2018

TOP 10
HOSPITAL C-SUITE

WATCH LIST

ECRI Institute
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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. ECRI Institute convened and operates the Partnership for Health IT Patient Safety, a multistakeholder collaborative.

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2018 TOP 10 HOSPITAL C-SUITE WATCH LIST

About This Free Resource

The *2018 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.

Introduction

What will healthcare bring in 2018? Mergers. Acquisitions. Uncertainty in U.S. healthcare insurance markets. The Triple Aim is still being pursued. Regulatory pressures continue. Population health refocuses on patient care wherever the patient roams, thanks to the burgeoning telehealth paradigm. Telehealth promises to expand access even in the midst of impending changes to the Affordable Care Act.

To aid healthcare leaders, ECRI Institute presents its *2018 Top 10 Hospital C-suite Watch List*. Each year, we aim to highlight new technologies and patient care developments that should be on the radar of healthcare leaders because these topics are likely to enter the conversation as you consider new technologies and infrastructure changes, large and small. This year's list includes topics such as direct-to-consumer genetic testing, which is changing the face of what front-line clinicians encounter when patients walk in with test results they received on their own, asking, "What do variants of unknown significance mean? Should I be worried?"

As usual, not all of our Top 10 topics are technologies or infrastructure changes that we recommend at this time, and, perhaps, neither should you. Often, hype precedes evidence, and healthcare leaders need to understand how to address the hype.

This year's list includes new telehealth approaches for treating individuals with opioid addiction. Addiction experts and families know that treatment is not a once-and-done thing. Ongoing, long-term support is critical to strengthen recovery, and telehealth tools offer a way to do that with some promising early results. This year's list also includes two new uses of computer/artificial intelligence technologies: virtual-reality environments developed especially to address pain and anxiety for kids with serious chronic health conditions, as well as a novel approach that uses noninvasive transcranial stimulation and computer-based cognitive training to support patients with Alzheimer's disease. We also highlight a possible disruptor in phlebotomy and an insertable cardiac monitor for individuals with atrial fibrillation. While phlebotomy and cardiac monitoring have long been practiced in healthcare, curious inventors are introducing new ways to perform each, with goals of improving patient convenience, adherence to care recommendations, and ultimately outcomes.

ECRI Institute has addressed many new technologies in each edition of its annual *Top 10 Hospital C-suite Watch List*. Some have panned out, some have not, and some, like Google Glass, continue to be studied for new healthcare uses. As ECRI Institute celebrates its 50th anniversary of separating fact from fiction in healthcare, we trust that this 9th edition of our Watch List will help you better understand some of the technology and infrastructure changes in patient care as you target your capital planning, value analysis, and strategic planning efforts.

We invite you to participate in discussions of the Top 10 topics at our curated LinkedIn group, Emerging Healthcare Technology in Patient Care. Our experts are ready to help you with your questions and projects. Contact us at clientservices@ecri.org, or call (610) 825-6000, ext. 5891.

1 Apps for Addiction:
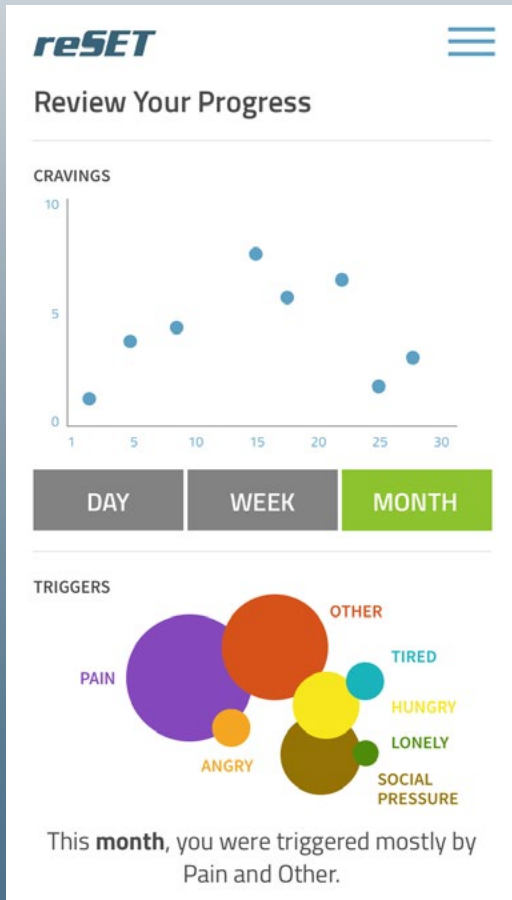## Can Digital Therapeutics Improve Treatment Adherence for Opioid Users?

In September 2017, FDA for the first time granted marketing clearance to a mobile medical app (reSET®, Pear Therapeutics, Inc., Boston, MA, USA) as a prescription-only adjunct treatment for patients with substance use disorder (SUD) under its *de novo* marketing authorization pathway. The reSET app is intended for use with outpatient therapy to treat alcohol, cocaine, marijuana, and stimulant SUDs in patients who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or whose primary substance of abuse is not opioids, according to Pear Therapeutics. The company claims the technology nearly doubled the rate of abstinence and increased retention in treatment compared to standard face-to-face therapy in a clinical trial of patients with diagnosed SUD. In October 2017, the company's reSET-O™ Prescription Digital Therapeutic received FDA's Expedited Access Pathway designation for medical devices that aim to address unmet medical needs for life-threatening or irreversibly debilitating conditions. Thus, the reSET-O is expected to reach market sometime in 2018.

