and improved therapeutics, admissions associated with sepsis, osteoarthritis, and renal failure could significantly increase as the population ages over the next two decades.

How can healthcare leaders set the right course with imperfect information? While hospital leaders can’t know all future conditions, they should build processes to guide long-term planning decisions. Every health system has a capital budget process already, but how effective is that process? Is it time to revisit and refresh? Does your technology assessment committee get bogged down in minutiae rather than try to understand the current and future overall landscape of a clinical service line to make sounder decisions for the long term? Do clinical service line leaders view your process as a blocking exercise and believe that radiology is the only department that receives major funding or approval? Inclusive capital budgeting and technology assessment processes are critical for gaining buy-in from staff, patients, and your board of trustees.

Related Report:

While hospital leaders can’t know all future conditions, they should build processes to guide long-term planning decisions.

WHAT TO DO

Charge someone in each clinical service line with conducting the appropriate horizon scanning about important new technology developments and care processes, paying attention especially to potentially disruptive innovations that could occur in the next decade.

- Ensure these horizon scanners present a clear picture to clinical service line planners.
- Review existing capital budgeting and technology assessment committee goals and practices to ensure transparency, accountability, and buy-in.
- Determine whether you need new energy/perspectives represented on your committees.
- Make sure committee members are engaged and actively participate; committees often become stale.
- Conduct look-backs to ensure that decisions result in achieved goals; amend practices if not.

Illustration courtesy of Shutterstock.
Healthcare-acquired infections continue to cause morbidity and deaths, adding billions to healthcare costs. Two of our previous Top 10 lists (2015 | 2016) featured devices using ultraviolet (UV) light (disinfection robots) and visible LED ceiling fixtures (Indigo-Clean™ lights). Challenges of using UV robots include their bulk, significant time required to disinfect a room, and lack of continuous disinfection protection. LED fixtures installed in the ceiling can provide continuous disinfection over areas they cover, but may provide undesirable lighting effects that patients don’t like for long periods in their rooms. And neither of these technologies is used to disinfect mobile technologies, such as phones and stethoscopes, that clinicians carry from patient to patient.

A new LED disinfection option, which comes in strips, has recently been introduced by the LED industry. Advances in LEDs that emit light in the “deep UV” range, also called UV-C, which is a range below 290 nm (wavelengths between 250 and 280 nm are known to have the greatest germicidal effect). These advances include innovation in LED materials to emit light in the germicidal range, reduced power consumption, stabilized and increased output power, and the longer life of the lights. These new LED lights are flexible enough that they can be arranged to disinfect out-of-the-way surfaces (e.g., under beds, under countertops). Manufacturers are developing LED lights for healthcare applications; devices like sanitizing wands and UV disinfecting cabinets for smartphones and tablets are under way.

In several studies using these UV-C LEDs, colony forming units for common pathogenic microbes were significantly reduced when treated with UV-C LEDs using at least 30 seconds of exposure time and placed 2 inches or closer to the light source. Other distinct advantages include availability in very compact sizes that offer enormous flexibility to create point-of-use disinfection devices with a smaller footprint. Also, arrays of LEDs can be mounted in any geometry to eliminate disinfection “cold spots” found in patient rooms. One of the biggest advantages is that LEDs have no warm-up time and can cycle on and off instantaneously, which provides faster disinfection. With a lower initial purchase cost and reduced maintenance compared to UV robots and UV lamps, LED disinfection systems may be more financially viable. Important to note is that none of these options replaces terminal cleaning of patient rooms—these are intended for use in conjunction with terminal cleaning protocols.

Related Reports:


**WHAT TO DO**

- Have your Infection Prevention and Value Analysis teams work together to trial some of these new offerings in small areas (e.g., under countertops) and for point-of-use disinfection of devices like cell phones and stethoscopes in disinfection boxes and workstation disinfection wands to combat pathogenic microbes with these well-known carrier locations.

- Consider using overhead arrays of UV-C LEDs instead of mercury vapor lamps in room-air-disinfection systems for an environmentally safer solution.

- Look for public and other areas in your facilities where low-cost UV-C LED disinfection devices could be used, such as overhead ambient air disinfection in waiting rooms or in laboratory workstations where point-of-use devices could be used.