Pear Therapeutics also announced that FDA included the company in its Digital Health Software Pre-Cert Pilot Program, designed to gain insight for developing a new digital health regulatory network. The FDA program's goal is to help healthcare providers deliver more effective care to patients with SUDs and opioid use disorders through new tools such as digital medical apps.
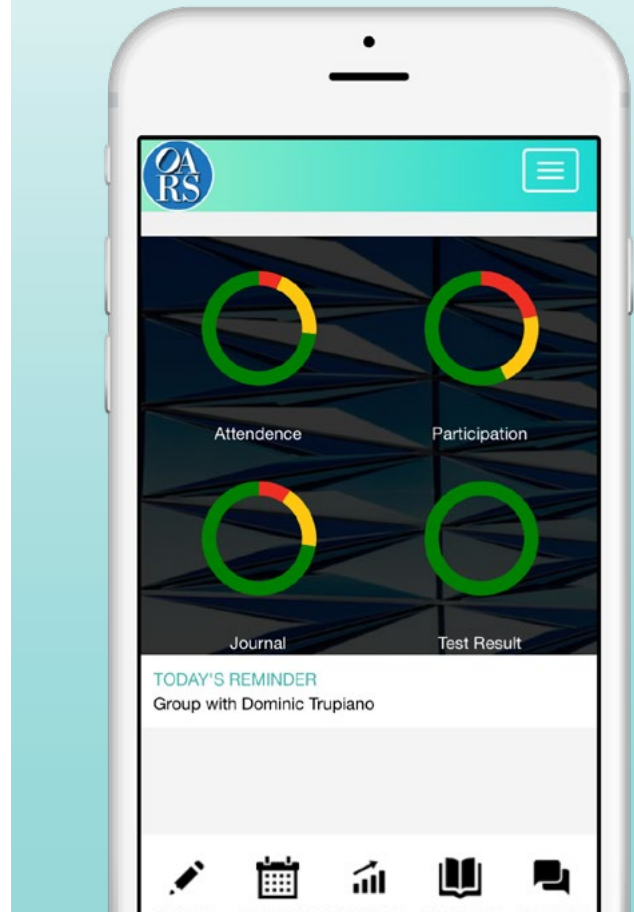
Other companies are marketing nonprescription software products to addiction clinics with similar goals. Q2i (Boston, MA, USA) asserts that its Opioid Addiction Recovery Support (OARS) may help substance abuse clinicians and their patients achieve fewer patient relapses, decrease in-patient admissions or readmissions, and reduce overdose incidents and emergency department visits. OARS purportedly helps addiction clinics better manage their patients and give patients extensive support through the software's healthcare team portal and patient mobile app.

Related Report:

▶ ECRI Institute. Health Technology Forecast News Brief. Nov 10, 2017. Medical App Added to Outpatient Therapy Improves Outcomes for People with Substance and Opioid Use Disorders.

Reprinted with permission from Pear Therapeutics.

Reprinted with permission from Q2i.

The technology nearly doubled the rate of abstinence and increased retention in treatment compared to standard face-to-face therapy in a clinical trial.

WHAT TO DO

▶ Evaluate the benefits of implementing patient management and patient support software to your substance abuse program.

▶ Consider teaming substance abuse clinical staff with information technology personnel to evaluate available prescription and nonprescription software products. Identify which products would best fit the needs of the patients your health system serves and your clinical staff.

▶ Have information technology personnel review the patient privacy and data security issues associated with all software products under consideration to inform product decision making.

▶ Establish procedures to gather feedback from patients and clinical staff to measure patient adherence and satisfaction with the software from both patients and clinical staff.

Direct-to-consumer (DTC) genetic testing accelerated in 2017 and shows no signs of abating in the months and years ahead. Technologic improvements have expanded use of genetic testing for clinical applications and have also attracted numerous companies seeking to adapt the technology for broad consumer use beyond the initial target of exploring one's ancestry. Many of the latest DTC genetic tests entering the market are more likely to have implications for healthcare provider and health system interactions with, and care for, their patients. Patients who receive unexpected results with healthcare implications or uncertain results that generate anxiety may increase patient demand for follow-up services.

However, the exact role of DTC genetic tests in healthcare is still evolving and may vary by the information that individual tests collect. Some tests purport to provide general information about genetics and health. For example, Zymo Research Corp. (Irvine, CA, USA) and Epimorphy, LLC (Costa Mesa, CA, USA) introduced the myDNAge™ Epigenetic Aging Clock test, based on the aging clock developed by Steven Horvath, PhD, UCLA professor of human genetics and biostatistics. The test costs $299 and uses epigenetic analysis of blood or urine samples to purportedly estimate a person's biological age versus chronological age. Epimorphy's website states, "Epigenetics may hold important keys to understanding a myriad of diseases and disorders, such as cancer, autism, Alzheimer's, and addictions," without specifically directing consumers on how to use the new information.

Other tests attempt to provide consumers with more detailed guidance to maintain health and well-being. DNA Diagnostics Center® (Fairfield, OH, USA) offers several tests that analyze DNA and give consumers health-related instructions based on their own genetic results. The HomeDNA™ Healthy Weight test provides diet and exercise strategies tailored to an individual genotype. The HomeDNA Skin Care test gives customized advice on the most effective topical ingredients, supplement ingredients, and professional treatments for healthy skin. The company also markets the HomeDNA Paternity, Joint Care DNA™ Test, Vitagene® Health Report + Ancestry, and about 12 other DTC genetic tests covering human ethnic origins and pet (dog and cat) health and breed/ancestry.

As costs of genetic testing decrease and data analysis becomes more sophisticated (with the help of artificial intelligence), DTC genetic tests could become ubiquitous. Hospitals and healthcare providers will have to keep up to date on this burgeoning field and be ready to respond to an increasing volume of related questions from patients.

Related Resource:

▶ ECRIgene information service

Photo courtesy of iStock.

Direct-to-consumer genetic tests are more likely to have implications for patient interaction and care for hospitals and health systems. Unexpected test results that generate anxiety may increase demand for follow-up services.

WHAT TO DO

► Designate someone in each clinical service line to monitor new entrants into the DTC genetic testing market, as well as changes to existing tests in the DTC landscape, so clinical service line leaders can be briefed on potential impacts from patients who have sought testing and seek follow-up consultation with providers.

► Ask front-line staff which DTC tests patients are bringing to their attention and asking for follow-up after receiving results. Estimate how frequently/widely and how the tests are affecting care encounters.

► Analyze this feedback and disseminate to clinical service line leaders throughout the health system to provide advance warning about potential impacts. Form a task force to educate key front-line staff on the downstream consequences of DTC genetic testing and the kinds of questions and requests they might anticipate from patients. Develop a coherent, uniform approach for responding to patients.

► Monitor whether patient experience with DTC genetic testing, in general or for specific tests, is leading to increased patient demand for specific or additional clinical care, testing, or procedures.

► Track whether any DTC genetic tests are associated with changes in care or patient management that increase costs unnecessarily, increase patient anxiety, increase requests for follow-up screening or diagnostic procedures, increase staff workload, or have other unexpected or unwelcome consequences.

3 Acuity-adaptable Rooms:
Will Staff Accept This Patient-centered Care Model?

Each time a patient is moved from intensive care to a step-down unit, from a telemetry unit to a regular med/surg unit, there is a risk to both the patient and the staff, as well as an impact on the patient's anxiety.

These patient handoffs are known to cause a risk with medication, and healthcare leaders are looking at ways to reduce or eliminate handoff risks. Some hospitals are experimenting with an acuity-adaptable care delivery model wherein a hospital keeps a patient in the same room from admission to discharge, regardless of acuity level. The aim is to improve workflows, enhance care continuity, improve patient safety, decrease length of stay, and reduce costs. Every patient handoff avoided when an intrahospital transport is eliminated is probably associated with a reduced risk exposure, either via minimized medication errors, preventing patient falls, or overburdening nursing staff that remain on the unit while one accompanies a patient transport.

Also, acuity-adaptable units eliminate the holding costs associated with keeping a patient in an intensive care unit while he/she awaits transfer to a step-down or telemetry unit.

While acuity-adaptable models make intuitive sense, many challenges exist in staffing, infrastructure, and workflow to actually improve patient outcomes. Just ensuring and maintaining staff competencies across all care levels requires a major rethink of nursing and hospitalist support models. How does a hospital using an acuity-adaptable model ensure that its highly trained critical care nurses are willing to work at lower care levels, and conversely, does every staff member have to be Advanced Cardiac Life Support certified?

Generally, hospitals that have implemented acuity-adaptable models focus on a particular type of patient to "house" in such a unit; cardiac, transplant, and oncology patients are likely patient groups that can be coordinated across acuity levels in one area.

For acuity-adaptable models to work, the medical equipment used for patient care is directed to the patient instead of transferring the patient to another unit. For that reason, some hospitals focus on step-down through discharge rather than critical care through discharge. The equipment intensity from step-down through discharge is much more manageable.

Infrastructure wise, acuity-adaptable rooms generally include shower facilities in the toilet area and, depending on local building codes, may have to adapt for nursing staff being able to view the patient's head in a critical care setting to a need for more privacy as the patient improves.

Some hospitals using acuity-adaptable rooms are reporting significant cost savings per patient. In value-based medicine, these will be important to sustain.

Related Report:

▶ ECRI Institute. Health Technology Assessment Information Service Special Report. Aug 2017. Acuity-adaptable Care Delivery Model for Inpatient Care.

WHAT TO DO

Acuity-adaptable rooms could improve workflows, enhance care continuity, improve patient safety, decrease length of stay, and reduce costs.

▶ Form a steering committee of multidisciplinary members to address training, room design, and patient charges.

▶ Include nursing staff early in the design consideration process to ensure competencies and buy-in to change the culture of care.

▶ Consider using a human factors expert in the design process to examine patterns of activity—current ones and future ones.

▶ Visit hospitals that have implemented acuity-adaptable care models.

4

Insertable Cardiac Monitor:
Can You Get in Front of Stroke by Going Inside the Heart?

About 6 million people in the United States have atrial fibrillation (AF), the most common heart arrhythmia often leading to stroke. For patients with AF, long-term continuous heart monitoring by electrocardiograph can help long-term medication management. Such monitoring is typically done using a Holter monitor for 24 hours to 7 days. However, Holter studies require placing several electrodes on the chest and abdomen and for the patient to carry a recorder, which patients find inconvenient. Also, Holter monitoring analysis is performed retroactively and requires multiple additional steps by both the patient and caregiver for data analysis and interpretation.

Enter the Confirm Rx™ Insertable Cardiac Monitor (ICM) (Abbott Laboratories, Abbott Park, IL, USA). The small device is an implantable loop recorder cardiac monitor. This ICM is the first of its type to interface directly with a patient's smartphone, which proactively transmits data to the patient's physician. While a Holter monitor is worn externally and can be bulky, the ICM is implanted and connects via Bluetooth to the patient's smartphone. Because the ICM transmits the data via a smartphone, the patient no longer needs to use a separate bedside telephone transmitter, and the transmitted data are fully encrypted and secure.