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*In several studies using UV-C LEDs, colony-forming units for common pathogenic microbes were significantly reduced when treated with UV-C LEDs using at least 30 seconds of exposure time and placed 2 inches or closer to the light source.*
Pepper, touted as the world’s first humanoid robot, interprets human body language to read emotions and respond accordingly. In June 2016, two Belgian hospitals introduced Pepper in their reception areas to support reception staff by meeting and greeting visitors, answer questions in any of 19 languages, collect information, and escort people as needed to physician offices or other areas. The robot body is about 4 feet tall, has a head filled with sensors and eyes with colored lights, a tablet integrated into the chest area, and arms that can move in 17 directions. The light color of the eyes changes according to the perceived mood of the surrounding individual(s). Pepper has embedded 3-D and two H-D cameras to help it process images with shape-recognition software to identify objects, faces, and emotional states.

Featured at TechWorld in New York in October 2016, Pepper has just arrived on U.S. shores. The developer, Aldebaran Robotics, a SoftBank Robotics company, said it designed the robot to perceive human emotions and respond appropriately to the individual with whom it interacts, adapting and evolving as it acquires information about the person or people. It can recognize faces, speak, hear someone speaking, move autonomously, and engage in conversation. Pepper can be programmed to suit the environment in which it is placed. Pepper’s base price is about $2,000, but the programming required for the Belgian hospitals’ applications raised the cost to about $34,000. Software developers can build use-specific applications using Python, C++, and Android SDK, according to SoftBank Robotics. Learn more from Pepper robot FAQ.
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**WHAT TO DO**

The public will start seeing Pepper’s use in real-world settings before too long, such as in banks and retail outlets. Could Pepper be a novel tool to manage human traffic in public reception or other spaces in your health system? The initial acquisition cost is relatively low for capital equipment, but the programming can raise the cost. Things to think about:

- Involve your hospitality, IT, and department heads to discuss visitor and patient assistance/issues that Pepper might be able to address and the pros and cons you envision of using a Pepper robot.

- Solicit ideas for where a Pepper robot might best be used in your health system (such as in the reception area, patient waiting areas, pediatric areas, and physician offices).

- Consider whether Pepper’s functionality would give you a competitive edge and improve patient satisfaction.

- Consider whether you need to offer information in different languages to communicate more effectively with some visitors or patients.

Photo courtesy of Getty Images.
Robotic Surgery: Could a Pricey Patient-repositioning Table Improve Workflow and Outcomes?

An operational challenge of da Vinci robotically assisted laparoscopic surgery (RALS) is the potential for longer operative times compared with traditional methods. Longer operations can tie up crucial operating room (OR) time and result in lost revenue. It can also lead to increased patient safety concerns, like increased intraocular pressure and prolonged discomfort. One workflow disruption during RALS occurs when the surgical team needs to undock and redock the patient from the robotic arms during a procedure to change the patient’s position. The surgical team has to extract the robotic arms from the patient, undock the robot from the surgical table, reposition the patient, redock the robot, and reinsert the robotic arms. The latest robot from Intuitive Surgical, the da Vinci Xi®, is designed to accommodate particularly complex surgeries, with four robotic arms that attach to an overhead boom, allowing repositioning of robotic arms without the need to undock the robot. However, the robotic arms must still be extracted from the patient to reposition the patient during a complex surgery if a standard surgical table is used.

To solve that problem, Intuitive partnered with Hill Rom/Trumpf Medical to design a new type of OR table integrated with the da Vinci Xi, the TruSystem® 7000dV. It entered the market in the first quarter of 2016. The table and da Vinci Xi system are linked by software that enables communication between the devices so that, as the patient table moves, the robotic arms automatically reposition while remaining in the patient’s body. One type of RALS procedure in which this may be a benefit is robotic-assisted colorectal surgery, a complex procedure that requires frequent patient repositioning. However, the great majority of procedures performed (hysterectomy and prostatectomy) require no such repositioning.

Under the partnership, Hill Rom/Trumpf Medical sells the TruSystem 7000dV OR table and Intuitive Surgical sells the integration software, Integrated Table Motion. The table lists for about $120,000, which is significantly costlier than nonintegrated OR tables, but quoted prices collected by ECRI Institute reflect discounts of about 30% in many cases. Intuitive Surgical indicates that, going forward, the Integrated Table Motion will be included in the Xi package; however, those who purchased an Xi before the advent of the Integrated Table Motion may be considering whether to purchase the new table. This new integrated table has no clinical studies showing that the ability to more quickly reposition patients improves patient safety or patient outcomes or significantly reduces OR time in complex surgical cases.

Related Report:

This new integrated table has no clinical studies showing that the ability to more quickly reposition patients improves patient safety or patient outcomes or significantly reduces OR time in complex surgical cases.