At intervals programed by the treating physician, the smartphone app automatically uploads patient data to the Merlin.net Patient Care Network for clinician access. Besides being able to detect AF, the device can also record the heart's electrical activity, which the patient controls by pushing a button on the app. This feature is useful when the patient has physical symptoms such as chest pain or syncope. The small device—49 mm x 9.4 mm x 3.1 mm (about 2 inches x 1/3 inch x 1/10 inch)—weighs 3 grams. The Confirm Rx has no contraindications for use.

Implanting Confirm Rx is similar to implanting a pacemaker or ICD. The procedure is usually performed under local anesthesia, but patients with certain medical conditions may warrant moderate sedation. In 2017, the estimated worldwide ICM market was approximately $800 million and was expected to grow by $100 million a year.

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Reprinted with permission from Abbott.

This is the first insertable cardiac monitor of its type to interface directly with a patient's smartphone, which proactively transmits data to the patient's physician, eliminating the need for a separate bedside transmitter.

WHAT TO DO

▶ Determine how many patients would benefit from the Confirm Rx ICM.

▶ Gauge your cardiologists' interest in using implantable monitoring devices.

▶ Evaluate the payer mix and your reimbursement issues.

▶ Carefully develop credentialing criteria for interested cardiologists.

5

Virtual Reality for Pediatrics:
Could It Help Reduce Pain and Anxiety during Procedures?

Recommendations from the American Academy of Pediatricians caution about overexposing children to digital media. However, increased use of some digital technologies may offer an important benefit to children with serious chronic conditions that require frequent procedures, such as infusion therapy or needlesticks and interaction with healthcare providers. Several children's hospitals and companies are collaborating to develop software for three-dimensional virtual-reality (VR) experiences to help children overcome or be suitably distracted from the fear and pain that come with repeated injections and infusions needed for treating many serious conditions. Researchers across the United States continue to explore the best ways to integrate VR technology into clinical care for treating hemophilia, numerous cancers, severe burns, and other applications. VR headsets let children play games and navigate simulated environments using only head movements, allowing clinical staff full access to their hands and arms to perform needlesticks, intravenous access, physical therapy (during severe burn rehabilitation), and other procedures.

The complexity of VR technology for pediatrics varies widely. At the higher end, appliedVR, Inc. (Los Angeles, CA, USA) reports selling its VR headsets (about $2,500 to $3,800 plus annual software licensing), which reportedly offer patients more than 20 different VR experiences, to about 100 hospitals. At the other end, a team at Nationwide Children's Hospital (Columbus, OH, USA) has developed disposable VR headsets for children with hemophilia who require multiple intravenous infusions during treatment. Users insert a smartphone into the front of the cardboard headset to create the VR experience for children, thus avoiding the potentially difficult task of cleaning the headsets between each patient use. Clinical staff can adjust the program's intensity or distraction level as needed with a wirelessly connected tablet computer, based on the invasiveness of the interventions they are performing. In September 2017, Lucile Packard Children's Hospital Stanford (Palo Alto, CA, USA) reported becoming one of the first hospitals in the United States to implement distraction-based VR therapy in all its patient units. Recent studies have shown significant declines in pain and anxiety scores in children and a decrease in anxiety of parents shepherding their child through difficult and numerous medical procedures.

With the increased diffusion of VR technology for general consumer use, the expanding applications of this technology in healthcare will increase as the technology improves, and pediatric patients and their parents and caregivers may come to expect access to this technology in patient care settings.

Recent studies have shown significant declines in pain and anxiety scores in children and a decrease in anxiety of parents shepherding their child through difficult and numerous medical procedures.

WHAT TO DO

▶ If you provide pediatric care for serious chronic illnesses, survey your front-line clinical personnel to determine which pediatric patient interactions and procedures might benefit from adding VR distraction technology.

▶ Consult your information technology staff about the best ways to integrate VR technology for pediatric patients into your healthcare system, leveraging existing technology when possible, and ensuring smooth integration into patient encounters.

▶ Team your nurses and other clinical staff with information technology personnel to evaluate available VR technology. Identify which devices or systems would best fit the needs of your pediatric patients and health system.

▶ If VR technology is deployed for pediatric patients, monitor outcomes to assess efficacy and utility. Availability of such data may inform decisions regarding expanding use of VR technology to adult patients.

▶ Reimbursement for use of VR technology is unavailable; thus, fundraising initiatives or other creative financing mechanisms may be needed to provide this technology.

Alzheimer's Disease:
Is a Noninvasive Device Set to Make More Headway than Medications?

Alzheimer's disease (AD) affects about 10% of people age 65 or older. The Alzheimer's Association estimates that 5.5 million Americans were living with Alzheimer's dementia in 2017. About 5.3 million of these patients are age 65 or older, and about 200,000 are younger with early-onset disease. Deaths from AD climbed 89% between 2000 and 2014, making AD the sixth leading cause of death in the United States. No curative therapies exist for AD, but the few pharmacologic (only five) therapies available may help reduce cognitive and memory symptoms for a limited time.

Neuronix Ltd. (Yoqneam, Israel) has recently received positive attention about its NeuroAD Therapy System for treating AD. The technology purportedly delivers sustained cognitive improvement by combining noninvasive transcranial magnetic stimulation (TMS) with computer-based cognitive training, added to existing pharmacologic therapy. Although TMS does not modify AD, a few small studies have suggested the therapy might improve scores on the Alzheimer's Disease Assessment Scale-cognitive subscale by about three to four points by six-month follow-up.

According to Neuronix, NeuroAD is the first device-based treatment for AD to receive the CE mark for clinical use in the European Union. A full six-week course of five daily, one-hour treatment sessions per week reportedly costs about $6,000 to $10,000. In November 2016, Neuronix applied to FDA for marketing clearance for the system under the agency's *de novo* classification paradigm. The company anticipated FDA clearance by the end of 2017, so if clearance is granted, the system could reach the U.S. market in 2018. FDA has cleared other TMS devices for treating major depressive disorders.

Although some local Medicare contractors have positive coverage policies for TMS as a depression treatment, the U.S. Centers for Medicare & Medicaid Services (CMS) has no national coverage determination on TMS for any indication. Several large private third-party payers (Aetna, Anthem, Cigna, Humana, Blue Cross of California) cover TMS for major depression but generally consider most other indications, including AD, investigational at this time and deny coverage. If cleared, the NeuroAD system would be the first FDA-cleared device to treat AD.

The technology purportedly delivers sustained cognitive improvement by combining noninvasive transcranial magnetic stimulation with computer-based cognitive training, added to existing pharmacologic therapy.

WHAT TO DO

▶ Monitor FDA's pending review of the NeuroAD system to inform your neurology services' consideration of the technology.

▶ Track potential CMS assessment of the NeuroAD system for treating AD, as well as any changes in existing noncoverage policies from major private third-party payers. Policies are usually revisited within three to six months of the approval of a novel device in an area of high unmet need.

▶ Evaluate the feasibility of implementing a NeuroAD program for AD while estimating patient demand. Be prepared to address cost concerns of patients and their families if the device is cleared and coverage policies remain negative. Given the high unmet need for AD therapies, expect strong marketing of the device to clinicians and patients.

7 (Nearly) Pain-free Blood Draw:
Will Microneedles Disrupt Phlebotomy?

The blood-draw process is time-consuming and unpleasant for patients: drive to the lab, sign in, wait for one or more painful needlesticks. A large percentage of people don't even show up for blood collection. From the health facility side, many laboratory tests require only small amounts of blood, but larger amounts of blood are drawn, producing excess waste that must be disposed of properly. Small-volume blood samples from fingersticks have also been problematic, as cell innards and interstitial fluids can be captured in the sample, and with small collections very little blood volume is available to wash out these extra components. Researchers have calculated that it takes 80 or more microliters to wash out excess material and reduce variability.

To address patient concerns and workflow inefficiencies, Seventh Sense Biosystems (Medford, MA, USA) developed the recently FDA-cleared TAP® (touch-activated phlebotomy) microneedle blood-collection device. The TAP single-use, 1.5-inch diameter device adheres to a patient's skin. Once tapped, the device uses 30 microneedles and a small vacuum to collect 100 microliters of capillary blood over 2 to 3 minutes until the fill indicator signals the collection is complete. The company says it is "nearly painless." The extracted blood can then be tested on standard laboratory equipment. One potential drawback is that TAP blood samples currently must be tested within six hours of collection, which may put a damper on use in rural areas, where samples must be mailed for testing.

The device could prove especially useful in pediatric populations, especially for children who require frequent blood draws for chronic conditions. A registration study rated traditional venipuncture or fingerstick at a pain level of five on the Wong-Baker Scale; pain from the TAP device was rated lower, at level two. Less pain also means less reliance on topical anesthetics and distraction techniques when blood is collected.

Currently, the only FDA-cleared use of TAP is for hemoglobin A1c testing (blood glucose level). However, many laboratory tests could be performed with 100 microliters of capillary blood. Seventh Sense is working on obtaining additional clearances and integrating a digital chip that can date and time stamp the blood sample. The time stamp would be useful, especially if patients were to take their own blood sample in a nonclinical setting and mail it to a lab. TAP has the potential to decentralize phlebotomy, disrupting the established workflow of laboratory phlebotomists.

Seventh Sense has since received a grant from the Bill and Melinda Gates Foundation and additional funding from Novartis, Siemens, and LabCorp. TAP's future may include integration with laboratory diagnostic platforms that analyze blood samples, allowing clinicians smartphone access to results within minutes of completion. Seventh Sense's recent partnership with LabCorp is likely to accelerate this integration. Seventh Sense indicates that future functionality, such as connectivity, additive array, sample separation, and dried blood spots, can be added.

A large infrastructure of automated laboratory equipment exists that is standardized around use of larger collection vials. Pediatrics may be the first area to benefit from TAP devices. Technicians are accustomed to using small vials of blood in pediatric patients, and these vials are not compatible with large automated lab equipment.

Beyond pediatrics, TAP devices can be used with existing point-of-use devices like Abbott's i-Stat® and Abaxis Piccolo®. However, variable results from fingerstick point-of-care testing have reinforced the physician practice of wanting repeat tests with central lab-based tests, so TAP may not facilitate cost or time savings until clinicians fully trust point-of-care test results.

Another company—Tasso, Inc. (Seattle, WA, USA)—is close behind in developing its HemoLink device for simplified blood sample collection. In 2015, Tasso received federal government funding from the Defense Advanced Research Projects Agency (DARPA). Tasso and its partner, GenTegra LLC (Pleasanton, CA, USA), are developing an integrated device that can collect blood from patients, stabilize biomarkers at ambient temperatures, and require no cold storage. In fall 2017, the companies were invited to participate in the Cedars-Sinai Accelerator in Los Angeles, CA, USA, but no further information on its status or an FDA submission is available at this time.

Once tapped, the single-use device uses 30 microneedles and a small vacuum to collect 100 microliters of capillary blood. The company says it is "nearly painless."

WHAT TO DO

▶ Watch for new tests to become available using TAP blood samples.

▶ Assess your laboratory technology to determine where smaller-volume samples can be used on your existing equipment. Develop plans for lab equipment slated to be replaced in the next five years so that it will be able to accept small sample sizes.