**WHAT TO DO**

- If considering new da Vinci systems, consider the types and numbers of RALS the system will be used for; you may find that less-complex, less-costly models that do not have Integrated Table Motion will fit your needs.
- If you already own a da Vinci Xi system, but don’t have the TruSystem 7000dV table, determine how many RALS procedures currently require repositioning and the benefits that Integrated Table Motion would provide.
- Establish clear communication protocols with both Trumpf and Intuitive to promptly address any problems that arise with these technologies.
Peering at images and cutting tissue through an endoscope can be challenging. Now, endoscopic surgery is taking advantage of fluorescence imaging techniques that ophthalmologists have long used to image retinal blood vessels and that cardiologists have long used during angiography to view deeper-lying blood vessels. Indocyanine green (ICG) imaging is a method that has recently proven to be an asset in endoscopy, and it may drive your replacement planning.

During endoscopy, ICG aids in visualizing malignant tissue that is undetectable under conventional white light. ICG allows the physician to easily distinguish malignant tumors from healthy tissue and surgically dissect the malignancy. Because ICG is a near-infrared imaging technique, physicians have the ability to evaluate the perfusion in organs and tissues, as well as visualize very small parts of the human body such as the bile duct.

ICG fluorescence endoscopic procedures are now being used during sentinel lymph node (SLN) mapping. Before ICG, gamma ray–emitting radiotracers and blue dye were considered the standard of care. This older method had some challenges: it required nuclear medicine physician involvement, and SLN localization using a handheld gamma probe was difficult. With the introduction of ICG, procedure time has been reduced and SLN visualization has improved. For example, a recent study of 548 patients with breast cancer completed before the introduction of ICG fluorescence imaging found that surgeons were able to detect SLN involvement in about 74% of patients. Use of ICG improved the percentage of SLN involvement identified to 99%.

ICG fluorescence has shown a benefit in detecting gastrointestinal (GI) cancer. One of the most important prognostic factors for GI cancer survival is determining the lymph node involvement, and the current clinical standard is prophylactic lymphadenectomy. Using ICG, draining the tumor is more easily visualized, and identification rates have increased to about 95%. In addition to ICG fluorescence, other recent developments in endoscopy include 3-D visualization and 4K video. 3-D endoscopy allows visualization of angles that were previously not viewable, but users have reported a steep learning curve. 4K UHD (ultra-high definition) video allows the operator to view structures at resolutions up to four-times that of conventional endoscopy. But 3-D and 4K video endoscopic systems can cost 40% to 50% more than conventional systems, so we recommend you budget accordingly if you are interested in this new technology.

Related Reports:

Using ICG, draining the tumor is more easily visualized, and identification rates have increased to about 95%.

**WHAT TO DO**

- Determine the number of procedures your health system is currently performing that could benefit from ICG fluorescence technology.
- Determine whether your endoscopy systems can be upgraded to use ICG, 3-D, and 4K techniques or whether they have to be replaced, if clinical demand warrants it.
Crohn’s Disease: Will Immunotherapy and Stem Cell Therapy Rescue Patients with Moderate-to-severe Symptoms?

About 600,000 individuals in the United States have Crohn’s disease, and many do not obtain satisfactory relief from available therapies and develop complications. Treatment-refractory Crohn’s affects more than 100,000 patients per year in the United States and Europe. Limited treatment options are available to mitigate severe Crohn’s symptoms, causing more than 20% of patients to turn to alternative therapies, such as melatonin, fish oil, and herbal medications. Novel treatments are in development that could make a difference, although their approval is likely one or two years away.

Ovasave® (TxCell SA) is an investigational, personalized T-cell immunotherapy that uses antigen-specific regulatory T cells, generated by in vitro exposure to ovalbumin, for treating patients with refractory Crohn’s. FDA granted Ovasave fast-track designation on July 27, 2015. In a phase I/IIa, open-label trial, researchers assessed the tolerability and efficacy of escalating multiple doses of Ovasave in patients with active, moderate-to-severe refractory Crohn’s. Patients in the “best dose” group had a 75% response rate and a 25% remission rate by week eight of treatment.

Two companies are developing mesenchymal stem cell treatments for Crohn’s. Kang Stem Biotech is taking cells from umbilical cord blood to develop Furestem-CD® for treating patients with active moderate-to-severe Crohn’s. Mesoblast Ltd. is taking adult mesenchymal stem cells cultured outside the body to make Prochymal® for treating Crohn’s refractory to steroids and immune suppressants. Both therapies are administered as intravenous infusions. In an early-phase study, all patients had reduced symptoms by day 28, and investigators reported a statistically significant reduction in the mean Crohn’s Disease Activity Index (CDAI) score of 105 points by day 28. The improvement was rapid, with an average CDAI reduction of 62 points by day 7.