▶ Consider transitioning to TAP for in-clinic use in your diabetes program for monitoring HbA1c.

▶ Work with your laboratory director, providers, and supply chain to assess feasibility of transitioning to TAP samples in place of traditional vials for care areas such as pediatrics. Consider trialing TAP as the blood sample source rather than fingerstick for your point-of-care testing in the ED and for in-home use.

▶ Be sure to obtain approval from your health system for any off-label use.

A Neonatal MRI System:
Should You Move One into the NICU?

Magnetic resonance imaging (MRI) applications are rapidly expanding for all patient populations, including infants in the neonatal intensive care unit (NICU). When clinicians suspect that a neonate has experienced edema or hemorrhage, MRI is crucial for diagnosis to inform effective interventions. However, standard neonatal MRI requires transporting these vulnerable infants to radiology departments to undergo MRI, usually in a large, noisy scanner remote from the NICU, making transport a risk for these critically ill newborns. Although MRI is relatively safe, rare accidents in the MRI environment do occur, and a neonate is particularly vulnerable to MRI potential hazards, including projectile accidents, radiofrequency electromagnetic field effects, noise hazards, physiologic instability, and trauma resulting from transport, positioning, handling, and sedation.

Enter the Embrace® Neonatal MRI System (Aspect Imaging, Shoham, Israel), which FDA cleared in 2017. This device is designed for point-of-care imaging in the NICU of the neonatal brain and head. This greatly reduces potential risk of transport issues and enables staff to rapidly perform emergency care. Also, when medically necessary, the neonate can be removed from the system quickly. The device has several unique features intended to minimize the risks of neonatal MRI and improve the imaging experience for the infant, parents, and clinicians. The Embrace is fully enclosed and does not require a safety zone or a radiofrequency-shielded room, so it can reside in close proximity to typical medical devices lacking "MR Safe" and "MR Conditional" designations. The device has an integrated incubator to control body temperature and measure vital signs during MRI. This removes the need for a hospital to invest in "MR Conditional" incubators compatible with standard MR systems. Aspect Imaging claims the system is significantly less noisy than conventional MR systems, which is particularly important because neonates can suffer hearing loss without noise protection while undergoing conventional MRI.

Limitations include contraindications for infants weighing more than 4.5 kg (9.9 lb) or with a head circumference larger than 38 cm (15 inches). It is also contraindicated for infants with metallic or electronically active implants because MR may cause tissue near the implant to heat or the implant to malfunction. These technical capabilities and potential workflow improvements are promising, but no evidence is available yet to show that these features improve patient safety or outcomes. Clinical studies are needed to assess the efficacy of this new and unique MR system.

The system greatly reduces potential risk of transport issues and enables staff to rapidly perform emergency care.

WHAT TO DO

▶ If considering a new Embrace system, assess the annual volume of neonate MRI scans at your facility. You may determine that the scan volume does not justify the capital investment and resource allocation to adjust current imaging practices.

▶ If you decide to invest in the Embrace system, hold multidisciplinary planning meetings between NICU clinicians, radiology leaders, and healthcare technology management professionals to establish and review policies and procedures for implementing and utilizing this system in the NICU.
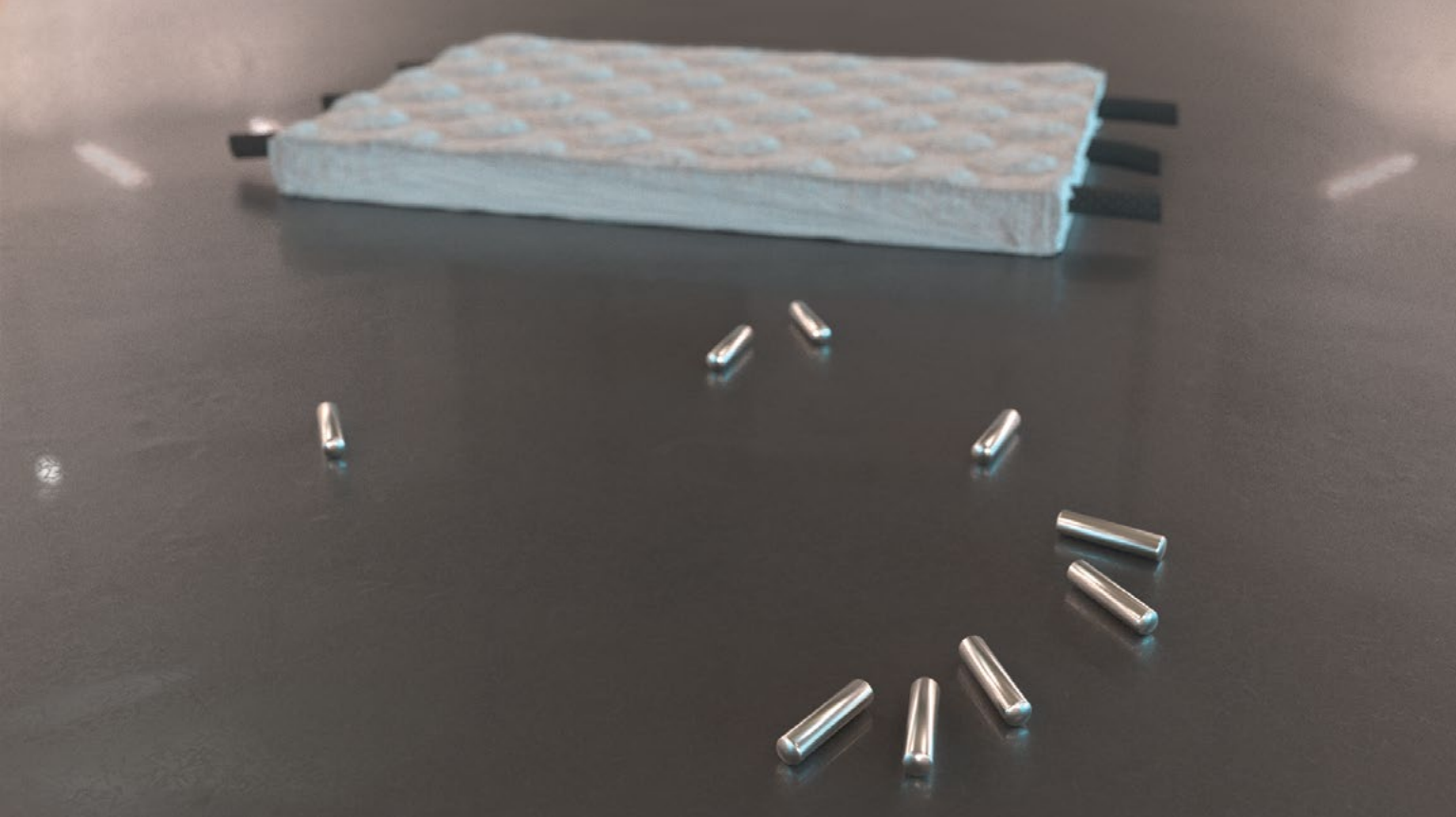
GammaTile™ Cesium-131 vs. Brain Tumors:
Can Intraoperative Brachytherapy Save Time, Money, *and* Lives?