Complex perianal fistulas affect up to one-third of adults with Crohn’s. This can be life-threatening and very hard to treat. TiGenix is developing Cx601 using extracted allogeneic stem cells from healthy donors. The cells purportedly modulate inflammation and promote healing by shifting helper T cell (Th) responses, from Th1 to Th2, to restore long-term homeostasis. Published data in July 2016 from a phase III, double-blind, randomized controlled trial indicated that by 24 weeks after treatment, more patients given Cx601 had remission (50%) than patients given placebo (34%). Adverse events were reported in 17% of the Cx601 group and 29% of the placebo group. Another phase III trial is expected to start in 2017, and the company is applying to FDA for fast-track status.

Related Reports:
Published data in July 2016 from a phase III, double-blind, randomized controlled trial indicated that by 24 weeks after treatment, more patients given Cx601 had remission (50%) than patients given placebo (34%).

**WHAT TO DO**

Although these treatments are on the horizon, with fast-track status and anticipated changes in the regulatory environment to speed up approval and access to new therapies, you need to prepare for new treatments that may be coming so you can answer patient questions.

- If your health system routinely sees and treats patients with Crohn’s, ensure that someone in the clinical service line and P&T committee is monitoring developments of these technologies.
- Ensure the clinicians who treat Crohn’s are aware of up-and-coming potential treatments so they can prepare and discuss with patients.
- Consider sponsoring a patient and family information session about what’s on the horizon for new treatments for Crohn’s.
Vaccines for type 1 diabetes mellitus (T1DM) encompass two approaches: therapeutic vaccines to slow or halt the autoimmune attack on insulin-producing islet cells in patients who retain some residual islet function, and preventive vaccines to induce immune tolerance of islet cells in children at increased genetic risk of developing T1DM. Ten diabetes vaccine approaches are in phase I and II trials in the United States and other countries, despite failure of two peptide-based diabetes vaccines that were in phase III trials (i.e., DiaPep277®, Diamyd®). By targeting diabetes-related immune cells, effective diabetes vaccines are expected to be safer for preventing autoimmune destruction of islet cells than broad-spectrum immunosuppressant drugs (e.g., cyclosporine A, azathioprine) that can increase risk of developing infection and some cancers.

For therapeutic vaccines for patients in whom T1DM has been diagnosed, most approaches are intended for patients younger than age 18 years who have a recent T1DM diagnosis (typically fewer than 3 to 4 months) and presumably some residual beta cell function. However, a few clinical trials are also enrolling older patients, including those through age 65 years. For preventive vaccines (i.e., for patients with a family history and high risk of developing T1DM), clinical trials of oral or intranasal insulin to induce immune tolerance to insulin are enrolling patients from age 6 months through 45 years. FDA has granted orphan drug designation to many of the vaccines in development. At least six early-phase trials have been completed, and several more ongoing trials for various vaccines are expected to complete in 2017 and 2018. If any vaccines are approved, they are expected to be very costly; however, if they prevent, slow progression of, or halt T1DM they could offset a lifetime of costly treatment and complications.

Related Report:

WHAT TO DO

Vaccines to prevent or treat T1DM remain on the horizon, and time will tell whether they sufficiently meet safety and efficacy endpoints to progress through FDA successfully.

- Ensure that someone in your metabolic and diabetes service lines monitors vaccine developments so the health system is prepared to make decisions about whether to offer them when they become available.

If any vaccines are approved, they are expected to be very costly; however, if they prevent, slow progression of, or halt T1DM they could offset a lifetime of costly treatment and complications.
There’s More than Meets the Eye

The 2017 Top 10 Hospital C-suite Watch List is just a snapshot of how we can help you keep up with the latest health technology developments in a rapidly changing industry.

Our Health Technology Assessment Information Service (www.ecri.org/htais) gives you direct access to unbiased evidence-based tools, resources, and consultations from our on-site multidisciplinary staff and the ability to commission custom rapid reviews on the latest brand-name drugs, health devices, processes, and procedures.

ECRIsiene (www.ecri.org/ecrigene), our genetic test service, helps you make timely decisions on the most clinically relevant, complex, and controversial genetic tests using unbiased, evidence-based information. The service includes an interactive database, evidence reports, and evidence consultations.

Our experienced team of health technology specialists, the Applied Solutions Group (www.ecri.org/appliedsolutions), offers custom consultations on technology decision making, medical equipment planning, and patient safety.

With our independent, unbiased guidance, you’ll know where to focus your efforts so you can make informed decisions that result in the best possible patient care while controlling your bottom line.

We’re here to help.

Contact us today at (610) 825-6000, ext. 5891, or clientservices@ecri.org.