Certain types of recurrent or metastatic brain tumors are often associated with a poor prognosis. Typically, several weeks after tumor removal, patients undergo external beam radiation therapy delivered over several weeks, or over days using more intensive stereotactic radiosurgery, to destroy any residual cancer cells. However, potentially critical time elapses between surgery and the follow-up radiation therapy regimen, which can place the patient at risk of harm from cancer cells reseeding the tumor surgical margins. GammaTile Radiation Therapy System (GT Medical Technologies, Inc., Gilbert, AZ, USA) is an investigational approach intended to enable intraoperatively delivered brachytherapy for brain tumors that standardizes seed placement, improves dose targeting and delivery, and decreases the risk of seed migration. The technology incorporates Cesium-131 brachytherapy seeds (IsoRay, Richland, WA, USA) embedded into a bioabsorbable collagen mesh that the neurosurgeon and radiation oncologist suture or staple into place in the cavity left by the excised tumor at the time of the surgery. The Cesium-131 brachytherapy seeds purportedly deliver their radiation dose to the target tissue more quickly (90% dose delivered in 33 days) and more directly than either external beam radiation therapy or other forms of brachytherapy using different radioisotopes, potentially improving outcomes and reducing injury to adjacent healthy tissue.

Developer GT Medical Technologies asserts that GammaTile therapy has demonstrated statistically significant improvements in survival compared to stereotactic radiosurgery, 15.5 months versus 11.3 months, in combination with brain tumor excision surgery, in a small (n = 49) retrospective cost-effectiveness study. GammaTile therapy plus neurosurgery reportedly costs on average about $19,200 compared with about $44,200 for neurosurgery plus stereotactic radiosurgery. GT Medical Technologies has submitted a 510(k) application to FDA for the GammaTile system, which the company expects to launch in 2018 after receiving FDA clearance. Further, the company reports that CMS recently assigned GammaTile to an ICD-10 code "with a favorable reimbursement amount" to implant the technology. Only about 35 U.S. centers experienced in brachytherapy use Cesium-131 at this time, primarily for prostate treatment.

Related Report:

▶ ECRI Institute. Health Technology Forecast. Dec 2017. GammaTile (Isoray Cs-131 Brachytherapy) Radiation Therapy System for Treating Brain Cancer.

The Cesium-131 brachytherapy seeds purportedly deliver their radiation dose to the target tissue more quickly and directly than other forms of therapy.

WHAT TO DO

▶ Determine whether implementing GammaTile Cesium-131 brachytherapy for brain tumors would be a feasible addition to your health system's existing neuro-oncology program in terms of infrastructure needs and staff experience. What protocols would need to change? Does your health system have the appropriate expertise to handle and administer intraoperative Cesium-131 brachytherapy? What infrastructure and processes would be needed to provide the necessary postprocedure patient isolation to ensure safety of bystanders?

▶ Estimate potential demand based on patient demographics and your system's historical use of radiotherapy for brain cancer.

▶ Monitor Medicare's review of GammaTile Cesium-131 brachytherapy to assess the reimbursement environment for the technology relative to other brachytherapy approaches and external beam radiation therapy for brain tumors. CMS policy regarding GammaTile therapy may influence similar coverage policies of private third-party payers.

▶ Determine potential financial impact of shifting treatment away from external radiotherapy to brachytherapy.

10

Microhospitals:
Could They Increase Access to Healthcare in Fast-growing Areas?

In this time of great uncertainty regarding how clinical care will be insured, many healthcare systems are experimenting with new care paradigms. They're looking at ways to increase access to acute care without investing in huge infrastructure projects so they can treat patients wherever they may need care: their home, the community, and anywhere else besides the high-cost acute care hospital. One experiment is a microhospital, an idea that many health systems—and investors—are pursuing to meet a healthcare need in fast-growing areas.

Microhospitals are neither urgent care centers nor full-service hospitals. Most microhospitals do not provide intensive care services, but they generally do provide emergency care and inpatient beds. Typically, a patient at a microhospital would have a lower acuity than a patient at a full-service acute care hospital.

Many administrators look at microhospitals as a way to distribute care throughout their system's service region, to brand their health system, and to capture covered lives by positioning microhospitals in fast-growing suburban areas. Typically, microhospitals are designed to be scalable so if population and care needs continue to grow, they may be expanded with additional services and beds as appropriate.

Microhospitals are held to the same licensing and regulatory standards as regular acute care hospitals, which may present challenges depending on state regulations. Typically, a microhospital is designed with 15,000 to 25,000 square feet of space and provides surgery, pharmacy, imaging, diagnostic services, and sometimes labor and delivery, as well as emergency and limited inpatient services. They have support functions such as dietary, materials management, and environmental services.

No definition exists of what a microhospital has to provide or what it cannot provide, so services may differ between microhospitals–even in a system with multiple microhospitals. Many health systems use the microhospital concept to be a feeder site for its larger acute care hospitals.

Microhospitals, if planned incorrectly, may drain capital resources away from other needs in the health system. Many aging hospitals have significant capital needs for facility upgrades, medical equipment replacement, and information technology investments. Implementing a microhospital without assessing the true need and its expected utilization can be dangerous.
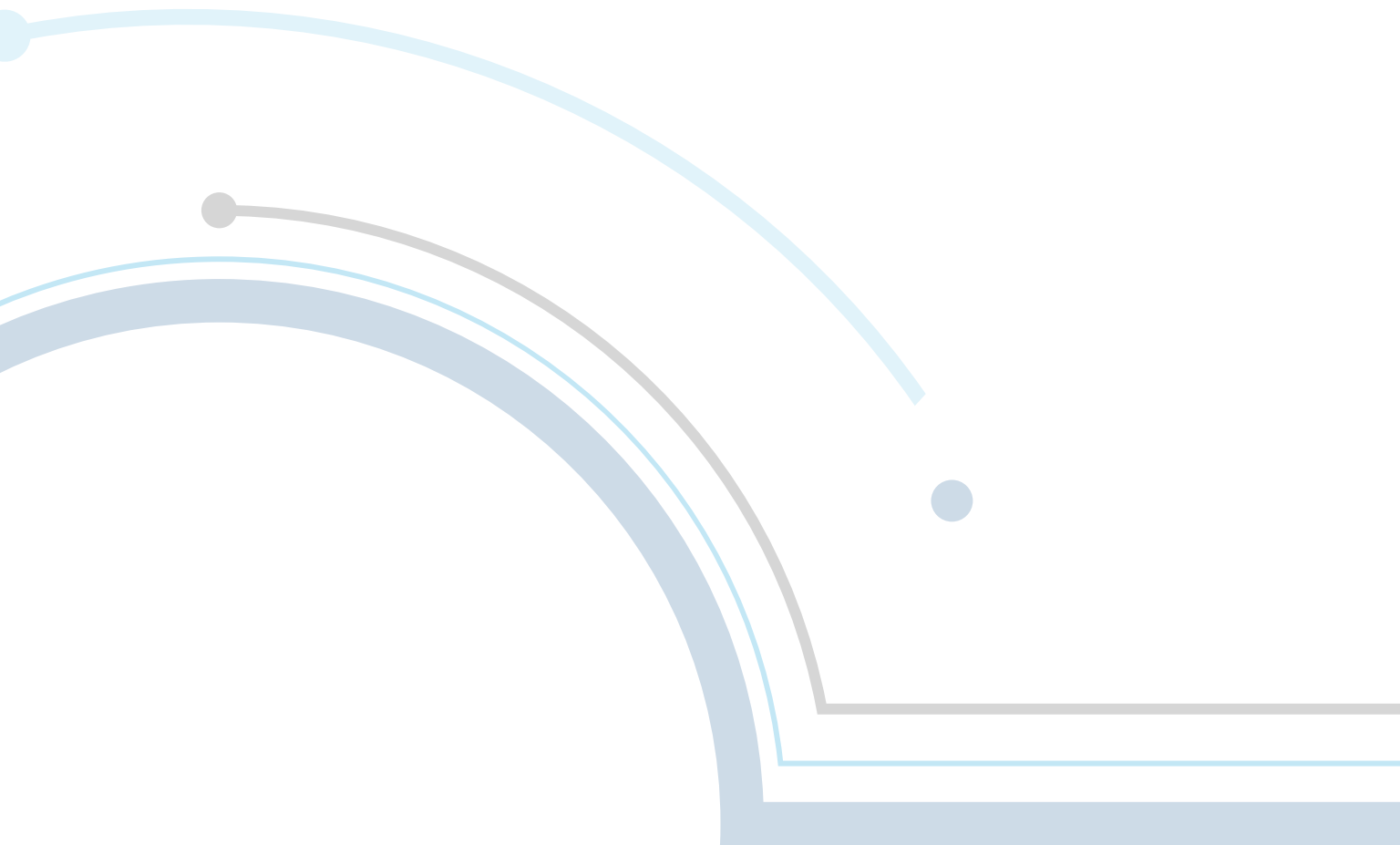
Microhospitals are a way to distribute care throughout a system's service region, to brand the health system, and to capture covered lives by positioning microhospitals in fast-growing suburban areas.

WHAT TO DO

▶ Research local building codes since some jurisdictions have specific requirements for hospitals of any size. Some certificate-of-need states may not even allow such a facility to be built.

▶ Assess demand and ease-of-access issues. Will the microhospital offer a way to capture patients from a fast-growing area and funnel them to the larger acute spoke?

▶ Assess physician support, which may include joint venture possibilities.

▶ Determine what future services might be necessary at the microhospital, and plan for scaling.

▶ Identify the branding elements of the health system necessary to incorporate into the microhospital design, whether that is entrance signage or hallway and lobby color schemes.

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